UNITED STATES PATENT AND TRADEMARK OFFICE ————— BEFORE THE PATENT TRIAL AND APPEAL BOARD ———— APPLE INC.

Petitioner, v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01715 U.S. Patent 10,631,765

DECLARATION OF VIJAY K. MADISETTI, PH.D.

Masimo Ex. 2004 Apple v. Masimo IPR2020-01715

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- I, Vijay K. Madisetti, Ph.D., declare as follows:
- 1. I have been retained by counsel for Patent Owner Masimo Corporation ("Masimo") as an independent expert witness in this proceeding. I have been asked to provide my opinions regarding the Petition in this action and the declaration offered by Thomas W. Kenny, Ph.D., (Ex. 1003) challenging the patentability of claims 1-29 of U.S. Patent No. 10,631,765 ("the '631 Patent"). I am being compensated at my usual and customary rate for the time I spend working on this proceeding, and my compensation is not affected by its outcome.

I. **QUALIFICATIONS**

- 2. My qualifications are set forth in my curriculum vitae, a copy of which is included as Exhibit 2005. A summary of my qualifications follows.
- 3. I am a professor in Electrical and Computer Engineering at the Georgia Institute of Technology ("Georgia Tech"). I have worked in the area of digital signal processing, wireless communications, computer engineering, integrated circuit design, and software engineering for over 25 years, and have authored, co-authored, or edited several books and numerous peer-reviewed technical papers in these area.
- 4. I obtained my Ph.D. in Electrical Engineering and Computer Science at the University of California, Berkeley, in 1989. While there, I received the

Demetri Angelakos Outstanding Graduate Student Award and the IEEE/ACM Ira M. Kay Memorial Paper Prize.

- I joined Georgia Tech in the Fall of 1989 and am now a tenured full professor in Electrical and Computer Engineering. Among other things, I have been active in the areas of digital signal processing, wireless communications, integrated circuit design (analog & digital), system-level design methodologies and tools, and software engineering. I have been the principal investigator ("PI") or co-PI in several active research programs in these areas, including DARPA's Rapid Prototyping of Application Specific Signal Processors, the State of Georgia's Yamacraw Initiative, the United States Army's Federated Sensors Laboratory Program, and the United States Air Force Electronics Parts Obsolescence Initiative. I have received an IBM Faculty Award and NSF's Research Initiation Award. I have been awarded the 2006 Frederick Emmons Terman Medal by the American Society of Engineering Education for contributions to Electrical Engineering, including authoring a widely used textbook in the design of VLSI digital signal processors.
- 6. During the past 20 years at Georgia Tech, I have created and taught undergraduate and graduate courses in hardware and software design for signal processing, computer engineering (software and hardware systems), computer engineering and wireless communication circuits.

- 7. I have been involved in research and technology in the area of digital signal processing since the late 1980s, and I am the Editor-in-Chief of the CRC Press's 3-volume Digital Signal Processing Handbook (1998, 2010).
- 8. I have founded three companies in the areas of signal processing, embedded software, military chipsets involving imaging technology, and software for computing and communications systems. I have supervised Ph.D. dissertations of over twenty engineers in the areas of computer engineering, signal processing, communications, rapid prototyping, and system-level design methodology.
- 9. I have designed several specialized computer and communication systems over the past two decades at Georgia Tech for tasks such as wireless audio and video processing and protocol processing for portable platforms, such as cell phones and PDAs. I have designed systems that are efficient in view of performance, size, weight, area, and thermal considerations. I have developed courses and classes for industry on these topics, and many of my lectures in advanced computer system design, developed under the sponsorship of the United States Department of Defense in the late 1990s, are available for educational use at http://www.eda.org/rassp and have been used by several U.S. and international universities as part of their course work. Some of my recent publications in the area of design of computer engineering and wireless communications systems and associated protocols are listed in Exhibit 2005.

- 10. In the mid 2006-2007 timeframe, I collaborated with Professor John Scharf and his colleagues at Emory Healthcare system in developing FFT-based pulse oximetry system prototypes on FPGAs, which extended technologies developed by Prof. Scharf and his colleagues from the 1996 time frame (See T. Rusch, R. Sankar, J. Scharf, "Signal Processing Methods for Pulse Oximetry", Comput. Bio. Med, Vol. 26, No. 2, 1996). Some of my more recent publications in the area of biological signal processing and bioinformatics are listed in my CV and include, A. Bahga, V. Madisetti, "Healthcare Data Integration and Informatics in the Cloud", IEEE Computer, Vol. 48, Issue 2, 2015, and "Cloud-Based Information Integration Informatics Framework for Healthcare Applications", IEEE Computer, Issue 99, 2013. In addition to my signal processing experience specific to pulse oximetry, I also have experience in developing systems for other physiological signals. Beginning in the early 1990s, I worked, in particular, with ECG/EKG signals, and, in general, with biomedical signals and systems.
- 11. In addition to my signal processing experience specific to pulse oximetry, I also have experience in developing algorithms and systems for other physiological signals. I worked with ECG/EKG signals in particular, and biomedical signals and systems in general, beginning in the early 1990s. In particular, I worked with graduate student Dr. Shahram Famorzadeh, in 1990 and 1991, to analyze and apply pattern recognition (a category of signal processing

algorithms that is based on correlation with a set of templates) to ECG/EKG waveforms to identify physiological conditions.

- 12. I have experience with biomedical signals and devices in the field of speech and image processing since the late 1980s. I worked on deconvolution algorithms to recover the state of the system based on observed measurements of the physiological signals in the 1993-1998 time-frame. These signal processing techniques can be applied to pulse oximetry signals, and I have been working with these techniques since the mid-1980s.
- 13. I have studied, researched and published in the area of adaptive filter signal processing for noise reduction and signal prediction, using correlation-based approaches since the mid-1980s, both in the time-domain and frequency domain, and also to ray-tracing applications, such as Seismic Migration for oil and shale gas exploration. See for instance, V. Madisetti & D. Messerschmitt, Dynamically Reduced Complexity Implementation of Echo Cancellers, IEEE International Conference on Speech, Acoustics and Signal Processing, ICASSP 1986, Tokyo, Japan, and M. Romdhane and V. Madisetti, "All-Digital Oversampled Front-End Sensors" IEEE Signal Processing Letters, Vol 3, Issue 2, 1996, and "LMSGEN: A Prototyping Environment for Programmable Adaptive Digital Filters in VLSI", VLSI Signal processing, pp. 33-42, 1994.

- 14. Deconvolution of symmetric (seismic) and asymmetric (pulse oximetry) signals has gained much importance in the past two decades, and some of my early work on "Homomorphic Deconvolution of Bandpass Signals" in IEEE Transactions on Signal Processing, October 1997, established several new methods for deconvolution of such signals that had several advantages of robustness, increased accuracy, and simplicity.
- 15. In the past decade I have authored several peer-reviewed papers in the area of computer systems, instruments, and software design, and these include:
 - V. Madisetti, et al., "The Georgia Tech Digital Signal Multiprocessor, IEEE Transactions on Signal Processing, Vol. 41, No. 7, July 1993.
 - V. Madisetti et al., "Rapid Prototyping on the Georgia Tech Digital Signal Multiprocessor", IEEE Transactions on Signal Processing, Vol. 42, March 1994.
 - V. Madisetti, "Reengineering legacy embedded systems", IEEE
 Design & Test of Computers, Vol. 16, Vol. 2, 1999.
 - V. Madisetti et al., "Virtual Prototyping of Embedded Microcontroller-based DSP Systems", IEEE Micro, Vol. 15, Issue 5, 1995.

- V. Madisetti, et al., "Incorporating Cost Modeling in Embedded-System Design", IEEE Design & Test of Computers, Vol. 14, Issue 3, 1997.
- V. Madisetti, et al., "Conceptual Prototyping of Scalable Embedded
 DSP Systems", IEEE Design & Test of Computers, Vol. 13, Issue 3,
 1996.
- V. Madisetti, Electronic System, Platform & Package Codesign,"
 IEEE Design & Test of Computers, Vol. 23, Issue 3, June 2006.
- V. Madisetti, et al., "A Dynamic Resource Management and Scheduling Environment for Embedded Multimedia and Communications Platforms", IEEE Embedded Systems Letters, Vol. 3, Issue 1, 2011.
- 16. I have been active in the areas of signal processing systems and mobile device communication systems for several years, and some of my publications in this area include "Frequency Dependent Space-Interleaving of MIMO OFDM Systems" Proc. of IEEE Radio and Wireless Conference (RAWCON '03), 2003, "Embedded Alamouti Space Time Codes for High Rate and Low Decoding Complexity", Proc. IEEE Asilomar Conf. on Signals, Systems, and Computers, 2008; and "Asymmetric Golden Codes for Fast Decoding in Time Varying Channels", Wireless Personal Communications (2011).

II. MATERIALS CONSIDERED

17. Below is a listing of documents and materials that I considered and reviewed in connection with providing this declaration. In forming my opinions, I considered those materials as well as anything cited or discussed in this declaration.

Exhibit	Description
1001	U.S. Patent No. 10, 631,765 ("'765 Patent")
1002	File History for the '765 Patent
1003	Declaration of Dr. Thomas W. Kenny
1004	Curriculum Vitae of Dr. Thomas W. Kenny
1005	Masimo Corporation, et al. v. Apple Inc., Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.)
1006	U.S. Pub. No. 2002/0188210 ("Aizawa")
1007	JP 2006-296564 ("Inokawa")
1008	Certified English Translation of Inokawa and Translator's Declaration
1009	U.S. Pub. No. 2001/0056243 ("Ohsaki")
1010	"A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," Y. Mendelson, et al.; Proceedings of the 28th IEEE EMBS Annual International Conference, 2006; pp. 912-915 ("Mendelson 2006")
1011	U,S, Pub. No. 2007/0093786 ("Goldsmith")
1012	U.S. Pat. No. 6,801,799 ("Mendelson '799")
1013	U.S. Pub. No. 2004/0054291 ("Schulz")
1016	U.S. Pat. No. 3,789,601 ("Bergey")

Exhibit	Description
1017	"Design and Evaluation of a New Reflectance Pulse Oximeter Sensor," Y. Mendelson, et al.; Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609; Association for the Advancement of Medical Instrumentation, Vol. 22, No. 4, 1988; pp. 167-173 ("Mendelson-1988")
1018	"Skin Reflectance Pulse Oximetry: In Vivo Measurements from the Forearm and Calf," Y. Mendelson, et al.; Journal of Clinical Monitoring, Vol. 7, No. 1, January 1991 ("Mendelson 1991")
1019	Design of Pulse Oximeters, J.G. Webster; Institution of Physics Publishing, 1997 ("Webster")
1020	QuickSpecs; HP iPAQ Pocket PC h4150 Series
1021	Excerpts from How to Do Everything with Windows Mobile, Frank McPherson; McGraw Hill, 2006 ("McPherson")
1022	Excerpts from Master Visually Windows Mobile 2003, Bill Landon, et al.; Wiley Publishing, Inc., 2004 ("Landon")
1023	"Stimulating Student Learning with a Novel 'In-House' Pulse Oximeter Design," J. Yao and S. Warren; Proceedings of the 2005 American Society for Engineering Education Annual Conference & Exposition, 2005 ("Yao")
1024	U.S. Pub. No. 2008/0194932 ("Ayers")
1025	U.S. Pat. No. 7,031,728 ("Beyer")
1027	National Instruments LabVIEW User Manual
1038	U.S. Patent No. 7,558,622 ("Tran")
1041	U.S. Patent No. 7,251,513 ("Kondoh")
1042	JP 2005-270543 ("Tanagi")
1043	Certified English Translation of Tanagi and Translator's Declaration
2006	Deposition Transcript of Dr. Thomas W. Kenny in <i>Apple Inc. v. Masimo Corp.</i> , IPR2020-01520, IPR2020-01537, IPR2020-01539 (April 22, 2021)

Exhibit	Description
2007	Deposition Transcript of Dr. Thomas W. Kenny in <i>Apple Inc. v. Masimo Corp.</i> , IPR2020-01520, IPR2020-01537, IPR2020-01539 (April 23, 2021)
2010	Frank H. Netter, M.D., Section VI Upper Limb, Atlas of Human Anatomy (2003), Third Edition ("Netter")
2019	Petition for <i>Inter Partes</i> Review IPR2020-01520
2020	Declaration of Dr. Thomas W. Kenny in <i>Apple Inc. v. Masimo Corp.</i> , IPR2020-01520
Paper 3	Petition for <i>Inter Partes</i> Review IPR2020-01715
Paper 8	Decision Granting Institution of <i>Inter Partes</i> Review IPR2020-01715

III. <u>UNDERSTANDING OF PATENT LAW</u>

18. I am not an attorney and will not be offering legal conclusions. However, I have been informed of several principles concerning the legal issues relevant to analyzing the challenges to the claims of the '765 Patent, and I used these principles in arriving at my conclusions.

A. Level Of Ordinary Skill In The Art

19. I understand that certain issues in an IPR, such as claim construction and whether a claim is invalid as obvious, are assessed from the view of a hypothetical person of ordinary skill in the relevant art at the time of the invention. I understand there are multiple factors relevant to determining the level of ordinary skill in the art, including (1) the level of education and experience of persons working in the field at the time of the invention; (2) the sophistication of the

technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems. I understand that this hypothetical person of ordinary skill is presumed to have had knowledge from the teachings of the prior art.

