

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS, INC.
Petitioner

v.

MASIMO CORPORATION
Patent Owner

Case No. IPR2020-00954
Patent No. 9,788,735

**DECLARATION OF BRYAN BERGERON, MD IN SUPPORT OF
PETITIONER'S REPLY TO ITS PETITION FOR *INTER PARTES*
REVIEW OF U.S. PATENT No. 9,788,735**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. QUALIFICATIONS AND EXPERIENCE.....	1
A. Education and Work Experience.....	1
B. Engagement	12
III. MATERIALS CONSIDERED	12
IV. RELEVANT LEGAL STANDARDS	16
A. A Person Having Ordinary Skill in the Art.....	16
B. General Principles of Claim Construction	17
C. Unpatentability Based On Obviousness.....	18
V. OVERVIEW OF THE PATENT AT ISSUE	21
VI. CLAIM CONSTRUCTION	22
VII. SUMMARY OF THE PRIOR ART.....	25
A. Goldberg.....	25
B. Money.....	26
C. Kiani	26
VIII. ARGUMENTS – GROUNDS 1 AND 3	27
A. Ports are obvious for any wired connection.....	27
B. Patent Owner’s motivation to combine arguments continue to assume Goldberg is hardwired	28
C. Patent Owner’s Misapprehends Petitioner’s Obviousness.....	34

D.	Patent Owner’s reasons not to combine are improper and fail to consider all of the circumstances	38
E.	Port with a blood pressure cuff	41
F.	Analog and digital sensors are equivalent.....	44
G.	No Hindsight Was Involved.....	45
IX.	GROUND 5-8 ARGUMENTS.....	45
A.	There is no evidence that Money’s device wasn’t worn on the wrist.	45
B.	Money Combined with Akai	48
X.	ESTEP IS ANALOGOUS ART	51
XI.	CONCLUSION.....	52

I, Bryan Bergeron, MD, FACMI, offer this declaration in support of Petitioner Sotera Wireless, Inc.'s ("Petitioner") Reply supporting its Petition for *Inter Partes* Review of U.S. Patent No. 9,788,735 ("the '735 Patent"). I am over the age of 18, competent to make this declaration, and have personal knowledge of the facts set forth below. If called to testify, I could and would testify honestly, under oath, to the matters set forth herein.

I. INTRODUCTION

1. I am paid for my time in this matter, at my normal rate of \$425/hour. I have no interest in the parties involved, financial or otherwise, and have nothing to gain if either party prevails over the other.

II. QUALIFICATIONS AND EXPERIENCE

A. Education and Work Experience

2. My qualifications can be found in my *curriculum vitae*, which includes my detailed employment background, professional experience, and list of technical publications and patents. A summary of relevant experience is provided below.

3. I taught in the Harvard-MIT Program in Health Sciences and Technology (HST) in Cambridge, Massachusetts for approximately 30 years. This program is a collaboration between the Massachusetts Institute of Technology (MIT), Harvard Medical School (HMS), Harvard University, and Boston area

teaching hospitals that integrates science, medicine, and engineering to solve problems in human health. I taught clinical medicine, including cardiac pathophysiology and pulmonary pathophysiology to medical students in the HST program, and well as Medical Informatics to these same students, faculty at MIT and Harvard Medical School, graduate students at the Harvard Law School, Harvard School of Public Health and Harvard Business School.

4. Medical Informatics is a discipline at the intersection of information science, computer science, and health care. It deals with the resources, devices, and methods for optimizing the acquisition, storage, retrieval, and use of information in various medical environments. In my course in Medical Informatics, I covered topics such as electronic medical record (EMR) systems, HIPAA privacy and security, large database design and implementation, physician performance, artificial intelligence, computer programming, microcontrollers and embedded systems, bedside monitoring and therapy systems, robotic surgery, mobile computing, modeling and simulation, and a variety of human factors issues associated with clinician acceptance and use of information technology.

5. I obtained my Bachelor of Science (B.S.) degree in Psychology, *with honors*, in the Tulane University Scholar's Program with minors in physics and chemistry, in 1980. Prior to receiving my B.S. degree, I studied electrical engineering at Louisiana State University in Baton Rouge, Louisiana, and

performed research in neurological signal detection and analysis at the Marine Biology Laboratory in Woods Hole, Massachusetts. I obtained my Doctor of Medicine (M.D.) degree from Louisiana State University Medical Center in 1984. From 1985 through 1987, I was a post-doctoral research fellow in medical informatics at Brigham & Women's Hospital, a Harvard Medical School teaching hospital located in Boston, Massachusetts. As part of my post-doctoral fellowship, I studied computer science at Harvard University. In parallel with coursework, my post-doctoral research focused on the development of computer hardware and software programs that could be used to train medical students and other medical professionals by simulating various medical patients or medical problems. This involved first acquiring representative physiologic data from the patient's bedside and then comparing the simulated and real-life data from various physiologic systems.

6. In 1984, when I was a fourth-year medical student, I founded my first company, Home Health Software, in New Orleans, Louisiana. I was the sole employee, and I worked as both the company president and chief programmer. Home Health Software focused on the development of software for various types of medical analyses and planning, including one of the first commercial nutritional analysis and planning applications that could be utilized by a lay-person on a home microcomputer.

7. Home Health Software produced several commercial patient simulation software titles, as detailed in my *curriculum vitae*, which were sold nation-wide. In late 1984, Apple Inc. made me one of a handful of Certified Developers for their new Macintosh Computer. I retired Home Health Software in 1985 when I moved to Boston to pursue my post-doctoral fellowship, but continued and expanded my relationship with Apple. During my post-doctoral fellowship at Brigham & Women's Hospital and Harvard Medical School (from 1985-1987), I developed HeartLab, the first commercial multimedia patient simulator for a microcomputer. HeartLab was sold and marketed by Williams and Wilkins Publishers, Baltimore, MD, to virtually all medical schools in the United States, as well as major medical schools in Canada and EU.

8. As a result of the success of the HeartLab system, as well as other work that I performed as a post-doctoral fellow, I competed for a First Independent Research Support and Transition ("FIRST") Award by the National Library of Medicine ("NLM") in 1988. This award provided six years of support and funding for me to develop and evaluate new technologies.

9. In 1987, after my post-doctoral fellowship, I began work as an Application Specialist at Children's Hospital, Boston. In this position, I managed the first HL7 installation on the East Coast, defined (with others) the hospital's data dictionary, and designing the clinical workstation. The clinical workstation

aggregated all clinical data on a particular patient or group of patients – including current labs, radiology, and physiological data (e.g., pulse, respiration, and EKG) from the bedside – under one intuitive interface. The workstation used an X- Windows client-server model with an Oracle back end.

10. In 1989, I began work as an Instructor at Harvard Medical School, as well as an Assistant Director of the post-doctoral fellowship program in Medical Informatics at Brigham & Women's Hospital and Harvard University. One of my major responsibilities as Assistant Director of the post-doctoral fellowship program was to facilitate the development of innovative, graphical, computer-based teaching programs—such as patient simulation software—that could be used to train students in the Harvard Medical School and Harvard-MIT Health Sciences and Technology (HST) programs. Accordingly, I continued my work on the software and research development funded by the FIRST Award during this time, utilizing the Harvard Medical School and HST programs as the testing and development environments.

11. As noted earlier, this work in modeling and simulation required me to obtain physiologic data from patients and then work to simulate these data. For example, in developing HeartLab, I first had to acquire the patient data that would later be simulated in software. As such, I developed a bedside heart monitoring system that acquired and digitized heart sounds in patients with various disease

states, e.g., aortic stenosis. Similarly, with EGKLab, a program that I developed to simulate the range of EKG tracings possible with a variety of disease states, I had to first design and develop a bedside data acquisition system. I also developed a pulmonary monitoring system to acquire auscultatory data for LungLab, a program that I co-developed to teach pulmonary pathophysiology.

12. As detailed in my *curriculum vitae*, starting in 1989, I managed and a team of post-doctoral fellows in medical informatics, medical students, and visiting fellows, students, and faculty in developing over a dozen commercial-grade patient simulators as well as backend infrastructures and databases for tracking and documenting learner progress in the various medical educational systems.

13. In 1996, I founded Archetype Technologies, Inc., in order to offer consulting services to industry and compete for government funding. As the head of Archetype, I also served as Chief Scientist for various clients—generally startup companies or other small companies.

