

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TALEXMEDICAL, LLC,
Petitioner,

v.

BECON MEDICAL LIMITED and
HENRY STEPHENSON BYRD, M.D.,
Patent Owner.

IPR2020-00028
Patent 8,167,942 B2

Before RICHARD H. MARSCHALL, JASON W. MELVIN, and
SEAN P. O'HANLON, *Administrative Patent Judges*.

MARSCHALL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision on Remand
Determining Challenged Claims 5–7 Unpatentable
35 U.S.C. §§ 144, 318(a)

This case returns on remand from the United States Court of Appeals for the Federal Circuit in *TalexMedical, LLC v. Becon Medical Ltd.*, Nos. 2021-2069, 2021-2071, 2021-2109, 2021-2110, slip op. 1 (Fed. Cir. July 22, 2022) (“CAFC Dec.”). In our prior Final Written Decision in this matter, we concluded that Petitioner, TalexMedical, LLC, proved by a preponderance of the evidence that claims 1–3 and 9 of U.S. Patent No. 8,167,942 B2 (Ex. 1001, “the ’942 patent”) are unpatentable but did not prove by a preponderance of the evidence that claims 4–7 are unpatentable. Paper 30 (“FWD”), 49. On appeal, the Federal Circuit affirmed our judgment of unpatentability for claims 1–3 and 9 of the ’942 patent and affirmed our judgment of no unpatentability for claim 4 of the ’942 patent. CAFC Dec. 2. The Federal Circuit also held that we erred in our construction of the “reversibly engage” claim limitation and, as a result, vacated our judgment of no unpatentability for claims 5–7 of the ’942 patent and remanded for further proceedings consistent with the Federal Circuit’s construction of “reversibly engage.” *Id.* at 2, 16. For the reasons that follow, we determine that Petitioner shown by a preponderance of the evidence that claims 5–7 are unpatentable under the Federal Circuit’s claim construction.¹

¹ The Federal Circuit also addressed a related case, IPR2020-00030, in the same decision on appeal. CAFC Dec. 2. The Federal Circuit affirmed our judgment in IPR2020-00030 in all respects. *Id.* at 23. Accordingly, because the remand only applies to the portion of the judgment as to claims 5–7 of the ’942 patent at issues in this matter, we do not view IPR2020-00030 as subject to the Federal Circuit’s remand, and we issue no further decision in that matter.

BACKGROUND

A. Procedural History

Petitioner filed a Petition (Paper 1, “Pet.”) requesting institution of an *inter partes* review of claims 1–7 and 9 of the ’942 patent. Patent Owner, Becon Medical Limited and Henry Stephenson Byrd, M.D. (collectively, “Patent Owner”), filed a Preliminary Response. Paper 7. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of claims 1–7 and 9 of the ’942 patent on all presented challenges. Paper 10 (“Inst. Dec.”). After institution, Patent Owner filed a Response (Paper 16, “PO Resp.”), Petitioner filed a Reply (Paper 20, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 23, “PO Sur-reply”). We held an oral hearing in this proceeding on January 21, 2021, and included a transcript of the hearing in the record. Paper 29.

After the remand, we authorized additional briefing. *See* Paper 34. Pursuant to that authorization, Petitioner filed an Opening Brief on Remand (Paper 38, “Pet. Rem.”), Patent Owner filed a Response on Remand (Paper 42, “PO Rem. Resp.”), Petitioner filed a Reply on Remand (Paper 43, “Pet. Rem. Reply”), and Patent Owner filed a Sur-reply on Remand (Paper 44, “PO Rem. Sur-reply”).

B. Related Matters

The parties identify two proceedings that may affect, or could be affected by, a decision in this proceeding. First, the parties identify co-pending litigation involving the ’942 patent, *Becon Medical, Ltd. and Henry Stephenson Byrd, M.D. v. Scott P. Bartlett, M.D. and TalexMedical, LLC*, No. 2:18-cv-04169-JD (E.D. Pa.) (filed on Sept. 27, 2018) (“district court litigation”). Pet. 3; Paper 4, 1. Second, the parties identify IPR2020-00030

as a related proceeding, which involves a related patent asserted by Patent Owner in the district court litigation, U.S. Patent No. 8,852,277 B2. Pet. 3; Paper 4, 1.