20. I understand that Apple Inc. ("Apple" or "Petitioner") and its Declarant Dr. Kenny have set forth the following definition for a person of ordinary skill in the art ("POSITA"): "someone with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies.." Ex. 1003 ¶21. Dr. Kenny further asserts: "Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline." Ex. 1003 ¶21. I discuss the asserted level of skill further below, in Section VI of this declaration.

B. Claim Construction

21. I understand that claim construction in an IPR is a legal question for the Board to decide. I also understand, however, that in construing claim terms, the Board asks what the terms would mean to a person of ordinary skill in the relevant art in view of the disclosures in the patent and the prosecution history of the patent.

I understand that the Board may also consider external evidence, such as dictionaries. In general, however, I understand that claim terms are given the ordinary and customary meaning one of ordinary skill in the relevant art would apply to them in the context of the patent at the time the patent was filed.

22. I understand that Apple did not identify any terms for construction. I have given the claim terms their plain and ordinary meaning in my analysis.

C. Obviousness

- 23. I understand that a patent claim is invalid under the patent law, 35 U.S.C. § 103, if, at the time the claimed invention was made, the differences between the prior art and the claimed invention as a whole would have been obvious to a person of ordinary skill in the art. I understand that the following facts are considered in determining whether a claimed invention is invalid as obvious in view of the prior art: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences, if any, between the claimed invention and the prior art.
- 24. I also understand there are additional considerations that may be used in evaluating whether a claimed invention is obvious. These include whether the claimed invention was the result of (a) a teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art to arrive at the claimed invention; (b) a combination of prior art elements combined according

to known methods to yield predictable results; (c) a simple substitution of one known element for another to obtain a predicable result; (d) the use of a known technique to improve similar things in the same way; (e) applying a known technique to a known thing ready for improvement to yield predictable results; (f) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (g) known work in one field of endeavor prompting variations of it for use in either the same filed or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art.

- 25. I have applied this understanding in my analysis.
- 26. I understand that Dr. Kenny carried out his analysis of patentability as of July 3, 2008. Ex. 1003 ¶¶16, 23. I likewise carry out my analysis of patentability as of July 3, 2008. I do not offer any opinions regarding priority in this declaration.

IV. <u>INTRODUCTION TO MASIMO'S '765 PATENT</u>

A. The '765 Patent

27. Masimo's U.S. Patent No. 10,631,765 ("'765 Patent") is generally directed to optical physiological sensor devices that use a combination of different design elements and improve optical detection efficiency. Masimo's claims are directed to physiological measurement systems that include physiological sensor

devices. These claims include at least four detectors, one or more emitters, and a cover with a protruding convex surface that works in conjunction with a wall to enhance the device's effectiveness. The '765 Patent explains that these different pieces work together to provide greater noise cancellation and an order of magnitude increase in signal strength. Ex. 1001 9:18-23, 20:14-30; see also 3:13-23, 4:16-27. For example, the '765 Patent helps address issues related to light attenuation and errors resulting from the variations in the path of light passing through tissue. The '765 Patent identifies several different benefits to the use of a protrusion in conjunction with the physiological sensor device. For instance, the protrusion thins out a measurement site on the body, resulting in less light attenuation by a measured tissue for the physiological sensor device. Ex. 1001 7:46-51. The protrusion also further increases the area from which attenuated light can be measured. Ex. 1001 7:51-53. The wall or housing may also play a role by allowing maximization of the amount of tissue-attenuated light that impinges on the detectors. Ex. 1001 36:35-41. Windows can be used, for example, to direct light from the measurement site to the photodetectors. See, e.g., Ex. 1001 19:28-38. The multiple detectors in the physiological sensor device of the '765 Patent allow for an averaging of measurements, and the averaging of measurements can reduce errors due to variations in the path of light passing through the tissue. Ex. 1001 9:18-23; see also 3:13-23, 4:16-27.

B. <u>Introduction To The Independent Claims Of The '765 Patent</u>

28. The '765 Patent has two independent claims: claims 1 and 21. Claim 1 reads as follows:

A physiological measurement system comprising:

a physiological sensor device comprising:

one or more emitters configured to emit light into tissue of a user;

at least four detectors, wherein each of the at least four detectors has a corresponding window that allows light to pass through to the detector;

a wall that surrounds at least the at least four detectors; and

- a cover comprising a protruding convex surface, wherein the protruding convex surface is above all of the at least four detectors, wherein at least a portion of the protruding convex surface is rigid, and wherein the cover operably connects to the wall; and
- a handheld computing device in wireless communication with the physiological sensor device, wherein the handheld computing device comprises:

one or more processors configured to wirelessly receive one or more signals from the physiological sensor device, the one or more

signals responsive to at least a physiological parameter of the user;

a touch-screen display configured to provide a user interface, wherein:

the user interface is configured to display indicia responsive to
measurements of the physiological parameter, and
an orientation of the user interface is configurable responsive to
a user input; and

a storage device configured to at least temporarily store at least the measurements of the physiological parameter.

29. Claim 21 reads as follows:

A physiological measurement system comprising:

a physiological sensor device comprising:

one or more emitters configured to emit light into tissue of a user; at least four detectors, wherein each of the at least four detectors has a corresponding window that allows light to pass through to the detector;

a wall that surrounds at least the at least four detectors; and

a cover comprising a protruding convex surface, wherein the protruding convex surface is positioned such that the protruding

convex surface is located between tissue of the user and all of the at least four detectors when the physiological sensor device is worn by the user, wherein at least a portion of the protruding convex surface is rigid, and wherein the cover operably connects to the wall; and

- a handheld computing device in wireless communication with the physiological sensor device.
- 30. Dr. Kenny applies the same combination of references against claim 1 (Ex. 1003 ¶¶106-140) and claim 21 (Ex. 1003 ¶¶173-179). Dr. Kenny's analysis generally treats claims 1 and 21 similarly, and Dr. Kenny relies on and refers back to his analysis for claim 1 for his analysis of claim 21. Ex. 1003 ¶¶173-179. In addressing Dr. Kenny's opinions, my analysis therefore likewise applies to claims 1 and 21.

V. THE PETITION'S PROPOSED COMBINATIONS

31. Petitioner presents three grounds. Ground 1 combines Aizawa (Ex. 1006), Inokawa (Ex. 1007, translation at Ex. 1008), Ohsaki (Ex. 1009), and Mendelson 2006 (Ex. 1010). Pet. 9-10. Ground 1 challenges claims 1-8, 10-13, and 15-29. Pet. 9-10. Ground 2 challenges dependent claim 9 and adds the additional reference Bergey (Ex. 1016) to the combination of Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Pet. 9-10. Ground 3 challenges dependent claim 14

and adds the additional reference Goldsmith (Ex. 1011) to the combination of Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Pet. 9-10.

VI. <u>LEVEL OF ORDINARY SKILL IN THE ART</u>

- 32. Petitioner asserts that a POSITA "would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies." Pet. 8-9. Alternatively, Petitioner asserts a POSITA could have "a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline." Pet. 8-9.
- 33. Dr. Kenny states that he applies a similar level of skill in his analysis stating that "one of ordinary skill in the art relating to, and at the time of, the invention of the '765 Patent would have been someone with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies.

Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline." Ex. 1003 ¶21.

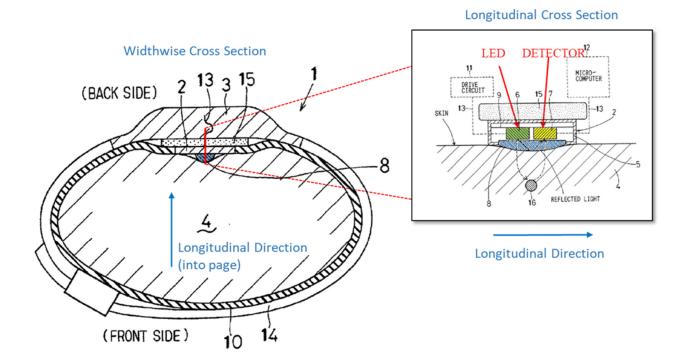
- 34. I note that the asserted level of skill (1) requires no coursework, training or experience with optics or optical physiological monitors; (2) requires no coursework, training or experience in physiology; and (3) focuses on data processing and not sensor design. In responding to Dr. Kenny's opinions in this proceeding, I apply Dr. Kenny's and Petitioner's asserted level of skill.
- 35. In addition, as noted above, I understand that Dr. Kenny carried out his analysis of patentability as of July 3, 2008. Ex. 1003 ¶¶16, 23. In responding to Dr. Kenny's opinions, I also apply the July 3, 2008 date in my analysis. I do not offer any opinions regarding priority in this declaration.

VII. GROUNDS 1, 2, AND 3 DO NOT ESTABLISH OBVIOUSNESS

A. Introduction To Ground 1

- 36. Dr. Kenny's combination for Ground 1 combines four references: Ohsaki, Aizawa, Inokawa, and Mendelson 2006. Ex. 1003 ¶¶106-191. Ground 1 challenges claims 1-8, 10-13, and 15-29. Pet. 9-10.
 - 1. Ohsaki Discloses A Pulse Rate Sensor With A Single Emitter And A Single Detector That Must Be Arranged Linearly On The Back Side Of The Wrist
- 37. Ohsaki is directed to a pulse rate sensor with a single emitter (*e.g.*, an LED) and a single detector that are positioned linearly, side-by-side, under a

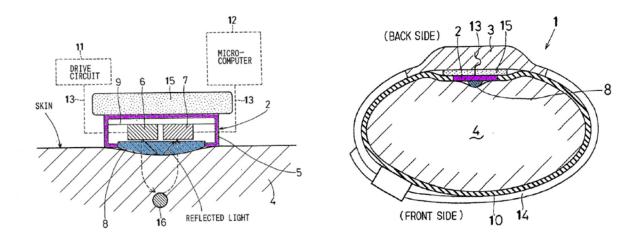
translucent "board." See, e.g., Ex. 1009 Abstract, Fig. 2, ¶[0019]. Ohsaki explains that the linearly arranged detector and emitter (shown in the figures below) likewise results in a longitudinal rectangular shape and directionality, which Ohsaki explains is important for its benefit of reducing slipping when placed against the backhand side of the wrist. See Ex. 1009 ¶[0019] (If longitudinal direction "agrees with the circumferential direction of the user's wrist 4, it has a tendency to slip off. Therefore it is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user's arm."). Ohsaki includes a "dedicated belt" 10 that "fix[es] the detecting element 2 on the user's wrist 4 in this way"—in a longitudinal direction up-and-down the user's wrist. Ex. 1009 ¶[0019]. Figure 1 of Ohsaki (below left) is a cross section of the device when "worn on the back side of the user's wrist 4 corresponding to the back of the user's hand in the similar manner as a wristwatch is normally worn." Ex. 1009 ¶[0016], Fig. 1.



Ohsaki Fig. 1 (left), showing the cross-sectional view of Ohsaki's sensor in the circumferential direction (across the wrist) and Fig. 2 (right) showing the cross-sectional view of Ohsaki's sensor in the longitudinal direction (up-and-down arm)

2. The Shape Of Ohsaki's Board

38. Ohsaki shows two cross-sectional views of its board that a POSITA would have considered together to confirm that the board is rectangular. Ohsaki Figure 2 (below left) illustrates the "long" side of Ohsaki's detector element (2) that extends from left to right in Ohskai's Figure 2, and is shown in the cross section as positioned in the longitudinal direction (up-and-down the arm) on a user's wrist. Ex. 1009 ¶[0019].

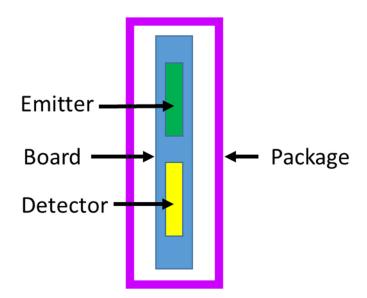


Ohsaki (Ex. 1009) Fig. 2 (left, showing long direction of the detecting element (2), pointing up-and-down the arm) & Fig. 1 (right, showing short direction of the detecting element (2), in the circumferential direction of the wrist) depict different cross-sections (color added)

(Purple: detecting element (2)/package (5); Blue: translucent board (8))

39. Figure 2 (shown above left) illustrates that Ohsaki's board (8, in blue) is nearly as long as the entire length of the package (5, in purple) in the direction of detecting element's (2) "long" side. Ohsaki explains that its "detecting element" includes the "package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8." Ex. 1009 ¶[0017]. Figure 1 (shown above right) illustrates the "short" side of Ohsaki's detecting element (2), which extends from left to right on the page in Figure 1 and shows the cross-section in the circumferential direction of the sensor on (around) the user's wrist. Ex. 1009 ¶[0012], [0019]. As shown in Ohsaki's Figure 1 (shown above right), the board's length (8, blue) is narrower (approximately one third the size) than the detecting element's length (2, purple) in the circumferential direction.

