

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WHOOOP, INC.
Petitioner

v.

OMNI MEDSCI, INC.,
Patent Owner.

Post Grant Review No. PGR2026-00003

U.S. Patent No. 12,193,790

**DECLARATION OF DR. PATRICK MERCIER IN SUPPORT OF
PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 12,193,790**

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1002	File History, U.S. Patent No. 12,193,790
1004	U.S. Patent No. 9,651,533
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1006	Docket Sheet, <i>Omni MedSci, Inc. v. WHOOP, Inc.</i> , No. 1:25-cv-00140 (D. Del.)
1007	Docket Sheet, <i>Omni MedSci, Inc. v. Samsung Elecs., et al.</i> , No. 2:24-cv-01070 (E.D. Tex.)
1008	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2019-00916, Paper No. 39 (P.T.A.B. Oct. 14, 2020) (Final Written Decision, '533 IPR)
1009	<i>Omni MedSci, Inc. v. Apple Inc.</i> , No. 21-1229, 2022 WL 2062168 (Fed. Cir. Jun. 8, 2022) (summary affirmance, '533 IPR)
1010	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Patent Owner's Notice of Appeal (P.T.A.B. Apr. 11, 2025)
1011	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Paper No. 22 (P.T.A.B. Aug. 3, 2022) (First Final Written Decision, '484 IPR)
1012	<i>Apple Inc. v. Omni MedSci, Inc.</i> , No. 23-1034, 2024 WL 3084509 (Fed. Cir. Jun. 21, 2024) (First Federal Circuit Decision, '484 IPR)
1013	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Paper No. 26 (P.T.A.B. Feb. 14, 2025) (Second Final Written Decision, '484 IPR)
1014	Docket Sheet, <i>Omni MedSci, Inc. v. Apple Inc.</i> , No. 25-1646 (Fed. Cir.) (Docket Sheet, Second Federal Circuit Appeal, '484 IPR)

Exhibit	Description
1015	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2019-00916, Paper No. 1 (P.T.A.B. Apr. 10, 2019) (Petition, '533 IPR)
1016	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2019-00916, Paper No. 10, (P.T.A.B. Oct. 18, 2019) (Patent Owner's Preliminary Response, '533 IPR)
1017	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2019-00916, Paper No. 16, (P.T.A.B. Oct. 18, 2019) (Institution Decision, '533 IPR)
1018	RESERVED
1019	RESERVED
1020	RESERVED
1021	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Paper No. 1, (P.T.A.B. Jan. 22, 2021) (Petition, '484 IPR)
1022	RESERVED
1023	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Paper No. 7 (P.T.A.B. Aug. 6, 2021) (Institution Decision, '484 IPR)
1024	<i>Apple Inc. v. Omni MedSci, Inc.</i> , IPR2021-00453, Paper No. 10 (P.T.A.B. Nov. 12, 2021) (Patent Owner Response, '484 IPR)
1025	RESERVED
1026	RESERVED
1027	U.S. Patent No. 9,241,676 ("Lisogurski")
1028	U.S. Patent App. Pub. No. 2005/0049468 ("Carlson")
1029	RESERVED
1030	U.S. Patent No. 6,304,767 ("Soller")
1031	RESERVED
1032	U.S. Patent Appl. Pub. No. 2012/0197093 ("Valencell-093")
1033	"The Biomedical Engineering Handbook," by Joseph D. Bronzino (1995)
1034	Patel, et al., A review of wearable sensors and systems with application rehabilitation, <i>Journal of Neuroengineering & Rehabilitation</i> (2012)
1035	A. Omre, Bluetooth Low Energy: Wireless Connectivity for Medical Monitoring, <i>Journal of Diabetes Science & Technology</i> (Mar. 2010)
1036	P. Baum, et al., Strategic Intelligence Monitor on Personal Health Systems, Phase 2: Market Developments - Remote Patient Monitoring

Exhibit	Description
	and Treatment, Telecare, Fitness/Wellnes and mHealth, JRC <i>Scientific and Policy Reports of European Commission</i> (2013)
1037	M. Kranz, et al., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, <i>Pervasive and Mobile Computing</i> (June 2012)
1038	M. Swan, Senior Mania! The Internet of Things, Wearable Computing, Objective Metrics, and the Quantified Self 2.0, <i>Journal of Sensor and Actuator Networks</i> (2012)
1039	RESERVED
1040	The Usage of Tablets in the HealthCare Industry,” by Rauf Adil (Aug. 2, 2012), available through the Internet Archive at https://web.archive.org/web/20121014002306/https://www.healthcareitnews.com/blog/usage-tablets-healthcare-industry (last accessed Sept. 4, 2025)
1041	RESERVED
1042	Curriculum Vitae of Patrick Mercier, PhD
1043	Docket Sheet, <i>Omni MedSci, Inc. v. Apple Inc.</i> , No. 4:19-cv-05924 (N.D. Cal.)
1044	RESERVED
1045	Webster, J. G. (1997) Design of Pulse Oximeters, IOP Publishing.
1046	RESERVED
1047	RESERVED
1048	RESERVED
1049	RESERVED
1050	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , IPR2025-01250, Paper No. 1 (P.T.A.B. Aug. 5, 20215) (533 IPR Petition)
1051	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , IPR2025-01251, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (304 IPR Petition)
1052	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , IPR2025-01252, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (455 IPR Petition)
1053	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , IPR2025-01253, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (790 IPR Petition)
1054	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , PGR2025-00064, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (790 PGR Petition)

Exhibit	Description
1055	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , IPR2025-01254, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (475 IPR Petition)
1056	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , PGR2025-00063, Paper No. 1 (P.T.A.B. Aug. 5, 2025) (475 PGR Petition)
1057	U.S. Patent No. 10,874,304
1058	U.S. Patent No. 11,160,455
1059	RESERVED
1060	12,268,475
1061	<i>Omni MedSci, Inc. v. Apple Inc.</i> , No. 25-1646, Dkt. 17 (Fed. Cir. Sept. 11, 2025) (Omni’s Corrected Opening Brief)
1062	U.S. Patent App. Pub. No. 2011/0237911 (“Lamego”)
1063	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , PGR2025-00064-1021, Ex. 1021 (P.T.A.B. Aug. 5, 2025) (Ex. 1021 to Samsung’s ’790 PGR Petition)
1064	<i>Samsung Elecs. Co. et al. v. Omni MedSci, Inc.</i> , PGR2025-00064-6 (P.T.A.B. Aug. 5, 2025) (Samsung’s Petition Ranking and Explanation of Parallel Petitions)
1065	Wu, et al., <i>A new generation of sensors for non-invasive blood glucose monitoring</i> , Am. J. of Translational Research 2023;15(6):3825-3827 (Jun. 30, 2023)
1066	<i>WHOOP, Inc. v. Omni MedSci, Inc.</i> , IPR2025-01583, Paper No. 1 (P.T.A.B. Sept. 26, 2025) (WHOOP ’533 IPR Petition)
1067	<i>WHOOP, Inc. v. Omni MedSci, Inc.</i> , IPR2025-01584, Paper No. 1 (P.T.A.B. Sept. 26, 2025) (WHOOP ’304 IPR Petition)
1068	<i>WHOOP, Inc. v. Omni MedSci, Inc.</i> , IPR2025-01583, Paper No. 1 (P.T.A.B. Sept. 26, 2025) (WHOOP ’455 IPR Petition)
1069	<i>WHOOP, Inc. v. Omni MedSci, Inc.</i> , 1:25-cv-140-WCB, D.I. 11-12 (D. Del. May 5, 2025) (Ex. 12 to Delaware action Amended Complaint)
1070	U.S. Pat. Provisional App. No. 61/747,472 (Dec. 31, 2012)
1071	U.S. Pat. Provisional App. No. 61/747,477 (Dec. 31, 2012)
1072	U.S. Pat. Provisional App. No. 61/747,487 (Dec. 31, 2012)
1073	U.S. Pat. Provisional App. No. 61/747,553 (Dec. 31, 2012)
1074	U.S. Pat. Provisional App. No. 61/754,698 (Dec. 31, 2012)

I, Dr. Patrick Mercier, hereby declare as follows:

I. INTRODUCTION

1. I have been retained on behalf WHOOP, Inc (“WHOOP” or “Petitioner”) as an independent expert in this Petition for post grant review by the U.S. Patent and Trademark Office to offer my technical opinion as to the following topics: (1) the disclosure of the U.S. Patent No. 12,193,790 (the “’790 Patent”) (EX1001); (2) the invalidity of claim 7 of the ’790 patent (the “Challenged Claim”) in view of the prior art; (3) whether the Challenged Claim, and specifically, the “identify an object” limitation is indefinite; and (4) whether the full scope of the Challenged Claim is enabled.

2. In summary, it is my opinion that the Challenged Claim is invalid in view of the prior art I discuss in this Declaration. In particular, it is my opinion that the prior art discussed herein discloses, teaches, or suggests the invention claimed in the Challenged Claim, rendering the Challenged Claim invalid as obvious over the prior art. It is also my opinion that, applying Omni’s interpretation of the scope of the “identifying an object” limitation of the Challenged Claim, as set forth in an ongoing *inter partes* review of a related patent, U.S. Patent No. 10,517,484 (the “’484 Patent”), the Challenged Claim would be indefinite. Specifically, a POSITA reading the ’790 Patent would not have understood which materials qualify as separate, identifiable objects (as opposed to sub-components or alternate forms of a

single object) under the interpretation of the claim limitation advanced by Omni. It is also my opinion that the Challenged Claim is not enabled across its full scope; in fact, numerous of the biomedical applications of the “identify an object” limitation described in the specification (and identified by Omni in the ’484 IPR) are inoperable in practice. For example, applying Omni’s understanding of the “identifying an object” limitation, the Challenged Claim purports to recite a non-invasive optical system for distinguishing and measuring certain blood constituents with only subtle spectral signature differences from one another, most notably glucose. But non-invasive optical measurement of glucose (to any useful degree of certainty) has not been achieved to the present day, and certainly would not have been possible by the alleged priority date of the ’790 Patent. The particular references, combinations, and reasoning that support my opinions and bases thereof, are set forth in detail below.

3. I am being compensated for my work on this case at my standard consulting rate of \$650. I am also being reimbursed for my expenses that I may incur. My compensation is in no way contingent upon the results of my study, the substance of my testimony, or the outcome of this case.

4. Based upon the facts and information available to me to date, I detail my opinions relevant to this petition for post grant review. I am prepared to provide expert testimony on the opinions formed herein if asked about those issues by the Board or others.

5. Additionally, I may discuss my own work, teachings, and knowledge of the state of the art in the relevant time period. I may rely on handbooks, textbooks, technical literature, and the like to demonstrate the state of the art in the relevant period and evolution of the technology.

6. Throughout this declaration, I refer to specific line numbers or page numbers of the relevant prior art or other technical documents. The citations are intended to be exemplary as opposed to being exhaustive and are not intended to convey that the citations are the only source of evidence to support the propositions for which they are cited.

II. QUALIFICATIONS AND EXPERIENCE

A. Overview of Qualifications and Experience

7. My educational background, professional experience, and a list of my publications are set forth in my *curriculum vitae*, attached to this Declaration as **Appendix B (EX1042)**.

8. As discussed in more detail below, I have particular expertise in the subject matter discussed in the '790 Patent as I am the co-founder and co-director of the Center for Wearable Sensors at the University of California San Diego ("UCSD").

9. I received my B.Sc. degree in Electrical and Computer Engineering in 2006 from the University of Alberta. I received my S.M. in 2008, and my Ph.D. in Electrical Engineering in 2012, both from the Massachusetts Institute of Technology.

10. In 2012, after receiving my Ph.D., I joined UCSD as an Assistant Professor, and I became a Full Professor in 2023 and Vice Chair of the Electrical and Computer Engineering department in 2024. My professional experience includes three main components: research, teaching, and service to the scientific community.

B. Research and Development

11. My research relates to the design of energy-efficient microsystems, including the design of RF circuits, power converters, and sensor interfaces for miniaturized systems. My research has involved the development of wearable sensors, low-power wireless sensing systems, and power management integrated circuits. My research has been and/or is being incorporated for use in retinal prosthetics, diagnostic saliva sensing, and wearable microneedle platforms.

12. I currently lead an approximately 20-person group undertaking high-impact research spanning multiple domains, from near-zero-power integrated circuits, power management, energy harvesting, neural interfaces, wearable physiochemical sensors, RFICs and RF systems, and beyond.

13. As noted above, I am the co-founder and co-director of the Center for Wearable Sensors at UCSD, which includes over 20 faculty across four engineering departments within UCSD, the School of Medicine, and the Arts and Humanities Department (Department of Visual Arts). The purpose of the Center is to bring together top UCSD faculty, students, and researchers with complementary expertise in areas such as sensors, low-power circuits, materials, electrochemistry, bioengineering, wireless network technologies, preventive medicine, and life sciences to create an environment that fosters the acceleration of research and system development.

14. I am also the Site Director for the Power Management Integration Center (“PMIC”), a National Science Foundation Industry University Collaborative Research Center that is a partnership between UCSD and Dartmouth College. The mission of the PMIC is to target innovations that support higher efficiency, smaller size, and reduced cost by considering system reliability, robustness, and performance in a diverse range of industry sectors and applications spanning consumer, industrial, and automotive electronics. My work with both the Center for Wearable Sensors and the PMIC includes hardware design for wearable, wireless, and power management systems.

15. My research has resulted in over 200 peer-reviewed publications, including 30 ISSCC papers, 33 JSSC papers, and several papers in high-impact

journals such as Science, Nature Biotechnology, Nature Biomedical Engineering, Nature Electronics, Nature Communications, Advanced Science, and Energy and Environmental Science. Some of the articles I have published on the topic of wearables and power management include, for example:

- E. De La Paz, N.H. Maganti, A. Trifonov, I. Jeerapan, K. Mahato, L. Yin, T. Sonsa-ard, N. Ma, W. Jung, R. Burns, A. Zarrinpar, J. Wang, P.P. Mercier, “A Self-Powered Ingestible Wireless Biosensing System for Real-Time in Situ Monitoring of Gastrointestinal Tract Metabolites,” *Nature Communications*, Vol. 13, 7405, Dec. 2022.
- F. Tehrani, H. Teymourian, B. Wuerstle, J. Kavner, R. Patel, A. Furnidge, R. Aghavali, H. Hosseini-Toudeshki, C. Brown, F. Zhang, K. Mahato, Z. Li, A. Barfidokht, L. Yin, P. Warren, N. Huang, Z. Patel, P.P. Mercier & J. Wang, “An Integrated Wearable Microneedle Array for the Continuous Monitoring of Multiple Biomarkers in Interstitial Fluid,” *Nature Biomedical Engineering*, May 2022.
- J. Tian, P. Mercier, C. Paolini, “Ultra Low-Power, Wearable, Accelerated Shallow-Learning Fall Detection for Elderly At-Risk Persons,” *Smart Health*, Vol. 33, Sept. 2024.
- A. Akinin, J.M. Ford, J. Wu, C. Kim, H.D. Thacker, P.P. Mercier, G. Cauwenberghs, “An Optically Addressed Nanowire-Based Retinal Prosthesis with Wireless Stimulation Waveform Control and Charge Telemetry,” *IEEE Journal of Solid-State Circuits*, Vol. 56, No. 11, pp. 3263-73, Nov. 2021.
- P.P. Mercier, J. Wang, “Why Sweat Will Power Your Next Wearable,” *IEEE Spectrum*, Jun. 2020 (Cover article).
- A. Abdulslam, P.P. Mercier, “A Symmetric Modified Multilevel Ladder PMIC for Battery-Connected Applications,” *IEEE Journal of Solid-State Circuits*, Vol. 55, No. 3, pp. 767-80, Mar. 2020. (CICC Special Issue).
- J. Warchall, P. Theilmann, Y. Ouyang, H. Garudadri, P. Mercier, “Robust Biopotential Acquisition Via a Distributed Multi-Channel FM-ADC,” *IEEE Transactions on Biomedical Circuits and Systems*, Vol. 13, No.

6, pp. 1229-42, Dec. 2019.

- J. Park, P.P. Mercier, “A Sub-10pJ/bit 5Mbps Magnetic Human Body Communication Transceiver,” *IEEE Journal of Solid-State Circuits*, Vol. 54, No. 11, pp. 3031-42, Nov. 2019.
- J. Kim, J.R. Sempionatto, S. Imani, M.C. Hartel, A. Barfidokht, G. Tang, A.S. Campbell, P.P. Mercier, J. Wang, “Simultaneous Monitoring of Interstitial Fluid and Sweat Using a Single Flexible Wearable Iontophoretic-Biosensor Platform,” *Advanced Science*, 5, 1800880, Aug. 2018.
- J. Park, H. Garudadri, P.P. Mercier, “Channel Modeling of Miniaturized Battery-Powered Capacitive Human Body Communication Systems,” *IEEE Transactions on Biomedical Engineering*, Vol. 64, No. 2, pp. 452-62, Feb. 2017.
- S. Imani, A.J. Bandodkar, A.M.V. Mohan, R. Kumar, S. Yu, J. Wang, P.P. Mercier, “A Wearable Chemical-Electrophysiological Hybrid Biosensing System for Real-Time Health and Fitness Monitoring,” *Nature Communications*, Vol. 7, May 2016.

16. I have also published chapters and edited books in the area of wearable and implantable medical monitors and power management. For example, I was co-editor of books entitled “Power Management Integrated Circuits,” “Ultra-Low-Power Short-Range Radios,” and “High-Density Integrated Electrocortical Neural Interfaces,” and also authored a chapter titled “Low-Power Integrated Circuits for Wearable Electrophysiology” in the book titled “Wearable Sensors – Fundamentals, Implementation and Applications 2nd Edition.”

17. Beyond my scientific articles and publications, I am also a named inventor on 28 U.S. patents, including several directed to wearable devices.

C. Teaching Experience

18. At UCSD, I have taught the following courses:

- Digital Integrated Circuits, ECE 165 (2013-2015, 2017-2025): a course that discusses fundamentals of transistor-based implementations of Boolean logic functions, then expands towards design of various combinational and sequential logic circuits. The final project involves the design of a high-speed, yet low-power digital arithmetic circuit for use in microprocessors.
- Biomedical Integrated Circuits and Systems, ECE 203 (2013-2025): a course of my own design that covers the basics of low-power integrated circuit design, including topics on pulse oximetry, instrumentation amplifiers, wearable medical devices, and more.
- VLSI Digital System Algorithms and Architectures (2014-2016): this is the graduate version of ECE 165 that includes advanced topics on microprocessor design.

19. These and the other courses I teach include a number of subjects that bear on the technology in this case. For example, in ECE 203 we discuss how pulse oximeters work, and discuss methods to develop low-power and low-noise optical readout technologies. Beyond this specific example, much of ECE 203 is focused on how to minimize power in both analog and digital circuits, while meeting performance (e.g., noise for analog, clock frequency/throughput for digital) targets. We discuss concepts like duty-cycling, power gating, power-saving modes, dynamic voltage and frequency scaling (and thus dynamic power scaling), and so on.

20. I have received a number of awards recognizing my teaching. For example, in 2016 I received the UCSD Academic Senate Distinguished Teaching Award, which is awarded yearly to five distinguished teachers across all departments

at UCSD. In 2023, I received the Teacher of the Year Award from the Jacobs School of Engineering at UCSD, which is selected by ballot of UCSD students.

21. Beyond my teaching at UCSD, I have taught tutorials as part of engineering organization conferences. For example, I taught a tutorial entitled “Interface Circuits for Wearable and Implantable Sensing Systems” at the IEEE International Solid-State Circuits Society. I also presented a tutorial entitled “Power Management for the Internet-of-Things” at the IEEE Custom Integrated Circuits Conference (CICC), and gave a keynote presentation entitled “Energy-Efficient Power Management Circuits for IoT and Wearable Devices” at the IEEE Sensor Interfaces Meeting. As part of these presentations, I dive into circuit design techniques that can deliver low-power operation.

D. Service to the Scientific Community

22. My most time-consuming role related to UCSD service is the directorship of the Center for Wearable Sensors and the Power Management Integration Center, covered earlier.

23. Beyond UCSD, I have been an Associate Editor with IEEE Solid-State Circuits Letters (2017-2023), IEEE Transactions on Biomedical Circuits & Systems (2013-2023), and IEEE Transactions on VLSI (2015-2017). I have been a Guest Editor with IEEE Open Journal of the Solid-State Circuits Society (OJ-SSCS) Special Issue on Low-Power RF Circuits and Systems (2023), and IEEE Journal of

Solid-State Circuits Special Issue on the 2018 International Solid-State Circuits Conference (ISSCC) (2018). I have chaired numerous committees for international conferences including, for example, as the Executive Committee member – Demo Chair – IEEE International Solid-State Circuits Conference (ISSCC) (2022-present), Technical Program Co-Chair – IEEE Sensor Interfaces Meeting (2022-2024), Subcommittee Chair – Power Management – IEEE Custom Integrated Circuits Conference (CICC) (2021-2023), Technical Program Committee member – IEEE VLSI Circuits Symposium (2018-2022), International Technical Program Committee member – IEEE International Solid-State Circuits Conference (ISSCC) Technology Directions subcommittee (2017-2022), and Technical Program Committee member – IEEE Custom Integrated Circuits Conference (CICC) (2017-2023). I am also a peer reviewer for numerous journals including, for example, *IEEE Journal of Solid-State Circuits* (JSSC), *IEEE Transactions on Circuits and Systems I* (T-CAS I), *IEEE Transactions on Circuits and Systems II* (T-CAS II), *IEEE Transactions on Microwave Theory and Techniques* (T-MTT), *IEEE Sensors Journal*, *IEEE Transaction on Power Electronics*, *Journal of Low Power Electronics and Applications* (JLPEA), *IET Circuits, Devices & Systems*, *IEEE International Conference on Ultra-Wideband* (ICUWB), *IEEE Transactions on Biomedical Circuits & Systems* (TBioCAS), *IEEE Transactions on Biomedical Engineering* (TBME), *IEEE International Conference on Circuits and Systems* (ISCAS), *IEEE*

Biomedical Circuits and Systems Conference (BioCAS), IEEE Journal of Emerging and Selected Topics in Power Electronics, and IEEE Transactions on Industrial Electronics.

III. PERSON OF ORDINARY SKILL IN THE ART

24. In evaluating the prior art references and other material, I have used the perspective of a person of ordinary skill in the art (“POSITA”) to which the patent is related as of the time of the patent’s priority date. I am informed by Counsel that a POSITA is presumed to be aware of pertinent prior art and the conventional wisdom in the art and is a person of ordinary creativity. I have applied this standard in my analysis throughout my declaration.

25. The ’790 patent is entitled “Wearable devices comprising semiconductor diode light sources with improved signal-to-noise ratio.” EX1001, Abstract. A POSITA in the December 2012 timeframe, which I am informed by Counsel is the earliest claimed effective filing date of the ’790 patent, would have had good working knowledge of optical sensing techniques and their applications, including the design of such systems and signal processing techniques used in such systems. Specifically, a POSITA would have had an undergraduate degree in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with either (a) relevant industrial experience studying or developing physiological monitoring devices (*e.g.*, non-invasive optical biosensors) in industry

or (b) additional education or experience in academia (e.g., a Ph.D) studying or developing physiological monitoring devices. In other words, additional education in the field could compensate for less professional experience, and vice versa.

26. I understand that the Board adopted this definition of a POSITA in *inter partes* reviews of certain parent patents to the '790 patent, including the '484 IPR I discussed above. EX1023, 7–8; EX1008, 8–9, *aff'd*, EX1009.

27. I meet the criteria described above and I am a person with at least ordinary skill in the art pertaining to the '790 patent. I would have qualified as such a person by at least December 31, 2012, which I understand is the earliest claimed priority date of the '790 patent.

IV. APPLIED LEGAL PRINCIPLES

28. I am informed by Counsel for the Petitioner about the following legal standards, which I have applied throughout my analysis.¹

¹ I am informed by Counsel that the patent laws were amended by the America Invents Act (AIA), but that the earlier statutory requirements still apply to pre-AIA patents. I have been informed by Counsel that the '790 patent was prosecuted as an AIA patent. Thus, my understanding of the law about patent invalidity as set forth in this Declaration relates to the AIA requirements, but

A. Prior Art

29. I am informed by Counsel that a patent, published patent application, or other publication, must first qualify as prior art before it can be used to invalidate a patent claim.

30. I am further informed by Counsel that a U.S. or foreign patent qualifies as prior art to a patent claim if the date of issuance and/or publication of the prior art patent is prior to the effective filing date of the challenged patent claim.

31. I am additionally informed by Counsel that a printed publication, such as a technical publication, a magazine article, or newsgroup post, qualifies as prior art to a patent claim so long as the date of publication is prior to the effective filing date of the challenged patent claim.

32. I am moreover informed by Counsel that a U.S. patent qualifies as prior art to a patent claim if the application for the prior art patent was filed in the United States before the effective filing date of the challenged patent claim.

33. I am further informed by Counsel that, if a U.S. Patent incorporates another patent or document by reference, it is considered to be part of that same reference.

from what I understand from Counsel for WHOOP, my opinion would not change under the pre-AIA requirements.

B. Anticipation

34. I am informed by Counsel that, once the claims of a patent have been construed, the second step in determining anticipation of a patent claim requires a comparison of the construed claim language to the prior art on a limitation-by-limitation basis.

35. I am further informed by Counsel that a prior art reference anticipates a claim, and thus renders the claim invalid, if all elements of the claimed process, system, or device are disclosed in the prior art reference, either explicitly or inherently.

36. I am also informed by Counsel that, under Section 102 of the Patent Act, claims of a patent are invalid for lack of novelty if they are anticipated by a single prior art reference. I am further informed by Counsel that a claimed invention is invalid as anticipated and hence lacks novelty if all of the limitations of the claim as construed by the Court are present in a prior art reference, or any document that the reference incorporates by reference. However, I am informed by Counsel that a limitation of the claim need not be shown directly in a reference so long as a POSITA would have understood the limitation to be inherent, or necessarily present in the reference.

C. Obviousness

37. I am informed by Counsel that an invention may also be obvious, even though the invention is not identically disclosed or described in a single prior art reference, which is required for anticipation. This is true if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art.

38. I am further informed by Counsel the Supreme Court has urged caution in granting a patent based on the combination of elements found in the prior art. This is because a patent for a combination that only unites old elements with no change in their respective functions withdraws what already is known from the public, giving it exclusively to the patentee. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

39. I am also informed by Counsel that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a POSITA can implement a predictable variation, the invention is likely obvious. For the same reason, if a technique has been used to improve one device, and a POSITA would recognize that it would improve similar devices in the same way, using the technique is obvious

unless its actual application is beyond his or her skill. Put another way, I am informed by Counsel that a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. I am further informed by Counsel that this is a flexible standard and it is not confined to any particular formalistic conception.

40. I am also additionally informed by Counsel that, when conducting an obviousness inquiry, the analysis should consider the scope and content of the prior art, differences between the prior art and the claims of the challenged patent claims, and the level of ordinary skill in the art. Secondary considerations of nonobviousness can also be considered, which include commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention. I am also informed by Counsel that there must be a nexus between these factors and the claims themselves for these secondary considerations to impact the analysis of obviousness.

41. I am informed by Counsel that there generally must be a motivation to combine the references in order to find obviousness. This motivation or reason to combine can arise from the references themselves, changing market dynamics, or from simple common sense.

42. I am further informed by Counsel that a single reference can render a patent claim obvious, even if that reference does not fully anticipate the claim. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art.

D. Claim Construction Standard

43. I am informed by Counsel that, during a post grant review, the same standard is used as during claim construction in district court civil actions. I am further informed by Counsel that, in the district court context and in this PGR, the words of a claim are generally given their ordinary and customary meaning. This is the meaning the term would have to a POSITA in the art in question at the time of the invention, which generally means the time the application was filed. I am further informed by Counsel that the specification informs the proper interpretation of a claim. This is because a POSITA is deemed to have read the claim term not only in the context of the particular claim in which the dispute term appears, but in the context of the entire patent, including the specification. I am also informed by Counsel that the prosecution history and extrinsic evidence concerning relevant

scientific principles, the meaning of technical terms, and the state of the art are also considered in ascertaining the meaning of claim terms.

44. I understand that in the final written decision of the Apple IPR of the '484 Patent, the Board construed “to identify an object” to mean “to recognize or establish an object as being a particular thing,” which the Federal Circuit affirmed on appeal. EX1011, 8–10; EX1012, *3–4.

E. Indefiniteness

45. I am informed by Counsel that a claim may be invalid as indefinite. Specifically, I understand that a claim must point out with particularity the subject matter of the invention. I further understand that definiteness is evaluated from the perspective of a POSITA at the effective filing date of the patent.

46. I further understand from Counsel that a POSITA, when reviewing the claim language with the specification and the prosecution history of the patent, must be able to understand the scope of the claimed invention, including its boundaries, with reasonable certainty. I understand from Counsel that if a claim fails to inform a POSITA of the scope and boundaries of the claimed invention with reasonable certainty, it is invalid as indefinite.

F. Enablement

47. I am informed by Counsel that a claim may be invalid as not enabled. In order to be enabled, I understand that a patent's specification must describe an

invention with sufficient detail to inform a POSITA how to make and use the full scope of the claimed invention without undue experimentation. I also understand that a patent's specification need not expressly teach what is already known in the art. I further understand that enablement is evaluated from the perspective of a POSITA at the effective filing date of the patent.

48. I understand from Counsel that certain non-exclusive factors may be used to assess whether the experimentation required to practice the invention is undue or unreasonable. I understand these factors to include the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the specification's disclosure.

49. I understand from Counsel that the broader the scope of a patent claim, the more embodiments its specification must enable, such that, if a claim covers an entire class of processes, machines, or compositions of matter, the specification must inform a POSITA how to make and use the entire class. If the specification fails to inform a POSITA how to make and use the full scope of the claimed invention, the claim is invalid as not enabled.

V. TECHNOLOGY BACKGROUND

50. To put in context my opinions on the validity of the Challenged Claim of the '790 Patent, in this section I provide some background on wearable optical sensors, including those used for physiological monitoring. All the concepts discussed in this section were well-known and widely used well before the alleged December 31, 2012, priority date for the '790 Patent.

A. Overview of Optical Sensing Techniques

51. Optical sensors have been used in medical monitoring systems for decades. EX1033, 764. Although these optical systems may vary in the details, they typically consist of “basic building blocks” that include (1) one or more light sources (*e.g.*, lasers, lamps, or light-emitting diodes (LEDs)) producing light of a particular wavelength; (2) certain “optical elements” (*e.g.*, filters and lenses) that can be used to manipulate the light from the light source and direct it to the target (*e.g.*, human tissue); (3) one or more photodetectors that capture the light reflected or transmitted back from the target; and (4) signal processing technology (*e.g.*, analog-to-digital conversion circuitry, digital signal processors, microprocessors, etc.) that processes the signal obtained from the photodetector and can thereby extract data relating to one or more physiological parameters. EX1033, 764–66. An illustration of a typical optical sensor system is shown below. EX1033, 765.

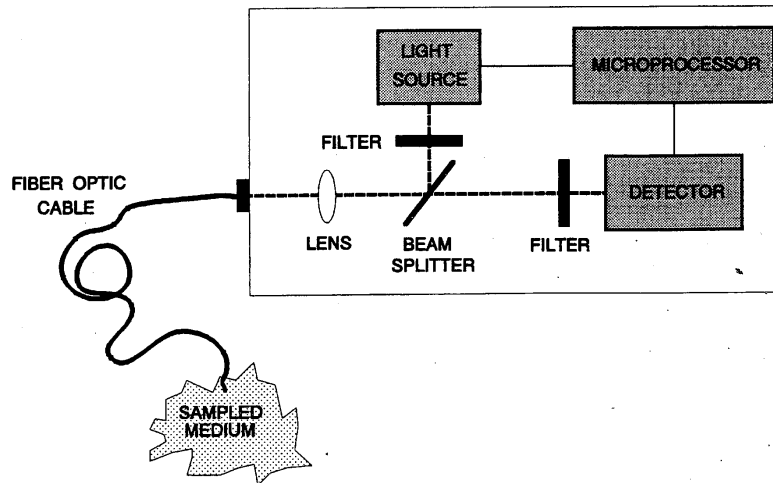


FIGURE 52.1 General diagram representing the basic building blocks of an optical instrument for optical sensor applications.

EX1033, 765.