C. The '942 Patent

The '942 patent issued on May 1, 2012, from an application filed February 10, 2009. Ex. 1001, codes (22), (45). The '942 patent relates to “correcting misshaped ears using a molding device.” *Id.* code (57).

Petitioner’s annotated version of Figure 1 of the '942 patent, reproduced below, provides a description of the parts of the ear that are relevant to this Decision. Pet. 7.

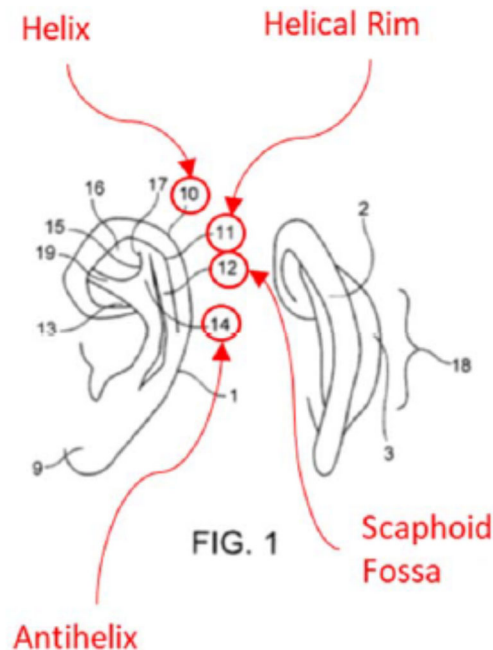


Figure 1 of the '942 Patent (annotated)

Annotated Figure 1 shows the structures of the ear that the molding device interacts with, including helix 10 having helical rim 11 on the outside of the ear, scaphoid fossa 12 just inward from helical rim 11, and antihelix 14 inward from scaphoid fossa 12. *Id.* at 4:2–7, Fig. 1.

Figure 5 of the '942 patent depicts molding device 29 and is reproduced below.

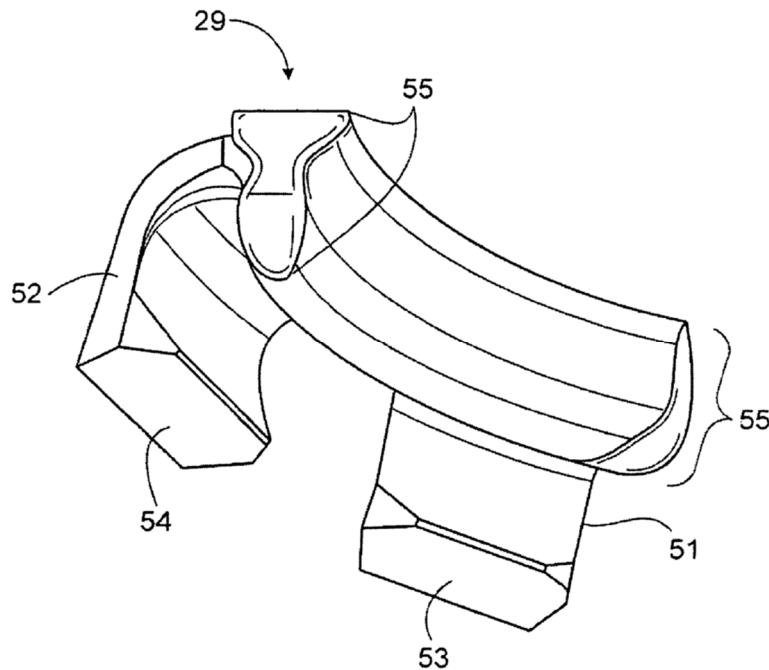


Figure 5 “is a slightly inferior and lateral view” of ear molding device 29. Ex. 1001, 3:53–54. Ear molding device 29 includes “scaphal mold 55 configured to mold the scaphoid fossa into a substantially correct anatomic shape.” *Id.* at 6:29–31. The '942 patent describes scaphal mold 55 as an extension of legs or braces 51, 52. *Id.* at 6:37–39. The inner surface of scaphal mold 55 facing the legs cooperates with the inner surfaces of legs 51, 52 “to form a space threewith configured to mold the helix and helical rim during their growth while in the ear molding device, such that the growth of the helix and helical rim conforms to a curvature defined by the space between the scaphal mold and the legs.” *Id.* at 6:41–47.