40. Ohsaki's figures and description would have thus indicated to a POSITA that the board (8) has a long rectangular shape with a pronounced longitudinal directionality, and thus is much longer than it is wide. Ex. 1009 ¶¶[0012], [0017], [0019], Figs. 1, 2. Based on Ohsaki's disclosure, a POSITA would have understood that the top-down view of Ohsaki's sensor's "detecting element", including the package, board, and emitter and detector, would look approximately like the figure below:



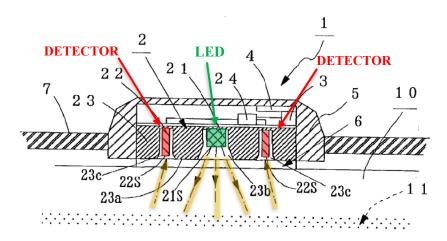
Drawing based on Ohsaki's disclosure, including Figs. 1 and 2 (Ex. 1009), illustrating the rectangular shape of Ohsaki's board and package/detecting element. The long direction of Ohsaki's sensor aligns with the longitudinal direction of the arm. Ex. 1009 ¶[0019].

41. This rectangular shape reflects the rest of Ohsaki's disclosure, which indicates that the sensor has a longitudinal direction, and that to prevent slipping the longitudinal (long) aspect of the sensor's shape must be aligned with the longitudinal direction (long direction) of the user's arm. Ex. 1009 ¶[0019]. Thus, a

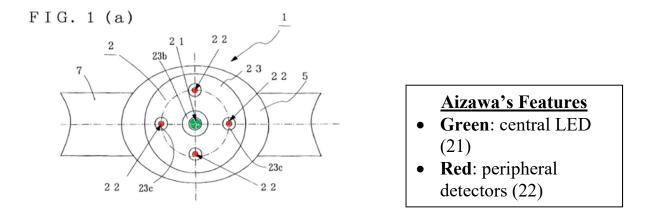
POSITA reading Ohsaki would have appreciated that Ohsaki discloses a long, rectangular shape for its sensor, as well as the board (8).

3. Aizawa Discloses A Circular Pulse Sensor

42. Aizawa discloses a sensor with four periphery-located photodetectors (22) around a single centrally located LED (21). Ex. 1006 Abstract, Fig. 1B.



Aizawa Fig. 1B (cross-sectional view, color added)



Aizawa Fig. 1A (top-down view, color added)

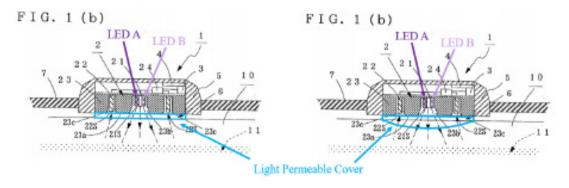
43. Aizawa's sensor is constructed with multiple detectors which are arrayed around a single LED. Aizawa uses this configuration in order to ensure at

least one detector is near the measurement site, which improves measurement Ex. 1006 ¶[0027]. Aizawa specifies that its sensor takes consistency. measurements "on the inner side of [the] wrist." Ex. 1006 ¶[0026]. As shown in Figure 2 of Aizawa, the "inner side" of the wrist is the palm side of the wrist. Ex. 1006 Fig. 2. Aizawa explains that its sensor "is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10." Ex. 1006 ¶[0026]. Aizawa explains that its circular arrangement is used because as long as "one of the photodetectors 22 is located near the artery 11," it is "possible to detect a pulse wave accurately." Ex. 1006 ¶¶[0026]-[0027], Fig. 2. Aizawa includes a flat transparent plate (6), which Aizawa indicates improves adhesion between the detector and the wrist. Ex. 1006 ¶[0030]. Aizawa states that its flat adhesive acrylic plate improves the detection efficiency of a pulse wave. Ex. 1006 ¶[0030]. Aizawa does not indicate that its sensor uses a lens.

4. Ground 1's Proposed Motivation To Combine Four References

44. Ground 1 is a four-reference combination with Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Dr. Kenny proposes a series of motivations to combine Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Ex. 1003 ¶79-87 (combination of Inokawa and Aizawa), 88-97 (addition of Mendelson 2006), 98-102 (addition of Ohsaki).

45. For the convex surface, Dr. Kenny asserts a POSITA would have combined the teachings of Ohsaki, Aizawa, and Inokawa. Ex. 1003 ¶¶98-102. Dr. Kenny asserts that a POSITA would have added Ohsaki's translucent board, designed for a linear sensor, to Aizawa's circular sensor. Ex. 1003 ¶101. Dr. Kenny identifies the following motivations: "the POSITA would have found it obvious to modify the sensor's flat cover (left) to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶101. Dr. Kenny's illustration of the result of the combination of Ohsaki, Aizawa, and Inokawa is shown below (right).

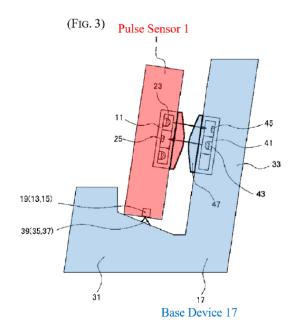


Dr. Kenny's illustration showing on right the alleged result of the combination of Ohsaki, Aizawa, and Inokawa (Ex. 1003 ¶101). The figure on the left shows a modified version of Aizawa's sensor with an extra LED added.

46. Dr. Kenny does not explain whether the modification of Aizawa to introduce a "lens/protrusion ... similar to Ohsaki's translucent board" (Ex. 1003 ¶101, see also ¶123) means that Ohsaki's longitudinal board is simply placed over

Aizawa, or whether it is changed to be circular to match Aizawa's shape and detector arrangement.

With respect to the combination of Aizawa and Inokawa, Dr. Kenny 47. proposes modifying Aizawa's single emitter/multi-detector embodiment based on Inokawa to create a multi-emitter/multi-detector device. Ex. 1003 ¶¶79-87. Inokawa does not disclose a multi-emitter/multi-detector device. Ex. 1008 Fig. 2, ¶[0058] ("the pulse sensor 1 is comprised of a pair of light-emitting elements...[and] a single photodiode"). Dr. Kenny identifies the following motivation to modify Aizawa's single emitter/multi-detector embodiment to add an LED: "To obtain the advantages described by Inokawa (e.g., to improve the detected pulse wave by enabling the sensor to distinguish between blood flow detection and body movement, in addition to enabling wireless communication between the sensor and a base station), a POSITA would have been motivated to modify Aizawa's pulse wave sensor to include an additional LED." Ex. 1003 ¶83. Dr. Kenny includes the following figure illustrating Inokawa's base station communication arrangement. Dr. Kenny also refers to the base station as a "base device." Ex. 1003 ¶69.



Dr. Kenny's illustration of Inokawa's sensor and base device (Ex. 1003 ¶69)

- 48. As shown in the illustration above, Inokawa's base station data transfer approach transmits data from the sensor to the base device when the sensor is removed from the user's body and mounted on the base device. *See, e.g.*, Ex. 1008 Abstract. Thus, Inokawa's system requires the user to remove the monitoring device and attach it to the base station before the sensor can transmit data that was stored in the memory. *See, e.g.*, Ex. 1008 Figs. 3, 5, 8, Abstract, ¶¶[0070], [0074].
- 49. Finally, Dr. Kenny uses Mendelson 2006 to attempt to meet the claims' requirement of a handheld computing device in wireless communication with the physiological sensor device. Ex. 1003 ¶88-97. Dr. Kenny asserts that "Mendelson-2006's system includes a sensor module that transmits signals wirelessly to a PDA through a receiver module." Ex. 1003 ¶90. Dr. Kenny further states: "Wireless communication with the handheld PDA is, moreover, said to

enable transfer of information pertaining to physiological and wellness parameters such as 'SpO₂, HR, body acceleration, and posture information' to the PDA; and, when the PDA is 'carried by medics or first responders,' this information is said to enhance their ability 'to extend more effective medical care, thereby saving the lives of critically injured persons." Ex. 1003 ¶94 (quoting Ex. 1010 at 4). Dr. Kenny asserts a POSITA "would have been motivated to implement Aizawa's pulse wave sensor as part of a physiological measurement system including a handheld computing device," based on "these and other advantages described by Mendelson-2006." Ex. 1003 ¶95. Thus, after changing Aizawa's sensor to use Inokawa's base station data transfer approach, Dr. Kenny suggests adding back the type of wireless transmitter removed from Aizawa to change it to the base station data transfer approach. See Ex. 1003 ¶¶82 (modification based on Inokawa motivated by desire to avoid "a separate RF circuit"), 93 (describing Mendelson 2006's use of an RF link with further use of "both 802.11b and BluetoothTM wireless communication").

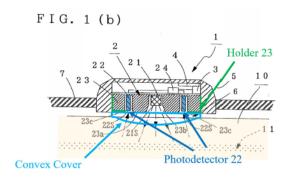
B. <u>A POSITA Would Not Have Been Motivated To Combine Ohsaki's Board With Aizawa's Sensor</u>

50. Dr. Kenny asserts that a POSITA would have modified Aizawa's flat adhesive acrylic plate "to include a lens/protrusion...similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶101; see also ¶123. As discussed in detail below, Dr. Kenny

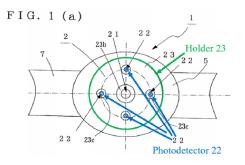
does not establish that any of these three motivations are present in the cited art, or that they would have motivated a POSITA to create Masimo's invention.

51. As I discuss below, a POSITA would have understood that Ohsaki's rectangular board would be incompatible with Aizawa's circular sensor arrangement, which undermines any motivation to improve adhesion of Aizawa's circular sensor to the user's tissue by adding a lens/protrusion similar to Ohsaki's rectangular board. Further, a POSITA would have understood that to obtain a benefit from Ohsaki's rectangular board, the sensor must be positioned on the backhand side of the wrist, which is far from the radial and ulnar arteries that are found on the palm side of the wrist, where Aizawa's sensor takes its pulse measurements. In addition, a POSITA would have believed that adding a convexshaped cover to Aizawa's sensor would have a detrimental optical impact by directing light away from Aizawa's peripherally located detectors, resulting in reduced signal strength and decreased detection efficiency. Further, a POSITA would not have selected a convex shape for protecting Aizawa's sensor components because of the complications and problems associated with adding a convex surface to Aizawa's flat plate.

- 1. <u>A POSITA Would Have Understood That Ohsaki's Rectangular Board Would Not Work With Aizawa's Circular Sensor Arrangement</u>
 - a) <u>Modifying Ohsaki's Rectangular Board Would</u> <u>Eliminate The Limited Advantage Of Reduced</u> <u>Slipping Taught By Ohsaki</u>
- 52. Dr. Kenny's combination changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's rectangular board the ability to fit within the user's anatomy and prevent slipping. Ex. 1003 ¶98-102; Ex. 1009 ¶[0019]. Dr. Kenny's illustrated combination changes Ohsaki's rectangular board (discussed in Sections VII.A.1-2, above) and makes it circular so that it can cover Aizawa's holder 23 (which Dr. Kenny identified in green in the figures below):



Dr. Kenny's illustration of the combination of Aizawa, Ohsaki, and Inokawa (Ex. 1003 ¶124)

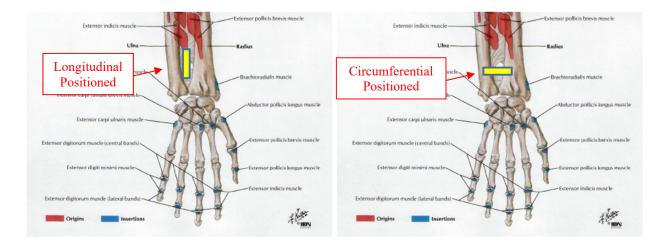


Dr. Kenny's illustration of Aizawa's circular sensor (Ex. 1003 ¶121)

53. Dr. Kenny asserts that a POSITA would have been motivated to add Ohsaki's rectangular board to Aizawa's circular sensor to improve adhesion. Ex. 1003 ¶101; see also, e.g., ¶¶98-102, 123. As an initial point, Ohsaki does not specifically discuss improving adhesion, and instead refers to a particular

configuration that prevents slipping and various other configurations that have a tendency to slip. Ex. 1009 ¶¶[0006], [0010], [0019], [0023], [0025]. Dr. Kenny equates Ohaski's disclosure of a convex surface that prevents slippage with "improving adhesion." Ex. 1003 ¶98 (citing Ex. 1009 ¶[0025]). But Dr. Kenny's proposed modification eliminates the longitudinal shape that Ohsaki identifies as an important part of reducing slipping. Ex. 1009 ¶[0019].

54. Ohsaki places its linear, longitudinal sensor on the backhand side of a user's wrist to avoid interacting with bones in the wrist. *See* Ex. 1009 ¶[0006] (discussing need to avoid pressing on "two bones (the radius and the ulna)"), ¶[0024] ("the radius and the ulna inside the user's wrist 4 are not pressed"); *see also*, *e.g.*, ¶¶[0023]-[0024], Abstract, Title, Fig. 1 (Ohsaki device worn on back side of wrist). As illustrated below (left), the forearm bones (the radius and ulna) on the arm's backhand (or watch) side create a longitudinal opening at the junction between the wrist and forearm with no muscle insertions. Ex. 2010 at 49 (Plate 434). The radius and ulna, against which Ohsaki warns against pressing (Ex. 1009 ¶¶[0006], [0024]), are on either side of this longitudinal opening.



Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))

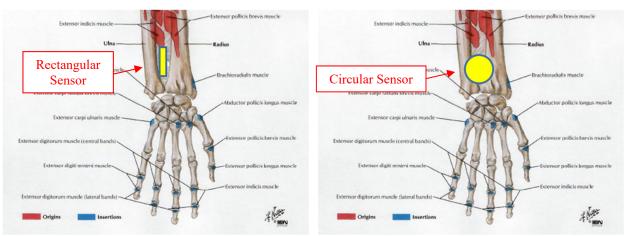
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna Right: Conceptual view of how the same rectangular sensor placed in the circumferential direction on wrist/forearm interacts with the radius and ulna

55. Ohsaki indicates that its sensor's longitudinal direction needs to be aligned with the longitudinal direction of the longitudinal opening of the user's arm to prevent slipping. Ex. 1009 ¶[0019]. If the sensor's longitudinal direction is aligned with the circumferential direction of the user's wrist, the undesirable result is "a tendency [for Ohsaki's sensor] to slip off." Ex. 1009 ¶[0019]. As illustrated above (right), a rectangular structure like Ohsaki's sensor and board that is aligned with the circumferential direction of the user's wrist undesirably interacts with the radius and ulna, which Osaki warns against. Ex. 1009 ¶[0006], [0024]. In contrast, a rectangular structure aligned with the longitudinal direction of the user's wrist can avoid pressing against the radius and ulna.

56. Thus, a POSITA would have understood that changing the shape of Ohsaki's rectangular board to circular would not preserve its ability to prevent slipping. Instead, if Ohsaki's rectangular board were changed into a circular shape, a POSITA would have believed it would have resulted in slipping, and thus eliminated the advantage of Ohsaki's board. This is because a circular shape extends equally in all directions, including in the circumferential direction of the user's wrist, which Ohsaki explains results in slipping. Ex. 1009 ¶[0019]. As a result, a circular shape cannot be placed in a longitudinal direction and thus cannot align with the longitudinal direction of the user's wrist, as taught by Ohsaki. As illustrated below, unlike a longitudinal sensor, a symmetrical circular shape (with a diameter equal to the long side of the rectangle, below left) would not fit within the user's anatomy in a way that it could avoid undesirably pressing against the user's radius and ulna, which Ohsaki cautioned against.

Ohsaki's Longitudinal Teachings

Dr. Kenny's Proposed Combination



Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))

Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna Right: Conceptual view of how a circular sensor with the same diameter as the length of the rectangular board interacts with the radius and ulna

- 57. Because a symmetrical circular shape will press on the user's arm in all directions, it will interact with the user's bone structure. Ohsaki teaches that such interactions with the user's anatomy are undesirable and result in slipping. Ex. 1009 ¶¶[0006], [0023]-[0024].
- 58. Dr. Kenny did not discuss Ohsaki's disclosure that when Ohsaki's rectangular sensor was placed in one orientation (up-and-down the arm), it helped prevent slipping. Ex. 1009 ¶[0019]. Dr. Kenny also did not discuss Ohsaki's explanation that rotating the sensor 90 degrees, such that the long direction points in the circumferential direction of the user's wrist, the sensor "has a tendency to slip." Ex. 1009 ¶[0019].

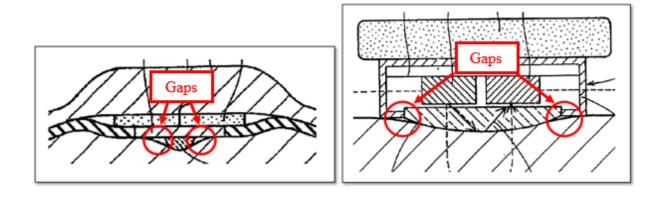
59. In my opinion, a POSITA would have understood that Ohsaki does not include a generalized teaching that any convex surface would prevent slipping. Ohsaki's explanation that rotating a sensor positioned on the back of the wrist 90 degrees results in "a tendency to slip off," would have confirmed for a POSITA that any benefit for reduced slipping stemming from Ohsaki's convex rectangular board was very specific and limited. Ex. 1009 ¶[0019]. A POSITA would have further understood that Ohsaki's use of a "dedicated belt" to keep the long side of the rectangular detecting element pointing up and down the arm indicated that this particular positioning was important. Ex. 1009 ¶[0019]. Further confirming the limited nature of any benefits taught in Ohsaki, Ohsaki teaches its convex board placed on the palm side (front side) of the wrist "has a tendency to slip off the detecting position" and does not prevent slipping. Ex. 1009 ¶¶[0023]-[0024], Figs. 3A-3B. While Ohsaki explains a particular sensor orientation can prevent slipping on the back of the wrist, Ex. 1009 ¶[0019], it does not indicate that a different orientation would help prevent slipping on the palm side of the wrist. In addition, Ohsaki repeatedly emphasizes that its sensor must be placed on the backhand side of the wrist: Ohsaki explains its "pulse wave sensor is worn on the back side of the user's wrist" and its "detecting element is attached on the back side of the user's wrist...." Ex. 1009 ¶¶[0008]-[0009]; see also, e.g., Title, Abstract, ¶¶[0016],

[0024]; see also ¶[0030] (single sentence identifying back side of user's forearm, which is connected to the wrist).

- 60. As a result, a POSITA would not have been motivated to eliminate the longitudinal shape that Ohsaki asserts helps prevent slipping. Ex. 1009 ¶[0019]. Indeed, Ohsaki underscores the unsuitability of the proposed combination, explaining that many sensor positions and orientations are ineffective. Ex. 1009 ¶¶[0019], [0023]-[0024]. Beyond the illustrated longitudinal shape (Ex. 1009) ¶[0019], Figs. 1-2) Ohsaki has no details or explanation that a POSITA could use to implement its board into other devices, other shapes, or other measurement locations. Ohsaki indicates that only one shape (rectangular), one position (back side of the wrist, discussed further below), and one orientation (up-and-down the arm) prevent slipping. Ex. 1009 ¶¶[0019], [0023]-[0025]. Ohsaki emphasizes that its benefit occurs only when the sensor has a longitudinal shape and is on the wrist's back side, in the anatomically appropriate orientation. Ex. 1009 ¶¶[0019], [0023]-[0024].
- 61. A POSITA would not have been motivated to change the shape of Ohsaki's rectangular board to combine it with Aizawa's circular sensor because a POSITA would have understood that changing Ohsaki's rectangular board into a circular shape would eliminate Ohsaki's benefit of preventing slipping.

- b) To The Extent Dr. Kenny Seeks To Raise A New Argument, A POSITA Would Not Have Been Motivated To Add A Rectangular Board To Aizawa's Circular Detector
- 62. Dr. Kenny illustrates the combination of Ohsaki and Aizawa (Ex. 1003 ¶¶120, 123) with a circular cover over Aizawa's circular housing. But then Dr. Kenny still asserts that the POSITA "would have found it obvious to modify the sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8." Ex. 1003 ¶101.
- Ohsaki's rectangular board in conjunction with Aizawa's circular sensor, this would disrupt Aizawa's circular sensor's symmetry, and any such argument is not supported. Aizawa distinguishes its symmetric array of peripheral detectors from linear sensors, such as Ohsaki's side-by-side emitter/detector configuration, explaining the "photodetectors [are] disposed around the light emitting diode and not linearly." Ex. 1006 ¶[0009]; see also ¶[0027], [0036]. Aizawa indicates this circular symmetry is beneficial because, unlike linear sensors, "[e]ven when the attachment position of the sensor is dislocated, a pulse wave can be detected accurately." Ex. 1006 ¶[0009]; see also ¶[0012], [0027], [0029], [0032], [0033].
- 64. Even assuming one could design a longitudinal structure that both covers all of Aizawa's circularly arranged detectors and also still avoids the user's physiology, applying Ohsaki's rectangular board to Aizawa's circular sensor would

result in undesirable asymmetrical pressure and inconsistent contact at the peripheral edge where Aizawa's detectors are located. Ohsaki illustrates the differential pressure created by its convex board. Ex. 1009 Figs. 1, 2. Figures 1 and 2 show that the center of the board exerts the greatest pressure and pushes into the skin, causing distention. Ex. 1009 Figs. 1, 2.



Magnified partial view of Ohsaki Figs. 1 (left) and 2 (right) with red circles annotating air gaps formed by Ohsaki's convex board

detectors may also create air gaps over some or all of Aizawa's peripherally arrayed detectors, but not others, which could result in degraded or inconsistent optical signals. A POSITA would have believed that Ohsaki's rectangular board would result in a substantially different optical environment for Aizawa's various detectors based on the redirection of light away from some detectors and towards others. For example, some detectors may be positioned directly under the center of the protrusion, and thus have more light directed towards them. Other detectors may be positioned at the edge of the protrusion, and thus receive relatively less light

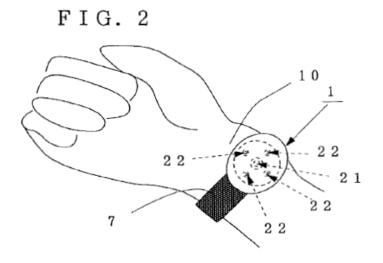
compared to a flat surface. Still other detectors may fall outside of the rectangular protrusion entirely, and thus experience yet another optical environment. *Compare* Ex. 1006 Fig. 1A (Aizawa's circular structure) *with* Ex. 1009 Figs. 1, 2 (Ohsaki's linear structure). A longitudinal shape might also cover some detectors completely and leave other detectors mostly uncovered. Disrupting Aizawa's circular symmetry with Ohsaki's rectangular board runs counter to Aizawa's disclosure. Ex. 1006 ¶[0009]; *see also* ¶¶[0012], [0027], [0029], [0032], [0033]. A POSITA would not have been motivated to make such a change.

- 2. A POSITA Would Have Understood That Ohsaki's Board Would Have Been Detrimental In Combination With Aizawa's Sensor Because Ohsaki's Board "Has A Tendency To Slip" At Aizawa's Measurement Location On The Palm Side Of The Wrist, Near The Artery
- 66. Dr. Kenny asserts that it would have been obvious to modify Aizawa's "flat cover" to add a "lens/protrusion...similar to Ohsaki's translucent board 8...." Ex. 1003 ¶101; see also ¶123. Dr. Kenny asserts this modification would "improve adhesion..." Ex. 1003 ¶101; see also ¶123. But Ohsaki indicates a convex surface only prevents slipping on the back (i.e., watch) side of the wrist in a specific orientation, but tends to slip when used in different locations or orientations. See Sections VII.A.1-2, VII.B.1, above. In contrast, a POSITA would have understood that Aizawa requires its sensor to be positioned on the palm side of the wrist, where its sensor measures light reflected from an artery (e.g. the radial or

ulnar arteries). Ex. 1006 ¶¶[0002], [0007], [0009], [0026], [0027], [0036], Fig. 2. A POSITA seeking to improve Aizawa would not incorporate a feature that only improves adhesion at a measurement location away from the radial and ulnar arteries on the palm side of the wrist.

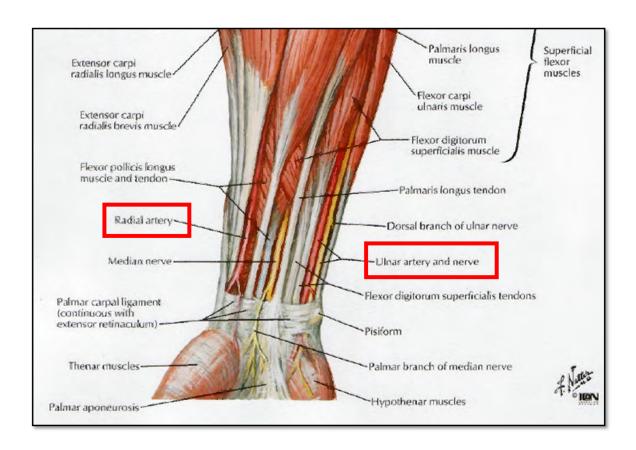
a) <u>Aizawa's Flat Acrylic Plate Improves Adhesion On</u> <u>The Palm Side Of The Wrist</u>

Aizawa (Fig. 2 below) discloses a sensor used on the palm side of the wrist. Aizawa's sensor uses a flat acrylic cover with a circular array of multiple detectors surrounding a single LED. Aizawa explains its sensor functions by "irradiating the artery of the wrist" and is thus shown worn on the palm side of the wrist, which is close to the large radial and ulnar arteries. Ex. 1006 ¶[0002]; see also ¶[0007], [0009], [0026], [0027], [0036], Fig. 2. Aizawa illustrates its sensor's positioning on the palm side, described by Aizawa as the "inner side," of the user's wrist. Ex. 1006 Fig. 2; Ex. 1006 ¶[0026]. Aizawa explains: "As shown in FIG. 2, a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 with a belt in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side)." Ex. 1006 ¶[0026].



