Paper No. 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Patent No. 9,885,698

Inter Partes Review No. IPR2019-00912

Petition for *Inter Partes* Review of
U.S. Patent No. 9,885,698

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Exhibit List

Exhibit #	Reference Name
1001	U.S. Patent No. 9,885,698 (“the ’698 Patent”)
1002	U.S. Patent No. 9,885,698 File History
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”)
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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	Provisional Application No. 61/747,477
1018	Provisional Application No. 61/754,698
1019	“The Biomedical Engineering Handbook,” by Joseph D. Bronzino (1995) (“BE Handbook”)
1020	M. Krantz, et al., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (June 2012)

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1021	Patel, et al., A review of wearable sensors and systems with application rehabilitation, Journal of Neuroengineering & Rehabilitation 2012 9:21
1022	ScienceDirect Report on M. Krantz, 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)
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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)
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)

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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)
1035	E.F. Schubert, Light-Emitting Diodes (Cambridge Univ. Press, 2nd ed. reprinted 2014)
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	Omni MedSci Inc.'s Opening Claim Construction Brief, No. 2:18-cv-134-RWS (filed December 20, 2018)
1040	Apple Inc.'s Preliminary Claim Constructions and Extrinsic Evidence Pursuant to Patent Local Rule 4-2, No. 2:18-cv-134-RWS (filed November 1, 2018)
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	Amended Joint Claim Construction and Prehearing Statement. Filed January 11, 2019. No. 2:18-cv-134-RWS
1044	Claim Construction Markman Hearing Transcript, February 6, 2019. No. 2:18-cv-134-RWS
1045	District Court Preliminary Claim Constructions. Case No. 2:18-cv-134-RWS
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")

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1052	U.S. Patent No. 4,972,331 ("Chance")
1053	Curriculum Vitae of Brian W. Anthony, PhD
1054	Dr. Mohammed Islam, Faculty Profile, University of Michigan, College of Engineering (available at https://islam.engin.umich.edu)
1055	Technology Transfer Policy, University of Michigan (available at https://techtransfer.umich.edu/for-inventors/policies/technology-transfer-policy/)
1056	Bylaws of the University of Michigan Board of Regents, (available at http://www.regents.umich.edu/bylaws/bylawsrevised_09-18.pdf)

Petitioner's Mandatory Notices

A. Real Party in Interest (§42.8(b)(1))

The real party in interest of this petition pursuant to § 42.8(b)(1) is Apple Inc. ("Apple") located at One Infinite Loop, Cupertino, CA 95014.

B. Other Proceedings (§42.8(b)(2))

1. Patents and Applications

U.S. Patent No. 9,885,698 ("'698 Patent") is related to the following issued patents or pending applications:

- U.S. Patent No. 9,494,567
- U.S. Patent No. 10,138,819
- U.S. Patent No. 10,201,283
- U.S. Application No. 16/272,069

2. Related Litigation

The '698 Patent has been asserted in the following litigations:

- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-18-cv-00134-RWS (pending).
- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-18-cv-00429-RWS (pending).

3. Patent Office Proceedings

The '698 Patent is subject to IPR2019-00914 filed by Apple.

C. **Lead and Backup Lead Counsel (§42.8(b)(3))**

Lead Counsel is: Jeffrey P. Kushan (Reg. No. 43,401), jkushan@sidley.com, (202) 736-8914. Back-Up Lead Counsel are: Ching-Lee Fukuda (Reg. No. 44,334), clfukuda@sidley.com, (212) 839-7364; Kathi Cover (Reg. No. 37,803), kcover@sidley.com, (202) 736-8377; and Thomas A. Broughan III (Reg. No. 66,001), tbroughan@sidley.com, (202) 736-8314.

D. **Service Information (§42.8(b)(4))**

Service on Petitioner may be made by e-mail (iprnotices@sidley.com), mail or hand delivery to: Sidley Austin LLP, 1501 K Street, N.W., Washington, D.C. 20005. The fax number for lead and backup lead counsel is (202) 736-8711.

I. Introduction

Health monitoring systems based on optical sensors, which measure physiological parameters of a user based on how light interacts with the user's tissue and blood, have been ubiquitous for decades. Once found only in hospitals and doctor's offices, these systems are now mainstream consumer devices. Over time, they evolved to become smaller, digital, wireless, and Internet-connected, an evolution driven by several market trends and forces. One sought to meet the needs and convenience of users for such devices to be wearable, unobtrusive and mobile. Another addressed the need to integrate these devices into a digital data processing environment based on real-time collection and delivery of user data. A third responded to consumer demand for personal health and fitness monitoring devices.

By 2012, the prior art described numerous wearable optical sensing devices with common attributes. They used LEDs emitting light at multiple wavelengths; were small, battery powered and wearable on the wrist or ear; and could wirelessly communicate with other devices. This prior art also described solutions to the various challenges of developing such devices, including mitigating noise caused by user movement and ambient light, minimizing power consumption, and arranging the electronic and optical components within the smallest possible space.

Relative to this extensive body of prior art, contested claims 1-3 and 5 of the ’698 Patent do not recite anything inventive. Rather, they cobble together well-known techniques for improving the signal-to-noise ratio of a sensor with routine and predictable combinations of known optical components, techniques a well-known textbook describes as the “basic building blocks” of such optical sensors. *See* Ex.1019 (“BE Handbook”), 765.

For example, U.S. Patent Publication No. 2012/0197093 (“Valencell-093”), describes an optical monitor with an LED-based sensor that measures heart rate and various blood constituents. Valencell-093 describes various signal processing techniques to extract accurate physiological information in a noisy environment, including modulating the LEDs and using a frequency shifting technique commonly known as “lock-in.” A related application—U.S. Patent Publication No. 2010/0217099 (“Valencell-099”)—describes applications of these devices including wireless communication of user health data between the sensor and a mobile device such as a smart phone, which in turn communicates with a database, computer or other remote device.

Other prior art, such as Carlson (Ex.1009) and Hanna (Ex.1007), describe conventional techniques used in the same kind of optical monitors. For example, Carlson uses a lock-in technique that a skilled person would have found obvious to use in the analogous Valencell-093 devices. Similarly, Hanna teaches benefits of

modulating the optical beam to include information.[1] It describes an optical physiological sensor analogous to that in Valencell-093 having multiple emitters, each configured to modulate light to include a unique identifying code, which makes it easier for the detector to discriminate signals of interest from noise. Claims 1-3 would have been obvious to a person skilled in the art based on Valencell-093, Carlson and Hanna.

Dependent claim 5 recites additional but entirely conventional features of a smart phone or tablet, each taught by Valencell-099. A skilled person would have been motivated to combine the teachings of the Valencell references as they both describe the same Bluetooth headset with an earbud sensor. Together, Valencel-093 and -099 (with Carlson and Hanna) would have rendered dependent claim 5 obvious to a skilled person.

Petitioner therefore respectfully requests that trial be instituted and claims 1-3 and 5 be cancelled.

[1] See, *infra*, § IV.C (discussing district court's preliminary construction of "modulating.")

II. Certifications; Grounds

A. Petitioner May Contest the ’698 Patent (§ 42.104(a))

Petitioner certifies that the ’698 Patent is available for *inter partes* review. Petitioner also certifies it is not barred or estopped from requesting *inter partes* review of the claims of the ’698 Patent. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the ’698 Patent. The ’698 Patent has not been the subject of a prior *inter partes* review by Petitioner or a privy of Petitioner.

Petitioner also certifies this petition for *inter partes* review is timely as it was filed within one year from April 10, 2018, the date Petitioner was first served with a complaint alleging infringement of the ’698 Patent. *See* 35 U.S.C. § 315(b); Ex.1004.

B. Identification of Claims Being Challenged (§ 42.104(b))

Claims 1-3 and 5 are unpatentable based on the following grounds.

(i) **Claims 1-3** are rendered obvious under 35 U.S.C. § 103 based on U.S. Patent Publication No. 2012/0197093 (“Valencell-093”) (Ex.1005) alone or with U.S. Patent Publication No. 2005/0049468 (“Carlson”) (Ex.1009).

(ii) **Claims 1-3** are rendered obvious under § 103 based on Valencell-093, alone or with Carlson, and U.S. Patent No. 6,505,133 (“Hanna”) (Ex.1007).

(iii) **Claim 5** is rendered obvious under § 103 based on Valencell-093, alone or with Carlson and Hanna, in combination with U.S. Patent Publication No. 2010/0217099 ("Valencell-099") (Ex.1006).

C. Fee for *Inter Partes* Review (§ 42.15(a))

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 50-1597.

D. Service on Patent Owner (§ 42.105)

Omni MedSci, Inc. is identified as the patent owner of record in the assignment records for the '698 Patent. Omni MedSci, Inc. is identified as the patent owner of record in the assignment records for the '698 Patent. The named inventor of the '698 Patent, Dr. Islam, has been a member of the faculty of the University of Michigan since 1992. Ex.1054. Based on the University of Michigan Bylaw 3.10 and Technology Transfer Policy, the University of Michigan is the owner of the '698 Patent. Ex.1055, Ex.1056 at 21-22. Dr. Islam has also purported to assign the patent to OmniMedSci. *Id*. Petitioner has thus served this petition on both the University of Michigan and Omni MedSci.

III. Relevant Background

A. Photoplethysmography

Optical health monitors use a sensing technique called photoplethysmography ("PPG") that has been known and used for decades in medical monitoring systems. Ex.1003, ¶37; Ex.1019, 769-76, 1346-55. PPG

works by shining light through a person's tissue and measuring the light that is either reflected back or transmitted through the tissue. Ex.1019, 766. Different components of blood and tissue absorb and reflect different wavelengths of light. Ex.1003, ¶38. By measuring how much light is absorbed over time, a device can calculate the components of the blood and tissue. Ex.1003, ¶38.

For example, hemoglobin (the substance in blood that carries oxygen to cells) reflects more red light when it is oxygenated and absorbs more red light when it is deoxygenated. Ex.1019, 769; *see* Ex.1003, ¶39. Hemoglobin, however, reflects the same amount of infrared (IR) light whether oxygenated or deoxygenated. Ex.1019, 769. If a device measures the absorbed red and IR light multiple times per second, the device can determine: (i) the ratio of oxygenated to deoxygenated hemoglobin (oxygen saturation), and (ii) how the volume of blood in the tissue changes over time, allowing detection of a person's pulse. Ex.1019, 769, 771; Ex.1003, ¶39.

PPG is an optical technique that uses conventional optical components. Ex.1003, ¶40. The 1995 BE Handbook explains that the "basic building blocks" of optical sensor systems include lenses, mirrors, filters, beam splitters, light sources, fiber optics, and detectors (Ex.1019, 765). As illustrated in the figure below, light from the LED is directed through a lens and onto a sample. Ex.1019, 765. The light reflects back from the sample, is filtered, and sensed by a photodetector. *Id.*;

Ex.1003, ¶¶41-43. The photodetector outputs a signal proportionate to the measured light intensity, and then analog-to-digital conversion and signal processing are performed to extract data. Ex.1019, 766. To improve the signal-to-noise ratio, the light source is typically modulated, and the detector uses "synchronized lock-in amplifier detection" to isolate signals that occur at the modulation frequency. Ex.1019, 764, 766. This allows the detector to reduce the noise in the detected signal. Ex.1003, ¶¶44-45.

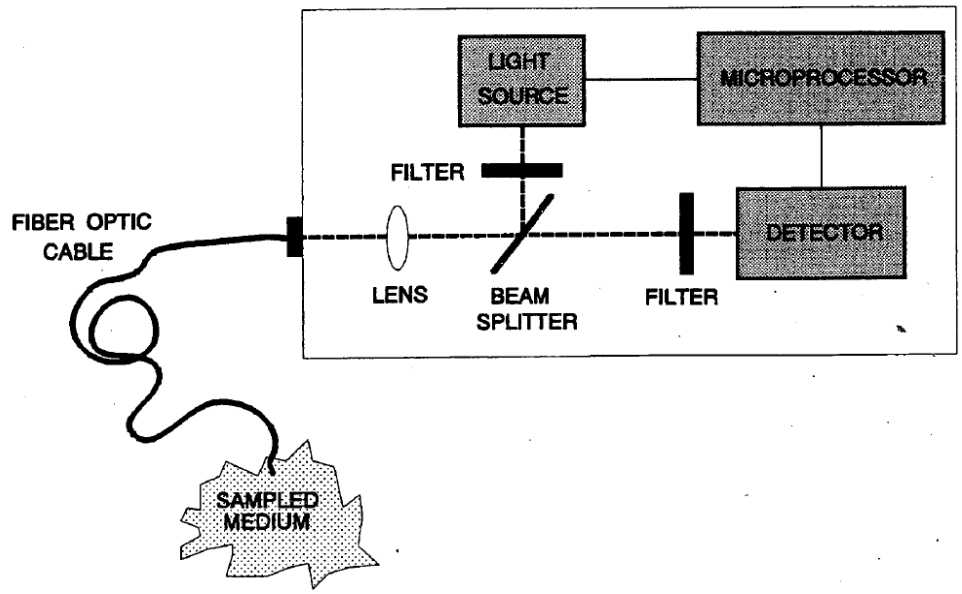


FIGURE 52.1 General diagram representing the basic building blocks of an optical instrument for optical sensor applications.

Portable devices conventionally use light emitting diodes (LEDs) as the light source because LEDs are small and have low power requirements. Ex.1019, 765; Ex.1003, ¶40.

B. Prevailing Industry Trends Before 2012

From 2000 to 2012, several market trends and needs drove the medical device industry to develop wearable, mobile sensor devices that could wirelessly communicate user data to remote devices. Ex.1003, ¶48.

One trend responded to the challenge of providing medical care for patients in their homes or in locations where there was not easy access to a physician. This drove development of wireless monitoring technologies that could be worn by the patient and used to transmit data to a remote physician or care provider. Ex.1021, 2; Ex.1024, 462; Ex.1027, 15-31; *see* Ex.1003, ¶¶48, 52-53.

Another trend was to bring heart rate sensing devices based on pulsoximetry to the consumer market for personal fitness tracking and other uses. Ex.1003, ¶¶49-50. As a June 2012 review observed:

> 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.1020, 3. *See also, e.g.*, Ex.1009, [0004] ("Pulsoximetry measuring devices are also used in sports for control and survey of athletes."); Ex.1029, 221 ("Wristband sensors are a predecessor to smartwatches and remain a successful product category on their own…"); Ex.1005, [0003] ("There is growing market demand for

personal health… monitors, for example, for gauging overall health, fitness, metabolism, and vital status during exercise, athletic training…"); Ex.1027, 33, 35.

A third trend sought to take advantage of the miniaturization of electronics and communication technology, which led to the development of smaller, wearable monitoring systems for mobile health and fitness applications. Ex.1021, 3; Ex.1020, 2; *see also* Ex.1003, ¶¶51-52.

