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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 PRELIMINARY RESPONSE

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
2001	Masimo's Opposition to Sotera's Motion to Stay Proceedings, dated June 8, 2020, filed in *Masimo Corp. v. Sotera Wireless, Inc.*, 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 *Inter Partes* 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 *In re: Sotera Wireless, Inc.*, BK No. 16-05968-LT11 (SD Cal. BK) (Exhibit 1019 in IPR2020-000967)

Pursuant to 35 U.S.C. § 313, 37 C.F.R. § 42.107 and the Notice of Filing Date Accorded to Petition, dated May 28, 2020, Masimo Corporation ("Masimo") hereby timely submits its Preliminary Response to the Petition for Inter Partes Review of U.S. Patent No. 9,788,735 filed May 18, 2020, by Sotera Wireless, Inc. ("Sotera" or "Petitioner"), which also names Hon Hai Precision Industry Co., Ltd. as a real party-in-interest.

I. INTRODUCTION

Masimo's claimed invention addresses challenges associated with portable patient monitoring. Ex. 1001 at Abstract; *see also* Ex. 2006 at 31 (noting Masimo's development of breakthrough technology in patient monitoring, including pioneering motion tolerant oximetry, and Masimo's mission to "take noninvasive monitoring to new sites and applications"). Recognizing that "[c]onventional physiological measurement systems are limited by the patient cable connection between sensor and monitor" and that "patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables," Ex. 1001 at 2:22-28, the '735 Patent claims a solution that overcomes those shortcomings: an untethered wearable body worn mobile medical monitoring device with ports for multiple sensors and cable management.

Petitioner's continual copying of Masimo's innovations has resulted in several lawsuits, including a parallel district court action involving Petitioner's infringement of the '735 Patent. Petitioner delayed until the very end of the one-year period from initiation of Masimo's district court action to bring this deficient IPR challenge and relies upon the same invalidity arguments already asserted in district court, other than one additional secondary reference here. The district court case is set for trial more than two months before the possible due date of any final written decision, and has progressed well into discovery and claim construction. The factors set forth in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) support denial of institution of the Petition, as it would be an inefficient use of Board resources.

In addition, Petitioner incorrectly assumes the presence of missing features, materially mischaracterizes the alleged prior art, and engages in hindsight analysis by using the claims of the '735 Patent as a roadmap to propose numerous modifications not taught by any of the asserted references. For example, all claims require a physiological sensor that is separate from a pulse oximetry sensor and that provides digital communications. Petitioner misleadingly describes Money, a reference used in all eight grounds, as teaching a system that receives both analog and digital information from various sensors. Pet. at 12. However, the data signal configuration of the Money sensors is the ***opposite*** of that recited in the claims.

Money receives digital data from a pulse oximeter sensor and analog data from all other sensors. Ex. 1008 at 5:18-51, 8:20-27, 6:15-20, 7:58-62, 13:26-28.

Petitioner also suggests modifications that are contrary to its own expert's opinions. Petitioner's expert, Dr. 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." Ex. 1003 ¶ 29. Yet, in Grounds 1-4, Petitioner combines references in a manner would require the addition of multiple sensors, wires, and ports. Each of those additions would increase the size of the devices in the asserted references, which directly contradicts Dr. Yanulis' reasoning.

Further still, Petitioner fails to address any reasonable expectation of success in combining the asserted references, which require numerous modifications to support Petitioner's proposed combinations. Because of this deficiency, Petitioner cannot establish a *prima facie* case of obviousness for any of the challenged claims.

Because Petitioner has not demonstrated a reasonable likelihood of success as to any challenged claim, the Board should deny institution.

II. BACKGROUND

A. The ’735 Patent Overcomes Challenges Associated With Portable Patient Monitoring

Conventional patient monitoring systems typically require that a patient be tethered to a nearby monitor. Ex. 1001 at 2:22-25. The tethering consists of wires for separate sensors for each monitored physiological parameter (e.g., blood oxygen saturation, blood pressure, respiratory gas, EKG, etc.), each being connected to the patient bedside monitoring system. *Id.* at 1:40-52, 2:22-24. Thus, patient relocation requires either an awkward simultaneous movement of patient equipment and cables or disconnecting multiple sensors from the monitor, resulting in the loss of monitoring. *Id.* at 2:25-28.

The ’735 Patent addresses the challenge of providing hospital grade portable patient monitoring. *Id.* at 2:28-38. The claimed solution includes a body worn mobile medical monitoring device that includes multiple connectors for connecting multiple sensors, including a pulse oximetry sensor. *Id.* at 4:49-57, 5:29-47, 11:57–12:3, FIGS. 3-4A and 13. The wearable mobile device includes a transmitter for wirelessly transmitting information to another device. *Id.* at 8:46-49. The claimed system therefore frees a patient from the tether. It allows for patient movement without being limited to the length of sensor cables. That freedom allows for rapid patient relocation and allows a patient to be monitored while walking, for example.

To facilitate that freedom, the body worn mobile medical monitoring device also includes a strap mountable for securing the housing to the arm of a patient, and arrangement of sensor ports. *Id.* at 6:59–7:21. The ports accommodate sensors by data type, digital or analog, based on where the sensors are designed to be placed on a patient. This combination of features reduces the potential tangling of sensor cables.

The claimed system recites a monitor with a display so that the patient or health care provider can observe sensor measurements while the system is attached to the patient. *Id.* at 5:29-47, 6:35-67, 11:57–12:35, FIGS. 6 and 13.

The ’735 Patent includes three independent claims—claims 1, 13, and 20. 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:

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.

B. Petitioner's Emphasis on the "Substantially Perpendicular" Limitation of Claim 1 Does Not Accurately Reflect All of the Claims or Prosecution History

Petitioner presents the prosecution history of the '735 Patent in a manner that overemphasizes Amano and one limitation in Claim 1, namely a path from the to the pulse oximetry sensor to the digit of the patient that is "substantially perpendicular to the side of the housing." Pet. at 10. For example, Petitioner mentions that "the application was rejected in view of U.S. Patent No. 6,241,684 to Amano". *Id.* at 9. But several of the Amano-based rejections also included other references. Ex. 1012 at 4-6 (applying Amano with three other references for application claims 10-12 and 15-22).

Petitioner also alleges that "the Examiner amended the claims to recite a path to the pulse oximetry sensor 'substantially perpendicular to the side of the housing' to overcome Amano." Pet. at 10. But the claims were not allowed based on a single limitation alone. The Examiner also amended then-pending claim 2 (corresponding to issued claim 1) to recite "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." Ex. 1014 at 6-7. The Examiner amended then-pending claims 15 and 22 (corresponding to issued claims 13 and 20) to include digital signal limitations. Further, the Examiner did not reject then-pending claim 13 based on any prior art, and the Examiner's amendment incorporated certain features of claim 13 (e.g., multiple additional ports providing wired communications with multiple sensors) into each of the independent claims. Petitioner has omitted these facts from its description of the prosecution history.

Petitioner also misrepresents the Notice of Allowance, *id.* at 12-14, by incorrectly arguing that "the Examiner specifically pointed to the pulse oximetry sensor port's positioning on the housing as the difference between Amano and the claims." Pet. at 10. In fact, the Examiner found that

> "The prior art does not teach or suggest ***the positioning of the port in conjunction with two additional ports and in relation to the optical sensor components,*** as recited in the amended claims, ***in combination with other claimed features***, but rather indicates the connector is positioned at the 6 o'clock position (Amano – at col 9, lines 4-9) and button/switches for data entry/mode selection are positioned at 2, 4, 8 and 10 o'clock positions."

Ex. 1014 at 14 (emphasis added). Contrary to Petitioner's description, the Examiner did not focus on a single difference between Amano and the claims as

the reason for allowance. In fact, the Examiner further found that "there is no teaching or suggestion in the prior art to receive some data in analog form through a first port and other physiological data in digital form through a second port." *Id.* The Examiner's identification of these additional data signal features further confirms the inaccuracy of Petitioner's description.

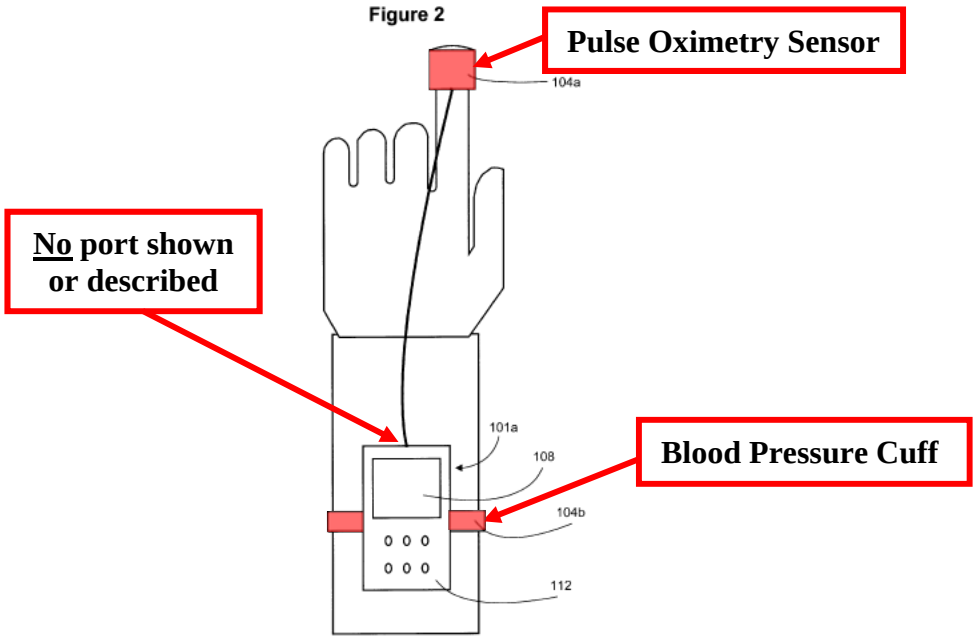
Accordingly, the Board should reject any suggestion by Petitioner that the only distinction between the '735 Patent and the prior art is the positioning of the pulse oximetry sensor port on the housing.

C. Overview of the Alleged Prior Art

Petitioner relies upon the following printed publications:

1. Goldberg (Ex. 1005)

Petitioner relies upon Goldberg, including the FIG. 2 embodiment below.



Ex. 1005 at FIG. 2 (annotated). FIG. 2 shows a device connected to a pulse oximetry sensor 104a and a blood pressure cuff sensor 104b. *Id.* at 4:57-67. Goldberg explains that the blood pressure cuff is also used to secure the device to a patient's wrist. *Id.* at 4:64-67. However, Goldberg has no port, either in the figures or the detailed description.

2. <u>Kiani (Ex. 1006)</u>

Petitioner also relies upon Kiani, in which a universal/upgrading pulse oximeter 210 (depicted in FIG. 2 of Kiani, reproduced below) receives a sensor signal through a patient cable 220, computes oxygen saturation and pulse rate, and synthesizes a signal that is sent to an external pulse oximeter 268 (which is part of a multiparameter patient monitoring system 260). Ex. 1006 at FIG. 2, 5:18-30.