52. Photoplethysmography (PPG) is a particular optical sensing technique that has also been used in medical monitoring systems for decades, since at least the 1930s. PPG works by shining a light through the subject's tissue and measuring the light that is either reflected back from the tissue or transmitted through the tissue. The various components of blood and tissue (*e.g.*, hemoglobin) reflect and absorb different wavelengths of light, such that a PPG device can calculate the composition of the blood flow or tissue by measuring how much light is absorbed and reflected over time at one or more wavelengths. For example, hemoglobin (the substance in blood that carries oxygen to the cells) reflects more red light when it has a higher oxygen content (*i.e.*, is oxygenated, HbO_2) and absorbs more red light when it has a lower oxygen content (*i.e.*, is deoxygenated, Hb), but reflects the same amount of

infrared (IR) light regardless of whether it is oxygenated or deoxygenated. EX1033, 769. Thus, by measuring the absorption of red and IR light multiple times per second, a PPG device can calculate a subject's (i) oxygen saturation (*i.e.*, ratio of oxygenated hemoglobin to deoxygenated hemoglobin) and (ii) pulse (based on the change in blood volume in the tissue over time). EX1033, 769–771. The measurement of the degree of oxygen saturation is referred to as “oximetry,” and the addition of the continuous monitoring of blood volume to evaluate pulse rate is referred to as “pulse oximetry.” *Id.*

53. Optical sensors, including those employing PPG and non-invasive pulse oximetry, can also be integrated into portable devices, which increases their usefulness for medical monitoring, since they can then travel with (or be worn by) the subjects anywhere. EX1033, 771. For portable optical sensors, LEDs are typically selected as the light source, due to the fact that they are small, inexpensive, consume low amounts of power, produce selective wavelengths of particular interest for medical monitoring, and are easy to manipulate and work with. EX1033, 765, 771

54. In order to return the most accurate data possible, optical sensors are designed to maximize the strength of the target signal received by the detector (corresponding to a particular physiological measurement from the tissue) relative to other light received by the detector (*e.g.*, ambient light reflected from the patient's

surroundings), known as “interference,” “background,” or “noise.” The better the system is able to isolate the target signal captured from the tissue from the surrounding noise, the higher the “signal-to-noise ratio” (SNR) of the sensor will be, and, thus, the more accurate the resulting health data will be. EX1045, § 8.4.1 (p. 119), § 9 (p. 138); § 11.4 (pp. 197-98).

55. Optical sensing systems, including those employing PPG, use various techniques to improve SNR. For example, many optical sensors use two or more photodetectors, with one functioning as a “reference detector” that tracks fluctuations in the intensity of the received light and temperature, so that a baseline measurement is collected that can then be compared to the reading from the sample in order to isolate the signal associated with the desired measurement from the sample. Other common techniques include modulating the light source by, *e.g.*, using “synchronized lock-in amplifier detection” techniques. EX1033, 764–766. Lock-in detection works by operating at a very narrow frequency range, such that noise at other frequencies can be largely eliminated

56. Optical sensing systems used for medical monitoring have traditionally been integrated with electronic devices to allow the physiological data they collect to be processed, transmitted, stored, and displayed. One example of such a system is depicted below and was published in the 1995 *Bioengineering Handbook*. EX1033, 1363. In this system, health data is collected by a wired, wearable sensor

and transmitted to a remote computer located in a physician's or primary care provider's office via a home monitor and landline phones. EX1033, 1363. The physician could then use the collected data to generate reports that would later be shared with patients. *Id.* As I discuss below, as electronics increasingly became wireless, the market moved from the 1995 wired system depicted in the *Bioengineering Handbook* to an analogous system that was able to collect, transmit, process, store, and display physiological data wirelessly using, *e.g.*, cell phones and cloud-based systems.

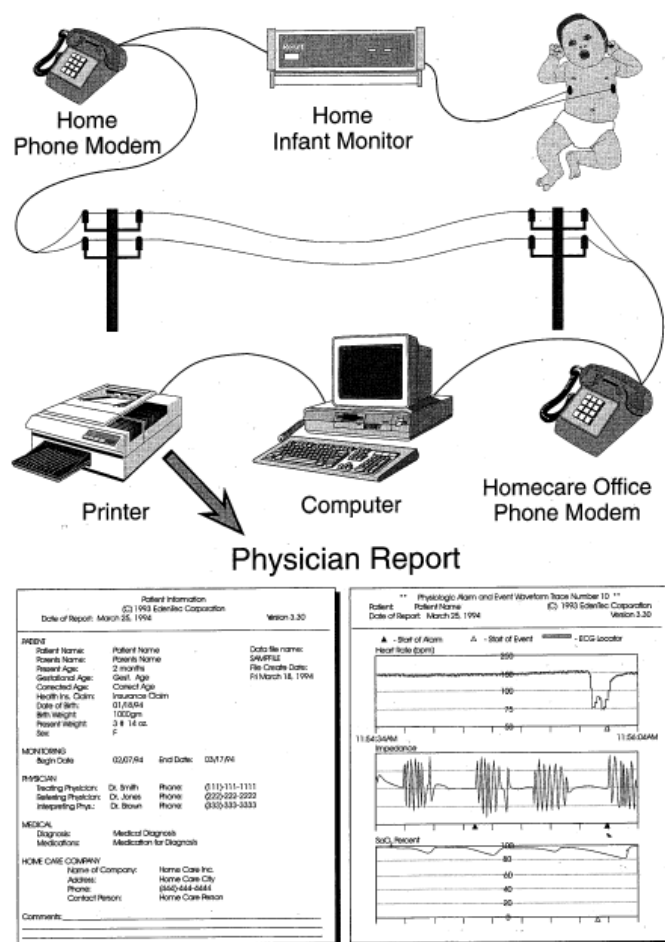


FIGURE 89.3 Infant apnea monitor with memory allows data to be sent by modem to generate physician report (drawing courtesy of EdenTec Corporation).

B. Market for Wearable Optical Sensors

57. As mentioned, optical sensors, including pulse oximeters, have been used for non-invasive medical monitoring for decades. Implementing such sensors into portable or wearable devices is similarly an old practice—indeed, beginning in the late 1990s, the market for wearable sensors that could be used to improve medical care and personal health/fitness developed rapidly. With the advent of personal devices like smartphones, as well as the proliferation of cloud-based computing systems in the early 2000s, it became desirable to transmit, store, display, and process the data collected by wearable sensors to remote systems for continuous medical monitoring.

58. Wearable optical sensors, including those integrated with personal devices and cloud-based architecture, were thus well-known and widely available by December 2012, the priority date of the '790 Patent. Indeed, I am very familiar with the market for wearable sensors in 2012 because, during that timeframe, I was in the process of establishing the Center of Wearable Sensors at UCSD. Below, I discuss some of these market trends.

59. As an initial matter, during the late 1990s and continuing to 2012, the market for miniaturizing electronics increased rapidly. EX1034, 3; EX1037, 2. This trend became particularly pronounced with the proliferation of personal devices, like cell phones and tablets, which became ubiquitous. As a result, the market moved to

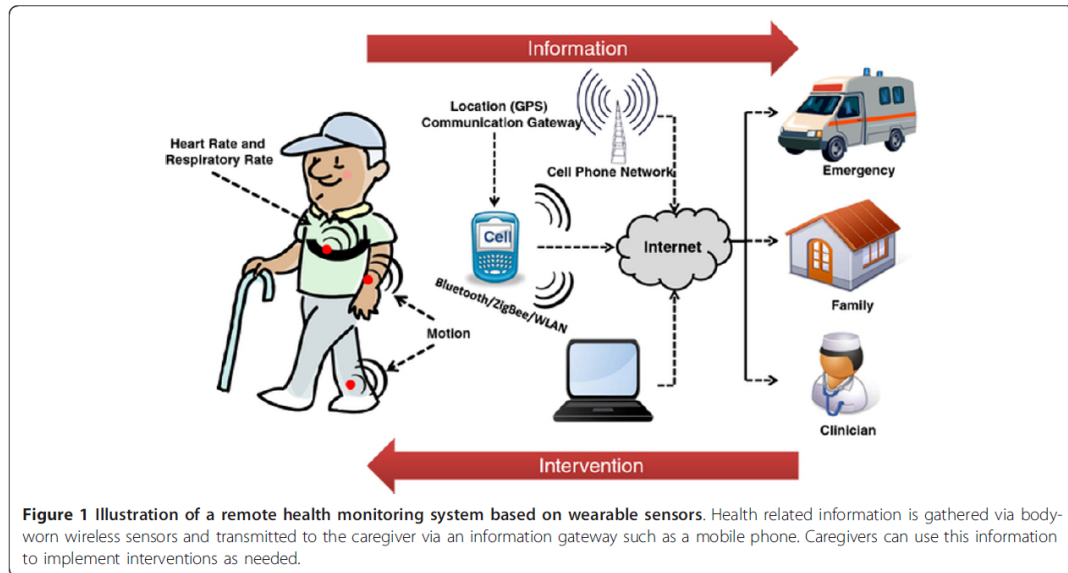
develop systems and products that could be integrated into or work with personal devices and used in a variety of fields, including health and personal fitness applications. EX1034, 3; EX1037, 1.

60. Similarly, beginning in the late 1990s, the medical device industry began responding to the challenge of monitoring the health of patients who were located in remote areas or who lacked easy, continuous access to a physician's office. EX1034, 2; EX1035, 462; EX1036, 15–31. One such response included the development of wireless, wearable devices that the patient could wear outside of the physician's office, for example, as a wristwatch or a waistband, to continuously monitor particular health parameters. EX1034, 2; EX1035, 462; EX1036, 15–31. Medical professionals recognized that the continuous monitoring of a patient's physiological data (like heart rate, oxygen saturation, and blood pressure) enabled by these wearable devices could improve both diagnosis and ongoing treatment of neurological, cardiovascular, and pulmonary diseases. EX1034, 2.

61. Along with the development of the wearable optical sensing devices themselves, the medical field began implementing systems for medical monitoring that could be used with personal devices (*e.g.*, cell phones), including via “apps” for such devices. EX1036, 9–10, 40–49; EX1034, 4; EX1040, 1–2 (“Doctors and nurses were the early adopters of tablets”), *id.* at 5 (describing “[p]atient monitoring and data collection” using “Bluetooth enabled sensor devices and Wi-Fi+ Bluetooth

enabled interfaces to patient monitoring devices”). These integrated medical monitoring systems (wearable sensor + personal device or application) enabled patients to transmit health data collected by the wearable sensor to their healthcare providers, including via a “cloud-based” system. EX1034, 4; EX1036, 9–10, 40–49; EX1040, 1–2, 5.

62. One example of a system integrating a wearable optical sensor and remote medical monitoring capabilities is illustrated below and was described in a 2012 article in the *Journal of NeuroEngineering and Rehabilitation*. EX1034. As depicted, the patient wears a band with an integrated optical sensor (“body-worn wireless sensors”), which “gather[s]” the patient’s heart rate and respiratory data. EX1034, 2. The wearable device then transmits the data it gathers to a healthcare provider or emergency responder “via an information gateway,” like a cell phone. *Id.* The cell phone can also transmit the health data it collects to a “cloud” based system for storage and retrieval at a later time. EX1034, 2, 5.



EX1034, 2.

63. In parallel with the expansion of wearable optical sensors used for medical monitoring and the corresponding applications and personal devices configured to work with such systems, a market began to emerge for commercial health devices that could be used for monitoring personal health and fitness. EX1037, 3; EX1028, [0004]; EX1032, [0003]; EX1038, 221. Indeed, by June of 2012, pulse oximeters and heart rate monitors—which had previously been “reserved for professional use”—were available to consumers as wearable devices (e.g., as a smartwatch) and could be connected to their smartphones. EX1037, 3; EX1028, [0004]; EX1032, [0003]; EX1038, 221. By the priority date of the ’790 patent, these integrated wearable device systems were generating “growing market demand” from consumers, including for “gauging overall health, fitness, metabolism, and vital status during exercise [or] athletic training.” EX1032, [0003].

The rising demand for such products impacted my own decision to start the Center for Wearable Sensors at UCSD.

64. One example of an integrated wearable device system that could be applied to both medical monitoring and personal fitness was described in the *Journal of Diabetes Science & Technology* in 2010 by Alf Helge Omre. EX1035, 459–61. Omre illustrates a system with three interconnected components: (1) a “sensor” that is integrated into a device worn or carried by a user (like a watch or a belt) and that gathers a particular type of data from the subject (*e.g.*, heart rate or blood pressure); (2) a “[h]ost device” (like a smartphone or laptop) that receives the data collected by the sensor; and (3) a remote “[w]eb service” that receives the health data from the host device and uses that data to assist with a service, including “[w]eight loss” or “fitness coaching.” *Id.*

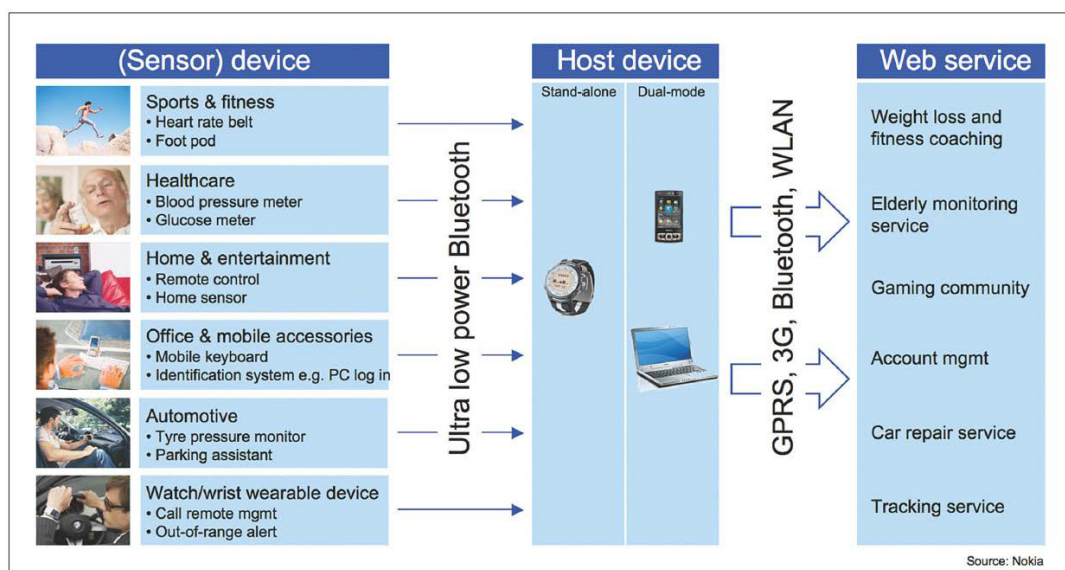


Figure 2. Bluetooth low energy will extend interoperable wireless connectivity to coin-cell-powered wireless sensors in health care, fitness, and related sectors. WLAN, wireless local area network; GPRS, general packet radio service.

EX1035, 459.

65. Other publications from the same timeframe illustrated interconnected networks that combined “cloud” based services or architecture with a wearable optical sensor and a personal device to improve health and fitness. For example, an article published in 2012 described a system for a “mobile fitness coach” “using personalized mobile devices.” EX1037, 1, 6–7, 12. That system, illustrated below, includes a smartphone that “records sensor data” from, for example, a heart rate monitor or other optical sensor, while the user is exercising. EX1037, 6–7, 12. The smartphone then sends the collected fitness data to a server for further processing by a fitness application, and the application then returns the processed data to the smartphone so it can be displayed to the user. EX1037, 6–7, 12.

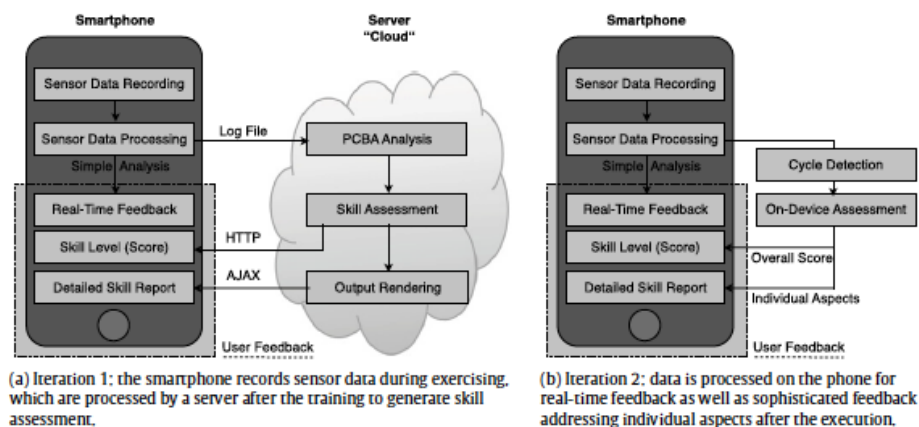
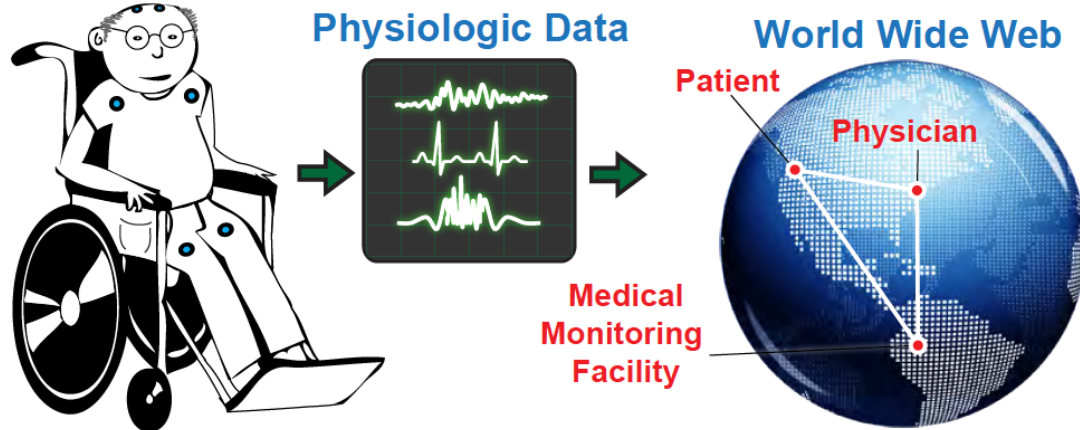


Fig. 3. Iterations of the GymSkill application.

66. In fact, I had personally written about using wearable sensors for medical monitoring applications in my Ph.D. thesis, published in June 2012. For example, I created a figure, shown below, describing the idea of using wearable

devices to capture physiological data from a user, and transmit this data from a patient to a physician or a medical monitoring facility.



67. The trends described above led to the proliferation of integrated systems (including, *e.g.*, a wearable optical sensor, a personal device, and a cloud-based architecture) that could be used for medical monitoring, personal health, and sport performance. As a result, rising demand for these products would have provided a strong motivation for a POSITA to explore ways of integrating optical sensing techniques into small, portable, and wearable devices that could be used to monitor health and fitness parameters and could remotely communicate with a user's personal device (like a smartphone), including ways of improving the quality of the health and fitness data by improving the SNR of the wearable sensor.

VI. BACKGROUND OF THE '790 PATENT

A. Summary of the '790 Patent

68. The '790 Patent relates to a “wearable device for measuring one or more physiological parameters,” where the device “comprises a light source with a plurality of semiconductor diodes and a detection system that measures reflected light from tissue comprising skin.” EX1001, Abstract. In one embodiment, the device is “adapted to be placed on a wrist of a user.” EX1001, 9:4–7.

69. More specifically, according to one embodiment, the wearable device includes:

a light source comprising a plurality of semiconductor diodes that are configured to generate an output optical light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The wearable device also comprises one or more lenses configured to receive at least a portion of the output optical light and to deliver a lens output light to tissue comprising skin. The wearable device further comprises a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source. In addition, the detection system comprises a plurality of detectors that

are spatially separated from each other, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors. The output signal is indicative of the one or more of the physiological parameters. Furthermore, the wearable device is configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor diodes from an initial light intensity. Also, the detection system is further configured to generate a first signal responsive to light received while the semiconductor diodes are off, generate a second signal responsive to light received while at least one of the semiconductor diodes is on, and increase the signal-to-noise ratio by comparing the first signal and the second signal. Moreover, the wearable device is at least in part configured to identify an object.

EX1001, 9:4–36.

70. Figure 24 of the '790 Patent shows “a medical measurement device as part of a personal or body area network.” EX1001, Fig. 24; *id.*, 11:47–53. In this depiction, the measurement device “communicates with another device (e.g., smartphone or tablet) that communicates with the cloud. The cloud may in turn communicate with the user, healthcare providers, or other designated recipients.”

EX1001, 11:47–53.

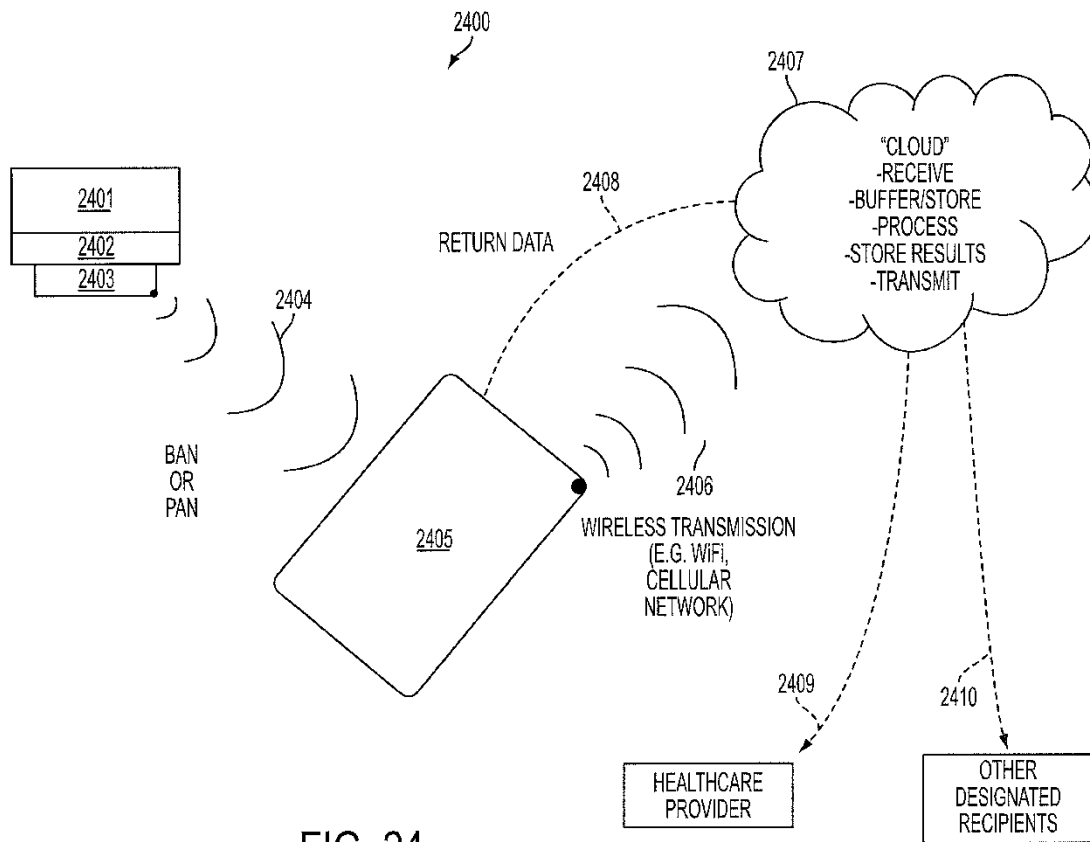


FIG. 24

EX1001, Fig. 24.

71. The '790 patent describes certain techniques to improve a “signal-to-noise ratio.” EX1001, 8:47–9:3. For example, and as already highlighted above, the '790 Patent teaches increasing the signal-to-noise ratio by “increasing light intensity of at least one of the plurality of light emitting diodes from an initial light intensity.” EX1001, 8:59–62. Another technique to increase signal-to-noise ratio described in the patent is to “generate a first signal responsive to light received while the light emitting diodes are off, generate a second signal responsive to light received while

at least one of the light emitting diodes is on, and increase the signal-to-noise ratio by comparing the first signal and the second signal.” EX1001, 8:63–9:1.

B. File History of the '790 Patent

72. As I state below, in forming my opinions, I have also reviewed the file history of the '790 patent.

73. The '790 Patent issued from U.S. Pat. App. 18/438,144, filed February 9, 2024. EX1001, at (21), (22). I understand the '790 Patent claims priority to December 31, 2012, provisional patent applications. EX1001, at (60). The applicant filed a terminal disclaimer to some of the patents in this chain. EX1001, at (*); EX1002 at 263–266. As mentioned above, I understand that the '790 Patent was prosecuted as an AIA patent application and that the applicant acknowledged that at least one claim in the '790 Patent “contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013,” such that the application was “examined under the first to file provisions of the AIA.” EX1002, 246, 271, 305–306. After the Applicant filed a terminal disclaimer in view of several patents in the priority chain, the pending claims were then allowed without any amendments or Office Actions. EX1002, 301.

74. I understand that the '790 Patent is the subject of an ongoing IPR and PGR filed by Samsung Electronics Co., Ltd. and other parties (“Samsung”) asserting

unpatentability of the Challenged Claim based on the combination of Lisogurski and Carlson. EX1054; EX1053.

75. I understand that a patent related to the '790 patent (U.S. Patent No. 9,651,533) (the "'533 patent") has been the subject of a previous IPR, in which all challenged claims (claims 5, 7–10, 13, and 15–17) were held unpatentable by the Board. EX1008. I understand the Federal Circuit affirmed that decision. EX1009. I further understand that this previous IPR asserted that the challenged claims were unpatentable based on two of the same references asserted here (Lisogurski and Carlson). EX1008. I am also aware that Petitioner has filed an IPR challenging claims 6, 11–12, 14, and 18 of the '533 patent based on the combination of Lisogurski and Carlson, among other references. EX1066.

76. I further understand that another patent related to the '790 patent (U.S. Patent No. 10,517,484) (the "'484 patent") is the subject of another ongoing IPR where all claims of the '484 patent have been found unpatentable based on a set of asserted references that includes Lisogurski and Carlson. EX1011; EX1012; EX1013. I understand that in the '484 IPR the Board initially determined that claims 1, 2, 7 and 15–23 were unpatentable, but that the Petitioner had not shown claims 3–6 and 8–14 to be unpatentable based on a limitation that required the claimed system to "identify an object." EX1011, 2. I understand the Petitioner appealed that determination to the Federal Circuit, and that the Federal Circuit reversed and

remanded for the Board to consider whether those claims are unpatentable as obvious under an alternative argument. EX1012. I understand that Omni did not cross-appeal as to the claims that had been held unpatentable and that the Federal Circuit therefore affirmed the unpatentability of those claims. EX1012, n.2. I understand that the Board held the remaining claims to be unpatentable as obvious on remand (EX1013), and that Omni has appealed that decision as to claims 3–6 and 8–14 (EX1061).

77. As discussed below, I have reviewed the challenged claims of the '533 patent and the related '484 patent that were the subject of the IPR proceedings and certain materials from those proceedings. It is my opinion that a POSITA would have understood the invention described in the Challenged Claims of the '790 Patent significantly overlaps with and is not meaningfully distinct from the challenged claims of those two patents.

VII. MATERIALS AND PRIOR ART CONSIDERED

78. I have considered information from various sources in forming my opinions. I have drawn on my decades of experience in this field. I have employed methods and analyses of a type reasonably relied upon by experts in my field in forming opinions or inferences on the subject. Additionally, in preparing this Declaration, I have relied upon '790 Patent and its file history, the exhibits cited to below, and the additional exhibits listed at the beginning of this Declaration. I have

also reviewed the related '533 and '484 patents, and materials from the previous IPR proceedings for the related '533 and '484 patents. Furthermore, I have reviewed U.S. Patent No. 12,268,475 (EX1060) (the "'475 patent"), which is a "child" patent in the same chain of continuations as the '790 patent. I have previously provided my opinions in support of Petitioner's requests for *inter partes* review of the '533 patent and two of its child patents: U.S. Patent Nos. 11,160,455 (the "'455 patent") (EX1058) and U.S. Patent No. 10,874,304 (the "'304 patent") (EX1057). EX1067; EX1068.

79. In this Declaration, I provide four prior art references with exemplary citations identifying the relevant features related to the claim language of the Challenged Claim.² I have also described combinations of these prior art references that, when combined, render the Challenged Claim of the '790 patent obvious. It is my opinion that the Challenged Claim of the '790 patent is rendered obvious in light of the prior art specifically discussed in this Declaration.

80. The citations presented in the body of this declaration correspond to the teachings disclosed in exemplary items of prior art that identify: (1) the problem(s) confronted by one of ordinary skill in the art; (2) an express suggestion to make one or more of the combinations; (3) an implicit suggestion to make one or more of the

² The complete text of the Challenged Claim is set forth in Appendix A hereto.

combinations; or (4) the knowledge of those skilled in the art as to the applicable field of technology at the relevant timeframe.

81. It is my opinion that a POSITA would consider at least the prior art references below:

Prior Art Reference	Date of Publication	Exhibit No.
U.S. Patent No. 9,241,676 (“Lisogurski”)	May 31, 2012 (filing date)	1027
U.S. Patent App. Pub. No. 2005/0049468 (“Carlson”)	March 3, 2005	1028
U.S. Patent App. Pub. No. 2011/0237911 (“Lamego”)	September 29, 2011	1063
U.S. Patent No. 6,304,767 (“Soller”)	October 16, 2001 (issue date)	1030

82. As mentioned, I understand that two of these references (Lisogurski and Carlson) have been considered by the Board in the previous IPR of the related ’533 patent, and in the ongoing IPR of the related ’484 patent, where the Board found all challenged claims of those two patents unpatentable.

83. It is also my opinion that, applying Omni’s interpretation of the scope of the “identifying an object” limitation of the Challenged Claim, as set forth in an ongoing *inter partes* review of a related patent, U.S. Patent No. 10,517,484 (the “’484 Patent”), the Challenged Claim would be indefinite. Specifically, a POSITA reading the ’790 Patent would not have understood which materials qualify as

separate, identifiable objects (as opposed to sub-components or alternate forms of a single object) under the interpretation of the claim limitation advanced by Omni.

84. It is also my opinion that the Challenged Claim is not enabled across its full scope. For example, applying Omni's understanding of the "identifying an object" limitation, the Challenged Claim purports to recite a non-invasive optical system for distinguishing and measuring certain blood constituents *with only subtle spectral signature differences from one another*, most notably glucose. But non-invasive optical measurement and distinguishment of glucose from other blood constituents that have only subtle spectral differences has not been achieved to the present day to any useful degree of certainty in practical or real-world applications, and certainly would not have been possible by the alleged priority date of the '790 Patent. The same is true for the other constituents listed in the '790 patent and highlighted in Omni's opening appeal brief (*e.g.*, triacetin, ascorbate).

85. It is my opinion that the Challenged Claim of the '790 patent would have been invalid on the following bases:

'790 Patent Claim	Basis of Invalidity
7	Obvious over Lisogurski in view of Carlson
7	Obvious over Lisogurski and Carlson in view of Lamego
7	Obvious over Lisogurski and Carlson in view of Soller
7	Indefinite under § 112
7	Lacks enablement under § 112

86. In analyzing the prior art combinations listed above, I explain how a POSITA would have understood the disclosures in these references and how a POSITA would have been motivated to modify or combine such references in light of the POSITA's existing knowledge and creativity.

87. I am also not aware of any secondary considerations of non-obviousness that affect my conclusions regarding the obviousness of these claims.

88. Other references and knowledge described earlier in this declaration are relevant to show the state of the art (*i.e.*, what a POSITA would have known when using the references identified above) or to use in combination with the references above to render the Challenged Claim invalid.

VIII. INVALIDITY ANALYSIS OF THE CHALLENGED CLAIM

89. Below is a detailed analysis of the bases of invalidity identified above. For my analysis, I have grouped claim limitations where they are substantively similar or where it made sense to discuss them together.

A. Overview of Prior Art References

1. Lisogurski

90. Lisogurski is directed to a portable “physiological monitoring system,” for example, a “pulse oximeter, which may non-invasively measure the oxygen saturation of a patient’s blood.” EX1027, 3:44–46, 3:60–4:5. The system includes an **optical sensor**, which includes “a light source and a photosensitive detector,” to measure the “physiological parameters of a patient,” such as the patient’s pulse, blood pressure, and oxygen saturation. EX1027, 3:44–4:8. The sensor can be worn by a patient in various locations, including “the neck to monitor carotid artery pulsatile flow, the wrist to monitor radial artery pulsatile flow, the inside of a patient’s thigh to monitor femoral artery pulsatile flow, the ankle to monitor tibial artery pulsatile flow, and around or in front of the ear.” EX1027, 4:15–20; *id.*, at 4:6–4:8 (“An oximeter may include a light sensor that is placed at a site on a patient, typically a fingertip, toe, forehead, or earlobe.”). The sensor may be battery-powered and configured to “wirelessly connect[]” to a **monitor**. EX1027, 17:55–58.

91. Figure 1 illustrates an embodiment of the physiological measurement system with a sensor, monitor, and remote devices (*e.g.*, servers), where “**monitor** 104 includes control circuitry 110, light drive circuitry 120, front end processing circuitry 150, back end processing circuitry 170, user interface 180, and

communication interface 190. **Monitor 104** may be communicatively coupled to **sensor 102.**” EX1027, 11:28–32. The “[c]ommunication interface 190 may enable monitor 104 to exchange information with external devices” and also may include “any suitable hardware, software, or both, which may allow **monitor 104** to communicate with electronic circuitry, a device, a network, a server, or other workstations, a display, or any combination thereof.” EX1027, 15:43–48.

