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Paper 7
Entered: August 6, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

IPR2021-00453
Patent 10,517,484 B2

Before GRACE KARAFFA OBERMANN, BRIAN J. McNAMARA, and SHARON FENICK, *Administrative Patent Judges.*

McNAMARA, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Apple, Inc. ("Petitioner") filed a petition, Paper 1 ("Petition" or "Pet."), to institute an *inter partes* review of claims 1–23 (the "challenged claims") of U.S. Patent No. 10,517,484 B2 ("the '484 patent"). 35 U.S.C. § 311. Omni MedSci, Inc. ("Patent Owner") filed a Preliminary Response, Paper 6 ("Prelim. Resp."), contending that the Petition should be denied as to all challenged claims. We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

A decision to institute under § 314 may not institute on fewer than all claims challenged in the petition. 37 C.F.R. § 42.208(a) (2021). Having considered the arguments and the associated evidence presented in the Petition and the Preliminary Response, for the reasons described below, we institute *inter partes* review of all challenged claims on all challenge grounds.

II. REAL PARTIES IN INTEREST

The Petition identifies Apple, Inc. as the sole real party-in-interest. Pet. 1. Patent Owner identifies itself as the sole real party-in-interest. Paper 3, 1.

III. RELATED MATTERS

The Petition states that the '484 patent is asserted against Petitioner in the following litigation: *Omni MedSci, Inc. v. Apple Inc.*, Action No. 2-20-cv-00563-YGR (N.D. Cal.) (pending). The Petition identifies several related U.S. patents and pending U.S. patent applications (*id.* at 1–2), litigations asserting the related patents against Petitioner (*id.* at 3), and *inter partes* reviews concerning the related patents (*id.*). The Petition states "[t]he '484 patent is not subject to any other proceedings before the Office." *Id.*

IV. THE '484 PATENT

The '484 patent concerns a device that can be placed on a user's ear or wrist to measure a physiological parameter. Ex. 1001 (code 57). A plurality of light emitting diodes generate light at an initial intensity and a receiver with spatially placed detectors receiving reflected light couples analog signals to an analog-to-digital converter ("A/D"). *Id.* Signal-to-noise ratio is improved by increasing light intensity relative to initial light intensity and increasing a pulse rate. *Id.* The system inspects a sample "by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity" of the sample. Ex. 1001 at 10:2–7.

Figure 24 of the '484 patent is reproduced below.

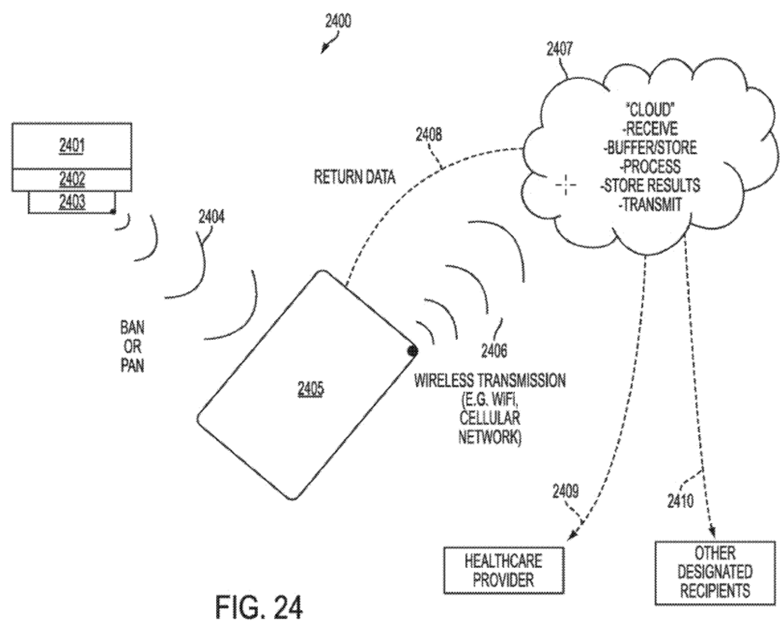

Figure 24 of the '484 patent

Figure 24 is a high level overview of physiological measurement system 2400, in which wearable measurement device 2401 with processor 2402 and transmitter 2403 communicates measurements over link 2404 to smart phone or tablet 2405. *Id.* at 32:45–33:4. An application program in smart phone or tablet 2405 communicates some or all of its processed data over link 2406 to cloud based server 2407, which can augment the data with additional value-added processing, e.g., historical processing and pattern matching algorithms. *See, id.* at 33:5–34:21.

The wearable device includes a light source having a plurality of LEDs, electronically driven to operate in a continuous or pulsed mode, that generate an output beam at one or more optical wavelengths between 700 and 2500 nanometers. Ex. 1001, 3:34–49, 11:3–9, 28:19–21, 26:29–34, Fig. 20. The '484 patent describes several techniques to improve signal processing to select the constituents of interest. *See, e.g., id.* at 15:49–17:15. According to the '484 patent, "using a wider wavelength range and using more sampling wavelengths may improve the ability to discriminate one signal from another." *Id.* at 15:64–66. In addition, "a higher light level or intensity may improve the signal-to-noise ratio for the measurement." *Id.* at 15:53–55. The '484 patent notes that

> it may be advantageous to pulse the light source with a particular pulse width and pulse repetition rate, and then the detection system can measure the pulsed light returned from or transmitted through the tissue. Using a lock-in type technique (e.g., detecting at the same frequency as the pulsed light source and also possibly phase locked to the same signal), the detection system may be able to reject background or spurious signals and increase the signal-to-noise ratio of the measurement.

Id. at 15:67–16:8. The '484 patent further explains that variations due to sunlight, time of day, and weather may also be reduced to improve the signal-to-noise ratio using a lock-in technique. *Id.* at 16:61–67.

> Higher signal-to-noise ratios may be achieved. For example, one way to improve the signal-to-noise ratio would be to use modulation and lock-in techniques. In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source. In a particular embodiment, the techniques from lock-in detection may be used, where narrow band filtering around the modulation frequency may be used to reject noise outside the modulation, frequency. In an alternate embodiment, change detection schemes may be used, where the detection system captures the signal with the light source on and with the light source off. Again, for this system the light source may be modulated. Then, the signal with and without the light source is differenced. This may enable the sun light changes to be subtracted out. In addition, change detection may help to identify objects that change in the field of view.

Id. at 16:64–17:13. Patent Owner also notes that the ’484 patent incorporates by reference PCT Application Serial No. PCT/US2013/075767 (Publication No. WO/2014/143276) (Ex. 2120), which describes the use of an active illuminator to achieve higher signal-to-noise ratios despite variations due to sunlight and weather, and U.S. Patent Application Serial No. 14/109,007, which discloses the modulation frequency of the light source can range between 0.1–100kHz. Prelim. Resp. 5 (citing Ex. 1001, 2:26–29, 2:36–39; Ex. 2120 ¶ 79; Ex. 2021 ¶ 45).

V. ILLUSTRATIVE CLAIM

Claim 1, reproduced below using the paragraph designations in the Petition, is illustrative of the subject matter of the challenged claims.

> 1(a). A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:
> (b) a wearable device adapted to be placed on a wrist or an ear of a user,
> (c) including a light source comprising a plurality of semiconductor sources that are light emitting diodes, each of

the light emitting diodes configured to generate an output optical light having one or more optical wavelengths;

(d) the wearable device comprising one or more lenses configured to receive a portion of at least one of the output optical lights and to direct a lens output light to tissue;

(e) the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio,

(f) wherein the detection system is configured to be synchronized to the light source;

(g) wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

(h) wherein a detector output from the at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity;

(i) the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

(j) a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

(k) wherein the output signal is indicative of one or more of the physiological parameters, and the cloud is configured to store a history of at least a portion of the one or more physiological parameters over a specified period of time;

(l) the wearable device configured to increase the signal-to-noise ratio

(1) by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity and

(2) by increasing a pulse rate of at least one of the plurality of semiconductor sources from an initial pulse rate; and

(m) the detection system further configured to:
generate a first signal responsive to light received while the light emitting diodes are off,

(n) generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

(o) increase the signal-to-noise ratio by comparing the first signal and the second signal.

VI. ASSERTED GROUNDS

Petitioner asserts that claims 1–23 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 7, 15, 17	103	Lisogurski,[1] Carlson[2]
1–4, 7–12, 15–22	103	Lisogurski, Carlson, Tran[3]
5, 13	103	Lisogurski, Carlson, Tran, Isaacson[4]
6, 14, 23	103	Lisogurski, Carlson, Tran, Valencell-093,[5] with or without Isaacson

Patent Owner does not contest that the references Petitioner relies upon are prior art to the ’484 patent. Prelim. Resp. 7.

VII. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner states that a person of ordinary skill would have a “working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques”

[1] U.S. Patent No. 9,241,676 (Ex. 1011)
[2] U.S. Patent Publication No. 2005/0049468 (Ex. 1009)
[3] U.S. Patent No. 8,108,036 (Ex. 1064)
[4] U.S. Patent No. 8,725,226 (Ex. 1063)
[5] U.S. Patent Publication No. 2012/0197093 (Ex. 1005)

gained via an undergraduate education in electrical, mechanical, biomedical or optical engineering or a related field, along with relevant academic or industrial experience studying or developing physiological monitoring devices, e.g., non-invasive optical biosensors. Pet. 16 (citing Ex. 1003 ¶ 35 (Declaration of Dr. Brian Anthony ("Anthony Decl."))). Patent Owner's Preliminary Response does not address the level of ordinary skill explicitly.

The level of ordinary skill in the art usually is evidenced by the references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978). As Petitioner's undisputed description of the level of ordinary skill appears to be consistent with subject matter of the '484 patent claims and the references, for purposes of this Decision, we apply Petitioner's description of the level of ordinary skill.

VIII. CLAIM CONSTRUCTION

For petitions filed after November 13, 2018, we interpret claim terms using "the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). In this context, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (citations omitted).

Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We construe only those claim terms that require analysis to determine whether to institute *inter partes* review. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

Patent Owner contends that no claim terms need construction. Prelim. Resp. 7–8. Petitioner notes that, although the parties have disputed the construction of some claim terms in district court and the court provided a final construction of these terms, in IPR2019-00916 the Board found it unnecessary to construe several of these terms. Pet. 19 (citing Exs. 1043, 1057). In this case the Petition identifies the following terms:

A. Lens

Petitioner notes that the only type of lens discussed in the '484 patent is one that collimates and focuses light and states that the plain and ordinary meaning of lens includes this feature. Pet. 20. Thus, Petitioner contends we need not address any dispute with Patent Owner concerning this term. *Id.* We need not explicitly construe this term in this proceeding because its construction is not determinative to our Decision.

B. Optical Light

Petitioner contends we should construe "optical light" to mean "photons or light transmitted to a particular location in space," as that construction would be consistent with the description in the Specification.

Id. (citing Ex. 1001, 10:66–11:1). We need not explicitly construe this term in this proceeding because its construction is not determinative to our Decision

C. Light Source

Petitioner notes the Board's construction of "light source comprising a plurality of semiconductor sources that are [LED] . . . [devices] configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources" in IPR2019-00916 to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes is capable of having its pulse rate increased to increase a signal-to-noise ratio." *Id.* at 20–21 (emphasis omitted). Noting that claims 1 and 7 of the '484 patent recite similar limitations, Petitioner does not object to applying the Board's prior construction. *Id.* However, Petitioner contends the term does not require construction. We need not explicitly construe this term in this proceeding because its construction is not determinative to our Decision.

D. Cloud

Petitioner notes that the '484 patent does not define "cloud," and argues we should give the term its plain and ordinary meaning, i.e., "a remote device (or network of devices) hosted on a network and used to store, manage, or process data." *Id.* at 21 (citing Ex. 1003 ¶ 65). We need not explicitly construe the term in this proceeding because its construction is not determinative to our Decision.

IX. ANALYSIS

A. Introduction

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

A reason to combine or modify the prior art may be found explicitly or implicitly in "market forces; design incentives; the 'interrelated teachings of multiple patents'; 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent'; and the background knowledge, creativity, and common sense of the person of ordinary skill." *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–21 (2007)).

Before determining whether a claim is obvious in light of the prior art, we consider any relevant evidence of secondary considerations of non-obviousness. *See Graham*, 383 U.S. at 17. Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that the challenged claims would not have been obvious to one of ordinary skill. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). No such evidence has been presented in the current record.

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of success at trial.[6]

[6] The Petition preemptively includes arguments directed to §§ 314(a) and 325(d). Pet. 5, 17–18. Patent Owner does not argue for discretionary denial under either § 314 or § 325. Thus, we do not consider these issues further.

B. Claims 1, 7, 15, 17 As Obvious Over Lisogurski and Carlson

Noting the distinctions between independent claims 1, 7, and 15 are inconsequential to patentability, Petitioner addresses these claims together and notes any difference at the start of its discussion of each limitation. Pet. 26–27. We agree and treat claim 1 as exemplary.

1. *Lisogurski*

Lisogurski discloses a "physiological monitoring system [that] monitor[s] one or more physiological parameters of a patient . . . using one or more physiological sensors." Ex. 1011, 3:44–46. The physiological sensors may include a "pulse oximeter [that] non-invasively measure[s] the oxygen saturation of a patient's blood." *Id.* at 3:62–64. The pulse oximeter includes "a light sensor that is placed at a site on a patient, typically a fingertip, toe, forehead, or earlobe." *Id.* at 4:6–7. The light sensor "pass[es] light through blood perfused tissue and photoelectrically sense[s] the absorption of the light in the tissue." *Id.* at 4:8–10. The light sensor emits "one or more wavelengths [of light] that are attenuated by the blood in an amount representative of the blood constituent concentration," and may include red and infrared (IR) wavelengths of light. *Id*. at 4:42–48. Figure 3 of Lisogurski is reproduced below.

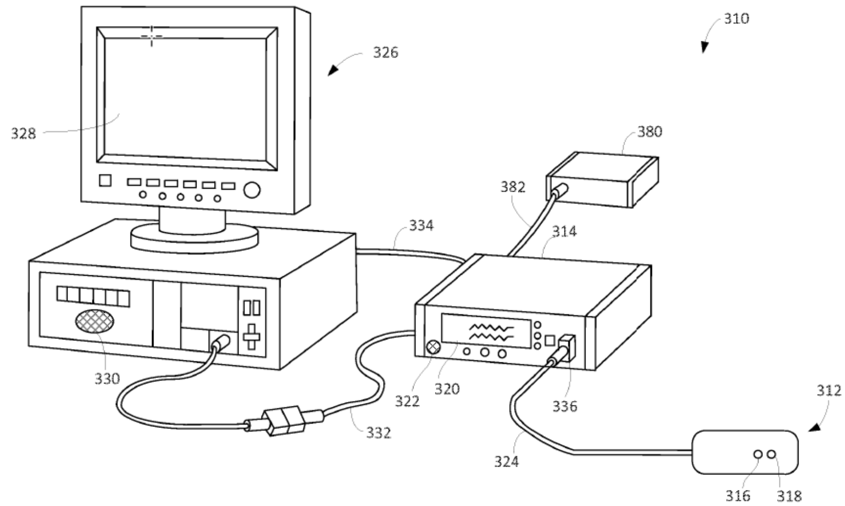

FIG. 3

Figure 3 of Lisogurski is "a perspective view of an embodiment of a physiological monitoring system." *Id*. at 2:23–25. The system includes sensor 312, monitor 314, and multi-parameter physiological monitor 326. *Id*. at 17:35–36, 18:44–45. Sensor 312 includes "one or more light source[s] 316 for emitting light at one or more wavelengths," and detector 318 for "detecting the light that is reflected by or has traveled through the subject's tissue." *Id*. at 17:37–42. Sensor 312 may have "[a]ny suitable configuration of light source 316 and detector 318," and "may include multiple light sources and detectors [that] may be spaced apart." *Id*. at 17:42–45. Light source 316 may include "LEDs of multiple wavelengths, for example, a red LED and an IR [LED]." *Id*. at 19:25–27. Sensor 312 may be "wirelessly connected to monitor 314." *Id*. at 17:57–59.

Monitor 314 "calculate[s] physiological parameters based at least in part on data relating to light emission . . . received from one or more sensor units such as sensor unit 312." *Id*. at 17:59–62. Monitor 314 includes "display 320 . . . to display the physiological parameters," and "speaker 322 to provide an audible . . . alarm in the event that a subject's physiological parameters are not within a predefined normal range." *Id*. at 18:3–10. Monitor 314 is "communicatively coupled to multi-parameter physiological monitor 326" ("MPPM 326") and "may communicate wirelessly" with MPPM 326. *Id*. at 18:58–61. Monitor 314 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id*. at 18:62–65. Multi-parameter physiological monitor 326 may also "calculate physiological parameters and . . . provide a display 328 for information from monitor 314." *Id*. at 18:49–52. MPPM 326 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id*. at 18:62–65. The remote network servers may also "be used to determine physiological parameters," and may display the parameters on a remote display, display 320 of monitor 314, or display 328 of MPPM 326. *Id*. at 20:53–58. The remote servers may also "publish the data to a server or website," or otherwise "make the parameters available to a user." *Id*. at 20:58–60. Lisogurski discloses that the monitoring system shown in Figure 3, described above, "may include one or more components of physiological monitoring system 100 of FIG. 1." *Id*. at 17:32–35. Lisogurski further discloses that although "the components of physiological monitoring system 100 . . . are shown and described as separate components . . . . the functionality of some of the components may be combined in a single component," and "the functionality of some of the components . . . may be divided over multiple components." *Id*. at 15:66–16:8. Figure 1 of Lisogurski is reproduced below.

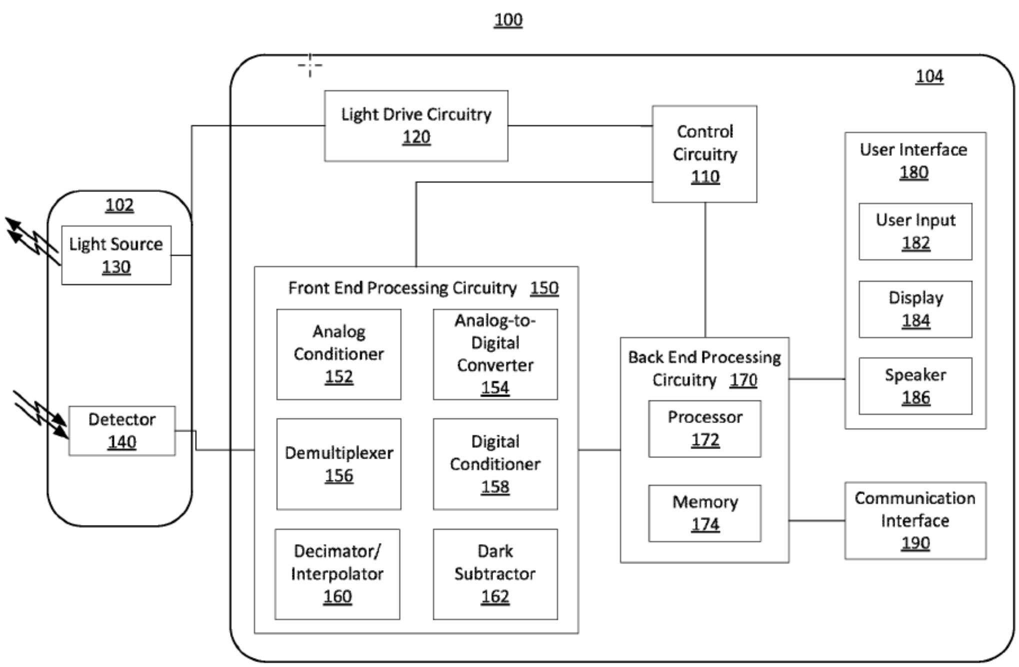

FIG. 1

Figure 1 of Lisogurski

Figure 1 of Lisogurski is a "block diagram of an illustrative physiological monitoring system." Ex. 1011, 2:11–13. The system includes "sensor 102 and a monitor 104 for generating and processing physiological signals of a subject." *Id*. at 10:44–46. Sensor 102 includes "light source 130 and detector 140." *Id*. at 10:48–49. Light source 130 includes "a Red light emitting light source and an IR light emitting light source," such as Red and IR emitting LEDs, with the IR LED emitting light with a "wavelength may be between about 800 nm and about 1000 nm." *Id*. at 10:52–58. Detector 140 "detect[s] the intensity of light at the Red and IR wavelengths," converts them to an electrical signal, and "send[s] the detection signal to monitor 104, where the detection signal may be processed and physiological parameters may be determined." *Id*. at 11:9–10, 11:20–23. Monitor 104 includes user interface 180, communication interface 190, and control circuitry 110 for controlling (a) light drive circuitry 120, (b) front end processing circuitry

150, and (c) back end processing circuitry 170 via "timing control signals." *Id*. at 11:33–38, Fig. 1. Light drive circuitry 120 "generate[s] a light drive signal . . . used to turn on and off the light source 130, based on the timing control signals." *Id*. at 11:38–40. The light drive signal "control[s] the intensity of light source 130 and the timing of when [the] light source 130 is turned on and off." *Id*. at 11:50–54. Front end processing circuitry 150 "receive[s] a detection signal from detector 140 and provide[s] one or more processed signals to back end processing circuitry 170." *Id*. at 12:42–45. Front end processing circuitry 150 also "synchronize[s] the operation of an analog-to-digital converter and a demultiplexer with the light drive signal based on the timing control signals." *Id*. at 11:43–46.

