Filed: February 26, 2021

Filed on behalf of: Patent Owner Masimo Corporation
By: Sheila N. Swaroop (Reg. No. 53,658) Irfan A. Lateef (Reg. No. 51,922)
Ben J. Everton (Reg. No. 60,659)
Brian C. Claassen (Reg. No. 63,051)
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, Fourteenth Floor Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
E-mail: SoteraIPR623@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS,

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01054 U.S. Patent 9,872,623

PATENT OWNER RESPONSE

Sotera, IPR2020-00954 Ex. 1046, Page 1 of 78

TABLE OF CONTENTS

I.	INTRODUCTION 1			
II.	BAC	BACKGROUND		
	A.	The OPatie	Claims of '623 Patent Require an Arm-Mountable nt Monitoring Device with at Least Three Sensor Ports 5	
	B.	Over	view of the Alleged Prior Art7	
		1.	Goldberg (EX1005)7	
		2.	Kiani (EX1006)	
		3.	Akai (EX1007) 11	
		4.	Money (EX1008)	
		5.	Estep (EX1010) 14	
		6.	Fujisaki (EX1009) 15	
		7.	Hylton (EX1012) 15	
III.	LEV	EL OF	ORDINARY SKILL	
IV.	CLAIM CONSTRUCTION			
	A.	The l Term	Plain and Ordinary Meaning Applies to All Claim ns, Including "Sensor Port"16	
	B.	Yanu Distr	Ilis' Contradictory Claim Construction Opinions in the ict Court Expose Result Oriented Opinions	
		1.	Yanulis' Claim Construction Opinions Are Inconsistent	

TABLE OF CONTENTS (cont'd)

Page No.

		2.	Yanulis' District Court Opinions on Claim Construction Specifically Excludes the Devices in Goldberg, Money, and Akai Relied upon in the Petition 21
		3.	Yanulis' Opinions on "Tail" Are Also Inconsistent 23
V.	ARG	UMEN	VT
	A.	Grour Demo	nd 1: The Combination of Goldberg and Kiani Fails to Instrate the Obviousness of Any Claims
		1.	Goldberg Does Not Disclose Any Sensor Ports 24
		2.	Petitioner Fails to Explain Why a PHOSITA Would Have Modified Goldberg with Kiani to Have Three Sensor Ports
			a) Kiani Teaches a Single Sensor Port
			b) Petitioner's Generic, Conclusory Statements Fail to Motivate the Addition of a First Sensor Port
		3.	Goldberg Does Not Disclose Second and Third Sensor Ports for EKG and Blood Pressure
		4.	A PHOSITA Would Not Have Been Motivated to Add a Third Sensor Port for Goldberg's Blood Pressure Cuff
		5.	The Claimed Second and Third Sensor Ports Are Not a Mere Duplication of Parts
	B.	Grour	nds 2 and 3 Fail for the Same Reasons as Ground 1

TABLE OF CONTENTS (cont'd)

Page No.

C.	Ground 4 Fails to Demonstrate the Obviousness of Claim 20 Because It Relies on Non-Analogous Art			
	1.	Hylto	on Is Not Analogous Art	46
	2.	Petit Art	ioner Fails to Explain Why Estep Is Analogous	48
D.	Grou Chal	nd 5 F lenged	Tails to Demonstrate the Obviousness of Any Claim	49
	1.	Petit Argu	ioner Has No Factual Basis for Its Core Iment	49
	2.	The Hind	Petition Reconstructs the Claimed Invention with sight	51
		a)	Money's Device Is Too Large and Bulky to Be Wrist-Worn	52
		b)	Petitioner Assumes that a PHOSITA Would Already Be Motivated to Combine Money and Akai	54
		c)	A PHOSITA Would Not Substitute Money's Pulse Oximetry Cuff Transducer with Akai's SpO ₂ Sensor	57
		d)	Yanulis Explained that a PHOSITA Would <i>Not</i> Be Motivated to Modify Money with an Analog SpO ₂ Sensor	60
	3.	The Sens	Proposed Combination Fails to Teach a First or Port Configured to <i>Electrically Receive</i> a al from the Pulse Oximetry Sensor	63

TABLE OF CONTENTS (cont'd)

Page No.

	E.	Ground 6 Does Not Remedy the Deficiencies in Ground 5	64
	F.	Ground 7 Fails to Establish a Reasonable Likelihood of	()
		Success	64
VI.	RESI	ERVATION OF RIGHTS	65
VII.	CON	CLUSION	65

TABLE OF AUTHORITIES

<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)
<i>In re Bigio</i> , 381 F.3d 1320 (Fed. Cir. 2004)
<i>Circuit Check Inc. v. QXQ Inc.</i> , 795 F.3d 1331 (Fed. Cir. 2015)
Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375 (Fed. Cir. 2015)
<i>InTouch Techs., Inc. v. VGO Cmmc'ns, Inc.,</i> 751 F.3d 1327 (Fed. Cir. 2014)
<i>In re Kahn</i> , 441 F.3d 977 (Fed. Cir. 2006)
<i>Kinetic Concepts</i> v. <i>Smith & Nephew, Inc.</i> , 688 F.3d 1342 (Fed. Cir. 2012)
<i>In re Magnum Oil Tools Int'l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)
<i>McGinley v. Franklin Sports, Inc.</i> , 262 F.3d 1339 (Fed. Cir. 2001)
<i>In re NTP</i> , 654 F.3d 1279 (Fed. Cir. 2011)
<i>Personal Web Techs., LLC v. Apple, Inc.,</i> 848 F.3d 987 (Fed. Cir. 2017)
<i>Personal Web Techs., LLC v. Apple, Inc.,</i> 917 F.3d 1376 (Fed. Cir. 2019)

TABLE OF AUTHORITIES(cont'd)

<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	16
<i>TVIIM, LLC v. McAfee, Inc.,</i> 851 F.3d 1356 (Fed. Cir. 2017)	
U.S. v. Arthrex, Inc., No. 19-1434, 141 S. Ct. 549 (Oct. 13, 2020)	65

OTHER AUTHORITIES

37 C.F.R. § 42.65	51
83 Fed. Reg., No. 197	16
Consolidated Trial Practice Guide (Nov. 2019)	45
Fed. R. Evid. 702	51

EXHIBIT LIST

Exhibit No.	Description
2001	Masimo's Opposition to Sotera's Motion to Stay Proceedings, dated June 8, 2020, filed in <i>Masimo Corp. v. Sotera Wireless,</i> <i>Inc.</i> , Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) ("District Court Action")
2002	Case Management Order Regulating Discovery and Other Pretrial Proceedings, dated December 9, 2019, filed in the District Court Action
2003	Order Granting Joint Motion to Modify Case Management Order, dated April 29, 2020, filed in the District Court Action
2004	Defendants' LPR 3.3 Invalidity Contentions, dated March 20, 2020, served in the District Court Action (without exhibits)
2005	Declaration of George E. Yanulis in Support of Petition for <i>Inter</i> <i>Partes</i> Review of U.S. Patent No. 9,795,300 (Exhibit 1003 in IPR2020-01515)
2006	Amended Memorandum of Decision Including Post-Trial Findings of Fact and Conclusions of Law [Redacted], filed July 18, 2017, in <i>In re: Sotera Wireless, Inc.</i> , BK No. 16-05968-LT11 (SD Cal. BK) (Exhibit 1019 in IPR2020-000967)
2007	Defendants' Amended Invalidity Contentions, dated September 8, 2020, served in the District Court Action (without exhibits)
2008	Reserved
2009	Order Granting in Part Defendants' <i>Ex Parte</i> Motion to Modify Case Management Order, dated October 6, 2020, filed in the District Court Action
2010	Declaration of Alan L. Oslan
2011	Curriculum Vitae of Alan L. Oslan

Exhibit List, Page 1

Exhibit No.	Description
2012	Transcript of Deposition of George E. Yanulis, taken on January 26, 2021 in connection with IPR20200-00912, -00954, -01015, -01054
2013	Transcript of Deposition of George E. Yanulis, taken on January 27, 2021 in connection with IPR20200-00912, -00954, -01015, -01054
2014	Transcript of Deposition of George E. Yanulis, 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 <i>Masimo</i> <i>Corp. v. Sotera Wireless, Inc.</i> , Case No. 3:19-cv-01100-BAS- NLS (S.D. Cal.)
2016	Transcript of Deposition of George Yanulis, conducted on September 10, 2020, in <i>Masimo Corp. v. Sotera Wireless, Inc.</i> , Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.)
2017	Excerpt of Stedman's Medical Dictionary (27th ed. 2000)
2018	Excerpt of <i>Dorland's Illustrated Medical Dictionary</i> (30th ed. 2003)
2019	Excerpt of <i>Webster's New World College Dictionary</i> (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)

Exhibit List, Page 2

Exhibit No.	Description
2024	Allison Rhodes Westover et al., <i>Human Factors Analysis of an ICU</i> , 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, <i>Clothed in Health</i> , 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 TM 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).

I. INTRODUCTION

The '623 Patent describes and claims a medical device designed for the unique purpose of monitoring mobile patients in a general-care floor hospital setting. Typical prior art hospital devices were designed for the surgical or more acute care settings, where critically ill patients require robust monitoring of many physiological parameters. Such monitors were typically bedside units with various sensors and wires that connect the patient to the monitor. On the other end of the spectrum, mobile devices (such as those disclosed in Goldberg) allowed remote monitoring of a parameter of interest primarily for users in a remote or home setting. Thus, their designs addressed basic core parameters with a focus on simplicity of use.

The '623 Patent presents a product that fills a need for a hospital grade device that not only monitors multiple physiological parameters, but also allows patients more mobility in a lower acuity clinical setting, such as a general care floor. Petitioner's obviousness grounds based on Goldberg improperly conflate the vastly different design considerations of high-acuity bedside monitors with those of remote home-use monitors by relying on the '623 Patent's claims as a roadmap to try to arrive at the claimed invention. Meanwhile, Petitioner's obviousness grounds based on Money begin with a bulky device that would not be suitable for a wrist-worn device, and then rely on Petitioner's expert's unsupported opinions to combine it with other references. These arguments reflect classic hindsight reconstruction.

-1-

Petitioner's obviousness combinations based both on Goldberg (Grounds 1-4) and Money (Grounds 5-7) fail to disclose all the limitations of the challenged claims. Petitioner's arguments also lack credible motivations to combine the references in general or to make the specific proposed changes. Rather, when Petitioner cannot find a specific limitation in the prior art, Petitioner and its expert simply invent the motivation to add that limitation or toss in non-analogous art regarding cable television systems to gap-fill.

For the Goldberg-based grounds, Yanulis admitted that "[t]he port is not explicitly shown" in Goldberg, much less the claimed three sensor ports. EX2013 at 102:5-20. Yanulis agreed that "Goldberg doesn't show any details of how this sensor is actually attached to the housing." *Id.* at 107:13-108:2. Petitioner's proposed combination of Goldberg with Kiani also lacks any teaching of three sensor ports, including the claimed third sensor port which connects to a blood pressure sensor. Yanulis admitted that Kiani "just show[s] one port, period." *Id.* at 130:10-14. Thus, neither Goldberg nor Kiani discloses a device with three sensor ports.