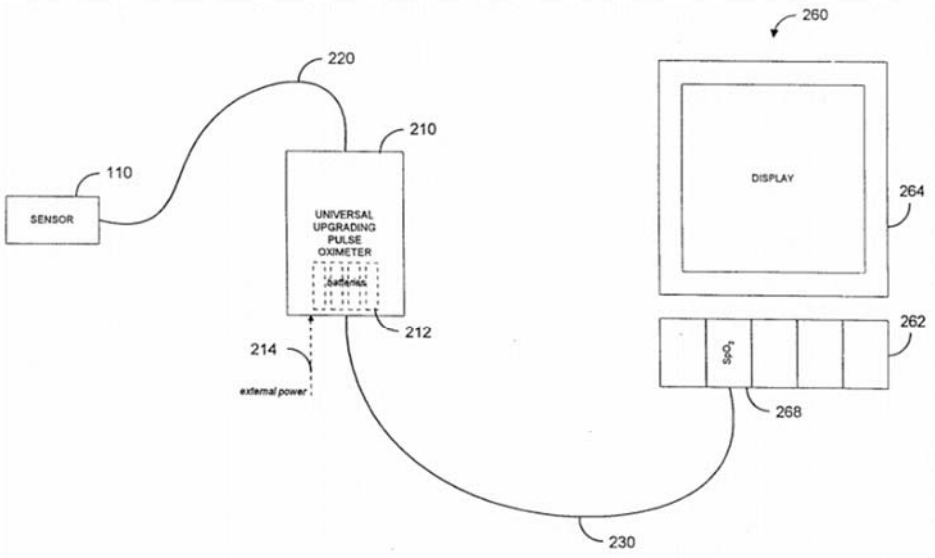


FIG. 2

Kiani also describes a handheld embodiment 500 (reproduced and annotated below) of the universal/upgrading pulse oximeter 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.

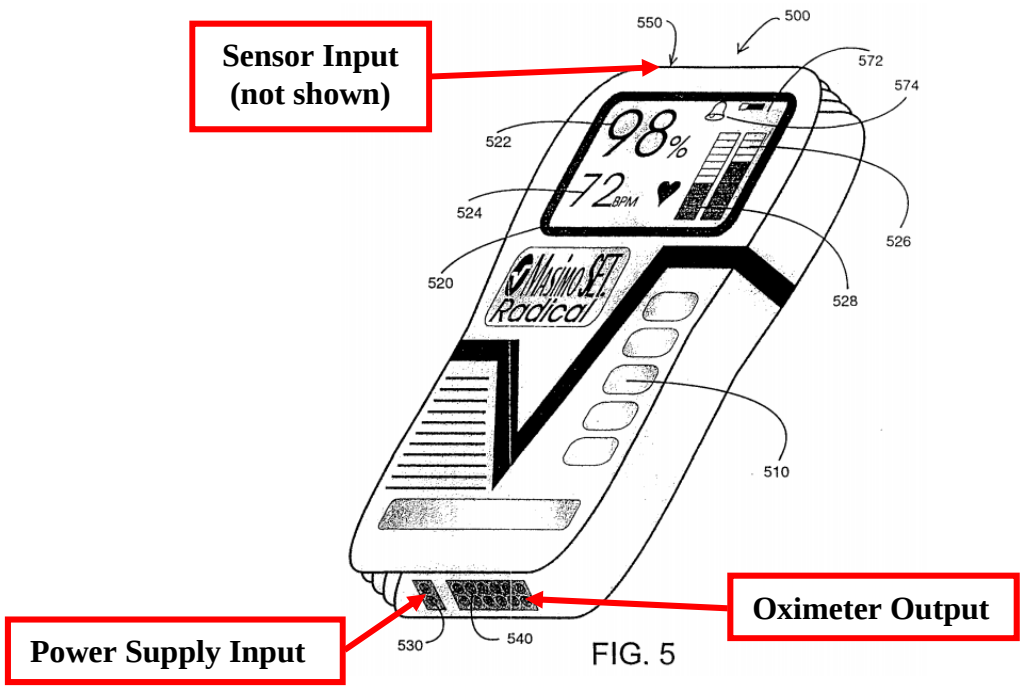


FIG. 5

3. Akai (Ex. 1007)

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. Ex. 1007 at 4:34-6:58, FIGS. 1-2 (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 to calculate a blood glucose value. *Id.* at 4:46-50, 5:30-42.

Fig. 1

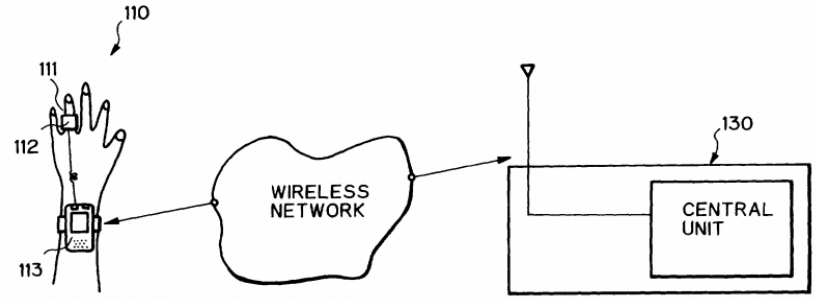
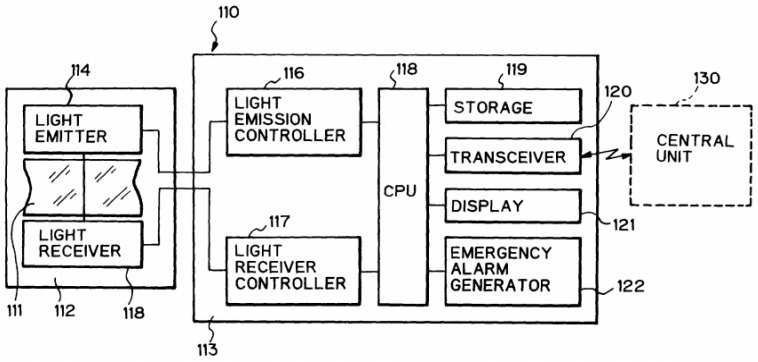


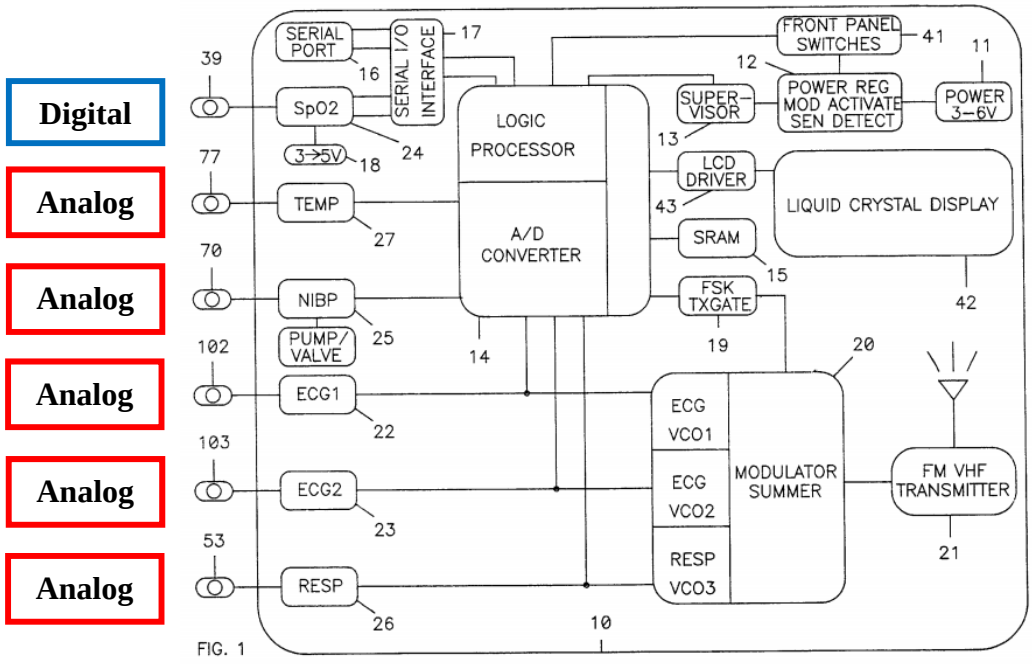
Fig. 2



4. <u>Money (Ex. 1008)</u>

Money describes a device with a housing that is approximately one inch thick, three inches wide, and six inches long, weighs up to sixteen ounces, and uses four AA batteries. Ex. 1008 at 3:39-45, 5:4-8. 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, none of

which is from a pulse oximeter. *Id.* at 5:18-51, FIG. 1 (reproduced and annotated below).



Money's disclosure also confirms that its device receives analog data from a temperature sensor (*id.* at 5:48-51, 8:20-27), a blood pressure sensor (*id.* at 5:42-44, 8:20-27), first and second ECG sensors (*id.* at 5:28-31, 8:20-27), and a respiration sensor (*id.* at 5:45-48, 8:20-27). The device receives digital data from a pulse oximeter sensor. *Id.* at 5:38-39, 6:15-20, 7:58-62, 8:20-27, 13:26-28. Money also discloses, and emphasizes the importance of, a particular power arrangement to achieve efficient power conversion and utilization. *Id.* at 3:37-62.

5. Estep (Ex. 1009)

Estep discloses an electrical signal measurement device for use in telecommunications measurement applications. Ex. 1009 at Abstract, 1:5-11.

Estep teaches the device can be a chest mounted unit. *Id.* at 2:8-12, 4:14-27, FIG. 3A (reproduced below).

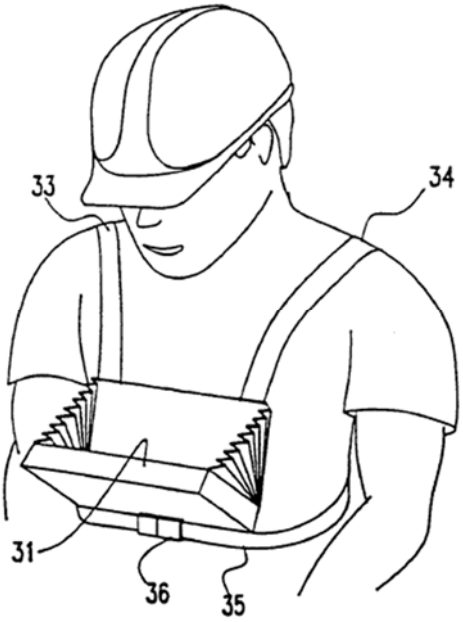
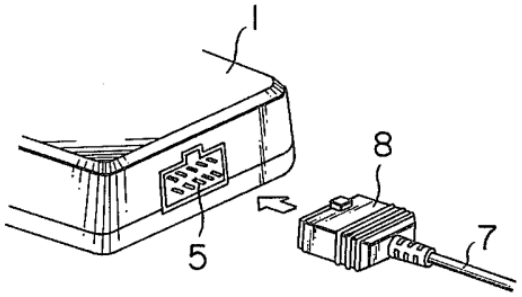


FIG.3A

6. <u>Fujisaki (Ex. 1016)</u>

Fujisaki discloses a wearable device for checking pulse rate or heart rate. Ex. 1016 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.