A fourth trend in the medical industry was to use apps and smartphones to not only deliver care to patients but to give individuals access to health data for fitness or health issues. This drove integration of miniaturized, network-connected monitoring devices with smartphones and similar devices. Ex.1027, 9-10, 40-49; Ex.1023, 1-2 ("Doctors and nurses were the early adopters of tablets"); Ex.1021, 4; *see* Ex.1023, 5 (One of "the biggest usage of tablets stems from… [p]atient 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, 41; *see* Ex.1003, ¶¶51-52. It also led to the prevalent use of cloud-based data transfer and storage of data. Ex.1003, ¶52.

These market trends provided a strong motivation to skilled persons to integrate medical optical sensing techniques into miniaturized wearable consumer devices that communicate wirelessly with smart devices and remote services.

Ex.1003, ¶¶49-50. They also led to a proliferation of products using a distributed architecture supporting personal health, sports, and mobile monitoring systems. Ex.1003, ¶53.

One example of this architecture was described in Patel 2012 (Ex. 2021):

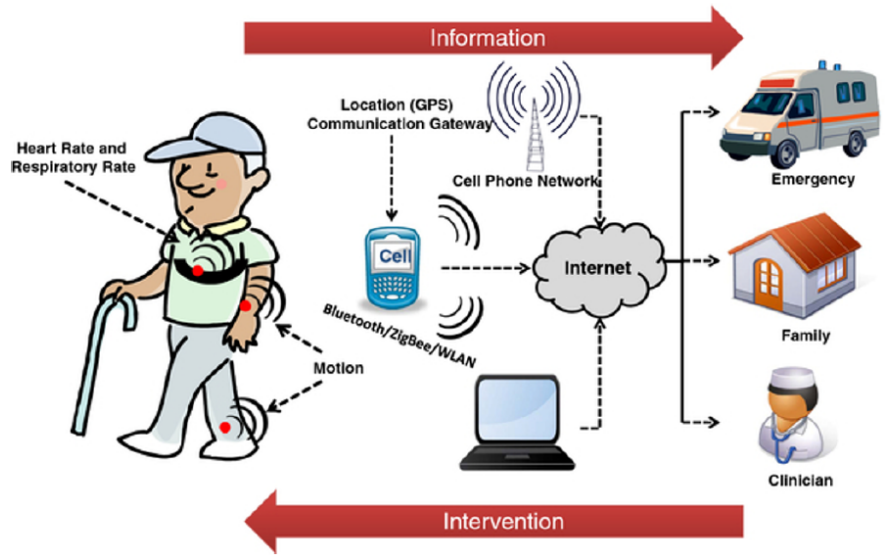


Figure 1 Illustration of a remote health monitoring system based on wearable sensors. Health related information is gathered via body-worn wireless sensors and transmitted to the caregiver via an information gateway such as a mobile phone. Caregivers can use this information to implement interventions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

Ex.1021, 2. As this figure illustrates, data from wearable sensors is transmitted to a cell phone, which in turn transmits the data, along with GPS information, to remote devices used by a clinician or maintained by an emergency responder. The data also is shown being transmitted to and stored in the cloud. Ex.1021, 4.

A 2010 publication described a similar architecture in which "medical data can be sent from a wireless monitor to a cell phone or PC and from there to a remote physician." Ex.1024, 459. As depicted, it comprised three network-interconnected components: (i) the "sensor" device on the person that collected

physiological data, (ii) a host device such as a smartphone, tablet, or computer that wirelessly captured and transmitted the physiological data, and (iii) a remote web service accessible over the Internet. Ex.1024, 460; Ex.1003, ¶54.

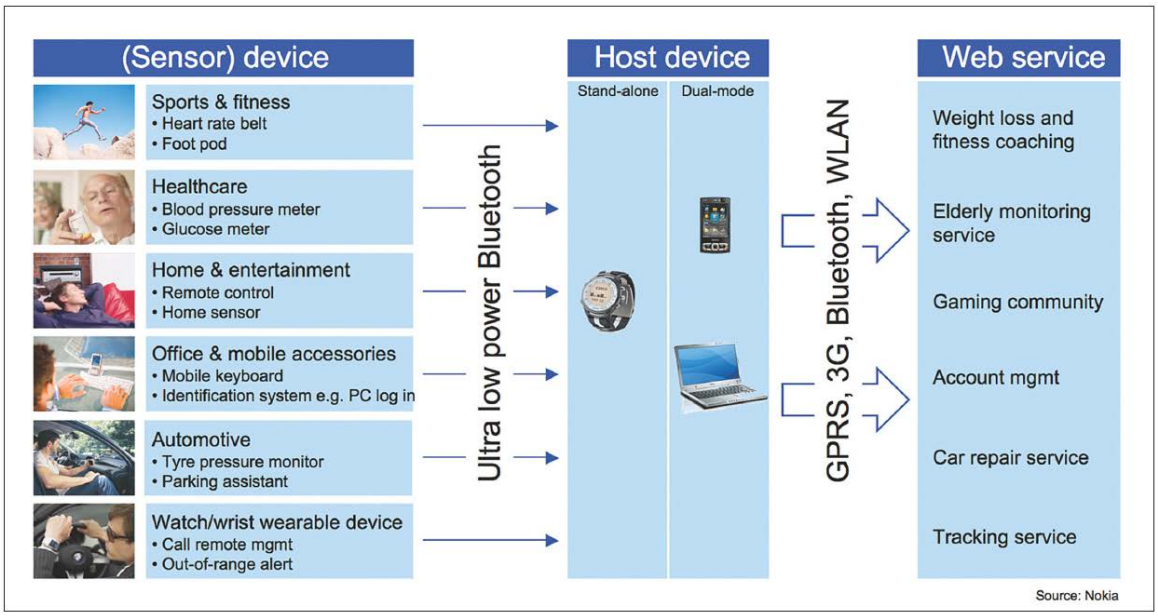
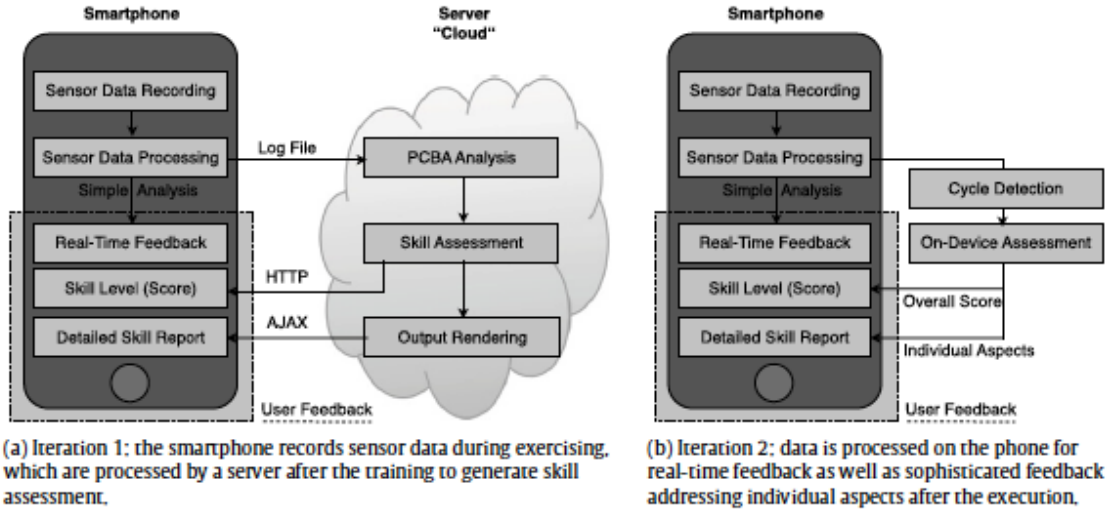


Figure 2. Bluetooth low energy will extend interoperable wireless connectivity to coin-cell-powered wireless sensors in health care, fitness, and related sectors. WLAN, wireless local area network; GPRS, general packet radio service.

Other articles from around 2012 similarly envisioned use of "cloud" based services to support this interconnected scheme. Ex.1003, ¶55. A 2012 article illustrated a cloud-based architecture implemented as a fitness app as follows:



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

(b) Iteration 2: data is processed on the phone for real-time feedback as well as sophisticated feedback addressing individual aspects after the execution.

Fig. 3. Iterations of the GymSkill application.

Ex.1020, 7. In this example, a smartphone records and processes sensor data, then sends the data to a cloud server for further processing, and then the cloud server returns processed data back to the smartphone for display to the user. Ex.1020, 7; Ex.1020, 6, 12. This same article specifically recognized this type of system could be used with heart rate monitors and optical sensors. Ex.1020, 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.").

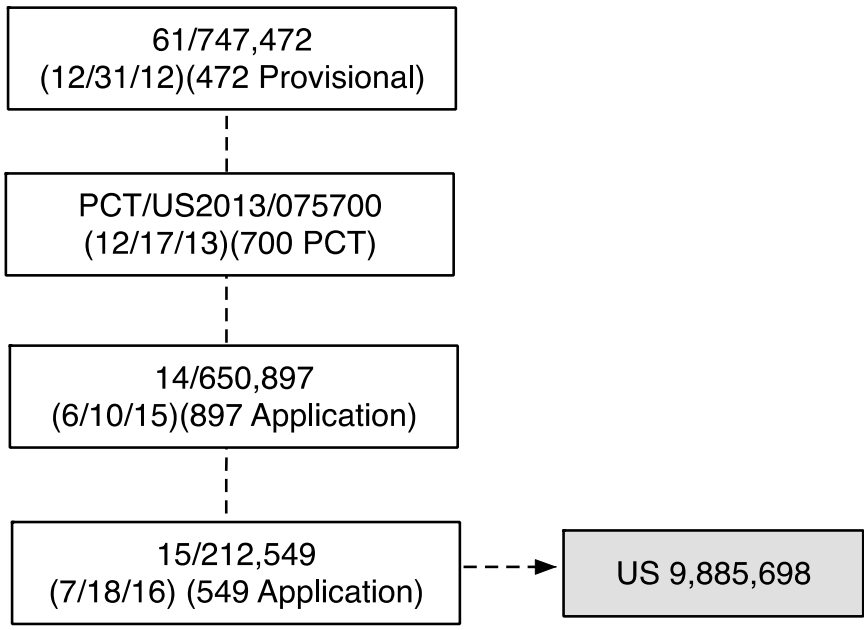
IV. The'698 Patent

A. Illustrative Claim

Independent claim 1 defines a wearable device comprising a number of well-known components of optical sensing systems. Claim 1, the only challenged independent claim, is reproduced in the attached claim appendix.

B. The ’698 Patent and Its Prosecution

The ’698 Patent issued from U.S. Application No. 15/212,549, which claims benefit or priority to a series of earlier filed applications (shown below):



The ’549 Application, like the ’897 Application and the ’700 PCT, claims the benefit of U.S. Provisional Application No. 61/747,472 (the ’472 Provisional). Ex.1001, 1:9-23; Ex.1002, 11.

The ’549 application and its two predecessors also state they are “related to” a series of provisional applications, including, *inter alia*, 61/747,477 (‘477 Provisional) and 61/747,485 (’485 Provisional). Ex.1002, 11. None of those provisionals was made the basis of a priority claim under 35 U.S.C. § 119(e).

C. The ’698 Patent Is Subject to AIA

Claims 1-3 and 5 of the ’698 Patent are not entitled to priority to the ’472 Provisional filed on December 31, 2012. As the ’698 Patent has no other basis for

an effective filing date prior to March 16, 2013, it is subject to the first-to-file provisions of the AIA.[2]

To be entitled to priority to an earlier filed application, the claimed subject matter must be supported in the manner required by 35 U.S.C. § 112 by the disclosure of the earlier application. *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 (Fed. Cir. 2018). Among other things, the earlier application's disclosure must establish the inventors had possession of the invention *as it is later claimed*—it is not sufficient if the earlier disclosure simply makes the claimed invention obvious. *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (1997) ("One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.") (citation omitted).

Here, the '472 Provisional does not demonstrate possession of a wearable device defined by claims 1-3 and 5 having a measurement device comprising a receiver that:

> the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors configured to:

[2] Pub. L. 112-29, §3(n); *see* MPEP 2159.02.

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 input optical beam reflected from the tissue;

***

the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue;

No passages in the ’472 Provisional provide written description support for these “lock-in” or “differencing” elements of claims 1-3 and 5. Ex.1003, ¶31. This can be easily appreciated by observing that passages in the ’698 Patent concerning these elements are absent in the ‘472 Provisional. *See, e.g.*, Ex.1001 at 14:36-44, 21:51-55 (“lock-in”); 16:43-45 (“differencing” signals); Ex. 1003, ¶31. Because the ’472 Provisional does not provide written description support for the claims as required by § 112 as of it filing date, claims 1-3 and 5 may not properly claim priority to the ‘472 Provisional.

Importantly, the ’549 application itself did not contain these passages when it was filed. Ex.1002, 56. Instead, the ’549 specification was amended on May 4, 2017 to add ¶[0077-1] and later, on June 8, 2017 to add ¶[0103-1]. Both additions

added for the first time text to the specification concerning the "lock-in" and "differencing" elements of claims 1-3 and 5. Ex.1002, 528, 545-546. In each case, Patent Owner justified the additions as proper amendments because the added text was found in the earlier-filed ' 477 and '485 Provisionals that Patent Owner contended had been "incorporated by reference."

The subject matter added by these amendments, however, is "essential material"—it is necessary to provide § 112 written description support for the claims. Pursuant to 37 C.F.R. §1.57(d), such "essential material" may not be incorporated by reference from a provisional application. 37 C.F.R. § 1.57(d). Rule 57(d) provides that essential material may only be incorporated by reference via "a U.S. patent or U.S. patent application ***publication*** which 'does not itself incorporate such essential material by reference.'" 37 C.F.R. § 1.57(d), *Droplets, Inc. v. E*trade Bank*, 887 F.3d 1309, 1318 (Fed. Cir. 2018) (claim amendments can transform nonessential material into essential material, causing a § 112 violation). A provisional application cannot be a "U.S. patent application

publication" specified in Rule 57(d) because it is never published.[3] The amendments made by Patent Owner during examination, thus, improperly added new "essential material" to the disclosure.

Patent Owner may contend the added material is not "essential material." Plainly it is—it corresponds to specific claim elements, and is the only text in the '698 Patent corresponding to these elements. Regardless, Patent Owner may not rely on disclosures in the '477 or '485 Provisionals *for any purpose* before the date on which they were incorporated by reference into the disclosure of an application to which the '698 Patent makes a valid claim of benefit or priority.

[3] A "patent application publication" is a non-provisional application filed under 35 U.S.C. § 111(a) that has been published pursuant to 35 U.S.C. § 122(b). A provisional patent application cannot be a patent application publication because it is filed under 35 U.S.C. § 111(b) and is expressly excluded from publication under § 122(b). *See* 35 U.S.C. §§ 122(b)(1), (b)(2)(A)(iii); 37 C.F.R. § 1.215; M.P.E.P. § 1121 (defining contents of a "patent application publication"); M.P.E.P. § 903.04.

The earliest date when this occurred was December 17, 2013, when applicant filed its PCT application.[4]

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("skilled person") would have a good working knowledge of optical sensing techniques and their applications, and 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. Ex.1003, ¶35. This description is approximate; varying combinations of education and practical experience also would be sufficient. *Id*.

