UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG ELECTRONICS CO., LTD., SAMSUNG ELECTRONICS AMERICA, INC., FOSSIL GROUP, INC., FOSSIL STORES I, INC., FOSSIL PARTNERS, L.P., OURA HEALTH OY, AND ONEPLUS TECHNOLOGY (SHENZHEN) CO., LTD.,

Petitioners,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Patent No. 12,193,790

Case No. PGR2025-00064

DECLARATION OF PROFESSOR IGOR EFIMOV, PH.D.

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I, Igor Efimov, declare as follows:

1. I make this declaration based upon my own personal knowledge and, if called upon to testify, would testify competently to the matters stated herein.

2. I have been retained on behalf of Omni MedSci, Inc., ("Omni" or "Patent Owner") as an independent expert consultant to provide this declaration concerning the technical subject matter relevant to U.S. Patent No. 12,193,790 ("the '790 Patent") (Ex. 1001) in connection with a post grant review ("PGR") petition filed by Samsung Electronics Co. Ltd., Samsung Electronics America Inc., Fossil Group, Inc., Fossil Stores I, Inc., Fossil Partners, L.P., Oura Health Oy, and OnePlus Technology (Shenzhen) Co., Ltd. ("Petitioners").

3. I am being compensated at my standard hourly rate of $700 per hour for the time I spend on this matter. My compensation is not based on the content of my opinions or the resolution of this matter, and I have no other interest in this proceeding.

4. I understand that Omni is asserting the '790 Patent against Samsung Electronics Co., Ltd., and others, in a related matter currently pending in the United States District Court for the Eastern District of Texas ("the Texas Case").

5. I also understand that Omni is asserting the '790 Patent against Whoop, Inc., in a related matter currently pending in the United States District Court for the District of Delaware ("the Delaware Case").

6. In this declaration, I offer opinions relating to the '790 Patent, claim construction, the references in the Petition, and the declaration of Brian Anthony Ph.D. submitted by Petitioners. The substance and bases of my opinions appear below.

I. BACKGROUND AND QUALIFICATIONS

7. In formulating my opinions, I have relied on my knowledge, training, and experience in the relevant field, which I will summarize briefly herein.

8. I am currently a Professor of Biomedical Engineering and a Professor of Medicine (Division of Cardiology) at Northwestern University, Chicago, Illinois. Prior to my tenure at Northwestern University, I was the Alisann and Terry Collins Professor of Biomedical Engineering at The George Washington University, Washington, D.C., where I also served as Founding Chair of the Department of Biomedical Engineering from 2015 to 2019. Before that, from 2004 to 2015, I served as the Lucy and Stanley Lopata Distinguished Professor of Biomedical Engineering at Washington University, Saint Louis, Missouri. I was also a Professor of Medicine, Professor of Radiology, and Professor of Cell Biology & Physiology at the Washington University School of Medicine. I also served on the faculty of the Department of Cardiology of the Cleveland Clinic

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Foundation (1994-2000) and Department of Biomedical Engineering of Case Western Reserve University (2000-2004), Cleveland Ohio.

9. My research focuses on the physiological mechanisms of cardiovascular disease and the development of diagnostic and therapeutic bioelectronics for heart rhythm disorders, heart failure, and vascular dysfunction. My laboratory develops implantable, wearable, and optical sensing systems for real-time physiological diagnostics and device-based therapy. These systems incorporate semiconductor light sources, photodiodes, and spectroscopic analysis.

10. I received my Master of Science degree in experimental nuclear physics from the Moscow Institute of Physics and Technology, USSR, in 1986. In 1992, I further received a Ph.D. in Biophysics from the Moscow Institute of Physics and Technology after completing a doctoral study on the mechanisms of sudden cardiac death due to ventricular arrhythmias. I completed my postdoctoral training in 1992-1994 in the field of fast fluorescent imaging, cardiac electrophysiology, and arrhythmia at the University of Pittsburgh in Pittsburgh, Pennsylvania. Then, I started my independent cardiac research career in the Department of Cardiology at the Cleveland Clinic Foundation (1994-2000), where I established an NIH-funded laboratory. Cleveland Clinic has been consistently

ranked the #1 Cardiology program nationwide since 1994 by the U.S. News & World Report.

11. For the past 25 years, I have taught undergraduate and graduate courses in Biomedical Engineering, including courses relating to quantitative physiology, applied bioelectricity, biomedical optics, biosignal acquisition, light-tissue interaction, physiology of the heart, introduction to biomedical engineering, clinical cardiovascular engineering, and cardiovascular engineering and technology. In these and other courses, I taught sections on engineering and physiological principles of cardiac electrophysiology, arrhythmia, and electrocardiography. Many of my trainees are currently working at leading national medical device companies such as Medtronic, Abbott, and Boston Scientific, developing novel cardiac antiarrhythmic therapy and diagnostics and sensing devices.

12. I also mentored over 30 clinical fellows and postdoctoral research fellows, many of whom are currently professors, cardiologists, cardiac surgeons, and clinical engineers throughout the national and world Universities and hospitals, including Harvard University, MA; University of California, CA; Ohio State University, OH; University of Wisconsin, WI; University of Fukuoka, Japan;

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University of Bordeaux, France; University of Brno, Czech Republic; Imperial College London, UK; etc.

13. I have published a book in 2009 on cardiac bioelectric diagnostics and therapy (Efimov I.R., Kroll, M.W., Tchou, P.J., Eds., Cardiac Bioelectric Therapy: Mechanisms and Practical Implications, Springer, 2009. ISBN 978-0-387-79402- 0), and I have published a second updated edition of this book in 2021 (Efimov I.R., Ng F.S., Laughner J.I., Eds., Cardiac Bioelectric Therapy: Mechanisms and Practical Implications, Springer, 2nd Edition. 2021. ISBN 978-3-030-63354-7). These volumes address optical imaging technology and electrophysiological principles of diagnosis and therapy, providing novel approaches to treatment of cardiac arrhythmias using implantable devices, percutaneous ablation therapies, machine learning, and other approaches.

