Trials@uspto.gov
571-272-7822

Paper No. 54
Entered: June 1, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC. and FITBIT, INC.,
Petitioner,

v.

VALENCELL, INC.
Patent Owner.

IPR2017-00318[1]
Patent 8,886,269 B2

Before BRIAN J. McNAMARA, JAMES B. ARPIN, and SHEILA F. McSHANE, *Administrative Patent Judges.*

McSHANE, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] *Fitbit, Inc. v. Valencell, Inc.*, Case IPR2017-01554, has been joined with this proceeding.

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–10 ("the challenged claims") of U.S. Patent No. 8,886,269 B2 (Ex. 1001, "the '269 patent") pursuant to 35 U.S.C. §§ 311–319. Paper 2 ("Pet."). *Fitbit, Inc. v. Valencell, Inc.*, Case IPR2017-01554, has been joined with this proceeding. Paper 30, 5–6. Valencell, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review as to claims 1–10 of the '269 patent on June 5, 2017 on all of the asserted grounds, which are:

Ground	Claim(s)	Reference(s)
§ 103	1, 2, 6, 7	Asada[2]
§ 103	3	Asada and Hicks[3]
§ 103	4, 5	Asada and Hannula[4]
§ 103	8	Asada and Delonzor[5]
§ 103	9, 10	Asada and Al-Ali[6]
§ 103	1, 2	Goodman[7]

[2] H. Harry Asada, *Mobile Monitoring with Wearable Photoplethysmographic Biosensors*, IEEE ENGINEERING IN MEDICINE AND BIOLOGY MAGAZINE, 22:3, 28–40, May–June 2003 (Ex. 1005).

[3] U.S. Patent No. 6,745,061 B1 (issued June 1, 2004) (Ex. 1008).

[4] U.S. Patent No. 7,190,986 B1 (issued March 13, 2007) (Ex. 1009).

[5] U.S. Patent No. 5,797,841 (issued August 25, 1998) (Ex. 1010).

[6] U.S. Publication No. 2007/0123763 A1, published May 31, 2007 (Ex. 1011).

[7] U.S. Patent No. 4,830,014 (issued May 16, 1989) (Ex. 1007).

Ground	Claim(s)	Reference(s)
§ 103	3	Goodman and Hicks
§ 103	4	Goodman and Hannula
§ 103	5	Goodman, Hannula, and Asada
§ 103	6, 7	Goodman and Asada
§ 103	8	Goodman and Delonzor
§ 103	9, 10	Goodman and Al-Ali

Paper 7 ("Dec." or "Institution Decision"), 25–26.

During the course of trial, Patent Owner filed a Corrected Patent Owner Response (Paper 22, "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 32, "Pet. Reply"). Petitioner submitted the Declaration of Brian W. Anthony, Ph.D. (Ex. 1003) and the Declaration of Brian W. Anthony, Ph.D. in Support of Petitioner's Reply (Ex. 1102). Patent Owner submitted the Declaration of Albert H. Titus, Ph.D. (Ex. 2007).

Patent Owner filed a Motion for Observations on the cross-examination of Dr. Anthony (Paper 42), and Petitioner filed a response thereto (Paper 45). Petitioner filed a Motion to Exclude Evidence (Paper 44, "Mot. Ex."), with Patent Owner filing an Opposition the Motion to Exclude (Paper 47, "Mot. Ex. Opp."), and Petitioner filing a Reply thereto (Paper 48, "Mot. Ex. Reply"). In support of Patent Owner's Opposition to the Motion to Exclude, the Declaration of Alex Wong (Ex. 2154) and the Declaration of Nathan L. Levenson (Ex. 2155) were submitted.

In addition, Patent Owner filed a Motion to Amend (Paper 21, "Mot."), which was opposed by Petitioner (Paper 33, "Opp."). Patent Owner submitted a Reply in Support of its Motion to Amend (Paper 37, "PO

Reply"), and Petitioner filed a Sur-Reply supporting its Opposition (Paper 39, "Sur-Reply"). In support of the Motion to Amend, Patent Owner submitted the Declaration of Dr. Titus (Ex. 2110), as well as the Supplemental Declaration of Dr. Titus (Ex. 2151). Petitioner submitted the Declaration of Dr. Anthony in support of the Opposition (Ex. 1103).

We held a consolidated oral hearing on February 27, 2018, in relation to this proceeding and that in Case IPR2017-00317. A transcript (Paper 53, "Tr.") of the oral hearing has been entered into the record.

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–10 of the '269 patent are unpatentable. We deny Patent Owner's Motion to Amend. Additionally, we deny Petitioner's Motion to Exclude.

B. Related Proceedings

The parties indicate that the '269 patent is at issue in *Valencell, Inc. v. Apple Inc.*, Case No. 5:16-cv-00001 (E.D.N.C), and *Valencell, Inc. v. Fitbit, Inc.*, Case No. 5:16-cv-00002 (E.D.N.C). Pet. 3; Paper 5, 1. Patent Owner indicates the '269 patent is also at issue in *Valencell, Inc. v. Bragi Store, LLC*, Case No. 5:16-cv-00895 (E.D.N.C.). Paper 5, 1.

In addition to this Petition, Petitioner indicates that it filed other *inter partes* review petitions challenging claims of U.S. Patent No. 8,989,830 B2 (IPR2017-00316 (institution denied) and IPR2017-00317 (instituted)). Pet. 3. U.S. Patent No. 8,989,830 B2 is a continuation of the '269 patent. *Id*.

C. The ’269 Patent

The ’269 patent is entitled “Wearable Light-Guiding Bands For Physiological Monitoring” and issued on November 11, 2014, from an application filed on February 19, 2014. Ex. 1001, [22], [45], [54]. The ’269 patent claims priority to the following applications: (1) U.S. Patent Application No. 12/691,388, filed on January 21, 2010 (now U.S. Patent No. 8,700,111); (2) U.S. Provisional Patent Application No. 61/208,567, filed on February 25, 2009; (3) U.S. Provisional Patent Application No. 61/208,574, filed on February 25, 2009; (4) U.S. Provisional Patent Application No. 61/212,444, filed on April 13, 2009; and (5) U.S. Provisional Patent Application No. 61/274,191, filed on August 14, 2009. *Id*. at [63], [60].

The ’269 patent is directed to monitoring devices capable of encircling a portion of the body of a subject. Ex. 1001, Abstract. The monitoring devices may include physiological sensors to measure, for example, heart rate, pulse rate, breathing rate, and a variety of other physical parameters. *Id*. at 4:31–65. Monitoring devices may be configured to be attached to earlobes, fingers, toes, and other digits. *Id*. at 27:59–61. The ’269 patent discloses various embodiments of the monitoring devices, such as that depicted in Figures 22A and 22B, reproduced below.

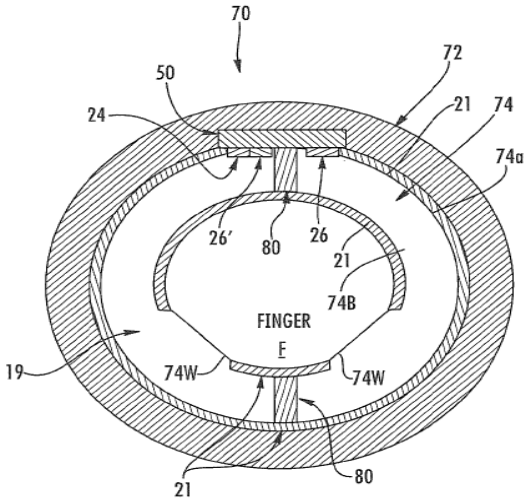


FIG. 22B

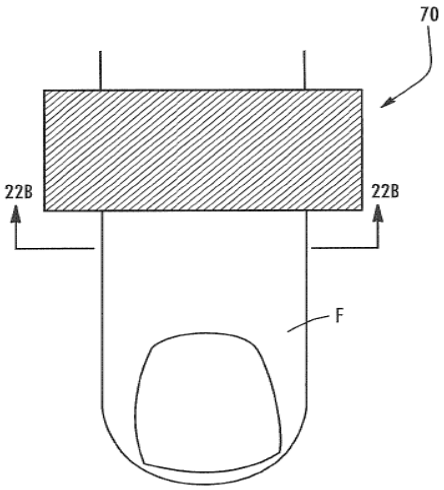


FIG. 22A

Figure 22A is a top plan of an embodiment of monitoring device configured to be attached to the finger of a subject, and Figure 22B is a cross-sectional view of the monitoring device. Ex. 1001, 8:13–17. Monitoring device 70 includes a generally circular band that may encircle finger F of a subject, and has cylindrical outer body portion 72 and generally cylindrical inner body portion 74 secured together. *Id*. at 27:61–28:1. Base 50 supports optical emitter 24, optical detector 26, and optical noise detector 26´. *Id*. at 28:15–17. Layer of cladding material 21 is applied to (or near) outer surface 74a of inner body portion 74, as well as inner surface 74b, to serve as a light guide to deliver light from optical emitter 24 to the finger and to collect light from the finger and deliver it to optical detectors 26, 26´. *Id*. at 28:26–34. "[W]indows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger." *Id*. at 28:40–42. Multiple emitters and/or detectors may assist in detecting motion artifacts. *Id*. at 28:62–29:11.

Claim 1 is the only independent claim at issue, and claims 2–10 depend directly or indirectly from claim 1. Claim 1, reproduced below, is illustrative of the challenged claims of the '269 patent.

> 1. A monitoring device, comprising:
>
> a band configured to at least partially encircle a portion of the body of a subject, the band comprising:
>
> a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship the inner body portion comprising light transmissive material, and having outer inner surface;
>
> a layer of cladding material near the inner body portion inner surface; and
>
> at least one window formed in the cladding material that serves as a light-guiding interface to the body of the subject; and
>
> at least one optical emitter and at least one optical detector attached to the band;
>
> wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector and is configured to deliver light from the at least one optical emitter to one or more locations of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

Ex. 1001, 30:30–53.

II. ANALYSIS

A. The Parties' Post-Institution Arguments

In our Decision on Institution, we concluded that the arguments and evidence advanced by Petitioner demonstrated a reasonable likelihood that claims 1–10 of the '269 patent are unpatentable under 35 U.S.C. § 103 over asserted prior art. Dec. 25–26. We now determine whether Petitioner has established by a preponderance of the evidence that claims 1–10 are

unpatentable under 35 U.S.C. § 103(a) over the cited prior art. 35 U.S.C. § 316(e). We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 8, 3; *see also* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted."); *In re Nuvasive, Inc.*, 842 F.3d 1376, 1379–82 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in Preliminary Response by not raising the same argument in the Patent Owner Response). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

With a complete record before us, we note that we have reviewed arguments and evidence advanced by Petitioner to support its unpatentability contentions where Patent Owner chose not to address certain limitations in its Patent Owner Response. In this regard, the record now contains persuasive arguments and evidence presented by Petitioner regarding the manner in which the asserted prior art teaches corresponding limitations of claims 1–10. Based on the preponderance of the evidence before us, we conclude that the art identified by Petitioner discloses, teaches, or suggests all of the limitations of the reviewed claims.

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we

give claim terms their ordinary and customary meaning, as they would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Three claim terms are identified and discussed by the parties: "cladding material," "light guiding interface," and "generally cylindrical." *See* Pet. 13–16, PO Resp. 21–26; Pet. Reply 3–8.

"cladding material"

In the Petition and in its Reply, Petitioner asserts that "cladding material" should be construed as "a material that blocks or reflects at least some light." Pet. 15; Pet. Reply 5. Petitioner refers to several portions of the Specification indicating that "cladding material" may be any kind of material such as "air, a polymer, plastic, or a soft material having a lower index of refraction than silicone" (Ex. 1001, 13:50–52), or could be a reflective material (*id*. at 16:65). Pet. 14–15 (citing also Ex. 1001, 16:66–17:1, 28:1–2, 28:26–29, 28:35–39, Figs. 22A, 22B; Ex. 1003 ¶¶ 52–53). Petitioner also asserts that Figure 3 of the '269 patent depicts two layers of cladding, and claim 1 requires only one layer of cladding material ("*a* layer of cladding"). Pet. Reply 4.

Patent Owner argues that "cladding material" should be construed as "a material that confines light within a region." PO Resp. 21. Patent Owner refers to the Specification's disclosure that "in the illustrated embodiment of FIG. 3 is defined by cladding material 21 that helps confine light within the light guiding region 19." *Id*. at 21–23 (quoting Ex. 1001, 14:58–61 (emphasis in Response), also citing *id.* at 16:14–22; 16:64–17:10; 18:44–46; 18:58–19:2; 28:26–39; 29:42–46, Figs. 3, 22B). Patent Owner argues that Petitioner's proposed construction deprives the term of its precise meaning.

