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Paper No. 45
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC. and FITBIT, Inc.,
Petitioner

v.

VALENCELL, INC.,
Patent Owner

Case IPR2017-00315
Patent 8,929,965 B2[1]

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

McNAMARA, *Administrative Patent Judge*.

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

[1] Case IPR2017-01552 has been joined to with this proceeding

BACKGROUND

On June 2, 2017, we instituted an *inter partes* review of all challenged claims (claims 1–12) of U.S. Patent No. 8,929,965 B2 ("the '965 patent"). Paper 9 ("Dec. to Inst."). Valencell, Inc. (Patent Owner) filed a Patent Owner Response (Paper 21, "PO Resp."), and Petitioner (Apple, Inc.) filed a Petitioner Reply (Paper 28, "Pet. Reply"). On December 1, 2017, we joined *Fitbit, Inc. v. Valencell, Inc*., IPR2017-01552, with this proceeding. Paper 12 in IPR2017-01552. Petitioners Apple, Inc. and Fitbit, Inc. are identified herein collectively as "Petitioner."

Patent Owner filed a Contingent Motion to Amend (Paper 22, "Mot. To Amend"), Petitioner filed an Opposition to Patent Owner's Motion to Amend (Paper 29, "Opp. To Mot. To Amend"), Patent Owner filed a Reply to Petitioner's Opposition (Paper 30, "Reply to Opp. to Mot. To Amend"), and, pursuant to our having granted leave, Petitioner filed a Surreply ("Paper 32 "Surreply).

Petitioner filed a Motion to Exclude (Paper 36, "Mot. To Exclude"), Patent Owner filed an Opposition (Paper 38 "Opp. To Mot. To Exclude"), and Petitioner filed a Reply to Patent Owner's Opposition (Paper 39, Reply to Opp. To Mot. To Exclude").

A transcript of an oral hearing held on February 27, 2018 (Paper 44, "Hr'g. Tr.") has been entered into the record.

Testimony of record includes the Declaration of Dr. Majid Sarrafzadeh In Support of the Petition (Ex. 1003, "Sarrafzadeh Decl."), the Declaration of Dr. Majid Sarrafzadeh in Support of Petitioner's Opposition to Patent Owner's Motion to Amend (Ex. 1017, "Sarrafzadeh MTA Decl."), the Declaration of Gerard Grenier (Ex. 1052 "Grenier Decl."), the transcript

of the deposition of Dr. Luca Pollonini (Ex. 1077 "Pollonini Dep. Tr."), the Declaration of Dr. Luca Pollonini In Support of the Patent Owner Response (Ex. 2009 "Pollonini Decl."), the transcript of the deposition of Dr. Majid Sarrafzadeh (Ex. 2010, "Sarrafzadeh Dep. Tr."), the Declaration of Steven LeBoeuf In Support of the Patent Owner Response (Ex. 2023, "LeBoeuf Decl."), the Declaration of Dr. Luca Pollonini In Support of Patent Owner Motion to Amend (Ex. 2014, "Pollonini MTA Decl."), the Supplemental Declaration of Dr. Luca Pollonini In Support of Patent Owner's Motion to Amend (Ex. 2139 "Pollonini Suppl. MTA Dec."), the Declaration of Dr. Steven LeBouef In Support of Patent Owner's Reply In Support of Its Conditional Motion to Amend (Ex. 2040, "LeBoeuf Suppl. Decl."), and the Declaration of Sung Il Paik In Support of Patent Owner's Reply In Support of its Conditional Motion to Amend (Ex. 2014, "Paik Decl.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. §318(a). We base our decision on the preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

Having reviewed the arguments of the parties and the supporting evidence, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are unpatentable. We also deny Patent Owner's Contingent Motion to Amend.

THE '965 PATENT (EXHIBIT 1001)

The '965 patent discloses a sensor module for detecting and measuring physiological information using a first light guide to deliver light from an optical emitter to a portion of a subject body and a second light guide to collect light from the subject body and deliver it to an optical detector. Ex. 1001, Abstract. The '965 patent states that optical coupling

may be the interaction between an optical emitter within an earbud and the light guiding region of the earbud, such that the earbud generates an optical signal related to blood flow through blood vessels. *Id.* at 16:26–29. According to the ’965 patent, it has been discovered that, in the anatomy of the human ear, photoplethysmography (PPG)[2] signals are strongest near the antitragus, tragus, lobule, and portions of the acoustic meatus, and the ear canal, with the antitragus being a particularly attractive location for photoplethysmography because a strong PPG signal can be derived with minimal motion artifacts associated with running and mouth motion. *Id.* at 25:48–55.

An example of an apparatus in the form of a headset is shown in Figure 1 of the ’965 patent, reproduced below.

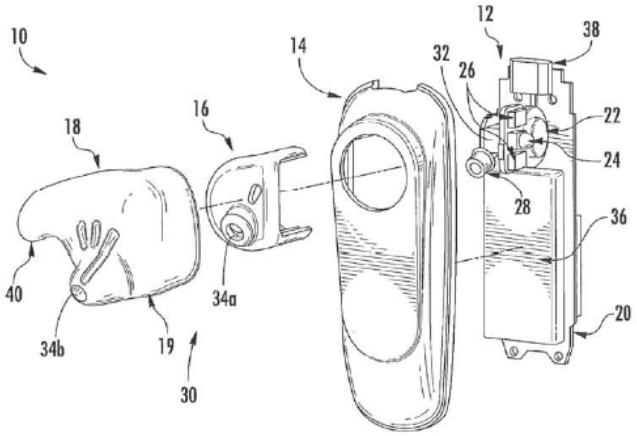


FIG. 1

Figure 1 of the ’956 Patent

[2] A plethysmograph is an instrument for determining and registering variations in the size of an organ or limb and in the amount of blood present or passing through it. WEBSTER’S NEW COLLEGIATE DICTIONARY, 833 (1977).

Figure 1 of the ’965 patent shows headset 10 including base 12, housing 14, main circuit board 20, secondary circuit board 32, speaker 22, apertures 34a and 34b through which sound can pass, optical emitter 24, optical detectors 26, earbud housing 16, and cover 18. *Id.* at 16:54–17:2, 51–56. Cover 18 includes light-transmissive material in light guiding region 19 that provides optical communication to deliver light to the ear canal of the subject from optical emitter 24 and to collect light for delivery to optical detectors 26. *Id.* at 17:66–18:9.

Figures 11A–12B illustrate sensor 70 near the earbud periphery and light guide extension 19a that serves as an additional light coupling region to improve skin contact between light guiding region 19 and the wearer’s skin. *Id.* at 26:27–41. Figure 12B also illustrates inertial sensors 27c that may be located on the earbud facing side of sensor module 70 and additional optical emitters 24a, 24b providing light that may be scattered off the earbud and detected by optical detectors 27d. *Id.* at 27:33–47. The optical scatter signal collected by detectors 27d provides a suitable noise reference for an adaptive filter to remove motion artifacts from the scattered light from the ear region, generating an output signal that is related primarily to blood flow. *Id.* at 27:50–57. The intensity, phase, and frequency of the scattered light reaching optical detectors 27d may be used to generate a measure of physical activity. *Id.* at 27:57–60. Figure 13 illustrates the basic configuration of an adaptive noise cancellation scheme for extracting from noise those physiological signals from which information, such as blood flow, heart rate, blood analyte levels, breathing rate or volume, blood oxygen levels, and the like may be calculated. *Id.* at 28:35–51. Noise

information may be post-processed to extract activity assessments, such as exertion, activity level, distance traveled, speed, step count, and the like. *Id.* at 28:51–63. The noise cancellation scheme may be integrated into firmware or a microprocessor. *Id.* at 28:63–64.

ILLUSTRATIVE CLAIM

Claims 1 and 12 are independent, and claims 2–11 depend directly or indirectly from claim 1. Independent claim 1, reproduced below is illustrative:

> 1. A sensor module for detecting and/or measuring physiological information from a subject, the sensor module comprising:
>
> a housing;
>
> at least one optical emitter supported by the housing;
>
> at least one optical detector supported by the housing;
>
> a first light guide supported by the housing, wherein the first light guide is in optical communication with the at least one optical emitter, wherein the first light guide comprises a distal end having an exposed end surface that is configured to engage a portion of a body of the subject, and wherein the first light guide is configured to deliver light from the at least one optical emitter directly into the body of the subject via the exposed end surface thereof; and
>
> a second light guide supported by the housing, wherein the second light guide is in optical communication with the at least one optical detector, wherein the second light guide comprises a distal end having an exposed end surface that is configured to engage a portion of the body of the subject, and wherein the second light guide is configured to collect light directly from the body of the subject via the exposed end surface thereof and deliver collected light to the at least one optical detector.

Id. at 40:8–31.

ART APPLIED IN PETITIONER'S CHALLENGES

Petitioner applied the following references in its challenges to patentability:

Reference	Designation	Exhibit No.
Japanese Patent Appl. Publication No. 2005/040261 A to Numaga *et al.*, published February 17, 2005	Numaga	Ex. 1009 Ex. 1010 (English Translation)
U.S. Patent Appl. Publication No. 2003/0065269 to Vetter *et al.*, published April 3, 2003	Vetter	Ex. 1011
U.S. Patent No. 6,702,752 to Dekker, issued March 9, 2004	Dekker	Ex. 1012
U.S. Patent Appl. Publication No. 2008/0081972 to Debreczeny, published April 3, 2008	Debreczeny	Ex. 1008
U.S. Patent No. 5,817,008 to Rafert *et al.*, issued October 6, 1998	Rafert	Ex. 1013
U.S. Patent Application Publication No. 2005/0212405 to Negley, published September 29, 2005	Negley	Ex. 1014

Reference	Designation	Exhibit
International Patent Appl. Publication No. 2005/036212 to Miao *et al.*, published April 21, 2005	Miao	Ex. 1015
U.S. Patent Appl. Publication No. 2005/0209516 to Fraden, published September 22, 2005	Fraden	Ex. 1006
U.S. Patent Appl. Publication No. 2003/0233051 to Verjus *et al.*, published December 18, 2003	Verjus	Ex. 1007
U.S. Patent Appl. Publication No. 2009/0105556 to Fricke *et al.*, published April 23, 2009	Fricke	Ex. 1016

Pet. vii.