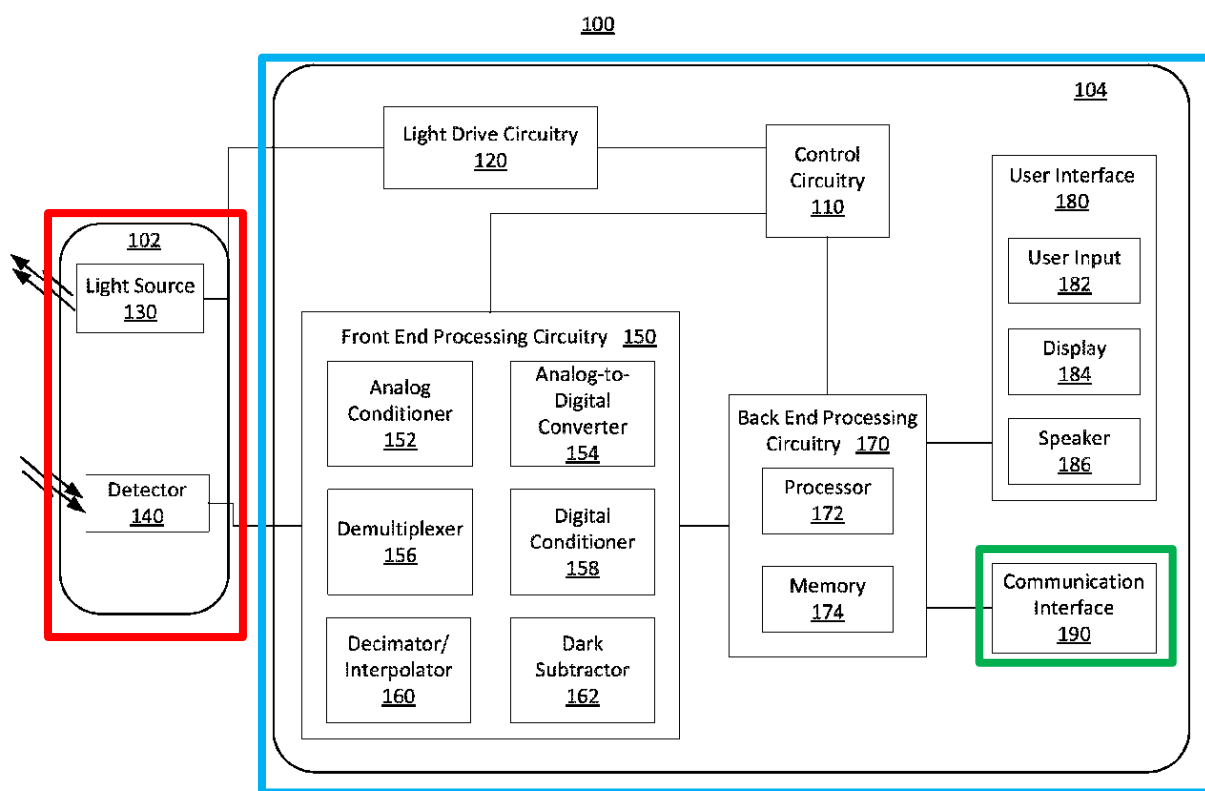


FIG. 1

EX1027, Fig. 1 (annotated).

92. The light source in the sensor may include one or more light-emitting diodes (LEDs) of “one or more wavelengths.” EX1027, 10:48–64; *see also* EX1027, 4:42–48, 11:9–13, 17:37–45. For example, “[r]ed and infrared (IR) wavelengths

may be used because it has been observed that highly oxygenated blood will absorb relatively less red light and more IR light than blood with a lower oxygen saturation.” EX1027, 4:42–48; *id.* at 10:48–64, 11:9–13, 17:37–45. The LEDs emit the light in beams; the beams pass through or are reflected back by the tissue, and the reflected and/or transmitted light is detected by the photodetector in the sensor. EX1027, 4:7–11 (“The oximeter may use a light source to pass light through blood perfused tissue and photoelectrically sense the absorption of the light in the tissue”), 10:48–56 (the light sources “emit” light of a particular wavelength, *i.e.*, a beam), 11:13–20 (the “light may enter detector 140 after passing through the subject’s tissue”). The photodetector then “convert[s] the intensity of the received light into an electrical signal.” EX1027, 11:14–16.

93. The **sensor** can then either (i) send the converted electrical signal directly to the **monitor** for processing, or (ii) it can pre-process the signal before sending it to the monitor. EX1027, 11:20–27 (“After converting the received light to an electrical signal, detector 140 may send the detection signal to monitor 104, where the detection signal may be processed and physiological parameters may be determined (e.g., based on the absorption of the Red and IR wavelengths in the subject’s tissue). In some embodiments, the detection signal may be preprocessed by the sensor 102 before being transmitted to monitor 104”). In either scenario, the system processes the signal using standard signal processing techniques to isolate

the desired signal from the reflected and/or transmitted light. EX1027, 7:16–21, 12:48–49 (“Front end processing circuitry 150 may perform various analog and digital processing of the detector signal.”), 13:7–14:55 (“Analog conditioner 152 may perform any suitable analog conditioning of the detector signal. The conditioning performed may include any type of filtering (e.g., low pass, high pass, band pass, notch, or any other suitable filtering), amplifying, performing an operation on the received signal (e.g., taking a derivative, averaging), performing any other suitable signal conditioning (e.g., converting a current signal to a voltage signal), or any combination thereof”).

94. Lisogurski’s system also regulates the “light drive signal” of the sensor, which refers to the electric current applied to the LEDs. EX1027, 1:60–61, 7:12–36, 8:4–8, 11:38–41, 11:50–54, 12:3–9. Thus, as the current applied to a particular LED increases, the light intensity emitted from that LED also increases. EX1027, 7:13–16, 7:24–31, 12:3–9, 12:16–22. The system can also modulate the LEDs and “vary light drive signal parameters” of the LEDs in response to a “trigger” caused by various conditions, *e.g.*, interference or noise. EX1027, 1:10–25, 1:60–2:3; *see also id.*, 8:4–8, 8:27–35, 16:24–32. For example, the measurement system can control the “light intensity, duty cycle, light source firing rate, any other suitable parameter, or any combination thereof” of the LEDs. EX1027, 1:60–2:3, 1:10–25, 5:48–54, 25:46–65 (“The system may vary parameters related to the light drive

signal including drive current or light brightness, duty cycle, firing rate, modulation parameters, other suitable parameters, or any combination thereof”). Lisogurski explains that varying these drive cycle parameters can increase the signal-to-noise ratio (SNR) of the measurement device, for example:

In some embodiments, **the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons, or any combination thereof.** The system may receive, for example, an increased level of background noise in the signal due to patient motion. **The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio.** In some embodiments, the system may increase brightness throughout the cardiac cycle because the system may require increased signal amplitudes to differentiate between fiducial and other points of interest related to physiological parameters and those related to noise or motion. In some embodiments, the system may change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light.

EX1027, 9:46–60.

2. Carlson

95. Carlson is directed to a system for “the acquisition and/or monitoring of medical data, in particular the state of the cardiovascular and pulmonary system,

blood values or blood composition.” EX1028, Abstract. The system includes “at least one measuring sensor for the acquisition of the medical data,” which further includes “at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted and/or reflected through a tissue” and “means in order to increase the optical Signal-to-Noise and/or Signal-to-Background ratio.” EX1028, Abstract. Carlson further teaches that the pulse oximetry system is portable, such that “[t]he measured values can be transmitted via a wire connection or wireless” (e.g., via “‘Bluetooth’ technology”) “to a medical doctor, to a hospital, etc.” EX1028, [0077]–[0078]; *see also* EX1028, [0072].

96. One embodiment of Carlson is directed to a wearable pulse oximeter that can be worn on the ear, finger, or “other parts of the human body.” EX1028, [0004], [0052], [0078]. The oximeter includes a conventional sensor with “two light emitting sources” (“which means **two LEDs**”) that emit optical wavelengths “at two wavelengths, at 660 nm, and a second wavelength within the range of 800 to 1000 nm.” EX1028, [0050], [0003]. A POSITA would have understood that optical wavelengths of 660 nm correspond to red light, whereas wavelengths of 800–1000 nm correspond to infrared (IR) light. Carlson further explains that the sensor can include “at least two light receivers,” as well as “**beam shaping optics**” that can be used to “direct the emitted optical radiation 8 from the **two LEDs**” to, e.g., “the

middle of the earlobe.” EX1028, [0052]–[0054]. These beam-shaping optics are illustrated in Figure 4:

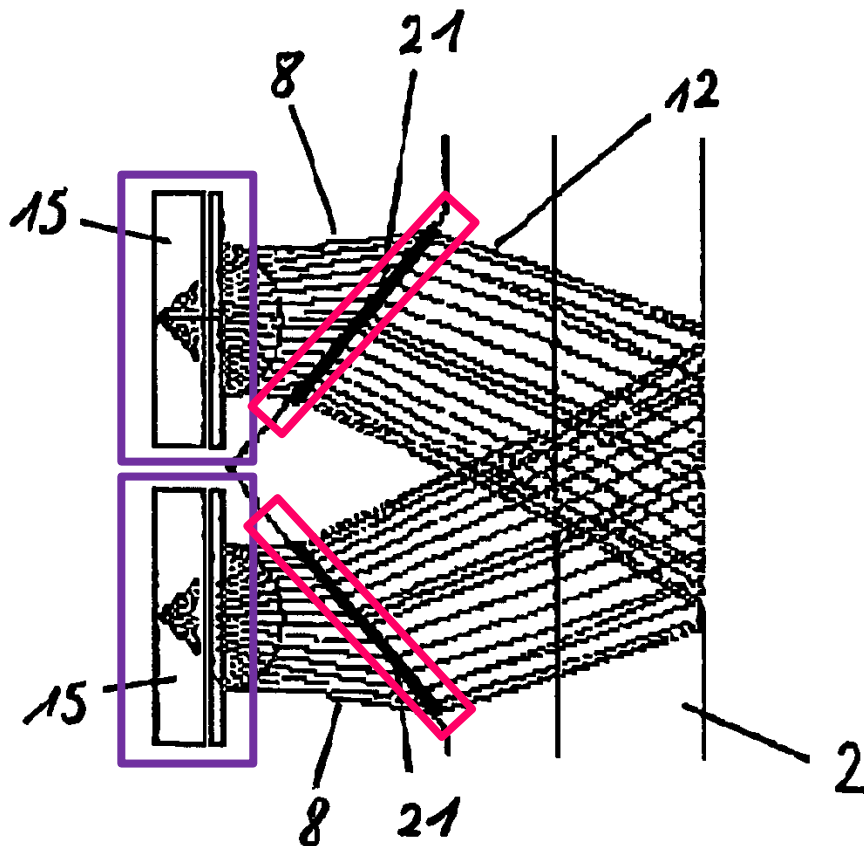


Figure 4

EX1028, Figure 4 (annotated).

97. Carlson is further directed to the objective of “increasing the technical performance of pulsoximetry in terms of quality and robustness of the measurement signal versus environmental disturbances and energy consumption.” EX1028, [0002]. For example, Carlson explains that “[w]hen using pulsoximetry in telemedicine” (*i.e.*, outside of a doctor’s office setting, such as in athletics or in “self-

testing”), “standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances.” EX1028, [0004].

Carlson states that:

It is therefore an object of the present invention to define optical and/or electronic means for increasing the Signal-to-Noise ratio (S/N) and Signal-to-Background ratio (S/B) of a pulsoximeter sensor for robust application of pulsoximetry in telemedicine- and near patient testing applications in rough (optical) environmental conditions, e.g. at changing light influences, such as sunlight, shadow, artificial light, etc.

EX1028, [0010].

98. Carlson provides multiple ways of accomplishing this objective, including “us[ing] a **beam-shaping element**, such as e.g., diffractive or refractive lenses, to direct the emitted optical radiation of, e.g., the **LED** light source into the human or animal tissue and the photon detecting element in order to increase the optical signal power detected by the pulsoximeter sensor.” EX1028, [0014]. The beam-shaping element is illustrated by Figure 4, above.

3. Lamego

99. Lamego is directed to a “multiple-wavelength physiological monitor,” that can determine a user’s blood oxygen saturation. EX1062, Abstract, Fig. 3. The device includes at least sensor, a signal processor, and a display. EX1062, Abstract.

The sensor includes “at least three” LEDs, which are each configured to “emit light of a different wavelength.” EX1062, Abstract. The sensor also includes a detector, which “receive[s] light” from the LEDs after it is “attenuated by tissue.” EX1062, Abstract. The detector “generates an output signal based at least in part upon the received light,” and the signal processor “determines blood oxygen saturation” based on the output signal. EX1062, Abstract. Lamego’s sensor may be applied in various parts of the body, including the finger and earlobe. *Id.*, [0024], [0027]-[0029], [0041]. Light may be propagated through, or reflected by, the tissue. *Id.*, [0024].

100. Lamego’s “multi-wavelength” monitor can be used to “provide a multi-dimensional calibration curve, which can be used to provide multiple degrees of freedom to compensate for variation in other physiologically-related parameters.” EX1062, [0035]. Through the addition of wavelengths, the system can “compensate for” and “calculate[] the concentration” of “additional significant absorbers” in the “patient’s tissue.” EX1062, [0035]. By way of example, Lamego explains that “an eight wavelength physiological monitor utilizes an eight-dimensional calibration curve, which provides eight degrees of freedom to compensate for various physiologically-related parameters.” EX1062, [0035]. These parameters may include, “noise, motion, various hemodynamic parameters, and/or blood constituent concentrations and/or levels.” EX1062, [0035].

101. Lamego further teaches that its multi-wavelength monitor may “utilize all infrared wavelength light sources and/or other non-red infrared light sources to derive an accurate plethysmographic waveform.” EX1062, [0036]. The multi-wavelength monitor can be “configured to determine several blood constituent concentrations,” including the “levels and/or concentrations of methemoglobin (MetHb), carboxyhemoglobin (COHb), low hemoglobin levels, high hemoglobin levels, bilirubin, methylene blue, deoxyhemoglobin, and lipids.” EX1062, [0036].

102. Lamego explains that one of the benefits of its multi-dimensional system is the ability of the system to compensate and account for the presence of certain blood constituents:

- The ability to measure a physiological parameter with a multi-dimensional system allows the system to compensate and account for the presence of other conditions that may affect the particular physiological parameter being measured. For example, many drugs cause the level of MetHb within a patient's blood to increase. MetHb also absorbs light at the two wavelengths used in a typical two-wavelength physiological monitor, which may cause inaccurate SpO2 readings. Increased levels of MetHb generally cause blood oxygen concentration level (e.g., SpO2) readings to decrease. A two-wavelength physiological monitor would provide reduced readings of blood oxygen concentration, but would not be able to identify the cause for the decreased reading, or to compensate for such

readings. On the other hand, a multi-wavelength physiological monitor, such as any of the multi-wavelength physiological monitors described below, could not only identify the cause of decreased SpO2 readings, but also (or alternatively) compensate for such cause when calculating the patient's SpO2 level and/or signal. For example, to compensate for MetHb, one or more wavelengths sensitive to MetHb can be used. The wavelength(s) used can be, for example, about 760 nm and/or about 805 nm or the like. This allows for one or more additional equation (s) and degree(s) of freedom so that solving the system may account for the effect of the level of MetHb on blood oxygen saturation readings. EX1062, [0037].

- Similarly, the system can compensate for other blood constituents with the addition of wavelengths sensitive to the other blood constituents of interest. For example, carboxyhemoglobin absorbs about the same amount of 660 nm light as oxyhemoglobin. Therefore, a typical two-wavelength physiological monitor can mistake carboxyhemoglobin for oxyhemoglobin, which can result in normal blood oxygen saturation level readings even though the actual level is abnormal. For example, for every about 1% of carboxyhemoglobin circulating in the blood, the monitor may over read by about 1%. Selecting one or more additional wavelengths sensitive to carboxyhemoglobin, for example, about 610, 630, and/or 640 or the like, can allow the system to compensate for this effect. The

system can compensate for other blood constituents, such as deoxyhemoglobin or lipids, with the addition of wavelengths sensitive to those constituents. More wavelengths can allow the system to compensate for more variables. EX1062, [0038].

103. Lamego's multi-wavelength monitor "provides improved accuracy as well as an improved signal-to-noise ratio," and is capable of compensating for, among other things, movement/motion and various blood constituents. EX1062, [0028]–[0029], [0034], [0040]. Lamego also explains, however, that, "[i]n addition to improving the accuracy of blood oxygen saturation level readings, using multiple wavelengths can also provide relatively more accurate measurements of other parameters, including, for example, the concentrations of any of the blood constituents or other parameters mentioned herein." EX1062, [0039].

104. Lamego also discusses several mathematical and statistical techniques for processing the measurements collected by the monitor in order to establish the presence and level/concentration of the various blood constituents discussed above. For example, Lamego discloses cross-correlation and modeling techniques that can be used to compensate for the presence of various blood constituents:

- The ratio of the intensity of different light wavelengths may be used to determine the oxygen saturation of the patient. In one embodiment, the ratio is provided to a saturation equation module 502, which includes a look-up table, a polynomial,

or the like. The saturation equation module 502 provides a saturation values at its output 504 based upon the ratio. In another embodiment, the n wavelengths' individual RMS values are also provided as outputs of the statistics operations module 404. EX1062, [0078], *see also, id.*, [0079]–[0082], [0090]–[0105].

4. Soller

105. Soller is directed to a “non-invasive optical and mathematical method to measure hematocrit with an accuracy of approximately 99%.” EX1030, 1:45–51. “Hematocrit is the volume percent of red blood cells in a blood sample” that can be “measured using only the concentrations of oxygenated and deoxygenated hemoglobin,” but also includes the concentrations of other components like “methemoglobin, carboxyhemoglobin, and sulphemoglobin.” EX1030, 1:19–44, 5:33–37. Soller teaches a method of “measur[ing] hematocrit with an accuracy of approximately 99%” by “quantifying all of the components of red blood cells,” in addition to oxygenated and deoxygenated hemoglobin. EX1030, 1:46–52, 5:33–54.

106. Soller further discloses a measuring device with an “illumination component” (like LEDs) that emits beams of light of one or more wavelengths in the “visible and near-infrared spectral region[s]” to measure the optical properties of a sample for the concentrations of various blood constituents. EX1030, 11:44–12:2; *see also id.*, 1:53–62, 13:13–28, 18:18–23. Soller teaches that the device may have “between 5 and 20 LEDs,” each emitting a different wavelength in the range of, *e.g.*,

500–1100 nm. EX1030, 13:13–28, 13:39–40. The LEDs are “evenly spaced and arranged in a circular pattern” and “preferably tilted inward,” which Soller teaches “increase[es] the accuracy of the measurement” for each blood constituent in hematocrit. EX1030, 13:35–49; 16:39–48 (a “ring-like pattern” for the LEDs “maximize[s] the amount of radiation” directed to the sample). The light is delivered to the skin with a probe “in close proximity to the skin,” such as via a “hand-held unit.” EX1030, 12:30–38. The device also includes interior and exterior detectors for capturing the light reflected back from or transmitted through the tissue. EX1030, 13:50–63. Soller teaches that “[b]ecause of its small size,” the device is “portable, handheld, and easily manipulated,” which allows the measurement of hematocrit in “remote locations, such as in an ambulance or outdoors.” EX1030, 15:50–56, 15:31–40 (Soller’s device is “particularly desirable for applications necessitating a portable or hand-held device”).

B. Motivations to Combine

1. Lisogurski and Carlson

107. A POSITA would have been motivated to combine Lisogurski and Carlson because both references concern miniaturized, wireless pulse oximetry devices directed to the same applications (in particular, remote monitoring of a person’s pulse, oxygen saturation, and other characteristics). Furthermore, both references teach techniques for improving the signal-to-noise ratio (SNR) of pulse

oximeter systems. Accordingly, as discussed in more detail below, Lisogurski and Carlson are directed to analogous systems that aim to solve the same problems; they thus would have been considered together by a POSITA.

108. Lisogurski teaches a PPG system that is designed to allow “for increased battery life” and “portability” by optimizing power consumption by the miniaturized, wearable monitoring system. EX1027, 1:4–6, 1:16–18, 3:50–53. For example, Lisogurski teaches a variety of techniques to reduce the power requirements necessary for a portable oximetry system, thereby allowing for a smaller device (*e.g.*, a wearable sensor worn on a wrist) or longer battery life. EX1027, 4:63–67, 4:15–20, 17:51–58. Lisogurski similarly teaches “improv[ing] the signal-to-noise ratio” of the measured signals from the user using various techniques, *e.g.*, by “alter[ing] the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons, or any combination thereof.” EX1027, 9:46–60. These teachings in Lisogurski would have motivated a POSITA to look for other techniques accomplishing the same objectives (minimizing power consumption and increasing SNR), particularly as applied to the same type of wearable sensor device. Indeed, evaluating Lisogurski’s system in view of complementary designs and techniques for accomplishing the same objectives in analogous wearable devices would have been part of a POSITA’s ordinary design process when seeking to improve the operation of a PPG device.

109. A POSITA would have looked to Carlson and considered it together with Lisogurski when designing an improved PPG system integrated with a wearable sensor. Carlson describes improvements to pulse oximetry devices, including improvements to energy consumption and signal measurement. EX1028, [0002]. For example, Carlson teaches increasing the signal-to-noise ratio of an optical sensor using various techniques (such as including a “beam-shaping element” “to direct the emitted optical radiation of, e.g., the LED light source into the human or animal tissue”). EX1028, [0010], [0014]. Carlson further teaches that its techniques permit for a small, battery-operated device that could be worn by a user (on, for example, the user’s earlobe, finger, or toe), which a POSITA would have understood to refer to an energy-efficient oximetry device. EX1028, [0048], [0052]. Finally, Carlson teaches that its system and techniques for improving the signal-to-noise ratio can be applied to a number of different health and fitness uses, including mobile monitoring, telemedicine, and sports. EX1028, [0004]. Carlson would have provided a direct motivation to a POSITA to incorporate its features into other pulse oximetry devices.

110. Thus, because Lisogurski and Carlson both describe analogous systems with overlapping applications and objectives (namely, techniques for improving performance, utility, and power consumption of portable, wearable, optical sensors), a POSITA would have considered the two references together when implementing

an optical measurement system based on Lisogurski's teachings. A POSITA further would have had a reasonable expectation of success in combining features from Carlson with Lisogurski's system because such modifications would be a routine part of a POSITA's ordinary design process and within the POSITA's skill. For example, it was well-known to use filters with detectors in light sensors to reduce the amount of unwanted signals being detected, and so a POSITA would have reasonable expectation of success implementing Carlson's filter teaching to Lisogurski. Similarly, modifying Lisogurski's system to include the "beam shaping element" disclosed by Carlson would have been a routine modification, because elements like lenses are considered "building blocks" of optical measurement systems used to focus the light of LEDs.

111. I understand that the Board has already considered whether a POSITA would have been motivated to combine the Lisogurski system with Carlson in the previous IPR for the related '533 patent and in the ongoing IPR for the related '484 patent, and found that such a motivation existed. EX1008, 22–25; EX1011, 22, 28, 36–43. I understand that the Board previously found in its Final Written Decision for the '533 IPR a motivation to combine Lisogurski and Carlson, which was affirmed by the Federal Circuit. EX1009. I further understand that Omni did not cross-appeal the finding in the Board's First Final Written Decision for the related '484 IPR that there would have been a motivation to combine Lisogurski and

Carlson, and that that decision has therefore been affirmed by the Federal Circuit. EX1012, n.2.

2. Lisogurski and Carlson in view of Lamego

112. A POSITA would have considered the optical measurement systems taught by Lisogurski and Carlson together with Lamego because (as described above for Lisogurski and Carlson, *supra* § VIII.B.1) all three references are analogous, disclosing techniques for improving the performance, including the signal-to-noise ratio of non-invasive optical devices directed to the monitoring of a person's pulse, oxygen saturation, and other characteristics. When reviewing Lisogurski and Carlson it would have been part of a POSITA's ordinary design process to look for ways to improve the accuracy and signal-to-noise ratio of the blood oxygen saturation measurement systems taught by those references.

113. As discussed, *supra* § VIII.B.1, Lisogurski and Carlson teach techniques for improving the signal-to-noise ratio (SNR) of pulse oximeter systems, including techniques related to modifying the operation of each system's respective light sources. EX1027, 9:46–60 (Lisogurski teaching “improv[ing] the signal-to-noise ratio” of the measured signals from the user using various techniques, *e.g.*, by “alter[ing] the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons, or any combination thereof”); EX1028, [0010], [0014] (Carlson teaching increasing signal-to-noise ration by, *e.g.*, including a

“beam-shaping element” “to direct the emitted optical radiation of, e.g., the LED light source into the human or animal tissue”).

114. Like Lisogurski and Carlson, *supra* § VIII.B.1, Lamego describes a non-invasive optical device that uses the attenuation of light by a user’s tissue to measure physiological parameters, including blood oxygen saturation. EX1062, Abstract. Lamego explains that its multi-wavelength sensor can improve the accuracy of measurements of physiological parameters, including blood oxygen saturation, and compensate for noise caused by patient motion (increasing the signal-to-noise ratio). EX1062, [0028]–[0029], [0035], [0037]–[0040].

115. A POSITA would have therefore looked to Lamego’s complementary teachings of a multi-wavelength monitor and related statistical modeling techniques in order to increase the accuracy and signal-to-noise ratio of the systems taught by Lisogurski and Carlson. A POSITA would have been motivated to implement Lamego’s multi-wavelength sensor teachings in a system based on Lisogurski (and Carlson) to improve the performance of that system; indeed, Lisogurski itself contemplates modifications to its light source configuration, explaining that its light source “may include any number of light sources with any suitable characteristics.” EX1027, 10:48–64. A POSITA would have had a reasonable expectation of success modifying Lisogurski’s light source to include additional LEDs with additional wavelengths because it was well-known to use a plurality of LED light sources

emitting light at different wavelengths in order to determine the presence and levels of blood constituents to improve SpO₂ readings. Therefore, combining features from Carlson and Lamego with Lisogurski's system would have required routine knowledge and skill and would have been a part of the ordinary design process for a POSITA.

3. Lisogurski and Carlson in view of Soller

116. A POSITA would have considered the optical measurement systems taught by Lisogurski and Carlson together with Soller because (as described above for Lisogurski and Carlson, *supra* § VIII.B.1) all three references are directed to analogous systems with common applications and utility. Specifically, a POSITA would have been motivated to combine Lisogurski, Carlson, and Soller because they all concern techniques for improving the performance of non-invasive, miniaturized, optical devices directed to the same applications (in particular, remote monitoring of a person's pulse, oxygen saturation, and other characteristics).

117. Like Lisogurski and Carlson, *supra* § VIII.B.1, Soller also describes a battery-operated, energy efficient optical sensor that can operate remotely and can be used to monitor physiological parameters, including oxygenated and deoxyhemoglobin. EX1030, 15:50–56 (“Because of its small size, the integrated device is portable, hand-held, and easily manipulated. Hematocrit can also be measured in remote locations, such as in an ambulance or outdoors.”); 15:6–22 (the

“power supply” includes “[s]tandard electrical batteries and circuits known in the art”); *id.* at 15:31–40 (describing applications for monitoring hematocrit in a “portable or hand-held device”). Furthermore, Soller teaches configuring an optical sensor in a manner that maximizes the accuracy of the measured physiological signal by using “a larger set of wavelengths in the measurement and by using a multivariate calibration technique” to “quantify[] . . . additional blood cell components,” such as “methemoglobin, carboxyhemoglobin, and sulfhemoglobin.” *Id.*, 5:35–51, *id.*, 5:55–67. Soller likewise teaches the processing of the optical data obtained through its sensor using “numerical algorithm[s]” that can improve signal-to-noise ratio. *Id.* 7:38–42.

118. Given their overlapping applications and the fact that the references are directed to the same problem of optimizing power consumption while obtaining accurate measurements, a POSITA would have been motivated to combine the optical and mathematical techniques from Soller, including the increased number of light sources and wavelengths, into Lisogurski’s system as part of the natural design process and would have had a reasonable expectation of success in doing so. A POSITA would have understood that Lisogurski’s system, which is not limited to the measurement of oxygenated and deoxygenated hemoglobin, could have been modified to measure other constituents, including the hematocrit components identified by Soller. Such a modification would have required only routine skill.

Further, a POSITA would have found the application of Carlson and Soller's teachings to Lisogurski's optical system to be a routine modification to Lisogurski for which a POSITA would have had a reasonable expectation of success, particularly because the modifying the configurations of the light sources in an optical measurement system was a well-known technique and consistent with Lisogurski's disclosures that its light source "may include any number of light sources with any suitable characteristics." EX1027, 10:48–64. Therefore, combining features from Carlson and Soller with Lisogurski's system would have required routine knowledge and skill and would have been a part of the ordinary design process for a POSITA.

C. Specific Grounds of Invalidity

1. Ground 1: Claim 7 would have been obvious over Lisogurski in view of Carlson

119. I have analyzed claim 7 and, in my opinion, it would have been obvious over Lisogurski in view of Carlson. I provide a detailed analysis of each claim limitation below.

a. 7[pre]: "An optical system, comprising:"

120. In my opinion, Lisogurski in view of Carlson discloses claim 7[pre].

121. Lisogurski discloses "an optical physiological monitoring system," which includes a sensor and a monitor, that "may be used to determine[] physiological parameters such as blood oxygen saturation, hemoglobin ..., [and]

pulse rate.” EX1027, 1:10-25; *id.*, 3:43-46. The system described in Lisogurski includes a “light sensor” and a “light source,” which passes “light through blood perfused tissue” and “photoelectrically sense[s] the absorption of the light in the tissue.” EX1027, 3:61-4:5, 4:6-25, 15:30-35. A POSITA would have understood Lisogurski’s disclosure to be an “optical system.”

122. I note that in the previous IPR of the related ’533 patent, the Board found that Lisogurski teaches a “measurement system” and a “wearable measurement device for measuring one or more physiological parameters. EX1008, 25. The Board’s finding was affirmed by the Federal Circuit. EX1009. In the context of the ’790 Patent, a POSITA would have understood an “optical system” to refer to a system that uses optical methods, such as those described in Section V, *supra*, to measure physiological parameters and/or constituents.

b. 7[a]: “a wearable device for measuring one or more physiological parameters, the wearable device adapted to be placed on a wrist of a user”

123. In my opinion, Lisogurski, alone or in view of Carlson, discloses claim 7[a].

(i) “wearable device for measuring one or more physiological parameters”

124. Lisogurski teaches or renders obvious a “**wearable device for measuring one or more physiological parameters.**”

125. Lisogurski teaches a “**physiological** monitoring system,” such as a “pulse oximeter, which may non-invasively **measure** the oxygen saturation of a patient’s blood.” EX1027, 3:43–66. Lisogurski’s monitoring system (100/310) includes a sensor (102/312) for measuring blood oxygen saturation that can be mounted on a user’s “earlobe” or “wrist to monitor radial artery pulsatile flow.” EX1027, 4:6–20; *see also id.*, 3:43–46, 3:61–4:5, 4:52–62, 17:55–59, Figs. 1, 3. Furthermore, Lisogurski states that the system “is directed towards power optimization in a medical device,” specifically an “oximeter” (or a “pulse oximeter”) that may “non-invasively measure the oxygen saturation of a patient’s blood” and that may be “placed at a site on a patient, typically a fingertip, toe, forehead, or earlobe.” EX1027, 3:43–4:20 (“An oximeter is a medical device that may determine the oxygen saturation of an analyzed tissue.”); *see also id.* at 4:52–62 (describing a system that “may process data to determine physiological parameters”). A POSITA would have understood from these disclosures that Lisogurski teaches a pulse oximeter device that can be worn by a user on various body parts, including the wrist and ear.

126. This system is an “optical” system that “may be used to determine physiological parameters such as blood oxygen saturation, hemoglobin, blood pressure, pulse rate, other suitable parameters, or any combination thereof.” EX1027, 1:10-25; *id.*, 3:43-46, 3:61-4:5, 4:22-25, 15:30-35. Lisogurski further

teaches that “[p]ulse oximeters may be included in patient monitoring systems that measure and display various blood flow characteristics, including but not limited to the oxygen saturation of hemoglobin,” as well as a “patient’s pulse rate and blood pressure.” EX1027, 3:61–4:5. Figure 1 of Lisogurski illustrates this “physiological monitoring system,” which consists of, *e.g.*, a sensor, a monitor, and a communication interface. EX1027, 2:11–13, Fig. 1.