PO Resp. 24. Patent Owner further asserts that the "one of ordinary skill would understand that the cladding material may consist of those otherwise transparent materials because total internal reflection can occur inside the silicone light-guiding area if the outer material has a lower index of refraction than the silicone," and, therefore, more than "some light" is being reflected. *Id*. (citing Ex. 1001, 13:22–26, 49–52; Ex. 2007 ¶¶ 82–86).

Although Patent Owner makes generalized assertions about cladding material in its arguments on the alleged obviousness of the'269 patent, Patent Owner does not make any specific arguments that the prior art asserted is deficient as to the teaching of cladding as used *per se* in the claims at issue. *See* PO Resp. 6, 49–53. As such, for the purposes of this proceeding, we determine that it is not necessary to provide an express interpretation of the term "cladding material." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

"*light-guiding interface*"

In the Petition, Petitioner did not provide a proposed construction for the term "light-guiding interface," except for the general application of broadest reasonable interpretation. Pet. 13–16. Within the Petition's mapping of the prior art to claim 1, however, Petitioner contends that Asada and Goodman's features include windows that serve as a "light-guiding interface." *See id*. at 32, 54.

Patent Owner alleges that the broadest reasonable interpretation of "light-guiding interface" is "an interface that delivers light along a path." PO Resp. 25. Patent Owner avers that its proposed construction is consistent

with the Specification that describes a light guide as delivering light along a path. *Id*. (citing, *inter alia*, Ex. 1001, 11:30–32, 14:18–23, 14:38–40, 16:21–22, 18:50–55, 19:54–55, 20:65–67; 28:26–34, 30:42–50). Patent Owner also refers to dictionary definitions. *Id*. Patent Owner argues that Petitioner's assertion that a construction that a light guiding interface would simply allow light to pass into something is broader than the plain and ordinary meaning. *Id.* at 26.

In its Reply, Petitioner refers to the '269 patent Specification that states "windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces," with window 74w shown, for example, in Figure 22B. Pet. Reply 6 (citing Ex. 1001, 28:40–42, 29:56–58). Petitioner also refers to Patent Owner expert's testimony, which generally states that a window does not change the direction of path of light. *Id*. at 6–7. Petitioner proposes that the term "light-guiding interface" be construed as "a window that allows the light to pass through the cladding material into the body." *Id*. at 8 (emphasis omitted).

Because we find that the claims at issue are rendered obvious even under Patent Owner's proposed construction of the term "light guiding interface," it is not necessary to provide an express interpretation of the term.

"generally cylindrical"

Petitioner asserts that under broadest reasonable construction, the term "generally cylindrical" should be interpreted as "having a convex shape." Pet. 13 (citing Ex. 1003 ¶ 50). Patent Owner contends that Petitioner's proposed construction is unreasonably broad, and the term should be

construed as "generally shaped like [a]cylinder," which is allegedly its plain and ordinary meaning. PO Resp. 26–27.

Although there is a difference in the parties' proposed constructions of the term "generally cylindrical," the parties do not identify or further argue any issues related to the claim term that require resolution. As such, for the purposes of this proceeding, we determine that it is not necessary to provide an express interpretation of the term "generally cylindrical."

C. Level of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art at the time of the '269 invention would have "had at least a four-year degree in electrical engineering, mechanical engineering, biomedical engineering, optical engineering, or related field of study, or equivalent experience, and at least two years' experience in academia or industry studying or developing physiological monitoring devices such as non-invasive optical biosensors." Pet. 12 (citing Ex. 1003 ¶¶ 25–26). Petitioner also asserts that a person of ordinary skill in the art would have also been familiar with optical system design and signal processing. *Id*. Patent Owner does not contest that assessment. PO Resp. 15.

We adopt and apply the level of ordinary skill in the art articulated by Petitioner to our obviousness analysis in this proceeding. In addition, we note that the prior art of record in this proceeding—namely, Goodman, Hicks, Hannula, Asada, Al-Ali, and Delonzor—is indicative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Asserted Obviousness of Claim 1 over Asada

In support of this asserted ground of unpatentability, Petitioner explains how Asada allegedly teaches the subject matter of claim 1. Pet. 29–34. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because Petitioner's ground rests upon faulty assumptions, and Asada fails to teach some of the claim limitations. *See* PO Resp. 27–36.

We find that Petitioner has demonstrated by a preponderance of the evidence that Asada teaches or suggests all of the limitations of claim 1 for the reasons discussed below.

We begin our analysis with a summary of Asada, and then address the arguments and evidence presented by the parties.

1. Asada (Ex. 1005)

Asada discloses "miniaturized data acquisition features with advanced photoplethysmographic (PPG) techniques to acquire data related to the patient's cardiovascular state." Ex. 1005, 28. For example, a ring configuration of the sensor may monitor a patient's heart rate, oxygen saturation, and heart rate variability, accounting for technical issues such as motion artifacts. *Id.* Asada describes a ring sensor prototype that includes an optical sensor unit with an LED and a photodetector; and an onboard microcomputer for data acquisition, signal processing, filtering, and bi-directional radio-frequency ("RF") communication. *Id.* at 30, 34. Asada's Figure 11 is reproduced below.

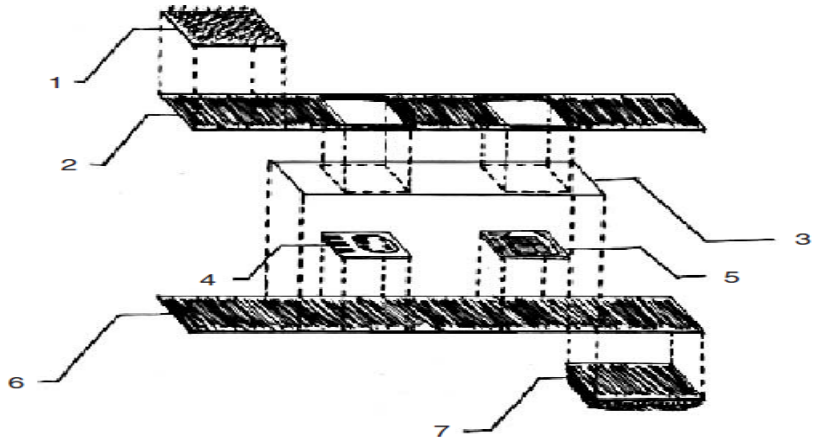


Figure 11 of Asada depicts a ring sensor band that protects optical components and hides wires from the outside environment. Ex. 1005, 35. The ring prototype configuration uses bands to hold the sensor unit and secure contact with the skin, as well as shield the unit. *Id*. at 34.

2. Analysis

To prevail on its challenges to the patentability of the claims, a petitioner must establish facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "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 the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) (discussing the burdens of persuasion and production in *inter partes* review).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that

the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). 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) when in evidence, objective evidence of nonobviousness.[8] *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966).

Petitioner asserts that claim 1 is unpatentable under 35 U.S.C. § 103(a) as obvious over Asada. Pet. 29–34; Pet. Reply 12–18.[9] Patent Owner disagrees with Petitioner's assertions. PO Resp. 27–36. The parties focus their arguments on: (1) whether the assertions made about Asada's components are faulty; (2) whether Asada teaches the limitation "the inner body portion comprising light transmissive material;" and (3) whether Asada teaches "deliver[ing] light" as the claim recites. *See id*. at 27–36; Pet. 29–34; Pet. Reply 12–17. We address the arguments regarding these disputed issues as to independent claim 1 in turn.

[8] Patent Owner does not present arguments or evidence of objective indicia of nonobviousness in its Patent Owner Response.

[9] Patent Owner asserts that portions of Petitioner's Reply are allegedly beyond the scope of what is considered appropriate for a reply. *See infra* Section III. As discussed below, however, we find that the disputed portions of Petitioner's Reply and associated evidence are within the scope of what is appropriate for a reply and may be considered. *See id.*

i. Alleged faulty assertions by Petitioner regarding Asada

Petitioner contends that Asada discloses a monitoring device as claimed, and refers to Figure 11 of Asada, as annotated by Petitioner, for correspondence of the claimed elements of claim 1 to Asada's structures. *See* Pet. 18–20. Annotated Figure 11 of Asada is reproduced below.

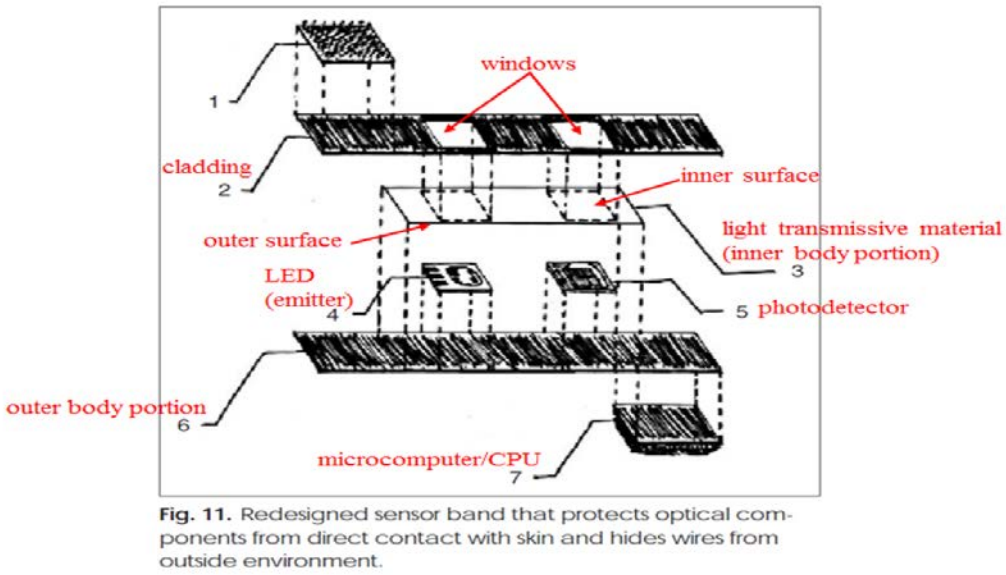


Fig. 11. Redesigned sensor band that protects optical components from direct contact with skin and hides wires from outside environment.

Figure 11 depicts a sensor band of Asada with Petitioner's annotations shown in red. Pet. 19. Dr. Anthony testifies that, although Asada does not correlate its descriptions with the reference numbers shown in Figure 11, this type of structure was known in the prior art. Ex. 1003 ¶ 61 (citing Ex. 1007, Fig. 2B; Ex. 1008, Fig. 6; Ex. 1009, Fig. 1B; Ex. 1011, Fig. 10; Ex. 1016, 3:42–46, Figs. 1A, 1B). Dr. Anthony alleges that one of ordinary skill in the art would have recognized the depicted elements and that the layered structure was known for decades. *Id*. Swedlow,[10] for example, describes a layered adhesive wrap for use around a finger, which discloses LEDs and photodetectors coupled to an outer bandage layer, coupled to a

[10] U.S. Patent No. 5,226,417 (issued July 13, 1993) (Ex. 1006).

clear polyethylene layer, with holes for receiving the optical elements. *See* Pet. 19–20 (citing Ex. 1003 ¶ 61; Ex. 1006, 5:43–49, 5:66–68, Fig. 2). Dr. Anthony asserts that a person of ordinary skill in the art would have understood that similar features logically would have been included in Asada's device. Ex. 1003 ¶ 61.

Petitioner's obviousness analysis, as supported by Dr. Anthony's Declaration, relies on testimony as to where each element of the challenged claims is taught in Asada. Pet. 29–38; Ex. 1003 ¶¶ 73–84. We agree with and adopt Petitioner's analysis and credit Dr. Anthony's testimony.

Patent Owner argues that "Asada never identifies or specifically discusses the enumerated components in Figure 11," and makes assumptions to "fit Asada to the claims." PO Resp. 28. Patent Owner avers that Petitioner did not have to make assumptions because Petitioner's expert, Dr. Anthony, knows Dr. Asada, and Dr. Anthony, or Petitioner's lawyers, could have asked Dr. Asada about the details of Figure 11. *Id*. at 29.

We do not find Patent Owner's argument on this issue persuasive. Dr. Anthony's testimony regarding the views of a person of ordinary skill in the art as to the structure in the Asada reference is supported by evidence that sensors with similar physical structures were known in the art. *See* Ex. 1007, Fig. 2B; Ex. 1008, Fig. 6; Ex. 1009, Fig. 1B; Ex. 1011, Fig. 10; Ex. 1016, 3:42–46, Figs. 1A, 1B; Ex. 1006, 5:43–49, 5:66–68, Fig. 2.

ii. "the inner body portion comprising light transmissive material"

Patent Owner asserts that, although Petitioner identifies element 3 in Figure 11 of Asada as "light transmissive material," there is nothing in Asada that identifies this element to be capable of transmitting light. PO Resp. 30–31. Patent Owner argues that, from the disclosure that "[t]he

sensor band was redesigned with the use of bio-compatible elastic materials to better hold the LED's and PD's, maintain a proper level of pressure, optically shield the sensor unit, and secure the contact with the skin consistently in the face of finger motion," a person of ordinary skill would understand that "element 3 is not light transmissive because it states that the materials used are designed to 'optically shield the sensor unit.'" *Id*. (citing Ex. 1005, 35; Ex. 2007 ¶ 100). Patent Owner also contends that the dotted lines in element 3 of Figure 11 of Asada are "apertures" to hold light emitter 4 and light detector 5 in place and would prevent detrimental "shunting," rather than providing a "light transmissive material." *Id*. at 31–33 (citing Ex. 2007 ¶¶ 102–104).

