

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. 9,055,868

Case No. IPR2025-01249

DECLARATION OF 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 to provide this declaration concerning the technical subject matter relevant to U.S. Patent No. 9,055,868 (“the ‘868 patent”) in connection with an *inter partes* review (“IPR”) 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 financial or other interest in this proceeding.

4. I understand that Omni is asserting the ‘868 patent against Samsung Electronics Co., Ltd., and others, in a related matter (Case No. 2-24-cv-01070) currently pending in the United States District Court for the Eastern District of Texas (“the Texas Case”).

5. I understand that Omni is asserting the ‘868 patent against Whoop, Inc., in a related matter (Case No. 1-25-cv-00140) 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 ‘868 patent, claim construction, the references in the Petition, and the declaration of Brian Anthony 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 & Stanley Lopata Distinguished Professor of Biomedical Engineering at Washington University, in 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 Foundation (1994-

2000) and the 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 and imaging 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 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 fields of fast fluorescent imaging / optical mapping, 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 by U.S. News & World Report since 1994.

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 and analysis, 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, including Medtronic, Abbott, and Boston Scientific, developing novel cardiac antiarrhythmic therapies, diagnostics, and sensing devices.

12. I have also mentored over 30 clinical fellows and postdoctoral research fellows, many of whom are currently professors, cardiologists, cardiac and vascular 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;

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 the 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, and their diagnostics and therapy. In collaboration with Professor John A. Rogers from Northwestern University, 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 journals. 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-Berlitz 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, Noland 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 as one of the Best Inventions of 2025 by the Time magazine.

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.

17. I am currently serving a 5-year term as the Editor-in-Chief of Cardiovascular Engineering and Technology, a journal of the Biomedical Engineering Society, published by Springer Nature. I am responsible for reviewing and publishing decision-making of approximately 250-300 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 other 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 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, the European Union, 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.

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, cardiac and neural stimulators, 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. Pat. App. 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 and the 2025 Ralph Lazzara Lectureship Award from the leading clinical cardiac electrophysiology professional association – the Heart Rhythm Society. In 2025, I was elected to the American Academy of Sciences and Letters.

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 ‘868 patent (Ex. 1001), the ‘868 patent’s file history (Ex. 1002), and at least the following additional materials:

- Petition for *Inter Partes* Review of the ‘868 patent (Paper 1);
- 2025-10-07 Patent Owner's Discretionary Denial Brief (Paper 11);
- Declaration of Brian W. Anthony (“Anthony Decl.”) (Ex. 1003);

- U.S. Patent Publication No. 2003/0208113 (“Mault”) (Ex. 1004);
- JP Publication No. 2000074829A (Certified English Translation) (“Mitsui”) (Ex. 1005);
- U.S. Patent No. 5,891,022 (“Pologe”) (Ex. 1006);
- U.S. Patent No. 6,526,300 (“Kiani”) (Ex. 1007);
- U.S. Patent No. 5,377,674 (“Kuestner”) (Ex. 1008);
- U.S. Patent No. 4,244,045 (“Nosu”) (Ex. 1009);
- U.S. Patent No. 6,067,463 (“Jeng”) (Ex. 1010);
- U.S. Patent No. 6,049,727 (“Crothall”) (Ex. 1011);
- U.S. Patent No. 5,660,163 (“Schulman”) (Ex. 1012);
- Defendants’ Supplemental Invalidity and Subject Matter Eligibility Contentions (July 18, 2025), *Omni MedSci, Inc. v. Samsung Electronics Co., Ltd. et al.*, No. 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Ex. 1013);
- *Omni MedSci, Inc. v. Apple Inc.*, No. 2:18-cv-00134-RWS, Dkt. No. 211 (E.D. Tex. June 24, 2019) (“CC Order”) (Ex. 1014);
- Petition for *Inter Partes* Review in *Apple Inc. v. Omni MedSci, Inc.*, No. IPR2019-00916, Paper 1 (P.T.A.B. Apr. 10, 2019) (“533-Pet.”) (Ex. 1015);
- Final Written Decision in *Apple Inc. v. Omni MedSci, Inc.*, No. IPR2019-00916, Paper 39 (P.T.A.B. Oct. 14, 2020) (“533-FWD”) (Ex. 1016);
- Declaration of Brian W. Anthony in Support of Petition for *Inter Partes* Review of U.S. Patent No. 9,651,533 (“533-Anthony Decl.”) (Ex. 1017);
- U.S. Patent No. 6,757,001 (“Allport”) (Ex. 1018);
- U.S. Patent No. 6,641,533 (“Causey”) (Ex. 1019);

- Second Amended Docket Control Order (June 16, 2025), Omni MedSci, Inc. v. Samsung Electronics Co., Ltd. et al., No. 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Ex. 1020);
- U.S. Patent No. 6,727,930 (“Currans”) (Ex. 1021);
- U.S. Patent No. 3,609,475 (“Kaposhilin”) (Ex. 1022);
- U.S. Patent No. 7,020,508 (“Stivoric”) (Ex. 1023);
- JP Publication No. 2000074829 (Original Japanese Publication) (“Mitsui Original”) (Ex. 1024);
- U.S. Patent No. 6,597,345 (“Hirshberg”) (Ex. 1025);
- U.S. Provisional Patent Application No. 60/212,319 (Ex. 1026);
- Petition for *Inter Partes* Review in Apple Inc. v. Omni MedSci, Inc., No. IPR2021-00453, Paper 1 (P.T.A.B. Jan. 22, 2021) (“484-Pet.”) (Ex. 1027);
- Final Written Decision in Apple Inc. v. Omni MedSci, Inc., No. IPR2021-00453, Paper 22 (P.T.A.B. Aug. 3, 2022) (“484-FWD”) (Ex. 1028);
- Declaration of Brian W. Anthony in Support of Petition for *Inter Partes* Review of U.S. Patent No. 10,517,484 (“484-Anthony Decl.”) (Ex. 1030);
- U.S. Patent No. 5,544,357 (“Huei”) (Ex. 1031);
- U.S. Patent No. 4,817,050 (“Komatsu”) (Ex. 1032);
- E.F. Schubert, Light-Emitting Diodes, Cambridge Univ. Press, 2nd ed., reprinted 2014 (Ex. 1033);
- Joseph D. Bronzino, The Biomedical Engineering Handbook, 1995 (Ex. 1034);
- U.S. Patent No. 5,122,943 (“Pugh”) (Ex. 1035);

- U.S. Patent No. 6,661,167 (“Eliashevich”) (Ex. 1036);
- U.S. Patent No. 7,001,058 (“Inditsky”) (Ex. 1037);
- U.S. Patent No. 6,424,851 (“Berman”) (Ex. 1038);
- U.S. Patent No. 9,651,533 (“’533”) (Ex. 1039);
- U.S. Patent No. 10,517,484 (“’484”) (Ex. 1040);
- Declaration of Jonathan Bradford in Support of Petition for *Inter Partes* Review of U.S. Patent No. 9,055,868 (“Bradford Decl.”) (Ex. 1041);
- Omni MedSci, Inc.’s Local Patent Rule 4-2 Disclosure Of Preliminary Claim Constructions And Extrinsic Evidence (October 31, 2025), Omni MedSci, Inc. v. Samsung Electronics Co., Ltd. et al., No. 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Ex. 2033);
- Defendants’ Preliminary Constructions And Extrinsic Evidence (October 31, 2025), Omni MedSci, Inc. v. Samsung Electronics Co., Ltd. et al., No. 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Ex. 2034).

24. I also considered any materials cited in this declaration to the extent they are not expressly listed above. My review of these materials was informed by my education, my work experience, and my experience designing medical devices.

III. LEGAL STANDARDS

25. 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.

A. Claim Construction

26. The patent claims describe the invention made by the inventor and describe what the patent owner owns and what the owner may prevent others from using. I understand that an independent claim sets forth all the requirements that must be met to be covered by that claim. I further understand that a dependent claim does not itself recite all of the requirements of the claim but refers to another claim and incorporates all of the requirements of the claim to which it refers.

27. I understand that claim construction is the process by which the scope and meaning of terms used in the claims of a patent are determined. I understand that the goal of this process is to give claim terms the ordinary and 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 extrinsic evidence, such as dictionaries, treatises, and expert opinions, may also be considered 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 claim limitation is interpreted as a “means-plus-function” term when it is expressly drafted in “means for” or “step for” language or other non-structural generic placeholders, and fails to recite sufficient structure for performing the claimed function. When a claim term recites or implies a specific structure that a person of ordinary skill in the art would recognize as capable of performing the function, the term is not considered a means-plus-function limitation.

32. I further understand that when “means-plus-function” interpretation applies, the claim is limited to the specific structure, material, or acts disclosed in the specification and any structural equivalents thereof. However, if the claim language itself identifies known components, such as optical or electronic elements, that convey a definite structure to a POSTIA.

