

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SOTERA WIRELESS,

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

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Case IPR2020-00954

U.S. Patent 9,788,735

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**DECLARATION OF ALAN L. OSLAN  
IN SUPPORT OF PATENT OWNER'S RESPONSE**

I, Alan L. Oslan, declare and state as follows:

**I. INTRODUCTION**

1. I have been retained by Knobbe, Martens, Olson & Bear, LLP, counsel for Masimo Corporation (“Masimo”). I understand that Sotera Wireless, Inc. (“Petitioner” or “Sotera”) filed for *inter partes* review (“IPR”) of claims 1-20 of U.S. Patent No. 9,788,735 (“the ’735 Patent”), and that the Patent Trial and Appeal Board instituted IPR for claims 1-20.

2. I have been asked by counsel to review relevant materials and render my independent analysis and expert opinion in connection with technical matters related to the ’735 Patent and Sotera’s petition for *inter partes* review of the ’735 Patent.

3. I am over 18 years of age. I have personal knowledge of the facts stated in this Declaration and could testify competently to them if asked to do so. My findings, as set forth herein, are based on my education, background, and experience in the fields discussed below.

4. I reserve the right to supplement this Declaration in response to additional evidence that may come to light.

5. I am being compensated by Patent Owner for my time, billed at my normal hourly rate of \$250, for time spent reviewing materials, and performing my analysis of the technical issues relevant to this matter, an hourly rate of \$300 for

deposition-related matters, and an hourly rate of \$350 for trial-related matters. My compensation is in no way dependent on the opinions I formulate or offer below and it is not dependent on the outcome of this proceeding.

## **II. QUALIFICATIONS AND BACKGROUND**

6. Attached as Exhibit 2011 is my current curriculum vitae. The following paragraphs briefly summarize my relevant expertise.

7. I am currently president of ElectroSurge LLC. I founded ElectroSurge in 2010 to consult for other companies based on my extensive experience in medical device development projects. As president of ElectroSurge, I have consulted for several medical device companies on device design and testing, NIH grant support, expert witness for medical device patent litigation, and understanding electrical properties of body tissues.

8. I received a B.S. in Engineering in the Electrical Engineering program from the University of Connecticut (1975). As an undergraduate, I took courses in statics, dynamics, electrical circuits, and engineering physics. After my sophomore year, I worked in a metallurgy research lab on campus as a lab technician. After my junior year, I worked at a United States Army research facility in Washington, D.C. on high-current pulsing of semiconductor devices. During my junior and senior years, I specialized in bioelectrical engineering and took an independent lab course on using miniature electrodes to measure nerve signals of insects. As an

undergraduate, I also worked on campus in a biobehavioral sciences research lab testing and repairing capacitive-based respiration monitors.

9. I received my M.S. in Biomedical Engineering from Boston University in Boston, MA on a part-time basis (1980). I took courses including biomaterials, human anatomy, and electrical signal analysis. My thesis topic was measurement and analysis of electromyography signals (EMGs). EMGs are physiological signals produced by the body to cause muscles to contract. EMG signals are similar to ECG signals, except that ECG signals are produced specifically by the heart muscle. The electrodes for this EMG medical device were surface electrodes and they interfaced with a biometric device that I designed.

10. I studied towards my Ph.D. in Electrical Engineering at the University of Connecticut with an anticipated thesis topic in medical ultrasound imaging (1980-81). I took courses in digital image processing. I was also a part-time instructor, teaching junior-level electrical engineering undergraduate students in electrical signals and systems analysis. I had full responsibility for preparing for and presenting in class, assigning and grading homework assignments, as well as preparing, administering, and grading quizzes and exams. At the end of my first year, my academic advisor started a two-year sabbatical to obtain his M.D. degree, and I therefore decided not to continue my Ph.D. degree studies.

11. I earned an M.B.A. degree, specializing in management of technology enterprises, from Babson College in Wellesley, MA (2013). While doing so, I took a course entitled “Patents and Licensing in the Life Sciences” and learned about analysis and management of manufacturing costs and other issues facing technology companies.

12. I have worked at a variety of medical device companies ranging from small start-ups to large mature companies, and have been involved with numerous technologies for a multitude of anatomical regions (1977 to present).

13. I was a Biomedical Equipment Technician at New England Medical Center, a teaching hospital of Tufts University School of Medicine in Boston, MA (1977-78). Some of my responsibilities included performing scheduled maintenance and calibration of medical equipment including electrocardiogram (ECG) and respiratory monitoring equipment. I also responded to and resolved problems with equipment, including issues with ECG snap electrodes and respiration impedance electrodes, in use on patients in wards, ICUs, and surgery.

14. I was a Research Engineer in a research lab at Children’s Hospital Medical Center, a teaching hospital of Harvard Medical School in Boston, MA (1978-80). My manager was an adjunct professor at Boston University and my lab project overlapped considerably with my M.S. thesis project discussed above, involving measurement and analysis of EMG signals and designing a biomedical

measuring device. At this time, I was also an advisor to a group of Boston University undergraduate students working towards their B.S. degrees in Biomedical Engineering.

15. I was a Project Engineer developing various medical devices based on microwave energy and sensing techniques at Microwave Medical Systems, a start-up company in Acton, MA (1988-92, 1996-97). As part of my responsibilities, I selected several connectors, with some containing alignment keys, for use with those medical devices. Additionally, I worked with a vacuum mold forming company to fabricate the plastic housing of a medical device.

16. I worked at Boston Scientific, a large and successful medical device company in Natick, MA, as a Sr. Biomedical/Electrical Engineer and Program Manager (1992-96, 2005-2006). In this role (1992-1996), I led a multidisciplinary team to develop a catheter for diagnosing and treating cardiac arrhythmias that was eventually released to the market.

17. I was a technical Program Manager at Aurora Imaging Corp. (no longer in business), a start-up company (1997-98, 2000-03). In this role, I was the technical and clinical lead for a breast biopsy system for use on an Aurora MRI machine dedicated to breast imaging that was eventually released to the market. I was also a co-inventor on a patent (US Pat. No. 7,171,256) relating to this device.

18. I was a technical Project Manager at Smith + Nephew (Endoscopy Division) in Andover, MA (1998-2000). In this role, I was the technical lead for an arthroscopic surgery device (used in joints such as shoulders and knees), which was eventually released to the market.

### **III. INFORMATION AND MATERIALS CONSIDERED**

19. To render my opinions in this matter, I have reviewed the specification and the claims of the '735 Patent (Ex. 1001). I have been informed that that the application leading to the '735 Patent was filed April 27, 2017 and that it claims priority to a provisional application that was filed on March 25, 2002.

20. I have also reviewed the following materials:

- Ex. 1002 – prosecution history of the '735 Patent;
- Ex. 1003 – Declaration of Dr. George Yanulis;
- Ex. 1004 – Dr. Yanulis' CV;
- Ex. 1005 – U.S. Patent No. 6,840,904 to Goldberg (“Goldberg”);
- Ex. 1006 – PCT Publication No. WO 00/42911 to Kiani et al. (“Kiani”);
- Ex. 1007 – European Patent Application EP 0 880 936 to Akai (“Akai”);
- Ex. 1008 – U.S. Patent No. 5,919,141 to Money et al. (“Money”);
- Ex. 1009 – WO 99/13698 to Estep et al. (“Estep”)

• Exs. 1010-1012, 1014 (Various excerpts from the prosecution history of the '108 Patent);

- Ex. 1013 – U.S. Patent No. 6,241,684 to Amano;
- Ex. 1016 – U.S. Patent No. 4,425,921 to Fujisaki et al. (“Fujisaki”);
- Ex. 1017 – PCT Publication No. WO 00/44274 to Pougatchev et al.;
- Ex. 1018 – Japanese Publication JP0558122A to Kodama;
- Ex. 1019 – U.S. Patent No. 4,338,950 to Barlow Jr. et al.;
- Ex. 1020 – U.S. Patent No. 4,450,843 to Barney et al.;
- Ex. 1021 – U.S. Patent No. 4,807,639 to Shimizu et al.;
- Ex. 1022 – U.S. Patent No. 5,539,706 to Takenaka et al.;
- Ex. 1023 – U.S. Patent No. 6,850,788 to Al-Ali;
- Ex. 1024 – U.S. Patent No. 7,844,314 to Al-Ali;
- Ex. 1025 – U.S. Patent No. 7,844,315 to Al-Ali;
- Ex. 1026 – U.S. Patent No. 8,548,548 to Al-Ali;
- Ex. 1027 – U.S. Patent No. 9,113,831 to Al-Ali;
- Ex. 1028 – U.S. Patent No. 9,113,832 to Al-Ali;
- Ex. 1031 – U.S. Patent No. 10,213,108.

In addition to these references cited by Petitioner, I also reviewed the related 10,213,108 (“’108”), 9,795,300 (“’300”), and 9,872,623 (“’623”) Patents that are the subject of related IPRs. I also reviewed the materials presented in those petitions



and Dr. Yanulis' declarations in those related IPRs against the '108, '300, and '623 Patents. Additionally, I reviewed additional materials that were provided to me by counsel and that I located or purchased, including:

- Ex. 2017 – Dictionary definitions of “oximetry,” “pulse oximetry,” and “invasive,” from *Stedman's Medical Dictionary* (27<sup>th</sup> ed. 2000);
- Ex. 2018 – Dictionary definitions of “oximeter,” “pulse oximeter,” and “invasive” from *Dorland's Illustrated Medical Dictionary* (30th ed. 2003);
- Ex. 2019 – Excerpt from *Webster's New World College Dictionary* (4th ed. 2001);
- Ex. 2020 – Excerpt from Webster's II New College Dictionary (2001);
- Ex. 2021 – Excerpt from *Microsoft Computer Dictionary* (5th ed. 2001);
- Ex. 2022 – Amal Jubran, MD, *Pulse oximetry*, Critical Care 3:R11-R17 (1999);
- Ex. 2023 – Joseph F. Kelleher, MD, *Pulse Oximetry*. Journal of Clinical Monitoring and Computing, 5:37-62 (1989);
- Ex. 2024 – Westover, AR, Moog, T, and Hyman, WA. *Human Factors Analysis of an ICU*. Journal of Clinical Engineering, 23(2), 110, 112, 1998;

- Ex. 2025 – Gianfranco Parati et al., *Self blood pressure monitoring at home by wrist devices: a reliable approach?* Journal of Hypertension 2002, 20:573-578;
- Ex. 2026 – U.S. Patent No. 4,896,676;
- Ex. 2027 – Japanese Publication JP4777640 (and English machine translation available on Espacenet);
- Omron Gold Wrist Blood Pressure Monitor (Model No. BP4350) (Physical device) (Photos of this device and its user manual are provided as Ex. 2028);
- Ex. 2029 – Hardesty, “Clothed in Health,” Technology Review (July 2001);
- Ex. 2030 – Datex AS/3™ Anesthesia Monitor Operator’s Manual (1995);
- Ex. 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);
- Ex. 2032 – Printouts of Apple’s and Samsung’s websites showing dimensions of common smartphones;
- Ex. 2033 – Siegfried Kästle et al., *A New Family of Sensors for Pulse Oximetry*, Hewlett-Packard Journal (February 1997);

- Ex. 2034 – Amazon listing for Portzon Set of 2 Neoprene Dumbbell Hand Weights, Anti-Slip, Anti-roll;
- Ex. 2035 – Design of Pulse Oximeters, JG Webster, ed., IOP Publishing, Bristol, UK, 1997.
- All other documents and exhibits cited in my declaration, to the extent they are not listed above.

#### **IV. RELEVANT LEGAL STANDARDS**

21. I am not an attorney. The opinions I am expressing in this report involve the application of my technical knowledge and experience to the evaluation of certain prior art and alleged prior art with respect to the '735 Patent, and the instruction counsel gave me for the legal standards relating to claim construction and patent validity.

##### **A. Level of Ordinary Skill**

22. I understand that my opinion must be taken from the perspective of what would have been known or understood by a person of ordinary skill in the art at the time of the invention. I have been informed by counsel and it is my understanding that the '735 Patent claims priority to a provisional application filed on March 25, 2002. I understand that date to be the time of the invention for my analysis. I have been informed that the level of ordinary skill in the art may be determined by various factors including: (a) the type of problems encountered in the

art, (b) prior art solutions to those problems, (c) the rapidity with which innovations are made, (d) the sophistication of the technology, and (e) the educational level of active workers in the field.

23. I understand that Petitioner has defined a person of ordinary skill in the art as of the claimed priority date of the '735 Patent as being a person having at least a B.S. degree in electrical or biomedical engineering or a related field, with at least two years of experience designing patient monitoring systems. I also understand that Petitioner has stated that a higher level of education may compensate for less work experience and vice versa. Pet. at 14.

24. Having reviewed the '735 Patent, its file history, and the asserted references, I agree with Petitioner's assessment of the level of ordinary skill in the art.

## **B. Claim Construction**

25. I understand that in *inter partes* review proceedings, the claims of a patent are to be construed under the same claim construction standard that would be applied in a district court patent case. I am informed that, under this standard, claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in context of the specification and the prosecution history. I am informed that there are two exceptions to this general rule: (1) when a patentee sets out a definition and acts as his own lexicographer, or (2)

when the patentee disavows the full scope of a claim term either in the specification or during prosecution.

26. I am informed that the Patent Trial and Appeal Board (“PTAB”) is not required to construe every limitation of the asserted claims and usually only construes claim terms to the extent necessary to resolve a dispute.

27. I am informed that claim construction starts with the intrinsic evidence: the claims, the specification, and the prosecution history (or file history). I understand that it is the claims that defines the scope of patent protection, but that the specification and prosecution history can help inform the meaning of a claim. After reviewing the intrinsic evidence, I am informed that courts may consider extrinsic evidence, including dictionaries, treatises, and expert testimony.

### **C. Obviousness**

28. I understand that a claim of an issued patent can be found to be unpatentable if the claim would have been obvious in view of the prior art. I understand that this determination is made from the perspective of a person having ordinary skill in the art who is presumed to be aware of all prior art.

29. I understand that a patent claim is unpatentable due to obviousness if it can be shown that the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time of the invention.

30. I understand that the following factors, which are sometimes referred to as the *Graham* factors, are considered in assessing obviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) objective indicia of non-obviousness, also referred to as secondary considerations of non-obviousness. Those objective indicia include considerations such as whether a product covered by the claims is commercially successful due to the merits of the claimed invention, whether there was a long felt need for the solution provided by the claimed invention, whether others copied the claimed invention, and whether there was acceptance by others of the claimed invention as shown by praise from others in the field.

31. I understand that a claim is not proved obvious merely by showing that each of the individual elements existed somewhere in the prior art. I understand that, when a combination of prior art references is relied upon to assert obviousness, the party asserting obviousness must identify a reason or motivation that would have prompted one of ordinary skill in the art to combine the elements of the references in the same way as the claimed invention with a reasonable expectation of success. I also understand that in assessing obviousness, it is improper to rely upon hindsight and that one should avoid using the claimed invention as a roadmap to piece together disclosures in the prior art.

## V. CLAIM CONSTRUCTION

32. I have been asked to provide my opinions regarding the construction of the term “sensor communication port” as it appears throughout the claims of the ’735 Patent. It is my understanding that the PTAB’s institution decision regarding the ’735 Patent stated:

We do note, however, that the claims require “sensor communication port(s).” *See, e.g.*, Ex. 1001, claim 1. To the extent the parties contend that the “sensor communication port” has any special meaning or otherwise should be construed, the parties should clearly identify what they contend the scope of a sensor communication port encompasses.

Institution Decision at 22.

33. In my opinion, the term “sensor communication port” should be given its plain and ordinary meaning, which is a “connector that mates with a compatible connector from a sensor.”

34. The claims of the ’735 Patent use the term “sensor communication port” in accordance with its plain and ordinary meaning as a connector that interfaces with a corresponding connector from a sensor cable. For example, Claim 1 recites “a first sensor communication port,” and “a plurality of additional sensor communications ports.” Ex. 1001 at 13:14-56 (Claim 1). Claim 13 recites “a first communications port,” “a second communications port,” and a third communications port.” *Id.* at 14:38-15:9 (Claim 13). Claim 20 recites “a first sensor port,” “a second sensor port,”

and “a third sensor port.” *Id.* at 15:59–18:19 (Claim 20). A PHOSITA would understand that a port is a type of connector. Thus, a PHOSITA would understand that the term “sensor communication port,” as used in the ’735 Patent, refers to a connector that mates with a compatible connector from a sensor. A PHOSITA would also understand that the terms “sensor port” and “sensor communication port,” as used in the ’735 Patent, are interchangeable.

35. This construction is also consistent with the specification of the ’735 Patent. The specification does not define the term “sensor communication port” or attempt to redefine it in a way that would be inconsistent with this construction. For example, the specification refers to Figure 3 and explains that “the monitor module 500 is advantageously plug-compatible with a conventional monitor 360. In particular, the monitor’s sensor port 362 connects to the monitor module 500 in a similar manner as to a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1).” Ex. 1001 at 5:1-5.