FIG. 2



III. THE BOARD SHOULD DENY INSTITUTION UNDER *FINTIV* BECAUSE THE DISTRICT COURT WILL DECIDE VALIDITY WELL BEFORE A FINAL WRITTEN DECISION

Congress created IPRs as a "complete substitute" for and an "alternative" to district court litigation for assessing validity of a patent. *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1317 (Fed. Cir. 2018). In the precedential *Apple Inc. v. Fintiv, Inc.* decision, the Board identified the following six factors the panel should consider under 35 U.S.C. § 314(a) to determine if an IPR trial would be an inefficient use of Board resources in view of a parallel district court proceeding: (1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; (2) proximity of the court's trial date to the Board's projected statutory deadline for a final written decision; (3) investment in the parallel proceeding by the court and the parties; (4) overlap between issues raised in the petition and in the parallel proceeding; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) other circumstances that impact the Board's exercise of discretion, including the merits.

Petitioner fails to acknowledge or address the *Fintiv* analysis. All six factors weigh strongly against institution in view of the parallel district proceeding, *Masimo Corp. v. Sotera Wireless, Inc.*, Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) ("District Court Action"), in which Masimo has asserted nine patents, including the '735 Patent, against Petitioner.

A. *Fintiv* Factor #1: there is currently no district court stay, and a stay is unlikely

There is currently no stay in the District Court Action, and a stay is unlikely. On May 20, 2020 Petitioner filed a Motion to Stay Proceedings, which remains pending with the district court. Masimo opposed because it has already incurred significant expenses related to the District Court Action and because a stay would unduly prejudice Masimo. The parties directly compete in the market, and Petitioner itself acknowledges that this competition is likely increasing. Ex. 2001 at 8-9. Many courts, including the one in which the District Court Action is pending, have found that direct competition between the parties evidences significant prejudice weighing against a stay. *See Whalen Furniture Mfg., Inc. v. Z-Line Designs, Inc.*, No. 3:11-cv-02958-H-DHB, Slip. Op. at 5 (S.D. Cal. July 12, 2013) (citing cases). A stay would also cause Masimo undue prejudice because it would likely push a trial date into late 2022, but the challenged patents will begin expiring in March 2022. Ex. 2001 at 10. Masimo diligently pursued Sotera for violating its patent rights, and the court is unlikely to grant a stay that would deprive Masimo of the ability to seek injunctive relief.

This factor weighs against institution.

B. *Fintiv* Factor #2: the court's trial date is months earlier than the Board's projected statutory deadline

"If the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*." *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 9 (PTAB Mar. 20, 2020). The scheduled district court trial date is September 21, 2021, consistent with the Court's Local Rules of having trial within 18 months of the June 2019 filing of Masimo's complaint. Ex. 2002 at 7; S.D. Cal. Patent L.R. 2.1(a)(3). The nine institution decisions are due between November 28 and December 16, 2020, and if instituted, final written decisions would be due between November 28 and December 16, 2021. Thus, the district court trial, which will resolve additional issues beyond patent validity, will proceed more than two months before final written decisions in these IPRs. *See Sotera Wireless, Inc. v. Masimo Corp*., IPR2020-00912, -00954, -00967, -01015, -01019, -01033, -01054, -01078, -01082 (PTAB).

The Board has routinely declined to institute petitions under *Fintiv* and *NHK* when the scheduled district court trial would occur before the Board's final written decisions. *See e.g., Next Caller Inc. v. TRUSTID Inc.*, IPR2019-00961, Paper 10, 9-15 (PTAB Oct. 16, 2019) (denying institution where district court trial was **three months** before FWD); *E-One, Inc. v. Oshkosh Corp.*, IPR2019-00161, Paper 16, 6-9 (PTAB May 15, 2019) (denying institution where trial was scheduled **one month**

before FWD); *ZTE USA Inc. v. Fractus SA*, IPR2018-01461, Paper 10, 16-17 (PTAB Feb. 28, 2019) (denying institution where district court "likely to go to **trial before** a final decision is reached"); *Intel Corp. v. VLSI Tech. LLC*, IPR2020-00112, Paper 15 (PTAB May 19, 2020) at 10.

This factor weighs against institution.

C. ***Fintiv* Factor #3: Petitioner waited as long as possible to file the petitions, after significant investment in the parallel proceeding**

If "the petitioner did not file the petition expeditiously . . . or even if the petitioner cannot explain the delay in filing its petition, these facts have favored denial." *Fintiv* (Paper 11) at 11–12; *see also Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019) (weighing the petitioner's unexplained delay in filing the petition in favor of denial). Here, Petitioner fails to explain why it waited until the very end of the one-year period, particularly as it employs essentially the same arguments presented in its March 20, 2020 invalidity contentions.

In the District Court Action, the parties are currently briefing claim construction with the hearing scheduled for November 3, 2020, before the expected institution decisions. Ex. 2003 at 2. Masimo served its infringement contentions on January 24, 2020 and Petitioner served invalidity contentions on March 20, 2020. Ex. 2004. Fact discovery will close on December 17, 2020, around the time of the institution decisions, and expert discovery is set to close March 9, 2021,

around the time Masimo's responses to these petitions would be due. *See* Ex. 2002 at 3. The District Court Action is far along, and the parties and Court have already invested substantial resources litigating the issues before the court—including patent validity.

In view of Petitioner's unexplained delay and the status of the District Court Action, this factor weighs against institution.

D. *Fintiv* Factor #4: there is substantial overlap between issues raised in the petition and in the parallel proceeding

Apart from the secondary reference Estep, Petitioner relies upon references and invalidity arguments in this Petition that it has already included in the District Court Action, confirming the substantial overlap in issues between the two proceedings. Petitioner uses the same two primary references—Goldberg and Money – that it has included in the District Court Action. Ex. 2004 at 6-7 (table rows A-01 through A-06). Petitioner also relies on similar secondary references for the same limitations it did in district court. *Id*. Estep is the only additional reference identified in the Petition and is used as a secondary reference in some of the grounds for a single limitation.

While Petitioner's contentions in the District Court Action include more grounds than the Petition, the Board has found that the assertion of additional invalidity grounds in district court is not a basis for institution under *Fintiv* or § 314(a). *See, e.g.*, *Google LLC v. Uniloc 2017 LLC*, IPR2020-00115, Paper 8, 8

(PTAB Mar. 27, 2020) (denying institution under *Fintiv* where petitioner raised "hundreds of obviousness combinations" in parallel district court action); *Sand Revolution II, LLC, v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 12, 16-17 (PTAB Feb. 5, 2020) (denying institution under § 314(a) where petitioner's litigation defenses raised 16 additional combinations).

This factor weighs against institution.

E. *Fintiv* Factor #5: Petitioner and the defendant in the parallel proceeding are the same party

It is undisputed that both Petitioner Sotera as well as Hon Hai Precision Industry Co., Ltd., whom Petitioner has named as a real party-in-interest here, are also defendants in the District Court Action. Pet. at 1.

This factor weighs against institution.

F. *Fintiv* Factor #6: the merits of Petitioner's arguments also weigh against institution

In view of the deficiencies in Petitioner's arguments identified in this Response, including obviousness grounds that lack support and explanation, the Board should deny institution on the merits. Thus, the sixth factor also weighs against institution.

In *Fintiv*, the Board denied institution where, as here, the petitioner raised substantially the same invalidity arguments in both forums and the district court trial date was two months before the IPR's final written decision. IPR2020-00019,

Papers 11 and 15 (PTAB Mar. 20, 2020). Petitioner's IPR also resembles the circumstances of *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, where the Board denied institution for similar reasons. IPR2018-00752, Paper 8, 20 (PTAB Sept. 12, 2018) (denying petition under §314(a) due to advanced stage of district court proceeding, the occurrence of the district court trial months before the scheduled final written decision, and the use of the same prior art and arguments in the district court and IPR proceedings). Consistent with *Fintiv* and *NHK*, the Board should deny institution here as an inefficient use of Board resources and a waste of the parties' time.

IV. PETITIONER FAILS TO SHOW A REASONABLE LIKELIHOOD OF UNPATENTABILITY OF ANY CLAIM

A. Petitioner Fails to Meet the Legal Standard for Institution Based on Obviousness

Petitioner has not demonstrated a reasonable likelihood of success with respect to *any* challenged claim of the '735 Patent due to its failure to establish a *prima facie* case of obviousness. These failures include insufficient motivations to combine, failure to address reasonable expectation of success, and improper reliance on hindsight.

1. Petitioner Has Not Demonstrated Sufficient Motivations to Combine

For Petitioner to prevail on any ground based on obviousness, it is not sufficient to simply identify individual components of the claims—it must show

why a "skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Petitioner must provide some motivation for each and every modification to a prior art reference, no matter how simple. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). To satisfy its burden of proving obviousness, a petition cannot rely on "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Rather, it must set forth "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007) (internal citation omitted). Similarly, a petition cannot simply rely on an expert's unsubstantiated and conclusory opinions to prove obviousness. *See* 37 C.F.R. § 42.65 ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (affirming that Petitioner failed to establish obviousness where expert testimony "add[ed] nothing beyond the conclusory statements in [the] petition."). As shown in Sections IV.A, IV.B.1, IV.B.2, IV.C.2, and IV.C.3 below, Petitioner's motivations to combine rely on conclusory and unsupported assertions, contradict other opinions offered by its expert, or are inconsistent with the references themselves.

2. Petitioner Is Silent on Reasonable Expectation of Success

A motivation to combine references must also be "accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Sys. Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016); *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1335 (Fed. Cir. 2013). Thus, to establish a *prima facie* case of obviousness, a petitioner must demonstrate "that the skilled artisan would have had a ***reasonable expectation of success***" for the alleged combination. *Magnum Oil*, 829 F.3d at 1381 (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (internal quotations omitted, emphasis added); *see also Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015). As the Federal Circuit explained, "a clear, evidence-supported account of the contemplated workings of the combination is a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so." *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017).

Petitioner fails to ***mention*** a reasonable expectation of success even once, let alone marshal evidence to support its position. Petitioner's failure to address this requirement for any of the grounds is fatal to its Petition. Indeed, Petitioner's expert, Dr. Yanulis, concedes that "the proper analysis of obviousness ***requires*** a

determination of whether a person of ordinary skill in the art would have a 'reasonable expectation of success.'" Ex. 1003 ¶ 50 (emphasis added). Yet Dr. Yanulis offers ***no*** opinion or evidence demonstrating an expectation of success exists for Petitioner's combinations and modifications of the myriad of cited art. Thus, the Petition is deficient on its face—it does not even satisfy its ***own*** expert's recitation of the showing required for a "proper analysis of obviousness."

Petitioner's passing comments that its proposed modifications would "predictably" result in the claimed invention fall short. *See, e.g.*, Pet. at 22, 27, 29, 46. First, Petitioner did not support these comments with any evidence. Second, predictability is not the same as an expectation of success, as recognized by Petitioner's own expert, who distinguishes them as two different inquiries. Ex. 1003 ¶ 50. In order to show a "predictable result" from the combination of multiple references, Petitioner must show "not only [] the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009). Yet, neither Petitioner nor Dr. Yanulis explain why a skilled artisan would have reasonably expected the proposed modifications or combinations to successfully result in the claimed invention. In some instances, the proposed combinations of references do not even disclose all of the claimed features (i.e., multiple sensor ports, a signal from the

second sensor arrangement that includes digital information). Petitioner's assertions of predictability to overcome such shortcomings is insufficient to establish a reasonable expectation of success.