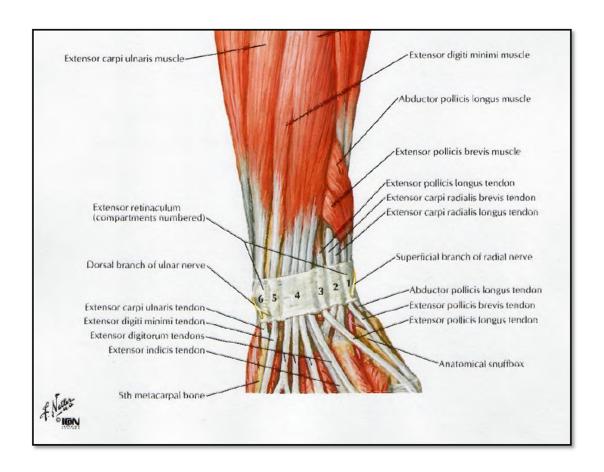
Aizawa's palm-side sensor positioning on the palm side of the wrist (Ex. 1006 Fig. 2, ¶[0026])

68. As illustrated in Aizawa Figure 2, Aizawa's sensor takes measurements from the palm side of the wrist, near the artery. As shown below, the ulnar and radial arteries are near the surface on the palm side of the wrist, and Aizawa's figure shows its sensor positioned towards the thumb side of the wrist, which corresponds to the location of the radial artery. Ex. 2010 at 44 (Plate 429) (showing radial and ulnar arteries in superficial layer of the anterior (palm side) of wrist); see also 71 (Plate 456) (showing arteries on palm side of upper limb).



Superficial layer of palm side (anterior) forearm and wrist, showing that the radial and ulnar arteries are close to the surface (partial view) Ex. 2010 at 44 (Plate 429), annotated

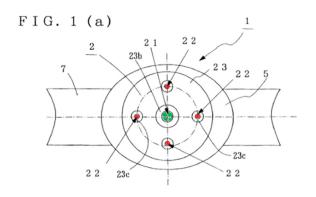
69. In contrast, as shown in the figure below, the radial and ulnar arteries are not near the surface of the wrist and forearm's back side.



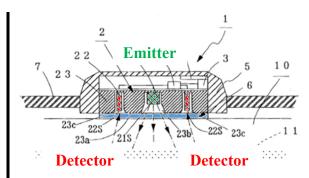
Superficial layer of back side (posterior) of forearm and wrist (partial view) Ex. 2010 at 42 (Plate 427)

- 70. Thus, a POSITA would have understood that Aizawa teaches its wrist-worn sensor is used on the palm side of the wrist and measures an optical signal from an artery, and thus should be positioned above, *e.g.*, the radial artery as shown in Aizawa Figure 2's sensor placement. Aizawa repeatedly confirms the positioning at "the artery of the wrist," explaining:
 - Its sensor functions by "irradiating the artery of the wrist with light." Ex. $1006 \, \P[0002]$.

- Its sensor detects "light output from a light emitting diode and reflected from the artery of a wrist of a subject." Ex. 1006 ¶[0009].
- That a belt fastens its sensor so "the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10." Ex. 1006 ¶[0026].
- That the light detected by its sensor's photodiodes "is reflected by a red corpuscle running through the artery 11 of the wrist 10." Ex. 1006 ¶[0027].
- That "the present invention...is constituted such that light output from a light emitting diode and reflected from the artery of the wrist...." Ex. 1006 ¶[0036].
- 71. As shown in the illustration below (left), Aizawa's sensor places detectors (red) symmetrically in a concentric circle around an emitter (green). Ex. 1006 Fig. 1A. Aizawa protects these optical components, which are in cavities, with a flat acrylic transparent plate (blue, below, right) placed on the top of the holder (23). Ex. 1006 ¶[0023], Fig. 1B; see also ¶[0024] (emitters and detectors "stored in cavities").



Aizwa Fig. 1A (top view) Red: detectors; Green: emitter



Aizawa Fig. 1B (cross-section) Red: detectors; Green: emitter, Blue: flat plate

- 72. Aizawa repeatedly teaches that its flat acrylic plate beneficially improves adhesion to the measurement site at the palm side of the wrist, explaining:
 - "[A] transparent plate-like member is provided on a portion including at least the light emitting face and the light receiving faces of the contact face.

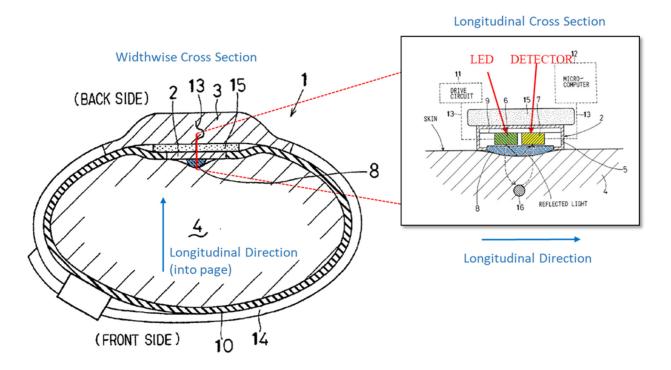
 This makes it possible to improve adhesion between the sensor and the wrist and thereby further improve the detection efficiency of pulse waves." Ex. 1006 ¶[0013].
 - "[T]he above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved." Ex. 1006 ¶[0026].
 - "Since the acrylic transparent plate 6 is provided on the detection face 23a of the holder 23, adhesion between the pulse rate detector 1 and the wrist 10

- can be improved, thereby further improving the detection efficiency of a pulse wave." Ex. 1006 ¶[0030].
- "In the above embodiment, the acrylic transparent plate 6 is provided on the detection face 23a of the holder 23 to improve adhesion to the wrist 10." Ex. 1006 ¶[0034].
- Thus, a POSITA reading Aizawa's disclosure as a whole would have understood that Aizawa requires that its sensor take measurements on the palm side of the wrist, near an artery (e.g., the radial artery, based on the sensor positioning in Ex. 1006 Fig. 2). A POSITA would have further understood based on Aizawa's disclosure that the flat acrylic plate used in Aizawa's sensor improves adhesion between the sensor and skin on the palm side of the wrist. *See, e.g.*, Ex 1006 ¶¶[0013], [0026], [0030], [0034]. Thus, for these reasons a POSITA would not have been motivated to modify Aizawa's flat plate, which improves adhesion on the palm side of the wrist where Aizawa's sensor is used, based on the teachings of Ohsaki's convex board.

b) Ohsaki's Convex Board Has "A Tendency To Slip" When Positioned On The Palm Side Of The Wrist

74. In contrast to Aizawa, Ohsaki discloses a pulse rate sensor with a single emitter (*e.g.*, an LED) and a single detector disposed linearly, side-by-side, under a translucent board. Ex. 1009 Fig. 2, ¶[0017]. Ohsaki's linearly arranged

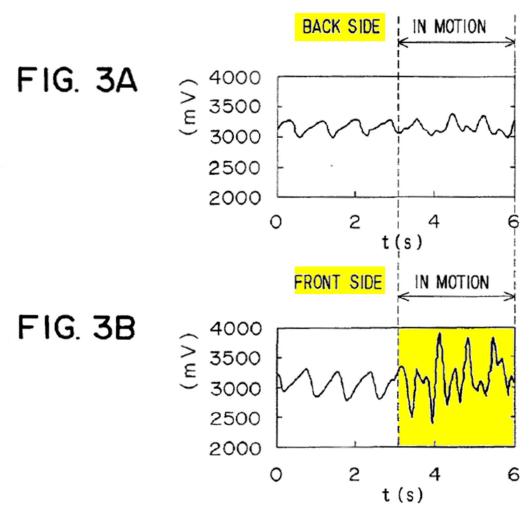
detector and emitter (below) results in a longitudinal directionality that contributes to Ohsaki's stated benefit of reducing slipping. Ex. 1009 ¶[0019].



Ohsaki Fig. 1 (left), showing the cross-sectional view of Ohsaki's sensor in the circumferential direction (across the wrist) and Fig. 2 (right) showing the cross-sectional view of Ohsaki's sensor in the longitudinal direction (up-and-down arm)

75. Ohsaki's sensor prevents slipping when it is positioned on the backhand side of the wrist, but only if its longitudinal (long) direction points up and down the user's arm. *See, e.g.*, Ex. 1009 ¶[0019], [0024]. In contrast, Ohsaki reports that its sensor "has a tendency to slip off" when it is turned 90 degrees on the back side of the user's wrist (resulting in the sensor's long side pointing across the user's wrist). Ex. 1009 ¶[0019]. Ohsaki also reports that its sensor "has a tendency to slip" if positioned on the palm side (which Ohsaki calls the "front side") of the user's wrist. *See, e.g.*, Ex. 1009 ¶[0023], Figs. 3A-3B.

76. Ohsaki illustrates the "tendency to slip" on the palm side ("front side") of the wrist using the pulse wave measurements shown in Figures 3A-3B (below). Ex. 1009 ¶¶[0023]-[0024].

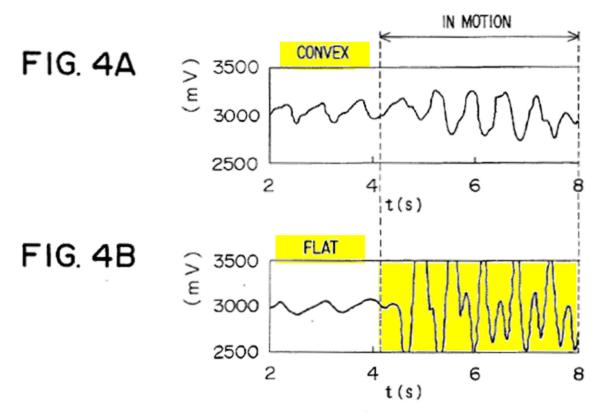


Ohsaki Figs. 3A-3B illustrating the tendency of its convex board "to slip" when positioned on the front side (palm side) of the wrist (highlighting added to show change in signal with motion on palm side of wrist)

77. Ohaski explains that for measurements taken on the palm side of the wrist, "when the user is in motion, the detected pulse wave is adversely affected by the movement of the user's wrist...." Ex. 1009 ¶[0023]. This "adverse" result

identified by Ohsaki corresponds to the irregular pattern shown in Figure 3B, compared to the pattern of measurements from the back side of the wrist shown in Figure 3A. For measurements using a convex board on the back side of the wrist, Ohsaki explains Figure 3A shows "the pulse wave is detected stably without being affected by the movement of the user's wrist…." Ex. 1009 ¶[0024].

78. Dr. Kenny does not cite or discuss Ohsaki's Figures 3A-3B when discussing the motivation for modifying Aizawa's palm-side sensor with a lens/protrusion similar to Ohsaki's board. Ex. 1003 ¶¶98-102; see also ¶123. Instead, Dr. Kenny discusses Ohsaki's Figures 4A-4B, which compares measurements using a sensor with a convex surface or a flat surface on the back (i.e., watch) side of the wrist. Ex. 1003 ¶¶98-102; see also ¶123.



Ohsaki Figs. 4A-4B comparing convex and flat surfaces for measurements taken from the back side of the wrist (color added)

79. Ohsaki states that Figure 4B shows that when measurements taken from the back side of the wrist using a sensor with a *flat* surface, "the detected pulse wave is adversely affected by the movement of the user's wrist." Ex. 1009 ¶[0025]. Ohsaki also indicates that a board with a *convex* surface prevents "slip[ping] off the detecting position" on the back side of the wrist, as shown in Figure 4A. Ex. 1009 ¶[0025]; *see also* ¶¶[0023]-[0024] (comparing tendency to slip on front and back side of wrist). Figure 4A, which illustrates Ohsaki's convex sensor placed on the back side of the wrist, contrasts with the measurements shown in Figure 3B (which illustrates a convex surface slips on the palm side of the wrist). Figure 4A is

consistent with Figure 3A (which illustrates a convex surface has comparatively less motion signal on the back side of the wrist). Taken together, A POSITA would have understood that Ohsaki's convex surface may prevent slipping on the back side of the wrist, if it is positioned appropriately (e.g., in the correct orientation with the long side up-and-down the wrist). Ex. 1009 ¶[0019], [0023]-[0025], Figs. 3A-3B, 4A-4B.

80. The rest of Ohsaki's disclosure recognizes the limitations on any benefit derived from its convex surface. Ohsaki repeatedly specifies that its sensor "is worn on the back side of a user's wrist corresponding to the back of the user's hand." Ex. 1009 Abstract; see also Title ("Wristwatch-Type Human Pulse Wave Sensor Attached On Back Side Of User's Wrist"), ¶[0008] (The "sensor according" to the present invention...is worn on the back side of the user's wrist corresponding to the back of the user's hand."), ¶[0009] ("attached on the back side of the user's wrist by a dedicated belt"), ¶[0016] ("worn on the back side of the user's wrist"), ¶[0024] ("[T]he detecting element 2 is stably fixed to the detecting position of the user's wrist" when arranged on the back side of the user's wrist 4.). The only other possible location mentioned for placement of Ohsaki's sensor is "the back side of the user's forearm," which is adjacent to the wrist. Ex. 1009 ¶¶[0016], [0030]. Thus, in my opinion, for these reasons a POSITA would not have been motivated to

use Ohsaki's longitudinal board, which is designed to be worn on the back of a user's wrist, with Aizawa's palm-side sensor.