Petitioner also fails to demonstrate that a PHOSITA would have modified Goldberg based on Kiani to have multiple sensor ports, including one for Goldberg's blood pressure cuff sensor. The Board observed at the institution stage that "Patent Owner's argument that a skilled artisan would be unable to implement a sensor port connection as part of a blood pressure cuff sensor, such as Goldberg's sensor 104b,

-2-

IPR2020-01054

Sotera Wireless v. Masimo Corporation

[was] inadequately supported by evidence of record." Institution Decision, Paper 12 at 37 ("Institution"). However, as Patent Owner's expert Alan Oslan explains, a PHOSITA would not have added any sensor port to Goldberg's housing for the blood pressure cuff because it would have conflicted with the design goals of simplicity of function and use, required the design and development of a new type of sensor port, would increase the likelihood of failure of the device, and would have added bulk to a device that was supposed to be wearable. Yanulis claims, without support, that such a blood pressure sensor port would allow for the exchange of a faulty blood pressure sensor—but nothing in the record supports the need for such a change, and a PHOSITA would not have implemented an unknown and undesirable design feature for a basic and remote monitoring product that was intended to provide remote monitoring of basic parameters while simplifying use. Thus, Petitioner's initial showing falls apart when the context of the prior art and the actual modifications being proposed are fully-understood.

For the Money-based grounds, Petitioner begins with a device that is 3 inches by 6 inches by 1 inch, weighs up to sixteen ounces, and requires four AA batteries and then relies upon its expert's unsupported testimony to attach that large and heavy device to a patient's wrist. However, as Mr. Oslan explains, such a device would have been too large and bulky to have been wrist-worn. Meanwhile, Petitioner and Yanulis criticize an undescribed "pulse oximetry cuff transducer" already supplied

IPR2020-01054

Sotera Wireless v. Masimo Corporation

with Money as "bulky," "uncomfortable," and "obsolete" in order to substitute it with another pulse oximetry sensor that more closely matches the claim limitations. But Yanulis revealed during deposition that he had *no idea* what Money's "pulse oximetry cuff transducer" looked like. When asked whether he could describe any feature of the allegedly bulky, uncomfortable, and obsolete cuff transducer, Yanulis admitted, "To be completely transparent, at this time I could not." EX2013 at 235:21-236:15. This is not the type of credible expert testimony that can support an obviousness conclusion. Rather, Yanulis' admitted lack of any factual support for his opinions, as well as his numerous other conflicting opinions, expose his testimony as result-oriented and guided solely by hindsight.

Yanulis even contradicts his other opinions in IPR2020-01015, challenging related U.S. Patent No. 9,795,300, where he testified that a PHOSITA would not combine an analog sensor with a digital sensor interface. Yet, that is exactly what he proposes in this IPR in order to swap Money's digital pulse oximetry sensor with an analog sensor to match the '623 Patent claims. In addition, the resulting combination would not be operable, as Petitioner and Yanulis attempt to combine a fiber optic cable with an incompatible electrical port. Petitioner cannot demonstrate the obviousness of any claims of the '623 Patent.

Sotera, IPR2020-00954 Ex. 1046, Page 14 of 78

II. <u>BACKGROUND</u>

A. <u>The Claims of '623 Patent Require an Arm-Mountable Patient</u> <u>Monitoring Device with at Least Three Sensor Ports</u>

The '623 Patent involves an arm-mountable patient monitoring device. The setting for this device is professional caregiver use in a clinic. *See, e.g.*, EX1001 at 2:22-38, 8:41-46. Thus, the context involves a high-acuity clinical grade design.

Claims 1, 17, and 20 are independent, and each require a portable patient monitoring device having at least three sensor ports. Claim 1 is reproduced below.

1. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:

a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:

a light emitter configured to emit light into a tissue site of the digit of the patient;

a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and

a tail configured to electrically convey the signal;

a housing configured for, and having a size and shape configured for, mounting to a lower arm of the patient, the housing including at least:

a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user;

a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand having the digit of the patient under measurement, the first sensor port configured to physically couple to the tail of the pulse oximetry sensor and to electrically receive the signal from the pulse oximetry sensor, wherein the first sensor port is positioned on the first side of the housing such that, when the tail is physically coupled to the first sensor port, the tail extends from the first sensor port along an axis perpendicular to a face of the first side of the housing on which the first sensor port is positioned;

a second sensor port configured to receive information from an EKG sensor arrangement via a wired connection;

a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection;

a rechargeable battery configured to power the portable patient monitoring device including the pulse oximetry sensor;

one or more signal processing arrangements configured to: receive the signal from the pulse oximetry sensor;

derive, based on the signal, measurements of oxygen saturation and pulse rate; and

Sotera, IPR2020-00954 Ex. 1046, Page 16 of 78

-6-

IPR2020-01054

Sotera Wireless v. Masimo Corporation

cause to be displayed, on the display, the measurements of oxygen saturation and pulse rate; and

a transmitter configured to:

wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and

a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient.

EX1001 at 13:14-14:6.

Claim 17 recites an arm mountable portable patient monitoring device with a first sensor port for a pulse oximetry sensor and second and third sensor ports for other sensors. *Id.* at 16:12-65. Claim 20 also recites an arm mountable portable patient monitoring device with three sensor ports and further requires, among many other limitations, "a multiplexer within the housing and configured to combine at least information indicative of the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter into a single digital word or bit stream." *Id.* at 17:59-20:31.

B. <u>Overview of the Alleged Prior Art</u>

1. <u>Goldberg (EX1005)</u>

Goldberg involves a different type of device primarily meant for basic, remote monitoring away from a clinical setting. *See, e.g.,* EX1005 at 1:6-18, 2:3-7, 5:28-

Sotera, IPR2020-00954 Ex. 1046, Page 17 of 78

33; EX2010 ¶¶ 49, 76-80. Petitioner relies on Goldberg's Figure 2 embodiment disclosing a housing 112, a pulse oximetry sensor 104a, and a blood pressure cuff sensor 104b. EX1005 at 4:57-67.



Id. at FIG. 2 (annotated). Goldberg explains that the blood pressure cuff is also used to secure the device to a patient's wrist. *Id.* at 4:64-67. Both experts agree that Goldberg neither shows nor discloses any sensor port. EX2010 ¶¶ 49, 64-69; EX2013 at 102:5-108:12.

2. <u>Kiani (EX1006)</u>

Kiani discloses a bedside universal/upgrading pulse oximeter 210 ("UPO") which receives a sensor signal through a patient cable 220 and computes oxygen saturation and pulse rate. EX1006 at FIG. 2, 5:18-30. The purpose of the UPO is to connect to an existing bedside patient monitor in order to upgrade that monitor to

Patent Owner's latest SET[®] technology. *See id.* at 2:24–3:27, 6:3-19. This upgrade involves the addition of more equipment to an already complicated bedside high-acuity monitor that uses multiple wired sensors connected to the patient. *See id.* at 5:25–6:2. To upgrade the existing patient monitor, the UPO synthesizes a signal that is recognizable by the old patient monitor. *Id.* That signal is sent to the existing external pulse oximeter 268 through cable 230. *Id.* The external pulse oximeter is part of a sophisticated and bulky multiparameter patient monitoring system 260. *Id.* Thus, once attached, there are actually two pulse oximeters in the patient room: (1) the new UPO connected to the patient via a cabled sensors, and (2) the old pulse oximeter that forms a part of the existing multiparameter patient monitor, as shown below. This collection of equipment is designed for relatively long-term installations in clinical patient rooms.



EX1006 at FIG. 2.

Kiani explains that the UPO solves the problem of incompatibility between different pulse oximeters made by different manufacturers. The UPO "function[s] as a universal interface that matches incompatible sensors with other pulse oximeter instruments" and thus allows hospitals to upgrade their existing patient monitors to use an improved pulse oximeter. *See id.* at 2:24–3:12.

Kiani also describes a portable handheld embodiment 500 (shown in FIG. 5, annotated below) of the UPO that includes an external power supply input 530, an oximeter output 540 for connection to the external pulse oximeter, and a single sensor input 550 at the top edge. *Id.* at FIG. 5, 8:31–9:2.



The sensor input is not depicted, but is described as being on the top. The connector labeled as 540 is not a sensor connection, but rather an output to the older oximeter that is being upgraded. EX1006 at 8:31-33; EX2010 ¶ 70.

3. <u>Akai (EX1007)</u>

Akai describes portable monitoring systems intended to monitor the location and blood glucose of elderly people at home. *See* EX1007 at 1:3-33, 3:44-46. Such a device should not restrict a person's everyday life or lower his/her quality of life, otherwise a person would not use it. *Id.* at 1:56-2:6, 10:3-8. Thus, Akai focuses on simplicity and ease of use in order to encourage use of its device.

Akai describes a blood glucose monitoring system with a sensor unit 112 attached to a person's body and a data processing unit 113 connected to the sensor unit 112. EX1007 at 4:34-6:58, FIGS. 1 and 2 (reproduced below). The sensor

unit 112 is an optical-type sensor attached to a person's finger or ear canal. *Id.* at 4:43-46, 5:21-30, 6:38-58. Light received by the sensor unit 112 is transferred via an optic fiber to the data processing unit 113. *Id.* at 5:14-17, 26-30. A light receiver controller then translates the light to electrical data and sends data to a CPU also in the processing unit 113. *Id.* at 4:46-50, 5:30-42. The CPU uses the data to calculate a blood glucose value. *Id.*

Fig. 1 Fig. 1 f_{H} f_{H



4. Money (EX1008)

Money describes a patient monitoring device for use with ambulatory patients in a hospital setting. EX1008 at 1:8-35. Money's device has a housing that is one inch thick, three inches wide, and six inches long, weighs up to sixteen ounces, and

> Sotera, IPR2020-00954 Ex. 1046, Page 22 of 78

IPR2020-01054

Sotera Wireless v. Masimo Corporation

requires four AA batteries. *Id.* at 3:40-45, 5:4-8. Money also generally states that the device is patient-wearable, but does not specify the device is worn on the patient's arm. *Id.* at 5:4-8. Based on the weight and size of Money's device, it is more likely that Money's device would be worn on the patient's waist. EX2010 ¶¶ 58, 128-131.

Money refers to a "pulse oximetry cuff transducer 39" for obtaining SpO₂ data, but does not provide details on this feature. EX1008 at 5:38-39. Money's device includes one interface circuit (identified as "SpO2") for receiving digital sensor data from a pulse oximeter sensor and five other interface circuits (identified as "TEMP," "NIBP", "ECG1", "ECG2", and "RESP") for receiving analog sensor data. *Id.* at 5:18-51, FIG. 1 (reproduced and annotated below). The experts agree that none of Money's analog sensor data is from a pulse oximeter sensor. EX2013 at 175:17–176:5; EX2010 ¶¶ 59, 108.



