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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 RESPONSE

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## 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	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.)
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2025	Gianfranco Parati et al., Self blood pressure monitoring at home by wrist devices: a reliable approach?, 20 J Hypertension 573 (2002)
2026	U.S. Patent No. 4,896,676 to Sasaki
2027	Japanese Publication JP4777640B2 to Junichi and English machine translation available from Espacenet
2028	Photographs of Omron Gold Wrist Blood Pressure Monitor (Model No. BP4350) taken by Alan Oslan
2029	Larry Hardesty, Clothed in Health, MIT Technology Review (July 1, 2001) (https://www.technologyreview.com/2001/07/01/235697/clothed- in-health ) (last accessed February 17, 2021)
2030	Datex AS/3 <sup>TM</sup> 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 '735 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 '735 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 for Goldberg improperly conflate the vastly different design considerations of high-acuity bedside monitors with those of remote home-use monitors by relying on the '735 Patent's disclosure as a roadmap to try to arrive at the claimed invention. Petitioner's obviousness grounds for Money begin with a bulky device that would not be a suitable starting point and

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then rely upon Yanulis' unsupported opinions for proposed modifications to Money. These arguments reflect classic hindsight reconstruction.

Petitioner's obviousness combinations based on both Goldberg (Grounds 1-4) and Money (Grounds 5-8) fail to disclose all the limitations of the challenged claims. Petitioner's obviousness arguments also lack credible motivations to combine the references in general or to make the specific changes proposed by Petitioner. Rather, when Petitioner cannot find a specific limitation in the prior art, Petitioner and its expert Yanulis simply invent the motivation to add that limitation.

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. The Institution Decision questioned whether port 540 in Kiani should be classified as a sensor input port. Institution Decision (Paper 13) at 30 n.6 ("Institution"). Yanulis admitted Figure 5 of Kiani "just show[s] one port, period." EX2013 at 130:10-14. Thus, neither Goldberg nor Kiani discloses a device with multiple ports or how multiple ports could be incorporated into a device mountable on the lower arm.

Yanulis does not support his supposed motivations for combining the single sensor port of Kiani into Goldberg with any contemporaneous evidence. Indeed, his motivations ignore numerous obstacles and disadvantages to the proposed modification. The Institution Decision recognized Patent Owner's arguments related to drawbacks of the proposed combination may have merit if supported. Contrary to Petitioner's assertion that the proposed combination would predictably result in a "secure, wired connection" (Pet. at 22), Yanulis admitted that ports are susceptible to coming loose and accidentally detaching. In his deposition, Yanulis acknowledged port connections coming loose "[h]appens lots of times," which would be undesirable because "you would stop sensing the parameter." EX2013 at 117:18–118:19.

Yanulis proposes to modify Goldberg's housing to include a sensor port for the blood pressure cuff. As Patent Owner's expert Alan Oslan explains, a PHOSITA would **not** have added any sensor port to Goldberg's housing for this purpose because it would have conflicted with the design goals of simplicity of function and use, required the design 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. Moreover, Goldberg's blood pressure cuff secures the device to a patient's wrist. EX1005 at 4:64-67. Yanulis confirmed that a PHOSITA would "want to attach the device so it won't easily be removed by the

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patient whether it be through movement or whatever," EX2012 at 40:4-19, but provided no explanation in his declaration about how a sensor port for the blood pressure cuff would be consistent with that objective. Thus, Petitioner's initial showing falls apart when the context of the prior art is understood.

As Mr. Oslan explains, the Money-based grounds rely upon a primary reference that a PHOSITA would have never selected as a starting point when designing a wrist-worn monitoring device. EX2010 ¶¶ 126-131. Money is too large and bulky to be wrist worn. Id. A PHOSITA would have considered other devices sufficiently small to be worn on a patient's wrist. Id. ¶ 127. Moreover, when asked to describe any features of Money's pulse oximetry cuff transducer, Yanulis stated: "simple answer, no, I don't know any specifics." EX2013 at 235:21–236:15. Yanulis nonetheless opined that a PHOSITA would have replaced Money's pulse oximetry cuff transducer with Akai's SpO<sub>2</sub> sensor. This proposed modification not only lacks support, but Petitioner also fails to address the incompatibility of Akai's optical SpO<sub>2</sub> sensor with Money's monitoring device. Absent further modification, which Petitioner never explains, Akai's SpO<sub>2</sub> sensor could not have conveyed any information to Money's monitoring device. Petitioner also fails to provide a rational basis, other than hindsight, to reconfigure Money's data signal configuration, which is the *opposite* of that recited in the claims.

#### II. <u>BACKGROUND</u>

## A. <u>The Claims of '735 Patent Require an Patient Monitoring Device</u> <u>Mountable on the Lower Arm with at Least Three Sensor Ports</u>

The '735 Patent involves a patient monitoring device mountable on the lower arm. 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, 13, and 20 are independent, and each require a portable patient monitoring device having at least three sensor ports and a specific data signal configuration. Claim 1 is reproduced below.

1. A body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement of one or more sensor communication ports, the mobile medical monitoring device comprising:

a housing configured to be secured on a lower arm of a patient being monitored via a strap extending around the lower arm of the patient;

a display positioned on a face of the housing, opposite the strap, so as to be visible to a user;

a first sensor communication port positioned on a side of the housing and configured to face a hand of the lower arm of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient, wherein:

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the side of the housing faces the hand of the lower arm of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient,

the first sensor communication port is configured to provide wired communication with a pulse oximetry sensor attached to a digit of the hand of the patient,

the wired communication with the pulse oximetry sensor provided at least partly in the analog domain, and

the first sensor communication port is positioned on the side of the housing such that a path from the first sensor communication port on the side of the housing to the digit of the patient is substantially perpendicular to the side of the housing and shorter than any other path from any other side of the housing to the digit of the patient;

a plurality of additional sensor communications ports positioned on the housing and configured to provide wired communication with a plurality of additional physiological sensors at least partly in the digital domain; and

one or more processors and a transmitter configured to:

display, on the display, physiological measurements derived from the pulse oximetry sensor and the plurality of additional physiological sensors; and

wirelessly transmit information indicative of the physiological measurements to a remote computing device.

Id. at 13:14-56.

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Claim 13 recites a device with three sensor communication ports and specifies the second communications port is configured to provide wired communications at least partly via digital communications. *Id.* at 14:38-67. Claim 20 also recites a device with three sensor ports, but specifies the third signal is provided at least partly as a digital signal. *Id.* at 18:2-3. The third signal is responsive to the at least one additional physiological parameter of the patient including at least one of: temperature or respiration rate. *Id.* at 17:19–18:1.

#### 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, 5:27-33; EX2010 ¶¶ 49, 76-80. Petitioner relies on Goldberg's FIG. 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<sup>®</sup> 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

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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 (annotated).

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. *Id.* at 8:31-33; EX2010  $\P$  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.* 

Flg. 1





#### 4. <u>Money (EX1008)</u>

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 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 lower 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 SpO<sub>2</sub> 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

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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 (EX1009)</u>

Estep discloses an electrical signal measurement device for use in telecommunications measurement applications. EX1009 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).



## 6. <u>Fujisaki (EX1016)</u>

Fujisaki discloses a wearable device for checking pulse rate or heart rate. EX1016 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.



## 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 Communication Port"</u>

The Board's institution decision requested that the parties "clearly identify what they contend the scope of a 'sensor communication port' encompasses." Institution at 21. Under *Phillips*, claim terms are 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, 1313-15 (Fed. Cir. 2005); *see also* 83 Fed. Reg. at 51,343; Institution at 20-21.