Some of Patent Owner's arguments presume that all of the components of Asada's sensor band have to be capable of "optically shield[ing]," without explaining why it should view Asada's description in that manner. *See* PO Resp. 30–31 (citing Ex. 1005, 35; Ex. 2007 ¶ 100). And Dr. Titus, Patent Owner's expert, provides testimony that this view is overly restrictive; Dr. Titus testified that all the materials of the sensor band "may not all have to do that," with "that" being to "better hold the LEDs and the PDs," "maintain[] proper level of pressure," [and] "optically shield the sensor unit." Ex. 1100, 98:12–99:5. Alternatively, Petitioner's assertion that element 3 of Asada is "light transmissive" so that "light can pass into and out of the finger" is supported by evidence within the context of Asada. *See* Pet. 31 (citing 1003 ¶ 77). As Dr. Anthony testifies, layer 3 is not shaded like layers 2 and 6, and the purpose of the device is to pass light into and out of the wearer's finger. Ex. 1003 ¶ 77. Further, Petitioner's view that the intent of the dotted lines in layer 3 is not intended to depict cut-outs or apertures has support because assuming cut-outs would be contrary to

Asada's explicit disclosure that the sensor band "protects optical components from direct contact with skin." *See* Pet. Reply 15 (citing Ex. 1005, 35 (caption of Fig. 11)).

Accordingly, we are persuaded that the evidence sufficiently supports the Petitioner's arguments for Asada's teaching of the claim limitation "the inner body portion comprising light transmissive material."

iii. "deliver[ing] light from the at least one optical emitter to one or more locations of the body"

Patent Owner disputes the teaching of the "deliver[ing] light" based on the arguments that no "light transmissive layer" is taught in Asada, as discussed above. PO Resp. 35. Patent Owner additionally argues that allowing light to be delivered to layer 3 would cause unwanted shunting between the light source and photodetector. *Id*. (citing Ex. 2007 ¶ 108).

As discussed above, the weight of the evidence supports that layer 3 is transparent and, as such, light would be "delivered" and "collected" from a finger as taught by Asada. Dr. Anthony's testifies that any possible shunting would be negligible (Ex. 1102 ¶ 24), and there is no evidence in the record that any possible shunting would be so significant that there would be no delivery or collection of light (*see* Ex. 2007 ¶¶ 102, 103, 108, 109).

Accordingly, we are persuaded that the evidence sufficiently supports the Petition regarding Asada's teaching of the claim limitation "deliver[ing] light."

In summary, for the reasons discussed above, we are persuaded Petitioner has shown by a preponderance of the evidence that claim 1 of the '269 patent is unpatentable as obvious over Asada.

E. Asserted Obviousness of Claims 2, 6, and 7 over Asada

For dependent claim 2, which additionally recites "the portion of the body comprises a limb, a nose, an earlobe, and/or a digit," Petitioner relies on Asada's disclosure of a finger sensor attachment for the teaching of the limitation because a finger is a digit. Pet. 34 (citing Ex. 1005 30, Figs. 5, 6, 9, 10). Patent Owner presents no additional arguments related to claim 2, and we agree with and adopt Petitioner's analysis and credit Dr. Anthony's supporting testimony.

For dependent claim 6, which recites "a signal processor configured to receive and process signals produced by the at least one optical detector," Petitioner asserts that a person of ordinary skill in the art "would have understood that the signals are produced by the photodetector and received by the microcomputer processing unit for signal processing." Pet. 35 (citing Ex. 1005, 34; Ex. 1003 ¶ 86). Dependent claim 7 recites "a transmitter configured to transmit signals processed by the signal processor to a remote device," and Petitioner includes references to Asada's teaching of an RF transmitter, as shown in Figures 9 and 10 of Prototype A. Pet. Reply 18 (citing Ex. 1005, 34). Patent Owner argues that, because Petitioner maps the components to the embodiment depicted in Figure 11 (Prototype B) that it should be limited to reliance on that embodiment of Asada. PO Resp. 37–39. Patent Owner also argues that, as to Petitioner's assertions as to claims 6 and 7, the ring sensor embodiments of Figures 9 and 10 of Asada were relied upon impermissibly. *Id*.

We are not persuaded by Patent Owner's argument because Dr. Anthony, Petitioner's expert, testifies that Prototype B of Figure 11 of Asada is a modified version of Prototype A shown in Figures 9 and 10, and a

person of ordinary skill in the art would have understood that Prototype B focuses on improvements and modifications to Prototype A. Pet. Reply 18 (citing Ex. 1102 ¶ 28). We agree with Petitioner that Asada discusses Prototype B relative to Prototype A, and also indicates that it is an improvement in some regards. *See* Ex. 1005, 35. As such, there is support for Dr. Anthony's testimony that one of skill would have understood that Prototype B includes a signal processor like earlier Prototype A, as well as including a transmitter. *See* Pet. 35–36; Ex. 1102 ¶ 28; Ex. 1005, 34–35. Moreover, Dr. Titus, Patent Owner's expert concurs that Prototype B is an improvement to Prototype A, and it is likely that Prototype B would also have a microprocessor. Ex. 1100, 119:12–18.

In summary, for the reasons discussed above, we are persuaded Petitioner has shown by a preponderance of the evidence that claim 2, 6, and 7 of the '269 patent are unpatentable as obvious over Asada.

F. Asserted Obviousness of Claim 3 over Asada and Hicks

In support of this asserted ground of unpatentability, Petitioner explains how the combination of Asada and Hicks allegedly teaches the subject matter of claim 3. Pet. 36–38. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because adding Hicks's lens to Asada would provide no discernable benefit, and one of ordinary skill in the art would have not been motivated to add Hicks's lens to Asada. *See* PO Resp. 40–44.

We have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments and evidence presented in the Patent Owner Response, Petitioner has demonstrated by a preponderance of the evidence that claim 3 is unpatentable as obvious over Asada and Hicks. We

begin our analysis with a summary of Hicks, and then address the arguments presented by the parties.

1. Hicks (Ex. 1008)

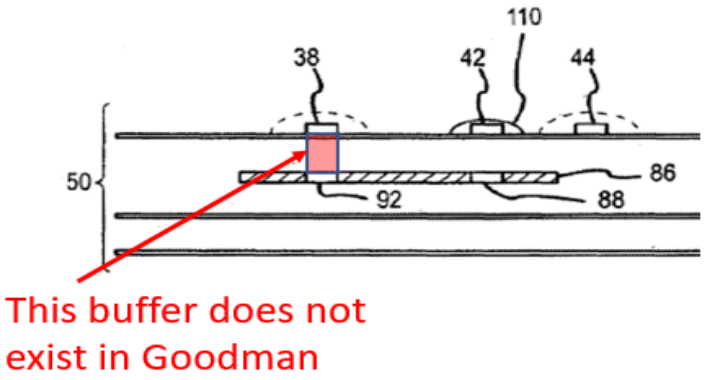
Hicks is directed to pulse oximetry sensors that may be used on fingers. Ex. 1008, 1:5–7, 8:3–8. Hicks discloses "a substantially clear flexible substrate that may be conformed about a portion of a patient's tissue, such as a finger . . . allowing for emitting and detecting light signals through this clear substrate," and "one or more LED's 40, 42 are disposed on a first surface of the finger and a photodetector 38 is disposed on an opposing surface of the finger." *Id*. at 2:4–10, 8:6–8. Hicks discloses "a compressible material layer may be disposed on the patient side surface" with "apertures aligned with each light emitter and/or light detector . . . allowing light to be emitted and/or detected through these apertures free from interference." *Id*. at 2:35–41. Hicks also discloses that a clear substrate can act partially as a lens with drops of clear adhesive used to provide some focusing function for the LEDs, or a lens, such as a frensel lens, may be formed integrally into the clear substrate to provide light focusing. *Id*. at 9:38–42, 13:42–48.

2. Analysis

Claim 3 recites the limitation of "a lens region in optical communication with the at least one optical emitter that focuses light emitted by the at least one optical emitter." Ex. 1001, 30:56–59. Petitioner alleges that Hicks teaches the use of a clear substrate that may act as a lens, or a separate lens structure that may be used in conjunction with the clear substrate. Pet. 38 (citing Ex. 1008, 9:38–40, 13:42–51). Petitioner contends that Asada and Hicks are directed to non-invasive optical biosensors and are

from the same field of endeavor. *Id*. at 36 (citing Ex. 1003 ¶ 88). Petitioner also alleges that including Hicks's lens structure with Asada's clear layer "would have simply been a combination of prior art elements according to known methods to yield predictable results," and would have improved the function of Asada's device. *Id*. at 37–38 (citing Ex. 1003 ¶ 90). As such, Petitioner avers that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Asada and Hicks. *Id*.

Patent Owner argues that there is no benefit to adding the lens of Hicks to Asada because Asada's device is already properly directed and focused. PO Resp. 40 (citing Ex. 1005, Fig. 2(b), Ex. 1008, 13:42–45; Ex. 2007 ¶ 120). Patent Owner asserts that one of ordinary skill in the art would have understood that a transmittal-type device like Asada benefits from having unfocused light (citing Ex. 1005, 31), and, therefore, would not have wanted to add a lens. *Id*. at 40–41. Patent Owner further asserts that adding Hicks's lens in Asada would cause problems as part of the modification. *Id*. at 41. Among the problems alleged is that the addition of Hicks's lens will make the skin "uncomfortably warm," increase the chances of focusing light to the wrong place in the body, and make the device more susceptible to disturbances. *Id*. at 41–43. Patent Owner additionally asserts that one of ordinary skill in the art would not have modified Asada to add Hicks's lens because Asada lacks Hicks's reason for having a lens. *Id*. at 43–44. Patent Owner argues that, because Hicks has a thermally insulative buffer, it needs a separate lens structure, and Asada (and Goodman) does not use an air pocket as a thermal buffer. *Id*. at 43–44. Patent Owner provides its own depiction, with an annotated version of Figure 6 of Hicks reproduced below.



Ex. 1008, Fig. 6 (excerpted and annotated); Ex. 2007 ¶ 128.

Patent Owner's annotations of Figure 6 of Hicks, depicted above, are disputed by Petitioner as a mischaracterization against combining Hicks with Goodman or Asada because Figure 6 is an "exploded cross sectional view," and the buffer as depicted in annotated Figure 6 of Hicks does not exist. Pet. Reply 19–20 (citing Ex. 1008, 8:34–35; Ex. 1100, 123:11–20, 126:2–24). Petitioner directs us to an unannotated version of Figure 6 of Hicks, reproduced below.

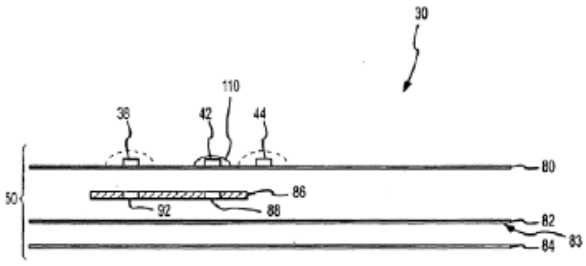


FIG.6

APL1008, Figure 6

Petitioner asserts that because, as assembled, foam layer 86 and clear substrate 80 of Figure 6 (the identification of which Patent Owner crops out of their annotated version), are in contact with each other, the red "buffer" depicted by Patent Owner does not exist. Pet. Reply 20 (citing Ex. 1008, 8:40–45; Ex. 1102 ¶ 32).

Petitioner's obviousness analysis, as supported by Dr. Anthony's Declaration, demonstrates where each limitation of challenged claim 3 is taught in Asada and Hicks. Pet.36–38; Ex. 1003 ¶¶ 88–90. We agree with and adopt Petitioner's analysis and Dr. Anthony's testimony.

In *KSR*, the U.S. Supreme Court stated "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 415. "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id*. at 417.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [inventor]." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). A reference does not teach away, however, if it merely expresses a general preference for an alternative configuration, but does not "criticize, discredit, or otherwise discourage" investigation into the invention claimed. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Petitioner provides a sufficiently persuasive rationale for combining the teachings of Asada and Hicks. For example, Dr. Anthony's testimony on the motivation of one of ordinary skill in the art to use Hicks's lens structure in conjunction with Asada's clear substrate is supported by the disclosures of the art. Hicks is a transmissive-type PPG (*see* Ex. 1008, 8:3–8), as is Asada's device, and Hicks's disclosure of "further enhanced sensor characteristics," states that a lens may be utilized in conjunction with clear substrate to "properly direct/focus the light emitted/received by the

emitters/detector" (*id*. at 13:39–47). Asada and Hicks's devices are similar and are directed to a similar use. Therefore, the record supports that a person of ordinary skill in the art would be motivated to seek this variation, as Petitioner contends.