5. <u>Estep (EX1010)</u>

Estep discloses an electrical signal measurement device for use in telecommunications measurement applications. EX1010 at Abstract, 1:5-11. The device can be a chest mounted unit. *Id.* at 2:8-12, 4:14-27, FIG. 3A (reproduced below).



Sotera, IPR2020-00954 Ex. 1046, Page 24 of 78

6. **Fujisaki (EX1009)**

Fujisaki discloses a wearable device for checking pulse rate or heart rate. EX1009 at Abstract. FIG. 2 (reproduced below) shows a device including a connector pin 5 for removably connecting a heart sensor or a pulse sensor 6. *Id.* at 5:37-40, FIG. 2.



7. <u>Hylton (EX1012)</u>

Hylton is directed to a system and method for the wireless distribution of interactive multimedia services to television subscribers. EX1012 at Title, 3:30-41. Petitioner relies on Hylton for its disclosure of a multiplexer. *See* Pet. at 16, 59, 95.

III. LEVEL OF ORDINARY SKILL

Patent Owner does not dispute Petitioner's characterization of the level of ordinary skill in the art.

IV. CLAIM CONSTRUCTION

A. <u>The Plain and Ordinary Meaning Applies to All Claim Terms,</u> <u>Including "Sensor Port"</u>

The Board requested that the parties "clearly identify what they contend the scope of a 'sensor port' encompasses." Institution at 23. Under *Phillips*, claim terms are generally construed in accordance with their ordinary and customary meaning as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-1315 (Fed. Cir. 2005); *see also* 83 Fed. Reg. at 51,343; Institution at 22. The Board should construe "sensor port," according to its plain and ordinary meaning of a "connector that mates with a compatible connector from a sensor."

The '623 Patent does not define the term "sensor port." However, the specification uses the term consistent with its plain and ordinary meaning as a "connector that mates with a compatible connector from a sensor." EX2010 ¶¶ 32-37. For example, the '623 Patent explains that "[a]s shown in FIG. 3, the monitor module 500 is advantageously plug-compatible with a conventional monitor 360" and "the monitor's sensor port 362 connects to the monitor module 500 in a similar manner as to a patient cable" EX1001 at 5:1-5; FIG. 3 (reproduced below); *see also* EX2010 ¶ 35.



Additionally, the '623 Patent explains, with respect to Figure 4A, that a wristmounted module 410 may have an auxiliary cable 420 that "mates to a sensor connector 318 and a module connector 414, providing a wired link between a conventional sensor 310 and the wrist-mounted module 410." *Id.* at 5:35-38. As shown in Fig. 4A below, the "module connector 414," which is on the wrist-mounted module 410, is a connector that mates with a compatible connector from a sensor 310. *See id.* at FIG. 4A (reproduced and annotated below); *see also* EX2010 ¶ 39.





Thus, Patent Owner's proposed construction is consistent with the '623 Patent specification. The prosecution history does not specifically address the meaning of "sensor port."

The parties do not appear to dispute the scope of the word "sensor." With regard to the word "port," contemporaneous dictionaries also confirm that a "port" in the phrase "sensor port" is a connector that mates with a compatible connector from a sensor. *See Port*, <u>Webster's II New College Dictionary (2001)</u> ("A connection point for a peripheral device") (EX2020); *Port*, <u>Microsoft Computer Dictionary</u> (5th ed. 2002) ("An interface through which data is transferred between a computer and other devices (such as a printer, mouse, keyboard, or monitor) … Ports typically accept a particular type of plug used for a specific purpose. For example, a serial data port, a keyboard, and a high-speed network port all use

IPR2020-01054

Sotera Wireless v. Masimo Corporation

different connectors, so it's not possible to plug a cable into the wrong port.") (EX2021); *Port*, <u>Webster's New World College Dictionary</u> (4th ed. 2001) ("the circuit, outlet, etc. which serves as a connection between a computer and its peripheral") (EX2019); *see also* EX2010 ¶ 38.

Importantly, the '623 Patent expressly distinguishes the "port" type connection illustrated in Figure 4A from a hardwired or direct connection between the sensor 310 and the sensor module 400. It describes that "[a]lternatively, the auxiliary cable 420 is directly wired to the sensor module 400." EX1001 at 5:38-39. Accordingly, a PHOSITA would understand the term "sensor port" to involve a removable connection, and does not include hardwired connections. *See* EX2010 ¶ 39. Notably, Yanulis also agreed during deposition and in his declaration that a port would provide a removable wired connection. EX2013 at 86:18-87:5; *see also* EX1003 ¶ 76 (distinguishing ports from hardwiring).

Petitioner did not offer a construction for "sensor port," but Yanulis has explained that "[a] port is typically a female connection or socket of a wired connection." EX1003 ¶ 76. But, Yanulis agreed during his deposition that a sensor port does not *require* a female/male connection. EX2013 at 90:16-91:6. Mr. Oslan agrees. EX2010 ¶ 40. Regardless of whether it is a male/female connection, the parties now seem to agree that a sensor port involves a removable connector. EX2010 ¶ 39; EX2013 at 86:18-87:5. Accordingly, Patent Owner proposes that the

term "sensor port" has its ordinary meaning in context, which is a connector that mates with a compatible connector from a sensor. All other terms in the '623 Patent should also be given their plain and ordinary meanings.

B. <u>Yanulis' Contradictory Claim Construction Opinions in the District</u> <u>Court Expose Result Oriented Opinions</u>

Yanulis' testimony regarding claim construction in these IPRs directly contradicts his testimony in the related district court proceeding. This contradiction exposes Yanulis' opinions as result-oriented and unreliable. His opinions on obviousness are not credible.

1. <u>Yanulis' Claim Construction Opinions Are Inconsistent</u>

In this IPR, Yanulis opined that no claim construction is necessary because all claim terms should be given their plain and ordinary meaning. EX1003 ¶¶ 34-36. Yanulis confirmed this position during his deposition. EX2013 at 246:14-247:4.

However, Yanulis opined in the district court that some terms should **not** be given their plain and ordinary meanings. Specifically, Yanulis opined that the "separate computing device," which appears in Claims 1, 6, 7, 9, and 17-20 of the '623 Patent, should **not** be given its plain and ordinary meaning. EX2015 ¶ 65. Instead, he opined that "separate computing device" should be limited to "a conventional bedside monitor." *Id.* ¶ 48. This was an attempt to narrow the claim for purposes of a non-infringement argument being advanced by Petitioner. EX2016 at 114:8-118:2. But, the case law makes clear that claim construction must be the

same for the determination of infringement as well as validity. *See TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017). The Board should not credit Yanulis' claim construction opinions, which shift to benefit whatever issue he is currently opining on.

2. <u>Yanulis' District Court Opinions on Claim Construction</u> <u>Specifically Excludes the Devices in Goldberg, Money, and Akai</u> <u>Relied upon in the Petition</u>

In this IPR, Sotera and Yanulis relied on Goldberg's "remote computer 302," Money's "central monitoring station," and Akai's "central unit 215" in order to satisfy the "separate computing device" limitation. *See, e.g.*, Pet. at 34-35, 75-76; EX1003 ¶¶ 105-106, 279-82. But Yanulis *specifically excluded* those structures from his proposed district court construction. Thus, under Yanulis' district court construction, Goldberg, Money, and Akai would not disclose that limitation.

In district court, Yanulis limited "separating computing device" to a conventional bedside monitor, but Goldberg does not describe "remote computer 302" as a conventional bedside monitor. Rather, Goldberg explains that "the remote computer may comprise a server" or "may comprise a webserver connected to the Internet, or an intranet or other network." EX1005 at 2:3-5, 2:56-57; *see also id.* at 3:17-37. That is precisely the type of "laptop," "PC," or "server" that Yanulis' district court construction of "separate monitoring device" would not include.

IPR2020-01054

Sotera Wireless v. Masimo Corporation

EX2015 ¶¶ 65-67. Yet Yanulis opines in this IPR that Goldberg includes this limitation.

Money also does not describe its "central monitoring station" as a "conventional bedside monitor." Instead, Money explains that the "central monitoring station" is "remotely located." EX1008 at 3:24-26; *see also id.* at 6:44-48. Again, Yanulis excluded servers from his construction of "separate computing device." EX2015 ¶¶ 65-67. Yanulis was questioned in the district court deposition whether his construction would encompass a central nurse's station. He confirmed it would not be, because it is not bedside. *See* EX2016 at 144:10-145:8.

Akai also does not describe its "central unit 215" as a "conventional bedside monitor." Rather, like Goldberg, Akai explains that "Central unit 215 is a computer system operating for 24 hours a day, 365 days a year which communicates with a plurality of monitoring units 212 attached to people living in the area" and is "installed at a medical institute of the area[.]" EX1007 at 7: 10-14. Again, Yanulis specifically excluded laptops, PCs, and servers from his district court construction of "separate monitoring device." EX2015 ¶¶ 65-67. Yet Yanulis opines in this IPR that Akai includes this limitation.

Petitioner cannot reconcile Yanulis' maintenance of directly conflicting opinions in two proceedings involving the same claim terms of the same patents under the same claim construction standard. *See TVIIM*, 851 F.3d at 1362. Because

-22-

Sotera Wireless v. Masimo Corporation

of Yanulis' inconsistent positions, the Board should disregard his unreliable testimony on claim construction in this proceeding, and recognize that his district court opinions would exclude the prior art references upon which he relies in this proceeding.

3. <u>Yanulis' Opinions on "Tail" Are Also Inconsistent</u>

Yanulis' treatment of the claim term "tail" in Claims 1 and 2 is also inconsistent between this IPR and the district court proceeding. In this IPR, Yanulis opined that "[a] PHOSITA would not understand how a tail is any different than a wire." EX1003 ¶ 67. Yet, in the district court, Yanulis declared "a PHOSITA would have *no idea* what a 'tail' is in the context of a medical device." EX2015 ¶ 76 (emphasis added). He further opined that "a 'tail,' whatever the term means is *not* an auxiliary cable" or a wired link. *Id.* ¶ 81 (original emphasis). Again, Yanulis offered one opinion for the purpose of this IPR while offering a contradictory opinion for the district court. These inconsistencies demonstrate why the Board should not rely upon Yanulis' opinions on the scope of claim terms.

V. <u>ARGUMENT</u>

A. <u>Ground 1: The Combination of Goldberg and Kiani Fails to</u> <u>Demonstrate the Obviousness of Any Claims</u>

Petitioner argues that Claims 1, 2, 4, 5, 12, and 14-17 are obvious over Goldberg and Kiani. Petitioner's argument suffers from multiple problems. First, the proposed combination lacks all of the claim elements. Both experts agree that

> Sotera, IPR2020-00954 Ex. 1046, Page 33 of 78

Goldberg does not disclose any claimed sensor ports and Kiani discloses only one sensor port. Second, Petitioner does not set forth any credible motivation to combine the asserted references. Instead, Petitioner relies on conclusory statements untethered to the actual proposed combinations. Third, the claims specifically require "a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection." But Petitioner does not cite to any prior art of record showing such a sensor port for a blood pressure sensor, and a PHOSITA would not have added such a port (if one even existed) to Goldberg.

