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)
Shannon Lam (Reg. No. 65,614)
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, Fourteenth Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
E-mail: SoteraIPR735@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS,

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-00954 U.S. Patent 9,788,735

PATENT OWNER SUR-REPLY

TABLE OF CONTENTS

PATI	ENT O OR E	WNER'S LIST OF IMPROPER REPLY ARGUMENTS VIDENCE PURSUANT TO PAPER 29	1
I.	INTR	ODUCTION	3
II.	"SEN PLAI	SOR COMMUNICATION PORT" SHOULD HAVE ITS N AND ORDINARY MEANING	3
III.	GOL	DBERG-BASED GROUNDS 1-4	8
	А.	Sotera Fails to Demonstrate that a Sensor Communication Port Could Be Implemented Between Goldberg's Housing and Blood Pressure Cuff Sensor with Any Expectation of Success	8
	В.	Sotera Presents an Unreasonable Assumption that Goldberg's Device Has <i>Seven</i> Sensor Ports	3
	C.	Goldberg's Device Was Meant for Personal, Not Clinical Use	4
	D.	Sotera Raises Improper New Arguments Regarding the Digital/Analog Limitations 1	6
IV.	MON	EY-BASED GROUNDS 5-8 1	7
	А.	Sotera's Improper New Reference Confirms the Petition Was Based on Hindsight1	7
	В.	Sotera Fails to Demonstrate that Money's Device Would be Suitable as a Device Worn on a Lower Arm of a Patient 1	9
		1. Sotera Does Not Respond to Masimo's Arguments	0

TABLE OF CONTENTS (cont'd)

Page No.

		2. Moore's Law Is an Observation about Transistors, Not Technology in General	21
	C.	Sotera Changes Its Argument to an Electrical Cable Rather Than Akai's Fiber Optic Cable	23
	D.	Sotera Relied on Hindsight to Propose Modifications to the Temperature Sensor	24
V.	CON	ICLUSION	26

TABLE OF AUTHORITIES

Ariosa Diagnostics v. Verinata Health, Inc., 805 F.3d 1359 (Fed. Cir. 2015)	11
Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 (Fed. Cir. 2016)	12
<i>United States v. Arthrex,</i> U.S (June 21, 2021)	3

OTHER AUTHORITIES

37 C.F.R. § 42	.65	15
Fed. R. Evid. 7	702	15

IPR2020-00954 Sotera Wireless v. Masimo Corporation

EXHIBIT LIST	1
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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	Reserved
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 No.	Description
2012	Transcript of Deposition of George E. Yanulis, Ph.D., taken on January 26, 2021 in connection with IPR20200-00912, -00954, - 01015, -01054
2013	Transcript of Deposition of George E. Yanulis, Ph.D., taken on January 27, 2021 in connection with IPR20200-00912, -00954, - 01015, -01054
2014	Transcript of Deposition of George E. Yanulis, Ph.D., taken on February 1, 2021 in connection with IPR20200-00912, -00954, - 01015, -01054
2015	Declaration of George E. Yanulis in Support of Defendants' Opening Markman Brief, filed September 22, 2020, in Masimo Corp. v. Sotera Wireless, Inc., Case No. 3:19-cv-01100-BAS- NLS (S.D. Cal.)
2016	Transcript of Deposition of George Yanulis, conducted on September 10, 2020, in Masimo Corp. v. Sotera Wireless, Inc., Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.)
2017	Excerpt of Stedman's Medical Dictionary (27th ed. 2000)
2018	Excerpt of Dorland's Illustrated Medical Dictionary (30th ed. 2003)
2019	Excerpt of Webster's New World College Dictionary (4th ed. 2001)
2020	Excerpt of Webster's II New College Dictionary (2001)
2021	Excerpt of Microsoft Computer Dictionary (5th ed. 2002)
2022	Amal Jubran, Pulse oximetry, 3 Crit Care R11 (1999)
2023	Joseph F. Kelleher, Pulse Oximetry, 5 J Clin Monit 37 (1989)

Exhibit No.	Description
2024	Allison Rhodes Westover <i>et al.</i> , Human Factors Analysis of an ICU, 23 J Clin Eng 110 (1998)
2025	Gianfranco Parati <i>et al.</i> , Self blood pressure monitoring at home by wrist devices: a reliable approach?, 20 J Hypertension 573 (2002)
2026	U.S. Patent No. 4,896,676 to Sasaki
2027	Japanese Publication JP4777640B2 to Junichi and English machine translation available from Espacenet
2028	Photographs of Omron Gold Wrist Blood Pressure Monitor (Model No. BP4350) taken by Alan Oslan
2029	Larry Hardesty, Clothed in Health, MIT Technology Review (July 1, 2001) (https://www.technologyreview.com/2001/07/01/235697/clothed- in-health) (last accessed February 17, 2021)
2030	Datex AS/3 TM Anesthesia Monitor Operator's Manual (1995)
2031	Claire C. Gordon <i>et al.</i> , 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 <i>et al.</i> , 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).