36. The specification also discusses “sensor port” in connection with Figures 5A-5C. Those figures show a monitor module 500. Although Figures 5A-5C and the corresponding descriptions refer to a conventional, full-size patient monitor, rather than a wrist-worn device as recited in the claims, the specification’s use of the term “sensor port” is still consistent with my proposed construction. For example, the specification states that “The monitor connector 514 mimics that of the



monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically and mechanically connects the monitor module 510 to the monitor 360 via the monitor's sensor port 362.” Ex. 1001 at 6:1-5. The specification also states, regarding Figure 5B, “the cable-connect module 540 utilizes the auxiliary cable 550, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically connects the cable-connect module 540 to the monitor sensor port 362.” *Id.* at 6:9-14.

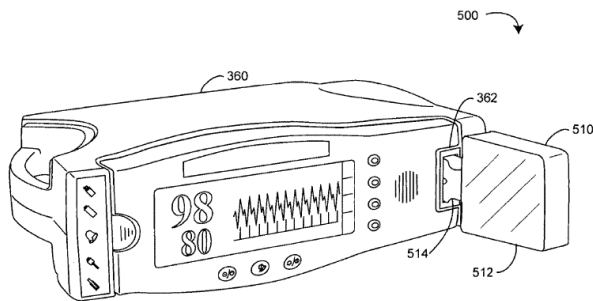


FIG. 5A

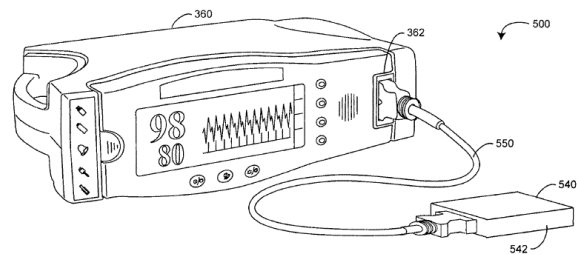


FIG. 5B

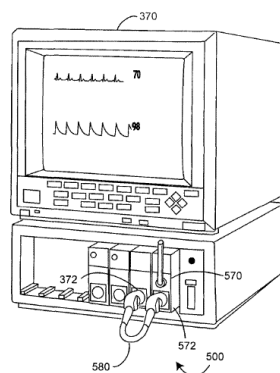


FIG. 5C

37. The term “sensor port” appears in a few other locations within the specification. Based on my review, my proposed construction is consistent with how the term is used throughout the ’735 Patent.

38. My proposed construction is also consistent with how contemporary dictionaries defined the term “port.” For example, Webster’s New World College Dictionary (4th ed. 2001) defined “port” as “the circuit, outlet, etc. which serves as a connection between a computer and its peripheral.” Ex. 2019 at 1121. Webster’s II New College Dictionary (2001) defined “port” as “[a] connection point for a peripheral device.” Ex. 2020 at 860. The Microsoft Computer Dictionary (5th ed. 2002) also defined “port” as “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.” Ex. 2021 at 412. For the ’735 Patent, the monitoring device would be the equivalent of the computer described in the Microsoft Computer Dictionary and the sensor would be the peripheral.

39. I note that the ’735 Patent differentiates a “port” type connection, or more specifically a “sensor connector,” from a hardwired connection. With respect to Figure 4A, the specification explains:

The auxiliary cable 420 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. **Alternatively, the auxiliary cable 420 is directly wired to the sensor module 400.**

Ex. 1001 at 5:35-39 (emphasis added). As shown in Fig. 4A 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. Thus, a PHOSITA would understand that a “sensor communication port” requires some removable connection and excludes a sensor that is directly wired to a housing (for example, a sensor where the wire is soldered directly to a printed circuit board within the housing).

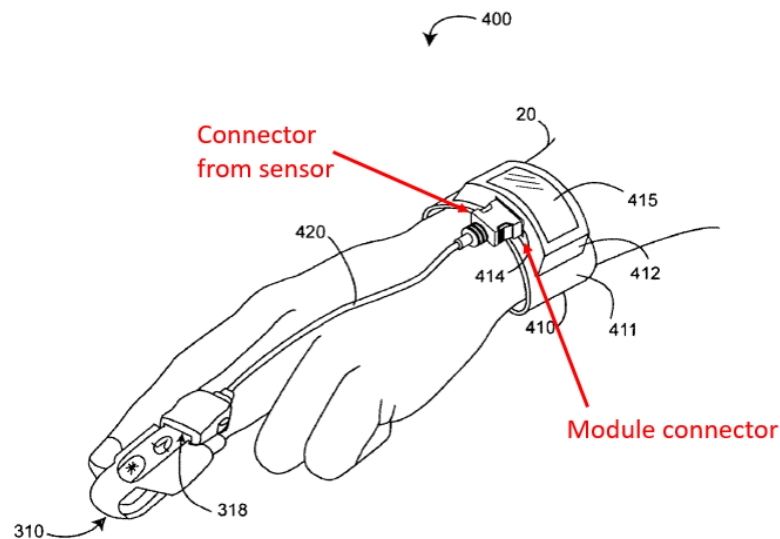


FIG. 4A

40. I have reviewed the Declaration of Dr. Yanulis and his statement that “A port is typically a female connection or socket of a wired connection.” Ex. 1003

¶ 73. As a high-level, general statement, I agree with aspects of Dr. Yanulis' statements. Many ports are often described as female and many are also described as sockets. However, if this were a proposed claim construction of the term "sensor communication port" or "sensor port," it would not be precise. Defining a "sensor communication port" or "sensor port" based on whether it is a male or female connection is not helpful. Some ports could have male characteristics. For example, serial ports, which were still common in the 1990s and early 2000s, were generally considered male because the port had pins:



(Image from

[https://simple.wikipedia.org/wiki/Serial\\_port#/media/File:Serial\\_port.jpg](https://simple.wikipedia.org/wiki/Serial_port#/media/File:Serial_port.jpg)) In

contrast, parallel ports, often used for printers, were also common at the same time and were generally considered female because they received corresponding plugs with pins:



(Image from

[https://en.wikipedia.org/wiki/Parallel\\_port#/media/File:Parallel\\_computer\\_printer\\_port.jpg](https://en.wikipedia.org/wiki/Parallel_port#/media/File:Parallel_computer_printer_port.jpg)).

Also, some ports have both male and female characteristics. For example, USB Type A ports have a tongue with electrical contacts that mate with a USB plug that also has a tongue with electrical contacts. Both USB ports and plugs could be characterized as having both male and female features. Therefore, while some ports were female, a PHOSITA would not understand the term “sensor port” or “sensor communication port” to require a female connector.

41. It is my understanding that Petitioner did not propose any other claim constructions in this IPR. Based on my review of the claims of the '735 Patent, I do not believe that the PTAB needs to construe any other claim terms.

## VI. BACKGROUND

### A. The '735 Patent

42. The '735 Patent explains that “Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor,” meaning that patients would need to be “located in the immediate vicinity of the monitor.” Ex. 1001 at 2:22-25. The need to be tethered to a monitor meant 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.” *Id.* at 2:25-28. The '735 Patent describes and claims an arm mountable portable patient monitoring device that enables a patient to be untethered from a conventional monitor and to have mobility about a hospital room or doctor’s office, for example. *Id.* at 8:41-46. The claims generally require an arm mountable patient monitor with a housing and a strap to mount the housing to a patient’s arm, at least three sensor ports for connecting a pulse oximetry sensor cable and at least two other sensors cable, a display and signal processing arrangements to interpret and display the measured physiological parameters, and a transmitter to wirelessly transmit the measured physiological parameters to a separate monitoring device. The '735 Patent further explains that the transmitter on the portable monitoring device is suitable for use within a hospital room, doctor’s office, emergency vehicle or critical care ward. *Id.* 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.

Ex. 1001, 13:14-56

43. Claim 13 recites a device with three sensor communications ports, and specifies the second communications port is configured to provide wired communications at least partly via digital communications. Claim 20 also recites a device with three sensor ports, but specifies the third signal is provided at least partly as a digital signal. 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.

**B. Pulse Oximetry**

44. The claims of the '735 Patent and the related '108, '300, and '623 Patents generally require a pulse oximetry sensor as one of the sensors connected to the arm mountable patient monitoring device. As of 2002, the fundamental principles of pulse oximetry were well-understood. “Pulse oximetry [is] a noninvasive method for evaluating arterial oxygen saturation, [and] has enjoyed widespread use since its invention in the early 1970s and its clinical introduction in the early 1980s.” Ex. 2023 at 56. Oximetry is defined as a “[p]rocedure using a device to measure oxygen saturation by fluctuations of light absorption in well-vascularized tissue during systole and diastole.” Ex. 2017 at 1292. Pulse oximetry is defined as being “performed noninvasively, usually on the finger or ear lobe, in which the small increase in absorption of light during the systolic pulse is used to calculate oxygen saturation.” *Id.* Oximeters available in the 1990’s used “two light-



emitting diodes (LEDs) that emit light at the 660 nm (red) and the 940 nm (infrared) wavelengths.” Ex. 2022 at R11. By measuring the detected light after it passes through tissue with a photodetector, a pulse oximeter is able to calculate arterial blood oxygen saturation based on the different absorption spectra of blood components at these two wavelengths of light. *See id.* at R11-R12. More details regarding the fundamental principles of pulse oximetry, including how oxyhemoglobin and hemoglobin absorb different amounts of red and infrared light are further explained in Exs. 2023 and 2022. A PHOSITA as of 2002 would have understood that pulse oximetry is a noninvasive method of measuring arterial blood oxygen saturation using spectral absorption properties of blood.

45. Based on my review of Dr. Yanulis’ declarations submitted with respect to the ’108, ’735, ’300, and ’623 Patents, there are some statements in those declarations regarding pulse oximetry that a PHOSITA would not agree with. For example, in his declaration for this IPR, Dr. Yanulis suggests that a “pulse oximetry cuff transducer” described in the Money reference (Ex. 1008) was not light-based and was invasive. Dr. Yanulis said:

It would have been obvious to modify Money’s housing in view of Akai primarily because it would have been obvious to substitute a pulse oximetry cuff transducer 39, as taught by Money, with a light-based, pulse oximetry sensor 112 that is positioned on a patient’s finger, as taught by Akai. Pulse oximetry cuff transducers are largely obsolete in

modern medicine and were largely obsolete even in 2002 (the priority date of the '735 Patent). Pulse oximetry cuff transducers, like the one taught in Money, are bulky and uncomfortable when worn by a patient. In contrast, light-based pulse oximetry sensors are completely non-invasive, far smaller, and thereby, more comfortable when worn by a patient.

Ex. 1003 ¶ 195.

46. To be clear, a PHOSITA would not agree with those statements. Pulse oximetry, by definition, is noninvasive. It uses light passing through intact skin to determine blood oxygen saturation. Therefore, in my opinion, a PHOSITA reading Money would know that the pulse oximetry cuff transducer was a noninvasive, light-based device. It would not be possible to perform pulse oximetry without light. Also, a PHOSITA would not consider pulse oximetry to be invasive.

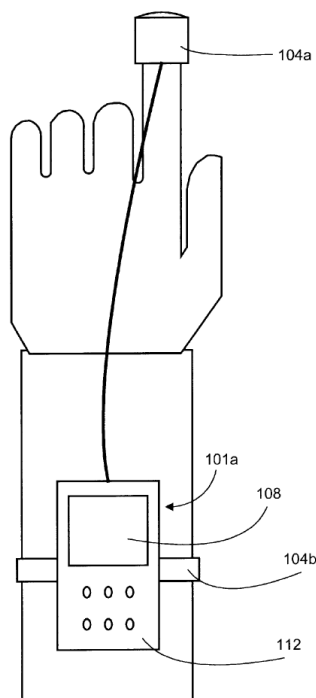
47. There are, however, invasive techniques to determine blood oxygen saturation without the use of light. For example, the oxygen content of a sample of blood drawn from a patient can be determined polarographically with a Clark electrode. *See, e.g.*, Ex. 2023 at 38. However, those techniques are just that—different techniques. A PHOSITA would not confuse those different techniques with pulse oximetry, which is a specific, non-invasive technique of determining blood oxygen saturation using light.

48. Although Money does not describe the pulse oximetry cuff transducer in any detail, a PHOSITA would be able to understand at the very least that the pulse oximetry cuff transducer is a noninvasive, light-based sensor for determining blood oxygen saturation. It is possible the cuff transducer could be a finger cuff type device where the red and infrared LEDs and a photodiode are contained in a flexible structure to wrap around a person's finger or other body part. If the cuff transducer were a finger cuff, a PHOSITA would not consider it to be bulky or invasive. Moreover, there is no description in Money that would suggest to a PHOSITA that the pulse oximetry cuff transducer in Money is bulky, uncomfortable, or an invasive device.

**C. Goldberg (U.S. Patent No. 6,840,904) (Ex. 1005)**

49. Goldberg involves a different type of device primarily meant for basic, remote monitoring away from a clinical setting. *See, e.g.*, Ex. 1005 at 1:6-18, 2:3-7, 5:28-33. Goldberg shows a device in Figure 2 that has a housing 112, a pulse oximetry sensor 104a, and a blood pressure cuff sensor 104b. Ex. 1005 at Figure 2 (reproduced below), 4:57-67. Goldberg does not show or disclose any sensor ports.

Figure 2



50. Goldberg explains that the blood pressure cuff is used as a strap to secure the device 101a to a person's forearm or wrist. *Id.* at 4:64-67. Goldberg did not limit his specification to what is shown in Figure 2 – he describes other embodiments. Goldberg also describes that “[i]n another embodiment, a non-invasive sensor is used to measure electrolyte levels by emitting an electric current to sense  $\text{Na}^{+1}$  and/or  $\text{K}^{+1}$  ions.” *Id.* at 4:67-5:3. Goldberg explains that other variations of its device are possible and could use other types of sensors. *Id.* at 5:3-8.

**D. Kiani (PCT Publication No. WO 00/42911) (Ex. 1006)**

51. Kiani describes a “universal/upgrading pulse oximeter” or UPO. Kiani explains that due to the incompatibility between pulse oximeters and sensors

between different manufacturers, hospitals cannot easily upgrade their existing pulse oximeters because that upgrade would also require upgrading their existing multiparameter patient monitors as well. Ex. 1006 at 2:24-33. Kiani also describes an additional problem that pulse oximetry may not be available for patients who are being transported between locations and the potential incompatibility between sensors in one location versus the other. *Id.* at 2:34-3:4.

52. Kiani explains that its UPO solves these problems by providing a transportable pulse oximeter that can stay with a patient as well as providing “a universal interface that matches incompatible sensors with other pulse oximeter instruments.” *Id.* at 3:5-9. This would allow hospitals to upgrade their existing monitoring equipment to use Masimo’s state-of-the-art pulse oximeters that have the SET® technology. *Id.* at 2:24-3:27, 6:12-19. Figure 2 of Kiani (below) shows a UPO in use with a hospital’s existing multiparameter patient monitoring system:

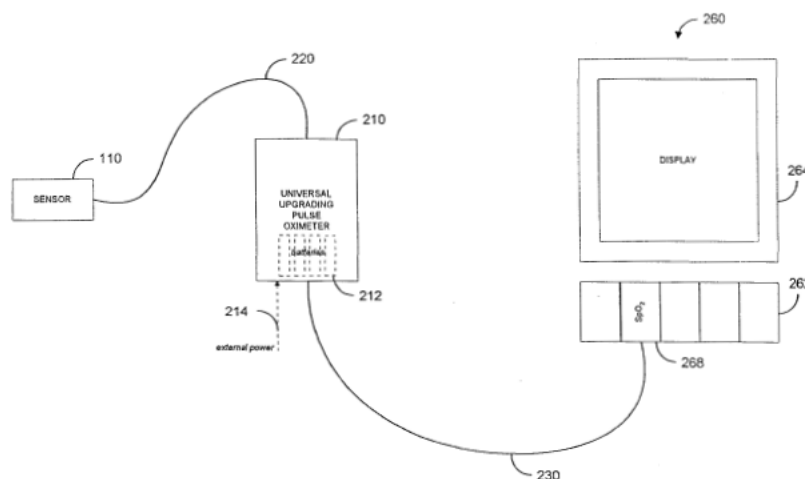


FIG. 2

53. Kiani explains that the UPO performs pulse oximetry measurements using the pulse oximetry sensor 110 and separately generates a signal that is received by an external pulse oximeter 268. *Id.* at 5:18-6:2. That signal is synthesized from the saturation calculated by the UPO such that the external pulse oximeter 268 is able to calculate the equivalent saturation and pulse rate that was calculated by the UPO. *Id.* Thus, once attached, there are two pulse oximeters in the hospital room—the existing pulse oximeter 268 and the UPO.

54. I understand that Petitioner and Dr. Yanulis generally rely on Kiani's Figure 5 for its alleged disclosure of sensor ports 540 and 550. Pet. at 22; Ex. 1003 ¶ 65. However, the UPO described in Figure 5 only has one sensor port, labeled as sensor input 550. Ex. 1006 at 8:31-33. Kiani explains that reference numeral 530 in Figure 5 is an external power supply input and that reference numeral 540 is an output port for connection to an external pulse oximeter, neither of which is a sensor port. *Id.* Kiani explains that the UPO generates a signal so that an external pulse oximeter can calculate the equivalent saturation and pulse rate that the UPO calculated. *Id.* at 5:25-30.