The Board should construe "sensor communication port," according to its plain and ordinary meaning of a "connector that mates with a compatible connector from a sensor." This is the same construction Patent Owner has offered for "sensor port" in the related IPRs, and Patent Owner views "sensor port" and "sensor communication port" as interchangeable for purposes of these proceedings.

The '735 Patent does not specially define the term "sensor communication 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. Patent Owner's proposed construction is consistent with the '735 Patent specification. For example, the '735 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 5:1-4; FIG. 3 (reproduced and annotated below); *see also* EX2010 ¶ 35.



Additionally, the '735 Patent explains, with respect to Figure 4A, that a wrist-mounted 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 (reproduced and annotated below), the "module connector 414,"

which is on the wrist-mounted module 410, is a connector that interfaces with a corresponding connector from the sensor 310. *See id.* at FIG. 4A; *see also* EX2010 ¶ 39.



FIG. 4A

Thus, Patent Owner's proposed construction is consistent with the '735 Patent specification. The prosecution history does not specifically address the meaning of "sensor communication port."

The parties do not appear to dispute the scope of the terms "sensor" or "communication." Contemporaneous dictionaries also confirm that a "port" is a connector that mates with a compatible connector from a sensor. *See Port*, Webster's II New College Dictionary (2001) ("A connection point for a peripheral

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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 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).

Importantly, the '735 Patent expressly distinguishes the "port" type connection illustrated in Figure 4A from a hardwired or direct connection. 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 that the term "sensor communication port" involves a removable connection and does not include hardwired connections. *See* EX2010 ¶ 39. Yanulis also agreed during deposition and in his declaration that in the context of the '735 Patent and related patents, a port would provide a removable wired connection. EX2013 at 86:18-87:5; *see also* EX1003 ¶ 64 (distinguishing ports from hardwiring).

Petitioner did not offer a construction for "sensor communication port," but Yanulis has explained that "[a] port is typically a female connection or socket of a

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wired connection." EX1003 ¶ 64. Yanulis later agreed during 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 communication 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 '735 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' sworn testimony in these IPRs directly contradicts his sworn testimony in the related district court proceeding on the issue of claim construction. Because of these contradictory opinions, the Board should disregard Yanulis' claim construction analysis.

### 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, when he testified that

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"separate computing device" in the '735 Patent should be given its plain and ordinary meaning. EX2013 at 248:19-22.

However, Yanulis opined in the district court that certain terms should **not** be given their plain and ordinary meanings. Specifically, Yanulis opined in district court that the term "separate computing device," which appears in Claim 20 of the '735 Patent, should be limited to "a conventional bedside monitor." EX2015 ¶ 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 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> Specifically Exclude Goldberg and Money Relied Upon Here

In this IPR, Petitioner and Yanulis relied on Goldberg's "remote computer 302" and Money's "central monitoring station" to satisfy the "separate computing device" limitation. Pet. at 30, 77; EX1003 ¶¶ 89, 229. But Yanulis *specifically excluded* those structures from his proposed district court construction. Thus, under Yanulis' district court construction, Goldberg and Money would not disclose that limitation.

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In district court, Yanulis limited "separating computing device" to a conventional bedside monitor, but in this IPR Yanulis contradicts his prior opinions because Goldberg does not teach a conventional bedside monitor. 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. Goldberg does not describe "remote computer 302" as a conventional bedside monitor. Goldberg's teachings are precisely the type of "laptop," "PC," or "server" that Yanulis' district court construction of "separate computing device" would exclude. EX2015 ¶ 65-67.

Money also does not describe its "central monitoring station" as "a conventional bedside monitor." Rather, like Goldberg, Money describes its "central monitoring station" as "remotely located." EX1008 at 3:24-26. Again, Yanulis excluded servers from his construction of "separate computing device." EX2015 ¶¶ 65-67. Yet Yanulis opines in this IPR that Money 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 of Yanulis' inconsistent positions, the Board should disregard his unreliable testimony on claim construction in this proceeding, and recognize that

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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 Claim 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 ¶ 90. 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. 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 the claim terms.

#### V. <u>ARGUMENT</u>

#### A. <u>Grounds 1-4 Do Not Demonstrate the Obviousness of Any Claim</u>

Petitioner argues that Claims 1-20 are obvious over the combination of Goldberg and other asserted references. Petitioner's argument suffers from multiple problems. First, the proposed combinations lack all of the claim elements. None of the asserted references discloses a device with ports that is mountable on the lower arm. Both experts agree that Goldberg does not disclose any sensor

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ports. Kiani discloses a handheld device with only one sensor port. Second, there is no credible motivation for the asserted combination and modifications. Petitioner fails to present a motivation to modify Goldberg to add sensor ports or provide the claimed data signal configuration. Finally, Petitioner and Yanulis misinterpret the asserted references and improperly reconstruct the claimed invention based on hindsight.

#### 1. Goldberg Does Not Disclose Any Sensor Ports

While the Institution Decision found that "Petitioner, and Dr. Yanulis, explain persuasively that Goldberg's sensors are wired connections that could be hard wired or use a port, and both options were well known," Institution at 36, the disclosure of Goldberg does not include any sensor ports. Petitioner relies on Figure 2 of Goldberg (EX1005) to argue that a "PHOSITA would assume that Goldberg teaches a port because Goldberg shows that a wire extends between the pulse oximetry sensor 104a and *into* the housing 112 and because Goldberg teaches the controller receives electronic signals from the sensor 104a." Pet. at 21 (original emphasis).



EX1005 at Figure 2 (annotated). But a wire extending into the housing describes a wire directly connected to a circuit board. EX2010 ¶ 65. As such, a PHOSITA would understand Figure 2 as showing a hardwired connection between sensor 104a and the housing 112. *Id.* ¶¶ 65-66. The hardwired sensor of Goldberg cannot be readily replaced with another sensor. *Id.* ¶ 65. Indeed, Figure 2 of Goldberg does not illustrate or teach any connector on the housing that mates with a compatible connector from the sensor 104a, which is the construction of "sensor communication port" proposed by Patent Owner.

Petitioner argues that a wire extending into the housing "complies with the meaning of a port to a PHOSITA" relying on Yanulis. Pet. at 21. 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 ¶ 64. Nowhere does Goldberg describe a female connection, a socket, a receptacle, or anything else that could potentially be

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construed as a port. EX2010  $\P$  65. Yanulis conceded as much. *See* EX2013 at 102:5-108:12, 121:14-20. Thus, Goldberg does not meet Yanulis' own definition of a typical port. The wired connection in Goldberg also would not satisfy Patent Owner's proposed construction.

Petitioner argues that a "PHOSITA would *assume* the wire shown [in FIG. 2] includes a port because ports are a common and typical electrical connection for a housing." Pet. at 21-22 (emphasis added). That assumption, however, is unsupported and legally improper. Petitioner cannot show that a reference teaches a claim limitation 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). The only evidence is that a PHOSITA would not assume that Goldberg implicitly discloses a port as opposed to a simple hardwired connection between the sensor 104a and the housing 112. EX2010 ¶ 65-66.

Because Goldberg does not meet either Yanulis' explanation of a port or Patent Owner's proposed construction, Petitioner's arguments for the additional port limitations also fall short. For those ports, Petitioner argues that any wired connection includes an implied port. *See* Pet. at 27. But Petitioner incorrectly assumes every wired connection would have a port. EX2010 ¶ 67. Yanulis

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admitted during his deposition that Goldberg does not show a second sensor port and that it was only "a conceivable arrangement." EX2013 at 121:14-122:7; *see also id.* at 122:17-123:10. Goldberg also does not show a third sensor, much less a third sensor port, in Figure 2. EX2010 ¶¶ 67, 69. Instead, Goldberg has no ports whatsoever. *Id.* ¶¶ 64-69.

