

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Patent No. 10,098,546

Inter Partes Review No. IPR2020-00029

**Petition for *Inter Partes* Review of
U.S. Patent No. 10,098,546**

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 Statutes	
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Other Authorities

37 C.F.R. § 1.57(d)13
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Exhibit List

Exhibit#	Reference Name
1001	U.S. Patent No. 10,098,546
1002	U.S. Patent No. 10,098,546 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-429 (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	RESERVED
1009	U.S. Patent Publication No. 2005/0049468 (“Carlson”)
1010	RESERVED
1011	U.S. Patent No. 9,241,676 (“Lisogurski”)
1012	RESERVED
1013	RESERVED
1014	RESERVED
1015	RESERVED
1016	RESERVED
1017	U.S. Provisional Application No. 61/747,477
1018	U.S. Provisional Application No. 61/754,698
1019	“The Biomedical Engineering Handbook,” by Joseph D. Bronzino (1995) (“BE Handbook”)
1020	M. Kranz, et al., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (June 2012)

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

Exhibit#	Reference Name
1035	E.F. Schubert, Light-Emitting Diodes (Cambridge Univ. Press, 2nd ed. reprinted 2014)
1036	Barolet, Daniel, Light-Emitting Diodes (LEDs) in Dermatology (Seminars in Cutaneous Medicine and Surgery 2008)
1037	RESERVED
1038	RESERVED
1039	Omni MedSci Inc.'s Opening Claim Construction Brief, No. 2:18-cv-134-RWS (filed December 20, 2018)
1040	RESERVED
1041	Exhibit E filed Jan. 14, 2019, No. 2:18-cv-134-RWS. The American Heritage Dictionary excerpts, 5th ed. 2012.
1042	RESERVED
1043	RESERVED
1044	Claim Construction Markman Hearing Transcript, February 6, 2019. No. 2:18-cv-134-RWS
1045	RESERVED
1046	Exhibit G filed Jan. 14, 2019. No. 2:18-cv-134-RWS, Merriam-Webster's Collegiate Dictionary excerpts, 11th ed. 2011.
1047	RESERVED
1048	U.S. Patent No. 6,044,283 ("Fein")
1049	U.S. Patent No. 5,774,213 ("Trebino")
1050	RESERVED
1051	RESERVED
1052	RESERVED
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/)

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1056	Bylaws of the University of Michigan Board of Regents, (available at http://www.regents.umich.edu/bylaws/bylawsrevised_09-18.pdf)
1057	Claim Construction Memorandum Opinion and Order. Case No. 2:18-CV-000429-RWS (August 14, 2019)
1058	Claim Construction Memorandum Opinion and Order. Case No. 2:18-CV-000134-RWS (June 24, 2019)
1059	U.S. Patent No. 5,795,300 (“Bryars”)
1060	Mark Nelson & Jean-Loup Gailly, <i>The Data Compression Book</i> (Cary Sullivan et al. eds.) (2nd ed. 1996)
1061	Exhibit 8 filed June 21, 2019. No. 2:18-cv-00429-RWS, Harry Newton, <i>Newton’s Telecom Dictionary</i> (18th ed. 2002)
1062	Order, <i>Omni MedSci, Inc. v. Apple Inc.</i> , No. 2:18-cv-134-RWS in the United States District Court for the Eastern District of Texas Marshall Division (8/23/2019), ECF No. 287

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. 10,098,546 (“’546 patent”) is related to following issued patents or pending applications:

- U.S. Patent No. 9,861,286 (“the ’286 patent”)
- U.S. Patent No. 9,757,040 (“the ’040 patent”)
- U.S. Patent No. 9,500,635
- U.S. Patent No. 10,098,546
- U.S. Appl. No. 16/016,649

2. Related Litigation

The ’546 patent has been asserted in the following litigations:

- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-19-cv-05673-YGR (N.D. Cal.) (pending);
- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-18-cv-00429-RWS (E.D. Tex.) (terminated).

The ’286 and ’040 patents have been asserted in the following litigations:

- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-19-cv-05924 (N.D. Cal.) (pending);
- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-19-cv-05673-YGR (N.D. Cal.) (pending) ('286 patent only);
- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-18-cv-00134-RWS (E.D. Tex.) (terminated);
- *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-18-cv-00429-RWS (E.D. Tex.) (terminated) ('286 patent only).

3. Patent Office Proceedings

The '546 patent is not subject to any other proceedings before the Office.

The '546 patent's parent, the '286 patent, is subject to IPR2019-00911 and IPR2019-00914, filed by Apple. And the '286 patent's parent, the '040 patent, is subject to IPR2019-00910 and IPR2019-00917 also 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 Counsel are: Ching-Lee Fukuda (Reg. No. 44,334), clfukuda@sidley.com, (212) 839-7364; 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 counsel is (202) 736-8711.

I. Introduction

Health monitoring systems based on optical sensors, which measure a user's physiological parameters 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 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.

The contested claims of the '546 patent do not define anything inventive. Rather, they cobble together what a well-known textbook describes as the "basic building blocks" of optical sensors (Ex.1019, 765), in a routine and entirely predictable manner. More specifically, the claims define a device that is comprised of conventional and common components, including multiple light emitting diodes (LEDs) that generate light at least in the near-infrared range, lenses for directing the light to the skin, a receiver, and standard signal processing techniques, which are used for their known and predictable purposes.

The prior art describes devices that are comprised of the same components, configured to function in the same manner, and used for the same purpose. 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. Its devices use well-known signal processing techniques to extract accurate physiological information, including those that improve device’s ability to accurately detect the signal within a noisy environment. Other prior art, such as Bryars (Ex.1059), describes conventional techniques used in such optical monitors—such as analyzing light signals using Fourier transforms—that a skilled person would have found obvious to use in the analogous devices described in Valencell-093. As explained below, the combined teachings of Valencell-093 and Bryars, along with additional art, would have rendered every contested claim obvious to a skilled person before the earliest filing date claimed for the ’546 Patent. Petitioner respectfully requests that trial be instituted and that these claims be cancelled.

II. Certifications; Grounds

A. Apple May Contest the ’546 Patent (§ 42.104(a))

Apple certifies that the ’546 patent is available for *inter partes* review (IPR). Apple also certifies it is not barred or estopped from requesting IPR of the claims of the ’546 patent. Neither Apple, nor any party in privity with Apple, has filed a

civil action challenging the validity of any claim of the '546 patent. The '546 patent has not been the subject of a prior IPR by Apple or a privy of Apple.

Apple also certifies this IPR petition is timely filed as this petition was filed less than one year after October 18, 2018, the date Apple was first served with a complaint alleging infringement of a claim of the '546 patent. *See* 35 U.S.C. § 315(b); Ex.1004.

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

Claims 1, 5, 8-9, 11-13, 15-16, and 18 are unpatentable based on the following prior art and grounds.

Reference	Short Name	Publication/Priority Date¹	Exhibit
U.S. Patent Publication No. 2012/0197093	Valencell-093	Aug. 2, 2012	1005
U.S. Patent No. 5,795,300	Bryars	Aug. 26, 2010	1059
U.S. Patent No. 9,241,676	Lisogurski	May 31, 2012	1011
U.S. Patent No. 6,505,133	Hanna	Jan. 7, 2003	1007
U.S. Patent Publication No. 2010/0217099	Valencell-099	Aug. 26, 2010	1006

Challenged Claims	Basis	References
1, 5, 8-9, 11, 13, 15-16, 18	§ 103	Valencell-093 and Bryars

¹ Lisogurski is prior art under §102(a) and (d) (AIA) or §102(a) and (e) (pre-AIA). The other references are prior art under §102(a) (AIA) and §§102(a) and (b) (pre-AIA).

1, 5, 8-9, 11, 13, 15-16, 18	§ 103	Valencell-093, Bryars, and Lisogurski
1, 5, 8-9, 11, 13, 15-16, 18	§ 103	Valencell-093, Bryars, and Hanna, with or without Lisogurski
12	§ 103	Valencell-093, Bryars, and Valencell-099, with or without Lisogurski and/or Hanna

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 '546 patent. The named inventor of the '546 Patent, Dr. Islam, has been a University of Michigan faculty member 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 '546 Patent. Ex.1055; Ex.1056, 21-22. Dr. Islam has also purported to assign the patent to Omni MedSci. *Id.* Petitioner has thus served this petition on both the University of Michigan and Omni MedSci.

III. Background Technology

A. Photoplethysmography

Optical health monitors use a sensing technique called photoplethysmography (“PPG”) that has been used for decades in medical monitoring systems. Ex.1003, ¶41; 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, ¶42. By measuring how much light is absorbed and its changes over time, a device can calculate the components of the blood and tissue. Ex.1003, ¶42.

For example, hemoglobin (the substance in blood that carries oxygen) reflects more red light when it is oxygenated and absorbs more red light when it is deoxygenated. Ex.1019, 769; *see* Ex.1003, ¶43. 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, ¶43.

PPG is an optical technique that uses conventional optical components. Ex.1003, ¶44. The 1995 BE Handbook explains that the “basic building blocks” of optical sensor systems include lenses, mirrors, filters, beam splitters, light sources, and detectors. Ex.1019, 765. As illustrated in the figure below, light 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, ¶¶45-47. 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 (“SNR”), the light source is typically modulated. Ex.1019, 764, 766. This allows the detector to reduce the noise in the detected signal. Ex.1003, ¶¶48-49. It was common to perform a spectral analysis of signals captured by sensors, and the “traditional method of frequency analysis [is] based on the Fourier transform.” Ex.1019, 846-47.

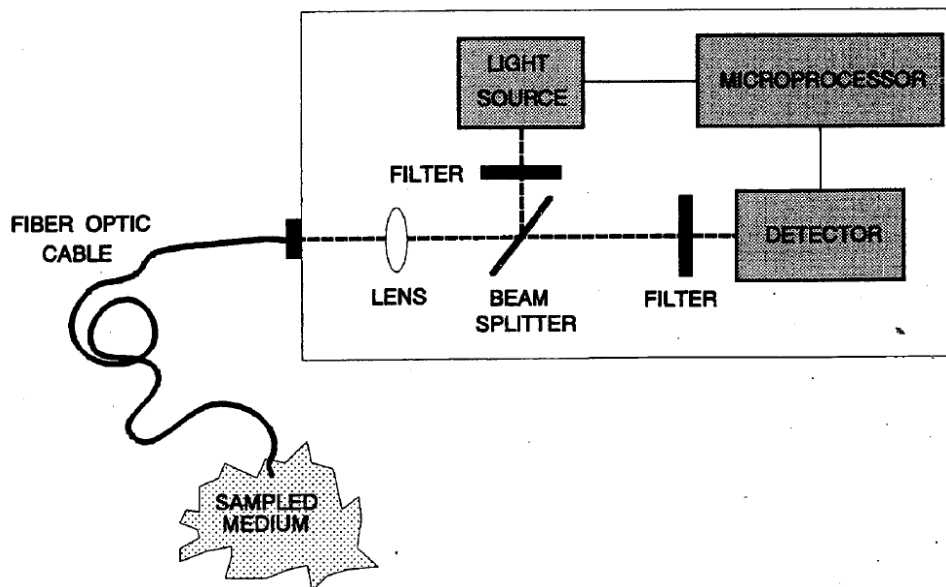


FIGURE 52.1 General diagram representing the basic building blocks of an optical instrument for optical sensor applications.

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, ¶44.

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, ¶52.

One trend was to bring heart rate sensing devices based on pulsoximetry to the consumer market for personal fitness tracking and other uses. Ex.1003, ¶¶53-54. 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...

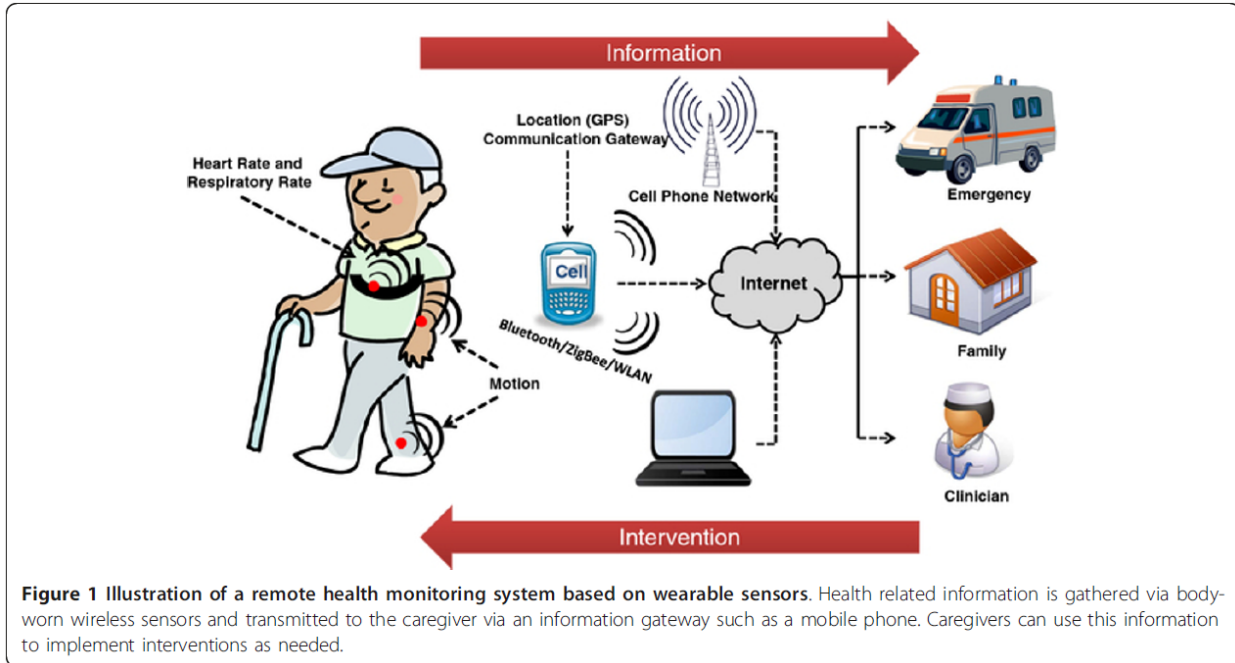
Ex.1020, 3; *see also* Ex.1009, [0004] (“Pulsoximetry measuring devices are also used in sports for control and survey of athletes.”); Ex.1029, 221; Ex.1005, [0003] (“There is growing market demand for personal health... monitors, for example, for gauging overall health, fitness..., and vital status during exercise, athletic training...”); Ex.1027, 33, 35.

A second 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.1022, 1; *see* Ex.1003, ¶¶55-56.

A third trend was to use apps and smartphones to not only deliver medical 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; 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... that can transmit information to the tablet when in the vicinity.”); Ex.1027, 41; *see* Ex.1003, ¶¶55-56. It also led to the prevalent use of cloud-based data transfer and storage of data. Ex.1003, ¶56.

These market trends provided a strong motivation to skilled persons to integrate medical optical sensing techniques into wearable consumer devices that communicate wirelessly with smart devices. Ex.1003, ¶¶53-54. They also led to a proliferation of products using a distributed architecture supporting personal health and mobile monitoring systems. Ex.1003, ¶57.

One example of this architecture was described in Patel 2012:



Ex.1021, 2. As this figure illustrates, data from wearable sensors are transmitted to a cellphone, which in turn transmits the data and GPS information to the cloud or to remote devices used by a clinician, family, or an emergency responder.

Ex.1021, 2, 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, 459-60; Ex.1003, ¶58.