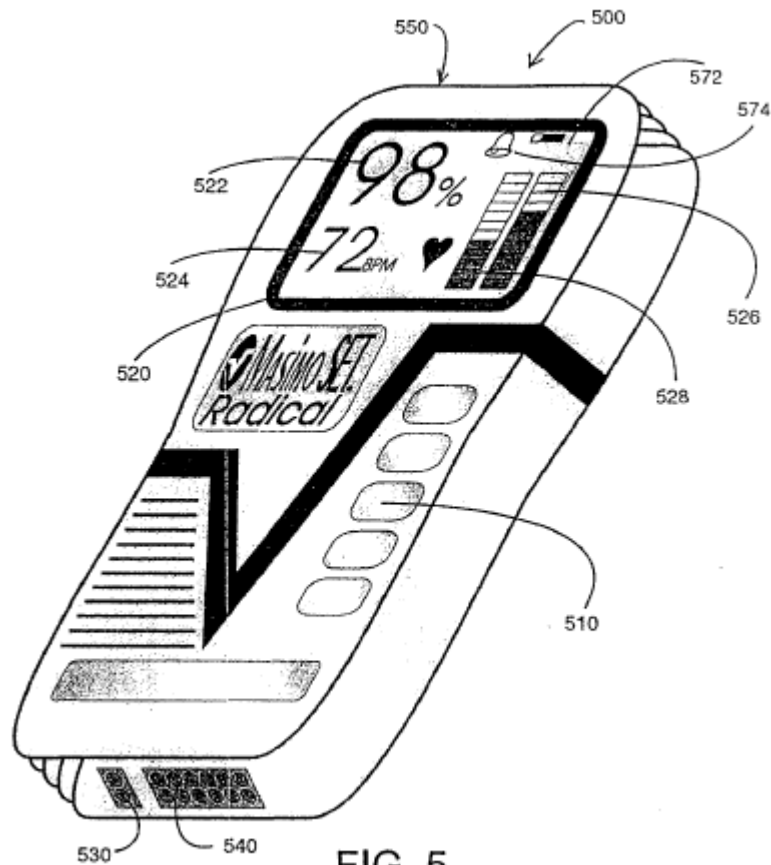
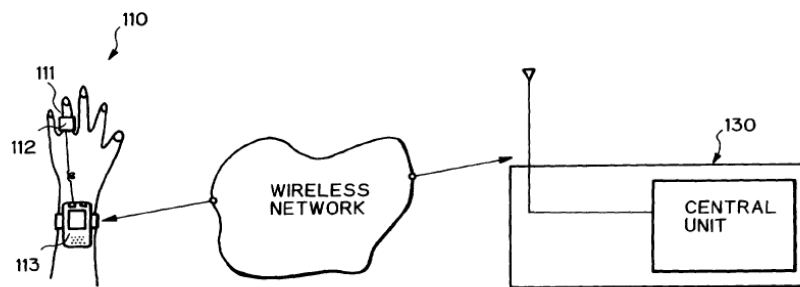
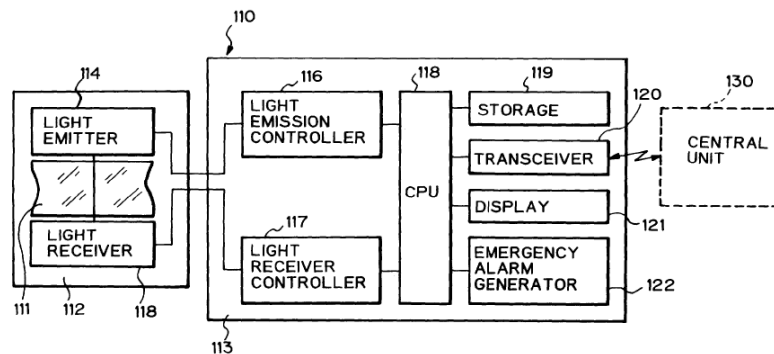


FIG. 5

*Id.* at Fig. 5.

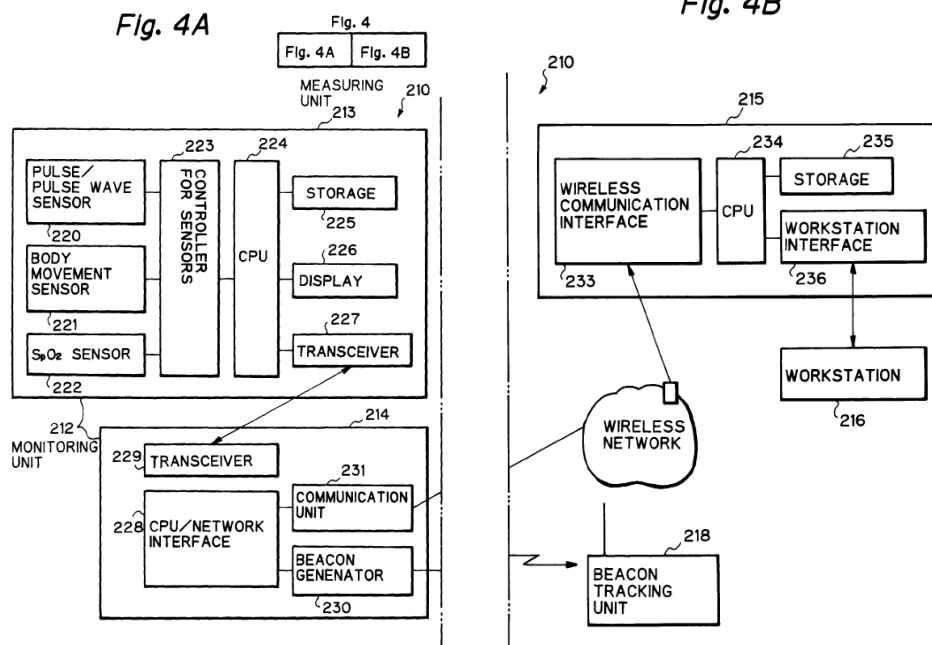
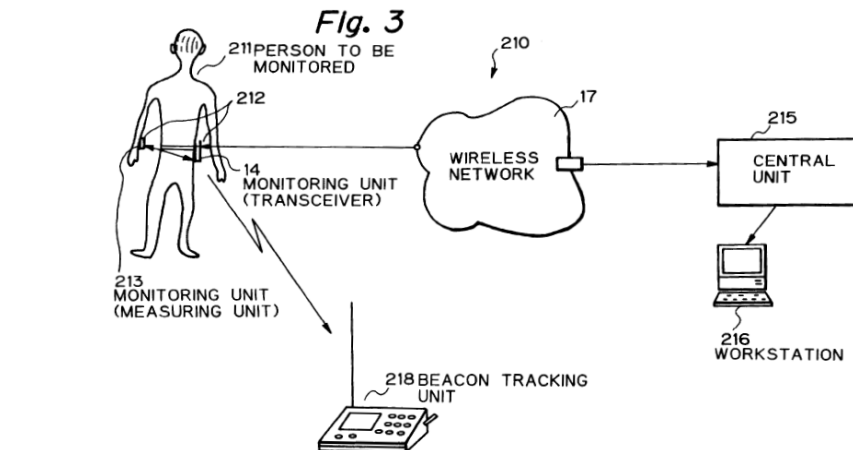
**E. Akai (EP0880936A2) (Ex. 1007)**

55. Akai describes three embodiments for remotely monitoring a patient. Akai's first embodiment, shown in Figures 1 and 2, is a blood glucose monitoring system 110. Ex. 1007 at Figs. 1, 2, 4:34-54. Akai explains that the system has a data processing unit 113 connected to an external sensor unit 112 via a fiber optic cable. *Id.* at 5:10-19. Akai also explains that the sensor unit 112 could also be an SpO<sub>2</sub> sensor instead of a blood glucose sensor. *Id.* at 6:9-14.

*Fig. 1**Fig. 2*

56. In the second embodiment, shown in Figures 3 and 4A-4B, Akai describes a monitoring unit 212 that comprises a measuring unit 213 for measuring the patient's physical data and a transceiver 214 for performing radio communication. *Id.* at 7:22-24. The measuring unit 213 contains three internal sensors integral to the housing: an SpO<sub>2</sub> sensor, a body movement sensor, and a pulse wave sensor. *Id.* at 7:41-58.





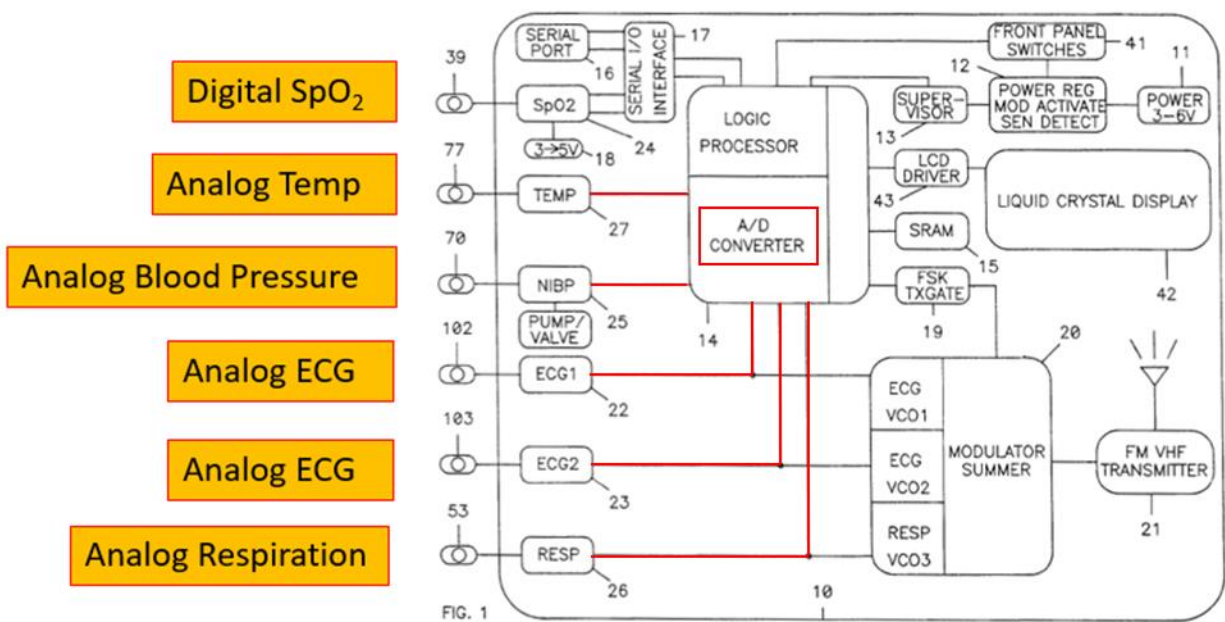
57. In the third embodiment, which is described as “similar” to the second embodiment, in Figures 5 and 6, Akai describes a terminal unit 312 that attaches to a patient and provides physical condition and location monitoring. *Id.* at 10:33-57.

#### F. Money (U.S. Patent No. 5,919,141) (Ex. 1008)

58. Money discloses a “remote patient monitoring device” for the “simultaneous monitoring of multi-channel ECG data, heart rate, pulse, pulse

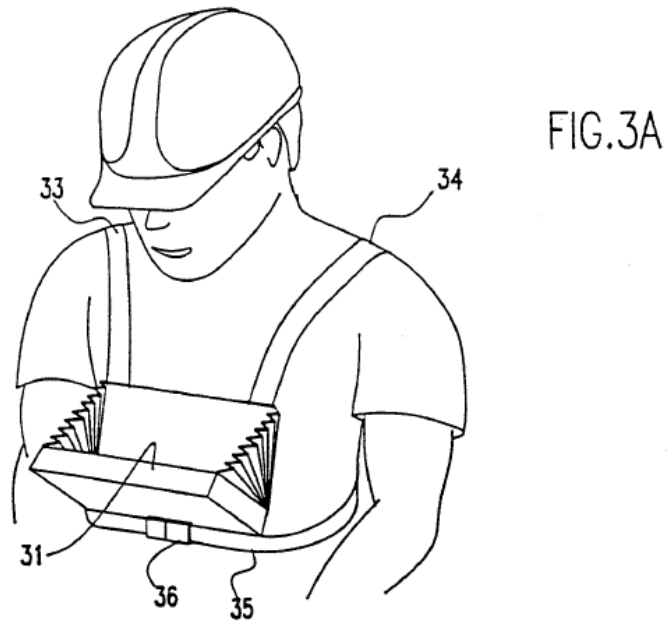
oximetry, temperature, respiration, and blood pressure, in a self-contained unit that can be worn by an ambulatory hospital patient.” Ex. 1008 at 2:64-3:2. Money does not describe exactly where the device would be worn on a patient’s body. However, the background section of Money describes a prior art device that is worn on a patient’s belt. *Id.* at 1:62-67. Money also describes its device as having dimensions of 3” x 6” x 1” and weighing up to 16 ounces. *Id.* at 3:39-40, 5:4-8.

59. Money explains that the device uses a “conventional pulse oximeter cuff transducer 39” for measuring SpO<sub>2</sub>. *Id.* at 5:38-41. Money explains that the SpO<sub>2</sub> signal is received digitally through a serial input/output (I/O) interface. *Id.* at 6:15-20, 7:58-62, 15:32-16:2. In contrast, the other signals for temperature, blood pressure, ECG, and respiration are received as analog signals and are later converted to digital by an analog-to-digital (A/D) converter within a processor 14 as shown with red annotations in Figure 1 below. *See id.* 1008 at FIG. 1. None of Money’s analog sensor data is from a pulse oximeter sensor.



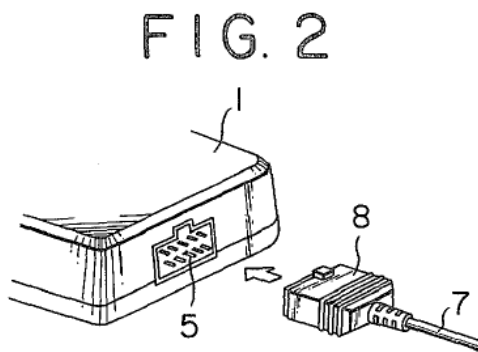
### G. Estep (WO 99/13698) (Ex. 1009)

60. Estep discloses an electrical signal measurement device for use in telecommunications measurement applications. Ex. 1009 at Abstract, 1:5-11. Estep states that an object of its invention is “to provide an electrical signal measurement device which can be worn by or attached to a technician so that the device [that] can be operated in a “hands-free” manner.” *Id.* at 1:22-23. The device of Estep may be “used in adverse conditions, usually in aerial situations (e.g., poles, platforms, bucket truck, etc.)” to protect against an accidental fall. *Id.* at 1:17-18. Estep teaches the device can be a chest mounted unit. *Id.* at 2:8-12, 4:14-27, FIG. 3A (reproduced below).



**H. Fujisaki (U.S. Patent No. 4,425,921) (Ex. 1016)**

61. Fujisaki discloses a “small portable-type apparatus for checking pulse or heart rate of a person engaged in exercise.” Ex. 1016 at Abstract. I understand that Petitioner and Dr. Yanulis rely on Fujisaki primarily to show a removable connection in Figure 2 (reproduced below).



## VII. OPINIONS

### A. Grounds 1-4: The Combinations Based on Goldberg Do Not Teach the Claimed Inventions

62. I understand Petitioner relies on the following Goldberg combinations to argue the claims are obvious.

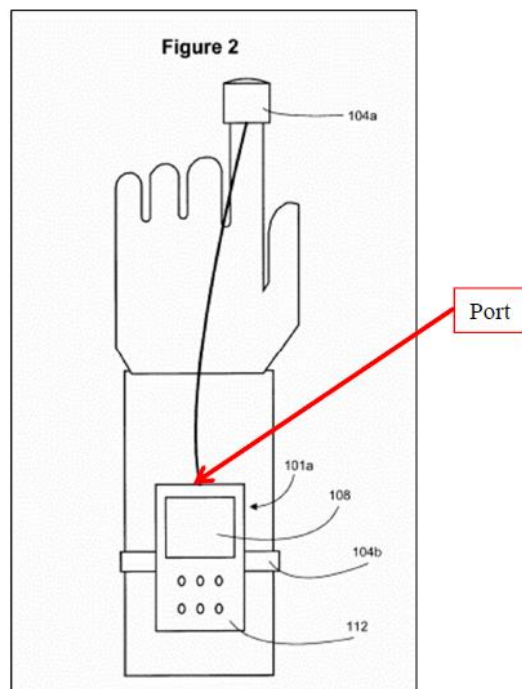
- Goldberg, Kiani, and Money to argue that Claims 1-2 and 7-9 of the '735 Patent are obvious;
- Goldberg, Kiani, Money, and Fujisaki to argue that Claims 3-6 and 13-19 of the '735 Patent are obvious;
- Goldberg, Kiani, Money, and Estep to argue that Claims 10-12 are obvious; and
- Goldberg, Kiani, Money, Fujisaki, and Estep to argue that Claim 20 is obvious.

63. However, in my opinion, the specific combinations that Petitioner advances with these references are based on an incorrect understanding of the references and the use of hindsight reasoning. Moreover, based on my review of Petitioner's arguments and its proposed combinations, I believe that a PHOSITA would not have been motivated to make the proposed combinations.

#### 1. Petitioner Incorrectly States that Goldberg Discloses Ports

64. Petitioner frequently and incorrectly states that Goldberg discloses sensor ports. For example, Petitioner states, "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 and because Goldberg teaches the controller receives electronic signals from the sensor 104a. . . . This teaching complies with the meaning of a port to a PHOSITA.” Pet. at 21. However, Goldberg does not discuss or show a port at all. Petitioner annotated Figure 2 of Goldberg with an arrow allegedly pointing to a port. *Id.* But Figure 2 does not show any port.