B. Anticipation

33. 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

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; and (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim. Where even one claim element is not disclosed in a reference, there is no anticipation.

34. 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.

35. 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 necessarily includes the undisclosed claim element and that it would be recognized to be necessarily present by a person of ordinary skill in the art. Inherency may not be established by probabilities or possibilities. The fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency. Rather, the inherent characteristic must be the natural result of the design and operation as taught in the prior art reference.

C. Obviousness

36. I understand that a patent claim is invalid under 35 U.S.C. § 103 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.

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

38. 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.

39. I further 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. In other words, one should avoid using the challenged patent as a guide through the prior art references, combining the right references in the right way so as to achieve the result of the claims at issue. Instead, one must put oneself in the place of a person of ordinary skill at the time the invention was made and consider only what was known before the invention was made, and not consider what was only known after the invention was made.

40. I also understand that when considering the obviousness of a patent claim, one must consider whether a teaching, suggestion, or motivation to combine the references exists so as to avoid impermissibly applying hindsight when considering the prior art. I understand that a teaching, suggestion, or motivation may be found explicitly or implicitly: (1) in the prior art; (2) in the knowledge of

those of ordinary skill in the art; or (3) from the nature of the problem to be solved.

I also understand that the motivation to combine references may include logic, judgment, and common sense, but that any such motivation to combine references must still avoid the improper application of hindsight or reliance on the patentee's disclosure of his invention as found in the patent specification, drawings, and claims.

41. I understand that it must also be shown that one having ordinary skill in the art at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded.

42. I understand that obviousness should be considered in light of the problems known to the person having ordinary skill in the art and the complexity of the alternatives for solving the problem. That individual elements of the claimed invention are disclosed in the prior art is not alone sufficient to reach a conclusion of obviousness.

43. While certain 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.

44. 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.

45. 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.

46. 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.

47. Because a dependent claim incorporates each limitation of the claim(s) from which it depends, I further understand that if a prior art reference fails to anticipate an independent claim, then that prior art reference also necessarily fails to anticipate all of its dependent claims. Similarly, my understanding is that if a prior art reference or combination of prior art references fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all of its dependent claims.

IV. OVERVIEW OF THE ‘868 PATENT

48. The ‘868 patent discloses and claims an integrated medical diagnostic system that combines optical, electronic, and software components to measure physiological parameters of a user. ‘868 patent, Claim 7. The specification explains that, in one embodiment, “a diagnostic system includes a light source comprising a plurality of semiconductor diodes with light beams, a multiplexer capable of combining the plurality of semiconductor diode light beams and generating at least a multiplexed light beam comprising one or more wavelengths, and one or more waveguide structures configured to receive at least a portion of the one or more wavelengths and to communicate at least the portion of the one or more wavelengths to an output end of the one or more waveguide structures to form an output beam. A lens system is configured to receive at least a portion of the output beam and to communicate at least the portion of the output beam onto a part of a user’s body comprising blood to perform a measurement on a user.” ‘868 patent, 1:39-51.

49. The disclosed system further includes a software application running on a control system and capable of generating data representing physiological information based on the measurements of the user. *Id.*, 1:51-55. Compared with earlier medical diagnostic systems, which had limited ability to integrate optical measurement with user interfaces or remote data processing, the “control system [that] may have a touch-screen, proximity sensor, and wireless transceiver to

transmit wireless data over a wireless link.” *Id.*, 1:58-60. The control system may also include circuitry for obtaining position information from a location sensor, and is further capable of receiving voice input signals and manually entered input signals. *Id.*, 2:19-22 and 1:61-63.

50. The disclosed control system also enables integration with a host which comprises a digital file for receiving and storing at least a portion of the wireless data, and control logic at the host that processes the wireless data to generate a status of the user. A memory storage device on the host allows for recording the status, and an output provides for communicating at least a portion of the status or associated information over a communication link to one or more display output devices. ‘868 patent, 1:63-2:4.

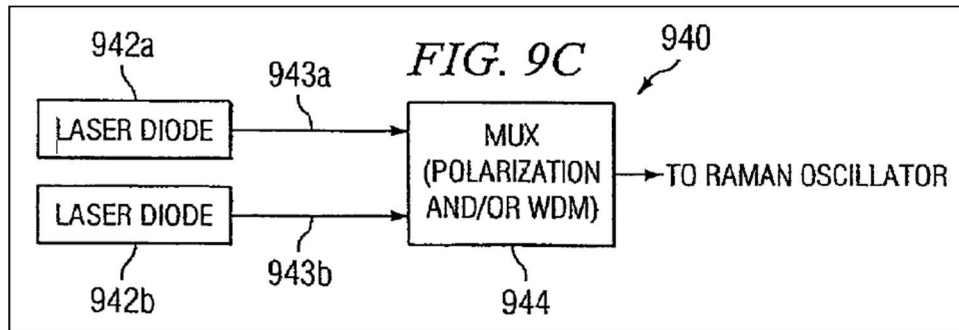
51. The ‘868 patent thus advances diagnostic technology by combining optical spectroscopic measurements with user-interactive and wireless communication capabilities, while also allowing data to be processed locally or transmitted to a remote host for storage and analysis. ‘868 patent, 1:61-63, 2:19-22, 41-45.

52. The inventor of the ‘868 patent recognized a need for a noninvasive, networked diagnostic platform capable of providing accurate physiological measurements while enabling responsive user control and remote monitoring. ‘868 patent, 2:34-3:2. The disclosed diagnostic system includes a light source and other

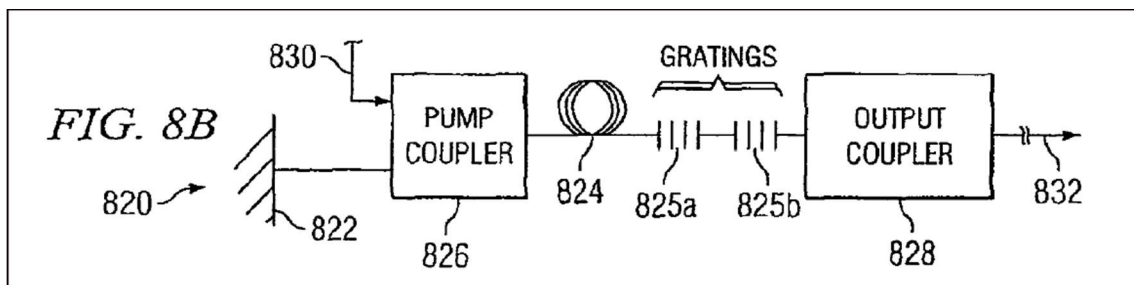
optical components for generating an output beam. For example, one disclosed embodiment utilizes multiple semiconductor diodes to generate pump beams, which are combined and passed through one or more waveguide structures to form an output beam. A lens system is configured to receive at least the portion of the input beam from the light source and to communicate at least the portion of the output beam for use in medical diagnostics. '868 patent, 2:34-3:2; 3:3-21. The specification states that "at least the portion of the output beam is adapted for use in medical diagnostics to measure a property of the patient's blood, wherein the medical diagnostics comprise a spectroscopic procedure ... based at least in part on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from the patient's blood." '868 patent, 3:21-28. Through this configuration, the system generates data representing "physiological information associated with the user" ('868 patent, 2:45-48) and "transmits wireless data comprising at least a part of the physiological information" ('868 patent, 2:53-55). This structure enables real-time optical measurement, wireless data transfer, and host-side processing for diagnostic reporting. '868 patent, 2:5-3:28.

53. The '868 patent provides examples of various optical configurations that may be used in implementing the lens system. For example, FIG. 9C (reproduced below) "is a block diagram illustrating one example embodiment of a pump source 940 capable of being coupled to a Raman wavelength shifter and/or a

Raman oscillator. In this example, pump source 940 includes a pump laser 942 and a multiplexer 944 capable of combining a plurality of pump signals into a pump output signal.” ‘868 patent, 22:56-61.



54. FIG. 8B (reproduced below) “is a block diagram illustrating one example of a Raman wavelength shifter 820 capable of shifting a shorter pump signal 830 wavelength to a longer output signal wavelength 832.” ‘868 patent, 20:18-21.



55. Independent claim 7 of the ‘868 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:

56. Independent claim 7 recites:

[7.pre]	A diagnostic system comprising:
[7.a.]	a light source comprising: one or more semiconductor diodes generating an input light beam; and,
[7.b]	a lens system configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user's body comprising blood, wherein at least the portion of the input light beam is used in a measurement on a user;
[7.c]	a software application capable of generating data based at least in part on the measurement on the user, wherein the data represents at least in part physiological information associated with the user;
[7.d]	the software application capable of operating on a control system adapted to receive, store and process at least a portion of the physiological information
[7.e]	the control system having a touch-screen, circuitry for obtaining position information from a location sensor, and a wireless transceiver to transmit wireless data over a wireless link, the wireless data comprising at least a part of the physiological information, wherein the control system is further capable of receiving voice input signals and manually entered input signals; and
[7.f]	a host comprising: a digital file for receiving and storing at least a portion of the wireless data; control logic at the host to process at least the portion of the wireless data to generate a status of the user; a memory storage device for recording the status; and an output for communicating at least a portion of the status or associated information over a communication link to one or more display output devices, wherein the one or more display output devices are located remotely from the host.