Exhibit No.	Description
2036	Japanese Publication JP4777640B2 to Junichi – Certified English translation (Served only on 3/12/2021)
2037	Transcript of June 3, 2021 Conference Call with the Board
2038	Transcript of Deposition of Bryan Bergeron, Ph.D., taken on June 9, 2021 in connection with IPR20200-00912, -00954, -01015, and -01054

IPR2020-00954 Sotera Wireless v. Masimo Corporation

PATENT OWNER'S LIST OF IMPROPER REPLY ARGUMENTS OR EVIDENCE PURSUANT TO PAPER 29

1. Sotera introduced a new reference, EX1043, and proposed a new combination of that reference with Goldberg and Kiani. Reply 19. Sotera now argues that EX1043 teaches a blood pressure sensor and microphone within the cuff.

2. Sotera argues that Goldberg discloses "other embodiments [that] include separate blood pressure sensors that are not also integrated as a strap for a housing" and relies on Kiani for "such blood pressure systems." Reply 18-19. The Petition presented no such argument with respect to limitation 1(h), and by extension, 13(h) and 20(s). *See* Pet. 26-28, 41, 56.

3. Sotera newly argues that Claim 13 (incorrectly identified by Sotera as Claim 19) "only requires that the second signal be 'at least partially [sic] via digital communications,' not be a purely digital signal" and proposes a new modification of the prior art. Reply 20. Specifically, Sotera now alleges "a PHOSITA would know an analog sensor could encode an analog signal with digital information." *Compare* Reply 20 *with* Pet. 28-29, 41.

Sotera introduces new reference, EX1057, and argues for a new combination of EX1057 with Money as a motivation to combine Money with Akai.
 Reply 26-27.

-1-

5. Sotera argues Money's device could be changed in size and relies on new exhibits EX1045, EX1058, and EX1059 in support. Reply 22-23. Sotera did not argue for a change in Money's size in the Petition. *See* Pet. 65, 96.

6. Sotera argues for substitution of an electrical wire for Akai's fiber optic cable. Reply 25. The Petition relied solely on Akai's fiber optic cable and never suggested substituting an electrical wire. *See* Pet. 95.

7. Sotera argues that Money discloses "a dual-purpose RS-232 port *and* a dual-purpose serial interface" as a motivation for modifying Money's temperature sensor to be digital. Reply 26-27 (emphasis added). The Petition, however, makes no mention of a "dual-purpose serial interface," but instead relies exclusively on a "dual-function RS232 port" as motivation for modifying the temperature sensor. *See* Pet. 74-76, 86, 101.

Sotera argues that Estep is analogous art to the '735 Patent. Reply
 28-29. Sotera made no such argument in its Petition, and it cannot cure this
 deficiency only on Reply. Patent Owner Response 50-51, 70.

-2-

I. INTRODUCTION

Sotera jettisoned its original expert for a new one who contradicts the original expert. Sotera also improperly adds new prior art, new combinations, new motivations to combine, and new arguments in Reply. The Board should disregard Sotera's new arguments and evidence because they were not in Sotera's Petition.

Masimo based its Response on the instituted grounds and arguments. The Board's rules preclude Masimo from now offering new expert testimony and evidence to address the flaws in Sotera's Reply fully. Thus, Sotera unfairly prejudices Masimo's ability to respond by raising such arguments in Reply only. Regardless, Sotera's new arguments and evidence fail to demonstrate the obviousness of any challenged claims. Rather, these new arguments and evidence reveal that Sotera cannot meet its burden on the instituted grounds.¹

II. <u>"SENSOR COMMUNICATION PORT" SHOULD HAVE</u> ITS PLAIN AND ORDINARY MEANING

Sotera argues that the Board need not adopt Masimo's proposed construction of "sensor communication port" because Masimo has not offered a special meaning. Reply 1-2. The Board should construe "sensor communication port"

-3-

¹ Masimo reserves the right to seek Director review of any final written decision in this proceeding. *United States v. Arthrex*, U.S. (June 21, 2021).

(and "sensor port")² according to its plain and ordinary meaning. Patent Owner Response ("POR") 15. At the Board's instruction, Masimo presented its proposed construction consistent with that plain and ordinary meaning. *See* Institution Decision 21. If the Board determines that no construction is necessary, Sotera still fails to demonstrate unpatentability for the same reasons set forth in Masimo's Response.

