

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC. and FITBIT, INC.,
Petitioner,

v.

VALENCELL, INC.
Patent Owner.

IPR2017-00317¹
Patent 8,989,830 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 IPR2017-01553, has been joined with this proceeding.

I. INTRODUCTION

A. Background

Apple Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–6, 8–16, and 18–20 (“the challenged claims”) of U.S. Patent No. 8,989,830 B2 (Ex. 1001, “the ’830 patent”) pursuant to 35 U.S.C. §§ 311–319. Paper 2 (“Pet.”). *Fitbit, Inc. v. Valencell, Inc.*, Case IPR2017-01553, has been joined with this proceeding. Paper 26, 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 1–6, 8–16, and 18–20 (“the challenged claims”) of the ’830 patent on June 5, 2017 on all the asserted grounds, which are:

Basis	Claims	Reference(s)
§ 103	1–4, 11–14	Goodman ²
§ 103	5, 15	Goodman and Hicks ³
§ 103	6, 16	Goodman, Hannula ⁴ , and Asada ⁵
§ 103	8, 9, 18, 19	Goodman and Asada
§ 103	10, 20	Goodman and Delonzor ⁶

Paper 7 (“Dec.” or “Institution Decision”).

² U.S. Patent No. 4,830,014 (issued May 16, 1989) (Ex. 1007).

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 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).

⁶ U.S. Patent No. 5,797,841 (issued August 25, 1998) (Ex. 1010).

During the course of trial, Patent Owner filed a Response (Paper 19, “PO Resp.”), and Petitioner filed a Reply to the Patent Owner Response (Paper 27, “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 37), and Petitioner filed a response thereto (Paper 39). Patent Owner additionally alleged that certain of Petitioner’s arguments exceed the proper scope of Petitioner’s Reply. *See* Ex. 1110.

In addition, Patent Owner filed a Motion to Amend (Paper 20, “Mot.”), which was opposed by Petitioner (Paper 28, “Opp.”). Patent Owner submitted a Reply in Support of its Motion to Amend (Paper 32, “PO Reply”), and Petitioner filed a Sur-Reply supporting its Opposition (Paper 34, “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 Opposition (Ex. 1103), and the Supplemental Declaration of Dr. Anthony in support of Sur-Reply (Ex. 1111).

We held a consolidated oral hearing on February 27, 2018, in relation to this proceeding and that of Case IPR2017-00318. A transcript (Paper 45, “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

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Petitioner has shown by a preponderance of the evidence that claims 1–6, 8–16, and 18–20 of the ’830 patent are unpatentable. Additionally, we deny Patent Owner’s Motion to Amend.

B. Related Proceedings

The parties indicated that the ’830 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 indicated the ’830 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 indicated that it filed another *inter partes* review petition challenging claims of the ’830 patent (IPR2017-00316), wherein institution of *inter partes* review was denied, and also filed another *inter partes* review petition (IPR2017-00318), in which *inter partes* review was instituted, challenging claims of U.S. Patent No. 8,886,269 B2, which is the parent of the ’830 patent. Pet. 3; *see also Apple Inc. v. Valencell, Inc.*, Case IPR2017-00316, (PTAB June 5, 2017) (Paper 7); *Apple Inc. v. Valencell, Inc.*, Case IPR2017-00318, (PTAB June 5, 2017) (Paper 7).

C. The ’830 Patent

The ’830 patent is entitled “Wearable Light-Guiding Devices For Physiological Monitoring” and issued on March 24, 2015 from an application filed on September 12, 2014. Ex. 1001, [22], [45], [54]. The ’830 patent claims priority to U.S. Patent Application No. 14/184,364, filed on February 19, 2014 (now U.S. Patent No. 8,886,269 B2), and U.S. Patent Application No. 12/691,388, filed on January 21, 2010 (now U.S. Patent 8,700,111). *Id.* at [63].

The '830 patent is directed to monitoring devices configured to be attached to 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 4:33–67. The sensors, for example, may be photoplethysmography (“PPG”) sensors for measuring blood flow properties, such as blood oxygen level. *Id.* at 3:67–4:5. The '830 patent discloses various embodiments of the monitoring devices, such as that depicted in Figures 22A and 22B, reproduced below.

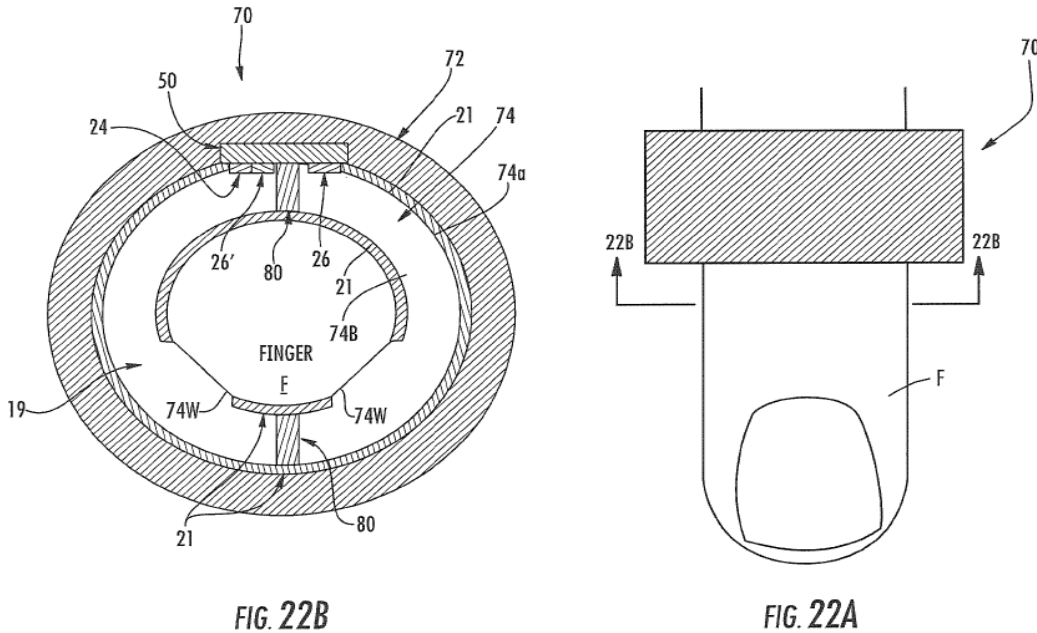


Figure 22A is a top plan of an embodiment of monitoring device 70 configured to be attached to the finger of a subject, and Figure 22B is a cross-sectional view of the monitoring device. Ex. 1001, 8:16–20. The monitoring device that fits over the finger has outer body portion 72 that may include a flex circuit, and base 50 secured to inner body portion 74 and outer body portion 72. *Id.* at 28:1–10. Base 50 supports optical emitter 24, optical detector 26, and optical noise detector 26'. *Id.* at 28:19–21. 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 28:30–38. “[W]indows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger.” *Id.* at 28:44–46. The device also may be embodied in “a patch, such as a bandage that sticks on a person’s body.” *Id.* at 11:53–58.

The '830 patent discloses an embodiment of the invention illustrated in Figure 3, reproduced below.

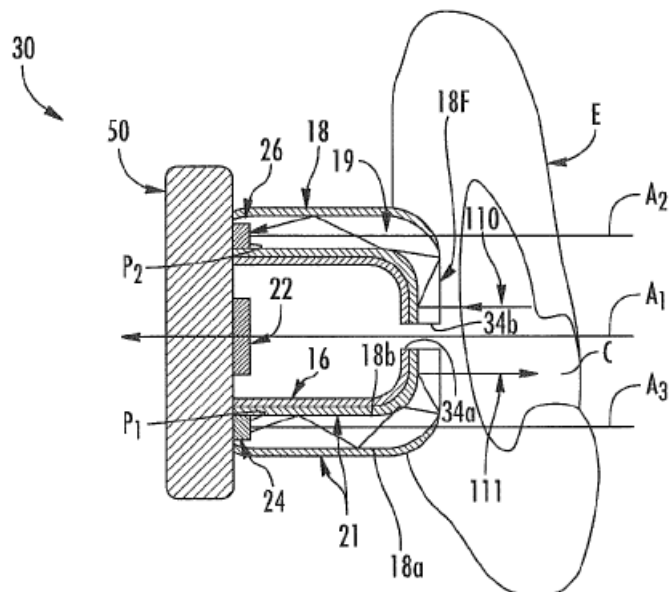


FIG. 3

Figure 3 depicts an embodiment of a monitoring device showing a side section view of a headset with a light-guiding earbud. Ex. 1001, 7:7–9.