V. PROSECUTION HISTORY OF THE '868 PATENT

57. I have reviewed and analyzed the prosecution history of the '868 patent. I understand that the '868 patent is issued from Application No. 14/476,082 ("the '082 application"), filed on September 3, 2014. The '082 application is a

continuation in a chain of related applications that claim priority to U.S. Provisional Application No. 60/408,025, filed on September 3, 2002.

58. The prosecution record shows that all pending claims, including claims 21–28 and 30–41 (which were later issued as claims 1–20), were allowed without amendment following examination by the Primary Examiner. The Notice of Allowance dated April 20, 2015, includes an Examiner’s Statement of Reasons for Allowance, confirming the Examiner’s conclusion that “the cited prior art does not teach or suggest the whole combination of elements set forth by [then-pending] claims 21–28 and 30–41.” Ex. 1002 at 179-183. The Examiner then went on to summarize examples of combinations of elements that were not disclosed or suggested by the prior art, stating:

For example, there is no teaching or suggestion in the prior art for combining:

a plurality of semiconductor diodes with light beams; a multiplexer capable of combining the plurality of semiconductor diode light beams and generating at least a multiplexed light beam comprising one or more wavelengths; one or more waveguide structures configured to receive at least a portion of the one or more wavelengths and to communicate at least the portion of the one or more wavelengths to an output end of the one or more waveguide structures to form an output beam; and a lens system configured to receive at least a portion of the output beam and to communicate at least the portion of the output beam onto a part of a user’s body comprising blood to perform a measurement on a use[r];

Wherein the combination above used with:

a software application capable of generating data based at least in part on the measurement on the user, wherein the data represents at least in part

physiological information associated with the user; the software application capable of operating on a control system adapted to receive, store and process at least a portion of the physiological information, the control system having a touch-screen, a proximity sensor, and a wireless transceiver to transmit wireless data over a wireless link, the wireless data comprising at least a part of the physiological information, wherein the control system is further capable of receiving voice input signals and manually entered input signals; and a host comprising: a digital file for receiving and storing at least a portion of the wireless data; control logic at the host to process at least the portion of the wireless data to generate a status of the user; a memory storage device for recording the status; and an output for communicating at least a portion of the status or associated information over a communication link to one or more display output devices, wherein the one or more display output devices are located remotely from the host.

Ex. 1002 at 182-183.

59. The Examiner's explanation makes clear that the reasoning quoted above was provided as an *example* illustrating the basis for allowance of some claims. Ex. 1002 at 182-183. The record contains no indication that the stated examples were the full rationale for allowance of all issued claims—including independent claim 7 and dependent claims 8-11, 13, 14, now challenged.

60. I disagree with the attempt by Petitioners' expert Dr. Anthony, to interpret the Examiner's comments as indicating that the Examiner did not fully examine application claim 27 (issued as claim 7) separately from application claim 21 (issued as claim 1). Anthony Decl., ¶¶58-59. The file history shows that the Examiner expressly allowed each individual one of claims 21–28 and 30–41, which indicates that the Examiner determined that the combination of elements recited in

each of those claims was patentable over the prior art. Ex. 1002 at 181. There is no statement or evidence in the prosecution history suggesting that the Examiner overlooked the specific limitations of application claim 27 or of any other allowed claim when evaluating patentability.

VI. LEVEL OF SKILL IN THE ART

61. 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.

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

On or before the claimed priority date of 9/3/2002, a person of ordinary skill in the art (“POSITA”) would have had a good working knowledge of optical sensing techniques and their applications, and some familiarity with optical system design and signal processing techniques. That knowledge would have been gained via an undergraduate education in engineering (electrical, mechanical, biomedical or optical) or a related field of study, along with relevant experience in studying or developing physiological monitoring devices (e.g., non-invasive optical biosensors) in industry or academia. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

Petition, 17; Anthony Decl., ¶61.

63. For purposes of this declaration, I have applied the Petitioners' proposed definition in my analysis. I reserve the right to identify a differing level of skill in the art for the '868 patent should an IPR be instituted.

64. As of the relevant time period of September 2002, I was at least a person of ordinary skill in the art through my education and experience under the definition Petitioners have proposed. I am also familiar with individuals having this level of skill in the relevant timeframe, and I am capable of addressing the issues from the perspective of such a person, and I have done so in this declaration.

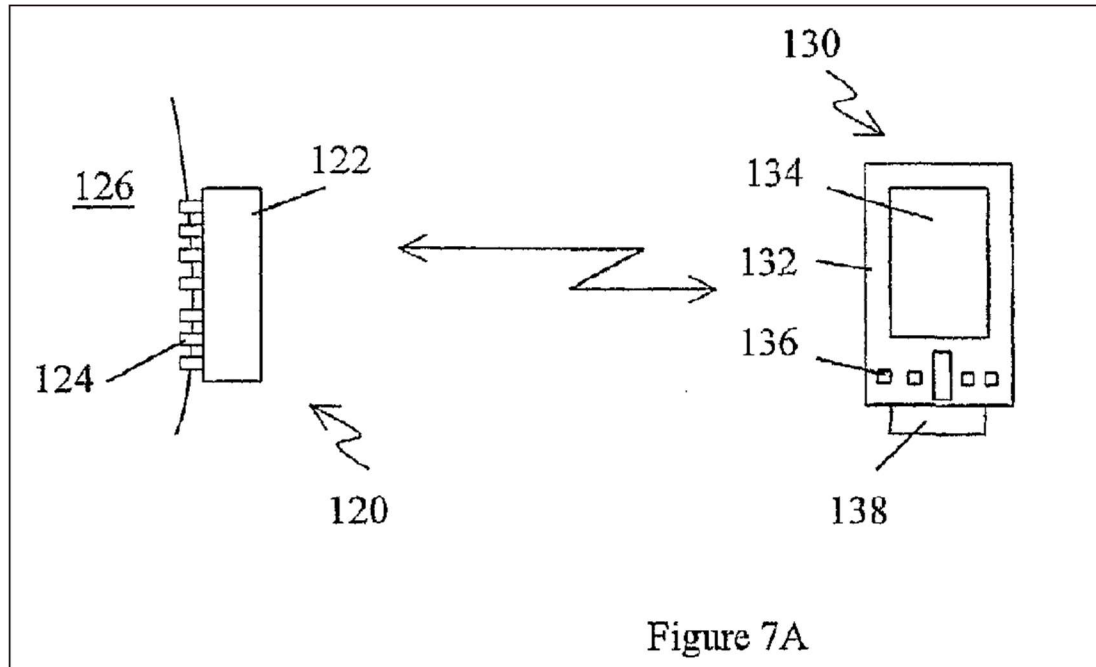
VII. SUMMARY OF REFERENCES IN THE PETITION

65. Below, I provide a summary of the references that are relied upon in Grounds 1-8 of the Petition.

A. Mault (Ex. 1004) – Grounds 1–8

66. Mault (U.S. Pub. No. 2003/0208113 A1, "Closed Loop Glycemic Index System") describes "blood glucose management systems that allow a person to view projected future levels of blood glucose, so as to assist the person to keep blood glucose levels within a predetermined range, such as a medically advisable healthy range." Mault, [0013]. Mault primarily illustrates an invasive method involving "a blood glucose sensor housing 60 having a plurality of microneedles 62 projecting from a surface 64 of the housing 60" as shown in Figures 3-7A. Mault, [0082]. "FIG. 7A [reproduced below] shows a blood glucose analysis module [120]

having a microneedle array placed against the skin of a person and in wireless communication with a PDA [130].” Mault, [0091].



67. Mault contains a very limited discussion of noninvasive optical measurement techniques. For example, Mault briefly mentions that “The blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through or reflected by blood-containing tissue, and then detected by a near-IR detector.” Mault, [0020]. In another instance, Mault describes that “using a non-invasive spectroscopic technique, the PDA/module combination may be placed against part of the body to obtain a blood glucose reading.” Mault, [0073].

68. Mault further discloses that “[a] remote computer system 22 may be a remote server, physician’s computer, home computer, or other computer system accessible over the communications network 20. The PDA can access the communications network ... Data can be transferred to the remote system over the communications network 20.” Mault, [0077]. Additionally, the “remote server system 56 ... can be used to store a database of physiological parameters, activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.” Mault, [0079].