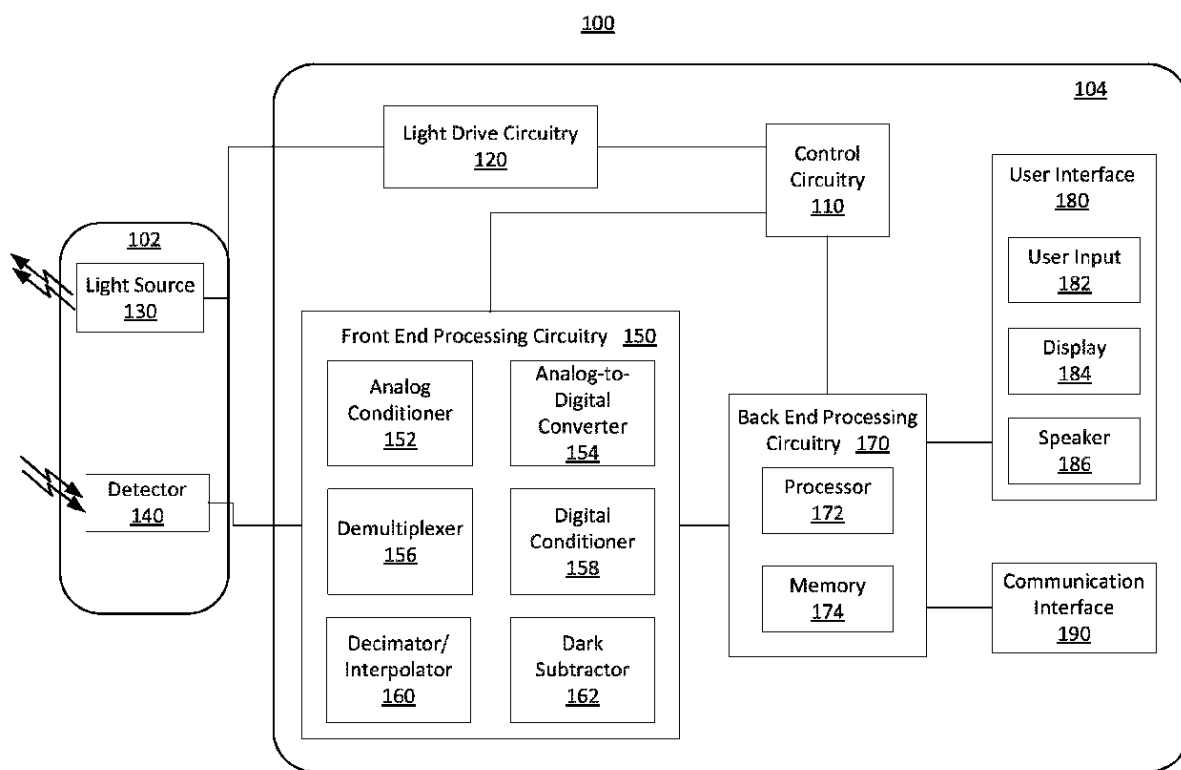


FIG. 1

EX1027, Fig. 1.

(ii) **“the wearable device adapted to be placed on a wrist of a user”**

127. Lisogurski teaches or renders obvious a **“wearable device adapted to be placed on a wrist of a user.”** As described above, Lisogurski describes a measurement system (100/310), which includes a sensor (102/312) for measuring blood oxygen saturation that can be mounted on a user’s **“wrist** to monitor radial artery pulsatile flow.” EX1027, 4:6–20; *see also id.*, 3:43–46, 3:61–4:5, 4:52–62, 17:55–59, Figs. 1, 3. Lisogurski states that the system “is directed towards power optimization in a medical device,” specifically an “oximeter” (or a “pulse oximeter”) that may “non-invasively measure the oxygen saturation of a patient’s blood” and that may be **“placed at a site on a patient, typically a fingertip, toe, forehead, or earlobe.”** EX1027, 3:43–4:20 (“An oximeter is a medical device that may determine the oxygen saturation of an analyzed tissue.”); *see also id.* at 4:52–62 (describing a system that “may process data to determine physiological parameters”). A POSITA would have understood from these disclosures that Lisogurski teaches a pulse oximeter device that can be worn by a user on various body parts, including the wrist.

128. Accordingly, Lisogurski teaches or renders obvious 7[a]. I note that the Board found in the ’533 IPR that Lisogurski teaches “a wearable measurement device...for measuring blood oxygen saturation” that can be “mounted on a user’s fingertip, toe, earlobe, wrist, or thigh.” EX1008, 7–8, 25. The Federal Circuit affirmed this finding. EX1009. The Board made a similar finding in the ’484 IPR.

EX1011, 5–6, 23, 26–27 (finding Lisogurski teaches “[a] system for measuring one or more physiological parameters....the system comprising” “a wearable device adapted to be placed on a wrist or an ear of a user”), *aff’d in relevant part*, EX1012, n.2.

- c. **7[b]: “the wearable device including a light source comprising a plurality of semiconductor diodes that are configured to generate an output optical light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;”**

129. In my opinion, Lisogurski, alone or in view of Carlson, discloses claim 7[b].

- (i) **“a light source comprising a plurality of semiconductor diodes that are configured to generate an output optical light having one or more optical wavelengths”**

130. Lisogurski teaches that the sensor, illustrated in Figure 1, in its wearable measurement system “may include multiple **light sources** and detectors.” EX1027, 17:42–45; Fig. 1 (130); Fig. 3 (316). Moreover, Lisogurski teaches that “**light source 130** may include any number of **light sources with any suitable characteristics**.” EX1027, 10:48–64.

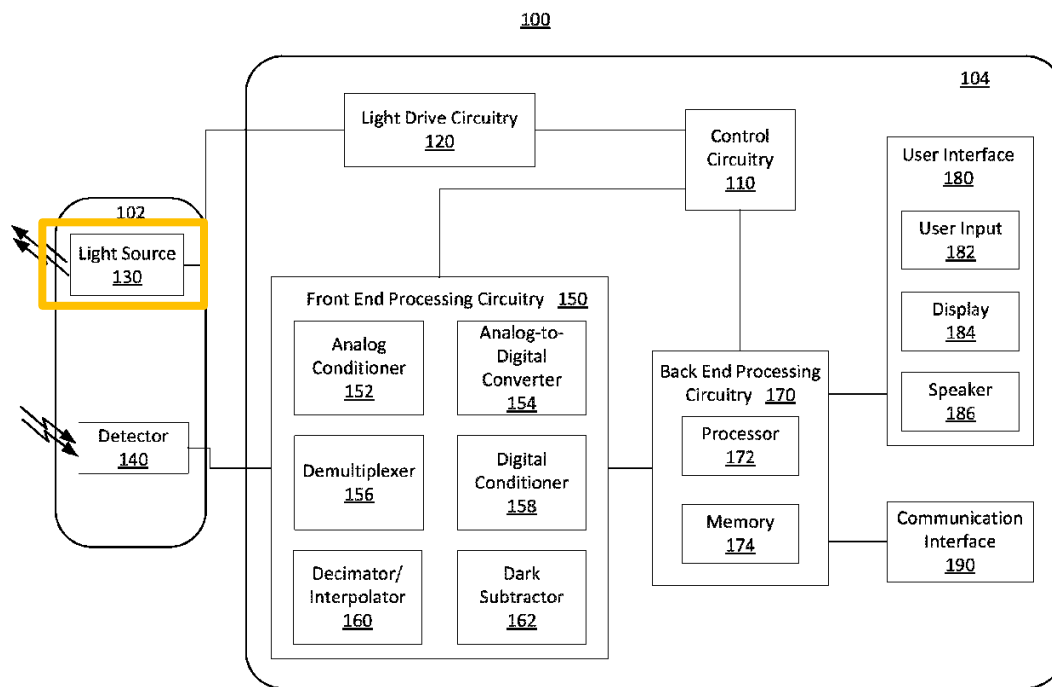


FIG. 1

EX1027, Fig. 1 (annotated).

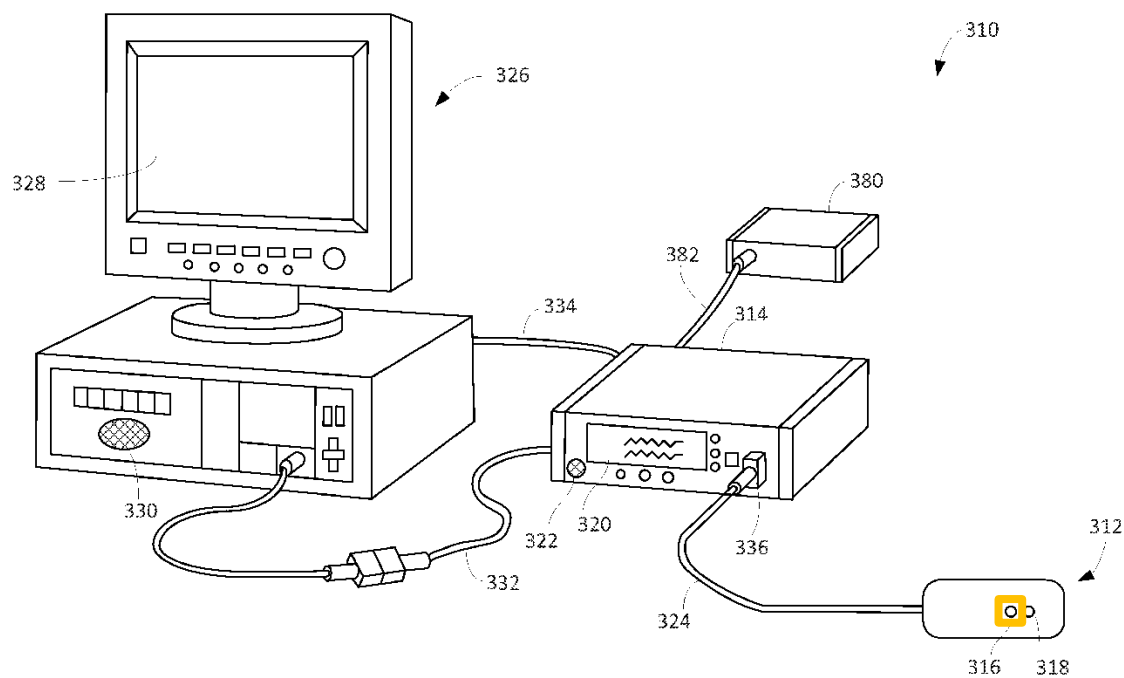


FIG. 3

EX1027, Fig. 3 (annotated).

131. Lisogurski further discloses that the “any number of light sources with suitable characteristics” comprising the light source may be light-emitting diodes (LEDs). EX1027, 7:38–67 (“For example, **the first light source may be a high efficiency infrared (IR) LED while the one or more additional light sources may be lower efficiency red LEDs**”), 19:20–39 (“ For example, the light source may include light source 130 of FIG. 1 or light source 316 of FIG. 3. In some embodiments, **the light source may include LEDs of multiple wavelengths**, for example, a red LED and an IR [LED]. In some embodiments, **the light source may include multiple LEDs of the same wavelength, multiple LEDs of different wavelengths, any other suitable arrangement, or any combination thereof.**”). LEDs are semiconductors, so it is my opinion that a POSITA would have understood the LEDs in the light source of Lisogurski to be a plurality of “semiconductor diodes.”

132. Lisogurski further teaches that the LEDs emit light of “one or more wavelengths” and that the light is transmitted to a particular location in space (specifically, the “subject’s tissue”). EX1027, 10:49–52 (“Light source 130 may be **configured to emit photonic signals having one or more wavelengths of light (e.g., Red and IR) into a subject’s tissue.**”); 17:37–45 (“Sensor unit 312 may include one or more light source 316 for **emitting light at one or more wavelengths into a subject’s tissue**”); *see also* EX1027, 7:38–67 (“For example, the first light

source may be a high efficiency **infrared (IR) LED** while the one or more additional light sources may be lower efficiency **red LEDs**"); *id.*, 10:49–64 (“For example, light source 130 may include a **Red light emitting source** and an **IR light emitting source, e.g., Red and IR light emitting diodes (LEDs) for emitting light into the tissue of a subject to generate physiological signals.** In one embodiment, the **Red wavelength** may be **between about 600 nm and about 700 nm**, and the **IR wavelength** may be **between about 800 nm and about 1000 nm**. It will be understood that light source 130 may include any number of light sources with any suitable characteristics.”); *id.*, 19:20–39 (“For example, the light source may include light source 130 of FIG. 1 or light source 316 of FIG. 3. In some embodiments, the **light source may include LEDs of multiple wavelengths**, for example, a red LED and an IR [LED]. In some embodiments, the light source may include multiple LEDs of the same wavelength, **multiple LEDs of different wavelengths**, any other suitable arrangement, or any combination thereof.”). It is my opinion that a POSITA would have understood these and other disclosures in Lisogurski to mean the LEDs emit an “optical output light” “of one or more wavelengths” in a “beam” toward a particular location, *e.g.*, tissue; thus, the LEDs are “configured to generate an output optical beam of one or more wavelengths.”

(ii) “wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers”

133. As discussed above, Lisogurski teaches that its LEDs may emit light in “one or more wavelengths,” including “**IR wavelength[s]**,” which may be **between about 800 nm and about 1000 nm**. EX1027, 10:49–64; *id.* 7:38–67 (“For example, the first light source may be a high efficiency **infrared (IR) LED** while the one or more additional light sources may be lower efficiency **red LEDs**”). A POSITA would have understood that optical wavelengths of 660 nm correspond to red light, whereas wavelengths of 800–1000 nm correspond to infrared (IR) light. The 800–1000 nm band disclosed in Lisogurski falls within the 700–2500 nm near-infrared range recited in the claim, and a POSITA would have understood the 800–1000 nm wavelength disclosed in Lisogurski to qualify as a “near-infrared” wavelength. A POSITA would have also understood that Lisogurski’s disclosure of the 800–1000 nm band is a representative and non-limiting example. It would have been an obvious and trivial modification for a POSITA to choose a light source, such as an LED, capable of emitting light in the 700–800 nm band, or in the 1000–2500 nm band. Selecting an LED capable of emitting wavelengths in different portions of the near-infrared spectrum would have been within a POSITA’s knowledge and skill.

134. Accordingly, Lisogurski teaches claim 7[b]. I note that the Board previously determined that Lisogurski discloses materially identical limitations to

claim 7[b], and the Federal Circuit affirmed these findings. Specifically, the Board found that Lisogurski teaches “a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers.” EX1008, 4-5, 7, 25-26; *aff’d*, EX1009; *see also* EX1011, 5-6, 23, 26-27 (finding Lisogurski teaches “[a] light source comprising a plurality of light emitting diodes, each of the light emitting diodes configured to generate an output optical light having one or more optical wavelengths”), *aff’d in relevant part*, EX1012, n.2.

- d. **7[c]: “the wearable device comprising one or more lenses configured to receive at least a portion of the output optical light and to deliver a lens output light to tissue comprising skin;”**

135. Lisogurski, or Lisogurski in view of Carlson, teaches this limitation.

136. As discussed, Lisogurski teaches a wearable device that includes a sensor 102/312 for measuring blood oxygen saturation that can be applied to a user’s wrist. EX1027, 4:6–20; *see also id.*, 3:43–46, 3:61–4:5, 4:52–62, 17:55–59, Figs. 1, 3; *supra* §§ VIII.C.1.b (cl. 7(a)). The LEDs emit the light in beams; the beams pass through or are reflected back by the tissue, and the reflected and/or transmitted light is detected by the photodetector in the sensor. EX1027, 4:7–11 (“The oximeter may use a light source to pass light through blood perfused tissue and photoelectrically

sense the absorption of the light in the tissue”), 10:48–56 (the light sources “emit” light of a particular wavelength, i.e., a beam), 11:13–20 (the “light may enter detector 140 after passing through the subject’s tissue”). A POSITA would have understood that the “tissue” discussed in Lisogurski may include skin. Indeed, Lisogurski discusses how variations in the user’s skin pigmentation may impact light waveforms. EX1027, 44:43-45 (“red waveforms may be 25% of the intensity of the IR waveform, as may occur in patients with dark skin pigmentation”).

137. Lisogurski further teaches that its wearable measurement device may include a light source that includes semiconductor sources (such as conventional red and infrared LEDs) configured to emit an “output optical light” in a particular direction. *Supra* §§ VIII.C.1.c (cl. 7(b)).

138. Lisogurski further teaches:

- “In some embodiments of cardiac cycle modulation, the system may modulate multiple light sources using a plurality of modulation techniques. For example, in a system with two light sources, the system may operate a first light source at full or regular brightness, while operating one or more additional light sources in a switched or otherwise modulated mode. In some embodiments, the system may operate a first light source according to a first cardiac cycle modulation technique and a second light source according to a second cardiac modulation technique. The first and second cardiac cycle

modulation techniques may be the same, correlated, or unrelated. In some embodiments, the system may use the first light source to determine periods of interest in the cardiac cycle. The system may, according to the periods of interest, power additional light sources, alter the modulation of the additional light sources, perform other suitable power optimization techniques, or any combination thereof. In some embodiments, the system may include a first light source (e.g., a light source powered at full or regular brightness) of a type that is a more efficient light source than the one or more additional light sources. For example, the first light source may be a high efficiency infrared (IR) LED while the one or more additional light sources may be lower efficiency red LEDs or laser diodes. In some embodiments, the first light source may be selected based on efficiency parameters and information from the first light source may be used only to control a second light source. For example, a highly efficient first light source that is not at a wavelength of interest for physiological parameter determination may be used to control one or more second light sources at wavelengths of interest. In this case, the light from the first light source may be used only for controlling the second light source and not for determining physiological parameters.” EX1027, 7:38–8:3.

- “For example, light source 130 may include a Red light emitting light source and an IR light emitting light source, e.g., Red and IR light emitting diodes (LEDs), **for emitting light into the tissue of a subject** to generate physiological signals.” EX1027, 10:52–56.
- “In some embodiments, the light source may include LEDs of multiple wavelengths, for example, a red LED and an IR [LED]. In some embodiments, the light source may include multiple LEDs of the same wavelength, multiple LEDs of different wavelengths, any other suitable arrangement, or any combination thereof.” EX1027, 19:25–31.

139. Based on the disclosures above, a POSITA would have understood that Lisogurski teaches the use of conventional LEDs for directing the emitted optical output light toward the tissue of a subject. In my opinion, a POSITA would have known that there are three primary types of LEDs: (i) LEDs without an encapsulant, (ii) LEDs with an optically inert encapsulant; and (iii) LEDs with an encapsulant functioning as a lens, *i.e.*, an optically active encapsulant. It is further my opinion that a POSITA would have understood that LEDs used in the optical systems discussed in Lisogurski and in the ’790 patent typically are conventional LED semiconductors, which are conventionally encapsulated in a medium, typically glass, to protect the LED. Thus, it is my opinion that a POSITA would have understood Lisogurski teaches an LED with an encapsulant that may or may not

function as a lens, rather than an LED with no encapsulant at all, as such an approach would not likely operate reliably under real-world use.

140. It is further my opinion, and a POSITA would have understood, that using an LED with an optically active encapsulant functioning as a lens can increase the efficiency of an optical system by focusing and directing more of the light beam toward the target/tissue. Focusing the light toward the tissue can be especially important in battery-powered mobile monitoring devices in order to optimize power consumption and avoid scattering the light away from the tissue. In my opinion, a POSITA would therefore have found it obvious to select an LED for Lisogurski's system that uses an encapsulant as a lens and would have been motivated to make such a selection to improve the accuracy and power consumption of the system, consistent with the stated goals of Lisogurski. *Supra* § VIII.B.1. A POSITA would have understood that using an LED with an encapsulant functioning as a lens would have been a common configuration requiring routine effort. Indeed, the *Biomedical Engineering* textbook I discussed above (*supra* § V.A) recognizes that a lens is a “basic building block[]” of an optical sensor. EX1033, 765.

141. Thus, a POSITA would have found Lisogurski to teach or render obvious a wearable device comprising one or more lenses that capture the output optical light from the semiconductor sources (LEDs) and deliver such light to the tissue, including skin.

142. Carlson further teaches or renders obvious the use of a lens in Lisogurski's system. Carlson teaches using "at least one beam shaping optical element" such as a "lens" "to direct the emitted light" from a semiconductor and deliver it to a sample, for example:

- "The posed problem is solved by means of a configuration/method according to the invention. Proposed is a configuration for monitoring which comprises at least one of the following components:

at least one measuring sensor for the acquisition of the medical data, such as the state of the cardiovascular and pulmonary system, as e.g. pulsation frequency, oxygen saturation of blood, breathing frequency, etc. of a human being or an animal, comprising at **least one light source which can emit light at least at two wavelengths**, as well as at least one light receiver for determining the light transmitted through a tissue portion of the person or the animal;

at least one beam shaping optical element to direct the emitted light to a human or animal tissue and the light receiver in order to increase the optical signal power.

EX1028, [0011]–[0013].

- "The basic idea therefore is to **use a beam-shaping element, such as e.g. diffractive or refractive lenses, to direct the emitted optical**

radiation of, e.g., the LED light source into the human or animal tissue and the photon detecting element in order to increase the optical signal power, detected by the pulsoximeter sensor, and **thus increasing the Signal/Noise—and signal/Background ratio.** The increase of the S/B ratio is estimated e.g. to a factor 5.”

EX1028, [0014].

- “Furthermore, the above mentioned problem is solved according to the invention by means of methods according to the invention. Proposed is a method for monitoring e.g. pulsation frequency, oxygen saturation in blood or breathing frequency, which comprises at least one of the following steps:

measuring or monitoring medically relevant data of a person or an animal, such as in particular data, which describe the cardiovascular and pulmonary function and/or contain data regarding blood values or blood composition with the use of at least one measuring sensor, which sensor comprises at **least one light source which can emit light at least at two wavelengths:**

direct the emitted light or optical radiation, respectively, by using a beam shaping element, such as e.g. a diffractive or refractive lens to the human or animal tissue;

receiving and detecting the emitted and shaped light with at least one light receiving element for determining the light transmitted through the tissue portion of the person or the animal.”

EX1028, [0022]–[0025].

143. Figure 4 of Carlson illustrates the role of the “**beam shaping element**” (21), which can be a “**lens**,” in receiving the emitted light beams from the LEDs (15) (the “at least a portion of the **optical output light**”) and delivering those **light beams** (12) to **sample** (2). Specifically, Carlson teaches:

- “Therefore, it is proposed, as shown in FIG. 4, to use **beam shaping optics** 20 to direct the emitted optical radiation 8 emitted from the **two LEDs** 15 to the middle of the earlobe. As it is shown clearly in FIG. 4, using the **beam shaping optics** 21, the **two initial light beams** 8 are guided **in form of bundled beams** 12 to a **relatively small area within the middle ear** 2. By using the **beam shaping optics** 21, of course the influence of environmental light or noise, respectively, can be reduced substantially by increasing the S/B ratio. First o[f] all, the light beam is bundled and, in addition, the optical signal power can be increased.”

EX1028, [0054].

- “According to the preferred embodiment of the invention, the various described optical and geometric means, such as **the beam shaping**

element as shown in FIG. 4, the wavelength filters, the sensor architecture, and the mentioned baffles, can be combined as shown in principle and perspective view in FIG. 6c. Again, light is emitted from the two LEDs 15 and is shaped by the two beam shaping elements or lenses 21 to be guided as beams 12 through the earlobe 2. After the earlobe, the double pass filter 33 is arranged to guarantee that only light in the range of approximately 660 nm and in the range of approximately 890 nm is transmitted through the filter. After the filter, any stray light, entered the sensor e.g. through the earlobe from the side, will be trapped within the baffles 37 which are arranged in circumferential direction. Finally, a photo detecting element 35 is arranged with specific spectrum sensitivity.”

EX1028, [0062].

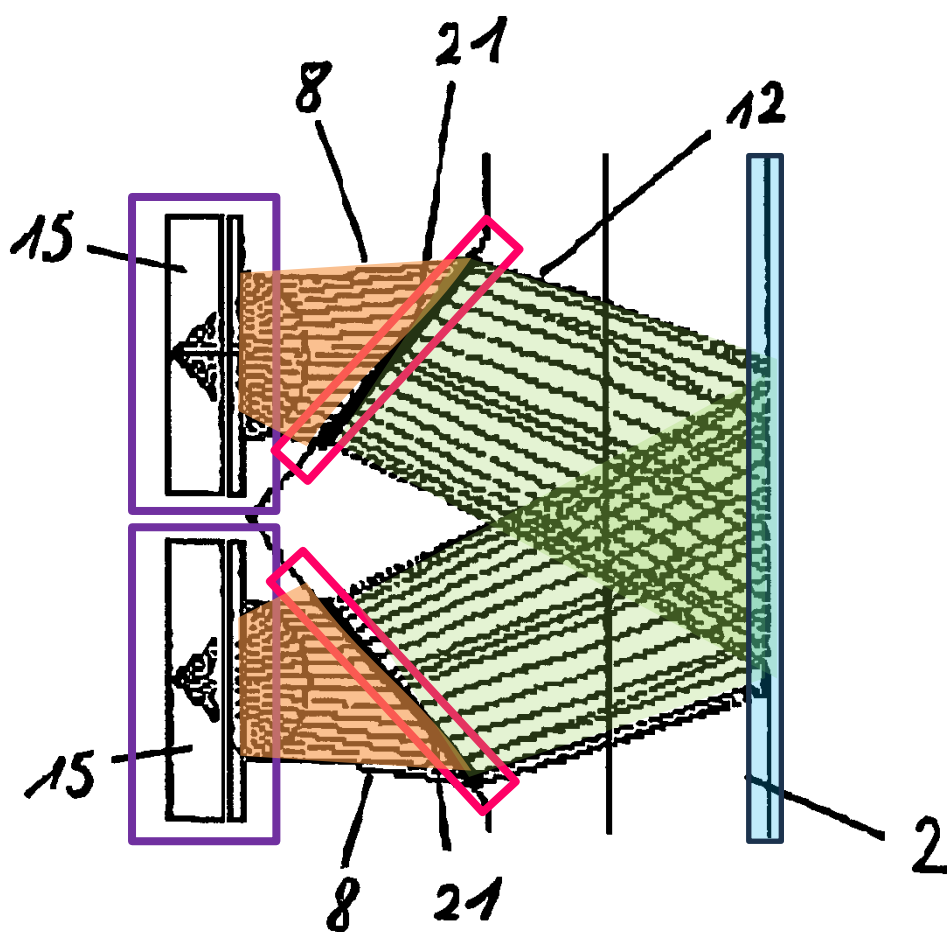


Figure 4

EX1028, Fig. 4 (annotated). A POSITA would have understood from these disclosures that Carlson teaches a lens, that receives a portion of an output optical light (illustrated in orange above) from the semiconductor sources (LEDs), and focuses the output optical light toward the tissue for delivery.

144. It is my opinion that a POSITA would have found it obvious to include one or more lenses (e.g. “beam shaping elements”) disclosed by Carlson to modify the output optical light from the conventional semiconductor LEDs taught by

Lisogurski, such that the emitted beam from those LEDs would be delivered to the sample as a lens output beam. For example, Carlson explains that including a beam shaping element (like a lens) improves SNR, which is a stated goal of Lisogurski. Supra §§ VIII.A.1–2, VIII.B.1. A POSITA would have been motivated to include the lens from Carlson in Lisogurski’s system based on their shared objective of improving the SNR in a portable pulse oximetry system, and would have found such a modification to be routine. Indeed, as mentioned above, beam-shaping elements (like lenses) are “basic building blocks” of conventional optical measurement systems. EX1033, 765. A POSITA would therefore have a reasonable expectation of success implementing Carlson’s beam shaping element into Lisogurski’s system.

145. Accordingly, Lisogurski, alone or in view of Carlson, teaches claim 7[c]. I note that the Board previously determined in the ’533 Apple IPR that Lisogurski, alone or in view of Carlson, discloses materially identical limitations to claim 7[c], and the Federal Circuit affirmed these findings. Specifically, the Board found that Lisogurski, in view of Carlson, teaches “the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample”, *aff’d*, EX1009. Similarly, in the ’484 Apple IPR, the Board found (and the Federal Circuit affirmed) that Lisogurski, alone or in view of Carlson, teaches “the wearable device having one or more lenses configured to receive a portion of at least one of the output optical

lights and to direct a lens output light to tissue.” EX1011, 5-6, 23-24, 26-27; *aff’d in relevant part*, EX1012, n.2.

- e. 7[d]: “the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;”

146. Lisogurski teaches this limitation.

- (i) “The wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal”

147. First, Lisogurski teaches “**a detection system** configured **to receive at least a portion of the lens output light reflected from the tissue.**” For example, Lisogurski teaches:

- “In some embodiments, **detector 140** may be configured to **detect the intensity of light at the Red and IR wavelengths.**” EX1027, 11:9–10.

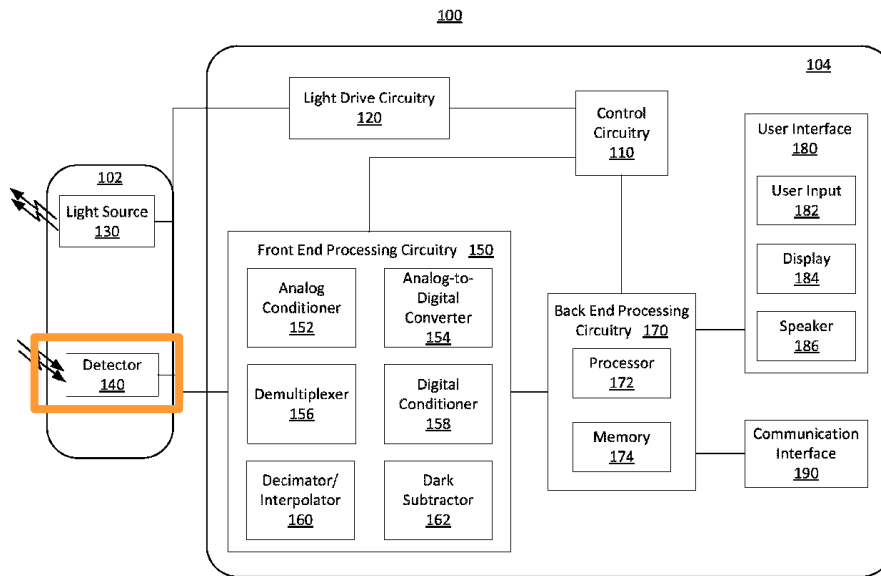


FIG. 1

EX1027, Fig. 1 (annotated).

- One or more **detector 318** may also be provided in sensor unit 312 for detecting the light that is reflected by or has traveled through the subject's tissue." EX1027, 17:39–42.

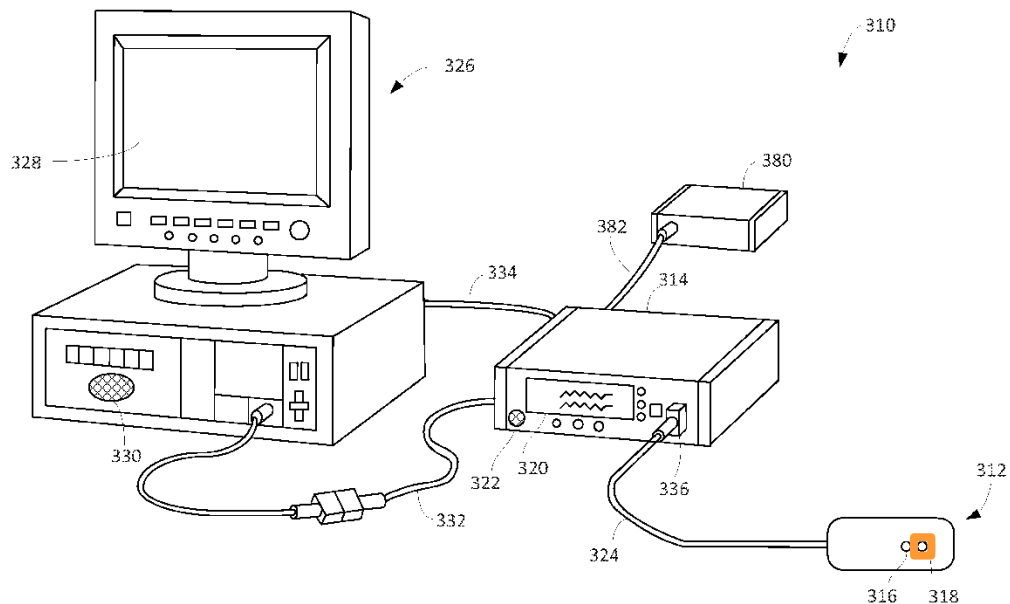


FIG. 3

EX1027, Fig. 3 (annotated).