14. Most of my 300+ peer-reviewed publications focus on cardiac electrophysiology, biomedical optics, device development, the physiological mechanisms of cardiac arrhythmias, its diagnostics and therapy. In collaboration with Professor John A. Rogers, we have developed a novel implantable, interventional, and wearable electronics platform for monitoring cardiac electrophysiology, optical image mapping, diagnosis of heart rhythm disorders due to brady- and tachyarrhythmias, and antiarrhythmic therapy. Several high-impact publications have been published on that subject recently in leading scientific

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journals of Nature family. For example, our recent paper on novel bioresorbable electronics platform (Choi YS, Yin RT, Pfenniger A, Koo H, Avila R, Lee KB, Chen SW, Lee G, Li G, Qiao Y, Murillo-Berlioz A, Kiss A, Han S, Lee SM, Li C, Xie Z, Chen YY, Burrell A, Geist B, Jeong H, Kim J, Yoon HJ, Banks A, Kang SK, Zhang ZJ, Haney CR, Sahakian AV, Johnson D, Efimova T, Huang Y, Trachiotis GD, Knight BP, Arora RK, Efimov IR, Rogers JA. Fully implantable and bioresorbable cardiac pacemakers without leads or batteries. Nature Biotechnology, June 28, 2021, https://doi.org/10.1038/s41587-021-00948-x.) was featured by over 150 international news outlets reaching at least 12 million listeners/viewers from 5 continents, including PBS, Guardian, and NIH Research Matters (NIH Director's office online publication).

15. Another 2025 publication in Nature (Zhang Y, Rytkin E, Zeng L, Kim JU, Tang L, Zhang H, Mikhailov A, Zhao K, Wang Y, Ding L, Lu X, Lantsova A, Aprea E, Jiang G, Li SG Seo, Wang T, Wang J, Liu J, Gu J, Liu F, Bailey K, L YFL, Burrell A, Pfenniger A, Ardashev A, Yang T, Liu N, Lyu Z, Purwanto NS, Ying Y, Lu Y, Hoepfner C, Melisova A, Gong J, Jeong J, Choi J, Hou A, Nolander R, Bai W, Jin SH, Ma Z, Torkelson JM, Huang Y, Ouyang W, Arora RK, Efimov IR, Rogers JA. Millimetre-scale, bioresorbable optoelectronic systems for electrotherapy. Nature, 2025, 640 (8057), 77-86.) was recognized by Time magazine as one of the Best Inventions of 2025.

16. I have also delivered 400+ invited lectures at prestigious professional conferences and leading Universities worldwide, most of them on biomedical imaging, semiconductor-based light emission, optical coupling through tissue, wireless control architectures, cardiac arrhythmias and therapy. On 2025/11/09, I presented at the annual sessions of the American Heart Association "New sensors for the future: bringing dreams to reality." Other presentations in 2025 included "Millimeter-scale Bioresorbable Stimulator (milli-pacemaker)", European Section Meeting of the International Academy of Cardiovascular Sciences. Prague, Czechia, 2025/11/04; "Millimeter-scale Bioresorbable Stimulator", RASA Europe conference, Berlin, Germany, 2025/11/1; "Cardiovascular Conformal Bioresorbable Devices", Abbott, 2025/10/21; "Heart-AI interface: Soft Bioresorbable Devices", Cardiology Grand Rounds, University of Rochester Medical Center, Rochester, NY, 2025/09/10; "Heart-AI interface: novel bioelectronic therapy for heart rhythm disorders", Department of Internal Medicine Grand Rounds at the University of Iowa Carver College of Medicine, Iowa City, IA, 2025/09/04; "Bioelectronics for Neurocardiology: Leducq Foundation Update", Lyric, University of Bordeaux, France, 2025/08/27; "Bioresorbable transient electronics", Abbott, 2025/06/16; "Bioresorbable transient electronics", Heart Rhythm Society, San Diego, CA, 2025/04/27; "Bioresorbable milli-pacemaker: transient arrhythmia therapy", Ralph Lazarra Lecture Award, Heart

Rhythm Society, San Diego, CA, 2025/04/24; "Selective p38γ silencing by rationally designed siRNA for mitigating anthracycline cardiotoxicity", Lurie Cancer Center, Feinberg School of Medicine, Northwestern University, Chicago, IL, 2025/04/22; "Transient bioelectronics for cardiovascular tissue engineering and medicine", Department of Biomedical Engineering, University of Alabama at Birmingham, AL, 2025/04/18; "Cardiac bioelectronics for heart rhythm disorders", Leiden University Medical Center, Leiden, Netherlands, 2025/01/21.

17. I am currently serving a 5-year term as the Editor-in-Chief of Cardiovascular Engineering and Technology, journal of Biomedical Engineering Society, published by Springer Nature. I am responsible for reviewing and publishing decision-making of approximately 200-250 manuscripts submitted for publication, including biomedical imaging mapping, cardiac electrophysiology, signal processing, arrhythmia therapy, etc. I have served on the editorial board of the American Journal of Physiology: Heart and Circulatory Physiology and Heart Rhythm Journal, where I manage and make decisions on manuscripts related to biomedical sensing and imaging, cardiac electrophysiology and electrotherapy. I have served or currently am serving on many editorial boards of leading cardiac journals, where I review papers on biomedical imaging technique, cardiac electrophysiology and arrhythmia. These journals include Circulation Research, Heart Rhythm, Journal of Cardiac Electrophysiology, Journal of Molecular and

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Cellular Cardiology, American Journal of Physiology, IEEE Transactions in Biomedical Engineering, Experimental Physiology, etc. I regularly review papers on biomedical imaging, cardiovascular physiology and arrhythmia for Nature, Science, Proceedings of the National Academy of Science, Circulation, and other leading journals.

18. I have served on numerous national and international expert panels, which consider grant applications from the leading experts in the field of biomedical optics, diagnostic sensing, cardiac electrophysiology and defibrillation from many countries, including the USA, Canada, the UK, France, Switzerland, Germany, the Netherlands, Russia, Australia, New Zealand, South Africa, Singapore, etc. From 2009-2013, I served as a chartered member of the leading US panel at the National Institutes of Health, the Electrical Signaling, Transporters and Arrhythmia (ESTA) Study section, which is the major funding source for leading US bioinstrumentation investigators. I have also served on many international panels that consider policy, research, and funding decisions in the field of biomedical sensing, cardiac electrophysiology and therapy in numerous countries from most continents. For example, I served on The Expert Panel on the Medical and Physiological Impacts of Conducted Energy Weapons, the Council of Canadian Academies.

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19. My research on biomedical imaging and electronics has been funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health and other federal and private foundations without interruptions since 1998, with an average of approximately $1M per year during recent years. I am also funded by the American Heart Association, National Science Foundation, Leducq Foundation, etc.