Petitioner's positions regarding how a skilled person would have understood the '698 Patent claims and the prior art are supported by the testimony of Brian Anthony, Ph. D., an expert in optical sensing devices with over 20 years of experience. Ex.1003, ¶¶2-9, 36.

[4] Petitioner reserves its right to dispute any assertion by Patent Owner that the claims are entitled to priority earlier than December 17, 2013.

V. Claim Construction

The parties in related district court litigation agreed that the claim language should be given its plain and ordinary meaning, except for three terms. The parties offered alternative constructions for these terms, and the Court provided a preliminary construction of each disputed term. *See* Ex.1043, 5, 8-10 (the parties' claim constructions), Ex.1040, 2-3 (preliminary claim construction).[5]

To avoid any dispute linked to claim scope, the grounds in this petition demonstrate the claims are unpatentable using the narrowest construction for each disputed claim term.[6] For "beam," that is Apple's proposed construction of "photons or light transmitted to a particular location in space." For "one or more lenses," the narrowest construction is Apple's proposed construction of "one or more transparent surfaces used to collimate (make parallel) or focus rays of light." For "modulating at least one of the LEDs," the narrowest construction is the

[5] The district court has not yet provided a final claim construction order, which is expected to issue in the next few months. Petitioner will file the final claim construction as an exhibit when the order issues.

[6] If Patent Owner contends that special constructions should be used that are different from those it has advanced in the co-pending litigation, Petitioner may request leave to file a reply to such assertions.

district court's preliminary construction of "varying the amplitude, frequency, or phase of the light produced by at least one of the LEDs to include information." As explained below, these constructions are faithful to the patentee's lexicography, the specification, and the extrinsic evidence.

A. "Beam"

The claim term "*beam*" is expressly defined in the specification: "As used throughout this disclosure, the terms 'optical light' and or 'optical beam' and or 'light beam' refer to photons or light transmitted to a particular location in space." Ex.1001, 9:29-31. This definition should be adopted verbatim as the patentee's chosen lexicography. *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). The definition is also consistent with extrinsic evidence reflecting that a skilled person would understand a "beam" to mean "a collection of nearly parallel rays." Ex.1047, 106; *see also* Ex.1042, 1. Such a collection of nearly parallel rays would necessarily travel to a particular location in space, as opposed to scattering in different directions. *See* Ex.1001, 10:42-47 (distinguishing a beam from "stray light from a reflection or scattering"), 24:12-14 (directing an array of beams), and 6:18-22 (delivering a beam to a sample). The district court's preliminary construction recognized that a beam does not include randomly directed light. *See* Ex.1045.

Petitioner submits that "beam" should be construed to mean "photons or light transmitted to a particular location in space."

B. "One or more lenses"

The only type of lens described by the '698 Patent is one that will "collimate or focus the light." Ex.1001, 20:57-58, 21:22-24, 23:40-42. In addition, the claims specify the lenses are "configured to receive and to deliver a portion of the input optical beam to tissue." To perform these claimed functions, the lens must be transparent so that the received light can pass through the lens and travel to the tissue. And, to deliver the received beam the lens must collimate or focus the beam, rather than scatter the beam. These defining characteristics of the claimed lens are consistent with the 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, 712; *see also* Ex.1041, 481 ("[a] piece of glass or other transparent material").

Petitioner therefore submits that "one or more lenses" should be construed to mean "one or more transparent surfaces used to collimate (make parallel) or focus rays of light."

C. "Modulating at least one of the LEDs"

The district court did not adopt either party's proposed construction for "modulating" and instead proposed the following construction: "varying the amplitude, frequency, or phase of the light produced by at least one of the LEDs to include information." This construction adopts definitional language in the '698 Patent stating that beams "may be modulated or unmodulated, *which also means that they may or may not contain information*." Ex.1001, 9:32-34 (emphasis added). It also is consistent with extrinsic evidence relied on by both parties, including a dictionary definition both parties employed:

> To vary the amplitude, frequency, or phase of (carrier wave or a light wave) for the transmission of information (as by radio).

Ex.1046, 798; *see also* Ex.1039, 14-15 (describing modulation in the context of AM and FM radio used to transmit audio information).

At the Markman hearing, Petitioner urged the court to revise its preliminary construction to delete "amplitude" because the specification and claims distinguish modulating from varying the amplitude of the signal. Ex.1044, 21:16-22:1. Petitioner observes that whether "amplitude" is included in the construction of modulating ultimately has no consequence in this proceeding, as the prior art renders the claims unpatentable under either construction. For simplicity, Petitioner proposes that the Board use the district court's preliminary construction

in this proceeding, with the express reservation that Petitioner may argue the narrow construction in district court.

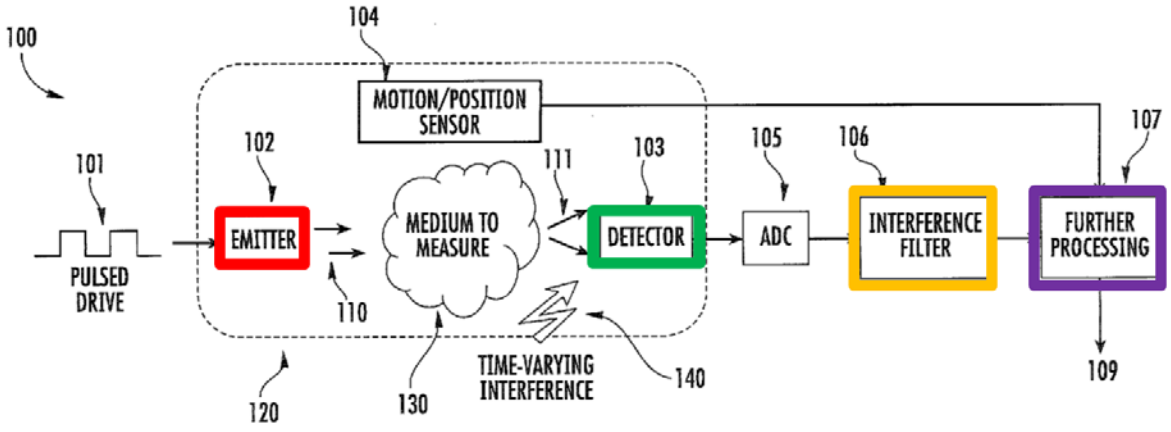
VI. Detailed Explanation Why The Claims Are Unpatentable

A. <u>Ground 1</u>: Valencell-093 with Carlson Renders Claims 1-3 Obvious

1. Valencell-093

Valencell-093 was filed on January 25, 2012, and published on August 2, 2012. It is prior art under 35 U.S.C. § 102(a).

Valencell-093 describes a Bluetooth headset with a sensor that can measure heart rate and blood constituents of the user such as blood oxygen level, cholesterol, and many others. Ex.1005, [0006], [0050], [0090], [0109]. Its objective is "to make a wearable monitor, such as an earbud monitor, that may provide accurate information on physiological conditions in the midst of environmental noise, such as noise from ambient light and/or sunlight." Ex.1005, [0112]. Annotated Figure 1 shows components of the wearable monitor:



As shown, at least one emitter 102 emits modulated optical energy 110 at a target region 120 of a medium 130. Ex.1005, [0107], [0108]. The target region can be a user's ear, wherein the medium "comprises blood vessels and/or blood flow within the ear region." Ex.1005, [0108]. The energy 110 interacts with the medium to generate a scattered light response 111, which is detected by at least one detector 103. Ex.1005, [0107]. "The outputs of the detector 103 may be sent to at least one analog-to-digital converter (ADC) 105 and the digitized output may be sent to at least one interference filter 106, which is configured to remove the effects of time-varying environmental interference 140 from the signal output of the detector 103." Ex.1005, [0107]. The output of the interference filter may be further processed by a signal extraction filter 107 "to extract accurate information from the medium" and produce an "extracted energy response signal" 109. Ex.1005, [0107]. "At least one signal processor (not shown) may be used to control the operations of the energy emitter 102, detector 103, filter 106 and/or other components of the interference filtering method 100." Ex.1005, [0107]. The processor processes the detected energy response signal to produce an output signal. Ex.1005, [0007]. This processed output signal can be wirelessly transmitted to a remote device such as a cellphone. Ex.1005, [0035], [0104].

Valencell-093 further describes that the physiological sensor can be incorporated into an earbud. Ex.1005, Figs. 4-5, 9-17. The earbud sensor shown

in Figure 14, for example, has one or more optical emitters 102 and two optical detectors each covered by a lens 715. Ex.1005, Fig. 14 (annotated), [0130].

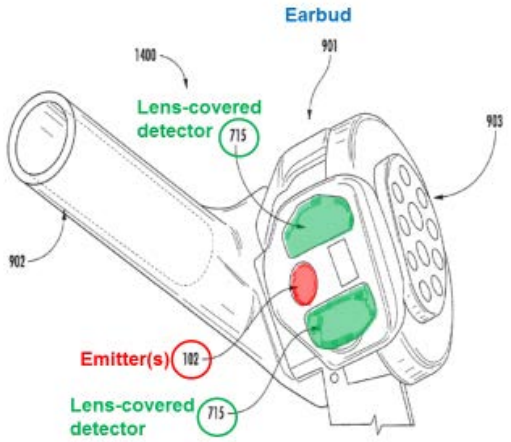


FIG. 14

Valencell-093 also teaches that the physiological sensor can be incorporated into a wristband or configured for application to other parts of a user. Ex.1005, Figs. 23-29, [0043], [0050].

2. Overview of Carlson

Carlson was published on March 3, 2005, and is prior art under 35 U.S.C. § 102(a) (AIA).

Carlson describes a wearable pulse oximeter that can be worn on the ear, finger, toe or "other parts of the human body." Ex.1009, [0052], [0078]. The device uses a conventional sensor known in "the state of the art" 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, [0003], [0050],

[0052]. The device uses beam shaping elements such as a lens to direct light from one or more LED light sources to tissue. Ex.1009, [0012]-[0014] [0054]. The light source is modulated, and lock-in detection is used to improve a signal-to-noise ratio. Ex.1009, [0020], [0027], [0064]-[0065], [0070]. The device is mobile and can wirelessly transmit data to a doctor or hospital. Ex.1009, [0072], [0077]-[0078]; Ex.1003, ¶78.

Carlson describes 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, [0002]; *see also* Ex.1003, ¶79. Carlson notes that while known 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, [0004]. Carlson's objective thus was "to define optical and/or electronic means for increasing the Signal-to-Noise ratio (S/N)…of a pulsoximeter sensor for robust application of pulsoximetry in telemedicine and near patient testing applications in rough (optical) environmental conditions, e.g. at changing light influences, such as sunlight, shadow, artificial light, etc." Ex.1009, [0010]. These observations in Carlson provide a direct motivation to a skilled person to incorporate its techniques, features and other improvements—including

its “lock-in” technique—into other pulsoximetry devices, such as those in Valencell-093. Ex. 1003, ¶¶80-81.

3. A Skilled Person Would Have Modified Valencell-093 to Incorporate Elements Shown in Carlson

A skilled person would have considered Valencell-093 with prior art that describes analogous pulsoximetry devices having the same applications (*e.g.*, mobile monitoring of pulse and other physiological characteristics of a person). Ex.1003, ¶80. That person following ordinary design processes would identify and evaluate known techniques and structures used in analogous systems that could improve performance, particularly in the presence of noise. *Id*. The latter is a specific objective of Valencell-093—“to make a wearable monitor…that may provide accurate information … in the midst of environmental noise.” Ex.1005, [0112], [0005].

That would have led the skilled person to Carlson, which describes complementary techniques for improving signal measurement in an optical sensor. Ex.1006, [0002]; Ex.1003, ¶81. The skilled person would have considered Carlson when implementing a system based on the teachings of Valencell-093. Ex.1003, ¶81. Moreover, as explained in §III.B, by 2012, there were trends in the industry to create wearable devices for mobile monitoring situations or for sports and personal fitness applications. Ex.1003, ¶¶48-56. These trends would have provided additional reasons for a skilled person to consider references like Carlson,

which describes desirable features for improving performance of wearable devices. Ex.1003, ¶82.

For example, Carlson teaches processes and structures for increasing the signal-to-noise ratio of the detected signal, even when optical conditions of the environment are changing. Ex.1009, [0010]. Like Valencell-093 (Ex.1005, [0003]), Carlson describes using its techniques in devices used in hospitals, mobile monitoring and telemedicine, and sports applications to monitor athletes. Ex.1009, [0004]. It also describes devices that can be worn, for example, on an earlobe or finger. Ex.1009, [0048], [0052]. Valencell-093 and Carlson thus describe analogous systems with common applications and utility, and both describe techniques for improving the performance of wearable optical sensors by removing noise. Ex.1003, ¶81.

4. Claim 1

a) "A wearable device"

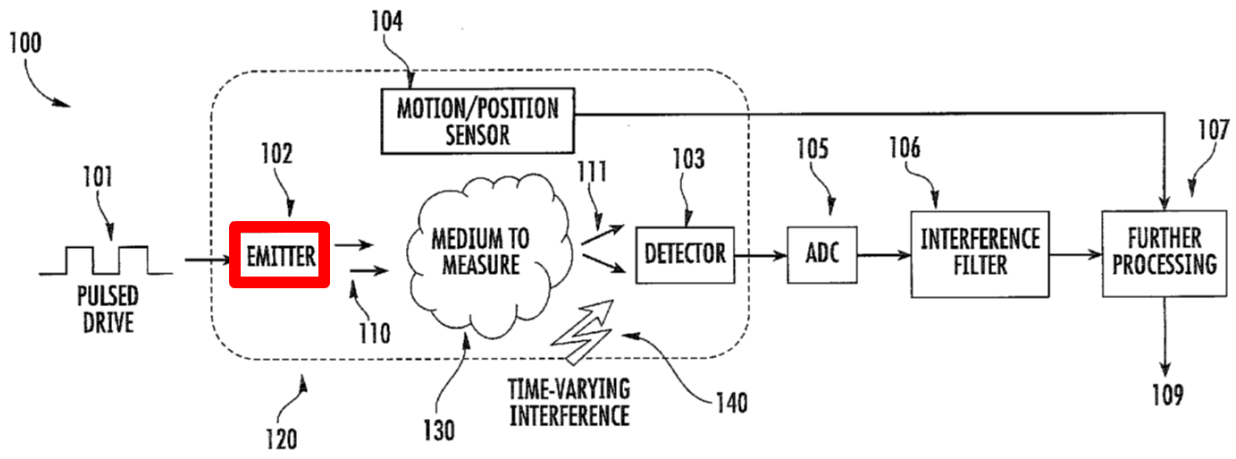
The preamble is non-limiting. The elements in the body of claim 1 define a structurally complete device, and none of those terms finds antecedent basis in the preamble. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Nor is the preamble necessary to breathe life, meaning, and vitality into the claim. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). In addition, the patentee did not rely on the preamble to distinguish art during prosecution, and

in the concurrent litigation, Omni agreed that the preamble is not limiting. Ex.1043, 2; *see* Ex.1002.

