

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WHOOOP, INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

U.S. Patent No. 9,651,533

Case No. IPR2025-01583

DECLARATION OF IGOR EFIMOV, PH.D.

TABLE OF CONTENTS

	Page
I. BACKGROUND AND QUALIFICATIONS	2
II. MATERIALS CONSIDERED.....	10
III. LEGAL STANDARDS.....	11
A. Level of Ordinary Skill in the Art.....	12
B. Claim Construction	12
C. Anticipation.....	14
D. Obviousness	15
E. Dependent Claims	19
IV. LEVEL OF SKILL IN THE ART	20
V. OVERVIEW OF THE '533 PATENT	21
VI. PROSECUTION HISTORY OF THE '533 PATENT	23
VII. CHALLENGED CLAIMS.....	24
VIII. CLAIM CONSTRUCTION	25
A. Prior Constructions of the Board	25
B. Texas Case Constructions.....	26
IX. OVERVIEW OF ASSERTED GROUNDS AND REFERENCES IN THE PETITION	28
A. Petitioner's Obviousness Grounds.....	28
B. Summary of Asserted References.....	28
X. OPINIONS ON GROUNDS IN THE PETITION	33
A. Ground 1: Obviousness Based on Lisogurski in view of Carlson (Claims 11, 12, and 18)	33
B. Ground 2: Obviousness Based on Lisogurski in view of Carlson and Walker (Claims 6 and 14).....	51
C. Ground 3: Obviousness Based on Lisogurski in view of Carlson and Tam (Claims 6 and 14).....	57
XI. CONCLUSION	63

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. 9,651,533 (“the ’533 Patent”) (Ex. 1001) in connection with an *inter partes* review (“IPR”) petition filed by Whoop, Inc. (“Petitioner”).

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 ’533 Patent against Whoop, Inc., in a related matter currently pending in the United States District Court for the District of Delaware (the “Delaware Case”).

5. I understand that Omni is asserting the ’533 Patent against Samsung Electronics Co., Ltd., and others, in a related matter currently pending in the United States District Court for the Eastern District of Texas (“the Texas Case”).

6. I further understand that the Defendants in the Texas Case have filed an IPR petition challenging the ’533 Patent in IPR2025-01250 (“the Samsung ’533

IPR”). I have offered certain opinions regarding the ’533 Patent and the grounds in the Samsung ’533 IPR in a declaration dated November 6, 2025 (Ex. 2031 in Samsung ’533 IPR). Ex. 2059. Certain content in this declaration may overlap with content in my declaration in the Samsung ’533 IPR. For example, the Overview of the ’533 Patent (Section V in this declaration) is the same or substantially the same in both declarations.

7. In this declaration, I offer opinions relating to the ’533 Patent, claim construction, the references in the Petition, and the declaration of Petitioner’s expert, Dr. Mercier. The substance and bases of my opinions appear below.

I. BACKGROUND AND QUALIFICATIONS

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

9. 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, from 2015 to 2022, 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.

10. 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.

11. 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.

12. 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, medical devices, 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, medical diagnostic, and therapeutic devices.

13. 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.

14. 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.

15. 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).

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

17. 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.

18. In 2021-2025, I served as the Editor-in-Chief of Cardiovascular Engineering and Technology, a journal of the Biomedical Engineering Society, published by Springer Nature. I was responsible for reviewing and decision-making of approximately 250-300 manuscripts submitted for publication, including biomedical imaging, medical devices, cardiac electrophysiology, signal processing, arrhythmia therapy, etc.

19. 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.

20. 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 to 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.

21. 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.

22. 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.

23. 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.

24. A more detailed listing of my credentials is set forth in my curriculum vitae (Ex. 2047).

II. MATERIALS CONSIDERED

25. 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 '533 Patent (Ex. 1001), the '533 Patent's file history (Ex. 1002), and at least the following additional materials:

- Petition for *Inter Partes* Review of the '533 Patent (Paper 1) (“Petition”);
- Declaration of Dr. Patrick Mercier in Support of Petition for *Inter Partes* Review of U.S. Patent No. 9,651,533 (Ex. 1003);
- Final Written Decision in *Apple Inc. v. Omni MedSci, Inc.*, IPR2019-00916, Paper 39 (PTAB Oct. 14, 2020) (Ex. 1008);

- U.S. Patent No. 9,241,676 (“Lisogurski”) (Ex. 1027);
- U.S. Pat. App. Pub. No. 2005/0049468 (“Carlson”) (Ex. 1028);
- “The Biomedical Engineering Handbook,” by Joseph D. Bronzino (1995) (Ex. 1033);
- U.S. Patent No. 6,144,867 (“Walker”) (Ex. 1044);
- U.S. Patent No. 7,029,628 (“Tam”) (Ex. 1046)
- Joint Claim Construction and Prehearing Statement, *Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.*, 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Nov. 21, 2025) (Ex. 2049).

26. I have 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.

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

III. LEGAL STANDARDS

28. 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. Level of Ordinary Skill in the Art

29. I understand that the claims and specification of a patent are addressed to and intended to be read by others of skill in the art to which the patent pertains, or to which the patent is most nearly connected, at the time of the filing of the patent application.

30. I understand that a person of ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to be aware of all of the pertinent art. The person of ordinary skill is not an automaton, and may be able to fit together the teachings of multiple prior art references employing ordinary creativity and the common sense that familiar items may have obvious uses beyond their primary purposes.

31. I understand that multiple factors should be used to decide the skill of the POSITA, including: the types of problems encountered in the art, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the education level of active workers in the field.

B. Claim Construction

32. 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.

33. I understand that claim construction is the process by which the scope and meaning of terms used in the claims of a patent is 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 POSITA at the time of the invention, after reading the patent and its prosecution history.

34. 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.

35. 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.

36. 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.

C. Anticipation

37. 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 under U.S. patent law: (1) each and every claim element must be identically disclosed, either explicitly or inherently, in a single prior art reference; (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, the anticipation contention fails. Moreover, 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.

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

D. Obviousness

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

45. 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 problems. That individual elements of the claimed invention are disclosed in the prior art is not alone sufficient to reach a conclusion of obviousness.

46. 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.

47. 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.

48. 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.

49. 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.

E. Dependent Claims

50. I understand that a dependent claim incorporates each and every limitation of the claim from which it depends. Thus, 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 dependent claims that depend from the independent claim.

IV. LEVEL OF SKILL IN THE ART

51. 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.

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

“A person of ordinary skill in the art (“POSITA”) at the time of the alleged invention (December 2012) would have had good working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques. EX1003 ¶ 25. The POSITA would have an undergraduate degree in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience studying or developing physiological monitoring devices (e.g., non-invasive optical biosensors) in industry or academia. *Id.* Lack of professional experience can be remedied by additional education, and vice versa. *Id.*”

Petition at 13.

53. For purposes of this declaration, I have applied Petitioner’s proposed definition in my analysis. I reserve the right to identify a differing level of skill in the art for the ’533 Patent should an IPR be instituted.

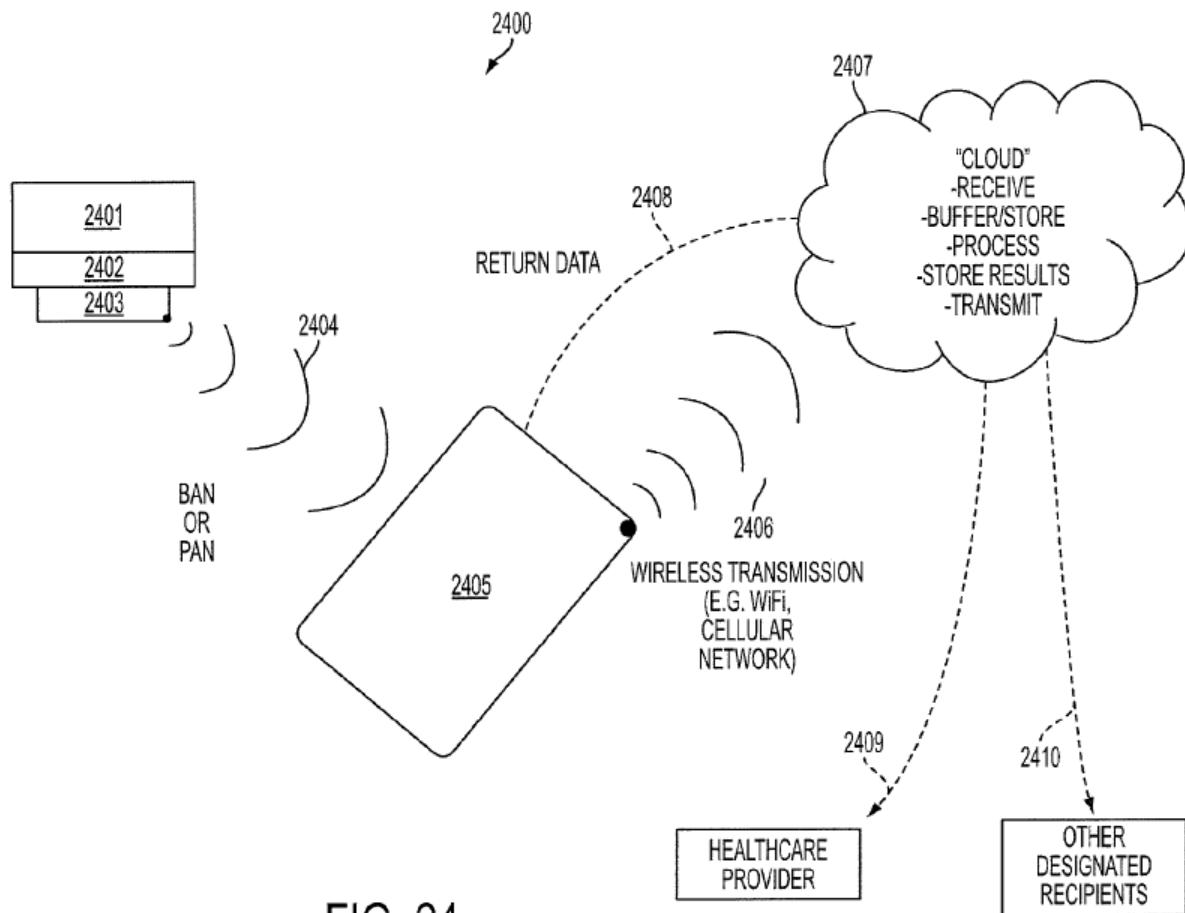
54. As of the relevant time period of December 2012, I was at least a person of ordinary skill in the art through my education and experience under the definition Petitioner has proposed. I am also familiar with individuals having this level of skill

in the relevant timeframe and am capable of addressing the issues from the perspective of such a person, and I have done so in this declaration.