As argued by Petitioner, "Goldberg teaches an embodiment that receives signals from a second sensor (blood pressure) and a third sensor (e.g., electrolyte or others) via wired connections via second and third sensor ports." Pet. at 27. But again, no ports are shown in Figure 2 or described in Goldberg at all. EX2010 ¶¶ 64-69. Moreover, a PHOSITA would understand that sensors for both blood pressure and electrolytes could be integrated into the housing. *Id.* ¶¶ 68-69. Thus, there would be no reason for a port.

## 2. <u>A PHOSITA Would Not Have Modified Goldberg with Kiani to</u> <u>Have Multiple Sensor Ports</u>

Because of the absence of ports in Goldberg, Petitioner turns to Kiani to supply these missing limitations. *See, e.g.,* Pet. at 22. But this proposed combination still lacks claimed elements and a credible motivation to combine.

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

While Yanulis initially – and incorrectly – described Kiani as disclosing "sensor input ports 540, 550," EX1003 ¶ 65, both experts now agree that Kiani teaches a single sensor port, **not** multiple ports. EX2010 ¶¶ 54, 70; 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 an oximeter output 540 for connection to another pulse oximeter. EX1006 at 8:31–9:2. The experts now agree that the oximeter output 540 is not a sensor port. EX2010 ¶ 70; EX2013 at 129:12-131:18.

Sensor Input (not shown) Sensor Input

The single sensor port 550 in Kiani is illustrated below:

EX1005, FIG. 5 (annotated).

Accordingly, the Board should disregard not only Yanulis' original opinion that element 540 is a sensor input port (that he has now recanted), but also his reliance upon that opinion to conclude that Kiani discloses multiple sensor ports. *See* Institution at 30 n.6 ("we question whether port 540 should be classified as a sensor input port.")

# b) <u>Petitioner Has Not Presented a Credible Reason to</u> <u>Combine Goldberg and Kiani to Arrive at Multiple Sensor</u> <u>Ports</u>

Petitioner also fails to demonstrate that a PHOSITA would have been motivated to combine Goldberg with Kiani to arrive at a device with multiple sensor ports that is mountable on the lower arm. As explained above, neither Goldberg nor Kiani discloses multiple ports. Kiani discloses a *single* sensor port, but this port is located on a much larger handheld device. Petitioner has not shown how a PHOSITA could have even incorporated multiple ports into a device mountable on the lower arm with limited space.

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

Petitioner alleges that a PHOSITA would add a sensor port between Goldberg's SpO<sub>2</sub> (pulse oximetry) sensor and the housing because "in a medical context, hardwired sensors are undesirable." Pet. at 22. Petitioner cites no evidence to support that extremely broad assertion other than Yanulis' similarly conclusory testimony. *Id.* (citing EX1003 ¶ 64). 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).

The Board found that "Petitioner has provided several persuasive rationales for the proposed combination of Kiani's sensor ports into Goldberg and for employing a second and third sensor with sensor communication ports in

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Goldberg." Institution at 38 (citing Yanulis' opinions of allowing easy removal and replacement of the third sensor and providing a secured wired connection between the blood pressure sensor and the housing). But Petitioner's stated motivation of a more "secure" connection is factually incorrect as confirmed by Yanulis himself. *See* Pet. at 22; EX2013 at 117:18–118:19 (quote reproduced in next paragraph). Petitioner provided no reason why adding a port would result in "a secure, wired connection" when Goldberg already provides a wired connection directly soldered to a circuit board. *See* Pet. at 22. Petitioner's "secure" assertion is also internally inconsistent with its other assertion of "easy removal and replacement." *See id.* Because port connections are removable, a port connection would provide a less secure connection than a connection directly soldered to a circuit board. EX2010 ¶ 73.

Yanulis' declaration failed to consider whether ports have any disadvantages compared to hardwired connections. *See* EX1003 ¶¶ 64-65, 78. The Board recognized that Patent Owner's arguments related to drawbacks of the proposed combination may have merit if supported. Institution at 37-38. Mr. Oslan explains that port connections can be accidentally detached; may have faulty or loose connections; may require more space and hardware to accommodate than a hardwired cable; and introduce additional parts, expense, and points of failure to a

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device. EX2010  $\P$  73. Indeed, Yanulis contradicted his only declaration testimony in his deposition:

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. As Mr. Oslan explains, a PHOSITA would also understand that ports can undesirably introduce contact noise, which may cause a measurement gap or error. EX2010 ¶¶ 73-74. Petitioner and Yanulis fail to

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consider whether any of these disadvantages of adding a port would dissuade a PHOSITA from making the alleged combination. *See* Pet. at 22-23; EX1003 ¶¶ 64-65. Instead, Yanulis performed the wrong comparison. Rather than comparing the claimed port to the hardwired connection shown in Goldberg to address the disadvantages associated with the replacement of a hardwired connection with a port connection, Yanulis compared a port to generically "merely *contacting* two electrical conductors." EX1003 ¶ 64 (emphasis added). Yanulis' analysis is unhelpful because it does not address the benefits and drawbacks of the proposed modification of adding a port to Goldberg's hardwired connection.

Petitioner asserts that that a PHOSITA would "know that patients suffer from a variety of ailments, which require monitoring of different sets of vital signs" and that clinicians "demand and expect patient monitors that conform and adapt as needed." Pet. at 22-23. Petitioner further argues that a PHOSITA would know "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 23. These general statements appear guided by hindsight, improperly extend motivations associated with bedside monitors to wearable devices, and draw on nothing from the references themselves. Goldberg selected a hardwire approach. 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

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proposed in this combination, where the reference itself elected a different approach. See id.; EX1003  $\P$  64.

The Board credits Petitioner's evidence that "using sensor communication ports would have predictably allowed for adaptability and flexibility in patient care that would have been desirable to a person of ordinary skill." Institution at 37 (citing EX1003 ¶¶ 64, 65). Yanulis stated in his declaration that "because Goldberg teaches an adaptable system, a PHOSITA would assume that the wired connections of this adaptable device 100 includes ports." EX1003 ¶ 64. 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 ¶ 81. If the use of ports was the more appropriate approach, as contended by Petitioner, one would expect Goldberg to have followed that approach. But Goldberg did not do so.

To the extent that clinicians did "demand and expect patient monitors that conform and adapt as needed," Pet. at 23, there were already devices that fulfilled that demand and expectation—conventional, full-sized patient monitors. EX2010 ¶¶ 75-76. Yanulis does not explain or provide any evidence that clinicians would have demanded or expected a similar level of conformability or adaptability from a device mountable on the lower arm that is a fraction of the size of a conventional patient monitor. *See* EX1003 ¶ 64. When asked to identify clinicians that would

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expect an adaptable and configurable patient monitor, Yanulis listed anesthesiologists trying to keep a patient alive during surgery and cardiologists with patients in heart failure. EX2013 at 114:5-18. However, specialized patient monitors that fulfilled clinicians' needs in those critical care situations already existed before the invention of the '735 Patent. EX2010 ¶¶ 75-76. Neither of Yanulis' examples requires a wearable monitor because those patients do not move. 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.

Additionally, 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 ¶¶ 75-80; *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. Goldberg describes a portable device for remote monitoring and contains numerous features that are directed toward the monitored person rather than a clinician. EX2010 ¶ 77. Thus, the correct user would be the monitored person or his/her family members or caregivers, not normally a professional clinician in a hospital where conventional patient monitors are available. *Id.* ¶¶ 77, 80. Moreover, in 2002, wrist-worn blood pressure monitors like that described in

Goldberg were not recommended for clinical use. *Id.* ¶¶ 78-79. 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.* Complicating Goldberg's device by requiring the user to connect/disconnect numerous wires and attach various sensors to his or her body would annoy users, as well as caregivers, and would tend to decrease usage. *Id.* ¶ 80; *see also* EX1003 ¶ 29. Thus, a PHOSITA would not have been motivated to simply 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 SpO<sub>2</sub> sensor 104a. A PHOSITA as of 2002 would not have expected such interoperability or adaptability between different types of sensors. EX2010 ¶ 82, 102-103. For example, Kiani explains:

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

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existing conventional patient monitors that did not have Patent Owner's revolutionary SET<sup>®</sup> technology. *See id.* 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 Goldberg and Kiani would not be motivated to simply 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 ¶¶ 82, 102-103.