3. Petitioner Improperly Uses Hindsight

An appropriate obviousness inquiry also must be made without any "hint of hindsight." *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011). Petitioner may not "simply retrace[] the path of the inventor with hindsight, discount[] the number and complexity of the alternatives, and conclude[] that the invention . . . was obvious." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). Likewise, "[c]are must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." *In re NTP, Inc.*, 654 F.3d 1279, 1299 (Fed. Cir. 2011) (internal quotations omitted). Petitioner improperly uses hindsight to argue for multiple changes to Goldberg and a reconfiguration of Money. *See* Sections IV.B.3, IV.C.5.

Petitioner is bound by its Petition. *See Magnum Oil*, 829 F.3d at 1381 (Board cannot "decide unpatentability theories never presented by the petitioner."). Because Petitioner has failed to articulate the necessary elements to make out a

prima facie case of obviousness, it has not met its burden of showing a reasonable likelihood of success on the merits.

B. Petitioner Fails to Show a Reasonable Likelihood of Unpatentability of Any Claim Based on Goldberg (Grounds 1-4)

Petitioner fails to show a reasonable likelihood of unpatentability of the claims in Grounds 1, 2, and 4, including independent claim 1 (Ground 1), independent claim 13 (Ground 2), and independent claim 20 (Ground 4), due to Petitioner's deficient arguments regarding the multiple sensor port limitations and the data signal limitations, as discussed below. Ground 3 challenges claims 10–12, which depend indirectly from independent claim 1. The arguments in Ground 3 do not address the deficiencies in Ground 1. Therefore, Petitioner has not shown a reasonable likelihood of unpatentability of any of the challenged claims in Grounds 1–4.

1. Petitioner's Arguments Regarding The Multiple Sensor Port Limitations Are Deficient

a) Petitioner Fails to Establish That The Combinations of Asserted References Teach Multiple Sensor Ports

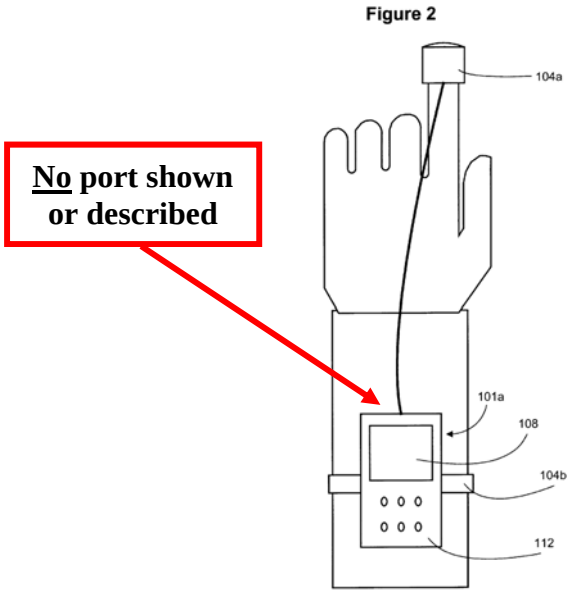
Petitioner fails to show that the references relied upon in Grounds 1-4 teach the following multiple port features required by the independent claims:

- "a first sensor communication port" and "a plurality of additional sensor communications ports" (Claim 1);

- "a first communications port," "a second communications port," and "a third communication port" (Claim 13); and
- "a first sensor port," "a second sensor port," and "a third sensor port" (Claim 20).

Petitioner argues that Goldberg and Kiani render these limitations obvious. Pet. at 20-23, 26-29. But the references do not teach these limitations, and Petitioner mischaracterizes the teachings of Goldberg and Kiani in its argument.

Petitioner improperly contends 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 (emphasis added). However, Goldberg's sole figure illustrating the physical configuration of the device, FIG. 2 below, does not show even one port.

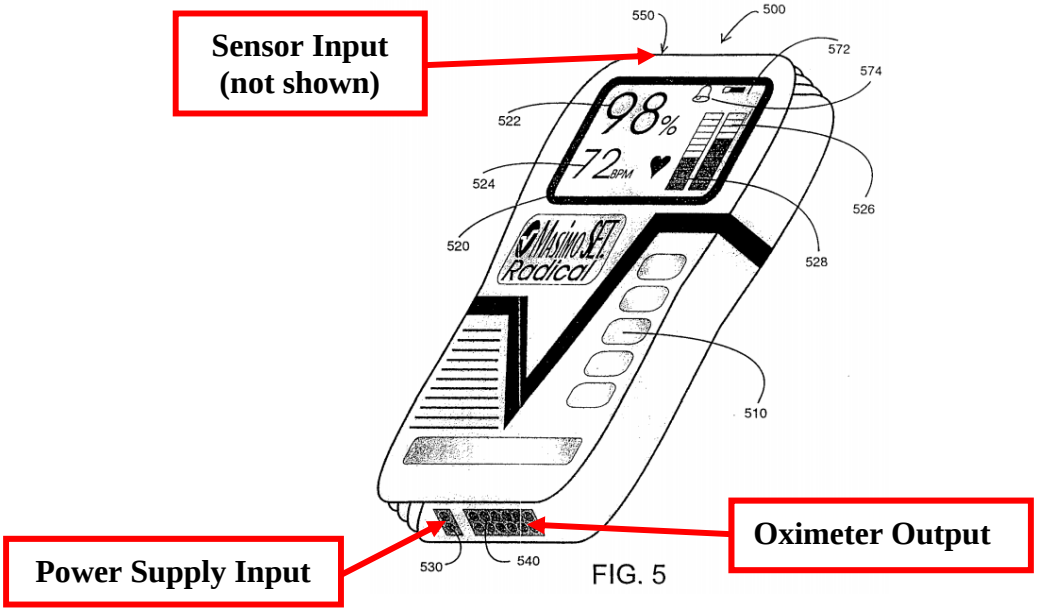


Ex. 1005 at FIG. 2 (annotated). Goldberg shows a hardwired connection between the sensor 104a and the housing 112. There is no connector shown, let alone a port. In fact, Petitioner's assertions are inconsistent with Dr. Yanulis' own statements that "[a] port is typically a female connection or socket of a wired connection." Ex. 1003 ¶ 64. Nowhere does Goldberg describe or show a female connection or a socket.

Petitioner then layers on an additional assumption. 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). However, Petitioner cannot show that a claim limitation is met by mere assumption. *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).

Petitioner incorrectly suggests that Kiani "merely states the inferences a PHOSITA would make when reading Goldberg." Pet. at 22. In particular, Petitioner inaccurately describes FIG. 5 of Kiani as showing "sensor input ports 540, 550." Pet. at 22. But Kiani actually discloses "an output port 540 for connection to an external pulse oximeter and a sensor input 550 at the top edge (not visible)." Ex. 1006 at 8:31-33, FIG. 5 (reproduced below, annotated). Kiani discloses only one sensor port 550. Indeed, Petitioner implicitly acknowledges that

Kiani does not disclose multiple sensor ports by relying on a duplication of parts argument to support additional sensor ports. *See* Pet. at 27.



Petitioner's representation that "Kiani teaches that sensor input ports 540, 550 were well-known for wired communication" is also unsupported. *Id.* at 22. Petitioner fails to provide any evidence other than Dr. Yanulis's conclusory testimony that ports on body worn medical devices were well-known at the time of the invention. Dr. Yanulis fails to support that opinion with even a single prior art reference showing multiple sensor ports on a wrist worn medical device. And he certainly did not find it in the prior art cited by Petitioner. Such an unsupported opinion cannot establish a prima facie case of obviousness. *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358-59 (Fed. Cir. 2019) ("Conclusory expert testimony does not qualify as substantial evidence."). This testimony is entitled to 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.").

b) A Person of Skill Would Not Have Been Motivated to Include Sensor Ports

Petitioner also fails to demonstrate that a person of skill would have been motivated to combine Goldberg with Kiani to arrive at multiple sensor ports.

(1) A Person of Skill Would Not Have Been Motivated to Include Even One Sensor Port

Petitioner argues "[i]t would have been obvious to include the port taught by Kiani on the portable device of Goldberg to establish easy removal and replacement of the sensor 104a, and predictably resulting in a secure, wired connection." Pet. at 22. Petitioner provides no reason why adding a port would result in "a secure, wired connection" when Goldberg already provides a wired connection. Petitioner's "secure" assertion is also internally inconsistent with its other assertion of "easy removal and replacement."

Petitioner next argues, without support, that a person of skill would have added a first sensor port to Goldberg because "in a medical context, hardwired sensors are undesirable." *Id.* Petitioner vaguely asserts that hardwired sensors are undesirable because clinicians "demand and expect patient monitors that conform and adapt as needed." *Id.* That statement has nothing to do with the modifications Petitioner proposes to Goldberg. Neither Petitioner nor Dr. Yanulis cites *any*

evidence of any specific demand or expectation by clinicians, nor do they explain how a general need to conform and adapt patient monitors would motivate the specific addition of the claimed sensor ports. *Id.*; Ex. 1003 ¶ 64. Moreover, Dr. Yanulis does not explain why clinicians would "demand" or "expect" all of those features from a wrist-worn patient monitor as opposed to a conventional bedside patient monitor. Instead, Dr. Yanulis asserts that clinicians would want to monitor different vital signs for different patients. Ex. 1003 ¶ 64. At best, Dr. Yanulis' reasoning suggests using different devices for different patients. It is wholly unrelated to Goldberg or Kiani. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (finding expert's testimony which was "[u]ntethered to any supporting evidence" was insufficient to support a finding of obviousness). Finally, Petitioner identifies no shortcomings with Goldberg, which already teaches the use of multiple sensors, that would motivate the proposed modification. *See* Ex. 1005 at 4:57-5:8. Goldberg already explains that additional sensors can be ***wirelessly*** connected to the monitoring device, *id.* at 4:26-29, thus undermining Petitioner's motivations for adding a sensor port to Goldberg.