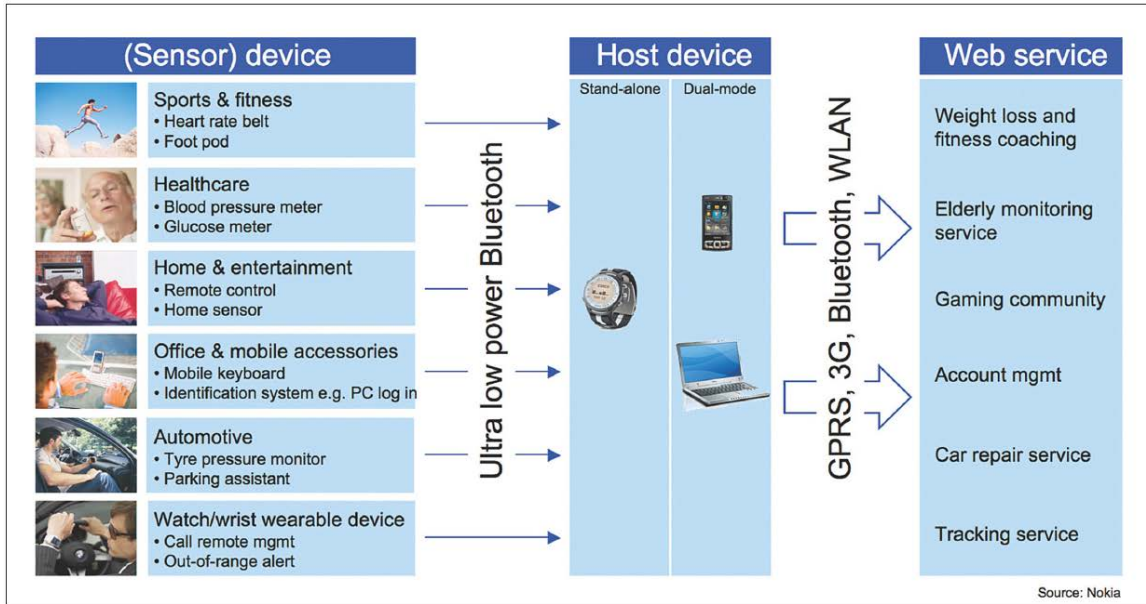


Figure 2. Bluetooth low energy will extend interoperable wireless connectivity to coin-cell-powered wireless sensors in health care, fitness, and related sectors. WLAN, wireless local area network; GPRS, general packet radio service.

Other articles from around 2012 similarly envisioned use of “cloud”-based services to support this interconnected scheme. Ex.1003, ¶¶59-60; Ex.1020, 7,12.

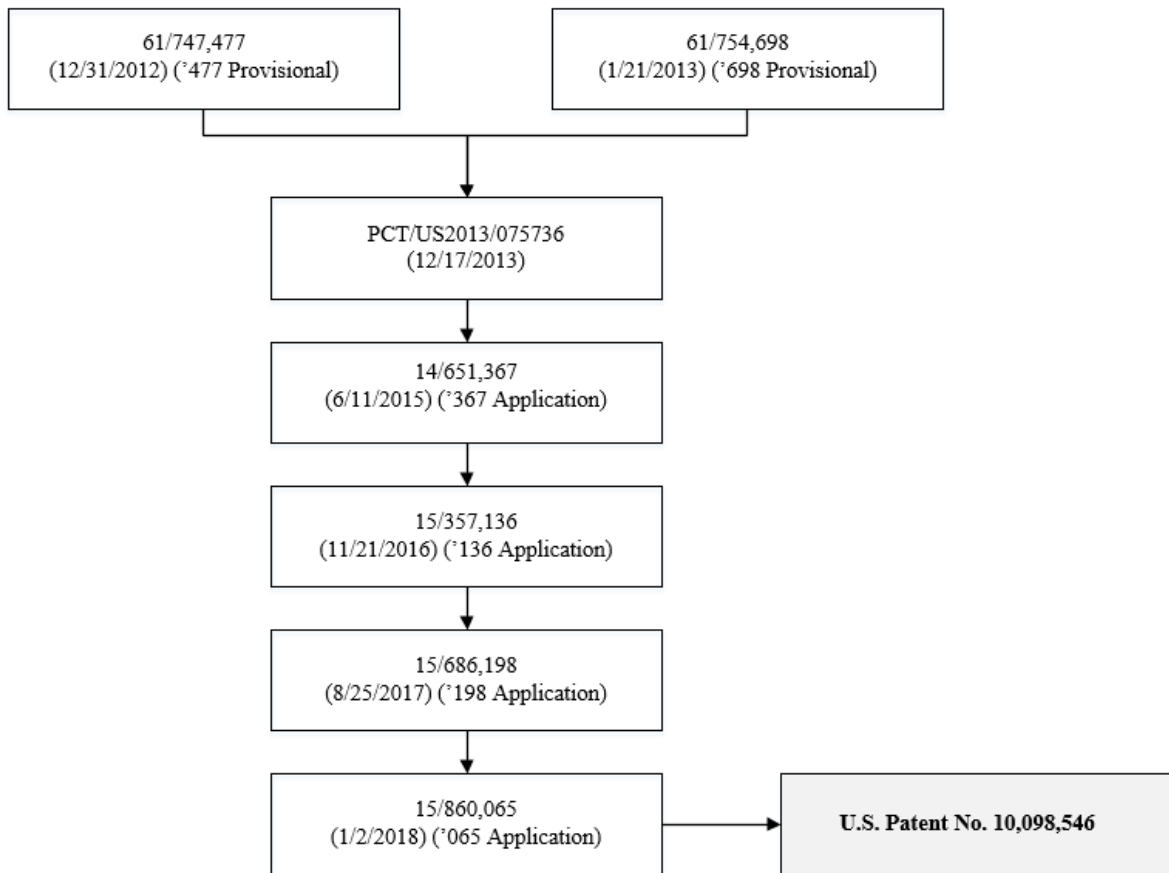
IV. The '546 Patent

A. Illustrative Claim

Independent claims 1, 8, and 15, reproduced in the attached claim appendix, are of similar scope and are addressed together in the analysis below.

B. The '546 Patent Is Subject to AIA

The '546 patent issued from U.S. Application No. 15/860,065 (filed January 2, 2018) and purportedly claims benefit to U.S. provisional applications 61/747,477 and 61/754,698, as shown below. Ex.1001, 1:7-18.



The application further incorporates by reference a number of other applications and provisional applications. Ex.1001, 1:19-53.

Neither the '477 nor '698 Provisionals to which applicant claims priority demonstrates possession of a measurement device as described by claims 1, 5, 11, 15, 16, and 18 comprising a receiver that: (i) captures light while the LEDs are off and converts that light into a first signal, (ii) captures light when at least one of the LEDs is on and converts that light into a second signal, and (iii) improves the SNR of the input optical beam reflected from the tissue by differencing the first and second signals.

This can be appreciated by observing that the passages in the '546 patent concerning these elements are absent in the '477 and '698 Provisionals. *See* Ex.1001, 24:2-6 (“the detection system captures the signal with the light source on and with the light source off... Then, the signal with and without the light source is differenced”); Ex.1003, ¶31. Neither the '477 nor the '698 Provisional contains this passage or one that otherwise describes “*differencing*” signals as these claims require. *See generally* Ex.1017 and Ex.1018. The only provisionals to which the '546 patent claims priority, thus do not demonstrate possession of a device with this element, as 35 U.S.C. § 112 requires. Claims 1, 5, and 15-18 may not properly claim priority to these provisionals.

Likewise, neither the '477 nor '698 Provisionals demonstrate possession of a measurement device as described by claims 1, 5, 8, 9, 11, 12, and 15-18 that generates an output signal “*generated at least in part by using a Fourier transform of signals from the receiver.*” Neither Provisional mentions a Fourier transform. *See generally* Ex.1017 and Ex.1018; Ex.1003, ¶32. The only Provisionals to which the '546 patent claims priority, thus do not satisfy 35 U.S.C. § 112 by demonstrating possession of a device with this element. These claims may not properly claim priority to these Provisionals.

Notably, applicant cannot rely on provisional applications that were incorporated by reference, but to which priority was not claimed, to provide

written description support. Any such disclosure is “essential material” that 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);² *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1319 (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

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 ’546 patent corresponding to these elements. Regardless, Patent Owner may not rely on disclosures in any of the incorporated by reference provisionals *for any*

² In this petition, all emphases added unless otherwise noted.

³ A “patent application publication” is a non-provisional application filed under 35 U.S.C. §111(a) that has been published pursuant to §122(b). A provisional application cannot be a patent application publication because it is filed under §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.

purpose before the date on which they were incorporated by reference into the disclosure of an application to which the '546 patent makes a valid claim of benefit or priority. The earliest possible date when this could have occurred was December 17, 2013, and therefore, for the purposes of this petition, this is the earliest possible priority date of the claims.⁴ Because that date is after March 16, 2013, every claim of the '546 patent is subject to the AIA's first-to-file provisions.⁵

C. 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

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

⁵ Pub. L. No. 112-29, §3(n); *see* M.P.E.P. 2159.02 ("AIA 35 U.S.C. 102 and 103 apply to any patent application that contains or contained at any time a claim to a claimed invention that has an effective filing date that is on or after March 16, 2013.").

with relevant experience studying or developing physiological monitoring devices (e.g., non-invasive optical biosensors) in industry or academia. Ex.1003, ¶39.

This description is approximate; varying combinations of education and practical experience also would be sufficient. *Id.*

Apple's positions regarding how a skilled person would have understood the '546 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. *Id.*, ¶¶1-9, 40.

D. File History

The claims of the '546 patent were never rejected. The examiner allowed the claims via an examiner's amendment that added the Fourier transform and the spectral filter limitations to independent claims 1 and 9. Ex.1002, 173-77. The examiner's reasons for allowance state (incorrectly) that the prior art did not teach several claim limitations, including the amended claim limitations above.

Ex.1002, 177-80, 421-25.

On July 30, 2018, applicant filed a request for continued examination along with an information disclosure statement (IDS) that included all of the prior art that Apple had identified in its Answer and Counter Claims filed on July 19, 2018, including Lisogurski (Ex.1011). Ex.1002, 465, 468, 470. The examiner considered the IDS, however, provided no additional reasons for allowance over

the new prior art. Ex.1002, 457-58. On September 11, 2018, applicant filed another request for reconsideration with two IDSs that listed the references Apple identified in its invalidity contentions in the litigation, including over 60 references. Ex.1002, 468-77, 480-81. Those references included Bryars (Ex.1059). Ex.1002, 468, 470. Again, the examiner did not discuss any of the references. Ex.1002, 519.

E. The Board Should Not Deny Institution under § 325(d) or § 314(a)

The Board should not deny institution because some references were merely listed in an IDS considered by the examiner. *Intex Recreation Corp. v. Team Worldwide Corp.*, IPR2018-00871, Paper 14, at 13 (PTAB Sept. 14, 2018) (references initialed in an IDS, but not discussed or used as basis for rejections, received only “[c]ursory consideration... [that] weighs against exercising discretion to deny under § 325(d)” (citation omitted)); *see Apple Inc. v. Qualcomm Inc.*, IPR2018-01315, Paper 7, at 22-26 (PTAB Jan. 18, 2019). During prosecution and after the examiner had allowed the claims, the applicant dumped in all of the references Apple identified in the litigation involving the ’546 patent’s parents, which included Bryars (Ex.1059). Neither the applicant nor the examiner, however, addressed the teachings in any of these references, much less explained why the claims were patentable over this prior art, either alone or in combination. Nothing in the prosecution history shows that the examiner substantively

considered any aspect of this additional prior art. Moreover, the examiner did not consider Dr. Anthony's declaration submitted herewith, Ex.1003, which provides additional evidence and facts about the teachings of the references and knowledge of a skilled artisan at the relevant period.

Nor should the Board deny the Petition because Valencell-093 was considered in IPR2019-00913 addressing a related patent (the '533 patent). This Petition addresses a different patent using different prior art (*e.g.*, Bryars and Lisogurski) in combination with Valencell-093. Patent Owner asserted the '546 patent against Petitioner in a distinct lawsuit that was filed more than six months after Patent Owner filed suit alleging Petitioner infringed the '533 patent. This Petition also contains additional explanation and grounds that address the issues the Board identified in denying institution in IPR2019-00913.

Thus, the Board should not deny institution under § 325(d) as this Petition advances unpatentability theories not considered during prosecution or by the Board.

The Board also should not deny institution under 35 U.S.C. § 314(a) because it is unlikely that the district court will resolve unpatentability issues before the Board issues its final written decision. The Eastern District of Texas stayed its proceedings and transferred the case to the Northern District of California on August 16, 2019. Ex.1062. Currently, the Northern District has scheduled a status

conference on December 16, 2019, and no case schedule is in place and no trial date set. If the Board decides to Institute, Petitioner plans to move to stay the district court proceedings until the IPRs are completed, and thus, the Board would be first to reach a decision on the patentability of the challenged claims (which include all claims asserted in district court).

Moreover, the Petition's filing date is objectively reasonable in view of events in the district court action. First, the Petition is timely filed within the statutory time period. 35 U.S.C. § 315(b). Second, Petitioner was precluded from filing a Petition until July 16, 2019, because the '546 patent is subject to AIA. 35 U.S.C. § 311(c). Third, Omni has not yet selected its Final Election of Asserted Claims which will narrow the claims at issue. The deadline for Omni's Final Election was stayed, and it was reasonable for Apple to wait to determine whether the Final Election would be made.⁶ Petitioner should not be penalized for filing within all applicable deadlines and for ensuring that its Petition challenged all asserted claims. The period between the initial complaint and its filing thus was reasonable and cannot be portrayed as a delay.

⁶ In a prior action, Omni changed its asserted claims even after it submitted its final election.

V. Claim Construction

The parties have disputed several claim terms in two related district court litigations. The parties offered alternative constructions for these terms, and the Court provided a final construction of each disputed term. *See* Ex.1058; Ex.1057.

For consistency, the PTAB should apply the district court's constructions of these terms. However, even if the PTAB were to apply Apple's proposed district court constructions, the art discloses the elements in these terms.⁷

A. "Beam"

The claim term "*beam*" is expressly defined in the specification: "As used throughout this disclosure, the terms... 'optical beam' and or 'light beam' refer to photons or light transmitted to a particular location in space." Ex.1001, 8:41-43. 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) (patentee who acts as lexicographer is bound by his definition). In the district court litigation, the parties offered the same construction, but disputed

⁷ 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.

whether this term excluded scattered, diffused, and randomly directed light. That dispute is irrelevant to the issues in this IPR.

Therefore, “*beam*” should be construed to mean “photons or light transmitted to a particular location in space.”

B. “One or more lenses”

The district court construed this term to have its plain and ordinary meaning, as Omni had proposed. That meaning encompasses the only type of lens described by the ’546 patent, which is one that will “collimate or focus the light.” Ex.1001, 12:22-24, 12:54-55, 13:21-23, 16:43-44, 23:18-21. This is consistent with dictionary definitions that define a lens as a transparent material that focuses rays of light. Ex.1046, 712; *see also* Ex.1041, 481 (“[a] piece of glass or other transparent material”). Thus, the plain and ordinary meaning of “*one or more lenses*” encompasses Apple’s proposed district court construction of one or more transparent surfaces used to collimate (make parallel) or focus rays of light. Because the art shows lenses that meet Apple’s proposed construction, the Board need not address this dispute.

C. “Modulating at least one of the LEDs”

The district court did not adopt either party’s proposed construction for “*modulating*” and instead adopted the following construction: “varying of 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 ’546 patent stating that beams “may be modulated or unmodulated, *which also means that they may or may not contain information.*” Ex.1001, 8:44-46. It also is consistent with a dictionary definition both parties relied on:

[T]o vary the amplitude, frequency, or phase of (a 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 to transmit audio information).