Patent Owner's assertions of a teaching away do not rise to the level of discouraging one of skill in the art from considering the variation of Asada taught by Hicks. The reference to which Patent Owner points to argue that lenses should not be used states that the use of a transmittal-type PPG compared to reflective-type PPGs "allows us to use devices having a weak polarity, which is, in general, more robust against disturbances," which is a generalized statement discussing tradeoffs in design. PO Resp. 40 (citing Ex. 1005, 31). Patent Owner also admits that the annotated version of Hicks's Figure 6 in its Response, with its depiction of a buffer (PO Resp. 19), was "mislabeled" and "misidentified." *See* Tr. 32:8–10. We, therefore, disregard the argument related to the annotated figure, and we also disregard Patent Owner's attempted revision of the argument related to the buffer issue that was raised for the first time at oral hearing. *Id*. at 32:8–33:7; *see also, infra* Section III.

For the reasons discussed above, we are persuaded Petitioner has shown by a preponderance of the evidence that claim 3 is unpatentable as obvious over Asada and Hicks.

G. Asserted Obviousness of Claims 4 and 5 over Asada and Hannula

Petitioner contends that claims 4 and 5 would have been obvious over Asada and Hannula. Pet. 41–43. In its Response, Patent Owner contends that adding Hannula's reflective mask to Asada would not direct more light

to the photodetector and Petitioner picks and chooses among Asada's embodiments. PO Resp. 44–48.

We have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments and evidence presented in the Patent Owner Response, Petitioner has demonstrated by a preponderance of the evidence that claims 4 and 5 are unpatentable as obvious over Asada and Hannula. We begin our analysis with a summary of Hannula, and then address the arguments and issues presented by the parties.

1. Hannula (Ex. 1009)

Hannula discloses a non-invasive optical biosensor that uses LEDs to emit light into tissue and measures the light passing through the tissue using a photodetector. Ex. 1009, 1:6–16, 2:44–47. Figures 1B and 1C are reproduced below:

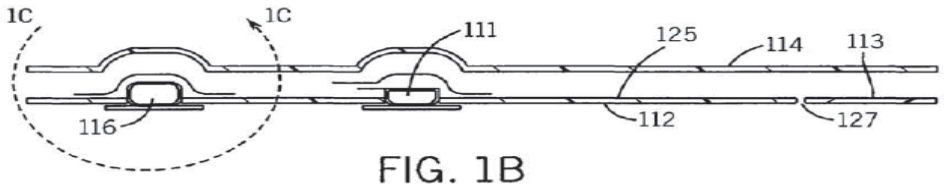


FIG. 1B

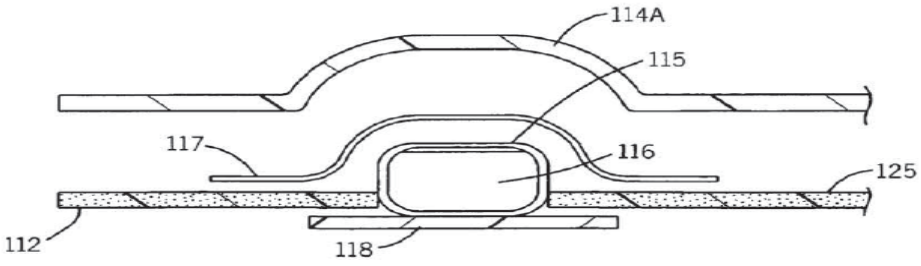


FIG. 1C

Figures 1B and 1C depict a cross-section and a detailed view, respectively, of an embodiment of the sensor. Ex. 1009, 2:26–29. As shown in Figures 1B and 1C, Hannula discloses components of the sensors such as LED 111,

photodetector 116, transparent window 118, and multiple laminated layers 112–114. *Id*. at 2:44–57, 3:9–13. Hannula also discloses that LED 111 and photodetector 116 may be surrounded by reflective mask 117, which may be made of polyester or polypropylene with a reflective metal surface. *Id*. at 2:58–59, 2:66–3:3, Figs. 1B, 1C. "Reflective mask 117 reflects light from LED 111 (that has passed through patient tissue and exited near the photodetector) back toward photodetector 116 like a mirror." *Id*. at 2:58-62. This increases the amount of LED light that the photodetector receives from the patient's tissue and also may assist in blocking ambient light and LED light that may shunt through the laminated layers. *Id*. at 2:63–66.

2. Analysis

Claims 4 and 5 recite the limitations of a "light reflective material" and "at least one optical detector comprises a first and second optical detectors, and further comprising a signal processor, and wherein a portion of light reflected by the light reflective material and detected by the second optical director is processed by the signal processor as a noise reference," respectively. Ex. 1001, 30:60–61, 30:63–31:1. Petitioner alleges that Asada teaches the need for reduction of noise, with multiple detectors for that purpose, as well as signal processing. Pet. 41–42. Hannula teaches the use of a light reflective material, and Petitioner contends that including Hannula's reflective mask in Asada is simply the combination of prior art elements according to known methods to yield predictable results. *Id*. at 39–40. Additionally, Petitioner alleges that modifying Asada with Hannula's teachings would improve Asada's function and reduce the amount of light that exits the body without reaching the photodetector. *Id*. at 40. As such,

Petitioner avers that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Asada and Hannula. *Id*. at 40, 43.

Patent Owner's argument that adding a reflective mask to Asada would not result in greater light reaching the photodetector is premised on its alleged interpretation of the configuration of Asada where layer 3 is alleged to have cut-outs or apertures so that "one layer [would be] directly on top of the other" when the components are secured together. *See* PO Resp. 45. However, as discussed, *supra* Section II.D.2, we are not persuaded by Patent Owner's argument because it is based on a configuration of Asada that we do not find to be supported by the evidence. Moreover, we do not find Patent Owner's contention that elements 4 and 5 would block any light that could be reflected to be persuasive because Hannula has a similar configuration and as explained by Petitioner's expert, functions to increase the amount of LED light that the photodetector receives. *See* Ex. 1009, 2:63–66; Ex. 1102 ¶ 42.

Additionally, Patent Owner argues that Petitioner impermissibly relies upon other embodiments of Asada for the teachings of claim 5, and one of ordinary skill in the art would not have been motivated to take Asada's device from Figure 11 and add it to a second photodetector and signal processor when the device was already producing a stable waveform. PO Resp. 47–48. As discussed, *supra* Section II.D.2, we have already addressed the issue of Petitioner's reliance on different embodiments of Asada, with teachings of signal processors. As to the issue of the addition of further noise attenuation, as the Petitioner indicates, Asada discloses that secondary noise attenuation was desirable. *See* Pet. 42–43; Ex. 1102 ¶ 43.

For the reasons discussed above, we are persuaded Petitioner has shown by a preponderance of the evidence that claims 4 and 5 are unpatentable as obvious over Asada and Hannula.

H. Asserted Obviousness of Claim 8 over Asada and Delonzor and Claims 9 and 10 over Asada and Al-Ali

Claim 8 recites a monitoring device wherein "at least one window comprises at least two windows," with "light blocking material positioned between the at least one optical emitter and the at least one optical detector such that" the emitter and detector are not in direct optical communication with each other. Ex. 1001, 31:10–16. Petitioner asserts that Asada and Delonzor are directed to optical biosensors. Pet. 43. Petitioner also asserts that Asada indicates the undesirability of a direct optical path between the LED and photodetector (Ex. 1005, 30), which would have led a person of ordinary skill in the art to Delonzor, which addresses the problem by the use of shunt barriers. *Id*. at 43–44 (citing Ex. 1003 ¶¶ 101, 102; Ex. 1010 1:6–9).

Claims 9 and 10 recite, respectively, that the band comprises at least one optical filter configured to selectively pass one optical wavelength, and that the wavelength is for transmission into the body of the subject. Ex. 1001, 31:17–23. Petitioner asserts that Asada and Al-Ali are directed to non-invasive optical biosensors and, thus, are from the same field of endeavor. Pet. 46. Petitioner also contends that Asada suggests that "the wavelength of the LED should be selected" based upon the LED and photodetector (Ex. 1005, 33), so a person of ordinary skill would have been led to Al-Ali and its teachings regarding optical filters. *Id*. at 46–47.

We have reviewed Petitioner's assertions of obviousness related to these claims 8–10 of the '269 patent and agree with Petitioner's analysis in

light of the supporting evidence. *See* Pet. 43–48. Patent Owner presents no additional arguments on these grounds in its Patent Owner Response, short of the arguments related to Ground 1, which are directed to claim 1, and we address *supra* Section II.D.2. PO Resp. 48.

Accordingly, we are persuaded Petitioner has shown by a preponderance of the evidence that claim 8 is unpatentable as obvious over Asada and Delonzor and claims 9 and 10 are unpatentable as obvious over Asada and Al-Ali.

I. Asserted Obviousness of Claims 1 and 2 over Goodman

In support of this asserted ground of unpatentability, Petitioner explains how Goodman allegedly teaches or suggests the subject matter of claims 1 and 2 of the '269 patent. Pet. 48–56. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because Goodman does not teach some of the limitations of claim 1. *See* PO Resp. 49–53.

We find that Petitioner has demonstrated by a preponderance of the evidence that Goodman teaches all of the limitations of claims 1 and 2 for the reasons discussed below.

We begin our analysis with a summary of Goodman, and then address the arguments and evidence presented by the parties.

1. Goodman (Ex. 1007)

Goodman generally discloses an optical biosensor that measures arterial oxygen saturation. Ex. 1007, 1:11–14. The sensors can be configured for use with fingertips, toes, hands, or feet, as well as on the skin of the nasal septum overlying the carotid cavity. *Id*. at 9:65–68, 10:7–9.

Figure 4, reproduced below, is a depiction of a sensor fastened over a fingertip.

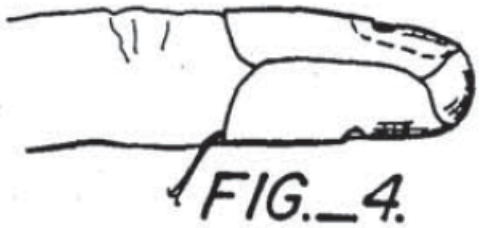


Figure 4 depicts a digit with the distal ends of the sensor fastened over the fingertip. Ex. 1007, 8:27–28, 9:60–61.

Goodman discloses an embodiment with a sensor that uses a flexible adhesive strip, depicted in Figure 2C and reproduced below.

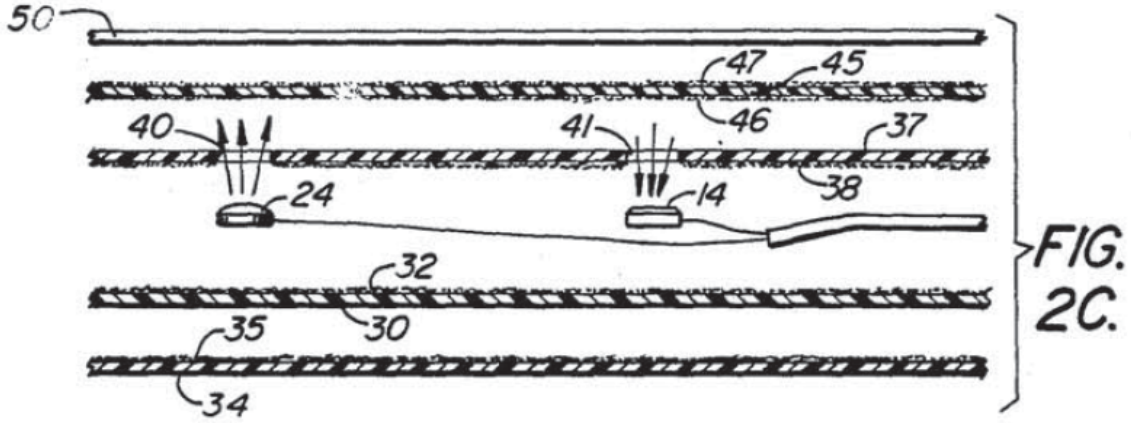


Figure 2C is an exploded view of an embodiment of a sensor with identification of individual elements. Ex. 1007, 8:15–18. In the depicted embodiment, the photo-active elements of the sensor substrate, that is, element 24 which has a light source mounted to it, and element 14, which has a photo-sensor mounted to it, are fastened to opaque vinyl strip 10. *Id*. at 8:50–52, 9:19–22. Second opaque tape, with strip 37 and adhesive layer 38, is placed over the photo-active elements with apertures 40 and 41 in strip 37. *Id*. at 9:32–37. Layer of clear polyester 45 is placed over the length of

the flexible adhesive strip, and a protective layer of release tape 50 that is in place during manufacture and before use. *Id*. at 9:45–52.