Back end processing circuitry 170 "use[s] the timing control signals to coordinate its operation with front end processing circuitry 150." *Id*. at 11:46–49. Back end processing circuitry 170 includes processor 172 and memory 174, and "receive[s] and process[es] physiological signals received from front end processing circuitry 150" in order to "determine one or more physiological parameters." Ex. 1011, 14:56–57, 14:60–64. Back end processing circuitry 170 is "communicatively coupled [to] user interface 180 and communication interface 190." *Id*. at 15:16–18. User interface 180 includes "user input 182, display 184, and speaker 186," and may include "a keyboard, a mouse, a touch screen, buttons, switches, [and] a microphone." *Id*. at 15:19–22. Communication interface 190 allows "monitor 104 to exchange information with external devices," and includes transmitters and receivers to allow wireless communications. *Id*. at 15:43–44, 15:48–57. Lisogurski teaches the physiological monitoring system may modulate the light drive signal to have a "period the same as or closely related to the period of [a] cardiac cycle." Ex. 1011, 25:49–51. Thus, "[t]he system may vary parameters related to the light drive signal including drive current or light brightness, duty cycle, firing rate, . . . [and] other suitable parameters." *Id*. at 25:52–55.

Lisogurski discloses that a system may use various cardiac cycle modulation techniques to adjust the brightness of a light source controlled by the light drive signal, e.g., using a sinusoid or triangle wave whose period is related to cardiac pulse rate. *Id.* at 6:31–41. In addition, to improve the quality of the physiological parameter determination, cardiac cycle modulation may align the period of the modulated light drive signal with a particular point in the cardiac cycle, e.g., the diastolic period, the systolic period, the dicrotic notch, or any other suitable point. *Id.* at 6:41–46. The cardiac cycle modulation may also be based on empirical data concerning the determined physiological parameter. *See id.* at 6:53–7:3.

Lisogurski also describes combining cardiac cycle modulation with drive cycle modulation. Ex. 1011, 6:29–31, 16:42–46. Drive cycle modulation is "a technique to remove ambient and background signals." *Id.* at 6:7–9. Drive cycle modulation operates by turning on a first light source, followed by a dark period, followed by a second light source, followed by a dark period, measuring the ambient light during the dark period and subtracting the ambient contribution from signal received during the first and second on periods. *Id.* at 6:11–19. Cardiac cycle modulation represents a lower frequency envelope function (about 1 Hz) on the higher frequency drive cycle (about 1 KHz). *Id.* at 6:26–30.

Figure 2C of Lisogurski is reproduced below.

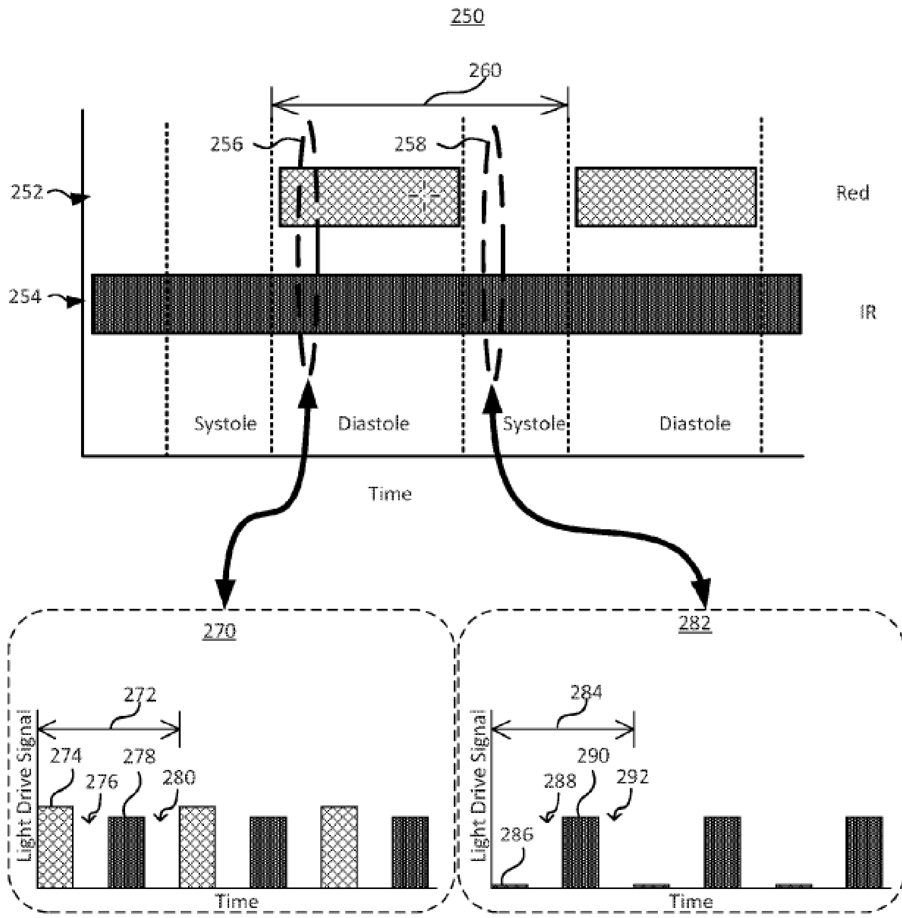

Figure 2C of Lisogurski

Figure 2C shows timing diagrams of drive cycle modulation and cardiac cycle modulation. *Id.* at 16:17–19. The period of the cardiac cycle modulation, i.e., time period 260, may be on the order of 1 second and the period of drive cycle modulation 272 may be on the order of 1 msec. *Id.* at 16:40–46. Plot 270 shows an illustrative portion of region 256, where both red light modulation 252 and IR modulation 254 are in an "on" portion of the cardiac modulation in the diastole. *Id.* at 16:33–38. Lisogurski explains:

> Time interval 272 may include a sequence of red "on" portion 274, a first "off" portion 276, IR "on" portion 278, and a second "off" portion 280. The first "off" portion 276 and second "off" portion 280 may be used to determine the level of ambient light, noise, dark current, other suitable signals, or any

> combination thereof. The system may subtract the background or dark level from the levels received during red "on" portion 274 and IR "on" period 278.

Id. at 16:47–53. Lisogurski provides a similar discussion of region 258 where red light modulation 252 is in an "off" portion of the cardiac cycle modulation and IR modulation is in an "on" portion of the cardiac cycle modulation. *Id.* at 16:54–17:10.

As discussed above, Lisogurski discloses combining cardiac cycle and drive cycle modulation techniques, "[f]or example, cardiac cycle modulation may be an envelope on the order of 1 Hz superimposed on a 1 kHz sine wave drive cycle modulation." *Id*. at 6:29–31. Lisogurski also states "[t]he system may use one or more cardiac cycle modulation techniques depending on the desired physiological parameter." *Id.* at 9:12–14. As an example, Lisogurski discloses that "the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons" and "[i]n some embodiments, the system may change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light." *See id.* at 9:45–60 (discussing options to reduce the effect of noise that can be implemented during a cycle of the cardiac cycle modulation).

2. *Carlson*

Carlson concerns optical pulsoximetry used for non-invasive measurement of pulsation and oxygenation in arterial blood. Ex. 1009 ¶ 2. An articulated object of Carlson is "define optical and/or electronic means for increasing the Signal-to-Noise ratio (S/N) and Signal to Background ratio (S/B) of a pulsoximeter sensor." *Id.* ¶ 10. Carlson seeks to improve S/N and S/B using one or more of the following techniques: beam shaping to direct optical radiation in a way that increases signal power (*id.* ¶ 14), employing light sources at more than one wavelength and optical wavelength filtering adapted to the power spectrum of the light source and absorption spectrum of the arterial blood (*id.* ¶¶ 16–17), and shifting the power spectrum of the pulsoximeter signals to a higher frequency range by temporarily amplitude modulating LED radiation using AC-Coupling or Lock-In Amplification. (*id.* ¶¶ 20, 27, 64–65).

Carlson recognizes that the spectrum of physiological event is within the range of 0.5–3 Hz (30–180 heartbeats per minute), sunlight is at 0 Hz, and artificial electrical light is about 120 Hz in the United States. Ex. 1009 ¶¶ 66–67, Fig. 7a–7b. Figure 7c of Carlson is reproduced below.

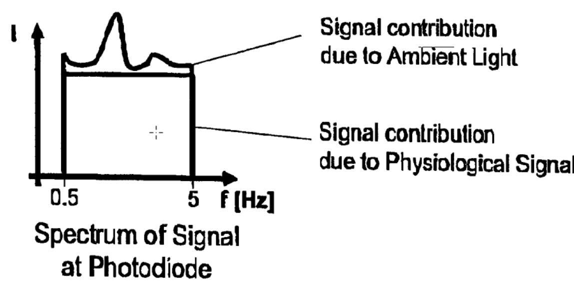

Figure 7c of Carlson

Figure 7c is a combined frequency spectrum showing the contribution of physiological signals, sunlight and ambient light. *Id.* ¶ 67. Carlson discloses discriminating the pulsoximeter sensor signals from the ambient noise by pulsing the LEDs at a frequency outside the range of sunlight or ambient light (e.g., at about f_o=1000 Hz, or some other higher frequency), thereby shifting the spectrum of signals from the photodiode to a range where there is little influence from the ambient noise. *Id.* ¶ 69, Fig. 8.