Petitioner urged the Court to revise its construction to delete “amplitude” because the specification and claims distinguish modulating from varying the amplitude of the signal and to find that pulsing an LED alone did not vary the produced signal’s amplitude. Ex.1044, 21:16-22:1. The Court disagreed and found “‘modulating’ light does not necessarily exclude pulsing the light or otherwise varying the amplitude of the light.” Ex.1057, 17. Whether “amplitude” is included ultimately has no consequence here as the prior art renders the claims unpatentable even under the narrower construction.

D. “Spectral filters”

The district court found that “*spectral filter*” means “physical component or coating configured in the device to selectively pass light of a particular wavelength or range(s) of wavelength.” Ex.1057, 22. This interpretation is consistent with the intrinsic record, which explains that filters are used to “discriminate between

different wavelengths.” Ex.1001, 11:29-31. It also is consistent with the extrinsic evidence which defines a “filter” as “[a] device which transmits a selected range of energy. An electrical filter transmits a selected range of frequencies, while stopping (attenuating) all others. It is used to suppress unwanted frequencies or noise.” Ex.1061. For purposes of this proceeding, Petitioner adopts the Court’s construction.

E. “Two receiver outputs”

The district court agreed with Omni that “*two receiver outputs*” has its plain and ordinary meaning. Ex.1057, 24. For purposes of this proceeding, Petitioner adopts the Court’s construction. Petitioner, in the district court, argued that “two receiver output” means “two outputs representing the intensity of the light received by a detector.” Under either construction, the cited prior art satisfies “*two receiver outputs*,” as shown below.

VI. Detailed Explanation Why the ’546 Patent Claims Are Unpatentable

A. Ground 1: Valencell-093 and Bryars Render Obvious Claims 1, 5, 8-9, 11, 13, 15-16, and 18

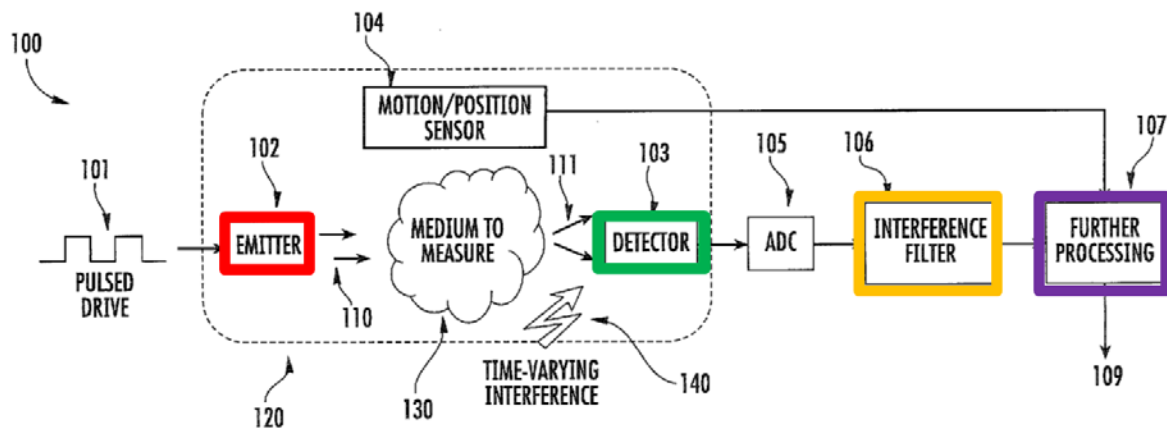
1. Overview of Valencell-093

Valencell-093 describes an optical sensor that can measure heart rate and blood constituents of the user such as blood oxygen level, and cholesterol, among many others. Ex.1005, [0006], [0050], [0090], [0109]. Its specific objective is “to teach 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, such as noise from ambient light and/or sunlight.*”

Ex.1005, [0112]. Thus, one of Valencell-093’s explicit purposes is creating a device that can function properly even in the presence of environmental noise such as sunlight, which Valencell-093 recognizes creates “time-varying” interference.

Ex.1005, [0108], [0110]-[0111], Fig. 1 (140). Annotated Figure 1 shows components of the wearable monitor:



Ex.1003, ¶73.

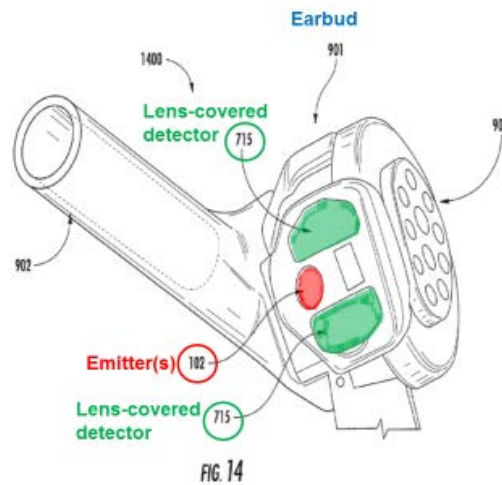
As shown above, at least one emitter 102 (red) emits modulated optical energy 110 at a target region 120 of a medium 130. Ex.1005, [0107], [0108]. The target region 120 can be a user’s ear, wherein the medium 130 “comprises blood vessels and/or blood flow within the ear region.” Ex.1005, [0108]. The energy 110 interacts with the medium 130 to generate a scattered light response 111, which is detected by at least one detector 103 (green). Ex.1005, [0107].

Valencell-093 explains that multiple emitters and multiple detectors may be used. Ex.1005, [0108], [0148].

“The outputs of the detector 103 may be sent to an analog-to-digital convertor (ADC) 105 and the digitized output may be sent to at least one interference filter 106 [(yellow)], which is configured to remove the effects of time-varying environmental interference 140 from the signal output of the detector 103.” Ex.1005, [0107]. Such time-varying interference includes sunlight. Ex.1005, [0108]. The output of the interference filter may be further processed by a signal extraction filter 107 (purple) “to extract accurate information from the medium 130” and produce an “extracted energy response signal” 109. Ex.1005, [0107]. Signal extraction filter 107 can use the output from motion sensor 104 to remove motion-related noise. Ex.1005, [0148].

The device includes a signal processor that 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].

In one example, the sensor is incorporated into an earbud that has one or more optical emitters 102 and two optical detectors each covered by a lens 715. Ex.1005, Fig. 14 (annotated below), [0130]; *see* Ex.1005, Figs. 4-5, 9-17.



Valencell-093 also teaches that the sensor can be incorporated into a wristband. Ex.1005, Figs. 23-29, [0043], [0050].

2. Overview of Bryars

Bryars describes a wrist-worn heart rate monitor. Ex.1059, Fig. 1, 1:8-14. The device uses an optical sensor (*e.g.*, an infrared LED and photodetector) to measure “the heart pulse rate from a radial artery.” Ex.1059, 5:33-36; *see id.*, 5:37-48.

Bryars describes techniques for improving optical sensor accuracy by filtering out noise caused from changing light conditions and body movement. Ex.1059, 2:64-69. To do so, Bryars’ device uses a fast Fourier transform (FFT) algorithm to detect a heart rate in a “relatively high level noise environment caused by body motion.” Ex.1059, 9:7-11; *see id.*, 9:17-21, 10:3-22. By using this technique, Bryars discloses an effective method for mitigating environmental noise

sources, such as noise caused by device movement and ambient light (*e.g.*, sunlight), to ensure accurate measurements of a heart pulse rate. Ex.1059, 2:64-68.

The noise mitigation achieved by Bryars' device thus provides a direct motivation to a skilled person to incorporate its techniques, features and other improvements into other optical sensing devices. Ex.1003, ¶¶78-79.

3. A Skilled Person Would Have Modified Valencell-093 to Incorporate Elements of Bryars

A skilled person would have considered Valencell-093 with prior art that describes analogous optical sensing devices having the same applications (*e.g.*, wearable devices for measuring pulse and other physiological parameters).

Ex.1003, ¶80. That person following ordinary design processes would evaluate known techniques 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].

Valencell-093 also recognizes the inherently varying nature of such environmental noise—it explains that one source of noise is "time-varying sunlight" that may "impart time-varying optical interference"—and identifies solutions that dynamically respond to such interference. Ex.1005, [0110], [0108].

These aspects of Valencell-093 would have led the skilled person to Bryars, which describes techniques for improving noise reduction when measuring a

subject's pulse using a wrist-worn device. Ex.1059, 3:31-38; Ex.1003, ¶81.

Bryars teaches techniques that mitigate time-varying noise such as motion and sunlight. Ex.1059, 2:56-67, 5:49-53, 6:41-57, 9:8-21. Bryars also describes incorporating these techniques in wrist-worn, battery-powered devices used for both medical and athletic purposes. Ex.1059, 1:8-31, 3:44-50, 6:50-57.

Valencell-093 and Bryars thus describe analogous systems with common applications and utility; both describe techniques for improving the performance of wearable optical sensing devices in the presence of noise. Ex.1003, ¶81. The skilled person would have considered the references together when implementing a system based on Valencell-093's teachings. Ex.1003, ¶82.

Moreover, as explained in §III.B, above, by 2012, there was a general industry trend to create wearable devices that can be used for sports and personal fitness applications. Ex.1003, ¶¶52-60, 82. Thus, the skilled person considering Valencell-093 would have had reason to look to references describing techniques for creating or improving wearable devices for these mobile health and consumer applications, such as Bryars. Ex.1003, ¶82.

4. Theoretical Distinctions Between Valencell-093 and Claims 1, 8, and 15

The contested claims generally define a wearable measurement device comprised of optical components configured to generate “a non-invasive measurement on blood” using near-IR light. As explained below, Valencell-093

alone describes a Bluetooth earbud headset with an optical physiological sensor that discloses or renders obvious every element of the contested claims. Patent Owner may contend that Valencell-093 does not teach an output signal “*generated at least in part by using a Fourier transform,*” “*modulating*” one or more LEDs to include information, “*improving signal-to-noise ratio by increasing the intensity*” of an LED, or a “*smartphone.*” However, to the extent any of these features are missing, modifying Valencell-093 to include each of these features would have been obvious based on additional references.

Valencell-093 and Bryars alone or in further view of Lisogurski, Hanna, and/or Valencell-099 would have rendered obvious independent claims 1, 8, and 15 as well as dependent claims 5, 9, 11-13, 16 and 18.

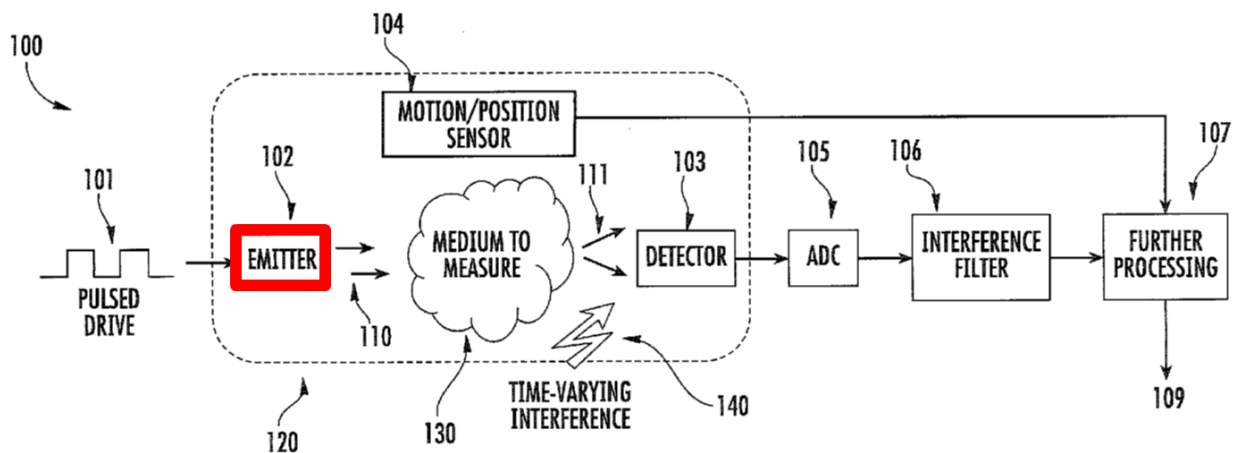
5. Independent Claims 1, 8, and 15

a) Preamble

The preambles of claims 1, 8, and 15 specify “[*a*] *wearable device.*” Valencell-093 teaches a wearable Bluetooth earbud headset with a physiological sensor. Ex.1005, Figs. 4-5, 9-17, [0006] (“a wearable monitoring apparatus”), [0104] (“Wireless, Bluetooth®-enabled... headsets may be configured to incorporate physiological... sensors”), [0112] (“an earbud monitor”); Ex.1003, ¶85. 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”**

Claims 1, 8, and 15 recite this limitation. The Valencell-093 sensor measures a user’s physiological parameters. Ex.1005, Figs. 1, 2, 4A, 4B, 5, 7-17, [0006] (“the detector detects... a physiological condition of the subject (e.g., heart rate..., blood oxygen level)”), [0050], [0108]-[0109].



The sensor shown in Figure 1 above includes 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]; Ex.1003, ¶¶87-88. A processor controls operation of the sensor. Ex.1005, [0007], [0107]. The sensor is “a measurement device... for measuring one or more physiological parameters.” Ex.1003, ¶88.

- c) **“the measurement device configured to generate, by modulating at least one of the LEDs having an initial light**

intensity, an optical beam having a plurality of optical wavelengths”

Claims 1, 8, and 15 recite this limitation. Valencell-093 discloses that the LED emitter emits a “pulsed beam of light,” Ex.1005, [0137], *see id.*, [0009], [0047], and “directs energy (e.g., optical energy...) at a target region of the subject.” Ex.1005, [0044]; *see id.*, [0012], [0019], [0033], [0044], [0109].

Valencell-093 describes the “pulsed beam” as light that is directed to a particular location in space (*i.e.*, the target region of the subject) and is, therefore, the same type of “*beam*” described in the ’546 patent. Ex.1003, ¶92. Valencell-093 thus teaches an LED that emits a “*beam*” of light transmitted to a particular location in space.

Valencell-093 teaches that the beam can be comprised of a plurality of wavelengths. Ex.1005, Fig. 2 (110), [0109] (“optical sources emitting *one or more optical wavelengths*”; “particularly useful are UV, visible, and *IR wavelengths*”; “to generate optical *wavelengths* 110”), [0114] (“at least one optical emitter that generates optical *wavelengths*”), [0130] (“*[m]ultiple wavelengths* may be generated”); Ex.1003, ¶¶102-103.

Valencell-093 describes changing the LED intensity *while the device is in operation*. Ex.1005, [0097] (“‘modulated energy’... refers to energy... that is emitted such that the amplitude... or intensity is varied”), [0108] (“The intensity of the pulsed optical energy 110 is modulated... such that the intensity is time-

varying with at least two states, preferably an on state and an off state... In some cases, [there may be] other modulated states of the pulsed energy 110.”).

Valencell-093 also 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]. Valencell-093, therefore teaches that the LED emitter has the claimed “*initial light intensity*” and that this initial light intensity can be increased to address interference from environmental conditions, particularly unwanted sunlight. Ex.1003, ¶¶90-91, 93.

Valencell-093 also teaches that it “*modulates*” the LED, except that Valencell-093 does not expressly indicate that the modulated beam includes information. Valencell-093 teaches that the LED emits “pulsed or *modulated energy*,” wherein modulated energy is defined as optical energy “that is emitted in pulses and/or that is emitted *such that the amplitude, frequency, phase, or intensity is varied.*”⁸ Ex.1005, [0008], [0097], [0107] (“modulated energy, such as pulsed energy, [is] generated by an energy emitter”), [0108] (“intensity of the pulsed optical energy 110 is modulated by at least one pulsed driving circuit 101”), [0143].

⁸ An ordinary artisan would have understood that “modulated energy” is being used with the same meaning as the ’546 patent. Ex.1003, ¶94.

While Valencell-093 is silent on whether its beam includes information, an ordinary artisan would have read Valencell-093 as describing use of a beam that includes information, and would also have considered it obvious to do so.