Even if the preamble is limiting, Valencell-093 teaches it by describing a wearable Bluetooth headset that incorporates a physiological sensor into an earbud. Ex.1005, Figs. 4-5, 9-17 [0006], [0104], [0112]. Valencell-093 also describes incorporating the sensor into a wearable wristband. Ex.1005, Figs. 23-29, [0151]-[0154].

b) "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters"

The Valencell-093 headset includes an earbud sensor that measures physiological parameters of the user's blood. Ex.1005, Figs. 1, 2, 4A, 4B, 5, 7-17, [0006] ("the detector detects an energy response signal… [that] is associated with a physiological condition of the subject (e.g., heart rate, pulse pressure…, blood metabolite level, blood oxygen level")), [0050], [0108]-[0109].



The sensor shown in Figure 1 (annotated) above includes a light source comprised of one or more emitters 102, which can be LEDs. Ex.1005, [0038] ("multiple emitters… may be employed"), [0108] ("Examples of optical emitters include light-emitting diodes (LEDs)"), [0130]. A processor controls operation of the sensor, Ex.1005, [0007], [0107], such that the earbud sensor operates as "*a measurement device…for measuring one or more physiological parameters*." Ex.1003, 86.

c) "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam"

Valencell-093 teaches that the LEDs emit "pulsed or ***modulated energy***," wherein modulated energy is defined as energy "that is emitted in pulses and/or that is emitted ***such that the amplitude, frequency, phase, or intensity is varied***."

Ex.1005, [0008], [0097], [0107], [0108], [0143] (emphasis added). Valencell-093 describes the same way of modulating light as the ’698 Patent. Ex.1003, ¶90.

Valencell-093 also discloses that the LED emits a “beam of light” and “directs energy (e.g., optical energy… etc.) at a target region of the subject.”[7] Ex.1005, [0006], [0009], [0012], [0019], [0033], [0044], [0047], [0109], [0137]. As “beam” is being used in Valencell-093, it is referring to light that is directed to a particular location in space (the target region of the subject) and is therefore the same type of “beam” described in the ’698 Patent. Ex.1003, ¶88. Valencell-093 thus teaches an LED that emits a beam comprised of photons or light transmitted to a particular location in space. *Id*.

Valencell-093 also teaches that the LEDs are modulated, as defined by the district court by varying amplitude, phase, or frequency, Ex.1005, [0097], except that it does not expressly indicate that it is modulating light to include information. But a skilled person would have read Valencell-093 as describing modulating a beam to include information, and would also have considered doing so to have been obvious. Ex.1003, ¶¶91-98.

[7] This disclosure also meets the definition of “beam” proposed by Omni in the related district court litigation. Ex.1003, ¶88.

As the ’698 Patent explains, a beam may be modulated (which contains information) or unmodulated (which does not).[8] Ex.1001, 9:32-33. This was a well-understood technical fact. Ex.1003, ¶91; Ex.1046, 798. The use of the term “beam” without further discussion in Valencell-093 would have been read by a skilled person as describing either known type of beams of light – those that are modulated to include information and those that are not. Ex.1003, ¶91; *see In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962) (disclosure of a limited class allows “one skilled in the art [to] at once envisage each member of this limited class….”).

A skilled person also would have found it obvious to select one of these known options for a beam, and doing so would have yielded predictable results when implemented in the Valencell-093 device. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a skilled person has good reason to pursue the known options within his or her technical grasp.”); *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328-29, (Fed. Cir. 2009) (claimed invention obvious to try based on only three possibilities).

[8] Omni conceded in its proposed district court claim construction that a beam “may be modulated or unmodulated, and which may or may not contain information.” *See* Ex. 1039, 14.

As Dr. Anthony explains, a skilled person would have had obvious reasons to use a beam in the Valencell device that was modulated to include information because of the benefits obtained by doing so. Ex.1003, ¶¶ 92-96. For example, the beam of light could be modulated to embed an identification code that would enable a detector to identify the source of received light. Ex.1003, ¶93. 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 Figure 9A of Valencell '093. Ex.1005, [0122], [0130]; Ex.1003, ¶93. Hanna (Ex.1007) describes such a technique. As Hanna teaches and was known in the prior art, a beam of light can be modulated to embed an identification code that would enable a detector to identify the source of received light. Ex.1007, 2:26-29 Ex.1003, ¶93.

Similarly, the signal could be modulated to encode a unique identifier in the modulated light keyed to the user or to the serial number of the device, to enable unique identification by the receiver in order to reduce the risks for device tampering. Ex.1003, ¶94. The signal also could be modulated to be encrypted for security purpose. *Id*. The signal also could be modulated to contain information about the operational characteristics of the LED, such as a number representing an expected intensity value, which would allow the detector to determine if the LED is operating properly. Ex.1003, ¶95.

A skilled person could have readily altered the Valencell-093 device to modulate a beam to create a signal that includes any of these types of informationEx.1003, ¶97. That person, knowing that "market demand for personal health and environmental monitors" required sensors that would produce "accurate health, fitness, and vital status monitoring," Ex.1005, [0003], would have been motivated to make one or more of such alterations to include information as one way to improve and enhance the performance of the sensor, or to ensure the sensor was operating properly, as one way to produce more accurate data. Ex.1003, ¶¶96-97.

Moreover, Patent Owner did not contend that the nature of the beam was relevant to patentability and the examiner did not rely on that aspect of the signal in allowing the claims. The '698 Patent does not identify any benefit of using modulated light, nor does it describe the nature of information to be conveyed or a reason for encoding a signal to contain it. Ex.1003, ¶98. The '698 Patent thus reflects the conventional nature of modulating a beam to contain information if desired. Indeed, modulating energy to include information is a technique that has been used for decades in any number of contexts, and it would have been obvious to do so in the context of the Valencell device as one way to achieve the performance benefits identified above. Ex.1003, ¶97.

Finally, Valencell-093 explains that "*the intensity* of the optical emitter 102 *may be increased* to increase the ratio of physiological optical scatter 111 from blood vessels with respect to unwanted sunlight." Ex.1005, [0123] (emphasis added). Valencell-093 therefore teaches that the LED emitter has the claimed "*initial light intensity*" (which then can be increased). A processor controls operation of these emitters, such that the "*measurement device is configured*" as claimed. Ex.1005, [0007], [0107]; Ex.1003, ¶89.

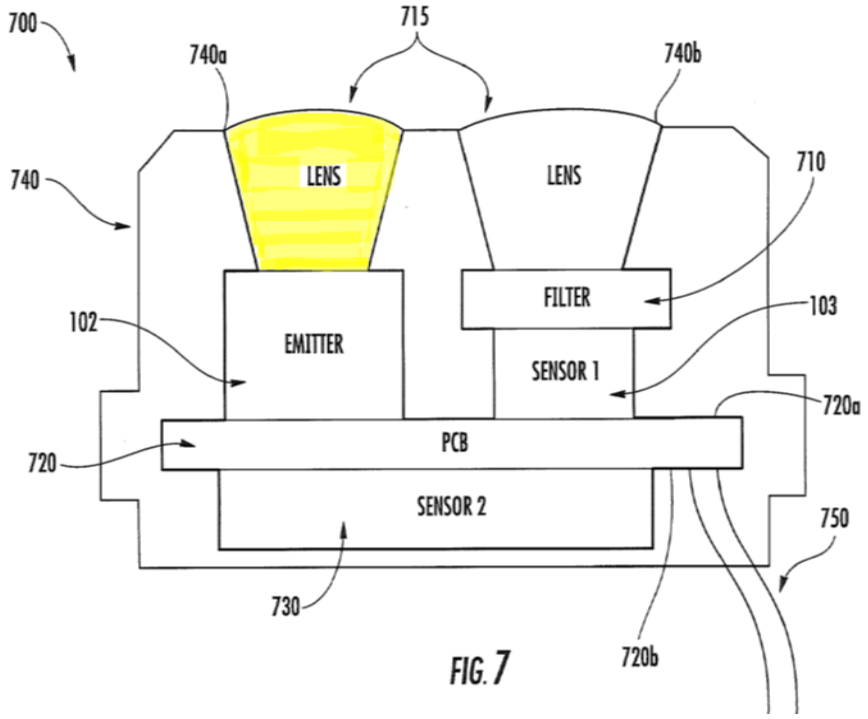
d) "[the input optical beam] having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers"

Valencell-093 teaches that the LEDs generate light beams having one or more optical wavelengths. Ex.1005, Fig. 2 (110), [0109] ("one or more optical sources emitting one or more optical wavelengths"), [0137]. In one embodiment, "the optical emitter 102 is configured to emit wavelengths centered around 930 nm." Ex.1005, [0117]. An LED with a wavelength centered around 930 nanometers emits a near-infrared wavelength of light as described by this limitation of the claim. Ex.1003, ¶100.

e) "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue,

wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue"

As shown in Figure 7 (annotated), Valencell-093 discloses one or more lenses for focusing light onto the user's tissue:



Ex.1005, Figs. 7 (715), [0016], [0135]. The disclosed lenses are transparent and can focus or collimate light. Ex.1005, [0118], [0119], [0125], [0128].[9] Valencell-093 therefore teaches one or more transparent surfaces used to collimate (make parallel) or focus rays of light. Ex.1003, ¶102.

[9] This disclosure also meets the definitions of lens proposed by Omni and by the court in the related district court litigation. Ex.1003, ¶¶102-103.

Valencell-093 also teaches that the lens is "is in optical communication with the optical emitter" ("*receive[s]… a portion of the input optical beam*") and "focuses light emitted by the optical emitter" onto a target region of the user's ear ("*deliver[s] a portion of the input optical beam to tissue*"). Ex.1005, [0017], [0117], Fig. 7 (showing lens in contact with emitter).

As shown in Figure 2 (annotated), the tissue of the target region scatters and reflects the light delivered by the lens-covered emitter(s) 102:

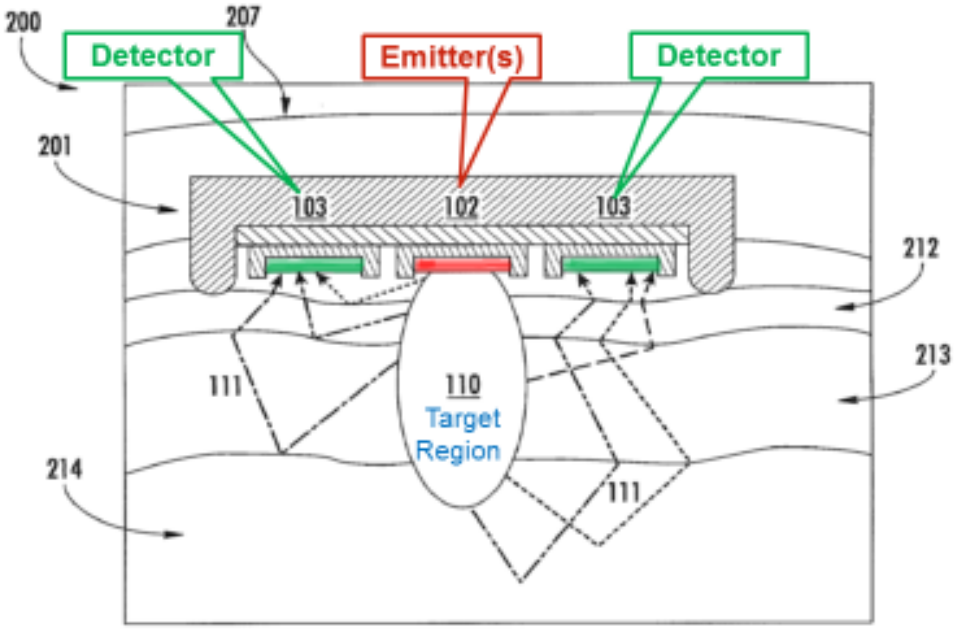
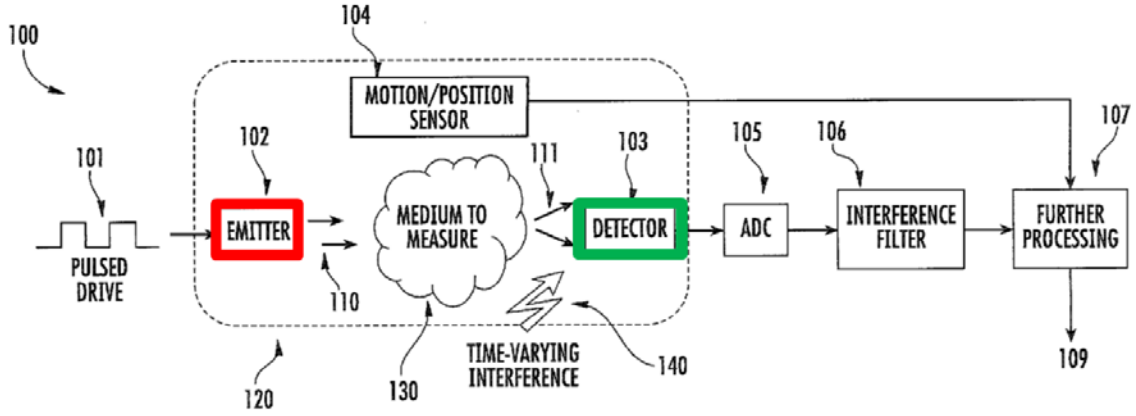


FIG. 2

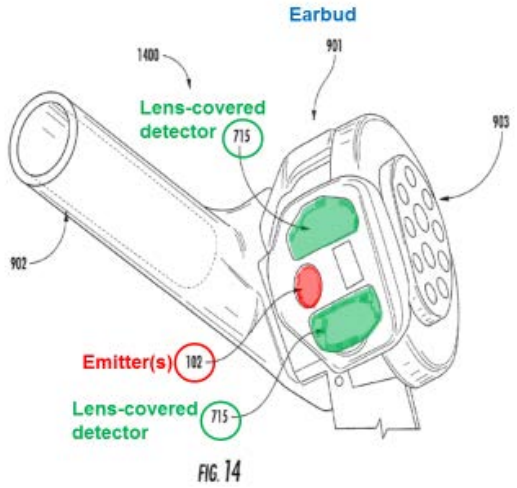
Ex.1005, Fig. 2 (111), [0107], [0109], [0118].

f) "the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors"

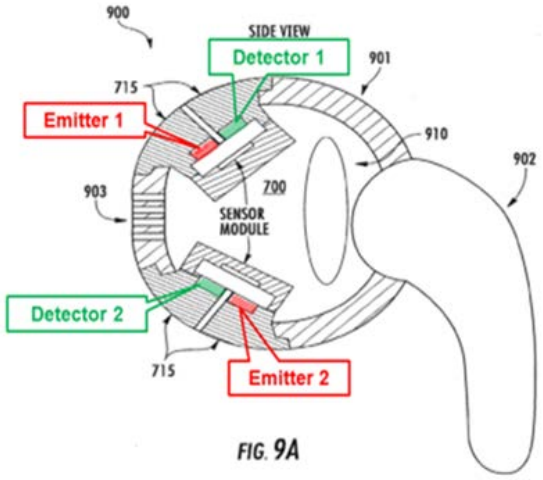
The Valencell-093 sensor includes a "*receiver*" comprising multiple optical detectors, which are controlled by a processor. Ex.1005, Figs. 2 (103), 9-11, 14, 15; [0007], [0107], [0038]; Ex.1003, ¶¶105-106.