*Id.* (annotating Fig. 2 of Ex. 1005 to incorrectly suggest a port).

65. Figure 2 shows a wire between the sensor 104a and the housing 112. A PHOSITA would understand that to be showing a hardwired connection (e.g., a wire directly connected to a printed circuit board inside the housing). Thus, in Figure 2, the sensor 104a cannot be easily removed or replaced with another sensor by the

user. There is no port shown or disclosed here and a PHOSITA would not assume the addition of features that are not shown or even described. As I stated above, the term “sensor communication port” and “sensor port” should be construed in accordance with its plain and ordinary meaning of a connector that mates with a compatible connector from a sensor. There is no connector shown in Figure 2 of Goldberg or anywhere else in Goldberg. Also, there is no female connection or socket shown or described in Goldberg. Thus, Dr. Yanulis’ statement that ports are typically female connections or sockets of a wired connection also shows that Goldberg does not teach the alleged ports.

66. Petitioner also says that a “PHOSITA would assume that the wire shown above includes a port because ports are a common and typical electrical connection for a housing. . . . Therefore, Goldberg teaches a sensor port.” Pet. at 21-22. This statement is incorrect as Petitioner is claiming that Goldberg teaches an implied or assumed sensor port. But there is no such port shown or described in Goldberg. A PHOSITA would assume that there is no port because there is no port shown or described. Instead, a PHOSITA would understand that Goldberg discloses a hardwired connection.

67. Petitioner states that “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. I

disagree. A PHOSITA would not infer a port existed between Goldberg's blood pressure cuff sensor and housing. The electrolyte or other sensor is not illustrated in Goldberg. No port is shown in Figure 2 or described in Goldberg. Petitioner is essentially arguing that every wired connection would have a port. That is not true.

68. As I explain below, a PHOSITA would not be motivated to include a sensor in the blood pressure cuff. *See infra* § VII.A.3.a. The pressure sensor would instead be in the housing. Goldberg also does not describe or suggest that the blood pressure cuff sensor 104b is removable from the housing 112.

69. With respect to the electrolyte sensor, the cited portion of Goldberg explains that in a different embodiment, a sensor could be used to measure electrolyte levels. Ex. 1005 at 4:67-5:3. That reference does not mention a third sensor with a wired connection or a third sensor port. Goldberg does not show an electrolyte sensor in any of the figures, so it is difficult to know exactly how that would be implemented. However, a PHOSITA would understand that electrodes can be integrated into a housing, so it would not be necessary to attach them with external wires. As I explained above, patient compliance would have been a concern to a PHOSITA designing a wearable monitoring device.

## **2. Kiani Teaches A Single Sensor Port**

70. Kiani only describes a single sensor input 550, which is hidden on Figure 5 (reproduced below). Ex. 1006 at 8:31-33. 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 the external pulse oximeter. The oximeter output 540 is not a sensor port nor is the external power supply input 530. Thus, Kiani does not describe multiple sensor ports. The single sensor port 550 in Kiani is shown below:

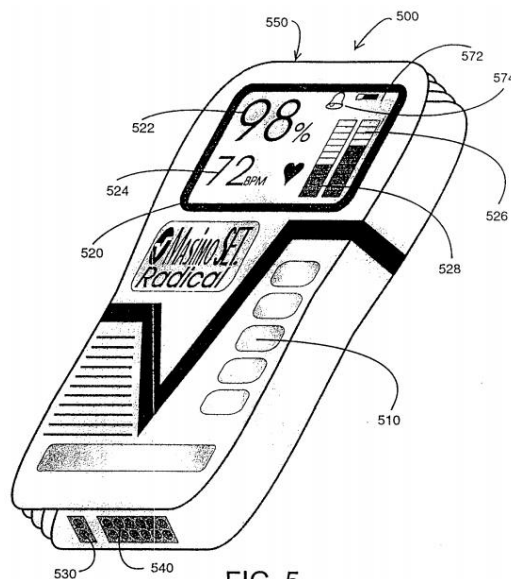


FIG. 5

### 3. A PHOSITA Would Not Have Been Motivated to Add Any Ports

71. Petitioner and Dr. Yanulis argue that Goldberg could be combined with Kiani to achieve the claimed sensor port arrangement. However, based on my review of their arguments, I believe that they have not provided an adequate reason for making such a modification to Goldberg. As I explain below, I believe that Petitioner and Dr. Yanulis are analyzing Goldberg in the wrong context by assuming Goldberg's device would be used by hospital clinicians. A PHOSITA would

understand that Goldberg's device was primarily intended for non-hospital use such as at-home monitoring by the monitored patient him or herself. When viewed in that correct context, a PHOSITA would have had reasons not to add sensor ports. Additionally, a PHOSITA would not have added a second sensor port between Goldberg's blood pressure cuff sensor and housing because that would have been undesirable for the reasons I will explain below.

72. Petitioner argued that "in a medical context, hardwired sensors are undesirable" and that "A PHOSITA would know that patients suffer from a variety of ailments, which require monitoring of different sets of vital signs. . . . In other words, a PHOSITA would know, using common sense and basic knowledge about the medical field, to build wired connections that allow for sensors to be readily connected and disconnected as needed, and ports were known to provide such adaptability." Pet. at 22-23. Dr. Yanulis also provides a very similar statement in his declaration at paragraph 64 and added that "because Goldberg teaches an adaptable system, a PHOSITA would assume that the wired connections of this adaptable device 100 includes ports." Ex. 1003 ¶ 64.

73. I do not see any evidence in the petition or explanation in Dr. Yanulis' declaration suggesting that hardwired sensors are undesirable in a medical context. Whether a particular sensor would be hardwired or not is a design decision that a PHOSITA designing the medical device would need to consider based on a variety

of factors. For example, if a sensor is intended for repeated use, a PHOSITA may decide that a hardwired connection is preferable over the removable connectivity of a port. The hardwired connection could include either an external cable that is non-removable or a sensor that is integrated directly into a device housing itself (and with no external cable and no port). Alternatively, a port connection may be appropriate if a sensor is designed to be disposable. Other considerations include the location on the body where the sensor is to be placed and whether significant patient movement would be expected. Also, the user has to take an extra step during device setup to connect the connector and then disconnect it after use. A removable connection may not be appropriate if patient movement can accidentally detach or dislodge a sensor from a sensor port, or worse, damage the sensor port, resulting in a faulty or loose connection, resulting in loss of critical information from the patient. As such, a removable connection introduces possible points of failure that provide a less secure connection than a hardwired connection where the connection is directly soldered to a circuit board and the cable is non-removably secured to the housing. A PHOSITA would understand that a hardwired connection may be more appropriate than a port for a number of reasons: (a) adding a connector increases cost, which may be critical in a competitive market, (b) a connector, having mechanical structures, can wear and be damaged, making connection difficult or impossible, (c) a connector may introduce contact noise due to poor or unstable

electrical connections (similar to “scratchy” noises and intermittent sounds in earphones due to poor connector contacts), which may cause a measurement gap or error, and (d) a connector takes up more space on a housing, adds bulk and weight, and may reduce the comfort of an arm-worn device. While these connector issues may not be as important for a conventional, full-sized patient monitor, a PHOSITA would be more concerned with them for an arm-worn device.

74. Signal noise is another factor a PHOSITA would need to consider when deciding whether a particular sensor would be hardwired or not. For pulse oximetry, in particular, the photodetector signal is typically low level. *See* Ex. 2033 at 6. As mentioned above, a PHOSITA would understand that the connector pair required for a port can cause open or poor electrical connections resulting in lost or inaccurate data (similar to “scratchy” noises and intermittent sounds in earphones due to poor connector contacts).

75. Additionally, Dr. Yanulis does not provide any evidence to support his conclusion that “a PHOSITA designing a medical monitor would know that the end user (clinicians, nurses, physicians, physician assistants) would expect an adaptable and configurable patient monitor that allows a clinician to utilize different sets of sensors to monitor the vital signs that the clinician deems most important in caring for a patient and monitoring the patient’s health.” Ex. 1003 ¶ 64. That statement may be true for a conventional, AC-powered, full-size patient monitor in a hospital

setting, but Goldberg shows a battery-powered (assumed because there is no external power connection), wrist-worn device. *See* Ex. 1005 at Fig. 2. A PHOSITA would understand that designing the device for portability would severely limit designing for adaptability and configurability and that clinicians needing portability would not necessarily expect adaptability and configurability as Dr. Yanulis has asserted. In other words, a PHOSITA would know that there are tradeoffs between portability and functionality. In my opinion, a PHOSITA as of 2002 would not have expected the same level of adaptability or reconfigurability in a wrist-worn monitoring device that a full-sized monitor would have. A wrist-worn device would be constrained by the power limitations of a battery, whereas a conventional patient monitor plugged into an electrical socket would not. A wrist-worn device would also have size and weight requirements that are more restrictive than those of a full-sized monitor. If a clinician in 2002 needed an adaptable and configurable system, he or she would have simply used a conventional patient monitor.

76. I also do not believe that Dr. Yanulis has analyzed Goldberg in the correct environment of use. He refers to “clinicians, nurses, physicians, physician assistants” as the end users for Goldberg’s device. *See* Ex. 1003 ¶ 64. However, that is not the correct group of end users for Goldberg’s device. I have been informed that during his deposition, Dr. Yanulis listed anesthesiologists in the middle of surgery and cardiologists with patients in heart failure as examples of clinicians who

would demand the level of adaptability and configurability stated in his declaration. However, those would be the wrong end users for the portable device as described in Goldberg. A PHOSITA would know that an anesthesiologist with a patient on an operating table or a cardiologist with a patient in heart failure are highly unlikely to use a portable, wrist-worn device to monitor vital signs. In such a scenario, the accuracy and reliability of the monitoring device is a matter of life and death. There are and were multiparameter patient monitors that were specifically designed for such critical care or surgical use scenarios. For example, the Datex Model AS/3 Anesthesia Monitor was available in 1995 and was specifically designed for anesthesia monitoring. Ex. 2030 at 2-1. That monitor had a central unit and display and eight slots for configurable parameter modules. *Id.* at 2-19. While Goldberg's device may be sufficient for basic monitoring, such as for personal, at-home use, a PHOSITA would not expect it to be used for a critical care situation when there are other monitors better suited to the task.

77. A PHOSITA would understand that Goldberg's device is primarily intended for personal use by members of the general public, and not clinicians in a critical care setting such as a hospital. Goldberg describes the device as "a portable medical monitoring device that is sized to be carried by a monitored person" and the "portable device may operate in a system including a remote computer and a wireless communication link to the portable device." Ex. 1005 at 1:6-18. Goldberg also

explains “In a network embodiment, the remote computer may comprise a server that can be accessed in push and/or pull modes by, for example, authorized client computers of parties such as the monitored person and his or her family members, and health care professionals.” *Id.* at 2:3-7. Goldberg further explains that the device can also retrieve and display “news, sports, or entertainment on the display device.” Ex. 1005 at 5:54-57. Additionally, Figures 6a-6d show messages directed toward the monitored person including: “Your Averages are as follows,” “Your Daily Averages,” “Your Weekly Averages,” and “Everything is just fine!!!!!!” *Id.* at Figs. 6a-6d. On the cover page, Goldberg also references an article titled, “Clothed in Health” by Hardesty. Goldberg at Cover. That article generally discusses “[h]ome health gauges” for day-to-day health monitoring. Ex. 2029 at 1. Thus, a PHOSITA would understand that Goldberg’s device is primarily intended for personal, remote use (typically at-home) rather than critical clinical use by a physician.

78. A PHOSITA would also understand that Goldberg’s device was not intended for clinical use, such as for monitoring patients under anesthesia or in heart failure, because wrist-worn blood pressure monitors (like the one described in Goldberg’s Figure 2) were generally understood to be unsuitable for clinical use at the time. For example, in *Self blood pressure monitoring at home by wrist devices: a reliable approach?*, published in 2002, the authors explained that wrist blood

pressure devices were gaining popularity for the self-measurement of blood pressure at home. Ex. 2025 at 575-76. However, those devices had well-known problems with accuracy and reliability due to the need to maintain the wrist at heart level during measurements and that flexion or extension of the wrist could lead to unreliable measurements. *Id.* at 576. The article concludes that “In spite of the time-honoured interest in wrist blood pressure measurement, the above observations strongly emphasize the need for great caution when dealing with wrist blood pressure measuring devices, and in agreement with recent Hypertension Management Guidelines, they support the view their general use in clinical practice should not at present be recommended.” *Id.* at 577. Thus, a PHOSITA as of the 2002 priority date for the ’735 Patent would not have been motivated to address a clinician’s demand for adaptability or conformability by modifying Goldberg’s device, because the actual end user was not intended to be a clinician in a critical care setting such as a hospital.

79. Instead, a PHOSITA designing a wearable device for personal or non-critical care use would have been motivated to address human factors such as use compliance and comfort. Dr. Yanulis touches on this topic only very briefly in his declaration where he states that “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.” Ex. 1003 ¶

29. Based on that reasoning, I believe a PHOSITA would not have been motivated to add sensor ports when that would have decreased patient comfort and patient compliance.

80. As mentioned above, Goldberg’s device was intended for remote monitoring in a non-hospital setting, where the user would typically be the monitored person and his or her family members, rather than a professional clinician. In this context, a PHOSITA would find it undesirable to add numerous sensors and sensor ports that would complicate the device. Monitored persons and family members, who may not be healthcare professionals or tech savvy, would have difficulty hooking up numerous sensors and wires to a device and to the monitored person’s body in order to simultaneously monitor a wide variety of physiological parameters. Instead, a PHOSITA would have wanted to make the device as simple as possible to encourage compliance. Lack of attention to these issues could lead to missed or incorrect data leading to incorrect therapy management. This desire not to complicate the device was well-known and documented. For example, the Akai reference explicitly states: “Even though appropriate monitoring is possible by using a device, if the use of such a device restricts everyday life and lowers the quality of life (QOL), then such a device will tend not to be used by a patient.” Ex. 1007 at 1:56-2:1. As another example, the article *Human Factors Analysis of an ICU*,

published in the Journal of Clinical Engineering in 1998, explained that, in the context of ICU instruments, the “Mechanical aspects of plugging multi-pin connectors into their respective ports were also a source of annoyance and connector degradation.” *See* Ex. 2024 at 110, 112. That article also explained that “The multitude of cables and tubing that were connected to the typical patient was also seen to be a problem. . . . There were several instances observed where the patient was nearly engulfed in cables, and when a nurse had to check the machines or the cables, you could see her tracing each one from patient to machine.” *Id.* at 112. If complicated and messy cables were already a problem for professional healthcare workers in the ICU, a PHOSITA would not be motivated to replicate that problem for the home user. Thus, a PHOSITA would understand that making a remote monitoring device for personal use more complicated, for example, by requiring the user to connect/disconnect numerous wires to numerous sensor ports or attach more things to his or her body, would be undesirable. The annoyance to an end user caused by an overly-complicated device would dissuade a PHOSITA from adding a sensor port, much less multiple sensor ports.

81. Dr. Yanulis also states that “Goldberg teaches an adaptable system” as a reason to assume that Goldberg has ports. Ex. 1003 ¶ 64. However, there is no discussion in Goldberg about adaptability and Goldberg never describes the device as adaptable. Dr. Yanulis cited Goldberg at 5:3-8 to support that statement.

However, the Goldberg citation states: “It is contemplated that the medical monitoring device may contain one, all, or any combination of the above-mentioned sensor types, as well as other sensors.” Ex. 1005 at 5:3-8. That statement does not suggest an adaptable system, only that Goldberg is compatible with multiple devices. Goldberg suggests that different versions of the device could be made with different sensors. A PHOSITA would not understand Goldberg to describe a device with interchangeable sensors.

82. Additionally, neither Petitioner nor Dr. Yanulis explains how a sensor port would allow for other types of sensors to be connected other than an SpO<sub>2</sub> sensor. As I explain in further detail below with respect to the third sensor port limitation, a PHOSITA would not have expected such interoperability or adaptability between different types of sensors. *See infra* § VII.A.3.b.

83. Looking at Goldberg’s Figure 2, there is no port shown and Goldberg does not describe the sensor 104a as removable. Additionally, because the device is primarily intended for personal use, a PHOSITA would assume that there is no port. Therefore, I do not believe that PHOSITA would have been motivated to add a sensor port or even multiple sensor ports to Goldberg’s device. In particular, Dr. Yanulis appears to have applied the wrong analysis, based on an incorrect understanding of Goldberg’s actual disclosure and who the end user would be.

84. Petitioner states that “it was very common in the medical field to monitor multiple vital signs simultaneously.” Pet. at 26. As I explained above, that would have been true of a more conventional, full-sized patient monitor. Additionally, that statement may be correct, but a PHOSITA would also understand that not every monitor needs to measure multiple vital signs simultaneously. Instead, it depends on the specific user needs for a particular system. As I also explained above, for a wrist-worn device, adding more sensor ports and more sensors could overly complicate the device and annoy the user, decreasing the likelihood that the user would actually wear the device. A PHOSITA would be particularly concerned with user compliance (actually using the device) because Goldberg’s device is intended for remote monitoring. Ex. 1005 at 1:6-18, 2:3-7.