# (2) <u>A PHOSITA Would Not Have Been Motivated to Add</u> <u>a Plurality of Ports</u>

In addition to failing to show a first sensor port in Goldberg or a motivation to add such a port, Petitioner has also failed to show any teaching or reason to add additional ports to Goldberg. While Goldberg mentions that the device "may contain one, all, or any combination of the above-mentioned sensor types, as well as other sensors," and "may be comprised of any type of physiological sensor 104 suitable or [sic] use with a portable monitoring device," those aspirational statements do not disclose or imply ports. EX1005 at 5:4-8; EX2010 ¶ 81. Yanulis is merely reciting what he thinks one "could" have done. However, a PHOSITA would have interpreted Goldberg to mean that different models could be manufactured with different selections of sensors. EX2010 ¶ 81. Moreover, Goldberg as modified by Kiani would not predictably include a plurality of ports

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because neither reference discloses a plurality of sensor ports. *See supra* § V.A.1, V.A.2.a.

Petitioner's addition of even more sensor ports contradicts Yanulis' opinion 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 (emphases added). Petitioner does not reconcile why a PHOSITA would find it obvious to add additional ports when its own expert has opined that a PHOSITA would want to minimize the number of sensors attached to a patient. Indeed, complicating a device by requiring a patient to attach numerous sensors and wires would decrease the likelihood that an end user would actually use the device of Goldberg. EX2010 ¶¶ 79-80. Accordingly, the benefits of easy removal and replacement articulated by Petitioner (Pet. at 22) and noted in the Institution Decision (Institution at 38) would increase complexity and decrease patient compliance.

Petitioner alleges that "it was very common in the medical field to monitor multiple vital signs simultaneously," citing Yanulis' declaration and portions of Goldberg and Kiani. Pet. at 26. But simultaneous monitoring at the time was accomplished with a multiparameter monitor, rather than a wrist-worn monitor. EX2010 ¶¶ 76, 84. A PHOSITA as of 2002 would have understood that portable devices, particularly wrist-worn devices, would entail significant tradeoffs for size

and battery life. *Id.* ¶ 75. For example, due to size, weight, and power constraints, a PHOSITA would not have expected such a device to provide a similar level of multiple, simultaneous parameter monitoring as a conventional bedside monitor. *Id.* 

# (a) A PHOSITA Would Not Have Been Motivated to Add a Port Between Goldberg's Blood Pressure Cuff and Housing

Petitioner relies on the blood pressure sensor in Goldberg for one of the additional sensor ports in each independent claim. Pet. at 27, 41, 56. Claim 20 specifically requires a second sensor port "configured to provide wired electrical communication with the blood pressure sensor arrangement." EX1001 at 16:58-62.

A PHOSITA would understand that a blood pressure cuff requires an airtight pneumatic connection to an air pump to inflate the cuff. EX2010 ¶ 89. An air leak would render the blood pressure cuff unusable. *Id.* Thus, a PHOSITA would understand that attempting to add a pneumatic or electrical and pneumatic port would be complicated, difficult and require significant, valuable space not readily available in a wearable device. *Id.* ¶¶ 89-101.

Petitioner and Yanulis do not identify any type of port that could be implemented between the housing and the blood pressure sensor. Instead, Yanulis relies on the generic disclosure of a "sensor input port 550" in Kiani. EX1003

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¶ 78. But Kiani's sensor input port 550 was for the SpO<sub>2</sub> sensor, not a blood pressure sensor. EX1006 at 8:31-9:2, FIG. 5; *see also* EX2010 ¶ 92. Neither Petitioner nor Yanulis explain how or why a PHOSITA would have added a sensor port between Goldberg's housing and blood pressure sensor based on Kiani's disclosure of an SpO<sub>2</sub> sensor port, much less modified that port to work with a blood pressure sensor. Yanulis was deposed at length regarding how this combination could be specifically achieved, but he could not give any details about where the sensor port would be located or what type of sensor port would be used. *See* EX2013 at 120:12-133:19.

A PHOSITA reading Goldberg would not assume that Goldberg's blood pressure sensor is removable or is connected via a port. *See supra* § V.A.1.; *see also* EX2010 ¶¶ 67-68, 88. Indeed, Petitioner has not submitted any contemporaneous evidence to support this proposed modification. Rather, a PHOSITA would have recognized that there is no need for a port at all because the pressure sensor would be positioned within the housing in order to measure cuff pressure and determine blood pressure. EX2010 ¶¶ 89, 93-100. Petitioner offers no reason for the pressure sensor—the actual electrical device measuring pressure—to be removable. Adding a sensor to the cuff is typically undesirable because a PHOSITA would not want to place a rigid electronic device within a

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flexible inflatable air bladder, and add an additional point of failure with all the connections and wire to the cuff. *Id.*  $\P$  97.

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 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 cuff and the housing. *Id.* ¶ 89. Petitioner's and Yanulis' hindsight 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 of Kiani, could provide an air-tight pneumatic connection between Goldberg's housing and blood pressure cuff. Instead, a PHOSITA would have understood the blood pressure cuff to be integral to Goldberg's housing so that it could maintain a reliable, air-tight connection with the air pump. *Id.* ¶¶ 89, 91.

Moreover, a blood pressure sensor port would prevent the housing from being sufficiently secured to a patient's wrist. *Id.* ¶¶ 89, 92. During his deposition, Yanulis confirmed:

You want to attach the device so it won't easily be removed by the patient -- whether it be through movement, or whatever. Or to give you an example, when a person is running -- especially one that's in

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very good shape -- you don't want to have a device that comes off very easily.

EX2012 at 40:4-19. However, Yanulis provided no explanation how such a sensor port 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 ¶¶ 91, 94-101.

As Oslan explains, a PHOSITA would have recognized these difficulties and would not have been motivated to add a sensor port to Goldberg's blood pressure sensor. *Id.* ¶¶ 91, 98. Even after the 2002 priority date, wrist-worn blood pressure monitors were generally manufactured with the blood pressure sensor integrated directly into the housing without a sensor port. *Id.* ¶¶ 94-101.

# (b) A PHOSITA Would Not Have Been Motivated to Duplicate a Port

Petitioner fails to provide any evidence, even from its expert, that adding "additional sensor ports is an obvious duplication of parts." Pet. at 27. The third sensor port would not have been a duplication of either the first or second sensor ports because, as Yanulis acknowledged, it would require modifications depending on what type of parameter is being monitored. *See* EX2013 at 136:11-139:1.

Kiani confirms that a PHOSITA would not have expected compatibility between sensors from different manufacturers, much less sensors for entirely different measurements. EX1006 at 2:25-27; EX2010 ¶¶ 102-103. Indeed, when

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asked whether the third port would be a duplication of the first port (for receiving a signal from a pulse oximetry sensor), Yanulis testified:

So the pulse oximetry sensor and port may not be exactly, if you're duplicating a second or third to monitor other parameters, that may be of a digital nature, then, no, you can't utilize the same type of design modification.

EX2013 at 136:11–137:3. 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. EX2010 ¶¶ 102-103.