Finally, Petitioner's proposed modification does not consider whether port connections have any disadvantages compared to hardwired connections that would dissuade a POSITA from making the alleged combination. For example, plug and port connections can be accidentally detached, may have faulty or loose

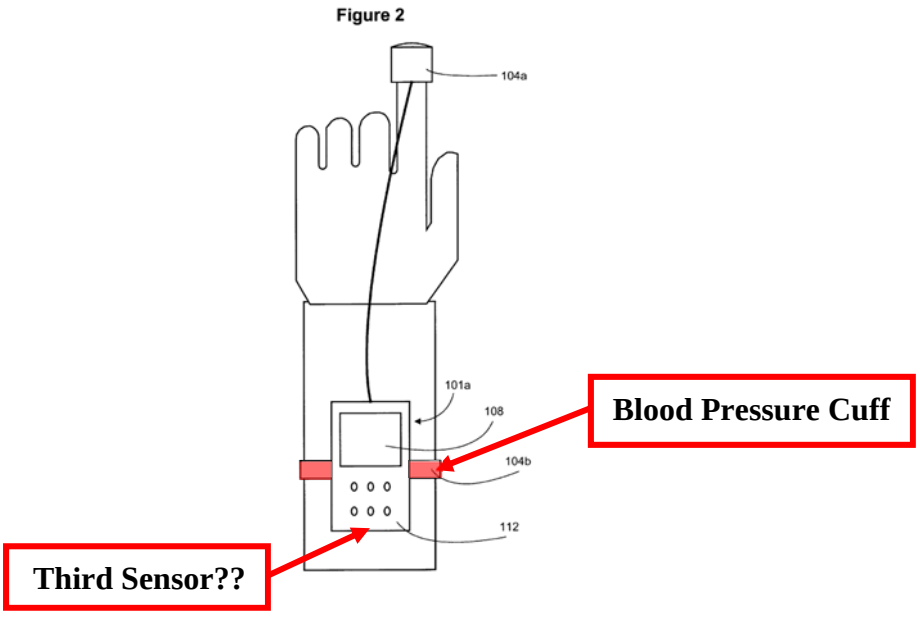
connections, require more space and hardware to accommodate than a hardwired cable, and introduce additional parts, expense, and points of failure to a device. Petitioner provides no explanation of how to add this port.

Accordingly, Petitioner fails to establish a person of skill would have been motivated to modify Goldberg to include even one sensor port.

(2) A Person of Skill Would Not Have Been Motivated to Include Multiple Sensor Ports

Goldberg as modified by Kiani would not predictably include a plurality of ports because neither reference discloses a plurality of sensor ports. *See supra* § IV.B.1.a. At best, Kiani discloses only one sensor port.

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; *see* Ex. 1005 at FIG. 2 (reproduced below, annotated).



Missing from Petitioner's analysis is an explanation of how or why a person of skill would have added port connections for Goldberg's blood pressure cuff sensor or electrolyte sensor. *See* Pet. at 26-27. Neither Petitioner nor its expert explains how multiple port connections could be integrated into Goldberg's device without increasing the portable size of the device. Dr. Yanulis does not explain why a person of skill would find it obvious to add ports, which require additional space and hardware, when he has offered a contradictory opinion that a person of skill would desire to ***minimize*** the size of the device and ***the number of sensors attached to a patient***. *See* Ex. 1003 ¶ 29 ("Generally, when designing wearable technology, PHOSITAs mainly attempted to improve patient comfort when the device is being worn. However, the best way to improve patient comfort would be to minimize the size of the wearable device and the number of sensors attached to the patient.").

Moreover, Petitioner completely neglects the fact that adding a port would be contrary to the stated purpose of the blood pressure cuff. Goldberg explains that the blood pressure cuff is used to secure the device 101a to a person's arm. Ex. 1005 at 4:64-67. Petitioner's proposed modification would not only add a wire connection between the cuff and device, but would also add a plug/port connection. A plug/port connection would not secure the device—it would make the cuff detachable. Petitioner does not address why a POSITA would have been

motivated to use a less secure connection between the blood pressure cuff and the housing, when the intended purpose of the cuff is to keep the device on a person's arm. *See* Pet. at 28-29. Neither Goldberg nor Kiani discloses a port through the back of a device, nor do they show a port that has any mechanism for securing an entire patient monitor to a wrist strap, let alone a blood pressure cuff. *See generally* Ex. 1005; Ex. 1006.

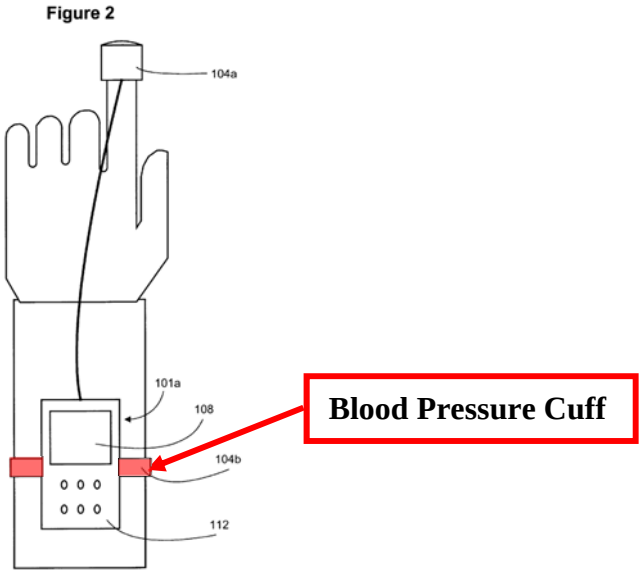
Dr. Yanulis argues that including second and third ports would allow "easy removal and replacement of the third sensor." Ex. 1003 ¶ 78. But he identifies no evidence that faulty sensors were a significant enough problem to warrant this modification. *Id.* Without such evidence, Dr. Yanulis's testimony is entitled to little or no weight. 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.").

Petitioner also fails to provide any evidence, even from its expert, that adding "additional sensor ports is an obvious duplication of parts." Pet. at 27. Because Petitioner has failed to explain why a person of skill would have added a first sensor port to Goldberg, there would be no port to duplicate. Additionally, Petitioner has not even alleged that different sensors could use the same type of sensor port. Petitioner has not shown the same port would be compatible with Goldberg's various sensors.

In view of these deficiencies, Petitioner has not shown that a person of skill would have been motivated to combine Goldberg and Kiani in the manner suggested to arrive at the claims.

c) A Person of Skill Would Not Have Had a Reasonable Expectation of Success in Adding Sensor Ports

Petitioner also fails to address whether a person of skill would have had a reasonable expectation of success in modifying Goldberg to include sensor ports. As mentioned above, ports require additional space and hardware to accept and retain a plug. Petitioner fails to demonstrate how multiple ports could be introduced into Goldberg's housing, while maintaining the portable size of Goldberg's device. Petitioner also fails to explain how a port connection could be integrated into the back side of Goldberg's housing. As argued by Petitioner, "the blood pressure cuff ***must*** mount to the back side of the housing to accurately detect blood pressure." Pet. at 34; *see* Ex. 1005 at FIG. 2 (reproduced below, annotated).



However, none of the asserted references show how a port could be integrated between the back side of Goldberg's housing and a patient's arm. Absent any such showing, Petitioner fails to show a reasonable expectation of success for its proposed modifications of Goldberg.

2. Petitioner's Arguments Regarding The Data Signal Configurations Are Deficient

a) Petitioner Fails to Establish the Combinations of Asserted References Teach the Claimed Data Signal Configurations

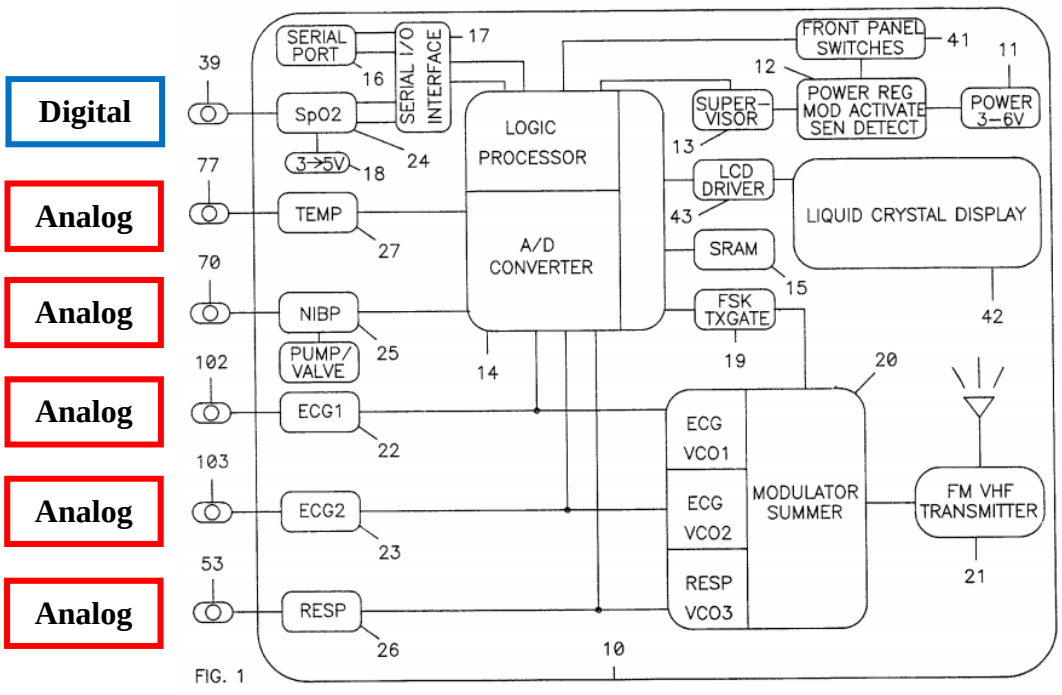
Petitioner also fails to demonstrate that any of the references relied upon in Grounds 1-4 teach or suggest the following data signal limitations of the independent claims:

- "the wired communication with the pulse oximetry sensor provided at least partly in the analog domain" and "a plurality of additional physiological sensors at least partly in the digital domain" (Claim 1);
- "the first communications port configured to removably couple with a cable of a finger- or thumb-type pulse oximetry sensor" and "a second communications port configured to provide wired communications with a second physiological sensor arrangement at least partly via digital communications" (Claim 13); and
- "receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, wherein the first signal is provided at least partly as an

analog signal" and "wherein the third signal is provided at least partly as a digital signal" (Claim 20).

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 recognizes that Goldberg alone does not disclose the claimed analog and digital requirements recited above. Petitioner suggests that modifying Goldberg with Money "would have predictably resulted in a system that receives both analog and digital information from various sensors." *Id.* at 29. Petitioner explains that "in Money, the patient monitor 10 receives discrete, digital data packets via an RS232 serial port, thereby unequivocally teaching data transmitted digitally." *Id.* However, Petitioner's general statements ignore 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. The only physiological sensor that provides digital data in Money is the pulse oximeter (SpO_2) sensor. Ex. 1008 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 the receipt of digital data from any sensors other than a pulse oximeter sensor. 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. 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) A Person of Skill Would Not Have Been Motivated to Include the Claimed Data Signal Configurations

Petitioner also fails to demonstrate that a person of skill would have been motivated to combine the references relied upon in Grounds 1-4 to arrive at the data signal configurations recited in the independent claims.

To meet the specific data signal limitations of the claims, which require a second sensor arrangement, separate from the pulse oximetry sensor, that provides digital communications, Petitioner argues "it would have been obvious to try transferring digital data, especially for discrete measurements (e.g., temperature or blood pressure), because there are only two signal possibilities: analog or digital" or "a temperature sensor would have been an obvious choice to transmit digital data". Pet. at 28, 59-60. However, none of the asserted references disclose transferring digital data for temperature or blood pressure sensors. Petitioner acknowledges that "Goldberg doesn't expressly teach whether the sensors communicate via digital (or analog) communications." *Id.* at 28. Money expressly discloses that "a conventional electronic temperature probe transducer 77 provides analog temperature data." Ex. 1008 at 5:48-51. Money also discloses the device receives "analog data from non-invasive blood pressure interface circuit 25." *Id.* at 5:42-44, 8:20-27. Thus, a person of skill would have no reason to try transferring digital data from the temperature or blood pressure sensors based on reading the asserted references. Petitioner provides no reason beyond hindsight

speculation for trying digital data for the temperature and blood pressure sensors in Money.