Earbud 30 includes optical detector 26 and optical emitter 24. Ex. 1001, 14:52–53. Cladding material 21 is used to confine light within light guiding region 19. *Id.* at 14:60–63.

Claims 1 and 11 are independent. Claims 2–6 and 8–10 depend directly from claim 1, and claims 12–16 and 18–10 depend directly from

claim 11. Independent claim 1, reproduced below, is illustrative of the challenged claims of the '830 patent.

1. A monitoring device configured to be attached to the body of a subject, comprising:

an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces;

a base secured to at least one of the outer and inner layers and comprising at least one optical emitter and at least one optical detector;

a layer of cladding material near the outer surface of the inner layer; and

at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject, wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector, wherein the light transmissive material is configured to deliver light from the at least one optical emitter to the body of the subject along a first direction and to collect light from the body of the subject and deliver the collected light in a second direction to the at least one optical detector, wherein the first and second directions are substantially parallel.

Ex. 1001, 30:35–55.

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 1–6, 8–16, and 18–20 of the '830 patent are unpatentable under 35 U.S.C. § 103 over asserted prior art. Inst. Dec. 26. We now determine whether Petitioner has established by a preponderance of the evidence that claims 1–6, 8–16, and 18–20 are unpatentable under 35 U.S.C. § 103(a) over

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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 art teaches corresponding limitations of claims 1–6, 8–16, and 18–20. Based on the preponderance of the evidence before us, we conclude that the art identified by Petitioner discloses, teaches, or suggests all of the uncontested limitations of the reviewed claims. The limitations and claim construction that Patent Owner contests in the Patent Owner Response are specifically addressed below.

B. Claim Construction

In an *inter partes* review, we interpret 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).

Two claim terms are identified and discussed by the parties: “cladding material” and “light guiding interface.” *See* Pet. 12–14, Prelim. Resp. 25–30, PO Resp. 23–30; 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. 12; 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, 13:51–54), or could be a reflective material (*id.* at 14:63–64). Pet. 13–14 (citing also Ex. 1001, 14:64–67, 29:21–23, 46–50, 54–59, 60–62; Ex. 1003 ¶¶ 47–48). Petitioner also asserts that Figure 3 of the ’830 patent depicts two layers of cladding, and claim 1 requires only one layer of cladding material (“a layer of cladding”). Pet. Reply 3–4.

Patent Owner argues that “cladding material” should be construed as “a material that confines light within a region.” PO Resp. 23. 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 23–24 (quoting Ex. 1001, 14:62–64 (emphasis added), also citing *id.* at 16:16–25, 16:66–17:12, 18:46–48, 18:60–19:4, 28:30–43, 29:46–50, Figs. 3 and 22B). Patent Owner argues

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that Petitioner’s proposed construction deprives the term of its precise meaning. PO Resp. 26. Patent Owner further asserts that “[o]ne of ordinary skill [in the art] 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 reflected. *Id.* at 26–27 (citing Ex. 1001, 13:52–54; Ex. 2007 ¶¶ 75–78).

Although Patent Owner makes generalized assertions about cladding material in its arguments on the alleged obviousness of the ’830 patent, Patent Owner does not make any specific arguments that the art asserted is deficient as to the teaching of cladding as used *per se* in the claims at issue. *See* PO Resp. 8, 12–14, 30–34. 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 guide interface,” except for the general application of broadest reasonable interpretation. Pet. 12–14. Within the Petitioner’s mapping of Goodman to claim 1, Petitioner contends that Goodman’s aperture that “allow[s] light to pass” and is described as a “window” meets the claim limitation of a “light guiding interface.” *See id.* at 29.

Patent Owner alleges that the broadest reasonable interpretation of “light-guiding interface” is “an interface that delivers light along a path.”

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PO Resp. 27. Patent Owner avers that its proposed construction is consistent with the Specification that describes a light guide as delivering light along a path. *Id.* at 28 (citing, *inter alia*, Ex. 1001, 1:66–2:3, 11:34–36, 14:20–25, 16:23–24). Patent Owner also refers to dictionary definitions. *Id.* at 28–29. 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 29.

In its Reply, Petitioner refers to the ’830 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 5–6 (citing Ex. 1001, 28:44–46, 29:60–62). Petitioner also refers to Patent Owner’s expert’s testimony, which generally states that a window does not change the direction of path of light. *Id.* at 5–6. 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 7.

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.

C. *Level of Ordinary Skill in the Art*

Petitioner argues that a person of ordinary skill in the art at the time of the ’830 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. 11–12 (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.* at 12. Patent Owner does not contest that assessment. PO Resp. 16–17.

We adopt and apply this assessment of the level of ordinary skill in the art articulated by Petitioner to our obviousness analysis in this proceeding. In addition, we note that the art of record in this proceeding—namely, Goodman, Hicks, Hannula, Asada, 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 Claims 1–4 and 11–14 over Goodman

In support of this asserted ground of unpatentability, Petitioner explains how Goodman allegedly teaches the subject matter of claims 1–4 and 11–14. Pet. 25–42. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because Goodman does not teach several limitations of independent claims 1 and 11. *See* PO Resp. 30–41.

We find that Petitioner has demonstrated by a preponderance of the evidence that Goodman teaches or suggests all of the limitations of claims 1–4 and 11–14 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.

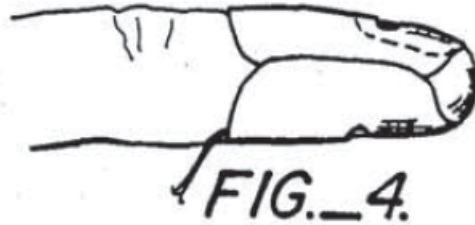


Figure 4 depicts a digit with the distal ends of the sensor fastened over the fingertip. Ex. 1007, 8:27–28, 9:60–61.

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

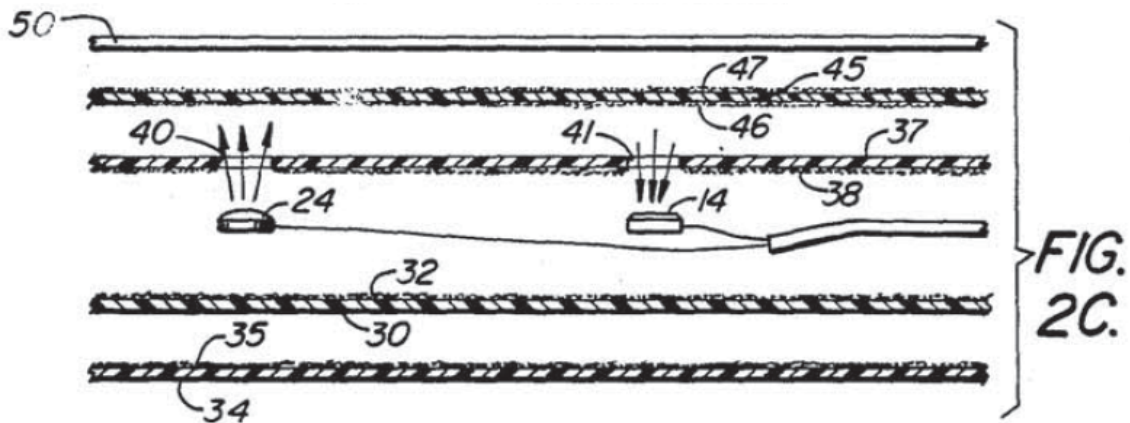


Figure 2C is an exploded view of an embodiment of a sensor with identification of individual elements. Ex. 1007, 8:15–18. In the depicted embodiment, the photo-active elements of the sensor substrate, that is, element 24 which has a light source mounted to it, and element 14, which has a photo-sensor 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

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.⁷ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner asserts that claims 1–4 and 11–14 are unpatentable under 35 U.S.C. § 103 as obvious over Goodman. Pet. 15–16, 25–42; Pet. Reply 8–19. Patent Owner disagrees with Petitioner’s assertions. PO Resp. 30–45. The parties focus their arguments on whether Goodman teaches the following claim limitations of independent claims 1 and 11: (1) a window that serves “as a light-guiding interface;” (2) “the first and second directions are substantially parallel;” and (3) whether the “light transmissive material is configured” to meet the “first and second directions.” *See id.* at 30–41; Pet. 24–40; Pet. Reply 8–18.⁸ As to the other limitations of the challenged claims 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 elements are disclosed as arranged in the claims related to dependent claims 2–4 and 12–14. *See* Pet. 15–39; PO Resp. 30–41. We address the arguments regarding the disputed claim limitations in turn.