To the extent Petitioner and Yanulis are arguing that the second sensor port for the blood pressure sensor would be duplicated, that argument also fails. As explained above, a PHOSITA would have had no motivation or expectation of success to modify Goldberg's blood pressure sensor to include a port. *See supra* § V.A.2.b.2.a. And even if a PHOSITA had done so, such as modification would have been unique to the blood pressure cuff. EX2010 ¶¶ 102-104. Thus, a third sensor port would not have been an obvious duplication of either the first or second sensor ports. Again, Petitioner's arguments do not have support in the contemporaneous references and improperly rely on hindsight.

# 3. <u>Petitioner's Arguments Regarding The Data Signal</u> <u>Configurations Are Deficient</u>

## a) <u>None of the Asserted References Teach the Claimed Data</u> Signal Configurations

For the analog and digital requirements also recited in the claims, Petitioner acknowledges that Goldberg does not teach whether the signals from its sensors are analog or digital, Pet. at 23-24, 28-29, and thus combines Goldberg with The Board found persuasive at the institution stage "Petitioner's Money. contention that Goldberg teaches its portable device can communicate with any sensor, which would include analog and digital devices." Institution at 40. But none of the asserted references disclose the specific data signal communications required by the claims—a physiological sensor, *separate from a pulse oximeter* sensor, that provides digital communications. The sensor configuration of Money is the opposite of that recited in the claims. EX2010 ¶¶ 108-109. The only physiological sensor that provides digital data in Money is the pulse oximeter (SpO<sub>2</sub>) sensor. EX1008 at 5:38-39, 6:15-20, 7:58-62, 8:20-27, 13:26-28, FIG. 1 (reproduced below, annotated). Money receives analog data from all of its other sensors. Id. at 5:18-51, 8:20-27, FIG. 1. Money thus does not teach receiving digital data from any sensors other than a pulse oximeter sensor. EX2010 ¶¶ 108-109. As a result, the proposed combination of Goldberg with Money does not

teach the claimed combination of analog and digital signals recited in Claims 1 and

20.



Claim 13 differs slightly from Claims 1 and 20, but nonetheless also requires a second sensor arrangement, *separate from the pulse oximetry sensor*, that provides digital communications. EX1001 at 14:48-64. As explained above, the only digital sensor communications described in any of the asserted references is the pulse oximeter sensor in Money. None of the asserted references describe a second sensor arrangement, separate from the pulse oximetry sensor, that provides the digital sensor communications required by Claim 13.

Accordingly, Petitioner fails to show how the combinations of asserted references teach the data signal limitations of the claims.

#### b) <u>A PHOSITA Would Not Have Been Motivated to Include</u> the Claimed Data Signal Configurations

Petitioner argues "it would have been obvious to try transferring digital data, especially for discrete measurements (e.g., temperature or blood pressure)." Pet. at 28. But none of the asserted references disclose a digital temperature or blood pressure sensor. Petitioner recognizes that Goldberg does not describe whether any of its sensors are analog or digital. *Id*. Money discloses an analog blood pressure and analog temperature sensor. EX2010 ¶ 108; EX1008 at 5:48-51, 8:20-27. Moreover, as explained below, a PHOSITA would not have been motivated to convert Money's analog sensors into digital sensors.

According to Petitioner, "there are only two signal possibilities: analog or digital" and "[a] temperature sensor would have been an obvious choice to transmit digital data". Pet. at 28, 59-60. Petitioner oversimplifies the design considerations at issue. Yanulis initially opined that it was "irrelevant" whether the signal received is analog or digital. EX1003 ¶ 71. However, Yanulis acknowledged during his deposition that whether a signal is received in analog or digital is a relevant consideration in designing a monitoring device. EX2013 at 160:6-13; *see also* EX2010 ¶¶ 110-116. Yanulis testified about several considerations that would affect a PHOSITA's decision to transmit an analog signal versus a digital signal, including at least "whether you want to display those particular signals as analog or digital," hardware, and power consumption. EX2013 at 151:20–153:11; *see also* 

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EX2010 ¶¶ 110-116. Petitioner and Yanulis fail to address any of these considerations in their analysis and provide no reason, other than hindsight, to reconfigure Money to have the opposite sensor configuration.

The Board found at the institution stage that "Money teaches data transmitted digitally and it would have been obvious to modify Goldberg with Money so that the system of Goldberg would function with more sensors and more sensor types in the digital domain." Institution at 41 (citing Pet. 29; EX1003 ¶¶ 83-85). But as explained above, a PHOSITA would not have expected a wrist worn device to be adaptable to work with more sensors. See supra § V.A.2.b.1. Moreover, adding sensors would have been contradictory to Yanulis' opinion 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 (emphasis added). During his deposition, Yanulis testified: "[I]t's well-known that you could add any number of sensors, but then again, you have to balance it. You're just adding sensors for the sake of adding sensors or you definitively need those sensors for those parameters to be sensed." EX2013 183:2–8. But Petitioner and Yanulis failed to perform this balancing analysis to support the proposed modification.

Even if a PHOSITA desired to modify Goldberg to function with more sensors, Petitioner has not shown that a PHOSITA would have modified Goldberg

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to work with more sensors in the *digital domain*. None of the asserted references disclose multiple sensors in the digital domain. *See supra* § V.A.3.a. The only physiological sensor that provides digital data in Money is the pulse oximeter sensor. EX1008 at 5:38-39, 6:15-20, 7:58-62, 8:20-27, 13:26-28. Thus, the combinations of asserted references provide no motivation to include any sensors in the digital domain, other than the pulse oximeter sensor.

The Board credited Yanulis' explanations of "why a digital signal would be advantageous based on Money teachings," Institution at 42, but those explanations ignore the disadvantages of the proposed modifications. Both experts agree that cost is an important consideration when deciding to transmit an analog signal versus a digital signal. EX2010 ¶ 114; EX2013 at 154:21–155:16. A PHOSITA would have understood that sensors in patient monitoring systems are often disposable. EX2010 ¶ 114. Yet, Yanulis fails to consider the increased cost of providing a digital sensor compared to an analog sensor. Unlike analog sensors, digital sensors require an analog-to-digital converter and other associated circuitry. *Id.* Adding hardware would unquestionably increase the cost of the sensor. *Id.* Petitioner and Yanulis fail to consider or explain how the increased cost of a disposable is justified by anything other than hindsight.

Thus, Petitioner has not shown that a PHOSITA would have been motivated to combine Goldberg, Kiani, and Money in the manner suggested to arrive at the claims.

## 4. <u>Petitioner Relies on Hindsight for Grounds 1-4</u>

The record provides no evidence to support all the changes required to modify Goldberg. Petitioner suggests modifications to Goldberg that are not disclosed by the references relied upon in Grounds 1-4, *see supra* §§ V.A.1, V.A.2.a, V.A.3.a. The suggested modifications also contradict Yanulis' opinion regarding the design need to minimize the size of the device and the number of sensors attached to a patient. *See* EX1003 ¶ 29. Petitioner plucks separate features from multiple references that would increase the size of the device, as explained above. *See supra* § V.A.2.b.2. For example, Petitioner proposes at least the following modifications to Goldberg for claim 20:

- [1] "use a light-based pulse oximetry sensor in view of Kiani" (Pet. at 51);
- [2] "display the status indicators of Kiani on the display of Goldberg" (Pet. at 54);
- [3] "include a bezel around the display 108 of Goldberg in view of Estep" (Pet. at 48, 55);
- [4] "include the port taught by Kiani" (Pet. at 22, 56);

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- [5] "make the cable removable from the first sensor port in view of Fujisaki" (Pet. at 35, 56);
- [6] "include a plurality of ports positioned on the housing 112 and configured to receive signals from the blood pressure and electrolyte (or other) sensors via wired connections" (Pet. at 27, 41, 56);
- [7] "include a battery in the portable device of Goldberg" (Pet. at 39, 57);
- [8] "use a rechargeable battery" (Pet. at 39, 57);
- [9] "include sensor interfaces for receiving and decoding sensor signals" (Pet. at 45-46, 57-59);
- [10] "provide the wired communication with the pulse oximetry sensor of Goldberg in the analog domain" (Pet. at 25, 57);
- [11] "a pulse oximetry sensor that detects both [pulse and oxygen saturation] parameters" (Pet. at 58); and
- [12] "communicate with a digital temperature sensor" (Pet. at 59).