B. Mitsui (Ex. 1005 (translation)) – Grounds 2–8

69. Mitsui (JP 2000-074829 A, “Glucose Sensor”) discloses “a glucose sensor comprising: a light emitting means for irradiating light having wavelength λ_1 in the glucose absorption wavelength band, light having wavelength λ_2 outside of the glucose absorption wavelength band, and light having wavelength λ_3 in the infrared wavelength band for measuring volume of blood flow at the light irradiation site.” Mitsui, Claim 1. Mitsui further discloses “a calculating means for calculating the blood glucose concentration at the light irradiation site from the temperature-corrected amount of glucose and the volume of blood flow.” Mitsui, [0007]. Figure 1 illustrates three semiconductor lasers (having respective wavelengths of 1.55 μm , 1.33 μm , and 0.83 μm) emitting through an earlobe, with corresponding respective photodetectors receiving transmitted light. Mitsui, [0009].

C. Pologe (Ex. 1006) – Grounds 3–8

70. Pologe (U.S. Pat. No. 5,891,022, “Apparatus for Performing Multiwavelength Photoplethysmography”) “relates in general to systems for performing photoplethysmographic measurements and is particularly apt for use in pulse oximetry systems.” Pologe, 1:6-8. Pologe describes that “signals from multiple light emitters are combined into a single multiplexed light signal in a test unit before being delivered to a physically separated probe head attached to a test subject.” Pologe, Abstract. It further explains that, “[l]ight pulses are then delivered from the main test unit 12 to the probe 14 via a single optical transmission line in the probe cable 16. The light pulses are then directed into the finger 36, travel through the finger 36, and emerge on the other side of the finger 36 where they are received by a light pick up device 38. The received light pulses may then be delivered back to the main test unit 12, via probe cable 16, where they are processed to determine the level of one or more blood analytes in the person’s arterial blood.” Pologe, 4:38–47.

D. Kiani (Ex. 1007) – Grounds 5–8

71. Kiani (U.S. Pat. No. 6,526,300 B1, “Pulse Oximeter Probe-Off Detection System”) describes “improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition.” Kiani, Abstract. It explains that “[i]n the present

configuration, the probe-off detector module 138 of the pulse oximeter 140 can verify that the optical probe 202 is properly secured simultaneously with checking the resistance of the coding resistor 132. An open circuit indicates that the probe has become dislodged, whereas a valid resistance of a coding resistor 132 indicates a proper attachment of the probe 202. If the probe has become dislodged, the pulse oximeter 140 can sound an alarm, display a warning message, or both.” Kiani, 5:27-36.

VIII. CLAIM CONSTRUCTION

72. I understand that Petitioners and Dr. Anthony have proposed a potential construction of one term/phrase in the ‘868 patent, but otherwise contend that all terms/phrases in the challenged claims of the ‘868 patent do not require construction and can be afforded their plain and ordinary meanings. Anthony Decl., ¶¶64-67; Petition, 17-18.

73. I am also informed and understand that Petitioners have proposed certain claim constructions for the ‘868 patent in the Texas Case.

A. “voice recognition module” (Claim 11)

74. Petitioners and their expert assert that the phrase “voice recognition module,” which appears in Claim 11, should be construed according to its plain and ordinary meaning as it would have been understood by a POSITA, but to the extent it is construed as a means-plus-function term, the function should be construed as

voice recognition, and the corresponding structure should be construed as “any hardware, software, firmware, or any combination thereof that is capable of converting a voice command signal [] into a control signal.” Anthony Decl., ¶¶65-67; Petition, 18. For purposes of this declaration, I apply Petitioners’ proposed construction for this phrase in my analysis of the grounds in the Petition.

B. Petitioners’ Constructions in the Texas Case

75. I understand that Petitioners and Dr. Anthony do not propose a specific claim construction for the term “beam” in the Petition or in Dr. Anthony’s supporting declaration. Anthony Decl., ¶¶64-67; Petition, 17-18. I further understand that the parties exchanged their preliminary claim constructions in the Texas Case. *See* Ex. 2033; Ex. 2034. The parties have proposed an agreed construction for the term “beam” in claims 7–9 of the ’868 patent which is “photons or light transmitted to a particular location in space.” *See* Ex. 2033; Ex. 2034. For purposes of this declaration, I apply this agreed construction of this term in

analyzing the grounds set forth in the Petition. However, my conclusion would remain the same even if the plain and ordinary meaning were applied.

IX. OPINIONS ON GROUNDS IN THE PETITION

76. The Petition and Dr. Anthony's declaration include eight grounds challenging the validity of the '868 Patent. Anthony Decl., ¶¶72; Petition, 7. My opinions on each ground follow.

A. Ground 1: Obviousness Based on Mault (Claims 7, 10-11, 14)

77. In Ground 1, Petitioners and Dr. Anthony assert that claims 7, 10-11, and 14 of the '868 patent are unpatentable for obviousness over Mault. Anthony Decl., ¶¶76-130; Petition at 19-46.

78. For at least the reasons discussed below, I disagree with Petitioners' and Dr. Anthony's analysis and conclusions.

79. Mault discloses a fundamentally different type of nutritional glucose management system—a biochemical glucose control algorithm that predicts blood glucose responses based on user input, dietary data, and insulin delivery parameters. Mault's disclosure is directed to predictive glucose management, not to the type of integrated spectroscopic diagnostic system recited in the challenged claims. Mault, [0090], [0125], [0130]. Nothing in Mault describes, suggests, or implies the claimed system's required hardware components, optical functionalities, or integrated

architecture for generating, processing, and analyzing light-based diagnostic signals.

80. Petitioners' and Dr. Anthony's theory rests entirely on hindsight reconstruction, unsupported expert conclusions, and speculative assertions about what a POSITA might have been able to do, rather than on what Mault actually teaches or suggests. A POSITA, relying only on Mault's disclosure, would not have been motivated to arrive at the claimed invention, nor would there have been a reasonable expectation of success in doing so. Accordingly, Mault neither anticipates nor renders the challenged claims obvious.

1. **Independent Claim 7**

a. Mault Fails to Disclose Or Render Obvious a Semiconductor Diode Light Source (Claim [7.a]: “a light source comprising one or more semiconductor diodes generating an input light beam;”) and a Lens System for Delivering Light to Tissue (Claim [7.b]: “a lens system configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user's body comprising blood, wherein at least the portion of the input light beam is used in a measurement on a user;”)

81. Dr. Anthony and Petitioners cite Mault's general mention of light emitting diodes (LEDs), asserting that “Mault discloses a light source comprising one or more semiconductor diodes.” Anthony Decl., ¶84.

82. When properly read together, claims [7.a] and [7.b] require a coordinated optical configuration in which a semiconductor diode generates an input light beam that is subsequently received and directed by a lens system onto the user's blood-containing tissue.

83. However, Mault merely states that “[t]he blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through or reflected by blood-containing tissue, and then detected by a near-IR detector.” Mault, [0020]. This passage provides only a general statement regarding possible light sources for glucose sensing and does not identify the structure, configuration, or optical behavior necessary to satisfy the claimed features of [7.a] and [7.b].

84. The mere mention of “semiconductor diodes” in Mault is not a disclosure of a light source that generates an “input light beam” for subsequent optical manipulation—specifically, for transmission through a downstream lens system as set forth in claim [7.b]. Mault’s generalized reference to LEDs or lasers provides no teaching of beam formation, collimation, or coupling into any optical train or lens system. Rather, it describes simple light emission from a diode, not the generation of an input beam configured for being input into a lens system.

Accordingly, even if Mault's LEDs emit light, the emitted light is not the "input light beam" recited in claim elements [7.a] or [7.b].

85. Contrary to the assertions of Petitioners and Dr. Anthony, Mault does not disclose "a lens system configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user's body comprising blood, wherein at least the portion of the input light beam is used in a measurement on a user" as required by claim [7.b]. Petitioners' and Dr. Anthony's broad characterization of Mault overlooks that the reference never describes, depicts, or implies any optical assembly or lensing configuration for transmitting light to tissue in the manner recited in the challenged claim.

86. By contrast, the '868 patent expressly teaches the presence and structure of a lens system, stating:

A lens system is configured to receive at least the portion of the output beam and to communicate at least the portion of the output beam through a patient's mouth onto a part of a patient's body comprising a patient's blood. In various embodiments, at least the portion of the output beam is adapted for use in medical diagnostics to measure a property of the patient's blood, wherein the medical diagnostics comprise a spectroscopic procedure comprising a differential measurement, wherein the differential measurement is based at least in part on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from the patient's blood.

'868 patent, 3:17-28.

87. In addition, the '868 patent provides examples of various optical configurations that may be used in implementing such systems. For instance, it

describes embodiments that employ multiple laser diodes combined by a multiplexer, and others in which Raman wavelength shifters and delivery optics, such as tapered ends or lenses, may be used.