14. As a result of my academic and non-academic work experiences, I have extensive experience with Electronic Medical Record (EMR) and Electronic Health Record (EHR) systems, and with the various technologies and techniques used to acquire patient data for inclusion in the EMR. I have also served as faculty advisor to several Masters and Ph.D. students on projects or theses that included EMR systems, integration challenge, and large database design.

15. Further, in my work with Kurzweil Applied Intelligence (from 1988-2000), which developed the first large-vocabulary medical dictation system, I helped define the medical vocabularies and edited the overall hierarchy of medical terms used in the speech recognition engine in Pathology, Radiology and Emergency Medicine.

16. In 1999, I served as Principal Investigator on a Small Business Innovation Research (SBIR) grant I won on behalf of Kurzweil Applied Intelligence, for which I co-developed a rule-based medical record quality assurance system for automatically reviewing (*e.g.*, parsing and evaluating) reports in EMR systems. This application of natural language understanding technology to EMR systems was immediately commercialized and sold by Lernout & Hauspie Speech Products.

17. My EMR and EHR experience also includes work with KFSH&RC, Riyadh to develop and extend a large data warehouse. As documented in four books, this data warehouse provides a central repository of EMR data from a variety of clinical and administrative systems, including an EMR system. My EMR experience further includes reviewing systems and associated applications for publication in various journals.

18. I also have extensive experience with computer hardware and software programming, especially as used and implemented in the medical

industry. I have experience in 6502 and 68000 Assembler, FORTH, LISP, PROLOG, PASCAL, NEON, SMALLTALK, C/C++, JAVA, PERL, SQL and numerous embedded processor, desktop, and server-based scripting languages, including DBMS languages.

19. As noted in my *curriculum vitae*, I obtained several endorsements from the Federal Communications Commission (FCC) starting in 1971, over a decade prior to obtaining my license to practice medicine and surgery. At 12, I repaired consumer electronics for Radio Shack. At 13, I worked for the Offshore Telephone Company, both onshore and on offshore platforms, installing and repairing microwave communications systems tied to analog flow sensors on oil production platforms in the Gulf of Mexico. I maintained and programmed a discrete component (i.e., individual transistor circuits) MOORE digital computer system that communicated with the hundreds of sensors on the oil platforms that we serviced and converted the data to audio signals sent to oil company computers over the phone lines. I also maintained LORAN-C navigation systems, ship-to-shore RADAR systems, analog autopilot systems, and SSB communications systems.

20. Prior to commercial work in communications and computers, I was also active in amateur radio. I developed EME (earth-moon-earth) communications systems, including antenna arrays of my own making and repurposed VHF

communications systems as well as Oscar satellite communications systems. In 1973, I received the Extra Class license, the highest license then available, and only available to those holding upper class licenses for a year or more. I was also active during this time with Civil Defense and trained in and then taught Radiological Monitoring (the basis for my subsequent work with the DoD). I also designed and built the UHF repeater system for Civil Defense, which included various RS-232 I/O ports, UART microcontrollers and A/D converters for sending data through the telephone network.

21. I demonstrated my knowledge of electronics at the regional and state science fairs in physics and electronics. At 11, I was the first student from my hometown to compete in, much less win a regional title, and the first to win state titles. My first entry was based on an array of multimodal analog sensors – light, sound, vibration – that converted one mode to another. I also built my first computer at 11, an analog computer kit from Edmund Science that performed basic multiplication, trig, and log functions. At 16, as a freshman at LSU, I was judge for physics and electronics at the state science fair and, at the request of the Dean, developed the curriculum for the Solid-State Laboratory course in electrical engineering at LSU. The course included analog, digital and hybrid circuits. I have continued my involvement in science fairs as judge in physics and electronics at the annual state fair at MIT, and my involvement in electronics as editor in chief of

both Nuts & Volts (for experimentalists in general electronics) and SERVO (for experimentalists in robotics) magazines, two major resources for STEM educators.

22. I have held a variety of posts in organizations that focus on the application of computing to the practice and teaching of medicine. For example, I have served as Chairman of the Mathematical Modeling & Simulation Committee for the Symposium on Computer Applications in Medical Care (SCAMC), Chairman of the SCAMC Human-Computer Interfacing Committee, and Chairman of the Healthcare Information and Management Systems Society (HIMSS) Conference on Innovative Informatics for Reducing Medical Errors. I have also served on fourteen editorial boards for various publications related to medical informatics, including e.MD (Founding Editor-in-Chief), Physicians Home Page, HealthStream, Medical Software Reviews, WebMD/Medscape Tech Med, and Healthcare Informatics.

23. I am a frequent contributor to the field of medical informatics. I have written numerous articles for various journals and publications, including Computer Methods and Programs in Biomedicine, the Journal of Medical Education Technology, the Journal of Educational Multimedia and Hypermedia, the Journal of Instructional Delivery Systems, Perspectives in Biology and Medicine, and the British Journal of Knowledge Management. I have also given hundreds of lectures and courses on topics regarding computer technology,

computer-assisted training, medical informatics, data dictionary design issues, and emerging technologies in healthcare.

24. I am a named inventor on 11 U.S. patents. Four of the patents on which I am a co-inventor are related to virtual, web-based, and processor-enabled training for medical personnel. Another patent deals with intelligent tutoring systems, and the two other patents deal with Translational Reality interfaces using embedded processors.

25. I presently serve as President of Archetype Technologies, Inc. (“Archetype”) in Brookline, Massachusetts, which designs and develops custom hardware and software solutions for medical device and medical information system companies, and is developing software and hardware systems for commercialization in the field of translational reality.

26. For the past decade, I have served as the Principal Investigator on a series of research grants sought by Accella Learning Company related to the development of electronic simulator hardware and software for intelligent tutoring systems that train medical first responders for nuclear, chemical, and biological warfare events. These grants were funded through the United States Department of Defense (DoD). Most recently, I served as the chief medical consultant on DoD funded grants to design and develop the software infrastructure for a national physiology research platform, BioGears. This platform is designed to build lifelike

mannequins, realistic online military games, and a variety of medically accurate scenarios for training and testing.

27. In view of my extensive experience with computers, electrical systems, and specifically medical electronic systems, my work experience would have qualified me as a person of ordinary skill in the art under Petitioner's definition of the level of ordinary skill. Paper 1, p. 13. It is my understanding that Patent Owner agrees with this statement. Paper 21, 16.

B. Engagement

28. I have been engaged by Sotera Wireless, Inc. ("Sotera") as an expert to assist Sotera in connection with the patent infringement lawsuit, *Masimo Corp. v. Sotera Wireless, Inc., et al*, at the direction of Husch Blackwell, LLP.

III. MATERIALS CONSIDERED

29. I have considered the following list of materials in formulating my opinions in this matter:

Ex #	Exhibit
1001	U.S. Patent No. 9,788,735 ("the '735 patent")
1002	Prosecution History of the '735 Patent
1003	Expert Declaration of George Yanulis
1004	<i>Curriculum Vitae</i> for George Yanulis
1005	U.S. Patent No. 6,840,904 to Goldberg ("Goldberg")
1006	PCT Publication No. WO 00/42911 to Kiani et al. ("Kiani")

1007	EP0880936A2 to Akai (“Akai”)
1008	U.S. Patent No. 5,919,141 to Money (“Money”)
1009	PCT Publication No. WO 99/13698 to Estep (“Estep”)
1010	’735 Patent File History Excerpt, Application as filed on April 27, 2017
1011	’735 Patent File History Excerpt, Preliminary Amendment filed May 22, 2017
1012	’735 Patent File History Excerpt, Pre-Interview Office Action issued July 3, 2017
1013	U.S. Patent No. 6,241,684 to Amano (“Amano”)
1014	’735 Patent File History Excerpt, Notice of Allowance with Examiner’s Amendment issued Aug. 28, 2017
1015	Masimo’s Adversary Complaint, United States Bankruptcy Court for the Southern District of California, <i>In re: Sotera Wireless, Inc.</i> , No. 16-05968-LT11, filed October 7, 2016
1016	U.S. Patent No. 4,425,921 to Fujisaki (“Fujisaki”)
1017	International Publication No. WO00/44274
1018	Japanese Publication No. JP0558122A, with English Machine Translation
1019	U.S. Patent No. 4,338,950
1020	U.S. Patent No. 4,450,843
1021	U.S. Patent No. 4,807,639
1022	U.S. Patent No. 5,539,706
1023	U.S. Patent No. 6,850,788 (Parent to ’735 Patent)
1024	U.S. Patent No. 7,844,314 (Parent to ’735 Patent)
1025	U.S. Patent No. 7,844,315 (Parent to ’735 Patent)
1026	U.S. Patent No. 8,548,548 (Parent to ’735 Patent)
1027	U.S. Patent No. 9,113,831 (Parent to ’735 Patent)
1028	U.S. Patent No. 9,113,832 (Parent to ’735 Patent)
1029	Masimo’s Complaint for Patent Infringement against Sotera (ECF No. 1), filed June 12, 2019