Valencell-093 discloses that "multiple emitters, detectors…may be employed within a sensor module." Ex.1005, [038], Figs. 2 (103), 9-11, 14, 15. Figure 14 provides an example, showing two spatially separated detectors 715:



Ex.1005, [0130] ("a multi-detector earbud 1400"). Similarly, Figure 9A shows an earbud having two spatially separated detectors.



Ex.1005, Fig. 9A, [0122].

g) "the detectors 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 input optical beam reflected from the tissue;"

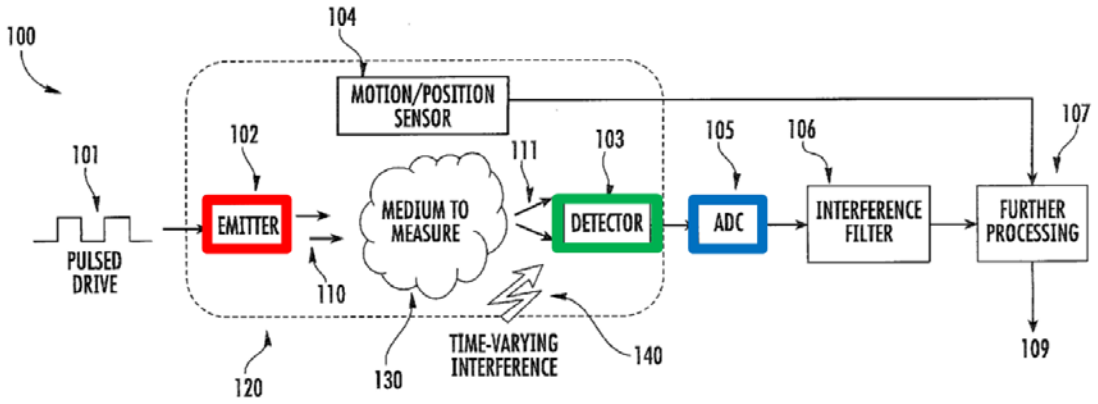
As described in limitation (f), Valencell-093 describes an earbud sensor having a "*receiver*" comprising a plurality of spatially separated detectors, controlled by a processor such that they are configured to operate as claimed. Ex.1005, Figs. 1, 2, 7-17, [0007], [0107], Ex.1003, ¶¶107-109. Each detector is configured to "*capture light*" when the near-infrared LED emitters are on and off as follows. Ex.1003, ¶108. Valencell-093 states that a "first optical interaction response is obtained by at least one detector" when the emitter is on and a "second optical interaction response, is obtained by the optical detector" when the emitter is off. Ex.1005, [0108], [0117]. Each optical interaction response represents "optical absorption, modulation, scatter, transmission, luminescence, or the like, from the physiological region 130" targeted by the LED emitters. Ex.1005, [0108]-[0109], [0117]. Thus, when an emitter is on and directing light to the user's tissue, the tissue reflects at least some of the light, which is then captured by the detectors. Ex.1005, Fig. 2, [0108], [0109], [0137], [0117]; Ex.1003, ¶108.

Each detector "*convert[s] the captured light*" into first and second energy response signals. Ex.1003, ¶109; Ex.1005, [0033] (detector "obtain[s] a first

energy response signal from the subject when the emitter is on" and "obtain[s] a second energy response signal from the subject when the emitter is off"), [0108] (detector produces "first and second energy response signals").

h) "wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at least a first data signal from the first signal and at least a second data signal from the second signal"

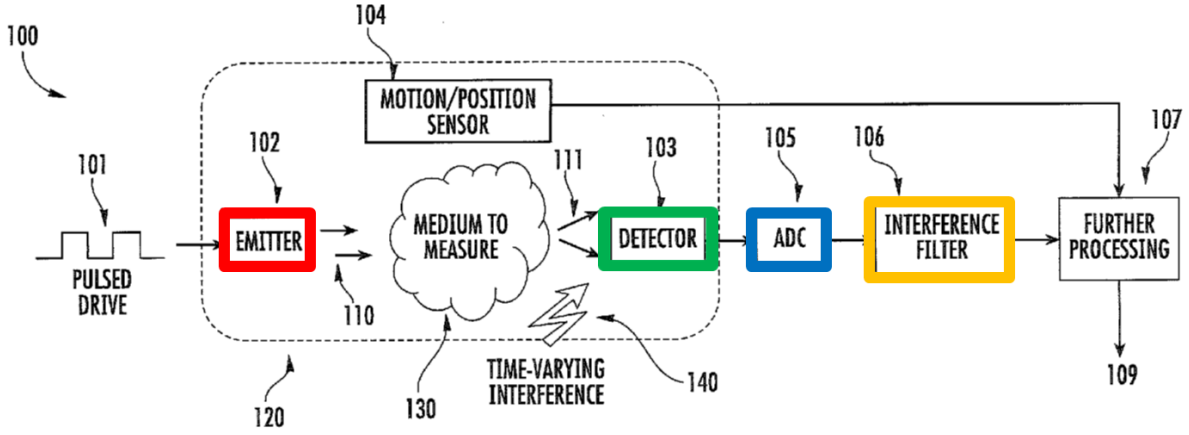
Figure 1 (annotated) of Valencell-093 shows analog-to-digital converter 105 coupled to detector(s) 103, which can be spatially separated. Ex.1005, Figs. 1, 9A, 14, [0107] ("The outputs of the detector 103 may be sent to at least one analog-to-digital convertor (ADC) 105"); Ex.1003, ¶¶ 11-112.



Valencell-093 explains that "[t]he first and second energy response signals are digitized by ***at least one ADC*** 105 and the ***digitized signals*** ("*at least a first data signal from the first signal and at least a second data signal from the second signal*") are processed via an interference filter 106 to produce a processed energy response signal." Ex.1005, [0108], Fig. 18, [0138]; Ex.1003, ¶¶111-112.

i) "the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue"

Valencell-093 explains that the "digitized signals" from the ADC ("*the first data signal and the second data signal*") "are processed via an interference filter 106." Ex.1005, [0108].



Ex.1005, Fig. 1. The interference filter "subtract[s] temporally neighboring emitter-off samples ("*first data signal*") … from temporally neighboring emitter-on samples ("*second data signal*")… and output[s] a 'subtraction' signal ("*differencing the first data signal and the second data signal*") for further processing." Ex.1005, [0139], Figs. 19A, 19B; Ex.1003, ¶114. The interference filter thus "produces a processed energy response signal that is associated with a physiological condition of the subject" ("*generate[s] an output signal representing*

at least in part a non-invasive measurement"). Ex.1005, [0108]; Ex.1003, ¶¶114-116. These physiological conditions can include "*measurements on blood*" such as blood oxygen level and cholesterol, among many others. Ex.1005, [0006], [0050], [0090], [0109]; Ex.1003, ¶116. These properties are non-invasively measured from light interaction with "blood vessels and/or blood flow within the ear region" ("*non-invasive measurement on blood contained within the tissue*"). Ex.1005, [0006], [0108], [109]; Ex.1003, ¶116.

Valencell-093 teaches that the purpose of this operation is to remove noise from a detected signal. Ex.1005, [0108] ("the filter removes time-varying environmental interference caused by an interferant, such as sunlight, ambient light, airflow, temperature, etc."), [0138], [0145]; Ex.1003, ¶117. A skilled person would have understood that removing noise from a detected signal increases a signal-to-noise ratio. Ex.1003, ¶117. The signal-to-noise ratio is calculated by dividing the signal power by the noise power: $\frac{S}{N}$. *Id*. Reducing or removing the noise power from this equation necessarily increases the signal-to-noise ratio. *Id*.

j) "wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency."

As explained for limitation (c), Valencell-093 teaches that the emitters are configured to emit "pulsed or modulated energy," that is "emitted in pulses and/or

that is emitted such that the amplitude, frequency, phase, or intensity is varied." Ex.1005, [0008], [0097], [0107] [0108] [0143]. As described by Valencell '093, these emitters have a "*modulation frequency*." Ex.1005, [0107] ("pulsed driving circuit 101 is used to drive at least one energy emitter 102 ***at one or more pulsed frequencies***"), [0097] ("'modulated energy'…is emitted such that …frequency… is varied"), [0108] ("time varying energy"). A skilled person would also understand that frequency modulated energy, as described by Valencell-093, would necessarily and inherently have a modulation frequency. Ex.1003, ¶119.

Valencell-093 further explains that this modulated "time-varying energy generates a time-varying energy response, typically an optical interaction response, such as optical absorption, modulation, scatter, transmission, luminescence, or the like, from the physiological region 130." Ex.1005, [0108]. Valencell-093 teaches that the detection of this time varying response is synchronized to the modulation frequency of the emitters as they turn on and off. Ex.1005, [0108] ("A first optical interaction response is obtained by at least one detector 103, typically an optical detector, when the pulsed optical energy 110 is in the on state. A second energy response, in this case a second optical interaction response, is obtained by the optical detector 103 when the pulsed optical energy 110 is in the off state."); Ex.1003, ¶120.

Valencell-093 explains that this technique "may modulate the physiological signal to a higher frequency." Ex.1005, [0144]. This is shown in Figure 21, annotated below, where "the modulated heart rate signal 2160 modulated by the emitter on/off sample rate" is shifted to the high end of a normalized frequency spectrum. Ex.1005, [0145]; Ex.1003, ¶120.

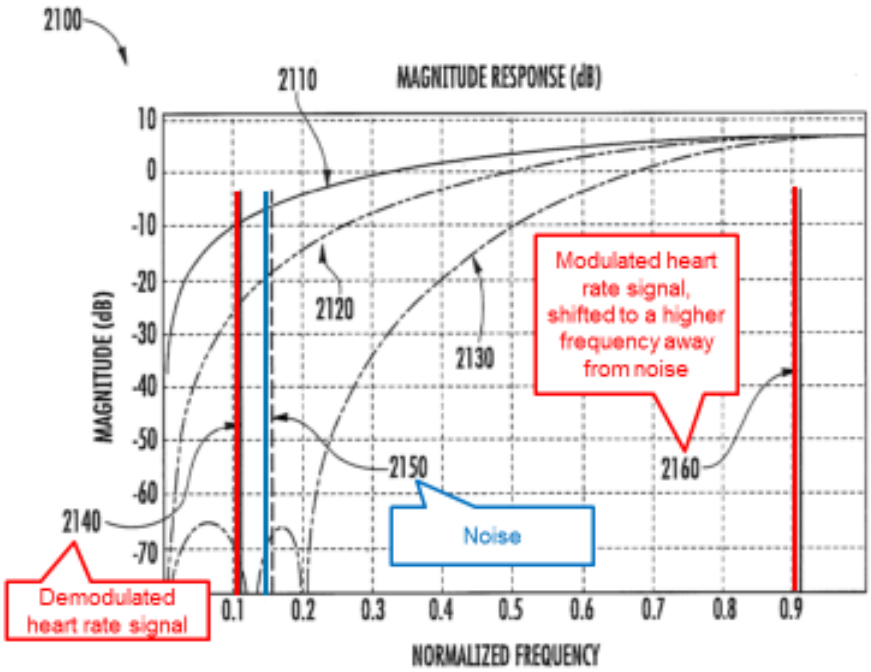


FIG. 21

A noise signal from sunlight 2150 is shown at the low end of the spectrum, away from the modulated heart rate signal. Three different exemplary filters 2110, 2120, and 2130, can be used to filter out this noise. Ex.1005, [0146] ("Because the dominant sunlight noise frequencies 2150 may be located at lower frequencies, and because the modulated heart rate signal frequency 2160 may be located at a much

higher frequency, most or all of the sunlight noise 2150 may be rejected by the interference filter 2130.”). Once the noise is removed, “the heart rate signal can be returned to the baseband [shown as signal 2140] so that real-time heart rate may be extracted.” Ex.1005, [0146].

Valencell-093 does not specifically call this frequency-shifting and filtering process a “lock-in technique that detects a modulation frequency.”[10] But a skilled person would have understood that the detection of the time varying response synchronized to the modulation frequency as described by Valencell-093 is one example of a lock-in technique. Ex.1003 ¶121. This conclusion is supported by Carlson, which describes the same kind of processing steps as part of what it calls

[10] While the parties originally proposed different constructions for “lock-in,” they agreed before the Markman hearing to the district court’s preliminary construction: “plain and ordinary meaning. The ‘lock-in technique’ is not any technique that ‘lessens noise outside the modulation frequency.’” Ex.1043, 6. The district court’s negative qualification was a rejection of Omni’s proposal that “the receiver is configured to detect the modulation frequency of the optical beam and lessens noise outside the modulation frequency.” Ex.1045. This petition uses the plain and ordinary meaning, as agreed to by the parties.

"Lock-in Amplification (synchronous detection)." Ex.1009, [0020]; Ex. 1003, ¶¶122-123. Carlson explains:

> at least one light source frequency modulating means to frequency modulate the optical radiation of the light source at a carrier frequency to shift the power spectrum of the pulsoximeter signals. ***The basic idea of using AC-Coupling or Lock-In Amplification (synchronous detection), is to temporarily modulate the amplitude of the optical radiation*** of, e.g., the LED at a carrier frequency f_c ***to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent***. Thus, the pulsoximeter signals are readily discriminated from electronic and parasitic contributions of environmental optical radiation outside the frequency range of, e.g. f_c +/-5 Hz, increasing significantly the S/N (Signal/Noise)- and S/B ratio.

Ex.1009, [0020], [0065]. Carlson explains that "Lock-in Amplification is well known out of the state of the art." Ex.1009, [0065].

A skilled person reading Valencell-093, which describes the same frequency shifting and filtering technique described by Carlson, would have recognized that the Valencell-093 technique is the well-known lock-in technique, even though it is not specifically labeled as such. Ex.1003, ¶123. This is also consistent with how the '698 patent describes lock-in, as "detecting at the same frequency as the pulsed light source and also possibly phase locked to the same signal" in order to "reject

background or spurious signals and increase the signal-to-noise ratio of the measurement." Ex.1001, 21:51-55. Valencell-093 therefore both discloses and renders obvious this claim limitation. Ex.1003, ¶¶113-123.

Should Patent Owner argues that Valencell-093 does not disclose the claimed lock-in technique, a skilled person would have found it obvious to include the lock-in technique of Carlson in the Valencell-093 device for the reason Carlson identifies: to increase signal-to-noise ratio. Ex.1009, [0020], [0069]; Ex.1003, ¶124. Carlson teaches that lock-in allows "pulsoximeter signals [to be] readily discriminated from electronic and parasitic contributions of environmental optical radiation…increasing significantly the Signal-to Noise and Signal-to-Background ratio." Ex.1006, [0069]. Like Carlson, Valencell-093 recognizes the desirability of removing noise from a signal, and a skilled person would have turned to the lock-in detection described by Carlson as a known way of doing so. Ex.1003, ¶124; Ex.1019, 766 (lock-in detection allows "improved selectivity and enhanced signal-to-noise ratio").