85. Dr. Yanulis states that “modifying Goldberg with Kiani would have been a combination of known concepts (wired electrical communication and wired electrical communication using ports) to yield predictable results.” Ex. 1003 ¶ 65. I disagree. As explained above, a PHOSITA would understand that switching from a wired connection to a port on a portable device is not an obvious or straightforward modification for an arm-wearable patient monitor.

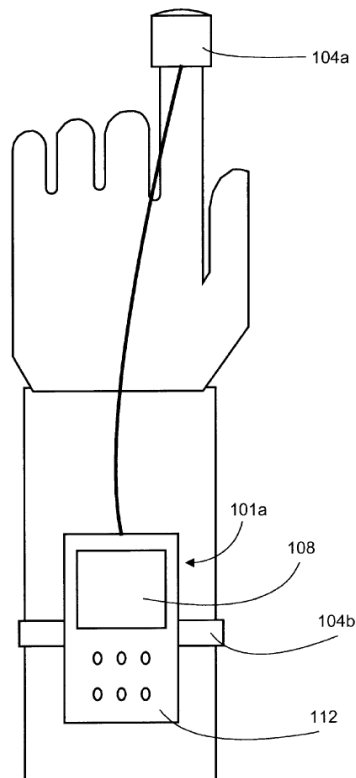
86. Kiani describes a single sensor input 550, which is not shown on Figure 5. Ex. 1006 at 8:31-33. The fact that one sensor port exists in Kiani’s device would not make multiple sensor ports on Goldberg obvious or a duplication of parts to a

PHOSITA, particularly in view of the complications and disadvantages I described above.

**a) A PHOSITA Would Not Add a Sensor Port between Goldberg's Housing and Blood Pressure Cuff**

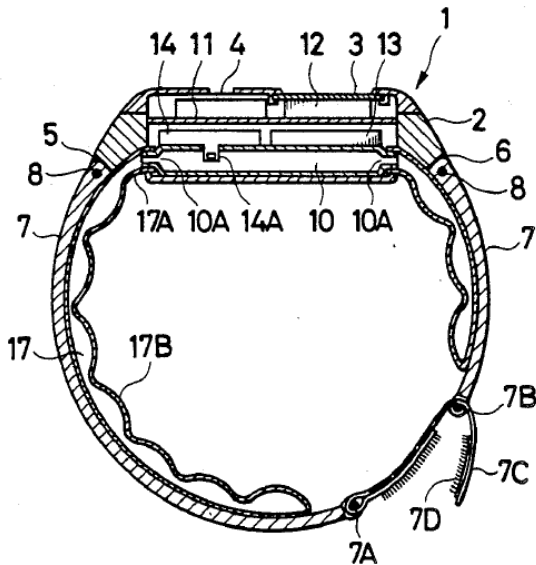
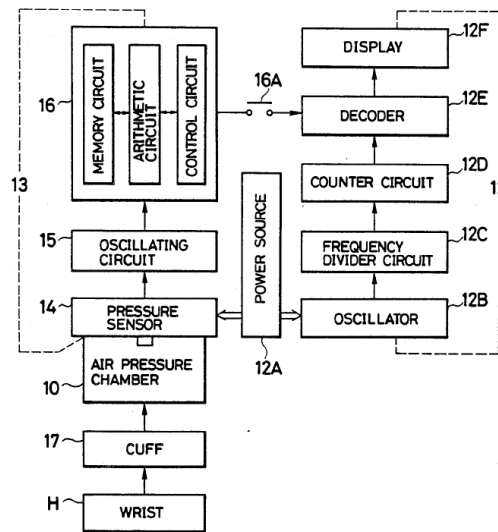
87. I understand that Petitioner relies on the blood pressure sensor in Goldberg for one of the additional sensor ports. Pet. at 27. In my opinion, a PHOSITA would not have been motivated to add a port between Goldberg's blood pressure sensor and housing and would not have had a reasonable expectation of success in doing so.

88. Goldberg explains that in Figure 2, the blood pressure cuff is used as a strap that secures the device to a patient's wrist. Ex. 1005 at 4:57-67. Because it serves that securing purpose, a PHOSITA would not be motivated to modify the blood pressure cuff sensor to make it removable from the housing. That modification would run counter to the purpose of the cuff, which is to secure the housing to a person's wrist. Additionally, as I explain below, the modification also would be nontrivial and would not provide any significant benefits that would outweigh the disadvantages.

**Figure 2**

Ex. 1005 at Fig. 2.

89. A PHOSITA would know that a blood pressure cuff needs to be inflated and deflated to measure a patient's blood pressure. A PHOSITA would also know that a pressure sensor would be positioned within a housing in order to measure cuff pressure and determine blood pressure. For example, U.S. Patent No. 4,896,676 to Sasaki describes a wrist-worn blood pressure measuring unit "composed of a pressure sensor 14 for measuring the air pressure in the air pressure chamber 10, an oscillating circuit 15 for converting the pressure measurements supplied from the pressure sensor into digital signals, and a processor 16 for comparing the digital signals supplied from the oscillating circuit 15." Ex. 2026 at 3:14-21, FIG. 4.

**FIG. 2****FIG. 4**

*Id.* at FIGS. 2, 4. A PHOSITA would understand that the pressure sensor is a part internal to the housing. There is no port to electrically communicate with the cuff. No sensor port would be involved because the pressure sensor would be within the housing, rather than in the cuff. If, for some unknown reason, the pressure sensor needed to be in the cuff instead of the housing and the cuff needed to be removable, a PHOSITA would understand that there would need to be a sensor port that also provides an airtight connection from the housing to the cuff. An air leak would render the blood pressure cuff unusable. A PHOSITA would most likely not be successful in moving the pressure sensor to the cuff and making the cuff removable from the housing. The reliability of the pressure sensor would be reduced. A sensor port would prevent the housing from being sufficiently secured to a patient's wrist. There would not be enough space for these additional structures. Further, the device

would become too large and cumbersome to be comfortably worn on the wrist. This is not mentioned anywhere in Dr. Yanulis' declaration, so it does not appear that he understood this technical requirement.

90. Additionally, because Goldberg explains that the blood pressure cuff also secures the device to a patient's wrist, a PHOSITA would understand that the connection between the housing and cuff must be able to support the weight of Goldberg's device and withstand sudden forces caused by patient movement.

91. A PHOSITA would understand that the simplest way to provide an airtight seal and secure connection for the blood pressure cuff would be to directly integrate the cuff with the housing (a permanent connection). A PHOSITA would know that a sensor port would not be adequate for this situation because wear and tear caused by repeated use and patient movement can damage a sensor port such that the pneumatic connection or electrical connection may become unreliable.

92. If, for some reason, a PHOSITA were to try to create such a removable blood pressure cuff and sensor port, he or she would find it to be prohibitively bulky and infeasible. As described above, such a sensor port to connect Goldberg's blood pressure cuff to Goldberg's housing would need to satisfy at least three requirements: (1) provide an airtight pneumatic connection between a housing and the cuff, (2) provide a sufficiently strong retention mechanism so that the housing remains attached to the cuff and person's wrist and withstand sudden forces, and (3)



provide a reliable electrical connection for the pressure sensor. Neither Petitioner nor Dr. Yanulis identify a sensor port in the prior art that can satisfy those three requirements while also being able to fit on a wrist-worn device without negatively impacting comfort or bulkiness. Petitioner and Dr. Yanulis also do not explain how that can be done simply based on Kiani's disclosure of an SpO<sub>2</sub> sensor port. In my opinion, a PHOSITA would understand that this would not have been a trivial mechanism to implement and is not a combination of known concepts to produce predictable results as Dr. Yanulis concluded. Ex. 1003 ¶ 78. This combination would require a PHOSITA to design and develop a new sensor port, not shown anywhere in Petitioner's references, to address these issues.

93. Even today, nearly two decades after the '735 Patent's priority date, wrist-worn blood pressure cuffs are still generally not designed for user detachment or replacement. Additionally, based on my review of patents from both before and after the March 2002 priority date and discussed below, I believe that a PHOSITA designing a wrist-worn blood pressure cuff would not have placed a pressure sensor within the blood pressure cuff. Instead, the sensor would have been placed within the housing.

94. For example, I purchased an Omron wrist-worn blood pressure monitor from Amazon on January 29, 2021 for inspection. (Model No. BP4350). According to the item description on Amazon and the copyright notice in the user manual, this

was first available in 2019. There are several things to note about this modern-day wrist-worn blood pressure monitor. First, the cuff does not appear to be user detachable. While I was able to disassemble the device by using a tool (not supplied with the device) to unscrew a screw, I do not believe this was intended for the end user to disassemble. Below are photos that I took of the device as I disassembled it.



Omron Gold Wrist Blood Pressure Monitor (Model BP4350).



Left: Wrist strap pulled back, revealing a screw on the back of the housing. Right: Screw removed and wrist strap detached from housing, showing two air-sealing pneumatic connectors.



Left and right: Housing and cuff disassembled.

95. The user manual for this device further confirmed my understanding that this was not intended for user disassembly. It contained a warning: “DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.” (See photo below from supplied Instruction Manual, annotated in red).

**Battery Handling and Usage**

- Keep batteries out of the reach of infants, toddlers and children.

**⚠ Caution**

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor on a wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the wrist cuff when it is applied on your wrist.
- Remove the wrist cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.

Ex. 2028.

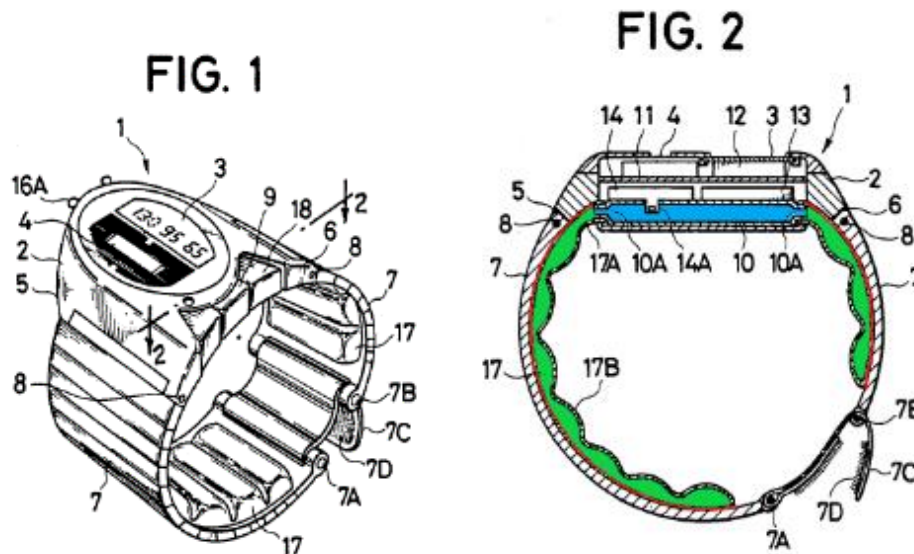
96. Additionally, as I suspected, there was no circuitry in the blood pressure cuff. As shown in the photos above, there is no sensor port or any other electrical connection between the blood pressure cuff and the housing. The cuff contains an air bladder and no electronics. That means that the pressure sensor is inside the housing, rather than in the cuff.

97. A PHOSITA would not choose to place a pressure sensor inside a cuff because a PHOSITA would then need to design a way to protect the pressure sensor and air bladder from damage that could be caused by placing a rigid object inside a

flexible, inflatable bag (e.g., puncturing the air bladder). Placing the sensor within the housing and having the sensor in fluid communication with the cuff would have been a much simpler design and would not have required a sensor port or extra wiring.

98. In my opinion, a PHOSITA at the time of the invention, nearly two decades ago, would not have been motivated to make the modifications Dr. Yanulis has proposed or would have expected any success in making the combination. Additionally, with general advances in electronics and connector miniaturization over those two decades, it would be simpler to have such a port and user-removable cuff in a device from 2019. Yet, the device I purchased and inspected did not have this feature.

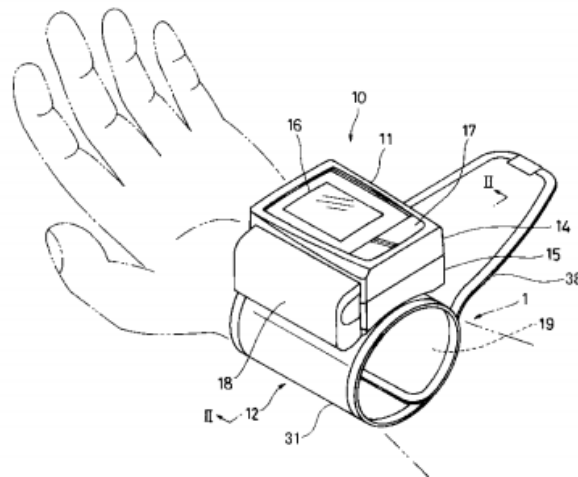
99. I also searched for and reviewed patents relating to wrist-worn blood pressure monitors. Based on my review of the patents, I do not believe a PHOSITA would have expected any of them to be removable from their respective housings. For example, U.S. Patent No. 4,896,676 to Sasaki (filed in 1988) is titled “Blood Pressure Measuring Unit” and generally describes a wrist-worn blood pressure measuring unit in the shape of a watch.



Ex. 2026 at FIGS. 1-2 (annotated). Sasaki teaches that the blood pressure cuff 17 is attached to the wristband 7 with an adhesive. *Id.* at 3:49-54. In Figure 2 above, I highlighted cuff 17 in green. The patent explains that the cuff 17 contains air that communicates with an air pressure chamber (highlighted in blue) which contains the pressure sensor 14 for measuring the air pressure in the air pressure chamber 10. *Id.* at 3:12-34.

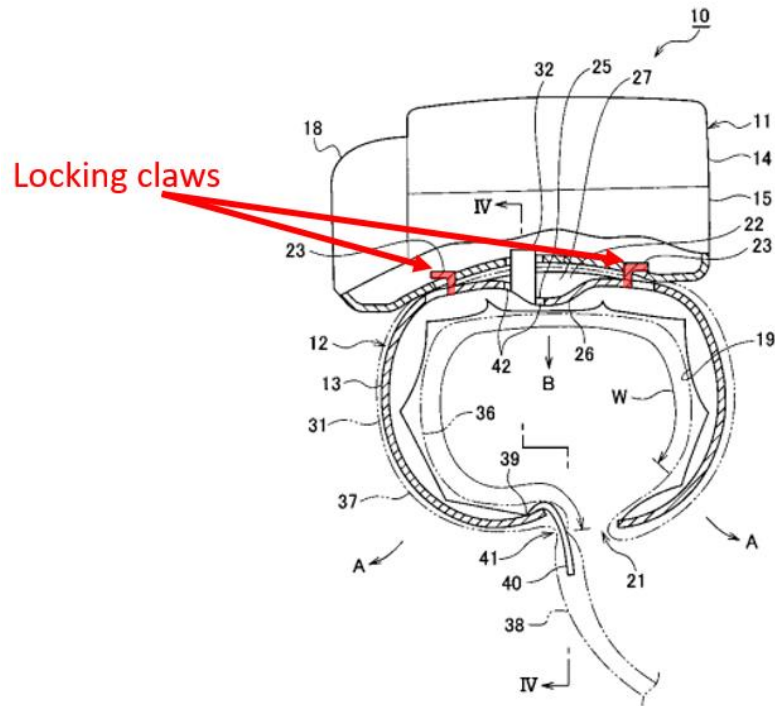
100. As another example, JP4777640B2 to Junichi (filed in 2004) describes a complex apparatus specifically for connecting a blood pressure cuff to a housing. Ex. 2027. Because this reference is in Japanese, I reviewed the English machine translation of the description that is available on espacenet.com. Based on my review, my opinion is that a PHOSITA would understand that Junichi discloses a permanent connection between a blood pressure cuff and a housing, which includes three locking claws 23 (hook mechanisms) and a screwing piece 24, both integrally

molded to the blood pressure cuff spring, in order to prevent movement of the two communications tubes 55 and 56 that pass between the insertion ports 57 and 58 to reach inside of the blood pressure monitor main body 51. *Id.* ¶¶ 4, 22. A PHOSITA would also understand that the pressure sensor is within the body of the housing itself and not within the cuff.

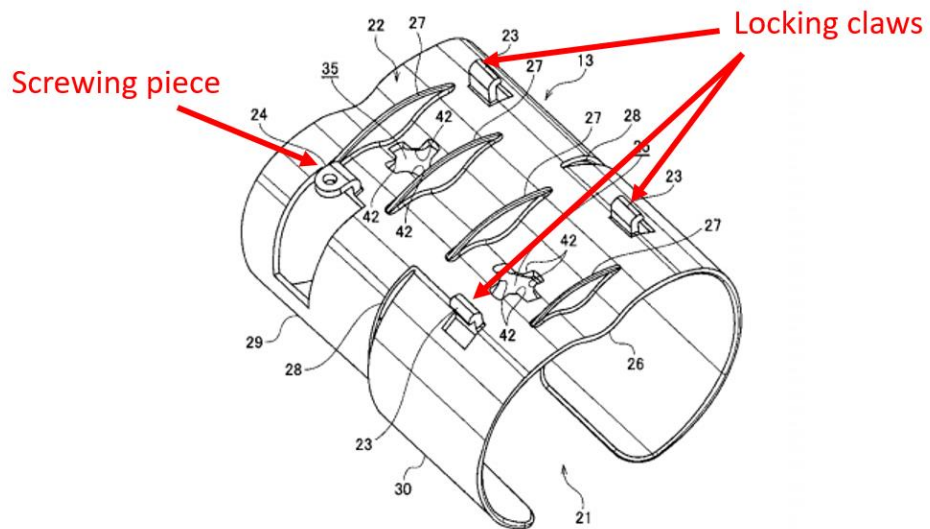


*Id.* at Fig. 1.