Further, the Board should reject Sotera's proposed construction of "a permanent or removable input/output interface for a sensor" for several reasons. Reply 5. First, Sotera's position that "sensor communication port" encompasses permanent connections *directly contradicts* the Petition and original expert declaration. Sotera and Yanulis originally argued that ports provide "readily connected and disconnected" connections and that ports differ from hardwired connections. Pet. 22-23; *see also* EX1003 ¶ 64. The Petition relied on the removability of sensors from ports to make its obviousness arguments. *Id.* By now arguing that "sensor communication ports" can include permanent connections, Sotera undermines the obviousness arguments in the Petition.

-4-

² Masimo uses the terms "sensor communication port" and "sensor port" interchangeably in this brief.

Second, Sotera never applies its proposed construction. Rather, Sotera consistently *distinguishes* a hardwired connection from a port. Sotera argues that "even if Goldberg discloses only a hardwired connection, it still would have been obvious to modify Goldberg to include ports for the wired sensor connections." Reply 5. Sotera also asserts "there are a finite number of options (two) for forming a wired connection with a sensor: hardwire or ports." *Id.* These statements confirm that Sotera does not believe that "sensor communication port" encompasses hardwired connections.

Third, Sotera's new expert, Bergeron, also agrees and distinguished a hardwired connection from a port, *see, e.g.*, EX2038, 101:8-21. EX1040 ¶ 70. Bergeron notes that "[p]orts had *clear advantages over hardwired connections*, such as the ability to replace a faulty sensor without replacement of the entire system." *Id.* (emphasis added). Thus, all parties and experts agree that "sensor communication ports" do not include hardwired connections.

Fourth, Sotera's claim differentiation argument fares no better. Sotera argues that Claim 1 must encompass permanent connections because "claim 3 further specifies a removable connection between the first sensor port and a cable." Reply 3; EX1040 ¶ 52. But, Claim 3 actually refers to "the tail" introduced in Claim 2. *See* EX1001, Claim 3. Claim 3 specifies that "the tail comprises a cable"

and further specifies that "*the cable is configured* to be removably attachable to the first sensor communication port." Thus, claim differentiation does not apply.

Fifth, Sotera relies on unrelated extrinsic evidence to allege the existence of permanent "ports." According to Sotera, EX1044—a PIC16C5X microcontroller datasheet—teaches "permanent, hardwired ports" (Reply 4 (citing EX1044, 35)), or as Bergeron describes, "processor pins soldered to a breakout board." EX1040 ¶ 49. But processor pins on a breakout board are irrelevant to the construction of "sensor communication port" in the '735 Patent.³ The word "port" in a processor datasheet does not clarify the construction of "sensor port" in the '735 Patent. A PHOSITA would not confuse the claimed "sensor communication port" on a housing with a "port" on a processor or a "port" of a boat.

The '735 Patent teaches a monitoring device with a housing that has ports used to connect sensors to the housing. *See, e.g.,* EX1001, Claims 1, 13, 20. Moreover, the '735 Patent distinguishes a sensor port connection from a hardwired or permanent connection. POR 18 (discussing EX1001, 5:38-39). Neither Sotera nor Bergeron addresses the '735 Patent specification in arguing that "sensor

³ Bergeron also confirmed in deposition that the cited portion of the datasheet does not refer to soldering anything. EX2038, 114:17-21.

communication port" as used in the claims includes a "permanent" connection. The Board should reject Sotera's construction as contrary to the '735 Patent.

Sotera's criticisms of Masimo's proposed construction are meritless. Sotera incorrectly asserts that Masimo's expert Mr. Oslan changed Masimo's proposed construction of "sensor communication port" by including additional limitations. Reply 3. But the alleged "additional requirements" are either limitations surrounding the term "sensor port" in the '735 Patent claims or are consistent with Masimo's proposed construction:

- limitations 1(g), 1(h), 13(e), 20(n), 20(s), and 20(t) specify that the sensor communication ports are located on the housing/case;
- a sensor port is only one side (or one half) of two connectors which mate together to form a connection. The other side would be the sensor connector; and
- because the claimed sensor communication ports are recited as being on the monitor housing, a sensor communication port would not come from a sensor.

Sotera also incorrectly suggests that Masimo's proposed construction encompasses hardwired connections. Reply 4; EX1040 ¶ 50. But it does not. POR 18. According to Sotera, a mere conductor soldered to another conductor would satisfy Masimo's construction of "a connector that mates with a compatible connector from a sensor." See Reply 4; EX1040 \P 50. Sotera's interpretation is unreasonable because there is no connector and compatible connector or mating in that situation, just two pieces of metal soldered together. Such an interpretation of "sensor communication port" would eviscerate the claim term.

Finally, Sotera criticizes Masimo for not including data input/output in its construction. Reply 4-5. But Sotera concedes that the claim language already specifies that the ports are "configured to provide wired communication" with sensors. *Id.* Bergeron agreed that a signal from a sensor contains data. EX2038, 46:11-21. Because the claims already recite communication with sensors, adding "data" would be superfluous to the construction of "sensor communication port."