- c) <u>A POSITA Would Not Have Been Motivated To Eliminate The Identified Benefits Of Aizawa's Flat Adhesive Acrylic Plate By Including A Lens/Protrusion Similar To Ohsaki's Board</u>
- 81. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate "to include a lens/protrusion...similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶101, 123. But a POSITA motivated to improve Aizawa's palm-side sensor would not have been motivated to add Ohsaki's convex board. As discussed above, Ohsaki teaches a POSITA that its convex board only provides advantages on the back side of the wrist, in a particular orientation. Ex. 1009 ¶[0019], [0025]. Ohsaki further teaches that on the palm side (front side) of the wrist, a sensor with a convex board, "has a tendency to slip off the detecting position of the user's wrist." Ex. 1009 ¶[0023], Figs. 3A-3B.
- 82. As discussed above, Aizawa teaches that a flat acrylic plate improves adhesion between the sensor and skin on the palm side of the wrist. *See* Sections VII.A.3, VII.B.2.a, above. Taken individually and together, both Ohsaki and Aizawa undermine Dr. Kenny's proposed addition of a convex lens/protrusion similar to Ohsaki's translucent board to Aizawa's palm-side sensor to improve

adhesion. Ex. 1003 ¶101; see also, e.g. ¶¶98-102, 123. This is because, as explained above (Sections VII.B.2.a-b): (1) Aizawa teaches a <u>flat</u> acrylic plate <u>improves</u> adhesion on the wrist's <u>palm</u> side; (2) Ohsaki teaches a <u>convex</u> board "has a tendency to <u>slip</u>" on the wrist's <u>palm</u> side. As a result, a POSITA reading Aizawa and Ohsaki would have affirmatively avoided modifying Aizawa's flat acrylic plate—which is taught to improve adhesion at Aizawa's sensor location on the palm side of the wrist—with a convex lens/protrusion similar to Ohsaki's convex board because Ohsaki's convex board is taught to slip on the palm side of the wrist where Aizawa's sensor is positioned. The table below summarizes these teachings.

	Front (Palm) Side	Back Side
Flat	Flat acrylic plate improves adhesion Ex. 1006 (Aizawa) ¶[0013]; see also ¶¶[0026], [0030], [0034], Fig. 1B (Aizawa's sensor)	Tends to slip Ex. 1009 (Ohsaki) ¶[0025], Figs. 4A-4B
Convex	Tends to slip Ex. 1009 (Ohsaki) ¶[0023], Figs. 3A-3B	Rectangular convex board prevents slipping Ex. 1009 (Ohsaki) ¶¶[0024]- [0025], Figs. 4A-4B (Ohsaki's sensor)

83. Dr. Kenny only considers Ohsaki's discussion of the impact of a convex versus flat surface on the back side of the wrist. *See, e.g.,* Ex. 1003 ¶¶98-102, 123. But a POSITA would have understood that Ohskai's discussion regarding the back side of the wrist has little relevance to Aizawa's sensor, which is

used on the palm side of the wrist, near the artery. Ex. 1006 ¶[0002]; see also ¶¶[0007], [0009], [0026], [0027], [0036], Fig. 2; see also Ex. 2010 at 44-45 (Plate 429-430) (showing radial and ulnar arteries in superficial layer of the anterior (palm side) of wrist); compare 71 (Plate 427) (showing arteries on palm-side of upper limb). Indeed, arteries are shown near the surface on the palm side of the wrist. Ex. 2010 at 44 (Plate 429) (showing radial and ulnar arteries in superficial layer of the anterior (palm side) of wrist); compare at 42 (Plate 427) (showing no radial and ulnar arteries near the surface of the back side (backhand side) of forearm and wrist). Because Aizawa specifies its sensor takes measurements from an artery on the wrist's palm side, a POSITA would have looked to Ohsaki's teachings regarding the impact of its convex surface when used on the palm side ("front side") of the wrist when considering whether to combine it with Aizawa. particular, a POSITA would have looked to Ohsaki's guidance that a convex lens/protrusion used on the wrist's palm side "has a tendency to slip." Ex. 1009 ¶[0023], Fig. 3. A POSITA would have found this teaching of Ohsaki, which corresponds to Aizawa's actual measurement location, much more relevant than Ohsaki's discussion of what features are required for a sensor on the back side of the wrist (e.g., longitudinal directionality in the same direction as the arm, a convex surface).

84. Based on Aizawa's teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki's teaching that a convex surface tends to slip on the palm side of the wrist, a POSITA would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa's flat adhesive plate "to include a lens/protrusion...similar to Ohsaki's translucent board" would not "improve adhesion..." See, e.g., Ex. 1003 ¶101. As discussed above in this section, as well as Section VII.B.1, above, generally, Aizawa and Ohsaki, individually and together rebut Dr. Kenny's assertion "that incorporating Ohsaki's convex surface is simply improving Aizawa-Inokawa's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor." Ex. 1003 ¶102. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's flat acrylic plate, which improves adhesion at the measurement site on the palm side of the wrist, to include a convex lens/protrusion similar to Ohsaki's board, which tends to slip at the measurement site on the palm side of the wrist.

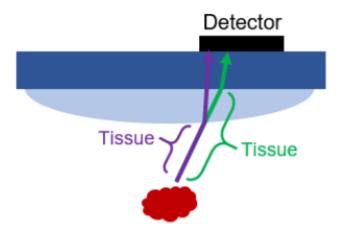
3. <u>A POSITA Would Not Have Been Motivated To Reduce The Measured Optical Signal By Adding A Convex Lens To Aizawa's Sensor</u>

85. Dr. Kenny's proposed combination is also problematic because Dr. Kenny detrimentally modifies Aizawa's flat cover to include a convex "lens/protrusion" positioned over peripheral detectors surrounding a centrally

located emitter. Ex. 1003 ¶¶101-102, 123. As discussed below, a POSITA would have understood that a convex "lens/protrusion" would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors—not increased signal strength as Dr. Kenny asserts.

a) <u>A POSITA Would Have Understood That A Convex</u> Cover Directs Light To The Center Of The Sensor

86. Petitioner and Dr. Kenny both admit that a convex cover condenses light passing through it towards the center of the sensor and away from the periphery. Petitioner and Dr. Kenny both illustrated this phenomenon in a petition filed against a related patent. In the Petition in IPR2020-01520 (Ex. 2019), Petitioner explained that a convex cover redirects light coming into the convex surface towards the center, as shown in Petitioner's figure below:



Petitioner's illustration from a related IPR showing that light hitting a convex surface is directed more centrally than light hitting a flat surface (Ex. 2019 at 45)

- 87. In his declaration in IPR2020-01520 (Ex. 2020), Dr. Kenny likewise confirmed that when using a convex surface as a lens, "the incoming light is 'condensed' toward the center." *See, e.g.,* Ex. 2020 at 69-70 (¶119); *see generally* Ex. 2020 at 69-70 (¶118-120), 115-117 (¶¶199-201). Dr. Kenny included the same illustration as Petitioner, which shows light passing through a convex surface is directed more towards the center, as compared to a flat surface. *See, e.g.*, Ex. 2020 at 69-71 (¶118-120).
- 88. The '765 Patent also confirms these admissions that a convex surface condenses light away from the periphery and towards the sensor's center. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:3-6. "When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422." Ex. 1001 36:13-15. As shown by Figure 14B of the '765 Patent, the convex shape directs light from the periphery toward the center. Ex. 1001 Fig. 14B.

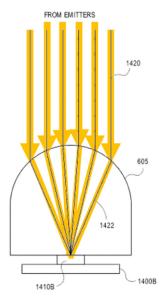


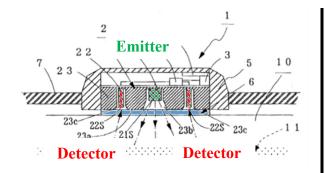
Illustration from the '765 Patent at issue, showing that light hitting a convex surface is directed towards the center '765 Patent (Ex. 1001) Fig. 14B (highlighting added to show direction of light)

89. Accordingly, Petitioner, Dr. Kenny, and the '765 Patent all support that a POSITA would have understood that a convex lens/protrusion would direct incoming light towards the center of the sensor, as compared to a flat surface. In my opinion, a POSITA would have believed that light passing through a convex surface would have been directed to a more central location as compared to light passing through a flat surface. This would have been viewed as a detrimental result because, as discussed in the next section below, Aizawa's detectors are at the periphery of the sensor.

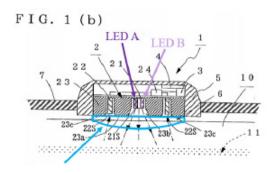
b) A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors

90. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate with "a lens/protrusion" for improved

detection efficiency. Ex. 1003 ¶101. As illustrated below, Aizawa has peripherally located detectors (in red, below left) and a centrally located emitter (in green, below left) under a flat acrylic adhesive plate (in blue, below left). Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0009], [0026]-[0027], [0033], [0036]. Dr. Kenny's combination introduces a convex "lens/protrusion" (in blue, below right) over Aizawa's peripherally located detectors and centrally located light source (*see, e.g.*, Ex. 1003 ¶101):



Aizawa Fig. 1B (cross-section) Red: detectors; Green: emitter, Blue: flat plate

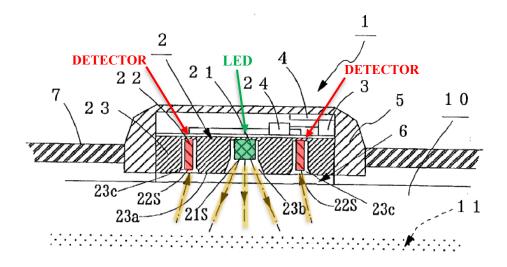


Dr. Kenny's proposed modifications (Ex. 1003 ¶101)

Aizawa (Ex. 1006 Fig. 1B) (color added) (left) versus Dr. Kenny's proposed combination (Ex. 1003 ¶101) (right)

- 91. Dr. Kenny asserts that Ohsaki's board "increases the strength of the signals obtainable by Ohsaki's sensor." Ex. 1003 ¶99.
- 92. As discussed above (Section VII.B.3.a), a POSITA would have believed that adding a convex lens/protrusion to Aizawa's flat adhesive acrylic plate would direct light away from the combination's detectors that are located on the

periphery. Aizawa illustrates that the light reaching Aizawa's detectors must travel from the center emitter to the outer periphery of the detectors. Ex. 1006 Fig. 1B, ¶[0027]. Aizawa shows the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors (light must travel from the center emitter to the outer periphery to the detectors. Ex. 1006 Fig. 1B, ¶[0027]):

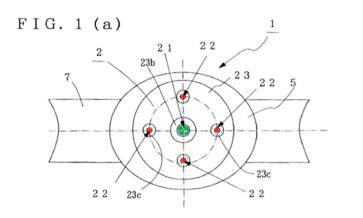


Aizawa Fig. 1B (cross-sectional view, color added)

93. Because of the configuration of Aizawa's sensor, with its central emitter and peripheral detectors, and the illustrated light path that requires light from the central emitter to reach the peripheral detectors, a POSITA would have understood that a change directing light to a more central location would decrease the optical signal at Aizawa's peripheral detectors. Ex. 1006 ¶[0026], [0030] (discussing benefits of Aizawa's flat "plate"). Because a POSITA would have believed that adding a convex lens/protrusion would have redirected light to a more

central location as compared to Aizawa's flat adhesive acrylic plate, a POSITA would have concluded that Dr. Kenny's proposed modification would decrease light-collection efficiency at Aizawa's peripheral detectors. Thus, I disagree with Dr. Kenny that a POSITA would have been motivated to modify Aizawa's flat plate to add a lens/protrusion similar to Ohsaki's translucent board based on the belief that it would have improved detection efficiency or otherwise increased signal strength. Ex. 1003 ¶101, see also ¶99. As discussed above (Section VII.B.3.a) Dr. Kenny, the Petitioner, and the '765 Patent all support that a POSITA would have believed that adding a convex lens/protrusion would result in the light gathered and refracted to a more central location, and thus away from Aizawa's peripheral detectors, as compared to Aizawa's existing flat plate.

94. In addition, the addition of a convex lens/protrusion similar to Ohsaki's is particularly problematic because both Aizawa and Dr. Kenny's illustration of his combination include small detectors with small openings surrounded by a large amount of opaque material. Ex. 1006 Figs. 1A, 1B, 2; *see, also, e.g.*, Ex. 1003 ¶101, 123-124, 141, 150, 152 (Dr. Kenny's illustrations). Aizawa's top-down view confirms the detectors' small size. Ex. 1006 Fig. 1A.