V. OVERVIEW OF THE '533 PATENT

55. The '533 Patent discloses systems for non-invasive physiological measurements. Ex. 1001 at 8:29-34, 3:66-4:32. The '533 Patent describes using spectroscopy to inspect a bodily sample of a user “by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, fluorescence, refractive index, or opacity.” Ex. 1001 at 8:29-34.

56. An exemplary physiological measurement system is depicted in Figure 24:



Ex. 1001 at FIG. 24

The system includes a wearable measurement device 2401, a personal device 2405, and a cloud server 2407. Ex. 1001 at 26:49-27:20.

57. The wearable measurement device includes a light source, including light-emitting diodes (“LEDs”), which emit light of particular wavelengths, and a detection system. Ex. 1001 at 19:23-30, 10:18-22. The specification discloses two types of LEDs: (1) those that “emit a wavelength band that is ... between about 20 nm to 40 nm” and (2) “so-called super-luminescent LEDs that may even emit over

a much wider wavelength range.” Ex. 1001 at 20:2-9. The LEDs may emit light with a wavelength band that is between 20 nm to 40 nm in width. Ex. 1001 at 20:2-4. Filters may be used in front of one or more detectors in the detection system to select the wavelengths of light to be detected. Ex. 1001 at 17:50-54. The detection system generates a signal in response to the detected light, which may be generated by comparing signals at different wavelengths of light. Ex. 1001 at 5:18-21, 8:29-34. The wearable measurement device improves the signal-to-noise ratio of the signal with various techniques, which improves the accuracy of the measurement of the user’s physiological parameters despite interference from spectral artifacts. Ex. 1001 at 16:54-17:6, 3:59-4:32.

58. The ’533 Patent includes 18 claims. Claims 1, 5, and 13 are independent claims. The Petition challenges dependent claims 6 and 11-12 (which depend from claim 5) and dependent claims 14 and 18 (which depend from claim 13).

VI. PROSECUTION HISTORY OF THE ‘533 PATENT

59. I have reviewed and analyzed the prosecution history of the ’533 Patent. I understand that the ’533 Patent issued from U.S. Patent Application No. 14/875,709, which was filed on October 6, 2015.

60. I understand that U.S. Patent Application No. 14/875,709 was a continuation of U.S. Patent Application No. 14/108,986, which was filed on December 17, 2013 and issued as U.S. Patent No. 9,164,032.

61. I understand that the '533 Patent claims priority to Provisional Application No. 61/747,487, which was filed on December 31, 2012 and drafted at least as early as October 10, 2012.

62. I understand that a third party previously filed a petition requesting *inter partes* review of claims 5, 7-10, 13, and 15-17 of the '533 Patent and that the Board found those claims unpatentable as obvious. I am informed and understand that the Board did not address the patentability of the challenged claims in this Petition during the prior proceeding.

VII. CHALLENGED CLAIMS

63. I understand that the Petition challenges claims 6, 11-12, 14, and 18 (“the challenged claims”) of the '533 Patent and Dr. Mercier offers opinions that claims 6, 11-12, 14, and 18 are obvious. Petition at 11; Ex. 1003, ¶ 80.

64. Claims 6 and 11-12 each depend on independent claim 5 and claims 14 and 18 each depend on independent claim 13.

65. Claim 6 recites: “at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers to 40 nanometers.” Ex. 1001 at 30:11-13.

66. Claim 11 recites: “the receiver further comprises one or more filters in front of one or more detectors to select a fraction of the one or more optical wavelengths.” Ex. 1001 at 30:38-41.

67. Claim 12 recites: “the output optical beam comprises a plurality of

optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths.” Ex. 1001 at 30:42-45.

68. Claim 14 recites: “at least one of the light emitting diodes emits light with a bandwidth between approximately 20 nanometers to approximately 40 nanometers.” Ex. 1001 at 31:21-24.

69. Claim 18 recites: “the receiver further comprises one or more filters in front of one or more detectors to select a fraction of the one or more optical wavelengths.” Ex. 1001 at 32:19-22.

VIII. CLAIM CONSTRUCTION

70. Petitioner and Dr. Mercier contend that “The only construction that is relevant to the Challenged Claims in this Petition is “beam”...[t]o the extent the Board finds it necessary to reach the construction of beam to resolve the issues below, “beam” should be construed to “refer to photons or light transmitted to a particular location in space.” Petition at 11; Ex. 1003 at ¶ 44.

71. For purposes of this declaration, I have been asked to apply this construction.

A. Prior Constructions of the Board

72. I understand that in the prior IPR of the ’533 Patent, the Board construed the term “personal device” as “a computer or microprocessor-based device having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker,

one or more buttons or knobs, a microprocessor, and a touch screen.” Ex. 1008 at 10.

73. I understand that in the prior IPR of the ’533 Patent, the Board construed the term “a light source comprising a plurality of semiconductor sources that are light emitting diodes ... configured to increase signal-to-noise ratio by ... increasing a pulse rate of at least one of the plurality of semiconductor sources” as “a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes is capable of having its pulse rate increased to increase a signal-to-noise ratio.” Ex. 1008 at 10, 12.

74. For purposes of this declaration, I have been asked to apply the Board’s constructions for these terms in my analysis of the grounds in the Petition.

B. Texas Case Constructions

75. I am informed and understand that certain claim constructions for the ’533 Patent have been proposed by the parties in the pending Texas Case.

76. I understand that the following constructions were proposed in the Texas Case for the term “one or more filters” in claim 11 of the ’533 Patent (Ex. 2049):

Patent Owner’s Construction	Texas Case Defendants’ Construction
Plain and ordinary meaning	“one or more physical components or coatings

	configured in the device to selectively pass light of a particular wavelength or range(s) of wavelengths”
--	---

77. The same term also appears in claim 18 of the '533 Patent, which I understand is not asserted in the Texas Case.

78. My opinions regarding Grounds 1-3 as set forth in this declaration would not change regardless of which of the competing constructions noted above is adopted. I reserve the right to update my opinions should the district court or the Board issue claim constructions for these terms/phrases (or any other term or phrase in the '533 Patent).

79. I am informed and understand the parties in the Texas Case agreed to construe the term “personal device” in claim 5 of the '533 Patent the same as the construction of the Board in the prior IPR of the '533 Patent, i.e., “a computer or microprocessor-based device having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen.” The term “personal device” also appears in claim 13 of the '533 Patent. As explained above, for purposes of this declaration, I have been asked to apply the Board’s construction for this term in claims 5 and 13 in my analysis of the grounds in the Petition.

80. I am informed and understand that the parties in the Texas Case agreed to construe the term “beam” in claim 12 of the ’533 Patent as “photons or light transmitted to a particular location in space.” The term “beam” also appears in claims 5 and 13 of the ’533 Patent. For purposes of this declaration, I have been asked to apply this construction for this term in claims 5, 12, and 13 in my analysis of the grounds in the Petition.

IX. OVERVIEW OF ASSERTED GROUNDS AND REFERENCES IN THE PETITION

A. Petitioner’s Obviousness Grounds

81. I understand that Petitioner has challenged claims 6, 11, 12, 14, and 18 of the ’533 Patent as allegedly obvious under 35 U.S.C. § 103 based on three (3) separate Grounds, as follows (Petition at 11):

Ground	Claims	Asserted Reference(s)		
1	11, 12, 18	Lisogurski	Carlson	
2	6, 14	Lisogurski	Carlson	Walker
3	6, 14	Lisogurski	Carlson	Tam

B. Summary of Asserted References

82. I understand that Grounds 1-4 assert various combinations of the following references: “Lisogurski” (Ex. 1027), “Carlson” (Ex. 1028), Walker (Ex. 1044), and “Tam” (Ex. 1046). Petition at 9-11. I understand that Petitioner’s Grounds rely on Lisogurski in various combinations with Carlson and/or Walker

and/or Tam. Petition at 11. Herein, I refer to these alleged prior art references individually or in various combinations (depending on context) as the “the asserted reference[s].” Below are brief summaries of the asserted references.