2. Analysis

Petitioner asserts that claims 1 and 2 are unpatentable under 35 U.S.C. § 103 as obvious over Goodman. Pet. 48–56; Pet. Reply 8–12. Patent Owner disagrees with Petitioner's assertions. PO Resp. 49–53. The parties focus their arguments on whether Goodman teaches a window that serves "as a light-guiding interface" under the limitations of claim 1. *See id*. at 49–53; Pet. 54; Pet. Reply 8–12. As to the other limitations of the challenged claim 2 under this ground, Patent Owner presents no additional issues, including as to whether or not Goodman discloses or suggests one or more of those limitations, and we have reviewed the evidence and arguments presented in the Petition and find that Petitioner has shown sufficiently that those other elements are disclosed as arranged in the claims 1 and 2. *See* PO Resp. 49–53; Pet. 56.

Petitioner contends that Goodman teaches or suggests a monitoring device, as claimed, and refers to Figure 2C of Goodman, as annotated by Petitioner, to show the correspondence of the recited limitations to Goodman's structures. *See* Pet. 23. Annotated Figure 2C of Goodman is reproduced below.

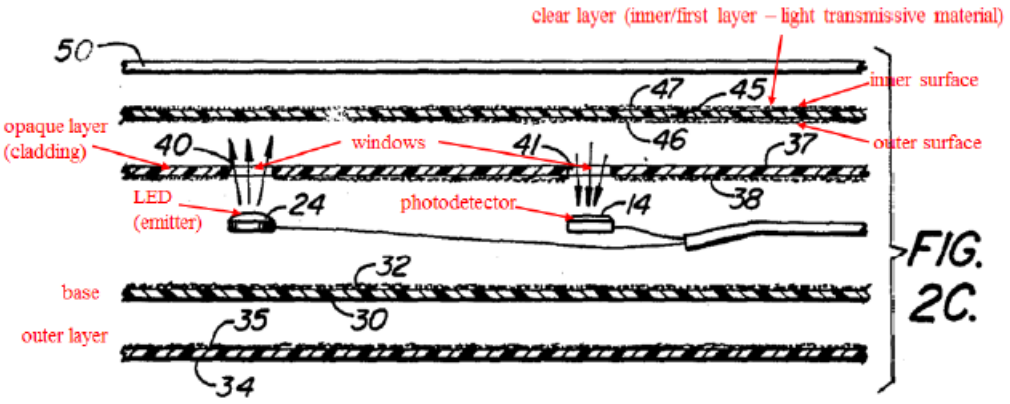


Figure 2C is a view of an embodiment of a sensor of Goodman with Petitioner's annotations shown in red. Pet. 16. As depicted, Petitioner asserts that the "cladding" limitation of claim 1 is taught by opaque layer 40 of Goodman, the "outer" and "inner" layers are part of clear polyester layer 45, and the "optical emitter" and "optical detector" are taught by Goodman's light-emitting diodes ("LEDs") 24 and photodetector 14. *Id*. at 50–54. Petitioner relies upon Goodman's disclosure that its "opaque tape layer (37) 'is apertured at respective apertures 40, 41 . . . [t]hese apertures allow light to pass,'" for the teaching of the claim limitation that "at least one window [is] formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject." *Id*. at 54 (citing Ex. 1007, 9:39–40, Figs. 2B, 2C).

Petitioner's obviousness analysis, as supported by Dr. Anthony's Declaration, demonstrates where each element of the challenged claims is taught in Goodman. Pet.48–56; Ex. 1003 ¶¶ 110–125. We agree with and adopt Petitioner's analysis and Dr. Anthony's testimony.

Patent Owner argues that apertures 40 and 41 do not "serve as light-guiding interfaces to the body" because, under the depiction of assembled sensor of Figure 2C that Patent Owner developed, and which is reproduced

below, the apertures in Goodman do not serve any purpose in guiding light to the body. PO Resp. 50–51.

In the above-annotated Patent Owner depiction, which is allegedly excerpted and modified by Patent Owner in accordance with the assembly description in the '269 patent, Patent Owner relies, in part, on Goodman's description. PO Resp. 50–51 (citing Ex. 1007, 9:43–45 ("Strip 37 is apertured at respective apertures 40, 41. These apertures allow light to pass. At the same time, they conform the thickness of the photo-active substrates to the overall thickness of the flexible adhesive strip to which attachment occurs.") (Emphasis in PO Resp.)). Patent Owner contends, based upon testimony provided by Dr. Titus, that:

> [b]ecause the apertures 40 and 41 conform photoactive substrates 14 and 24 to the overall thickness of the flexible adhesive strip, one of ordinary skill in the art would understand that the apertures do not serve any purpose in guiding light to the body. In that situation, light from the light source never interacts with the aperture itself, meaning that the apertures cannot deliver any light to the body.

PO Resp. 51 (quoting Ex. 2007 ¶ 145).

Patent Owner further alleges that "Goodman's device is designed to have cutaneous conformance, meaning that it is intended to be pressed against the skin without any light-guiding interface between the light source and the body." PO Resp. 51–52 (citing Ex. 1007, 1:11–12, 4:64–66, 5:41–44, 7:13–18; Ex. 2007 ¶ 146). Patent Owner avers that "[b]ecause the device of Goodman cutaneously conforms to the body, the apertures allow

light to pass through the body, but they do not also deliver light to the body (guide light)." *Id*. at 51–52 (emphasis in original) (citing Ex. 1007, 4:50–52; Ex. 2007 ¶ 147).

We agree with the Petitioner that the Patent Owner's modified depiction does not depict accurately the Goodman Figure 2C device cross-section when assembled. *See* Pet. Reply 10. Petitioner points out that the Patent Owner's depicted assembly shows light source 24 and photo-sensor 14 extending beyond the apertures. *Id*. Petitioner asserts that Patent Owner's version of the assembly fails to include clear polyester layer 45 and release tape 50. *Id*. As such, Dr. Anthony testifies that a person of ordinary skill would have understood that the light source does not extend all the way through the aperture and would not do so when attached to the body. Ex. 1102 ¶ 15.

We find that the weight of the evidence supports that light source 24 and photo-sensor 14 of Goodman could not extend above the sensor assembly as Patent Owner depicts. Referring to Figure 2C, even if release tape 50 is removed before use (Ex. 1007, 9:45–52), clear polyester layer 45 would be present in the assembled sensor, which Patent Owner ignores in its depiction of an assembly.[11] Given the location of clear polyester layer 45, the evidence supports that it would impede the light source 24 and photo-sensor 14 from extending through the apertures.

[11] At oral hearing, Patent Owner was asked about its omission of clear polyester layer 45 in the depiction that Patent Owner itself developed and presented. Tr. 38:12–22. Although Patent Owner identified additional layers that were not shown, there was no explanation for the omission. *Id*. Upon further inquiry, directed to the absence of an indentation in clear polyester layer 45 in Figure 2C, Patent Owner stated that the clear polyester layer 45 would rest on top of the photodiodes. *Id*. at 39:3–14. We find the positions presented by Patent Owner are inconsistent.

Petitioner contends that, even under Patent Owner's proposed claim construction of "light-guiding interface," Goodman teaches the claim limitation, "window formed in the cladding material that serves as a light-guiding interface to the body of the subject." Pet. Reply 11–12 *see also* Pet. 52–53. The Petition refers to Goodman's disclosure that opaque tape layer 37 "is apertured at respective apertures 40, 41. These apertures allow light to pass." Pet. 52 (citing Ex. 1007, 9:39–40, Figs. 2B, 2C). Petitioner argues that in Goodman, light source 24 does not extend entirely through aperture 49 and there is space between the emitting surface of the light source and the end of the aperture, and the light interacts with the aperture itself. Pet. Reply 11 (citing Ex. 1102 ¶ 17). Petitioner also asserts that "Goodman's apertures function the same as the windows [in] the '269 Patent—they allow light to pass through." *Id*. at 12 (citing Ex. 1102 ¶ 18; Ex. 1100, 88:2–11, 94:23–95:5, 179:4–12, 186:16–187:7).

We are persuaded that the preponderance of the evidence supports that Goodman teaches the claim limitation of "window formed in cladding material that serves as a light-guiding interface to the body of the subject," even under Patent Owner's proposed construction of a "light guiding interface" as "an interface that delivers light along a path." Under Goodman, the apertures are described as allowing "*light* to pass"—not, instead, that the light source element completely "passes" through the aperture. *See* Ex. 1001, 9:39–40. This is further supported by the depiction in Figure 2C of Goodman. Dr. Anthony testifies that "[a]s specified by the arrows in Figure 2C . . . , the light from the *light* source (24) passes *through the aperture* (40) . . . [l]ikewise, arrows also show that light returns through aperture (41) to the photo-sensor (14)." Ex. 1102 ¶ 13. Moreover, Goodman discloses that its apertures "conform the thickness of the photo-

active substrates to the overall thickness of the flexible adhesive strip," and that the substrates are "captured" to be tactilely indistinguishable from the flexible adhesive strip. *See* Ex. 1007, 9:39–45. Goodman's "capture" of photoactive substrates within the flexible adhesive strip would not require strict "conform[ance]," such that the photoactive substrates extend all the way through and beyond the aperture, as Patent Owner argues. As discussed above, extension beyond the apertures would be impeded under Goodman's structure, nor is full extension through the strip necessary to accomplish a "capture" of the photoactive substrates in the apertures for the purposes of tactile indistinguishability. *See* Ex. 1102 ¶ 15.

Accordingly, we determine that the evidence sufficiently supports the Petition regarding Goodman's teaching of the claim limitation "at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject," even under Patent Owner's proposed construction of "light-guiding interface."

In summary, for the reasons discussed above, we are persuaded Petitioner has shown by a preponderance of the evidence that claims 1 and 2 of the '269 patent are unpatentable as obvious over Goodman.

J. Asserted Obviousness of Claims 3–10 over Goodman and Other Prior Art

In support of its obviousness grounds, Petitioner provides argument and evidence that claim 3 is taught by the combination of Goodman and Hicks; claim 4 is taught by the combination of Goodman and Hannula; claim 5 is taught by the combination of Goodman, Hannula, and Asada; claims 6 and 7 are taught by the combination of Goodman and Asada; claim 8 is taught by the combination of Goodman and Delonzor; and claims 9 and 10 are taught by the combination of Goodman and Al-Ali. Pet. 56–73.

In its Response, Patent Owner contends that one of ordinary skill in the art would not be motivated to combine the asserted prior art in the manner asserted by Petitioner. *See* PO Resp. 53–72.

We find that Petitioner has demonstrated by a preponderance of the evidence that the teachings of Goodman in combination with those of other prior art teach all of the limitations of claims 3–10 and there is sufficient rationale for one of skill in the art would to combine the references. Issues specific to the dependent claims are discussed below.

1. Claim 3

Petitioner contends that claim 3 would have been obvious over Goodman and Hicks. Pet. 56–58. In its Response, Patent Owner contends that one of skill in the art would have not been motivated to add Hicks's lens to Goodman because it provides no discernable benefit, and the addition of Hicks's lens would make the skin "uncomfortably warm," increases the chances of focusing light to the wrong place in the body, increase cost and decrease disposability, and makes the device more susceptible to disturbances. PO Resp. 53–56.

The majority of Patent Owner's arguments are common to those asserted for the combination of Asada and Hicks, and we do not find them persuasive for the reasons discussed, supra Section II.F.2. Additionally, we do not find that other of Patent Owner's assertions concerning teaching away rise to the level of discouraging one of skill in the art from considering the variation of Goodman taught by Hicks. Patent Owner overstates some of the alleged disadvantages of the use of a lens. For example, we credit Dr. Anthony's testimony that the cost of lenses would be low, and the type

of lenses disclosed in Hicks, that is, Fresnel lenses, can be thin and would have minimal effect on conformance. Ex. 1102 ¶ 38.

Accordingly, we have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments and evidence presented in the Patent Owner Response, we are persuaded Petitioner has demonstrated by a preponderance of the evidence that claim 3 is unpatentable as obvious over Goodman and Hicks.

2. Claim 4

Petitioner contends that claim 4 would have been obvious over Goodman and Hannula. Pet. 59–61. Petitioner asserts that Hannula teaches the use of a light reflective material, and a person of ordinary skill in the art would have had reason to modify Goodman's teachings, which concern poor signal pick-up during periods of low blood flow, in view of Hannula's teachings to increase signal pick-up by increasing the amount of LED light that the photodetector receives from the patient's tissue. *Id*. at 59–60. In its Response, Patent Owner contends that one of skill in the art would have not been motivated to combine also argues that one of ordinary skill in the art would not have been motivated to combine Goodman with Hannula because the references encourage the use of different methods of attachment—in Goodman, adhesive is used, and in Hannula, hook-and-loop layers (Velcro) is used. PO Resp. 57–59. Patent Owner contends that Petitioner's basis for combining Goodman and Hannula is faulty because under Goodman's teachings there should be no concern about poor signal pick-up during periods of low blood flow. *Id*. at 54–55 (citing Ex. 1007, 6:51–63; Ex. 2007 ¶ 166). Patent Owner also alleges that adding Hannula's reflective mask to

Goodman would serve to increase the chances of impeding blood flow, which is contrary to Goodman's purpose. *Id*. at 60.