GROUNDS OF INSTITUTION

In our Decision to Institute, we instituted trial on the following challenges to patentability:

Claims 1, 2, and 12 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga;

Claims 3 and 4 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Vetter;

Claim 5 as unpatentable as under 35 U.S.C. § 103(a) as obvious over Numaga in view of Vetter and in further view of Dekker;

Claims 6 and 7 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Debreczeny;

Claims 8 and 9 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Rafert;

Claim 10 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Negley;

Claim 11 as unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Miao;

Claims 1 and 8–12 as unpatentable under 35 U.S.C. § 102(b) as anticipated by Fraden;

Claims 2–4 as unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Verjus;

Claim 5 as unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Verjus and in further view of Fricke; and

Claims 6–7 as unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Debreczeny.

Dec. to Inst. 31–32.

CLAIM CONSTRUCTION

In our Decision to Institute, we applied the ordinary and customary meaning to the terms not construed. Applying the broadest reasonable interpretation we construed:

"physiological information" to mean "information about physical and/or psychological matter and energy of or from the body of a creature" (Dec. to Inst. 9);

"engage a portion of the body" to mean "contacting the skin or closely adjacent to the skin of a subject" (*id.* at 9–10);

"headset" to mean "any type of device or earpiece that may be attached to or near the ear of a user, including peripheral devices" (*id.* at 10);

"housing" as "one or more parts that covers, encloses, supports, or protects, [a] casing" (*id.*)

"light guide" to mean "a mechanism for delivering light along a path" (*id*);

"distal end" to mean "end opposite the proximal end." (*id.* at 10–11); and

"distal free end" to mean "an end opposite the proximal end of a light guide that may be used with many different parts of the body" (*id.* at 11–13).

In the Preliminary Response, Patent Owner proposed that "distal free end" be construed to mean the "end opposite of the proximal end that protrudes from the housing." Prelim. Resp. 20. We declined to adopt that proposed construction because it fails to distinguish the claimed "distal free end" from the claimed "distal end," which the Specification states is opposite the proximal end and may extend outward from the housing. Dec. to Inst. 13 (citing Ex. 1001, 6:58–63, 35:43–44). Arguing that our construction incorporates functional language, Patent Owner now contends that we should construe "distal free end" to mean "an end opposite the proximal end of a light guide that is unencumbered from the housing." PO Resp. 15.

According to Patent Owner, a person of ordinary skill would have understood the plain and ordinary meaning of the word "free" to mean "unencumbered" or "unfettered" from the base. *Id.* (citing Ex. 2009,

Pollonini Decl. ¶ 49). Patent Owner cites the Specification's description of "free end 119 C of the light guide 119" in Figure 26 and the description of "free end surface 119 C of the light guide 119" of Figure 31, as evidence that the distal end of these elongated light guides is unencumbered by the base, as distinguished by distal ends encumbered by the housing shown in Figures 24A and 34. *Id*. at 15–17. However, Patent Owner does not propose to limit the claimed "distal free end" to the ends of elongated light guides.

At oral hearing, Patent Owner circularly argued that the "distal *free* end" is "unencumbered or unfettered by the base" and stated "that's another way of saying that it's *free*, that it's not surrounded by the base." Hr'g. Tr. 20:16–21. When we declined to allow Patent Owner to argue the construction of "distal free end" based on a theory that it does not mean what the Numaga reference discloses, Patent Owner stated that "unencumbered" is not surrounded and is not "flush with the base." *Id.* at 20:25–21:15. Patent Owner also agreed that it is fair to define "unencumbered" as "not having any burden or impediment." *Id.* at 21:16–18. Thus, the construction of "distal free end" proposed in the Patent Owner Response effectively has the same meaning as that proposed by Patent Owner in its Preliminary Response, i.e., that the distal free end protrudes from the base. As discussed above, in the Decision to Institute we observed that the '965 patent states the "distal end" is opposite the proximal end and may extend outward from the housing, meaning that Patent Owner has failed to provide a construction that distinguishes the claimed "distal free end" from the claimed "distal end." Dec. to Inst. 13 (citing Ex. 1001, 6:58–63, 35:43–44).

Noting that claims 1 and 12 were amended simultaneously to add the above quoted claim language, Petitioner argues that there is no meaningful distinction between the distal end and distal free end. Pet. Reply 2–3.

Patent Owner criticizes our initial construction as incorporating into the term a functional limitation, i.e., that the light guide is free to "be used with many different parts of the body." PO Resp. 17. Patent Owner's argument fails to acknowledge, however, that the claims already recite functional language, i.e., the first and second light guides in claim 1 comprise "a distal end having an exposed end surface that *is configured to engage a portion of a body of the subject.*" (emphasis added). Claim 12 recites the same functional language describing the function of the "distal free end," i.e. the first and second light guides comprise "a distal *free* end having an exposed end surface that *is configured to engage a portion of the body*." (emphasis added). *Id.* at 41:14–16, 23–25; Ex. 1001, 40:16–19, 26–28. This recitation of the same functions performed by the configurations of the "distal end" and "distal free end" does not point to any physical characteristic that distinguishes the terms.

To the extent that there is any distinction between "distal end" and "distal free end," it lies in the configuration of the light guide end to engage the body. In our Decision to Institute, we noted that the Specification states that, referring to Figure 26, the Specification states that "the free end 119c of the light guide 119 may branch out to two or more 'legs' that may be used to couple with many different parts of the body." Dec. to Inst. 11–12 (citing Ex. 1001, 37:54–57). Hence, we construed the "free end" of a light guide, as that term is used in the Specification, to mean an end of the light guide that is "free for use with many different parts of the body" in contrast to a "distal

end," which is an end remote or opposite from a proximal end. *Id.*at 10–13. We recognize that this construction does not inform as to any difference between the physical structure of the "distal end" and the "distal *free* end." Indeed, as further discussed herein, the distinction between "distal end" and "distal free end" likely is not determinative of the issues in this proceeding. However, no other construction has been offered by either party that distinguishes the physical structure, and our construction is consistent with the description in the Specification.

In consideration of the above, consistent with our Decision to Institute, we construe the "distal free end" to mean "an end opposite the proximal end of a light guide that may be used with many different parts of the body." We also note, as discussed further herein, Petitioner's contention that under our construction *or* Patent Owner's construction, Numaga discloses the claimed "distal free end." Pet. Reply 12.

ANALYSIS OF PRIOR ART CHALLENGES

The Numaga-Based Challenges

Claims 1, 2, and 12 as Obvious Over Numaga

Numaga discloses pulse wave sensor 20 (shown in Figures 1(a) and (b)) as an improvement over conventional pulse wave sensor 20A (shown in Figures 2(a) and (b)). Ex. 1010 ¶¶ 2–6, 9–13. Numaga seeks to improve the sensitivity of a conventional, wrist-worn pulse wave sensor using a configuration that eliminates a light scattering acrylic board separating the light emitting and receiving devices from the wrist and allows the light emitting and light receiving surfaces to project outward and abut the wrist under test to directly touch the wrist. *Id.* at ¶¶ 7, 8. In Numaga, portions of the light emitting and light receiving devices, except for the light emitting

and receiving surfaces, are covered with a light shielding member, and the outer peripheries of the wrist side of the devices are covered by a shell support member. *Id.* at ¶¶ 3, 8, Fig. 2b. The shell support member maintains light shielding without the light shielding tube 26 used to cover the light guide 22b in conventional pulse wave sensor 20A. *Id.*

Claim 1

Petitioner cites Numaga as disclosing a wrist-worn pulse wave sensor that emits light directly onto a subject's wrist and detects the subject's pulse waves from light reflected by red corpuscles in the arteries. Pet. 18 (citing Ex. 1010 ¶ 1). Petitioner states that, as recited in claim 1 of the '965 patent, Numaga discloses a housing (case 23, enclosure adhesive 28, and shell support member 29) that encloses and supports an optical emitter (light emitting device 21 with a light emitting chip embedded on pedestal 21a), and an optical detector (light receiving device 22 with a light receiving chip embedded on pedestal 22a). Pet. 21 (citing Ex. 1010 ¶¶ 2, 9; Ex. 1003, Declaration of Dr. Majid Sarrafzadeh ("Sarrafzadeh Decl.") ¶ 54). We addressed these features of Numaga as disclosing the claimed housing, and optical emitter and optical detector by the housing. Dec. to Inst. 15. The Patent Owner Response does not dispute explicitly that Numaga discloses these elements. Instead, the parties' dispute centers on whether Numaga teaches or suggests the claimed first and second light guides.

Petitioner cites Numaga's "light guide part" 21b as disclosing the recited first light guide in optical communication with the optical emitter. Petitioner argues that light guide part 21b abuts pedestal 21a in light emitting device 21, and, although Numaga does not state explicitly that light guide part 21b is in optical communication with the light emitter, such optical communication is apparent. Pet. 22 (citing Ex. 1010 ¶¶ 2, 10, Fig. 1(a); Ex. 1003, Sarrafzadeh Decl. ¶ 57). Petitioner further notes that, consistent with the recitations of claim 1, Numaga describes the tip of first light guide part 21b having an exposed end (light emitting surface 21s) at the distal end of light emitting device 21 configured to engage a portion of the subject's body (the wrist) to deliver light into the body. *Id.* at 22–23 (citing Ex. 1010 ¶ 2, 9–13). As to the claimed second light guide, in a manner similar to light emitting device 21, Petitioner cites Numaga's light receiving device 22 as including light guide part 22b directly abutting pedestal 22a in apparent optical communication with an optical detector (not shown) and with a distal end having exposed light receiving end surface 22s that engages a portion of the subject body and collects light directly from the subject body. *Id.* at 23–25.

Patent Owner responds that Numaga does not disclose a light guide, as we have construed that term, because Numaga's light guide parts 21a and 21b do not "deliver light along a path," but allow light to go in multiple directions. PO Resp. 19–20. Patent Owner argues that Numaga's component 21b does not limit the path through which light can depart because light shielding tube 26 is necessary to ensure that light from light emitting device 21 is not incident on light receiving device 22. *Id*. at 19.