1. Goldberg Does Not Disclose Any Sensor Ports

While the Board found that "[t]he record before us does present some uncertainty as to the presence of multiple sensor input 'ports' as a part of either Goldberg or Kiani," the Board nevertheless credited Petitioner's argument and Yanulis' testimony at the institution stage as "more persuasive than Patent Owner's attorney argument." Institution at 35-36. However, under the correct construction of "sensor port," Goldberg does not disclose any sensor ports.

Petitioner relies on Figure 2 to argue that a "PHOSITA would assume Goldberg teaches a port because Goldberg shows that a wire extends between the pulse oximetry sensor 104a and *into* the housing and because Goldberg teaches the controller receives electronic signals from the sensor 104a." Pet. at 27 (original emphasis).

-24-



EX1005 at FIG. 2 (annotated). But a wire extending into the housing suggests a wire directly soldered to a circuit board. EX2010 ¶¶ 66-67. A PHOSITA would understand Figure 2 to show a hardwired connection between sensor 104a and the housing 112. *Id.* The hardwired sensor of Goldberg cannot be readily replaced with another sensor. *Id.* Thus, Goldberg's Figure 2 does not teach or illustrate any connector on the housing that mates with a compatible connector from the sensor 104a, which is Patent Owner's proposed construction of "sensor port."

Petitioner nonetheless argues that a wire extending into the housing "complies with the meaning of a port to a PHOSITA." Pet. at 27. But Yanulis' only offer of a plain and ordinary meaning of port still requires a socket connection: "[a] port is typically a female connection or socket of a wired connection." EX1003 ¶ 76.

IPR2020-01054

Sotera Wireless v. Masimo Corporation

Nowhere does Goldberg describe a female connection, a socket, a receptacle, or anything else that could potentially be construed as a port. EX2010 ¶¶ 66-67. Yanulis conceded as much. *See* EX2013 at 102:5-108:12, 121:14-20. Thus, Goldberg does not even meet Yanulis' own explanation of a typical port or Patent Owner's proposed construction of "sensor port."

Petitioner next argues that "a PHOSITA would *assume* the wire shown [in Figure 2] includes a port because ports are a common and typical electrical connection for a housing." Pet. at 27-28. But that assumption is unsupported and legally improper. EX2010 ¶ 68. Petitioner cannot show that a reference teaches a claim by mere assumption. That would allow any petitioner to invalidate any patent by assuming features not present in the art. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366 (Fed. Cir. 2016) (common sense cannot supply a missing limitation in an obviousness analysis); *see also Personal Web Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1382-83 (Fed. Cir. 2019) (improper to rely on inherency for an element in an obviousness analysis where the element does not necessarily exist in the reference).

Because Goldberg does not meet either Yanulis' explanation of a port or Patent Owner's proposed construction of this term, Petitioner's arguments for the second and third sensor port limitations also fall short. For those sensor ports, Petitioner argues that any wired connection would include an implied port. *See* Pet.
Sotera Wireless v. Masimo Corporation

at 31. The Board appears to have preliminarily credited Yanulis' statement that "Goldberg teaches that 'all sensors 104 communicate with the controller 102 via a wired connection." Institution at 35 (quoting EX1003 ¶ 86). But Yanulis' statement is incorrect because Goldberg actually states that "sensor(s) 104 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 at 4:26-29; *see also* EX2010 ¶ 69-72. Goldberg does not support Yanulis' opinion that all of its sensors communicate via a wired connection.

Yanulis also admitted during deposition that Goldberg does not show a sensor port between Goldberg's blood pressure cuff and the housing, which is required by limitation 1(l), and that this was only "a conceivable arrangement." EX2013 at 121:14-122:7; *see also id.* at 122:17-123:10. He conceded that it was equally plausible that there could be a hard connection between Goldberg's blood pressure sensor 104b and the housing. *Id.* at 123:3-10. In view of these admissions, Petitioner has not shown that Goldberg discloses multiple sensor ports.

2. <u>Petitioner Fails to Explain Why a PHOSITA Would Have</u> <u>Modified Goldberg with Kiani to Have Three Sensor Ports</u>

Because of the absence of sensor ports in Goldberg, Petitioner turns to Kiani to supply these missing limitations. *See* Pet. at 28-29, 31-32. However, this proposed combination still lacks claimed elements and lacks a credible motivation to combine.

Sotera, IPR2020-00954 Ex. 1046, Page 37 of 78

a) <u>Kiani Teaches a Single Sensor Port</u>

While Yanulis initially – and incorrectly – described Kiani as describing "sensor input ports 540, 550," EX1003 ¶ 77, both experts now agree that Kiani teaches a single sensor port, **not** multiple ports. EX2010 ¶ 73; *compare* EX2013 at 131:16-18. Kiani describes a handheld embodiment of a universal pulse oximeter that connects to a single sensor through sensor input 550 and also contains as oximeter output 540 for connection to the external pulse oximeter. The single sensor port 550 in Kiani is shown below:



EX1006 at FIG. 5 (annotated).

Although not depicted in Figure 5, the specification describes the sensor port as referenced by the numeral 550. That is the only sensor port. EX2010 \P 73. Accordingly, the Board should disregard not only Yanulis' original opinion that

element 540 is a sensor input port (which he has now recanted), but also his reliance upon that opinion to conclude that Kiani discloses multiple sensor ports. *See* Institution at 34 n.8 (noting that Yanulis uses the term "sensor input ports" in reference to Kiani's components 540 and 550).

b) <u>Petitioner's Generic, Conclusory Statements Fail to</u> <u>Motivate the Addition of a First Sensor Port</u>

Petitioner argues that a PHOSITA would add a sensor port between Goldberg's pulse oximetry sensor 104a and the housing because "in a medical context, hardwired sensors are undesirable." Pet. at 28. Petitioner cites no evidence to support that extremely broad assertion other than Yanulis' similarly conclusory testimony. Id. (citing EX1003 ¶ 76). But "mere conclusory statements" cannot supply the missing evidence. In re Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1380 (Fed. Cir. 2016). While the Board initially credited Petitioner's and Yanulis' arguments regarding Goldberg and Kiani at the institution stage, the Board also noted that "Patent Owner has not yet cross-examined Dr. Yanulis or provided countervailing testimony from its own expert on the matter." Institution at 37. Yanulis failed to consider whether sensor ports have any disadvantages compared to hardwired connections. See EX1003 ¶ 76. As Mr. Oslan explains, port connections can be accidentally detached, may introduce contact noise caused by unstable electrical connections which could cause a measurement gap or error, require more space and hardware to accommodate than a hardwired cable, and introduce

-29-

additional parts, expense, and points of failure to a device. EX2010 ¶¶ 76-77. Yanulis even agreed during deposition that port connections can be accidentally detached by patient movement, which would have been undesirable:

Q. With the port connection, is it possible for the connection to come loose?

A. Happens lots of times. I've seen it.

Q. And a loose connection would be undesirable, correct?

A. Yes, then you would stop sensing the parameter, that would not be good especially if you were the operating room trying to sense very critical factors or any type of critical care environment.

Q. With a port connection is it possible for the connection to accidentally detach?

A. Yes, because, give you an example moving a patient from a gurney to a operating table or you're moving a critical care patient as an example, for example, having an MRI and patients are not always cooperative with moving around a lot. So that happens a lot of times. So you want to make sure they are at least somewhat connected well, especially transporting a patient, in moving the patient around.

Q. And accidental detachment would be undesirable, correct?

A. Yes, because then you would stop the sensing of that particular parameter.

EX2013 at 117:18–118:19.

Sotera, IPR2020-00954 Ex. 1046, Page 40 of 78

Petitioner and Yanulis fail to consider whether any disadvantages of adding a sensor port would dissuade a PHOSITA from making the alleged combination. Pet. at 28-29; EX1003 ¶¶ 76-77. Instead, Yanulis performed the wrong comparison. Rather than comparing the claimed sensor port to the hardwired connection in Goldberg to address the disadvantages associated with the replacement of a hardwired connection with a port connection in a wrist mounted device, Yanulis compared a port to "merely contacting two electrical conductors." EX1003 ¶ 76. That comparison is unhelpful because it compares the contact of two wires to a port connection, rather than addressing the benefits and drawbacks of the proposed modification of adding a port to Goldberg's hardwired connection.

Petitioner next asserts that "[a] PHOSITA would know that patients suffer from a variety of ailments, which require monitoring of different sets of vital signs," and that "doctors demand and expect patient monitors that conform and adapt as needed, based on a particular patient, the patient's ailment, and the monitored vital signs associated with that ailment." Pet. at 28-29. Petitioner further argues that a PHOSITA "would know, using common sense and basic knowledge about the medical field, to build wired connections that allow for sensors to be readily connected and disconnected as needed, and ports were known to provide such adaptability." *Id.* at 29. These general statements appear guided by hindsight, improperly extend motivations associated with bedside monitors to wrist worn

-31-

Sotera Wireless v. Masimo Corporation

devices, and draw on nothing from the references themselves. See EX2010 ¶¶ 74-75, 78. Yanulis provides no reason to modify Goldberg's hardwired sensor to

include a port. Neither Petitioner nor Yanulis explain how a general need to conform and adapt patient monitors would motivate the specific addition of the claimed sensor ports proposed in this combination, where the reference itself elected a different approach. *Id.*; EX1003 ¶ 76. Yanulis claimed in his declaration that "Goldberg teaches an adaptable system." EX1003 ¶ 76. But he did not support that position in his deposition. Instead, he admitted that Goldberg does not state that it is an "adaptable" system, only that it is portable. EX2013 at 115:1-117:17; *see also* EX2010 ¶ 84. If the use of ports were the more appropriate approach, as contended by Petitioner, one would expect Goldberg to have followed that approach. But Goldberg did not do so.

Further, to the extent that clinicians did "expect an adaptable and configurable patient monitor," EX1003 ¶ 76, there were already devices that fulfilled that demand and expectation—conventional, full-sized patient monitors. EX2010 ¶¶ 78-79. Yanulis does not explain or provide any evidence that clinicians would have demanded or expected a similar level of conformability or adaptability from a wrist-worn device that is a fraction of the size of a conventional patient monitor. *See* EX1003 ¶ 76. Yanulis also provided no examples of that demand or expectation. During deposition, Patent Owner asked Yanulis to provide an example of a clinician

Sotera Wireless v. Masimo Corporation

that would expect an adaptable and configurable patient monitor, and Yanulis responded by listing anesthesiologists trying to keep a patient alive during surgery and cardiologists with patients in heart failure. EX2013 at 114:5-18. Yanulis also listed clinicians with "patients with high blood pressure and pneumonia [who] are particularly susceptible to death." EX1003 ¶ 85. However, specialized patient monitors that fulfilled clinicians' needs in those critical care situations already existed before the invention of the '623 Patent. EX2010 ¶ 79. Yanulis did not link those examples to portable, wearable monitors, and points to nothing in the references for the supposed motivation. He merely concludes it would have been obvious because he says so.