⁷ Patent Owner does not present arguments or evidence of objective indicia of nonobviousness in its Response.

⁸ 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. “light guiding interface”

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. 14–15, 25–32. Annotated Figure 2C of Goodman is reproduced below.

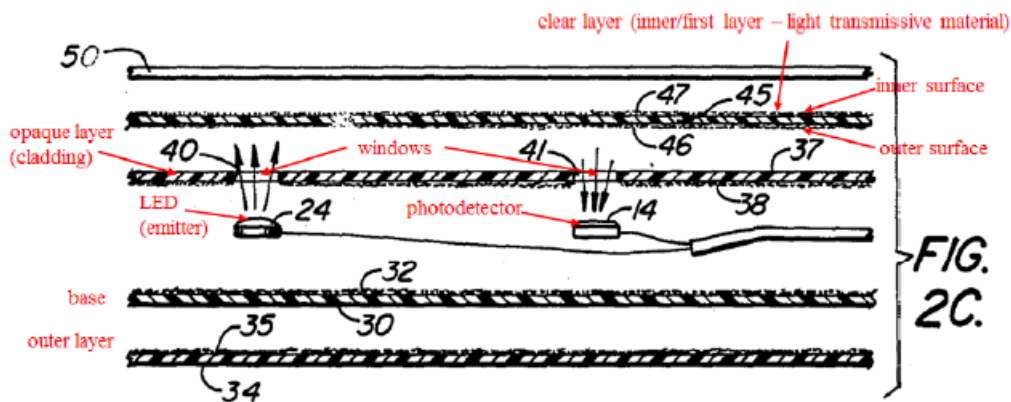


Figure 2C is a view of an embodiment of a sensor of Goodman with Petitioner’s annotations shown in red. Pet. 16. As depicted, Petitioner asserts that the “cladding” limitation of claim 1 is taught by opaque layer 40 of Goodman, the “outer” and “inner” layers are part of clear polyester layer 45, and the “optical emitter” and “optical detector” are taught by Goodman’s light-emitting diodes (“LEDs”) 24 and photodetector 14. *Id.* at 26–28. 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 29–30 (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. 25–42; Ex. 1003 ¶¶ 68–98. 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 that Patent Owner developed of assembled sensor of Figure 2C, and which is reproduced below, the apertures in Goodman do not serve any purpose in guiding light to the body. PO Resp. 32–34.



In the above-annotated Patent Owner depiction, which is allegedly excerpted and modified by Patent Owner in accordance with the assembly description in the '830 patent, Patent Owner relies, in part, on Goodman’s description. PO Resp. 32 (citing Ex. 1007, 9:39–43 (“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 guide any light to the body and cannot deliver light along a path.

PO Resp. 33 (quoting Ex. 2007 ¶ 94).

Patent Owner further alleges that “Goodman’s device has complete cutaneous conformance, meaning that it is adhered to the skin without any light-guiding interface between the light source and the body.” PO Resp. 33 (citing Ex. 1007, 1:11–12, 4:64–66, 5:41–44, 7:13–18; Ex. 2007 ¶ 95). 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 33–34 (emphasis in original) (citing Ex. 1007, 4:50–54; Ex. 2007 ¶ 96).

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 ¶ 14.

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.⁹ Given the location of clear polyester layer 45,

⁹ 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

the evidence supports that it would impede the light source 24 and photo-sensor 14 from extending through the apertures.

Petitioner contends that, even under Patent Owner’s proposed claim construction of “light-guiding interface,” Goodman teaches the claim limitation, “window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject.” Pet. Reply 11–13; *see also* Pet. 29–30. 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. 29 (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 12 (citing Ex. 1102 ¶ 16). Petitioner also asserts that “Goodman’s apertures function the same as the windows in the ’830 Patent—they allow light to pass through.” *Id.* at 12–13 (citing Ex. 1102 ¶ 17; 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 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 a “light guiding interface” as “an interface that serves to deliver 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

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.

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 ¶ 12; *see also* Ex. 1003 ¶ 79. 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 ¶ 14.

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.”

ii. “first and second directions are substantially parallel”

Patent Owner argues that the Petition makes assumptions that fail to support that Goodman teaches the limitation of claim 1 that the light delivered to the optical detector is substantially parallel to the emitted light. PO Resp. 35–40. Patent Owner refers to Goodman’s embodiment depicted

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in Figure 6, arguing that emitters and detectors positioned on opposite sides of the nose do not result in the directions of light emitted and detected being substantially parallel. *Id.* at 38–40. Patent Owner also alleges that under Goodman’s finger embodiment, Petitioner jumps from the assumption of the orthogonal direction of some light emitted and received from the LEDs and photodiode surfaces to a conclusion that the LEDs and photodiode and their surfaces are disposed substantially opposite each other. *Id.* at 35–36. Patent Owner argues that, although Goodman discloses that the first and second end of the substrates are disposed on “opposite side[s] of the flesh,” there is no guidance on the orientation of the light emitting or receiving surfaces. *Id.* at 36 (citing Ex. 1007 at 4:37–45, 46–47; Ex. 2007 ¶ 102). Patent Owner refers to Asada as an example, asserting that the position of the light source and detector impacts the relative angle between the surfaces. *Id.* at 36–37. Patent Owner additionally argues that the relative orientation of the photodiode or photo-sensor depends on the placement of the elements on the finger. *Id.* at 38 (citing Ex. 2007 ¶¶ 105, 106).

On this record, we are persuaded that Petitioner has provided sufficient evidence that Goodman’s teachings are consistent with and support the teaching of the claim limitation of “deliver light from the at least one optical emitter . . . along a first direction and . . . deliver the collected light in a second direction . . . wherein the first and second directions are substantially parallel.” In addition to Goodman’s disclosure of a nose embodiment, the Petition also relies on an embodiment that depicts a sensor applied to a finger. *See* Pet. 31 (citing, *inter alia*, Ex. 1007, Fig. 4). In its discussion of Goodman, and the finger supported embodiment, Petitioner asserts that “the light source is disposed approximately on an opposite side of the body part being transilluminated [sic] from the detector.” *Id.*

Goodman also explicitly states that “[t]he sensor includes a first end for disposition on one side of the transilluminated flesh and a second end for disposition on the *opposite and opposed side* of the trans-illuminated flesh. A *light source* is mounted to the *first side* and a *photo-sensor* is mounted to the second side.” See Pet. Reply 14 (with emphases in the Reply) (citing Ex. 1007, Abstract); see also Ex. 1007, 5:33–41. As discussed in the Institution Decision, Goodman’s finger supported embodiment (Ex. 1007, Fig. 4), is the preferred configuration that uses elongated tape 35 formed into a butterfly design. See Dec. 13 (citing Ex. 1007, 9:25–32, Figs. 2B, 4). In Figures 2B and 4 of Goodman, with the use of the butterfly design, the locations of LED and photo-sensor, and their respective surfaces, are approximately opposite of each other. See *id.* Dr. Anthony’s testimony that a person of ordinary skill in the art would understand that the direction of some of the light emitted and received (the first and second directions) would be orthogonal to the respective surfaces and, therefore, would be substantially parallel is further supported by evidence that the LEDs and photodiode are disposed approximately opposite from each other. Ex. 1003 ¶ 80.