1. Lisogurski (Ex. 1027) (Grounds 1, 2, and 3)

83. U.S. Patent No. 9,241,676 (“Lisogurski”) describes a non-invasive physiological monitoring system using pulse oximetry to measure blood oxygen saturation and related parameters. Ex. 1027 at 3:61-4:5. The system is illustrated in Figures 3 and 1:

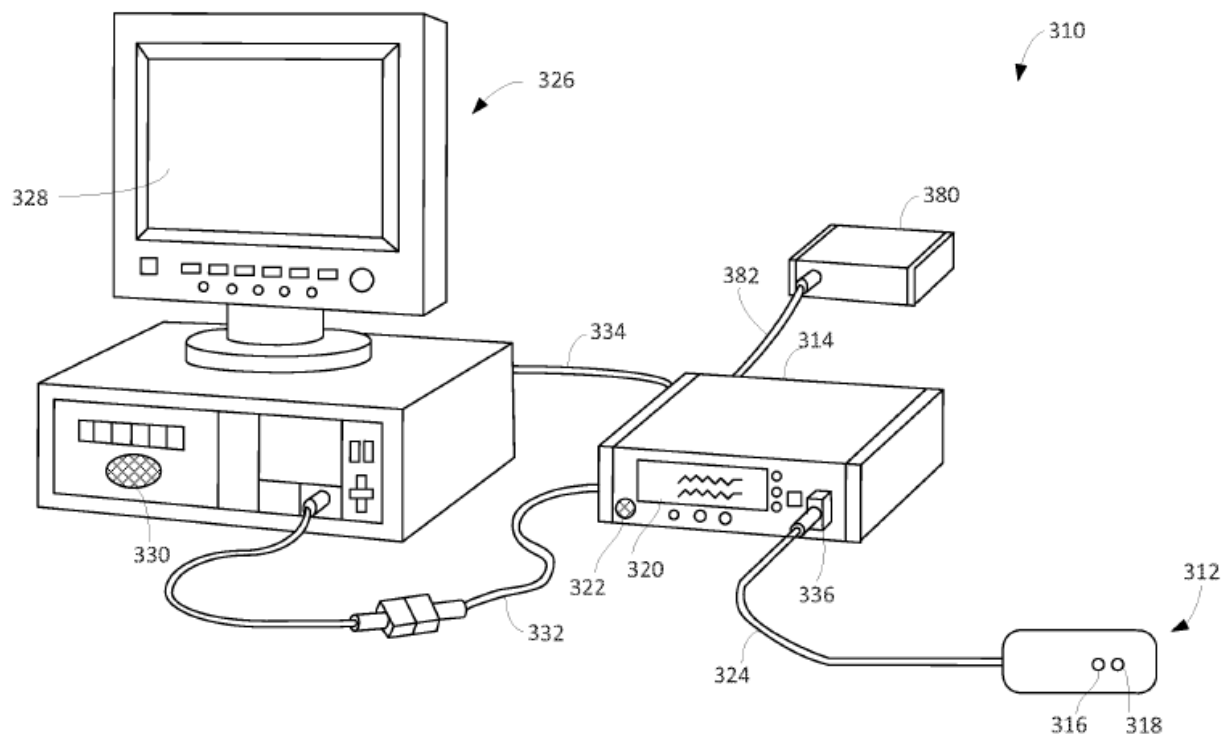


FIG. 3

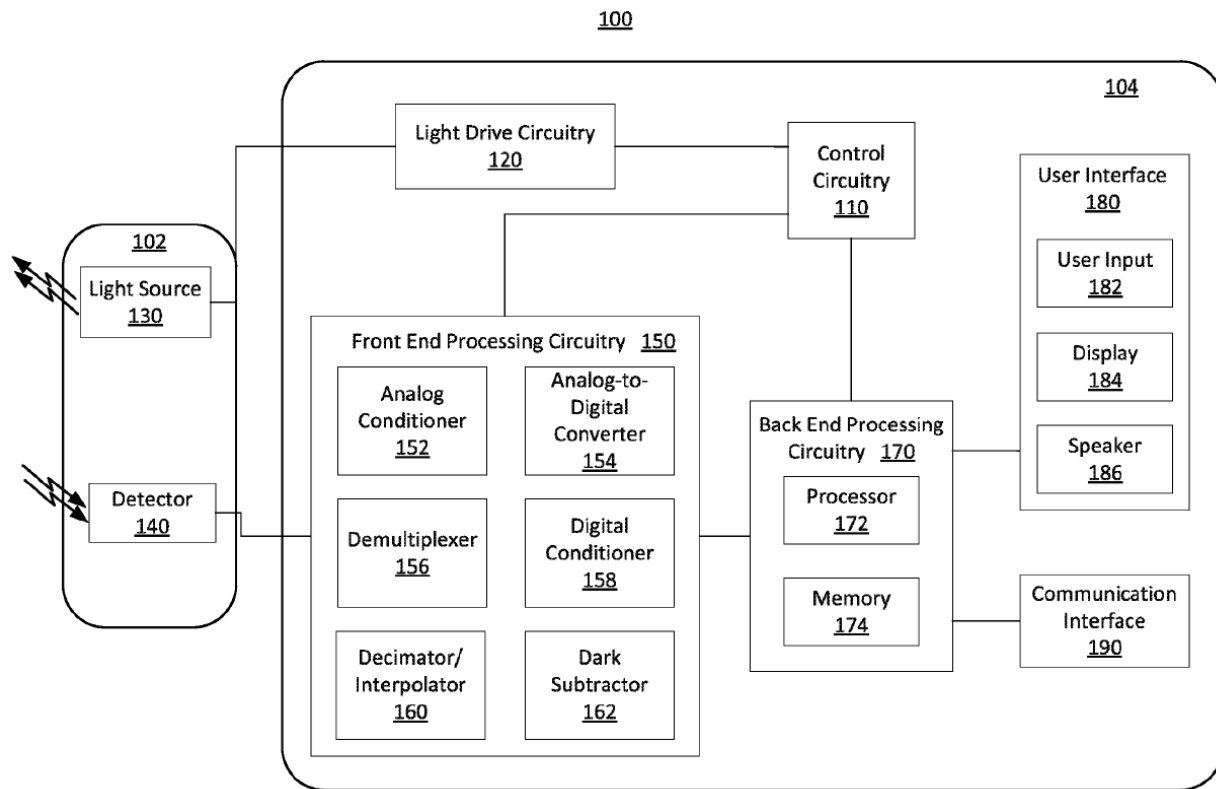


FIG. 1

Ex. 1027 at FIGS. 3, 1

84. Sensor unit 312 is wearable by a user, while the other components calibrate the system, process collected data, and display information. Ex. 1027 at 17:54-18:15, 18:32-67. The system uses semiconductor emitters at different wavelengths to illuminate tissue, and a photodetector receives light and converts it into an electrical signal. Ex. 1027 at 4:42-62; 10:48-64. Front end processing circuitry 150 processes the electronic signal. Ex. 1027 at 12:42-49. Then, “[p]rocessor 172 may receive and process physiological signals received from front end processing circuitry 150. For example, processor 172 may determine one or

more physiological parameters based on the received physiological signals.” Ex. 1027 at 14:60-64. Based on known differences in the absorption spectra of oxyhemoglobin or deoxyhemoglobin, the system compares the intensities at the different wavelengths to estimate blood oxygen saturation. Ex. 1027 at 24:58-25:5.

2. Carlson (Ex. 1028) (Grounds 1, 2, and 3)

85. U.S. Pat. App. Pub. No. 2005/0049468A1 (“Carlson”) describes an optical pulse oximeter for non-invasive measurement of pulsation and blood oxygen saturation. Ex. 1028 at ¶ [0002]. Carlson describes an ear-clip form factor. Ex. 1028 at ¶¶ [0048]-[0049]. That form factor is illustrated in Figures 1 and 2:

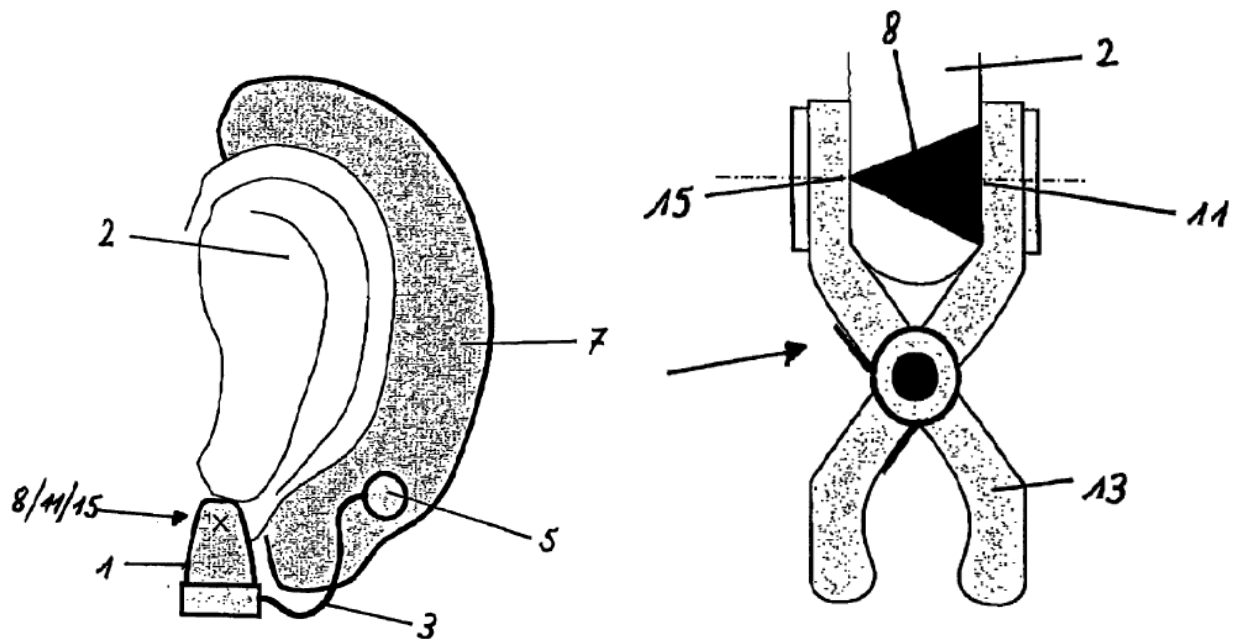


Figure 1

Figure 2

Ex. 1028 at FIGS. 1-2

86. Carlson describes optical and/or electronic means to improve signal-to-

noise and signal-to-background performance by using beam shaping optical elements, such as diffractive or refractive lenses, to direct light into tissue and a photo detecting element. Ex. 1028 at ¶¶ [0010], [0013]-[0014], [0062]. Carlson also discloses the use of “optical wavelength filters” for filtering light to a particular range of wavelengths before it reaches a photo detecting element. Ex. 1028 at ¶¶ [0026], [0062]. Finally, Carlson describes module packaging arrangements integrating these optical elements. Ex. 1028 ¶¶ [0041], [0062], FIG. 6c.