The '942 patent also discloses cradle 20 that includes cradle base 21 and cradle cover 22. Ex. 1001, 4:33–34, Fig. 2. During use, the patient’s

ear, fitted with molding device 29, fits within the compartment formed between cradle base 21 and cradle cover 22. *Id.* at 4:36–38, 5:1–3.

D. Challenged Claims

Petitioner challenged claims 1–7 and 9 in the Petition. Pet. 1. Only dependent claims 5–7 are the subject of the remand, and we reproduce those claims below, along with independent claim 1, from which they depend.

1. A molding device for a human ear, wherein the ear includes an antihelix, a superior limb of the triangular fossa, a helix, a helical rim, a base, a concha, and a scaphal area, the molding device comprising:

one or more braces; and

a scaphal mold supported by the one or more braces, wherein the one or more braces and the scaphal mold are constructed to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and further constructed to maintain a substantially correct anatomical shape of the helix and the helical rim, wherein the scaphal mold and one or more braces are constructed to mold the helix and helical rim during their growth such that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces.

...

5. The ear molding device of claim 1, wherein the one or more braces includes a vertical support surface constructed to **reversibly engage** a second surface.

6. The ear molding device of claim 5, wherein the one or more braces include a horizontal support surface constructed to **reversibly engage** a third surface.

7. The ear molding device of claim 6, wherein the vertical and horizontal support surfaces when engaged to the second and third surfaces, respectively, stabilize the ear molding device.

Ex. 1001, 10:19–34, 10:46–55 (emphasis added).

E. Asserted Grounds

Petitioner asserts that claims 5–7 would have been unpatentable as part of the following ground (Pet. 6).

Claim(s) Challenged	35 U.S.C. § ²	Reference(s)/Basis
1–7, 9	103	Dancey, ³ Gault ⁴

Petitioner also relies on the Declarations of Dr. Meir D. Hershcovitch. Ex. 1007 (Hershcovitch Declaration pre-remand); Ex. 1032 (Hershcovitch Remand Declaration). Patent Owner relies on Declarations of Rohit K. Khosla, M.D. and Lily N. Daniali, M.D. *See* Ex. 2021; Ex. 2022. Patent Owner did not introduce any declarations addressing the merits of the parties’ disputes post-remand.

F. Prior Final Written Decision

In our prior Final Written Decision, we construed several claim limitations, including “reversibly engage” found in dependent claims 5 and 6. *See* FWD 8–14. Patent Owner argued that we should construe “reversibly engage” to mean “to engage a surface on a reverse side facing away from the ear.” *Id.* at 13 (citing PO Resp. 17). Petitioner argued that we should construe the limitation “to mean simply to engage, or contact, to stabilize the device.” *Id.* (citing Pet. Reply 6); Pet. 10–11. Petitioner argued

² The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the ’942 patent issued was filed before that date, unless otherwise stated, our citations to Title 35 are to its pre-AIA version.

³ Dancey et al., *Acrylic Ear Splints for Treatment of Cryptotia*, Plastic and Reconstructive Surgery, Vol. 115, No. 7, 2150–2152 (2005) (Ex. 1005) (“Dancey”).

⁴ GB 2304579 A, published March 26, 1997 (Ex. 1015) (“Gault”).

that “the surfaces that reversibly engage stabilize the device, but do not need to face away from the ear, and at least one example from the ’942 patent uses the term reversible in a different manner.” FWD 13 (citing Pet. Reply 5–6). We agreed with “Patent Owner’s proposed construction because it more accurately tracks the claim language and specification” and construed “reversibly engage” to mean *to engage a surface on a reverse side facing away from the ear*. *Id.* at 13–14.

Turning to the obviousness challenges, we found that “the combination of Dancey and Gault discloses all of the limitations of claim 1” and that “Petitioner establishes sufficiently that one of ordinary skill in the art would have been motivated to incorporate Gault’s teachings into Dancey’s device.” FWD 24. As to claim 5, we noted that “Petitioner provides no argument or evidence that the structure it identifies as the vertical support surface in Dancey’s device reversibly engages the skin of the patient” using Patent Owner’s proposed claim construction, which we had already adopted. *Id.* at 30. Using that construction, we found that “[b]ecause the engagement Petitioner relies on takes place on the side of the vertical support facing the ear, rather than facing away from the ear, Petitioner has not shown that the combination of Dancey and Gault discloses all of the limitations of claim 5.” *Id.* We further found that “[b]ecause claims 6 and 7 ultimately depend from claim 5, for the same reasons Petitioner has not shown that the combination of Dancey and Gault discloses all of the limitations of claims 6 and 7.” *Id.* As a result, we determined that Petitioner did not establish by a preponderance of the evidence that any of claims 5–7 are unpatentable. *Id.* at 38.