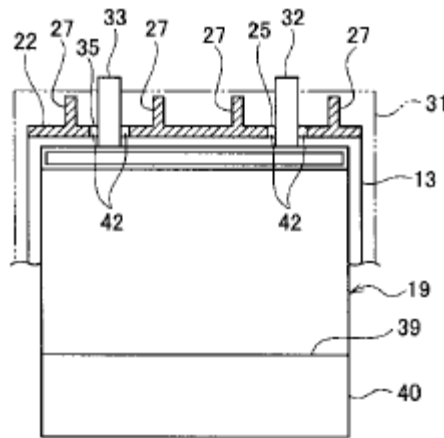


*Id.* at Fig. 2 (annotated in red).



*Id.* at Fig. 5 (annotated in red).





*Id.* at Fig. 4.

101. I am not currently aware of any example of a wrist-worn blood pressure monitor as of 2002 where the cuff is removable from the housing, nor of one with a sensor in the cuff requiring a sensor port on the housing. Again, in my opinion, a PHOSITA would not have had a motivation to design a removable cuff and sensor port and would not reasonably expect success in doing so, because such a combination would require a PHOSITA to design a sensor port that can satisfy all the requirements I explained above. Accordingly, I do not agree with Petitioner or Dr. Yanulis that a PHOSITA would have been motivated to modify Goldberg to add a second sensor port between the blood pressure cuff and housing of Goldberg.

**b) A Third Sensor Port Would Not Be a Duplication of Parts**

102. Petitioner and Dr. Yanulis also argue that a third sensor port would have been obvious in view of Kiani and that it would have been an obvious duplication of

parts. Pet. at 27; Ex. 1003 ¶ 79. I disagree that a third sensor port would have been a duplication of parts. A PHOSITA would understand that each sensor port needs to have a unique connector, unique keying, or any combination of these such that each sensor can be connected to only one sensor port. Additionally, a PHOSITA would know that the interface circuit associated with each sensor port would be electrically different for each sensor type. A PHOSITA would understand this from, for example, Money (Ex. 1008) where the circuits for sensor types to measure SpO<sub>2</sub>, temperature, NIBP, ECG, and respiration are all unique. *See* Ex. 1008 at Figs. 2C, 5B, 5A, 3A/4A, 6 (respectively). Furthermore, even for sensors of the same type, Kiani explicitly teaches: “Unfortunately, there is **no standard** for either performance by, or **compatibility between, pulse oximeters or sensors**. As a result, sensors made by one manufacturer may not work with pulse oximeters made by another manufacturer.” Ex. 1006 at 2:25-27 (emphasis added). Therefore, a PHOSITA would not expect a sensor port for a third or any other sensor to just be a generic duplication of another sensor port.

103. The article *Human Factors Analysis of an ICU*, which I mentioned above, also documented the incompatibility problem. It stated:

The ICU has a history of having human factor problems, including clutter of the workspace, confusing alarms and alarm controls, inadequate or inconsistent color coding, and the lack of standardization between similar or interrelated devices from different manufacturers.

Ex. 2024 at 111.

Mechanical aspects of plugging multi-pin connectors into their respective ports were also a source of annoyance and connector degradation. On the blood pressure modules of the patient monitoring system, the female connection point of the 12-pin connector had wear grooves that were created during the many incorrect attempts at inserting the connector into its socket. This could have been caused by two things. First, nurses could have repeatedly attempted to install an incorrect wire into the port. For example, they could have tried to insert the EKG connector into the blood pressure port.

*Id.* at 112-13.<sup>1</sup> Thus, even on a conventional monitor, a PHOSITA would not have expected a third sensor port to be a duplication of another port.

104. As I also explained above, a PHOSITA would not have been motivated to add a second sensor port for the blood pressure cuff either, so there would not have been a sensor port to duplicate there. But even if a PHOSITA felt compelled to make a second sensor port for whatever reason, a PHOSITA would have understood that the sensor port would have had to have been unique for the blood pressure cuff. The problems associated with maintaining the housing on a patient's

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<sup>1</sup> A PHOSITA would know that the blood pressure modules referenced in this article are referring to invasive blood pressure measurements due to the ICU setting.

wrist, providing an air-tight connection, and support circuitry for a different sensor type, would not translate to a duplicate sensor port.

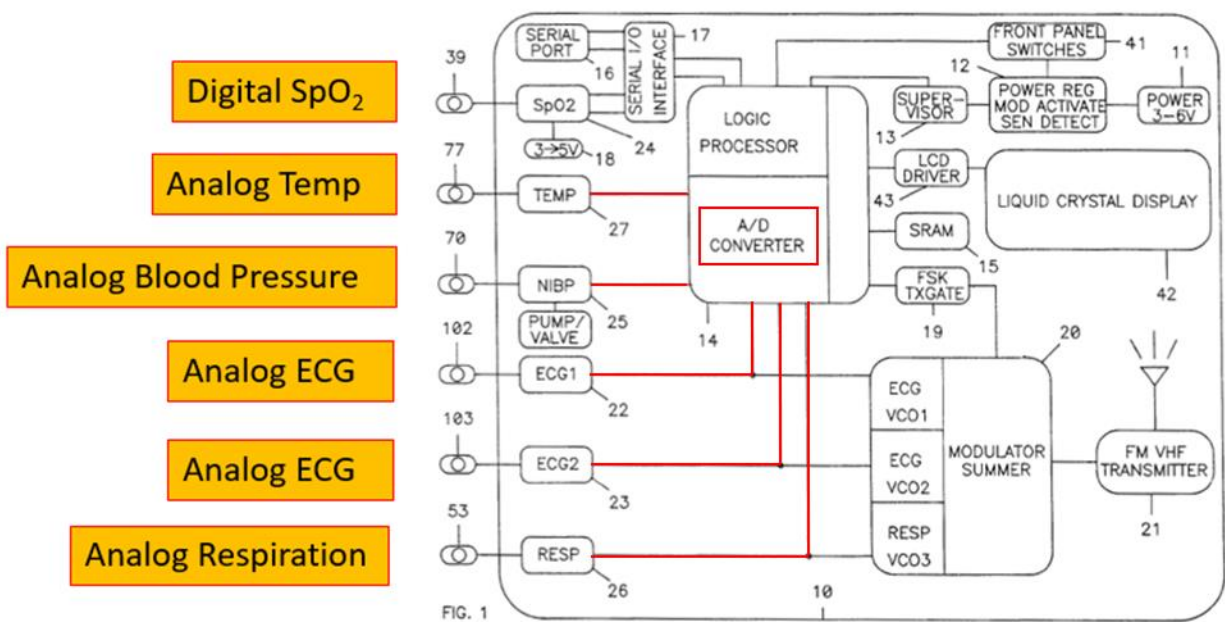
105. Accordingly, for at least these reasons above, I believe that a PHOSITA would not have been motivated to combine Goldberg with the other asserted references to arrive at a wrist-worn patient monitor with three sensor ports.

#### **4. The Combinations of Asserted References Do Not Teach the Claimed Data Signal Configurations**

106. I understand that each of the independent claims requires a physiological sensor, other than a pulse oximetry sensor, that provides a digital signal.

107. Goldberg does not describe whether any of its sensors are analog or digital.

108. Money also does not teach the claimed data signal configurations but, rather, describes the opposite arrangement. As I described above, all of the sensors in Money are analog except for Money's SpO<sub>2</sub> sensor, which is digital. Ex. 1008 at 5:18-51, 6:15-20, 7:58-62, 8:20-27, 13:26-28. In fact, Money's SpO<sub>2</sub> sensor is the only sensor in any of Petitioner's asserted references that is digital. Thus, none of Petitioner's asserted references describes a physiological sensor, other than a pulse oximetry sensor, that provides a digital signal, as required by the independent claims.



Ex. 1008, FIG. 1 (annotated). The red annotations show how the signals for temperature, blood pressure, ECG, and respiration are received as analog signals and later converted to digital by an analog-to-digital (A/D) converter within a processor 14. *See* Ex. 1008 at FIG. 1.

109. Because Money only discloses a digital SpO<sub>2</sub> sensor, a PHOSITA would not understand how the combination of Goldberg as modified by Money would have a digital sensor other than the SpO<sub>2</sub> sensor.

### 5. A Person of Skill Would Not Have Been Motivated to Include the Claimed Data Signal Configurations

110. I understand Petitioner and Dr. Yanulis argue it would have been obvious to try transferring digital data because there are only two signal possibilities. Pet. at 28 (citing Ex. 1003 ¶ 80). Dr. Yanulis further states that “It’s irrelevant

whether the signal received is analog or digital because it will eventually be converted into a digital signal regardless of what form it is received in.” Ex. 1003 ¶ 71. However, there are many factors to consider when choosing whether to transfer data as analog or digital. I therefore am of the opinion that a PHOSITA would not agree with Dr. Yanulis’ statement. Rather, a PHOSITA would recognize that there are tradeoffs associated with data transmission via analog or digital signals. Examples of such tradeoffs include component costs, component sizes and weights, power consumption, and susceptibility to noise. These differences are not irrelevant, especially within the constraints of a device intended to be worn on the arm. To summarize, it is not “irrelevant” whether a signal is analog or digital and a PHOSITA would know to do a thorough analysis in deciding which domain is appropriate.

111. As an example of this analysis, for a typical pulse oximetry sensor, the signal generated by the sensor’s light detector is inherently an analog signal produced by a photodetector. Additionally, the photodetector signal is typically a low level of about 1  $\mu$ A (one millionth of an amp). Ex. 2033 at 6. A PHOSITA designing the sensor interface circuit would analyze the tradeoff between using an analog or digital circuit. Transmitting analog data by wire and through a connector may introduce noise due to interference from environmental sources. Thus, a PHOSITA would consider design options to prevent this noise, such as shielding techniques. A PHOSITA may also consider placing a high-gain analog amplifier in

the structure containing the photodetector to amplify and convert the low-level photodetector current to a voltage level less prone to noise interference and suitable for a typical A/D converter. The A/D converter would then convert the analog voltage to a digital signal. However, a PHOSITA would also recognize that including an amplifier and an A/D converter near the sensor itself would increase the sensor's cost (an important consideration in the case of a disposable sensor) and power requirements (an important consideration for a battery-operated device). Alternatively, a PHOSITA may consider a design that transmits the "raw" (unamplified) analog signal to the monitoring device. The high-gain amplifier would now reside in the wrist-worn housing and would use an A/D converter in the monitoring device. The PHOSITA would recognize that transmission of the analog signal by wire could reduce the cost of the sensor.

112. A PHOSITA would also consider the differing effects of noise on transmission of digital versus analog signals. For example, transmission of a low-level analog signal may be more susceptible to the effects of noise and interference from environmental sources as compared to a high-level digital signal. Thus, a PHOSITA would consider design options such as wire shielding techniques to reduce the effects of noise, depending on the signal transmission type. However, a PHOSITA would also recognize that shielded wires and shielded connectors needed for the low-level analog signal may take up more space as compared to unshielded

wires and connectors that may be used to send a high-level digital signal. Additionally, a PHOSITA would consider that analog and digital sensors could require a different number of conductors in the corresponding cable. These differences could affect the cost of the cable, its diameter, its flexibility, or a combination of the three.

113. These discussions show that a PHOSITA would recognize the tradeoffs needed for analog versus digital signal transmission implementations, and it would not be irrelevant to a PHOSTIA whether the signal received was analog or digital. Although the above-described examples are with respect to a pulse oximetry sensor, these same design considerations apply to other types of sensors such as blood pressure and ECG.

114. A PHOSITA would have also understood there were disadvantages with digital sensors compared to analog sensors. For example, digital sensors require additional hardware, such as an A/D converter and associated circuitry, increasing the size and cost of the sensor. A PHOSITA would know that sensors in patient monitoring systems are often disposable to eliminate cleaning and possible cross-contamination between patients. Disposable sensors have advantages over reusable ones such as convenience and guaranteed sterility. See, for example, the discussion of the disposable SpO<sub>2</sub> sensor described in Ex. 2035 §§ 5.2.10, 7.5, 7.6. For disposable probes, cost is an important issue. A PHOSITA would understand



that adding components and their resultant additional cost to a disposable device needs consideration. Thus, a PHOSITA would not be motivated to make changes to a sensor that would increase its cost. Increasing the size and weight of the sensor could also adversely affect patient comfort.

115. A PHOSITA would take these factors into account and therefore disagree with Petitioner's oversimplification of the issues. I understand that Petitioner and Dr. Yanulis assert that "providing digital temperature data is simply a design decision as to where temperature readings get converted into a digital value: either before being provided to a monitor or within the monitor." *See* Pet. at 60 (citing Ex. 1003 ¶ 186). However, as I have explained above, there are several other design considerations, including choice of hardware, size of the sensor, and cost of the sensor that Dr. Yanulis has not considered.

116. Accordingly, for at least these reasons, I believe that a PHOSITA would not have been motivated to combine Goldberg and the other asserted references to arrive at the claimed data signal configuration.

**B. Estep is Non-Analogous Art for Grounds 3 and 4**

117. I understand Petitioner uses Estep in combination with Goldberg and other references. I also understand that a reference must be analogous art to qualify as prior art. To qualify as analogous art, I understand 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. In my opinion, Estep is not analogous art for the reasons outlined below.

**1. Estep is in a different field of endeavor than the '735 Patent**

118. Based on the disclosure of the '735 Patent, in my opinion, the '735 Patent is in the field of medical monitoring devices. The abstract of the '735 Patent describes “[a] body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement of one or more sensor communication ports.” Ex. 1001 at Abstract. The claims are directed toward a body worn portable patient monitoring device configured to “provide on-patient and remote monitoring of patient physiological parameters.” *See, e.g., id.* at 14:38-41, 15:59-61. In particular, the claimed invention is secured to an arm of the patient. *Id.* at 13:18-20, 14:46-47, 16:16-17.

119. Estep is concerned with “[a]n electrical signal measurement device compris[ing] sections which are carried by an operator in a belt, jacket, vest, harness (or the like) and a headpiece (10) with a headphone and a visual display (13).” Ex. 1009 at Abstract. Estep describes an “electrical signal measurement device which can be worn by or attached to a technician so that the device [that] can be operated in a ‘hands-free’ manner.” *Id.* at 1:21-23. The device of Estep may be “used in adverse conditions, usually in aerial situations (e.g., poles, platforms, bucket truck, etc.)” to protect against an accidental fall. *Id.* at 1:17-18.

120. In my opinion, a person of ordinary skill in the art would understand that the field of endeavor of Estep is signal level meters for field use in cable television systems. This environment of use is quite different from and has no relation to a medical device worn by a patient as in the '735 patent. Thus, in my opinion, Estep is not in the same field of endeavor as the '735 Patent.

**2. A skilled artisan would not have found Estep “reasonably pertinent” to the problems faced by the inventors of the '735 Patent.**

121. In my opinion, based on its description, the '735 Patent addresses the challenge of providing hospital grade, portable patient monitoring without the loss of physiological measurements. The '735 Patent details the problem the inventors were addressing. For example, the '735 Patent explains:

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, 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. Typically, the patient is tethered to a patient bedside monitoring system by wires for separate sensors for each monitored physiological parameter.

*Id.* at 1:40-52, 2:22-24.

122. In my opinion, the technology described in Estep is different from the problem faced by the inventors of the '735 Patent, and is the type of reference that a

skilled artisan would not have discovered when seeking to address the problems of the '735 Patent. The technicians using Estep's signal level meters are not tethered to a non-portable monitoring device.

123. As mentioned above, the environment for Estep's device is quite different from a medical device worn by a patient as in the '735 patent. Thus, Estep also is not reasonably pertinent to providing patient monitoring without loss of physiological parameters. *Id.* In my opinion, the teachings of Estep would not have been reasonably pertinent to a skilled artisan addressing the problems faced by the inventors of the '735 Patent.

**C. Grounds 5-8: The Combinations Based on Money Do Not Teach the Claimed Inventions**

124. I understand Petitioner relies on the following Money combinations to argue the claims are obvious.

- Money, Akai, and Kiani to argue that Claims 1-2 and 7-9 of the '735 Patent are obvious;
- Money, Akai, Kiani, and Fujisaki to argue that Claims 3-6 and 13-19 of the '735 Patent are obvious;
- Money, Akai, Kiani, and Estep to argue that Claims 10-12 are obvious; and
- Money, Akai, Kiani, Fujisaki, and Estep to argue that Claim 20 is obvious.

125. However, in my opinion, the specific combinations that Petitioner advances with these references are based on an incorrect understanding of the references and on hindsight reasoning. Moreover, based on my review of Petitioner's arguments and its proposed combinations, I believe that a PHOSITA would not have been motivated to make the proposed combinations.