3. Walker (Ex. 1044) (Ground 2)

87. U.S. Patent No. 6,144,867 (“Walker”) describes a self-piercing pulse oximeter sensor assembly designed for attachment to pierced or pierceable body parts, such as ear lobes, webbing between fingers or toes, or other tissues. Ex. 1044 at 1:8-11. Walker addresses the problem of securing pulse oximeter sensors to patients who need freedom of movement or lack suitable attachment sites due to injury, burns, or amputation, providing enhanced “versatility” for monitoring an extremely mobile population. Ex. 1044 at 1:48-2:28; 4:18-37. The device includes a flexible pulse oximeter sensor with a light source and detector, an earring post that may either pierce tissue or slide into an existing pierced hole, and a grommet that secures the post after it passes through the body part. Ex. 1044 at 2:8-15. The light source may include LEDs, such as a red LED near 660 nm and a near-infrared LED emitting in the range of 890 to 950 nm, and may emit light having a bandwidth in

the range of 20 to 50 nm. Ex. 1044 at 2:60-3:4. The system functions in a transillumination mode by transmitting light through the pierced body part to measure blood oxygen saturation. Ex. 1044 at 3:5-12.

4. Tam (Ex. 1046) (Ground 3)

88. U.S. Patent No. 7,029,628 (“Tam”) describes a portable co-oximeter for measuring hemoglobin derivatives in a blood sample using LED light. Ex. 1046 at 1:48-65. Tam describes LEDs having bandwidths between 7 to 100 nm. Ex. 1046 at 13:45-52. Light is transmitted through the blood sample and absorbed by photodetectors. Ex. 1046 at 13:2-5. The detected light is then analyzed by a processor. Ex. 1046 at 11:22-41.

X. OPINIONS ON GROUNDS IN THE PETITION

89. The Petition and Dr. Mercier’s declaration include three grounds challenging the validity of the ’533 Patent. My opinions on each ground follow.

A. Ground 1: Obviousness Based on Lisogurski in view of Carlson (Claims 11, 12, and 18)

90. In Ground 1, Petitioner and Dr. Mercier assert that claims 11, 12, and 18 of the ’533 Patent are obvious over Lisogurski in view of Carlson. Petition at 27-30; Ex. 1003 at ¶¶ 85-93, 103-107. For the reasons discussed below, I disagree.

1. Dependent Claim 12

91. Petitioner asserts that claim 12 is rendered obvious by Lisogurski (Ex. 1027), alone or in view of Carlson (Ex. 1028), which allegedly “teaches the output

optical beam comprises a plurality of optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths.” Petition at 41, Ex. 1003 at ¶¶ 85-93, 103-107. For the reasons discussed below, I disagree.

92. Claim 12 depends on independent claim 5, which recites, among other things, “light emitting diodes configured to generate an output optical beam with one or more optical wavelengths” and “a receiver configured ... to generate an output signal.” Ex. 1001 at 29:44-50, 29:59-62, 30:42. Claim 12 further recites: “wherein the output optical beam comprises a plurality of optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths.” Ex. 1001 at 30:42-45.

93. In his analysis of claim 12, Dr. Mercier largely reproduces sections of Lisogurski and recites the Board’s conclusion from the prior Final Written Decision of claims 13 and 17 without providing new, independent technical analysis. *See, e.g.*, Ex. 1003 at ¶¶ 127–129 (reciting that the Board and Federal Circuit previously found that Lisogurski teaches an output beam with “one or more” wavelengths and that the receiver’s output signal is “generated in part by comparing the first and second signals,” and citing Exhibits 1008, 1009, and 1027). He then asserts that these prior findings show that “Lisogurski, alone or in view of Carlson, discloses claim 12.” Ex. 1003 at ¶ 126.

94. I note that there are differences between claim 12 and the claims of the

‘533 Patent that were at issue in the prior IPR that Petitioner and Dr. Mercier rely on. Claim 12 requires that “the output optical beam comprises a *plurality* of optical wavelengths.” Ex. 1001 at 30:42-43. By contrast, claims 13 and 16-17, which were at issue in the prior IPR, do not recite “a plurality of optical wavelengths.” Instead, claim 13 recites “an output optical beam with *one or more* optical wavelengths.” Ex. 1001 at 30:51-53. Claims 16 and 17 do not contain the word “wavelength.” Ex. 1001 at 32:10-18. Thus, claim 12 is narrower than the previously considered claims in the sense that it requires that the output optical beam includes a plurality (i.e., two or more) optical wavelengths, whereas claims 13 and 16-17 only require that the output optical beam includes one optical wavelength.

95. Additionally, claim 12 recites that “the output signal is generated in part by comparing signals at different optical wavelengths.” Ex. 1001 at 30:43-45. Claim 16 recites that “the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode.” Ex. 1001 at 32:10-16. Claim 17 adds that “the output signal is generated in part by comparing the first and second signals.” Ex. 1001 at 32:17-18. Unlike claim 12, these claims do not specify that the first and second signals that are compared for generating the output signal are at different optical wavelengths.

96. I understand that in the prior IPR for the '533 Patent, the Board stated that “[t]he receiver [of Lisogurski] generates an output signal because front end processing circuitry 150 ‘receive[s] a detection signal from detector 140 and provide[s] one or more processed signals to back end processing circuitry 170.’” Ex. 1008 at 39. The Board identified the “output signal” on a modified version of Lisogurski’s Figure 1:

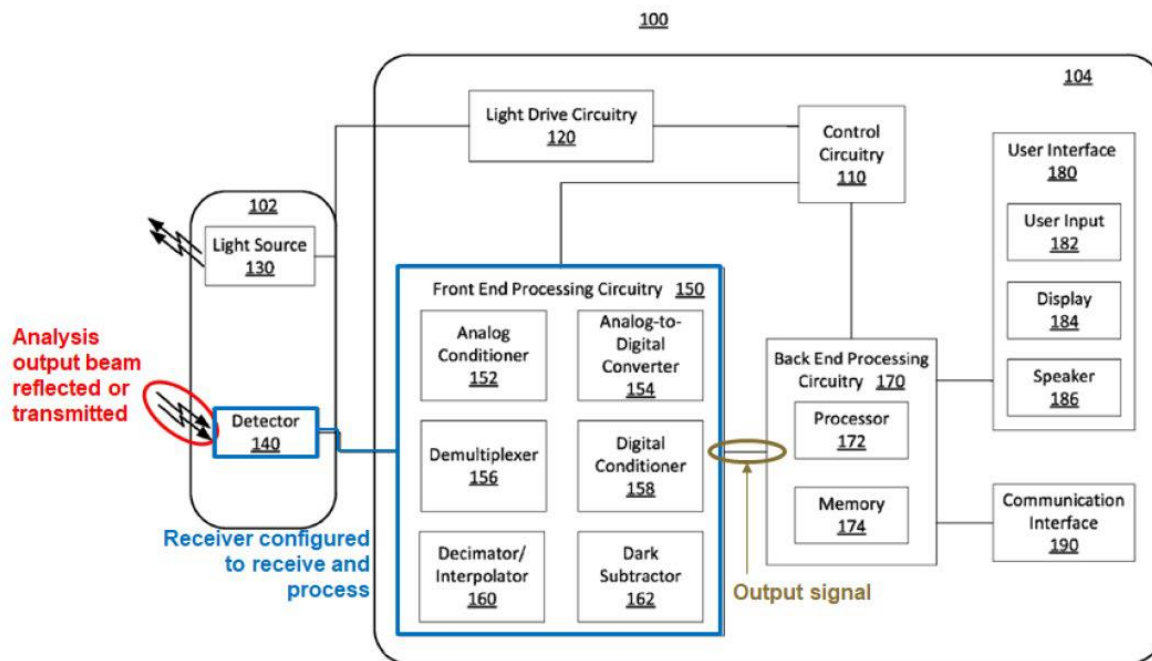


FIG. 1

Ex. 1008 at 38 (annotating Ex. 1027 at FIG. 1). Thus, I understand the Board determined that the “output signal” limitation of the '533 Patent is disclosed by the “processed signals” of Lisogurski, which are provided by “front end processing circuitry 150” to “back end processing circuitry 170.” Ex. 1008 at 38-39. The prior Board Decision did not address whether the “processed signal” of Lisogurski is

“generated in part by comparing signals at different optical wavelengths” as claim 12 requires, nor did it analyze where or when any such comparison occurs in Lisogurski’s architecture. Ex. 1008 at 38-39.

97. Petitioner and Dr. Mercier assert that the “processed signal” of Lisogurski is generated in part by comparing signals at different optical wavelengths based on Lisogurski’s disclosure that “[b]y comparing the intensities of two wavelengths at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood.” Petition at 42-43; Ex. 1003 at ¶¶ 130–131 (citing Ex. 1027 at 4:42–51); Ex. 1027 at 4:42-56. I disagree.

98. Lisogurski does not disclose that its “processed signal” is “generated in part by comparing signals at different optical wavelengths” as required by claim 12. Lisogurski does not disclose *where* in the system the “comparing the intensities of two wavelengths” is allegedly performed. Ex. 1027 at 4:42-56. Petitioner and Dr. Mercier do not explain where they believe the “comparing the intensities of two wavelengths” takes place, either. Petition at 42-43; Ex. 1003 at ¶ 132. Their assertion that the processed signal is generated through comparing the signals of two different optical wavelengths (“red and infrared”) is not supported by the disclosure in Lisogurski that they cite. Petition at 42-43; Ex. 1003 at ¶ 131; Ex. 1027 at 4:42-56. According to Figure 1 from Lisogurski (*see above*), the processor 172 receives the “processed signal” (output signal) after it has already been generated by the detector

140 and front end processing circuitry 150. Ex. 1008 at 38 (Fig. 1). Accordingly, Lisogurski does not disclose that the output signal is generated in part by comparing signals at different optical wavelengths.