Figure 8 of Carlson is shown below.

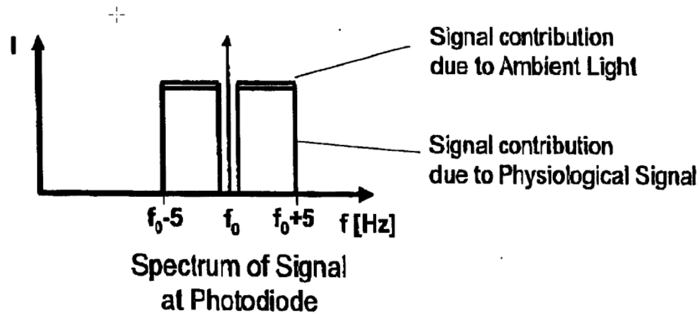

Figure 8 of Carlson

Figure 8 illustrates noise or sunlight in the range of 0–120 Hz contributes little to the pulsoximeter measurements between f_o–5 Hz and f_o+5 Hz.

Figure 9 of Carlson is reproduced below.

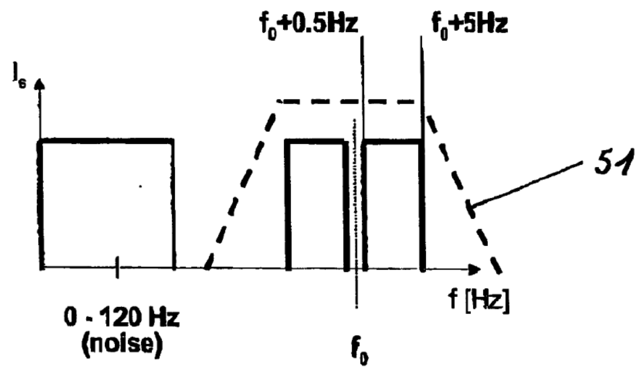

Figure 9 of Carlson

As shown in Figure 9, bandpass filter 51 can be used to remove any frequencies between 0 Hz and 120 Hz. *Id.* ¶ 69.

After measurements with pulse light have been executed, Carlson employs reverse phase shifting or modulation, as known in the art, to calculate the real values of the pulsoximetric measurement. *Id.* ¶ 70.

3. *Reasons to Combine Lisogurski and Carlson*

Petitioner notes that Lisogurski and Carlson both concern analogous miniaturized pulse oximetry devices that have the same applications. Pet. 24 (citing Ex. 1003 ¶ 85 (Anthony Decl.)). Petitioner also argues that Lisogurski and Carlson teach techniques for improving energy efficiency and signal-to-noise ratios in such devices. *Id.* at 24–25 (citing Ex. 1011, 1:4–6, 1:16–18, 3:50–53, 9:46–52; Ex. 1009 ¶¶ 2, 4, 10, 48, 52; Ex. 1003 ¶¶ 83–84 (Anthony Decl.)). According to Petitioner a person of ordinary skill would have considered the references together, given the common applications and utility. *Id.* at 25–26 (citing Ex. 1003 ¶ 85 (Anthony Decl.)). Petitioner further argues that general trends in the industry to create wearable mobile monitoring devices in sports and personal fitness applications would have given a person of ordinary skill reason to look to the references to develop such devices for consumer applications. *Id.* (citing Ex. 1003 ¶¶ 48–56, 86 (Anthony Decl.)).

Patent Owner does not respond explicitly to Petitioner's contentions concerning a reason to combine the teachings of Lisogurski and Carlson, other than its arguments, addressed below in Section X.B.5, that such a combination changes Lisogurski's principle of operation.

Based on the current record, we find that, for purposes of institution, Petitioner has demonstrated that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Carlson.

4. *Claim Limitations 1(a)–1(k)*

Petitioner cites Lisogurski as disclosing a system for measuring one or more physiological parameters for use with a smart phone or tablet, as recited in the preamble (claim limitation 1(a)), and that the system may be placed on a user's ear or wrist (claim limitation 1(b)). Pet. 27–28 (citing, e.g., Ex.1011, 1:10–25, 3:43–46, 4:6–20; Ex. 1003 ¶¶ 89–92, 97 (Anthony Decl.)).

Petitioner also cites Lisogurski's wearable sensor as disclosing a plurality of LED light sources generating photonic signals having one or more wavelengths configured to direct light into a subject's tissue (claim limitation 1(c)); Petitioner further states that a person of ordinary skill would have understood that glass encapsulating LEDs serves as a lens, i.e., a basic building block of an optical sensor, to receive the LED's light and transmit that light to a particular location (claim limitation (d)). *See id.* at 29–30. Petitioner further argues that Carlson discloses such lenses and that they can be diffractive or refractive and direct the emitted optical radiation into human or animal tissue. *See id.* at 31–33 (citing, e.g., Ex. 1009 ¶¶ 13, 14, 24, 62; Ex. 1003 ¶ 111 (Anthony Decl.)). According to Petitioner, a person of ordinary skill would have had reason to employ lenses as taught by Carlson in Lisogurski's sensor to focus light from the LED onto a person's skin and in doing so, increase optical power and improve signal to noise ratio. *Id.* at 32–33 (citing Ex. 1009 ¶ 14; Ex.1011, 6:3–6, 9:49–60, 13:60–14:10, 14:40–55, 37:6–20; Ex. 1003 ¶¶ 82, 112–114 (Anthony Decl.)).

Claim limitation 1(e) recites "the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio." Petitioner cites Lisogurski as disclosing the recited detection system in the form of a sensor with one or more detectors connected to front-end processing circuitry that may receive a detection signal, i.e., light that is reflected by or has traveled through the subject's tissue, from detector 140, and provides processed signals, i.e., electrical signals based on the intensity of the reflected light, to back-end circuitry 170. Pet. 33–34 (citing Ex. 1011, 11:14–22, 12:42–45, 17:40–42, Ex. 1003 ¶ 116 (Anthony Decl.)). Petitioner further notes that the processed signals originate from detection signals that have a signal-to-noise ratio. *Id.* at 34 (citing Ex. 1011, 14:49–50 (discussing the effect of ambient light on signal-to-noise ratio of the detection signal in the context of the available resolution of an A/D converter), 9:46–52 (noting background noise in the detected signal and modifying light drive parameters of the LEDs to improve signal-to-noise ratio), 11:20–27 (detection signal processed); Ex. 1003 ¶ 117 (Anthony Decl.)).

Turning to claim limitation 1(f), which recites that the detection system is configured to be synchronized to the light source, Petitioner cites Lisogurski as disclosing front end processing circuitry 150 operating synchronously with light drive circuitry 120, e.g., by synchronizing the sampling rate of an analog to digital converter to a modulated LED firing rate to provide, e.g., one or more samples to be averaged per period. *Id.* at 34–35 (citing Ex. 1011, 2:1–2, 27:44–52, 33:49–47, 35:17–23; Ex. 1003 ¶¶ 119–121 (Anthony Decl.)). Acknowledging that Lisogurski depicts front end processing circuitry 104 as separate from wearable sensor 102, Petitioner asserts that incorporating the front end processing circuitry into the same device with the detector would have been consistent with Lisogurski's teaching that the functionality of some components of monitor 104 can be divided over multiple components and is an obvious modification to a person of ordinary skill. *See* Pet. 36–38.

Petitioner cites Lisogurski as disclosing claim limitations 1(g) and 1(h). Pet. 38–40. Claim limitation 1(g) recites that the detection system comprises a plurality of multiple spaced detectors with at least one A/D converter coupled to at least one of the spatially separated detectors. Claim limitation 1(h) recites that a detector output from at least one of the spatially separated detectors is coupled to an amplifier to improve detection sensitivity.[7] Petitioner cites Lisogurski as disclosing that signals generated by the detectors are passed to front end processing circuitry that includes an A/D converter and an amplifier having a gain that can be adjusted so that the signal matches the range of the A/D converter to increase resolution and detection sensitivity. *Id*. (citing Ex. 1011, 11:9–10, 13:6–60, 17:43–45, 19:52–53, 19:56–58, 26:38–45; Ex. 1003 ¶¶ 192–131, 134–135 (Anthony Decl.)).

Claim limitation 1(i) recites a smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, buttons, a microprocessor, and a touch screen, configured to receive and process at least a portion of the output signal, such that a portion of the processed output signal is configured to be transmitted over a wireless transmission link. Petitioner cites Lisogurski as disclosing its sensor is designed to be used with a monitor that may be a portable, battery powered system that includes a touchscreen and has back-end processing that receives signals from the front end and includes a microprocessor and an interface with a display, speaker and microphone. *See* Pet. 40–42. Petitioner further notes that the back-end processing disclosed by Lisogurski can be configured for wireless communication. *Id.* at 40–41 (citing Ex. 1011, 15:49–56; Ex. 1003 ¶ 138 (Anthony Decl.)).

Claim limitation 1(j) recites "a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data." Petitioner cites

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[7] Claim 7 and 15 do not include a limitation corresponding to claim limitation 1(h). Pet. 39.

Lisogurski as disclosing that physiological parameters and other data may be wirelessly transmitted to a server or a multi-parameter physical monitor (MPPM 326) that can be coupled to a network to enable sharing of information with servers or other workstations, i.e., a cloud based server. *See* Pet. 42–43.

Claim limitation 1(k) recites "the output signal is indicative of one or more of the physiological parameters[, and the cloud is configured to store a history of at least a portion of the one or more physiological parameters over a specified period of time]."[8] Petitioner cites Lisogurski as disclosing that data, i.e., an output signal, transmitted to a server, monitor, or remote device may be stored or published, that MPPM 326 is configured to calculate physiological parameters, and that these devices can perform historical analysis or prior cardiac cycles and calculate statistical information. *Id.* at 44 (citing Ex. 1011, 26:55–60, 18:49–53, 20:8–9, 19:1–19: Ex. 1003 ¶¶ 149–152 (Anthony Decl.)).