**1. A PHOSITA Would Recognize that Money Is Too Large and Bulky for a Wrist-Worn Device**

126. As I mentioned above, when designing a patient monitor a PHOSITA would know that there are tradeoffs when designing a portable monitoring device. *See supra* § VII.A.3. For example, if portability was not a primary design goal, a PHOSITA would focus less on power usage, size, and weight of the monitor, and instead focus on designing to monitor several parameters. Alternatively, if portability was a design goal, a PHOSITA would focus more on size, weight, and power considerations, recognizing that there would be tradeoffs on functionality, including the number of parameters to be monitored.

127. Size and weight would be important design considerations for a wrist-worn device due to concerns with patient comfort and compliance. For example, a PHOSITA would recognize that a large and/or heavy device would be a deterrent to the extended wearing of the device by the patient on their wrist because it might be uncomfortable and/or limit arm movement. A PHOSITA would not have started with Money's design when designing a wrist-worn device. Instead, a PHOSITA

would have considered other designs sufficiently small to be worn on a patient's wrist.

128. Money describes a device as being “portable and patient-wearable”. Ex. 1008 at 5:5-6. In my opinion it would not have been obvious to a PHOSITA to strap Money's device to a patient's wrist in view of design considerations I discussed above. Instead, it is much more likely that Money's device would be attached to a patient's waist where its weight and size would be more manageable. I discuss this further below.

129. Money explains its invention “pertains to devices and systems used in hospitals to monitor vital signs associated with a hospitalized patient.” Ex. 1008 at 1:8-10. Money also says that its device would weigh up to 16 ounces (1 lb.) and would use four AA batteries. *Id.* at 3:39-45. A PHOSITA would consider a one pound, wrist-worn device as being too heavy for a patient to wear without causing patient discomfort and fatigue, even after a short time wearing the device. This would be especially true for hospitalized patients, who may already be quite uncomfortable, and who may have difficulty supporting the weight of the device. Additionally, one-pound weights are available for strengthening exercises, (*see, e.g.*, Ex. 2034 at 1), indicating that a PHOSITA would not consider a device of this weight to be easily accepted by a hospitalized patient.

130. Money also says that its device is approximately one inch thick, three inches wide, and six inches long. Ex. 1008 at 5:6-8. Dr. Yanulis alleges that “a housing of this size would **easily** be worn on a patient’s wrist.” Ex. 1003 ¶ 197 (emphasis added). A PHOSITA would disagree with this statement and be concerned about a device of this size being attached to the wrist of a patient because it might limit the patient’s movement. Assuming the device was attached to the patient’s wrist so that the longer dimension (the 6 in. dimension) ran lengthwise on the patient’s arm (which appears to be the orientation proposed by Dr. Yanulis, see, e.g., Ex. 1003 ¶ 202), 6 inches is more than half the length of an average adult’s forearm (and more so for a pediatric patient’s forearm). *See* Ex. 2031 (showing mean forearm-hand length measurements on pg. 124 and hand length measurements on pg. 132; based on those measurements the mean forearm length for males would be 11.3 inches and 10.19 inches for females, calculated by subtracting mean hand length from mean forearm-hand length for each gender). A PHOSITA would more likely consider attaching a device of this size to a patient’s waist, perhaps with a belt loop or clip, rather than a patient’s arm. Additionally, the background section of Money describes a prior art device that is worn on a patient’s belt. Ex. 1008 at 1:62-67. Additionally, a one-pound weight would cause the patient discomfort and fatigue, even after a short use time and especially true for hospitalized patients who may have difficulty supporting this amount of weight.

131. I also note that the weight and size of Money's device would be similar to three modern smartphones stacked one upon another (for example, it would be a bit larger, quite a bit thicker, and about as heavy, as three present-day smartphones stacked up). *See* Ex. 2032 (showing dimensions of common iPhones and Samsung smartphones). A PHOSITA would recognize that wrist mounting a device of this size and weight would not be viable, and that the device would therefore have to be substantially resized, redesigned, and reconstructed. It is my opinion that a PHOSITA, after reviewing design considerations for a wrist-worn device, would recognize that Money's device, with its size and weight characteristics, would be too large and bulky to be suitable as a wrist-worn device for patient monitoring. Therefore, a PHOSITA designing a wrist-worn device for patient monitoring would not have started with Money's design.

**2. Akai's SpO<sub>2</sub> Sensor Uses a Fiber Optic Cable Which Does Not Send Signals Electrically**

132. As noted above, Dr. Yanulis states that it would have been obvious to substitute the pulse oximetry cuff transducer of Money with the "light-based pulse oximetry sensor 112" of Akai. Ex. 1003 ¶ 195. In addition to the reasons I have given above, I believe a PHOSITA would also recognize that this proposed substitution is not feasible because Akai's sensor 112 is incompatible with Money's monitoring device.



133. Akai's sensor 112 connects to its data processing unit 113 via a fiber optic cable (Ex. 1007 at 5:10-19), while all the sensors in Money (including the pulse oximetry cuff transducer 39) connect to the monitoring device of Money via electrical connections (see, e.g., Ex. 1008 at 5:18-51). A PHOSITA would know that a fiber optic cable transmits signals using light, while electrical connections transmit electrical signals. A PHOSITA would also know that different hardware components and interface methods are associated with fiber optic connections as compared to electrical connections. For example, hardware components needed for fiber optic connections include optoelectronic devices such as light emitters, photodetectors, and optical receivers for interfacing with signals conveyed via an optical fiber. In contrast, hardware components for electrical connections include none of those items because the electrical connections do not require converting optical signals to electrical signals. Additionally, due to the differing mediums of communication (e.g., fiber optic vs. metal wire), fiber optic cables and electrical cables require different types of connectors. A PHOSITA would thus recognize that Akai's sensor 112, with its fiber optic cable, would not be compatible with Money's monitoring device, and would not be able to communicate signals to Money's monitoring device without significant modifications.

134. None of Money's ports would have been compatible with Akai's sensor. For Akai's sensor 112 to communicate with Money's monitoring device, it

would be necessary to provide an optical communication means for the SpO<sub>2</sub> port to Money's device because Money's electrical communication means for the SpO<sub>2</sub> port would not be compatible with Akai's sensor. This would also require adding an optical-to-electrical interface for the SpO<sub>2</sub> sensor to Money's device to enable communications with Akai's sensor. Such modifications may require additional conversion circuitry for communications between Akai's sensor and Money's processor. A PHOSITA would recognize that such additions to Money would increase the size and weight of Money's monitoring device. I understand Claim 20 requires "a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal." Ex. 1001 at 16:4-5. Even if a PHOSITA was able to make Money's monitoring device compatible with Akai's optical fiber, the modified device still would convey the signal optically through Akai's optical fiber and not electrically, as the claim requires.

135. A PHOSITA would understand that modifying Akai's sensor to be an electrically communicating analog sensor would also be impractical. This approach would include significant hardware changes to Akai's sensor, and would still require modifications to Money's device to enable connection with an analog SpO<sub>2</sub> sensor. For example, it would at least be necessary to replace the fiber optic cable of Akai's sensor with an electrical cable. It would also be necessary to modify other hardware and functionality of Akai's sensor to enable compatibility with an electrical SpO<sub>2</sub>

sensor interface. Additionally, Money's device would still have to be modified to add an analog SpO<sub>2</sub> sensor interface as it only contains a digital one. Such modifications would substantially modify Akai's sensor and, in my opinion, be done for no apparent reason other than to support Dr. Yanulis' proposed combination.

136. Thus, in my opinion, at least due to the incompatibilities I have described above, a PHOSITA would not be motivated to replace the pulse oximetry cuff transducer of Money with the pulse oximetry sensor 112 of Akai.

**3. A PHOSITA Would Not Be Motivated To Replace Money's Pulse Oximetry Cuff Transducer With Akai's Pulse Oximetry Sensor**

137. Dr. Yanulis argues that "It would have been obvious to modify Money's housing in view of Akai primarily because it would have been obvious to substitute a pulse oximetry cuff transducer 39, as taught by Money, with a light-based pulse oximetry sensor 112 that is positioned on a patient's finger, as taught by Akai." Ex. 1003 ¶ 195. Dr. Yanulis also argues that, in contrast to Money's pulse oximetry cuff transducer, "light-based pulse oximetry sensors are completely non-invasive, far smaller, and thereby, more comfortable when worn by a patient." *Id.* A PHOSITA would know that Money's pulse oximetry cuff transducer is already non-invasive and light-based and the proposed modification is unnecessary.

138. By definition, all pulse oximetry sensors use light to measure blood oxygen saturation and are therefore light-based. For example, *Stedman's Medical*

*Dictionary*, published in 2000, defines “oximetry” as a “Procedure using a device to measure oxygen saturation by fluctuations of light absorption in well-vascularized tissue during systole and diastole”, and further defines “pulse oximetry” as “performed noninvasively, usually on the finger or ear lobe, in which the small increase in absorption of light during the systolic pulse is used to calculate oxygen saturation.” Ex. 2017 at 1292. As another example, the article *Pulse oximetry*, published in *Critical Care* in 1999, describes that oximeters available in the 1990’s used “two light-emitting diodes (LEDs) that emit light at the 660 nm (red) and the 940 nm (infrared) wavelengths.” Ex. 2022 at R11. Thus, a PHOSITA in 2002 would understand the pulse oximetry cuff transducer of Money to be light-based.

139. Moreover, a PHOSITA in 2002 would understand that in the medical context “invasive” refers to procedures that involve inserting things into the patient’s body (e.g., through the skin or an orifice), while “noninvasive” refers to procedures that do not involve inserting things into the patient’s body. For example, *Stedman’s Medical Dictionary*, published in 2000, defines “invasive” as “[d]enoting a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment.” Ex. 2017 at 919. All pulse oximetry is by definition noninvasive. See, for example, the definitions I quote above.

140. In my opinion, a PHOSITA would understand that the pulse oximetry cuff transducer of Money is light-based and noninvasive. Money contains no description of the cuff transducer, but a likely configuration is one that attaches to the patient's finger. In 2002 (and even now) the finger or ear lobe were the usual locations for attaching a pulse oximetry sensor. *See* Ex. 2017 at 1292.

141. I disagree with Dr. Yanulis' opinion that Money's pulse oximetry cuff transducer is "bulky and uncomfortable." *See* Ex. 1003 ¶ 195. With the understanding of Money's pulse oximetry cuff transducer described above, a PHOSITA would understand that Money's pulse oximetry cuff transducer is not bulky or uncomfortable.

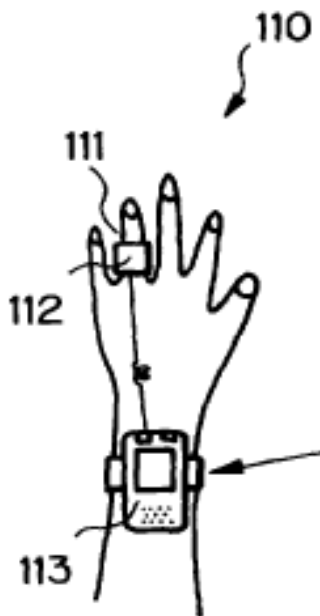
142. Money describes a light-based and noninvasive pulse oximetry cuff transducer. Therefore, a PHOSITA would not be motivated to substitute Money's pulse oximetry cuff transducer with Akai's SpO<sub>2</sub> sensor. Moreover, the substitution would create several problems explained in the previous section. Thus, it is my opinion that a PHOSITA would not be motivated to make this replacement.

#### **4. A PHOSITA Would Not Be Motivated To Attach Money's Device To A Patient's Wrist Based On Akai**

143. Petitioner and Dr. Yanulis argue that "a PHOSITA would have been further motivated to augment Money's housing in view of Akai so that the housing attached to a patient's wrist." Pet. at 66, Ex. 1003 ¶ 196. As I have explained above, a PHOSITA would recognize that Money's device is too large and heavy to be a

wrist-worn device. Thus, I believe there are several reasons that a PHOSITA would disagree with Petitioner's and Dr. Yanulis' regarding modifying Money based on Akai.

144. Dr. Yanulis claims that "Akai teaches a similarly sized housing 113 [compared to Money] that attaches to a person's wrist via a strap." Ex. 1003 ¶ 198. Akai provides no dimensions for its device 113, but does provide the drawings shown in Figure 1, showing the housing attached to a wrist. Based on Figure 1, I believe a PHOSITA would understand that Akai's device is substantially smaller than Money's 3 in. by 6 in. by 1 in. device. Thus, a PHOSITA would not agree with Dr. Yanulis' statement that Akai's housing is similarly sized as compared to Money and would understand that Money's device would require significant modification to be reduced to the size of Akai's device and would not be motivated to do so.



Ex. 1007 at Fig. 1 (partial).

145. Dr. Yanulis also claims that “it would have been obvious to position the strap in the same way as taught by Akai when modifying Money in view of Akai, especially considering that Money’s housing 5 looks so similar to Akai’s housing 113.” Ex. 1003 ¶ 202. Again, the only information Akai provides regarding the “look” of housing 113 is the drawing shown above from Figure 1, showing the device attached to the wrist. When comparing Akai’s drawing with Money’s device, a PHOSITA would understand their similarities to be limited to having generally rectangular shapes and displays on the front. A PHOSITA would not be motivated to include a strap on Money’s housing based on both devices being rectangular in shape and having a display on the front when, as discussed above, Akai’s device is substantially smaller than Money’s device.

**5. A PHOSITA Would Not Have Been Motivated to Modify Money to Include an Analog Pulse Oximetry Sensor**

146. As I explained above, Money does not disclose the claimed data signal configuration of a physiological sensor, other than a pulse oximetry sensor, that provides a digital signal. *See supra* § VII.A.4. All of the sensors in Money are analog except for Money’s SpO<sub>2</sub> sensor, which is digital. Ex. 1008 at 5:18-51, 6:15-20, 7:58-62, 8:20-27, 13:26-28. Money’s SpO<sub>2</sub> sensor is the only digital sensor disclosed in the asserted references. A PHOSITA would not be motivated to substitute Money’s SpO<sub>2</sub> sensor with Akai’s SpO<sub>2</sub> sensor because Money’s SpO<sub>2</sub> sensor is already light-based and noninvasive, and Akai’s optically communicating

SpO<sub>2</sub> sensor would be incompatible with Money's electrically communicating SpO<sub>2</sub> port. *See supra* §§ VII.C.2, VII.C.3. None of Money's other sensor ports would have been compatible with Akai's SpO<sub>2</sub> sensor. As I explained above, if one were to replace Money's digital SpO<sub>2</sub> sensor with Akai's SpO<sub>2</sub> sensor, it would be necessary to add a port and sensor interface components to Money to enable communication with Akai's SpO<sub>2</sub> sensor. Such modifications would increase the size and weight of Money's monitoring device, making it even less viable as a wrist-worn device. In my opinion, A PHOSITA would not have been motivated to add yet another port to accommodate Akai's SpO<sub>2</sub> sensor.

**6. A PHOSITA Would Not Be Motivated To Modify Money's Temperature Sensor From Analog To Digital**

147. I understand that each of the independent claims requires a physiological sensor, other than a pulse oximetry sensor, that provides a digital signal. In contrast with the claims, and as I described above, all of the sensors in Money are analog except for Money's SpO<sub>2</sub> sensor, which is digital. In fact, Money's SpO<sub>2</sub> sensor is the only sensor in any of Petitioner's asserted references that is digital. Thus, none of Petitioner's asserted references describes a physiological sensor, other than a pulse oximetry sensor, that provides a digital signal, as required by the independent claims.

148. As discussed above, Petitioner and Dr. Yanulis argue that a PHOSITA would replace the SpO<sub>2</sub> sensor of Money with the SpO<sub>2</sub> sensor from Akai, which is

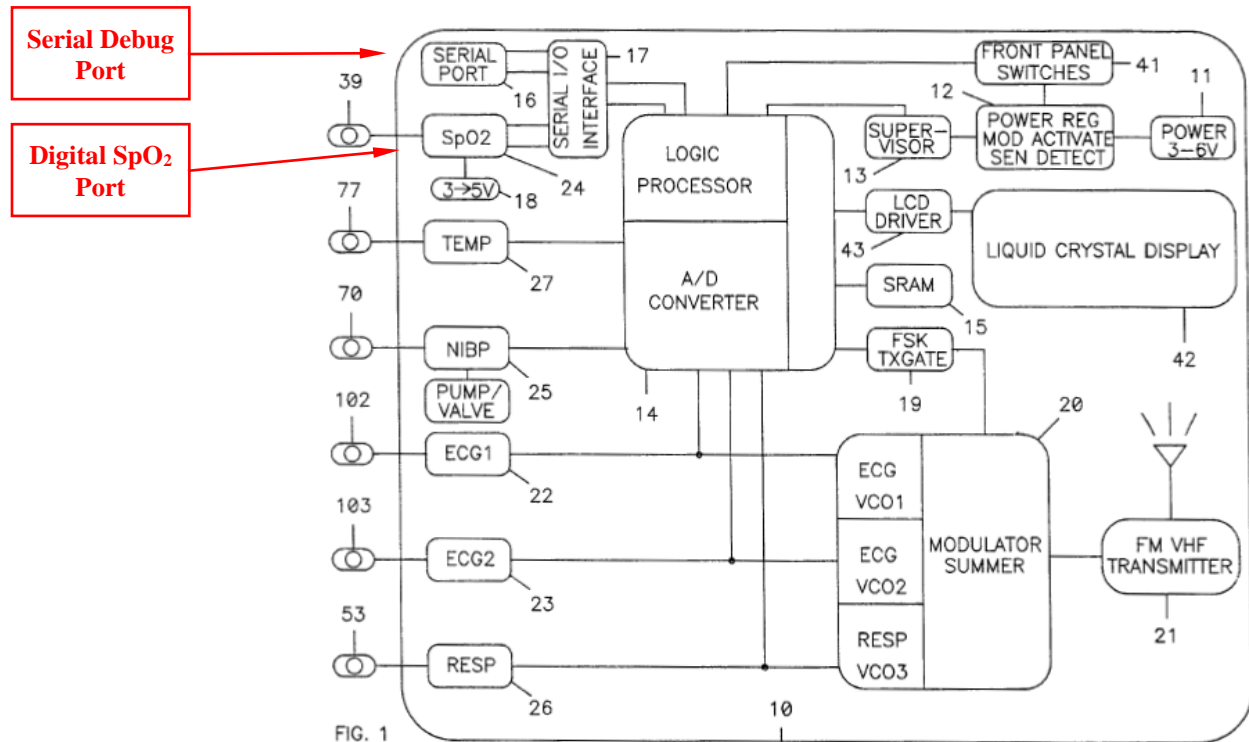


not digital. Ex. 1007 at 5:26-45. As I stated above, it is my opinion that a PHOSITA would not have been motivated to substitute Money's SpO<sub>2</sub> sensor with Akai's SpO<sub>2</sub> sensor. However, if one were to make the substitution proposed by Petitioner and Dr. Yanulis (even though it is not feasible for the reasons I stated above), Money's monitoring device would then not include **any** digital sensors. Thus, Petitioner's proposed combination would not include all the limitations of the independent claims.