1030	Service of Summons and Complaint upon Sotera (ECF No. 5)
1031	U.S. Patent No. 10,213,108 (“the ’108 patent”)
1032 - 1035	<i>Intentionally omitted</i>
1036	Defendant Sotera Wireless, Inc.’s Motion to Stay Proceedings, ECF No. 48
1037	Order Vacating Claim Construction Hearing, ECF No. 81
1038	Defendants’ Stipulation of Invalidity Contentions, ECF No. 86
1039	<i>Intentionally omitted</i>
1040	Expert Declaration of Bryan Bergeron, MD
1041	Bergeron CV
1042	Deposition Transcripts (Vols. I & II) from the April 28, 2021 and April 29, 2021 Depositions of Alan Oslan with signed errata
1043	U.S. Patent No. 4,889,132
1044	Datasheet for EPROM/ROM-Based 8-bit CMOS Microcontroller Series, PIC16C5X
2010	Declaration of Alan L. Oslan
2011	Curriculum Vitae of Alan L. Oslan
2012	Transcript of Deposition of George E. Yanulis, Ph.D., taken on January 26, 2021 in connection with IPR20200-00912, -00954, -01015, -01054
2013	Transcript of Deposition of George E. Yanulis, Ph.D., taken on January 27, 2021 in connection with IPR20200-00912, -00954, -01015, -01054
2014	Transcript of Deposition of George E. Yanulis, Ph.D., taken on February 1, 2021 in connection with IPR20200-00912, -00954, -01015, -01054
2015	Declaration of George E. Yanulis in Support of Defendants’ Opening Markman Brief, filed September 22, 2020, in Masimo Corp. v. Sotera Wireless, Inc., Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.)
2016	Transcript of Deposition of George Yanulis, conducted on September 10, 2020, in Masimo Corp. v. Sotera Wireless, Inc., Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.)
2017	Excerpt of Stedman’s Medical Dictionary (27th ed. 2000)

2018	Excerpt of Dorland's Illustrated Medical Dictionary (30th ed. 2003)
2019	Excerpt of Webster's New World College Dictionary (4th ed. 2001)
2020	Excerpt of Webster's II New College Dictionary (2001)
2021	Excerpt of Microsoft Computer Dictionary (5th ed. 2002)
2022	Amal Jubran, Pulse oximetry, 3 Crit Care R11 (1999)
2023	Joseph F. Kelleher, Pulse Oximetry, 5 J Clin Monit 37 (1989)
2024	Allison Rhodes Westover et al., Human Factors Analysis of an ICU, 23 J Clin Eng 110 (1998)
2025	Gianfranco Parati et al., Self blood pressure monitoring at home by wrist devices: a reliable approach?, 20 J Hypertension 573 (2002)
2026	U.S. Patent No. 4,896,676 to Sasaki
2027	Japanese Publication JP4777640B2 to Junichi and English machine translation available from Espacenet
2028	Photographs of Omron Gold Wrist Blood Pressure Monitor (Model No. BP4350) taken by Alan Oslan
2029	Larry Hardesty, Clothed in Health, MIT Technology Review (July 1, 2001) (https://www.technologyreview.com/2001/07/01/235697/clothed-in-health) (last accessed February 17, 2021)
2030	Datex AS/3™ Anesthesia Monitor Operator's Manual (1995)
2031	Claire C. Gordon et al., 2012 Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics, U.S. Army Natick Soldier Research (2014)
2032	Printouts from apple.com and samsung.com websites showing common smartphone specifications
2033	Siegfried Kästle et al., A New Family of Sensors for Pulse Oximetry, Hewlett-Packard Journal (February 1997)
2034	Amazon listing for Portzon Set of 2 Neoprene Dumbbell Hand Weights, Anti-Slip, Anti-roll
2035	Design of Pulse Oximeters, JG Webster, ed., IOP Publishing, Bristol, UK (1997).

IV. RELEVANT LEGAL STANDARDS

30. I am not an attorney. I have, however, been instructed by my attorneys regarding the relevant legal standards that apply in this litigation. These standards include obviousness and claim construction principals.

31. I am not an expert in patent law, and do not opine on the correct legal standards to apply. Rather, I have been given the following legal standards by counsels for Petitioner and have applied those legal standards to the facts and circumstances of this case in rendering my opinions.

A. A Person Having Ordinary Skill in the Art

32. I have been told that several of the legal standards must be applied from the perspective of a person having ordinary skill in the art (POSITA) at the time of the invention of the '735 Patent. I have been told that the invention date of the '735 Patent is no later than the filing date of its provisional application, which is March 25, 2002.

33. Unless otherwise stated, when I provide my understanding and analysis below, it is consistent with the level of one of ordinary skill in these technologies at the time of the invention of the '735 Patent.

B. General Principles of Claim Construction

34. My understanding is that, in an inter partes review, claim construction is for the PTAB to decide, but I am able to offer my opinion of how some claim terms would be understood by a person of ordinary skill.

35. I have been told that a claim term must be given the ordinary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. The person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.

36. I have been told that both intrinsic evidence and extrinsic evidence can be used to interpret the claims. Intrinsic evidence includes the language of the claim itself, the specification and drawings of the patent, and the prosecution history of the patent. The intrinsic record may indicate that the inventor has acted as her own lexicographer, or has disclaimed the full scope of the ordinary meaning of a term. I also understand that the specification is highly relevant to the claim construction analysis.

37. I have been told that extrinsic evidence may also be consulted. But I have also been told that extrinsic evidence, while useful, is less significant than the intrinsic record in determining the meaning of claim language. Extrinsic evidence

may include dictionaries and authoritative technical publications, as well as expert and inventor testimony.

C. Unpatentability Based On Obviousness

38. I have been informed by counsel that 35 U.S.C. § 103(a) reads “[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

39. Counsel has told me that I am to do the following when considering the obviousness of the challenged claims: determine the scope and content of the prior art; ascertain the differences between the prior art and the claims at issue; resolve the level of ordinary skill in the pertinent art; and consider evidence of secondary indicia of non-obviousness.

40. I have been told that I should considered obviousness to a POSITA at the time of alleged invention, which is March 25, 2002 for this matter.

41. I have been told that a reference may be modified or combined with other references or with the POSITA’s own knowledge if the person would have found the modification or combination obvious. A POSITA is presumed to know

all relevant prior art, and the obviousness analysis may consider the inferences and creative steps that a POSITA would employ.

42. In determining obviousness, counsel has informed me I can consider the following principles when determining if one or more references can be combined or modified: (1) a combination of familiar elements according to known methods is likely to be obvious if it yields predictable results; (2) the substitution of one known element for another is likely to be obvious if it yields predictable results; (3) the use of a known technique to improve similar items or methods in the same way is likely to be obvious if it yields predictable results; (4) the application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results; (5) any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed; (6) a person of ordinary skill often will be able to fit the teachings of multiple references together like a puzzle; and (7) the proper analysis of obviousness requires a determination of whether a person of ordinary skill in the art would have a “reasonable expectation of success”—not “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

43. I have been informed by counsel that whether a prior art reference renders a patent claim unpatentable as obvious is determined from the perspective

of a POSITA. Further, I have been told that while there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of one skilled in the art. I have also been told that the inferences and creative steps a POSITA would employ are also relevant to the determination of obviousness.

44. I have been informed by counsel that when a work is available in one field, design alternatives and other market forces can prompt variations of it, either in the same field or in another. If a POSITA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. In many fields, there may be little discussion of obvious combinations, and in these fields market demand—not scientific literature—may drive design trends. When there is a design need or market pressure and there are a finite number of predictable solutions, a POSITA has good reason to pursue those known options.