Patent Owner does not respond to Petitioner's assertions concerning claim limitations 1(a)–1(k). Having reviewed the evidence of record, we are persuaded that Petitioner has demonstrated that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Carlson and that the combined teaching of these reference disclose each of the claim limitations 1(a)–1(k) to an ordinarily skilled artisan.

5. *Claim Limitation 1(l)*

Petitioner identifies claim limitation 1(l) as reciting "the wearable device configured to increase the signal-to-noise ratio." Pet. 45. Petitioner cites Lisogurski as disclosing its control circuitry improves signal-to-noise

[8] The language in brackets does not appear in claims 7 and 15.

ratio by providing signal modulation to vary light drive signal parameters such as light intensity (brightness), firing rate (frequency) and duty cycle (pulse width duration for each pulse of light). *Id.* at 45–48.

a) Claim Limitation 1(l)(1)

Petitioner identifies as claim limitation 1(l)(1) the recitation "[the wearable device configured to increase the signal-to-noise ratio] by increasing light intensity of at least one of the [plurality of] semiconductor sources from an initial light intensity." Pet. 48 (second alteration in original). Petitioner cites Lisogurski as disclosing that by increasing light intensity the system may increase the brightness of light sources in response to noise to improve signal to noise ratio. Pet. 48 (citing Ex. 1011, 37:6–22, 6:3–6; Ex.1003 ¶¶145–48, 166–171 (Anthony Decl.)). Patent Owner does not respond to Petitioner's assertion that Lisogurski discloses claim limitation 1(l)(1). We are persuaded that Petitioner has demonstrated Lisogurski teaches this claim limitation.

b) Claim Limitation 1(l)(2) ("The Pulse Rate Limitation")

Petitioner identifies as claim limitation 1(l)(2) the recitation "[the wearable device configured to reduce the signal-to-noise ratio] . . . by increasing a pulse rate of at least one of the plurality of semiconductor sources from an initial pulse rate." Pet. 48. Patent Owner refers to claim limitation 1(l)(2) as "the pulse rate limitation." Prelim. Resp. 8 (emphasis omitted).

Petitioner asserts that a person of ordinary skill would have understood that an LED's "firing rate" is the same as the claimed pulse rate. Pet. 49 (citing Ex. 1003 ¶¶ 175–177 (Anthony Decl.)).

Petitioner argues Lisogurski teaches the pulse rate limitation because it discloses increasing firing rate from an initial rate in order to correlate the firing rate to the sampling rate of an analog to digital (A-D) converter, thereby spreading the noise across more samples (*see* Pet. 49–51, citing Ex. 1011, 9:46–52, 37:6–22; Ex. 1003 ¶178–180, 182 (Anthony Decl.); Ex. 1060, 37:13–38:3, 82:5–15 (Transcript of Deposition of Dr. Duncan Leo MacFarlane ("MacFarlane Tr."))). Petitioner also argues that cardiac cycle modulation (CCM) varies the light drive signal to remain synchronous with a subject's heart rate, thereby increasing the pulse rate as the subject's heart rate increases and reducing noise by 1–4%. Pet. 50–51 (citing Ex. 1011, 25:46–55, 25:50–61; Ex. 1003 ¶¶ 181–182 (Anthony Decl.)).

Petitioner also argues Carlson as expressly disclosing shifting the frequency of emitted light during operation from a first frequency to a second frequency so it is substantially outside the frequency of noise and environmental signals. Pet. 52 (citing Ex. 1009, claim 10–11, ¶¶ 67–69); *see* Ex. 1003 ¶¶ 186–188 (Anthony Decl.)). Petitioner further contends that in view of Carlson's recognition that sunlight interference is temporary and can occur at different frequencies, a person of ordinary skill would have recognized the pulse frequency can vary. Pet. 52 (citing Ex. 1009 ¶ 68; Ex. 1003 ¶ 187 (Anthony Decl.)); *see also* Ex. 1003 ¶¶ 188–190 (Anthony Decl.).

Petitioner contends that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Carlson because both references identify and address the same problem, i.e., the negative impact of ambient light on signal-to-noise ratio. Pet. at 53 (citing Ex. 1011, 9:46–60; Ex. 1009 ¶¶ 67–69; Ex. 1003 ¶190 (Anthony Decl.)). Petitioner contends that because Lisogurski teaches adjusting LED firing rate in response to changing environmental conditions such as background noise or ambient light, a skilled artisan would have recognized Lisogurski could be configured to increase LED firing rate as taught by Carlson. *Id.* (citing Ex. 1011, 1:67–2:3, 5:55–61, 9:46–60, 37:6–18; Ex. 1009 ¶¶ 67–69; Ex.1003 ¶¶ 190–191 (Anthony Decl.)).

Patent Owner contends that trivial changes in firing rate during Lisogurski's cardiac cycle modulation merely keep modulation synchronized to the photoplethysmograph (PPG) signal (*see* Ex. 1011, 4:6–41) and have no measureable effect on SNR (Prelim. Resp. 13). Patent Owner also argues that modifying Lisogurski as taught by Carson abolishes Lisogurski's principle of operation (*see id.* at 14–18).

According to Patent Owner, "Petitioner consistently refers to CCM and no other form of modulation." *Id*. at 8–9. Patent Owner cites the declaration testimony of its expert, Dr. MacFarlane, that trivial pulse rate increases during CCM do not improve signal-to-noise ratio, and that his statement of the general principle that increasing LED pulse rate can improve signal-to-noise ratio does not implicate CCM. *Id.* at 10–12 (citing Ex. 2131 ¶ 81 (noting that Petitioner's cross examination of Dr. MacFarlane did not inquire about whether his statement of this general principle applies to CCM). Patent Owner also contends that, contrary to Petitioner's assertion that Patent Owner admitted CCM is a technique for improving signal-to-noise ratio, Patent Owner merely acknowledged that Lisogurski teaches that some points on the CCM cycle are less noisy than others, so taking measurements at those points may be preferable. *Id.* at 12.

According to Patent Owner, both Lisogurski and Carlson confirm that modulating LEDs at physiological frequencies does not improve signal-to-noise ratio, stating that "[w]hen they modulate LEDs to avoid noise, both Lisogurski and Carlson teach that the modulation frequency must be 1000 Hz (or higher)—far above ambient noise and the 0.5–3 Hz heart rate where CCM operates." Prelim. Resp. 9. Patent Owner argues that "Lisogurski adds a separate 1000 Hz modulation, called 'drive cycle modulation' (Ex. 2131, ¶ 83), which 'cycle[s] light output at a rate significantly greater than the cardiac cycle.'" *Id.* (alteration in original) (citing Ex. 1011, 6:9–19). Patent Owner acknowledges that similar to Lisogurski, Carlson teaches choosing the pulse rate of the LED to be 1000 Hz or higher, i.e., outside the frequency spectrum of sunlight an ambient light. *Id.* at 10 (citing Ex. 1009 ¶ 69). In view of these disclosures and Patent Owner's acknowledgement, we find unavailing Patent Owner's argument that a person of ordinary skill would not have had reason to combine the teachings of Lisogurski and Carlson or that such a combination would abolish Lisogurski's principle of operation. Prelim. Resp. 14–18.

Patent Owner also overlooks Petitioner's discussion and Dr. Anthony's declaration testimony concerning the effect of increasing the "firing rate." Petitioner notes that Lisogurski uses the term "pulse rate" to refer to the heart rate of the user and "firing rate" to refer to the frequency at which the LED blinks, or the number of times per second that the light is turned on and off. Ex. 1003 ¶¶ 175, 177 (Anthony Decl.) (citing Ex. 1011, 1:22–25, 2:1–2). As Petitioner observes, Lisogurski's "firing rate" is the same as the "pulse rate" recited in claim limitation 1(l)(2) because both terms refer to rate or frequency at which the LED is turned on and off. *Id.* at ¶ 176.

Petitioner's discussion of CCM is in the context of Petitioner's argument that "Lisogurski's 'cardiac cycle modulation' *also* teaches [the pulse rate] limitation." Ex. 1003 ¶ 181 (Anthony Decl.) (emphasis added);

see Pet. 50. Petitioner's references to "firing rate" in its discussion of the pulse rate limitation refers to the pulse rate of the LED, not to the rate of CCM. Petitioner cites cardiac cycle modulation as varying light drive signal parameters, such as firing rate, to remain substantially synchronous with a subject heart's rate. Pet. 50 (citing Ex. 1011, 25:46–61). The same paragraph of Lisogurski states "the system may apply this cardiac cycle modulation to the light drive signal *in addition to* a drive cycle modulation, as illustrated in FIG. 2C." Ex. 1011, 25:61–64 (emphasis added); *see also* Sec. X.B.1 above.

The Petition explicitly states "Carlson teaches one such way of improving signal-to-noise ratios, including to deal with the same problems of ambient light identified in Lisogurski." Pet. 51 (citing Ex. 1003 ¶¶ 187–187 (Anthony Decl.)). In particular, Petitioner's expert, Dr. Anthony states "[l]ike Lisogurski, Carlson describes techniques for removing noise from a signal, such as noise from ambient [sunlight] . . . . by pulsing the LEDs at an increased rate to reduce the effects of ambient light whenever present," i.e., at a pulse frequency outside the frequency spectrum of sun and ambient light, e.g., 1000Hz. Ex. 1003 ¶ 186 (Anthony Decl.) (citing Ex. 1009 ¶¶ 67–69). Carlson's disclosure is consistent with Lisogurski's discussion of employing an LED firing rate of 1 kHz (1 ms period) with a 1 Hz (1 sec. period) CCM modulation. Ex. 1011, 6:7–53, 16:17–17:10. Carlson discloses:

> it is furthermore possible to use a light source modulation to temporarily modulate the optical radiation of the LED.
>
> The basic idea of using AC-Coupling or Lock-In Amplification (synchronous detection), is to temporarily modulate the optical radiation of the LED at the carrier frequency fc in order to shift the power spectrum of the pulsoximeter signals into a higher

> frequency range where environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent. AC-Coupling or Lock-In Amplification is well known out of the state of the art and is described in literature.