Petitioner replies that Patent Owner's response has shown no structural distinction between the light guide of the '965 patent and the disclosure in Numaga. Pet. Reply 5, 8. As to the difference in terminology between "light guide" in the '965 patent and "light guide part" in Numaga, noting that the relevant inquiry is whether light guide parts would have been considered light guides, Petitioner observes that there is no reason to read Numaga's light guide part as anything other than a part that constitutes a light guide. *Id.* Petitioner cites the similarity of the structures disclosed in the '965 patent and Numaga. Noting that no "path" is described explicitly in the '965 patent, Petitioner contends that Patent Owner infers such a path in the '965 patent, but has no basis for its assertion that no such path exists in Numaga. Responsive to Patent Owner's arguments concerning shield 26, Petitioner cites the disclosure in the '965 patent that the light guide may be fully or partially surrounded by light blocking material to confine light or prevent external light source intrusion. *Id.* at 8 (citing Ex. 1001, 37:16–20). Petitioner also refutes Patent Owner's assertion that Numaga's light guide parts cannot be the claimed light guides because they are wrapped in cladding, by citing the testimony of Patent Owner's expert, Dr. Pollonini, that light guides are commonly wrapped in cladding. *Id.* at 7 (citing Ex. 1070 Pollonini Tr. 68:9–69:13).

Based on Numaga's assertion that light emitted from light emitting devices is injected into the wrist without loss, Patent Owner also argues that Numaga's light guide part 21b actually is part of the emitter detector and not the distinctly claimed light guide in optical communication with the optical emitter. PO Resp. 21–23. Patent Owner argues that Numaga's component 21b instead should be understood as encapsulation of an NIR LED or similar

type device. *Id*. at 21. Petitioner notes that these arguments are not based on the delivery of light along a path, but on the emission of light from the light guide. Pet. Reply 7. Patent Owner's arguments based on the absence of light loss in Numaga are not persuasive. Numaga explicitly discloses directing light with light guide parts and Patent Owner's expert, Dr. Pollonini, states that a properly designed light guide does not leak light. Ex. 1070 Pollonini Tr. 77:16–78:8.

Petitioner further notes that Numaga does not explicitly state that light guide part 21b is in "optical communication" with the light emitting chip in pedestal 21a. Pet. 22. Petitioner argues such optical communication would have been obvious to one of ordinary skill in the art because Numaga discloses light from the light emitting chip is injected into the subject's wrist. *Id.*, Pet. Reply 13. Thus, according to Petitioner, a person of ordinary skill would have been motivated to modify Numaga to provide the claimed optical communication. *Id.* at 13–14.

We agree with Petitioner that Numaga discloses light guide parts that structurally and functionally teach the light guides recited in independent claims 1 and 12 of the '965 patent. We further agree that, to the extent that Numaga does not disclose explicitly the light guide in communication with the emitter, a person of ordinary skill would have been motivated by Numaga to provide such communication. Like the '965 patent, Numaga teaches transmitting light from an emitter thorough a clad light guide directly to and from the skin of the subject with the goal of eliminating or reducing loss of light along the path. Ex. 1010 ¶¶ 9, 10. Patent Owner does not dispute explicitly Petitioner's remaining contentions concerning claim 1. In consideration of the above, we conclude that Petitioner has demonstrated

that Numaga teaches the light guides recited in the claims 1 and 12 of the '965 patent and has shown by a preponderance of the evidence that all of the limitations of claim 1 are taught or suggested by Numaga.

Claim 2 depends from claim 1 and recites that the housing is configured to be integrated with an audio headset, wrist strap, wrist watch, ankle bracelet, or armband. Patent Owner does not explicitly dispute Petitioner's contentions concerning claim 2 of the '965 patent. As discussed above, Numaga clearly discloses a wrist-worn implementation. Therefore, we conclude that Petitioner has demonstrated that Numaga teaches the limitations of claim 2.

Independent claim 12 recites several limitations that, for purposes of our analysis, are similar to those of claim 1. However, unlike claim 1, which recites that the first and second light guides comprise a "distal end having an exposed end surface that is configured to engage a portion of a body of a subject," claim 12 recites that each of the first and second light guides comprises a "distal *free* end having an exposed end surface that is configured to engage a portion of a body of a subject." Claim 12 also recites that the respective "distal free ends of the first and second light guides are in adjacent, spaced apart relationship."

As discussed above, Petitioner contends that, as a result of having amended claim 12 to recite the distal free end has the same "exposed end surface that is configured to engage a portion of the body of the subject" as the distal end recited in claim 1, there is no structural distinction between the "distal end" recited in claim 1 and the "distal free end" recited in claim 12. Therefore, for the same reasons that Numaga teaches the limitations of claim 1, Numaga teaches the limitations of claim 12. Pet. 26, Pet. Reply, 2–3.

Petitioner also argues that under our construction, or even under Patent Owner's proposed construction, Numaga teaches the claimed distal free end. Pet. Reply 11–12. Patent Owner contends the distal end in Numaga that Petitioner alleges is the light guide cannot be "free" because it is contained within the base. *Id.* (citing PO Resp. 23). Petitioner correctly points out, however, that Numaga's light guides cannot be completely contained within shell 29 because such complete containment would block transmission and prevent contact with the subject and that Numaga shows light guide parts 21b and 22b protrude from shell support member 29. *Id.* at 12 (citing Ex. 1010, Fig. 1(a)).

Numaga explicitly discloses eliminating light scattering acrylic board 25 from the prior art device shown in Figure 2, such that light guide 21b protrudes from the device to make direct contact with the subject, as shown in Figure 1a. Ex. 1010, Fig. 1(a), ¶¶ 9, 10. Thus, contrary to Patent Owner's argument, the distal end of the light guide is free to engage the surface of the body of the subject. The parties do not dispute that the first and second light guides are in adjacent spaced relationship in Numaga. In consideration of the above, we conclude that Numaga teaches the distal free end recited in claim 12 of '965 patent and that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claim 12 are taught or suggested by Numaga.

Claims 3 and 4 as Obvious Over Numaga in view of Vetter

Claim 3 depends from claim 1 and recites that the sensor module comprises at least one motion sensor configured to sense motion information from the subject. Claim 4 depends from claim 3 and recites that the sensor module comprises a processor configured to remove motion artifacts from

signals produced by the optical detectors in response to signals produced by the motion sensor.

Vetter discloses a device and method for detecting pulse rate that operates with a light source emitting radiation at the surface or through human tissue, measuring the intensity of the radiant energy after propagation through human tissue using light detectors located at a predetermined distance for the source, and providing signals representative of the propagation. Ex. 1011, Abstract. Petitioner notes that Vetter also discloses simultaneously using motion detecting devices, such as accelerometers to provide a motion reference signal and processing signals, for example, using digital signal processor 50 within the device, to remove motion related contributions due to the motion of the detecting device using a model that subtracts motion related signals from the input signals. Pet. 28; Ex. 1011, Fig. 3.

Patent Owner observes that Numaga does not disclose its pulse wave sensor is intended to be used when a subject is moving and does not mention a desire to sense motion at all. PO Resp. 26.

Both Numaga and Vetter disclose a wrist-worn PPG device. Ex. 1010, Abstract; Ex. 1011, Fig.1, ¶ 26. Vetter discloses it was known to remove motion artifacts from PPG devices. Ex. 1011 ¶ 12. According to Patent Owner, a person of ordinary skill would not have looked from Numaga to Vetter or any other reference to remove motion artifacts. PO Resp. 27. Patent Owner's analysis fails to recognize that a person of ordinary skill is a person of ordinary creativity, as well, and that there is no requirement for such a "one-way" analysis of obviousness. The issue is what the combined teachings of the references would have suggested to

those of ordinary skill in the art. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015) (citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). In this case, both Numaga and Vetter concern wrist-worn PPG devices. There is no support for Patent Owner's argument that a person of ordinary skill would not have considered removing motion artifacts from PPG signals in applications where the removal of such artifacts was appropriate or desirable. Vetter discloses such a technique in the same kind of device as that disclosed by Numaga.

In consideration of the above, we agree with Petitioner that a person of ordinary skill would have been motivated to combine the teachings of Numaga and Vetter and that this combination discloses the features recited in claim 3. Therefore, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all the elements of claims 3 and 4 of the '965 patent are taught or suggested by the combined teachings of Numaga and Vetter.

Claim 5 as Obvious Over Numaga Vetter and Dekker

Claim 5 depends from claim 3 and recites that the sensor comprises a processor configured to process signals produced by the optical detector and the motion sensor to determine heart rate and respiration rate. Petitioner cites Dekker as teaching a method of noninvasive monitoring of respiration rate based on optical signals and, in particular, based on the processing of received optical signals to identify heart rate variability associated with respiration. Pet. 30 (citing Ex. 1012, 1:7–15; Sarrafzadeh Decl. ¶ 80). Dekker discloses obtaining a PPG signal, monitoring the signal to obtain heart rate samples, monitoring the heart rate samples to identify heart rate

variability associated with respiration and determining a respiration rate based on the heart rate variability. Ex. 1012, Abstract.

Patent Owner contends that a person of ordinary skill would not have combined these references because neither Numaga nor Vetter is concerned with respiration and Dekker does not disclose a motion sensor. PO Resp. 29. According to Patent Owner, Petitioner fails to provide a "detailed rationale" for why a person of ordinary skill would have had reason to combine the references or how Vetter's motion sensor would be used in connection with other components to detect respiration. *Id.*

Nevertheless, "[i]t is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Obviousness requires showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention. *Unigene Labs v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir 2011).

Noting that Numaga is directed to improving PPG device sensitivity and Vetter and Dekker are directed to processing of PPG signals, Petitioner contends that a person of ordinary skill would have recognized that the processing taught in Vetter and Dekker could be used to improve the capabilities of Numaga's device, i.e., by determining a respiration rate based on heart rate variability. Pet. Reply 15–16. We find Petitioner's arguments persuasive. An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of

ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), *see also Translogic Tech., Inc.*, 504 F.3d at 1259. We agree that using signal processing techniques disclosed as explicitly applicable to PPG devices by Vetter and Dekker would have been apparent to a skilled artisan familiar with Numaga's PPG device aimed at improving signal sensitivity. In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claim 5 are taught or suggested by the combined teachings of Numaga, Vetter, and Dekker.