Ex.1003, ¶¶95-100.

As the '546 patent explains, a beam either contains information or it does not. Ex.1001, 8:45-46 (beams “may be modulated or unmodulated, which also means that they may or may not contain information”). The skilled person would have read the term “beam,” particularly where Valencell-093 states that it can be modulated, as describing both types of beams—those that are modulated to include information and those that are not. Ex.1003, ¶94; *see In re Petering*, 301 F.2d 676, 681 (CCPA 1962) (disclosure of a limited class allows “one skilled in this art [to] at once envisage each member of this limited class....”). Moreover, Patent Owner did not contend the nature of the beam was relevant to patentability, and the examiner did not rely on that feature in allowing the claims. The '546 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, ¶100.

In addition, a skilled person would have found it obvious to select either one of these known options for a beam, and use of either would yield predictable results. *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 person of ordinary skill 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) (finding claimed invention obvious to try based on only three possibilities).

As Dr. Anthony explains, a skilled person would have found it obvious to use a beam that was modulated to include information because of the benefits obtained by doing so. Ex.1003, ¶¶95-100. For example, the beam could include an embedded identification code that would enable a detector to identify the source of received light. Ex.1003, ¶96. This technique would be particularly useful in a device with multiple emitters located at different distances from the detector, such as the devices in Figure 9A of Valencell-093. Ex.1005, [0122], [0130]; Ex.1003, ¶96. This technique was well-known and is described in, for example, Hanna. Ex.1007, 2:26-29; Ex.1003, ¶96.

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 tampering. Ex.1003, ¶97.

A skilled person could have readily altered the Valencell-093 device to modulate a beam to include any of these types of information. Ex.1003, ¶99. That

person would have been motivated to make such alterations to improve the performance of the sensor (*e.g.*, to produce more accurate data), and because Valencell-093 recognized that “the market demand for personal health... monitors” required sensors that would produce “accurate health, fitness, and vital status monitoring.” Ex.1005, [0003]; Ex.1003, ¶98.

- d) “wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers”**

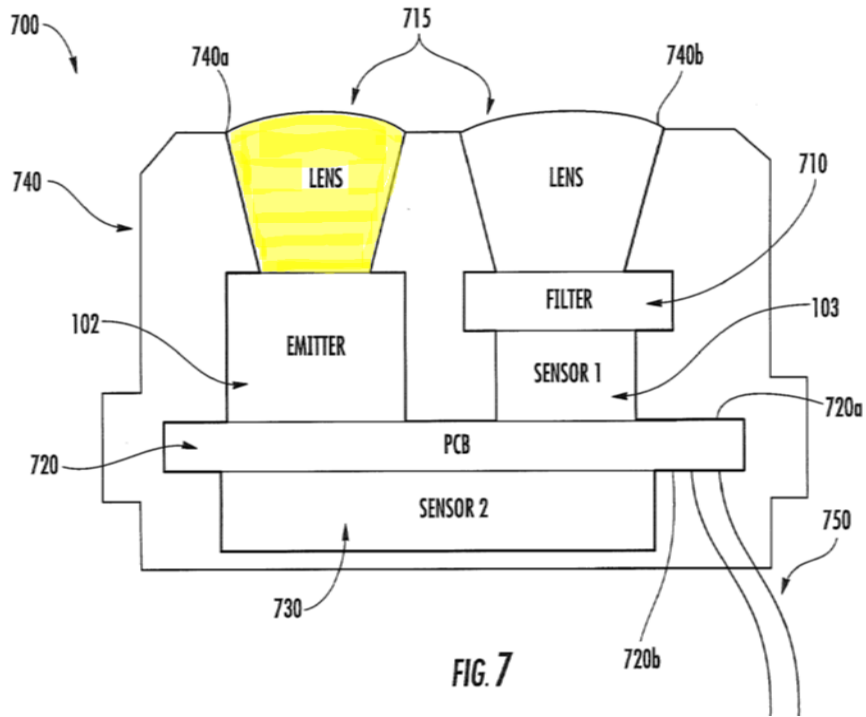
Claims 8 and 15 recite this limitation. Claim 1 recites the same limitation but replaces “*plurality of optical wavelengths*” with “*optical beam.*”

As explained above (§VI.A.5.c), Valencell-093 discloses that the LEDs generate light beams (“*the optical beam*”) having one or more optical wavelengths (“*the plurality of optical wavelengths*”). Ex.1005, Fig. 2, [0109] (“one or more optical sources emitting ***one or more optical wavelengths***”), [0114], [0130]. In one embodiment, “the optical emitter 102 is configured to emit wavelengths centered around 930 nm” (“*a near-infrared wavelength*”). Ex.1005, [0117]; *see id.*, [0109] (“particularly useful are UV, visible, and ***IR wavelengths***”); Ex.1003, ¶¶102-103.

- e) “the measurement device comprising one or more lenses configured to receive and to deliver [at least] a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue”**

Claims 1, 8, and 15 recite this limitation with claim 1 adding “*at least.*”

As Figure 7 shows, the sensor can include one or more lenses for focusing light onto the user's tissue:



Ex.1005, Fig. 7 (annotated), [0016] (“the sensor module includes a lens positioned above at least one of the optical emitter”), [0135]; Ex.1003, ¶106. The disclosed lenses are “*lenses*” within that term’s plain and ordinary meaning and within Apple’s district court construction, as they are transparent and can focus or collimate light. Ex.1005, [0017] (“lens focuses light emitted by the optical emitter”), [0118], [0125] (“the lenses 715 are completely transparent to the light of interest”); Ex.1003, ¶¶107-108.

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 of the user’s ear (“*deliver[s] a portion of the input optical beam to tissue*”). Ex.1005, [0017], [0118] (lenses “guide light from the optical emitter 102 towards the skin 130 of a subject”), Fig. 7 (showing lens in contact with emitter); Ex.1003, ¶106.

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

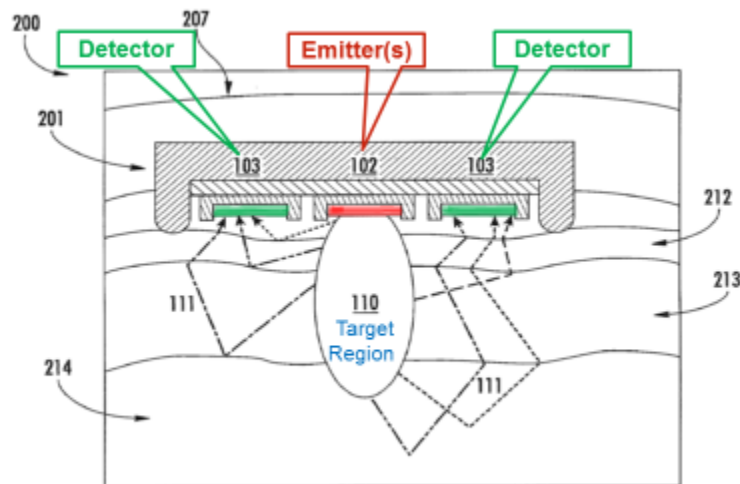


FIG. 2

Ex.1005, Fig. 2, [0107], [0109], [0118]; Ex.1003, ¶109.

f) “wherein the measurement device is adapted to be placed on a wrist or an ear of a user”

Claims 8 and 15 (not claim 1) recite this limitation. Valencell-093 teaches wearable Bluetooth earbuds. Ex.1005, Figs. 4-5, 9-17, [0006] (“a wearable monitoring apparatus”), [0104] (“Wireless, Bluetooth®-enabled... communication headsets may... incorporate physiological... sensors”), [0112] (“an earbud

monitor”); Ex.1003, ¶¶111-112. Valencell-093 also teaches incorporating the sensor into a wearable wristband. Ex.1005, Figs. 23-29, [0151]-[0154].

- g) **“the measurement device further comprising a receiver, the receiver having a plurality of spatially separated detectors”**

Claims 1, 8, and 15 recite this limitation. The Valencell-093 sensor includes a “receiver” comprising multiple optical detectors, which are controlled by a processor. Ex.1005, Figs. 2, 9-11, 14, 15, [0007], [0107], [0038]; Ex.1003, ¶¶114-115.

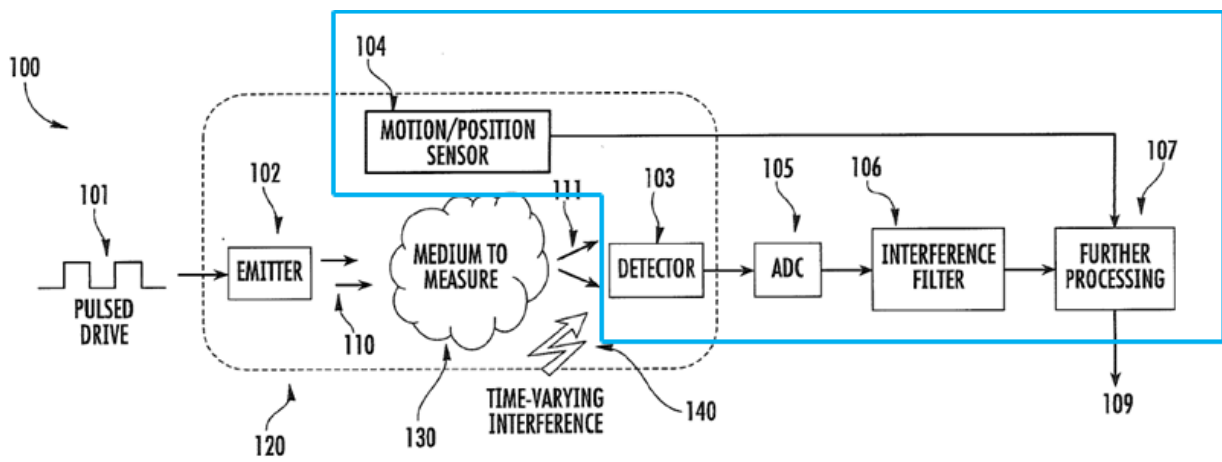
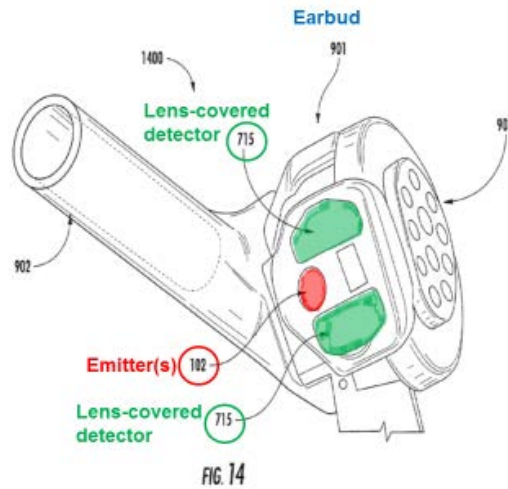
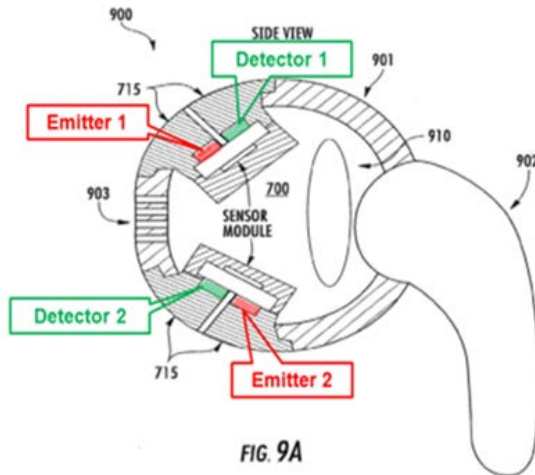


FIG. 1

Valencell-093 discloses that “multiple emitters, detectors... may be employed within a sensor module.” Ex.1005, [0038]; *see id.*, [0148], Figs. 2 (103), 9-11, 14, 15. Figure 14 (annotated) below provides an example, showing two spatially separated detectors 715:



Ex.1005, [0130] (“a multi-detector earbud 1400”); Ex.1003, ¶115. Similarly, Figure 9A shows an earbud having two spatially separated detectors.



Ex.1005, Fig. 9A, [0122]; Ex.1003, ¶115.

- h) “[the receiver having] one or more analog to digital converters coupled to the spatially separated

detectors, the one or more analog to digital converters configured to generate at least two receiver outputs”

Claims 1, 8, and 15 recite this limitation. The Valencell-093 sensor includes a “receiver” comprising, inter alia, one or more optical detectors 103 and one or more analog-to-digital converters 105 (ADC). Ex.1005, Figs. 1, 2, 7-17, [0007], [0107]; Ex.1003, ¶¶118.

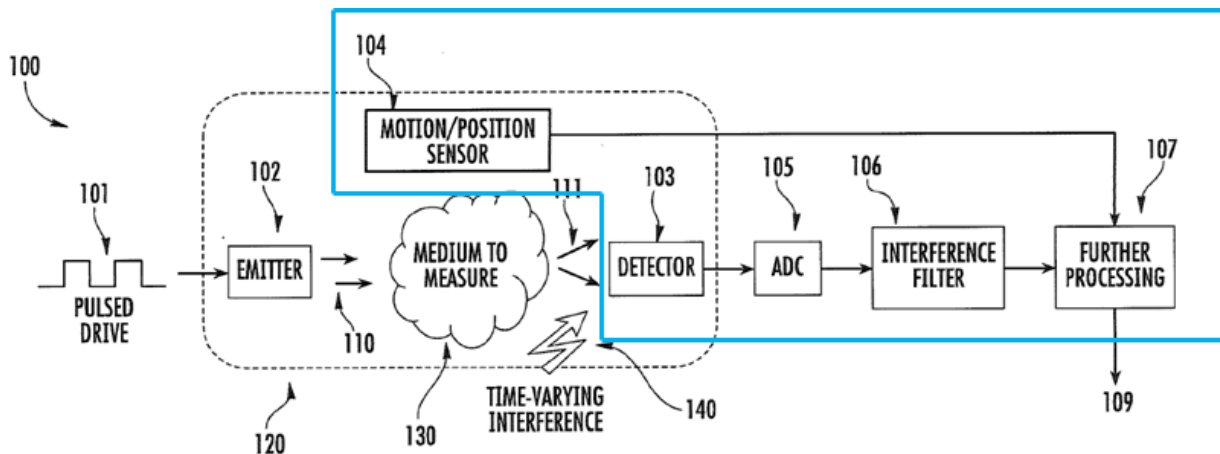


FIG. 1

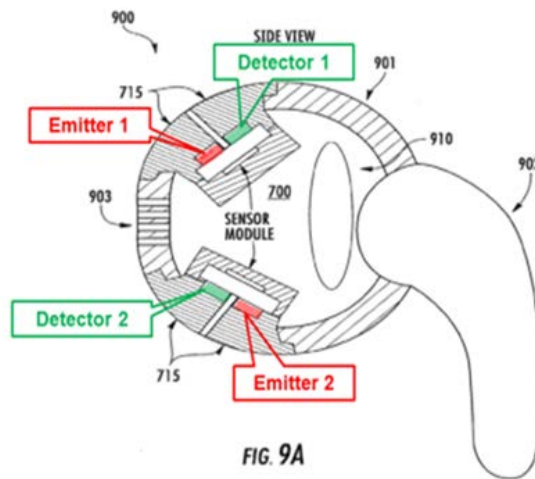
As Figure 1 shows, an ADC 105 is “coupled to” detector(s) 103. Ex.1005, [0107]; Ex.1003, ¶¶117-118. Valencell-093 states that each device can include multiple (e.g., at least two) detectors 103. Ex.1005, Figs. 2, 9A, 14, [0148] (“*at least one optical detector* (e.g., 103, FIG. 1) may also serve as a motion sensor [104]” and “by employing *multiple optical detectors* (e.g., 102, FIG. 1), motion-related signals may be identified from physiological-related signals by processing signals from the *multiple detectors*”), [0108] (“at least one detector”), [0109]

(“detectors 103”). These detectors can be spatially separated. Ex.1005, Figs. 2, 9A, 14 (each showing multiple detectors, spatially separated).