In this particular example, pump source 900 comprises a first laser diode 942 a and a second laser diode 942 b each centered at a desired wavelength and capable of generating pump signals 943 a and 943 b. Although this example includes two laser diodes, any number of laser diodes may be used without departing from the scope of the present disclosure. In various embodiments, laser diodes 942 a and 942 b can be centered on substantially the same wavelength, such as 980 nm, 1310 nm, 1390 nm, 14xx nm, or 1510 nm. In this particular embodiment, pump signals 943 a and 943 b are combined by multiplexer 944. Multiplexer 944 can comprise any device capable of combining pump signals 943, such as a wavelength division multiplexer. In various embodiments, multiplexer 944 can be capable of polarization and/or wavelength multiplexing pump signals 943 a and 943 b to form a pump output signal.

In some embodiments, a Raman wavelength shifter, such as those illustrated in FIGS. 8A through 8D, may be used to deliver an optical signal wavelength directly to the patient. In other embodiments, a second mid-IR waveguide structure, that at least partially transmits in at least a portion of the mid-IR wavelength range, may be coupled to the output of the Raman wavelength shifter to deliver the optical signal wavelength to the patient. Coupling a second mid-IR waveguide structure to the Raman wavelength shifter can advantageously allow the delivery waveguide structure to be disposed after use within the patient. In addition, coupling a second mid-IR waveguide structure can substantially reduce the chance of breaking a fiber associated with a Raman wavelength shifter. Furthermore, it may be desirable to couple a tapered end or lens on the delivery fiber for improved focusing of optical signal on the patient.

‘868 patent, 23:3-25.

88. Mault, by contrast, contains no such disclosure. It never describes or implies a “lens system” that receives an “input light beam” and communicates it

onto blood-containing tissue. The only relevant statement appears in paragraph [0020], which merely provides that “[t]he blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through or reflected by blood-containing tissue, and then detected by a near-IR detector.” Mault, [0020]. This generalized description does not mention or suggest any lens or other optical component that provides a lens system that receives at least a portion of an input light beam and communicates at least a portion of the input light beam onto part of a user’s body. It simply identifies emission and detection in functional terms, without specifying any optical geometry, beam path, or lens system mechanism. Mault, [0020].

89. Recognizing the absence of any lens system in Mault, and without citing a single relevant passage from the Mault reference, Petitioners and Dr. Anthony instead attempt to fill this gap by relying on the concept of “lens encapsulants.” Anthony Decl., ¶¶87-90. They cite prior IPR final written decisions (’533-FWD, 36; ’484-FWD, 23) to suggest that LEDs commonly include encapsulating material that can act as a lens. *See* Anthony Decl., ¶88 (“For example, as the Board previously found in its final written decisions in the prior ’533 and ’484 IPRs, “a [person of ordinary skill in the art] would have known that LEDs are often covered by lensing encapsulants, and would have selected such LEDs for

wireless sensor 102/312 in order to ‘direct more of the light produced by the LED outward toward the tissue.’”).

90. However, Petitioners and Dr. Anthony fail to explain why the Board’s findings in unrelated IPRs, involving different patents and later priority dates, would apply to this proceeding concerning the ’868 patent. The cited explanation in those prior decisions specifically addressed the Lisogurski reference, not Mault. *See* Anthony Decl., ¶88 (“a [person of ordinary skill in the art], knowing a lens is a basic building block of an optical sensor, would have included lenses in Lisogurski’s wireless sensor 102/312.”). Dr. Anthony himself acknowledges that “the ’533 and ’484 have a later claimed priority date (in 2012) than the earliest claimed priority date of the challenged ’868 patent here (in 2002),” yet he fails to address the ten-year technological gap or provide any rationale for applying those findings retroactively. The additional reliance on unrelated U.S. Patent Nos. 5,122,943 (Ex. 1035) and 6,661,167 (Ex. 1036) likewise does not supply the missing disclosure, as Petitioners identify no motivation to combine those references with Mault, nor do they demonstrate that the alleged encapsulant structure performs the claimed function. Anthony Decl., ¶89.

91. In any case, Dr. Anthony does not show that the purported “lens encapsulants,” even if assumed to exist, would be “configured to receive at least a portion of the input light beam and to communicate at least the portion of the input

light beam onto a part of a user's body comprising blood," as expressly required by claim [7.b]. Anthony Decl., ¶¶87-90. The prior Board findings concerned different patents and addressed whether LEDs inherently have encapsulants capable of directing emitted light, not whether such encapsulants constitute a lens system that receives an input light beam formed upstream of the lens system. '533-FWD, 36; '484-FWD. The issue of a "lens system" was never at stake in those IPRs, making those findings irrelevant to the '868 patent's distinct claim requirements. '533-FWD; '484-FWD.

92. Moreover, a POSITA can understand that any lens covering or encapsulant typically associated with an LED merely assists the light emission from that LED—it does not constitute a "lens system configured to receive" an already formed input beam as required by claim [7.b] for further optical communication. In the context of the '868 patent, the claimed "lens system" is a distinct and downstream optical component that receives, focuses, and communicates at least a portion of the input light beam onto the user's tissue. The LED's integral encapsulant or lens cover forms part of the diode package itself and serves only to assist emission; it is not a distinct optical system receiving an input beam. Thus, even if Mault's LEDs have encapsulating materials, those structures do not meet the claimed "lens system" requirement.

93. In summary, neither Petitioners nor Dr. Anthony identifies any disclosure in Mault describing or implying a lens system positioned in the light beam path that performs the claimed optical function. Mault provides no teaching of a lens structure that receives, focuses, or directs an input light beam from a semiconductor source to a user's body. Accordingly, Mault does not disclose, suggest, or render obvious at least the "input light beam" and "lens system" limitations of claim [7.a] and [7.b].

b. Mault Fails to Disclose Or Renders Obvious a Host Receiving and Processing Wireless Data (Claim [7.f]: "a host comprising: a digital file for receiving and storing at least a portion of the wireless data; control logic at the host to process at least the portion of the wireless data to generate a status of the user; a memory storage device for recording the status; and an output for communicating at least a portion of the status or associated information over a communication link to one or more display output devices, wherein the one or more display output devices are located remotely from the host.")

94. Mault fails to disclose the claimed host "comprising a digital file for receiving and storing at least a portion of the wireless data" and "control logic ... to generate a status of the user." Petitioners and Dr. Anthony misread Mault's system architecture and overextend its disclosure to suggest functionality that does not exist in the reference.

95. Petitioners and Dr. Anthony rely on Mault's "remote server system 56" as supposedly corresponding to the claimed "host." *See* Anthony Decl., ¶112.

However, their reliance is misplaced because Mault's remote server performs a fundamentally different function.

96. In Mault, the remote server stores user input data such as diet, activity, and insulin dosage, but is not configured to receive or store wirelessly transmitted physiological data based on an optical measurement of the user. Mault, [0077], [0079], [0106]. Nor does Mault's remote system include "control logic" capable of generating a "status of the user" as claimed. Petitioners' and Dr. Anthony's interpretation that Mault's remote server equates to the claimed "host" is unsupported by the intrinsic disclosure and technically inaccurate. Anthony Decl., ¶¶113-117.

97. For example, Mault discloses only that:

Remote computer system 22 may be a remote server, physicians computer, home computer, or other computer system accessible over the communications network 20. The PDA can access the communications network, such as the Internet, using a wireless connection. Data can be transferred to the remote system over the communications network 20, allowing examination by a dietician, physician, other specialist, or by the person themselves using the PDA or any computer. Feedback, generated by a specialist or computer expert system, may be transmitted to the PDA from the remote computer over the communications network.

Mault, [0077].

The portable computing device 30 is in linked to a communications network 52, allowing communication a remote computer system 54, which may be located at the person's home, doctor's office, or other remote location. A remote server system 56 is also accessible through the communications network 52, and can be used to store a database of physiological parameters,

activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.

Mault, [0079].

The electronic device 240 is used as a diet log and to store blood glucose readings. The device provides dietary feedback to the mother based on a measured and modeled (or estimated) glycemic response. The device also collects data from physiological sensors monitoring the health of the baby and/or mother. An audible alert can sound if projected or actual blood glucose levels deviate from a predetermined range.

Mault, [0106].

98. None of these passages disclose or suggest that the “remote server system 56” receives wireless physiological data from sensors and processes that data using host-side logic to determine a user’s physiological “status.” Rather, Mault’s system operates as a database and communication node for logging and reviewing nutritional information. Mault, [0077], [0079], [0106].

99. Mault likewise fails to disclose “a digital file for receiving and storing at least a portion of the wireless data.” Petitioners and Dr. Anthony incorrectly equate Mault’s mention of a “database” on a “remote server” with a “digital file” as claimed. Claim [7] of the ’868 patent expressly requires that “at least the portion of the input light beam is used in a measurement on a user; ... generating data based at least in part on the measurement on the user, wherein the data represents at least in part physiological information associated with the user; ... the wireless data comprising at least a part of the physiological information.” Nothing in Mault

describes or implies that a digital file receives and stores transmitted physiological wireless data based on optical measurement results, as required by the claim. '868 patent, claim 7.