20. I have been designing and developing medical devices and diagnostic systems for more than twenty-five years. My inventions and patent portfolio include methods for low-voltage cardiac defibrillation, optical and electrical biosensors, and hybrid optoelectronic systems for tissue monitoring and physiological diagnostics. Many of these devices integrate semiconductor light sources, photodetectors, and optical mapping technologies. For example, I am the inventor or co-inventor on several patents and patent applications, including "Systems and Methods for Triple-Parametric Optical Mapping" (U.S. Patent Pub. No. 2023/0085578), "Distributed Neuromorphic Computing for High-Definition Bioelectric Diagnostics and Therapy" (U.S. Patent No. 11,701,002), and "High-Resolution Multi-Function and Conformal Electronics Device for Diagnosis and Treatment of Cardiac Arrhythmias" (PCT/US18/16499). With the support of NIH funding, I have invented a method for low-voltage defibrillation of cardiac arrhythmias by effectively unpinning anatomical reentry (U.S. Patent No.

8,175,702), a method for cardiac pacing using the inferior nodal extension (U.S. Patent No. 8,391,995), and a method and device for low-energy termination of atrial tachyarrhythmias (U.S. Patent No. 8,509,889). I founded Cardialen, Inc. to develop clinical defibrillators based on this method, which received over $30M in venture and NIH funding. Cardialen was acquired in 2022.

21. I have received many awards in recognition of my research and innovation in the field of bioengineering and diagnostic device development. For example, I was elected to the United States National Academy of Inventors in 2019; and I have received the 2021 Distinguished Scientist Award from the leading clinical cardiac electrophysiology professional association – the Heart Rhythm Society.

22. A more detailed listing of my credentials is set forth in my curriculum vitae (Ex. 2032).

II. MATERIALS CONSIDERED

23. In forming the opinions set forth herein, I have considered and relied upon my education, knowledge of the relevant field, and my experience. I have also reviewed and considered the ’790 Patent (Ex. 1001), the ’790 Patent’s file history (Ex. 1002), and at least the following additional materials:

- Petition for Post Grant Review of the ’790 Patent (Paper 1) (“Petition”);

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- Declaration of Brian Anthony in Support of Petition for Post Grant Review of U.S. Patent No. 12,193,790 (Ex. 1003);
- Petition for Inter Partes Review of the '533 Patent (Ex. 1005);
- '533 Patent Final Written Decision (Ex. 1008);
- *Apple Inc. v. Omni Medsci, Inc.*, No. IPR2021-00453, Paper 11 (P.T.A.B. Feb. 4, 2022) ("'484-Pet.-Reply") (Ex. 1014)
- *Apple Inc. v. Omni Medsci, Inc.*, No. IPR2021-00453, Paper 22 (P.T.A.B. Aug. 3, 2022) ("'484-FWD") (Ex. 1015)
- *Apple Inc. v. Omni Medsci, Inc.*, No. IPR2021-00453, Paper 26 (P.T.A.B. Feb. 14, 2025) ("'484-RFWD") (Ex. 1016)
- *Omni MedSci, Inc. v. Apple Inc.*, 2:18-cv-00134-RWS, Dkt. No. 211 (E.D. Tex. June 24, 2019) (Ex. 1018);
- *Omni MedSci, Inc. v. Apple Inc.*, 2:18-cv-00429-RWS, Dkt. No. 152 (E.D. Tex. Aug. 14, 2019) (Ex. 1019);
- U.S. Patent No. 9,241,676 ("Lisogurski") (Ex. 1025);
- U.S. Patent Pub. No. 2005/0049468A1 ("Carlson") (Ex. 1028);
- Omni MedSci Inc.'s P.R. 4-2 Disclosure of Preliminary Claim Constructions and Extrinsic Evidence (Ex. 2033)
- Samsung Electronics, Co. Ltd., Samsung Electronics America, Inc., Fossil Group, Inc., Fossil Stores I, Inc., and Fossil Partners, L.P., and Oura Health

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Oy's P.R. 4-2 Disclosure of Preliminary Claim Constructions and Extrinsic Evidence (Ex. 2034)

24. I also considered any materials cited in this declaration to the extent they are not expressly listed above.

25. I reserve the right to supplement my opinions or express additional opinions should additional and/or presently unknown information about this matter become known by me at a later date.

III. LEGAL STANDARDS

26. As a technical expert, I am not offering any legal opinions. Rather I am offering technical assessments and opinions. In rendering my analysis, I have been informed by counsel regarding various legal standards for determining patentability. I have applied those standards in forming my technical opinions expressed in this declaration. I understand that a post grant review may be instituted only if the petition shows it is more likely than not that at least one challenged claim is unpatentable, or presents a novel or unsettled legal question important to other patents or patent applications.

A. Claim Construction

27. I understand that claim construction is the process by which a court determines the scope and meaning of terms used in the claims of a patent. I understand that the goal of this process is to give claim terms the ordinary and

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customary meaning they would have had to a person of ordinary skill in the art ("POSITA") at the time of the invention, after reading the patent and its prosecution history.

28. I understand that the patent specification may reveal a special definition given to a claim term by the patentee that differs from the plain and ordinary meaning it would otherwise have to a POSITA. In such cases, I understand that the patentee's definition usually controls.

29. I understand that the prosecution history of a patent can inform the meaning of some claim language and that the prosecution history must be considered when construing the claims.

30. I understand that the court may consider extrinsic evidence, such as dictionaries, treatises, and expert opinions, to understand the technology at issue and the way in which claim terms would be understood by a POSITA in the relevant timeframe.

31. I understand that a dependent claim incorporates each and every limitation of the claim or claims from which it depends.

B. Anticipation

32. I have been informed and understand that a patent claim may be unpatentable as "anticipated" under 35 U.S.C. § 102. I understand that anticipation analysis is a two-step process. The first step is to determine the meaning and scope

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of the asserted claims. Each claim must be viewed as a whole, and it is improper to ignore any element of the claim. For a claim to be anticipated: (1) each and every claim element must be identically disclosed, either explicitly or inherently, in a single prior art reference; (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, there is no anticipation.

33. I understand that to serve as an anticipatory reference, the reference itself must be enabled, i.e., it must provide enough information so that a person of ordinary skill in the art can practice the subject matter of the reference without undue experimentation.

34. I further understand that where a prior art reference fails to explicitly disclose a claim element, the prior art reference inherently discloses the claim element only if the prior art reference must necessarily include the undisclosed claim element. Inherency may not be established by probabilities or possibilities. The fact that an element may result from a given set of circumstances is not sufficient to prove inherency.