Dr. Anthony's testimony that one of ordinary skill in the art would have sought to combine Goodman and Hannula is supported by the evidence; each of the references is directed to non-invasive optical biosensors and Petitioner's rationale to combine provided by the Petitioner identifies the alleged improvements with specificity, as well as why one of skill in the art would have sought to make those improvements, and finally identifies that the improvements would perform predictably in combination. See Pet. 59–61; *KSR*, 550 U.S. at 421 (A rationale for a claim to be obvious is when "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense.") We do not discern that the variations in the specific uses of Goodman and Hannula would serve to dissuade or deter one of skill in the art from the combination in light of the common features of the sensors and the identified improvements.

For the combination of Hannula with Goodman, we do not agree that any of the issues alleged by Patent Owner rise to the level of teaching away. For instance, the evidence supports Petitioner's view that Patent Owner's allegation that one of ordinary skill in the art would not be motivated to modify poor signal pick-up focuses on a nose embodiment in Goodman—however, in fingers and other extremities, blood flow would be reduced and, therefore, increases in signal pick-up would be an issue that one of ordinary skill would want to address by the modification taught by Hannula. *See* Pet. Reply 24 (citing PO Resp. 60; Ex. 1007, Figs. 6A, 6B; Ex. 1102 ¶ 40; Ex. 1101, 84:17–21). We also credit Dr. Anthony's testimony that

Hannula's reflective mask is thin and flexible and would have a negligible effect on the forces applied to the skin. *See* Ex. 1102 ¶ 41. Additionally, we do not find that alternative type of attachments—that is, adhesive in Goodman compared to Velcro in Hannula, which Patent Owner argues is a teaching away—is relevant to the issue of whether one of ordinary skill in the art would have looked to Hannula and its light reflective material to improve signal pick-up. *See* Pet. 59–61.

Accordingly, we have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments and evidence presented in the Patent Owner Response, we are persuaded Petitioner has demonstrated by a preponderance of the evidence that claim 4 is unpatentable as obvious over Goodman and Hannula.

3. Claims 5, 6, and 7

Petitioner contends that claim 5 would have been obvious over Goodman, Hannula, and Asada, and claims 6 and 7 would have been obvious over Goodman and Asada. Pet. 61–67. Petitioner contends that Asada is from the same field of endeavor as Goodman. *Id*. at 61. It is alleged that Goodman discloses that "motion artifacts" are a common problem, and this concern would have led a person of ordinary skill in the art to Asada, which discloses "measure[ing] the finger motion with another sensor or a second PD and us[ing] it as a noise reference for verifying the signal as well as for canceling the disturbance and noise." *Id*. at 61–62 (citing Ex. 1003 ¶ 136–137; Ex. 1005, 30; also citing Ex. 1005, 32–33). Petitioner refers to Asada's on-board signal processor, and alleges that, because Goodman discloses that "long term, uninterrupted measurement" is desirable, a person of ordinary skill in the art would have had reason to make

Goodman's system wireless, like the Asada system. *Id*. at 65 (citing Ex. 1007, 2:33–35; Ex. 1003 ¶¶ 37–38, 143). Dr. Anthony testifies that, although Asada's device appears bulky (see Ex. 1005, Fig. 9), it is small in volume and mass, and one of ordinary skill in the art would have understood that the device would have even less volume and mass when transitioned to bulk manufacturing. Ex. 1003 ¶ 136. Additionally, Dr. Anthony opines that the combination of the teachings of Asada with Goodman's teachings would yield predictable results, improve the function of Goodman's similar device, and would introduce desirable redundancy. *Id*. ¶ 138. As such, Petitioner avers that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Goodman and Asada. Pet. 61–62, 65.

Patent Owner argues that, when Goodman and Asada are viewed as a whole, one of ordinary skill in the art would not have had reason to combine their teachings. PO Resp. 62–64. For instance, Patent Owner argues that Goodman is a wired-device for continuous monitoring in a hospital and satisfies a need to provide information critical to patient treatment even under dire conditions, whereas Asada is a wearable, wireless device for every-day use. *Id*. at 62–63. Patent Owner alleges that because Asada is a wireless device, it is concerned about power consumption and battery-life, where Goodman is tethered, so there are no similar concerns. *Id*. at 63. Patent Owner argues that Asada and Goodman take different approaches to addressing motion artifacts—Goodman eliminates motion artifacts by its low-mass and conformance with the skin, whereas Asada reduces motion artifacts via a second photodetector to filter noise. *Id*. at 63–64 (citing Ex. 2007 ¶ 174). Patent Owner argues that one of ordinary skill in the art would not have combined Goodman and Asada because they are "very different devices." *Id*. at 64. Patent Owner further asserts that adding a processor,

second optical detector, and reflective mask layer to Goodman would add mass, no longer make it "entirely disposable," inhibit its conformance to the skin, and add unwanted pressure to the skin. *Id*. at 66–69.

Patent Owner also argues that Petitioner's premise for combining Goodman and Asada is faulty. PO Resp. 64–65. Patent Owner alleges that a person of ordinary skill in the art would not have been led to Asada because Goodman is described to have eliminated motion artifacts. *Id*. at 64 (citing Ex. 1007, 5:41–44 ("The disclosed adhesive fastening conforms the elements of the apparatus so completely to the patient's skin that motion artifact is eliminated"); Ex. 2007 ¶ 176). Patent Owner, therefore, argues that there would have been no perceived need to seek out Asada for motion reduction. *Id*. at 65. It is alleged that one of ordinary skill in the art "would have seen Asada as a potential source of motion artifacts, working against Goodman's invention that eliminated it." *Id*. (citing Ex. 2007 ¶ 177). More specifically, Patent Owner contends that one of ordinary skill would have viewed Asada's ring-type device as the kind that has appreciable mass and a high-aspect ratio that would increase motion artifacts. *Id*. (citing Ex. 1007, 2:54–60). Patent Owner also argues that Petitioner's alleged motivation to seek wireless capabilities in light of Goodman's goal of "long term, uninterrupted measurement" that "would have been more easily achieved with a wireless device [like Asada] when that technology became available" is flawed. *Id*. at 69–71. Patent Owner contends that one of skill in the art would have recognized that "a wireless device comes with the risk of unreliability and interrupted monitoring," which should be avoided in light of Goodman's service with intensive care patients. *Id*. at 69 (citing Ex. 2007 ¶ 186).

Moreover, Dr. Anthony's opinion that one of ordinary skill in the art would have sought to combine Goodman and Asada is supported by the evidence; each of the references is directed to non-invasive optical biosensors and Petitioner's rationale to combine identifies the alleged improvements with specificity, as well as why one of skill in the art would have sought to make those improvements, and identifies that the improvements would perform predictably in combination. *See* Pet. 61 –67. We do not discern that the variations in the specific uses of the prior art references would serve to dissuade or deter one of skill in the art from the combination in light of the common features of the sensors and the identified improvements. Although Patent Owner argues that Asada's every-day use should be distinguished from Goodman's use in patient treatment, Asada also discloses the utility of wearable sensors "[f]or hospital inpatients who require cardiovascular [CV] monitoring, current biosensor technology typically tethers patients in a tangle of cables, whereas wearable CV sensors could increase inpatient comfort . . . and may even reduce the risk of tripping and falling," and, additionally, prototypes of Asada's sensor were tested at Massachusetts General Hospital. Tr. 54–55 (referring to Ex. 1005, 28, 35). Thus, we do not find Patent Owner's arguments regarding insufficient support for the rationale to combine Goodman and Asada overcomes Petitioner's arguments and evidence of a rationale to combine.

Turning to the alleged faulty premise for the combination of Goodman and Asada, we do not discern any of the issues alleged by Patent Owner rises to the level of teaching away. For instance, Patent Owner argues that one of skill art would not have been led to Asada because Goodman is described to have eliminated motion artifacts fails to fully consider the evidence. Goodman discloses that with adhesive conforming an apparatus to the skin

motion artifact is eliminated (Ex. 1007, 5:41–44), however, Petitioner asserts that there can be different sources of motion artifacts that arise (*see* Ex. 1003 ¶ 35; Ex. 1102 ¶ 38), and motion artifacts include those due to inertia that cannot be eliminated by reducing motion of the device relative to the skin. Pet. Reply 27 (citing Ex. 1006, 2:17–27; Ex. 1102 ¶ 45). Patent Owner's expert, Dr. Titus, acknowledges that there are more sources of motion artifacts in sensors other than those due to motion of the device in relation to the skin.[12] At the oral hearing, Patent Owner continued with the argument that Goodman eliminates all motion artifacts, but added that even if inertial motion artifacts were considered, they would not be of concern in Goodman due to its use with intensive care unit ("ICU") patients.[13] *See* Tr. 24–25.

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[12] Patent Owner's expert, Dr. Titus, testified at deposition:

> Q (BY MR. SPECHT) Do you know what causes motion artifacts?
> A Yes, various -- various sources, yes.
> Q So what are the sources of motion artifacts?
> A It could be because of the -- primarily because of the motion of the sensor as it's applied to the skin so that it's -- it moves around as it's sitting on the skin.
> Q Are there other sources of motion artifacts?
> A I think that that's what those are -- I think that's the -- the primary -- I think that's the primary source of the -- of the motion artifacts.
> * * *
> Q So you say one of the most common sources. What are the other sources?
> A I'm not sure that I can state all of what the possible sources are. So potentially there's other motion such as walking and running, potentially.
> Q So that would be motion of the body part itself, correct?
> A Yes.

Ex. 1100, 137:14–138:12; *see also id.* at 138:13–139:7.

[13] Patent Owner argued at oral hearing: "Then they [Petitioner] say that you might have motion artifacts due to inertial movement. But they forget that

Considering the evidence, we are persuaded that Petitioner's stated rationale to modify Goodman with Asada's additional motion artifact reduction is supported by the evidence. Goodman discloses motion artifact elimination by skin conformance, but it is undisputed that there can be other types of motion artifacts that may occur besides those due to the motion of the device relative to the skin. The need to address different sources of motion artifacts supports Petitioner's rationale to combine.

Additionally, Petitioner's expert, Dr. Anthony, testifies that design tradeoffs should be recognized, and he was aware of and took into consideration the alleged deficiencies of a combination in his analysis, and confirmed that one of ordinary skill in the art would have sought to combine Goodman and Asada. *See* Ex. 1003 ¶¶ 37–38; Ex. 1102 ¶ 46; Ex. 2010, 202:9–203:14. In considering the evidence, we do not find that the alleged disadvantages rise to the level of deterring the combination in light of evidence indicating the art was weighed as a whole, with the advantages and disadvantages considered. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another."). Thus, Patent Owner's arguments that one of skill would not have looked to Asada due to alleged issues of increased mass and motion artifacts, reduced disposability, reduced skin conformance, and

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Goodman is designed for use with an ICU patient. There's not a lot of movement, not a lot of jogging going on in that intensive care hospital bed." Tr. 25:3–6.

wireless unreliability does not overcome Petitioner's persuasive arguments and evidence to the contrary.

Accordingly, we have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments and evidence presented in the Patent Owner Response, we are persuaded Petitioner has demonstrated by a preponderance of the evidence that claim 5 is unpatentable as obvious over Goodman, Hannula, and Asada, and claims 6 and 7 are unpatentable as obvious over Goodman and Asada.

4. Claims 8, 9, and 10

We have reviewed Petitioner's assertions of obviousness under Goodman and other prior art related to claims 8–10 of the '269 patent and agree with the Petition's analysis in light of the supporting evidence. *See* Pet. 68–73. Patent Owner presents no additional arguments on these grounds in its Response, short of the arguments related to Ground 6, which are directed to claim 1, and we address *supra* Section II.I.2. PO Resp. 72.

Accordingly, we are persuaded Petitioner has shown by a preponderance of the evidence that claim 8 is unpatentable as obvious over Goodman and Delonzor and claims 9 and 10 are unpatentable as obvious over Goodman and Al-Ali.