100. Lacking such a disclosure in Mault, Dr. Anthony attempts to rely on extrinsic reasoning outside the reference, asserting that:

A person of ordinary skill in the art would have known, or at minimum found obvious, that the remote server's database is a digital file ... because databases are stored in files in a server or system's storage. Since system information is stored in files and a database is a structured collection of information, a database would also be stored on the system as one or more files—and at minimum it would have been obvious to do so, as illustrated by e.g., U.S. Patent Nos. 5,544,357 [Ex. 1031] and 4,817,050 [Ex. 1032].

See Anthony Decl., ¶114.

101. This statement merely generalizes how data storage works and does not establish that Mault's "database" corresponds to the claimed "digital file" for receiving wireless physiological data generated from an optical measurement. Nor does it provide any articulated reasoning or motivation to combine Mault with the unrelated patents cited. Anthony Decl., ¶114.

102. The disclosure in Mault of "stor[ing] a database of physiological parameters" (Mault, [0079]) is distinct from storing transmitted wireless physiological data based on optical measurement as claimed. Mault's server functions as a static repository of input information, not a receiver of active wireless measurement data. Mault, [0079] ("A remote server system 56 is also accessible

through the communications network 52, and can be used to store a database of physiological parameters, activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.”). Likewise, Mault’s general reference to data does not equate to the transmitted wireless physiological data based on optical measurement as claimed. Mault, [0077] (“Data can be transferred to the remote system.”).

103. Mault also fails to disclose “control logic at the host to process ... the wireless data to generate a status [of the user].” None of the Petitioners’ or Dr. Anthony’s cited portions of Mault identify any host-side control logic, computation, or algorithm for generating a user status based on transmitted measurement data. The only relevant disclosure refers to a “PDA ... used to monitor the physiological state of the person” based on “a variety of monitoring methods from other physiological sensors.” Mault, [0201]. This description concerns the handheld device’s monitoring capability, not any host-side computation or logic.

104. Mault’s references to “computer expert system” and “feedback” are undefined and likewise fail to disclose the required control logic. Anthony Decl., ¶117. For example, Mault states: “The PDA can access the communications network, such as the Internet, using a wireless connection. Data can be transferred to the remote system over the communications network 20, allowing examination by a dietician, physician, other specialist, or by the person themselves using the

PDA or any computer. Feedback, generated by a specialist or computer expert system, may be transmitted to the PDA from the remote computer over the communications network.” Mault, [0077]. These generic statements describe communication and user interaction, not algorithmic processing or logical generation of a user’s “status” at the host. Mault, [0077].

105. The generic connectivity and display functionality described for Mault’s remote systems do not attribute any host-side computation to the transmitted physiological data. *See* Anthony Decl., ¶117.

106. Because Mault does not disclose or render obvious any of the host-related limitations—including a digital file for receiving and storing wireless data, control logic for generating a user status, or host-side output of such information—Ground 1 fails with respect to claim 7.

2. Dependent Claims 10-11, 14

107. Petitioners and Dr. Anthony’s discussion of these dependent claims does not address the deficiencies I discussed above with respect to Claim 7. Thus, I disagree with Petitioners’ and Dr. Anthony’s conclusions for dependent claims 10-11, and 14 for at least the same reasons as independent claims 7. Anthony Decl., ¶¶119-130.

B. Ground 2: Obviousness Based on Mault in view of Mitsui (Dependent Claim 9)

108. In Ground 2, Petitioners and Dr. Anthony assert that dependent claim 9 of the ‘868 patent is obvious over Mault in view of Mitsui. Anthony Decl., ¶¶131-141; Petition, 46. Dependent claim 9 depends from independent claim 7, and therefore incorporates all of its limitations.

109. Petitioners’ and Dr. Anthony’s analysis of claim 9 fails to address the same fundamental deficiencies discussed above with respect to claim 7. Because Mault does not disclose or render obvious the essential features of claim 7—including the semiconductor light source, lens system, and host for wireless data processing—the combination of Mault and Mitsui necessarily fails to render dependent claim 9 obvious. Accordingly, I disagree with Petitioners’ and Dr. Anthony’s conclusions regarding claim 9 for at least the same reasons explained for claim 7.

110. Claim 9 recites: “The diagnostic system of claim 7, wherein at least the portion of the input light beam is adapted for use in a diagnostics to measure a property of the blood, wherein the diagnostics comprise a spectroscopic procedure, wherein the spectroscopic procedure is based at least in part on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from the blood.” ‘868 patent, claim 9.

111. Dr. Anthony and Petitioners assert that “The additional limitation in claim 9 is met by Mault in view of Mitsui.” *See* Anthony Decl., ¶131. I disagree.

Neither Mault nor Mitsui teaches or suggests the claimed spectroscopic diagnostic procedure based on the comparison of amplitudes at multiple associated wavelengths transmitted or reflected by blood.

112. Mitsui discloses that:

Using the present invention, the blood glucose concentration can be measured without collecting blood, thereby reducing the burden placed on the subject and enabling real-time measurement, which also allows for the measurement of the glucose concentration as it changes over time. Also, by calculating the amount of glucose from the ratio of the intensity of light having wavelength λ_1 , which is within the glucose absorption wavelength band, to the intensity of light having wavelength λ_2 , which is outside of the glucose absorption wavelength band, and then performing temperature correction, the measurement becomes less susceptible to variations in the measurement device and environmental conditions, enabling accurate measurements.

Mitsui, [0007].

113. Mitsui further discloses that:

FIG. 1 shows the glucose sensor in the present invention. This device measures the blood glucose concentration of blood flowing through the microvessels in the earlobe 4 of the human body. The wavelength of the light outputted from the first semiconductor laser 1 is $1.55\ \mu\text{m}$, which is within the glucose absorption wavelength band. It passes through the earlobe 4 and is received by the first photodetector 20. The wavelength of the light outputted from the second semiconductor laser 2 is $1.33\ \mu\text{m}$, which is outside of the glucose absorption wavelength band. It passes through the earlobe 4 and is received by the second photodetector 21. The third semiconductor laser 22 is used to measure the volume of blood flow, and the wavelength of the light that it emits has a wavelength of $0.83\ \mu\text{m}$. It passes through the earlobe 4 and is detected by the third photodetector 22. The volume of blood flow is measured using the Doppler effect, so infrared light, which has good transmissibility through biological tissue, is used to minimize the attenuation of light reflected by hemoglobin.

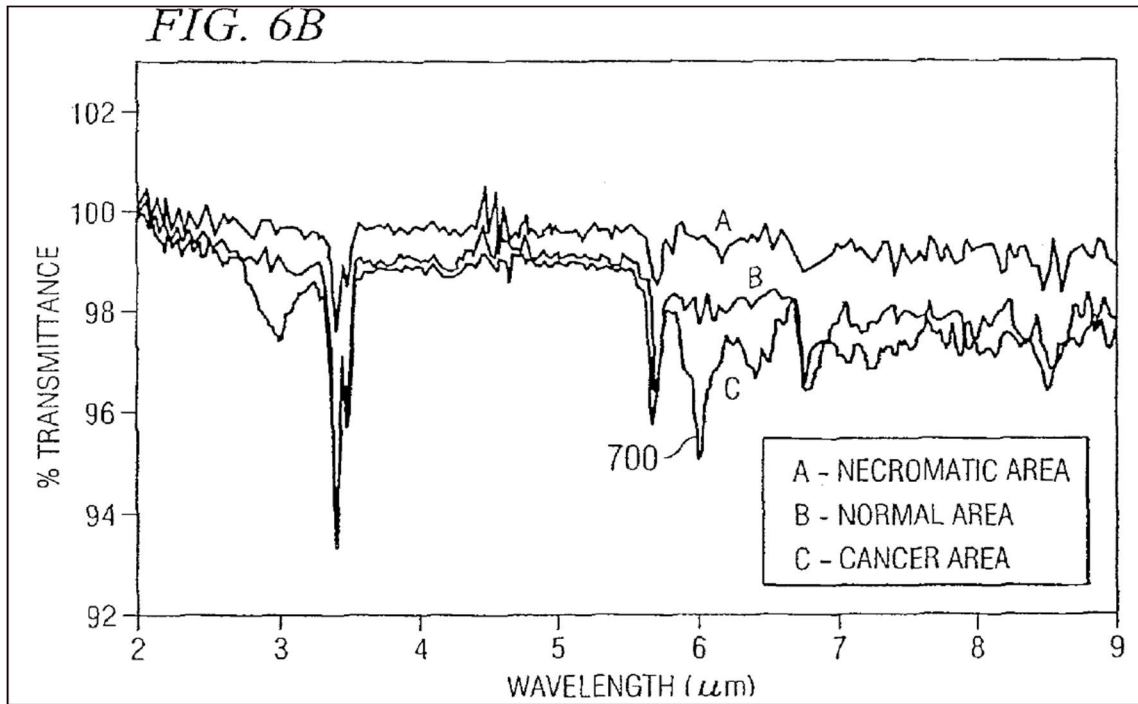
Mitsui, [0009].