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C. Obviousness

35. I understand that a patent claim is invalid under 35 U.S.C. § 103 as being obvious only if the differences between the claimed invention 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 of ordinary skill in that art. An obviousness analysis requires consideration of four factors: (1) scope and content of the prior art relied upon to challenge patentability; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) the objective evidence of non-obviousness, such as commercial success, unexpected results, the failure of others to achieve the results of the invention, a long-felt need which the invention fills, copying of the invention by competitors, praise for the invention, skepticism for the invention, or independent development.

36. I understand that a prior art reference is proper to use in an obviousness determination if the prior art reference is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met. First, a prior art reference is analogous art if it is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution. Second, a prior art reference is analogous art if the prior art reference is reasonably

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pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

37. Furthermore, I understand that a claim may be obvious in view of a single prior art reference, without the need to combine references, if the elements of the claim that are not found in the reference can be supplied by the knowledge or common sense of one of ordinary skill in the relevant art. However, I understand that it is inappropriate to resolve obviousness issues by a retrospective analysis or hindsight reconstruction of the prior art and that the use of "hindsight reconstruction" is improper in analyzing the obviousness of a patent claim.

38. I further understand that the law recognizes several guidelines that inform the obviousness analysis. First, I understand that a reconstructive hindsight approach to this analysis, i.e., the improper use of post-invention information to help perform the selection and combination, or the improper use of the listing of elements in a claim as a blueprint to identify selected portions of different prior art references in an attempt to show that the claim is obvious, is not permitted. Second, I understand that any prior art that specifically teaches away from the claimed subject matter, i.e., prior art that would lead a person of ordinary skill in the art to a specifically different solution than the claimed invention, points to non-obviousness, and conversely, that any prior art that contains any teaching, suggestion, or motivation to modify or combine such prior art reference(s) points

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to the obviousness of such a modification or combination. Third, while many combinations of the prior art might be "obvious to try," I understand that any obvious to try analysis will not render a patent invalid unless it is shown that the possible combinations are: (1) sufficiently small in number so as to be reasonable to conclude that the combination would have been selected; and (2) such that the combination would have been believed to be one that would produce predictable and well understood results. Fourth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references uses known methods or techniques that yield predictable results, then that factor also points to obviousness. Fifth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of known work in one field prompting variations of it for use in the same field or a different one based on design incentives or other market forces that yields predicable variations, then that factor also points to obviousness. Sixth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of routine optimization, then that factor also points to obviousness. Seventh, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of a substitution of one known prior art

element for another known prior art element to yield predictable results, then that factor also points to obviousness.

39. I understand that each alleged prior art reference in a proposed obviousness combination must be evaluated in its entirety, i.e., including those portions that would argue against obviousness, and must be considered for everything that it teaches, not simply the described invention or a preferred embodiment. I understand that it is impermissible to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art, or to ignore portions of the reference that argue against obviousness. I also understand that all of the supposed prior art to be combined as proposed must also be evaluated as a whole and should be evaluated for what they teach in combination as well as separately.

40. I also understand that if the teachings of a prior art reference would lead one skilled in the art to make a modification that would render that prior art device, system, or method inoperable, then such a modification would generally not be obvious. I also understand that if a proposed modification would render the prior art device, system, or method unsatisfactory for its intended purpose, then there is strong evidence that no suggestion or motivation existed at the time of the subject invention to make the proposed modification.

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41. I understand that it is improper to combine references where the references teach away from their combination. I understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. It is also my understanding that the degree of teaching away will depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. I understand that a reference teaches away, for example, if (1) the combination would produce a seemingly inoperative device, or (2) the references leave the impression that the product would not have the property sought by the applicant or would no longer achieve the intended purpose(s) of the references being modified or combined.

IV. OVERVIEW OF THE '790 PATENT

42. The '790 Patent discloses wearable optical systems, such as a smartwatch or other wrist-worn device, that generate optical light, including near-infrared wavelengths, deliver that light to tissue (such as skin at the wrist), detect returned light with one or more detectors, and process the resulting signals to obtain physiological information and, in certain embodiments, identify an object or material based on its optical response. Ex. 1001 at 87:32-33.

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43. The specification describes implementations employing a plurality of semiconductor diodes (e.g., LEDs or laser diodes) capable of emitting at one or more wavelengths, including near-infrared wavelengths in the 700-2500 nm range. Optical lenses are used to deliver source light efficiently into tissue, while a detection system receives reflected or transmitted light and produces an electrical signal for subsequent analysis. Ex. 1001 at 20:56-22:34, FIG. 65B.

44. The '790 Patent discloses synchronization between the light source and the detection system to improve the signal to noise ratio, and various modulation techniques to improve the signal to noise ratio. Ex. 1001 at 9:19-21; 59:64-67. Improving the signal to noise ratio provides greater accuracy by reducing the relative contribution of ambient light and other background influences. For example, the specification describes the use of an active illuminator to modulate sunlight and use synchronous or lock-in detection such that sun light changes are factored out, improving the signal to noise ratio. Ex. 1001 at 58:24-45.

45. As another example, the specification teaches that "narrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency," thereby also improving the signal to noise ratio. Ex. 1001 at 58:34-36.

46. As another example, the specification teaches that "change detection schemes may be used, where the detection system captures the signal with the light

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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." Ex. 1001 at 58:37-41. This technique improves the signal to noise ratio.

47. In addition to physiological monitoring (such as by deriving parameters from the optical signal), the '790 Patent describes identification capabilities by applying algorithmic analysis to spectral of multi-wavelength data. Examples include comparison against reference libraries, the use of mathematical modeling (such as multivariate techniques), and signal processing technologies to determine material identity. Ex. 1001 at 18:10-27; 20:28-32; 21:7-28; 54:32-59. "In addition, change detection may help to identify objects that change in the field of view." Ex. 1001 at 58:42-45 (emphasis added).

48. The '790 Patent describes correlating spectral data with a spectral library to identify the blood constituents of interest, including, for example, glucose, triacetin, ascorbate, lactate, alanine, and others. Ex. 1001 at 18:10-27. "Although glucose has a distinctive signature in the SWIR wavelength range, one problem of non-invasive monitoring is that many other blood constituents also have hydro-carbon bonds." Ex. 1001 at 18:3-6. "To *identify* the blood constituents of interest…the spectrum may be correlated with a library of known spectra." Ex. 1001 at 18:19-24.

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49. The ’790 Patent describes identifying other blood constituents such as proteins, albumin, urea, creatine, or nitrates through SWIR optical techniques, including pattern matching libraries and algorithms. Ex. 1001 at 20:28-32.