Accordingly, we determine that the evidence sufficiently supports the Petition regarding Goodman’s teaching of the claim limitation “wherein the first and second directions [of light] are substantially parallel.”

iii. “light transmissive material is configured” to meet the “first and second directions”

Patent Owner also argues that Goodman does not teach or suggest that the “light transmissive material is configured” meets the “first and second directions” limitations. PO Resp. 40–41. Patent Owner contends that the “light transmissive material” must be configured to deliver light according to

the first and second directions, and Goodman fails to disclose any specific direction in which polyester layer 45—which Petitioner maps to the “light transmissive material”—is configured to deliver light. *Id.* at 41.

We agree with the Petitioner that the claims do not require that the light transmissive material change the direction of the path of light. Pet. Reply 17–18. As Petitioner indicates, the polyester layer of Goodman delivers light from the light source 24 to the body and some of that light will be delivered in a “first direction.” *Id.* at 18. Similarly, the polyester layer on the opposite side of a finger delivers light to photo-sensor 14, and some of that light will be in a “second direction.” *Id.* Contrary to the Patent Owner’s suggestions, under the claims, the “light transmissive material” delivers “light” that has a direction—the claims do not require that the “light transmissive material” itself causes the light to be “substantially parallel”—rather, the “light transmissive material” only has to “deliver” light that is in a “direction.”

Accordingly, we determine that the evidence sufficiently supports the Petition regarding Goodman’s teaching of the claim limitation, “wherein the light transmissive material is configured to deliver light . . . along a first direction” and “in a second direction.”

In summary, for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that claims 1–4 and 11–14 are unpatentable as obvious over Goodman.

E. Asserted Obviousness of Claims 5 and 15 over Goodman and Hicks

Petitioner contends that claims 5 and 15 would have been obvious over Goodman and Hicks. Pet. 43–45. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because adding

Hicks's lens to Goodman would provide no discernable benefit, and one of ordinary skill in the art would have not been motivated to add Hicks's lens to Goodman. PO Resp. 41–48.

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 5 and 15 are unpatentable as obvious over Goodman and Hicks. We begin our analysis with a summary of Hicks, and then address the arguments presented by the parties.

1. Hicks (Ex. 1008)

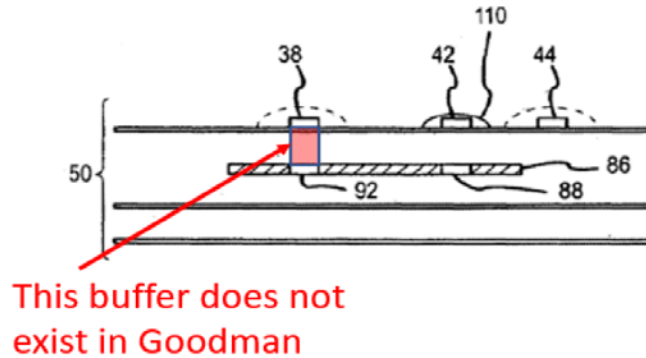
Hicks is directed to pulse oximetry sensors that can be used on fingers. Ex. 1008, 1:5–7, 8:3–8. Hicks discloses “a substantially clear flexible substrate that may be conformed about a portion of a patient's tissue, such as a finger . . . allowing for emitting and detecting light signals through this 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 the clear substrate may 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 fresnel lens, may be formed integrally into the clear substrate to provide light focusing. *Id.* at 9:38–42, 13:42–48.

2. Analysis

Claims 5 and 15 recite that “the light transmissive material comprises 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, 30:66–31:2, 32:14–17. 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. 43–44 (citing Ex. 1008, 9:38–40, 13:42–51). Petitioner contends that Goodman and Hicks are directed to non-invasive, optical bio-sensors and are from the same field of endeavor. *Id.* at 43 (citing Ex. 1003 ¶ 99). Petitioner also alleges that a person of ordinary skill would have understood “that it is important to guide or focus the light so that it exits the light source window, transmits across the flesh, and enters the photo-sensor window,” and further that “one well-known way of controlling or diminishing the effect of light refraction is by using a lens.” *Id.* (citing Ex. 1003 ¶¶ 99, 100). Petitioner then asserts that “[t]his would have logically led a [person of ordinary skill in the art (POSA)] to Hicks, which discloses a similar device and discloses using a lens to focus the light emitted by the emitters.” *Id.* (citing Ex. 1008, 13:44–45; Ex. 1003 ¶ 100). Petitioner avers that “Hicks describes that a separate lens structure may be utilized in conjunction with the clear substrate [of Goodman] ‘to allow the light emitting from the LED 40 to be concentrated into a more unidirectional light beam.’” *Id.* at 44 (citing Ex. 1008, 13:42–51). Petitioner also argues that the combination of Hicks’s lens structure with Goodman’s clear polyester 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 Goodman’s

similar device. *Id.* at 44 (citing Ex. 1003 ¶ 101). As such, Petitioner contends that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Goodman and Hicks. *Id.*

Patent Owner argues that there is no benefit to adding the lens of Hicks to Goodman because Goodman's device is already properly directed and focused. PO Resp. 42 (citing Ex. 1007, 4:59–62; Ex. 1008, 13:42–45; Ex. 2007 ¶ 113). Patent Owner asserts that one of ordinary skill in the art would have understood that a transmittal-type PPG like Goodman benefits from having unfocused light (citing Ex. 1005, 31), and, therefore, would not have wanted to add a lens. *Id.* at 42–43. Patent Owner further asserts that adding a lens in Goodman may “cause many problems.” *Id.* at 43. Among the problems alleged are 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, make the device more susceptible to disturbances, decrease its ability to cutaneously conform to the skin, make the device more expensive and decrease its disposability, and, finally decrease blood flow by adding pressure from the lens. *Id.* at 43–46. Patent Owner additionally asserts that one of ordinary skill in the art would not have modified Goodman to add Hicks's lens because it lacks Hicks's reason for having a lens. *Id.* at 46–47. Patent Owner argues that, because Hicks has a thermally insulative buffer, it needs a separate lens structure, and Goodman has little space between the light source and the skin so there is no reason for Hicks's lens. *Id.* at 46–48. Patent Owner provides its own depiction, with an annotated version of Figure 6 of Hicks reproduced below.



Ex. 1008, Fig. 6 (excerpted and annotated); Titus Dec. at ¶ 120.

Patent Owner’s annotations of Figure 6 of Hicks, depicted above, are disputed by Petitioner as a mischaracterization because Figure 6 is an “exploded cross sectional view,” and the buffer as depicted will 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, reproduced below.

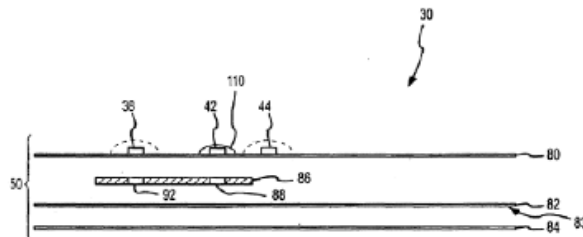


FIG.6

APL1008, Figure 6

Petitioner asserts that because, as assembled, foam layer 86 and clear substrate 80 of Figure 6 above (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 19–20 (citing Ex. 1008, 8:40–45; Ex. 1102 ¶ 27).

Petitioner's obviousness analysis, as supported by Dr. Anthony's Declaration, demonstrates where each limitation of challenged claims 5 and 15 is taught in Goodman and Hicks. Pet. 43–45; Ex. 1003 ¶¶ 98–101. 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 sufficiently persuasive rationale for combining the teachings of Goodman 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 Goodman'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 Goodman'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). Hicks and Goodman’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 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 ¶ 33. Moreover, 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. 42–43 (quoting Ex. 1005, 31). Finally, Patent Owner 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 determine Petitioner has shown by a preponderance of the evidence that claims 5 and 15 are unpatentable as obvious over Goodman and Hicks.