114. However, Mitsui does not disclose a spectroscopic diagnostic procedure based on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from blood, as required by claim 9. Instead, Mitsui describes a system using three discrete laser sources, each paired with its own detector, to calculate glucose concentration using ratios of individual intensity measurements. Mitsui, [0009].

115. As Mitsui explains, its system employs multiple discrete photodetectors, each dedicated to a specific laser wavelength. Three semiconductor lasers (at 1.55 μm , 1.33 μm , and 0.83 μm) are used, and each has a corresponding photodetector (photodetectors 20, 21, and 22). Mitsui, [0009]. These detectors merely measure the intensity of light transmitted or reflected at their respective wavelengths. The signals are then compared to determine glucose concentration and blood flow characteristics. Mitsui, [0009]. This approach represents a simple multi-point intensity comparison, not a spectroscopic analysis that resolves and compares amplitudes across a continuous spectrum or finely sampled range of wavelengths.

116. In contrast, the spectroscopic diagnostic system described in the '868 patent operates fundamentally differently. The '868 patent employs broadband or multiwavelength light dispersed through a grating or prism and detected by a single

spectrometer or detector array capable of recording an entire spectrum simultaneously, as shown in FIG. 6B (reproduced below) of the '868 patent. *See* '868 patent at FIGS. 8A through 8D and associated descriptions.



117. Rather than using separate detectors for each wavelength, the '868 patent's system disperses the "input light beam" into its component wavelengths and measures the amplitude across hundreds of spectral channels at once. *See* '868 patent at FIGS. 8A through 8D and associated descriptions. This enables comparison of spectral amplitudes over a wide wavelength range to detect subtle biochemical and structural variations in blood. '868 patent at 18:24-41. This type of spectroscopic procedure—based on amplitude comparisons at a plurality of

associated wavelengths—is not disclosed or suggested by Mitsui’s limited, discrete-wavelength system or by Mault’s generalized glucose control algorithm.

118. In sum, neither Mault nor Mitsui, alone or in combination, discloses or renders obvious the spectroscopic diagnostic system required by claim 9. Their teachings are technologically distinct from the claimed method, and the combination proposed by Petitioners and Dr. Anthony fails to meet the limitations of the ‘868 patent.

C. Grounds 3-4: Obviousness Based on Grounds 1-2 in view of Pologe (Claims 7-11, 14)

119. In Grounds 3-4, Petitioners and Dr. Anthony assert that claims 7-11, 14 of the ‘868 Patent are obvious over Grounds 1-2 in view of Pologe. Anthony Decl., ¶¶142-169; Petition, 51. For the reasons discussed below, I disagree.

1. Lack of Motivation to Combine Mault with Pologe

120. Pologe’s photoplethysmographic (PPG) device operates using one or two fixed wavelengths to measure blood oxygen level or volume changes. Pologe 1:6-8;19-29. PPG in Pologe is a fundamentally different technique: it measures time-dependent signal variations resulting from cardiac pulsation. Pologe 5:60-6:3 (“TDM [time division multiplexing] can be implemented by appropriately timing the pulsing of the individual light sources in the plurality of light sources 20.”). PPG systems are therefore incapable of producing the physiological or biochemical information derived from glucose level detection spectroscopic methods such as

those described in Mault, even when a wavelength-division multiplexing (WDM) coupler is used.

121. As illustrated in FIG. 1 of Pologe reproduced below, Pologe describes that “Light pulses are then delivered from the main test unit 12 to the probe 14 via a single optical transmission line in the probe cable 16. The light pulses are then directed into the finger 36, travel through the finger 36, and emerge on the other side of the finger 36, where they are received by a light pick up device 38. The received light pulses may then be delivered back to the main test unit 12, via probe

cable 16, where they are processed to determine the level of one or more blood analytes in the person's arterial blood.” Pologe, 4: 38-47.

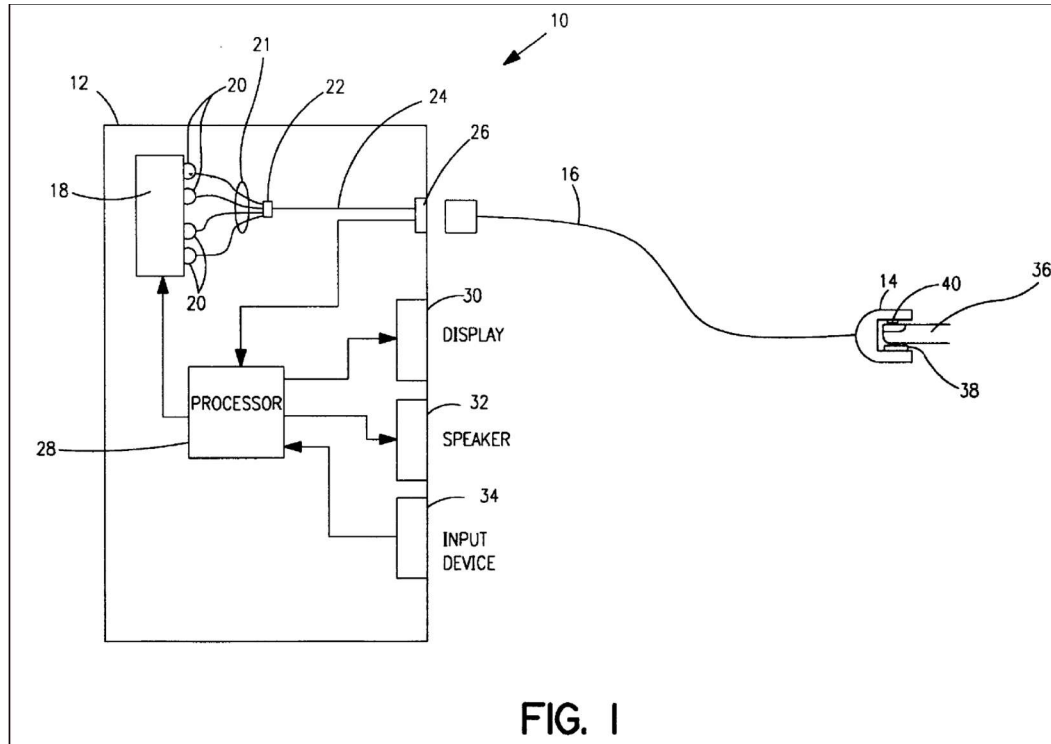


FIG. 1 of Pologe.

122. The Pologe and Mault references address distinctly different technical problems in unrelated contexts, and thus, there is no motivation for a POSITA to combine their teachings.

123. Pologe expressly states that it “relates in general to systems for performing photoplethysmographic measurements and is particularly apt for use in pulse oximetry systems.” Pologe 1:6-8. Pologe further explains that “[o]ne type of photoplethysmographic [(PPG)] process, known as pulse oximetry, is used to measure the oxygen saturation level of a person’s arterial blood. In a pulse oximetry

system, pulses of light having different spectral contents and center wavelengths are directed into the tissue under test, such as a finger or an earlobe. Transmitted light pulses are then received on the other side of the tissue under test (or in the case of a reflectance measurement, a small distance away on the same side) and are processed by the pulse oximetry system to determine the oxygen saturation level of the person's arterial blood.” Pologe, 1:19-29.

124. The purpose of Pologe is to improve the physical configuration of photoplethysmographic devices through the use of wavelength-division multiplexing (WDM) to deliver light from multiple narrowband emitters - “relatively narrow band light pulses having different center wavelengths” (Pologe, 1:11-17) - through a single light guide. Pologe, 2:7-16. As described in Pologe, the invention seeks to reduce the number of signal carriers, minimize probe heating, and make the probe small, lightweight, and inexpensive so that it can be disposable. Pologe, 2:16-44. To achieve this, Pologe positions the light sources in the main test unit and transmits a combined multiplexed light signal to a passive probe via a single fiber optic cable. *See* Pologe, 2:41-44 (“because the light sources are included in the main test unit, rather than the probe, the probe may be relatively lightweight, is not prone to heating, and is relatively inexpensive to produce, allowing it to be disposable.”) This configuration addresses mechanical and ergonomic concerns—

specifically simplifying cabling and reducing probe complexity—without changing the physiological measurement method or analyte being detected.