G. The Federal Circuit's Decision

As to the proper construction of “reversibly engage,” the Federal Circuit agreed with Petitioner’s argument that we erred in adopting Patent Owner’s proposal when construing the limitation. CAFC Dec. 14. The Federal Circuit also held that neither Petitioner nor Patent Owner “offered the Board a plausible construction of the ‘reversibly engage’ limitation” and that we “failed to consider the possibility that both constructions are inconsistent with the intrinsic evidence.” *Id.* The Federal Circuit stated that Petitioner “failed to propose a sufficiently narrow construction to the Board” and that Petitioner’s “strategic choice led the Board down the wrong path.” *Id.*

As to the substance of the construction of “reversibly engage,” the Federal Circuit determined that our adoption of Patent Owner’s construction “improperly narrowed the scope of the claims by importing a directional limitation based on embodiments described in the specification.” CAFC Dec. 14. The Federal Circuit reviewed relevant portions of the specification and determined that “[c]onsistent with the claim language, the ’942 patent’s specification describes the horizontal and vertical supports adapted to reversibly engage with respective surfaces.” *Id.* at 15 (citing Ex. 1001, 7:57–63, 8:6–13). As to “reversible engagement,” the court determined that “the specification describes supports that engage and disengage” and “explains that this engagement may be facilitated by the use of adhesive, which further implies disengagement as well as engagement.” *Id.* at 16 (citing Ex. 1001, 3:24–37). The court also noted that “the plain meaning of the word ‘reversibly,’ . . . clearly implies a two-way direction for engagement.” *Id.*

Based on its analysis, the Federal Circuit construed the “reversibly engage” limitation to mean “interchangeably engage with and disengage from, to stabilize the device.” CAFC Dec. 16. The Federal Circuit did not provide further guidance as to the meaning of “to stabilize the device.” *See id.* The court vacated “the Board’s construction of the ‘reversibly engage’ limitation,” vacated our “judgment of no invalidity for claims 5–7 of the ’942 patent,” and remanded our decision in this matter “for the limited purpose of having the Board apply the correct claim construction.” *Id.*

ANALYSIS

A. Legal Standards

To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). “In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burdens of proof in an *inter partes* review).

Petitioner relies on obviousness in its challenges to the claims of the ’942 patent. A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

B. Prior Determinations that Apply on Remand

As part of our prior Final Written Decision, we made a number of findings and determinations, and with the exception of the construction of “reversibly engage” and its application to our analysis of claims 5–7, our previous findings and determinations were part of the judgment that the Federal Circuit affirmed on appeal. *See* CAFC Dec. 23. Several of those previous findings and determinations are relevant to our consideration of claims 5–7 on remand, including (1) a person having ordinary skill in the art “would have advanced medical education and knowledge of nonsurgical ear molding devices,” as Petitioner proposed in the Petition; (2) Patent Owner failed to establish a nexus to any objective indicia of nonobviousness; (3) the combination of Dancey and Gault discloses all of the limitations of claim 1; and (4) Petitioner establishes sufficiently that one of ordinary skill in the art would have been motivated to incorporate Gault’s teachings into Dancey’s device. *See* FWD 8–38. Unless noted otherwise, we will apply these and the other factual and legal determinations made in our prior Final Written Decision here. We also apply the Federal Circuit’s construction of the

“reversibly engage” limitation, which means “interchangeably engage with and disengage from, to stabilize the device.” CAFC Dec. 16.

C. Challenge Under 35 U.S.C. § 103 Based on Dancey and Gault

Petitioner challenged claims 1–7 and 9 under 35 U.S.C. § 103 based on Dancey and Gault. Pet. 15–22. On remand, we only revisit Petitioner’s challenge to claims 5–7, which ultimately depend from independent claim 1. See Pet. 28–31. The parties appear to agree that “[t]he only issue now is whether Dancey in view of Gault discloses the recited limitations of claims 5–7 when applying the Federal Circuit’s construction of the term “reversibly engage.” Pet. Rem. 2. Petitioner relies on Dancey as disclosing the “reversibly engage” limitation in these claims. See Pet. 28–31. We first provide an overview of Dancey, then address the parties’ arguments.