Petitioner fails to address another important teaching in Money. Power utilization is key to the success of Money's device. *See* Ex. 1008 at 3:37-39 ("Efficient power conversion and utilization are key factors in determining the success of a remote patient monitor, with patient mobility and comfort being a chief concern."). Petitioner argues that changing signals from analog to digital and vice versa could be done with converters. Pet. at 25. But adding parts would unquestionably increase the power consumption and decrease efficiency. Petitioner and its expert failed to address this issue.

Petitioner also argues that a person of skill "would have been motivated to modify Goldberg with Money to expand the number of devices the portable device of Goldberg can communicate with." *Id.* at 29. But Goldberg is already compatible with multiple devices. Indeed, Dr. Yanulis recognizes that a person of skill "would readily appreciate that the monitor [in Goldberg] should work in connection with the types of sensors that clinicians frequently need to use to monitor vital signs on patients." Ex. 1003 ¶ 76. Petitioner does not identify a single additional device that could be added to Goldberg simply through Money's data signal configuration.

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

c) A Person of Skill Would Not Have Had a Reasonable Expectation of Success in Including the Claimed Data Signal Configurations

Petitioner also fails to address whether a person of skill would have had a reasonable expectation of success in modifying Goldberg to include the claimed data signal configurations. As explained above, none of the asserted references disclose a physiological sensor, separate from the pulse oximetry sensor, that provides a digital signal. As argued by Petitioner, Money teaches "the pulse oximetry cuff[] connects to the RS232 serial port and provides ***digital packets*** representing oxygen saturation values." Pet. at 74 (emphasis added). Money also explains "a conventional electronic temperature probe transducer 77 provides ***analog*** temperature device 10." Ex. 1008 at 5:48-51 (emphasis added). Money also discloses blood pressure interface circuit 25 that provides ***analog*** data. *Id.* at 5:42-44, 8:20-27. Nevertheless, Petitioner suggests the combination of Goldberg, Kiani, and Money would have yielded the reverse configuration—a pulse oximetry sensor provided at least partly in the analog domain and a plurality of additional physiological sensors (e.g., temperature or blood pressure) at least partly in the digital domain. Pet. at 28-29, 59-60. Petitioner gives no explanation

why a person of skill would have reasonably expected the proposed modification to be successful when Money teaches the opposite configuration for efficient power conversion and utilization. *See* Ex. 1008 at 3:37-39 ("Efficient power conversion and utilization are key factors in determining the success of a remote patient monitor, with patient mobility and comfort being a chief concern.").

3. Petitioner Relies on Hindsight to Arrive at the Claimed Invention

The record provides no evidence to support all of the changes required to modify Goldberg. Indeed, Petitioner suggests modifications to Goldberg that are not disclosed by any of the references relied upon in Grounds 1-4, *see supra* §§ IV.B.1.a, IV.B.2.a. And the suggested modifications also contradict its own expert's opinion regarding the design need to minimize the size of the device and the number of sensors attached to a patient. *See* Ex. 1003 ¶ 29. Petitioner plucks separate features from multiple references that would increase the size of the device and complicate cable management. 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);

[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);

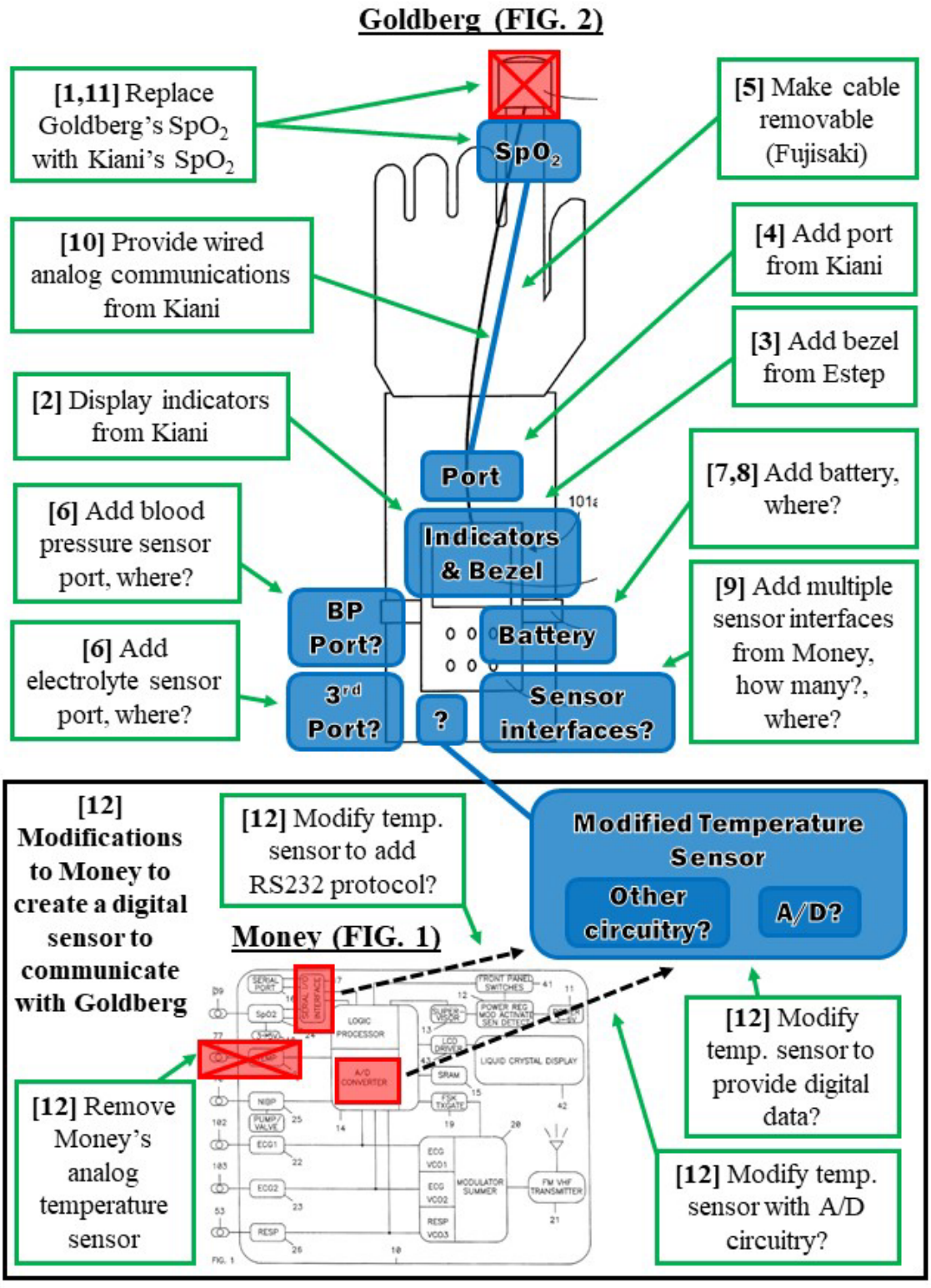
[9] "include sensor interfaces for receiving and decoding sensor signals" (Pet. at 45-46, 57-59);

[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* Ex. 1005 at FIG. 2 (annotated), Ex. 1008 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 person of skill would not have made the numerous modifications to Goldberg or combined the teachings of other asserted references.

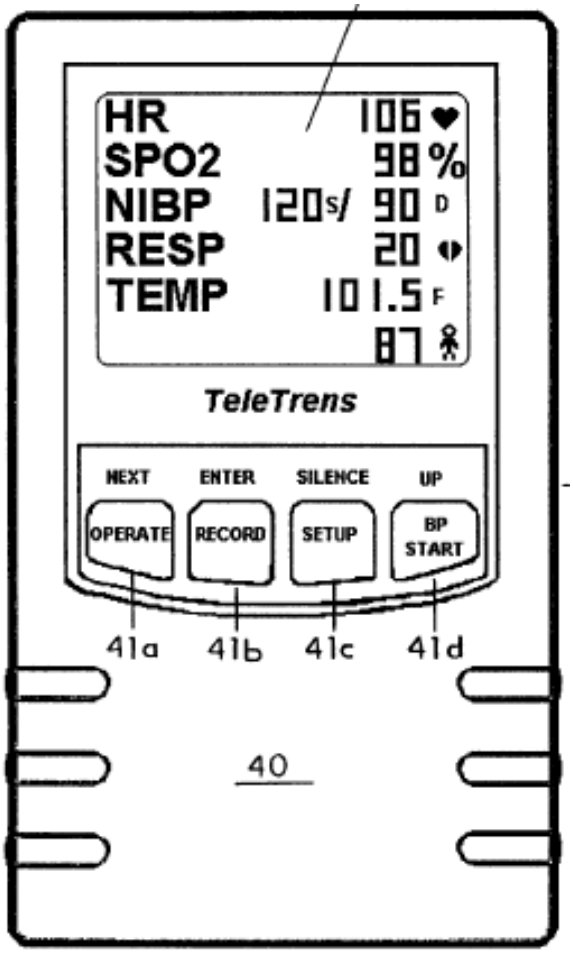
C. Petitioner Fails to Show a Reasonable Likelihood of Unpatentability of Any Claim Based on Money (Grounds 5-8)

Petitioner has also not shown a reasonable likelihood of unpatentability of any of the challenged claims in Grounds 5-8, which use Money as a primary reference. Petitioner fails to show a reasonable likelihood of unpatentability of the claims in Grounds 5, 6, and 8, including independent claim 1 (Ground 5), independent claim 13 (Ground 6), and independent claim 20 (Ground 8). Ground 7 challenges claims 10-12, which depend indirectly from independent claim 1. The arguments in Ground 7 do not address the deficiencies in Ground 5 of the Petition.

1. A Person of Skill Would Not Have Selected Money as a Reference

Petitioner fails to demonstrate why a person of skill would have been motivated to make a combination that includes Money, particularly when

Petitioner describes this reference as including an allegedly "outdated pulse oximetry cuff transducer." *See* Pet. at 74, fn. 3; *see also 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."). Besides disclosing the ***opposite*** sensor configuration of that recited in the claims (*see infra* § IV.C.2.a), Money does not disclose a device configured to be secured on a lower arm of a patient. Indeed, Money's device is roughly the size and weight of three modern smartphones stacked together.



Ex. 1008 at FIG. 10 (partial). Money's device includes a housing that is at least the actual size of the drawing shown on the previous page—approximately one inch thick, three inches wide, and six inches long, weighs up to sixteen ounces, and uses four AA batteries. *Id.* at 3:39-45, 5:4-8. Petitioner does not explain why such a large, bulky, device would be suitable to be worn on a patient's lower arm or how a person of skill would decrease the size and weight of Money's device.