Petitioner's multiple modifications are illustrated in the annotated drawings below. *See* EX1005 at FIG. 2 (annotated), EX1008 at FIG. 1 (annotated).



Petitioner ignores the teachings of the asserted references and uses hindsight to retrace the claims of the '735 Patent. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983). Without the '735 Patent as a roadmap, a PHOSITA would not have made the numerous modifications to Goldberg or combined the teachings of other asserted references.

# B. <u>Estep is Non-Analogous Art and Cannot be Combined with Goldberg or</u> <u>Money for Grounds 3 and 4</u>

For Grounds 3 and 4, Petitioner relies on Estep in combination with multiple references. But Petitioner fails to argue, much less establish, that Estep qualifies as analogous prior art, which 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, Estep must be either: (1) from the same field of endeavor as the '735 Patent; or (2) reasonably pertinent to the particular problem the inventor is trying to solve. *See id.* The '735 Patent and Estep are in different fields of endeavor because the '735 Patent addresses portable medical monitoring devices secured to the lower arm of a patient, EX1001 at

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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 EX1009 at Abstract, 1:13-19; EX2010 ¶¶ 118-120; see also In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (internal citations omitted). In addition, 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 '735 Patent, which was to provide hospital grade, portable patient monitoring without the loss of physiological measurements. See EX1001 at 1:40-52, 2:22-28; EX2010 ¶¶ 121-123. Petitioner has failed to show that Estep is analogous art to the '735 Patent, and it cannot cure this deficiency 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 Grounds 3 and 4.

# C. <u>Petitioner Fails to Show Unpatentability of Any Claim Based on Money</u> (Grounds 5-8)

Petitioner's grounds based on Money are deficient for multiple reasons. First, a PHOSITA would not have selected Money as a primary reference. Money is not a wrist-worn device. Second, Money describes a data signal configuration opposite to the claimed data signal configuration, and Petitioner presented no credible motivation to modify Money to create a device with the claimed data

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signal configuration. Petitioner failed to present a reason to substitute Money's pulse oximetry cuff transducer with Akai's optically-communicating SpO<sub>2</sub> sensor or to convert Money's analog temperature sensor to a digital temperature sensor. Third, the proposed combinations with Money still lack all the claim elements. These failures demonstrate that hindsight guided an improper reconstruction.

#### 1. <u>A PHOSITA Would Not Have Selected Money as a Reference</u>

Petitioner fails to demonstrate why a PHOSITA would have selected Money as a primary reference for a wearable monitor. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1336-37 (Fed. Cir. 2016) ("Whether a skilled artisan would be motivated to make a combination includes whether he would select particular references in order to combine their elements."). Petitioner's expert testified that, when designing a wearable monitor in March 2002, a person of skill would start with designs most accepted by clinicians at that time. (EX2012 at 48:10-12.) However, Petitioner characterized Money as including an allegedly "outdated pulse oximetry cuff transducer." *See* Pet. at 74, fn. 3. Petitioner provides no reason a skilled artisan would begin with an outdated product.

Money's device receives digital data from a pulse oximeter sensor and receives analog data from all of the other sensors. EX1008 at 5:18-51; EX2010  $\P\P$  59, 108, 146. This is the *opposite* sensor configuration of that recited in the claims.

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Moreover, Money does not disclose a device configured to be secured on a lower arm of a patient. Mr. Oslan confirms that a PHOSITA would not have selected Money as a primary reference for at least that reason. EX2010 ¶¶ 126-Money explains its invention "pertains to devices and systems used in 131. hospitals to monitor vital signs associated with a hospitalized patient." EX1008 at 1:8-10. Yanulis admitted that a PHOSITA usually tries to design a wearable device that wears comfortably over the wrist because patients "are already, first of all, very sick to begin with, [and] no. two, they are already in a lot of discomfort, so you don't need to add any device that's going to be bigger or uncomfortable for these patients to wear." EX2012 at 32:14-22. But Money's device is roughly the size and weight of three modern smartphones stacked together. EX2010 ¶ 131. Money's device includes a housing that is at least the actual size of the drawing shown below—approximately one inch thick, three inches wide, and six inches long, weighs up to sixteen ounces, and uses four AA batteries. EX1008 at 3:39-45, 5:4-8.

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*Id.* at FIG. 10 (partial). A PHOSITA would have understood that it would have been difficult for a hospitalized patient to support the weight of Money's device on their lower arm. EX2010 ¶ 130. Based on the weight and dimensions of Money's device, a PHOSITA would have understood that a patient would most likely wear this device on his or her waist, not strapped to a wrist. *Id.* ¶¶ 128-131. Strapping Money's housing to the patient's wrist would require resizing the housing and reconstructing the hardware components within the housing. *Id.* ¶¶ 143-145. But as outlined below, Petitioner's proposed modifications would have increased the overall size of Money's monitor and sensors. *Id.* ¶ 143; *see infra* § V.C.4, V.C.5.a.

# 2. <u>None of the Asserted References Teach The Claimed Data Signal</u> <u>Configurations</u>

Petitioner also fails to demonstrate that the proposed combination includes a physiological sensor, separate from the pulse oximetry sensor, that provides a digital signal, which is required by all the independent claims. As argued by Petitioner, Money teaches a pulse oximetry cuff transducer that provides digital communication. Pet. at 74 ("Money teaches the pulse oximetry cuff connects to the RS232 serial port and provides digital packets representing oxygen saturation values."). Petitioner does not argue that any other sensors in Money provide digital communication. Nor could it, because the sensor configuration of Money is the opposite of that recited in the claims. *See* EX1008 at FIG. 1 (reproduced below, annotated); EX2010 ¶ 108, 146.



Money receives digital data from only its pulse oximeter sensor. EX1008 at 5:38-39, 6:15-20, 7:58-62, 8:20-27, 13:26-28. Money receives analog data from all its other sensors. *Id.* at 5:18-51, 8:20-27, FIG. 1. Petitioner also fails to demonstrate that any of the other asserted references teach or suggest digital sensor communication. Accordingly, Petitioner fails to show how the combinations of asserted references would teach the data signal configurations recited in the claims.

## 3. <u>The Combinations of References Do Not Teach Electrically</u> Conveying the First Signal in Claim 20

Specific to Claim 20, Petitioner fails to demonstrate the references relied upon in Ground 8 disclose "a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal." Petitioner alleges "[i]t would have been obvious to substitute the finger-mounted SpO<sub>2</sub> sensor of Akai for the pulse oximetry transducer cuff taught by Akai." Pet. at 94. Besides failing to provide evidentiary support for this substitution (*see infra* § V.C.4), such a modification would have provided a cable configured to *optically* convey the first signal, not electrically as required by Claim 20. EX2010 ¶¶ 132-136.