Claims 6–7 as Obvious Over Numaga in View of Debreczeny

Claim 6 depends from claim 1 and recites that the first light guide comprises optical dye configured to filter one or more wavelengths of light guided by the first light guide. Similarly, claim 7 depends from claim 1 and recites that the second light guide comprises optical dye configured to filter one or more wavelengths of light guided by the second light guide. Debreczeny discloses that a pulse oximeter utilizing a non-invasive sensor transmitting or reflecting through a patient's tissue electromagnetic radiation, such as light, may use light sources that emit in at least two different spectral regions, e.g., red and near infrared. Ex. 1008 ¶¶ 8, 9, 12–15. Petitioner cites Debreczeny's teaching that filtering out undesirable light may be accomplished by adding an optical coating with light-absorbing dye. Pet. 34 (citing Ex. 1008 ¶ 43).

Patent Owner does not respond explicitly to Petitioner's arguments concerning claims 6 and 7 and the combination of the teachings of Numaga and Debreczeny. As Debreczeny discloses subject matter that pertains to the spectral properties of light used in PPG devices, such as Numaga's device,

we are persuaded that Petitioner has demonstrated that the combination of their teachings teaches or suggested the limitations of claims 6 and 7 and that a person of ordinary skill would have had reason to combine the teachings of the references. In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claims 6 and 7 of the '965 patent are taught or suggested by the combined teachings of Numaga and Debreczeny.

Claims 8–9 as Obvious Over Numaga in View of Rafert

Claim 8 depends from claim 1 and recites that the light guide comprises elastomeric light transmissive material. Claim 9 depends from claim 1 and recites that the light guide comprises substantially rigid light transmissive material. Petitioner notes that Rafert discloses a pulse oximetry sensor that physically conforms to the body of a patient, such as to a finger, with a light source assembly for transmitting light to the patient's body portion and a light detector assembly for measuring transmitted light. Pet. 36; Ex. 1013, Abstract. As to claim 9, Petitioner cites the disclosure in Rafert of rigid transparent housing 26, 28 enclosing the components of the light source and light detector and providing a firm pressing engagement between them and the subject's body portion. Pet. 37 (citing Ex. 1013, 2:48–49, 4:59–66, Figs. 1–2). As to claim 8, Petitioner notes that Rafert discloses that LEDs 30, 32 and photodetector 38 may be protected by elastomeric light-transmissive material. *Id.* (citing Ex. 1013, 2:55–58, 5:5–8, 14–16).

Petitioner argues that a person of ordinary skill would have selected a known material based on its suitability for its intended use, e.g., to conform to the body shape of the intended body placement of the PPG device, and

thus would have had reason to combine the teachings of Rafert and Numaga. *Id.* at 38.

Patent Owner argues that Rafert does not disclose light guides and does not explain why a person of ordinary skill would have chosen to fabricate light guides out of materials Rafert discusses in the context of housings and protective coverings. PO Resp. 30–32. Patent Owner also argues that Petitioner does not address Rafert's disclosure of covering an elastomeric material with a rigid material. *Id.* at 33.

As discussed above, Petitioner cites Numaga as disclosing light guides. Petitioner cites Rafert only for the proposition that rigid and elastomeric materials having desired light transmissive properties were known to be used in pulse oximeter devices, for example, as housings and protective covers. The terms elastomeric and rigid are used in the '965 patent without limitation and arguably cover the universe of light transmissive materials. We agree with Petitioner that it would have been obvious to make light guides with the desired light transmissive properties using rigid or elastomeric materials, as required for the particular body part application. In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claims 8 and 9 are taught or suggested by the combined teachings of Numaga and Rafert.

Claim 10 as Obvious Over Numaga in View of Negley

Claim 10 depends from claim 1 and recites that the optical emitter comprises optical coupling material, and the first light guide is in optical communication with the optical emitter via the optical coupling material. Petitioner cites Negley as disclosing an optical emitter (LED 140)

configured to emit light through a light guide (optical element 130) in optical communication with optical emitter LED 140 through optical coupling media 170. Pet. 39.

Patent Owner does not respond explicitly to Petitioner's contentions concerning claim 10. Negley explicitly states that an optical coupling media may be placed between a semiconductor light emitting element and an optical coupling element. Ex. 1014 ¶¶ 6, 21–24, Fig. 1; Ex. 1003, Sarrafzadeh Decl. ¶¶ 96–99. In view of this teaching, we agree that a person of ordinary skill would have recognized from Negley that using a coupling material between a light emitting device and a light directing element, such as Numaga's light guide, was a conventional technique that could be used to maximize signal quality of a pulse sensor. In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claim 10 are taught or suggested by the combined teachings of Numaga and Negley.

Claim 11 as Obvious Over Numaga and Miao

Claim 11 depends from claim 1 and recites that the optical detector comprises optical coupling material and that the second light guide is in optical communication with the optical detector via the optical coupling material. Petitioner cites Miao as disclosing that light loss due to reflection in an air gap between a photodetector and a lens or fiber (light guide) may be reduced by using optical thick film 13 (optical coupling material) disposed on photodetector 7 (optical detector). *Id.* at 41–42.

Patent Owner does not respond explicitly to Petitioner's contentions concerning claim 11. Miao uses optical coupling material (i.e. an optical thick film 13) disposed on an optical detector (i.e., photodetector 7) in the

optical coupling region between a light guide (i.e., optical transmission medium 15) and the optical detector (i.e., photodetector 7), such that the light guide is in optical communication with the optical detector via the optical coupling material. Ex. 1015, 4:28-5:23, Figure 3A. In view of these teachings, we agree that a person of ordinary skill would have applied the teachings of Miao in the context of Numaga to arrive at the limitations of claim 11.

In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claim 11 of the '965 patent are taught or suggested by the combined teachings of Numaga and Miao.

The Fraden-Based Challenges

The Fraden-based challenges include both anticipation and obviousness challenges. Therefore, we turn to the Fraden-based challenges before addressing objective criteria under 35 U.S.C. § 103(a) that apply to both the Numaga-based challenges and the Fraden-based challenges.

Claims 1 and 8–12 as Anticipated By Fraden

Fraden discloses a combination of a patient core temperature sensor and dual wavelength optical sensors in an ear probe or body surface probe for computing vital signs, such as arterial blood oxygenation in a pulse oximeter, from photoplethysmograph (PPG) signals. Ex. 1006 ¶ 19. In relevant part, Fraden discloses a pilot light connected to the ear canal via a contact illuminator and a light transparent ear plug conducting reflected light back to a light detector, such that photons of light are modulated by the pulsatile blood to produce PPG signals that pass through the translucent ear

plug. *Id.* at ¶¶ 19, 55. Thus, Petitioner cites Fraden as disclosing a sensor module for detecting and measuring physiological information from a subject, as recited in the preamble of claim 1. Pet. 47.

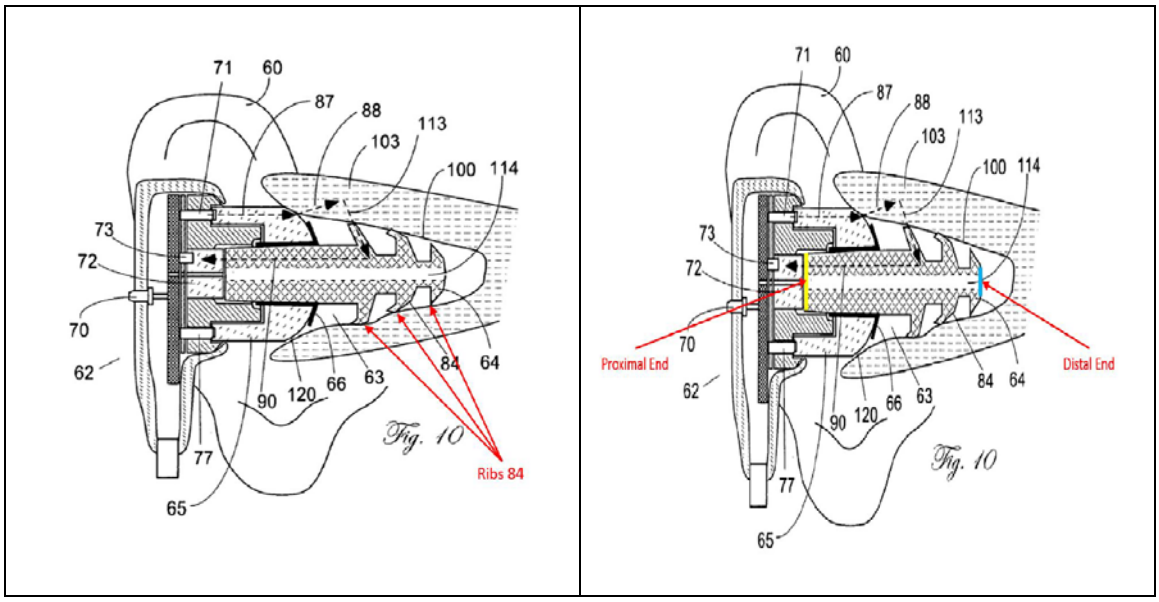
Referencing the cut-out view of the probe in Figure 7, Petitioner cites Fraden's encapsulation 78, circuit board 68, and holder 76, as disclosing the claimed housing; Fraden's LEDs 71 and 77, as disclosing the claimed optical emitter supported by the housing; and Fraden's light detector 73, as disclosing the claimed optical detector supported by the housing. *Id*. at 48. Referencing the Figure 1 of Fraden, Petitioner cites ear probe 2 and extension 3, as disclosing a housing; detector/emitter 18 containing LEDs 50, 52, as disclosing the claimed optical emitter; and light detector 51, as disclosing the claimed optical detector. *Id.*

Petitioner cites illuminator 65 and light guide 64 in support of its contention that Fraden discloses the limitation in dependent claim 8 that the first and second light guides comprise light transmissive elastomeric material, e.g., clear silicon resin, and the limitation in claim 9 reciting that the light guides comprise a substantially rigid light-transmissive material, e.g., acrylic resin. Pet. 51.