Each detector sends its outputs to an ADC 105 so it can produce digitized outputs. Ex.1005, [0107] (“The outputs of the detector 103 may be sent to at least one... ADC[] 105 and the digitized output may be sent to at least one interference filter 106”); Ex.1003, ¶119.

Valencell-093 states that a “first optical interaction response is obtained” when an LED is on and a “second optical interaction response is obtained” when the LEDs are off. Ex.1005, [0108], [0117], [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”). These two signals are passed to the ADC, which creates a separate digitized “on” signal and a separate digitized “off” signal. Ex.1005, [0108] (detector produces “first and second energy response signals” that are digitized), [0137] (detector produces “off/on samples 1920/1930”), Fig. 18.

As stated above, Valencell-093 shows a sensor can have multiple (*e.g.*, two or more) detectors and each detector creates two output signals (on samples and off samples). Ex.1003, ¶120. A multiple-detector example is shown in annotated Figure 9A below.



Ex.1005, Fig. 9A, [0122]. The set of “on” samples (one “*receiver output*”) and set of “off” samples (another “*receiver output*”) from one detector (*e.g.*, from Detector 1 in annotated Figure 9A or from a detector used in the motion sensor 104) together meet the “*at least two receiver outputs*” limitation. Ex.1003, ¶¶121, 125.

- i) “[the receiver configured to] capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue”

Claims 1 and 15 recite this limitation and claim 8 does not.

As explained for the “*two receiver outputs*” above, each Valencell-093 detector is configured to “*capture light*” when a near-infrared LED emitter is on and when all LEDs are off. Ex.1003, ¶123. The receiver “*convert[s] the captured light*” into first and second energy response signals. Ex.1005, [0033] (detector

obtains “a first energy response signal... when the emitter is on” and “a second energy response signal... when the emitter is off”), [0108] (detector produces “first and second energy response signals”), [0137] (“off/on samples 1920/1930”); Ex.1003, ¶124.

Valencell-093 states that each device can include multiple (*e.g.*, at least two) detectors. Ex.1005, Figs. 2, 9A, 14, [0148]; Ex.1003, ¶¶125-126. As explained above, the outputs of one detector (*e.g.*, in motion sensor 104 or Detector 1 in annotated Figure 9A) map to the “*at least two receiver outputs*” limitation. The set of “off” samples and set of “on” samples output from another detector (*e.g.*, one of the detectors 103 such as Detector 2 in annotated Figure 9A) map to the “*first signal*” and “*second signal,*” respectively.

The optical signal detected when an LED is on represents “optical absorption..., transmission, luminescence, or the like, from the physiological region 130” targeted by the LED emitters. Ex.1005, [0108]-[0109], [0117]. Thus, the tissue reflects at least some of the light, which is then captured by the detector (“*the captured light including at least a portion of the optical beam reflected from the tissue*”). Ex.1005, Fig. 2, [0108], [0109], [0137], [0117]; Ex.1003, ¶126.

- j) **“the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue**

**[by differencing the first signal and the second signal and]
by differencing the two receiver outputs”**

Claims 1, 8 and 15 recite this limitation. Only claims 1 and 15, however, recite differencing the first and second signals.

Valencell-093 explains that “[t]he first and second energy response signals... are processed via an interference filter 106 to produce a processed energy response signal... [by] remov[ing] time-varying environmental interference caused by an interference, such as sunlight.” Ex.1005, [0108], Fig. 1 (106), [0137], [0138]; Ex.1003, ¶¶128-130.

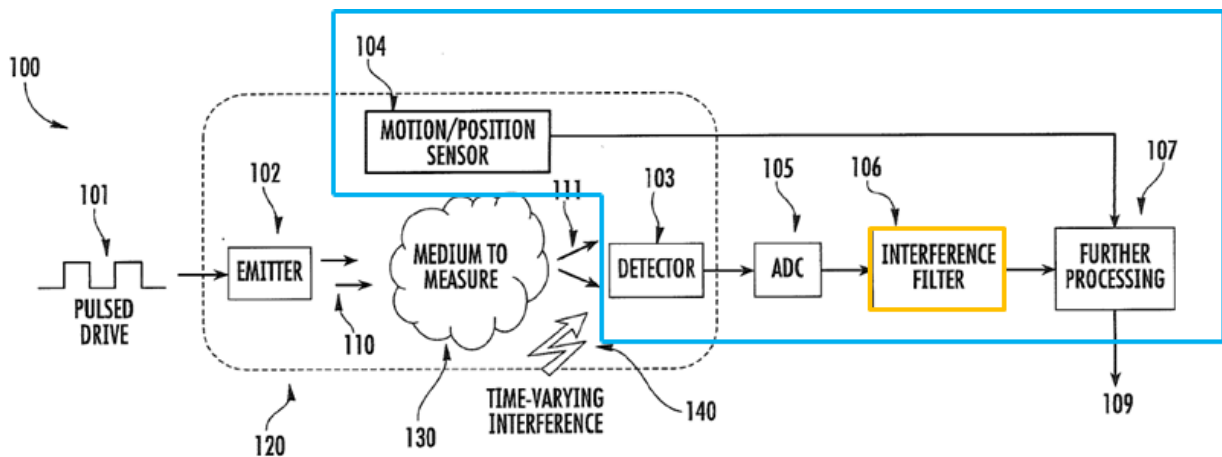


FIG. 1

As explained for the previous two claim elements, each of at least two detectors measures a “first energy response signal” when an LED is on (“second signal” and a “receiver output”), and a “second energy response signal” when the LEDs are off (“first signal” and another “receiver output”). The interference filter 106 “subtract[s]” (“differencing”) “temporally neighboring emitter-off samples”

(“*the first signal*” and “*receiver output*”) “from temporally neighboring emitter-on samples” (“*the second signal*” and “*receiver output*”) “and output[s] a ‘subtraction’ signal for further processing.” Ex.1005, [0139], Figs. 19A, 19B; Ex.1003, ¶129. Therefore Valencell-093 “*differences*” the two sets of signals identified by the claims.

Valencell-093 teaches that the differencing is performed to remove noise from the signal. Ex.1005, [0138] (describing “removing environmental noise from a sensor signal via an interference filter”), [0145] (“interference filter 2000, for removing sunlight interference from a PPG signal... to extract heart rate”). A skilled person would have understood that removing noise from a detected signal increases a SNR. Ex.1003, ¶130. The SNR 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 SNR. *Id.*

- k) **“the measurement device configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs”**

Claims 1, 8, and 15 recite this limitation. Valencell-093 describes changing the LED intensity while the device is in operation. Ex.1005, [0097] (“‘modulated energy’ ... refers to *energy... that is emitted* such that the amplitude... or *intensity is varied*”), [0108] (“The intensity of the *pulsed optical energy 110 is*

modulated... such that the intensity is time-varying with at least two states, preferably an on state and an off state... In some cases, [there may be] other modulated states of the pulsed energy 110.”), [0143] (“the modulated light 110 may be pulsed completely on or completely off, or it may be *pulsed partially on or partially off*... [T]he modulated light *may be sinusoidal*.”). When the LED switches from a lower intensity state to a higher intensity state (*e.g.*, from partially on to completely on or from the trough to the peak of a sinusoidal wave), that increase would necessarily be relative to an initial light intensity of the emitter prior to the increase. Ex.1003, ¶133. 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 varying the intensity of the emitted light to dynamically address forms of optical interference that are inherently variable (*e.g.*, unwanted sunlight), stating 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]; Ex.1003, ¶134. 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, [0107] (“an optical scatter signal 111 between emitted optical energy 110 and the medium 130”), [0108]. In addition, it teaches that

unwanted sunlight is noise. Ex.1005, [0112], [0145]. A skilled would have understood 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 intensity of an LED would “*further improve*” this SNR by increasing the signal. Ex.1003, ¶135.

One specific objective Valencell-093 is solving problems due to interference caused by sunlight. Ex.1005, [0112] (“to teach how to make a wearable monitor...that may provide accurate... physiological [measurements]... *in the midst of environmental noise... from... sunlight.*”), [0107], [0108], [0110]-[0111]. Valencell-093 recognizes sunlight is not a constant level of optical interference, but is instead “time-varying interference.” Ex.1005, [0108], [0110] (“Time-varying sunlight... may impart time-varying optical interference”). In view of these objectives, the skilled person reading Valencell-093’s statement 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], thus would understand that Valencell-093’s system will change the LED intensity as part of a dynamic process to mitigate the interference caused by the time-varying nature of sunlight. Ex.1003, ¶136.

Valencell-093 also describes use of an optical filter 710, which is a static filter that Valencell-093 discloses can serve as both a wavelength filter and an

attenuation filter. Ex.1003, ¶137. A wavelength filter blocks certain wavelengths and allows a small band to pass (*e.g.*, near the wavelength of the LEDs) and its use decreases the amount of sunlight reaching the detector, which can thereby increase the ratio of the optical scatter to sunlight. Ex.1005, [0116]; Ex.1003, ¶137. An attenuation filter reduces the total amount of light that passes and does not discriminate based on wavelength, and it does not change the ratio of optical scatter to sunlight. Ex.1003, ¶137. Thus, increasing the intensity of the LEDs (and therefore the optical scatter) would not address an SNR problem caused by use of an optical filter. Instead, a skilled person would understand that where Valencell-093 describes increasing the intensity to increase the ratio of optical scatter to sunlight, Valencell-093 is describing increasing the intensity of the LED in response to variations in sunlight intensity to address the drop in SNR that occurs when sunlight increases relative to an initial LED intensity. Ex.1003, ¶137.

To the extent Omni argues that Valencell-093 does not explicitly disclose this limitation, a skilled person would have found it obvious to increase the intensity of light being generated by the emitters (LEDs) in Valencell-093 in a manner that counteracts the varying degree of interference caused by “time-varying sunlight” (*i.e.*, noise), Ex.1005, [0110]. Ex.1003, ¶138. Valencell-093 explains that “varying sunlight intensity” causes varying amounts of noise to be present in the signal being measured. Ex.1005, [0147]; *see id.*, [0110] (“Time-

varying sunlight... may impart time-varying optical interference”); Ex.1003, ¶138. Valencell-093 also explains that the LED intensity can be varied during operation. Ex.1005, [0097], [0108], [0143]. A skilled person would have recognized that increasing the LED intensity from an initial LED intensity (as Valencell-093 teaches can be done) in response to changes in sunlight would help mitigate the variable amount of interference caused by the varying amount of sunlight being captured by the sensors, particularly in view of Valencell-093’s general teaching that it is beneficial to mitigate time-varying interference caused by sunlight. Ex.1003, ¶138. In this configuration, the increases in LED intensity would “*improve the signal-to-noise ratio*” as required by the claim. Ex.1005, [0111], [0123]; Ex.1003, ¶138.

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

Claims 1, 8, and 15 recite this limitation. As described above (§VI.A.5.h), Valencell-093 discloses that an interference filter subtracts noise from a detected signal to improve a SNR. Ex.1003, ¶141. The output of the interference filter is then passed to signal extraction filter 107 “to accurately extract at least one physiological property of the subject.” Ex.1005, [0108]; *id.*, [0107]. The measurement device then outputs the resulting “desired physiological signal” 109

(“output signal”). Ex.1005, [0108], [0147]-[0149]; *id.*, [0112], [0007] Ex.1003, ¶¶141-142.

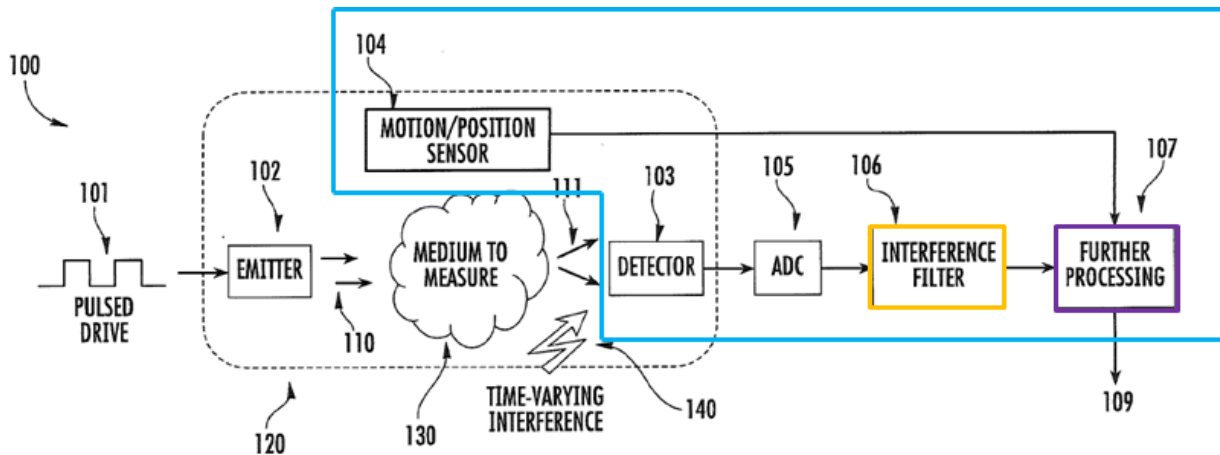


FIG. 1

The desired physiological signal 109 can represent a variety of “*non-invasive measurement[s] on blood*” such as blood metabolite level, blood oxygen level, and cholesterol among many others. Ex.1005, [0006], [0050], [0090], [0109]. These properties are non-invasively measured from light interaction with “blood vessels and/or blood flow” (“*blood contained within the tissue*”). Ex.1005, [0006], [0108], [0109]; Ex.1003, ¶143.