A PHOSITA would not expect a clinician to swap out the sensors in Goldberg's device because Goldberg's device is intended for personal use directly by the monitored person, rather than for a clinician in a critical care setting. EX2010 ¶¶ 80-81; *see also* EX1005 at 1:6-10, 2:3-15, 3:17-24, 6:28-30, 7:6-33. Petitioner and Yanulis therefore analyze Goldberg through the wrong lens, and the Board should not rely upon that proposed combination as "provid[ing] adaptability" required by clinicians. Institution at 43. Goldberg describes a portable device for remote monitoring and contains numerous features that are directed toward the monitored person rather than a clinician. EX2010 ¶ 80. Thus, the correct end user would be the monitored person or his/her family members or caregivers, not

Sotera Wireless v. Masimo Corporation

normally a professional clinician in a hospital where conventional patient monitors are available. Id. ¶¶ 80, 83. Moreover, in 2002, wrist-worn blood pressure monitors, like that described in Goldberg, were not recommended for clinical use. Id. ¶ 81. When viewed in this context, a PHOSITA designing a wearable monitoring device would be more concerned with simplicity and other human factors such as user compliance. Id. ¶ 82-83. Complicating Goldberg's device by requiring the user to connect/disconnect numerous wires and attach various sensors to his or her body would annoy the user, as well as caregivers, and would tend to decrease usage. Id. ¶ 83; see also EX1003 ¶ 29 ("Generally, when designing wearable technology, PHOSITAs mainly attempted to improve patient comfort when the device is being worn. However, the best way to improve patient comfort would be to minimize the size of the wearable device and the number of sensors attached to the patient."). Thus, a PHOSITA would not be motivated to add a sensor port, much less three sensor ports, to complicate Goldberg's remote monitoring device. The only motivation here is hindsight.

Moreover, Petitioner and Yanulis fail to explain how combining Goldberg and Kiani to add a sensor port would enable the Goldberg device to connect with different types of sensors other than the pulse oximetry sensor 104a. A PHOSITA as of 2002 would not have expected such interoperability or adaptability between different types of sensors. EX2010 ¶¶ 85, 110-113. For example, Kiani explains:

-34-

Sotera Wireless v. Masimo Corporation

Unfortunately, there is no standard for either performance by, or compatibility between, pulse oximeters or sensors. As a result, sensors made by one manufacturer are unlikely to work with pulse oximeters made by another manufacturer.

EX1006 at 2:25-27. In fact, the invention described in Kiani—the Universal/Upgrading Pulse Oximeter—was designed as an intermediary device to allow hospitals to use Patent Owner's state-of-the-art pulse oximeters with their existing patient monitors. *See* EX1006 at 2:24-3:12; EX2010 ¶¶ 51-53. Kiani's invention was driven *because* of the need for the ability to use his revolutionary technology with older monitors that did not provide interchangeability with the newer technology. EX1006 at 2:24-3:12. Thus, a PHOSITA reading the Goldberg and Kiani references would not be motivated to add a sensor port to allow Goldberg's device to work with other sensors because such interchangeability was not expected and would not have been a predictable result. EX2010 ¶¶ 85, 105-108.

3. <u>Goldberg Does Not Disclose Second and Third Sensor Ports for</u> <u>EKG and Blood Pressure</u>

Limitations 1(k) and 1(l) specifically recite second and third sensor ports that receive information via wired connections from an EKG sensor arrangement and blood pressure arrangement, respectively. However, Petitioner misrepresents Goldberg by relying upon an undisclosed embodiment in order to allege that "Goldberg teaches an embodiment that receives signals from a second sensor (ECG)

Sotera Wireless v. Masimo Corporation

and a third sensor (e.g., blood pressure) via wired connections at second and third sensor ports." Pet. at 31.

First, Petitioner alleges that Goldberg's "portable device 100a communicates with three or more sensors (SpO₂, blood pressure, and ECG)." Pet. at 31. But Petitioner mixes scattered citations from Goldberg's summary section and discussion of Figure 2 to create an embodiment that is not present in Goldberg. *Id.* (citing EX1005 at 1:37-44, 4:24-27, 4:50-56, 4:57-5:8); see also EX2010 ¶ 71. Second, Petitioner again claims that "Goldberg teaches sensors communicate with the controller via wired connections." Pet. at 31. But that ignores Goldberg's actual teaching, which is that sensors may be connected by wires or wirelessly. EX1005 at 4:27-29. Indeed, there is no wire shown between Goldberg's housing and Goldberg's blood pressure cuff 104b in Figure 2. See EX1005 at FIG. 2; EX2010 ¶ 72. Third, Petitioner argues that Goldberg already teaches three sensor ports. Pet. at 31. But Yanulis agreed that Goldberg does not disclose even a single sensor port and that a sensor port between the housing and blood pressure cuff was only a "conceivable" arrangement. EX2013 at 102:5-108:12, 121:21-123:10. Petitioner has not shown that Goldberg teaches the three sensor ports recited in the claims.

4. <u>A PHOSITA Would Not Have Been Motivated to Add a Third</u> <u>Sensor Port for Goldberg's Blood Pressure Cuff</u>

Because Goldberg does not disclose second and third sensor ports for ECG and blood pressure sensors, Petitioner combines Goldberg with Kiani. But Petitioner

Sotera Wireless v. Masimo Corporation

does not present any specific arguments as to why a PHOSITA would be motivated to modify Goldberg with Kiani to add second and third sensor ports specifically for ECG and blood pressure. Instead, Petitioner relies on the same generic argument that it would be "obvious to include sensor ports for all wired connections with sensors." Pet. at 31. While Patent Owner identified deficiencies with this argument, the Board found at the institution stage that there was inadequate support for the undesirability of this proposed modification. Institution at 37.

Mr. Oslan now explains in detail why a PHOSITA would have had no motivation to add such a third sensor port between Goldberg's housing and blood pressure cuff, and would not have had a reasonable expectation of success in doing so. See EX2010 ¶¶ 90-109. A PHOSITA would understand that a wrist-worn blood pressure cuff needs to inflate in order to measure blood pressure. Id. ¶ 92, 96. Additionally, a pressure sensor would be located within a housing in order to measure the cuff pressure. Id. ¶¶ 92, 96. Thus, if Goldberg's blood pressure cuff were to be removable from the housing, a PHOSITA would know that there would also need to be an airtight pneumatic connection between the housing and the blood pressure cuff. Id. ¶ 96. Petitioner's proposed modification to Goldberg goes further, requiring the addition of a sensor port that also transmits data between the blood pressure cuff and the housing. A PHOSITA would understand that attempting to add a sensor port that can provide a pneumatic and electrical connection would be

Sotera Wireless v. Masimo Corporation

complicated, difficult, and require significant valuable space not readily available in a wearable device. *Id.* ¶ 96.

Petitioner and Yanulis do not identify any type of sensor port that could be implemented between the housing and the blood pressure cuff. Instead, they merely rely on the same generic disclosure of a "sensor input port 550" in Kiani. Pet. at 31; EX1003 ¶ 91. But Kiani's sensor input port 550 was for the SpO₂ sensor, not a blood pressure cuff. EX1006 at 8:31-9:2, FIG. 5; *see also* EX2010 ¶¶ 88-89, 93. Neither Petitioner nor Yanulis explain why or how a PHOSITA could have added a sensor port between Goldberg's housing and blood pressure cuff based on Kiani's disclosure of an SpO₂ sensor port, much less how a PHOSITA would modify that port to work with a blood pressure cuff. Yanulis was deposed at length regarding how this combination could be achieved, yet he could not give any details about the location or type of sensor port that would be used. *See* EX2013 at 120:12-133:19.

Instead, a PHOSITA reading Goldberg would not assume that Goldberg's blood pressure cuff is removable or is connected via a sensor port. EX2010 ¶¶ 92-95. Petitioner has not submitted any contemporaneous evidence to support the proposed modification. Rather, a PHOSITA would have recognized that there is no need for a sensor port at all because the pressure sensor that measures the cuff pressure would typically be placed within the housing. EX2010 ¶¶ 92. Petitioner offers no reason for the pressure sensor—the actual electrical device measuring

Sotera Wireless v. Masimo Corporation

pressure to be contained in a blood pressure cuff. Instead, the blood pressure cuff only needs to have an air bladder in fluid connection with the housing, and the pressure sensor would typically be placed within the housing. *Id*. Adding a sensor to the cuff is typically undesirable because a PHOSITA would not want to place a rigid electronic device within a flexible inflatable air bladder, and add an additional point of failure. *Id*. ¶¶ 99, 105.

Even if a pressure sensor were placed in the blood pressure cuff, a PHOSITA would further understand that adding a sensor port between the housing and the blood pressure cuff would not be desirable or feasible given the size limitations for a wrist-worn device and the need for an air-tight seal between the blood pressure cuff and the housing. EX2010 ¶¶ 96, 100. Petitioner's and Yanulis' hindsight-based, generic arguments fail to address these significant disadvantages and difficulties that would teach away from the configuration they propose.

Petitioner and Yanulis do not explain how a sensor port, much less the sensor input port 550 mentioned in Kiani, can provide an air-tight pneumatic connection between Goldberg's housing and blood pressure cuff. Instead, a PHOSITA would assume that the blood pressure cuff is integral to Goldberg's housing so that the cuff can maintain a reliable, airtight connection with the housing. *Id.* ¶¶ 96, 98.

Further, a PHOSITA as of the March 2002 priority date of the '623 Patent would not have been motivated to or have had a reasonable expectation of success

Sotera Wireless v. Masimo Corporation

in making the blood pressure cuff removable or in adding a sensor port for it. Id. 90-91, 100, 106-109. Compared to a hardwired connection, a sensor port would require additional space and hardware to accept and retain a corresponding connector. Id. ¶ 76. However, a sensor port for a blood pressure cuff would need to further provide: 1) an air-tight pneumatic connection that can be repeatedly connected and disconnected without failure, 2) a sufficiently strong retention mechanism that can support the entire weight of Goldberg's housing, as well as jostling caused by patient movement, and 3) a reliable electrical connection for the pressure sensor. Id. ¶ 100. Yanulis confirmed that a PHOSITA would "want to attach the device so it won't easily be removed by the patient -- whether it be through movement or whatever..." EX2012 at 40:4-19. However, Yanulis provided no explanation how a sensor port for a blood pressure cuff would be so secure. A PHOSITA at the time would more likely rely on a more reliable and available connection, namely, a fixed connection. EX2010 ¶ 98, 101-109.

A PHOSITA would have recognized these difficulties and would not have been motivated to add a sensor port to Goldberg's blood pressure cuff when the more reasonable approach would have been to integrate the blood pressure cuff directly into Goldberg's housing. *Id.* ¶ 98, 105. Even after the 2002 priority date, wristworn blood pressure monitors were generally manufactured with the blood pressure cuff integrated directly into the housing without a sensor port. *Id.* ¶¶ 101-109.