Petitioner cites Fraden's lens 81 and LEDs 71 and 77 as disclosing the limitation in claim 10 reciting that the first light guide is in optical communication with at least one optical emitter via coupling material. *Id.* at 52. Similarly, Petitioner cites light coupler 72 and optical detector 73 in Fraden as disclosing the limitation in claim 11 reciting that the second light guide (e.g., Fraden's ear plug 64) is in optical communication with the optical detector via the coupling material. *Id*.

As to the limitation in independent claim 12 that first and second light guides are in an adjacent, spaced apart relationship, Petitioner cites illuminator 65 and ear plug 64, as shown in cross-section in Fraden's Figures 7, 9, and 10. *Id.* As discussed above, we have construed the term distal end in "distal free end" to mean an end opposite the proximal end of an elongated light guide. In our Decision to Institute, we determined that rounded edge 65 of Fraden and ribs 84 of Fraden constitute ends opposite the proximal end of an elongated light guide. Dec. to Inst. 24–25.

Patent Owner contends that the portion of ribs 84 that engage the body of the subject in Fraden are not opposite the proximal end of plug 63 and cannot be either the claimed distal end or distal free end. PO Resp. 33–38. Patent Owner illustrates its arguments using two annotated versions of Figure 10 of Fraden, as shown below:



PO Resp. 36–37. Patent Owner's first annotated version of Figure 10, shown on the left, points to Fraden's multiple ribs 84 that make contact with the subject's ear. Patent Owner's second annotated version of Figure 10,

shown on the right, points out Petitioner's contentions concerning the claimed proximal and distal ends. Patent Owner argues that Fradens's ribs 84 do not constitute a distal end (or in the case of claim 12, a distal free end) at the end opposite the proximal end of the Fraden's plug 63 and that Fraden's distal end, which does not contact the subject's ear, is not a distal end configured to engage a portion of the body of the subject. *Id*. at 34–38.

As Patent Owner notes we construed "distal end" to mean "an end opposite the proximal end." *Id*. at 35. We did not limit "distal end" to mean any particular end or to be limited to a single end at the farthest distance from the proximal end. Our construction is consistent with the disclosure in the '965 patent that the light guide "may branch out into two or more 'legs' that may be used to couple with many different parts of the body, such as multiple parts of the ear." Ex. 1001, 37:54–57.

Patent Owner does not respond explicitly to any of Petitioner's other arguments concerning Fraden that we addressed in the Decision to Institute. Dec. to Inst. 23–27. As we are not persuaded by Patent Owner's arguments based on the construction of "distal end," we agree that Petitioner has demonstrated Fraden discloses all the elements of claim 1 and 8–12 of the '965 patent. In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 8–12 of the '965 patent are unpatentable as anticipated by Fraden.

Claims 2–4 as Obvious Over Fraden in View of Verjus

Petitioner acknowledges that Fraden does not disclose expressly the housing configured to be integrated within an audio headset (claim 2), a motion sensor configured to sense motion information from the subject (claim 3) and a processor configured to remove motion artifacts (claim 4).

Pet. 52–53. As to claim 2, Petitioner cites Verjus as disclosing each of these features. *Id.* Petitioner notes that Verjus discloses a heart rate monitor in which the housing (casing 2) may be an ear cushion and may be integrated with an audio headset. *Id.* at 53 (citing Ex. 1007 ¶¶ 6, 24–26, 49, Fig. 1; Sarrafzadeh Dec. ¶ 141).

As to claim 3, Petitioner notes that Verjus discloses a motion sensor (accelerometer 8) configured to be integrated within an audio headset to remove artifacts from an optical signal. *Id.* at 53–54. As to claim 4, Petitioner notes that Verjus discloses processor unit 9 or 9A supported by the housing (casing 2) configured to remove motion artifacts from signals produced by an optical detector (optical radiation receiver 6) in response to signals from the motion sensor (accelerometer 8).

Petitioner argues that a person of ordinary skill would have had reason to combine the teachings of Fraden and Verjus as a rearrangement of known elements (claim 2) and to solve a known problem, i.e., motion artifacts, using known techniques and conventional processing devices (claim 3–4). Pet. 56–57.

Patent Owner does not respond explicitly to Petitioner's contentions concerning claim 2. As to claims 3 and 4, Patent Owner acknowledges that Fraden teaches motion artifacts are a concern and securing the plug in the ear canal in a way the reduces such motion artifacts. PO Resp. 38. However, according to Patent Owner, Petitioner's assertions that a person of ordinary skill would have been motivated to look to the improvement teachings of similar art is insufficient to explain how a motion sensor would have improved Fraden or been used with Fraden. *Id.* Patent Owner also

asserts that a motion sensor used with Fraden would be expensive, uncomfortable, and consume a large amount of power. *Id.* at 38–40.

Petitioner contends that Patent Owner's arguments are based on the false assumption that Fraden's mechanical methods of reducing motion artifacts operate to the exclusion of the signal processing methods disclosed by Verjus. Pet. Reply 21. A clear, evidence-supported account of the contemplated workings of the combination is a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so. *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). The Petition explains that, although mechanical methods can help reduce artifacts induced by relative motion between the subject and the sensor, Verjus teaches methods to address motion artifacts originating from user movement, rather than movement of the sensor relative to the user. Pet. Reply 21 (citing Pet. 55–56). Thus, as to claims 2–4, we agree with Petitioner that a person of ordinary skill would have had reason to combine teachings of Fraden's mechanical methods to reduce motion artifacts induced by sensor motion with the signal processing methods taught by Verjus to reduce motion artifacts induced by user movement.

In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claims 2–4 of the '965 patent are taught or suggested by the combined teachings of Fraden and Verjus.

Claim 5 as Obvious Over Fraden, Verjus, and Fricke

Petitioner acknowledges that the combination of Fraden and Verjus does not teach expressly the processor further configured to determine

respiratory rate. Pet. 57. However, Petitioner notes that Fraden suggests preference for a device capable of providing multiple vital signs. *Id.* (citing Ex. 1006 ¶ 2). Fricke discloses an optical sensor and signal processing module, in which a light source illuminates a capillary bed in an area of the skin, a photodetector receives an optical signal resulting from the illumination that characterizes the fluctuation in the flow of blood in the capillary bed, and the optical signal is converted to an electrical signal and processed to obtain a signal related to heart rate and respiration rate. Ex. 1016, Abstract. Petitioner cites Fricke's ear worn monitoring device as, like Verjus, disclosing removal of motion artifacts in the optical signal in response to signal produced by accelerometer 130. Pet. 58–59. Petitioner argues that a person of ordinary skill would have had reason to combine the teaching in Fricke with those of Fraden and Verjus, given the disclosure in Fraden that integrating monitoring of multiple vital signs is a desirable feature and the use of known techniques to achieve this result. *Id*. at 59–60.

Patent Owner does not respond explicitly to Petitioner's arguments concerning the combination of Fraden, Verjus, and Fricke. For the reasons discussed above, and as discussed in our Decision to Institute, we are persuaded that Petitioner has demonstrated that a person of ordinary skill would have had reason to combine the teachings of Fraden, Verjus, and Fricke to arrive at a sensor module with the limitations recited in claim 5.

In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that all of the limitations of claim 5 are taught or suggested by the combined teachings of Fraden, Verjus, and Fricke.

Claims 6–7 as Obvious Over Fraden in View of Debreczeny

The disclosures in Debreczeny are discussed above and not repeated here. Petitioner argues that a person of ordinary skill would have had reason to combine the teachings in Debreczeny with those of Fraden to arrive at the subject matter recited in claims 6 and 7, as this art combines well-known techniques and removes ambient optical noise through the use of an optical filter, such as light absorbing dye.

Patent Owner does not respond explicitly to Petitioner's arguments concerning the combination of Fraden and Debreczeny. For the reasons discussed above, and as discussed in our Decision to Institute, we are persuaded that Petitioner has demonstrated that a person of ordinary skill would have had reason to combine the teachings of Fraden and Debreczeny to arrive at sensor module having the limitations recited in claims 6 and 7 of the '965 patent.

Objective Indicia of Non-Obviousness

Introduction

The Federal Circuit "has repeatedly emphasized that the objective indicia constitute 'independent evidence of non-obviousness.'" *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2013(quoting *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1319 (Fed.Cir.2010)). Objective criteria may include any of the following: long-felt but unsolved needs, failure of others, unexpected results, commercial success, copying, licensing, and praise. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *Leapfrog Enters., Inc. v. Fisher–Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). To be of relevance, evidence of

nonobviousness must be commensurate in scope with the claimed invention. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (citing *In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971)); *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)). In order to be accorded substantial weight, there must be a nexus between the merits of the claimed invention and the evidence of secondary considerations, i.e., that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). "Nexus" is a legally and factually sufficient connection between the objective evidence and the claimed invention, such that the objective evidence should be considered in determining nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). We now turn to Patent Owner's contentions concerning objective criteria.

Licensing and Industry Praise

Citing products identified in Exhibit 2002 and its product partners in Exhibit 2020, Patent Owner argues that it licenses its technology to partners, such as Samsung, LG, Sony, Bose, and Intel. PO Resp. 2. Exhibit 2004 appears to be a portion of one of Patent Owner's marketing presentations that identifies products such as watches, earbuds, and bracelets and states that "[p]roducts powered by Valencell PerformTek® have won over 18 different awards form CES, StuffTV, Red Dot and more." According to the Federal Circuit, "the relevant inquiry is whether there is a nexus between the patent and the licensing activity itself, such that the factfinder can infer that the licensing 'arose out of recognition and acceptance of the subject matter claimed' in the patent." *South Alabama Medical Science Foundation v. Gnosis S.p.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (quoting *In re GPAC Inc.*,

57 F.3d 1573, 1580 (Fed. Cir. 1995)). Here, Patent Owner shows no such nexus.

Citing Exhibit 2002, Patent Owner states that its "technology has served and continues to serve as an industry benchmark and has been independently validated by the Center for Living of Duke University, North Carolina State University, the Human Performance Laboratory, and a fellow of the American College of Sports Medicine." PO Resp. 1. We do not ascribe significant weight to Exhibit 2002, as one of its authors is the inventor, Dr. Steven LeBoeuf. Moreover, neither Exhibit 2002 nor the Patent Owner Response states explicitly that the subject matter claimed in the '965 patent is included in the PerformTek® line or in any of the products identified in Exhibit 2004 or 2020. Patent Owner has not established the requisite nexus between the patent or recited limitations of the challenges claims and its licensing activities or purported awards and industrial praise, nor has it provided supporting market analysis.