- m) “wherein the output signal is generated at least in part by using a Fourier transform of signals from the receiver including at least one of the first and second signals and signals from the at least two receiver outputs”

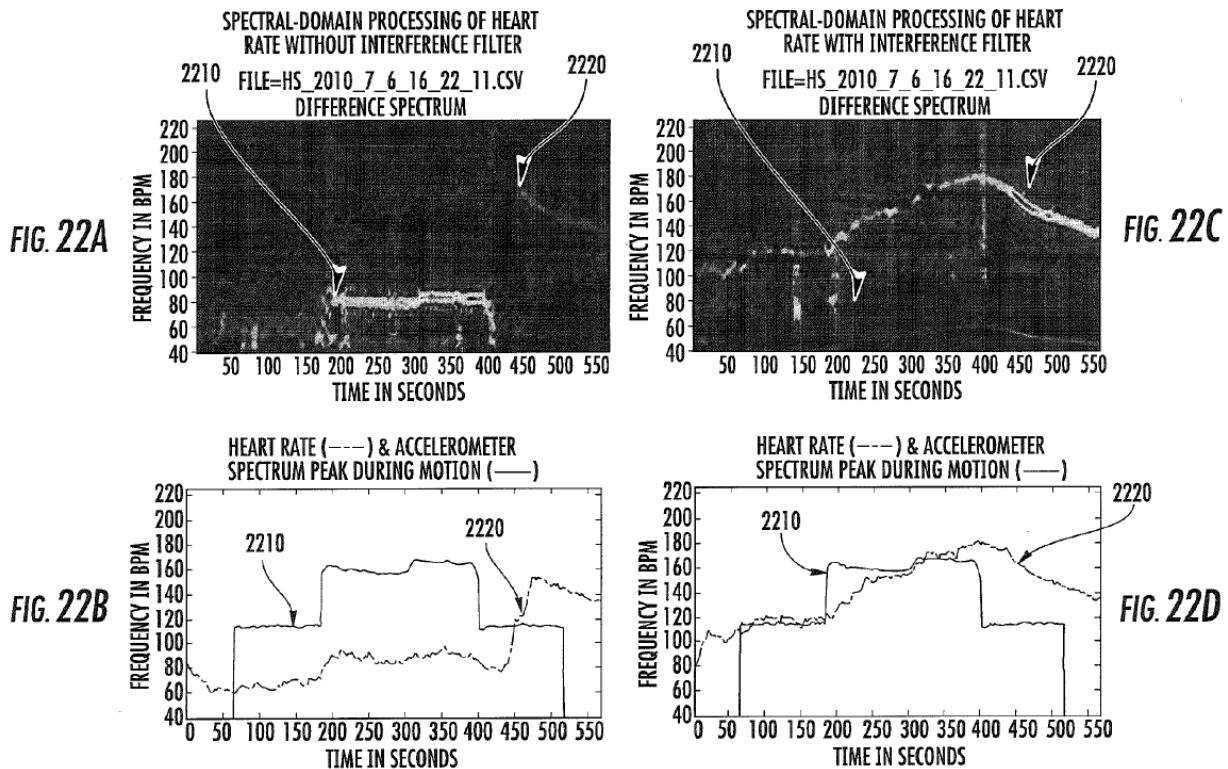
Claims 1 and 15 recite this limitation. Claim 8 similarly recites “*wherein the output signal is generated at least in part by using a Fourier transform of a signal resulting from differencing signals from the at least two receiver outputs.*”

Valencell-093 describes generating a “spectral representation” of all signals from the detectors, and then analyzing the frequencies present in each. Ex.1005, [0148] (“generate a spectral representation of all signals in all detectors”). For each detector 103, the interference filter 106 first subtracts (“*differences*”) the signal measured when the LEDs are off (“*first signal*” and a “*receiver output*”) from the signal measured when an LED is on (“*second signal*” and another “*receiver output*”) and it outputs a processed energy response signal that is passed to filter 107. Ex.1005, [0108]. The processed energy response signal embodies both signals that were used to create it. Ex.1003, ¶145. For one detector, the processed energy response signal embodies both the “*first*” and “*second*” signal, and for another detector the processed energy response signal embodies both “*receiver outputs.*” Ex.1003, ¶145.

The processed energy response signal for each detector is passed from interference filter 106 to signal extraction filter 107 to remove motion-related noise. Ex.1005, [0107], [0108], Fig. 18. Ex.1005, [0148] (“the output of at least one detector 103 may be processed with a digital filter... to identify only motion-related signals and remove these signals from the desired response (e.g., 109, FIG. 1)”).

The signal extraction filter 107 receives the outputs of interference filter 106 and motion sensor 104, and it creates a “spectral representation” of the signal from

each detector. Ex.1005, [0148]. This includes the processed energy response signal that includes the “*first*” and “*second*” signals as well as the processed energy response signal that includes and was created by differencing the “*two receiver outputs.*” Ex.1003, ¶¶146-147. Valencell-093 shows generating these spectral representations as spectrographs of frequency versus time (Ex.1005, [0149]), and includes exemplary depictions of them as follows:



A skilled person would have known that there are a finite number of known ways to generate the “spectral representations” described in Valencell-093. Ex.1003, ¶¶148-149. That person reading Valencell-093 would have immediately envisioned use of a fast Fourier transform (FFT) as a technique for creating the

spectral representations. Ex.1003, ¶149; *see Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). Prior art textbooks provide that the “traditional method of frequency analysis [is] based on the Fourier transform... through the fast Fourier transform (FFT) algorithm.” Ex.1019, 846-47. Although there are several ways of generating spectral representations of signals that do not use Fourier transforms (*e.g.*, wavelet transform), those techniques are not often used in real time, consumer systems. Ex.1003, ¶149. A skilled person would have known that an FFT was the most computationally efficient algorithm that could be used to generate the spectral representations described in Valencell-093, and that person would have immediately envisioned using this algorithm. Ex.1003, ¶149. As Dr. Anthony explains, the skilled person would have understood that Valencell-093 discloses use a “*Fourier transform.*” Ex.1003, ¶¶148-149.

To the extent that the Board finds the fact that Valencell-093 does not explicitly state that it uses an FFT means that Valencell-093 does not anticipate, it would have been obvious to use a Fourier transform on any of Valencell-093’s signals for the same reasons the skilled person would have understood Valencell-093 to disclose doing so. In addition, as Dr. Anthony explains, a Fourier transform was a well-known, conventional technique to perform signal analysis. Ex.1019, 846-47; Ex.1003, ¶¶149-151. A skilled person would have been motivated to use a Fourier transform on any of the above signals to filter unnecessary harmonics, such

as background noise from the sun, and to improve the measurement accuracy of each signal of interest. Ex.1003, ¶151.

In addition, the skilled person considering Valencell-093 also would have found use of a Fourier transform to generate the spectral representations obvious based on Bryars. Ex.1003, ¶¶152-154. Because Valencell-093 does not explicitly disclose the algorithm used to generate a spectral representation, a skilled person would have looked to known methods for doing so. Ex.1003, ¶¶153-154. That person would have looked to Bryars, which discloses known methods of creating a spectral representation of a signal in a wearable device. Ex.1003, ¶¶154. Bryars shows a wearable device that calculates a wearer's heart rate by computing a frequency spectrum of an optical signal and taking the highest peak of the spectrum as the heart rate frequency. Ex.1059, 9:11-15, 10:39-45. This is the same technique shown in Valencell-093. Ex.1005, [0149] (the algorithm "pick[s] out the strongest frequency as heart rate"); Ex.1003, ¶153. Bryars teaches that the spectrum is generated by using an FFT. Ex.1059, 10:7-9, 10:35-38. The skilled person considering Bryars with Valencell-093 would have found it obvious to use an FFT to generate the spectral representations of the signals described in Valencell-093. Ex.1003, ¶154. This would have been a predictable use of a known technique, and it would have been a matter of routine engineering effort to implement it in Valencell-093. Ex.1003, ¶154.

optical filter is “tuned to a wavelength region of interest” and “all other light is blocked.” Ex.1005, [0116]. Accordingly, Valencell-093’s optical filter is a physical component that selectively passes light of particular wavelengths while excluding other wavelengths, thereby meeting the Court’s claim construction. Moreover, a skilled person would have recognized that Valencell’s optical filter would have been designed for whatever wavelength the sensor needs to detect, *e.g.*, light from emitter 102 “centered around 930 nm,” and thus meets Apple’s district court construction. Ex.1003, ¶157; Ex.1005, [0117] (an optical emitter emits light “centered around 930 nm”).

6. Claims 5, 13, and 18

Claims 5 and 13 depend from claims 1 and 8, respectively, and specify “*wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.*” Claim 18 depends from claim 15 and has a similar limitation that replaces “*modulation*” with “*modulating.*”

Valencell-093 teaches that the sample rate of the receiver’s ADCs is synchronized to the pulse rate of the emitters. Ex.1005, Figs. 18, 19A, 19B (showing digital sampling of a signal), [0137] (“A pulsed emitter (*e.g.*, 102, FIG. 1) generates a pulsed beam of light such that some samples 1920 represent signal 1911 from a detector with the emitter turned off and other samples 1930 represent signal 1911 from the detector with the emitter turned on”), [0144] (“Pulsing an

emitter (e.g., 102, FIG. 1) and selectively sampling on/off signals”); Ex.1003, ¶¶160-161. 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.

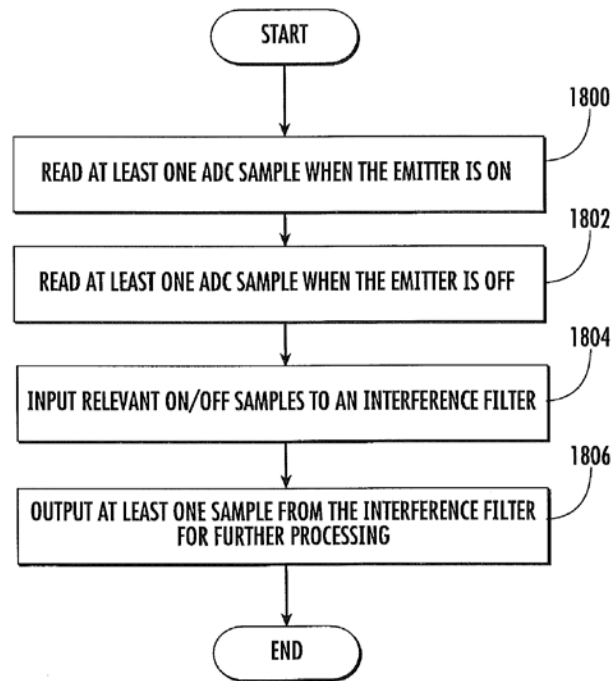


FIG. 18

Ex.1005, Fig. 18, [0137]. Groups of ADC samples, called a “batch of data,” may be selected using “a time delay.” Ex.1005, [0141] (“The time delay may be adjusted to generate the desired batch rate or batch frequency”). By adjusting a time delay to match the emitted pulses, the timing of the detector/ADC is synchronized to capture a specific number of emitted pulses (“*the modulation of the at least one of the LEDs*”), e.g., 6 on/off samples. *Id.* (“The batch rate may be chosen to avoid aliasing of interfering harmonics from the desired physical

condition monitored, such as the heart rate.”), Ex.1003, ¶161. The operations of the modulated LED emitter and the receiver ADC are, therefore synchronized. Ex.1003, ¶¶160-161. Thus, Valencell-093 teaches that “*the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.*” *Id.*

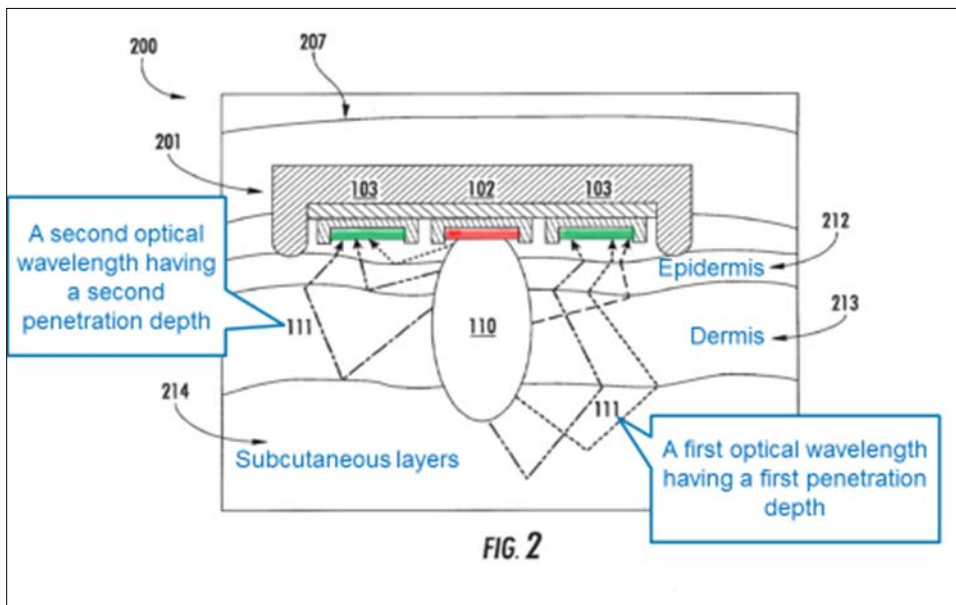
Alternatively, Valencell-093’s receiver ADC selects “the sampling frequency” according to the “Nyquist criteria for pulsing the emitter.” Ex.1005, [0139]. Nyquist criteria (or Nyquist frequency or rate), *id.*, is a well-known technique for ensuring the sampling rate allows accurate reproductions of the signal. Ex.1060, 295 (“Harry Nyquist... determined that to accurately reproduce a signal of frequency f , the sampling rate has to be greater than $2*f$...commonly called the Nyquist Rate.”); *id.*, 533. As Dr. Anthony explains, selecting a detector’s sampling rate according to the Nyquist rate of the pulsed emissions must sample twice as fast as the emitted pulses. Accordingly, a related timing (“*synchroniz[ation]*”) exists between the sampling rate and emitted pulses. Ex.1003, ¶162. Valencell-093 thus discloses that the receiver’s sampling rate is calculated using (“*synchronized*”) the pulsing of the emitter (“*the modulation of the at least one of the LEDs*”). Ex.1005, [0139]; Ex.1003, ¶162.

7. Claims 9 and 16

Claims 9 and 16 depend from claims 8 and 15, respectively, and further specify “*wherein at least one LED emits at a first wavelength and at least another*

LED emits at a second wavelength, and wherein the first wavelength... and... second wavelength ha[ve]... different... penetration depths.”

Valencell-093 discloses “one or more optical sources emitting one or more optical wavelengths.” Ex.1005, [0109], [0130] (“[m]ultiple wavelengths may be generated by ... multiple optical emitters”). Figure 2, annotated below, “illustrates a multi-wavelength reflection-mode pulse oximetry apparatus” (pulse oximetry requires different wavelengths of light (*e.g.*, red and IR), Ex.1019, 769), and shows different wavelengths penetrating different layers (*i.e.*, depths) of a user’s skin. Ex.1005, [0109], [0054]; Ex.1003, ¶164.



Some “reflected optical wavelengths 111” (right) penetrate to the deeper subcutaneous layers of a user’s tissue (“*a first optical wavelength having a first penetration depth*”) and other reflected optical wavelengths 111 (left) penetrate

only the more shallow dermis or epidermis layers (“*a second optical wavelength having a second penetration depth*”). Ex.1005, [0109]; Ex.1003, ¶¶164-165.

As Dr. Anthony explains, a skilled person also would have understood that light having different wavelengths (*e.g.*, those used in pulse oximetry) would inherently have different penetration depths into human tissue. Ex.1003, ¶166. He explains that the Beer-Lambert Law provides that light’s transmittance distance through a medium (*e.g.*, its penetration depth) is dependent upon the light’s wavelength, as was well-known and described by, for example, the International Union of Pure and Applied Chemistry (“IUPAC”) and others. *Id.*; *see* Ex.1028, 153-54, 394; Ex.1034, 2550, 2552-53.

The IUPAC’s description of the depth penetration of light is consistent with Valencell-093’s recognition that light of different wavelengths is absorbed differently depending on the composition of the blood. Ex.1005, [0109]; Ex.1003, ¶167. Pulse oximetry itself depends on the fact that blood and tissue absorb different wavelengths at different rates. Ex.1003, ¶167; Ex.1019, 766, *id.* at 769 (“The measurement is performed at two specific wavelengths: λ_1 ... (*e.g.*, 660 nm red light), and λ_2 ... (*e.g.*, 805 nm infrared light)”), *id.* at 1347. *See* Ex.1019, 1347.

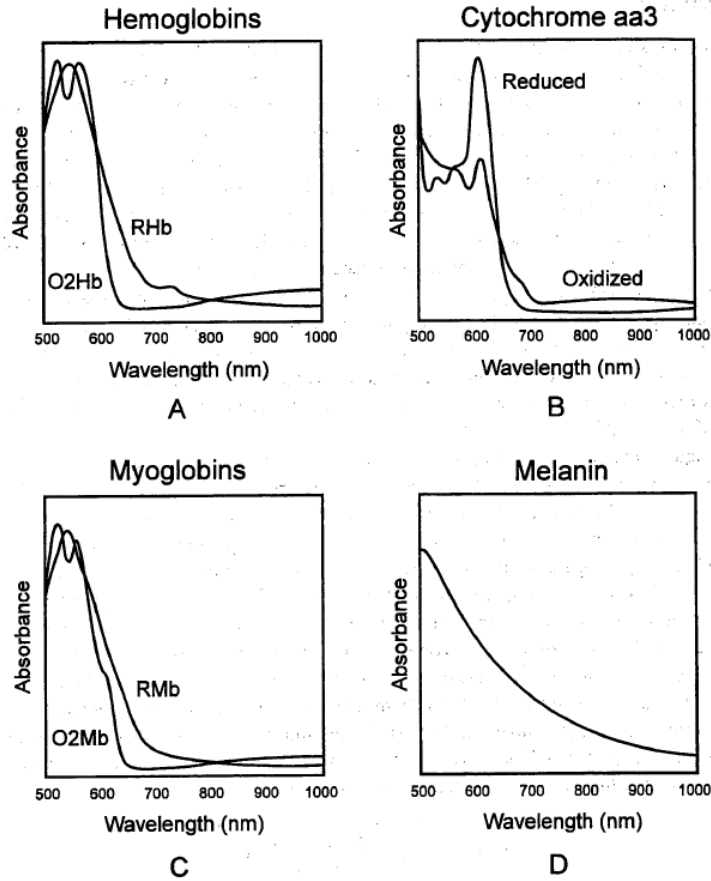


FIGURE 88.1 Absorption spectra of some endogenous biologic materials (a) hemoglobins, (b) cytochrome *aa3*, (c) myoglobins, and (d) melanin.