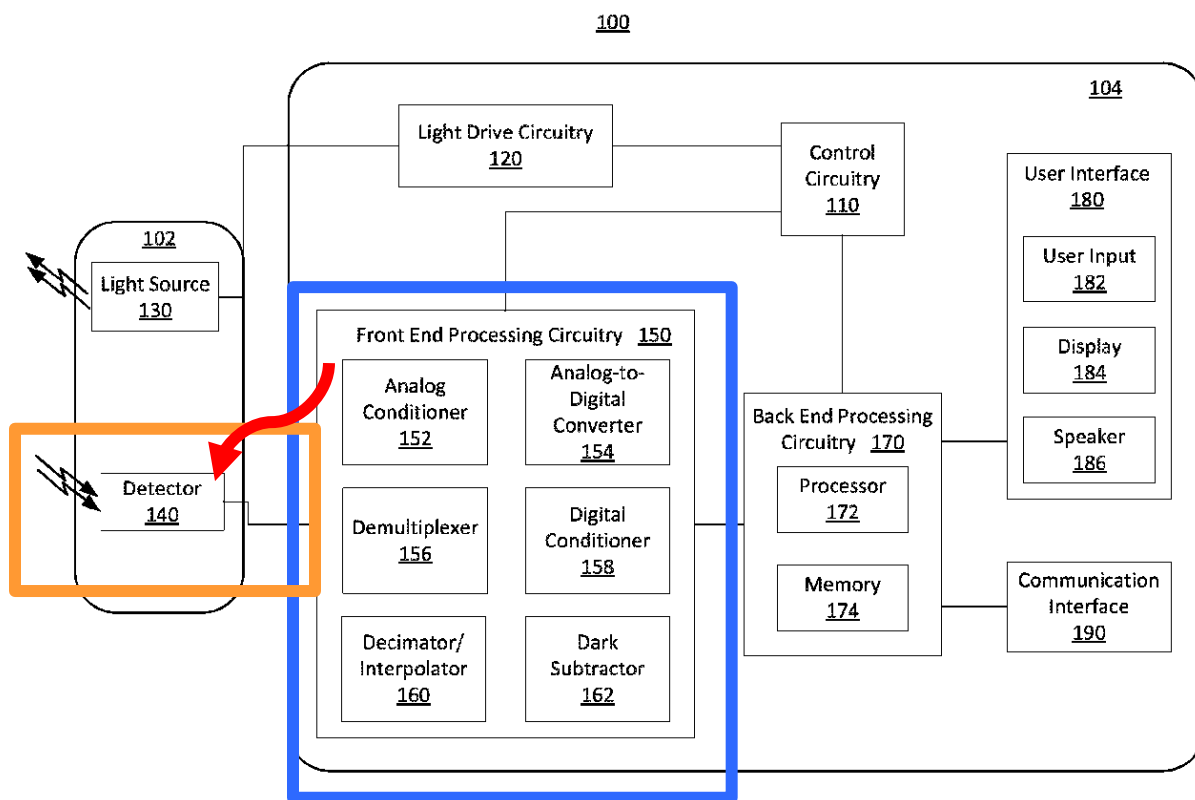
- “Detector 140 may be chosen to be specifically sensitive to the chosen targeted energy spectrum of light source 130. In some embodiments, detector 140 may be configured to detect the intensity of light at the Red and IR wavelengths. In some embodiments, an array of sensors may be used and each sensor in the array may be configured to detect an intensity of a single wavelength. **In operation, light may enter detector 140 after passing through the subject's tissue. Detector 140 may convert the intensity of the received light into an electrical signal. The light intensity may be directly related to the absorbance and/or reflectance of light in the tissue. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by detector 140.** After converting the received light to an electrical signal, **detector 140** may send the detection signal to monitor 104, where **the detection signal may be processed and physiological parameters may be determined (e.g., based on the absorption of the Red and IR wavelengths in the subject's tissue).** In some embodiments, the detection signal may be preprocessed by sensor 102 before being transmitted to monitor 104.” EX1027, 11:6–27.

- “Referring back to FIG. 1, **front end processing circuitry 150** may receive a detection signal from **detector 140** and provide one or more processed signals to back end processing circuitry 170. The term “detection signal,” as used herein, may refer to any of the signals generated within **front end processing circuitry 150** as it processes the output signal of **detector 140**. **Front end processing circuitry 150** may perform various analog and digital processing of the detector signal. One suitable detector signal that may be received by **front end processing circuitry 150** is shown in FIG. 2B.” EX1027, 12:42–50.
- “In step 410, the system may determine a physiological parameter using information from the attenuated photonic signals. The physiological parameter may be determined using any suitable hardware technique, software technique, or combination thereof. **In some embodiments, processing equipment remote to the system may be used to determine physiological parameters.** The system may display the determined physiological parameter using a local display (e.g., display 320 of FIG. 3 or display 328 of FIG. 3), display them on a remote display, publish the data to a server or website, make the parameters available to a user by any other suitable technique, or any combination thereof.” EX1027, 20:49–60.

148. Lisogurski therefore teaches that its **detectors** receive “**light that is reflected by or has traveled through the subject’s tissue.**” EX1027, 17:39–42. Lisogurski further teaches that the detector(s) “convert[s] the intensity of the received light into an electrical signal.” EX1027, 11:14–16. Lisogurski’s detectors are connected via “**front end processing circuitry,**” which may “**receive** a detection signal from **detector 140** and provide one or more processed signals to back end processing signal 170.” EX1027, 12:42–45.

149. A POSITA would have understood the **detector** and the **front end processing circuitry** in Lisogurski to comprise the “detection system” that is configured to perform the functions described below. *Infra* § VIII.C.1.e.ii-iii (cl. 7(d)(ii-iii)). Nevertheless, because the **front end processing circuitry** in Lisogurski is depicted in monitor 104 (which, as shown below, is depicted as a separate device from the **detector** in the wearable sensor), it is further my opinion that if Lisogurski does not expressly teach a detection “system” comprising detector(s) and processing circuitry, this limitation would have been an obvious modification to Lisogurski. Specifically, a POSITA would have considered it obvious to integrate **the front end processing circuitry** (150) and **detector (140)** in the same device in the manner shown below. This is particularly evident in light of Lisogurski’s teachings that the detector may “preprocess[]” the electrical signal before sending it to the monitor and that the sensor may be a separate device wirelessly connected to the monitor.

EX1027, 11:20–25, 17:55–59 (“Sensor unit 312 may be powered by an internal power source, e.g., a battery (not shown).... [T]he sensor may be wirelessly connected to monitor 314 (not shown).”), 18:23–25 (“In some embodiments, a wireless transmission device (not shown) or the like may be used instead of or in addition to cable 324); *see also id.*, 17:32–35. Further, a POSITA would have considered this modification obvious in view of existing wearable sensors (e.g., Nonin Onyx 9500 finger clip sensors) that had this functionality and existed prior to the purported priority date of the ’790 patent.



EX1027, Fig. 1 (annotated).

150. A POSITA would have considered it obvious and routine to integrate **front end processing circuitry 150** into the **detector** and would have been motivated to make such a modification. It is my opinion that a POSITA would have understood the functional relationship between the detector and the monitor; specifically, the signal received by the detector would preferably need to be converted from analog to digital form in order to be wirelessly transmitted to the monitor. A POSITA would have understood, and indeed, Lisogurski teaches, that the front end processing circuitry in Lisogurski can perform analog-to-digital conversion and other initial signal processing. *See* EX1027, 12:42–50 (**Front end processing circuitry 150** may perform various analog and digital processing of the detector signal.”).

151. Thus, in order to satisfy Lisogurski’s disclosed embodiment of wirelessly connecting the monitor to the detector, a POSITA would have understood that the analog-to-digital conversion processing circuitry would need to be integrated into the sensor where the signal is initially captured/received by the detection system. A POSITA would have understood that adding this additional necessary circuitry in the sensor would not affect the device’s operation, because such circuitry is small and power efficient, and would have been straightforward to integrate into the wearable sensor. Furthermore, a POSITA would have understood this variation to be consistent with Lisogurski’s disclosure that “[i]n some embodiments the

functionality of some of the components may be combined in a single component... [or] the functionality of some of the components of monitor 104... may be divided over multiple components.” EX1027, 16:2–9. A POSITA would have been motivated to make this routine adjustment to Lisogurski’s optical sensor based on the market trends toward miniaturized, power-efficient electronics used for health and fitness applications that I discussed above (*supra* § V.B), rather than implementing Lisogurski with a wired connection between sensor and monitor.

152. Thus, in my opinion, a POSITA would have understood the “**detector**” and the “**front end processing circuitry**” taught by Lisogurski to be a “detection system” **configured to receive light at least a portion of the lens output light reflected from the tissue**, and further configured to perform particular functions, described further below. *Infra* § VIII.C.1e (7(d)(ii-iii)).

153. Lisogurski further teaches that the **detector** “convert[s] the intensity of the received light into an **electrical signal**,” which a POSITA would have understood to mean “generat[ing] an output signal.” EX1027, 11:6–27. As discussed, Lisogurski’s detectors are connected via “front-end processing circuitry,” which may “receive a **detection signal** from **detector 140** and provide one or more processed signals to back end processing signal 170.” EX1027, 12:42–45. “After converting the received light to an **electrical signal**,” Lisogurski’s detectors may send the “**detection signal** to monitor 104,” and “and physiological parameters may be

determined” by monitor 104 based on the received signal (“output signal”) from the detector(s). EX1027, 11:20–27.

154. I note that the Board found in the ’533 IPR that Lisogurski discloses a “receiver,” which is materially identical to a detection system; that the receiver was configured to “generate[] an output signal,” and that Lisogurski further teaches a monitor that receives the output signal, which refers to physiological signals from the detector that have been obtained non-invasively from a sample. EX1008, 7–8, 38–39. I understand this decision has been affirmed by the Federal Circuit. EX1009. I understand similar determinations were made by the Board in the ’484 IPR regarding a materially identical limitation to 1[c][i] (“a detection system configured to receive at least a portion of the lens output light reflected from the tissue”) and that Omni did not cross-appeal those decisions, which were therefore affirmed by the Federal Circuit. EX1011, 23–25, 26–27; EX1012, n.2.

155. Accordingly, Lisogurski teaches or renders obvious a “detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal.”

(ii) “[A]n output signal having a signal-to-noise ratio.”

156. It is further my opinion that Lisogurski teaches or renders obvious that the **detection system** is “**configured to generate an output signal having a signal-to-noise ratio.**” First, all signals measured via an optical system have noise and

thus, by definition, have a signal-to-noise ratio. Second, Lisogurski describes multiple aspects of a detection system that generates an output signal having a signal-to-noise ratio:

- “**Detector 140** may be chosen to be specifically sensitive to the chosen targeted energy spectrum of light source 130. In some embodiments, **detector 140** may be configured to detect the intensity of light at the Red and IR wavelengths. In some embodiments, an array of sensors may be used and each sensor in the array may be configured to detect an intensity of a single wavelength. In operation, light may enter **detector 140** after passing through the subject's tissue. **Detector 140 may convert the intensity of the received light into an electrical signal.** The light intensity may be directly related to the absorbance and/or reflectance of light in the tissue. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by detector 140. **After converting the received light to an electrical signal, detector 140** may send the **detection signal** to monitor 104, where the **detection signal** may be processed and physiological parameters may be determined (e.g., based on the absorption of the Red and IR wavelengths in the subject's tissue). In some

embodiments, the **detection signal** may be preprocessed by sensor 102 before being transmitted to monitor 104.” EX1027, 11:6–27.

- “Referring back to FIG. 1, front end processing circuitry 150 may receive a **detection signal** from **detector 140** and provide one or more processed signals to back end processing circuitry 170. **The term “detection signal,” as used herein, may refer to any of the signals generated within front end processing circuitry 150 as it processes the output signal of detector 140. Front end processing circuitry 150 may perform various analog and digital processing of the detector signal. One suitable detector signal that may be received by front end processing circuitry 150 is shown in FIG. 2B.**” EX1027, 12:42–51.
- “**FIG. 2B shows an illustrative plot of detector signal 214** that may be generated by a sensor in accordance with some embodiments of the present disclosure. The peaks of detector current waveform 214 may represent current signals provided by a detector, such as **detector 140** of FIG. 1, when light is being emitted from a light source. The amplitude of detector current waveform 214 may be proportional to the light incident upon the detector. The peaks of detector current waveform 214 may be synchronous with light “on” periods driving one or more emitters of a light source, such as light source 130 of FIG. 1. For example, detector current waveform 214

may be generated in response to a light source being driven by the light drive signal of FIG. 2A. The valleys of detector current waveform 214 may be synchronous with periods of time during which no light is being emitted by the light source. While no light is being emitted by a light source during the valleys, detector current waveform 214 may not fall all of the way to zero. Rather, dark current 222 may be present in the detector waveform. Since dark current 222 may interfere with accurate determinations of physiological characteristics, dark current 222 may be removed as discussed in more detail below.” EX1027, 12:52–13:6.

- “When the analog gain is reduced, the portion of the signal corresponding to the light source may map to a smaller number of analog-to-digital conversion bits. Thus, more ambient light noise in the input of analog-to-digital converter 154 may result[] in fewer bits of resolution for the portion of the signal from the light source. This may have a detrimental effect on the **signal-to-noise ratio of the detection signal**. Accordingly, passive or active filtering or signal modification techniques may be employed to reduce the effect of ambient light on the detection signal that is applied to analog-to-digital converter 154, and thereby reduce the contribution of the noise component to the converted digital signal” EX1027, 14:44–55.

- **“In step 410, the system may determine a physiological parameter using information from the attenuated photonic signals. The physiological parameter may be determined using any suitable hardware technique, software technique, or combination thereof. In some embodiments, processing equipment remote to the system may be used to determine physiological parameters. The system may display the determined physiological parameter using a local display (e.g., display 320 of FIG. 3 or display 328 of FIG. 3), display them on a remote display, publish the data to a server or website, make the parameters available to a user by any other suitable technique, or any combination thereof.”**

EX1027, 20:49–53.

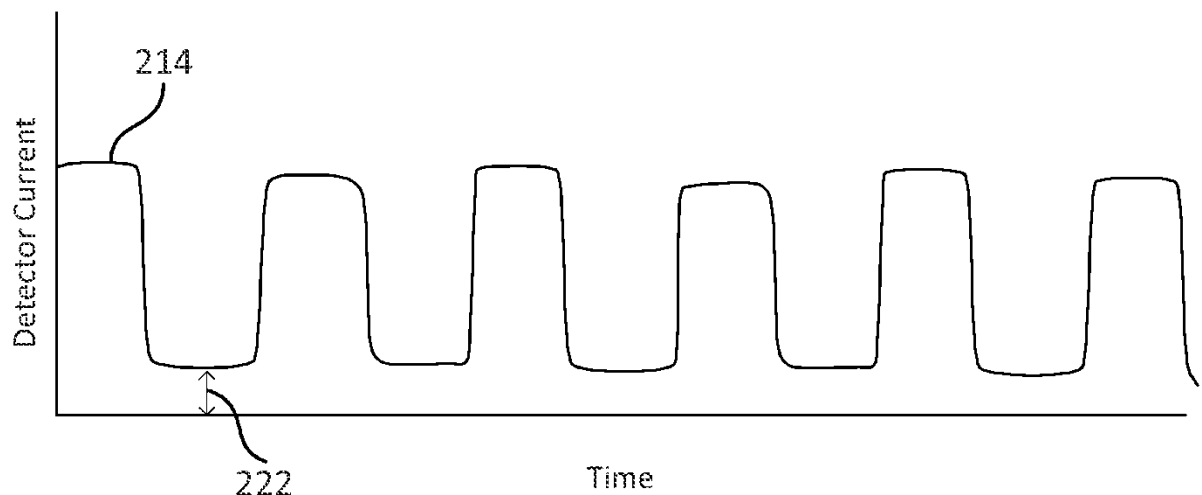


FIG. 2B

EX1027, Fig. 2B; *see also id.*, 2:17–19 (“FIG. 2B shows an illustrative plot of a detector signal that may be generated by a sensor in accordance with some embodiments of the present disclosure.”).

157. As discussed above, Lisogurski therefore teaches that its detection system receives “light that is reflected by or has traveled through the subject’s tissue,” (EX1027, 17:39–42). *Supra* § VIII.C.1.d.i. Lisogurski further teaches that the **detector** “convert[s] the intensity of the received light into an **electrical signal**,” which a POSITA would have understood to mean “generat[ing] an output signal.” EX1027, 11:6–27. As discussed above, Lisogurski’s detectors are connected via “front-end processing circuitry,” which may “receive a **detection signal** from **detector 140** and provide one or more processed signals to back end processing signal 170.” EX1027, 12:42–45. “After converting the received light to an **electrical signal**,” Lisogurski’s detectors may send the “**detection signal** to monitor 104,” and “physiological parameters may be determined” by monitor 104 based on the received signal (“output signal”) from the detector(s). EX1027, 11:20–27. Lisogurski further teaches that its **detection signal** has a “**signal-to-noise ratio**” that can be impacted by varying light parameters. EX1027, 14:40–55 (“the signal-to-noise ratio *of* the detection signal”); 9:46–52 (noting the detected signal may include “background noise” and that the light drive parameters of the LEDs may be modified to “improve the signal-to-noise ratio”).

158. Lisogurski's system can modulate the LEDs and "vary light drive signal parameters" of the LEDs in response to a "trigger" caused by various conditions, e.g., interference or noise. EX1027, 1:10–25, 1:67–2:3; *see also id.*, 1:60–61, 8:4–8, 8:27–35, 16:24–32. For example, the measurement system can control the "light intensity, duty cycle, light source firing rate, any other suitable parameter, or any combination thereof" of the LEDs. EX1027, 1:60–61, 1:67–2:3, 1:10–25, 5:48–54, 25:46–65 ("The system may vary parameters related to the light drive signal including drive current or light brightness, duty cycle, firing rate, modulation parameters, other suitable parameters, or any combination thereof"). Lisogurski explains that varying these drive cycle parameters can increase the signal-to-noise ratio (SNR) of the measurement device: "The system may receive, for example, an increased level of background noise in the signal due to patient motion. The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio." EX1027, 9:46–60. Varying the brightness (intensity) of the light sources may be accomplished using "[l]ight drive circuitry 120," which is "configured to generate a light drive signal that is provided to light source 130" in order to "control the intensity of light source 130 and the timing of when light source 130 is turned on and off." EX1027, 11:50–60. Thus, Lisogurski expressly teaches the light source is configured to increase the signal-to-noise ratio by increasing a light intensity (brightness) of at least one of the LEDs (the semiconductor sources).

EX1027, 11:38-54 (signal modulation techniques are controlled by control and light drive circuitry, which generate a light drive signal for activating and controlling the sensors of the light source(s)), Fig. 2B.

159. A POSITA would have understood that “light intensity” corresponds to the brightness of the emitted light, “firing rate” corresponds to the frequency of the emitted light, and “duty cycle” corresponds to the pulse width of the emitted light (i.e., the duration of each pulse of light from the LED). Thus, a POSITA would have understood that Lisogurski teaches varying the intensity (or brightness) of the semiconductor sources, which would necessarily include increasing light intensity from an initial light intensity. E.g., EX1027, 9:50–52 (“The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio.”), 1:44–47, 11:38–41, 11:50–54.

160. I note that the Board found in the ’533 IPR that Lisogurski discloses a receiver configured to “generate[] an output signal” and that Lisogurski further teaches a monitor that receives the output signal, which refers to physiological signals from the detector that have been obtained non-invasively from a sample. EX1008, 7, 37–39, 41. I understand this decision has been affirmed by the Federal Circuit. EX1009. I understand similar determinations were made by the Board in the ’484 IPR (specifically, finding that Lisogurski teaches a materially identical limitation requiring “a detection system configured to generate an output signal

having a signal-to-noise ratio”) and that Omni did not cross-appeal those decisions, which were therefore affirmed by the Federal Circuit. EX1011, 5, 23–25, 26–27; EX1012, n.2.

(iii) “Wherein the detection system is configured to be synchronized to the light source.”

161. Lisogurski teaches “wherein the detection system is configured to be synchronized to the light source.” As discussed above, Lisogurski teaches light drive circuitry that together with control circuitry controls the light drive parameters of the light source. As I discussed above, Lisogurski further teaches that the detector(s) are coupled to “front end processing circuitry” in the monitor that receives the “detection signal from detector 140 and provide[s] one or more processed signals to back end processing circuitry 170.” EX1027, 12:42–45 As I discussed above, a POSITA would have found it obvious to integrate the front end processing circuitry into the detector such that they comprise one “detection system.”

162. Lisogurski further teaches that the front end processing circuitry is synchronized with the light drive circuitry that I discussed above (specifically, the light drive circuitry that controls the modulation of certain parameters of the LEDs). EX1027, 11:33–49 (“**front end processing circuitry 150 may... operate synchronously with light drive circuitry 120.** For example, front end processing circuitry 150 may **synchronize** the operation of an analog-to-digital converter and a demultiplexer with the light drive signal based on the timing control signals.”). To

the extent the claims require the light drive circuitry to be integrated into Lisogurski's sensor (similar to the front end processing circuitry), this would have been an obvious modification for a POSITA to make to Lisogurski for the reasons discussed *infra* § 181.

163. Lisogurski also teaches embodiments in which “sampling rate modulation may be correlated with light drive signal modulation.” EX1027, 33:47-49, *id.*, 2:1-2, 27:44-52 (LED firing rating modulated). A POSITA would understand that in these embodiments the firing rate of an LED is correlated to the sampling rate of an analog-to-digital converter. Lisogurski further explains that “the system may employ any suitable sampling rate and any suitable sampling rate modulation.” EX1027, 36:6–22. As an example, Lisogurski explains: “at a low sampling rate, the system may sample once per ‘on’ period, while at a high sampling rate the system may take several samples per ‘on’ period and average them. In some embodiments, averaging multiple samples for the same ‘on’ period may include oversampling techniques.” EX1027, 35:17-19. Thus, Lisogurski discloses an embodiment in which the measurements taken by the receiver have a one-to-one correlation, with one sample taken per period, as well as an embodiment where multiple samples are taken per period and averaged. A POSITA would have understood that, in the one-to-one embodiment, the LED light sources and the receiver are synchronized. Lisogurski's disclosure of the timed synchronization of the operation of the LED

light sources and the detection system is consistent with the specification of the '790 Patent, which discloses an embodiment in which “the light source may be modulated, and then the detection system would be synchronized with the light source.” EX1001, 58:30-32.

164. Thus, a POSITA would have understood that the detection system in Lisogurski is “synchronized” to the light source in Lisogurski.

165. I note that the Board found in the '533 IPR that Lisogurski, or Lisogurski in view of Carlson, teaches a limitation requiring “wherein the wearable measurement device receiver is configured to be synchronized to the light source.” EX1008, 37–39, 41. I understand this decision has been affirmed by the Federal Circuit. EX1009. I understand similar determinations (specifically, that Lisogurski teaches a materially identical limitation to claim 1[c](iii)—“wherein the detection system is configured to be synchronized to the light source”) were made by the Board in the '484 IPR and that Omni did not cross-appeal those decisions, which were therefore affirmed by the Federal Circuit. EX1011, 5, 24–27; EX1012, n.2.

166. Accordingly, Lisogurski teaches claim 7[d]. As previewed above, I note that the Board previously determined in the '533 and '484 Apple IPRs that Lisogurski, alone or in view of Carlson, discloses materially identical limitations to claim 7[d], and the Federal Circuit affirmed these findings. Specifically, the Board found that Lisogurski teaches “the wearable measurement device further comprising

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source.” EX1008, 7-8, 37-39, *aff’d*, EX1009; EX1011, 5-6, 23-24, 26-27 (finding Lisogurski teaches or renders obvious a limitation identical to 7[d]), *aff’d in relevant part*, EX1012, n.2

- f. **7[e]: “wherein the detection system comprises a plurality of detectors that are spatially separated from each other, and wherein at least one analog to digital converter is coupled to at least one of the plurality of detectors;”**

167. In my opinion, Lisogurski teaches limitation 7[e].

- (i) **“Wherein the detection system comprises a plurality of detectors that are spatially separated from each other.”**

168. Lisogurski teaches that its sensor, which includes the detection system, “may include **multiple** light sources and **detectors, which may be spaced apart.**” EX1027, 17:43–45. A POSITA would understand this to disclose “a plurality of detectors that are spatially separated from each other.”

- (ii) **“[W]herein at least one analog to digital converter is coupled to at least one of the plurality of detectors.”**

169. As discussed above, *supra* § VIII.C.1.e (cl. 7(d)), Lisogurski further teaches that the electrical signals generated by the detectors are received by the front-end processing circuitry and passed between components of the circuitry:

- “Referring back to FIG. 1, **front end processing circuitry 150**, which may receive a **detection signal**, such as detector current waveform 214, may include analog conditioner 152, **analog-to-digital converter 154**, demultiplexer 156, digital conditioner 158, decimator/interpolator 160, and dark subtractor 162. Analog conditioner 152 may perform any suitable analog conditioning of the **detection signal**. The conditioning performed may include any type of filtering (e.g., low pass, high pass, band pass, notch, or any other suitable filtering), amplifying, performing an operation on the received signal (e.g., taking a derivative, averaging), performing any other suitable signal conditioning (e.g., converting a current signal to a voltage signal), or any combination thereof. **The conditioned analog signal may be processed by analog-to-digital converter 154**, which may convert the conditioned analog signal into a digital signal. **Analog-to-digital converter 154** may operate under the control of control circuitry 110. **Analog-to-digital converter 154** may use timing control signals from control circuitry 110 to determine when to sample the analog signal. **Analog-to-digital converter 154** may be any suitable type of **analog-to-digital converter** of sufficient resolution to enable a physiological monitor to accurately determine physiological parameters.

Demultiplexer 156 may operate on the analog or digital form of the detector signal to separate out different components of the signal. For example, detector current waveform 214 of FIG. 2B includes a Red component, an IR component, and at least one dark component. Demultiplexer 156 may operate on detector current waveform 214 of FIG. 2B to generate a Red signal, an IR signal, a first dark signal (e.g., corresponding to the dark component that occurs immediately after the Red component), and a second dark signal (e.g., corresponding to the dark component that occurs immediately after the IR component). Demultiplexer 156 may operate under the control of control circuitry 110. For example, demultiplexer 156 may use timing control signals from control circuitry 110 to identify and separate out the different components of the detector signal.

Digital conditioner 158 may perform any suitable digital conditioning of the detector signal. The digital conditioner may include any type of digital filtering of the signal (e.g., low pass, high pass, band pass, notch, or any other suitable filtering), amplifying, performing an operation on the signal, performing any other suitable digital conditioning, or any combination thereof.

Decimator/interpolator 160 may decrease the number of samples in the digital detector signal. For example, decimator/interpolator 160 may decrease the

number of samples by removing samples from the detector signal or replacing samples with a smaller number of samples. The decimation or interpolation operation may include or be followed by filtering to smooth the output signal.”

EX1027, 13:6–59.

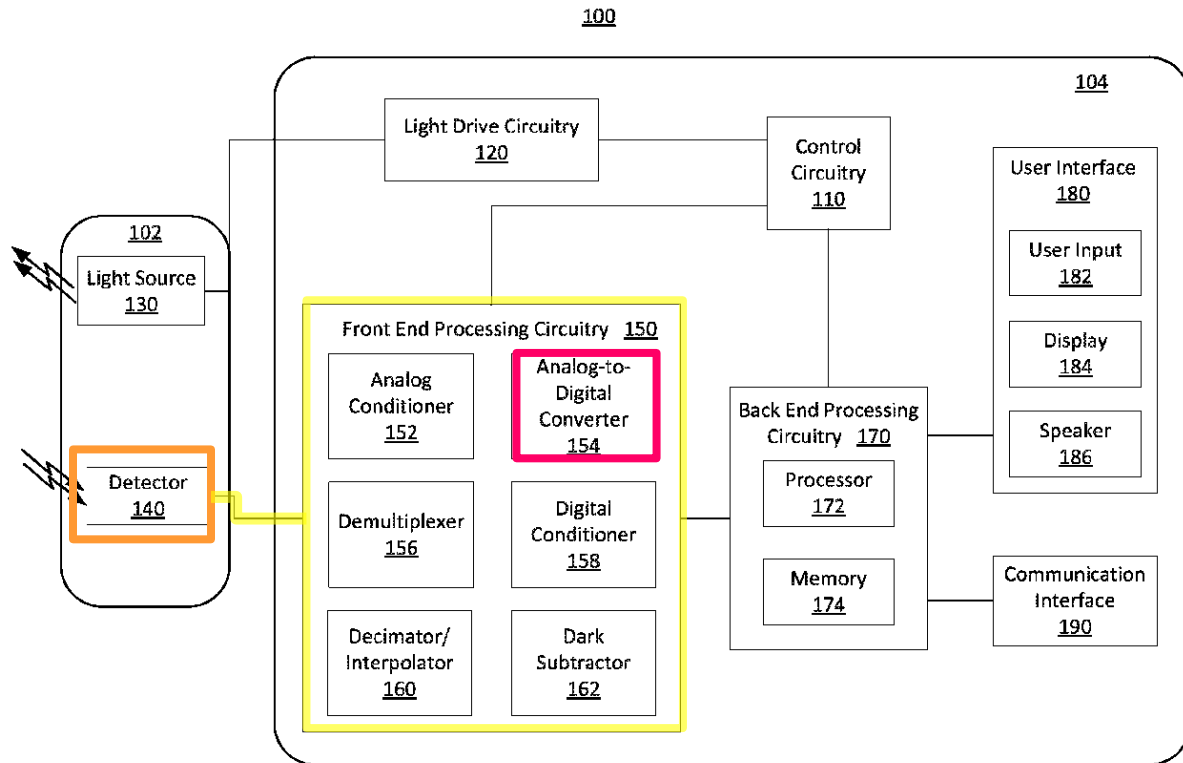


FIG. 1

EX1027, Fig. 1 (annotated).

170. Thus, a POSITA would have understood that Lisogurski teaches an analog to digital converter that is coupled to at least one of the spatially separated detectors, as shown above in yellow in annotated Figure 1. Indeed, Lisogurski expressly teaches that the front end processing circuitry that includes the analog to digital convertor may be coupled to the detector. EX1027, 11:28–32 (“[M]onitor

104 includes control circuitry 110, light drive circuitry 120, **front end processing circuitry 150**, back end processing circuitry 170, user interface 180, and communication interface 190. Monitor 104 [which includes the front end processing circuitry 150 and the analog to digital converter 154] **may be communicatively coupled to sensor 102**”); 18:16–31 (“In some embodiments, sensor unit 312 may be communicatively **coupled** to monitor 314” via wired or wireless transmission). Further, as I explained above, it would have been obvious to a POSITA to integrate the front end processing circuitry into sensor unit 102. *Supra* § VIII.C.1.e.i.

171. Accordingly, Lisogurski teaches claim 7[e]. I also understand that, in the prior ’484 Apple IPR, the Board determined that Lisogurski discloses a materially identical limitation to claim 7[e], and the Federal Circuit affirmed these findings. Specifically, the Board found that Lisogurski teaches or renders obvious “wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital convertor is coupled to at least one of the spatially separated detectors.” EX1011, 5-6, 25-27, *aff’d in relevant part*, EX1012, n.2.

g. 7[f]: “wherein the output signal is indicative of the one or more of the physiological parameters;”

172. In my opinion, Lisogurski teaches 7[f]. As I discussed previously, Lisogurski teaches an output signal and further teaches a system for measuring one or more physiological parameters. *Supra* §§ VIII.C.1.b, VIII.C.1.d. (cl. 7[a], 7[c]).

Lisogurski explains that its system “may be configured to determine pulse rate, blood pressure, blood oxygen saturation (e.g., arterial, venous, or both), hemoglobin concentration (e.g., oxygenated, deoxygenated, and/or total), any other suitable physiological parameters, or any combination thereof.” EX1027, 17:59–67, 4:6-62 (measuring “various blood flow characteristics including, but not limited to, the oxygen saturation of hemoglobin in arterial blood ...” and “a patient’s pulse rate and blood pressure”), 12:9:16, 14:60-64. A POSITA would have understood that the measurement values for these physiological parameters and blood flow characteristics would be based on data collected by the detector(s).

173. Lisogurski further teaches:

- Detector 140 may be chosen to be specifically sensitive to the chosen targeted energy spectrum of light source 130. In some embodiments, detector 140 may be configured to detect the intensity of light at the Red and IR wavelengths. In some embodiments, an array of sensors may be used and each sensor in the array may be configured to detect an intensity of a single wavelength. In operation, light may enter detector 140 after passing through the subject's tissue. Detector 140 may convert the intensity of the received light into an electrical signal. The light intensity may be directly related to the absorbance and/or reflectance of light in the tissue. That is, when more light at a certain wavelength is absorbed or

reflected, less light of that wavelength is received from the tissue by detector 140. After converting the received light to an electrical signal, detector 140 may send the detection signal to monitor 104, where the detection signal may be processed and physiological parameters may be determined (e.g., based on the absorption of the Red and IR wavelengths in the subject's tissue). In some embodiments, the detection signal may be preprocessed by sensor 102 before being transmitted to monitor 104.” EX1027, 11:6–27.

- “Referring back to FIG. 1, front end processing circuitry 150 may receive a detection signal from detector 140 and provide one or more processed signals to back end processing circuitry 170. The term “detection signal,” as used herein, may refer to any of the signals generated within front end processing circuitry 150 as it processes the output signal of detector 140. Front end processing circuitry 150 may perform various analog and digital processing of the detector signal. One suitable detector signal that may be received by front end processing circuitry 150 is shown in FIG. 2B.” EX1027, 12:42–51.
- “One or more detector 318 may be provided in sensor unit 312 for detecting the light that is reflected by or has traveled through the subject’s tissue.” EX1027, 17:39–42

- “In step 410, the system may determine a physiological parameter using information from the attenuated photonic signals. The physiological parameter may be determined using any suitable hardware technique, software technique, or combination thereof. In some embodiments, processing equipment remote to the system may be used to determine physiological parameters. The system may display the determined physiological parameter using a local display (e.g., display 320 of FIG. 3 or display 328 of FIG. 3), display them on a remote display, publish the data to a server or website, make the parameters available to a user by any other suitable technique, or any combination thereof.” EX1027, 20:49–60.

174. Lisogurski therefore teaches that its detectors generate an output signal using “light that is reflected by or has traveled through the subject’s tissue,” (EX1027, 17:39–42), *i.e.*, indicative of physiological parameters. Indeed, as mentioned, Lisogurski further teaches that the detector “convert[s] the intensity of the received light into an electrical signal,” which a POSITA would have understood to mean “generat[ing] an output signal.” *Supra* § VIII.C.1.e.i-ii (cl. 7(d)(i-ii)); EX1027, 11:6–27. As discussed, Lisogurski’s detectors are connected via “front end processing circuitry,” which may “receive a detection signal from detector 140 and provide one or more processed signals to back end processing signal 170.” EX1027, 12:42–45. “After converting the received light to an electrical signal,” Lisogurski’s

detectors may send the “detection signal to monitor 104,” and monitor 140 can “determine[] **physiological parameters**” based on the received signal (“output signal”) from the detector(s). EX1027, 11:20–27, 20:49–53.