45. I have been informed by counsel that there is no rigid rule that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. But I also have been told that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. This test poses the question whether there is

an express or implied teaching, suggestion, or motivation to combine prior art elements in a way that yields the claimed invention and avoids impermissible hindsight analysis.

V. OVERVIEW OF THE PATENT AT ISSUE

46. The patent at issue in this case, US Patent No. 9,788,735 (the ‘735 patent), is, as indicated by the title of the patent, about a “Arm Mountable Portable Patient Monitor”. EX1001, (54). As illustrated by the Figures 1 and 3, the ‘735 Patent teaches moving from a tethered system in which patient sensor(s) are connected, by cable (140), to a monitor (Figure 1) to a system where the patient sensor(s) are connected via a wireless communications link (340). EX1001, FIGs. 1 and 3. The ‘735 Patent focused on removing the wiring between a sensor and a conventional bedside monitor and was not an invention directed to the use of ports for wired connections or dictating signal type (analog, digital) to use for receiving signals from sensors. EX1001, 2:19-35, 7:12-21, 6:31-34. Indeed, these conventional features appear to be afterthoughts from the inventor. *Id.*

47. The use of a wireless communications link between sensor(s) and a monitor means that the patient need not be located in the immediate vicinity of the monitor. In addition, patient relocation need not involve disconnecting monitoring equipment and the associated loss of data and also need not attempt to move both patient and monitoring equipment. EX1001, 2:19-35.

48. The claims, 1-20, describe the particulars about the medical device worn by patients, including sensor types (e.g., pulse oximetry) and the physical configuration of the worn device (e.g., the nature of the attachment of the local cable to the housing). These features were all conventional.

VI. CLAIM CONSTRUCTION

49. The primary claim construction term at issue “sensor communication port(s)”, for which I propose to define as “a permanent or removable I/O interface for a sensor”. The rationale for this definition includes the existence of both permanent (e.g., processor pins soldered to a breakout board) and temporary/removable (e.g., a USB port) ports, and the importance of data communication in understanding the concept of a port. EX1044, p. 35 (permanent ports/soldered pins on a processor); EX1016, FIG. 2; EX2021 (removable port connections).

50. The Patent Owner’s construction is broad enough to include hardwired (e.g., soldered) connections, and yet they argue against soldered connections. Furthermore, Patent Owner’s construction includes component connections – such as a light bulb and socket – that aren’t considered ports. As such, either their position lacks a logical foundation or construction is wrong because it includes a hardwired connection and connections without any data transmission.

51. Yanulis offers a description of common male/female ports, but he did not offer that description as a construction. EX1003, ¶ 64. Furthermore, even if the description was offered as a construction, I don't accept it. As I understand it, Dr. Yanulis explained that the male/female relationship for ports was merely a "typical" example. *Id.* I would agree that many ports have this configuration, but not all ports. Thus, I read Dr. Yanulis's statement as merely exemplary, not definitive.

52. Claim differentiation supports my construction that a port need not be temporary or removable. I have been informed by counsel that dependent claims are presumed to be more limiting than an independent claim, and the Doctrine of Claim Differentiation provides that no two claims should be interpreted to cover the same scope. Dependent claim 3 of the '735 patent calls for removability of a port connection, while independent claim 1 simply claims a sensor port. So, a removable port connection, under the Doctrine of Claim Differentiation, would be more limited in scope than the generic sensor port recited in claim 1. As such, the port described in claim 1 is not limited to one that is removable and must be broad enough to cover both permanent and removable port connections under the Doctrine of Claim Differentiation.

53. My proposed construction of a port comports with the claim language context, which I have been informed is the most important consideration in

construing claim language. I note that the independent claims all recite that the port is configured to provide wired communication with a sensor. *E.g.* EX1001, 13:32-34. A connector alone is not configured for data communication, as an I/O aspect or interface would be further required for the data *communication*. Otherwise electrical signals would be meaningless from one device to another as they would not be able to understand each other. Also, nothing that I have considered in the specification or prosecution history suggests that the data communication aspect of a port should not be included in the construction of a port, as that is the plain and ordinary understanding to a POSITA.

54. Regardless, it is my opinion that the claim terms are invalid under either party's construction because ports in this context are so obvious. While Patent Owner's construction of a port captures some of what a port typically does, they still have not argued that the prior art ports are different from the claimed ports, nor could they because Kiani is a Masimo patent. Petitioner persuasively demonstrated that ports were conventional and known in 2002. As such, it is my opinion that including ports on the device of Goldberg or Money would have been obvious whether the Board construes ports as suggested by Petitioner or Patent Owner. Therefore, construction of this term seems unnecessary as it has no bearing on invalidity.

VII. SUMMARY OF THE PRIOR ART

55. The prior art clearly illustrates that the Patent Owner's arguments for patentability are baseless, in that they ignore basic, fundamentals of electrical and electronic engineering. Patent Owner takes the position that whether a signal is analog or digital is inventive. Similarly, Patent Owner proposes that the use of ports for a wired connection somehow is inventive. In reality, both positions are obvious and uninventive. At the time of the claimed invention, these techniques and technologies were well known to technicians and hobbyists, much less engineers or POSITAs. Indeed, the concepts Patent Owner relies on for patentability were known to me as a freshman engineering student at LSU at age 16. (See ¶ 21 herein).

A. Goldberg

56. Goldberg teaches "wired connections" for a wearable medical monitoring device and known ways of coupling (i.e. ports). EX1005, 4:23-29. Ports would have been an obvious possibility because wired connections occur either via a hardwired connection or a port, both of which were well-known to a POSITA in 2002. Goldberg supports ported connections because he says the system can talk to different combinations of sensors. EX1005, 4:50-56, 5:3-8. A POSITA would assume this configuration teaches or at least implies ports, otherwise different combinations would not be possible. Moreover, Patent Owner

never refutes that Goldberg teaches wired connections. Furthermore, despite Mr. Oslan's position that it would be difficult to know how to implement an electrolyte sensor from the figures, a POSITA would easily envision the connection of another sensor. EX2010, ¶ 69. For example, a POSITA would position the additional connection at a port on the bottom of the device Goldberg taught in FIG. 2.

B. Money

57. Although Money does not expressly call out ports, Money shows what appear to be ported connections in FIGs. 17A and B. Patent Owner has not argued that Money does not teach ports.

58. Additionally, Money teaches that one wearable, medical device can communicate with analog and digital sensors simultaneously. EX1008, 7:4-6. The fact that Money teaches a slightly different combination of analog sensors and digital sensors than claimed by the '735 Patent would not dissuade a POSITA from modifying Money to communicate with different sensor types, such as an analog pulse oximetry sensor and a digital temperature sensor or digital blood pressure sensor. Indeed, modifying a device to communicate with a digital device, rather than an analog one, would have been particularly routine for a POSITA.

C. Kiani

59. Kiani expressly discloses ports as conventional and obvious, including in the measurement of SpO₂. EX1006, 3:21-22. Kiani teaches that a wired

connection with a sensor can include a port. *Id.* Furthermore, a POSITA would extrapolate that ported connection for each wired connection with a sensor, i.e., it would be obvious to duplicate ports. A POSITA would not need to be taught how to connect multiple sensors via multiple ports once taught how to connect one sensor via one port – such an extrapolation would have been obvious to a POSITA.

60. Both reference numerals 550 and 540 in FIG. 5 of Kiani teach a bi-directional communications port that forms a wired connection and, as such, Masimo is incorrect in saying Kiani teaches a single port. EX1006, FIG. 3. Kiani teaches three port connections (at least according to Patent Owner’s construction), each of which take up space, demonstrating to a POSITA that three electrical connections can fit within a small, “handheld” device. EX1006, FIG. 5, Abstract.

VIII. ARGUMENTS – GROUNDS 1 AND 3

A. Ports are obvious for any wired connection

61. Ports are among the limited, obvious possibilities for a wired connection. Ports were both well-known and conventional at the time of the ‘735 patent. Wired connections occur either via a hardwired connection or a port, both of which were well-known to a POSITA in 2002. EX1006, 3:21-22.