The skilled person also would have recognized that incorporating the lock-in technique described by Carlson into the Valencell-093 sensor would involve combining familiar elements according to known methods, yielding predictable results. Ex.1003, ¶125. Lock-in is a known technique commonly used with optical sensors. Ex.1009, [0065]; Ex.1003, ¶125. Indeed, the '698 specification provides

little explanation of this technique, reflecting its conventional nature. *See* Ex.1001, 13:36-44, 21:51-55. A skilled person would have been able to reasonably predict that the effect of incorporating this known technique into the Valencell-093 device would be to filter out noise and improve a signal-to-noise ratio. Ex.1003, ¶125.

Thus, Valencell-093, either alone or in view of Carlson, teaches this element of claim 1.

5. Claim 2

Claim 2 depends from claim 1 and specifies "*wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply*."

The Valencell-093 sensor includes a plurality of LEDs and a plurality of spatially separated detectors. Ex.1005, [038]; Figs. 2 (103), 9-11, 14, 15. These components may be integrated within a printed circuit board ("PCB") assembly such that they are "*mounted on a common structure*" as claimed.

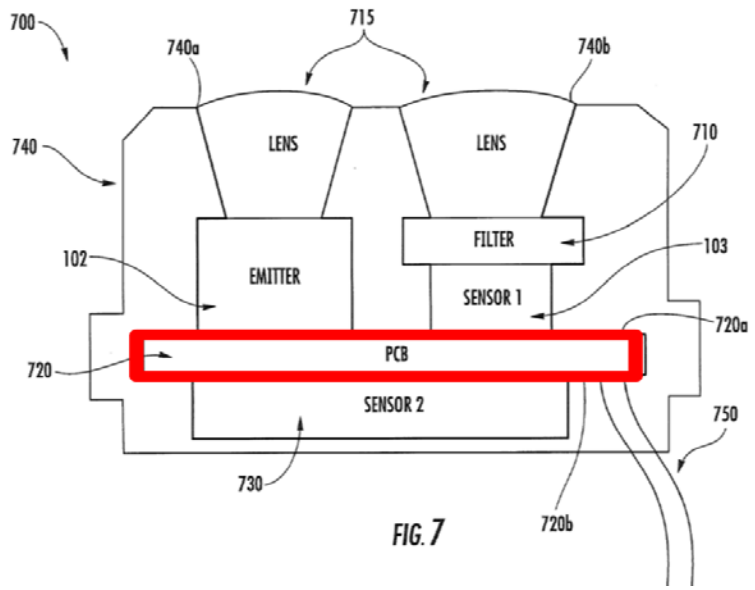


FIG. 7

Ex.1005, Fig. 7 (annotated), [0120]. Figure 9A (annotated) shows these components mounted on an earbud housing, another example of a "common structure." Ex.1005, Fig. 9A (700, 901), [0122]. Figure 14 (annotated) likewise shows the LED emitters and detectors mounted on a common structure, highlighted in yellow:

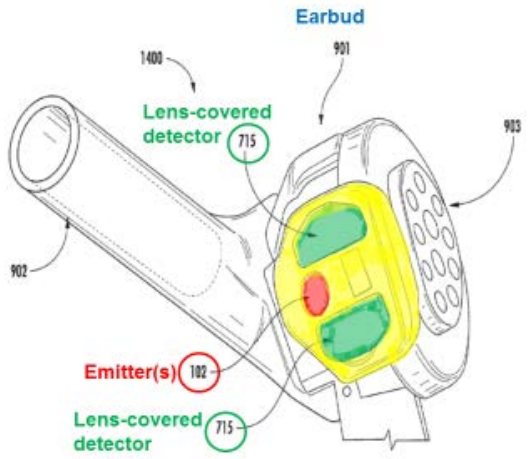


FIG. 14

Valencell-093 teaches that these components are part of a Bluetooth headset, which a skilled person would have understood to include an internal power supply, such as a battery, electronically coupled to components of the headset, including the LEDs. Ex.1003, ¶130. Such an internal power supply is necessary for the headset to operate wirelessly according to its intended purpose, unconnected by a wire or cable to an external power source. *Id*. A skilled person would have been motivated to put a battery in an electronic device to make it portable thereby granting the user more freedom to move around while using the device. *Id*.

Should Patent Owner argue that the earbud embodiment of Valencell-093 does not include a power supply, the wristband embodiment of Valencell-093 includes this aspect of claim 2. Ex.1003, Fig. 23-29. Valencell-093 teaches that "[t]he wristband 2300 houses ***a power source***…." Ex.1005, [0151] (emphasis added). A skilled person would have understood that the terms "power source" and "power supply" in the context of these devices would be used interchangeably, and that the described power source is a power supply as that term is used in claim 2. Ex.1003, ¶131. A skilled person would have further understood that the LEDs are electrically coupled to this power supply so that the LEDs can be powered on. *Id*. While this coupling is not explicitly identified in Valencell-093, a skilled person would have understood that it is necessarily present in order for the LEDs to function. *Id*.

A skilled person also would have understood that a power supply as described in the wristband embodiment would be included in the earbud embodiment. Ex.1003, ¶132. As explained by Valencell-093, "aspects of the invention described with respect to one embodiment may be incorporated in a different embodiment although not specifically described relative thereto. That is, all embodiments and/or features of any embodiment can be combined in any way and/or combination." Ex.1005, [0051], [0151] ("[t]he wristband 2300 includes a power source…as described above with respect to the various earbud embodiments").

Should Patent Owner contend that Valencell-093 does not teach that the described headset has a power supply, it would have been obvious to include the power supply identified in the wristband embodiment in the headset. Ex.1003, ¶133. This simple arrangement of known elements (a power supply and optical sensor), with each performing the same function it had been known to perform (the battery supplying power; the optical sensor emitting, detecting, and processing light), would have yielded precisely the expected result of this arrangement: the optical device operates using power from the power supply. Ex.1003, ¶133.

6. Claim 3

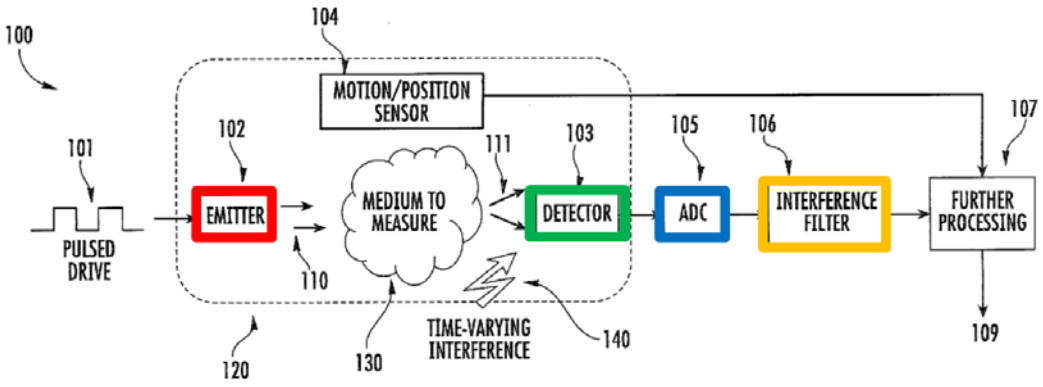
Claim 3 depends from claim 1 and specifies "*wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected*

from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs." Valencell-093 teaches these limitations.

Valencell-093 teaches that "the intensity of the optical emitter 102 may be increased to increase the ratio of physiological optical scatter 111 from blood vessels with respect to unwanted sunlight." Ex.1005, [0123], [0117]. The LED emitter is controlled by a processor such that it is configured to operate as claimed. Ex.1005, [0007], [0107], [0108]; Ex.1003, ¶¶135-138. Increasing the light intensity of optical emitter 102 as Valencell-093 describes would necessarily be relative to an initial light intensity of the emitter prior to the increase. Ex.1003, ¶135. Valencell-093 therefore teaches increasing the light intensity of at least one of the LEDs relative to an initial light intensity. *Id*.

Valencell-093 also teaches that "physiological optical scatter 111 from blood vessels" is comprised of light from the input optical beam reflected from the user's tissue. Ex.1005, [0123], [0107], [0108]. It also teaches that unwanted sunlight is noise. Ex.1005, [0112], [0145]. A skilled person would understand that the ratio of optical scatter 111 to unwanted sunlight is a "*signal-to-noise ratio of the input optical beam reflected from the tissue,*" and that increasing the disclosed ratio would "*further improve*" this signal-to-noise ratio. Ex.1003, ¶136.

Valencell-093 also teaches that the "*receiver*" includes an analog-to-digital converter ("ADC") that receives and digitizes output signals from the optical detectors.



Ex.1005, Figs. 1, 18, [0107]; Ex.1003, ¶137. The sample rate of the ADCs is synchronized to the pulse rate of the emitters. Ex.1005, Figs. 18, 19A, 19B (showing digital sampling of a signal), [0137], [0144]; Ex.1003, ¶137. As shown in Figure 18, at least one ADC sample is read when the emitters are on and then at least one ADC sample is read when the emitters are off.

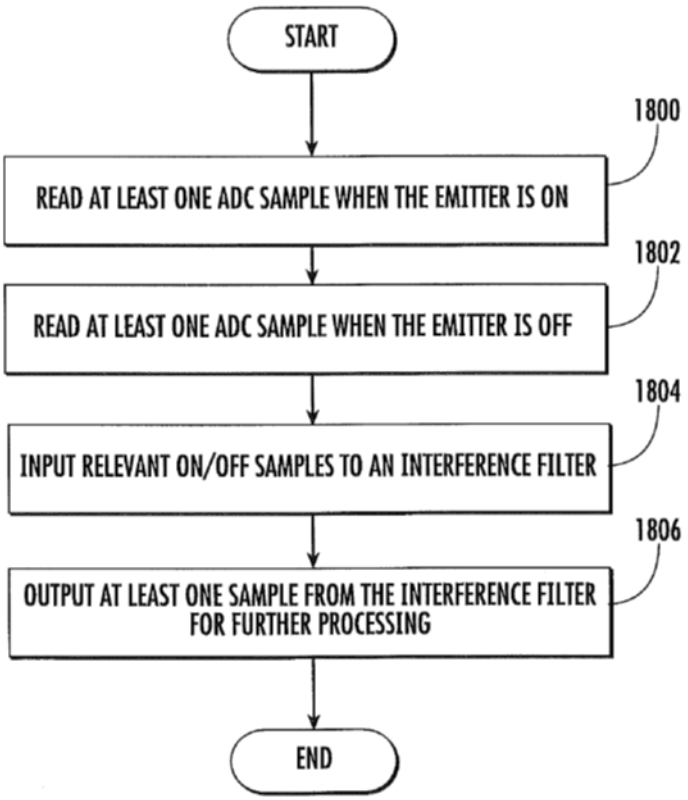


FIG. 18

Ex.1005, Fig. 18, [0137]. The operations of the modulated LED emitter and the receiver, comprised of the detectors and at least one ADC, are therefore synchronized. Ex.1003, ¶137. This is consistent with the only statement in the ’698 Patent about what it means to be “synchronized.” Ex.1001, 14:38-40 (“In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source.”). Valencell-093 therefore teaches that “the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.” Ex.1003, ¶137.

Thus, Claim 3 would have been obvious based on Valencell-093, alone or in combination with Carlson, as described for Claim 1.

B. <u>Ground 2</u>: Valencell-093, With or Without Carlson, and Hanna Render Obvious Claims 1-3

As indicated in Ground 1, Patent Owner may contend that Valencell-093 does not teach modulating one or more LEDs to include information. Modifying the Valencell-093 device to do that, however, would have been obvious based on Hanna (Ex.1007). Hanna issued on January 7, 2003, and is prior art under 35 U.S.C. § 102(a)(AIA).

Hanna describes a pulse oximeter that can be applied to a user's ear or finger to measure oxygen saturation or other constituents of the user's blood:

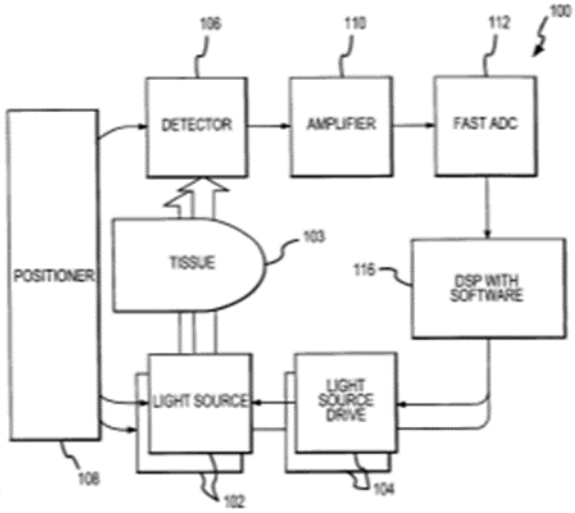


FIG.1

Ex.1007, Fig. 1, 1:25-39. As shown, the sensor has multiple emitters 102, which can be a red LED and an infrared LED. Ex.1007, 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. Hanna explains that the purpose of encoding the light is to "allow the contribution of each source to the detector output to be determined." Ex.1007, 1:49-51, 2:23-29. The described coding technique also allows the detector to discriminate between noise and a signal of interest, 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 describes, each code is identifying information that is included in a modulated emitter signal. Ex.1007, 6:13-8:25, Ex.1003, ¶140. Thus, Hanna teaches modulating light to include information, as required by the district court's preliminary claim construction. Ex.1003, ¶140.

Hanna teaches using this technique in the same kind of optical sensor described by Valencell-093, and identifies the benefits of doing so, including to better extract discrete optical signals from multiple emitters in the presence of noise. Ex.1003, ¶¶143-145. Both Hanna and Valencell-093 recognize the desirability of removing noise from a signal of interest. Ex. 1007, 2:3-31; Ex.1005, [0112], [0005]. A skilled person would have understood the importance of removing noise this in the context of a wearable device and would have considered

known techniques for accomplishing this objective. Ex.1003, ¶¶141-143. A skilled person would have considered the coding technique described by Hanna as a known way of accomplishing this objective, recognizing that implementing the Hanna technique in the Valencell sensor would improve its performance in the same way the techniques improved the performance of the Hanna sensor. Ex.1003, ¶¶144-145. That skilled person would have been motivated to incorporate the modulated coding techniques described by Hanna into the sensor described by Valencell, with or without modifications as described by Carlson, to improve the performance of a wearable, wireless device consistent with prevailing market demands. Ex.1003, ¶¶143-146.

Hanna, Valencell-093 and Carlson also would have been considered together because they describe analogous devices for measuring physiological parameters and applications of those devices. Ex.1003, ¶146. The skilled person would have considered these analogous references together when implementing a system based on these teachings. Moreover, as explained in § III.B, by 2012, there was a general trend in the industry to create wearable devices that can be used in mobile monitoring situations or for sports and personal fitness applications. The skilled person would have had reason to look to references describing analogous devices with similar applications when considering how to create or improve wearable devices for these mobile health and consumer applications. Ex.1003, ¶146.