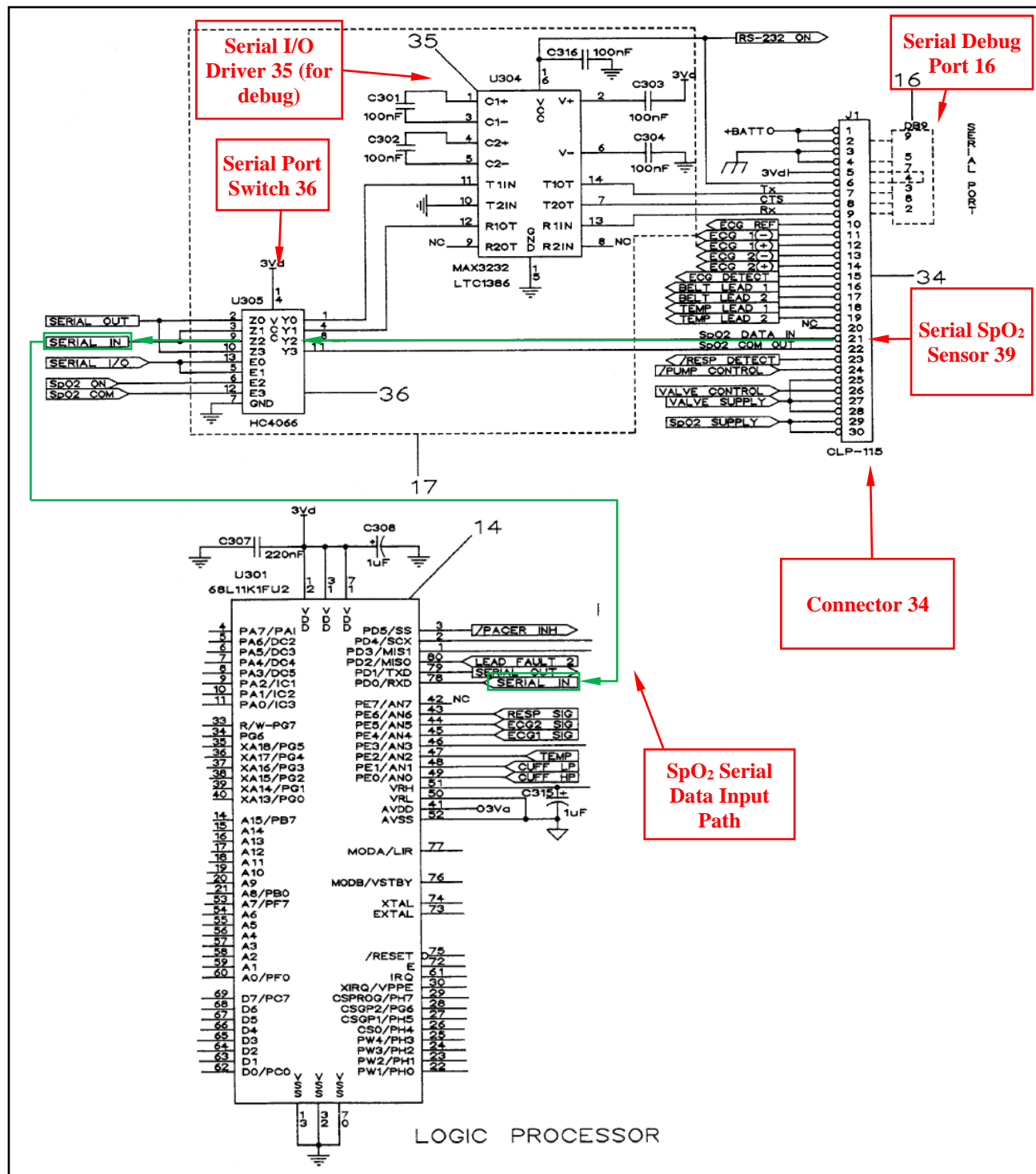
149. Money's "temperature probe transducer", shown as thermistor 77 in Fig. 5B of Money, provides "analog temperature data" to Money's monitoring device through "temperature interface circuit 27." Ex. 1008 at 5:48-51. To meet the digital signal limitations of the independent claims, Petitioner and Dr. Yanulis argue that a PHOSITA would be motivated to modify Money's temperature sensor to output digital data. Pet. at 74-75, Ex. 1003 ¶ 220-224. However, similar to the reasons given for modifying Money based on Akai (discussed above), the reasons Petitioner and Dr. Yanulis give for modifying Money's temperature sensor reflect a misunderstanding of Money's device, and do not address the design considerations a PHOSITA would make.

150. Dr. Yanulis argues that, following the substitution of Money's SpO<sub>2</sub> sensor with Akai's SpO<sub>2</sub> sensor, "the SpO<sub>2</sub> sensor would no longer plug into the RS232 port because the RS232 port only receives digital data." Ex. 1003 ¶ 220.

Thus, Dr. Yanulis acknowledges, as I have discussed above, that a different SpO<sub>2</sub> port and sensor interface would have to be provided to enable communication with Akai's SpO<sub>2</sub> sensor. Dr. Yanulis then argues that "a PHOSITA would have been motivated to continue using the RS232 serial port for dual purposes (debug and receiving digital data from a sensor) because of limited space on the monitor 10 or Money's power requirements." *Id.* Thus Dr. Yanulis indicates that "the RS232 port" of Money is a single external port that can be used for either plugging in serial debugging and programming device, or for plugging in a digital SpO<sub>2</sub> sensor ("dual purposes"). That is incorrect. Instead, Money describes two **separate** external connectors: (1) a "serial debug and programming port 16" using a DB9 connector, and (2) a connector for the digital SpO<sub>2</sub> sensor. Ex. 1008 at 3:33-36, 6:11-14, 8:28-40, Fig. 2C. These two connectors enable digital/serial communications with processor 14 via serial data I/O interface unit 17, as illustrated in Figure 1. Ex. 1008 at 6:11-20.



151. In further detail, Money explains that “processor 14 is electrically connected to a serial port switch 36 which directs the RS232 port on processor 14 to **either** external debug/programming port 16 **or** to serial data received from pulse oximetry transducer 39.” Ex. 1008 at 7:58-62 (emphasis added). The circuit schematics provided in Money make this arrangement clear:



152. In the diagram above I have reproduced and annotated in red and green portions of Figures 2A and 2C of Money, which show circuit schematics for Money's device. As shown, Money includes connector pins for connecting to its

various external sensors, including its digital SpO<sub>2</sub> sensor. The connector pins also include **separate** pins that lead to a DB9-type serial port 16 for connecting devices for debugging or programming purposes. Ex. 1008 at 6:11-20, 13:8-22. The pins from the DB-9-type serial port connect to a serial I/O driver 35, *Id.* 1008 at 6:15-20, and then the pins from both the serial I/O driver 35 and the digital SpO<sub>2</sub> sensor connect to the same serial port switch 36. *Id.* 1008 at 6:15-20, 7:58-62. The serial port switch 36 then connects to serial input and output pins on the logic processor 14. *Id.* 1008 at 7:58-62. Thus, Money's circuit schematics show that there are two separate connectors, one for the digital SpO<sub>2</sub> sensor and one for debugging or programming purposes, and one or the other signal is internally selected by serial port switch 36.

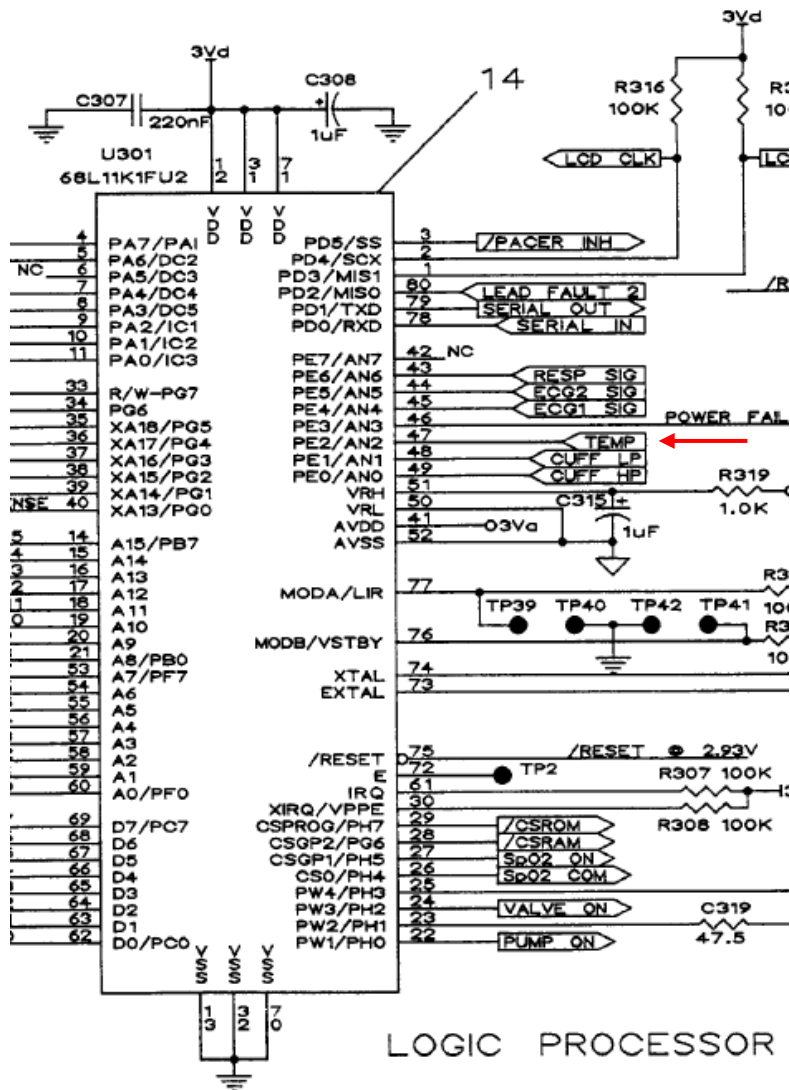
153. Petitioner's and Dr. Yanulis' argument that a PHOSITA would have been motivated to continue using the serial port because of limited space on the Money's monitor is unworkable when Money's device is more accurately understood as I have described above. Indeed, because Money's digital SpO<sub>2</sub> sensor port is separate from Money's external DB9-type serial port (which is used for debugging and programming purposes), the proposed modification to remove Money's digital SpO<sub>2</sub> sensor (and substitute in Akai's non-digital SpO<sub>2</sub> sensor with an associated new SpO<sub>2</sub> sensor port and interface) would not motivate a PHOSITA to keep the unused digital SpO<sub>2</sub> sensor port. Instead, a PHOSITA who was

concerned about limited space would more likely be motivated to **remove** the unused digital SpO<sub>2</sub> sensor port. The same would be true if a PHOSITA were concerned with power requirements: removal of an unnecessary digital SpO<sub>2</sub> sensor port (and its associated sensor interface components) could only improve power usage. A PHOSITA would certainly not be motivated to modify Money's temperature sensor just to be able to plug it into the unused digital SpO<sub>2</sub> sensor port. This is because Money already provides a port for its temperature sensor. A PHOSITA would have no reason to arbitrarily move Money's temperature sensor from one port to another port. Thus, I do not believe a PHOSITA would agree with Dr. Yanulis' statement.

154. Dr. Yanulis also argues that a PHOSITA would “move the temperature determining circuitry and the analog-to-digital conversion to the temperature sensor 77,” and that “[t]he motivation to move this temperature digitization circuitry either inside or outside of the monitor 10 is simply a design choice because this basic circuitry would predictably function exactly the same way regardless of its location in the electronic circuit (inside or outside the monitor).” Ex. 1003 ¶¶ 222-223. However, Dr. Yanulis fails to acknowledge other factors that a PHOSITA would consider when modifying Money's analog temperature sensor. These factors include design considerations associated with analog and digital signals (which I discussed above), disposable versus reusable version, cost, and power usage. A PHOSITA would know that sensors in patient monitoring systems are often

disposable to eliminate cleaning and possible cross-contamination between patients. For disposable probes, cost is an important issue. A PHOSITA would understand that adding components and their resultant additional cost to a disposable device needs consideration. Thus, a PHOSITA would not be motivated to make changes to a sensor that would increase its cost. Money's analog temperature sensor consists mainly of a thermistor (an analog device that changes its resistance value in a predictable manner with temperature). Converting Money's sensor to a digital sensor would include a number of changes that would increase cost. It would be necessary to incorporate the interface circuit 27, including temperature detector circuit 76 and reference voltage unit 75, into the sensor assembly. Ex. 1008 at 10:60-11:5, Fig. 5B. Additionally, a PHOSITA would consider that analog and digital sensors require a different number of conductors in the corresponding cable. These differences could affect the cost of the cable, the diameter of the cable, and the flexibility of the cable.

155. It would also be necessary to *duplicate* an A/D converter, which already exists as integral to the processor, as shown by the red arrow in the figure below, and cannot be removed and then added to the sensor.



Partial and annotated Fig. 2A of Money

Ex. 1008 at Fig. 2A. The A/D converter of the processor is shown to have eight channels (AN0 to AN7) and is used for several sensor inputs. Thus, it would not be possible to *move* the A/D converter as suggested by Petitioner because it is integrated into the processor 14. The additional sensor circuitry would increase the cost of a single-use temperature sensor. The additional circuitry would be power consuming and increase power usage (e.g., as a result of duplication of Money's A/D converter).



These changes would also increase the size and weight of the temperature sensor, which may adversely affect patient comfort. A PHOSITA would consider these factors and would therefore disagree with Dr. Yanulis' assertion that modifying Money's temperature sensor from an analog to digital data "is simply a design choice." Ex. 1003 ¶ 223.

**D. Ground 8: The Combination of Money, Akai, Kiani, Fujisaki, and Estep Does not Render Claim 20 Obvious**

156. I understand that Petitioner is relying on the combination of Money, Akai, Kiani, Fujisaki, and Estep to argue that Claim 20 is obvious. Ex. 1003 ¶ 286. However, because Petitioner is still relying on the same misunderstandings of both Money and Akai, I do not believe that Claim 20 is obvious over Money, Akai, Kiani, Fujisaki, and Estep for the same reasons as I described above. *See supra* § VII.C. Moreover, I believe Petitioner's combination fails to include at least one limitation of Claim 20.

157. I understand Claim 20 is independent and requires "a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal" (limitation 20i). I also understand that Petitioner and Dr. Yanulis believe the pulse oximetry sensor 112 of Akai, which connects to the data processing unit 113 via a fiber optic cable, teaches this limitation. Pet. at 95; Ex. 1003 ¶ 291. I disagree. As I explained above, the fiber optic cable of the sensor 112 does not send signals electrically, so this combination cannot meet the limitation 20(e). *See supra* §

VII.C.2. A PHOSITA would know that a fiber optic cable is different from an electrical wire in that a fiber optic cable transmits signals using light. In contrast, an electrical wire transmits electrical signals. *Id.*

158. For at least these reasons, I do not believe that Petitioner has shown that Claim 20 in Ground 8 is obvious based on Money, Akai, Kiani, Fujisaki, and Estep.

**E. Estep is Non-Analogous Art for Grounds 7 and 8**

159. I understand Petitioner uses Estep in combination with Goldberg and other references. But as explained above, in my opinion, Estep is not analogous art. *See supra* § VII.B.

**VIII. CONCLUSION**

160. For at least the foregoing reasons, it is my opinion that the Petition fails to show the challenged claims would have been obvious to a skilled artisan at the time of the invention.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on Feb 23, 2021.



Alan L. Oslan

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