B. Patent Owner's motivation to combine arguments continue to assume Goldberg is hardwired

62. Contrary to Patent Owner's position, Goldberg does not teach a hardwired connection. Indeed, it is plausible and reasonable to assume that Goldberg has ports. EX1005, 4:50-56, 5:3-8.

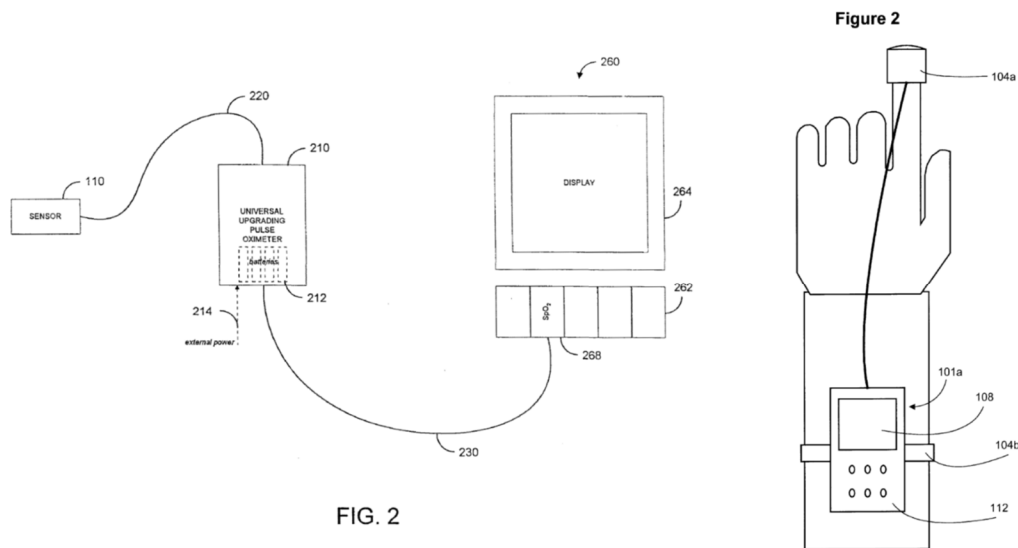
63. First, Goldberg teaches that the sensors "can be coupled to the controller 102 and/or memory by wire or wirelessly, and such ways of coupling are well-known in the art". EX1005, 4:26-29. This is true, and a POSITA would know that one of the "well-known" "ways of coupling" uses ports. EX1006, 3:21-22. Thus, Goldberg implies ports by teaching wired ways of coupling. EX1005, 4:26-29. Similarly, Goldberg teaches that it can communicate with "any type of physiological sensor", which would include ported physiological sensors as ported physiological sensors were known in 2002. EX1005, 4:50-56, 5:3-8; EX1006, 3:21-22. I know that ported medical sensors were known and widely available in 2002, but both Kiani and Money prove this knowledge to be true. EX1006, 3:21-22, EX1008, 11:17-20.

64. Actually, a POSITA would be surprised if Goldberg did teach hardwired connections. Hardwired connections are unusual when connecting a peripheral device, such as a medical sensor. Given how common and wide-spread ports are in the medical field, or any electronic device for that matter, a POSITA

would read Goldberg to teach ports because that is the default. As I explained above, Goldberg's teachings also confirm that Goldberg teaches ports.

65. In reading Masimo's Patent Owner Response and Mr. Oslan's Declaration, it is clear to me that they conclude that Goldberg teaches hardwired connections solely from looking at FIG. 2 of Goldberg. EX2010, ¶¶ 64-66. However, I do not understand FIG. 2 of Goldberg to be a device specification or schematic; I view it as a simplified diagram, exactly as Goldberg describes FIG. 2. EX1005, 3:56-57. Thus, a POSITA would not make the conclusions that Mr. Oslan made when looking at FIG. 2 alone. A POSITA's understanding that ports were well-known for wired connections would guide their understanding of what Goldberg teaches, not solely Goldberg's simplified diagram. Mr. Oslan appears to have read Goldberg through a very narrow lens that ignores what he admitted to be true: ports were known. EX1042, 23:3-5.

66. In fact, drawing figures like Goldberg appears to be common in patent literature. For example, Kiani, which I understand is owned by Patent Owner Masimo, drew its diagrams almost identically as Goldberg.



67. As can be seen above, FIG. 2 of Kiani draws a line 220 representing a wire simply touching a box 210 representing the universal pulse oximeter (UPO), which is exactly how Goldberg drew its wire from the SpO₂ sensor 104a to the housing 112. Despite this simplistic drawing in Kiani, Kiani's teaches that the UPO includes a sensor port where that wire connects to the UPO. EX1006, 3:21-23. Thus, a POSITA would not make unequivocal conclusions based solely on how patent drawings are drawn; more is required for a POSITA to be certain that Goldberg teaches and illustrates a hardwired connection, teachings which Goldberg lacks.

68. In my opinion, no POSITA would ever design Goldberg's device to be hardwired while trying to meet Goldberg's design goals, namely the ability to connect to any type of physiological sensor. EX1005, 4:13-16, 4:50-56, 5:3-8. A

POSITA would read these teachings and understand that Goldberg designed an adaptable and flexible device capable of various sensor connections schemes, not just the one shown in FIG. 2, which only includes an SpO₂ sensor and a blood pressure sensor. EX1005, FIG. 2. A hardwired system provides no adaptability whatsoever – the wiring is fixed or permanent, and sensors cannot be replaced, changed, or removed. As such, a POSITA would not read Goldberg as hardwired because a hardwired system would not be able to communicate with “one, all, or any combination of” blood pressure, pulse, oxygen-hemoglobin saturation, glucose, body temperature, respiration, and electrolyte sensors. EX1005, 4:13-16, 4:50-56, 5:3-8. Goldberg would not have taught adaptability and hardwired connections, and a POSITA would know that.

69. Patent Owner’s expert asserts, incorrectly, that Goldberg teaches different versions that could be manufactured. EX2010, ¶ 81. However, I disagree that Goldberg only envisions different versions of the device, and Mr. Oslan’s assertion should be ignored. Goldberg taught connection to at least seven sensors (although more were envisioned when he taught connection to “any” type of physiological sensor). EX1005, 4:50-56, 5:3-8. So, because Goldberg teaches connection to at least seven different sensors, and Goldberg teaches connection to “one, all, or any of the combination of” blood pressure, pulse, oxygen-hemoglobin saturation, glucose, body temperature, respiration and electrolyte sensors, then

Goldberg would need to manufacture at least 120 different versions of the wearable system if the systems were hardwired.¹ While some manufacturers offer different versions of a product, the number of offered versions is often a much lower number, especially in electronics (≈ 3 -10). Any more would not be economical or practicable for large-scale manufacturing. A POSITA would know that variations in fabrication affect cost margins and are undesirable. I have personally never seen 120 different versions of a medical device. So, it's far more logical that Goldberg taught one model or a few models that had ports for connection to "one, all, or any of the combination of" the sensor types.

70. Regardless of whether Goldberg teaches hardwired connections or not, it still would be obvious to modify any supposed hardwired connections with ports. I have been informed by counsel that when there are a finite number of conventional options, it would be obvious to try each of the options. Here, there are only two options for wired communication: hardwire and ports. Ports had clear

¹ The number 120 results from simple statistics for determining the number of unrepeated, unordered combinations for a given set of 7 sensors. The known statistical formula is $n!/k!(n-k)!$ where n is the number of elements in a set (7) and k is the number of chosen elements in the set. I then added together the results of the formula for $k = 1, 2, 3, 4, 5, 6, 7$.