III. GOLDBERG-BASED GROUNDS 1-4

A. <u>Sotera Fails to Demonstrate that a Sensor Communication Port Could</u> <u>Be Implemented Between Goldberg's Housing and Blood Pressure Cuff</u> <u>Sensor with Any Expectation of Success</u>

Sotera's obviousness combination has major deficiencies. Goldberg does not have a sensor communication port located between the housing and the blood pressure cuff sensor 104b. Moreover, Sotera failed to demonstrate a reasonable expectation of success to add such a sensor port. *See* POR 37-40. Sotera's Reply raises three distinct arguments to rehabilitate its obviousness contention: (1) Goldberg's Figure 2 includes a cuff outside the housing, thereby implying that the electrical sensor measuring pressure is outside the housing (Reply 17); (2) Goldberg teaches "other embodiments [that] include separate blood pressure sensors that are not also integrated as a strap for a housing" (*id.* at 18); and (3) some blood pressure monitors used microphones to detect Korotkoff sounds and those microphones would be outside the housing, as allegedly shown in a new reference (*id.* at 19). Each is deficient.

For the first argument, Sotera relies on the phrase "blood pressure cuff sensor 104b" and Figure 2 of Goldberg to conclude that the sensor must be outside the housing. *Id.* at 17. But Sotera misses the point—the location of the pressure sensor is not the claim limitation. Sotera failed to show a "sensor communication port" between the cuff and the housing. Moreover, Sotera conceded that Figure 2 "doesn't include details" (*id.* at 7) and that "a simple diagram cannot be the sole basis of making conclusions." *Id.* at 8. Goldberg does not explain any implementation details for its blood pressure cuff sensor, nor is there any mention of a sensor port between cuff and housing. *See* EX2010 ¶ 67. Sotera cannot carry its burden of showing a "sensor communication port" by speculating about Goldberg's Figure 2.

Further, Bergeron improperly relies on inherency to argue that a sensor port exists between Goldberg's cuff and housing. *See* EX1040 \P 83. Bergeron speculates that "[t]his wired connection and the sensor's location outside the housing would necessarily include a port," but provides no explanation why a

sensor port would be inherent. *Id.* Sotera's Petition should have included such a critical explanation. Oslan explained in detail (1) why a PHOSITA would not infer the existence of a sensor port and (2) that he was not aware of any wrist-worn blood pressure monitors with such a sensor port. *See* EX2010 ¶¶ 87-101. In fact, Junichi (EX2027) and the modern-day wrist-worn blood pressure monitor that Oslan examined both have configurations with a blood pressure cuff attached to the back of the housing. *See* EX2010 ¶¶ 94, 100. Yet, those devices *do not* have a sensor port between the cuff and housing. *Id.* These references, which Bergeron ignored, demonstrate that a sensor port is not "necessarily" included.

Oslan also explained that adding a sensor port in the cuff would not be trivial because the sensor port would need to satisfy several design requirements, including, *inter alia*, the ability to provide an airtight pneumatic connection for the cuff. *Id.* ¶ 92. Sotera does not address those design requirements or identify any sensor port that could meet those requirements. *See* Reply 17-19; EX1040 ¶¶ 83-85. Sotera, therefore, has not demonstrated a sensor port between Goldberg's housing and blood pressure cuff sensor 104b or a reasonable expectation of success in adding one there.⁴

⁴ In related IPRs, Sotera further argues that the pressure sensor in Goldberg must be in the cuff (referred to as the "air chamber"). Paper 24 in IPR2020-01054 18. Although Sotera did not make that argument here, it fails because Sotera's

Sotera's remaining two arguments are improper new theories of unpatentability. Reply 18-19. Sotera argues that "FIG. 2 of Goldberg is merely 'an embodiment' of the invention" and that "other embodiments include separate blood pressure sensors that are not also integrated as a strap for a housing." Id. at 18 (emphasis added). However, Sotera's Petition did not present those "other embodiments." See Pet. 26-29. Moreover, Goldberg does not actually disclose those "other embodiments." Sotera also cites Kiani as allegedly disclosing such a blood pressure system. Id. at 18-19. But again, the Petition did not rely on a blood pressure system in Kiani. See id. Instead, the Petition expressly relied on the blood pressure cuff sensor 104b to meet both the sensor communication ports limitation 1(h) and the strap limitation 1(b), as well as the strap limitations in Claims 13 and 20. See Pet. 18-19, 27. The Board should reject this new obviousness combination. See Ariosa Diagnostics v. Verinata Health, Inc., 805 F.3d 1359, 1367-68 (Fed. Cir. 2015).