Petitioner's discussion of this limitation is limited to one sentence—"Akai teaches the wired connection between the SpO<sub>2</sub> sensor and the CPU is a cable." Pet. at 95. But the cited portion of Akai recites that "data processing unit 113 has an appropriate interface such as an *optic fiber* between itself and sensor unit 112." EX1007 at 5:14-17 (emphasis added). The differences between electrical cables

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and optical fibers are not trivial. EX2010 ¶¶ 132-136. First, optical fibers transmit signals using light, not electricity. *Id.* ¶ 133. Second, the sensor hardware for controlling light and providing an optical signal to an optical fiber is different from the sensor hardware for controlling electricity and providing an electrical signal to an electrical cable. *Id.* Petitioner fails to demonstrate that Akai's SpO<sub>2</sub> sensor is even capable of providing an electrical signal. Petitioner also fails to demonstrate how a PHOSITA could have modified Akai's SpO<sub>2</sub> sensor to provide an electrical signal.

Thus, Petitioner has failed to establish that the combination of Money, Akai, Kiani, Fujisaki, and Estep teaches all of the features of Claim 20.

# 4. <u>Petitioner Fails to Demonstrate a PHOSITA Would Have Been</u> <u>Motivated to Substitute Money's Pulse Oximetry Cuff</u> <u>Transducer with Akai's SpO<sub>2</sub> Sensor</u>

For all claims, Petitioner relies upon an unsupported motivation to substitute Money's pulse oximetry cuff transducer with Akai's light-based SpO<sub>2</sub> sensor by arguing that this modification would "predictably measure pulse oximetry noninvasively." Pet. at 63; *see also id.* at 71, 86, 94. But Petitioner presents no evidence that Money lacks a light-based sensor. *See* EX2012 at 15:17–16:9 (admitting that pulse oximetry sensors "have to use light in some way.") Petitioner also presents no evidence that Akai's SpO<sub>2</sub> sensor would "predictably measure pulse oximetry non-invasively" any better than Money's cuff transducer. *See* Pet.

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at 63. Indeed, Yanulis could not recall ever seeing a pulse oximetry cuff transducer, and he could not describe a single feature of such a device. EX2013 at 235:21–236:15. Thus, Yanulis' opinions related to Money's pulse oximetry cuff transducer and his reasons for substituting the light-based SpO<sub>2</sub> sensor of Akai are entitled to little or no weight. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). As Mr. Oslan explains, a PHOSITA would have known that Money's pulse oximetry cuff transducer is already non-invasive and light-based, EX2010 ¶¶ 137-142, thus eliminating Yanulis' reasons for the proposed modification.

A PHOSITA would also have understood that Akai's SpO<sub>2</sub> sensor and optic fiber would have been incompatible with Money's monitoring device, without further modifications. EX2010 ¶¶ 132-135. If Akai's SpO<sub>2</sub> sensor and optic fiber were connected to Money's electrically communicating SpO<sub>2</sub> port, a PHOSITA would have understood that Akai's SpO<sub>2</sub> sensor would be unable to convey any signals to Money's monitoring device. *Id.* ¶¶ 133-134. It would not have been possible to connect Akai's optic fiber to Money's monitoring device without replacing Money's SpO<sub>2</sub> port and sensor interface with an optical-to-electrical port and sensor interface. *Id.* ¶ 134. Even then, the optical signal from Akai's SpO<sub>2</sub> sensor would have been incompatible with the electrical circuitry of Money's

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monitoring device without additional conversion circuitry, which would undesirably increase the overall size of Money's monitoring device. *Id.* Moreover, even if a PHOSITA were capable of making Akai's optic fiber compatible with Money's monitoring device, the modified device still would not electrically convey a signal, as required by Claim 20. *Id.* 

Finally, a PHOSITA would not have been motivated to modify the  $SpO_2$  sensor to provide an electrical signal because replacing the optic fiber with an electric cable would amount to substantially redesigning the entire sensor. *Id.* ¶ 135.

Petitioner and Yanulis fail to address any of these considerations in their analysis and provide no reason, other than hindsight, to make Akai's SpO<sub>2</sub> sensor compatible with Money's monitoring device.

## 5. <u>A PHOSITA Would Not Have Been Motivated to Modify Money</u> to Include the Claimed Data Signal Configurations

Petitioner also fails to demonstrate that a PHOSITA would have been motivated to combine the references relied upon in Grounds 5-8 to arrive at the data signal configurations recited in the independent claims.

Petitioner ignores the only sensor arrangement taught by Money (i.e., digital signals from the pulse oximetry sensor and analog signals for the other sensors) and suggests, without evidence, that a PHOSITA would have been motivated to provide the opposite data signal configuration. *See Polaris Indus., Inc. v. Arctic* 

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*Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018) (a reference's "statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference"). As explained above, it is not "irrelevant" whether the signal received is analog or digital. *See supra* § V.A.3.b; EX1003 ¶ 71. Petitioner and Yanulis fail to address any of the considerations that would affect a PHOSITA's decision to transmit an analog signal versus a digital signal. *See supra* § V.A.3.b.

#### a) <u>A PHOSITA Would Not Have Been Motivated to Modify</u> Money to Include an Analog Pulse Oximetry Sensor

Because Money does not disclose a pulse oximetry sensor with an analog signal, Petitioner argues for replacing Money's pulse oximetry cuff with Akai's light-based, finger-positioned pulse oximetry sensor. Pet. at 71. However, as explained above, neither Petitioner nor Yanulis explains why Money's pulse oximetry cuff does not already predictably measure oxygen saturation non-invasively. *See supra* § V.C.4. In addition, neither Petitioner nor Yanulis acknowledges the consequences of this substitution. Replacing Money's pulse oximetry cuff with Akai's finger-positioned pulse oximetry sensor would remove the only sensor in the asserted references that provides a digital signal. EX2010 ¶ 146. Petitioner has not explained how the results of the substitution would have predictably measured oxygen saturation given the substantial reconstruction of Money required to accommodate Akai's SpO<sub>2</sub> sensor. *See supra* § V.C.4.

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Petitioner also fails to address the design considerations involved in designing wearable monitors, such as size and power utilization. For example, Petitioner fails to address how the proposed modifications would affect the size of Money's already large, bulky device. See supra § V.C.1. Yanulis explained that "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. But adding parts to Money's monitoring device to process the analog and optical signal of Akai's SpO<sub>2</sub> sensor would increase the size of Money's monitoring device. EX2010 ¶ 134. Petitioner also fails to address how the proposed modifications would affect the power utilization of Money's device. When asked whether power consumption is a consideration that would affect a person of skill's decision to transmit in analog versus digital, Yanulis testified:

Very much so. A lot of the devices, especially in these patents, power consumption is a very important consideration. The type of battery used, how long are you going to be -- is there a mechanism to quickly charge the battery. Or do the components utilize too much power which increases the probability of component failure. As a PHOSITA, you should be concerned with these parameters.

EX2013 at 158:22–159:11. Nowhere does Petitioner or Yanulis address these important design considerations.

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Moreover, Petitioner never explains where Akai's SpO<sub>2</sub> sensor would connect to Money's device in the proposed modification. Because none of Money's other ports would have been compatible with Akai's SpO<sub>2</sub> sensor, a PHOSITA would need to add another port to accommodate Akai's SpO<sub>2</sub> sensor. EX2010 ¶ 146. But a PHOSITA would not have been motivated to add another port to Money's already oversized housing to accommodate Akai's SpO<sub>2</sub> sensor. *Id.* Petitioner itself recognizes that "addition of a fifth analog port, in addition to the RS232 port, might affect Money's careful power management." Pet. at 75.

# b) <u>A PHOSITA Would Not Have Been Motivated to Modify</u> <u>Money to Include a Digital Temperature Sensor</u>

To support its argument that the proposed combination includes the digital signal required by the claims, Petitioner proposes that a PHOSITA would have been motivated to "modify Money's [analog] temperature sensor to communicate via the RS232 port" and to "move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor." Pet. at 74-75. Yanulis offers no rational explanation as to why the proposed modifications would be desirable or effective.