2. Petitioner Fails to Demonstrate the Combinations of Asserted References Teach All of the Claimed Features

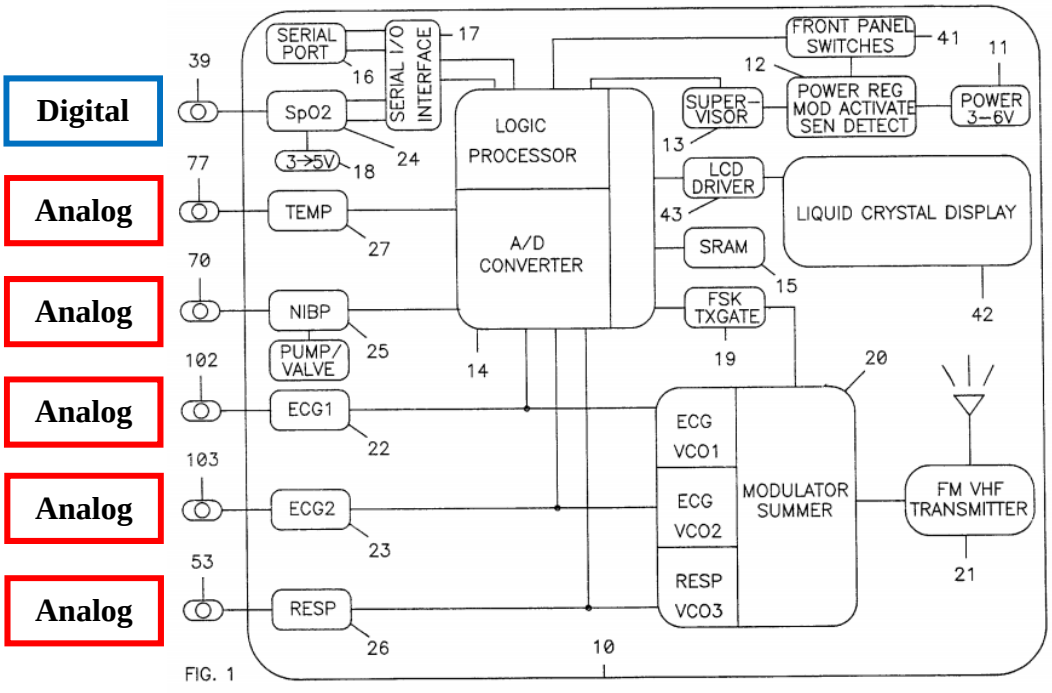
a) The Combinations of References Do Not Teach The Claimed Data Signal Configurations

None of the asserted references disclose the following data signal configurations of the independent claims:

- "the wired communication with the pulse oximetry sensor provided at least partly in the analog domain" and "a plurality of additional physiological sensors at least partly in the digital domain" (Claim 1);
- "the first communications port configured to removably couple with a cable of a finger- or thumb-type pulse oximetry sensor" and "a second physiological sensor arrangement at least partly via digital communications" (Claim 13); and
- "receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, wherein the first signal is provided at least partly as an

analog signal" and "wherein the third signal is provided at least partly as a digital signal" (Claim 20).

All of the independent claims require a physiological sensor, separate from the pulse oximetry sensor, that provides a digital signal. As argued by Petitioner, Money teaches a pulse oximetry cuff 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. Indeed, Petitioner cannot make this argument because the sensor configuration of Money is the opposite of that recited in the claims. See Figure 1 of Money (reproduced below, annotated).



Money receives digital data only from a pulse oximeter sensor. Ex. 1008 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.

Although claim 13 does not require the pulse oximetry sensor to provide analog communications, claim 13 still requires a second sensor arrangement, separate from the pulse oximetry sensor, that provides digital communications. 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 digital sensor communications.

Accordingly, Petitioner fails to show how the combinations of asserted references would teach the data signal configurations recited in the claims.

b) <u>The Combinations of References Do Not Teach Electrically Conveying the First Signal in Claim 20</u>

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's inaccurate discussion of this limitation is limited to one sentence—"Akai teaches the wired connection between the SpO_2 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." Ex. 1007 at 5:14-17 (emphasis added). Thus, Akai uses an optic fiber to communicate information optically, not electrically. Petitioner fails to demonstrate that any of the other asserted references in Ground 8 make up for this deficiency. Thus, Petitioner has failed to establish that the combination of Money, Akai, Kiani, Fujisaki, and Estep teaches all of the features of claim 20.

3. A Person of Skill Would Not Have Been Motivated to Modify Money to Include the Claimed Data Signal Configurations

Petitioner also fails to demonstrate that a person of skill 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 plainly 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 person of skill would have been motivated to provide the opposite data signal configuration. *See Polaris Indus., Inc. v. Arctic 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").

Recognizing that Money does not disclose a pulse oximetry sensor with an analog signal, Petitioner tries to replace Money's "outdated" pulse oximetry cuff with the light-based, finger-positioned pulse oximetry sensor taught by Akai. Pet. at 63, 74, fn. 3. As modified, Petitioner alleges that "Money's housing would receive an analog signal from Akai's SpO_2 sensor." *Id.* at 71. However, Petitioner fails to demonstrate why a person of skill would have found Money's pulse oximetry cuff "outdated" based on the teachings in Akai, when the filing date of Money is within one year of the priority date of Akai.

Petitioner argues that a person of skill "would have been motivated to substitute the cuff transducer of Money with a light-based SpO_2 sensor of Akai in order to predictably measure oxygen saturation non-invasively." *Id.* at 63. However, neither Petitioner nor its expert explains why Money's pulse oximetry cuff does not already predictably measure oxygen saturation non-invasively. Petitioner also fails to explain how the results of the substitution would have predictably measured oxygen saturation given the substantial reconstruction of Money required to accommodate Akai's SpO_2 sensor. Akai uses an optic fiber to communicate information optically. *See supra* § IV.C.2.b. To accommodate optical communication, a person of skill would either need to reconfigure Money to receive an optical signal or reconfigure Akai's sensor to be compatible with Money.

Moreover, replacing Money's pulse oximetry cuff with Akai's finger-positioned pulse oximetry sensor would remove the only sensor in Money that provides a digital signal. *See supra* § IV.C.2.a.

Petitioner also fails to address the importance of power utilization to the success of Money's device. *See* Ex. 1008 at 3:37-39 ("Efficient power conversion and utilization are key factors in determining the success of a remote patient monitor, with patient mobility and comfort being a chief concern."). Petitioner explains that changing signals from analog to digital and vice versa could be done with converters. Pet. at 25, 71. But adding parts would unquestionably increase the power consumption and decrease efficiency. Petitioner and its expert fail to address this issue.

For at least the foregoing reasons, Petitioner has not shown that a person of skill would have been motivated to combine the teachings of Money with the other asserted references to arrive at the claims.

4. A Person of Skill Would Not Have Had a Reasonable Expectation of Success in Modifying Money

Petitioner fails to demonstrate why a person of skill would have had a reasonable expectation of success in reconstructing the arrangement of analog and digital inputs in Money when Money teaches "[e]fficient power conversion and utilization are key factors in determining the success of a remote patient monitor." Ex. 1008 at 3:37-39. As argued by Petitioner, Money teaches "the pulse oximetry

cuff[] connects to the RS232 serial port and provides digital packets representing oxygen saturation values." Pet. at 74. Money also teaches "a conventional electronic temperature probe transducer 77 provides analog temperature data to device 10." Ex. 1008 at 5:48-51. Nevertheless, Petitioner proposes that a person of skill would have been motivated to "include a light-based, analog SpO_2 sensor," "modify Money's temperature sensor to communicate via the RS232 port" and "move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor." Pet. at 74-75. Dr. Yanulis offers no explanation as to why the proposed modifications would be desirable or effective, particularly in view of Money's emphasis on efficient power conversion and utilization.

5. <u>Petitioner Relies on Hindsight to Arrive at the Claimed Invention</u>

Petitioner proposes numerous modifications to Money that would require a substantial reconstruction and redesign of the elements shown in Money. Petitioner also fails to demonstrate a person of skill would have been motivated to make the proposed modifications. *See supra* § IV.C.3. 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.3d1270, 1275 (Fed. Cir. 2004).

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

[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_2 sensor" (Pet. at 71);

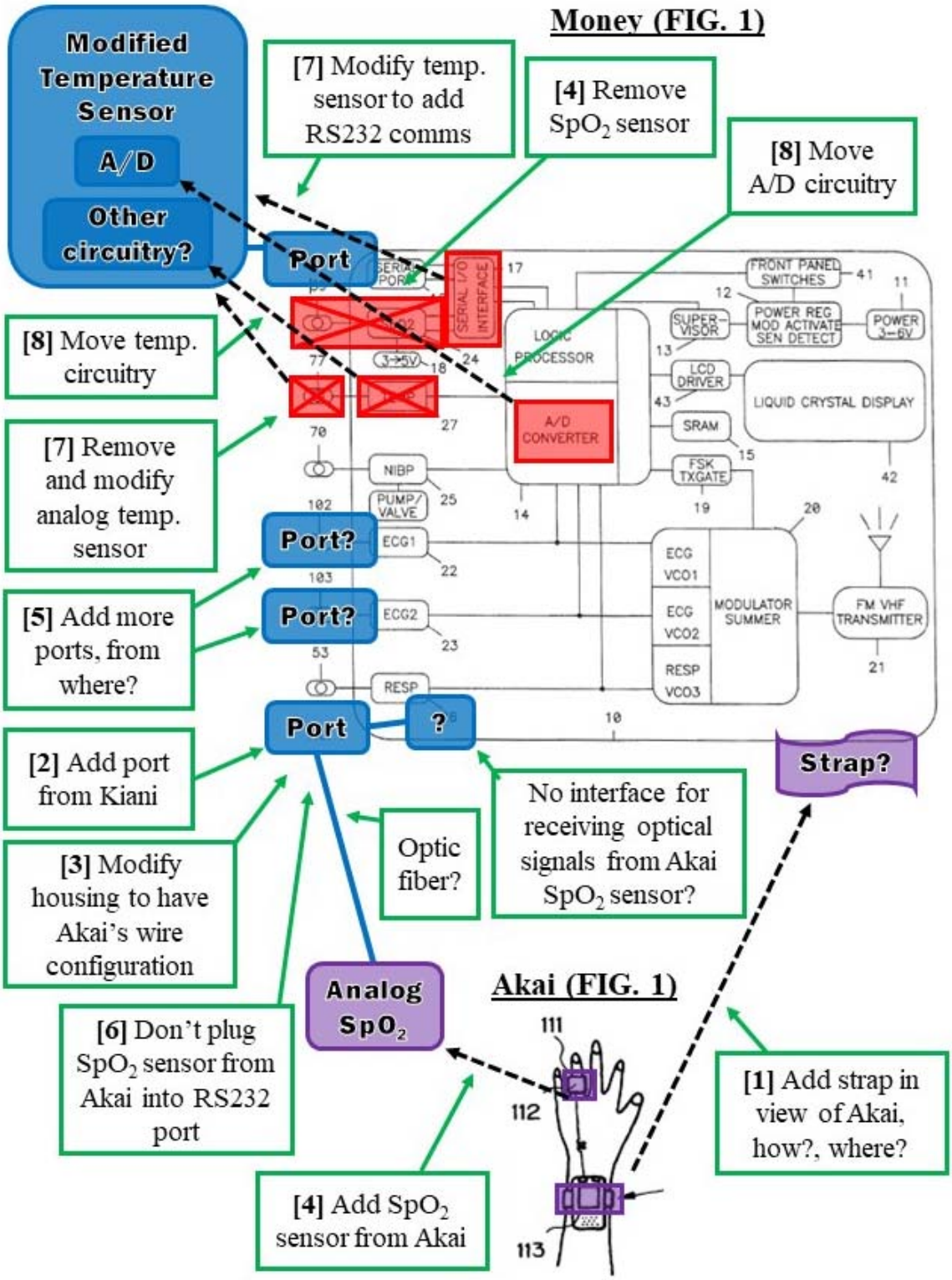
[5] "include a plurality of ports configured to receive signals from the pulse sensor, body sensor, or ECG sensor via wired connections" (Pet. at 73);

[6] "would not plug [the SpO_2 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. Ex. 1008 at FIG. 1 (annotated), Ex. 1007 at FIG. 1 (annotated).