Even if considered, Sotera's new proposed combination does not teach the strap limitations 1(b), 13(d), and 20(i). Sotera relied on Goldberg's blood pressure

improper new reference, EX1043, teaches away from that configuration, explaining that a pressure sensor needs to be connected separately to a cuff to isolate it from pressure variations caused by a pump. EX1043, 9:17-20.

-11-

cuff sensor 104b to meet those strap limitations. *See* Pet. 18-19, 40, 52-53. By pivoting to "blood pressure sensors that are not also integrated as a strap for a housing," (Reply 18), Sotera's new combination fails.

Finally, Sotera relies on the improper new reference, EX1043 ("Hutcheson"), to argue that "some pneumatic blood pressure cuffs also included electrical devices such as microphones, to detect Korotkoff sounds and more accurately detect blood pressure." Reply 19 (citing EX1043). The Board should ignore Hutcheson because it is not part of the instituted grounds. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016).

Regardless, this new argument fails. First, Sotera fails to explain both a motivation to combine Goldberg with Hutcheson and a reasonable expectation of success in doing so. The cited portion of Hutcheson demonstrates that it was *not a wrist-worn device* like Goldberg's device, but was instead placed "over the brachial artery of the patient." EX1043, 11:67-12:12. Bergeron confirmed that the brachial artery is not in the wrist, but in the upper arm. EX2038, 156:8-157:15. Hutcheson also describes the invention as "housed in a relative[ly] small molded plastic case weighing less than five pounds and carried in a leather pouch suspended from the patient by means of a shoulder strap and belt around the patient's waist") EX1043, 6:59-68. Sotera does not explain how Hutcheson's

-12-

device could be implemented into a wrist-worn blood pressure monitor like the one shown in Goldberg's Figure 2. *See* Reply 19; EX1040 ¶ 85.

Second, Sotera asserts that "[t]hese blood pressure sensors place the microphone within the cuff, not in the housing." Reply 19. However, Hutcheson explains that "K-sound transducer 108 is preferably placed over the brachial artery of the patient under the bicep *with cuff 114 retaining it in place*." EX1043, 12:2-5 (emphasis added); *see also id.* at 9:1-3, 11:67-12:2. Thus, the K-sound transducer is not *within* the cuff, but merely retained in place by it.

Finally, Sotera's discussion of Hutcheson focuses on whether the supposed microphone is inside the cuff, but neglects to identify a "sensor communication port" as required by the claims. *See* Reply 19. Thus, Sotera fails to meet its burden to show that (1) Goldberg discloses a sensor communication port between the housing and blood pressure cuff and that (2) a PHOSITA would have been motivated to add one there with a reasonable expectation of success.

B. <u>Sotera Presents an Unreasonable Assumption that Goldberg's Device</u> <u>Has Seven Sensor Ports</u>

Sotera's new position that Goldberg's device has seven sensor ports (Reply 9) is unreasonable given its original expert's opinion that "[g]enerally, when designing wearable technology, PHOSITAs mainly attempted to improve patient comfort when the device is being worn" and that "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." EX1003 ¶ 29. Neither Sotera nor Bergeron explains why a PHOSITA would design a wrist-mounted device and expect the user to attach seven different sensors to it. Moreover, Sotera fails to reconcile its position that Goldberg contemplated a device with *seven* sensor ports when Goldberg's figures and specification do not mention even a single port.

C. Goldberg's Device Was Meant for Personal, Not Clinical Use

Sotera and Yanulis relied on the supposed demand from clinicians for "patient monitors that conform and adapt as needed" as the motivation to modify Goldberg with ports. Pet. 22-23; see also EX1003 ¶ 64. However, they incorrectly assumed that clinicians would be the end-users for Goldberg's device. See id. Masimo pointed out that Goldberg's device was meant for use by the monitored person. See POR 33-34, EX2010 ¶¶ 76-78. Sotera criticizes Masimo's argument as unsupported, but Sotera omits key evidence. Reply 15-16. Oslan cited specific portions of Goldberg explaining that the device can display news, sports, and entertainment, as well as providing reassuring statements to the user that "Everything is just fine!!!!!!" EX2010 ¶ 77 (citing EX1005, 5:54-57, Figs. 6a-6d). Those portions demonstrate that Goldberg's device was meant for use by the monitored person, not a clinician. Sotera ignores them. Reply 15-16; EX1040 ¶ 79. Sotera and Bergeron also do not dispute that a wrist-worn blood pressure monitor, like the one described in Goldberg, was not recommended for clinical use

as of 2002. POR 33-34. These facts confirm the intended non-clinical use for Goldberg's device.