50. The ’790 Patent describes that the selection of the blood constituent of interest may be improved by a number of techniques. Ex. 1001 at 21:7-28. These techniques include a higher light level or intensity to improve the signal to noise ratio. Ex. 1001 at 21:11-13. Mathematical modeling and signal processing methodologies reduce interference and help to accentuate differences between spectra. Ex. 1001 at 21:13-22. “In addition, by using a wider wavelength range and using more sampling wavelengths may improve the ability to discriminate one signal from another.” Ex. 1001 at 21:22-28.

51. The ’790 Patent describes referencing the chemical signature of data from a spectral library in order to identify materials. Ex. 1001 at 54:32-59. Active remote sensing can be used to distinguish different materials, such as gypsum, painted structures, and others, from plant life, soil, and trees. Ex. 1001 at 54:32-59. This is “namely, *identification of objects* based on their chemical signature.” Ex. 1001 at 54:58-59.

52. Independent claim 7 of the ‘790 Patent, which I understand is the challenged independent claim, is reproduced below with the identifiers used in the Petition and Dr. Anthony’s declaration for ease of reference:

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[7.pre]	An optical system, comprising:
[7.a.]	a wearable device for measuring one or more physiological parameters,
[7.b]	the wearable device adapted to be placed on a wrist of a user;
[7.c]	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.d]	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.e]	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,
[7.f]	wherein the detection system is configured to be synchronized to the light source;
[7.g]	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.h]	wherein the output signal is indicative of the one or more of the physiological parameters;
[7.i]	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.j]	the detection system further configured to: generate a first signal responsive to light received while the semiconductor diodes are off,
[7.k]	generate a second signal responsive to light received while at least one of the semiconductor diodes is on, and
[7.l]	increase the signal-to-noise ratio by comparing the first signal and the second signal; and
[7.m]	wherein the wearable device is at least in part configured to identify an object.

V. LEVEL OF SKILL IN THE ART

53. I understand that the level of ordinary skill in the relevant art at the time of the invention is relevant to inquiries such as the meaning of claim terms, the meaning of disclosures found in the prior art, and the reasons one of ordinary skill in the art may have for combining references.

54. I have reviewed the definition of the level of ordinary skill in the art proposed in the Petition, which is:

> a POSITA would have [had] a good working knowledge of optical sensing techniques and their applications, and familiarity with optical design and signal processing techniques. Such a person would have obtained such knowledge through an undergraduate education in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience studying or developing physiological monitoring devices…in industry or academia.

Petition, 15-16 (internal citations omitted).

55. For purposes of this declaration, I have been asked to apply Petitioner's proposed definition in my analysis. I reserve the right to identify a differing level of skill in the art for the '790 Patent should a PGR be instituted.

56. I was, as of at least December 2012, and still am, a person of ordinary skill in the art through my education and experience under the definition Petitioner has proposed. I am also familiar with individuals having this level of skill in the relevant timeframe.

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VI. OVERVIEW OF ASSERTED GROUNDS AND REFERENCES IN THE PETITION

A. Petitioners' Obviousness Grounds

57. I understand that Petitioners have challenged claim 7 of the '790 Patent as allegedly obviousness under 35 U.S.C. § 103 based on two grounds:

Ground	Claims	Asserted Reference(s)		
1	7	Lisogurski		
2	7	Lisogurski	Carlson	

B. Summary of Asserted References

58. The Petition relies on Lisogurski (Ex. 1025) alone (Ground 1) and Lisogurski in combination with Carlson (Ex. 1028) (Ground 2). Herein, I refer to these alleged prior art references individually or in various combinations (depending on context) as the "the asserted reference[s]." Below are brief summaries of the asserted references.

1. Lisogurski (Ex. 1025) (Grounds 1-2)

59. Lisogurski discloses a stationary multi-component doctor's office medical device. Only sensor unit 312 in the figure below is wearable. Ex. 1025, FIG. 3.

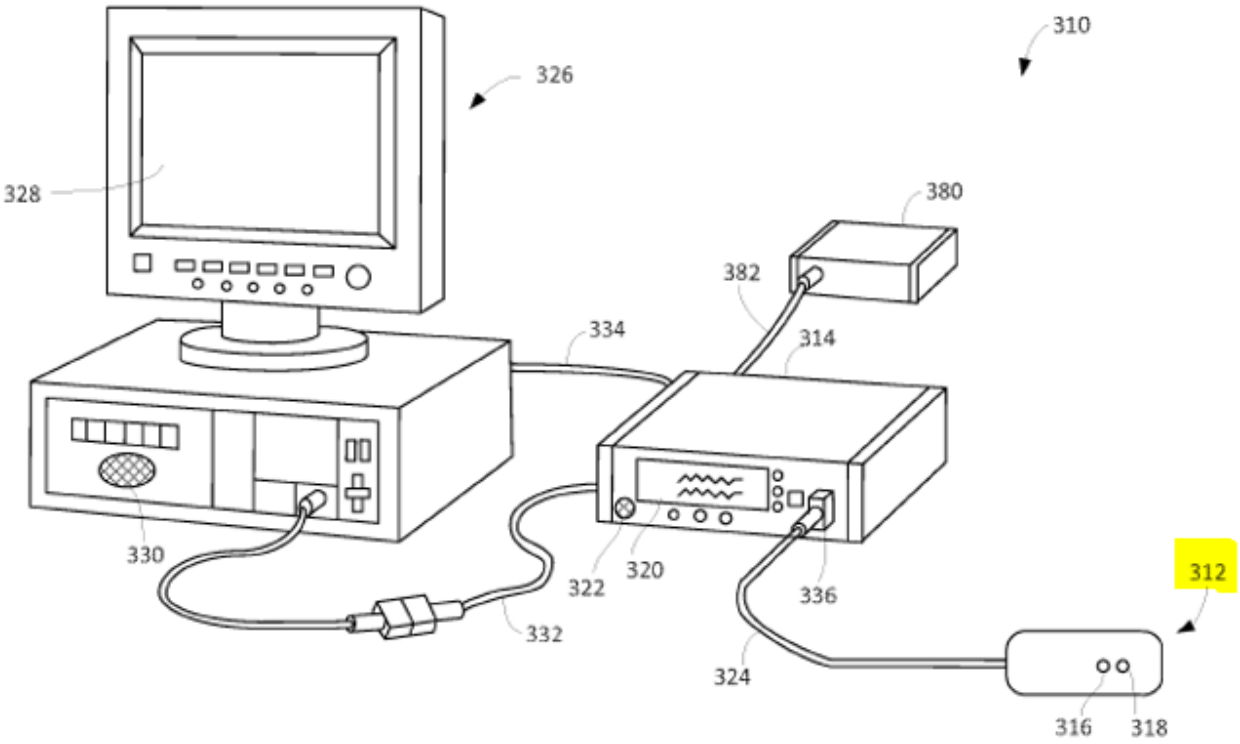


FIG. 3

Ex. 1025 at FIG. 3

60. The remaining stationary components perform data calculations, display information, and calibrate the system. Ex. 1025 at 17:54-18:15, 18:32-67.