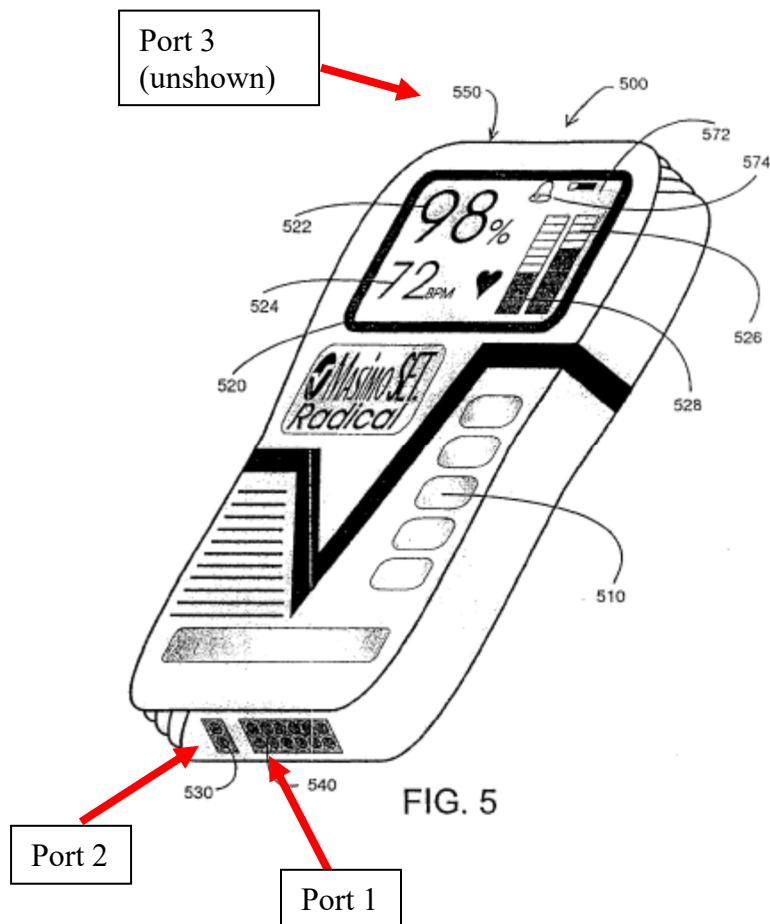
advantages over hardwired connections, such as the ability to replace a faulty sensor without replacement of the entire system. Also, ports would allow for connections to “one, all or any combination of” any known physiological sensor. EX1005, 4:50-56, 5:3-8. So, a POSITA would have been motivated to choose ported connections, especially for a flexible system like the one Goldberg taught. EX1005, 4:13-16, 4:50-56, 5:3-8. If Goldberg were hardwired, Goldberg would not be capable of communicating with “any type of physiological sensor” because it could only communicate with *one* combination of sensors physically soldered to the device. Thus, using ports on Goldberg’s system would have been obvious under any circumstance but especially in view of Goldberg’s teachings regarding adaptability. *Id.*

71. Finally, I note that Mr. Oslan asserts that Dr. Yanulis provided no evidence that ports are undesirable in a medical context, and that he doesn’t agree that clinicians demand adaptability in medical monitors. EX2010, ¶¶ 73-74. I disagree with Mr. Oslan. I am a medical doctor, and thus, I am a clinician, and I agree with Dr. Yanulis. A POSITA designing a multi-parameter monitor would design it to have ports and adaptability via ports. If given the choice between a static, hardwired monitor and a monitor that offered flexibility, a POSITA would choose the monitor that offered adaptability for patients. Mr. Oslan is not a clinician (EX2010, ¶¶ 6-18), whereas I am.

C. Patent Owner's Misapprehends Petitioner's Obviousness

72. I understand that Patent Owner argues that Petitioner's obviousness argument fails because Kiani allegedly only teaches one sensor input port. EX2010, ¶ 102. But that argument misapprehends the proposed modifications. Ports are among the limited, obvious possibilities for a wired connection. Ports were both well-known and conventional at the time of the '735 patent. EX1006, 3:21-22, EX1016, FIG. 2. Petitioner argued that because ports were known to be conventional in view of Kiani, a POSITA would have been motivated to replace each respective wired connection, if not already ported, to include a port in view of Kiani. A POSITA having knowledge of Kiani would know how to create a ported connection for each respective wired connection to a sensor that was taught by Goldberg. EX1005, 4:50-56; EX1006, 3:21-22. So, it doesn't matter whether Kiani discloses one or more than one sensor input port(s); what matters is that Goldberg teaches multiple wired connections to multiple sensors. Also, wearable devices were known to include multiple ports. EX1008, FIG. 17A-B, 11:17-20.

73. Still, it is my opinion that Kiani teaches multiple ports. In viewing FIG. 5 of Kiani, there are quite clearly three ports, at least under Masimo's proposed construction of "a connector that mates with a compatible connector".



74. Whether or not the port is a “sensor” port doesn’t matter for the purposes of Patent Owner’s arguments against combination. Patent Owner argues that the number of ports impacts the size of the device. EX2010, ¶ 73. However, if size is the concern, then it shouldn’t matter whether a port is a sensor input port, an output port, a power port, or what device is connected to a port. All ports have hardware and weight, including ports 530, 540, and 550 of Kiani. EX1006, 8:31-9:10, FIG. 5. Regardless of a port’s function (input, output, sensor, power), all ports/connectors take up space on a housing, as shown by Kiani. EX1006, FIG. 5. Kiani showed a device having three ports, at least according to Patent Owner’s

construction, and the device of Kiani was still small enough to be “handheld”.

Such a configuration did not add too much bulk or weight to prevent being handheld.

75. I note that in a Patent Owner’s statement in a related patent proceeding, Patent Owner argued that Kiani’s device is larger than a device “mountable to the lower arm”. EX1046, p. 28. I fail to see how Kiani’s device is larger just because it is described as handheld. I am not aware of any evidence or POSITA knowledge that imparts a specific size to a device either “handheld” or “secured on a lower arm”. I am similarly not aware of any evidence or relative POSITA knowledge that “handheld” necessarily means a device larger than one “secured on a lower arm”. Consider, for example, the common use of arm/wrist bands to hold the popular iPhone (a handheld device) when running. EX1045, p. 1. In my opinion, a POSITA would know that a “handheld” device would be mountable on the arm without resizing or reconfiguration.

76. Finally, even if the addition of ports on Goldberg’s housing did result in an increase in size, the increase in size would be negligible. A POSITA would know that the electronics necessary to form wired connections are relatively simple and do not take up much space. EX1055, p. 25 (showing 5.35 x 3.45 x 4.7 mm space for a port), *see also* EX1052, Abstract, 1:8-10, EX1053; EX1054. At worst, the addition of ports would make Goldberg’s device slightly longer, but that would

not increase Goldberg's device size beyond a size mountable to the arm, especially with a proper strap. Patent Owner never explained by how much the device would increase in size.

77. Lastly, I note that Patent Owner argued that ports are not a mere duplication of parts because the claimed "ports" connect to different sensors. That argument would make sense if the claims also recited sensor-specific mechanical structures or electrical protocols, but the claims merely recite a generic port "for wired communication" with sensors. The claims never specify any structural or electrical difference between, for example, the first port and the second port. To a POSITA, that generic language is broad enough to include a universal port that can connect with various sensor types, similar to how a USB port can connect to various types of peripherals (e.g. keyboards, mice, printers, iPhones, etc.). Also, Patent Owner's construction only defines a connection point, which would apply to all wired connections with sensors. In other words, Patent Owner's proposed construction further shows that the term "port" within the context of the '735 Patent is a term that does not include sensor-specific electronics, protocols, or connectors.

D. Patent Owner's reasons not to combine are improper and fail to consider all of the circumstances

78. The Patent Owner's reasons not to combine are improper. They fail to consider all circumstances, including:

- a. Sensors can fail. Ease of replacing a failed port is the primary advantage of using a removable port over a hardwired, non-removable connection.
- b. Patent Owner argues that ports allow for accidental disconnection. Such disconnection may occur but does not occur often. Also, there are well-known guards against accidental disconnection, such as clips, snaps and various retainers that predate this patent. EX1047, p. 1; EX1048, p. 3; EX1049, p. 1; EX1050, Abstract. Oslan agrees. EX1042, 88:6-89:1.
- c. Non-clinical settings are no more difficult to manage than clinical settings. Sensors can fail and need to be replaced regardless of where the sensor is used. Hardwired sensors that fail cannot be replaced easily, so a POSITA would know to use ports to allow for removal and replacement of faulty sensors in any setting.