Aizawa's Features

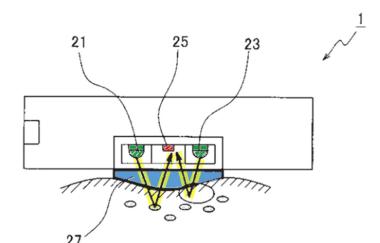
• Green: central emitter (21)

• **Red**: peripheral detectors (22)

Aizawa's sensor, showing small detectors (Ex. 1006 Fig. 1A), color added)

- 95. Thus, Dr. Kenny provides no evidence that a POSITA would have expected a convex lens/protrusion similar to Ohsaki's board to improve signal strength or detection efficiency at Aizawa's peripheral detectors. Ex. 1003 ¶99, 101. Instead, as explained above (Section VII.B.3.a), a POSITA would have expected that changing Aizawa's flat acrylic plate to a convex lens/protrusion similar to Ohsaki's board would reduce the amount of light gathered and refracted to Aizawa's peripheral detectors. The optical changes resulting from modifying Aizawa's flat surface to include a convex lens/protrusion similar to Ohsaki's board are thus another reason why a POSITA would not have been motivated to make that change.
- 96. I further note that the third reference in the Ground 1 combination, Inokawa, confirms that a POSITA would have expected that adding the illustrated "lens/protrusion" would detrimentally decrease the optical signal in the proposed combination. Unlike Aizawa's circular sensor, Inokawa is a linear sensor that uses

a convex lens (27) to focus light from LEDs (21, 23) on the periphery of a sensor to a single detector (25) in the center. Ex. 1008 ¶[0058], Fig. 2; see also ¶[0015] ("This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.").



Inokawa's Features

- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- Blue: convex lens (27)
- Arrows showing the direction of light in original, highlighting in yellow added

Inokawa Fig. 2 (color added)

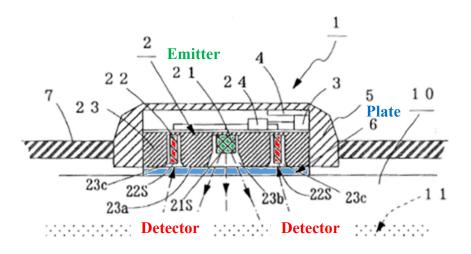
97. As show in the illustration of Inokawa's sensor (above), Inokawa has a different detector/emitter configuration than Aizawa, and requires a different light path to move from emitter to detector. As shown in Inokawa's illustration, for Inokawa's sensor, light from Inokawa's periphery-located emitters reflects off the body and passes through the lens in order to reach a single centrally located detector. Ex. 1008 ¶[0058]. Thus, consistent with the discussion above (Section VII.B.3.a) a POSITA would have believed that Inokawa's convex surface increases the light gathered to the center of the sensor, and thus focuses incoming light away from the periphery and towards the sensor's centrally located detector. Ex. 1008

¶[0058], Fig. 2. This is the opposite of Aizawa's illustrated light path, which requires light from a central emitter to reach peripheral detectors. Ex. 1006 Fig. 1B. As a result, Inokawa would have further confirmed a POSITA's belief that the proposed combination using a convex lens/protrusion would decrease light gathering at Aizawa's detectors—the opposite of Dr. Kenny's asserted motivation to combine.

4. A POSITA Would Not Have Selected A Convex Cover To Protect The Sensor's Optical Elements

98. Dr. Kenny also asserts that a POSITA would have been motivated "to include a lens/protrusion...similar to Ohsaki's translucent board...[to] protect the elements within the sensor housing." Ex. 1003 ¶101; see also ¶123. As illustrated below, Aizawa already includes a flat adhesive acrylic plate (blue) that protects the elements (emitter, detectors) within the sensor housing. Ex. 1006 Fig. 1B; see also, e.g., ¶¶[0023]-[0026], [0030]. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's existing flat adhesive acrylic plate to add a convex lens/protrusion similar to Ohsaki's board for protection because a POSITA would have understood that Aizawa's flat cover already protects the sensor's components. Ex. 1006 Fig. 1B; see also, e.g., ¶¶[0023]-[0026], [0030]. Dr. Kenny asserts that the convex lens/protrusion "protect[s] the elements within the sensor housing" (Ex. 1003 ¶123) but does not explain why that protection would be any different from Aizawa's flat plate without the modification. Thus, in my opinion, a

POSITA would not have been motivated to change the shape of Aizawa's flat acrylic plate based on the desire to protect the optical elements, because a POSITA would have understood that Aizawa's flat plate already provided that benefit. Indeed, based on the problems discussed above (Sections VII.B.1-3), a POSITA would have been wary of changing the shape of Aizawa's flat plate to include a convex lens/protrusion like Ohsaki's board.



Aizawa Fig. 1B (cross-section) (color added)

99. In addition, a POSITA would have believed that Aizawa's flat cover would be a better choice to provide better protection than a convex surface because, as taught by Inokawa, a flat surface would be less prone to scratches than a convex surface. Ex. 1008 ¶[0106]. Likewise, as discussed above (Section VII.B.2), Aizawa teaches that its flat surface improves adhesion and detection efficiency for measurements at the palm side of the wrist, next to the artery. *See* Ex. 1006 ¶[0013] ("[A] transparent plate-like member…makes it possible to improve adhesion

between the sensor and the wrist and thereby further improve the detection efficiency of pulse waves."). In contrast, Ohsaki teaches a convex surface at Aizawa's detection location "has a tendency to slip." Ex. 1009 ¶[0023]. Thus, in my opinion, there would have been no reason for a POSITA to modify Aizawa's flat adhesive acrylic plate, which already protects the elements within the sensor housing and does not introduce the complications and concerns arising from a convex shape.

C. <u>Dr. Kenny Does Not Identify Any Viable Motivation To Add A Second Emitter To Aizawa's Multi-Detector/Single Emitter Embodiment</u>

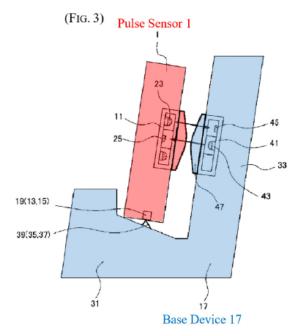
100. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's multi-detector single-LED embodiment to include an additional LED. *See, e.g.*, Ex. 1003 ¶¶79-87, 109-110. But none of Aizawa, Ohsaki, or Inokawa disclose or suggest using both multiple detectors and multiple emitters in the same sensor. For example, Aizawa discloses two different emitter-detector arrangements. In the first arrangement, multiple detectors surround a single centrally located LED. Ex. 1006 ¶[0033], Figs. 1, 2, 4, 5. In the other Aizawa arrangement, multiple LEDs surround a single centrally located detector. Ex. 1006 ¶[0033] ("The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22."). There is no disclosure in Aizawa of a sensor that simultaneously includes both multiple emitters and multiple detectors.

- 101. Inokawa discloses a linear sensor arrangement that uses two LEDs on either side of a single detector. Ex. 1008 ¶[0058], Fig. 2. Aizawa and Inokawa thus each use a consistent approach for a multi-emitter sensor: multiple emitters are placed around a single detector. Ex. 1006 ¶[0033], Figs. 1A-1B, 2, 4A-4B, 5; Ex. 1008 Fig. 2. Inokawa, like Aizawa, does not disclose or suggest a sensor with multiple emitters used with multiple detectors.
- 102. Ohsaki discloses a sensor with one emitter and one detector, arranged side-by-side. Ex. 1009 ¶¶[0017], [0019], Fig. 2. Ohsaki does not disclose or suggest using multiple detectors or multiple emitters together.
- 103. Dr. Kenny, in particular, asserts that a POSITA would have been motivated to modify Aizawa's multi-detector single-LED embodiment to include an additional LED based on Inokawa. *See, e.g.*, Ex. 1003 ¶79-87, 109-110. Dr. Kenny explains: "Aizawa-Inokawa would have utilized two LEDs that emit two different wavelengths" and "Aizawa's LED 21 would have been replaced with two LEDs." Ex. 1003 ¶85. But a POSITA who wanted to use Aizawa's sensor with multiple emitters would not have created an entirely new sensor with multiple detectors and multiple emitters—a POSITA would have used Aizawa's disclosed multiple LED embodiment. Ex. 1006 ¶[0033]. The multi-emitter embodiment in Aizawa, like the peripheral emitters/single central sensor configuration in Inokawa, includes multiple peripheral emitters around a single detector. Ex. 1006 ¶[0033];

Ex. 1008 ¶[0058], Fig. 2. In my opinion, a POSITA seeking to use multiple emitters in Aizawa would have followed the consistent teachings of both Aizawa and Inokawa and used multiple emitters around a single detector.

104. In addition, I disagree with Dr. Kenny that Inokawa would have motivated a POSITA to add a second LED to Aizawa. Dr. Kenny asserts two different motivations to add an additional LED to Aizawa's multi-detector/singleemitter embodiment. First, Dr. Kenny asserts that a second LED would "improve the detected pulse wave by distinguishing blood flow detection and body movement." Ex. 1003 ¶80; see also ¶¶83, 110. Aizawa, however, indicates that it already provides a "device for computing the amount of motion load from the pulse rate" based on its measured data. Ex. 1006 ¶[0015]. I note that Dr. Kenny acknowledges that Aizawa already records and accounts for or compensates for motion load. Ex. 1003 ¶80, 85. Thus, Aizawa's sensor already includes a way to detect body movement. While Dr. Kenny asserts that by adding a second LED, "Aizawa's sensor is improved by using a separate LED to account for motion load" (Ex. 1003 ¶85), Aizawa already includes that functionality. The cited portions of Inokawa do not indicate the addition of a second LED would have improved Aizawa's existing approach. Ex. 1003 ¶¶83 (citing Ex. 1008 ¶¶[0058]-[0059]), 110 (citing Ex. 1008 ¶¶[0014], [0040], [0058]-[0059], Figs. 2, 3, 19).

105. Second, Dr. Kenny asserts that a second LED would have also allowed "wireless communication between the sensor and a base station...." Ex. 1003 ¶83. Inokawa's base device, as illustrated by Dr. Kenny, is shown below (Ex. 1003 ¶88):



Dr. Kenny's illustration of Inokawa's sensor and base device (Ex. 1003 ¶80; Ex. 1008 Fig. 3)

106. Aizawa's device, however, already includes a transmitter in its structure, so Aizawa does not need to incorporate Inokawa's base-device data transmission arrangement to be able to transmit data. Ex. 1006 ¶¶[0023] ("4 a transmitter for transmitting the above pulse rate data to an unshown display"), [0028] ("the transmitter[] 4 transmits the pulse rate to a display for displaying the above pulse rate data"), [0035] ("the pulse rate data is transmitted to the display or the device for computing the amount of motion load"), Fig. 1B. In addition,

Aizawa's goal is "real-time measuring" (Ex. 1006 ¶[0004]) with the transmitter "transmitting the measured pulse rate data to a display" (Ex. 1006 ¶[0015]). Thus, a POSITA would have understood that the ability to take and transmit measurements to a display is already part of Aizawa's approach, without the need to use a base station. Ex. 1006 ¶[0028]; see also ¶¶[0023], [0035].

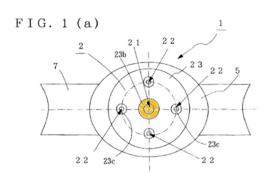
107. Because Inokawa's sensor relies on the same LEDs that are used in sensing, and because Inokawa's sensor requires data transfer using a base station, Inokawa's data transfer approach does not allow real-time display of measurements. Inokawa requires that the user remove sensor from the measurement site and then mount it on the base device before transferring stored data. See, e.g., Ex. 1008 Abstract, ¶¶[0070], [0074], Fig. 8. After mounting the sensor on the base device, the base device can then receive and download data stored in the sensor's memory. See, e.g., Ex. 1008 Abstract, ¶¶[0070], [0074], Fig. 8. Thus, to use Inokawa's base device, the sensor must be removed, and attached to the base device before any data transfer can start. A POSITA would understand that changing Aizawa into a sensor that requires a base-device eliminates the ability to take and display real-time measurements, one of Aizawa's stated goals, while increasing power consumption and cost. See, e.g., Ex. 1006 ¶¶[0004], [0016], [0023], [0028], [0035], see also ¶[0033] (Adding additional LEDs increases "the size and power consumption" of the sensor.).

108. In my opinion, Inokawa does not provide a motivation to make such changes to Aizawa. As Inokawa explains, it adds a second LED to provide an improvement in two situations. First, Inokawa suggests that it might be beneficial to use its data transmission approach if the "pulse sensor is connected to the base station via a cable" and thus there is a "risk of contact failure due to damage or deterioration." Ex. 1008 ¶[0004]. That is not relevant to Aizawa because Aizawa uses a transmitter and not a mechanically connected cable to send data to a display. See, e.g., Ex. 1006 ¶¶[0016], [0023], [0028], [0035], Fig. 1(b), Fig. 2. Inokawa's second explanation is a desire to avoid having to add "a dedicated wireless communication circuit." Ex. 1008 ¶[0004]. As discussed, Aizawa's sensor already includes a transmitter to provide real-time heart measurements, and the proposed modification requires a redesign of Aizawa's sensor to add the existing LED and also to remove the existing transmitter. Dr. Kenny does not explain why a POSITA would (1) redesign a sensor by adding a second LED to an existing multidetector/single emitter device, (2) add the mandatory use of a separate base station, and (3) require the user to remove the device to transmit data with the ultimate benefit being the ability to remove a transmitter circuit already present in Aizawa's design.

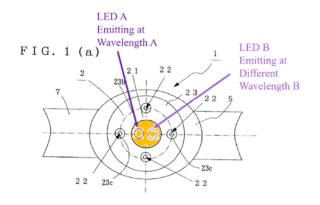
109. Dr. Kenny also does not address other complications that would result from adding an extra LED to Aizawa's sensor. As noted above, adding an extra

LED will result in increased power consumption—a key consideration for a watch-device like Aizawa's. Ex. 1006 ¶[0033]. The addition of an LED could create issues for sensor performance. *See* Ex. 1019 at 76-77 (discussing power and thermal considerations). Such a redesign requires explanation, which is absent from Dr. Kenny's analysis. For example, the '765 Patent specification describes using a thermistor and heat sinks and adjusting for temperature drift in the measurements. *See*, *e.g.*, Ex. 1001 29:22-24.