125. By contrast, Mault briefly discloses that the “blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR.... two wavelengths may be chosen, one absorbed and one not absorbed by blood glucose, the absorption ratio then being used to compute the blood glucose level of the person.” Mault, [0020]. Mault also states on a high level that “Infrared and Raman spectroscopy can also be used for noninvasive analysis of blood glucose levels. A module may be placed against the skin to detect the IR signature of glucose of fluid beneath the skin, or a spectroscopic mechanism can be included into the analysis module described above so as to detect levels of glucose within the interstitial fluid extracted from the skin.” Mault, [0089].

126. Mault’s problem is biochemical, not mechanical: its invention is aimed at identifying and analyzing subtle absorption differences to determine glucose concentration. Mault, [0089]. The structure and purpose of Mault’s device are fundamentally different from Pologe’s. Mault requires the light sources and photodetectors located at or near the tissue measurement site to perform differential analysis (Mault, [0020], [0089]), whereas Pologe deliberately relocates all light sources to the main unit to maintain a passive and disposable probe (Pologe, 2:16-

44). Because these two inventions pursue entirely different objectives - one analytical, the other ergonomic; and one nutritional, the other blood oxygen - there is no logical reason or technical motivation to combine them. Any such combination would not advance either reference's purpose and would instead represent hindsight reconstruction.

127. Moreover, combining Pologe and Mault would change the principle of operation of both systems and render the resulting device inoperable for its intended purposes. Integrating Mault's glucose-sensing architecture into Pologe's passive probe would defeat the very advantages that Pologe explicitly teaches. As Pologe emphasizes, "the light sources are included in the main test unit, rather than the probe, [so] the probe may be relatively lightweight, is not prone to heating, and is relatively inexpensive to produce, allowing it to be disposable." Pologe, 2:41-44. Mault's system, by contrast, requires emitters and detectors positioned at the earlobe or skin interface. Mault, [0020], [0089]. Incorporating such components into Pologe's probe would reintroduce heat, weight, and cost—the precise drawbacks Pologe sought to eliminate. As a result, the combination would fundamentally alter each device's mode of operation and render it unsuitable for either pulse oximetry or spectroscopic glucose detection.

128. For these reasons, a POSITA would neither have been motivated to combine Pologe and Mault nor have had a reasonable expectation of success in

doing so. The references address unrelated problems, rely on incompatible optical architectures, and depend on contradictory design principles. Any such combination would defeat the core objectives of both inventions and produce a system that is nonfunctional for either application. Accordingly, the claimed invention remains non-obvious over the proposed combination.

2. Independent Claim 7

a. Claim [7.b]

129. Pologe does not remedy or otherwise cure the deficiencies identified above with respect to Claim [7.b] in view of Mault. As previously explained, Mault fails to disclose claim [7.b].

130. Dr. Anthony asserts that “Pologe discloses a “lens system” (e.g., “lenses” within “WDM coupler”) configured to receive at least a portion of the input light beam (e.g., “light pulses” from “light sources, such as light emitting diodes”).” Anthony Decl., ¶154. For the same reasons as discussed above, a POSITA would not have been motivated to apply Pologe’s teaching of wavelength division multiplexing (WDM) couplers to Mault’s “blood glucose sensor.”

3. Dependent Claims 8-11, 14

131. Petitioners and Dr. Anthony’s discussion of these dependent claims does not address the deficiencies I discussed above with respect to Claim 7. Thus, I disagree with Petitioners’ and Dr. Anthony’s conclusions for dependent claims 8-

11, 14, for at least the same reasons as independent claims 7. Anthony Decl., ¶¶162-169.

D. Grounds 5-8: Obviousness Based on Grounds 1-4 in view of Kiani (Claims 7-11, 13-14)

132. In Grounds 5-8, Petitioners and Dr. Anthony argue that claims 7-11, 13-14 of the '868 Patent are obvious over Grounds 1-4 in view of Kiani. Anthony Decl., ¶¶170-187; Petition, 61. For the reasons discussed below, I disagree.

133. As explained in detail below, the teachings of Kiani do not remedy the deficiencies in Mault, Mitsui, or Pologe. In particular, Kiani fails to disclose or suggest the claimed “circuitry for obtaining position information from a location sensor” or “control system ... further coupled to a proximity sensor,” as recited in at least independent claim 7 and dependent claim 13.

1. Independent Claim 7

a. Limitation [7.e] (“circuitry for obtaining position information from a location sensor”)

134. Petitioners’ and Dr. Anthony’s reliance on Kiani’s “contact sensor” does not establish that claim 7’s “control system” includes “circuitry for obtaining position information from a location sensor” within the claimed system architecture. Anthony Decl., ¶¶170-187. Kiani’s disclosure concerns a fundamentally different sensing mechanism that does not provide positional or proximity data as required by the '868 patent. Kiani, 5:27-36; 6:53-62.

135. The '868 patent expressly describes sensors configured to generate positional or proximity information rather than binary contact data: “In one embodiment, sensors 442 are capable of generating and transmitting data associated with insertable portion’s 420 proximity to tissue of the patient.” ‘868 Patent at 13:37-40. This description makes clear that the claimed sensors are designed to measure spatial relationships or distances, enabling the system to detect how close the insertable portion is to the tissue.

136. In contrast, Kiani discloses only a “probe-off” detection system that determines whether a pulse oximeter sensor remains attached to the patient’s skin. Kiani states: “FIG. 6 illustrates one embodiment of a method 600 by which a pulse oximeter 140 detects a dislodged probe and/or a probe-off condition. At a step 604, the probe off detector module 138 checks for continuity between the skin contacts 341 and 342. If, at a step 608, there is continuity between the contacts 341 and 342, the oximeter 140 passes control to a step 612. If, on the other hand, there is no continuity at the step 608, the oximeter 140 passes control to a step 620. At step 620, the oximeter 140 sounds an alarm to alert a condition necessitating attention.” Kiani, 6:53-62.

137. This disclosure describes only binary contact detection, not the acquisition of “position information.” Kiani’s system determines merely whether the probe is in contact with the skin; it does not calculate spatial coordinates,

measure proximity, or determine the distance between the sensor and tissue. Kiani, 5:27-36; 6:53-62. Consequently, Kiani cannot determine the location of the device on the body or its relative position to a reference point. Simply detecting the presence or absence of contact does not satisfy the claim limitation requiring “circuitry for obtaining position information.”

138. Furthermore, the use of Kiani’s contact sensor is inconsistent with the safety objectives of the ‘868 patent. The ‘868 patent explicitly warns that:

Injury may occur when a medical professional accidentally or mistakenly causes insertable portion 420 to contact tissue associated with the patient, which can cause bruising or damage to the tissue. Sensors 442 can comprise any device capable of providing data and/or a signal to a medical professional. Sensors 442 may be capable of generating and transmitting, for example, positioning information associated with insertable portion 420, physiological information associated with the patient, control signals, a signal indicating the presence or absence of blood, or any other data. In one particular embodiment, sensors 442 are capable of generating and transmitting data associated with insertable portion’s 420 proximity to tissue of the patient.

‘868 patent at 13: 27-40.

139. The ‘868 patent’s system is explicitly designed to avoid physical contact with tissue by monitoring proximity (‘868 patent at 13: 27-40), whereas Kiani’s design requires physical contact to function (Kiani, 5:27-36; 6:53-62). Thus, substituting Kiani’s contact sensor into the claimed architecture would defeat the safety and functional purpose of the ‘868 patent and render the resulting system non-operational for its intended use.

140. Kiani's sensor is operational only when it makes contact with the patient's skin (Kiani, 6:53-62), while the '868 patent requires sensors capable of detecting positional or proximity information to prevent unwanted contact ('868 patent at 13: 27-40). Combining Kiani with Mault or other cited references would not produce an operative system as disclosed and intended by the '868 patent. Accordingly, Kiani does not disclose or suggest the circuitry for obtaining position information from a location sensor as recited in claim 7.

2. Dependent Claims 8-11, 13-14

a. Claim 13 (“wherein the control system is further coupled to a proximity sensor.”)

141. Petitioners' and Dr Anthony's reliance on Kiani's “contact sensor” also fails to establish that the claimed “control system” is “further coupled to a proximity sensor” as required by claim 13. Anthony Decl., ¶¶182-187. The Kiani reference does not disclose any proximity-based sensing function or circuitry for non-contact positional detection. Its “probe-off” feature merely detects the presence or absence of electrical continuity between contacts, which does not equate to the claimed proximity sensing. Kiani, 5:27-36; 6:53-62.

142. For the same reasons discussed above with respect to the “location sensor” in claim 7, Kiani, alone or in combination with Mault, Mitsui, or Pologe, does not teach or suggest the claimed “proximity sensor,” nor would any such combination produce an operable invention consistent with the system architecture

disclosed in the '868 patent. The Kiani system's contact-based design directly contradicts the '868 patent's proximity-based, non-contact sensing objective.

X. CONCLUSION

143. 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.

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

Date: November 6, 2025



Igor Efimov