Ex. 1009 ¶¶ 64–65. Lisogurski discloses:

> a technique to remove ambient and background signals may be used in addition to or in place of a power saving light modulation scheme. In a drive cycle modulation technique, the system may cycle light output at a rate significantly greater than the cardiac cycle . . . The cardiac cycle modulation may represent a lower frequency envelope function on the higher frequency drive cycle. For example, cardiac cycle modulation may be an envelope on the order of 1 Hz superimposed on a 1 KHz sine wave drive cycle modulation.

Ex. 1011, 6:7–31. Thus, we are persuaded, for purposes of institution, that Petitioner has demonstrated Lisogurski and Carlson teach pulsing the LEDs at a frequency, e.g., 1000 Hz, that avoids noise introduced by ambient and environmental conditions and that a person of ordinary skill would have been motivated to combine their teachings to achieve that effect.

Petitioner also notes that Carlson expressly discloses shifting the frequency of emitted light during operation. Pet. 52 (citing Ex. 1009 ¶¶ 67–69, claims 10–11). Carlson explicitly states:

> The basic idea of using AC-Coupling or Lock-In Amplification detection means is to temporarily modulate the optical radiation of, e.g., the LED at the carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where an environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent.

Ex. 1009 ¶ 27; *see also id.* ¶ 64–65 (describing "temporarily" modulating the optical radiation), ¶ 68 (discussing the variable effect of shadows attenuating sunlight when passing under trees). We also note Lisogurski's disclosure of combining CCM and drive cycle modulation and its suggestion of changing from modulated light output to a constant light output in response to noise or ambient light during a CCM cycle or from one CCM cycle to another. Ex. 1011, 9:58–60, *see id*. at 6:27–31, 9:12–60, 16:17–17:29.

On the current record, for purposes of institution, we are persuaded that Petitioner has demonstrated Lisogurski and Carlson disclose claim limitation 1(l)(2) to a person of ordinary skill in the art and that a person of ordinary skill would have had reason to combine their teachings.

6. *Claim limitations 1(m)–1(o)*

Claim limitation 1(m) recites the detection system generates a first signal responsive to light received while the LEDs are off; claim limitation 1(n) recites the detection system generates a second signal responsive to light when at least one of the LEDs is on. Claim limitation 1(o) recites the detection system is configured to increase the signal-to-noise ratio by differencing the first and second signals.

As to claim limitation 1(m), Petitioner cites Lisogurski as disclosing the front end processing uses the current measured when the LEDs are off to generate a dark signal representative of ambient light. Pet. 54–55 (citing Ex. 1011, 6:12–19; 11:14–16, 12:59–13:6, 13:67–14:6, Figs. 2A–B; Ex. 1003 ¶¶ 197–198 (Anthony Decl.)). As to claim limitation 1(n), Petitioner cites Lisogurski as disclosing the front end processing circuitry measuring the signal when at least one LED is on to capture a portion of the optical beam, e.g., a red signal and an IR signal, reflected from the tissue. *Id.* at 55–56 (citing Ex. 1011, 6:12–19, 11:12–20, 13:35–41, 13:67–14:2, 16:52–53, 17:8–10, 17:40–42, Figs. 2A–B; Ex. 1003 ¶¶ 200–202 (Anthony Decl.).

Turning to claim limitation 1(o), noting that Lisogurski describes ambient light as noise, Petitioner cites Lisogurski as disclosing a "dark subtraction" technique that subtracts the dark signal from the red and IR signals to generate adjusted red and IR signals with noise removed, thereby improving signal-to-noise ratio. *Id.* at 54, 57 (citing Ex. 1011, 6:7–19, 13:60–14:10, 16:33–54 (describing the dark subtraction process); Ex. 1003 ¶¶ 194, 204–206 (Anthony Decl.)).

Patent Owner does not respond explicitly to Petitioner's contentions. Based on the current record, we are persuaded that Petitioner has demonstrated for purposes of institution that Lisogurski discloses claim limitations 1(m), 1(n), and 1(o) to a person of ordinary skill.

7. *Conclusion as to Claim 1*

In consideration of the above, we find that, on the current record, and for purposes of institution, Petitioner has demonstrated that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Carlson and the combined teachings of Lisogurski and Carlson disclose the limitations of claim 1 to an ordinarily skilled artisan.

8. *Claims 7 and 15*

We addressed the difference between claim 1 and claims 7 and 15 in our discussion of the individual limitations of claim 1. We apply the same reasoning to claims 7 and 15 as we apply to claim 1 and make the same finding.

9. *Claim 17*

Claim 17 depends from claim 15 and recites the additional limitation "wherein a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to be adjusted to improve detection sensitivity." In support of its argument that Lisogurski discloses the additional limitation recited in claim 17, Petitioner cites its arguments concerning claim limitation 1(g). Pet. 57–58 (citing *id.* at 38–39); *see also id.* at 39–40 (discussion of claim limitation 1(h)). Patent

Owner does not respond explicitly to Petitioner's arguments concerning the additional limitation recited in claim 17. Based on the current record we are persuaded that, for purposes of institution, Petitioner has demonstrated that combined teachings of Lisogurski and Carlson disclose the limitations of claim 17 to a person of ordinary skill.

C. Claims 1–4, 7–12, and 15–22 As Obvious Over Lisogurski, Carlson, and Tran

Petitioner asserts that, to the extent Lisogurski is found not to teach a smartphone or tablet, Trans provides this teaching. Pet. 58. Petitioner further asserts that Tran discloses the limitations of dependent claims 2–4, 8–12, 16, and 18–22 that relate to artificial intelligence.

1. *Tran (Ex. 1064)*

Petitioner cites Tran as disclosing a heart monitoring system in which a monitoring devices, such as a watch worn by patient, communicates health information to a server that passes the information to statistical and data driven analyzers. Pet. 58 (citing Ex. 1064, (code 57), 8:28–53, 9:23–54, 11:1–31, 54:14–57; Ex. 1003 ¶ 209 (Anthony Decl.)). Petitioner notes that Tran's monitoring device can be used with a smartphone that collects data when a patient is away from home, that the monitored health information includes pulse oximetry measurements, and that the statistical analyzers use artificial neural networks to help track and classify patient risk and provide warnings. *See id.* at 58–59.

2. *Petitioner's arguments*

a) Reason to combine

Petitioner asserts that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Carlson with those of Tran as part of the ordinary design process for such devices and systems.

Pet. 59 (citing Ex. 1003 ¶¶ 210–214 (Anthony Decl.)). Noting that Lisogurski discloses processing its collected data to track patient status, Petitioner argues a person of ordinary skill would have been motivated to seek additional ways to use tracked data, such as pulse oximetry data, in a remote or mobile scenario, e.g., using Tran's artificial neural network to analyze such data and provide warnings. *Id.* (citing Ex. 1064, 22:23–28; Ex. 1011, 15:43–65, 18:58–65; comparing Ex. 1064, 36:62–37:13 with Ex. 1011, 10:48–64).

Patent Owner does not respond explicitly to Petitioner's assertions concerning the reasons to combine the teachings of Lisogurski and Carlson with those of Tran. As we agree with Petitioner that Lisogurski, Carlson, and Tran each describe techniques applicable to measurements taken by wearable optical sensing device (Pet. 60), we are persuaded for purposes of institution that Petitioner has demonstrated a person of ordinary skill would have reason to combine the teachings of these references

b) Claims 1, 7, 15 and 17

As to independent claims 1, 7, 15, and 17, Petitioner argues that a person of ordinary skill would have recognized Tran's smartphone could be used in place of Lisogurski's monitoring device, which Lisogurski describes as a computing device that is portable, battery powered, and has a touchscreen. Pet. 60 (citing Ex. 1003 ¶ 216 (Anthony Decl.)). Petitioner further notes that Tran teaches using a smartphone with a portable, wearable sensor to send data to remote devices and other monitoring devices, facilitating the detection of emergencies in a manner consistent with the use of smartphones and tablets. *See id.* at 60–61.

c) Claims 2, 10, and 18

Claims 2, 10, and 18 depend from claims 1, 7, and 15, respectively, and recite the wearable device is configured to use artificial intelligence in making decisions associated with (claims 2 and 18) or to process (claim 10) at least a portion of the output signal. Petitioner notes that Tran discloses feeding data from a wearable patient monitoring device such as those disclosed by Lisogurski, to a statistical analyzer, such as Tran's neural network, which is a form of artificial intelligence. *Id.* at 61 (citing Ex. 1064, 3:6–13, 11:6–30, 22:24–30; Ex. 1003 ¶ 218 (Anthony Decl.)). Petitioner further explains that Tran's analysis of patient data can flag potentially dangerous conditions that can be specified as an event or pattern that can harm the patient. *Id.* (citing Ex. 1064, 11:16–19).

d) Claims 3, 8, and 16

Claims 3 and 16 depend from claims 2 and 15, respectively, and recite "the wearable device is at least in part configured to identify an object, and to compare a property of at least some of the output signal to a threshold." Claim 8 depends from claim 7 and recites that the wearable device or smartphone or tablet performs the comparison. Petitioner argues that Lisogurski discloses the device can identify an object, such as an ear or a wrist, because it can distinguish when it has fallen off. Pet. 62 (citing Ex. 1011, 36:66–37:2; Ex. 1003 ¶ 221 (Anthony Decl.)). Petitioner further cites Lisogurski as disclosing comparing a detected signal to a threshold or target value and using the outcome to change the operational mode of the device. *Id.* at 63 (citing Ex. 1011, 24:41–57). Petitioner points out that Lisogurski compares the output signal to thresholds that identify portions of interest for further processing or to change light source modulation, e.g., by comparing changes in ambient light and noise to a threshold to determine changes in noise level. *Id.* (citing Ex. 1011, 9:46–52, 37:8–14; Ex. 1003 ¶ 222 (Anthony Decl.)).

e) Claim 9

Claim 9 depends from claim 8 and further recites "a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity." In support of its argument that Lisogurski discloses the additional limitation recited in claim 9, Petitioner cites its arguments concerning claim limitation 1(g). Pet. 57–58 (citing *id.* at 38–39); *see also id.* at 39–40 (discussion of claim limitation 1(h)).