III. ALLEGED IMPERMISSIBLE NEW ARGUMENTS IN PETITIONER REPLY AND AT ORAL HEARING

Patent Owner argues that Petitioner asserted new arguments in Petitioner's Reply that are allegedly beyond the scope of what can be considered appropriate for a reply, and objects to the related portions presented in Petitioner's demonstratives. *See* Ex. 1118; Paper 49, 2. Many of the issues raised in this proceeding overlap with objections raised in Case

IPR2017-00317. Specifically, in a telephonic hearing, Patent Owner objected to the following arguments in Petitioner's Reply: (1) Petitioner's reference to Figure 7A of Goodman; (2) Petitioner's reference to Prototype B of Asada; (3) Petitioner's discussion of the term "light guiding interface;" and (4) Dr. Anthony's testimony related to the alleged detriments of Goodman in combination with other art. *See* Ex. 1118. Patent Owner was also provided the opportunity to address the alleged appropriateness of the reply arguments at oral hearing. *See id*. at 21.

We have considered Patent Owner's identification of the portions of Petitioner's Reply that are alleged to be beyond the scope of a reply, and determine that the cited portions of Petitioner's Reply and associated evidence are within the scope of what is appropriate for a reply. Replies are a vehicle for responding to arguments raised in a corresponding patent owner response. Petitioner's arguments and evidence that Patent Owner objects to are not beyond the proper scope of a reply because we find that they fairly respond to Patent Owner's arguments raised in Patent Owner's Response. *See* Ex. 1118, 9:12–10:12, 11:8–19, 12:23–14:5, 17:17–18:23; *see also Idemitsu Kosan Co. v. SFC Co.*, 870 F.3d 1376, 1381 (Fed. Cir. 2017) ("This back-and-forth shows that what Idemitsu characterizes as an argument raised 'too late' is simply the by-product of one party necessarily getting the last word. If anything, Idemitsu is the party that first raised this issue, by arguing—at least implicitly—that Arakane teaches away from non-energy-gap combinations. SFC simply countered, as it was entitled to do.").

Patent Owner raised several arguments at the oral hearing, to which Petitioner objected. *See* Tr. 52–53. Petitioner specifically objected to Patent Owner's alleged newly-raised arguments at oral hearing related to a new theory for Hicks's buffer, an alleged reliance by Petitioner on Hannula's

Velcro® fastener, and a new theory applied to Asada regarding alleged hiding of wires in the device. *See id.* at 54, 57–58. We agree with Petitioner that Patent Owner impermissibly raised new arguments related to Hicks's alleged buffer and Asada's alleged wiring configuration at oral hearing, and these arguments, therefore, have not been considered due to lack of notice. *See* Tr. 32:13–33:9 (Slide 82); 45:25–46:13 (Slide 10).

IV. MOTION TO AMEND

Having determined that claims 1–10 of the '269 patent are unpatentable, we address Patent Owner's contingent Motion to Amend.

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). We must assess the patentability of the proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017). Thus, we determine whether substitute claims are patentable by a preponderance of the evidence based on the entirety of the record. Patent Owner's proposed substitute claims still must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.221. *See* "Guidance on Motions to Amend in view of *Aqua Products*" (Nov. 21, 2017).[14] Accordingly, Patent Owner must demonstrate (1) the amendment responds to a ground of unpatentability involved in the trial; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment proposes a reasonable

[14] The guidance memorandum is publicly available at https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf.

number of substitute claims; and (4) the original disclosure sets forth written description support for each substitute claim. *See* 37 C.F.R. § 42.221.

A. Proposed Substitute Claims

Patent Owner proposes substitute claims 12–21 in its Motion to Amend, with claim 12 being independent (corresponding to original independent claim 1).[15] *See* Mot. 1–2, Claim Listing at 28–31. Patent Owner characterizes the proposed amendments as not broadening the claims, wherein the proposed substitute independent claims include all of the limitations of original independent claims, as well as several additional limitations, and the substitute dependent claims merely change the dependency from the original independent claims and correct for antecedent basis. Mot. 1–2. Patent Owner also indicates that the substitute claims are responsive to a ground of unpatentability involved in the proceeding. *Id.*

Proposed substitute claim 12 is representative, and is reproduced below, with underlined material indicating language added to original claim 1.

> 12. A monitoring device, comprising:
>
> a band <u>and light-guiding structure</u> configured to at least partially encircle a portion of the body limb of a subject, the band and <u>light-guiding structure</u> comprising:
>
> a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship, the inner body portion comprising light transmissive material, and having outer and inner surface;

[15] In the Motion to Amend, Patent Owner indicates that it requests that substitute claim 22 replace claim 11. Mot. 1–3, Claim Listing 28, 31. In Patent Owner's Reply, Patent Owner "withdraws the request to cancel claim 11 and replace it with proposed substitute claim 22." PO Reply 1.

a layer of cladding material near the inner body portion inner surface; and

at least one window formed in the cladding material that serves as a light-guiding interface to the body of the subject; and

a base comprising at least one optical emitter and at least one optical detector attached to the band and light-guiding structure;

a signal processor configured to (i) receive and process signals produced by the at least one optical detector and a motion sensor to extract physiological and motion-related information, (ii) reduce motion artifacts by removing frequency bands from the signals that are outside of a range of interest using at least one band-pass filter to produce preconditioned signals and (iii) generate parsed output data by executing one or more processing methods to provide information that is fed into a multiplexed output serial data string comprising motion-related and physiological information;

wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector and is configured to deliver light from the at least one optical emitter to one or more locations of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

Mot. 2–3, Claims Listing at 28–29.

B. Unpatentability Analysis

1. Obviousness of Substitute Claims

We determine, based on a preponderance of the evidence, that substitute claims 12–21 are unpatentable under 35 U.S.C. § 103(a). We discuss the obviousness issues related to the specific claims in turn.

As discussed *supra* Section II.D.2, we are persuaded Petitioner has shown by a preponderance of the evidence that independent claim 1 is unpatentable under 35 U.S.C. §103(a) as obvious over Asada. Substitute independent claim 12 contains all of the limitations of original claim 1 and

adds the limitation that modifies the base to recite a "base and light guiding structure" and further to comprise a "base" and a "signal processor." *See* Claim Listing at 28–29. Petitioner asserts that Asada does not disclose the newly-recited base, that its signal processor is configured to perform the reduction of motion artifacts or "generate parsed output data" as recited, however, Swedlow, Fricke, and Gupta allegedly cure Asada's deficiencies. Opp. 3. Petitioner, therefore, asserts that substitute claims 12–21 would have been obvious over the combined teachings of Asada, Swedlow, Fricke, and Gupta. *Id*. at 3–25.

Petitioner argues that it would have been obvious to modify Asada with Swedlow because Swedlow discloses a layered adhesive wrap with photodetectors and LEDs mounted on a flexible substrate and this feature would improve reliability and comfort and would reduce the production costs of Asada. Opp. 4–5. Frick discloses "[a]melioration of vibrational noise effects," and Petitioner asserts that one of ordinary skill in the art would have had reason to modify Asada teachings with this feature because Asada recognizes the importance of reducing noise and in view of Asada's use for monitoring patients. *Id*. at 5–6. Petitioner also contends that Gupta discloses a system with sensors to measure a patient's heart rate and detects impacts that indicate the patient has fallen, and, given that Asada is beneficial for monitoring patient's cardiovascular state and can increase surveillance for cardiovascular catastrophe in high-risk subjects, a person of ordinary skill would have had reason to combine Gupta's impact detection teachings to those of Asada. *Id*. at 6–7. Petitioner also asserts that Gupta's system multiplexes the heart rate and impact information together into a serial string of parsed physiological and motion-related information forming a packet, and because the heart rate and impact information are both

separately useful pieces of information as disclosed by Asada, a person of ordinary skill would have had reason to modify Asada's signal processor teachings to multiplex these two pieces of information, as taught by Gupta, to allow each piece of information to be separately recovered and monitored after being received. *Id*. at 6–7. Petitioner also asserts Asada and Gupta describe similar physiological monitoring devices in the same field for similar purposes of communicating physiological parameters, and Gupta's technique to output Asada's data would have amounted to the obvious use of a known signal processing technique to improve a similar physiological monitoring device. *Id*. at 7. With this, Petitioner asserts that a person of ordinary skill in the art would have had reason to modify Asada's sensor to include the features of Swedlow, Fricke, and Gupta. *Id*. at 2–7.

Petitioner also asserts that Asada discloses a sensor band that encircles the finger. Opp. 8 (citing Ex. 1005, 35). Petitioner contends that "a finger is a body limb," as recited in substitute claim 12. *Id*. (citing Ex. 1108, 436; Ex. 1103 ¶ 59). Petitioner also asserts that Asada's sensor band is a "light guiding structure," as recited. Petitioner bases this contention on Asada's illustration of windows in the sensor band through which light can pass, and "[t]he window serves to deliver light along a path." *Id*. at 9. Swedlow is relied upon for the teaching of the "base," as recited. *Id*. at 9–10. Petitioner further argues that Asada, as modified by Fricke, "discloses a signal processor configured to 'reduce motion artifacts by removing frequency bands from the signals that are outside of a range of interest using at least one band-pass filter to produce pre-conditioned signals,'" as recited in substitute claim 12. *Id*. at 11–12. Petitioner contends that the combination of the teachings of Gupta and Asada would teach the multiplexing limitation of substitute claim 12. *Id*. at 12–13.

Alternatively, Petitioner asserts that the teachings of Goodman, in combination with those of Asada, Fricke, and Gupta, also would teach the limitations of substitute claim 12. Opp. 13–21. The proferred rationale to combine the teachings of Goodman with those of Fricke and Gupta is similar to that asserted for the combination with the teachings of Asada: greater noise reduction and increased surveillance for cardiovascular catastrophe in high-risk subjects. *See id*. at 13–16. Petitioner contends that the combination of the teachings of the prior art references would teach all of the limitations of substitute claim 12. *Id*. at 17–21.

Patent Owner focuses on two aspects of Petitioner's assertions to dispute obviousness: (1) an alleged lack of reason to combine the teachings of Asada and Swedlow, as well as those of Asada and Gupta; and (2) an alleged lack of reason to combine the teachings of Goodman and Asada, as well as those of Asada and Gupta. PO Reply 3–12. Patent Owner, however, does not assert that the combination of the teachings of the applied prior art references fails to teach any of the limitations of substitute claim 12. *See id.*

More specifically, Patent Owner argues that there is insufficient reason to combine the teachings of Asada and Swedlow because there is no need to make the wearer of Asada's device more comfortable because there is nothing to suggest that a problem with comfort exists with Asada's device. PO Reply 5–6. Patent Owner asserts that there is no disclosure in Asada that wire comfort or disconnection is a problem, and Asada and Swedlow teach solutions to similar problems, so a person of skill in the art would not look to Swedlow to solve a problem that Asada already solved. *Id*. at 6–7. Patent Owner additionally argues that one of skill in art would not have looked to combine the teachings of Gupta with Asada because Gupta has larger and more power-hungry components that are incompatible with Asada. *Id*. at 9–

10. Patent Owner contends that Asada teaches against the use of a microelectromechanical systems ("MEMS") device, stating "[t]he motion of the finger can be measured with an accelerometer attached to the body of the ring. MEMS accelerometers are now available at low cost, but they are still too bulky and/or consume too much power to use for the ring sensor." *Id*. at 9 (citing Ex. 1005, 32–33). Patent Owner asserts that Gupta's impact sensor is an "ADXL311 accelerometer," which is a MEMs device. *Id*. at 8 (citing Ex. 2152, 1;[16] Ex. 2110 ¶¶ 29, 30). Because Asada expressly states not to use a MEMS device, Patent Owner contends that this constitutes an express teaching away from the modification based on Gupta's teachings. *Id*.

Patent Owner also alleges that one of skill in the art would not have combined the teachings of Goodman and Asada because Goodman is intended for use on patients who are primarily bedridden, and, therefore, would not have looked to combine the teachings of Goodman with those of Asada to solve motion problems for a device that is intended to be used on people in whom there is little motion. PO Reply 11. Patent Owner contends that there would be no reason to seek the combination because Goodman does not exhibit any problems due to motion. *Id*. at 10. Patent Owner also asserts that one of ordinary skill would not have added Gupta's teachings in combination with those of Goodman, Asada, and Fricke because of the alleged teaching away related to MEMS use, discussed above. *Id*. at 12.

Nevertheless, we find that substitute independent claim 12 is not patentable by a preponderance of the evidence based on the entirety of the record. The evidence sufficiently shows that each of Petitioner's asserted

[16] Petitioner filed a Motion to Exclude to exclude Exhibits 2152 and 2153 from the record. We address and deny the Motion to Exclude, *infra* Section IV.E.

combinations, i.e. the combination of the teachings of Asada, Swedlow, Fricke, and Gupta, as well as the combination of the teachings of Goodman, Asada, Fricke, and Gupta, teaches all of the limitations of the claim 12, and the rationale to combine the references is supported by the evidence of record. *See* Opp. 3–21. Petitioner's expert provides testimony explaining the rationale to combine Swedlow, Fricke, and Gupta with Asada, where one of skill in the art would have had reason to add the features taught by the additional reference, and we find sufficient evidentiary support for this testimony. *See id.* at 13–17.