175. As noted above, Lisogurski teaches that the “determined physiological parameter,” which corresponds to the processed output signal, may be “display[ed] [] on a remote display,” or published to “a server or website.” EX1027, 20:49–60. The output signal may also be transmitted wirelessly via techniques or methods such as “WiFi, IR, WiMax, BLUETOOTH, UWB, or other standards.” EX1027, 15:43–65. For example, Lisogurski explains that its system may include a multi-parameter physical monitor 326 (MPPM), which is capable of receiving the output signal via wireless communication. EX1027, 18:58–67. The MPPM “may be configured to calculate physiological parameters,” including through statistical and “historical analysis” of, e.g., prior cardiac cycles, pulse cycles, and/or respiration rate. EX1027, 26:55-06, 18:49-53, 20:8-9, 19:1-19.

176. Accordingly, Lisogurski teaches or renders obvious claim 7[f]. I also understand that that the Board found in the ’533 IPR that Lisogurski discloses limitations materially identical to 7[f]. EX1008, 7, 37–39, 41. I understand this decision has been affirmed by the Federal Circuit. EX1009. I understand similar determinations were made by the Board in the ’484 IPR and that Omni did not cross-

appeal those decisions, which were therefore affirmed by the Federal Circuit.
EX1011, 26–27; EX1012, n.2.

- h. 7[g]: “the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor diodes from an initial light intensity; and;”

177. Lisogurski, alone or in view of Carlson, teaches or renders obvious claim 7[g].

178. Lisogurski teaches that the certain drive parameters of the LEDs (semiconductor diodes) in its wearable device may be varied by the measurement system using a “cardiac cycle modulation technique” in response to a number of factors, including “the level of noise, ambient light, other suitable reasons.” EX1027, 9:46–52. Specifically, Lisogurski teaches that the “[p]arameters [of the semiconductor sources] that may be varied include **light intensity**, firing rate, duty cycle, other suitable parameters, or any combination thereof.” EX1027, 1:19–21. A POSITA would have understood that “**light intensity**” corresponds to the brightness of the emitted light, “firing rate” corresponds to the frequency of the emitted light, and “duty cycle” corresponds to the pulse width of the emitted light (*i.e.*, the duration of each pulse of light from the LED). Thus, a POSITA would have understood that Lisogurski teaches varying the intensity (or brightness) of the semiconductor sources, which would include increasing light intensity from an initial light intensity. *E.g.*, EX1027, 9:50–52 (“The system may **increase the brightness of the light**

sources in response to the noise to improve the signal-to-noise ratio.”), 1:44–47, 11:38–41, 11:50–54.

179. Lisogurski further teaches that altering the parameters of the semiconductor sources improves the signal-to-noise ratio, for example:

- “In some embodiments, conventional servo algorithms may be used in addition to any combination of cardiac cycle modulation and drive cycle modulation. Conventional servo algorithms may adjust the light drive signals due to, for example, ambient light changes, emitter and detector spacing changes, sensor positioning, other suitable parameters, or any combination thereof. Generally, conventional servo algorithms vary parameters at a slower rate than cardiac cycle modulation. **For example, a conventional servo algorithm may adjust drive signal brightness due to ambient light every several seconds.** The system may use conventional servo algorithms in part to keep received signal levels within the range of an analog to digital converter’s dynamic range. For example, a signal with amplitudes that are large may saturate an analog to digital convertor. In response to a signal with high amplitudes, the system may reduce emitter brightness. In a further example, **the quality of a low amplitude signal may be degraded by quantization noise by an analog**

to digital converter. In response, the system may increase the emitter brightness.” EX1027, 5:55–6:6.

- “In some embodiments, the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons, or any combination thereof. The system may receive, for example, an increased level of background noise in the signal due to patient motion. **The system may increase the brightness [*i.e.*, intensity] of the light sources [from an initial intensity] in response to the noise to improve the signal-to-noise ratio.** In some embodiments, the system may increase brightness throughout the cardiac cycle because the system may require increased signal amplitudes to differentiate between fiducial and other points of interest related to physiological parameters and those related to noise or motion. In some embodiments, the system may change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light.” EX1027, 9:46–60.
- “However, if the contribution of ambient light is large relative to the contribution of light from a light source, the total analog gain applied to the detection current may need to be reduced to avoid saturating analog-to-digital converter 154. When the analog gain is reduced, the portion of the signal corresponding to the light source may map to a smaller number

of analog-to-digital conversion bits. **Thus, more ambient light noise in the input of analog-to-digital converter 154 may result[] in fewer bits of resolution for the portion of the signal from the light source. This may have a detrimental effect on the signal-to-noise ratio of the detection signal. Accordingly, passive or active filtering or signal modification techniques may be employed to reduce the effect of ambient light on the detection signal that is applied to analog-to-digital converter 154, and thereby reduce the contribution of the noise component to the converted digital signal.”** EX1027, 14:40–55.

- “It will be understood that the output rate may not be a constant rate. It will also be understood **that sampling rate is one of the components that may be modulated in cardiac cycle modulation as described above.** It will also be understood that the earlier described embodiments relating to varying light output may also apply to sampling rate.” EX1027, 35:4–9.

180. In particular, as noted above, Lisogurski teaches, “the system may receive, for example, an increased level of background noise in the signal due to patient motion. **The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio.”** EX1027, 9:46–60. Varying the brightness (intensity) of the light sources may be accomplished using “[l]ight drive circuitry 120,” which is “configured to generate a light drive signal

that is provided to light source 130” in order to “**control the intensity of light source 130** and the timing of when light source 130 is turned on and off.” EX1027, 11:50–60; *see also id.*, 1:44–48 (“The system may generate a light drive signal for activating a light source to emit a photonic signal, wherein at least one parameter of the light drive signal is configured to vary substantially synchronously with physiological pulses of the subject.”); *id.*, 11:38–41 (“For example, **light drive circuitry 120** may generate a light drive signal, which may be used to turn on and off the **light source 130**, based on the timing control signals. The front end processing circuitry 150 may use the timing control signals to operate synchronously with light drive circuitry 120”).

181. Furthermore, to the extent required by the claims for the light drive circuitry to be in the same unit as the light source, a POSITA would have understood that the **light drive circuitry 120** and **control circuitry 110** (which together with the front end processing circuitry 150 control the parameters of the **light source 130**) could be integrated from the monitor 104 directly into the sensor unit 102 in the manner depicted below. Modifying Lisogurski in this manner would have been a routine design modification that would not have affected Lisogurski’s operation, because the circuitry is small and power-efficient, so a POSITA would have had a reasonable expectation of success. Furthermore, this modification is consistent with industry trends to miniaturize electronics (and mimics the design of existing sensors

in 2012) and consistent with the express recognition in Lisogurski that “the functionality of some of the components may be combined in a single component... [or] the functionality of some of the components of monitor 104... may be divided over multiple components,” so a POSITA would have been modified to make this modification. EX1027, 16:2–9. I understand the Board previously held that Lisogurski could be modified in the manner I describe and that the Federal Circuit affirmed. EX1008, 22–23; EX1009; EX1011, 24–25; EX1012 n.2. Thus, Lisogurski expressly teaches the light source is configured to increase the signal-to-noise ratio by increasing a light intensity (brightness) of at least one of the LEDs (the semiconductor sources).

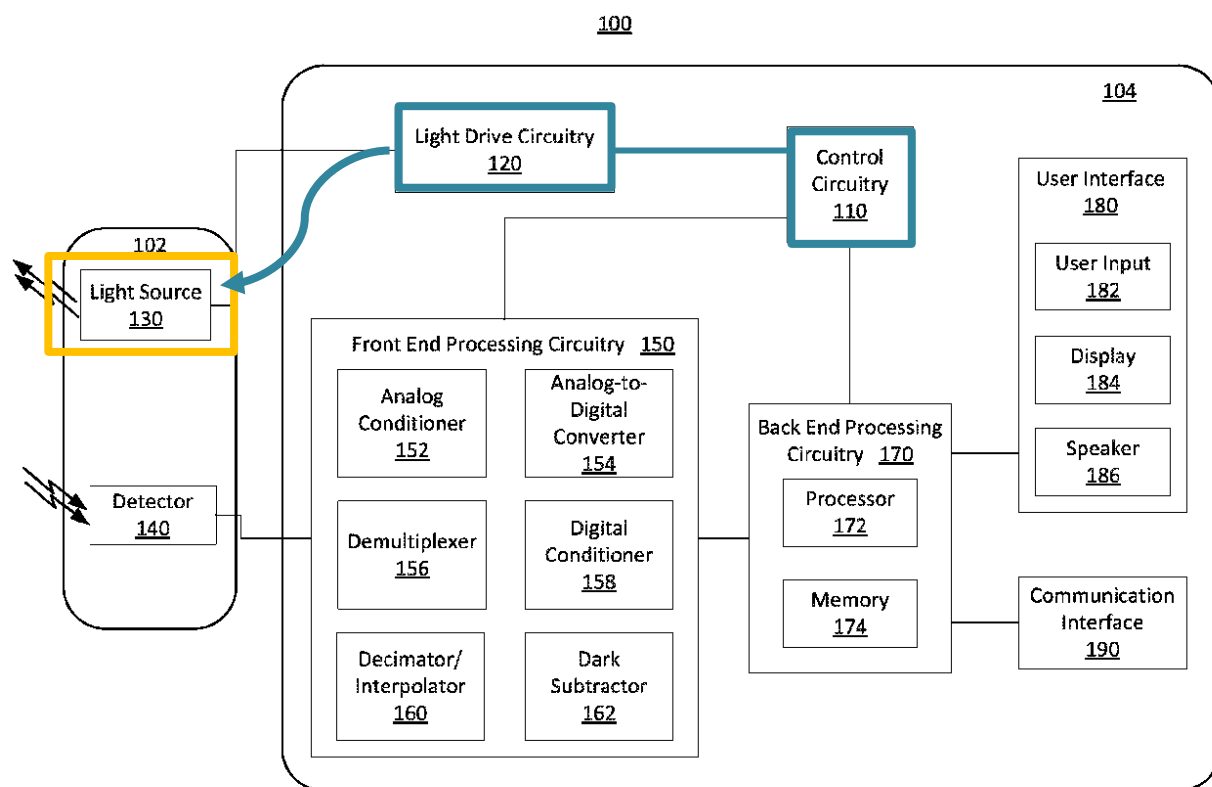


FIG. 1

EX1027, Fig. 1 (annotated).

182. Accordingly, Lisogurski teaches or renders obvious claim 7[g]. I note that the Board found in the '533 IPR that Lisogurski discloses a “light source including a plurality of LEDs” and “[t]he light source configured to increase the signal-to-noise ratio by increasing a light intensity.” EX1008, 25–26. I understand this decision has been affirmed by the Federal Circuit. EX1009. I further note that the Board found in the '484 IPR that Lisogurski teaches “the wearable device configured to increase the signal-to-noise ratio (1) by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity,” and that Omni did not cross-appeal as to those findings, such that they were affirmed by the Federal Circuit. EX1011, 5–6, 23, 26–27; EX1012, n.2.

i. 7[h]: “the detection system further configured to:”

183. As discussed above, in Section VIII.C.1.e, Lisogurski teaches or renders obvious a detection system. I explain how the detection system is configured to perform the claimed functions on a limitation-by-limitation bases below. *Infra* §§ VIII.B.1.j-l. I also understand that the Board previously found that Lisogurski discloses an identical limitation, and that this determination was affirmed by the Federal Circuit. *See* EX1011, 5-6, 43-44 (finding Lisogurski teaches or renders obvious a limitation identical to 7[h]), *aff’d in relevant part*, EX1012, n.2.

j. 7[i]: **“generate a first signal responsive to light received while the semiconductor diodes are off”**

184. Lisogurski teaches limitation 7[i].

185. Lisogurski teaches a dark subtraction technique to “remove ambient and background signals.” EX1027, 6:7–19. Specifically, Lisogurski teaches:

- “In some embodiments, a technique to remove ambient and background signals may be used in addition to or in place of a power saving light modulation scheme. In a drive cycle modulation technique, the system may cycle light output at a rate significantly greater than the cardiac cycle. For example, a drive cycle modulation cycle may include the system turning on a first light source, followed by a “dark” period, followed by a second light source, followed by a “dark” period. **The system may measure the ambient light detected by the detector during the “dark” period and then subtract this ambient contribution from the signals received during the first and second “on” periods.**” EX1027, 6:7–19.
- “Detector 140 may convert the intensity of the received light into an electrical signal.” EX1027, 11:14–16.
- “FIG. 2B shows an illustrative plot of detector signal 214 that may be generated by a sensor in accordance with some embodiments of the present disclosure. The peaks of detector current waveform 214 may represent current signals provided by a detector, such as detector 140 of FIG. 1, when

light is being emitted from a light source. The amplitude of detector current waveform 214 may be proportional to the light incident upon the detector. The peaks of detector current waveform 214 may be synchronous with light “on” periods driving one or more emitters of a light source, such as light source 130 of FIG. 1. For example, detector current waveform 214 may be generated in response to a light source being driven by the light drive signal of FIG. 2A. **The valleys of detector current waveform 214 may be synchronous with periods of time during which no light is being emitted by the light source. While no light is being emitted by a light source during the valleys, detector current waveform 214 may not fall all of the way to zero. Rather, dark current 222 may be present in the detector waveform. Since dark current 222 may interfere with accurate determinations of physiological characteristics, dark current 222 may be removed as discussed in more detail below.”** EX1027, 12:52–13:6.

- “Dark subtractor 162 may operate on the digital signal. In some embodiments, dark subtractor 162 may subtract dark values from the Red and IR components to generate adjusted Red and IR signals. **For example, dark subtractor 162 may determine a subtraction amount from the dark signal portion of the detection signal and subtract it from the**

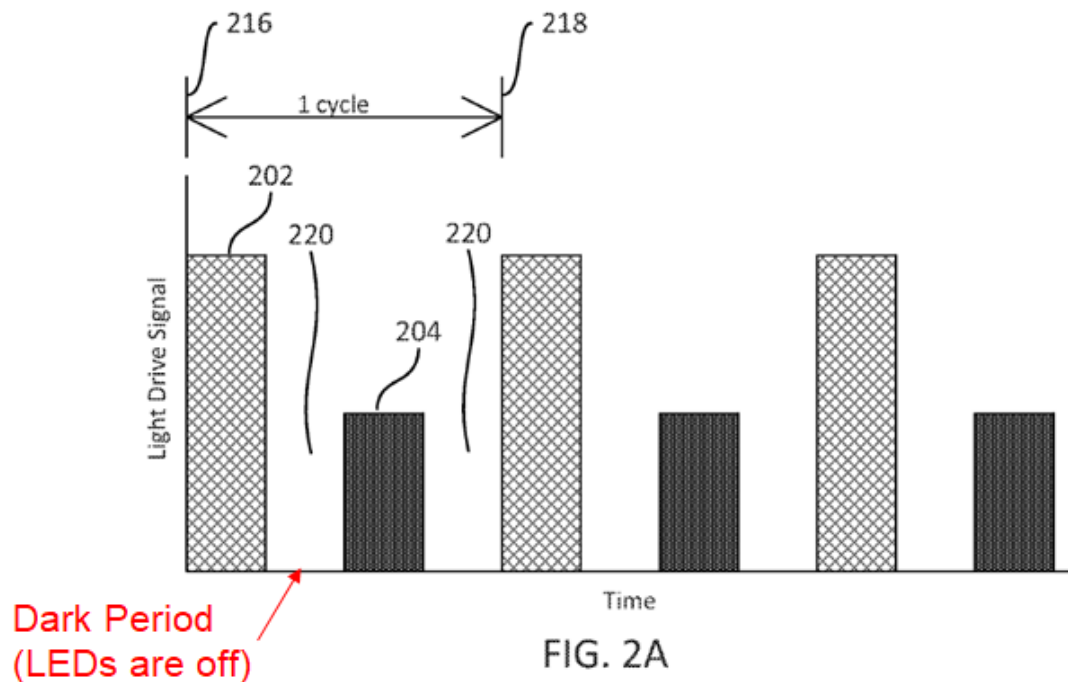
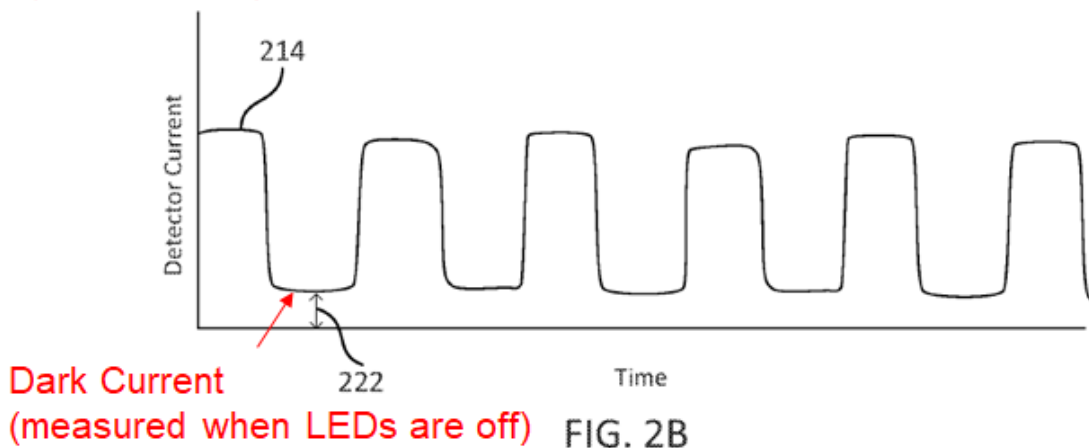
peak portion of the detection signal in order to reduce the effect of the dark signal on the peak. For example, in reference to FIG. 2A, a detection signal peak corresponding to red “on” period 202 may be adjusted by determining the amount of dark signal during the “off” period 220 preceding red “on” period 202. The dark signal amount determined in this manner may be subtracted from the detector peak corresponding to red “on” period 202. Alternatively, the “off” period 220 after red “on” period 202 may be used to correct red “on” period 202 rather than the “off” period 220 preceding it. Additionally, an average of the “off” periods 220 before and after red “on” period 202 may be used.” EX1027, 13:60–14:10.

- “Demultiplexer 156 may operate on detector current waveform 214 of Fig. 2B to generate a Red signal, an IR signal, **a first dark signal (e.g., corresponding to the dark component that occurs immediately after the Red component), and a second dark signal (e.g., corresponding to the dark component that occurs immediately after the IR component).**” EX1027, 13:35–41.
- “Region 256 of plot 250 indicates an interval of the timing diagram where both red light modulation 252 and IR light modulation 254 are in an “on” portion of the cardiac cycle modulation. Plot 270 shows an illustrative

portion of region 256, where the system is employing a cardiac cycle modulation in addition to the drive cycle modulation. Plot 250 may include a drive cycle modulation technique with a period of time interval 272. The time scale of plot 270 may be significantly shorter than the time scale of plot 250, such that time interval 272 is significantly shorter than time interval 260. For example, time interval 260 (i.e., the period of the cardiac cycle modulation) may be on the order of 1 second, while time interval 272 (i.e., the period of the drive cycle modulation) may be on the order of 1 ms. Time interval 272 may include a sequence of red “on” portion 274, a first “off” portion 276, IR “on” portion 278, and a second “off” portion 280. **The first “off” portion 276 and second “off” portion 280 may be used to determine the level of ambient light, noise, dark current, other suitable signals, or any combination thereof. The system may subtract the background or dark level from the levels received during red “on” portion 274 and IR “on” period 278.”** EX1027, 16:33–54.

186. A POSITA would have understood from the above disclosures in Lisogurski that Lisogurski teaches that its “system may measure the ambient light detected by the detector” by generating a signal corresponding to the captured light during a “dark period” (a “dark signal”). EX1027, 6:12–19, 13:35–14:6.

Specifically, Lisogurski measures the current that is captured by the detector during a period when the semiconductor sources are turned “off.” EX1027, 6:12–19, 13:67–14:10, 13:35–41. After measuring this current (which corresponds to the amount of ambient light), the demultiplexer in Lisogurski’s front-end processing circuitry “converts the intensity of the received light into an electrical signal” EX1027, 11:14–16, 12:59–13:6, 13:35–41. This process of generating a dark signal 222 (also called dark current 222) by capturing the ambient light when the semiconductor sources are turned “off” is illustrated in Figures 2A and B of Lisogurski, annotated using figures from the ’484 IPR:



EX1027, Figs. 2A, 2B (annotated in view of EX1021, pp 54–56); see also, EX1027, 12:64–13:6, 13:67–14:6.

187. Accordingly, Lisogurski teaches claim element 7[i]. I further understand that the Board previously found that Lisogurski discloses a materially identical limitation. Specifically, the Board determined Lisogurski teaches or renders obvious a detection system that can “generate a first signal responsive to

light received while the light emitting diodes are off.” EX1011, 5-6, 43-44. I understand that Omni did not cross-appeal this finding, and it is therefore final. EX1012, n.2.

k. 7[j]: “generate a second signal responsive to light received while at least one of the semiconductor diodes is on, and”

188. Lisogurski teaches limitation 7[j]. As I discussed above, Lisogurski teaches a dark subtraction technique to “remove ambient and background signals.” EX1027, 6:7–19; *supra* § VIII.C.2.j (cl. 7[i]). Specifically, Lisogurski teaches:

- “In some embodiments, a technique to remove ambient and background signals may be used in addition to or in place of a power saving light modulation scheme. In a drive cycle modulation technique, the system may cycle light output at a rate significantly greater than the cardiac cycle. For example, a drive cycle modulation cycle may include **the system turning on a first light source, followed by a “dark” period, followed by a second light source, followed by a “dark” period. The system may measure the ambient light detected by the detector during the “dark” period and then subtract this ambient contribution from the signals received during the first and second “on” periods.**” EX1027, 6:7–19.
- “Detector 140 **may convert the intensity of the received light into an electrical signal.**” EX1027, 11:14–16.

- “FIG. 2B shows an illustrative plot of detector signal 214 that may be generated by a sensor in accordance with some embodiments of the present disclosure. **The peaks of detector current waveform 214 may represent current signals provided by a detector, such as detector 140 of FIG. 1, when light is being emitted from a light source. The amplitude of detector current waveform 214 may be proportional to the light incident upon the detector. The peaks of detector current waveform 214 may be synchronous with light “on” periods driving one or more emitters of a light source, such as light source 130 of FIG. 1. For example, detector current waveform 214 may be generated in response to a light source being driven by the light drive signal of FIG. 2A. The valleys of detector current waveform 214 may be synchronous with periods of time during which no light is being emitted by the light source. While no light is being emitted by a light source during the valleys, detector current waveform 214 may not fall all of the way to zero. Rather, dark current 222 may be present in the detector waveform. Since dark current 222 may interfere with accurate determinations of physiological characteristics, dark current 222 may be removed as discussed in more detail below.**” EX1027, 12:52–13:6.

- “Dark subtractor 162 may operate on the digital signal. In some embodiments, dark subtractor 162 may subtract dark values from the Red and IR components to generate adjusted Red and IR signals. **For example, dark subtractor 162 may determine a subtraction amount from the dark signal portion of the detection signal and subtract it from the peak portion of the detection signal in order to reduce the effect of the dark signal on the peak. For example, in reference to FIG. 2A, a detection signal peak corresponding to red “on” period 202 may be adjusted by determining the amount of dark signal during the “off” period 220 preceding red “on” period 202. The dark signal amount determined in this manner may be subtracted from the detector peak corresponding to red “on” period 202. Alternatively, the “off” period 220 after red “on” period 202 may be used to correct red “on” period 202 rather than the “off” period 220 preceding it. Additionally, an average of the “off” periods 220 before and after red “on” period 202 may be used.**”
EX1027, 13:60–14:10.

- **“Demultiplexer 156 may operate on detector current waveform 214 of Fig. 2B to generate a Red signal, an IR signal, a first dark signal (e.g., corresponding to the dark component that occurs immediately after the Red component), and a second dark signal (e.g., corresponding to the dark**

component that occurs immediately after the IR component).” EX1027, 13:35–41.

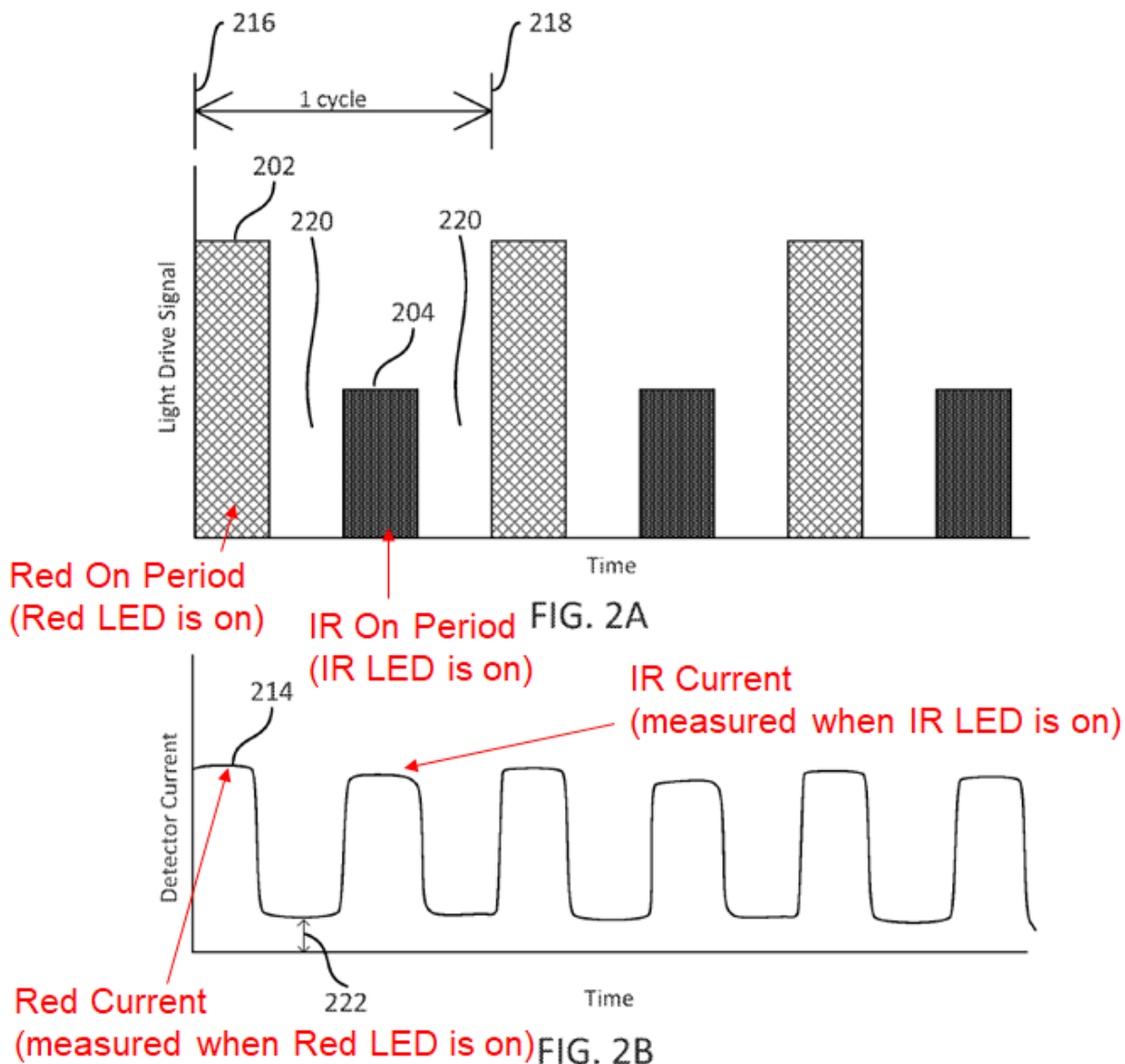
- **“Region 256 of plot 250 indicates an interval of the timing diagram where both red light modulation 252 and IR light modulation 254 are in an “on” portion of the cardiac cycle modulation.** Plot 270 shows an illustrative portion of region 256, where the system is employing a cardiac cycle modulation in addition to the drive cycle modulation. Plot 250 may include a drive cycle modulation technique with a period of time interval 272. The time scale of plot 270 may be significantly shorter than the time scale of plot 250, such that time interval 272 is significantly shorter than time interval 260. For example, time interval 260 (i.e., the period of the cardiac cycle modulation) may be on the order of 1 second, while time interval 272 (i.e., the period of the drive cycle modulation) may be on the order of 1 ms. **Time interval 272 may include a sequence of red “on” portion 274, a first “off” portion 276, IR “on” portion 278, and a second “off” portion 280.** The first “off” portion 276 and second “off” portion 280 may be used to determine the level of ambient light, noise, dark current, other suitable signals, or any combination thereof. **The system may subtract the background or dark level from the levels**

received during red “on” portion 274 and IR “on” period 278.”

EX1027, 16:33–54.

189. A POSITA would have understood from the above disclosures that Lisogurski teaches a system where one or more detectors and front end processing circuitry receive “light that is reflected by or has traveled through the subject’s tissue” when one or more semiconductor sources (LEDs) are turned “on.” EX1027, 17:40–42 (light received by the detectors includes “light that is reflected by or has traveled through the subject’s tissue”); *id.*, 11:12–20; 6:12–19 (the system “may measure...the signals received during the first and second ‘on’ periods”). A POSITA would further have understood that during “light ‘on’ periods,” light is “being emitted from a light source,” and the detector therefore receives and generates “current signals” that are “proportional to the light incident upon the detector” from those light sources after they pass through or are reflected by the tissue. EX1027, 12:52–13:6. Thus, a POSITA would have understood that Lisogurski teaches generating a second signal responsive to light received while at least one of the semiconductor diode sources is on.

190. This process of capturing light when the semiconductors are “on” is illustrated by Figures 2A and 2B of Lisogurski (annotated in accordance with the ’484 IPR):



EX1027, Figs. 2A, 2B (annotated in view of EX1021, pp 54–56); see also, EX1027, 12:52–13:6.

191. As depicted in Figures 2A and 2B above, Lisogurski’s system can generate a “red” signal and an “IR” signal (“second signal”) when the respective LED is “on.” EX1027, 13:67-14:2, 16:33-53, 11:14-16; *see also id.*, 13:35-41, 17:8-10.

192. Accordingly, Lisogurski teaches claim limitation 7[j]. I also understand that the Board found in the '484 IPR that Lisogurski “generates a second signal responsive to light when at least one of the LEDs is on” and that Omni did not cross-appeal that decision, which was therefore affirmed by the Federal Circuit. EX1011, 7, 43–44; EX1012, n.2.

l. 7[k]: “increase the signal-to-noise ratio by comparing the first signal and the second signal; and”

193. Lisogurski teaches limitation 7[k]. As I discussed above, Lisogurski teaches a dark subtraction technique to “remove ambient and background signals,” *i.e.*, noise, from the measurement of a desired analog signal corresponding to a particular physiological parameter. EX1027, 6:7–19; *supra* §§ VIII.C.1.j–k (cl. 7[i]–[j]). Specifically, Lisogurski teaches:

- **“In some embodiments, a technique to remove ambient and background signals may be used in addition to or in place of a power saving light modulation scheme. In a drive cycle modulation technique, the system may cycle light output at a rate significantly greater than the cardiac cycle. For example, a drive cycle modulation cycle may include the system turning on a first light source, followed by a “dark” period, followed by a second light source, followed by a “dark” period. The system may measure the ambient light detected by the detector during the “dark” period and then subtract this ambient contribution from**

the signals received during the first and second “on” periods.”

EX1027, 6:7–19.

- “FIG. 2B shows an illustrative plot of detector signal 214 that may be generated by a sensor in accordance with some embodiments of the present disclosure. The peaks of detector current waveform 214 may represent current signals provided by a detector, such as detector 140 of FIG. 1, when light is being emitted from a light source. The amplitude of detector current waveform 214 may be proportional to the light incident upon the detector. The peaks of detector current waveform 214 may be synchronous with light “on” periods driving one or more emitters of a light source, such as light source 130 of FIG. 1. For example, detector current waveform 214 may be generated in response to a light source being driven by the light drive signal of FIG. 2A. The valleys of detector current waveform 214 may be synchronous with periods of time during which no light is being emitted by the light source. While no light is being emitted by a light source during the valleys, detector current waveform 214 may not fall all of the way to zero. Rather, dark current 222 may be present in the detector waveform. **Since dark current 222 may interfere with accurate determinations of physiological characteristics, dark current 222 may be removed as discussed in more detail below.**” EX1027, 12:52–13:6.