*F. Asserted Obviousness of Claims 6 and 16 over
Goodman, Hannula, and Asada and Claims 8, 9, 18, and 19 over Goodman
and Asada*

Petitioner contends that claims 6 and 16 would have been obvious over Goodman, Hannula, and Asada, and claims 8, 9, 18, and 19 would have been obvious over Goodman and Asada. Pet. 45–55. In its Response, Patent Owner contends that Petitioner did not consider the asserted prior art references as a whole and the rationale to combine the references is based upon faulty premises. PO Resp. 48–66.

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 6 and 16 are unpatentable as obvious over Goodman, Hannula, and Asada, and claims 8, 9, 18, and 19 are unpatentable as obvious over Goodman and Asada. We begin our analysis with a summary of Hannula and Asada, 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:

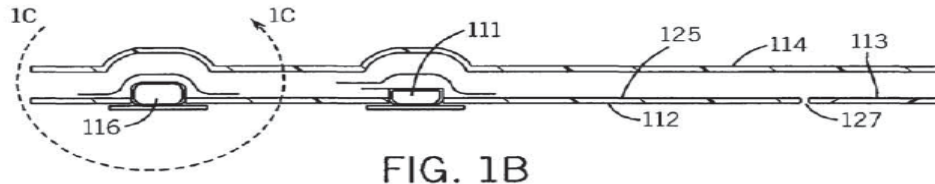


FIG. 1B

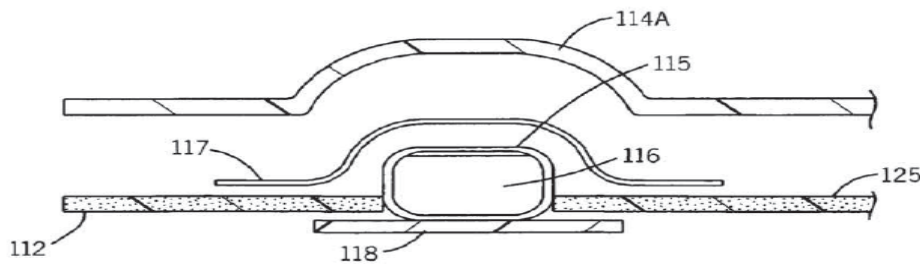


FIG. 1C

Figures 1B and 1C depict a cross-section and a detailed view, respectively, of an embodiment of the sensor. Ex. 1009, 2:26–32. 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 can be made of polyester or polypropylene with a reflective metal surface. *Id.* at 2:58–59, 2:66–3:3, Figs. 1B and 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. 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.

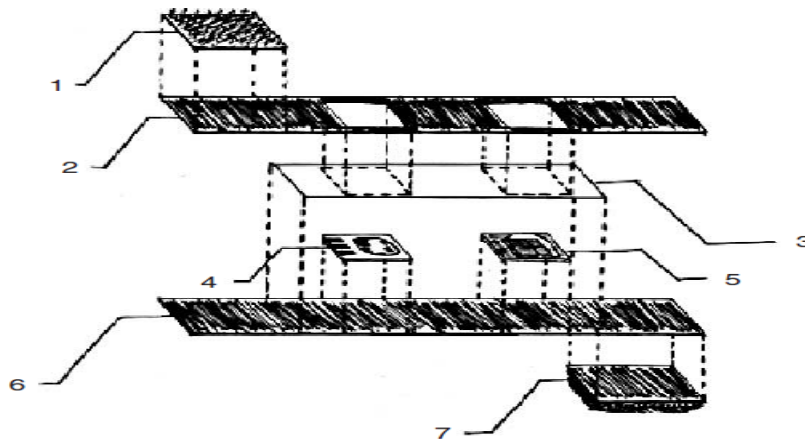


Figure 11 of Asada depicts a ring sensor band that protects optical components and hides wires from the outside environment. Ex. 1005, 35. The ring prototype configuration uses bands to hold the sensor unit and secure contact with the skin, as well as shield the unit. *Id.* at 34.

3. Analysis

Claims 6 and 16 recite the limitation of “a light reflective material on at least a portion of one or both of the inner and outer surfaces of the inner layer, wherein the 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 detector is processed by the signal processor as a motion

noise reference.” Ex. 1001, 31:3–10, 32:19–25. 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. Pet. 45–46. Petitioner also contends that Asada is from the same field of endeavor as Goodman and Hannula, that is, they are directed to non-invasive optical bio-sensors. *Id.* at 47. 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 “measur[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 47–48 (citing Ex. 1003 ¶ 108; Ex. 1005, 30; also citing Ex. 1005, 32–33, 37, Figs. 6 and 15). 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 48 (citing Ex. 1007, 2:33–35, Ex. 1003 ¶¶ 109, 110). 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 ¶ 107. 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.* ¶ 110. As such, Petitioner avers that it

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would have been obvious to a person of ordinary skill in the art to combine the teachings of Goodman, Hannula, and Asada. Pet. 48.

Claims 8 and 9 recite, respectively, that the monitoring device has “signal processor” and “a transmitter configured to transmit signals processed by the signal processor to a remote device.” Ex. 1001, 31:24–29. Claims 18 and 19 recite similar respective limitations. *Id.* at 32:39–44. Petitioner asserts that Asada teaches the use of signal processing and bidirectional RF communication, with transmission to a cellular phone through an RF link. Pet. 54–55 (citing Ex. 1005, 34).

Petitioner’s obviousness analysis, as supported by Dr. Anthony’s Declaration, demonstrates where each element of the challenged claims is taught in the prior art. Pet. 44–45; Ex. 1003 ¶¶ 105–118. Additionally, adequate rationale is provided to support the combination of the prior art references. We agree with and adopt Petitioner’s analysis and Dr. Anthony’s testimony.

Patent Owner argues that, when Goodman, Hannula, and Asada are viewed as a whole, one of ordinary skill in the art would have known that they were not combinable. PO Resp. 48. 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 49. 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 50–51 (citing Ex. 2007 ¶¶ 125, 126). 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

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the skin, whereas Asada reduces motion artifacts via a second photodetector to filter noise. *Id.* at 51 (citing Ex. 2007 ¶ 127). 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.* 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 61–64.

Patent Owner also argues that Petitioner’s premise for combining Goodman and Asada is faulty. PO Resp. 57. 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.* (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 ¶ 136). Patent Owner argues, therefore, that there would have been no perceived need to seek out Asada for reduction of motion artifacts. *Id.* at 57. 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 ¶ 136). 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.* at 57–58 (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 58–59. Patent Owner

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contends that one of skill in the art would recognize 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 58–59 (citing Ex. 2007 ¶ 138).

Patent Owner 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. 52–54. 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 and bases its discussion on a nasal septum application with high blood flow. *Id.* at 54–55 (citing Ex. 1007, 6:51–63; Ex. 2007 ¶ 132). 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 55.

We do not find Patent Owner’s arguments regarding insufficient support for the rationale to combine the prior art references to be persuasive. Dr. Anthony’s opinion that one of ordinary skill in the art would have sought to combine Goodman, Asada, and Hannula 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 finally identifies that the improvements would perform predictably in combination. *See* Pet. 45–48; *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.

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If this leads to the anticipated success, it is likely the product [was] not of innovation but of ordinary skill and common sense.”) 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.

Moreover, although Patent Owner argues that Asada’s use in every-day use should be distinguished from Goodman’s use in patient treatment, Asada also discloses the utility of wearable sensors “[f]or hospital inpatient 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. *See* Tr. 54:25–55:5 (referring to Ex. 1005, 28, 35).

Turning to the alleged faulty premises 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 in the art would not have been led to Asada because Goodman is described to have eliminated motion artifacts. 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 26 (citing Ex. 1006, 2:17–27; Ex. 1102 ¶ 38); *see also* Ex. 1003 ¶ 35. 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.¹⁰ 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.¹¹ *See* Tr. 24–25. 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

¹⁰ 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.