Patent Owner's arguments disputing the combination of the teachings of Swedlow and Gupta with Asada are directed to teaching away, that is, that one of skill in the art would have been dissuaded from the combination because Asada indicates no need for additional comfort and Asada discourages the use of the MEMS of Gupta. *See* PO Reply, 6–10. Asada discloses, however, a recognition that comfort of its sensor is an identified design consideration (Ex. 1005, 29–30, 36), which supports Petitioner expert's testimony for the combination with Swedlow's teachings. As to the combination of the teachings of Gupta with those of Asada, Patent Owner bases its teaching away argument on the bodily incorporation of Gupta's specific model of an accelerometer, which is a MEMS-type device, into Asada's device. Bodily incorporation, however, is not the standard for obviousness. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."). Here, Petitioner's expert, Dr. Anthony, testifies that Gupta's teachings of detection of patient falls and

multiplexing of signals as features would have provided a rationale for combination with Asada's teachings in the view of one of ordinary skill in the art—but there is no suggestion of a bodily incorporation of Gupta's specific accelerometer as part of the basis for the rationale. *See* Ex. 1104 ¶¶ 54–57.

For the alleged teaching away of the combination of Goodman's teachings and those of Asada, we addressed similar issues, *supra* Section II.I.3. We are not persuaded of a teaching away of the proposed combination for similar reasons to those discussed above.

Patent Owner identifies no additional distinctions related to substitute dependent claims 13–21, except for the alleged failures of rationale to combine discussed above. PO Reply 12. We have reviewed Petitioner's assertions of obviousness related to the substitute dependent claims based upon the alternative combinations identified above, and in further view of Tran for claim 13, in further view of Hicks for claim 14, in further view of Hannula for claim 15, in further view of Hannula and Fraden for claim 16, in further view of Fraden for claim 17, with no additional art for claim 18, in further view of Delonzor for claim 19, and in further view of Al-Ali for claims 20 and 21. *See* Opp. 21–25. Based upon the combinations of the teachings of the prior art references, we agree with and adopt Petitioner's analysis, as supported by Dr. Anthony's testimony. *See id*.

Accordingly, in light of the foregoing, we determine that the preponderance of the evidence based upon the entirety of the record demonstrates that substitute claims 12–21 would have been obvious based on the teachings of the combinations of the prior art references identified above.

C. Written Description

Petitioner argues that the Specification of the '269 patent fails to provide written description support for the recited portion of "reduce motion artifacts by removing frequency bands from the signals that are outside of a range of interest using at least one band-pass filter to produce pre-conditioned signals," where "the signals" are "produced by the at least one optical detector and a motion sensor" of substitute claim 12. Opp. 1. Petitioner asserts that there is no support in the '269 patent for a band-pass filter that reduces motion artifacts from a signal produced by an optical detector or a signal produced by a motion sensor. *Id*.

Patent Owner responds that the Specification provides that:

> The first block (block 510) represents the pre-adaptive signal conditioning stage. **This process may utilize a combination of filters to remove frequency bands outside the range of interest.** For example, a combination of band-pass, low-pass, and/or high-pass filters (such as digital filters) may be used. . . . **This process may utilize the pre-conditioned signals from block 510 as inputs into an adaptive filter that reduces motion or environmental artifacts** and noise in the primary data channel.

PO Reply 2 (citing Ex. 2107, 39:5–13 (emphases in Reply)).

Under substitute claim 12, "a signal processor [is] configured to"…. "reduce motion artifacts by removing frequency bands from the signals that are outside of a range of interest using at least one band-pass filter to produce preconditioned signals." *See* Claim Listing 28. Patent Owner asserts, however, that "[t]he reduction of motion artifacts is done, in part, by the processor producing pre-conditioned signals through the removal of frequency bands outside the range of interest." PO Reply 2. Patent Owner

argues that it is the signal processor that is used to reduce motion artifacts, and not the filter. *See* Tr. 52:7–26.

Nevertheless, substitute claim 12 recites that the "reduc[tion]" of the motion artifacts is "by removing frequency bands . . . *using at least one band-pass filter*." Thus, the signal processor has to use the filter to perform the step, and we fail to see how the Specification discloses the details of the recited step.

Accordingly, in light of the foregoing, we determine that the preponderance of the evidence based upon the entirety of the record demonstrates that Patent Owner fails to meet the requirements of 37 C.F.R. § 42.221(a)(2) for substitute claim 12, and claims 13–21 that depend from it.

D. Indefiniteness

Petitioner asserts that substitute claims 12–21 are indefinite under 35 U.S.C. § 112 because the recital of claim 12 of "extract[ing] physiological and motion-related information" then recites a "string comprising motion-related and physiological information," which leaves ambiguous as to whether these terms identify the same or different physiological and motion related information. Opp. 2. Petitioner also asserts that substitute claim 17 is indefinite "because it recites 'the first and second optical emitters . . . and the third and fourth optical emitters' without antecedent basis" leaving it unclear as to whether these emitters are the same or different than the "at least one optical emitter" recited in claim12. *Id*. Petitioner additionally argues that substitute claim 22 is indefinite because "it recites 'a signal processor' and it is unclear whether this signal processor is the same or different than the signal processor" of claim 12. *Id*. Patent Owner responds that "[n]o other physiological and/or motion related information is

referenced in the claim so Patent Owner cannot understand Petitioner[']s claim of ambiguity." PO Reply 2–3.

We agree with Petitioner that there is ambiguity introduced by the inconsistencies in the antecedent basis for the claim terms identified. Thus, the proposed substitute claims use language that is unclear and ambiguous under *In re Packard*, 751 F. 3d 1307, 1310, 1314 (Fed. Cir. 2014) and does not identify the inventive subject matter with reasonable certainty under *Nautilus, Inc. v. Biosig Instruments, Inc*., 134 S. Ct. 2120, 2130 (2014).

In consideration of the above, we agree with Petitioner that the proposed substitute claims do not comport with 35 U.S.C. § 112.

E. Motion to Exclude

Patent Owner filed Exhibits 2152 and 2153 in support of its Motion to Amend. Petitioner moves to exclude Exhibits 2152 and 2153 as late-served supplemental evidence and also as inadmissible hearsay and improperly authenticated evidence. Mot. Ex. 1–6. Petitioner additionally asserts that Exhibit 2153 is prejudicial, confusing, and potentially misleading. *Id*. at 4. On the issue of the late service, Petitioner states that Patent Owner filed Exhibits 2152 and 2153 on December 29, 2017, and Petitioner filed its objections within five business days, that is, on January 8, 2018. *Id*. at 1. Petitioner states that Patent Owner served the related supplemental evidence on January 24, 2018, one day after the deadline. *Id*. at 2.

Patent Owner responds that there is good cause for the late service of the supplemental evidence because Patent Owner's counsel timely attempted to obtain declarations related to Exhibits 2152 and 2153, but there were extenuating circumstances, including short staffing at the company that was

providing the declarations. Mot. Ex. Opp. 2–4 (citing Ex. 2157). Patent Owner also avers that there is no prejudice to Petitioner by the one day delay. *Id*. at 4. Patent Owner also asserts that sufficient authentication for the exhibits has been provided under the Declaration of Alex Wong. *Id*. at 5 (citing Ex. 2154). Moreover, Patent Owner contends that Exhibits 2152 and 2153 are self-authenticating under FRE 902(7) because they bear the trademark and copyright of Analog Devices. *Id*. at 6–7.

Patent Owner further argues that the exhibits fall within certain hearsay exceptions because they are generally-relied upon by engineers as well as other professionals in the technical field and, therefore, are admissible under FRE 803(17), and they additionally fall under the business record exception, as attested to by Mr. Wong. *Id*. at 8–11 (citing Ex. 2154). Patent Owner also disputes Petitioner's assertion that Exhibit 2153 is inadmissible because of alleged prejudice and confusion due to the presence of an "OBSOLETE" watermark on it. *Id*. at 12. Patent Owner argues that there is no explanation provided for the alleged prejudice.

Petitioner replies that Patent Owner knew that it was filing its supplemental evidence late and, rather than alert Petitioner or the Board, it instead late-filed the evidence without providing notice. Mot. Ex. Reply 1–3. Petitioner also asserts that Patent Owner's excuses for the delay are insufficient, and the efforts should have been started sooner. *Id*. at 3–4. Petitioner also contends that the exhibits do not qualify for the hearsay exception under FRE 803(17), and do not fall under the business record exception because they are not "[a] record of an act, event, condition, opinion, or diagnosis." *Id*. at 5.

We find that the evidence of the authentication of Exhibits 2152 and 2153 is sufficient. We also note that Exhibits 2152 and 2153 were cited in

the Titus Supplemental Declaration and were relied upon to form the expert's opinions expressed in his Declaration. *See* Ex. 2151 ¶¶ 30, 32. Because the record reflects that Dr. Titus reviewed these exhibits in reaching the opinions he expressed in this case, and with no evidence provided by Petitioner that the exhibits are irrelevant, we, therefore, decline to exclude Exhibits 2152 and 2153 from evidence under FRE 703. *Id*.

As to the late filing, we agree that Patent Owner should have provided notice of the issues it was having in acquiring the supplemental evidence and the lateness of the filing. Given that Petitioner apparently did not seek to depose Mr. Wong, Petitioner appears to have suffered only limited prejudice – if any – due to Patent Owner's one day delay in filing the supplemental evidence. Thus, under these particular circumstances, we excuse Patent Owner's one day filing delay.

For the above reason, Petitioner's Motion to Exclude is denied.

F. Conclusion

Accordingly, we determine, based on a preponderance of the evidence, that proposed substitute claims 12–21 are unpatentable for the reasons discussed above. We, therefore, deny Patent Owner's Motion to Amend with respect to the proposed substitute claims. We also deny Petitioner's Motion to Exclude.

V. PROCEDURAL ISSUES

Patent Owner also objects to the constitutionality of this *inter partes* review. PO Resp. 73 (citing *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712 (U.S. Nov. 23, 2016, cert. granted June 12, 2017)). However, on April 24, 2018, the U.S. Supreme Court held that "inter partes review does not violate Article III or the Seventh

Amendment" of the Constitution. *Oil States Energy Servcs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct.1365 (2018). Therefore, Patent Owner's argument is moot.

VI. CONCLUSION

For the foregoing reasons, we are persuaded Petitioner has demonstrated by a preponderance of the evidence, that the challenged claims 1–10 of the '269 patent are unpatentable based on the following grounds:

Basis	Claim(s)	Prior Art
§ 103	1, 2, 6, 7	Asada
§ 103	3	Asada and Hicks
§ 103	4, 5	Asada and Hannula
§ 103	8	Asada and Delonzor
§ 103	9, 10	Asada and Al-Ali
§ 103	1, 2	Goodman
§ 103	3	Goodman and Hicks
§ 103	4	Goodman and Hannula
§ 103	5	Goodman, Hannula, and Asada
§ 103	6, 7	Goodman and Asada
§ 103	8	Goodman and Delonzor
§ 103	9, 10	Goodman and Al-Ali

Additionally, we determine that (1) Patent Owner's Motion to Amend does not meet the requirements set forth in 37 C.F.R. § 42.221 with respect to proposed substitute claims 12–21; and (2) the preponderance of the evidence based on the entirety of the record demonstrates that proposed substitute claims 12–21 are unpatentable as obvious under 35 U.S.C. § 103(a). More specifically, proposed substitute claims 12 and 18 are

unpatentable as obvious over the combined teachings of Asada, Swedlow, Fricke, and Gupta or over the combined teachings of Goodman, Asada, Fricke, and Gupta; proposed substitute claim 13 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Tran; proposed substitute claim 14 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Hicks; proposed substitute claim 15 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Hannula; proposed substitute claim 16 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Hannula and Fraden; proposed substitute claim 17 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Fraden; proposed substitute claim 19 is unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Delonzor; and proposed substitute claims 20 and 21 are unpatentable as obvious over the prior art combinations asserted for claim 12 and in further view of Al-Ali.

VII. ORDER

Accordingly, it is

ORDERED that claims 1–10 of the ’269 patent are determined to be *unpatentable*;

FURTHER ORDERED that Patent Owner’s Motion to Amend is *denied*;

FURTHER ORDERED that Petitioner’s Motion to Exclude is *denied*;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Michael D. Specht
Michelle K. Holoubek
Jason A. Fitzsimmons
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, N.W.
Washington, D.C. 20005
mspecht-PTAB@skgf.com
holoubek-PTAB@skgf.com
jfitzsimmons-PTAB@skgf.com

PATENT OWNER:

Justin B. Kimble
Nicholas C Kliewer
Jonathan H. Rastegar
BRAGALONE CONROY PC
2200 Ross Ave.
Suite 4500 – West
Dallas, TX 75201
JKimble-IPR@bcpc-law.com
nkliewer@bcpc-law.com