Unexpected Results

Patent Owner contends that, at the time of invention, its approach to improving the signal to noise ratio in a PPG device, i.e., by directing light through light tubes configured to engage a specific body part to tailor the field of view, was contrary to the conventional practice of increasing the amount of light transmitted and collected. PO Resp. 2–14. According to Patent Owner the use of light tubes permits a wider field of view in cases where that is preferable and a narrow field of view in other cases, for example, where less optical scatter and fewer motion artifacts are preferable. *Id.* at 4. Patent Owner contends that conventional approaches do not use light tubes, but instead merely engage the skin with a light emitter. *Id.* at 5.

Patent Owner contends that "[c]onfiguring the claimed sensor module such that the first and second light guides each comprise "***an exposed end surface that is configured to engage the body of the subject***" was a non-obvious modification from devices that existed in the prior art. PO Resp. 5 (emphasis in original). According to Patent Owner, its unconventional approach produced unexpected results in performance tests. *Id.* at 8. Patent Owner describes "integrated sphere testing" it performed on two modules, SM1 (constructed without a light guide) and SM2 (constructed with a light guide on the optical emitter). Patent Owner notes that using a first light guide having an exposed end surface configured to engage the body of the subject reduced the amount of light entering the body by 5–6% based on light output. *Id.* at 11–12. Using a second light guide extended to have a distal end that engages the body of the subject reduced the amount of optical energy received by the detector by 75.8 to 81.9% based on DC measurements. *Id.* at 12. With the second light guide, the amplitude of the subject's perceived pulsatile waveform (as an AC measurement) was reduced between 63.5 % and 78.3% over 3 five minute test runs. *Id.* at 13. However, the AC/DC ratio improves between 19.2 % and 67.1%. *Id.* at 14. Patent Owner asserts that these measurements demonstrate an unexpected, non-obvious result because, in this counterintuitive approach, lower amounts of light produce an improvement in the amount of light that correlates to the subject's heart rate —a fact Patent Owner argues is contrary to conventional belief. *Id.* at 14.

Petitioner argues that these results are not unexpected and that, because each of Numaga and Fraden teaches an exposed end surface configured to engage the body; this is not a novel feature of the claims. Pet.

Reply 24–25 (citing *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1385 (Fed. Cir. 2015) and *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If commercial success is due to an element in the prior art, no nexus exists."). Petitioner further notes that Patent Owner does not contend that the end surface feature of claim 1 is novel, but instead argues that Numaga does not disclose light guides that direct light along a path. *Id.* at 24–25; *see* PO Resp. 19–20.

We agree with Petitioner that the results would not have been unexpected to a person of ordinary skill familiar with Numaga. Although Patent Owner argues the conventional approach is to increase the intensity of the light, Numaga does not describe increasing the intensity of the light. Instead, Numaga discloses improving both the sensitivity and the accuracy of pulse waves by directing light to the end surface that contacts the body of the subject and reducing unnecessary light entering the receiving device. Ex. 1010 ¶ 6. To achieve this result, Numaga eliminated the prior art light scattering and lossy acrylic board 25 that reduced device sensitivity and, instead, directed light through light guide parts 21b and 22b to end surfaces 21s and 22s. *Id.* ¶ 5. In the absence of increasing the amount of light from the emitter, Numaga effectively increased the amount of useful signal at end surfaces 21s and 22s and lowered the amount of ambient noise, i.e., Numaga improved the signal to noise ratio without increasing the amount of light.

Conclusion

In consideration of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–12 of the '965 patent are unpatentable based on the challenges asserted in the Petition.

Specifically Petitioner has demonstrated by a preponderance of the evidence that:

Claims 1, 2, and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga;

Claims 3 and 4 are unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Vetter;

Claim 5 is unpatentable as under 35 U.S.C. § 103(a) as obvious over Numaga in view of Vetter and in further view of Dekker;

Claims 6 and 7 are unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Debreczeny;

Claims 8 and 9 are unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Rafert;

Claim 10 is unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Negley;

Claim 11 is unpatentable under 35 U.S.C. § 103(a) as obvious over Numaga in view of Miao;

Claims 1 and 8–12 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Fraden;

Claims 2–4 are unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Verjus;

Claim 5 is unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Verjus and in further view of Fricke; and

Claims 6–7 are unpatentable under 35 U.S.C. § 103(a) as obvious over Fraden in view of Debreczeny.

MOTION TO AMEND

Patent Owner filed a contingent motion to substitute independent claim 13 for claim 1, if found unpatentable, substitute independent claim 24 for claim 12, if found unpatentable, to alter the dependencies of claims 2–11 from claim 1 to claim 13 and to limit claim 14 (which substitutes for original claim 2) to a wrist strap or wrist watch, by striking language drawn to an audio headset, an ankle bracelet, or an armband.

In a Motion to Amend, responsive to a ground of unpatentability involved in the trial, a Patent Owner may propose a reasonable number of substitute claims that do not expand the scope of the claim or introduce new matter. 35 U.S.C. § 316(d)(3), 37 C.F.R. § 42.121, *see Aqua Prod., Inc. v. Matal*, 872 F.3d 1290, 1300–1 (Fed. Cir. 2017). A final substantive decision on the patentability of originally issued and amended claims must be based on the entirety of the IPR record, without placing the burden of persuasion on the Patent Owner. *See Aqua Prod.*, 872 F.3d at 1325–6, 1328.

Proposed substitute claim 13 further limits original claim 1 by adding a recitation that the first light guide distal end has "a substantially flat-faced surface narrowing a field of view of the first light guide" and the second light guide comprises a distal end having "a substantially flat-faced surface."

Proposed substitute claim 24 further limits original claim 12 by adding a recitation that the first light guide comprises a distal free end having "a substantially curved surface widening a field of view of the first light guide" and an exposed end surface that "are both" configured to "protrude beyond the housing" and engage a portion of the body of the subject. Substitute claim 24 further limits the second light guide over that recited in original claim 12 to one that comprises a distal free end having "a

substantially curved surface" and an exposed end surface that "are both" configured to "protrude beyond the housing" and engage a portion of the body of the subject.

Responsiveness to a Ground of Institution

Petitioner contends that Patent Owner's Motion to Amend is not responsive to a ground of unpatentability involved in the trial because the Motion to Amend does not discuss the Numaga or Fraden reference in detail. Opp. to Mot. To Amen. 7–9 (citing *Aqua Prod.*, 872 F.3d at 1341 (Reyna concurring)). Although the Motion to Amend includes a heading entitled "The Claim Amendments Overcome the Asserted Grounds of Patentability [sic]," the Motion to Amend provides no analysis in support of this position. Instead, Patent Owner identifies and attempts to distinguish over other prior art, without any discussion of the grounds in the Decision on Institution. Although we do not place the burden of persuasion on the Patent Owner, Patent Owner's silence provides no information as to how the proposed claim amendments distinguish over the art applied in the challenges on which we instituted *inter partes* review. Thus, the significance of the Motion to Amend in the context of the challenges presented in the Petition is unclear. As Petitioner points out, "[t]he structure of an IPR does not allow the patent owner to inject a wholly new proposition of unpatentability into the IPR by proposing an amended claim." Opp. To Mot. To Amend 7 (citing *Aqua Prod.*, 872 F. 3d at 1306). Patent Owner's silence does not preclude Petitioner from addressing the challenges on which we instituted trial, as we discuss further in this Decision.

Written Description Support

Petitioner contends that proposed claim 24 lacks written description support because it would require that the free end of the light guides have two distinct surfaces—a substantially curved surface and an exposed end surface. Opp. To Mot. To Amend 4–7. Patent Owner argues that Figures 24A, 24B, and 31 of the '965 patent depict the claimed embodiment, i.e., a light guide comprised of a distal end 119a having a substantially curved surface and an exposed surface 119c. Reply to Opp. To Mot. To Amend. 3. Referring to Figures 24A and 24B, the Specification of the '965 patent discusses the implications of the distal end having a flat face distal end surface to achieve a narrow field of view, e.g., in an earbud to focus the field of view between the anti-tragus and concha, or a rounded distal end surface in application that seeks to capture a wider field of view, but could be subject a larger amount of motion artifacts. Ex. 1001, 35:51–36:9, 38:44–61. The Specification does not provide any examples of circumstances where it is desirable to widen the field of view, or include any further description of the meaning of substantially flat-faced or substantially curved surface. Nevertheless, in view of the disclosures in the '965 patent, we are not persuaded by Petitioner's argument that the proposed substitute claims do not have written description support.

Indefiniteness

Petitioner contends that substitute claims 13 and 24 are indefinite because the terms "flat-faced", "narrowing," and "widening" do not provide a standard against which to determine context. Opp. To Mot. To Amend. 10. Patent Owner contends that Petitioner's ability to cite prior art against

the proposed substitute claims is indicative that the claims are not indefinite. Reply to Opp. To Mot. To Amend, 5. Patent Owner further contends that the term "substantially" is a descriptive term commonly used in patent to avoid a strict numerical boundary to a specified parameter or accommodate minor variations and is not indefinite. *Id.* (citing *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) and *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). Petitioner distinguishes the proposed substitute claims from those addressed in *Ecolab,* arguing that indefiniteness in *Ecolab* was not an issue because the specification provided a meaningful standard against which infringement could be judged. Surreply 5.