99. While the '533 Patent claims *generating* an output signal by comparing signals, Lisogurski discloses comparing intensities *after* output signals have been generated. *See, e.g.*, Ex. 1008 at 38 (Fig. 1). Lisogurski “compar[es] the intensities of two wavelengths” in the back end processing circuitry 170, which includes the processor 172. Ex. 1027 at 4:48-51. Lisogurski states that “[p]rocessor 172 may receive and process physiological signals received from front end processing circuitry 150. For example, processor 172 may determine one or more physiological parameters based on the received physiological signals.” Ex. 1027 at 14:60-64. Lisogurski lists “blood oxygen saturation” as one such physiological parameter. Ex. 1027 at 1:22-25. In other words, the processor 172 *receives* output signals and then *compares* them to determine blood oxygen saturation. Ex. 1027 at Fig. 1, 1:22-25, 14:60-64. Accordingly, the “output signals” of Lisogurski (i.e., the “processed signals”) are not generated in part by comparing signals at different optical wavelengths.

100. Dr. Mercier asserts that Lisogurski teaches generating an output signal “in part by comparing signals at different optical wavelengths” as required by claim 12. Ex. 1003 at ¶¶ 129-131. Specifically, Dr. Mercier relies on Lisogurski’s

statement that “[b]y comparing the intensities of two wavelengths at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood.” Ex. 1003 at ¶ 130 (quoting Ex. 1027 at 4:42–51).

101. Dr. Mercier’s analysis contains a technical error regarding the timing and location of signal generation versus signal comparison in Lisogurski’s system. The passage Dr. Mercier cites describes the general principle of pulse oximetry—how blood oxygen saturation can be estimated—but does not describe where or when this comparison occurs in Lisogurski’s specific system architecture.

102. Lisogurski’s system architecture clearly shows that the “output signal” (*i.e.*, the “processed signal”) is generated by the front end processing circuitry 150 before being sent to the back end processing circuitry 170. Ex. 1027 at Fig. 1, 14:60–64; Ex. 1008 at 38–39. The comparison of intensities at two wavelengths occurs in the processor 172, which is part of the back end processing circuitry 170. Ex. 1027 at 4:48–51, 14:60–64.

103. To summarize, in Lisogurski: (1) the detector 140 and front end processing circuitry 150 generate the output signal; (2) this output signal is then transmitted to the back end processing circuitry 170; and (3) the processor 172 in the back end processing circuitry 170 then compares the signals to determine physiological parameters like blood oxygen saturation. The comparison happens after the output signal is generated, not during its generation, as required by claim

12.

104. Dr. Mercier does not identify any disclosure in Lisogurski showing that the “processed signal” itself is generated through a comparison process. Instead, the cited portions of Lisogurski show that processed signals are first generated, then subsequently compared.

2. Dependent Claims 11 and 18

105. Claim 11 depends on independent claim 5, which recites, among other things, “light emitting diodes configured to generate an output optical beam with one or more optical wavelengths” and “a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample.” Ex. 1001 at 29:44-47, 29:56-62, 30:38. Claim 11 further recites: “wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths.” Ex. 1001 at 30:38-41.

106. Claim 18 depends on independent claim 13, which recites, among other things, “light emitting diodes configured to generate an output optical beam with one or more optical wavelengths” and “a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample.” Ex. 1001 at 30:50-52, 30:64-67, 32:19. Claim 18, similar to claim 11, further recites: “wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths.” Ex. 1001 at

32:19-22.

107. Petitioner and Dr. Mercier assert that claims 11 and 18 are obvious over Lisogurski (Ex. 1027) in view of Carlson (Ex. 1028). Petition at 32-33; Ex. 1003 at ¶¶ 118-125, 133-135. I disagree.

108. Based on my review, page 31 of the Petition includes the following assertion regarding an alleged motivation to combine Carlson with Lisogurski: “a POSITA would have looked to Carlson, which describes improvements to pulse oximetry devices as they relate to both signal measurement and energy consumption.” Petition at 31. Dr. Mercier offers a similar assertion. Ex. 1003 at ¶¶ 105-107. This assertion fundamentally mischaracterizes both the problems addressed in Lisogurski and the solutions offered in Carlson.

109. Dr. Mercier’s motivation to combine argument fails to account for the distinct technical approaches in Lisogurski and Carlson. Carlson addresses limiting received light to target wavelengths through optical filtering, while Lisogurski addresses removing background noise from signals already received at those target wavelengths through electronic signal processing. A POSITA would understand these are different problems requiring different solutions.

110. Dr. Mercier states that combining these references would be a “routine part of a POSITA’s ordinary design process.” Ex. 1003 at ¶ 106. However, this conclusory statement ignores the technical reality that Lisogurski already teaches

multiple solutions for the problems Dr. Mercier identifies, including (1) drive cycle modulation with dark subtraction (Ex. 1027 at 6:7-31, 13:60-14:10); (2) increased LED brightness (Ex. 1027 at 9:46-57); (3) constant light output mode (Ex. 1027 at 9:57-60); and (4) passive or active filtering techniques (Ex. 1027 at 14:46-55).

111. A POSITA reviewing Lisogurski would understand that adding Carlson's optical wavelength filter would be redundant given these existing solutions. The "routine design process" that Dr. Mercier references would actually counsel against adding unnecessary components that provide no additional benefit over existing techniques already disclosed in Lisogurski.

112. A POSITA would have understood that the disclosures of Carlson address a desire to limit the light received by detecting element 35 to a target wavelength(s) of light, which Carlson addresses with a "[wavelength] filter[]" that limits the received light to the target wavelength(s). Ex. 1028 at ¶¶ [0059], [0062], [0063] (disclosing that "double pass filter 33" (a "wavelength filter[]") only transmits "light in the range of approximately 660 nm and in the range of approximately 890 nm"), [0026] ("wavelength filters"); *see also* ¶ [0038], FIG. 5C (showing a "transmission spectrum of a double band pass filter" where the filter limited the received light to target wavelengths of approximately 660 nm and 890 nm).

113. By contrast, a POSITA would have understood that the disclosures of Lisogurski address a different desire to remove background noise (e.g., based on ambient light) from the signal (a.k.a. peak) *at the target wavelength*, with no discussion regarding limiting the received light to that target wavelength to begin with, as in Carlson. Ex. 1027 at 6:7-31 (“The system may measure the ambient light detected by the detector during the ‘dark’ period and then subtract this ambient contribution from the signals received during the ... ‘on’ periods”—i.e., as further explained at 13:60-14:10, “determine a subtraction amount from the dark signal portion of the detection signal and subtract it from the peak portion of the detection signal ... to reduce the effect of the dark signal on the peak” and “generate adjusted Red and IR signals”), 14:46-55 (reducing the effect of ambient light on the detection signal), 12:42-49, 11:9-27.

114. The Petition and Dr. Mercier’s declaration conflate and oversimplify these two different problems in Lisogurski and Carlson as the same purported problem. A POSITA would have understood, as depicted in the annotated figures below, that the cited portions of Carlson and Lisogurski address different problems because Carlson addresses excluding light (blue) outside of a target wavelength (red), whereas Lisogurski addresses adjusting the detected signal at that target wavelength (red) by removing a portion of the detected signal attributable to background/ambient noise (green). *E.g.*, Ex. 1027 at 6:7-31; Ex. 1028 at ¶ [0062].

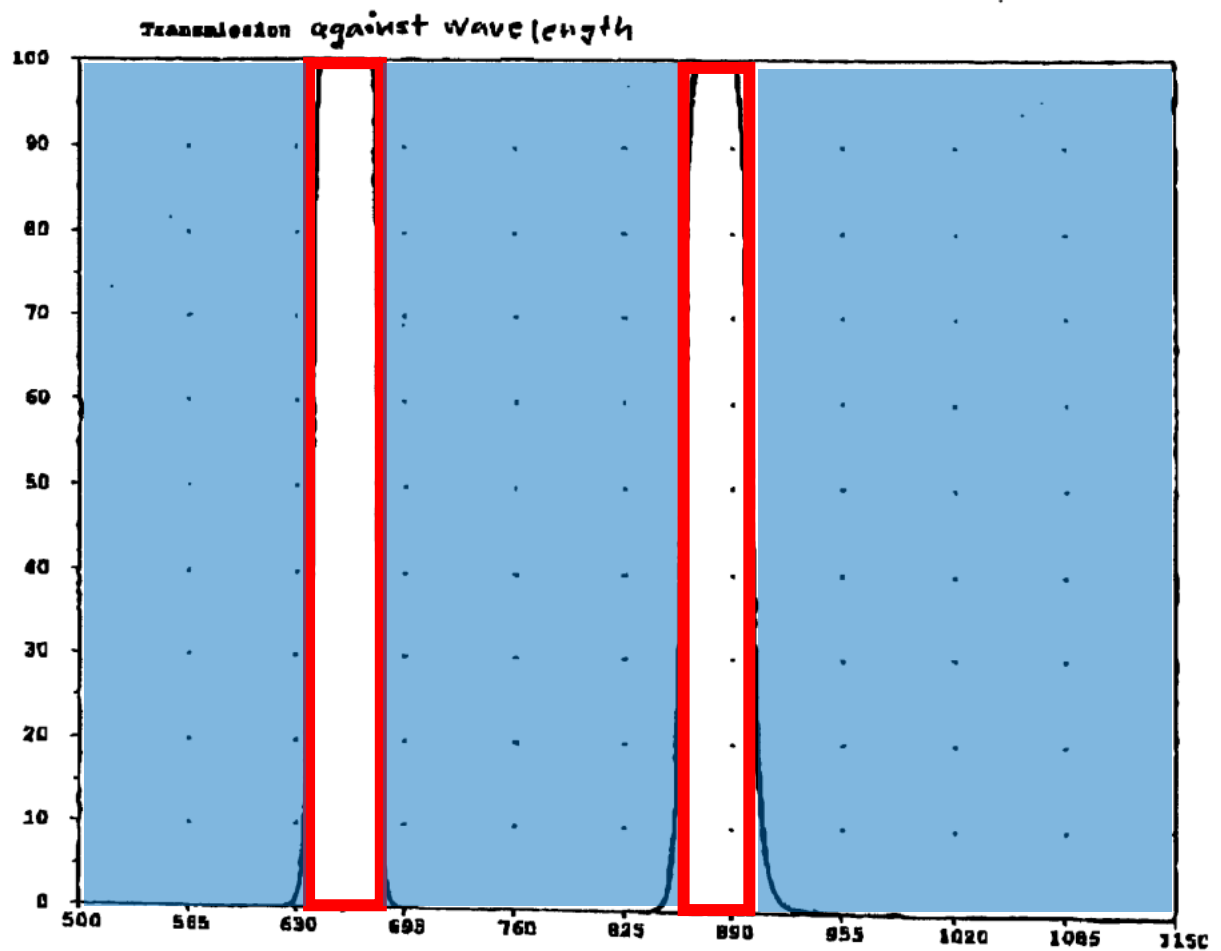


Figure 5c

Ex. 1028 at FIG. 5C (annotated); *see* Ex. 1028 at ¶¶ [0038], [0056].