Sotera suggests that an average home user was "very familiar with ports in 2002" and "would not be intimidated by ports." Reply 16. Sotera relies solely on Bergeron's declaration which merely parrots the Reply. EX1040 ¶ 80. Bergeron adds no further analysis. *Id.; see also* 37 C.F.R. § 42.65(a); Fed. R. Evid. 702. In contrast, Oslan opined—with citation to record evidence—that adding numerous ports and wires to a personal device would overcomplicate the device and be undesirable. EX2010 ¶ 80.

Sotera argues that the context of Goldberg's device does not matter because "[a] patient monitoring herself desires customization so that she monitors the parameters important for her." Reply 16; EX1040 ¶ 81. But context matters. A layperson is not a clinician. Sotera and Bergeron present no evidence that a layperson would even know which parameters to measure, let alone demand a fully customizable monitor.

The Petition relied on the demand of clinicians for patient monitors to "conform and adapt as needed" as the basis for a motivation to combine. Pet. at 23. Because that fundamental assumption that clinicians are the end-users for Goldberg's device is incorrect, Sotera's conclusion that there would be a motivation to combine Goldberg with sensor ports is also incorrect.

D. <u>Sotera Raises Improper New Arguments Regarding the Digital/Analog</u> <u>Limitations</u>

Masimo explained that the proposed combination of Goldberg, Kiani, and Money fails to teach the specific arrangement of analog and digital inputs required by the claims. POR 42-47. Sotera concedes that Money does not teach the correct combination of analog and digital signals. Reply 20. However, Sotera argues that a PHOSITA would be able to "swap one for the other." *Id.* But Masimo explained why a PHOSITA would not have been motivated to include the claimed data signal configurations. POR 44-47. Moreover, Sotera bears the burden to explain why a PHOSITA *would* make that modification, not simply that it *could* be done.

Sotera next argues that "claim [13] only requires that the second signal be 'at least partially [sic] via digital communications,' not be a purely digital signal," and that "[i]t was known to encode digital information on an analog signal." Reply 20. Sotera never presented this theory of unpatentability in the Petition. Pet. 28-29, 41. Even if considered, Sotera does not identify any prior art sensor that transmits data in that fashion and fails to explain any motivation to modify Goldberg's device to do so with any reasonable expectation of success. Sotera relies on a section of Money for its assertion, but that cited portion of Money describes an RF transmitter, not a sensor port or sensor. Reply 20 (citing EX1008, 6:8-10). Sotera also comments on the Examiner's statements during prosecution and argues that "Money refutes the statement of allowance." Reply 21. However, the Examiner's statements are not a substitute for the '735 Patent claim limitations, and discussing the Examiner's statements in no way addresses the deficiencies in Sotera's specific combination of prior art.

Finally, Sotera criticizes Masimo for not making a similar argument in a related IPR regarding a claim of the '623 Patent. *Id.* at 20 n.3. That criticism is irrelevant and illogical. Masimo explained in that other IPR that Sotera's arguments regarding that claim failed for a more fundamental reason—reliance on non-analogous art. *See* Paper 20 in IPR2020-01054 at 44-48, 64. Sotera fails to meet its burden of demonstrating unpatentability by criticizing Masimo's arguments in a different proceeding regarding a different patent.

IV. MONEY-BASED GROUNDS 5-8

A. <u>Sotera's Improper New Reference Confirms the Petition Was Based on</u> <u>Hindsight</u>

Sotera and Yanulis originally argued that a PHOSITA would substitute Money's pulse oximetry cuff transducer with Akai's SpO₂ sensor. They denigrated Money's pulse oximetry cuff transducer as "obsolete," "bulky," and "uncomfortable." EX1003 ¶ 195.) Then, they praised Akai's "light-based SpO₂ sensor" for its ability to "predictably measure oxygen saturation non-invasively." Pet. 63. However, Masimo demonstrated that Yanulis had *no factual basis for* *these assertions*. POR 57-58. Indeed, Yanulis admitted that he had *no idea* what Money's "pulse oximetry cuff transducer" looked like and could not describe any of its features. EX2013, 235:21-236:15. Masimo's expert, on the other hand, explained pulse oximetry is already light-based and non-invasive, so Akai's sensor would provide no benefit over Money's transducer. POR 57-58; EX2010 ¶¶ 137-142. Accordingly, Sotera presented no credible motivation to combine Money and Akai—only hindsight.