f) Claims 4, 11, 12, 19, 21, and 22

Claims 11 and 19 depend from claims 10 and 18 respectively and recite that the artificial intelligence includes pattern identification or classification and a pattern matching algorithm. Petitioner cites Tran as disclosing neural networks are used to recognize patterns. Pet. 64 (citing Ex. 1064, 23:39–50). Claims 4, 12, and 21 depend from claims 3, 10, and 15, respectively, and recite "the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal." Similarly, claim 22 depends from claim 21 and recites the pattern identification or classification comprises a pattern matching algorithm. According to Petitioner, Tran uses neural networks to track and flag patterns in a patient's vital signs to recognize possibly dangerous conditions. *Id.* at 63–64 (citing Ex. 1064, 22:23–59, 23:4–16, Ex. 1003 ¶ 227 (Anthony Decl.)). Petitioner further notes that Tran teaches using the neural network with a Hidden Markov Model (a derived set of reference pattern templates) to perform pattern matching and pattern identification or classification. *Id.*

at 64–65 (citing Ex. 1064, 24:45–60, 80:24–81:3; Ex. 1003 ¶ 227 (Anthony Decl.)).

g) Claim 20

Claim 20 depends from claim 18 and recites "the artificial intelligence comprises spectral fingerprinting." Petitioner cites Tran as disclosing its neural networks analyze blood oxygen saturation by measuring the ratio of oxygenated to unoxygenated hemoglobin in blood. Pet. 65 (citing Ex. 1064, 11:1–8, 36:61–37:13, 52:31–35); Ex. 1003 ¶ 231). Petitioner notes that Tran further discloses using "a form of spectral fingerprinting by measuring the blood's absorbance or reflectance of different wavelengths of light to determine how much oxygenated hemoglobin and unoxygenated hemoglobin is present." *Id.* (citing Ex. 1064, 37:2–13, 50:10–15).

3. *Conclusion*

Other than Patent Owner's arguments previously discussed concerning the combined teachings of Lisogurski and Carlson, Patent Owner does not respond specifically to Petitioner's assertions concerning the combination of Lisogurski, Carlson, and Tran. *See* Prelim. Resp. 8–18. On the current records, we are persuaded that Petitioner has demonstrated, for purposes of institution, that a person of ordinary skill would have had reason to combine the teachings of Lisogurski, Carlson, and Trans and that the combined teachings of these references disclose the limitations of claims 1–4, 7–12, and 15–22.

D. Claims 5 and 13 As Obvious Over Lisogurski, Carlson, Tran, and Isaacson

Petitioner notes that claims 5 and 13 further limit claims 4 and 12, respectively, and recite spacing requirements for LEDs and photodetectors. Pet. 66. Petitioner cites Isaacson as teaching the additional limitations recited in claims 5 and 13. *Id.* Patent Owner does not respond explicitly to Petitioner's assertions. Prelim. Resp. 18.

1. *Isaacson (Ex. 1063)*

Petitioner cites Isaacson as disclosing a pulse oximetry system sensor for use on a patient's arm and that has two emitters and two detectors separated by varying distances. Pet. 66 (citing Ex. 1063, 1:21–40, 2:57–58, 2:63–66, 3:66–4:3, 3:44–54, 6:32–34). Petitioner notes that Isaacson teaches selecting the distances between the emitters and detectors to allow measuring light that has penetrated different depths of tissue, with greater spacing allowing measuring of greater depth. *Id.* (citing Ex. 1063, 1:41–45, 5:10–15; Ex. 1003 ¶¶ 234–235 (Anthony Decl.)). In Isaacson, each emitter is separated from one of the detectors by a long path, with the length of each of the two long paths being equal and the length of the two short paths being equal. *Id.* at 66 (citing Ex. 1063, 1:28–40, 4:63–5:15; Ex. 1003 ¶¶ 234–235 (Anthony Decl.)). The long paths transverse a region of interest and the short paths transverse an exclusion region along the surface of the tissue. *Id.* at 67–68 (citing Ex. 1063, Fig. 1; Ex. 1003 ¶¶ 235–237 (Anthony Decl.)). Measurements of the short paths are used to remove contributions from the exclusion region to the long path measurements by subtracting the optical absorbance corresponding to the short paths from the optical absorbance corresponding to the long paths. *Id.* at 68 (citing Ex. 1063, 7:59–60; Ex. 1003 ¶ 237 (Anthony Decl.)).

2. *Reasons to Combine*

Petitioner contends a person of ordinary skill would have combined the teachings of Lisogurski with those of Isaacson as a matter of routine design practice in order to arrange multiple light sources and detectors properly for pulse oximetry applications. Pet. 68–69. Petitioner notes that

Lisogurski discloses light is attenuated differently depending on tissue and skin pigmentation and that skin interference can be addressed by using signals detected by detectors placed at different distances from an emitter. *Id.* at 68–69 (citing Ex. 1011, 19:42–50; Ex. 1003 ¶ 243 (Anthony Decl.)). Petitioner also notes that Isaacson explains the benefits of measuring oxygen saturation of particular areas of biological tissues to allow, e.g., measurement to be focused on deeper layers of tissue to exclude surface region contributions. *Id.* (citing Ex. 1063, 1:21–26, 2:47–52, 4:64–5:15, 7:59–62; Ex. 1003 ¶¶ 241–242 (Anthony Decl.)). Patent Owner does not respond explicitly to Petitioner's assertions concerning whether a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Isaacson. Prelim. Resp. 18. Based on the current record, we find that, for purposes of institution, Petitioner has demonstrated sufficiently that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Isaacson.

3. *Claims 5 and 13*

Figure 1 of Isaacson, as annotated by Petitioner, is reproduced below.

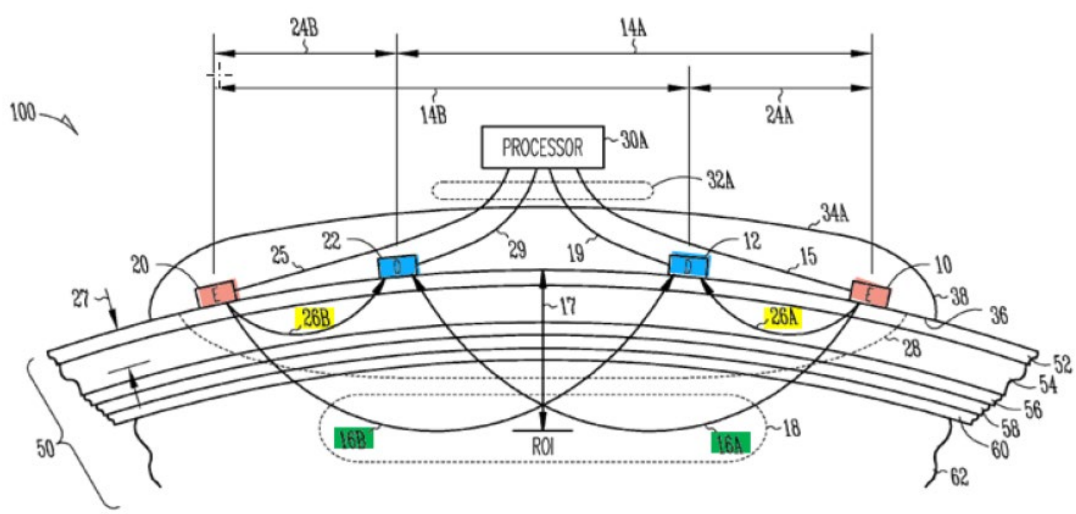

Figure 1 of Isaacson as annotated by Petitioner

Pet. 71. Petitioner notes that Isaacson discloses emitters that can be configured to emit light at difference wavelengths (red light emitter 10 and IR light emitter 20), and detectors 12 and 22 receiving reflected light from emitters 10 and 20. Pet. 71 (citing Ex. 1063, 3:52–54, 4:35–49, 6:21–29, 6:37–39). Petitioner notes that Isaacson explains each detectors capture light from the LEDs reflected off the patient, i.e., detector 22 receives light 26B (annotated in yellow) from IR emitter 20 and light 16A (annotated in green) from red light emitter 10 and detector 12 capture light 16B (annotated in green) from IR emitter 20 and light 26A (annotated in yellow) from red light emitter 10. *Id.* (citing Ex. 1063, 1:27–40). Petitioner notes that Isaacson uses these signals to remove the contribution of light from surface regions. *Id.* (citing Ex. 1063, 1:46–51, 7:59–62).

Referencing Figure 1 of Isaacson to claims 5 and 13, Petitioner notes that IR emitter 20 ("one [LED]") is at a "first distance" from detector 12 ("one . . . detector") and a "second distance," different from the first distance, from detector 22 ("another . . . detector"). *Id.* at 72. Petitioner points out that detector 12 ("one . . . detector") generates a "third signal" from light 16B from IR emitter 20 ("one [LED]") and detector 22 ("another . . . detector") generates a "fourth signal" from light 26B from IR emitter 20 ("one [LED]"). *Id.*

Petitioner further notes that detector 12 ("one . . . detector") is at a "third distance" from IR light emitter 20 ("first . . .[LED]") that is different from a "fourth distance" from red light emitter 10 ("second . . . [LED]"). *Id.* Detector 12 ("one . . . detector") generates a "fifth signal" from light 16B from IR emitter 20 ("first . . . [LED]") and a "sixth signal" from light 26A from red light emitter 10. *Id.* at 72 (citing Ex. 1003 ¶¶ 249–254 (Anthony Decl.)).

In consideration of the above, we find that Petitioner has demonstrated, for purposes of institution, a person of ordinary skill would have had reason to combine the teachings of Lisogurski, Carlson, Tran and Isaacson, and that the combination of these references discloses the limitations of claims 5 and 13.

E. Claims 6, 14, and 23 As Obvious Over Lisogurski, Carlson, Tran and Valencell-093

1. *Valencell-093*

Valencell-093 describes a wearable monitoring apparatus, with a sensor module "includ[ing] an energy emitter that directs energy at a target region of the subject" and a detector that detects an energy response signal or physiological condition from the subject. Ex. 1005, code (57), ¶ 5. The wearable apparatus may be an earbud or earpiece, a wristband, armband, or headband, among others. *Id*. ¶¶ 6, 50, 110, 151, Figs. 4A, 4B, 23. Valencell-093 describes that physiological conditions that may be detected, including heart rate, blood pressure, and blood constituent data such as blood oxygen level. *Id*. ¶¶ 6, 50, 109.