61. Lisogurski states that this system may be implemented as a non-invasive physiological monitoring system using pulse oximetry to measure blood oxygen saturation and related parameters. Ex. 1025 at 3:61-4:5. The system uses semiconductor emitters at different wavelengths to illuminate tissue, and a photodetector receives light and converts it into an electrical signal. Ex. 1025 at 4:42-62. Based on known differences in wavelength absorption of oxyhemoglobin

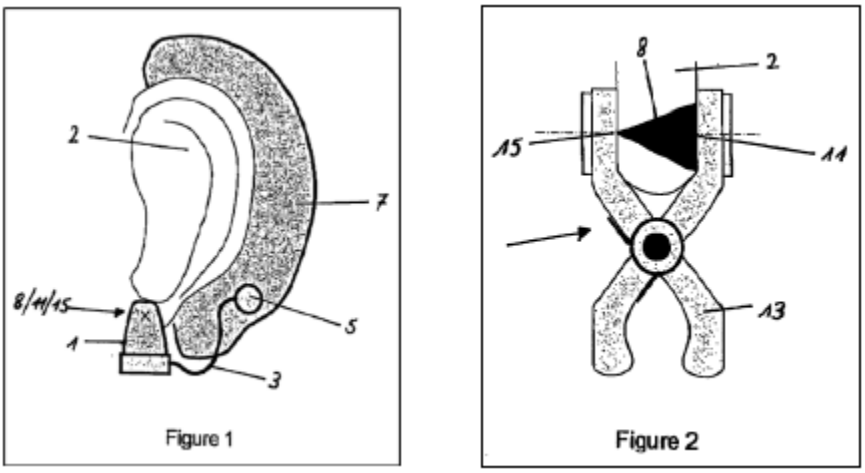
or deoxyhemoglobin, the system compares the intensities at the different wavelengths to estimate blood oxygen saturation. Ex. 1025 at 24:58-25:5.

62. The system also addresses challenges for reducing power consumption to extend battery life. Ex. 1025 at 4:63-5:12.

2. Carlson (Ex. 1028) (Ground 2)

63. Carlson describes an optical pulse oximeter for non-invasive measurement of pulsation and blood oxygen saturation. Ex. 1028 at ¶ [0002]. Carlson describes an ear-clip form factor specifically for telemedicine and patient-controlled self-testing settings. Ex. 1028 at ¶¶ [0002], [0004], [0032]-[0033], [0048]-[0049], FIGS. 1 and 2.

64. The ear clip design of Carlson is shown in Figures 1 and 2:



Ex. 1028 at FIGS. 1-2

65. Carlson describes optical and/or electronic means to improve signal to noise ratio and signal to background performance by using beam shaping optical

elements, such as diffractive or refractive lenses, to direct emitted and reflected light into tissue and the photon detecting element. Ex. 1028 at ¶ [0010]; Ex. 1028 at ¶¶ [0013]-[0014]. The light is directed in a particular fashion "to increase the optical signal power" in order to increase the signal to noise ratio. Ex. 1028 at ¶ [0014]. Finally, Carlson describes module packaging arrangements integrating these optical elements. Ex. 1028 at ¶¶ [0041], [0062].

VII. CLAIM CONSTRUCTION

66. I understand that Petitioners and Dr. Anthony note that certain terms in the '790 Patent have already been construed in prior Board or district court proceedings but otherwise contend that the remaining terms or phrases in the challenged claims of the '790 Patent do not require construction and can be afforded their plain and ordinary meanings. Petition at 16-18; Ex. 1003 at ¶ 63.

A. "to identify an object" (limitation [7.m])

67. Petitioner and Dr. Anthony note that "In the '484-FWD, 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. Petition at 17; Ex. 1003 at ¶ 56.

68. I have reviewed the Board's discussion of this claim construction in the Decision concerning the '484 Patent, which summarized the parties' claim construction arguments. Ex. 1015 at 8-10. The Patent Owner had argued that there

is a difference between (1) identification, which requires recognizing or establishing an object is a particular thing and (2) detection, which merely requires noticing an object's presence." *Id*. at 8. The petitioner in that proceeding argued that the phrases "identify an object" and "detect an object" should have the same meaning. *Id*. at 9. The Board stated:

> [W]e decline to adopt Petitioner's proposal to construe the terms "identify an object" and "detect an object" to have the same meaning. Instead, we construe these terms consistent with the dictionary definitions of "identify" and "detect," i.e., we construe "to identify an object" to mean "to recognize or establish an object as being a particular thing," and we construe "to detect an object" to mean "to discover or notice the existence or presence of something."

Ex. 1015 at 10.

69. I understand that in the Texas Case, consistent with the previous claim construction by the Board, the parties have both proposed that the phrase "to identify and object" is construed as "to recognize or establish an object as being a particular thing." Ex. 2033 at 9; Ex. 2034 at 7.

70. For purposes of this declaration, I have been asked to apply Petitioner's proposed construction for this phrase in my analysis of the grounds in the Petition.

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B. Additional Constructions in '484 and '533 IPRs, and District Courts

71. Petitioners note that in the '533 IPR, the Board declined to construe "plurality of lenses." Petition at 17; Ex. 1005 at 19-20; Ex. 1008 at 9-10.

72. My understanding is that in a previous litigation in the Eastern District of Texas, the court determined that the term "lenses" should be given its "plain and ordinary meaning without the need for further construction." Petition at 17; Ex. 1003 at ¶¶64-65; Ex. 1018, 10-13 (construing "plurality of lenses" in claims 5 and 13 of the '533); Ex. 1019, 12-15 (construing "lens" and "one or more lenses" in related patents).

73. For purposes of this declaration, I have applied the plain and ordinary meaning of "lenses" and "plurality of lenses" for my analysis of the grounds in the Petition.