In addition to the modifications outlined above, independent claim 13 (Ground 6) and independent claim 20 (Ground 8) require additional references and further modifications. For example, Petitioner relies on Estep for teaching "the front side of the housing comprises a single user interface and a bezel," as recited in claim 20. Pet. at 91-92, 97. But Estep is a non-analogous reference directed to equipment for use in measuring electrical signals in telecommunication systems. Ex. 1009 at 3:5-8.

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* § IV.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. Without the application of hindsight, a person of skill would not have made the numerous modifications required to combine the teachings of Money with the other asserted references.

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 below. *See* Pet. at 61-77.

a) "include a strap and mount the housing of Money to the patient's wrist in view of Akai"

Money discloses "a self-contained, portable and patient-wearable unit, with all hardware and software mounted in a housing approximately one inch thick, three inches wide, and six inches long." Ex. 1008 at 5:4-8. Money's device weighs up to sixteen ounces and requires four AA batteries. *Id.* at 3:39-45. Petitioner concludes, without any further explanation by Dr. Yanulis, that "[a] PHOSITA would know that a housing of this size would easily be worn on a patient's wrist." *See* Pet. at 65; Ex. 1003 ¶ 197. However, Petitioner's proposal to mount Money's housing to the patient's wrist would require resizing the housing and reconstructing the hardware components within the housing. Petitioner fails to establish that a person of skill at the time of the invention would have been able to make these modifications and maintain the functionality of Money's device with a reasonable expectation of success.

b) "include the port taught by Kiani"

Petitioner argues "[it] would have been obvious to include the port taught by Kiani to establish easy removal and replacement of the sensor and predictably resulted in a secure wired connection." Pet. at 69. However, Petitioner fails to explain why a removable sensor would have resulted in a more secure wired connection than the connection already provided in Money. Petitioner also fails to explain how a person of skill could have accommodated the hardware for this port,

let alone the additional ports described below, in Money's resized housing with a reasonable expectation of success.

c) <u>"modify Money's housing (if necessary) to have a wire configuration like Akai's"</u>

Petitioner argues "[it] would have been obvious to modify Money's housing (if necessary) to have a wire configuration like Akai's." Pet. at 70. To use Akai's wire configuration, a POSITA would need to move the pulse oximeter cuff transducer of Money to the side of the housing facing the hand of the patient if Money were mounted to the patient's wrist. A POSITA would also need to move the pulse oximetry interface circuit and associated hardware components within Money's housing to a portion of the housing that would face the patient's hand. Petitioner fails to demonstrate that a person of skill at the time of the invention could have rearranged these parts and resized the housing with a reasonable expectation of success.

d) <u>"substitute the cuff transducer of Money with a light-based, finger positioned, SpO_2 sensor"</u>

Petitioner argues, "[a] PHOSITA would have been motivated to substitute the cuff transducer of Money with a light-based, finger-positioned, SpO_2 sensor of Akai in order to predictably measure pulse oximetry non-invasively." Pet. at 71. However, Petitioner fails to demonstrate that the pulse oximetry cuff transducer of Money does not already predictably measure pulse oximetry non-invasively or that

the proposed substitution would justify reconstructing the hardware components in Money. Substituting the finger-positioned SpO_2 sensor from Akai would require adding a wired connection and moving the pulse oximetry interface circuit and associated hardware components within Money's housing. Further, because Akai uses an optic fiber to communicate information optically, a person of skill would need to reconfigure Money to receive an optical signal or reconfigure Akai's sensor to be compatible with Money. *See* Ex. 1007 at 5:14-17. Petitioner fails to address those reconfigurations.

Recognizing that Money discloses a pulse oximeter sensor that provides a digital signal, Petitioner suggests changing the digital signal to an analog signal. Pet. at 71. This substitution would change the power utilization of the device, which runs contrary to Money's emphasis on efficient power conversion and utilization as keys to its success. *See* Ex. 1008 at 3:37-39. Changing the digital signal to an analog signal would also be inconsistent with Dr. Yanulis' opinions in related IPR proceedings, in which he discussed the preference for incorporating an interface that has the same circuitry as the one being modified. In *Sotera Wireless v. Masimo*, IPR2020-01015, Dr. Yanulis observed that "Money's pulse oximetry sensor interface 24 expects to receive digital packets of data, and thus ***would not understand analog data transmitted by an analog sensor***." Ex. 2005 ¶ 124 (emphasis added). In that proceeding, Dr. Yanulis opined that it would be more

likely for a POSITA to incorporate an interface that has the same circuitry as the one being modified. *Id.* Here, however, Petitioner and Dr. Yanulis propose that a POSITA would change Money's pulse oximetry sensor, and its digital data signal, to an analog sensor, without acknowledging the changes to Money's internal circuitry that such a reconfiguration would entail. Petitioner's and Dr. Yanulis's inconsistent positions further confirm that the proposed combination is the product of hindsight.

e) "include a plurality of ports configured to receive signals from the pulse sensor, body sensor, or ECG sensor via wired connections"

Petitioner argues that "Money as 'modified' by Kiani would predictably include a plurality of ports configured to receive signals from the pulse sensor, body sensor, or ECG sensor via wired connections." Pet. at 73. However, Petitioner fails to establish that Money's pulse sensor, body sensor, or ECG sensor even require ports.

Dr. Yanulis suggests "including ports on Money's housing would have predictably enabled wired communication with the sensors while allowing easy removal and replacement of the sensors and providing a secure, wired connection between the sensors 53, 70, 77, 102, 103 and the housing 10." Ex. 1003 ¶ 218. However, Dr. Yanulis fails to explain why a replaceable sensor would have provided a more secure, wired connection than the connections already provided in

Money. Port connections introduce additional points of possible failure that could lead to accidental detachment.

f) "would not plug [the SpO_2 sensor] into the RS232 port"

Petitioner asserts "a PHOSITA would not have been motivated to connect Akai's analog SpO_2 sensor to the RS232 port [for Money's existing SpO_2 sensor] because the analog SpO_2 sensor outputs continuous data." Pet. at 74. However, Petitioner fails to explain how a person of skill would have added another port to Money's resized housing to accommodate Akai's SpO_2 sensor. To the extent Petitioner suggests moving the SpO_2 connection to the temperature connection, Petitioner fails to show the sensors are compatible with the same connections.

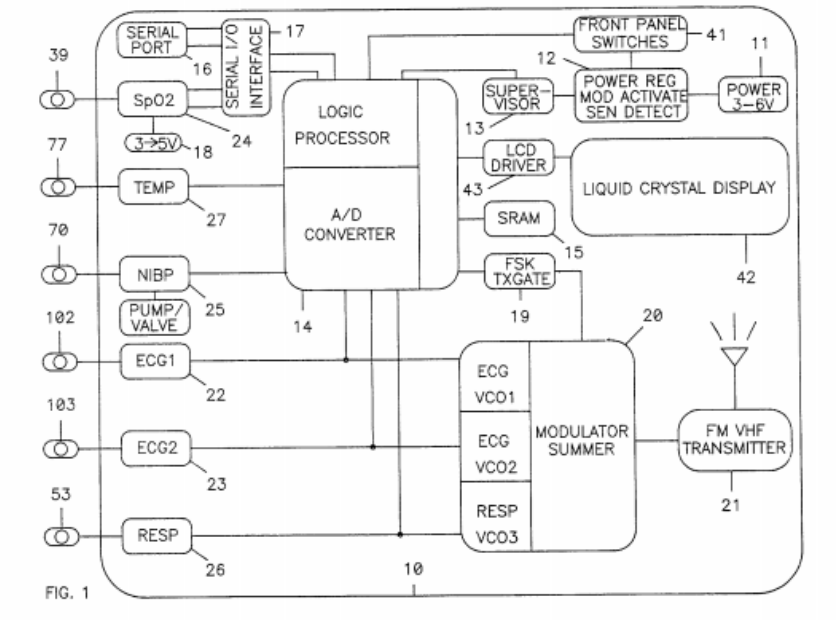
g) "modify Money's temperature sensor to communicate via the RS232 port"

Petitioner acknowledges that substituting Money's pulse oximetry cuff transducer with a light-based, finger-positioned SpO_2 sensor "might affect Money's careful power management" and "the RS232 port would not serve the dual-purpose taught by Money" of "either communicating with an external terminal for debug purposes or receiving data from [the pulse oximetry] sensor" Pet. at 75. Petitioner attempts to side-step these deficiencies by proposing additional modifications including modifying Money's temperature sensor to communicate via the RS232 port. *See id.* However, Petitioner fails to establish that Money's analog temperature sensor would have been compatible with the RS232 port or that a

person of skill would have been able to modify Money's analog temperature sensor to communicate with the RS232 port without further affecting Money's careful power management. *See* Ex. 1008 at 3:37-39.

h) <u>"move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor"</u>

Petitioner alleges 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. However, as shown below in FIG. 1 of Money, the analog-to-digital converter is integral with processor 14, which connects to several sensor inputs. Petitioner fails to explain how a person of skill would modify Money, for example, by moving the analog-to-digital converter outside the processor, without disturbing the analog-to-digital conversion for the other sensors.



Further, Petitioner fails to establish that a person of skill would have been able to move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor without further affecting Money's careful power management. *See* Ex. 1008 at 3:37-39.

The variety and extent of Petitioner's modifications to Money, and the lack of any explanation as to how a POSITA would successfully implement these modifications, confirm the deficiencies in Petitioner's proposed combinations.

V. RESERVATION OF RIGHTS

Should the Board decide to institute an *inter partes* review, Masimo reserves all rights to make additional arguments in and present additional claim constructions and evidence with its Patent Owner Response. Masimo's silence on any particular claim or limitation at this time is not a concession that the Petition's discussion of that claim or limitation is properly based. Patent Owner also reserves the right to dispute the level of ordinary skill in the art if the Board decides to institute *inter partes* review. Accordingly, Masimo reserves the right to submit additional or alternative arguments and nothing in this Preliminary Response acts or should be construed to act as an admission, acquiescence, or estoppel on the merits of the Petition.

VI. CONCLUSION

The Board should not institute trial on the proposed grounds.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 28, 2020

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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). According to Microsoft Office Word 2010's word count, this document contains approximately 12,224 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: August 28, 2020

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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 PRELIMINARY RESPONSE AND EXHIBITS 2001-2006** are being served electronically on August 28, 2020, to the e-mail addresses shown below:

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