¹¹ Patent Owner argued at oral hearing: “Then they [Petitioner] say that you might have motion artifacts due to inertial movement. But they forget that 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.

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, we do not find persuasive Patent Owner's arguments that one of skill would not look to Asada due to alleged issues of increased mass and motion artifacts, reduced disposability, reduced skin conformance, and wireless unreliability. 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 ¶ 39; 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.”)

Finally, as to the combination of Hannula with Goodman and Asada, we do not discern 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

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Hannula. *See* Pet. Reply 23–24 (citing PO Resp. 55, Ex. 1003 ¶ 35; Ex. 1102 ¶ 35; 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 in comparison to Dr. Titus’s testimony that the use of the reflective surface would “increase the probability of applying pressure.” *Compare* Ex. 1102 ¶ 36 *with* Ex. 2007 ¶ 134. Additionally, we are not persuaded 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. 45–46.

For the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that claims 6 and 16 would have been obvious over Goodman, Hannula, and Asada, and claims 8, 9, 18, and 19 would have been obvious over Goodman and Asada.

G. Asserted Obviousness of Claims 10 and 20 over Goodman and Delonzor

Petitioner contends that claims 10 and 20 would have been obvious over Goodman and Delonzor. Pet. 43–45. In its Response, Patent Owner contends that Petitioner fails to demonstrate obviousness because one of ordinary skill in the art would have not been motivated to import “light blocking material” of Delonzor into Goodman. PO Resp. 66.

We have reviewed the arguments and evidence provided by Petitioner, and, taking into account the arguments presented in the Patent Owner Response, Petitioner has demonstrated by a preponderance of the evidence that claims 10 and 20 are unpatentable as obvious over Goodman and

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

1. Delonzor (Ex. 1010)

Delonzor discloses pulse oximeter sensors, with elements “preventing the shunting of light between the emitter and detector without passing through blood-perfused tissue.” Ex. 1010, 1:6–9. Delonzor describes problems associated with ambient light which can distort the signal at the photodetector, as well as shunting of light directly from the photo-emitter to the photodetector. *Id.* at 1:39–45. Delonzor describes different types of “shunt barriers” (e.g., fiber material, perforations or air gaps, and opaque material) that may be included in the sensor devices to block light transmission directly from the emitter to the detector. *Id.* at 3:7–48.

2. Analysis

Claim 10 recites a monitoring device 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, 31:30–36. Claim 20 contains a similar limitation. *Id.* at 32:48–51. The Petition asserts that Goodman and Delonzor are directed to optical biosensors. Pet. 56. Petitioner also asserts that Goodman describes shielding the photo-sensor and use of opaque vinyl tape (Ex. 1007, 9:13–16, 9:34–40), which would have suggested to a person of ordinary skill in the art “that it is undesirable to have extraneous light reaching the photo-sensor and that light blocking material is one way to shield the photo-sensor from unwanted light.” *Id.* (citing Ex. 1003 ¶ 119). Petitioner contends that this concern would have led a person of ordinary

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skill in the art to Delonzor, and its shunt barriers. *Id.* at 56–57 (citing Ex. 1010, 3:7–48).

As addressed in the Institution Decision, Patent Owner argued that Delonzor does not teach a light blocking material positioned between an optical emitter and an optical detector, so that the emitter and detector are not in direct optical communication with each other, and rather includes a “shunt barrier . . . between the first and second portions of the overlying layer to substantially block transmission of radiation of the wavelengths emitted by the emitter(s).” Dec. 25. Although Delonzor discloses shunt barriers, as described by Patent Owner, Delonzor also describes embodiments that would result in the emitter and detector not being in direct optical communication with each other. *See, e.g.*, Pet. 56–57; Ex. 1010, 3:44–48.

Patent Owner also argues that one of ordinary skill in the art would not have been motivated to modify Delonzor to include its “light blocking material,” because it would add mass, reduce skin conformance, and add tissue pressure, which allegedly will cause motion artifact in Goodman, as well as add cost that and would decrease Goodman’s disposability. PO Resp. 66 (citing Titus Ex. 2007 ¶ 150). This argument is similar to that presented, *supra* Section II.F, and, we are not persuaded by it for similar reasons discussed above, that is, we do not find that the alleged disadvantages rise to the level of deterring the combination in light of evidence indicating the advantage of the modification of shielding the photo-sensor from unwanted light and the predictability of the modification suggested by an optical biosensor device.

For the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that claims 10 and 20 are unpatentable as obvious over Goodman and Delonzor.

H. Conclusion

For the foregoing reasons, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–6, 8–16, and 18–20 would be unpatentable under § 103(a) under all asserted grounds.

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. 1110; Paper 41, 2. Many of the issues raised in this proceeding overlap with objections raised in Case IPR2017-00318. 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. 1110. 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

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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. 1110, 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 Arkane 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 some 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 1–6, 8–16, and 18–20 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

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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).¹² 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 number of substitute claims; and (4) the original disclosure sets forth written description support for each proposed claim. *See* 37 C.F.R. § 42.221.

A. Proposed Substitute Claims

Patent Owner proposes substitute claims 21–38 in its Motion to Amend, with claims 21 and 33 being independent (corresponding to original independent claims 1 and 11, respectively). *See* Mot. 1–2, Claim Listing at 27–38. 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

¹² The guidance memorandum is publicly available at https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf.

claims are responsive to a ground of unpatentability involved in the proceeding. *Id.*

Proposed substitute claim 21 is representative of the proposed substitute independent claims, and is reproduced below, with strike-through material indicating deleted language and underlined material indicating language added to original claim 1.

21. ~~The monitoring device of claim 1,~~ A monitoring device configured to be attached to the body of a subject, comprising:

an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces;

a base secured to at least one of the outer and inner layers and comprising at least one optical emitter and at least one optical detector and at least one motion sensor;

a layer of cladding material near the outer surface of the inner layer; and

at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject, wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector, wherein the light transmissive material is configured to deliver light from the at least one optical emitter to the body of the subject along a first direction and to collect light from the body of the subject and deliver the collected light in a second direction to the at least one optical detector, wherein the first and second directions are substantially parallel;

wherein the base comprises a signal processor configured to receive and process signals produced by the at least one optical detector and the motion sensor to (i) reduce footstep motion artifacts from the at least one optical detector during running by the subject and (ii) extract physiological and motion parameters.

Mot. 3, Claims Listing at 32–33.

B. Unpatentability Analysis

1. Obviousness of Substitute Claims

We determine, based on a preponderance of the evidence, that substitute claims 21–38 are unpatentable under 35 U.S.C. § 103(a). We discuss the obviousness issues related to the specific claims in turn.

i. Claims 21–24, 27, 28, 30–33, 36, and 37

As discussed *supra* Section II.D, Petitioner has shown by a preponderance of the evidence that independent claims 1 and 11 are unpatentable under 35 U.S.C. §103(a) as obvious over Goodman. Substitute claims 21 and 30 contain all of the limitations of original claims 1 and 11 and add a limitation that modifies the base to further comprise a motion sensor and a signal processor. *See* Claim Listing at 32–33. Petitioner asserts that Goodman does not disclose or teach the additional limitations, but Han does so. *Opp.* 3–4. Petitioner, therefore, asserts that substitute claims 21–24, 27, 28, 30–33, 36, and 37 would have been obvious over the combined teachings of Goodman and Han. *Id.* at 3–19.

Petitioner argues that it would have been obvious to modify Goodman with Han because, although Goodman seeks to reduce differential-based motion artifacts by the use of a low mass sensor that conforms to the skin, another source of motion artifacts is inertia-caused that “alters the amount of light transmitted through the blood and ultimately detected by the sensor.” *Opp.* 7–8 (citing Ex. 1007, 1:44–56, 3:23–25, 3:57–63, 4:30–36; Ex. 1006, 2:17–27). Petitioner asserts that Goodman’s techniques for conforming the sensor to the skin would not be effective at reducing inertia-based motion artifacts, so a person of ordinary skill in the art would have looked to mechanisms to reduce these artifacts. *Id.* at 8 (citing Ex. 1103 ¶¶ 43, 44).