Thus, Valencell-093, with or without Carlson as described in Ground 1, in combination with Hanna renders claims 1-3 obvious.

C. <u>Ground 3</u>: Valencell-099 Would Have Made Dependent Claim 5 Obvious

Claim 5 depends from claim 1 and specifies:

> wherein the wearable device is configured to communicate with ***a smart phone or tablet***,
>
> the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen,
>
> the smart phone or tablet configured to ***receive and to process*** at least a portion of the output signal, wherein the smart phone or tablet is configured to ***store and display*** the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a ***wireless transmission link***.

As explained below, claim 5 would have been obvious based on Valencell-093, with Carlson and Hanna as described in Grounds 1 and 2, and Valencell-099.

1. Overview of Valencell-099

Valencell-099 was filed on February 22, 2010, and published on August 26, 2010. It is prior art under 35 U.S. § 102(a) (AIA).

Like Valencell-093, Valencell-099 describes a Bluetooth headset that includes a sensor for measuring physiological conditions such as blood metabolite level, blood oxygen level, protein levels and water content of blood, and

cholesterol, among many others. Ex.1006, [0007], [0010], [0076]. The headset is part of a health and environmental monitoring system that can be used by doctors, dieticians, the user, and others for a variety of health and fitness related applications based on data collected by the system. Ex.1006, [0110]-[0130]. The headset includes a sensor module, shown below as element 21 of Fig. 2, which can be an optical sensor. Ex.1006, [0095].

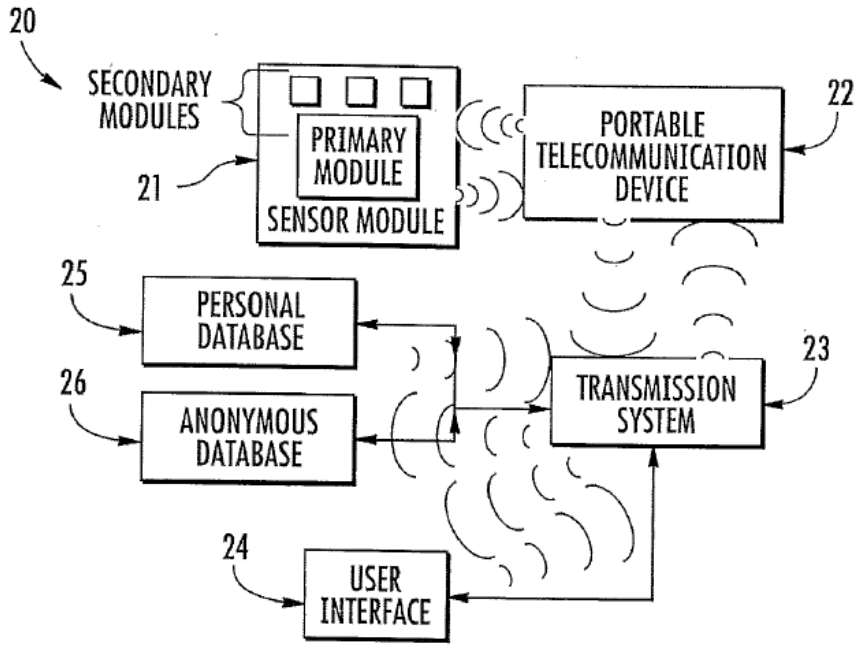


FIG. 2

Valencell-099 explains that the sensor module 21 communicates wirelessly with portable telecommunication device 22, which can be a smart phone, laptop computer, or other portable device. Ex.1006, [0096]. Valencell-099 explains that the portable telecommunication device can store, analyze, summarize, and display

data from the sensor. Ex.1006, [0097]. It also transmits the local wireless signal from the sensor over long distances not attainable by the short range (Bluetooth) transmitter within the sensor. Ex.1006, [0096]. Using transmission system 23, the portable telecommunication device can wirelessly transmit information to remote databases 25 and 26 for storage, analysis and retrieval of data. Ex.1006, [0098].

2. A Skilled Person Would Have Considered Valencell-099 with Valencell-093, Carlson and Hanna

Before December of 2013, a skilled person would have considered the systems and devices described by Valencell-093 in conjunction with those in Valencell-099, as both describe a Bluetooth headset designed by Valencell to measure physiological conditions using a physiological sensor, and to collect and use data generated by this device to monitor health and other conditions. Ex.1003, ¶¶152-155. A skilled person reading either reference would have naturally considered other Valencell references describing the same device to understand its operational aspects, as well as its applications and uses. Ex.1003, ¶156.

Both Valencell references identify the same objective of meeting a "growing market demand for personal health and environmental monitors," while describing complementary aspects of a device and system that meet this objective. Ex.1005, [0003]; Ex.1006, [0003]; Ex.1003, ¶157. Valencell-093 focuses on teaching "how to make a wearable monitor, such as an earbud monitor, that may provide accurate information on physiological conditions in the midst of environmental noise,"

while Valencell-099 focuses on improved ways to collect "health and environmental exposure statistics" of users "to direct healthcare resources to where they are most highly valued." Ex.1005, [0003]; Ex.1006, [0003].

Driven, *inter alia*, by general market trends and needs, a skilled person reading Valencell-093 would have looked to Valencell-099 for guidance on how its remote device could be used to store and analyze collected data. Ex.1003, ¶158. Valencell-093 identifies this application, stating that a "processed energy response signal [from the described sensor] is transmitted to a remote device, for example wirelessly transmitted." Ex.1005, [0035]. Valencell-093 also identifies the benefits of incorporating a physiological sensor into a Bluetooth headset, which was commonly known to wirelessly communicate with another device such as a cell phone. Ex.1005, [0104].

Valencell-093 does not describe how the cellphone or other remote device should be configured to process the signals received from the sensor. That precise guidance, however, is provided by Valencell-099, which teaches that "[h]ealth and environmental information, sensed by the sensors [in an earpiece of a Bluetooth headset] is transmitted wirelessly, in real-time, to a recording device, capable of processing and organizing the data into meaningful displays, such as charts." Ex.1006, [0018]. Valencell-099 then describes in Figures 1 and 2 a smart phone for receiving "data from a wearable sensor module 21" that can be "stored,

analyzed, summarized, and displayed" by the smart phone. Ex.1006, [0097]; Figs. 9-21. It also teaches that the smart phone "sends/receives wireless information directly to/from a transmission system 23 for transmission to a database … for storage, analysis, and retrieval of data." Ex.1006, [0098]. The databases can include "aggregated health and environmental data" from multiple users or "health and environmental data that is personalized" for each user. Ex.1006, [0099].

Conversely, the skilled person reading Valencell-099 would have looked to Valencell-093 for guidance on how to build an optical sensor incorporated into its Bluetooth headset. Ex.1003, ¶¶157-159. Figures 1 and 2 of Valencell-099 show a monitoring device and system that includes physiological sensors 11 and sensor module 21. Ex.1006, Figs. 1, 2. Sensor 11 "can be any compact sensor for monitoring the physiological functioning of the body." Ex.1006, [0076]. Sensor module 21 can be a PPG sensor placed in or near an ear of the user. Ex.1006, [0101]. Valencell-099 does not describe the specific structure or operation of sensor 11 or sensor module 21, but Valencell-093 provides that information, teaching an optical sensor incorporated into an earbud that can remove or prevent environmental noise, as described above in Ground 1.

In addition, skilled persons recognized that building an optical health monitor to meet the evolving demand for a small, wearable, wireless device would turn to the prior art to find solutions to challenges encountered in developing such

devices. *See, e.g.*, Ex.1005, [0003] ("traditional wearable health monitors cannot measure physiological information accurately in typical daily environments"); Ex.1003, ¶152. One such challenge was extracting information of interest generated by these devices from a noisy signal. Ex.1003, ¶152. Such noise comes from many different sources, such as "environmental interference from sunlight, temperature changes, and motion-coupled environmental noise, [which] can present measurement artifacts on wearable health monitors." Ex.1005, [0003]. "These measurement artifacts can reduce sensor accuracy, generate false measurements, and prevent accurate health, fitness, and vital status monitoring." Ex.1005, [0003]. Valencell-093 teaches how to build a sensor that can mitigate the effects of noise, and a skilled artisan looking to build the device described by Valencell-099 would have incorporated the teachings of Valencell-093 to build a wearable, wireless device that can provide accurate data. Ex.1003, ¶¶153-156.

Moreover, a skilled person would have combined the lock-in teachings of Carlson as described in Ground 1 and the coding technique of Hanna as described in Ground 2 with the teachings of Valencell-093 to build a sensor that mitigates the effects of noise. Ex.1003, ¶160. A skilled person looking to build the device described by Valencell-099 would have incorporated the combined teachings of Carlson, Hanna and Valencell-093 to build a wearable wireless device that can

provide accurate data, in accordance with prevailing market demands. Ex.1003, ¶¶152-155, 160.

A skilled person looking to build a "personal and health environmental monitor" would therefore look to the complementary teachings of Valencell-093, with or without Carlson or Hanna, in combination with Valencell-099 to build a wireless, wearable device that can collect accurate physiological information in the presence of noise and then communicate that information to other devices for storage and analysis. Ex.1003, ¶159. A skilled 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 all three references place on providing accurate health data. *Id*.

Valencell '099, Valencell '093, Hanna and Carlson also would have been considered because they describe analogous devices for measuring physiological parameters and applications of those devices. Ex.1003, ¶160. The skilled person would have considered these analogous references together when implementing a system based on these teachings. Moreover, as explained in § III.B, by 2012, there was a general trend in the industry to create wearable devices that can be used in mobile monitoring situations or for sports and personal fitness applications. Thus, the skilled person would have had reason to look to references describing analogous devices with similar applications when considering how to create or

improve wearable devices for these mobile health and consumer applications. Ex.1003, ¶160. Thus, the skilled person would have had reason to look to references describing analogous devices with similar applications when considering how to create or improve wearable devices for these applications. *Id*.

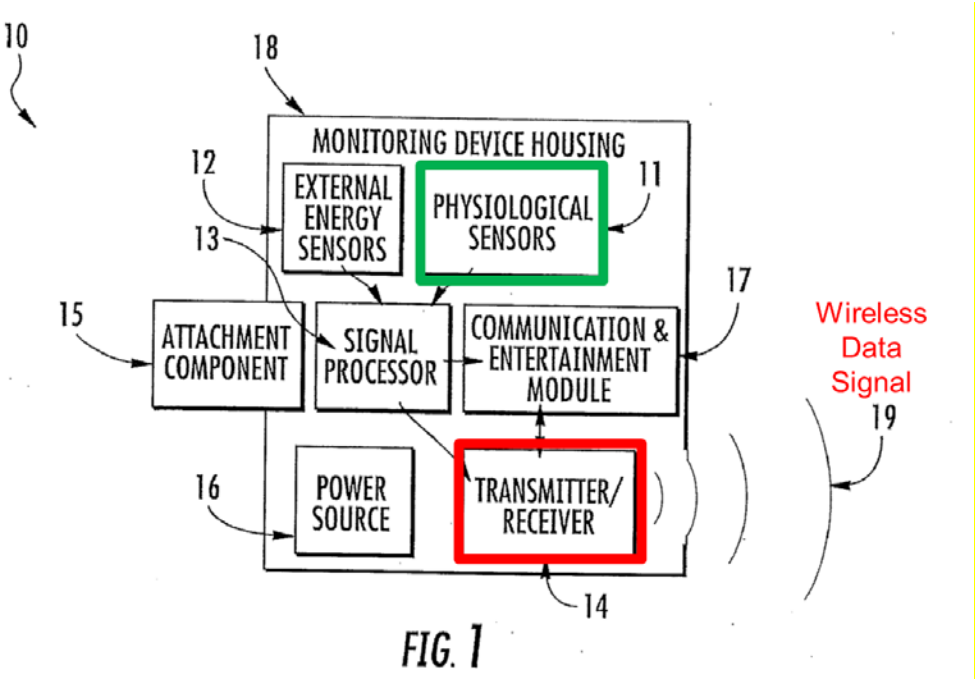
3. Claim 5

a) "wherein the wearable device is configured to communicate with a smart phone or tablet,"

Valencell-093 teaches that its physiological sensor can be incorporated into a wearable Bluetooth headset that can wirelessly communicate with a remote device such as "cell phone." Ex.1005, [0035] [0104]. It was well-known before December of 2013 that a smart phone is a type of cell phone, and a skilled person would have used the terms interchangeably. Ex.1003, ¶163. Bluetooth headsets also were routinely used at that time with smart phones and tablets for both "personal communications and multimedia applications." Ex.1005, [0104]; Ex.1003, ¶163. Thus, a skilled person would have considered Valencell-093 to teach configuration of its wearable headset for use with a remote device such as a smart phone or tablet. Ex.1003, ¶163.

Valencell-099 teaches that this remote device is a smart phone or tablet configured to receive, process, store and display output signals received from a wearable device such as that in Valencell-093. Figure 1 of Valencell-099 shows

such a “wearable monitoring device” 10, which includes physiological sensors 11 and a transmitter/receiver 14 for transmitting and receiving wireless data 19:



Ex.1006, [0074] (wearable monitoring device 10), [0076] (physiological sensor 11); [0083]-[0086] (wireless transmitter/receiver 14); [0085] (wireless data signal 19); [0070] (“Bluetooth® enabled and/or other personal communication headsets may be configured to incorporate physiological and/or environmental sensors, according to some embodiments of the present invention.”). The wireless data signal 19 can represent a “*non-invasive measurement on blood*,” like the output of the sensor described by Valencell-093. Ex.1006, [0010] (listing physiological information, including “blood metabolite levels or ratios, blood pH level”), [0139] (“noninvasive”), [0145]-[0146] (listing noninvasive physiological information).

Valencell-099 also explains that the wireless data signal 19 can be sent to a "portable telecommunications device 22" such as a smart phone or tablet. Ex.1006, [0018], [0096] ("telecommunication device 22 can be any portable device, such as a cell phone (which includes a 'smartphone'), PDA, laptop computer, Blackberry, another earpiece, or other portable, telemetric device."). A skilled person would immediately envisage a tablet from these teachings. Ex.1003, ¶164.

Both Valencell references thus teach this limitation of dependent claim 5.

Should Patent Owner content that Valencell-093 does not teach this limitation, it would have been obvious based on the complementary teachings of the Valencell references to use a Bluetooth headset with a sensor as described in Valencell-093 with a smart phone or tablet as described in Valencell-099 in order to produce a wearable wireless device meeting market demands. Ex.1003, ¶164

b) "the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen,"

Valencell-099 teaches that the portable telecommunications device 22 can be a smart phone or tablet, as described above. Nothing in the '698 Patent suggests that the terms "smart phone" or "tablet" were being used with a special meaning. Ex.1003, ¶166. It was well known that smart phones and tablets include a wireless

receiver, a wireless transmitter, a display, a voice input module such as a microphone, a speaker, and a touch screen. *Id*.