> Sotera, IPR2020-00954 Ex. 1046, Page 50 of 78

Yanulis opined that the ability to replace a faulty blood pressure sensor would motivate the addition of a sensor port. EX1003 ¶ 91. But a PHOSITA would understand that adding a sensor port would *increase* the likelihood of a failure. A broken sensor port or loose connection, caused by wear and tear, would prevent an air-tight seal for the cuff or an unreliable electrical connection. EX2010 ¶ 99. Adding a sensor port would increase the likelihood of failure because the sensor port would need to maintain the full weight of Goldberg's housing through unpredictable patient movements and also maintain an airtight seal for repeated connections and disconnections. EX2010 ¶ 97-99. A failure in the sensor port cannot be fixed by simply replacing the blood pressure cuff. EX2010 ¶ 99. Thus, a PHOSITA would not be motivated to add a sensor port between Goldberg's housing and cuff because that would *increase the likelihood of a failure* rather than allowing an end-user to replace a faulty cuff. Id.

Given the difficulties in designing such a port, including its bulkiness and requirements for maintaining an airtight seal and securing the full weight of the housing to a patient's wrist, a PHOSITA would not have had a reasonable expectation of success in doing so as of 2002. Instead, Petitioner's proposed modification would require the design and development of a new type of sensor port and would not have been a combination of known concepts to produce predictable results. EX2010 ¶¶ 100, 109. Neither Petitioner nor Yanulis explain at any level of

detail how such a non-trivial modification could be done. Accordingly, Petitioner has not shown a reasonable expectation of success in combining Kiani's teaching of a single sensor port with the specific sensors disclosed in Goldberg. *See Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) ("a clear, evidence-supported account of the contemplated workings of the combination is a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so.").

5. <u>The Claimed Second and Third Sensor Ports Are Not a Mere</u> <u>Duplication of Parts</u>

Petitioner also alleges that "adding generic, additional sensor ports is an obvious duplication of parts." Pet. at 32. But beyond that single sentence, Petitioner offers no analysis to support that conclusion. Yanulis' declaration is similarly lacking—explaining only that counsel informed him that duplication of parts is an obvious modification and his belief that a "PHOSITA would understand that a third sensor and a third port would have been easily included with the portable device 100 just as the first or second sensor and the first and second port." EX1003 ¶ 92. But again, Yanulis provides no analysis to support his conclusion.

Yanulis conceded that a third sensor port would not have been a duplication of either the first or second sensor ports because it would require modifications depending on what type of parameter is being monitored. EX2013 at 136:11-139:1.

Accordingly, Petitioner's reliance merely on the existence of ports in prior art devices is inadequate to address the claimed combination that recites specific ports for specific parameters.

As recited in Claim 1, the first, second, and third sensor ports are for receiving signals from a pulse oximetry sensor, an ECG sensor, and a blood pressure sensor, respectively. Kiani confirms that a PHOSITA would not have expected compatibility between sensors from different manufacturers, let alone sensors for entirely different measurements. EX1006 at 2:25-27; EX2010 ¶ 110. Different sensor types may require different ports. EX2010 ¶¶ 110-112. Thus, a PHOSITA would not have expected a sensor port for a different sensor arrangement to be a duplicate of the first sensor port that receives a signal from a pulse oximetry sensor. *Id.*

Accordingly, Petitioner has not demonstrated the obviousness of Claim 1 or any of its dependent claims. Petitioner's arguments regarding independent Claim 17 rely entirely on cross-references to Petitioner's arguments regarding Claim 1. Thus, for the same reasons, Petitioner has not demonstrated the obviousness of Claim 17.

B. Grounds 2 and 3 Fail for the Same Reasons as Ground 1

The arguments in Ground 2 and 3 fail to address the deficiencies in Ground 1 as explained above. Thus, Grounds 2 and 3 also fail to demonstrate the obviousness of Claim 3, 6-11, 13, and 18-19. *See* EX2010 ¶ 113.

C. <u>Ground 4 Fails to Demonstrate the Obviousness of Claim 20 Because It</u> <u>Relies on Non-Analogous Art</u>

Petitioner argues that independent Claim 20 is obvious over the seven-way combination of Goldberg, Kiani, Fujisaki, Money, Taylor, Estep, and Hylton.¹ Claim 20 also contains similar sensor port limitations as Claim 1 and Petitioner's arguments regarding the sensor port limitations refer entirely back to Petitioner's arguments regarding Claim 1. Thus, for the same reasons as Claim 1, Petitioner does not demonstrate the obviousness of Claim 20.² However, Ground 4 also fails for the threshold reason that Estep and Hylton are not analogous art to the '623 Patent.

¹ Estep does not appear in the section heading for Ground 4, but Petitioner relies on it for limitation 20(1). *See* Pet. at 51-52.

² Claim 20 differs slightly from Claim 1 in that the sensor port for the blood pressure sensor further requires "wherein the second sensor port is connectable to wire extending from the blood pressure sensor arrangement to provide electrical communication with the blood pressure sensor arrangement" (limitation 20(u)). Goldberg does not disclose any electrical wire extending from the blood pressure

The Board noted that "Patent Owner presents plausible arguments challenging, in-part, Petitioner's reliance on Hylton and Estep" and stated that "we will carefully consider whether Hylton or Estep satisfy either of [the analogous art] requirements." Institution at 45. Here, Petitioner fails to argue, much less demonstrate, that Hylton and Estep are analogous art.

Whether Hylton and Estep qualify as analogous prior art is a threshold issue for which Petitioner bears the burden. *See, e.g., Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-79 (Fed. Cir. 2015). To qualify as analogous art, each reference must be either: (1) from the same field of endeavor as the '623 Patent; or (2) reasonably pertinent to the particular problem the inventor is trying to solve. *See id*. Petitioner cannot cure its failure to establish Hylton and Estep as analogous art on Reply. *Consolidated Trial Practice Guide* (Nov. 2019) at 73 ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability.") Accordingly, the Board should affirm the patentability of the challenged claims in Ground 4.

cuff and Petitioner does not address this additional limitation. See Pet. at 55; EX1005 at FIG. 2; EX2010 ¶ 127. Thus, Petitioner's arguments also fail for this additional reason.

1. <u>Hylton Is Not Analogous Art</u>

Hylton is not in the same field of endeavor as Patent Owner's claimed invention. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). The '623 Patent is in the field of portable medical monitoring devices. EX1001 at Abstract. The '623 Patent describes "[a]n arm mountable portable patient monitoring device configured for both on patient monitoring of parameter measurements using one or more sensors[.]" *Id.* Moreover, Claim 20 is directed to "[a]n arm mountable portable patient monitoring device[.]"

In contrast, Hylton is directed to "routing and access control and billing functionalities in video distribution networks capable of providing subscribers with access to multiple information service providers." EX1012 at 1:11-15. The background art described in Hylton's specification relates to cable TV and video-on-demand services. *See id.* at 1:19-3:26. That has nothing to do with portable medical monitoring. EX2010 ¶¶ 114-117. A PHOSITA looking to create a portable medical monitor has no reason to look to video distribution networks. EX2010 ¶ 117. Thus, Hylton is not in the same field of endeavor as the '623 Patent.

Additionally, Petitioner fails to identify *any* problem for which Hylton would have logically commended itself to a PHOSITA building a portable medical monitor. Pet. at 59. Instead, Petitioner simply states that "Hylton teaches exactly what multiplexers do: combine multiple signals into one signal" and that "to the extent

-46-

[Goldberg] doesn't expressly teach a multiplexer, it would have been obvious to include a multiplexer to combine multiple signals from multiple sensors into one signal for wireless transmission." Pet. at 59. Nowhere does Petitioner explain why a PHOSITA would look specifically to Hylton for its description of a multiplexer to the exclusion of everything else in Hylton. Yanulis also does not perform this analysis. EX1003 ¶ 223. Rather, as Mr. Oslan explains, Hylton is concerned with the many-to-many transmission and reception of cable television signals, whereas the '623 Patent is concerned with transmitting medical data from a portable patient monitor to a separate computing device. EX2010 ¶¶ 118-120. Additionally, the multiplexers that Petitioner and Yanulis reference from Hylton are for optical signals and would be incompatible with Goldberg or Money. Id. ¶ 121. Thus, a PHOSITA would have no reason to look to Hylton to solve any problem associated with the '623 Patent.

In the absence of any explanation why a PHOSITA would have looked to Hylton, Petitioner's only reason for selecting Hylton appears to be hindsight. *See In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) ("We have explained that [the analogous art] test begins the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight.").

Petitioner also suggests that "Goldberg likely includes a multiplexer." Pet. at 59. However, Goldberg does not disclose a multiplexer and Petitioner cannot show that a claim limitation is met by a mere assumption. *Arendi*, 832 F.3d at 1366.

2. <u>Petitioner Fails to Explain Why Estep Is Analogous Art</u>

Petitioner also relies in part on Estep, arguing that "it would have been obvious to include a bezel around the display 108 in view of Estep." Pet. at 52. As with Hylton, Petitioner skips the analogous art analysis for Estep altogether.

The '623 Patent and Estep are in different fields of endeavor because the '623 Patent addresses portable medical monitoring devices secured to the arm of a patient, EX1001 at Abstract, 13:18-20, 14:46-47, 14:38-41, 15:59-61, 16:16-17, while Estep is directed toward an unrelated area of signal level meters for field use in cable television systems. *See* EX1010 at Abstract, 1:13-19; EX2010 ¶¶ 122-123; *see also In re Bigio*, 381 F.3d at 1320 (internal citations omitted). In addition, the problem addressed by the signal level meter technology described in Estep used by electricians in cable television systems is different from the problem faced by the inventors of the '623 Patent, which was to provide hospital grade, portable patient monitoring without the loss of physiological measurements. *See* Ex. 1001 at 1:40-52, 2:22-28; EX2010 ¶¶ 124-126.

Petitioner has not demonstrated that Hylton and Estep are analogous art, and Petitioner's use of both in the combination demonstrates impermissible hindsight.

-48-

D. <u>Ground 5 Fails to Demonstrate the Obviousness of Any Challenged</u> <u>Claim</u>

In Ground 5, Petitioner argues that Claims 1, 2, and 4-19 are obvious over Money, Kiani, and Akai. However, Petitioner's entire argument is an exercise in hindsight reconstruction. Yanulis' deposition testimony demonstrates there is *no factual basis* for his opinions. Moreover, Yanulis' opinions even directly contradict his other opinions in related IPRs. Even if the Board were to credit Yanulis' unsupported opinions, the proposed combination does not result in the claimed inventions.

1. <u>Petitioner Has No Factual Basis for Its Core Argument</u>

Petitioner's argument to combine Money with Akai rests on the allegation that Money's pulse oximetry cuff transducer 39 was somehow "obsolete," "bulky," and "uncomfortable when worn by a patient." EX1003 ¶ 236. Petitioner uses this rationale to justify combining Money with Akai, explaining that "it would have been obvious to substitute the pulse oximetry cuff transducer 39 of Money with the lightbased, finger-positioned pulse oximetry sensor taught by Akai" and that this would have provided the predictable result of measuring oxygen saturation non-invasively. Pet. at 62. This was also the same justification Petitioner gave for attaching Money's housing to a patient's wrist. *Id.* at 62-63. In its preliminary response, Patent Owner questioned how Petitioner and Yanulis came to this conclusion since Money does

Sotera Wireless v. Masimo Corporation

not describe the pulse oximetry cuff transducer in any detail. Yanulis' deposition testimony *confirms* that this entire rationale has *no basis in any facts*.