Petitioner emphasizes that both Petitioner's and Patent Owner's experts testified that an ordinarily skilled artisan would have no way to determine what structures fall within the scope of the claims. Surreply 4. Patent Owner's expert, Dr. Pollonini, testified that he could not quantify at what point of curvature a surface goes from being substantially flat to substantially curved, referring to surfaces that are "unequivocally" flat and curved and having a "clearly detectable curvature." Pollonini Tr. 129:3–21. Responding to a question of whether a surface is substantially flat or curved is a matter of interpretation, Dr. Pollonini also stated that "[i]t's possible they could be falling under the virtue of either one claim or the other." *Id.* 129:22–130:4. After testifying that a flat surface at the end of a light guide narrows a field of view, compared to a curved surface, Dr. Pollonini also could not state whether a flat-faced surface would narrow a field of view relative to a surface with a concave curvature. *Id.* at 126:8–127:3.

As Dr. Pollonini's testimony indicates, proposed substitute claims 13 and 24 recite a structure and result in general terms, but do not provide sufficient specificity for one of ordinary skill to determine the scope of the claims. Patent Owner's attempt to define substantially flat-faced and substantially curved end surfaces fails because the defining language, i.e., narrowing or widening the field of view of the light guide, does not provide a comparative reference from which the field of view is widened or narrowed. Thus, the proposed substitute claims use language that is unclear and ambiguous under *In re Packard*, 751 F. 3d 1307, 1310, 1314 (Fed. Cir. 2014) and does not identify the inventive subject matter with reasonable certainty under *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2130 (2014).

In consideration of the above, we agree with Petitioner that the proposed substitute claims do not pass muster under 35 U.S.C. § 112 because they are indefinite.

Patent Owner's Evidence To Antedate Haisley

As discussed below, Petitioner contends that proposed substitute claim 13 is unpatentable over the combination of Numaga and Haisley. Patent Owner attempts to antedate Haisley on the basis that it actually had reduced the invention to practice before Haisley's filing date. Reply to Opp. To Mot. To Amend 6–9. In order to establish an actual reduction to practice, the inventor must establish that: (1) the inventor constructed an embodiment or performed a process that met all of the claim limitations; and (2) the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). The inventor's testimony must be corroborated by independent evidence. *Id*. at 1330.

The Haisley application was filed on December 16, 2011. Ex. 1072, 1. Patent Owner contends that it physically constructed and reduced to practice its Ork Tilt product as early as September 10, 2010, and that it reduced its Tribork product to practice on February 28, 2011. Reply to Opp. To Mot. To Amend 6–9; Hr'g. Tr. 23:12–24:22. Patent Owner acknowledges that Mr. Paik, who wore the devices for testing purposes, does not know whether they incorporated all of the elements of the original or substitute claims. Hr'g. Tr. 24:5–8.

Patent Owner relies on the testimony of the '965 patent inventor, Dr. LeBoeuf, to establish that every claim element was present in the devices being tested. Ex. 2140 LeBoeuf Decl. ¶¶ 8–21, Hr'g Tr. 23:25–26:3, 19–22. Patent Owner also provides photographs of the Oak Tilt C prototype (Ex. 2142), invoices for parts used in construction the prototype (Ex. 2143), results of testing conducted on September 10, 2010 (Ex. 2145), and a claim chart purporting to show correspondence between proposed substitute claim 13 and Ork Tilt prototype images (Ex. 2144). Patent Owner provides similar evidence for the Tribork product. *See* Reply to Opp. To Mot. To Amend 9.

Petitioner contends that Patent Owner has failed to show it reduced the invention to practice before Haisley's filing date. Surreply 5–9. "There cannot be a reduction to practice of the invention . . . without a physical embodiment which includes all limitations of the claim." *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652 (Fed. Cir. 1987). Every limitation of the [claim] must exist in the embodiment and be shown to have performed as intended. *Newkirk v. Lulejian*, 825 F.2d 1581, 1582 (Fed. Cir. 1987) (emphasis added).

Petitioner notes several shortcomings in Patent Owner's evidence. We agree with Petitioner that the prototype images offered to show correspondence with the elements of claim 13 provide insufficient detail to identify the relevant parts. For example, Exhibit 2144 appears to be an external view of an earbud, but no internal connections or light guides are shown. As Petitioner notes, the chart does not include an explanation of how the images illustrate the optical communication between the emitter/detector and the light guide, or how a recessed surface of the emitter is configured to engage a portion of the subject's body and deliver light directly into the body. Surreply 7. We also agree with Petitioner that, although inventor LeBoeuf's declaration states the limitations of claim 13 are found in the Ork Tilt C and Tribork prototypes, the declaration fails to explain how some of the limitations are present in the prototype. Petitioner points out, for example, that Dr. LeBoeuf's declaration does not show how the emitter is supported by the housing. Surreply 6–7.

Inventor Steven LeBoeuf is also Patent Owner's co-founder and president and has a clear interest in outcome of this trial. Ex. 2023, LeBoeuf Dec. ¶ 3. Independent corroboration requires evidence other than the inventor's testimony. *In re NTP, Inc.*, 654 F.3d 1279, 1291 (Fed. Cir. 2011). Petitioner notes that Mr. Paik, who was the subject for the testing performed on the Ork Tilt C and Tribork prototypes, testified he has no knowledge of the inner workings of the senor modules, is a personal friend of inventor LeBoeuf and holds 25,000 shares of stock in Patent Owner. Surreply 9 (citing Ex. 1076 Paik Tr. 54:16–55:15, 58:12–19). Mr. Paik testified that, as a "tester" he wore prototypes over 50 times, but he could not tell the difference between prototypes, that he only remembers the Ork Tilt C and

Tribork prototypes (but not different version of them), that his background is in corporate finance not engineering, that he did not participate in designing the tests or analyzing the results, and that he is not familiar with the '965 patent. Ex. 1076, Paik Tr., 10:1–2, 26:6–28:5, 32:4–20, 33:2–36:1, 43:12–44:4. In view of his lack of knowledge of the prototypes relative to the elements of the claims, his personal interest in Patent Owner's business, and his personal relationship with inventor LeBoeuf, Mr. Paik cannot provide the requisite corroboration of the inventor's testimony.

In view of the above evidence, we agree with Petitioner that Patent Owner has not provided sufficient evidence to antedate Haisley.

Obviousness Over Numaga in View of Haisley

Although we agree that the proposed substitute claims are indefinite, we consider Petitioner's arguments that the proposed substitute claims are unpatentable over the prior art. Petitioner cites Numaga as disclosing the features of Patent Owner's proposed substitute claims common to the claims discussed above. Opp. To Mot. To Amend 11. Petitioner cites Haisley as disclosing a solution to discomfort caused by pressing a medical sensor against the subject by employing optical medical sensor 12 having housing 38, optical emitter 16, and optical detector 18. *Id.* at 12–13. Haisley discloses that emitter and detector lenses 180, 182, are in optical communication with exposed ends 210, 212, respectively arranged to engage the subject, that may be protrude from, be flush with, or be recessed into the housing and may be substantially flat, as shown in Figures 11–13, or rounded, as shown in Figure 15. Opp. To Mot. To Amend 12–13 (citing. Ex. 1072 ¶¶ 67, 73, 76, 78, 85, 86, Figs. 20, 26).

Petitioner contends that Haisley's disclosure of a substantially flat end surface and a substantially rounded end surface is evidence that the shape of the end surface is a matter of design choice between known alternatives. *Id.* at 14–15. Petitioner acknowledges that Numaga does not disclose explicitly that the distal end has a substantially flat shape, (in Figure 1 of Numaga tips 21s and 22s of respective light guide parts 21b and 22b appear rounded). *Id.* at 14 (citing Ex. 1010, Figs 1, 2). Petitioner contends that modifying Numaga's protruding end surfaces to be flat-face surfaces that abut the wearer's wrist to reduce the localized pressure at regions free of any edges that could press into the wearer's skin would have been within the abilities of a person of ordinary skill. *Id*. at 15 (citing Ex. 1071, Sarrafzadeh Suppl. Decl. ¶¶ 50–53, 62–64, 75, 84).

Patent Owner responds that a person of ordinary skill would not have been motivated to use Haisley's flat-face end surface with Numaga because Numaga discloses replacing the flat-face surface in Figure 2b with protruding rounded tips, as shown in Numaga Figure 1. Reply to Opp. To Mot. To Amend 10 (citing Ex. 2139 Suppl. Pollonini Decl. ¶ 19, Ex. 1010 ¶¶ 5–7). We do not find this argument persuasive. Numaga discloses eliminating flat acrylic board 25 between the end surface of light guide parts 21b, 22b and the subject's wrist to reduce light scattering and reduce unnecessary light entering the light receiving device, thereby improving device sensitivity. Ex. 1010 ¶¶ 5, 6. Without the acrylic board Numaga's light emitting surfaces abut the subject's wrist, allowing direct transmission and reception of light with minimal loss. *Id.* ¶ 7. However, Numaga neither explicitly discloses nor rejects using a flat-face surface at the tip of the light guide.

As discussed above, Haisley teaches using flat or rounded tips for comfort purposes. Substitute claim 13 recites using a flat-face surface to narrow the field of view. Petitioner argues that the recitation in proposed substitute claim 13 of narrowing the field of view over that of a curved surface is inherent in the use of a flat-faced surface, so that employing Haisley's flat-faced surface in Numaga results in a structure and function that is the same as that recited in substitute claim 13. Opp. To Mot. To Amend, 16. Petitioner's arguments are consistent with positions taken by Patent Owner's expert, Dr. Pollonini in his declaration. Ex. 2009 ¶¶ 57, 58 (annotating light emitted by rounded end surface of prior art shown in Fig. 2b of Numaga), 45, 46 (Patent Owner's illustration of light cone emitted by flat-faced end surface of light guide shown on left of side of illustration). We agree with Petitioner and Patent Owner that in a comparison of flat-faced to rounded light guide ends, a rounded end surface that protrudes from the end of the light guide inherently has a wider field of view than a flat end surface.

Thus, having considered the evidence of record, we find that, to the extent the proposed substitute claim 13 is understood as reciting a light guide with a flat-faced end surface that has a narrower field of view than a light guide with a rounded end surface, Petitioner has demonstrated that the claim is obvious over the combination of Numaga and Haisley. The limitations in proposed substitute claims 14–23 are the same as those in original claims 2–11 and are unpatentable for the same reasons as discussed above relative to those claims.