- **“Dark subtractor 162 may operate on the digital signal. In some embodiments, dark subtractor 162 may subtract dark values from the Red and IR components to generate adjusted Red and IR signals. For example, dark subtractor 162 may determine a subtraction amount from the dark signal portion of the detection signal and subtract it from the peak portion of the detection signal in order to reduce the effect of the dark signal on the peak. For example, in reference to FIG. 2A, a detection signal peak corresponding to red “on” period 202 may be adjusted by determining the amount of dark signal during the “off” period 220 preceding red “on” period 202. The dark signal amount determined in this manner may be subtracted from the detector peak corresponding to red “on” period 202. Alternatively, the “off” period 220 after red “on” period 202 may be used to correct red “on” period 202 rather than the “off” period 220 preceding it. Additionally, an average of the “off” periods 220 before and after red “on” period 202 may be used.” EX1027, 13:60–14:10.**
- “However, if the contribution of ambient light is large relative to the contribution of light from a light source, the total analog gain applied to the detection current may need to be reduced to avoid saturating analog-to-digital converter 154. When the analog gain is reduced, the portion of

the signal corresponding to the light source may map to a smaller number of analog-to-digital conversion bits. **Thus, more ambient light noise in the input of analog-to-digital converter 154 may results in fewer bits of resolution for the portion of the signal from the light source. This may have a detrimental effect on the signal-to-noise ratio of the detection signal. Accordingly, passive or active filtering or signal modification techniques may be employed to reduce the effect of ambient light on the detection signal that is applied to analog-to-digital converter 154, and thereby reduce the contribution of the noise component to the converted digital signal.”** EX1027, 14:40–55.

- “Region 256 of plot 250 indicates an interval of the timing diagram where both red light modulation 252 and IR light modulation 254 are in an “on” portion of the cardiac cycle modulation. Plot 270 shows an illustrative portion of region 256, where the system is employing a cardiac cycle modulation in addition to the drive cycle modulation. Plot 250 may include a drive cycle modulation technique with a period of time interval 272. The time scale of plot 270 may be significantly shorter than the time scale of plot 250, such that time interval 272 is significantly shorter than time interval 260. For example, time interval 260 (i.e., the period of the cardiac cycle modulation) may be on the order of 1 second, while time

interval 272 (i.e., the period of the drive cycle modulation) may be on the order of 1 ms. **Time interval 272 may include a sequence of red “on” portion 274, a first “off” portion 276, IR “on” portion 278, and a second “off” portion 280. The first “off” portion 276 and second “off” portion 280 may be used to determine the level of ambient light, noise, dark current, other suitable signals, or any combination thereof. The system may subtract the background or dark level from the levels received during red “on” portion 274 and IR “on” period 278.”** EX1027, 16:33–54.

194. A POSITA would have understood from these teachings in Lisogurski that the dark subtraction process removes “noise” (which Lisogurski often refers to as “ambient light”) from an analog signal received by Lisogurski’s detector. EX1027, 14:46–55. Specifically, the dark subtractor subtracts the dark signal (captured while the semiconductor sources are off) from each of the red and IR signals (captured while the semiconductor sources are on) to generate “adjusted Red and IR signals.” EX1027, 13:60–14:10, 16:51–54 (“The system may subtract the background or dark level from the levels received during red [or IR] ‘on’ period[s]”). Thus, a POSITA would have understood that Lisogurski teaches subtracting (“*comparing*”) the dark level (*first signal*) from the IR or red level (*second signal*), which a POSITA would have understood increases the SNR (“*improves the signal-*

to-noise ratio”). This is because the SNR is calculated by dividing signal power by noise power, and decreasing noise necessarily increases SNR.

195. Accordingly, Lisogurski teaches limitation 7[k]. I also understand that the Board found in the ’484 IPR that Lisogurski a limitation materially identical to 7[k], and that Omni did not cross-appeal that decision, which was therefore affirmed by the Federal Circuit. EX1011, 5–6, 43–44; EX1012, n.2.

m. 7[l]: wherein the wearable device is at least in part configured to identify an object.

196. Lisogurski teaches claim limitation 7[l]. I understand that the Board previously construed “identify[ing] an object” to mean “to recognize or establish an object as being a particular thing,” a construction affirmed by the Federal Circuit. EX1011, 10, *aff’d*, EX1012, *5. I apply that construction here.

197. Lisogurski discloses optical techniques for measuring blood oxygen saturation through the measurement of oxygenated and deoxygenated hemoglobin, as well as other blood constituents. For example, Lisogurski states: “The light intensity or the amount of light absorbed may then be used to calculate...an amount of a blood constituent (e.g., oxyhemoglobin).” EX1027, 4:36-62. Lisogurski additionally teaches:

- For example, if a cardiac cycle modulation technique only detects the peaks and valleys of a pulse cycle, a first type of blood oxygen saturation algorithm may be used (e.g., discrete oximetry based only on the peak and

valley information). If the cardiac cycle modulation technique detects the entire pulse, a different blood oxygen saturation detection algorithm may be used (e.g., a regression based algorithm). EX1027, 9:38-45.

- In some embodiments, the blood oxygen saturation may be compared to a threshold or target value, such as threshold 830. For example, threshold 830 may be approximately 70-80% of maximum blood oxygen saturation. During time interval 824, when the SpO2 signal is greater than threshold 830, the system may operate in a first mode. For example, as illustrated, the system may use IR light drive signal 840 to monitor cardiac activity throughout a cardiac pulse cycle, and may modulate red light drive signal 838 accordingly. At time point 826, SpO2 signal may cross threshold 830 at point 834. In some embodiments, this may be indicative of decreasing blood oxygen saturation. During time interval 828 following time point 826, the system may operate in a second mode. For example, as illustrated, the system may use red light drive signal 838 to monitor cardiac activity throughout a cardiac pulse cycle, and may modulate IR light drive signal 840 accordingly. EX1027, 24:41-57.
- The system may detect the physiological condition using information obtained through measurements in step 1902, from an external sensor or controller, by any other suitable technique, or any combination thereof. In

some embodiments, the system may detect a condition where a second mode is required that is not related to a physiological condition. For example, the system may detect a change in background noise, a change in ambient light, a change in the available power, other suitable changes, or any combination thereof. In some embodiments, an increase in the number of identified fiducial points (e.g., zero crossings of the derivatives) may cause the system to vary drive signals. EX1027, 37:2-12

198. To measure blood oxygen saturation, Lisogurski's system must select, identify, and quantify oxygenated and deoxygenated hemoglobin (from among other blood constituents). Lisogurski's system accomplishes this by capturing light reflected by tissue, analyzing the wavelengths in the reflected light, and then identifying and quantifying each constituent based on the correlation between particular wavelengths and each blood constituent. EX1027, 4:42-61.

199. I understand that Omni has argued that oxygenated and deoxygenated hemoglobin are two forms of a single blood constituent (*i.e.*, that these are simply two "forms" of a single object). EX1061, 38-39. I further understand that Omni relied on this position to argue that Lisogurski does not "identify" an object because it is not distinguishing between different constituents or objects. EX1061, 38-39.

200. Even assuming Omni's position that oxygenated and deoxygenated hemoglobin are two forms of a single constituent, a pulse oximeter like the one

taught in Lisogurski must distinguish between the two forms in order to measure blood oxygen saturation. As Lisogurski itself makes clear, deoxygenated and oxygenated hemoglobin absorbs light at different wavelengths. EX1027, 4:45–49 (“it has been observed that highly oxygenated blood will absorb relatively less red light and more IR light than blood with a lower oxygen saturation”). That is why Lisogurski’s system teaches measuring blood oxygen saturation using at least two wavelengths of light—to distinguish between oxygenated hemoglobin and deoxygenated hemoglobin. EX1027, 4:53–56 (teaching determining “blood oxygen saturation using two wavelengths of light and a ratio-of-ratios calculation.”); 11:54–55 (describing the light source to be configured to emit two or more wavelengths of light). In measuring the two forms of hemoglobin, which absorb different wavelengths of light, and comparing the intensities of the two wavelengths, Lisogurski necessarily must “recognize or establish an object as being a particular thing,” specifically, a particular form of hemoglobin. If oxygenated and deoxygenated hemoglobin were instead considered the same object, as Omni argues, then there would be no need to use different wavelengths of light to identify the allegedly same object – but if that were the case, it would not be possible to measure blood oxygenation, as it is a measurement technique that specifically relies on the ratio of measurement of two different forms of hemoglobin. Thus, measurement of blood oxygenation, as taught in Lisogurski, necessarily requires recognizing or

establishing the presence of two different things – oxygenated hemoglobin and deoxygenated hemoglobin.

201. Lisogurski’s measurement of at least two objects (oxygenated and deoxygenated hemoglobin) through analysis of the wavelengths of light absorbed versus reflected from the sample is consistent with the teachings of the ’790 Patent. I note that the ’790 Patent itself refers to the different “forms” of hemoglobin (“hemoglobin and hemoglobin A1c,” or glycosylated hemoglobin) as “different blood constituents.” EX1001, 10:21-24; *see also id.*, 76:37-49 (describing using “markers from oxy and deoxygenated hemoglobin...to improve the diagnostics and/or therapeutics for breast and other types of cancer,” and describing the two forms of hemoglobin as “tissue constituents” with specific “spectral signatures”).

202. Lisogurski’s teachings can be applied to identify other “objects,” or blood constituents, as well. A POSITA would have understood that the basic technique taught in Lisogurski (analyzing the reflection, transmission, and absorption of light in tissue) was not limited only to oxygenated and deoxygenated hemoglobin (and the wavelengths associated with those constituents). Indeed, Lisogurski expressly teaches that other wavelengths may be used to identify and measure other parameters. For example, Lisogurski states that the “light intensity or the amount of light absorbed may be used to calculate any number of physiological parameters, including an amount of a blood constituent,” and that

“generated signals may be used to determine[] physiological parameters such as blood oxygen saturation, hemoglobin, blood pressure, pulse rate, other suitable parameters, or any combination thereof.” EX1027, 1:22-24, 4:36-41. Lisogurski also teaches that wavelengths of light may be chosen as appropriate for the use case and constituent to be measured. EX1027, 10:65–11:6 (explaining that “light” as used in Lisogurski may include “any wavelength within the radio microwave, infrared, visible, ultraviolet, or X-ray spectra”), 19:45–50 (explaining that “the attenuation of light” depends on “the wavelength of the light and the tissue with which the light interacts”), 4:43–54 (“the photonic signal interacting with the tissue is selected to be one of more wavelengths that are attenuated by the blood in an amount representative of the blood constituent concentration”).

203. Accordingly, Lisogurski teaches limitation 7[1]. I also understand that the Board previously found that Lisogurski teaches or renders obvious an “identify[ing] an object limitation” in the ’484 IPR. Specifically, the Board found that Lisogurski’s teaching of identifying the levels of oxygenated and deoxygenated hemoglobin in the blood required “us[ing] different wavelengths to distinguish hemoglobin from oxygen carrying hemoglobin, *i.e.*, oxyhemoglobin,” which taught “identifying an object, *i.e.*, the blood constituent oxyhemoglobin.” EX1013, 4-7. I understand that Omni has appealed that determination. EX1061.

2. Ground 2: Claim 7 would have been obvious over Lisogurski and Carlson in view of Lamego.

204. I have analyzed claim 7 and conclude that it would have been obvious over Lisogurski and Carlson in view of Lamego. I provide a detailed analysis below.

a. Claims 7[pre]–7[k]

205. In my opinion, limitations 7[pre]–7[k] would have been obvious over Lisogurski and Carlson for the reasons discussed above. *Supra* §§ VIII.C.1.a-l.

b. Claim 7[l]

206. In my opinion, Lisogurski and Carlson, in view of Lamego, render obvious claim limitation 7[l]. I understand that the Board previously construed “identify[ing] an object” to mean “to recognize or establish an object as being a particular thing,” a construction affirmed by the Federal Circuit. EX1011, 10, *aff’d*, EX1012, *5. I apply that construction here.

207. I further understand that in its brief appealing the Second Final Written Decision (i.e., the Final Written Decision on Remand) of the Board in the ’484 IPR, Omni argues that the “identify an object” limitation, as understood in view of the ’484 Patent specification (which overlaps with the specification of the related ’790 Patent), refers to “spectral techniques that ‘identify and distinguish between spectrally similar materials’” with “only subtle signature differences.” EX1061, 40. I further understand that Omni pointed to certain examples described in the ’484 Patent specification (which are also present in the ’790 Patent specification), to

illustrate the “identify an object” limitation. Specifically, I understand that Omni points to the specification’s description of measuring “a multitude of blood constituents such as glucose, triacetin, ascorbate, lactate, alanine, and urea” and using “mathematical methods, pattern matching algorithms, and spectral signature libraries” to identify these constituents. EX1061, 40-41. Taking Omni’s argument and examples into consideration, it is my opinion that Lisogurski and Carlson, in view of Lamego, teach or render obvious element 7[1].

208. Lamego teaches a multi-wavelength physiological monitor with at least three LEDs. EX1062, Abstract, [0036]. Each LED is configured to emit different wavelengths of light. EX1062, Abstract, [0036]. Lamego explains that, through the use of its multi-wavelength sensor and certain mathematical modeling techniques, its system is capable of determining the levels and/or concentrations of constituents (including constituents not inherently present in the body), such as “methemoglobin (MetHb), carboxyhemoglobin (COHb), low hemoglobin levels, high hemoglobin levels, bilirubin, methylene blue, deoxyhemoglobin, and lipids.” EX1062, [0035]-[0036]. Specifically, Lamego teaches:

- A multi-wavelength physiological monitor provides additional advantages over a two-wavelength device, as well. For example, utilizing multiple wavelengths provide a multi-dimensional calibration curve, which can be used to provide multiple degrees of freedom to compensate for variation in

other physiologically-related parameters. As discussed above, when only two wavelengths are used but there are more than two significant absorbers in the patient's tissue, the system may be underdetermined. Therefore, adding wavelengths sensitive to additional significant absorbers can help the system compensate for the additional significant absorbers and enable more accurate calculation of the concentration of each absorber and the blood oxygen saturation. For example, an eight wavelength physiological monitor utilizes an eight-dimensional calibration curve, which provides eight degrees of freedom to compensate for various physiologically-related parameters. Such parameters can include, for example, noise, motion, various hemodynamic parameters, and/or blood constituent concentrations and/or levels. On the other hand, the system may be overdetermined if, for example, more wavelengths are used than there are significant absorbers and/or wavelengths are used for constituents not present in the particular patient's blood. EX1062, [0035].

- Furthermore, traditional physiological monitors that utilize two light sources to derive a patient's plethysmographic signal generally require one light source's wavelength to fall in the red spectrum and the other light source's wavelength to fall in the infrared spectrum. However, a multi-wavelength physiological monitor advantageously provides the ability to utilize all

infrared wavelength light sources and/or other non-red infrared light sources to derive an accurate plethysmographic waveform. One advantage of utilizing non-red wavelength light sources (for example, all infrared wavelength light sources) is that the multi-wavelength physiological monitor can be further configured to determine several blood constituent concentrations based upon signals measured from just the non-red light sources. For example, such a multi-wavelength physiological monitor can determine levels and/or concentrations of: methemoglobin (MetHb), carboxyhemoglobin (COHb), low hemoglobin levels, high hemoglobin levels, bilirubin, methylene blue, deoxyhemoglobin, and lipids. EX1062, [0036].

- The ability to measure a physiological parameter with a multi-dimensional system allows the system to compensate and account for the presence of other conditions that may affect the particular physiological parameter being measured. For example, many drugs cause the level of MetHb within a patient's blood to increase. MetHb also absorbs light at the two wavelengths used in a typical two-wavelength physiological monitor, which may cause inaccurate S_pO_2 readings. Increased levels of MetHb generally cause blood oxygen concentration level (e.g., S_pO_2) readings to decrease. A two-wavelength physiological monitor would provide reduced readings of blood oxygen concentration, but would not be able to identify the cause for the

decreased reading, or to compensate for such readings. On the other hand, a multi-wavelength physiological monitor, such as any of the multi-wavelength physiological monitors described below, could not only identify the cause of decreased S_pO_2 readings, but also (or alternatively) compensate for such cause when calculating the patient's S_pO_2 level and/or signal. For example, to compensate for MetHb, one or more wavelengths sensitive to MetHb can be used. The wavelength(s) used can be, for example, about 760 nm and/or about 805 nm or the like. This allows for one or more additional equation (s) and degree(s) of freedom so that solving the system may account for the effect of the level of MetHb on blood oxygen saturation readings. EX1062, [0037].

209. As described above, by “identify[ing]” the presence and determining the concentrations and/or levels of other constituents in a user’s blood, Lamego’s multi-wavelength monitor can “compensate” for these blood constituents to provide a more accurate S_pO_2 reading. EX1062, [0035], [0037]-[0038], [0040] (“the multi-wavelength physiological monitor compensates for conditions, such as motion and/or blood constituents”). For instance, in the MetHb example excerpted above, Lamego discloses a technique for identifying MetHb as an object causing decreased S_pO_2 readings, measuring the concentration of MetHb in the blood, and then compensating for the presence of MetHb in the calculation of the user’s blood oxygen saturation. EX1062, [0037].

210. Lamego also discloses techniques for distinguishing between blood constituents that have overlapping absorption ranges. For example, Lamego explains that “carboxyhemoglobin absorbs about the same amount of 660 nm light as oxyhemoglobin.” EX1062, [0038]. The overlap may “result in normal blood oxygen saturation level readings even though the actual level is abnormal. For example, for every about 1% of carboxyhemoglobin circulating in the blood, the monitor may over read by about 1%.” EX1062, [0038]. Through the selection of additional wavelengths sensitive to carboxyhemoglobin, however, “can allow the system to compensate for this effect.” EX1062, [0038] (“The system can compensate for other blood constituents, such as deoxyhemoglobin or lipids, with the addition of wavelengths sensitive to those constituents. More wavelengths can allow the system to compensate for more variables.”). In other words, Lamego’s multi-wavelength monitor can recognize, establish, and separate carboxyhemoglobin and oxyhemoglobin as different constituents. In short, Lamego’s system increases the accuracy of its blood oxygen saturation measurements by identifying the presence of a blood constituent that may cause an aberrant S_pO_2 reading, measuring the concentration of that blood constituent, and then compensating for the measured concentration of that identified blood constituent.

211. Lamego further explains that its techniques are not limited to improving the measurement of blood oxygen saturation; they can be deployed to “provide relatively more accurate measurements of other parameters, including, for example, the concentrations of any of the blood constituents or other parameters mentioned herein.” EX1062, [0039].

212. Lamego also teaches mathematical modeling and statistical techniques for processing the data collected by its multi-wavelength monitor to determine which wavelength corresponds to which constituent. For example, Lamego explains that the data collected from the deployment of multiple wavelengths may be used to create a “multi-dimensional calibration curve,” which can be used to compensate for the presence of various constituents in the blood. Specifically:

- A multi-wavelength physiological monitor provides additional advantages over a two-wavelength device, as well. For example, utilizing multiple wavelengths provide a multi-dimensional calibration curve, which can be used to provide multiple degrees of freedom to compensate for variation in other physiologically-related parameters. As discussed above, when only two wavelengths are used but there are more than two significant absorbers in the patient's tissue, the system may be underdetermined. Therefore, adding wavelengths sensitive to additional significant absorbers can help the system compensate for the additional significant absorbers

and enable more accurate calculation of the concentration of each absorber and the blood oxygen saturation. For example, an eight wavelength physiological monitor utilizes an eight-dimensional calibration curve, which provides eight degrees of freedom to compensate for various physiologically-related parameters. Such parameters can include, for example, noise, motion, various hemodynamic parameters, and/or blood constituent concentrations and/or levels. EX1062, [0035].

213. Lamego also teaches techniques for the separation, processing, and analysis of the data collected from its multi-wavelength monitor. EX1061, [0064]-[0065]. For example, Lamego explains that the “demodulation” process “separates each of the multi-wavelength signals from the composite signal and removes the carrier frequency, leaving raw data points.” EX1061, [0065]. The data is “subjected to statistics operations” as well as “a saturation transform model.” EX1061, [0064]-[0065]. The result is a “a saturation value, which is very tolerant to motion artifacts and other noise in the signal.” EX1061, [0065]. Lamego further describes cross-correlation and modeling techniques to account for noise and/or interference caused by motion or by blood constituents. For example:

- The ratio of the intensity of different light wavelengths may be used to determine the oxygen saturation of the patient. In one embodiment, the ratio is provided to a saturation equation module 502, which includes a look-up table, a polynomial,

or the like. The saturation equation module 502 provides a saturation values at its output 504 based upon the ratio. In another embodiment, the n wavelengths' individual RMS values are also provided as outputs of the statistics operations module 404. EX1062, [0078], *see also, id.*, [0079]–[0082].

- Within the ratiometric model: (i) a , b and bias are known constants derived from and/or defined based on fitting and/or calibration using experimental data and/or one or more models; (ii) $x_{a,rms}$ is a vector of arterial rms-normalized plethysmographic data. For example, in the case of a nine-wavelength system, $n=9$, and each entry of x_a is arterial rms-normalized plethysmographic data associated to a specific wavelength; and (iii) $f:R \rightarrow R$ is a functional mapping defining a “calibration” curve. It may assume any shape as long as it is invertible. EX1062, [0092], *see also, id.*, [0090]–[0105].

214. Lamego describes, among other techniques, how its “statistics module 404 provides first order oximetry calculations and RMS signal values for each of the n wavelengths of light. The statistics module 404 also provides a cross-correlation output which indicates a cross-correlation between the n wavelengths of light.” EX1061, [0073]. Lamego further explains how the “ratio of the intensity of different light wavelengths may be used to determine the oxygen saturation” of a user. EX1061, [0077]–[0078]. The ratio may be “provided to a saturation equation module 502, which includes a look-up table, a polynomial, or the like.” EX1061,

[0078]. The saturation equation module “provides a saturation values at its output 504 based upon the ratio.” EX1061, [0078]. The data collected from the multi-wavelength monitor is further “subjected to a cross-correlation operation as represented in a first cross-correlation module 506.” EX1061, [0079]. Data is further analyzed using a ratiometric model to compensate for noise in the measured signals. EX1061, [0090]-[0105] (describing ratiometric model used to estimate blood oxygen saturation incorporating the number of wavelengths, “n,” utilized in the optical system).

215. As discussed *supra* § VIII.B.2., a POSITA would have been motivated to combine the teachings of Lamego into the optical measurement system of Lisogurski (as modified by Carlson) with the goal of improving the accuracy and signal-to-noise ratio of the system’s blood oxygen saturation measurements. A POSITA would have had a reasonable expectation of success implementing Lamego’s multi-wavelength sensor into a system based on Lisogurski because Lamego’s sensor is comprised of conventional LEDs. Integrating those LEDs into Lisogurski’s sensor would not have impeded the functioning of Lisogurski’s device and would have been consistent with Lisogurski’s disclosure that its sensor can include “any number of light sources with any suitable characteristics.” EX1027, 10:48–64.

216. A POSITA would have understood Lisogurski and Carlson, in view of Lamego, as teaching a wearable physiological monitor that is capable of “recognizing or establishing” various blood constituents as particular things (*e.g.*, as MetHb, as carboxyhemoglobin, or as a lipid) and measuring their concentrations through optical and mathematical techniques. Therefore, a POSITA would have understood Lisogurski and Carlson, with Lamego, to teach a wearable device configured to “identify an object.”

3. Ground 3: Claim 7 would have been obvious over Lisogurski and Carlson in view of Soller.

217. I have analyzed claim 7 and further conclude that it would have been obvious over Lisogurski and Carlson in view of Soller. I provide a detailed analysis below.

a. Claims 7[pre]–7[k]

218. In my opinion, limitations 7[pre]–7[k] would have been obvious over Lisogurski and Carlson for the reasons discussed above. *Supra* §§ VIII.C.1.a-l.

b. Claim 7[l]

219. In my opinion, Lisogurski and Carlson, in view of Soller, render obvious claim limitation 7[l]. As noted above, I understand that the Board previously construed “identify[ing] an object” to mean “to recognize or establish an object as being a particular thing,” a construction affirmed by the Federal Circuit. EX1011, 10, *aff’d*, EX1012, *5. I apply that construction here.

220. As discussed above in §§ VIII.C.1.m and VIII.C.2.b, I understand that Omni argues in its appeal of the Second Final Written Decision (or Written Decision on Remand) of the '484 IPR that Lisogurski does not teach “identify[ing] an object” because, in Omni’s view, Lisogurski does not distinguish between different objects. EX1061, 38-41. Omni argues that oxygenated hemoglobin and deoxygenated hemoglobin are simply two “forms” of one constituent (hemoglobin) and that Lisogurski’s blood oxygen saturation measurement device does not distinguish between two separate “objects.” EX1061, 38-41. Pointing to the '484 Patent’s specification, Omni appears to argue in its appeal brief that the “identify[ing] an object” limitation would be satisfied by an optical system that is capable of distinguishing among blood constituents such as “glucose, triacetin, ascorbate, lactate, alanine, and urea,” using, *e.g.*, “mathematical methods, pattern matching algorithms, and spectral signature libraries.” EX1061, 41–42. Applying Omni’s interpretation of the “identify[ing] an object” limitation, Soller teaches claim element 7[1].

221. Soller teaches “a non-invasive optical and mathematical” method and device used “to measure hematocrit with an accuracy of approximately 99%.” EX1030, 1:46-48. Hematocrit is “the volume percent of red blood cells in a blood sample.” EX1030, 1:17-21. In order to “accurately measure hematocrit,” Soller explains that oxygenated hemoglobin, deoxygenated hemoglobin, methemoglobin,

carboxyhemoglobin and sulfhemoglobin, as well as the nucleus and cell membranes of red blood cells must be accounted for. EX1030, 5:33-41. To accomplish the accurate measuring of hematocrit, Soller teaches a device that can quantify “all of the components of red blood cells” “by using a larger set of wavelengths in the measurement and by using a multivariate calibration technique.” EX1030, 5:41-58. Soller’s small, portable, and hand-held device comprises LEDs, detectors (photodiodes), and a signal processor. EX1030, 15:50-16:38. For example, Soller teaches that:

- Hemoglobin constitutes approximately 90% of the red blood cell, and is mostly present in the oxygenated and deoxygenated forms. However, other forms of hemoglobin are also present in the red blood cell, including methemoglobin, carboxyhemoglobin and sulfhemoglobin. To accurately measure hematocrit, not only must these additional forms of hemoglobin be accounted for, but so must the remaining 10% of the cellular components, such as the nucleus and cell membranes, which do not contain hemoglobin. The invention provides an optical and mathematical method to measure hematocrit with increased accuracy relative to other methods, *e.g.*, impedance and oximetric methods. The increased accuracy results from the more complete analysis provided by the new optical method, which measures blood hematocrit by quantifying all of the components of the red blood cells. The invention quantifies these additional blood cell

components both by using a larger set of wavelengths in the measurement and by using a multivariate calibration technique. In addition, by using a larger set of wavelengths for analysis, the method compensates for variations in blood volume by accounting for factors relating to blood volume. EX1030, 5:33–54.

- The invention is an accurate, small and easy-to-use hematocrit monitoring device using visible and near-infrared light including a set of wavelengths, e.g., 7 or more wavelengths, to record optical spectra of blood. The multi-wavelength spectra measured with this device are analyzed with multivariate calibration techniques, e.g., Partial Least Squares (PLS), to relate the reflected or transmitted light intensities to blood hematocrit determined by standard methods, e.g., the capillary tube method or a Coulter counter. This multivariate analysis approach accounts for all forms of hemoglobin as well as the additional cellular components that both absorb and scatter light and for changes in blood volume. EX1030, 5:55–67.
- The mathematical model relates actual blood hematocrit to optical data. The model is generated by taking optical spectra for a range of wavelengths affected by the plurality of red blood cell constituents from a number of samples at known hematocrit values, and then processing the spectra and the hematocrit values with a multivariate calibration procedure, e.g., a Partial Least Squares (PLS) fitting algorithm. The model is then used to determine the blood hematocrit of a blood

sample, e.g., tissue containing blood, by measuring a reflection or Transmission spectrum from the blood, and then comparing the spectrum to the model. Multivariate calibration procedures incorporate information from a variety of chemical species and physical processes without having to measure separately the effect of each one. PLS accounts for all of the different red blood cell constituents, e.g., various forms of hemoglobin and other cellular bodies, by relating the optical measurements to a single parameter, hematocrit. EX1030, 6:42–59.

222. Soller thus teaches “quantifying all of the components of the red blood cells” through the use of “a larger set of wavelengths in the measurement and by using a multivariate calibration technique.” EX1030, 5:47–51. The larger set of wavelengths (in the example excerpted above, 7 wavelengths) is chosen to include “the absorption and scattering affects of the plurality of blood cell constituents.” EX1030, 6:38–41.

223. The device may have “seven light sources,” including LEDs. EX1030, 3:3–5. The device may also include a “detector array” and/or an “optical detection system,” which include, among other features, photodiodes. EX1030, 12:26–54. The detection system can generate “an electrical signal in response to the radiation” detected, and the electrical signal can be “analog or digital.” EX1030, 12:53–59. The device can thus measure the “[o]ptical data taken over a range of wavelengths,”

wherein wavelengths “affected by the plurality of red blood cell constituents are generated from blood samples having varying blood hematocrit.” EX1030, 7:3–25.

224. Soller teaches that the optical data that is collected by its device may be analyzed using mathematical modeling methods in order to “determine the blood hematocrit of a blood sample.” EX1030, 6:49–50. For example, Soller explains that a mathematical model may be generated by “by taking optical spectra for a range of wavelengths affected by the plurality of red blood cell constituents from a number of samples at known hematocrit values,” and then applying a “multivariate calibration procedure, e.g., a Partial Least Squares (PLS) fitting algorithm” to the spectra and the hematocrit values. EX1030, 6:44–49. The model “relates actual blood hematocrit to optical data.” EX1030, 6:42–43. Soller further explains how the spectral “signature” of blood constituents, such as hemoglobin, can be identified as part of its method. EX1030, 20:36-47 (explaining that “a sharp peak near 576 nm and the wide band over the region of 750-1100 nm is the signature of hemoglobin” in a series of reflection spectra).

225. Additionally, Soller teaches the use of “statistical analysis” as part of its method of calculating the “actual blood hematocrit.” EX1030, 6:63–11:4. For example, the PLS algorithm described above is “based on a statistical regressive analysis” and can “determine[] small hematocrit-related changes in the reflection spectra and correlate[] these to the hematocrit value. EX1030, 8:59–9:27. The PLS

algorithm “generates a mathematical equation relating the reflection spectra to the predicted hematocrit value of the sample.” EX1030, 9:24–27. The PLS algorithm method may be used to “create the calibration model relating hematocrit to optical spectra,” including for devices that use multiple LEDs emitting light at various wavelengths. EX1030, 22:25–42. In the creation of the model, a spectrum that “was identified as an outlier” is removed. EX1030, 22:25–42.

226. Soller further teaches the use of mathematical techniques to increase signal-to-noise ratio. For example, Soller teaches that “data containing large amounts of noise can be filtered using well-known smoothing algorithms to improve their signal-to-noise ratio.” EX1030, 7:38–42.

227. In sum, Soller teaches the quantification of “all of the components of red blood cells,” including methemoglobin, carboxyhemoglobin, and sulfhemoglobin, as well as other cellular components, through the use of an optical device that utilizes a “larger set of wavelengths” to collect optical data and mathematical modeling techniques to analyze the optical data to produce an accurate measuring of hematocrit. EX1030, 5:33–51. A POSITA would have understood that Soller therefore teaches or renders obvious a portable, optical device that can “establish or recognize” various blood constituents through optical measurement followed by statistical and spectral analysis. A POSITA would have understood

Soller to teach “identifying an object,” specifically, hematocrit and its various constituents.

228. I note that Soller refers to oxygenated and deoxygenated hemoglobin, as well as methemoglobin, carboxyhemoglobin, and sulphemoglobin as “forms” of hemoglobin. EX1030, 5:33–40. Soller also refers to *e.g.*, the different “forms” of hemoglobin and the structures of red blood cells, such as the nucleus and cell membrane, as “components.” EX1030, 5:40–51 (describing the invention as “quantifying all of the components of the red blood cells”). Whether they are referred to as “constituents” (as in Lamego, *see* EX1062 [0038]), as “forms,” or as “components,” a POSITA would have understood the various hemoglobin molecules discussed in Soller and Lamego to be “objects,” as recited claim 7 of the ’790 Patent.

229. As discussed in § VIII.B.3, *supra*, a POSITA would have been motivated to implement Soller’s teachings into Lisogurski’s system (as modified by Carlson). Lisogurski and Soller are analogous references that disclose the comparison and analysis of two or more wavelengths of light to determine the presence and calculate the measurements of physiological parameters, such as blood oxygen saturation or hematocrit. A POSITA would have been motivated to improve the accuracy of Lisogurski’s system through the use of additional wavelengths, as Soller teaches. EX1030, 5:50-54 (“using a larger set of wavelengths for analysis... compensates for variations in blood volume by accounting for factors relating to

blood volume”). A POSITA would have had a reasonable expectation of success modifying of Lisogurski’s light source to include additional wavelengths, as altering the configurations of the light sources in optical measurement systems was a well-known technique that would have been within a POSITA’s skillset.

230. Accordingly, Lisogurski and Carlson, in view of Soller, teach limitation 7[1].

4. Ground 4: Claim 7 is indefinite.

231. I have analyzed claim 7, the specification and prosecution history of the ’790 Patent, and Omni’s arguments in its opening appeal brief in the ’484 IPR. In my opinion, and applying the interpretation advanced by Omni in its opening appeal brief, the language of claim 7, in view of the specification and the prosecution history, would not have informed a POSITA of the scope and boundaries of the “identify an object” limitation with reasonable certainty.