Yanulis was questioned at length as to how he knew that the pulse oximetry cuff transducer of Money was bulky, uncomfortable, or outdated. He conceded that he had *no idea what it looked like and could not even describe a single feature* of Money's cuff transducer.

Q. What is your understanding of what a pulse oximetry cuff looks like?

A. *I'll be honest with you, Counsel, I've not seen many, and I can't recall when I have seen one.* Most of the ones I've seen in this time frame that are pretty well-known utilize the lightweight and the so-called light technology of the LED emission and the LED detector technology to measure the ratios of the infrared, red waves that were left after being absorbed. *So I'll be honest with you, I have not seen any. I know they existed, but I don't recall ever seeing one.*

Q. Can you describe for me any features of the pulse oximetry cuff transducer?

A. Honestly, I - I couldn't, because I'd have to go back, and look at some of the old pulse pressure cuff. *To be completely transparent, at this time I could not.* I could after looking at a few. I really didn't spend a lot of time because that's not the current technology. Obviously, I did look at Akai. But, again, Akai is not the way they do things. During this time with this patent. The prior art utilized in the IPR that was used for the '735 declaration – or in the other declaration.

So the answer – simple answer, no, I don't know any specifics. And I'm not sure you'd want to use a cuff, because they're very uncomfortable.

EX2013 at 233:18-236:15 (emphases added).

In view of Yanulis' inability to identify even a single feature of Money's cuff transducer, he has no credible basis to testify that it was bulky, uncomfortable, and obsolete, or that a PHOSITA would replace this feature with Akai's sensor. The Board should not credit his testimony. Fed. R. Evid. 702(b); *see also* 37 C.F.R. § 42.65 ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Because this wholly-unsupported allegation that Money's pulse oximetry cuff transducer is bulky, uncomfortable, and obsolete is the foundation for all of Petitioner's Ground 5 arguments, Petitioner cannot demonstrate the obviousness of any claim.

2. <u>The Petition Reconstructs the Claimed Invention with Hindsight</u>

"Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." *In re NTP*, 654 F.3d 1279, 1299 (Fed. Cir. 2011). Here, Petitioner improperly used the '623 Patent as a roadmap to piece together Money, Kiani, and Akai to advance its arguments regarding obviousness.

Sotera, IPR2020-00954 Ex. 1046, Page 61 of 78

a) <u>Money's Device Is Too Large and Bulky to Be Wrist-Worn</u>

Petitioner takes Money's device, which is disclosed as being three inches wide, six inches long, one inch thick, requiring four AA batteries, and weighing up to sixteen ounces, and argues it would be obvious to convert that into a wrist-worn device. Ex. 1008 at 3:39-45, 5:4-8, FIGS 10, 17B (shown below); Pet. at 61-64, 76. However, Petitioner and Yanulis offer no evidence to support their argument that a PHOSITA would be motivated to mount Money's device to a patient's wrist. Pet. at 62-63. Both already criticized, without evidence, a pulse oximetry cuff transducer as bulky and uncomfortable and argued that was sufficient reason to substitute the cuff transducer for a different sensor. Pet. at 62. With that in mind, it is inexplicable why Petitioner would argue that Money's device is not also too bulky and uncomfortable for a wrist. See Pet. at 76; EX1008 at 3:39-45, 5:4-8. As Mr. Oslan explains, a PHOSITA would recognize that Money's device is too large and heavy for a patient's wrist—in fact, it would take up more than half of an average person's lower arm. EX2010 ¶¶ 128-134. Money's device is approximately the size and weight of three present-day smartphones stacked together. EX2010 ¶ 135.

Petitioner also fails to provide any credible evidence that a PHOSITA would have attached a strap to Money's device, as required by the claims. Instead, Petitioner and Yanulis simply point to the existence of a strap on Akai's device. *See* Pet. at 76-78; EX1003 ¶ 283-286. But simply showing that a strap exists in Akai's

-52-

Sotera Wireless v. Masimo Corporation

device, as Petitioner and Yanulis have done, is not sufficient to explain *why* a PHOSITA *would* then mount Money's very large and heavy device to a patient's wrist with a strap. EX2010 ¶ 136.

Petitioner and Yanulis also compare Money's device to a wristwatch to suggest that their combination is just "common sense." Pet. at 77; EX1003 ¶ 284-85. But there is no common sense in that comparison. Wristwatches are usually less than two inches in diameter and only a fraction of an inch thick. EX2010 ¶ 137. Money's device is an entire order of magnitude larger than a wristwatch. Id. ¶ 138. Neither Petitioner nor Yanulis explain why a comparison between a wristwatch and a 3"x6"x1", 16 ounce medical device makes any sense. Nor do Petitioner and Yanulis cite any prior art reference showing a medical device of a similar size to Money's device being wrist-worn. Even if it were physically possible to attach a wrist strap to Money's device, in the same way that it would be physically possible to attach a brick to a person's arm, that does not mean that a PHOSITA would make such a modification. See InTouch Techs., Inc. v. VGO Cmmc'ns, Inc., 751 F.3d 1327, 1352 (Fed. Cir. 2014) (concluding that party's expert "succumbed to hindsight bias in her obviousness analysis" where her analysis "primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they *would* have been motivated to do so").

Beyond offering the similarly conclusory statements of its expert, Petitioner never fully explains why such a large and bulky device would be desirable on a patient's wrist. The only discernable reason is hindsight in an attempt to match the '623 Patent claims.

b) <u>Petitioner Assumes that a PHOSITA Would Already Be</u> <u>Motivated to Combine Money and Akai</u>

Petitioner employs circular reasoning to disguise the fact that its entire argument is based on hindsight. As explained above, Petitioner begins with Money's device, which is too large and bulky for mounting on a patient's wrist. Pet. at 61-64; EX2010 ¶ 138.



Id. at FIGS. 10, 17B.

Sotera, IPR2020-00954 Ex. 1046, Page 64 of 78

Nevertheless, Petitioner looks to Akai's Figure 1, which shows a completely different device comprising a *single* finger-based SpO₂ sensor attached to a small, wrist-worn device (shown below). *See* Ex. 1007 at 5:2-6:58 (no discussion of more than one sensor in connection with the embodiment shown in Figure 1).



Fig. 1

Ex. 1007 at FIG. 1.

Based on Akai, Petitioner asserts that "[i]t would have been obvious to attach Money's housing to a patient's wrist . . . for two reasons." Pet. at 62. However, Petitioner's two alleged motivations to attach Money's housing to a patient's wrist *are themselves two other modifications*. "First," according to Petitioner, "it would have been obvious to substitute the pulse oximetry cuff transducer 39 of Money with the light-based, finger-positioned pulse oximetry sensor taught by Akai." *Id.* Then, "[a]fter substituting a cumbersome pulse oximetry cuff transducer . . . a PHOSITA would have been further motivated to mount the monitor 10 of Money to a patient's wrist in view of Akai and position a port configured to communicate with the finger-

Sotera Wireless v. Masimo Corporation

placed, pulse oximetry sensor closest to a patient's hand in order to minimize patient discomfort." *Id.* at 62-63.

In other words, Petitioner argues that a PHOSITA would have been motivated to modify Money in view of Akai for the wrist-worn features because a PHOSITA already would have been motivated to modify Money in view of Akai to replace Money's cuff transducer with Akai's pulse oximetry sensor. Yanulis confirms this circular reasoning: "It would have been obvious to modify Money's housing so that it was worn on a patient's wrist in view of Akai primarily because it would have been obvious to substitute a pulse oximetry cuff transducer 39, as taught by Money, with a light-based pulse oximetry sensor 112 that is positioned on a patient's finger, as taught by Akai." Ex. 1003 ¶ 236 (emphasis added); see also id. ¶ 237 ("it would have been obvious to position the wearable monitor 10 on a patient's wrist after modified by Akai because the pulse oximetry measurement site would be moved to the patient's finger.") (emphasis added). Both Petitioner and Yanulis assume a PHOSITA would have already been motivated to modify Money in view of Akai in order to motivate further modifications. These arguments assume the truth of the conclusion rather than supporting it and do not provide a sufficient motivation to combine.

c) <u>A PHOSITA Would Not Substitute Money's Pulse</u> <u>Oximetry Cuff Transducer with Akai's SpO₂ Sensor</u>

In addition to lacking any factual basis that Money's pulse oximetry cuff transducer was bulky, uncomfortable, and obsolete, Petitioner and Yanulis make further incorrect allegations regarding Money in order to justify the combination with Akai. Specifically, Petitioner alleges that a "PHOSITA would have been motivated to substitute the cuff transducer of Money with a light-based SpO₂ sensor of Akai *in order to predictably measure oxygen saturation non-invasively*." Pet. at 62 (emphasis added). Yanulis similarly argued:

Pulse oximetry cuff transducers, like the one taught in Money, are bulky and uncomfortable when worn by a patient. *In contrast*, light-based pulse oximetry sensors are *completely non-invasive*, far smaller, and thereby, more comfortable when worn by a patient.

EX1003 ¶ 236 (emphases added). Thus, Yanulis' contrast of Money with Akai implies that the pulse oximetry cuff transducer in Money was (a) not light-based, and (b) invasive.

However, *a PHOSITA would not agree with those statements because pulse oximetry, by definition, is non-invasive and requires light to measure blood oxygen saturation*. EX2010 ¶¶ 44-48, 139-141. Pulse oximetry is a specific technique of measuring blood oxygen saturation by shining light at red and infrared wavelengths into body tissue (typically at a finger or ear lobe) and measuring the relative amounts of absorption of red and infrared light. *Id.* ¶¶ 44-48, 140. This is also confirmed by

> Sotera, IPR2020-00954 Ex. 1046, Page 67 of 78

Sotera Wireless v. Masimo Corporation

multiple contemporaneous medical dictionaries defining pulse oximetry to be lightbased and noninvasive. See pulse oximetry, Stedman's Medical Dictionary (27th ed. 2000) ("performed noninvasively, usually on the finger or ear lobe, in which the small increase in absorption of light during the systolic pulse is used to calculate oxygen saturation") (EX2017); pulse oximeter, Dorland's Illustrated Medical Dictionary (30th ed. 2003) ("an oximeter that measures the oxygen saturation of arterial blood by passing a beam of red and infrared light through a pulsating capillary bed, the ratio of red to infrared transmission varying with the oxygen saturation of the blood; because it responds only to pulsatile objects, it does not detect nonpulsating objects like skin and venous blood") (EX2018). Contemporaneous articles about pulse oximetry confirm that a PHOSITA would know that pulse oximetry is noninvasive and light-based. EX2010 ¶ 44; EX2023 at Abstract ("The pulse oximeter, a widely used noninvasive monitor of arterial oxygen saturation, has numerous applications in anesthesiology and critical care."). Yanulis even admitted in deposition that pulse oximetry requires light to work. EX2012 at 15:17-16:9; EX2013 at 234:21-235:20.³

³ Yanulis also appears to testify in these transcript sections that non-light based pulse oximetry sensors may exist. To the extent Yanulis believes non-light

Sotera Wireless v. Masimo Corporation

Petitioner's argument that a PHOSITA would have been motivated to combine Money with Akai "in order to predictably measure oxygen saturation non-invasively" lacks support because the alleged advantage of non-invasive light-based monitoring was already present in Money. EX2010 ¶¶ 142-143. There is no reason to combine two references when the alleged advantage provided by one reference is already present in the other. *See Kinetic Concepts* v. *Smith & Nephew, Inc.*, 688 F.3d 1342, 1369 (Fed. Cir. 2012). There is *no benefit to be gained* by combining Money with Akai's sensor, when as Mr. Oslan explains, the pulse oximetry cuff transducer of Money was already a light-based, noninvasive sensor. EX2010 ¶¶ 142-143. The only discernable motivation is hindsight.