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Petitioner asserts that Goodman recognizes that motion artifacts cause distortion in the sensor signal. *Id.* (citing Ex. 1007, 2:54–66). Petitioner argues that the use of a motion sensor to measure motion and a signal processor to reduce inertia-based motion artifacts in a PPG signal based on the measured motion were conventional techniques known well prior to the '830 patent, and Han discloses these types of techniques. *Id.* (citing *e.g.*, Ex. 1006, 4:40–66; Ex. 1103 ¶ 44). With this, Petitioner asserts that a person of ordinary skill in the art would have had reason to modify Goodman's sensor to include Han's accelerometer and filters which would be capable of reducing inertia-bases motion artifacts. *Id.* at 8–9 (citing Ex. 1103 ¶ 45).

Petitioner also asserts that, in the Petition, Goodman's opaque vinyl strip 30, was mapped to the "base" of the claim, the claimed "outer layer" was mapped to Goodman's flexible tape layer (34), and the "inner/first layer" was equated to the clear polyester layer (45). *Opp.* 10 (citing Ex. 1003 ¶¶ 70, 72, 84, 85). The interpretation is modified to correspond to Goodman's flexible tape layer 34 to the claimed "base," opaque vinyl strip 30 is the "outer layer," and clear polyester layer 45 is the "inner/first layer." *Id.* at 11. Under this interpretation, Petitioner asserts that Goodman teaches the claim limitations of "a base secured to at least one of the outer and inner layers" and "a base secured to the first layer," as recited by substitute claims 21 and 30. *Id.* Petitioner further argues that Han's on-board electronics would be included as an attachment to Goodman's flexible tape 34 to reduce the impact of motion artifacts in the signal measured by Goodman's optical biosensor. *Id.* Petitioner contends that in the combined device, "Han's fourth order adaptive filter and digital filter would implement Han's active noise cancellation algorithm to reduce motion artifacts in the signal measured by Goodman's optical biosensor." *Id.* at 13 (citing Ex. 1103 ¶ 54).

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Petitioner avers that, when employed, Han’s “active noise cancellation algorithm is capable of removing artifacts from daily movement, including movements limited to the finger, all the way up to walking or running.” *Id.* at 14 (citing Ex. 1104, 1584; Ex. 1103 ¶ 54). With this, Petitioner argues that Goodman and Han teach or suggest the “wherein” limitation of proposed substitute claims 21 and 30. *Id.*

Patent Owner focuses on two aspects of Petitioner’s assertions to dispute obviousness: (1) an alleged lack of motivation to combine Goodman and Han; and (2) an alleged failure of the art to teach the proposed amended limitation of reducing footstep motion artifacts during running. PO Reply 4–12. More specifically, Patent Owner argues that Goodman is directed to a device that is conformed to the skin for use in patients in intensive care, thus, for use with patients with limited motion and mobility, directed to not disturbing patient blood flow as applied, where the device “is entirely disposable” and low cost. *Id.* at 5 (citing Ex. 1007, 5:3–6, 5:56–68, 6:22–23; Ex. 2151 ¶ 9). Patent Owner alleges that Han’s device “is composed of a number of components with a larger mechanical structure to secure it to the finger, and a battery for power.” *Id.* at 6 (citing Ex. 1104, 1582; Ex. 2151 ¶ 10). Patent Owner also contends that hand and finger motion is used to simulate running in Han, and filtering appears to be done on a remote computer. *Id.* at 6–7 (citing Ex. 1104, 1582–84; Ex. 2151 ¶¶ 11–12). Patent Owner argues that one of ordinary skill in the art would not be motivated to combine Han with Goodman because Han’s device “adds significant complexity, size, weight and mass, all of which defeat Goodman’s intended form and function,” and, in particular, “adding mass and a high aspect ratio creates the problem that Goodman is trying to solve.” *Id.* at 7–8 (citing Ex. 1007, 2:54–68; Ex. 2151 ¶¶ 13–14). Patent Owner also

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contends that “the size, weight, and costs of the additional components of Han would defeat the purpose of the flexible and disposable device of Goodman,” and a person of ordinary skill would find that “Goodman teaches away from a circumferential device such as a ‘tight’ ring.” *Id.* at 8–9 (citing Ex. 1104, 1581–82; Ex. 2151 ¶ 15).

Patent Owner also argues that the combination of Goodman and Han does not teach the newly-added final claim limitation of claims 21 and 30 because Petitioner fails to address a reduction in footstep motion artifacts during running. PO Reply 10–11. Patent Owner alleges that artifacts of running, which are alleged to be different than those of walking and jogging, are not addressed in Han as it “only discloses finger and/or hand waving without either ever contacting a surface.” *Id.* at 11 (citing Ex. 2151 ¶ 18). Dr. Titus refers to Han’s testing using hand motions testing, and testifies that the “Han device has not demonstrated in theory or practice to be capable of reducing footstep motion artifacts.” Ex. 2151 ¶ 11.

We find that substitute independent claims 21 and 30 are not patentable by a preponderance of the evidence based on the entirety of the record. The evidence sufficiently supports that the art teaches all of the limitations of the claims 21 and 30, and the rationale to combine Goodman and Han is supported by the evidence of record. *See* Opp. 3–19. Petitioner’s expert provides testimony explaining that Goodman and Han are similar in structure, function, and design and one of skill in the art would have had reason to add the motion artifacts reduction features taught in Han. *See id.* at 7–9. Patent Owner’s arguments on the combination of Goodman and Han are directed to teaching away, that is, that one of skill in the art would have been dissuaded from the combination because Goodman is conformed to the skin for use in patients in intensive care and is for use with patients with

limited motion and mobility, it is directed to not disturbing patient blood flow as applied, and the device “is entirely disposable” and low cost.

However, Han indicates that it “should be small and light and attach to [the] body tightly to reduce noise effect and feel comfortable to wear,” (Ex. 1104, 1581–1582), which supports Petitioner’s expert’s testimony that a person of ordinary skill in the art would have had reason to integrate Han’s components into Goodman’s device with minimal drawbacks and with predictable results. *See* Ex. 1111 ¶¶ 10, 11.

As to the “wherein” limitation of substitute claims 21 and 30, we are not persuaded by Patent Owner’s argument that “[r]unning is different from walking and jogging,” and Han fails to teach “reduc[ing] footstep motion artifacts from the at least one optical detector during running by the subject.” *See* Claim Listing 32–33. Han discloses the use of a digital filter that processes a measurable noise signal (x_k) from the accelerometer to produce body motion data (n_k), which is then subtracted from the body motion corrupted signal (d_k) to produce the reconstructed raw pulsation signal (\hat{s}_k), and then employs a fourth order adaptive filter and a motion artifact reduction algorithm, so that, as Han states, “[w]hen employed, the active noise cancellation algorithm is capable of removing artifacts from daily movement, including movements limited to the finger, all the way up to walking or running.” *Opp.* 5–6 (citing Ex. 1104, 1582–84). Han’s teachings disclose the reduction of motion artifacts generally, which could include those due to footsteps. Additionally, Petitioner’s expert’s testimony that one of ordinary skill in the art would understand that the “during running” limitation disclosed in Han is supported under Han’s explicit disclosure of the removal of noise during running. *Ex.* 1111 ¶ 15.

Patent Owner identifies no additional distinctions related to substitute dependent claims 22–24, 27, 28, 31–33, 36, and 37. We have reviewed Petitioner’s assertions of obviousness related to these claims based upon Goodman and Han, and agree with and adopt Petitioner’s analysis, as supported by Dr. Anthony’s testimony. *See* Opp. 3–19.