Valencell-099 also describes these claimed features as aspects of the portable telecommunication device 22. For example, the portable telecommunications device has a wireless receiver and wireless transmitter. Ex.1006, Fig. 2, [0096]-[0098]. The portable telecommunication device also has a display, voice input module, speaker and screen (see annotated Figure 9 below).

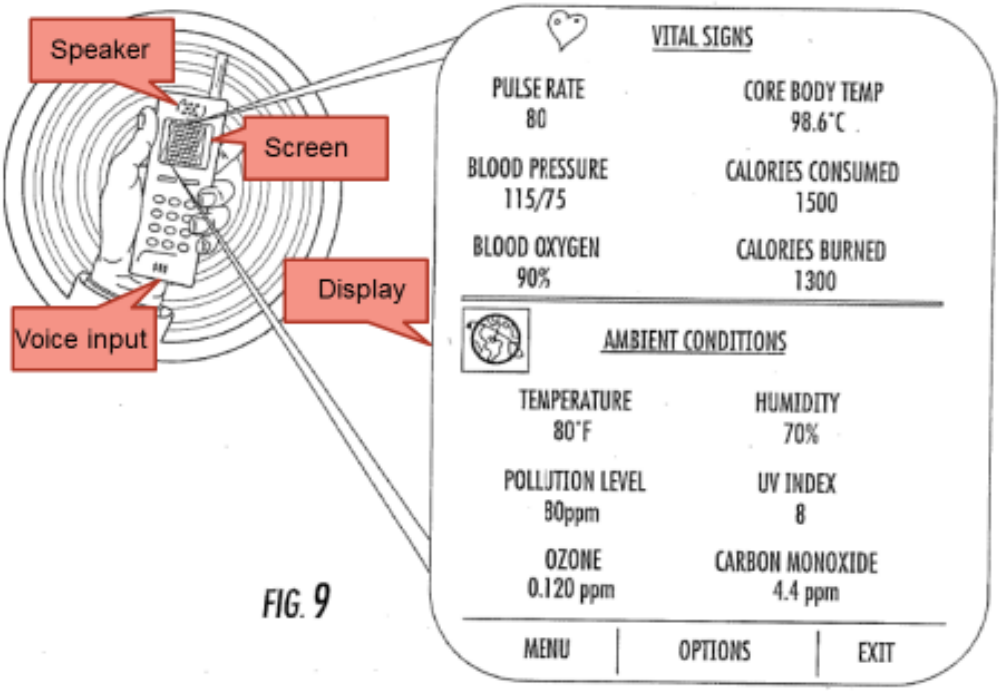


FIG. 9

Should Patent Owner contend that Valencell-099 does not explicitly describe the disclosed screen as being a touch screen, a skilled person would have considered a touch screen to be an obvious choice for this screen. Ex.1003, ¶168.

Valencell-099 describes a user interacting with handheld devices to view and manipulate the information obtained from the remote sensor. *See, e.g.,* Ex.1006, Figs. 9, 10. The logical and known options for handheld devices were smart phones and tablets with user interfaces that incorporate touch screens. Ex.1003, ¶166. A skilled person reading Valencell-099 also would have immediately envisaged a touch screen as one of a small number of known types of screens suitable for the types of described user devices. Ex.1003, ¶168. *See Kennametal, Inc. v. Ingersoll Cutting Tool Co.,* 780 F.3d 1376, 1381 (Fed. Cir. 2015); *In re Petering,* 301 F.2d at 681.

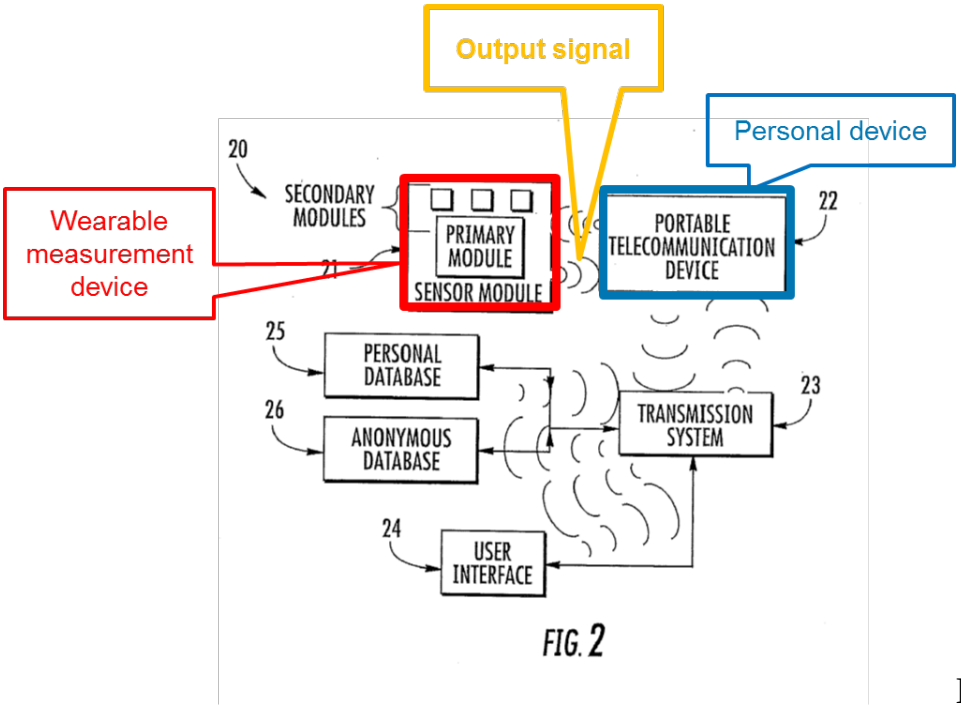
Valencell-093 (alone or with Carlson and/or Hanna as described in Grounds 1 and 2) in combination with Valencell-099 thus teaches and suggests a wearable device as described in claim 1 configured to communicate with a smart phone or tablet per claim 5.

c) "the smart phone or tablet configured to receive and to process at least a portion of the output signal,"

Valencell-093 and Valencell-099 each teach a wearable measurement device that generates an output signal—physiological signal 109 and wireless data signal 19, respectively. Both also teach wirelessly transmitting these signals to a smart phone or tablet. Ex.1005, [0035], [0096], [0104], [0110]; Ex.1006, [0018], [0083]-[0086], [0096], [0124]. A skilled person would understand that both Valencell

references teach a smart phone or tablet "*configured to receive …at least a portion of*" the transmitted "*output signal*." Ex.1003, ¶171.

Valencell-099 also teaches that personal communication device 22 (e.g., a smart phone or tablet) *receives* output signal 19 transmitted by sensor module 21 (corresponding to the wearable monitoring device shown in Figure 1):



Ex.1006, Fig. 2

(yellow represents wireless signals received by portable communication device), [0094]. Valencell-099 further teaches that "[t]he portable telecommunication device 22 and the wearable sensor module 21 can *telemetrically communicate both to and from each other*." Ex.1006, [0096] (emphasis added); *see also* [0014]; [0018].

Valencell-099 further teaches that the portable telecommunication device 22 is configured to receive ***and process*** the output signal 19. Ex.1003, ¶172. For example, "[i]n one embodiment, raw or preprocessed data from the sensor module 10, 21 is transmitted wirelessly to the telecommunication device 22, and *this device executes various algorithms* to convert the raw sensor data (from one or more sensors) into a meaningful assessment for the user." Ex.1006, [0124], [0014] ("receiving …and *analyzing the received information*"); (information "may undergo virtually any type of analysis" by a remote device), [0018] (sensor wirelessly transmits data to a remote device "*capable of processing and organizing the data* into meaningful displays, such as charts.") (emphases added).

Valencell-093 (alone or with Carlson and/or Hanna as described in Grounds 1 and 2) in combination with Valencell-099 thus teaches and suggests a wearable device as described in claim 1 configured to communicate with a smart phone or tablet, wherein "*the smart phone or tablet [is] configured to receive and to process at least a portion of the output signal*" received from the wearable measurement device described in Valencell-093. Ex.1003, ¶¶171-173.

d) "wherein the smart phone or tablet is configured to store and display the processed output signal,"

Valencell-099 explains that

> The portable telecommunication device 22 may also contain an end-user graphical interface, such as a user interface 24 in the monitoring

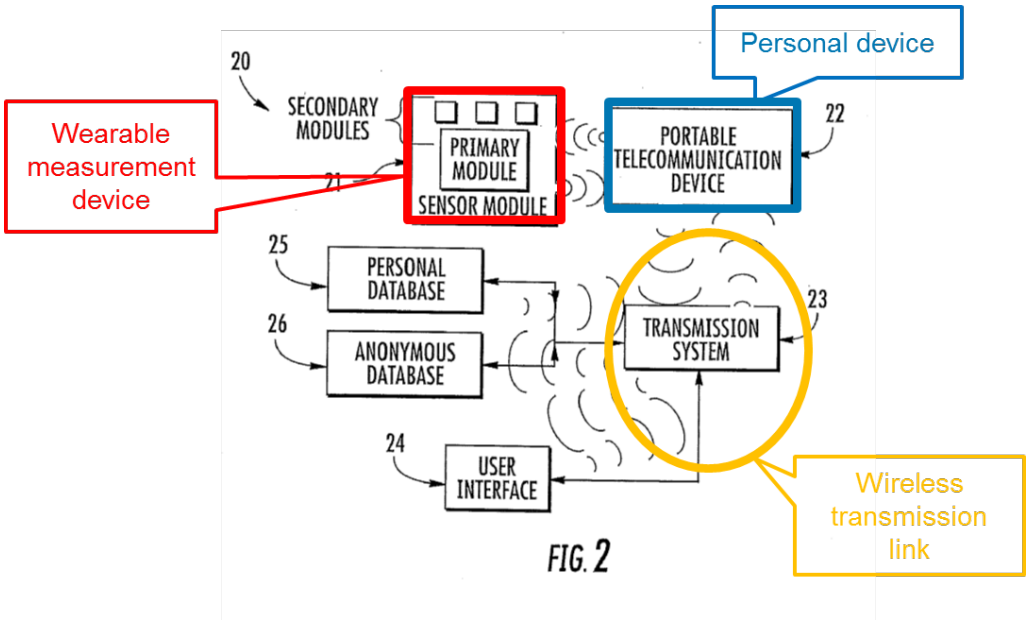
> system 20, such that data from the wearable sensor module 21 can be ***stored, analyzed, summarized, and displayed*** on the portable telecommunication device 22. For example, charts relating health and environment, as well as real-time biofeedback and the like, can be displayed on a cell phone, media player, PDA, laptop, or other device."

Ex.1006 [0097] (emphasis added); [0107], Fig. 9 (mobile device displaying processed data). In addition, a "data storage component" included in the portable telecommunication device 22 "allows ***processed*** signal data to ***be stored, analyzed and manipulated.""*** Ex.1006, [0108] (emphases added).

Valencell-093 in combination with Valencell-099 thus teaches a wearable device configured to communicate with a smart phone or tablet, "*wherein the smart phone or tablet is configured to store and display the processed output signal*" created by receiving and processing the output signal. Ex.1003, ¶¶175-176.

e) "wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link."

Figure 2 of Valencell-099 describes a portable telecommunication device 22 that can wirelessly communicate with other devices via transmission system 23.



Ex.1006, Fig. 2, [0098] ("The portable telecommunication device 22 sends/receives wireless information directly to/from a transmission system 23). The transmission system 23 is a *wireless transmission link* such as the Internet or "reception tower and routed through a base station." Ex.1006, [0098]. Ex.1003, ¶178.

The information transmitted over the wireless transmission system 23 to other devices such as databases 25, 26 or user interface 24 can include *at least a portion of the processed output signal* generated by personal telecommunication device 22, per claim limitation 5(d) above. Ex.1006, [0096] ("portable telecommunication device … transmit[s] the local wireless signal from the sensor module 21"), [0099] (databases store health data from multiple wearable sensor devices), [0100] (user interface displays health data). Figure 3 provides an

example of the health data displayed by user interface 24 based on information collected from one or more wearable measurement devices:

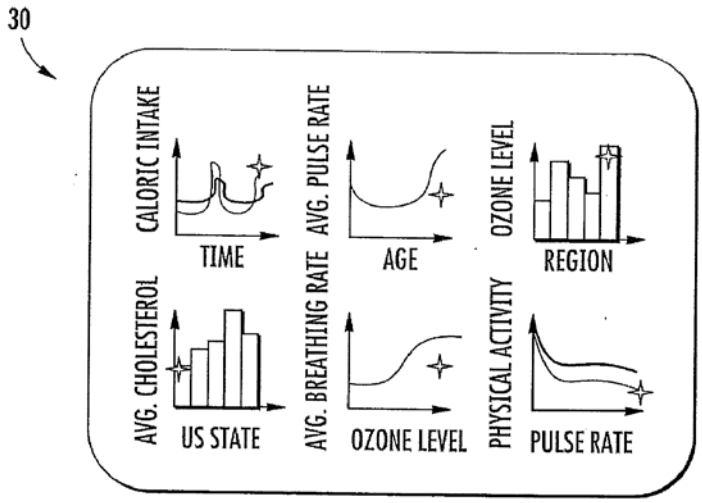


FIG. 3

Ex.1006, Fig. 3; *see also* Figs. 10-21 (providing additional display examples).

Valencell-093 (alone or with Carlson and/or Hanna as described in Grounds 1 and 2) in combination with Valencell-099 therefore teaches a wearable device configured to communicate with a smart phone or tablet that generates a processed output signal, "*wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link*." Ex.1003, ¶¶178-180.

D. No Secondary Considerations Exist

As described above, Valencell-093, alone and with Carlson and Hanna, teaches devices that render obvious claims 1-3 of the '698 Patent. Those references with Valencell-099 render obvious devices and systems per dependent

claim 5. No secondary indicia of non-obviousness exist having a nexus to the putative "invention" of the '698 Patent. Apple reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced by Patent Owner.

VII. Conclusion

Petitioner respectfully submits that the evidence presented in this Petition establishes a reasonable likelihood that Petitioner will prevail in establishing the challenged claims are unpatentable, and requests that Trial be instituted.

Dated: April 10, 2019

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Claim Appendix

1. A 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 input optical beam having one or more optical wavelengths, wherein at least a portion of the one or more 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 input optical beam to tissue, wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue;

the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors 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 input optical beam reflected from the tissue;

wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at

least a first data signal from the first signal and at least a second data signal from the second signal;

the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and

wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency.

2. The wearable device of claim 1, wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply.

3. The wearable device of claim 1, wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs.

5. The wearable device of claim 1, wherein the wearable device is configured to communicate with a smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a

portion of the processed output signal is configured to be transmitted over a wireless transmission link.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,494 words (as determined by the Microsoft Word word-processing system used to prepare the brief), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of April, 2019, copies of this Petition for *Inter Partes* Review, Attachments and Exhibits have been served in its entirety by Federal Express on the following counsel of record for Patent Owner:

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