Notably, Yanulis' use of the terms "invasive" and "noninvasive" are not how a PHOSITA would understand them. Rather, Yanulis revealed during deposition that his understanding of whether a monitoring device is "invasive" is actually just a matter of patient comfort. EX2014 at 289:2-290:6. He even described a blood pressure cuff as invasive. *Id.* at 281:14-20. That is not how a PHOSITA would understand the term. EX2010 ¶ 141. Medical dictionaries explain that a procedure or device is "invasive" if it requires insertion through a patient's skin or into a body

based pulse oximetry sensors exist, his belief would be factually incorrect for the reasons above.

Sotera Wireless v. Masimo Corporation

orifice. *See invasive*, <u>Stedman's Medical Dictionary</u> (27th ed. 2000) ("Denoting a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment") (EX2017); *invasive*, Dorland's Medical Dictionary (30th ed. 2003) ("involving puncture or incision of the skin or insertion of an instrument or foreign material into the body") (EX2018). Yanulis' incorrect usage of a term critical to his argument confirms that his opinions do not reflect those of a PHOSITA.

d) <u>Yanulis Explained that a PHOSITA Would Not Be</u> <u>Motivated to Modify Money with an Analog SpO₂ Sensor</u>

Petitioner and Yanulis also fail to address why a PHOSITA would be motivated to substitute Money's pulse oximetry cuff transducer with Akai's sensor, when Yanulis testified that such a modification would be unworkable. In IPR2020-01015, Yanulis testified that a PHOSITA *would not* make such a substitution because Money's pulse oximetry sensor interface is digital while Akai's sensor is analog. Yanulis testified that "Money's pulse oximetry sensor interface 24 expects to receive digital packets of data, and *thus would not understand analog data transmitted by an analog sensor*." Ex. 2005 ¶ 124 (emphasis added). He then explained that it "would have been obvious to include a sensor interface that corresponds to the signal received (analog with analog; digital with digital), otherwise the sensor interface would be unable to understand the received signal." *Id.* ¶ 125.

Thus, Yanulis explained in that IPR that a PHOSITA would be dissuaded from combining a sensor and a sensor interface that are not like-for-like (e.g., combining an analog sensor with a digital sensor interface). Based on Yanulis' own opinions, a PHOSITA would not be motivated to replace Money's digital SpO₂ sensor (the pulse oximetry cuff transducer) with the *analog* SpO₂ sensor from Akai. EX2010 ¶¶ 149-151. Yanulis' inconsistent testimonies in these IPRs further confirm that the reason behind this combination is hindsight reconstruction of the patent claims.

Petitioner attempts to address this serious flaw by arguing for dependent claim 4 that "[o]nce modified by the light-based SpO₂ sensor of Akai, a PHOSITA would have been motivated to modify the sensor interface 24 to communicate with the new sensor." Pet. at 79-80. That discussion is absent from Petitioner's arguments regarding independent Claims 1 and 17. *See Magnum Oil*, 829 F.3d at 1381 (Board cannot "decide unpatentability theories never presented by the petitioner."). Even if Petitioner had made that argument with respect to Claims 1 and 17, Petitioner's solution is simply to make *yet another* modification to swap out Money's digital sensor interface with the analog sensor interface from Kiani. But that puts the cart before the horse. A PHOSITA would not be motivated to modify Money's digital sensor interface only *after* already modifying Money to accept Akai's analog sensor. As Yanulis explained, a PHOSITA would not have been motivated to replace the

Sotera Wireless v. Masimo Corporation

sensor in the first place because Money's sensor interface is digital while Akai's sensor is analog. Ex. 2005 ¶ 124; EX2010 ¶¶ 152-153.

Furthermore, Petitioner's proposed combination of Money, Akai, and Kiani would create an inoperable device. EX2010 ¶ 153. Akai's SpO₂ sensor is connected via a fiber optic cable. Ex. 1007 at 5:14-17 ("data processing unit 113 has an appropriate interface such as an optic fiber between itself and sensor unit 112."). In contrast, Kiani's sensors are connected electrically. Pet. at 72 ("Kiani teaches sensor ports physically couple wires and *receive electrical signals* from medical sensors.") Even if Petitioner had attempted to make this post hoc (emphasis added). explanation in its discussion of Claims 1 and 17, Petitioner does not explain how replacing Money's sensor interface with an *electrical* sensor interface from Kiani to receive an *optical* signal from Akai's sensor would result in a working device. A PHOSITA would understand that a fiber optic cable would not be compatible with an electrical interface. EX2010 ¶ 153. The Federal Circuit explained that "[i]f references taken in combination would produce a seemingly inoperative device, we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness." McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) (internal quotation marks omitted). Accordingly, a PHOSITA would not have been motivated to combine
Money with Akai for Claim 1, or Money with Akai and Kiani as argued for Claim 4.

3. <u>The Proposed Combination Fails to Teach a First Sensor Port</u> <u>Configured to Electrically Receive a Signal from the Pulse</u> <u>Oximetry Sensor</u>

Limitations 1(i) and 17(h) both require that the first sensor port be configured to "electrically receive the signal from the pulse oximetry sensor." Petitioner's proposed combination of Money, Kiani, and Akai does not disclose this limitation, and would be inoperable, as discussed above.

For limitation 1(i), Petitioner's entire argument states: "Kiani teaches sensor ports physically couple wires and receive electrical signals from medical sensors." Pet. at 72. However, for limitations 1(b)-1(e), which describe the pulse oximetry sensor that is connected to the claimed first sensor port, Petitioner relied on the pulse oximetry sensor 112 of Akai. *Id.* at 64-65. As explained above, Akai's sensor 112 sends signals using a fiber optic cable. *See* EX1007 at 5:10-30; EX2010 ¶¶ 144-145. A PHOSITA would understand that a fiber optic cable transmits data using light, not electricity. EX2010 ¶ 145. Kiani's electrical sensor port is therefore incompatible with Akai's fiber optic cable. *Id.* ¶¶ 145-148. Thus, the resulting combination does not teach this limitation and is not operable. *See McGinley v. Franklin Sports, Inc.,* 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperative device,' we have held that such references teach

away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.").

Accordingly, for at least the reasons above, Petitioner has not demonstrated the obviousness of any claims in Ground 5.

E. Ground 6 Does Not Remedy the Deficiencies in Ground 5

The arguments in Ground 6 fail to address the deficiencies in Ground 5 as explained above. Thus, Ground 6 also fails to demonstrate the obviousness of Claim 3. EX2010 ¶ 154.

F. Ground 7 Fails to Establish a Reasonable Likelihood of Success

Ground 7 addresses only independent Claim 20 and relies on the seven-way combination of Money, Kiani, Akai, Fujisaki, Taylor, Estep, and Hylton.⁴ For the same reasons as explained with respect to Ground 4, Ground 7 fails because Petitioner does not demonstrate that Hylton and Estep are analogous art to the '623 Patent.⁵ EX2010 ¶¶ 114-126, 155.

⁴ Petitioner leaves Estep out of the section heading, but relies on Estep for Ground 7. *See* Pet. at 7, 90-91.

⁵ While Petitioner alleges that Money contains a "summer," neither Petitioner nor Yanulis explain how that "summer" meets the specific requirements of limitation 20(dd), which requires a "multiplexer within the housing and configured to combine

Additionally, Claim 20 includes, *inter alia*, the same "pulse oximetry sensor," "electrically receive," and "strap mountable to the back side of the housing" limitations that were in Claims 1 and 17. Petitioner's arguments relating to those limitations simply refer back to its arguments in Ground 5. Petitioner's reliance on its Ground 5 hindsight reconstruction and its addition of even more non-analogous art is fatal to this ground. Accordingly, Ground 7 does not demonstrate the obviousness of Claim 20.

VI. <u>RESERVATION OF RIGHTS</u>

The constitutionality of Appointments Clause issues concerning IPR is currently before the Supreme Court. *See, e.g., U.S. v. Arthrex, Inc.*, No. 19-1434, 141 S. Ct. 549 (Oct. 13, 2020). To the extent the Supreme Court determines that the Appointments Clause has not been complied with, Patent Owner objects to this proceeding on that basis.

VII. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated that any claims of the '623 Patent are unpatentable by a preponderance of the evidence.

at least information indicative of the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter into a single digital word or bit stream." *See* Pet. at 95; EX1003 ¶ 386-87.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 26, 2021

/Sheila N. Swaroop/ Sheila N. Swaroop (Reg. No. 53,658) Customer No. 64,735

Attorneys for Patent Owner Masimo Corporation

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Patent Owner Masimo Corporation hereby certifies that this document complies with the type-volume limitation of 37 C.F.R. § 42.24(b). This document contains approximately 13,669 words, including any statement of material facts to be admitted or denied in support, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, exhibit list, certificate of service or word count, or appendix of exhibits or claim listing.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 26, 2021

/Sheila N. Swaroop/ Sheila N. Swaroop (Reg. No. 53,658)

Attorneys for Patent Owner Masimo Corporation

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement

of counsel for Petitioner, a true and correct copy of PATENT OWNER

RESPONSE AND EXHIBITS 2010-2035 are being served electronically on

February 26, 2021, to the e-mail addresses shown below:

Rudolph A. Telscher, Jr. Nathan P. Sportel Daisy Manning Jennifer E. Hoekel Husch Blackwell LLP 190 Carondelet Plaza, Suite 600 St. Louis, MO 63105 (314) 480-1500 Tel (314) 480-1505 Fax PTAB-RTelscher@huschblackwell.com Nathan.sportel@huschblackwell.com PTAB-DManning@huschblackwell.com

Dated: February 26, 2021

/Sheila N. Swaroop/ Sheila N. Swaroop (Reg. No. 53,658)

Attorneys for Patent Owner Masimo Corporation

34119545