232. The specification of the related ’790 Patent uses the term “object” to denote the target of the measurement and monitoring functions of the claimed device. For example, the specification explains that light (from the claimed device) is “directed to” and “reflected from” the target object. EX1001, 9:46-47 (“Also, at least a portion of the light generated by the array is configured to be directed to an object”), 9:51-62 (referring to the light directed to and reflected from the target object). As another example, the specification describes “measuring” the properties

of an object via “remote sensing.” EX1001, 48:34-43. Examples of “objects” include a fish, building materials (gypsum, painted structures, plywood, and concrete), and plant life, soil, and trees. EX1001, Fig. 65B, 54:54-59. The specification describes identifying objects as establishing the presence of the target. In the building materials and flora example cited above, the specification discloses:

- In yet another embodiment, different building materials may be identified and distinguished from surrounding vegetation and forestry . . . As an example, active remote sensing can be used to distinguish different concrete structures, including roadways, buildings, and reinforced structures such as bridges. Also, building materials such as gypsum, painted structures, plywood, and concrete of various sorts, may be distinguished from plant life, soil and trees. Thus, beyond three dimensional imaging, this can add a fourth dimension—namely, identification of objects based on their chemical signature. EX1001, 54:33–59.

233. In regards to other embodiments, the specification describes:

- By use of an active illuminator, a number of advantages may be achieved. First, the variations due to sunlight and time-of-day may be factored out. The effects of the weather, such as clouds and rain, might also be reduced. Also, higher signal-to-noise ratios may be achieved. For example, one way to improve the signal-to-noise ratio would be to use modulation and lock-in techniques. In one embodiment, the light source may be modulated, and then the detection system

would be synchronized with the light source. In a particular embodiment, the techniques from lock-in detection may be used, where narrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency. In an alternate embodiment, change detection schemes may be used, where the detection system captures the signal with the light source on and with the light source off. Again, for this system the light source may be modulated. Then, the signal with and without the light source is differenced. This may enable the sun light changes to be subtracted out. In addition, change detection may help to identify objects that change in the field of view. In the following some exemplary detection systems are described. EX1001, 58:24-45, *see also, id.*, 70:39–52.

234. The specification thus describes the recognition of a wide variety of materials and constituents as the identification of an object, without expressly delineating or limiting what sorts of things may qualify as “objects.” Indeed, as noted above, the specification suggests that building materials, blood constituents, and soil may all be “objects.”

235. I understand that in its brief in the ’484 IPR appeal, Omni argues that a pulse oximeter that measures oxygenated and deoxygenated hemoglobin in a user’s blood does not “identify an object” because oxy- and deoxy- hemoglobin are two “forms” of a “single blood constituent,” hemoglobin. EX1061, 37–42. In support

of its position, Omni argues that a pulse oximeter is “configured to know from the outset precisely what it [is] measuring,” (blood oxygen saturation), and therefore does not “identify” an object. EX1061, 39. Omni attempts to distinguish the “identification” performed by the device claimed in the ’484 patent as capable of considering “a sample with an array of unidentified constituents” and determining its contents. EX1061, 37–42. This purported distinction between what materials or things that can qualify as an object is not supported by the disclosures in the specification and is not a distinction that would be readily apparent to a POSITA reading the ’790 patent.

236. Omni appears to be arguing that oxygenated hemoglobin and deoxygenated hemoglobin are not, in the terms of the ’484 and ’790 patents, separate objects capable of identification through optical (spectral) methods. EX1061, 39-41. At the same time, Omni appears to be arguing that other blood constituents such as glucose, triacetin, ascorbate, lactate, alanine, and urea are separate blood constituents capable of identification through optical methods. EX1061, 39-41.

237. A POSITA reading the specification of the ’790 patent would not have understood the distinction between using different wavelengths of light to identify oxygenated and deoxygenated hemoglobin, and using different wavelength of light to identify other kinds of blood constituents in a sample. The specification makes no such distinction. In fact, the ’790 specification describes oxygenated and

deoxygenated hemoglobin as “tissue constituents” that can be monitored based on their own specific “spectral signatures.” EX1001, 76:37–49, *see also, id.*, 19:47–20:21 (identifying hemoglobin A1c as a “blood constituent” of “interest” that may be monitored and describing hemoglobin A1c as a “form of hemoglobin”). In the same way, the ’790 specification explains that blood constituents such as glucose, triacetin, ascorbate, lactate, alanine, and urea have their own “spectral features,” and can be distinguished through the use of “multiple wavelengths.” EX1001, 18:4-27.

238. In sum, under Omni’s apparent interpretation of the “identify an object” limitation, a POSITA reading the specification of the ’790 Patent would not have understood with reasonable certainty which materials and things qualify as “objects” for identification by the optical system, and which materials and things (such as the various “forms” of hemoglobin) do not.

5. Ground 5: Claim 7 is not enabled.

239. I have analyzed claim 7, the specification of the ’790 Patent, and Omni’s arguments in its opening appeal brief in the ’484 IPR. In my opinion, the specification’s disclosures would not have enabled a POSITA to make and use a device capable of identifying, under Omni’s definition and arguments in the ’484 IPR appeal, the constituents cited in the specification with certainty and without undue experimentation.

240. The specifications of the related '484 and '790 patents describe exemplary constituents that I understand Omni argues can purportedly be “identified” by the claimed devices. EX1001, 18:3–27; EX1005, 12:51–54. These constituents include glucose, triacetin, ascorbate, lactate, alanine, and urea. EX1001, 18:3–27; EX1005, 12:51–54. The specifications of both the '790 and the '484 patents discuss the non-invasive monitoring of glucose at length. EX1001, 15:12–18:27; EX1005, 11:21–67. For example, both specifications identify glucose as a “molecule of interest” for health and disease monitoring, expressly recognizing an “unmet need for non-invasive glucose monitoring.” EX1001, 2:60–3:30, 16:49; EX1005, 2:45–3:15, 11:22. Both specifications also discuss the “[s]pectrum for [g]lucose,” including its “infrared transmittance.” EX1001, 16:48–17:4; EX1005, 11:20–44.

241. In its brief in the appeal of the '484 IPR, Omni argues that the '484 Patent teaches “advantageously using mathematical methods, pattern matching algorithms, and spectral signature libraries, among other tools, to ‘identify’ the various constituents in the sample.” EX1061, 40–41. Omni identifies the constituents cited above as exemplary “objects” that can be identified with the device claimed in the '484 Patent. EX1061, 39–41 (listing glucose, triacetin, ascorbate, lactate, alanine, and urea). Omni further appears to argue that the device of the '484 Patent can “identify and distinguish” at least these blood constituents, including

glucose, from one another. EX1061, 39-40, 27–28 (stating that the '484 specification discloses “spectroscopy techniques, spectral signatures, and pattern matching to recognize and establish the identity of an array of various chemical materials and/or biological markers, such as glucose and cholesterol”).

242. Under Omni’s interpretation of the “identify an object” limitation, the specification of the '790 Patent would not have informed a POSITA how to make and use a device capable of non-invasively identifying and monitoring glucose levels in a patient with any degree of certainty and without undue experimentation. Indeed, non-invasive optical monitoring of glucose, to a degree of certainty that would be useful in health or disease monitoring and that would distinguish glucose reliably in practical applications from other blood constituents with only subtle spectral differences, has not been accomplished in the art to the present day, never mind by the priority date of the patent.

243. The persistent challenges with reliably and specifically distinguishing and monitoring glucose (via non-invasive means) are well known and widely discussed in the art. For example, a 2023 scientific paper published observed that, “[s]pecificity remains one of the most important challenges in non-invasive blood glucose measurement,” and that “accurate detection of blood glucose concentration is not feasible without stable measurement conditions.” EX1065. This observation, published a decade after the claimed priority date of the '790 patent, highlights a fact

known to those skilled in the art: reliably and accurately measuring glucose using non-invasive optical techniques is not possible in practice *to this day*. These challenges persist despite considerable market pressure and demand for a device capable of reliable non-invasive glucose monitoring. *See* EX1001, 2:60–3:11 (the specification of the '790 patent recognizing the “unmet need for non-invasive glucose monitoring” and estimating an “annual market of over \$10B in 2011 for self-monitoring of glucose levels.”).

244. Like glucose, the other blood constituents identified in the '790 specification (and by Omni in its appeal brief), triacetin, ascorbate, lactate, alanine, and urea, cannot be reliably monitored and distinguished via non-invasive optical methods to the present day.

245. Accordingly, claim 7 of the '790 patent is not enabled for the full set of embodiments claimed because a POSITA would not have been able to make and use a device capable of distinguishing among the exemplary blood constituents with reliability or certainty without undue experimentation.

IX. ADDITIONAL REMARKS

246. I currently hold the opinions expressed in this Declaration. I reserve the right to further explain and supplement my opinions as I may acquire additional information and/or attain supplemental insights that may result in added observations.

247. I hereby declare that to the best of my knowledge all statements made are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this proceeding.

Executed this 9th day of October, 2025.

A handwritten signature in black ink, appearing to read "P. Mercier", with a stylized flourish at the end.

Dr. Patrick Mercier

APPENDIX A – TEXT OF CHALLENGED CLAIMS

Claim	Claim Language
7[pre]	An optical system, comprising:
7[a]	a wearable device for measuring one or more physiological parameters, the wearable device adapted to be placed on a wrist of a user;
7[b]	the wearable device including a light source comprising a plurality of semiconductor diodes that are configured to generate an output optical light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;
7[c]	the wearable device comprising one or more lenses configured to receive at least a portion of the output optical light and to deliver a lens output light to tissue comprising skin;
7[d]	the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;
7[e]	wherein the detection system comprises a plurality of detectors that are spatially separated from each other, and wherein at least one analog to digital converter is coupled to at least one of the plurality of detectors;
7[f]	wherein the output signal is indicative of the one or more of the physiological parameters;
7[g]	the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor diodes from an initial light intensity; and
7[h]	the detection system further configured to:
7[i]	generate a first signal responsive to light received while the semiconductor diodes are off,
7[j]	generate a second signal responsive to light received while at least one of the semiconductor diodes is on, and
7[k]	increase the signal-to-noise ratio by comparing the first signal and the second signal; and
7[l]	wherein the wearable device is at least in part configured to identify an object.

APPENDIX B

Patrick P. Mercier

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Professional Highlights

- Currently leading a ~20-person group undertaking high-impact research spanning multiple domains, from near-zero-power integrated circuits, power management, energy harvesting, neural interfaces, wearable physiochemical sensors, RFICs and RF systems, and beyond
- Over 220 peer-reviewed publications, including 30 *ISSCC* papers, 37 *JSSC* papers, and several papers in high-impact journals such as *Science*, *Nature Biotechnology*, *Nature Biomedical Engineering*, *Nature Electronics*, *Nature Communications*, *Advanced Science*, *Energy and Environmental Science*, and more
- Recognized as one of the top contributors of all time at the 2023 *IEEE International Solid-State Circuits Conference (ISSCC)*
- Co-founder and co-director of the successfully industry-supported UCSD Center for Wearable Sensors
- Site Director of the successfully industry/NSF-supported IUCRC Power Management Integration Center, partnered with Dartmouth College
- Multiple young investigator awards: DARPA YFA, NSF CAREER, Beckman YIA
- ISSCC Jack Kilby Award for Outstanding Student Paper
- Over \$40MM in research fundraising to date
- UCSD-wide Academic Senate Teaching Award, and two ECE department teaching awards
- IEEE Fellow, Class of 2025
- ISSCC Executive Committee member; former ISSCC, VLSI, and CICC TPC member
- Startup co-founder (Traq), board member (QuantalRF), and scientific advisory board member (Nanovision and NeuroVigil)
- 24 issued US patents

Education

Ph.D. **Massachusetts Institute of Technology**, Electrical Engineering, June 2012

Thesis title: *Communication and Power Delivery Architectures for Personal Medical Devices* (GPA: 5.0/5.0)

Advisor: Anantha P. Chandrakasan

- S.M. **Massachusetts Institute of Technology**, Electrical Engineering, June 2008
Thesis title: *An All-Digital Transmitter for Pulsed Ultra-Wideband Communication* (GPA: 5.0/5.0)
Advisor: Anantha P. Chandrakasan
- B.Sc. **University of Alberta**, Electrical and Computer Engineering, May 2006
GPA: 4.0/4.0

Related Experience

University of California, San Diego

Vice Chair, Electrical and Computer Engineering (2024-present)
Professor, Electrical and Computer Engineering (2023-present)
Site Director, Power Management Integration Center (2021-present)
Associate Professor, Electrical and Computer Engineering (2018-2023)
Co-Founder/Co-Director, Center for Wearable Sensors (2014-present)
Assistant Professor, Electrical and Computer Engineering (2012-2018)

Expert Witness

Providing expert technical advice, reports, and depositions on a variety of patent litigation cases (2020-present)

NeuroVigil

Scientific Advisory Board Member (2020-present)

Nanovision

Scientific Advisory Board Member (2019-present)

Quantal RF

Board Member (2018-2024)

Traq / Mouthsense Inc.

Co-Founder/Scientific Advisor (2016-present)

Mercier Engineering

Owner, providing engineering and technical expertise to technology companies. (2013-present)

Massachusetts Institute of Technology, Microsystems Technology Laboratory, *Research Assistant* (2006-2012)

Intel Corporation, Circuits Research Lab, *Graduate Technical Intern* (2008)

Selected Honors and Awards

- **IEEE Fellow** – awarded to less than 0.1% of voting members in the IEEE Solid-State Circuits Society – Class of 2025
- **Teacher of the Year Award** – Jacobs School of Engineering at UC San Diego Annual Best Teacher Award Selected by Ballot of the Students – 2023

- **IEEE International Solid-State Circuits Conference (ISSCC) Author-Recognition Award** – Awarded to authors who have contributed more than 20 papers to ISSCC – 2023
- **San Diego County Engineering Council Outstanding Engineer Award** – Awarded annually to a single local engineer who has made significant technical contributions to their society – 2020
- **National Academy of Engineering Frontiers of Engineering Speaker** – A competitive invitation-only event for those who have demonstrated accomplishment in engineering research and technical work with recognizable contributions to advancing the frontiers of engineering – 2019
- **IEEE Solid-State Circuits Society Distinguished Lecturer** – Nominated to deliver invited lectures at local chapters and regional meetings across the world for a two-year term – 2019
- **NSF CAREER Award** – The National Science Foundation’s most prestigious awards in support of early-career faculty – 2018
- **Biocom Catalyst Award** – Awarded to ten academics, entrepreneurs, investors, corporate leaders, and business advisers under 40 years old who are igniting innovation and growth in the San Diego and Los Angeles life sciences industry – 2017
- **IEEE Senior Member** – Elected for showing significant performance over a 10+ year career – 2017
- **Moore Inventor Fellow Finalist** – Selected as a top-10 fellow amongst >200 other applicants at top US universities; received \$25k award – 2017
- **UCSD Academic Senate Distinguished Teaching Award** – Awarded yearly to five distinguished teachers across all departments at UCSD (totaling ~2200 senate members – i.e., the top 0.2% of teachers). First winner in the ECE department since Jack Wolf in 1999. Received 2016
- **DARPA Young Faculty Award** – Awarded to young faculty members who propose high-impact, high-risk research programs – 2015
- **Beckman Young Investigator Award** – Awarded to eight junior faculty members across the US for innovating research within the chemical and biological sciences – 2015
- **Hellman Fellowship Award** – Awarded to junior faculty members who show capacity for great distinction in their research and creative activities – 2014
- **Graduate Teaching Award** – Awarded annually to one (of ~50) faculty in the UCSD ECE department for outstanding teaching and service – 2013
- **Jack Kilby Award** – One awarded per year for outstanding student paper at the *International Solid-State Circuits Conference (ISSCC)* – received 2010
- **Intel Foundation Ph.D. Fellowship** – awarded to 26 applicants across the US – 2009
- **Post Graduate Scholarship** – Natural Sciences and Engineering Council of Canada (NSERC) – 2007, 2009
- **Best Presentation Award**, Microsystems Technology Lab Annual Research Conference – 2008, 2010
- **Julie Payette Postgraduate Research Fellowship** – Awarded to the top 24 Master’s NSERC applicants in Canada – 2006
- **APEGGA Medal** – Highest undergraduate GPA in Electrical Engineering – 2006
- **Atco Electric Centennial Award** – March 2005
- **Schlumberger Scholarship** in Electrical Engineering – 2004, 2005

Other Awards and Recognitions

- **IEEE Custom Integrated Circuits Conference (CICC) 2025** – Best Paper Award Finalist
- **IEEE International Solid-State Circuits Conference (ISSCC) Student Research Preview Poster Award** – 2024
- **IEEE Solid-State Circuits Society (SSCS) Outstanding Reviewer Reward** – 2024.
- **IEEE ISCAS Women in Circuits and Systems (WiCAS)** – Runner Up Paper Award – 2023.
- **IEEE International Symposium on Circuits and Systems (ISCAS)** – Best Runner Up Paper – 2023.
- **Qualcomm Innovation Fellowship (QIF) 2023** – Winner
- **IEEE Applied Power Electronics Conference (APEC)** – Outstanding Presentation Award 2023 – “A Series/Parallel Magnetic-Less Step-Down Converter Based on Piezoelectric Resonators”
- **IEEE Brain Technical Community and IEEE Solid-State Circuits Society** – Brain-Related Best Paper Award 2021 – “An Optically-Addressed Nanowire-Based Retinal Prosthesis with 73% RF-to-Stimulation Power Efficiency and 20nC-to-3°C Wireless Charge Telemetry” presented at ISSCC 2021.
- **IEEE Symposium on Very Large Scale Integration (VLSI Symposium) 2020** – Best Student Paper Award Nominee – “A -105dB THD 87dB-SNDR VCO-based Sensor Front-end Enabled by Background-Calibrated Differential Pulse Code Modulation”
- **IEEE Symposium on Very Large Scale Integration (VLSI Symposium) 2020** – Best Student Paper Award Nominee – “A 4.4μW -92/-90.3dBm Sensitivity Dual-mode BLE/Wi-Fi Wake-up Receiver”
- **Qualcomm Innovation Fellowship (QIF) 2020** – Winner
- **IEEE EMBS Workshop on Brain, Mind and Body – Cognitive Neuroengineering for Health and Wellness 2019** – Third place poster award
- **IEEE Custom Integrated Circuits Conference (CICC) 2019** – Outstanding Student Paper Award Nominee
- **IEEE Custom Integrated Circuits Conference (CICC) 2018** – Outstanding Student Paper Award Nominee
- **IEEE Custom Integrated Circuits Conference (CICC) 2015** – Outstanding Student Paper Award Nominee
- **Qualcomm Innovation Fellowship (QIF) 2014** – Finalist

List of Publications

BOOKS

- [1] S. Ha, C. Kim, P.P. Mercier, G.C. Cauwenberghs, **High-Density Integrated Electrocortical Neural Interfaces**, Elsevier Academic Press, 2019, 187 pages.
- [2] M.M. Hella and P.P. Mercier (eds), **Power Management Integrated Circuits**, CRC Press, 2016, 329 pages.
- [3] P.P. Mercier and A.P. Chandrakasan (eds), **Ultra-low-power Short-Range Radios**, Springer, 2015, 394 pages.

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- [2] S. Ha, C. Kim, H. Wang, Y.M. Chi, P.P. Mercier, G. Cauwenberghs, “Low-power integrated circuits for wearable electrophysiology,” in **Wearable Sensors – Fundamentals, Implementation and Applications 2nd Edition**, E. Sazonov, Ed., Academic Press, 2021.
- [3] L.G. Salem and P.P. Mercier, “Recursive Switched-Capacitor DC-DC Converters,” in **Power Management Integrated Circuits**, M.M. Hella and P.P. Mercier, Eds., CRC Press, 2016.
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- [1] N.S.K. Fathy, R. Vatsyayan, A.M. Bourhis, S.A. Dayeh, P.P. Mercier, “A TDMA Neural Recording SoC With IIR-RLS Adaptive Filters for 83.4 dB Artifact Suppression Across 256 Channels,” *IEEE Journal of Solid-State Circuits*, 2025.
- [2] D. Valencia, P.P. Mercier, A. Alimohammad, “An Efficient Brain-Switch for Asynchronous Brain-Computer Interfaces,” *IEEE Transactions on Biomedical Circuits and Systems*, vol. 19, no. 1, pp. 130-141, Feb. 2025.
- [3] W.-C.B. Liu, G. Pillonnet, P.P. Mercier, “An Integrated Dual-Side Series/Parallel Piezoelectric Resonator-Based DC–DC Converter,” *IEEE Journal of Solid-State Circuits*, vol. 59, no. 12, pp. 4162-4174, Dec. 2024.
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- [26] L.G. Salem, P.P. Mercier, "Successive approximation digital voltage regulation methods, devices and systems," U.S. Patent 10,224,944, Mar. 5, 2019.
- [27] K. Stankovich, A. Chandrakasan, P. Mercier, S. Bandyopadhyay, A. Lysaght, "Energy Extraction," U.S. Patent 9,369,005, Jun. 14, 2016.
- [28] P.P. Mercier and A.P. Chandrakasan, "Multi-Taped Inductively-Coupled Charging System," U.S. Patent 9,293,942, Mar. 22, 2016.

Teaching Experience

University of California, San Diego

La Jolla, CA

Instructor

Fall 2024: ECE 203 – Biomedical Integrated Circuits and Systems

Spring 2024: ECE 165 – Digital Integrated Circuits

Fall 2023: ECE 203 – Biomedical Integrated Circuits and Systems (87% instructor rating)

Spring 2023: ECE 165 – Digital Integrated Circuits (98% instructor rating)

Fall 2022: ECE 203 – Biomedical Integrated Circuits and Systems (92% instructor rating)

Spring 2022: ECE 165 – Digital Integrated Circuits (93% instructor rating)

Fall 2021: ECE 203 – Biomedical Integrated Circuits and Systems (83% instructor rating)

Spring 2021: ECE 165 – Digital Integrated Circuits (85% instructor rating)

Fall 2020: ECE 203 – Biomedical Integrated Circuits and Systems (94% instructor rating)

Spring 2020: ECE 165 – Digital Integrated Circuits (92% instructor rating – **even during fully virtual instruction due to COVID-19**)

Fall 2019: ECE 203 – Biomedical Integrated Circuits and Systems (94% instructor rating – **TA won the best ECE TA Award**)

Spring 2019: ECE 165 – Digital Integrated Circuits (96% course rating)

Fall 2018: ECE 203 – Biomedical Integrated Circuits and Systems (95% instructor rating)

Winter 2018: ECE 165 – Digital Integrated Circuits (100% instructor rating)

Winter 2018: ECE 203 – Biomedical Integrated Circuits and Systems (91% instructor rating)

Spring 2017: ECE 165 – Digital Integrated Circuits (100% instructor rating)

Spring 2017: ECE 203 – Biomedical Integrated Circuits and Systems (93% instructor rating)

Fall 2016: ECE260A - VLSI Digital System Algorithms and Architectures (93% instructor rating)

Spring 2015: ECE 165 – Digital Integrated Circuits (**100% instructor & course rating from an 82 student class – ECE dept. record**)

Winter 2015: ECE 203 – Biomedical Integrated Circuits and Systems (93% instructor rating)

Fall 2014: ECE260A - VLSI Digital System Algorithms and Architectures (87% instructor rating)

Spring 2014: ECE 165 – Digital Integrated Circuits (**100% instructor & course rating from a 77 student class – ECE dept. record**)

Winter 2014: ECE 203 – Biomedical Integrated Circuits and Systems (98% instructor rating)

Spring 2013: ECE 283 – Biomedical Integrated Circuits and Systems (99% instructor rating)

Winter 2013: ECE 165 – Digital Integrated Circuits (94% instructor rating)

Massachusetts Institute of Technology

Cambridge, MA

Teaching Assistant

Spring 2010: MIT EECS Course 6.776 – High Speed Communication Circuits.

Funding

Energy-Efficient Microsystems Lab

As PI of the Energy-Efficient Microsystems Lab, I have raised over \$40MM for research at UCSD from the following sources:

- DARPA
- NIH
- NSF
- The Arnold and Mabel Beckman Foundation
- Semiconductor Research Corporation
- ONR
- iARPA
- Army Research Lab
- KETI
- NextFlex
- The Fetzer Franklin Fund
- The Hellman Foundation
- Samsung
- Qualcomm
- Dockon Inc.
- Mouthsense Inc.
- Peregrine Semiconductor
- IMA Life North America
- Moore Foundation
- University of California Multi-Campus Research Programs and Initiatives
- California Energy Commission
- The UCSD Center for Brain Activity Mapping
- The UCSD Center for Wireless Communications (corporate sponsored)
- The UCSD Center for Wearable Sensors (corporate sponsored)
- The Power Management Integration Center (corporate sponsored)

UC San Diego Center for Wearable Sensors

As co-director of the Center for Wearable Sensors, I have been instrumental in fundraising over \$7MM from corporate partners, with the bulk of this funding used to support collaborative

efforts across six engineering departments, the School of Medicine, and the Department of Visual Arts.

Power Management Integration Center

As Site Director of the Power Management Integration Center, I have help recruit corporate members to support research at both UCSD and at Dartmouth College.

Service

Journal service

- Guest Editor – *IEEE Open Journal of the Solid-State Circuits Society (OJ-SSCS) Special Issue on Low-Power RF Circuits and Systems (2023)*
- Guest Editor – *IEEE Journal of Solid-State Circuits* Special Issue on the 2018 *International Solid-State Circuits Conference (ISSCC) (2018)*
- Associate Editor – *IEEE Solid-State Circuits Letters* (2017-2023)
- Associate Editor – *IEEE Transactions on Biomedical Circuits & Systems* (2013-2023)
- Associated Editor – *IEEE Transactions on VLSI* (2015-2017)
- Guest Editor – *IEEE TBioCAS Special Issue on the 2014 International Solid-State Circuits Conference (ISSCC) (December, 2014)*
- Guest Editor – *IEEE TBioCAS Special Issue on the 2013 International Solid-State Circuits Conference (ISSCC) (December, 2013)*

Conference service

- Executive Committee member – Demo Chair – *IEEE International Solid-State Circuits Conference (ISSCC) (2022-present)*
- Technical Program co-Chair – *IEEE Sensor Interfaces Meeting (2022-2024)*
- Subcommittee Chair – Power Management – *IEEE Custom Integrated Circuits Conference (CICC) (2021-2023)*
- Technical Program Committee member – *IEEE VLSI Circuits Symposium (2018-2022)*
- International Technical Program Committee member – *IEEE International Solid-State Circuits Conference (ISSCC) Technology Directions subcommittee (2017-2022)*
- Technical Program Committee member – *IEEE Custom Integrated Circuits Conference (CICC) (2017-2023)*
- Technical program committee – *IEEE Biomedical Circuits and Systems Conference (BioCAS) (2014-2015)*
- Session chair – *International Symposium on Low-Power Electronics and Design (ISLPED) (2014)*
- Technical program committee - *CMOS Emerging Technologies Research Symposium (2013-2016)*

Peer reviewer (2009-present)

- *IEEE Journal of Solid-State Circuits (JSSC)*
- *IEEE Transactions on Circuits and Systems I (T-CAS I)*
- *IEEE Transactions on Circuits and Systems II (T-CAS II)*
- *IEEE Transactions on Microwave Theory and Techniques (T-MTT)*
- *IEEE Sensors Journal*
- *IEEE Transaction on Power Electronics*

- *Journal of Low Power Electronics and Applications (JLPEA)*
- *IET Circuits, Devices & Systems*
- *IEEE International Conference on Ultra-Wideband (ICUWB)*
- *IEEE Transactions on Biomedical Circuits & Systems (TBioCAS)*
- *IEEE Transactions on Biomedical Engineering (TBME)*
- *IEEE International Conference on Circuits and Systems (ISCAS)*
- *IEEE Biomedical Circuits and Systems Conference (BioCAS)*
- *IEEE Journal of Emerging and Selected Topics in Power Electronics*
- *IEEE Transactions on Industrial Electronics*
- *Nature Nanotechnology*
- *Advanced Materials*
- *Nature Biomedical Engineering*
- *Science Advances*

Grant review service

- NSF SenSE panel reviewer (July 2020)
- NSF ECCS panel reviewer (February 2019)
- NSF ECCS panel reviewer (January 2018)
- NSF ECCS panel reviewer (March 2015)
- ARL ARL Director's Research Initiative (DRI) reviewer (June 2015)

UCSD Campus-wide Service

- Chair, Academic Senate Faculty Affairs Committee (2024-present)
- Co-Director – *Center for Wearable Sensors* – including 23 faculty across four engineering departments, the School of Medicine, and Arts and Humanities (Department of Visual Arts). Funding comes from the membership of 6-10 corporate partners. (2014-present)
- Site Director – *Power Management Integration Center* – includes 5 faculty across multiple engineering departments. Funding comes from the membership of 8-12 corporate partners. (2021-present)
- Vice Chair Academic Senate Faculty Affairs Committee (2023-2024)
- Chair, UCSD Academic Senate Awards Committee (2020-2022)
- Member, UCSD Academic Senate Awards Committee (2018-2020)
- Member, Office of Research Affairs Center Launch Review Panel. (2017-2018)
- Member, UCSD School of Public Health Advisory Committee (2017-2019)
- UCSD representative on Capitol Hill – presented to congressional staffers via an event hosted by the American Institute for Medical and Biological Engineering, then met, alongside UCSD's Executive Director of Government Research Relations, with the offices of three San Diego Congressmen and one California Senator to discuss research at UCSD. (2017)
- Faculty representative, Campus-wide commencement ceremony (2017)
- Organizer & presenter, KAIST-UCSD Symposium on Micro/Nanotechnologies and Electronics for Next-Generation Mobile, Wearable, and IoT Systems, Deajeon, Korea (2015)
- Faculty representative, Welcome Week Convocation Ceremony (2013)

UCSD ECE Departmental Service

- Vice Chair, ECE Department (2024-present)
- Member, Faculty search committee, Systems Focus (2024)
- Adhoc committee member, faculty review files (2x in 2024)
- Chair, ECE Faculty Awards Committee (2023-present)

- Chair, ECE Admissions Steering Committee (2020-2022)
- Member, ECE Admissions Committee (2019-present)
- Medical Devices and Systems curriculum advisor (2018-2020)
- ECE 50th Anniversary planning committee (2015-2016)
- MS Exam committee (2014-present)
- Alumni Initiative (2014-2020)
- Undergraduate/Graduate Affairs and Student Award Nomination committee (2012-2014)
- Medical Devices and Systems curriculum director (2013-2014)
- Medical Devices and Systems Ad-hoc committee - responsible for creating a new program in this area (2012-2013)

Co-Chair, Microsystem Technology Lab Annual Research Conference (2011)

Annual research conference with over 200 academic and industrial attendees. Responsible for steering committee leadership and conference organization including: solicitation of papers, managing paper edits, keynote speaker invitation, opening and closing remarks, and general planning. Created interactive attendee activities to solicit social and technical engagement amongst industry members and students. Cited by a high-ranking industry member as “the best student run conference in the country”.

Broader Impacts & Outreach

- Presented a webinar at BioXTech, a country-wide club founded and run by high school women interested in the intersection of biology and technology, and answered questions about technology and gave career advice (2023)
- Featured in the publication entitled “Building Blocks for Better Science: Case Studies in Low-Cost and Open Tools for Science”, which describes my work in low-cost COVID-19 symptoms monitoring devices (2020)
- Guest instructor at Hands-on-Technology summer camp at Wangenheim Middle School focused on accelerating the understanding of computer science in elementary and school-aged children (2014-present)
- Directly mentored ten B.S., M.S., and Ph.D. students from historically underrepresented backgrounds, including two high school students (2012-present)
- Directly mentored two high school students from historically underrepresented backgrounds (2013, and 2016-2017)
- Keynote speaker at ENSPIRE: one of the largest outreach at UCSD, where over 300 middle-school children visit UCSD to learn about higher education and engineering (Feb. 2015)

Press Articles

Prof. Mercier’s work across several different projects and his expert opinion have been featured in hundreds of press articles and in other forms of media (e.g., TV and radio). A few select articles/videos are shown below.

- [1] Adee, S. “Cyborg moth gets a new radio,” *IEEE Spectrum*, Feb. 2009.
<http://spectrum.ieee.org/robotics/military-robots/cyborg-moth-gets-a-new-radio>
- [2] Dillow, C. “Researchers turn animals ears into bio-batteries,” *Popular Science*, Nov. 7, 2012.
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- http://www.popularmechanics.com/how-to/blog/scientists-tap-into-the-battery-in-your-ear-14556133?click=pm_latest
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<http://spectrum.ieee.org/tech-talk/consumer-electronics/gadgets/body-talk-with-magnets>
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<http://phys.org/news/2015-08-mouth-health-markers-transmits-wirelessly.html>
 - [15] Pell, R., "Smart Mouth Guard Monitors Health Markers in Real Time," *EE Times*, Sep. 2, 2015.
http://www.eetimes.com/document.asp?doc_id=1327580
 - [16] Orcutt, M., "Smart Mouthguard Monitors Your Saliva, and Your Health," *Technology Review*, Sep. 9, 2015.
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<https://www.electronicsworld.com/news/business/piezoelectric-based-dc-dc-converter-achieves-310-loss-reduction-2024-02/>
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