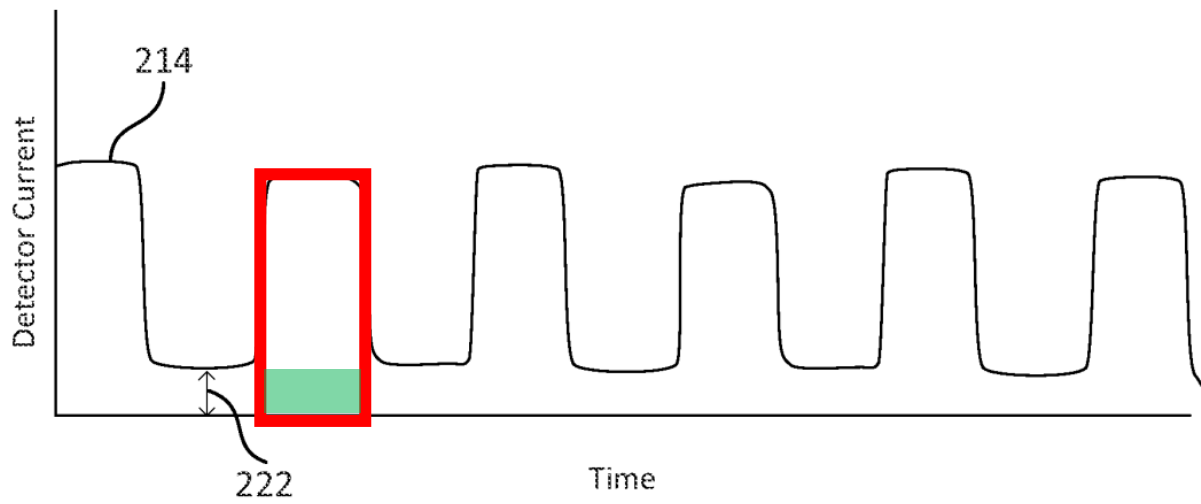


FIG. 2B

Ex. 1027 at FIG. 2B (annotated); *see* Ex. 1027 at 2:17-19, 12:42-13:6, 13:60-14:10.

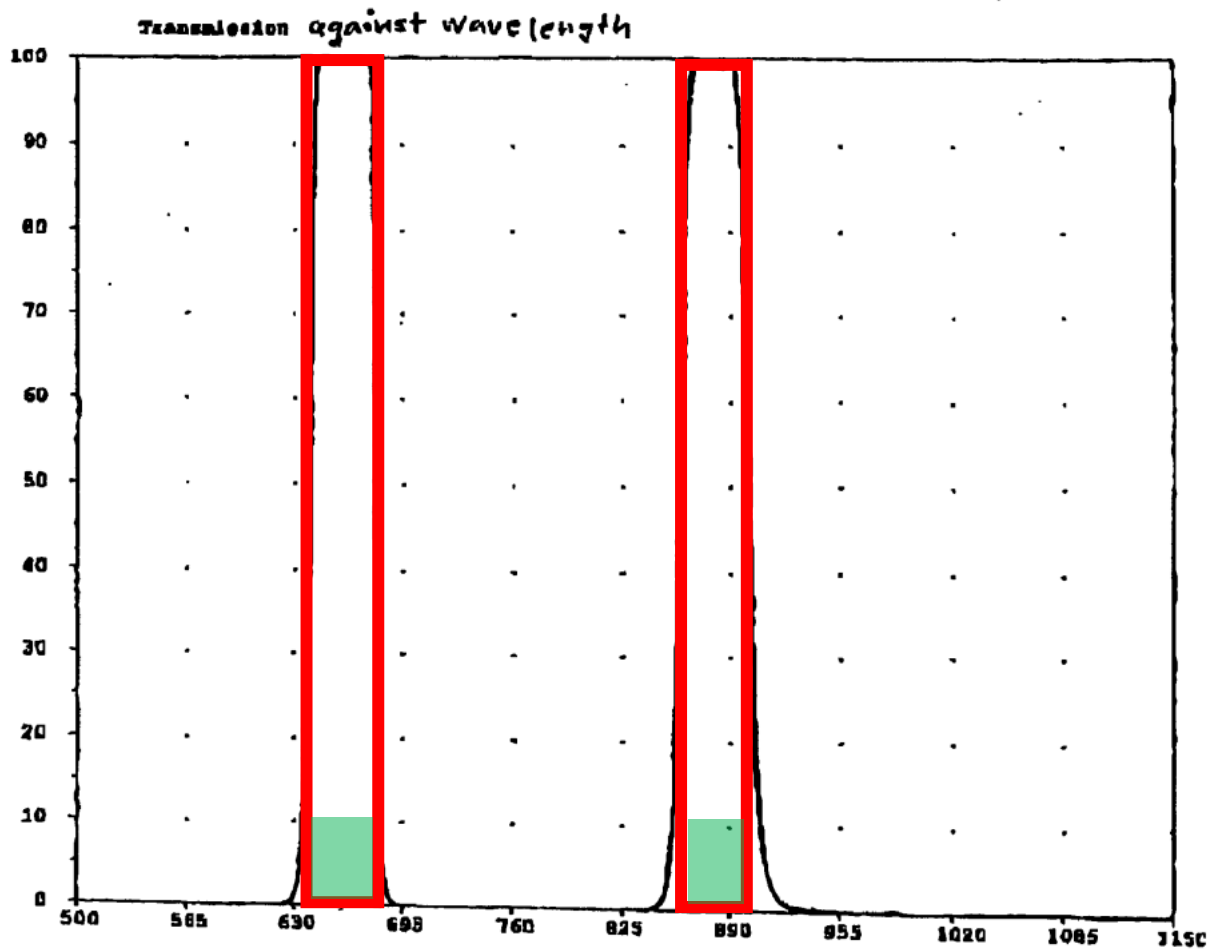


Figure 5c

Ex. 1028 at FIG. 5C (annotated).

115. Further, a POSITA would have understood that Carlson's solution of an optical wavelength filter would not address or solve the problem described in Lisogurski because Carlson's wavelength filter can only limit the detected light to a target wavelength and cannot, as Lisogurski addresses, identify or remove the background noise detected at that target wavelength. Ex. 1028 at ¶¶ [0026], [0062]; Ex. 1027 at 6:7-31. Thus, a POSITA would not have been motivated to incorporate

and use Carlson's optical wavelength filter to address the alleged problem in Lisogurski. A POSITA would have instead used Lisogurski's electronic signal processing techniques described below, not Carlson's optical wavelength filtering, to address the problem of background noise as described in the cited portions of Lisogurski. *See* Ex. 1027 at 6:7-31, 12:42-51, 13:7-12, 13:60-14:10. As discussed below, the Petition and Dr. Mercier's declaration fail to consider these signal processing techniques in Lisogurski for addressing background noise. *See* Petition at 52-53; Ex. 1003 at ¶ 170.

116. Additionally, not all of the portions of Lisogurski discuss a desire to remove background noise to improve measurements. *See, e.g.*, Ex. 1025 at 12:42-49, 11:9-27 (no discussion of removing background noise from ambient light).

117. To the extent that Lisogurski suggests that background noise is problematic and that removing background noise is desirable, a POSITA would have understood that Lisogurski already teaches solutions for removing background noise, such that there would be no reason for a POSITA to turn to Carlson. *See* Ex. 1027 at 6:7-31 (disclosing "a technique to remove ambient and background signals," i.e., Lisogurski's dark subtraction process), 14:46-55 (disclosing that "filtering or signal modification techniques may be employed to reduce the effect of ambient light," referring to Lisogurski's teachings of filtering or signal modification, for example, by components 152, 156, 158, 160, and 162 disclosed at 13:13-20, 13:31-

14:10), 12:42-49 (disclosing that Lisogurski's "[f]ront end processing circuitry 150 may perform various analog and digital processing of the detector signal").

118. Petitioner and Dr. Mercier's arguments for incorporating Carlson's optical filter into Lisogurski fail to consider or discuss the existing aspects of Lisogurski, including Lisogurski's teachings directed to addressing background noise and ambient light. For example, a POSITA would have understood that Lisogurski already discloses several techniques for excluding unwanted background noise and ambient light, such as a "drive cycle modulation technique" (Ex. 1027 at 6:7-31) with a dark subtractor (Ex. 1027 at 13:60-14:10), increasing the LED brightness (Ex. 1027 at 9:46-57), changing to a "constant light output" (Ex. 1027 at 9:57-60), and "passive or active filtering or signal modification techniques" (Ex. 1027 at 14:46-55). With the "drive cycle modulation technique," the system of Lisogurski "may measure the ambient light detected by the detector during the 'dark' period and then subtract this ambient contribution from the signals received during the first and second 'on' periods." Ex. 1027 at 11:16-19. The dark subtractor "determine[s] a subtraction amount from the dark signal portion of the detection signal and subtract[s] it from the peak portion of the detection signal in order to reduce the effect of the dark signal on the peak." Ex. 1027 at 13:63-65, FIG. 2A.