Sotera now argues that a new reference, EX1057 ("Merrick"), would motivate a PHOSITA to replace Money's pulse oximetry cuff transducer with Akai's pulse oximetry sensor. Reply 26; see also EX1040 ¶ 96. But Yanulis never considered that reference. Sotera insinuates that Merrick was an example of Money's pulse oximetry cuff transducer and that such a pulse oximetry cuff transducer was undesirable as uncomfortable. Id. However, Sotera does not provide any basis to conclude that Merrick's device was anything like Money's pulse oximetry cuff transducer. Id. The cuff disclosed in Merrick was not the pulse oximetry cuff transducer in Money. Rather, Merrick discloses a cuff that squeezes a body member to artificially induce a stronger-than-normal pulse for use with a pulse oximeter. See EX1057, Abstract, 1:6-55. Money contains no such disclosure. Thus, Merrick sheds no light on whether Money's pulse oximetry cuff transducer was undesirable or uncomfortable. Sotera cannot meet its burden to

demonstrate a motivation to combine by creating a problem that did not exist in Money.

Moreover, Sotera argues that Merrick's squeezing of a body member provides a reason not to use a pulse oximeter cuff transducer. Reply 26. But Merrick touted the cuff as providing an "advantage" in that "artificial pulse can replace normal blood pulses which are too weak utilization [sic] by devices such as a pulse oximeter." EX1057, 1:66-68. There is no basis to argue for a modification of Money based on the undesirability of Merrick, when Merrick's cuff was touted as an advantage.

B. <u>Sotera Fails to Demonstrate that Money's Device Would be Suitable as</u> <u>a Device Worn on a Lower Arm of a Patient</u>

The Petition never argued that Money could be made smaller or lighter, but instead expressly relied on Money's dimensions as "three inches wide, six inches long, and one-inch thick" and argued that "a housing of this size would easily be worn on a patient's wrist." Pet. 65; *see also id.* at 85, 95-96. After Masimo explained that a PHOSITA would not have looked to Money's device because it is too large and heavy to attach to a patient's lower arm (POR 52-54, EX2010 ¶¶ 126-131), Sotera raises an improper new argument that Money's device "*could* be smaller and weigh less." Reply 22 (emphasis added). Even if considered, Sotera's argument, and its characterizations of Masimo's positions, are incorrect.

1. <u>Sotera Does Not Respond to Masimo's Arguments</u>

Sotera represents that "Masimo states Money's maximum length and width are the size of a modern smartphone...." Reply 22. But Masimo argued that Money's device is approximately the size and weight of *three* smartphones stacked together. POR 53. Sotera's response that "runners strap smartphones to their arms" is thus irrelevant. Sotera did not argue that runners strap *three* smartphones stacked together to their arms. Nor would a runner.

Sotera states that "Masimo also asserts, without evidence, that Money is worn on a patient's belt." Reply 24. But Masimo and Oslan explained, supported by record evidence, that a PHOSITA would not have understood Money's device to strap to a patient's wrist based on Money's weight and size. POR 54, EX2010 ¶¶ 128-131. Strapping Money's housing to a patient's wrist would require resizing and reconstructing Money's device. *Id.* Thus, Masimo and Oslan suggested that Money's device is *most likely* worn on a waist, not a patient's wrist. *Id.*

Sotera's rebuttal of Masimo's argument is contradicted by Sotera's own evidence. Sotera argues that "patients do not wear belts; they wear hospital gowns" (Reply 24) and relies on Bergeron to assert that "[a] POSITA would *never* choose a belt attachment for a hospitalized patient...." EX1040 ¶ 93 (emphasis added). But Sotera's own reference, Hutcheson, discloses a blood pressure system "carried in a leather pouch suspended from the patient by means of a shoulder strap

and belt around the patient's waist." EX1043, 6:64-68 (emphasis added). Accordingly, Sotera's conclusory assertion that "it would be obvious to attach [Money's] device to a patient's arm" (Reply 24) is contradicted by its own reference showing other attachment locations.

2. <u>Moore's Law Is an Observation about Transistors, Not</u> <u>Technology in General</u>

Sotera newly argues "a PHOSITA would surely recognize Money's technology would shrink, at least according to Moore's law", and that "a PHOSITA would have been motivated to use modern technology at a subsequent date, which would have obviously resulted in a smaller device." Reply 23. Sotera fails to explain what "modern technology" would have been combined with Money, or why a PHOSITA would be motivated to make such modifications to Money with a reasonable expectation of success. Moreover, Sotera's reliance on Moore's Law is misplaced. Its own expert explained that Moore's Law is an observation about transistors and solid-state devices. EX2038, 186:9-13, 187:14-17. It is not applicable to other components in Money, such as the four AA batteries, air pump, housing, and ports. *Id.* at 188:18-190:14.

Sotera also introduces two new references, EX1058 and EX1059, to show devices that are purportedly "larger and heavier" than Money. Reply 23. These references are shown below.

-21-



EX1058.



EX1059. But neither reference is a medical device for use by a hospitalized patient—one is a diving watch (EX1058), and the other is a "rugged" keyboard for

"military and public safety applications" (EX1059, 1). Additionally, neither reference teaches a device that is *both* as heavy *and* as large as Money's device.