VIII. OPINIONS ON GROUNDS IN THE PETITION

74. The Petition and Dr. Anthony's declaration include two grounds challenging the validity of the '790 Patent. My opinions on each ground follow.

A. Ground 1: Obviousness Based on Lisogurski (Claim 7)

75. In Ground 1, Petitioners and Dr. Anthony assert that claim 7 of the '790 Patent is obvious over Lisogurski. Petition at 21. For at least the reasons discussed below, I disagree.

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76. Limitation [7.m] recites "wherein the wearable device is at least in part configured to identify an object." As noted above, the Board previously construed the phrase "to identify an object" to mean "to recognize or establish an object as a particular thing," and Petitioners agree this construction should be applied in this proceeding. Petition at 17.

77. For this limitation, the Petition relies on the Board's finding following remand for the '484 Patent that Lisogurski's sensor allegedly "calculate[es] an amount of a blood constituent, e.g., oxyhemoglobin" and that this allegedly "involves distinguishing and identifying oxyhemoglobin in blood." Petition at 41 (citing Ex. 1016 at 6; Ex. 1014 at 24; Ex. 1025 at 4:36-51). Petitioners also quote the following from the Board's remand decision: "[a]s Lisogurski discloses a method of measuring oxygen saturation that uses different wavelengths to distinguish hemoglobin from oxygen carrying hemoglobin, i.e., oxyhemoglobin, Lisogurski teaches identifying an object, i.e., the blood constituent oxyhemoglobin." Petition at 41 (citing Ex. 1016 at 4-7; Ex. 1025 at 4:36-62; Ex. 1003 at ¶¶ 186-88).

78. I am informed and understand that the Board's remand decision concerning the '484 Patent is currently on appeal.

79. Dr. Anthony also quotes the Board's remand decision concerning the '484 Patent and states that "Lisogurski's calculation and measurement of the amount of oxyhemoglobin exists in blood includes distinguishing and identifying the

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oxyhemoglobin blood constituent." Ex. 1003 at ¶ 187. Dr. Anthony claims that "[t]his is consistent with my opinions regarding this '484 limitation provided in my Prior '484 Declaration, which I incorporate by reference as if fully set forth herein." *Id*. (citing Ex. 1010 at ¶¶ 220-22). I note that these paragraphs of Dr. Anthony's declaration for the '484 Patent are not consistent with the Board's findings in the remand decision concerning the '484 Patent. There, Dr. Anthony asserts that "Lisogurski's sensor can identify when an object (e.g., a wrist or ear) is in range of the sensor." Ex. 1010 at ¶ 220. He does not offer opinions in these paragraphs supporting the Board's finding that Lisogurski identifying the oxyhemoglobin blood constituent. Dr. Anthony appears to merely restate the Board's findings from the '484 remand decision and does not explain how Lisogurski allegedly meets this limitation through identifying blood constituents, when Lisogurski simply measures a known blood constituent. Ex. 1003 at ¶ 187.

80. As the Board found in the decision concerning the '484 Patent, in the context of the '790 Patent, a POSITA would recognize that identifying an object is different from merely detecting something or measuring a parameter of a presumed object. Ex. 1015 at 10. To identify an object, the system must determine what the object is, recognizing the object as a particular thing. This is distinct from assuming an object and simply quantifying one of its attributes. The '790 Patent's specification is consistent with this approach, describing identification in terms of classifying

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materials or constituents, such as via spectral analysis and library matching, as opposed to signal measurement. Ex. 1001 at 18:20-27; 78:51-79:12.

81. Distinguishing an object is distinct from measurement, and the specification explains this in further detail with examples. One example in the specification makes this clear, describing how building materials such as gypsum, painted structures, plywood, and others may be distinguished from plant life:

> [B]uilding 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."

Ex. 1001 at 54:54-59 (emphases added).

82. The specification describes spectral techniques that support identification. For example, the specification explains that other blood constituents besides glucose have spectral features in the same wavelength range. Ex. 1001 at 18:3-27. To distinguish glucose from these other blood constituents, the '790 Patent describes collecting information in multiple wavelengths. Ex. 1001 at 18:3-27.

83. The specification also describes using pattern-matching techniques to support identification. "In addition, it may be advantageous to use pattern-matching algorithms and other software and mathematical methods to identify the blood constituents of interest." Ex. 1001 at 18:17-20.

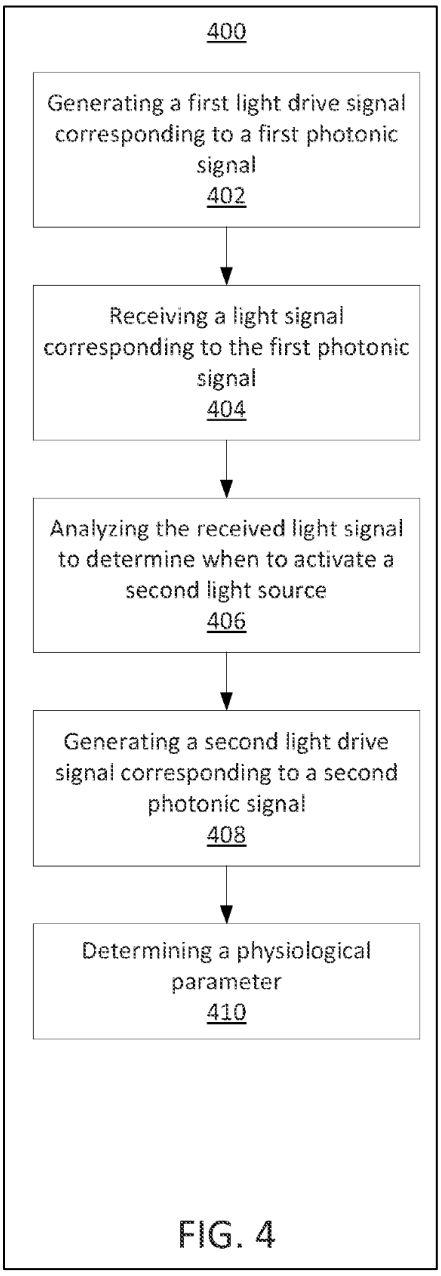
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84. The specification describes using software and mathematical modeling to support identification: "software and mathematical methods to identify the blood constituents of interest." Ex. 1001 at 18:19-20. "This is just one way to perform the signal processing, and many other techniques, algorithms, and software may be used and would fall within the scope of this disclosure." Ex. 1001 at 18:24-27.