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 21–24, 27, 28, 30–33, 36, and 37 would have been obvious based on the combined teachings of Goodman and Han.

ii. Claims 25 and 34

Substitute claims 25 and 34 correspond to the original dependent claims 5 and 15, respectively, and similarly add a limitation related to a lens region. *See* Claim Listing 34, 37. Petitioner asserts that claims 25 and 34 are obvious over Goodman, Han, and Hicks. Opp. 19–20. Petitioner further contends that Hicks teaches the limitation related to the lens region for reasons similar to that presented in the Petition related to the original corresponding claims. *Id.*

We have reviewed Petitioner’s assertions of obviousness related to these claims based upon Goodman, Han, and Hicks and agree with the analysis in light of the supporting evidence for similar reasons to those discussed, *supra* Section II.E. Patent Owner presents no additional issues or arguments specifically related to substitute dependent claims 25 and 34. *See* PO Reply 4–12.

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 25 and 34 would have been obvious based on the combined teachings of Goodman, Han, and Hicks.

iii. Claims 26 and 35

Substitute claims 26 and 35 correspond to the original dependent claims 6 and 16, respectively, and similarly add a limitation related to a reflective light material addition. *See* Claim Listing 34–37. Petitioner asserts that claims 26 and 35 are obvious over Goodman, Han, Hannula, and Asada. *Opp.* 20–24. Petitioner further contends that Hannula teaches the limitation related to the reflective material for reasons similar to that presented in the Petition related to the original corresponding claims. *Id.*

We have reviewed Petitioner’s assertions of obviousness related to these claims based upon Goodman, Han, Hannula, and Asada and agree with the analysis in light of the supporting evidence for similar reasons to those discussed, *supra* Section II.F.¹³ Patent Owner presents no additional issues or arguments specifically related to substitute dependent claims 26 and 35. *See* PO Reply 4–12.

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 26 and 35 would have been obvious based on the combined teachings of Goodman, Han, Hannula, and Asada.

¹³ As discussed below, Section IV.C, Petitioner asserts, and we agree, that claims 26 and 35 are unclear because it is uncertain whether “a signal processor” of these claims is the same “signal processor” as that in independent claims 21 and 30. For the purposes of the obviousness evaluation, we have interpreted “a signal processor” in these claims as the same “signal processor” as that in the independent claims.

iv. Claims 29 and 38

Substitute claims 29 and 38 correspond to original dependent claims 10 and 20 and similarly add a limitation related to the addition of light blocking material. *See* Claim Listing 35, 38. Petitioner asserts that claims 29 and 38 are obvious over Goodman, Han, and Delonzor. *Opp.* 24–25. Petitioner further contends that the limitations are taught in the prior art for reasons similar to those presented in the Petition for the original corresponding claims. *Id.*

We have reviewed Petitioner’s assertions of obviousness related to these claims based upon Goodman, Han, and Delonzor and agree with the analysis in light of the supporting evidence for similar reasons to those discussed, *supra* Section II.G. Patent Owner presents no additional issues or arguments specifically related to substitute dependent claims 29 and 38. *See* PO Reply 12.

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 29 and 38 would have been obvious based on the combined teachings of Goodman, Han, and Delonzor.

B. Overbroadening of Substitute Claims

Patent Owner’s substitute claims 24 and 33, which substitute for original claims 4 and 14, respectively, delete the claim limitation “layer comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.”¹⁴ *See* Mot. 10, 13; Claim

¹⁴ In Patent Owner’s Conditional Motion to Amend, the revisions to claim 24 consistently reflect the deletion of the “layer” limitation within the body of the Motion (*see* Mot. 10), as well as in its Claim Listing (*see id.* at 34).

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Listing 34, 36–37. Patent Owner asserts that the substitute claims narrow the scope of the challenged claims being replaced, by the dependence from independent claims that have been narrowed. *See* Mot. 4. Patent Owner also asserts that an additional limitation of “at least one optical detector is a PPG sensor” has been added to the claims. *Id.*

We find that Patent Owner impermissibly broadens substitute claims 24 and 33. Under 37 C.F.R. § 42.221(a)(2), a proposed substitute claim is not responsive to an alleged ground of unpatentability of a challenged claim if it does not include or narrow each feature of the challenged claim being replaced. *See, e.g., Square, Inc. v. Protegrity Corp.*, Case CBM2014-00182, slip op. at 41–42 (PTAB Mar. 2, 2016) (Paper 60). Here, Patent Owner seeks to impermissibly delete the “layer” limitation from substitute claims 24 and 33.

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 claims 24 and 33.

C. Indefiniteness of Substitute Claims

Petitioner asserts that substitute claims 26 and 35 are indefinite under 35 U.S.C. § 112 because the claims recite “a signal processor” and “it is unclear whether it is the same or a different signal processor than recited

For claim 33, the Motion indicates a deletion of the same limitation as that reflected in claim 24 in a part of the Motion (*see id.* at 13), but the deletion in claim 33 is not reflected in the version in the Claim Listing (*see id.* at 36–37). It appears that Patent Owner’s intent was to also include the same version of claim 33 in the Claim Listing as that in the body of the Motion, and our evaluation is, therefore, based on claim 33 with the “layer” limitation deleted.

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earlier in claims 21 and 30 from which claims 26 and 35, respectively, depend.” Opp. 3.

We agree with Petitioner that it is unclear whether the “signal processor” is the same or a different signal processor in claims 26 and 45, as it is in claims 21 and 30. Thus, the proposed substitute claims use claim 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 26 and 35 do not comport with 35 U.S.C. § 112.

D. Failure to Respond to Any Instituted Ground

Petitioner asserts that the Motion to Amend does not respond to the ground of unpatentability involved in the trial as required, and the Patent Owner does not meaningfully address the instituted grounds, with no detailed discussion of the trial prior art references, and general statements that the art does not disclose a particular limitation is not a sufficiently detailed response. (Opp. 1–2). Patent Owner asserts that it reviewed identified art, including the art of record in the proceeding, and that “[t]he Substitute Claims are independently patentable over the prior art because the prior art does not disclose or suggest the features they added in this motion.” Mot. 17–23; *see also* Tr. 47:20–48:23. More specifically, Patent Owner refers to the final limitation of the “signal processor” and its functions that were added to the substitute independent claims as the differentiating limitation over the applied art. *Id.* at 23–24. Although we do not place the burden of persuasion on the Patent Owner, Patent Owner’s conclusory

statement provides no detailed information as to how the proposed claim amendments distinguish over the art applied in the challenges on which we instituted *inter partes* review. Patent Owner’s silence, however, does not preclude Petitioner from addressing the challenges on which we instituted trial, which we have discussed above.

E. Conclusion

Accordingly, we determine based on a preponderance of the evidence that proposed substitute claims 21–38 are unpatentable for the reasons discussed above. We, therefore, deny Patent Owner’s Motion to Amend with respect to the proposed substitute claims.

V. PROCEDURAL ISSUES

Patent Owner also objects to the constitutionality of this *inter partes* review. PO Resp. 67 (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 conclude Petitioner has demonstrated by a preponderance of the evidence, that the challenged claims of the ’830 patent are unpatentable based on the following grounds:

Claims	Basis	Reference(s)
1–4, and 11–14	§ 103	Goodman

Claims	Basis	Reference(s)
5 and 15	§ 103	Goodman and Hicks
6 and 16	§ 103	Goodman, Hannula, and Asada
8, 9, 18, and 19	§ 103	Goodman and Asada
10 and 20	§ 103	Goodman and Delonzor

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 24, 26, 33, and 35; and (2) the preponderance of the evidence based on the entirety of the record demonstrates that proposed substitute claims 21–24, 27, 28, 30–33, 36, and 37 are unpatentable as obvious under 35 U.S.C. § 103(a) over the combined teachings of Goodman and Han, that proposed substitute claims 25 and 34 are unpatentable as obvious under 35 U.S.C. § 103(a) over the combined teachings of Goodman, Han, and Hicks, that proposed claims 26 and 35 are unpatentable as obvious under 35 U.S.C. § 103(a) over the combined teachings of Goodman, Han, Hannula, and Asada, and that proposed substitute claims 29 and 38 are unpatentable as obvious under 35 U.S.C. § 103(a) over the combined teachings of Goodman, Han, and Delonzor.

VII. ORDER

Accordingly, it is

ORDERED that claims 1–6, 8–16, and 18–20 of the '830 patent are determined to be *unpatentable*;

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

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.

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