Petitioner also argues that proposed substitute claim 24 is unpatentable over the combination of Numaga and Hete. Opp. To Mot. To

Amend, 17–20. Petitioner cites Numaga as disclosing light guides with protruding end surfaces and argues that, although Numaga does not explicitly state that the substantially curved light surface 21s of light guide part 21b has a widening field of view, surface 21s inherently disperses emitted light to a greater degree than an equivalent flat surface. *Id.* at 17–18. Hete discloses a small bore PPG sensor for animals with a fiber optic cable coupled to the sensor and an opto-electrical converter coupled to the fiber optic cable. Ex. 1075 Abstract. Petitioner cites Hete as disclosing first and second light guides having a substantially curved exposed end surface that protrudes into tissue to improve transmission and gathering of light. Opp. to Mot. To Amend 19. Petitioner argues that in Hete drum lens 72 is a glass cylinder that is flat on one end and hemispherical on the other to improve dispersion of LED light and collection of received light. *Id.*; Ex. 1075 ¶¶ 60–62.

Patent Owner argues Petitioner employs improper hindsight and that a person of ordinary skill would not have been motivated to combine the teachings of Hete's small bore PPG sensor for animals with those of Numaga, which concerns a device worn on a human wrist. Reply to Opp. To Mot. To Amend 11–12. Petitioner does not cite Hete as a modification to Numaga. Petitioner notes, there is no dispute Numaga discloses a curved end surface. Instead, Petitioner relies on Hete to demonstrate that the principle of widening the field of view recited in claim 24 was known in the art, i.e., "to illustrate that such a curved surface exhibited the property of widening a field of view as compared to a flat surface." Surreply 10.

In consideration of the above, we are persuaded that, to the extent proposed substitute claim 24 is understood to recite a curved surface that

widens the field of view as compared to a flat-faced surface, Petitioner has demonstrated by a preponderance of the evidence that proposed substitute claim 24 would have been obvious to a person of ordinary skill in light of the art cited and applied by Petitioner and is unpatentable.

Conclusion

In consideration of all the evidence discussed above, we deny Patent Owner's Motion to Amend.

MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2013–2019 and the portions of the Declaration of Dr. Pollonini (Ex. 2009 at ¶¶ 84–98) that rely on these exhibits as improper hearsay under Federal Rule of Evidence ("FRE") 802 and on the basis that Exhibits 2013–2019 are unauthenticated under FRE 901. Mot. To Exclude, 1.

Inventor LeBoeuf testifies that each of Exhibits 2014–2019 is a true and correct copy of raw and processed data from tests performed by Patent Owner's employee Seth Long, working at Dr. LeBoeuf's direction, on the sensor module 1 (SM1) and sensor module 2 (SM2) worn by three subjects in a five minute test scenario on September 6, 2017. Ex. 2023, LeBoeuf Decl. ¶ 11, 17. Inventor LeBoeuf testifies that SM1 and SM2 are prototypes of an ear based heart rate monitor developed by Patent Owner and are identical, except that SM2 has first and second light guides, each comprising an exposed end surface that is configured to engage the body of the subject that is not present in SM1. *Id.* at ¶¶ 16, 19–20. Inventor Steven LeBoeuf testifies that Exhibit 2013 is a true and correct copy of the results of integrating sphere tests conducted on SM1 and SM2 on September 19, 2017

by Valencell employee Keith Richardson, working at Dr. LeBoeuf's direction. *Id.* ¶¶ 12, 14, 18.

Inventor LeBoeuf's Declaration does not state when SM1 and SM2 were assembled, does not state if SM1 and SM2 were prepared for this trial, does not provide details of the construction of SM1 and SM2, does not describe the tests in detail, does not state how Dr. LeBoeuf directed Patent Owner's employees conducting the tests, does not state whether inventor LeBoeuf was present or observed the tests, and does not state whether inventor LeBoeuf reviewed or assessed the results. There is no testimony in the record from either of Patent Owner's employees (Seth Long and Keith Richard) who performed the tests.

Dr. Pollonini testified that she met with inventor LeBoeuf and inventor Michael Aumer, to discuss the SM1 and SM2 testing and its results. Ex. 2009, Pollonini Decl. ¶¶ 84, 85. No testimony from inventor Aumer has been cited in the record. Dr. Pollonini testifies that as a result of the meeting with the inventors, "Based on my conversation with Drs. LeBoeuf and Aumer, it is my understanding that the AC signal in this data refers to the average value of the peak-to-peak amplitude of the perceived pulsatile waveform and that the DC signal in this data refers to a PPG sensor." *Id.* ¶ 85. Dr. Pollonini also stated "[i]t is my understanding that a true and correct copy of the raw and processed data that was collected from the SM1 and SM2 devices is included in Exhibits 2014-2019." *Id.* As to the integrated sphere testing, Dr. Pollonini testified "[d]uring my meeting with Drs. LeBoeuf and Aumer, we discussed the integrated sphere testing that Valencell performed on the SM1 and the SM2. . . . It is my understanding that Valencell performed three separate integrated sphere tests on SM1 and

SM2. It is my understanding that a true and correct copy of the results from this testing is included in Exhibit 2013." *Id.* ¶ 90. Dr. Pollonini also described an integrated sphere test and stated "Integrated spheres are an accepted method to measure the light produced by a source." *Id.*

Petitioner contends that Patent Owner's out of court testing data in Exhibits 2013–2019 is hearsay because it is offered to prove the truth of the matter asserted, i.e., a purported difference in the performance of the SM1 and SM2 devices that are alleged to be different because the SM1 does not have light guides and SM2 has first and second light guides. Mot. To Exclude 4. Petitioner further argues that Exhibits 2013–2019 are unreliable and do not fall within any hearsay exception. *Id.* at 5–7.

Patent Owner responds to Petitioner's assertions that graphical data in Exhibit 2013 may have required human input or analysis as speculative and argues that there is no evidence to support Petitioner's assertion. *Id.* at 10 (citing Ex. 2023, LeBoeuf Supp. Decl. ¶¶ 12, 14, stating that sensor module was put into the sphere, light was received, and total output was measured in nWatts). As to Exhibits 2014–2019, Patent Owner cites only to testimony that the data was from the SM1 device. *Id.* at 10–11 (citing Ex. 2023, LeBoeuf Decl. ¶ 11).

Patent Owner argues that, as machine readouts, the test results in Exhibits 2013–2019 are not statements by a person and, therefore, are not hearsay. Opp. To Mot. To Exclude 8–11. Examples of machine data found not to be statements for purposes of hearsay cited by Patent Owner (fax header, electronic tracer on telephone) involve machines whose operation and performance are standard and well documented. *Id.* at 9. With the possible exception of the integrated sphere test in Exhibit 2013, it is not

clear that the test data in Exhibits 2014–2019 is obtained using a standard, well-documented procedure on a known machine. To the extent that data is acquired by a machine programmed to do so, the programming and processing of the data constitutes an out of court statement by the machine designer. In that case, the data presented by the machine is a mere expression of its programming and may constitute hearsay.

As to authentication, noting that there is no testimony that either Dr. Pollonini or inventor LeBoeuf had first had knowledge of the testing, Petitioner contends that Patent Owner fails to correlate properly data from SM1 and SM2 testing. *Id.* at 7–11. Patent Owner emphasizes that, as an officer of Patent Owner, inventor LeBoeuf's testimony that the results are a true and correct copy is sufficient. Opp. To Mot. To Exclude 11 (citing Fed. R. Evid. 901, requiring sufficient proof a reasonable juror could find in favor of authenticity or identification).

We have already discussed Dr. LeBoeuf's potential conflict in the context of corroboration for antedating purposes. Having not chosen to rely upon those who actually conducted the testing, the basis for asserting that the test results are the actual test results without alteration is unclear. As discussed above, the scope of inventor LeBoeuf's activity when he "directed the testing" is also unclear. The intent of authentication is undermined, as we have no testimony concerning what procedures were used to acquire the test results and assure that the results have not been subsequently manipulated.

In consideration of the above, we agree that Exhibits 2014–2019 are hearsay and that Exhibits 2013–2019 have not been properly authenticated. Our Decision in this trial does not rely upon Exhibits 2103–2019 directly.

Whether or not Exhibits 2013–2019 are properly authenticated or hearsay, however, the heart of the issue is Dr. Pollonini's reliance on the test data provided by the inventors. Petitioner moves to exclude paragraphs 84–98 of Dr. Pollonini's Declaration, Exhibit 2009. The Federal Rules of Evidence provide that:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703. The documents need not be admissible for the expert to rely upon them. *Id.* Dr. Pollonini testified that the integrated sphere test is an accepted method to measure light from a source. Ex. 2009 ¶ 90. Although Dr. Pollonini cannot ascertain whether the differences in the SM1 and SM2 structures are reflective of the claimed structures, as an expert, Dr. Pollonini would be expected to recognize integrated sphere test results that are inconsistent with a properly performed test. Thus, we find that Dr. Pollonini's reliance on the test results in Exhibit 2013 and his interpretation of the results as to the amount of light emitted from the source is reasonable.

Dr. Pollonini's reliance on the test results in Exhibits 2014–2019 is less clear, as Dr. Pollonini testified only that, based on his discussions with the inventors, it was his "understanding" that the AC and DC test data has specific implications. Nevertheless, as an expert in the field, Dr. Pollonini would be expected to recognize a test procedure that was not adequate to

demonstrate the features the test is purported to show. Ex. 2009, Pollonini Dec. ¶¶ 84, 85. Thus, we find it was reasonable for Dr. Pollonini to rely on the test data to show the difference in performance between SM1 and SM2. As Dr. Pollonini has no personal knowledge of the differences between SM1 and SM2, and there is no evidence Dr. Pollonini inspected SM1 and SM2, the implications of Dr. Pollonini's analysis of the different results is limited.

Finally, we note that because this case does not involve a jury, we are less concerned with the comparison of the probative value against prejudicial effect noted in Fed. R. Evid. 703 and that Dr. Pollonini and inventor LeBoeuf were available for cross examination on the relevant topics.

In consideration of the above, Petitioner's Motion to Exclude is denied.

ORDER

In consideration of the above it is:

ORDERED that claims 1–12 of the '965 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend is DENIED;

FURTHER ORDERED that Petitioner's Motion to Exclude 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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