110. Adding an LED would also require structural changes to Aizawa's sensor. As shown below, Dr. Kenny substantially widened the size of Aizawa's emitter cavity to accommodate the extra LED. Ex. 1003 ¶84. Changing the size of the emitter cavity could affect the optical performance of the sensor, for example, because it changes Aizawa's sensor from a symmetrical arrangement with all of the detectors an equal distance from the single emitter, to less symmetrical arrangement where different detectors are different distances to each of the two emitters. Dr. Kenny did not address how the structural change to Aizawa would impact its sensor. But a POSITA would have understood that such changes can impact the performance of the sensor.



Aizawa's sensor original emitter/cavity (21/23b) (Ex. 1006 Fig. 1A) (orange highlighting added)



Dr. Kenny's proposed combination which widens central emitter cavity

(Ex. 1003 ¶84)

(orange highlighting added)

111. Thus, as explained above, none of Aizawa, Inokawa, or Ohsaki disclose or suggest Dr. Kenny's multi-detector/multi-emitter combination. In addition, the proposed multi-emitter/multi-detector combination runs counter to both Aizawa and Inokawa's disclosures, which each implement multiple emitters in the same way: with multiple emitters around a single detector. Further, the benefits and motivations Dr. Kenny identifies are either already present in Aizawa or would actually hurt Aizawa's goal of real-time measurement and display of data. Thus, in my opinion, it would not have been obvious to modify Aizawa's sensor and transform it into a sensor that includes multiple emitters and at least four detectors, as in the '765 Patent claims 1 and 21.

D. <u>Dr. Kenny's Motivation To Add Mendelson 2006 Undermines His</u> Motivation To Add A Second Emitter In The Proposed Combination

- 112. Mendelson 2006 is the final reference in Dr. Kenny's four reference combination. Claims 1 and 21 each require "a handheld computing device in wireless communication with the physiological sensor device." Ex. 1001 Claims 1, 21. Dr. Kenny asserts that Mendelson 2006 discloses a sensor in communication with a PDA and attempts to combine Mendelson 2006 with Aizawa, Ohsaki, and Inokawa. Ex. 1003 ¶88-97. Dr. Kenny asserts that a POSITA, having just modified Aizawa to eliminate its wireless transmitter in favor of Inokawa's base station, would then add that wireless transmitter functionality back into the system "to enable the physiological sensor device to communicate wirelessly with the handheld computing device." Ex. 1003 ¶89; see generally ¶88-97, 125-132.
- 113. Dr. Kenny cites the ability of Mendelson 2006 "to enable transfer of information" to a PDA carried by medics "to enhance their ability 'to extend more effective medical care, thereby saving the lives of critically injured persons." Ex. 1003 ¶94 (quoting Ex. 1010). But Mendelson 2006 employs wireless transmission to allow "continuous real-time monitoring." Ex. 1010 at 4. Dr. Kenny's addition of Mendelson 2006's wireless approach makes no sense given that, as discussed above, the combination of Aizawa, Inokawa, and Ohsaki already replaced Aizawa's wireless transmitter with Inokawa's base station approach. *See* Section VII.C, above; *see also* Ex. 1003 ¶82 ("A POSITA would have recognized that Aizawa's

LED could have been used for wireless data communication with a personal computer to eliminate problems associated with a physical cable, and, as taught by Inokawa, without requiring a separate RF circuit."); Ex. 1006 Fig. 1B (showing feature 4), ¶[0023] ("4 a transmitter for transmitting the above pulse rate data to an unshown display").

- 114. Dr. Kenny asserts that a POSITA considering Aizawa, Ohsaki, Inokawa, and Mendelson 2006 would (1) eliminate Aizawa's existing transmitter so the resulting device will not require "a separate RF circuit" (Ex. 1003 ¶82); (2) change Aizawa's structure to add a second LED to transmit data using a base station, which would also require that a user remove the sensor before any data transfer can occur and thus eliminate the ability to display data in real-time (Ex. 1003 ¶82-83, 125-126); and then (3) add back in a separate communications circuit to the base station based on Mendelson 2006 so that the base station can send data to a PDA with a touch screen display (Ex. 1003 ¶127, see also Ex. 1010 at 2 (Mendelson 2006's sensor module includes an "RF transceiver.")).
- 115. The result of this series of alterations is a more complicated system with reduced functionality and no added benefit. As explained above (Section VII.C), modifying Aizawa to a base station approach eliminates real time monitoring because the device must be removed from the body and positioned on the base station before any data transfer can begin. *See, e.g.*, Ex. 1008 Abstract,

¶¶[0070], [0074], Fig. 8. This also eliminates Mendelson 2006's stated benefit of "continuous real-time monitoring" of data. Ex. 1010 at 4. Thus, the proposed combination undermines both Aizawa's and Mendelson 2006's goal of real-time display of data by requiring a base device. Ex. 1010 at 4; *see also, e.g.*, Ex. 1006 ¶¶[0004], [0015], [0023].

- 116. The proposed combination with Mendelson 2006 also undermines the argument that "using two LEDs to perform such communication would result in enhanced accuracy of the transmitted information." Ex. 1003 ¶82. Even if this were true (Aizawa gives no reason to believe there were any problems with its existing wireless transmitter), the subsequent transfer of data from base station to handheld device is not carried out using LEDs. Ex. 1010 at 2. Instead it would have been carried out with the same type of RF circuit that Dr. Kenny asserted should be eliminated in the first place. See Ex. 1003 ¶82 (arguing against a separate RF circuit); Ex. 1010 at 2 (sensor module and receiver module use "RF transceiver"). The combination thus reintroduces the purported problem of the "accuracy of the transmitted information" that allegedly would have motivated the change to the base-station approach.
- 117. Finally, Dr. Kenny acknowledges that Mendelson 2006, like Aizawa, Inokawa, and Ohsaki, is not a multi-emitter/multi-detector sensor. Ex. 1003 ¶73. Instead, Dr. Kenny explains that Mendelson 2006 uses "two LEDs and a

photodiode." Ex. 1003 ¶73; see also Ex. 1010 at 1 ("an annular photodetector"), 4 ("an annular photodetector"). Accordingly, no reference in Ground 1 discloses both multiple emitters and at least four detectors used in the same sensor.

118. Thus, in my opinion, the addition of Mendelson 2006 does not render the claims obvious.

E. Dr. Kenny Does Not Provide Evidence Of An Expectation Of Success

Dr. Kenny does not provide any specific discussion in his declaration 119. of whether his illustrated alleged combination would have been reasonably expected to be a successful physiological measurement system. As discussed above, a POSITA would not have expected Ohsaki's longitudinal directionality to work with Aizawa's circular, radially arranged detectors along with the other claimed features. See Section VII.B (above). Dr. Kenny provides no explanation why a POSITA would have had a reasonable expectation of success in adapting the rectangular board in Ohsaki to Aizawa's circular radial sensor design and obtain an effective sensor. As discussed above, a POSITA understanding the problems associated with using a convex surface in combination with Aizawa's peripheral detectors would have expected decreased signal strength and additional optical and mechanical problems that undercut the expectation of success. See Section VII.B. The possibility that the proposed modification could be manufactured (Ex. 1003 ¶96) does not demonstrate that the resulting device would successfully function.

F. The Challenged Dependent Claims Are Nonobvious Over Ground 1

1. The Challenged Dependent Claims Are Nonobvious For The Same Reason As The Independent Claims

120. As discussed above, in my opinion claims 1 and 21 would not have been obvious over the cited references of Ground 1. In addition, in my opinion, the dependent claims would be nonobvious for at least the same reasons. *See* Sections VII.A-C, above.

2. Claims 12, 18, And 29

121. Claim 12 ultimately depends from claim 1 and includes the additional limitation: "wherein the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters." Claim 18 ultimately depends from claim 1 and includes the additional limitation: "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." Claim 29 ultimately depends from claim 21 and includes the same limitation as claim 18. The '765 Patent discloses, among other things, particular example convex shapes that improve signal strength. Ex. 1001 20:14-30. The '765 Patent explains: "For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes." Ex. 1001 20:18-22. Thus, as explained in the '765 Patent, an appropriately sized protrusion can dramatically increase the accuracy of the measurements. Ex. 1001 20:14-30.

- 122. Dr. Kenny does not point to any corresponding teaching in Aizawa, Ohsaki, Inokawa, or Mendelson 2006 for a specific protrusion height of either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters. Ex. 1003 ¶158-161, 169, 191. Instead, Dr. Kenny asserts that when "incorporating Ohsaki's teachings, a POSITA would have found it obvious that a device designed to fit on a user's wrist would be on the order of millimeters," and "there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user." Ex. 1003 ¶160-161. But Dr. Kenny's cited references in Ground 1 do not teach or suggest a protrusion with a height either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters would have been beneficial in terms of enhancing signal strength or user comfort.
- 123. Dr. Kenny cites alleged disclosures of sensor sizes in two references, Mendelson 2006 (Ex. 1010) and Mendelson-1988 (Ex. 1017). Ex. 1003 ¶160. But neither Mendelson 2006 nor Mendelson-1988 disclose a cover, and therefore do not disclose a cover with a protrusion. Ex. 1010 Fig. 1 (no view of cover); Ex. 1017 Fig. 2 (showing flat layer of epoxy encapsulating optical components). The flat surface of encapsulating epoxy used with Mendelson-1988's sensor would not have informed or motivated a POSITA to include a cover, and likewise would not have

motivated a POSITA to include a cover with a convex protrusion of a particular height.

Dr. Kenny appears to have selected Mendelson 2006 and Mendelson-124. 1988 because the references discuss a similar size (22 mm diameter and 19x19 mm square), which Dr. Kenny argues would also be used with a wrist-worn device. Ex. 1003 ¶160. Both Mendelson 2006 and Mendelson-1988, however, are forehead sensors, not wrist sensors. Ex. 1010 Abstract ("wireless wearable pulse oximeter developed based on a small forehead mounted sensor"); Ex. 1017 at 1 ("SpO₂ obtained from the forehead...."). I further note that other references use different For example, Mendelson-1991 uses an assembled sensor that sized sensors. "measures approximately 38 mm in diameter and is 15 mm thick." Ex. 1018 at 3. Dr. Kenny does not explain why a POSITA would have been motivated to select one sensor size over another, or to select one protrusion height as opposed to any other. Dr. Kenny suggests that "a height between 1 millimeter and 3 millimeters" would "prevent[] slippage" and "would have been comfortable...." Ex. 1003 ¶161. But that disclosure is not in any of the references which are part of Ground 1. In fact, as discussed above (Sections VII.A.1, VII.A.2, VII.B), Ohsaki explains that its sensor's width and length (including the board) are important, but does not say anything about the height of the convex surface of the board. See Ex. 1009 ¶[0019] ("the length of the detecting element 2 from the right side to the left side in FIG. 2

POSITA would not have found it obvious to include a cover with a protruding convex surface "wherein the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters" based on the cited references of Ground 1.

VIII. GROUND 2 FAILS FOR AT LEAST THE SAME REASONS AS GROUND 1

125. Ground 2 is a five-reference combination that adds Bergey (Ex. 1016) to the combination of Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Ex. 1003 ¶¶192-194. Ground 2 only challenges dependent claim 9. Pet. 9-10; Ex. 1003 ¶¶192-194. Dr. Kenny adds Bergy to Aizawa, Inokawa, Ohsaki, and Mendelson 2006 because those references do not disclose that the substrate, wall, and cover hermetically seal the at least four detectors. Ex. 1003 ¶192. Bergey's disclosure, which is related to a wristwatch, does not fix the deficiencies identified for Ground 1. As a result, in my opinion, the challenged claim of Ground 2 is nonobvious for the same reasons discussed above for Ground 1.

IX. GROUND 3 FAILS FOR AT LEAST THE SAME REASONS AS GROUND 1

126. Ground 3 is a five-reference combination that adds Goldsmith (Ex. 1011) to the combination of Aizawa, Inokawa, Ohsaki, and Mendelson 2006. Ex.

1003 ¶¶197-202. Ground 3 only challenges dependent claim 14. Pet. 9-10; Ex. 1003 ¶¶197-202. Dr. Kenny adds Goldsmith to Aizawa, Inokawa, Ohsaki, and Mendelson 2006 because those references do not disclose "wherein the displayed indicia are further responsive to temperature." Ex. 1003 ¶¶199-202. Goldsmith's disclosure of a temperature-responsive display does not fix the deficiencies identified for Ground 1. As a result, in my opinion, the challenged claim of Ground 3 is nonobvious for the same reasons discussed above for Ground 1. In addition, claim 14 is nonobvious for the following additional reasons.

X. OATH

127. I declare that all statements made herein of my own knowledge are true and that 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.

Dated:	July 27, 2021	_ By:	- Viz KIN Pileto
		-	Vijay K. Madisetti, Ph.D

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