#### (1) <u>Money Does Not Have a Dual-Purpose External</u> <u>Sensor Port</u>

Petitioner's motivations to change the temperature sensor to send a digital signal rely entirely on Petitioner's first proposed modification of replacing
Money's pulse oximetry cuff transducer with Akai's SpO<sub>2</sub> sensor in a manner that would leave an external port on Money unoccupied. But a PHOSITA would not have been motivated to make that first modification. *See supra* § V.C.4.

Moreover, Petitioner argues a PHOSITA would be motivated "to modify Money's temperature sensor to communicate via the RS232 port because otherwise the RS232 port would not serve the dual-purpose taught by Money." Pet. at 75. Yanulis identifies the dual purpose of the RS232 port as "receiving data from a sensor" and "maintain[ing] the debug versatility provided by the RS232 serial port[]." EX1003 ¶ 223. But this dual-purpose argument regarding the RS232 port is incorrect and conflates Money's description of multiple different connections into a single connection. Money provides two *separate external* connectors: a port for connecting to a digital SpO<sub>2</sub> sensor, and a separate DB9-type serial port 16 used for debugging purposes. EX2010 ¶¶ 150-152. Thus, contrary to Yanulis' statement, there is no single external port on Money that serves the dual purpose of receiving data from a digital SpO<sub>2</sub> sensor and providing debug functionality. *Id.* Petitioner cannot support its proposed motivation of maintaining a dual purpose of an external port on Money.



EX1008 at FIG. 1.

### (2) <u>Petitioner's Motivations to Use a Digital Signal are</u> <u>Hindsight-Driven</u>

Petitioner's selection of Money's temperature sensor as "the most obvious candidate" to transmit digital data (Pet. at 75) also lacks any analysis as to whether a PHOSITA would be motivated to provide the temperature data as an analog signal or a digital signal. Yanulis initially opined that "[t]ransmitting a digital value of a patient's temperature via a digital packet would have been particularly obvious because the temperature sensor 77 only measures one discrete value (exactly like oxygen saturation)." EX1003 ¶ 224. However, he admitted during his deposition that the transmission of temperature measurements as analog or digital would "depend on what critical -- or what clinical setting you're in." EX2013 at

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147:1-14. Yanulis acknowledged there are conditions in which PHOSITA would want to receive information from a thermistor as an analog signal, for example if a patient is in the operating room. *Id.* at 147:15–148:4. Yanulis' testimony demonstrates that Petitioner's arguments to modify the temperature sensor do not fully consider the design considerations at issue.

Petitioner also suggests that "[a] PHOSITA would obviously move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor such that the temperature sensor outputted the digital temperature value to the RS232 port," Pet. at 75, but does not address any costbenefit analysis of the proposed modifications. Yanulis acknowledged that hardware is "an important consideration" that would affect a person of skill's decision to transmit an analog versus digital signal because "[y]ou want to be somewhat cognizant of, I mean, cost analysis benefit." EX2013 at 154:21–155:16. But Yanulis' opinions contain no cost-benefit analysis of this issue. In patient monitoring systems, the sensors are typically disposable and the monitoring device is reusable. EX2010 ¶¶ 114, 154. Moving the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor would unquestionably increase the cost of the temperature sensor. Id. ¶ 154-155. Petitioner fails to explain how the increased cost of the temperature sensor is justified by anything other than hindsight.

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Petitioner also argues that PHOSITA would be motivated to modify Money's temperature sensor to communicate via the RS232 port to "continue efficient use of the RS232 port" because the addition of a "fifth analog port" to accommodate Akai's SpO<sub>2</sub> sensor "might affect Money's careful power management". Pet. at 75. But modifying the temperature sensor to output a digital signal rather than an analog signal would negatively increase power consumption. EX2010 ¶ 155. As shown below in FIG. 1 of Money, the analog-to-digital converter is integral with processor 14, which connects to several sensor inputs. *Id.* Thus, a PHOSITA would have to *duplicate* power consuming components like the analog-to-digital converter for the modified temperature sensor, which would undesirably increase power consumption. *Id.* 



Finally when explaining why hardware is a consideration that would affect a PHOSITA's decision to transmit in analog versus digital, Yanulis testified: "If it works, don't fix it." EX2013 at 155:4-16. Petitioner and Yanulis have not articulated anything wrong with the sensor configuration of Money that justifies the proposed modifications.

Petitioner's lack of support for these modifications, and the numerous other modifications discussed below, demonstrate that Petitioner's numerous changes to Money are hindsight-driven.

### 6. <u>Petitioner's Additional Modifications to Money Rely on Hindsight</u> to Try To Arrive at the Claimed Invention

Petitioner's numerous modifications to Money would require a substantial reconstruction and redesign of Money, and as explained above, Petitioner has not demonstrated that a PHOSITA would be motivated to make several of these changes. *See supra* §§ V.C.4, V.C.5. Without an actual motivation to combine the teachings of the asserted references, the proposed modifications evidence hindsight reconstruction, not obviousness. Counter to the "as a whole" requirement under 35 U.S.C. § 103, Petitioner uses the claims of the '735 Patent as a roadmap to piece together individual elements from different references. *See Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004).

For all independent claims, Petitioner suggests at least the following modifications:

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- [1] "include a strap and mount the housing of Money to the patient's wrist in view of Akai" (Pet. at 66);
- [2] "include the port taught by Kiani" (Pet. at 69);
- [3] "modify Money's housing (if necessary) to have a wire configuration like Akai's" (Pet. at 70);
- [4] "substitute the cuff transducer of Money with a light-based, finger positioned, SpO<sub>2</sub> sensor" (Pet. at 71);
- [5] "include a plurality of ports configured to receive signals from the pulse sensor, body sensor, or ECG sensor via wired connections" (Pet. at 73);
- [6] "would not plug [the SpO<sub>2</sub> sensor] into the RS232 port" (Pet. at 74);
- [7] "modify Money's temperature sensor to communicate via the RS232 port" (Pet. at 75); and
- [8] "move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor" (Pet. at 75).

Petitioner's multiple modifications are illustrated in the annotated drawings below. EX1008 at FIG. 1 (annotated), EX1007 at FIG. 1 (annotated).



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In addition, independent claim 13 (Ground 6) and independent claim 20 (Ground 8) require additional references and further modifications. The record provides no evidence to support the numerous changes required to modify Money. Indeed, Petitioner suggests modifications to Money that are not disclosed by any of the references relied upon in Grounds 5-8. *See supra* § V.C.2. Petitioner simply ignores the teachings of the asserted references and uses hindsight to retrace the claims of the '735 Patent. *See W.L. Gore*, 721 F.2d at 1553.

Petitioner suggests that several of the proposed modifications are "purely conventional," a "simple substitution," or "uses a known technique," but the proposed modifications would not have been as simple as Petitioner suggests for at least the reasons outlined above. *See supra* §§ V.C.4, V.C.5.

### D. <u>Estep is Non-Analogous Art and Cannot be Combined with Goldberg or</u> <u>Money for Grounds 7 and 8</u>

Because Petitioner's grounds (Grounds 7 and 8) additionally use Estep in combination with multiple references, a threshold issue affecting those grounds is whether Estep qualifies as analogous prior art. As explained in Section V.B, Petitioner has not shown that Estep is analogous art. The Board should affirm the patentability of the challenged claims in Grounds 7 and 8 due to Petitioner's failure to establish a *prima facie* case of obviousness.

## VI. RESERVATION OF RIGHTS

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. <u>CONCLUSION</u>

For the foregoing reasons, Patent Owner respectfully requests that the Board confirm the patentability of all challenged claims of the '735 Patent.

Respectfully submitted,

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Dated: February 23, 2021

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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 13,512 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 23, 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 23, 2021, to the e-mail addresses shown below:

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