C. <u>Sotera Changes Its Argument to an Electrical Cable Rather Than</u> <u>Akai's Fiber Optic Cable</u>

Sotera states that it "never suggested modifying Money to include Akai's [fiber optic] *cable*." Reply 25 (original emphasis). But Sotera expressly relied on Akai's fiber optic cable to teach limitation 20(e), which recites "a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal." Pet. 95; EX1003 ¶ 291. Sotera also expressly relied on Akai's fiber optic cable (incorrectly labeling it a "wire") for limitations 1(g) and 13(g). Pet. 71, 86; EX1003 ¶¶ 214, 261.

Sotera now seemingly concedes that a fiber optic cable does not send electrical signals as claimed in the '735 Patent. Reply 25. Instead, Sotera now relies on Money's electrical wire in combination with Akai's SpO₂ sensor, ditching Akai's fiber optic cable. *Id.* Sotera's new argument demonstrates that the instituted Money grounds did not teach the claimed electrical signals.

Sotera's new argument also fails. Akai's sensor 112 *does not work* with an electrical wire. Akai explains that "[t]he light that has permeated finger 111 is received by light receiver 115 [sic] located at the other side of the finger and *transferred via an optic fiber* to controller of light receiver 117." EX1007, 5:26-30 (emphasis added); *see also id.* at Fig. 2 (reproduced below).



Merely replacing the fiber optic cable with an electrical wire would result in an inoperable device because an electrical wire cannot transmit light. *See* EX2038, 181:19-182:6 (Bergeron agreeing that an electrical wire cannot transmit light). Thus, Sotera cannot meet its burden with this new combination.

D. <u>Sotera Relied on Hindsight to Propose Modifications to the</u> <u>Temperature Sensor</u>

The Petition engaged in hindsight reconstruction by selecting only specific components of Money and Akai to unplug, swap, convert between digital and analog, and replug in order to match the '735 Patent claims. Pet. 75-76, 86, 101. After Sotera swapped Money's digital SpO₂ sensor with Akai's analog SpO₂ sensor, an alleged "dual purpose" port on Money's housing would be unoccupied. *Id.* at 74-76 (discussing where the sensors would "plug into"). Sotera then relied on that unoccupied "dual purpose" port to motivate a further modification: changing Money's temperature sensor from analog to digital. *Id.* Masimo

explained that argument was wrong, in part, because Money does not teach a "dual purpose" port on the housing. POR 62-64; EX2010 ¶¶ 150-153. Rather, Sotera used the '735 Patent claims as a roadmap for hindsight analysis. POR 62-67.

On Reply, Sotera dodges the hindsight issue. Instead, Sotera dismisses Masimo's argument that Money has no "dual purpose" port. Reply 26-27. Sotera criticizes Masimo as "pointing only to a picture" from Money. Reply 26 n.5. But Masimo and Oslan analyzed Figures 1, 2A, 2C, and Money's detailed description, which explained that "the serial data input and output port of processor 14 is electrically connected to a serial port switch 36 which directs the RS232 port on processor 14 to *either* external debug/programming port 16 *or* to serial data received from pulse oximetry transducer 39." EX1008, 7:58-62 (emphases added); POR 62-64; EX2010 ¶¶ 150-153. Thus, port on processor 14 differs from debug port 16 and pulse oximetry transducer 39.

Sotera and Bergeron have no response to Oslan's detailed technical analysis. Instead, they assert in conclusory manner that "Money clearly explains SpO_2 data and debug data *share the same port.*" Reply 26 n.5 (citing EX1008, 11:51-53) (original emphasis). But the shared port in Money is the port on processor 14, not a sensor port on a housing. Thus, Sotera's alleged "dual-purpose" port refers to a pin on a processor, not a connector for mating with a sensor connector. Regardless, Sotera never provides a cohesive motivation to make all the numerous modifications it proposes to Money. Instead, Sotera's expressed motivations are conditional on one another. For example, Sotera does not reach the problem of reusing the "dual purpose" port without first changing Money's SpO₂ sensor. Pet. 71, 74. In so doing, Sotera discounts the simpler possibility of instead changing Money's SpO₂ port to accommodate Akai's SpO₂ sensor. Without the contrived reason for keeping Money's digital SpO₂ port, Sotera has no reason to modify the temperature sensor from analog to digital. These convoluted motivations demonstrate that hindsight guided Sotera's analysis, rather than the need to solve some problem with Money.

V. CONCLUSION

Masimo respectfully requests that the Board confirm the patentability of all challenged claims of the '735 Patent.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 30, 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(c)(4). This document contains approximately 4,992 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: June 30, 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 SUR-REPLY AND EXHIBIT 2038** are being served electronically on June 30, 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: June 30, 2021

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

Attorneys for Patent Owner Masimo Corporation