85. The specification describes signal processing techniques that support object identification. "Different signal processing techniques can be used to enhance the spectral differences between different constituents." Ex. 1001 at 19:29-47. These signal processing techniques include the process of taking first or second derivatives of the spectra in order to "remove any flat offset or background," thereby improving the analysis of the spectral data to improve the identification of objects. Ex. 1001 at 19:29-47. Ketone or glucose are *identified*, not simply measured, using this technique to distinguish the derivative spectra from protein, urea, and creatine. Ex. 1001 at 19:29-47.

86. Lisogurski is directed to a physiological monitoring system incorporating a pulse oximeter to non-invasively measure oxygen saturation. Ex. 1025 at 3:61-4:41. Lisogurski describes a system where a wearable sensor emits light at two wavelengths and detects the transmitted or reflected light with a detector. Ex. 1025 at 4:42-62. The system calculates a physiological parameter based on the ratio of absorbed light at the two wavelengths. Ex. 1025 at FIG. 4, 4:52-62.

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Ex. 1025 at FIG. 4

87. Lisogurski is describing oximetry, which exclusively focuses on one blood constituent, hemoglobin and measuring the ratio of oxygenated and deoxygenated hemoglobin, without discriminating hemoglobin from other blood constituents. Ex. 1025 at 3:61-4:3. In other words, Lisogurski system is designed to

monitor a known constituent (hemoglobin) and to compute a known metric (oxygen saturation) from the optical signals. Ex. 1025 at 3:61-4:3.

88. A POSITA would recognize that Lisogurski's pulse oximeter is performing parameter measurement, not object identification, among other objects. Ex. 1025 at 3:61-4:3. Lisogurski operates on the presupposition that the object of interest, hemoglobin, is present. Ex. 1025 at 4:35-41. It uses known characteristics of that constituent to estimate oxygen saturation. Ex. 1025 at 4:35-41. Lisogurski does not include any step where the system attempts to determine what the substance or object is. Ex. 1025 at 4:35-41. Instead, Lisogurski assumes the object. Ex. 1025 at 4:35-41. A POSITA would understand that this approach does not amount to identifying an object as required under the claim construction.

89. Although Dr. Anthony references 4:36-62 to explain that "a blood constituent *could* be identified and distinguished from others," the text of Lisogurski does not support this. Ex. 1003 at ¶ 191. Lisogurski's description at 4:36-62 does not mention identifying and distinguishing a blood constituent from others. Instead, it describes a system which will "estimate the blood oxygen saturation of hemoglobin"—which is a specific and known constituent—and determine "physiological parameters." Ex. 1025 at 4:36-62. Dr. Anthony's analysis inserts a capability which is not in the text of Lisogurski. Ex. 1003 at ¶ 191.

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90. To identify an object as required by [7.m] under the claim construction, a POSITA would understand that discernment of the object's identity is required. The '790 Patent describes how a wearable device may use spectral data and algorithms to classify unknown samples, identifying them through techniques including spectral analysis and library matching, as opposed to simply signal measurement. Ex. 1001 at 18:20-27; 78:51-79:12. "Different signal processing techniques can be used to enhance the spectral differences between different constituents," identifying glucose among a mixture of other blood constituents. Ex. 1001 at 19:29-47. This is object identification.

91. For at least these reasons, I disagree with Petitioners' and Dr. Anthony's conclusions for Ground 1 and claim 7 of the '790 Patent.

B. Ground 2: Obviousness Based on Lisogurski in further view of Carlson (Claim 7)

92. In Ground 2, I understand that Petitioners and Dr. Anthony assert that claim 7 of the '790 Patent is obvious over Lisogurski in further view of Carlson. Petition at 41; Ex. 1003 at ¶¶192-207. For at least the reasons discussed below, I disagree.

93. Claim 7 of the '790 Patent includes a limitation, designated [7.m], reciting: "wherein the wearable device is at least in part configured to identify an object." As I noted above, the Board previously construed the phrase "to identify an

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object" to mean "to recognize or establish an object as a particular thing," a construction affirmed by the Federal Circuit. Petition at 17. Nothing in Lisogurski or Carlson, whether alone or in combination, teaches or suggests a wearable device configured to identify an object among other objects as recited in claim 7.

94. As discussed above in connection with Ground 1, Lisogurski does not disclose the claimed "identify an object." Carlson likewise contains no teaching or suggestion of object identification as required by claim 7. Petitioners and Dr. Anthony do not assert that Carlson discloses object identification as required by claim 7. Thus, even if a POSITA were to combine Lisogurski and Carlson, the combination fails to meet limitation [7.m] for the same reasons provided for Ground 1.

95. Carlson is focused on improving the performance of optical pulse oximeters by enhancing signal quality and signal to noise ratio. Ex. 1028 at ¶ [0010]. For example, Carlson describes using optical hardware like beam-shaping lenses, geometrical baffles, and optical filters to direct and filter the light. Ex. 1028 at ¶¶ [0017], [0026]. Carlson describes methods for monitoring data such as pulse rate, blood oxygen saturation, and breathing frequency. Ex. 1028 at ¶¶ [0011]-[0012]. But Carlson does not disclose any computational means to recognize or identify an unknown object from optical data. Carlson does not include discussion of pattern recognition, library matching, or material classification.

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96. A POSITA would recognize that Carlson is describing enhancement of the detection and measurement capabilities of a pulse oximeter to improve accuracy. It is my opinion that a POSITA would recognize that Carlson is not adding any object-identification functionality.

97. Combining Lisogurski and Carlson allegedly results a more noise-resistant pulse oximeter. But the combination does not describe a device configured to identify an object. Neither reference provides any configuration directed to object identification as the claim requires.

98. For at least these reasons, I disagree with Petitioners' and Dr. Anthony's conclusions for Ground 2 and claim 7 of the '790 Patent.

IX. CONCLUSION

99. In my opinion, the challenged claims of the '790 Patent would not have been obvious to a POSITA as of the priority date of the '790 Patent in view of the asserted references that Petitioners and Dr. Anthony rely upon in Grounds 1-2. Accordingly, it is my opinion that all challenged claims of the '790 Patent are patentable over the asserted references.

100. I reserve the right to modify or supplement my opinions, if necessary, based on further review and analysis of the evidence in this case, including review and analysis of information that may be provided to me subsequent to the date of this Declaration.

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I declare that all statements made herein of my own knowledge are true and all statements made on information and believe are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: November 11, 2025

Igor Efimov

Igor Efimov

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