- d. Noise and interference are easily prevented with simple structures, such as shields. EX1051, Abstract; EX1055, p. 33 (4.2.1A.1), 185 (A.2)). I am told there is an entire USPTO classification on just this concept - U.S. Patent Class 439/607.01. Structures such as shields on connectors have been known for many years. *Id.*
- e. Single-use, disposable sensors are commonplace. Dr. Yanulis argued persuasively that ports offer the ability to remove and replace faulty sensors. The same logic applies to disposable sensors. Patent Owner never refuted this motivation, and Mr. Oslan supported it. EX2010, ¶ 73.
- f. Ports are not complications, but benefits. EX1049, p. 1.
Consider ports on the iPhone that extend the use of the phone for enhanced image and data collection. Simply put, ports are simple, known, and users have been using ports for many years.

79. Masimo also argues that Goldberg is not directed to a clinical setting, but an at-home setting. However, I see no evidence that Goldberg is limited to an at-home setting. None of the sections of Goldberg cited by Patent Owner to support their “at-home” argument support their argument – these sections only describe a remote server. EX2010, ¶¶ 76-78; EX1005, 1:6-10, 2:3-15, 3:17-24,

6:28-30, 7:6-33. However, clinical devices often had remote servers too. EX1008, 1:8-15. If anything, Goldberg taught a device useful for both at-home and clinical settings.

80. Even if Masimo were correct about Goldberg's setting, I fail to see why a POSITA wouldn't include ports on a device used at home. Lay people were very used to ports in many settings around their home, such as Ethernet ports, USB ports, telephone jacks, RCA cables on TVs, coaxial cable connections, parallel ports, serial ports, etc. So, a POSITA would not believe that ported connections would intimidate a non-medical user or result in a device too complicated for an at-home user.

81. Also, the motivation to combine arguments in the Petition apply equally to both at-home use and clinical use. Sensors fail in both at-home settings and clinical settings, so a POSITA would be motivated to use a port to allow a user or a clinician to remove and replace a sensor. Also, an at-home user would prefer to customize the set of sensors based on their ailment. Not all patients are alike, and some diseases need to be monitored differently. For example, a physician would not monitor the glucose in a patient diagnosed with high blood alone but would monitor both blood glucose and blood pressure in a patient diagnosed with diabetes. The same is true for a patient monitoring themselves. So, exactly as

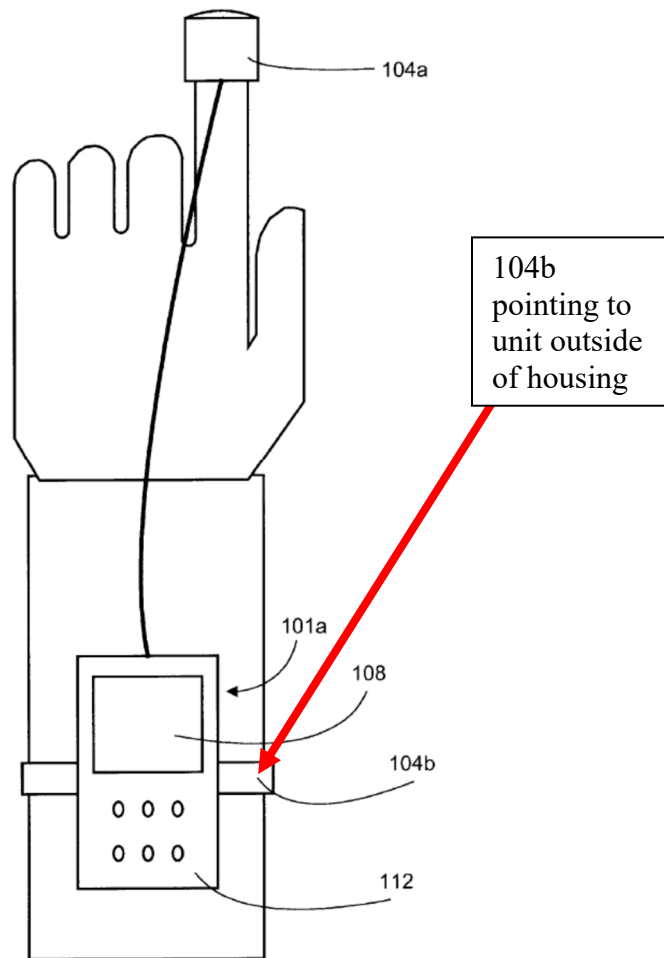
Goldberg envisioned, patients and clinicians alike prefer customization and adaptability. EX1005, 4:50-56, 5:3-8.

82. In any setting, ports are obvious to a POSITA.

E. Port with a blood pressure cuff

83. Goldberg teaches that the blood pressure cuff *sensor* 104b is outside of the housing and that the communications with the sensor is wired. EX1005, 4:64-67, FIG. 2. This wired connection and the sensor's location outside the housing would necessarily include a port. EX1005, 4:26-29, 4:64-67, FIG. 2. I don't follow Masimo's argument suggesting that the air pump and pressure sensor were supposedly both within the housing 112, given that Masimo argued that the Goldberg housing 112 is too small for ports. This seems to be a contradiction. Instead, it's more likely that the blood pressure sensor was outside the housing 112 facilitated by a wired connection to the housing 112. EX1005, FIG. 2.

Figure 2



84. Also, I note that the specific configuration shown in FIG. 2 is merely one of Goldberg’s embodiments. EX1005, 4:59. Goldberg also discloses a controller that communicates with all sensor via wires. EX1005, 4:23-29. A POSITA would understand this embodiment to involve a controller connected to a blood pressure sensor that is not also functioning as strap that secures the device to a person’s wrist. *Id.* This understanding would be confirmed by Goldberg teaching that it can communicate with “any” type of sensor, which a POSITA would

understand to include self-contained blood pressure sensors connected via ports, such as the blood pressure sensor described by Kiani. EX1005, 5:3-8; EX1006, 16:24-33.

85. In addition, blood pressures sensors that included a microphone were also known before 2002. EX1043, Abstract, 11:67-12:12. Blood pressure sensors that used a microphone enhanced accuracy by measuring Korotkoff sounds, which are sounds that blood makes as it passes through a constricted blood vessel. EX1043, Abstract, 1:22-37. In a blood pressure sensor that included a microphone, the electrical connection to the microphone would include a port connection, just like any wired connection to an electrical device. Exactly as taught by U.S. Patent No. 4,889,132, the microphone cannot be positioned inside a housing because a POSITA would know that the housing would muffle Korotkoff sounds. Instead, a POSITA would position the microphone against the person's skin within the blood pressure cuff. EX1043, Abstract, 11:67-12:12. Again, because Goldberg teaches that it can communicate with any known physiological sensor, Goldberg envisioned communication with a blood pressure sensor having a microphone positioned outside the housing, which would necessarily or obviously include a port for the reasons discussed above. EX1005, 5:3-8; EX1043, Abstract, 11:67-12:12.

F. Analog and digital sensors are equivalent

86. A POSITA would be equally facile working with analog and digital versions of a given sensor, would know that manufactures offer most sensors in both analog and digital version, and would match the interface of the microcontroller or port to the signal type transmitted by the sensor (either analog or digital). A POSITA would know not to connect an analog interface to a digital sensor, and vice versa. Any differences in cost would be negligible and not part of an obviousness consideration. As Money points out, and what the Examiner apparently was not aware of, microcontroller cards and other hardware circa 2002 intended to communicate with sensors commonly received both analog and digital signals from both analog and digital sensors and other devices. EX1008, 7:4-8. Furthermore, claim 19 only requires that the blood pressure sensor “include digital information”, but the signal does not need to be a purely digital signal. This claim limitation does not preclude the possibility of a combined analog and digital signal, as such signals were known. EX1001, 6:59-63; EX1008, 6:8-10. Said differently, the signal from the blood pressure sensor could be an analog signal with digital information encoded on the analog signal, and this signal would include digital information, exactly as claimed. Encoding an analog signal with digital information would have been routine for a POSITA. EX1008, 6:8-10.

G. No Hindsight Was Involved

87. Patent Owner asserts that Petitioner's proposal of several changes is somehow evidence of hindsight. However, these proposals – gap fillers – are what a POSITA would know or think when reading Goldberg. Additionally, in my review of Petitioner's obviousness motivations all of them included at least some citation to the references that provide motivation to combine the references together, which cannot be argued as hindsight.

IX. GROUND 5-8 ARGUMENTS

A. There is no evidence that Money's device wasn't worn on the wrist

88. Money is a very similar device as the claimed monitor – both are directed to wearable, multi-parameter monitors. EX1008, Abstract; EX1001, Abstract. A POSITA would know that Money's device was worn on a patient's body somewhere, but Money does not specify. EX1008, Abstract. A POSITA would know that there are only a few locations where a medical monitor could be worn by an ambulatory patient: the leg, the arm, or around the neck.