119. Lisogurski itself never discloses any filter physically "in front of" a detector, and instead Dr. Mercier imports without basis that spatial arrangement

from Carlson’s module packaging in Figure 6C. Ex. 1003 at ¶¶ 123–124; *see also id.* ¶¶ 118-122. Nothing in Lisogurski suggests any need to physically relocate its existing filter or decimator elements to a position “in front of” the detector. On the contrary, Lisogurski’s architecture is already solving its noise and ambient light problems at the circuit level. A POSITA would not, without the benefit of the claims, pick out Carlson’s particular packaging arrangement and transpose it wholesale into Lisogurski solely to match the “in front of” language.

120. Additionally, increasing the brightness of the LEDs in Lisogurski would reduce noise (to the extent reducing noise is required) because “the system may require increased signal amplitudes to differentiate between fiducial and other points of interest related to physiological parameters and those related to noise or motion.” Ex. 1027 at 9:50-57. Lisogurski’s system can “change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light.” Ex. 1027 at 9:57-60. Lisogurski further teaches that “passive or active filtering or signal modification techniques may be employed to reduce the effect of ambient light on the detection signal that is applied to analog-to-digital converter 154, and thereby reduce the contribution of the noise component to the converted digital signal.” Ex. 1027 at 14:51-55.

121. Further, Petitioner does not allege that there would be any benefit or advantage to applying Carlson’s filter teachings in addition to, or as a substitute for,

any of Lisogurski's disclosed techniques for addressing background noise. Even assuming that the problem of background noise as discussed in Lisogurski could be addressed by Carlson, a POSITA would have understood Carlson's filter teachings to be redundant and unnecessary given that Lisogurski already discloses how to address that problem. *See, e.g.*, Ex. 1027 at 6:7-31, 9:46-60, 13:60-14:10, 14:46-55, 16:48-53, 17:5-10.

122. A POSITA would have understood that together, the relied-upon teachings in Lisogurski include a method of first measuring detected light when the LEDs "on," including light emitted from the LEDs at the target wavelength (such as red or infrared light) and any light outside of the target wavelength, then measuring detected light when the LEDs are "off," which again includes any light outside of the target wavelength, and finally subtracting the second measurement from the first measurement, which retains the LEDs' emitted light at the target wavelength and effectively excludes any light outside of the target wavelength. *See* Ex. 1027 at 10:48-64, 12:23-27; 6:7-31. Thus, a POSITA would have understood in light of Lisogurski's teachings that adding Carlson's wavelength filter to Lisogurski would be redundant and unnecessary, and a POSITA therefore would not have been motivated to incorporate Carlson's filter into Lisogurski.

123. For at least these reasons, I disagree with Petitioner's and Dr. Mercier's conclusions for Ground 1.

B. Ground 2: Obviousness Based on Lisogurski in view of Carlson and Walker (Claims 6 and 14)

124. In Ground 2, Petitioner and Dr. Mercier assert that claims 6 and 14 of the '533 Patent are obvious over Lisogurski in view of Carlson and Walker. Petition at 45; Ex. 1003 at ¶¶ 108-111, 138-144. For the reasons discussed below, I disagree.

125. Claim 6 depends on independent claim 5, which recites, among other things, “a light source comprising a plurality of semiconductor sources that are light emitting diodes.” Ex. 1001 at 29:44-45, 30:11. Dependent claim 6 further recites: “wherein at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers to 40 nanometers.” Ex. 1001 at 30:11-13.

126. Claim 14 depends on independent claim 13, which recites, among other things, “a light source comprising a plurality of semiconductor sources that are light emitting diodes.” Ex. 1001 at 30:48-50, 31:21. Claim 14 further recites: “wherein at least one of the light emitting diodes emits light with a bandwidth between approximately 20 nanometers to approximately 40 nanometers.” Ex. 1001 at 31:21-24.

127. Walker does not disclose or suggest LEDs that emit light with a bandwidth between 20 and 40 nm. Instead, Walker discloses that “[t]he light source 20 may emit light having a bandwidth in the range of 20 to 50 nm.” Ex. 1044 at 3:3-4. The range described in Walker is broader than the range required in claims 6 and

14.

128. Petitioner and Dr. Mercier do not specifically argue that a POSITA would have narrowed the 20-50 nm bandwidth range described in Walker to meet the more precise 20-40 nm bandwidth range required in claims 6 and 14 of the ‘533 Patent. Petition at 47-50; Ex. 1003 at ¶¶ 138-44. Instead, the Petition merely argues in conclusory fashion that “[a] POSITA would therefore have understood Walker to teach or render obvious a measurement system where “at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers and 40 nanometers.” Petition at 48-49; Ex. 1003 at ¶ 139 (“Because a bandwidth of 20 to 40 nm falls within the range of 20 to 50 nm, a POSITA would have understood Walker to teach or render obvious an LED emitting light with a bandwidth of 20–40 nm”). I disagree.

129. The claimed 20 to 40 nm bandwidth range is narrower than the range described in Walker. A POSITA would understand that narrowing the range in Walker would involve tradeoffs and drawbacks, which Petitioner and Dr. Mercier do not acknowledge or address. For example, narrower bandwidth LEDs were more expensive, and in some cases, significantly more expensive. Tam, which I discuss below in connection with Ground 3, confirms that “tighter bandwidths” for LEDs comes “at a premium price.” Ex. 1046 at 9:61-62.

130. Another tradeoff with narrower bandwidth LEDs is that they are more

complex and complicated relative to broader bandwidth LEDs. For example, narrowing the bandwidth often requires additional components like filters that increase component count and the size of the device. A POSITA would recognize that this tradeoff would be counter to Lisogurski's goal of providing a portable device given that it may require a corresponding increase in the size of the device. Narrowing the bandwidth may pose further tradeoffs including power budget, thermal headroom, and optical loss. In short, a POSITA would recognize that narrowing the bandwidth described in Walker would involve significant tradeoffs.

131. In a section entitled "Motivation to Combine," the Petition gives reasons why a POSITA would allegedly combine Lisogurski, Carlson, and Walker. The Petition first argues that a "POSITA would have considered the systems taught by Lisogurski and Carlson together with Walker, as all three are analogous art directed to pulse oximeters and mobile, medical monitoring systems." Petition at 47; Ex. 1003 at ¶¶ 108-109. I am informed and understand that while prior art references must be "analogous art" for purposes of obviousness, the mere fact that certain references are "analogous art," standing alone, does not mean that a POSITA would have been motivated to combine them to arrive at the claimed invention.

132. Petitioner then argues that a "POSITA looking to improve the system in Lisogurski would therefore have been motivated to consider the teachings of Walker, which discusses an improved wearable sensor that offers increased

‘versatility,’ including for monitoring the oxygen saturation of an extremely mobile population.” Petition at 47; Ex. 1003 at ¶¶ 110-111. Petitioner does not explain if or how Walker’s wearable sensor is “improved” relative to Lisogurski or if or how Walker offers “increased ‘versatility’” for monitoring oxygen saturation relative to Lisogurski. As Petitioner and Dr. Mercier acknowledge, Lisogurski already describes a portable and wearable sensor, so Walker’s teachings in this regard are redundant.

133. Petitioner next argues that “[i]ncorporating the teachings of Walker into the sensor unit in Lisogurski would have required routine effort, yielded predictable results, and would have been part of the POSITA’s natural design process.” Petition at 47; Ex 1003 at ¶ 111. Petitioner, however, does not explain what “teachings of Walker” would allegedly be implemented in Lisogurski in the motivation to combine section of the Petition. Similarly, Petitioner argues that a “POSITA would also have been motivated to incorporate the teachings of Walker’s miniature, wearable pulse oximeter into Lisogurski given the trends in the market in 2012” but fails to explain what “teachings” from Walker would allegedly be implemented in Lisogurski. *Id.*

134. In the “Analysis of Ground 2” section of the Petition, Petitioner points to Walker’s statement that “[t]he light source 20 may emit light having a bandwidth in the range of 20 to 50 nm.” Petition at 48 (quoting Ex. 1044 at 3:3-4); *see also* Ex. 1003 at ¶ 139 (quoting same). Petitioner then argues that a “POSITA would have

been motivated to implement the light emitting diodes from Walker into the sensor unit of Lisogurski because this would have been a straightforward design modification that would have achieved the objectives of both systems; specifically, an improved wearable sensor that can be worn by a patient for continuously monitoring blood oxygen with increased accuracy.” Petition at 49. Dr. Mercier makes the same assertions. Ex. 1003 ¶¶ at 140-41. I disagree.

135. Contrary to Petition and Dr. Mercier’s suggestions, there is no teaching or suggestion in Walker that selecting LEDs with a bandwidth between 20 nm and 40 nm would lead to increased “accuracy, portability, and versatility of a wearable optical sensor” (Petition at 48; Ex. 1003 at ¶ 111) or would lead to “improved wearable sensor that can be worn by a patient for continuously monitoring blood oxygen with increased accuracy” (Petition at 49; Ex. 1003 ¶ 141). Petitioner and Dr. Mercier do not allege, let alone explain, how using a bandwidth between 20 and 40 nm would lead to increased accuracy, portability, or versatility relative to a bandwidth outside of that range. The accuracy of pulse oximetry measurements depends on many factors including signal processing algorithms, sensor placement, and ambient light rejection—not merely the bandwidth of the LEDs used.

136. With respect to “versatility,” Walker’s discussion of “versatility” relates to its ability to pierce body parts or attach to existing piercings (Ex. 1044 at 1:48-2:28, 4:8-18), not to any characteristic of its LEDs. The LED bandwidth

specifications in Walker have nothing to do with the device's versatility or its suitability for mobile populations. Indeed, Petitioner and Dr. Mercier do not explain why the LEDs of Walker contribute more toward "versatility" than the LEDs of Lisogurski.