Consistent with the IUPAC, the '546 patent likewise states: “the penetration depth may be defined as the inverse of the absorption coefficient, although it may also be necessary to include the scattering for the calculation.” Ex.1001, 6:45-48; Ex.1003, ¶¶167-168.

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

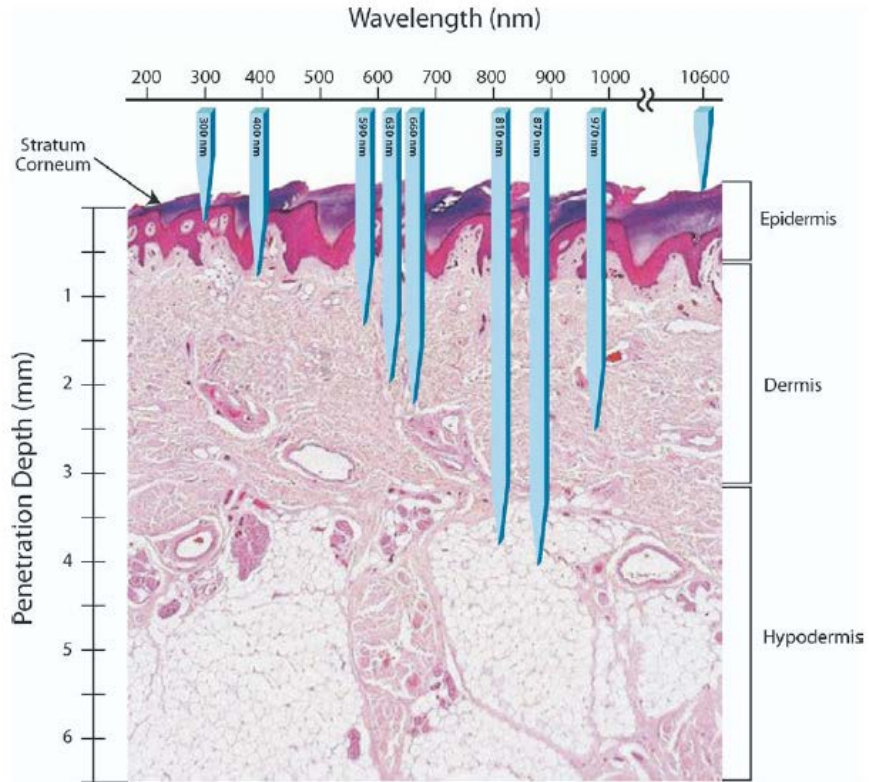


Figure 6 Optical penetration depth.

Ex.1036, 230. As Dr. Anthony explains, tissue inherently absorbs different wavelengths of visible light (*e.g.*, in the 600-700 nm range compared to the 800-1000 nm range) at different rates, and therefore, each wavelength penetrates the tissue a different depth. Ex.1003, ¶169. Pulse oximetry itself depends on this fact. Ex.1003, ¶169.

Thus, by teaching use of a plurality of differing wavelengths of light, Valencell-093 teaches this element, both expressly and inherently.

8. Claim 11

Claim 11 depends from Claim 8 and specifies the same limitation in claims 1(i) and 15(i). As shown above for claims 1 and 15 (*see* §VI.A.5.i) above), Valencell-093 discloses this limitation. Ex.1003, ¶171.

Claim 11 further specifies the same limitation in claims 1(j) and 15(j). As shown above for claims 1 and 15 (*see* §VI.A.5.j) above), Valencell-093 discloses this limitation. Ex.1003, ¶172.

B. Ground 2: Valencell-093, Bryars, and Lisogurski Render Obvious Claims 1, 5, 8-9, 11, 13, 15-16, and 18

Patent Owner may argue that Valencell-093 and Bryars, as combined above, do not disclose “*improv[ing] the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs.*” This distinction, even if established, would not render the claims patentable. Instead, a skilled person would have recognized that increasing SNR by increasing LED intensity as taught by Lisogurski would have been a known and predictable option for further addressing the problems with time-varying noise identified by Valencell-093 and Bryars,. Ex.1003, ¶¶173.

Lisogurski describes a portable physiological monitoring system that uses a wearable optical sensor to measure a person’s pulse rate and oxygen saturation (*e.g.*, a pulse oximetry system). Ex.1011, 3:66-4:8. The sensor can include several light emitting diodes (LEDs) and photodetectors. Ex.1011, 17:37-45, 10:48-64,

11:9-13. The system regulates a light drive signal, which is the electric current that is applied to the LEDs. Ex.1011, 11:38-41, 11:50-54, 12:3-9; Ex.1003, ¶174. For a particular LED, the emitted light intensity increases as a higher current is applied thereby improving the SNR in some circumstances. Ex.1011, 9:46-60, 12:3-9, 12:16-22, 7:13-16, 7:24-31.

A skilled person following their ordinary design processes would consider and evaluate known techniques and structures used in analogous systems such as Lisogurski that could improve performance. Ex.1003, ¶175. Valencell-093 teaches that time-varying interference, caused by both sunlight and user motion, can interfere with accurately measuring physiological parameters. Ex.1005, [0110]. In fact, one of Valencell-093's goals is to mitigate such time-varying environmental noise. Ex.1005, [0112]. While Valencell-093 discloses several techniques for reducing motion-related noise, a skilled person would have been motivated to look for additional techniques that could supplement Valencell-093's approach. Ex.1003, ¶175.

Lisogurski teaches techniques for improving SNR when a subject is in motion. Lisogurski teaches increasing the SNR by increasing the "brightness" of a light source, which corresponds to the light intensity of that light source ("*increasing a light intensity*"). Ex.1003, ¶176. For example, Lisogurski explains that the sensor may receive "an increased level of background noise in the signal

due to patient motion. The system may *increase the brightness of the light sources* in response to the noise *to improve the signal-to-noise ratio.*” Ex.1011, 9:46-52; *see id.*, 37:6-22.

A skilled person would have been motivated to incorporate Lisogurski’s technique for improving SNR when a user is in motion into Valencell-093. Ex.1003, ¶177. Valencell-093 teaches that the intensity of the LED can be adjusted, Ex.1005, [0097], and the skilled person would have found it obvious to use that functionality to improve SNR to mitigate noise caused by motion as taught by Lisogurski. Ex.1003, ¶177. This would have been nothing more than a predictable combination, using one technique for its known purpose, that could be done using routine engineering effort. Ex.1003, ¶177. Thus, Valencell-093, Bryars, and Lisogurski render this limitation obvious.

C. Ground 3: Valencell-093, Bryars, and Hanna (with or without Lisogurski) Render Obvious Claims 1, 5, 8-9, 11, 13, 15-16, and 18

Patent Owner may argue that Valencell-093 and Bryars, as combined above, do not disclose modulating at least one of the LEDs to include information, as required by the district court’s claim construction. This distinction, even if established, would not render the claims patentable. Instead, a skilled person would have recognized that modulating to contain information would have been a known and predictable option for implementing the devices suggested by the

combination of Valencell-093 and Bryars, particularly in view of Hanna. Ex.1003, ¶178.

Hanna describes a pulse oximeter, shown below, that can be worn on a user's ear or finger to measure oxygen saturation:

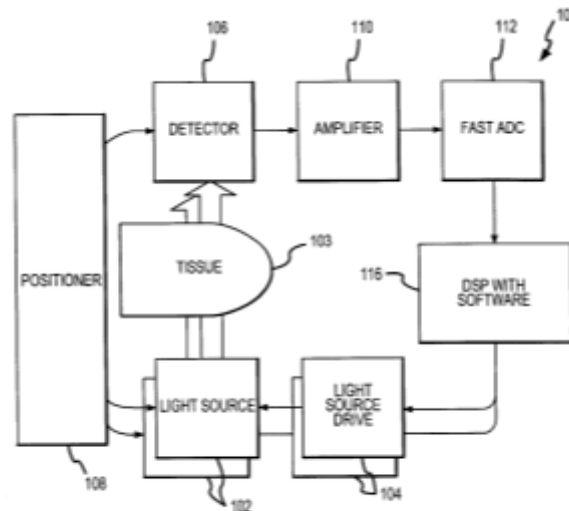


FIG. 1

Ex.1007, Fig. 1, 1:25-39. The sensor has multiple emitters 102, which can be red and infrared LEDs. Ex.1007, 4:34-43. The light emitted from these LEDs is “modulated using different code sequences.” Ex.1007, 4:43-51, Figs. 2-4, 6:13-8:25 (describing encoded signals). One or more detectors 106 pick up the light reflected back from the user's tissue 103. Ex.1007, 4:67-5:18, 8:26-33, 1:48-49.

Hanna teaches 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. Modulating the light to include the codes creates non-periodic signals, which allows the detector to discriminate between noise sources that are

naturally periodic and the modulated signal, because the modulated light 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 embedded in the modulated light is identifying information. Ex.1007, 6:13-8:25; Ex.1003, ¶¶179-180. Thus, Hanna teaches modulating light to include information, as required by the district court's construction. Ex.1003, ¶180.

A skilled person would have found it obvious to include Hanna's coding technique in the Valencell-093 device to increase the detectability of the signals from multiple emitters in the presence of noise. Ex.1003, ¶¶181-184. Valencell-093 teaches use of multiple LEDs, as shown in Figure 9A for example, and adding Hanna's technique would have allowed the detector to efficiently determine the signal contribution from each LED. Ex.1003, ¶¶183-185.

A skilled person following his or her ordinary design processes would consider and evaluate known techniques used in analogous systems such as Hanna that could improve performance. Ex.1003, ¶186. Improving performance by making signals of interest more detectable in the presence of noise is a specific objective of Hanna's coding technique. Ex.1007, 2:3-31. Hanna explains that use of its non-periodic codes provides a specific benefit when in the presence of periodic noise sources as compared to time division multiplexed signals. Ex.1007, 2:59-62, 4:51-54. Like Hanna, Valencell-093 recognizes the desirability of

removing noise from a signal of interest. Ex.1005, [0003]. A skilled person would have turned to the coding technique described by Hanna as a known way of accomplishing this objective. Ex.1003, ¶¶184-186. Thus, a skilled person would have been motivated to include the Hanna technique in the Valencell-093 device in order to obtain the performance benefits described by Hanna. Ex.1003, ¶¶185-186.

The skilled person also would have recognized that incorporating Hanna's coding technique into the Valencell-093 sensor would involve combining familiar elements according to known methods, yielding predictable results. Ex.1003, ¶¶184-186. Modulating light to convey information was also a well-known technique in the context of optical sensors and other contexts.⁹ Ex.1003, ¶186. Valencell-093 teaches using modulation, and a skilled person would have been able to reasonably predict that incorporating Hanna's known modulation technique into the Valencell-093 device would be to make it easier to distinguish signals of interest from each other and from noise and to thereby improve performance. Ex.1003, ¶186.

⁹ The '546 specification provides no explanation of how or why a signal would be modulated to include information (*see* Ex.1001, 8:44-46), presumably because this was well known at the time.

Hanna and Valencell-093 also describe analogous optical sensors for measuring physiological characteristics. Ex.1005, [0006]; Ex.1007, 1:24-26; Ex.1003, ¶186. Both references, directed to the same technology with common applications and utility, describing techniques for improving noise reduction in optical sensors. Ex.1003, ¶186.

D. Ground 4: Valencell-093, Bryars, and Valencell-099 (with or without Lisogurski and/or Hanna) Render Obvious Claim 12

Claim 12 depends from claim 8, and further specifies that the wearable device communicate with “*a smart phone or tablet*” that can further process the output signal and transmit the processed signal to another device. Valencell-093 describes a headset that communicates with a cellphone but does not explicitly recite a smartphone. Configuring Valencell-093 to include a smartphone would have been obvious based on Valencell-093 and Bryars (with or without Lisogurski and/or Hanna) in further view Valencell-099.

1. Overview of Valencell-099

Valencell-099 describes a Bluetooth headset that includes a sensor for measuring physiological parameters such as blood oxygen level, and cholesterol, among many others. Ex.1006, [0007], [0010], [0076]. The headset is part of a health monitoring system that can be used for a variety of applications. Ex.1006, [0110]-[0130]. The headset includes a sensor module (element 21 of Figure 2, below), which can be an optical sensor. Ex.1006, [0095].

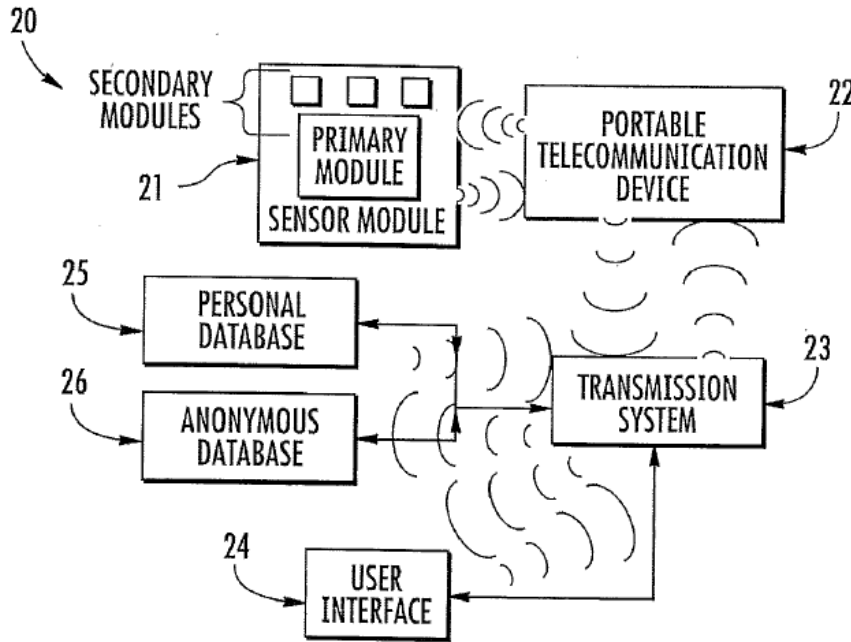


FIG. 2

Valencell-099 explains that the sensor module 21 communicates wirelessly with portable telecommunication device 22, which can be a smartphone, laptop computer, or other portable device. Ex.1006, [0096]. Valencell-099 explains that the portable telecommunication device can store, analyze, and display sensor data. Ex.1006, [0097]. Using transmission system 23, the portable telecommunication device can wirelessly transmit information to remote databases 25 and 26 for storage, analysis, and retrieval. Ex.1006, [0098].

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

A skilled person would have considered Valencell-093 with Valencell-099, as both describe a Bluetooth headset designed by Valencell that uses an optical sensor to measure physiological parameters. Ex.1003, ¶¶192-195. 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, ¶¶195-196.

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, ¶197. Valencell-093 focuses on teaching “how to make a wearable 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, [0112]; Ex.1006, [0003].