89. It would have been obvious to put Money's system on the wrist. The Patent Owner focuses on size, but adjusting size, especially as technology improves, is an obvious change. MPEP 2144.04(IV)(A). More specifically, according to Moore's law, transistor density doubles for a given chip size every two years, and there were *eight* years between Money's priority date and the '735

Patent's priority date. EX1008, (63); EX1001, (60). A POSITA would know what Moore's Law is (EX1042, 156:9-16), and a POSITA would know that Moore's Law posits that electronics shrink in size while also increasing in efficiency and performance due to increases in chip density. A POSITA would also know that history has validated the Moore's Law observation to be true over the past 50 years (including from 1994-2002). Moore's Law applies to any electronic device having transistors, which is most of Money's device. EX1008, FIGs. 2A-9, 18A-24. As such, most of Money's circuitry would be smaller in 2002 simply due to advances in technology, as represented by Moore's Law. Hence, by 2002, Money's device would have shrunk significantly in size by using modern versions of the semiconductors and electrical components taught by Money. *Id.* Thus, a POSITA would have been motivated to use modern technology to design Money's device in 2002, eight years after Money's initial filing, resulting in a smaller device due to advances in technology. EX1042, 156:9-16. So, Patent Owner's arguments regarding size would not deter a POSITA from placing Money's device on the wrist.

90. Furthermore, it isn't clear that any change in size was necessary. Money merely lists approximate dimensions and a maximum weight. EX1008, 5:6-8, 3:40-41. Hence, a POSITA would understand that smaller sized versions of Money's device were envisioned, all of which could be strapped to the wrist.

91. Furthermore, a device the size of Money's maximum dimensions and maximum weight have been known to be worn on wrists. Some watches weigh in at over a pound (EX1058, p. 5), I am aware of wrist-worn devices far larger in dimension than Money (EX1059, p. 2, showing a device that is 6.65" x 3.06" x .8"), and it's commonplace for runners to strap on the arm and wrist smart phones – the very device Patent Owner suggests is too large for wrist attachment (EX1045, p. 1). Knowing this, a POSITA would not be deterred from Money's descriptions about size from attaching a wearable device, like the device of Money, on a person's wrist. As I said above, there are relatively few locations on a patient's body for attaching a wearable device.

92. Of those few options, a POSITA would be motivated to place Money's device on the arm because Money teaches a device with a screen. EX1008, FIG. 10. A POSITA would be motivated to place the device of Money somewhere where the patient could see the screen and a doctor could easily read the screen. There is no support for placing a device with a screen anywhere other than the arm or wrist.

93. One place the device of Money definitely would not be placed in on a patient's belt, as Patent Owner suggests. Money teaches a device for an ambulatory patient in a hospital setting. EX1008, Abstract, 1:8-10. Hospitalized patients do not wear belts; they wear hospital gowns. A POSITA would know that hospital gowns do not have belts. So, Patent Owner suggested attaching the device to an article of

clothing that a patient would not be wearing in a hospitalized setting. A POSITA would never choose a belt attachment for a hospitalized patient because a POSITA would know that patients do not wear belts.

B. Money Combined with Akai

94. Furthermore, any modifications required to wear the device on the wrist would have been obvious in view of Akai, as Dr. Yanulis properly analyzed. EX1003, ¶ 196. Akai provides further motivation to ensure that Money's device could be attached to the wrist, and Akai provides a device sized and configured for convenient wrist attachment.

95. I note that Patent Owner misconstrued the obviousness argument when asserting that the combination with Akai would result in optical transmission of signals. I disagree. Petitioner merely suggested to use Akai's SpO2 sensor and Akai's housing configuration, not also modify Money with an optical cable, like the one taught in an embodiment of Akai. Furthermore, the fiber optic taught by Akai was only an example, and Akai also recognized that other cables would similarly function. EX1007, 5:14-19. A POSITA would know that "a material having an appropriate flexibility" would include a wire. *Id.* Thus, Akai is not limited to optical signals, Akai teaches electrical signals, and a POSITA would not have been motivated to use a fiber optic cable in the system of Money. Also,

Petitioner never suggested that any cables in Money get substituted. Paper 1, pp. 63-65.

96. Additionally, Petitioner and Dr. Yanulis were correct that a POSITA would be motivated to substitute Money's pulse oximetry cuff transducer with a pulse oximetry sensor that does not also engage an artery using a cuff. A POSITA would know that a "cuff" in the medical field is a device that constricts an artery. EX1057, 1:44:56. Some pulse oximetry systems were known to both constrict a blood vessel to measure pulse oximetry. EX1057, Abstract, 1:42-48. However, it is not required to constrict a blood vessel to measure pulse oximetry, and pulse oximetry can be measured using light without constricting a blood vessel. EX1057, 1:7-39; EX1006, 1:15-21. So, the use of a pulse oximetry *cuff* transducer would be unnecessary and uncomfortable for the patient because the cuff would squeeze a body part and constrict a blood vessel while frequently measuring SpO₂. EX1057, FIG. 2. Constricting a blood vessel is further uncomfortable for patients because constricting a blood vessel results in a throbbing feeling or paresthesia. So, knowing that pulse oximetry can be measured without an uncomfortable cuff and without constricting an artery, I agree with Dr. Yanulis that a POSITA would be motivated to substitute Money's pulse oximetry cuff transducer with a pulse oximetry sensor that omits the cuff. EX1003, ¶ 195. The result of the substitution

would be increased patient comfort and a less complicated system for measuring SpO₂.

97. The Petition suggested substituting Money's pulse oximetry cuff transducer with Kiani's pulse oximetry sensor, which transmits analog signals. A POSITA would find analog signals representing SpO₂ sensor readings desirable because SpO₂ sensors, like Kiani's, measure continuous data, as Dr. Yanulis correctly opined. EX1003, ¶¶ 224-225. So, a POSITA would be motivated to receive analog signals from the SpO₂ sensor. *Id.*

98. However, Money teaches a clever dual-purpose serial port and serial interface. EX1008, 6:15-20, 7:58-62, 11:51-53. The serial port and interface receive digital data so that a user can debug the system or update firmware. *Id.* However, a POSITA would know that debugging and firmware upgrades are rare occurrences, so Money included a dual-purpose serial port and serial interface that also receives digital data from a sensor, which occurs far more frequently. *Id.* In this way, the serial port and interface for debugging does not take up space for a rare occurrence, and Money efficiently used a serial port and serial interface for two purposes. *Id.* A POSITA would desire to maintain that dual functionality because it is efficient and useful.

99. Money chose the pulse oximetry sensor to be that sensor connected to the dual-purpose serial port and dual-purpose serial interface. However, a POSITA

would instantly recognize that any sensor could connect to this dual-purpose serial port and dual-purpose serial interface with minimal reconfiguration, preferably a sensor transmitting discrete data, such as the blood pressure sensor or the temperature sensor. A POSITA would be motivated to continue using the serial port and serial interface in the dual-purpose manner, so a POSITA would modify Money's device and receive digital signals from another sensor, most preferably a sensor transmitting discrete signals, in view of substituting the SpO₂ cuff with Akai's SpO₂ sensor. Such a change would be well within the ordinary skill of a POSITA. EX1003, ¶¶ 224-225.

X. ESTEP IS ANALOGOUS ART

100. Estep, like Goldberg, teaches a wearable unit having a screen and is analogous art. While both Goldberg and Money show a bezel already, Estep goes farther by explicitly identifying a bezel as the border around a screen. EX1009, 4:24:25, Fig. 3C. Thus, Estep is pertinent to the problem of including a display on a wearable unit, which was a problem facing the '735 Patent. EX1001, 2:10-18. But still, these arguments are unnecessary because Estep merely defines what a bezel is. Petitioner did not suggest modifying Goldberg or Money with Estep because such a modification would be unnecessary – Goldberg and Money already have bezels. Patent Owner did not refute that Goldberg and Money already teach bezels.

XI. CONCLUSION

101. For these reasons, it is my opinion that all claims of the '735 patent are unpatentable.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 19th day of May, 2021.


Bryan Bergeron, MD, FACMI