137. With respect to Petitioner and Dr. Mercier's suggestion that selecting LEDs with the bandwidth range in Walker would be a routine design choice, they do not acknowledge that LEDs outside the claimed 20 nm to 40 nm bandwidth existed and would have been viable options. For example, the specification distinguishes LEDs with a bandwidth between 20 nm to 40 nm from "so-called super-luminescent LEDs that may even emit over a much wider wavelength range." Ex. 1001 at 20:4-9. Tam, for example, discloses LEDs with bandwidths of up to 100 nm. Ex. 1030 at 13:45-48. Petitioner and Dr. Mercier provide no reasoning as to why a POSITA would allegedly use the bandwidth range in Walker. I also note that Walker itself merely states that the light source "*may* emit light having a bandwidth in the range of 20 to 50 nm," i.e., that range is merely optional in Walker and not required, which further supports the notion that there are many other bandwidths that could be used in this context. Ex. 1044 at 3:3-4. The selection of LED bandwidth is not an arbitrary design choice but rather depends on the specific application, measurement modality, tissue characteristics, and signal processing approach.

138. For at least these reasons, I disagree with Petitioner's and Dr. Mercier's conclusions for Ground 2.

C. Ground 3: Obviousness Based on Lisogurski in view of Carlson and Tam (Claims 6 and 14)

139. In Ground 3, Petitioner and Dr. Mercier assert that claims 6 and 14 of the '533 Patent are obvious over Lisogurski in view of Carlson and Tam. Petition at 50; Ex. 1003 at ¶¶ 112-116, 147-152. For the reasons discussed below, I disagree.

140. Petitioner and Dr. Mercier assert that a POSITA would consider Lisogurski, Carlson, and Tam together because "all three are analogous art." Petition at 51; Ex. 1003 at ¶¶ 112-113. I am informed and understand that while prior art references must be "analogous art" for purposes of obviousness, the mere fact that certain references are "analogous art," standing alone, does not mean that a POSITA would have been motivated to combine them to arrive at the claimed invention.

141. Petitioner and Dr. Mercier assert that "[a] POSITA looking to improve the system in Lisogurski would therefore have been motivated to consider the teachings of Tam, which discusses an improved miniaturized sensor that offers increased portability." Petition at 51 (citing Ex. 1046 at 2:44-46); Ex. 1003 at ¶ 114 ("A POSITA would therefore have been motivated to combine the teachings of Tam with Lisogurski and Carlson because they are directed to the same objectives, including increased portability"). I disagree.

142. First, Lisogurski, Carlson, and Tam were all directed to a portable device for oximetry, that alone does not mean that a POSITA would combine them to arrive at the claimed inventions. Petitioner and Dr. Mercier do not allege that Tam discloses increased portability for co-oximetry compared to the devices in Lisogurski and Carlson. Since, according to Petitioner and Dr. Mercier, Lisogurski and Carlson already teach portable devices for oximetry, a POSITA would have no reason to look to Tam for increased portability because Lisogurski and Carlson are already portable.

143. Second, Petitioner and Dr. Mercier's motivation to combine analysis does not specifically identify which teachings or components from Tam a POSITA would allegedly be motivated to implement in Lisogurski (including as modified by Carlson). For example, the Petition alleges that "[i]ncorporating the teachings of Tam into the sensor unit in Lisogurski, with Carlson, would have required routine effort, yielded predictable results, and would have been part of the POSITA's natural design process." Petition at 51-52. However, Petitioner does not specifically identify what "teachings of Tam" would allegedly be incorporated into Lisogurski.

144. Later in their analysis, Petitioner and Dr. Mercier suggest that a POSITA would have been motivated to modify Lisogurski to implement the LEDs described in Tam. Petition at 56; Ex. 1003 ¶ 150. However, Petitioner and Dr.

Mercier do not address key teachings in Tam that undermine their alleged motivation to combine.

145. Tam explains that multiple light sources were available for co-oximetry and states that “[s]ome examples of the type of light sources suitable for use in the present invention include, but are not limited to, light emitting diodes, laser diodes or small monochromatic light sources.” Ex. 1046 at 2:46-49. Tam explains that “the difficulty in using compact light sources for the measurement of hemoglobin derivatives was that differentiating between the optical characteristics of the various hemoglobin derivatives heretofore required the use of tightly controlled diffraction gratings or very narrow bandwidth bandpass filters due to the overlapping visible absorption spectra of the various hemoglobin derivatives.” Ex. 1046 at 2:53-59.

146. Importantly, Tam teaches that “[i]t is clear that small optical components alone, such as LEDs having bandwidths *from about 7 to 100 nm*, would *not allow accurate measurements* or even have the capability of distinction between hemoglobin derivatives.” Ex. 1046 at 13:45–52 (emphases added). Tam goes on to explain that “[i]t is for this reason that co-oximeters of the past have relied upon tightly controlled optical components requiring diffraction gratings, tight bandpass filters, tightly controller laser diodes and the like as the optical components of choice.” Ex. 1046 at 13:48-52. Tam acknowledges “LEDs are available in tighter

bandwidths” relative to the 7 to 100 nm range but these come “at a premium price.”

Ex. 1046 at 9:61-62.

147. In contrast to prior co-oximetry systems, Tam’s invention “is generally enabled to be portable by three design characteristics,” including (1) using small optical components that do not require tight controls; (2) performing the measurement on whole blood; and (3) using ratiometric calculations.” Ex. 1046 at 13:19-25. Tam states that “it is specifically the use of small optical components that allow the mechanical design and electronics of the co-oximeter to be small enough to be portable” and “[u]se of whole blood allows the design to be smaller still.” Ex. 1046 at 13:26-30.

148. To achieve these benefits, Tam discloses “procedures for measurement have been developed to accommodate the performance characteristics of the smaller optical components utilized” (Ex. 1046 at 13:40-44) and provides a detailed discussion of a “Ratiometric Refinement” that can be used with smaller optical components to achieve accurate measurements (Ex. 1046 at 14:57-16:29). By using ratiometric calculations, Tam’s invention “utilizes compact light sources with bandwidths in the range of 7-100 nm without the use of narrow bandpass filters and/or complex diffraction gratings” to achieve increased portability. Ex. 1046 at 2:36-39.

149. Taken together, the above disclosures in Tam make clear that using LEDs with a bandwidth between 20 nm and 40 nm will not result in accurate multi-species hemoglobin measurements unless one uses (1) tightly controlled optical components such as complex diffraction gratings and tight bandpass filters or (2) the ratiometric calculations. Tam is clear that only the latter option achieves increased portability for the device. Ex. 1046 at 13:19-23 (explaining that “the co-oximeter of the present invention is generally enabled to be portable by three design characteristics” including “using small optical components *that do not require tight controls*”) (emphasis added).

150. Petitioner and Dr. Mercier do *not* propose modifying Lisogurski to use Tam’s ratiometric calculations. Petition at 50-57; Ex. 1003 at ¶¶ 112-116, 145-154. Instead, they only propose modifying Lisogurski “to implement the LEDs from Tam’s portable oximeter into the system described by Lisogurski (including as modified in view of Carlson).” Petition at 56; Ex. 1003 at ¶ 150. But as the above discussion illustrates, Tam makes clear that LEDs with a bandwidth between 20 nm and 40 nm would *not* allow for accurate measurements without using Tam’s ratiometric calculations or tighter controls. Thus, a POSITA would not modify Lisogurski (including as modified by Carlson) as Petitioner and Dr. Mercier propose because Tam teaches that the modification would not allow for accurate measurements.

151. The Petition asserts that “Tam teaches increasing the accuracy of the measured signal from the components of hemoglobin by using bandwidth filters (like those taught by Carlson and Lisogurski) or by using LEDs with a bandwidth ranging from 15-40 nm.” Petition at 56 (citing Ex. 1046 at 13:45-14:10, 14:42-47, Figs. 2-4); *see also* Ex. 1003 at ¶ 150. In my view, this mischaracterizes Tam’s teachings. Tam does not teach that one can improve accuracy “by using LEDs with a bandwidth ranging from 15-40 nm). Quite the contrary, as discussed above, Tam teaches “that small optical components alone, such as LEDs having bandwidths *from about 7 to 100 nm*, would *not allow accurate measurements* or even have the capability of distinction between hemoglobin derivatives.” Ex. 1046 at 13:45–52 (emphases added). While Tam does say that tight controls like bandwidth filters and complex diffraction gratings can be used in conjunction with LEDs with bandwidths between 7 to 100 nm for measurements, as discussed above, Tam is clear that this is undesirable for a portable device and the improvements in portability achieved in Tam are attributable to using ratiometric calculations rather than bandwidth filters. Thus, if a POSITA were motivated to increase portability, as Petitioner and Dr. Mercier suggest, Tam teaches away from using bandwidth filters in combination with LEDs with bandwidths from about 7 to 100 nm.

152. The Petition alleges that “[a] POSITA looking *to improve* the system in Lisogurski would therefore have been motivated to consider the teachings of

Tam.” Petition at 51 (emphasis added). Petitioner, however, does not explain why modifying Lisogurski to include Tam’s LEDs would “improve” Lisogurski in any way. In fact, as discussed above, simply using Tam’s LEDs without ratiometric calculations or tightly controlled components would not improve Lisogurski and would make the measurements less accurate.

153. For at least these reasons, I disagree with Petitioner’s and Dr. Mercier’s conclusions for Ground 3.

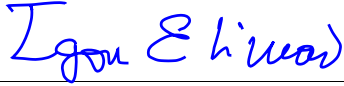
XI. CONCLUSION

154. In my opinion, the challenged claims of the ’533 Patent would not have been obvious to a POSITA as of the priority date of the ’533 Patent in view of the asserted references that Petitioner and Dr. Mercier rely upon in Grounds 1-3. Accordingly, it is my opinion that all challenged claims of the ’533 Patent are patentable over the asserted references.

155. 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: January 5, 2026



Igor Efimov, Ph.D.