Figures 4A and 4B of Valencell-093, reproduced side-by-side below, show a side view (Figure 4A on the left) and front view (Figure 4B on the right) of a human ear with an earbud monitor according to one embodiment of the invention. *Id*. ¶¶ 57, 58.

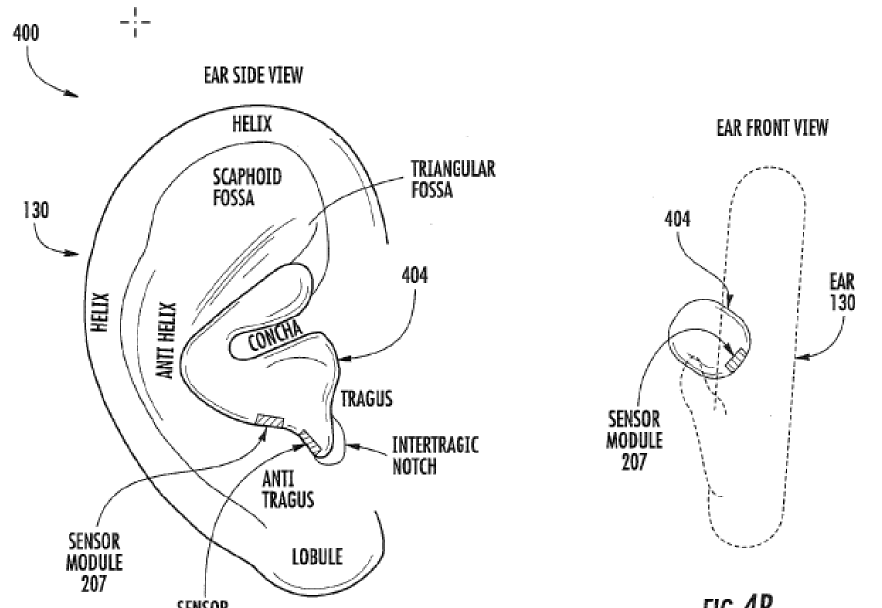

FIG. 4A

FIG. 4B

Figures 4A and 4B show ear 130 with biometric audio earbud 404 including sensor modules 207. *Id.* ¶ 110.

Sensor module 207 of Valencell-093 is illustrated in Figure 2, reproduced below. *Id.* ¶¶ 54, 109.

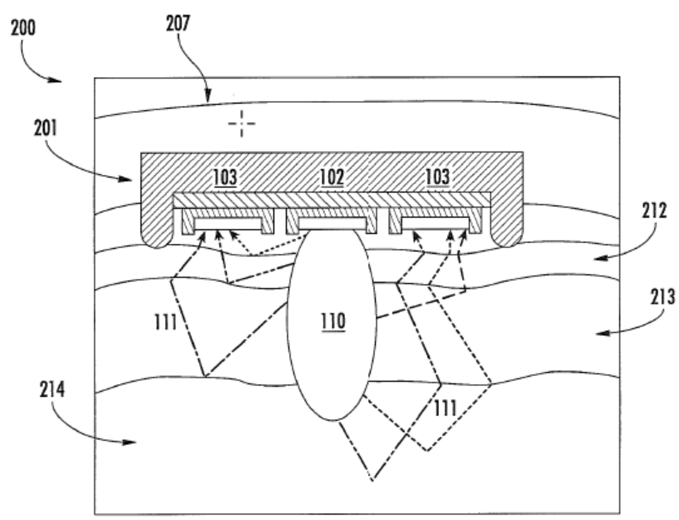

FIG. 2

Figure 2 illustrates sensor module 207, which includes optical emitter 102 and optical detectors 103. Emitter 102 generates one or more optical wavelengths 110, producing scattered optical energy 111, which is modulated by changes in the skin tissue (epidermis 212, dermis 213, and subcutaneous layers of skin tissue 214), and thus may contain information associated with a physiological condition of the subject. *Id.* ¶ 109.

Figure 7 of Valencell-093, reproduced below, depicts a sensor module configuration according to some embodiments of Valencell-093. *Id.* ¶ 60.

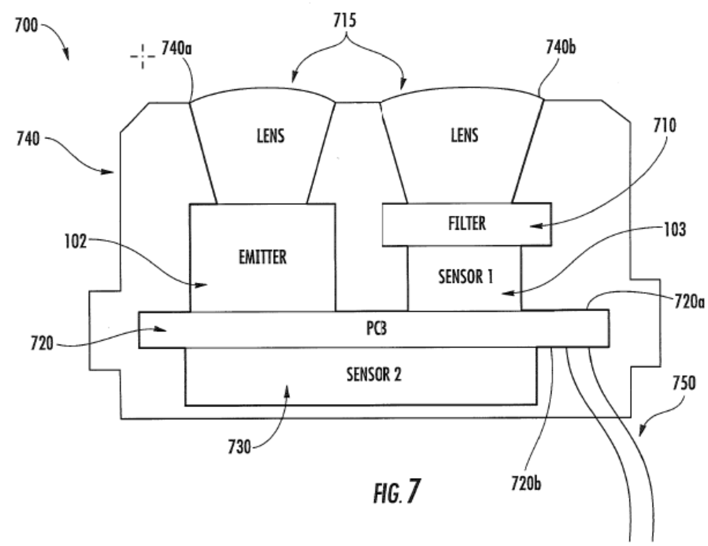

FIG. 7

Figure 7 shows a sensor with over-molded design that includes sensor lenses 715, respectively covering emitter 102 and sensor 103, which are used "[t]o guide light from the optical emitter 102 towards the skin 130 of a subject and to direct light from the skin 130 to the optical detector 103." *Id.* ¶¶ 116, 118. In the embodiment shown in Figure 7, the emitter and sensor lenses 715 are physically separate. *Id.* ¶ 118. In such cases, Valencell-093 teaches that the lenses "may be isolated by at least one light opaque barrier region greater than 50 μm in thickness," which may be metal. *Id.* Filter 710 "may serve as both an optical wavelength filter and an attenuation filter" to block unwanted sunlight but still allow wavelengths from the optical emitter to be received at sensor 103 in the form of attenuated optical scatter 111. *Id.* ¶¶ 117, 123. "To offset this unwanted reduction in optical scatter 111, the intensity of the optical emitter 102 may be increased to increase the ratio of physiological optical scatter 111 from blood vessels with respect to unwanted sunlight." *Id*. ¶ 123. Because there may be environmental interference from, e.g., "sunlight, ambient light, airflow, [or] temperature" the monitoring apparatus of Valencell-093 may obtain an "optical interaction response" at the detector (sensor 103) when the pulsed optical energy 110 is produced, and a second response when the pulsed optical energy is in an off state. *Id*. ¶ 108. These two signals are used to remove the environmental interference and generate an accurate physiological signal. *Id*.

2. *Reason to Combine*

Petitioner notes that Lisogurski, Carlson, Tran, and Valencell-093 are analogous systems with common applications and utility. Pet. 74. Petitioner asserts that a person of ordinary skill would have been motivated to combine the teachings of Lisogurski with those of Valencell-093 because they both concern analogous miniaturized pulse oximetry devices having the same applications. *Id.* at 73. Petitioner notes that Lisogurski teaches several techniques for improving signal-to-noise ratio of measured signals in a wearable sensor, while minimizing power consumption. *Id.* (citing Ex.1011, 1:4–6, 1:16–18, 3:50–53, 4:15–20; 4:63–67, 9:46–52, 17:51–58). Petitioner further notes that Valencell-093 seeks to achieve similar objectives by configuring an optical sensor to maximize coupling and minimize relative motion between the user's skin and a wearable device, e.g., by using light guides positioned to focus on the blood flow and reduce the effect of environmental noise. *Id.* at 74 (citing Ex. 1005 ¶ 153).

Patent Owner does not respond explicitly to Petitioner's assertions concerning whether a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Valencell-093. Prelim. Resp. 18.

Based on the current record, we find that, for purposes of institution, Petitioner has demonstrated sufficiently that a person of ordinary skill would have had reason to combine the teachings of Lisogurski and Valencell-093.

3. *Claims 6, 14, and 23*

Claims 6, 14, and 23 depend from claims 5, 13, and 15, respectively, and recite "a reflective surface positioned to reflect at least a portion of [the lens output] light reflected from the tissue." Petitioner cites Valencell-093 as teaching that a sensor can be surrounded by a light guiding region to direct light to and from a sensor module and that the light guiding regions can include a reflector, such as a metal or alloy. Pet. 75–76 (citing Ex. 1005 ¶ 152, Figs. 24, 26, 27). As a further basis for combining the teachings of Valencell-093 with those of Lisogurski, Petitioner further notes that Valencell-093 explains that using such a reflective surface increases signal-to-noise ratio. *Id.* at 76 (citing Ex. 1005 ¶153).

Patent Owner does not respond to Petitioner's arguments concerning Valencell-093. Based on the current record, we find that, for purposes of institution, Petitioner has demonstrated that the combined teachings of Lisogurski, Carlson, Tran, Isaacson, and Valencell-093 would have disclosed the limitations of claim 6, 14, and 23 to a person of ordinary skill in the art.

X. CONCLUSION

For the reasons discussed above, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it will succeed on all of the following challenges to patentability:

Claims 1, 7, 15, and 17 as obvious under 35 U.S.C. § 103 over Lisogurski and Carlson;

Claims 1–4, 7–12, and 15–22 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, and Tran;

Claims 5 and 13 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, Tran, and Isaacson; and

Claims 6, 14, and 23 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, Tran, Isaacson, and Valencell-093.

XI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a) an *inter partes* review of the ’484 patent is hereby instituted, commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is authorized on all grounds set forth in the Petition, in particular:

Claims 1, 7, 15, and 17 as obvious under 35 U.S.C. § 103 over Lisogurski and Carlson;

Claims 1–4, 7–12, and 15–22 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, and Tran;

Claims 5 and 13 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, Tran, and Isaacson; and

Claims 6, 14, and 23 as obvious under 35 U.S.C. § 103 over Lisogurski, Carlson, Tran, Isaacson, and Valencell-093; and

FURTHER ORDERED that the trial will be conducted in accordance with a corresponding separately issued Scheduling Order.

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