Valencell-093 identifies the benefits of incorporating a physiological sensor into a Bluetooth headset, which was intended to wirelessly communicate with another device such as a cell phone. Ex.1005, [0104]. Valencell-093 further

explains that a “processed energy response signal [from the described sensor] is [wirelessly] transmitted to a remote device.” Ex.1005, [0035]. Valencell-093 does not, however, describe the features of the remote device. 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 with the headset. Ex.1003, ¶198.

A skilled person reading Valencell-093 would have considered the combined teachings of Bryars, Lisogurski, Hanna, and Valencell-099, which describe analogous devices for measuring physiological parameters. Ex.1003, ¶200. A skilled person would consider such analogous references as part of the ordinary design process he or she follows to improve the operation of a device, particularly given the emphasis all the references place on providing accurate health data. *Id.*

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 applications. Ex.1003, ¶200.

3. Claim 12

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 smartphone is a type of cellphone, and a skilled person would have used the terms interchangeably. Ex.1003, ¶203. Bluetooth headsets also were routinely used at that time with smartphones and tablets for both “personal communication and multimedia applications.” Ex.1005, [0104]; Ex.1003, ¶203. Thus, a skilled person would have considered Valencell-093 to teach a configuration where the remote device was a smartphone or tablet. Ex.1003, ¶203.

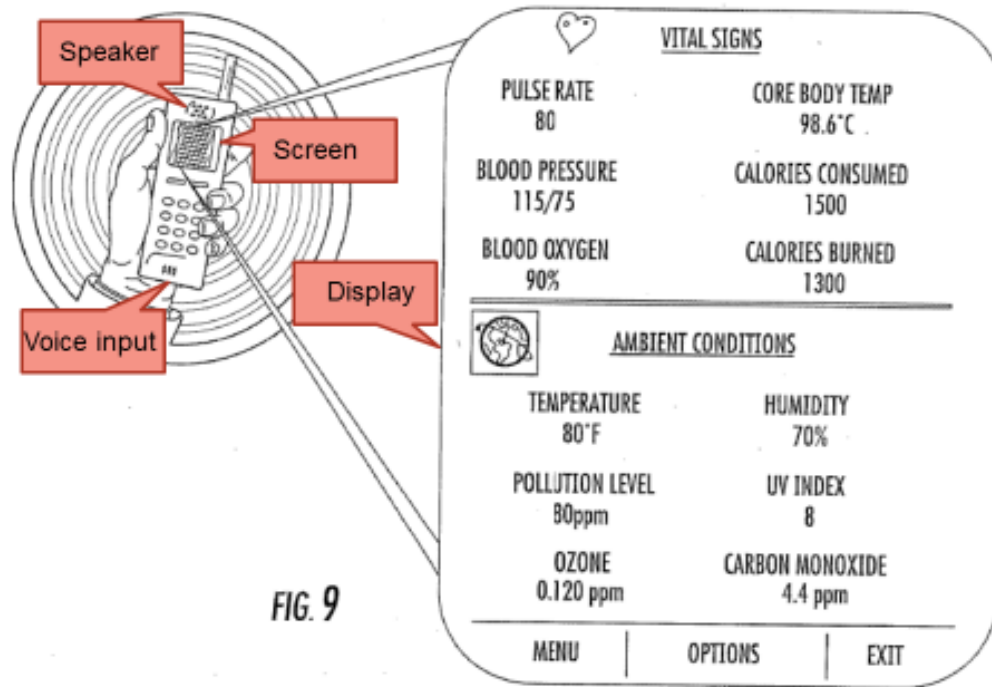
Patent Owner may contend that Valencell-093 does not disclose a remote device that is a smartphone. Valencell-099, however, describes an analogous system that uses a smartphone as the remote device. In particular, Valencell-099 describes a wearable device (e.g., a Bluetooth headset), Ex.1006, [0070], [0074], that transmits a wireless data signal 19 to a “portable telecommunications device 22 such as... a ‘smartphone’” or tablet. Ex.1006, [0018], [0096] (“telecommunication device 22 can be any portable device, such as a cell phone (which includes a ‘smartphone’), PDA..., or other portable, telemetric device.”),

[0085]. A skilled person would immediately envisage a tablet from these teachings. Ex.1003, ¶204.

- 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 smartphone or tablet, as described above. Ex.1006, [0018], [0096]. Nothing in the '546 patent suggests that the terms “*smart phone*” or “*tablet*” were being used with a special meaning. Ex.1003, ¶¶205-206. It was well known that smartphones and tablets include a wireless transmitter and receiver, a display, a voice input module such as a microphone, a speaker, and a touch screen. *Id.*

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



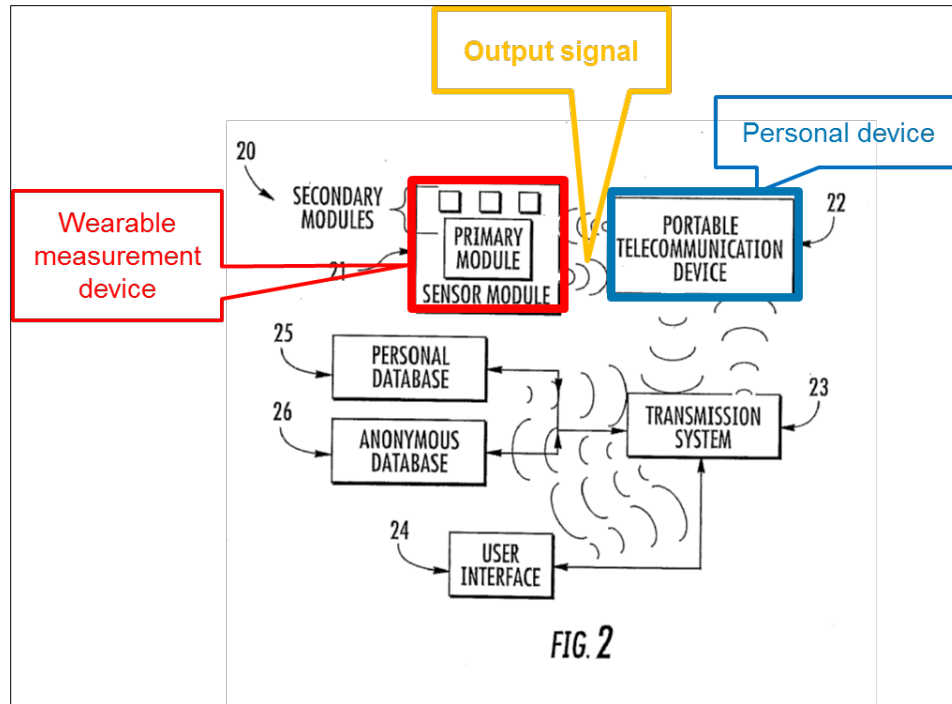
Patent Owner may contend that Valencell-099 does not explicitly describe a touch screen. A skilled person, however, would have considered a touch screen to be an obvious choice for the smartphone's screen. Ex.1003, ¶¶207-208.

Valencell-099 describes a user interacting with handheld devices to view and manipulate information. *See, e.g.*, Ex.1006, Figs. 9, 10. The logical and known options for handheld devices were smartphones and tablets with user interfaces that incorporate touch screens. Ex.1003, ¶208. 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, ¶208. *See Kennametal*, 780 F.3d at 1381; *In re Petering*, 301 F.2d at 681.

- 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 remote device, which Valencell-099 explicitly teaches can be a smartphone. Ex.1005, [0035], [0096], [0104], [0110]; Ex.1006, [0018], [0083]-[0086], [0096], [0124]. A skilled person would understand that both Valencell references teach a smartphone or tablet “*configured to receive ...at least a portion of*” the transmitted “*output signal.*” Ex.1003, ¶211.

Valencell-099 teaches that personal communication device 22 (*e.g.*, a smartphone or tablet) *receives* output signal 19 transmitted by sensor module 21 (“*wearable measurement device*”):



Ex.1006, Fig. 2 (annotated), [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]; *see also* [0014], [0018]; Ex.1003, ¶211.

Valencell-099 further teaches that the portable telecommunication device 22 *processes* the output signal 19. Ex.1003, ¶212. For example, “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... 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”); Ex.1003, ¶212.

- d) **“wherein the smart phone or tablet is configured to store and display the processed output signal”**

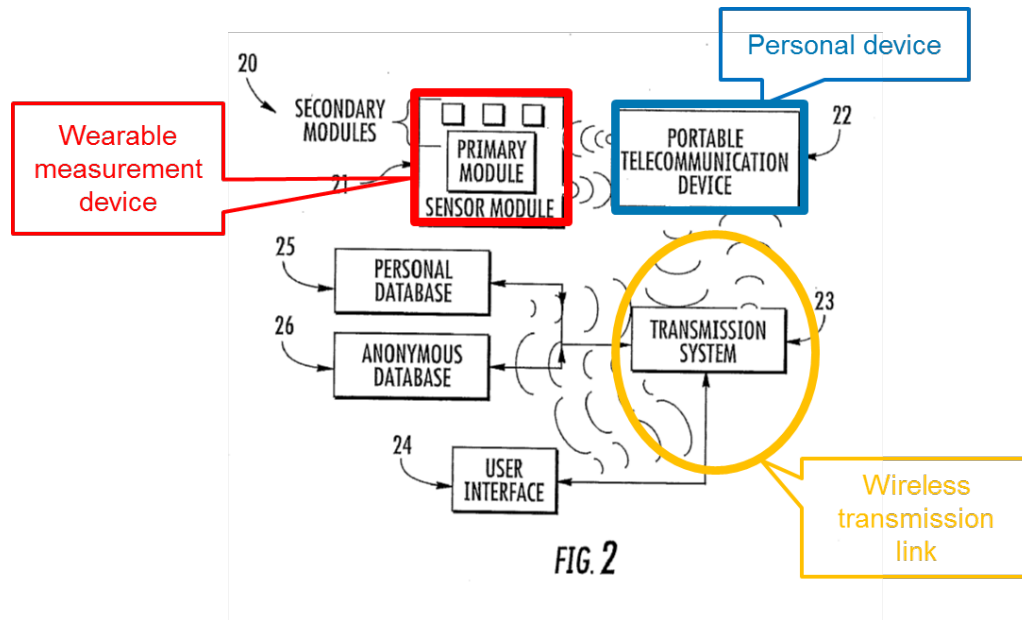
Valencell-099 explains that the

“The portable telecommunication device 22 may also contain an end-user graphical interface... such that data from the wearable sensor module 21 can be *stored, analyzed, summarized, and displayed* on the portable telecommunication device 22.”

Ex.1006, [0097], [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]; Ex.1003, ¶215.

- 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 shows portable telecommunication device 22 can wirelessly communicate with other devices via transmission system 23.



Ex.1006, Fig. 2 (annotated) above, [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, ¶218.

The information transmitted over the wireless transmission system 23 to other devices, such as databases 25, 26 or user interface 24, includes ***at least a portion of the processed output signal***, per claim limitations 12(c)-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), Fig. 3 (showing the processed data displayed by user interface 24), Figs. 10-21 (providing additional display examples); Ex.1003, ¶219.

E. No Secondary Considerations Exist

As described above, Valencell-093 and Bryars, alone or in combination with Lisogurski and/or Hanna and/or Valencell-099 teaches systems that render *prima facie* obvious the challenged claims of the '546 patent. No secondary indicia of non-obviousness exist having a nexus to the putative “invention” of these claims contrary to that conclusion. Petitioner reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced by Patent Owner.

VII. Conclusion

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

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Respectfully submitted,

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Backup Counsel for Petitioner

Claim Appendix

Independent claims 1, 8, and 15 and their dependent claims have many overlapping features with some minor differences (highlighted), shown in the table below:

Claim 1 & Dependent Claims	Claim 8 & Dependent Claims	Claim 15 & Dependent Claims
<p>1. A wearable device, comprising:</p> <p>[1A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters, the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths, wherein at least a portion of the optical beam includes a near-infrared wavelength between 700 nanometers and 2500 nanometers;</p>	<p>8. A wearable device, comprising:</p> <p>[8A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters, the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths, wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;</p>	<p>15. A wearable device, comprising:</p> <p>[15A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters, the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths, wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;</p>
<p>[1B] the measurement device comprising one or more lenses configured to receive and to deliver at least a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue;</p>	<p>[8B] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue, and wherein the measurement device is adapted to be placed on a wrist or an ear of a user;</p>	<p>[15B] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue, and wherein the measurement device is adapted to be placed on a wrist or an ear of a user;</p>

Claim 1 & Dependent Claims	Claim 8 & Dependent Claims	Claim 15 & Dependent Claims
<p>[1C] the measurement device further comprising a receiver, the receiver having a plurality of spatially separated detectors and one or more analog to digital converters coupled to the spatially separated detectors, the one or more analog to digital converters configured to generate at least two receiver outputs;</p>	<p>[8C] the measurement device further comprising a receiver, the receiver having a plurality of spatially separated detectors and one or more analog to digital converters coupled to the spatially separated detectors, the one or more analog to digital converters configured to generate at least two receiver outputs;</p>	<p>[15C] the measurement device further comprising a receiver, the receiver having a plurality of spatially separated detectors and one or more analog to digital converters coupled to the spatially separated detectors, the one or more analog to digital converters configured to generate at least two receiver outputs,</p>
<p>[1D] the receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and to convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;</p>		<p>[15D] the receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;</p>
<p>[1E] the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal and by differencing the two receiver outputs;</p>	<p>[8D] the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the two receiver outputs;</p>	<p>[15E] the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal and by differencing the two receiver outputs;</p>

Claim 1 & Dependent Claims	Claim 8 & Dependent Claims	Claim 15 & Dependent Claims
<p>[1F] the measurement device configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;</p>	<p>[8E] the measurement device configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;</p>	<p>[15F] the measurement device configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;</p>
<p>[1G] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue,</p>	<p>[8F] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue,</p>	<p>[15G] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue,</p>
<p>[1H] wherein the output signal is generated at least in part by using a Fourier transform of signals from the receiver including at least one of the first and second signals and signals from the at least two receiver outputs; and</p>	<p>[8G] wherein the output signal is generated at least in part by using a Fourier transform of a signal resulting from differencing signals from the at least two receiver outputs; and</p>	<p>[15H] wherein the output signal is generated at least in part by using a Fourier transform of signals from the receiver including at least one of the first and second signals and signals from the at least two receiver outputs; and</p>
<p>[1I] wherein the receiver further comprises one or more spectral filters positioned in front of at least some of the plurality of spatially separated detectors.</p>	<p>[8H] wherein the receiver further comprises one or more spectral filters positioned in front of at least some of the plurality of spatially separated detectors.</p>	<p>[15I] wherein the receiver further comprises one or more spectral filters positioned in front of at least some of the plurality of spatially separated detectors.</p>
<p>[5] The wearable device of claim 1, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.</p>	<p>[13] The wearable device of claim 8, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.</p>	<p>[18] The wearable device of claim 15, wherein the receiver is configured to be synchronized to the modulating of the at least one of the LEDs.</p>

Claim 1 & Dependent Claims	Claim 8 & Dependent Claims	Claim 15 & Dependent Claims
	<p>[9] The wearable device of claim 8, wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth.</p>	<p>[16] The wearable device of claim 15, wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth.</p>
<p><i>See [1D]</i></p>	<p>[11A] The wearable device of claim 8, wherein the receiver is further configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;</p> <p>[11B] the measurement device configured to further improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal.</p>	<p><i>See [15D]</i></p>

Claim 1 & Dependent Claims	Claim 8 & Dependent Claims	Claim 15 & Dependent Claims
	<p>[12] The wearable device of claim 8, 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.</p>	

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 13,998 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.

Dated: October 17, 2019

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I hereby certify that on this 17th day of October, 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 Omni:

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