1. Dancey

Dancey discloses an acrylic ear splint to treat cryptotia, a congenital deformity of the ear. Ex. 1005, 9–10. Dancey describes various non-surgical methods that have been used to treat such ear deformities in the past. *Id.* at 10. Dancey discloses its own device for non-surgical treatment, which includes “a two-part pressure splint” custom made to fit the ear and move the upper portion of the ear into an anatomically correct position. *Id.*

Figure 1 of Dancey, reproduced below, shows two photographs of a device on a patient’s ear.

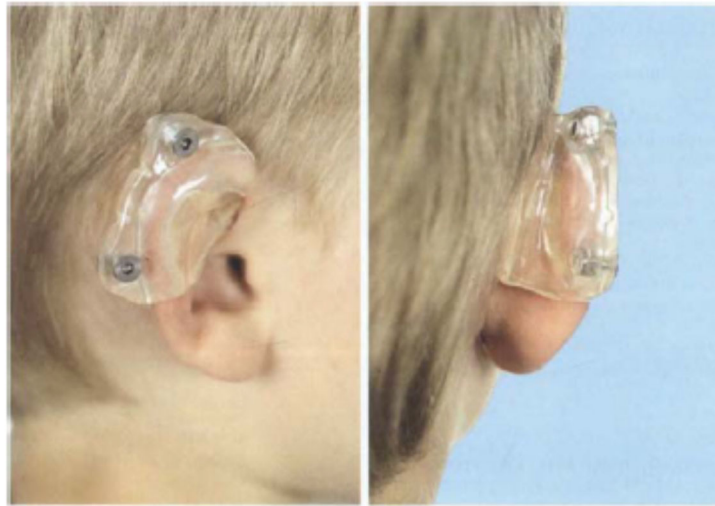


Figure 1 depicts a lateral (on the left) and posterior (on the right) view of Dancey's device on a patient. Ex. 1005, Fig. 1. Dancey describes the splint as "made from translucent acrylic to allow regular inspection" of the ear to note any "pressure necrosis" during treatment. *Id.* at 10. "The splint was worn continuously for 1 year and then intermittently for 9 months." *Id.* According to Dancey, after that treatment, the "patient now has a satisfactory cosmetic result, with an essentially normal-looking ear." *Id.*

2. Claim 5

a. The Parties' Positions

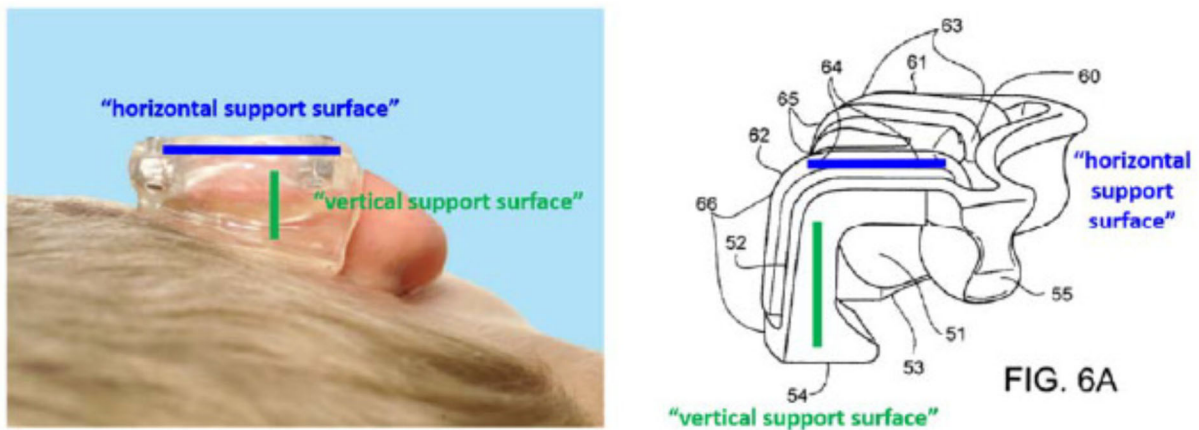
In the Petition, Petitioner argued that Dancey discloses a splint to correct "an ear deformity where the upper pole of the ear appears buried within the skin of an infant's head." Pet. 28 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 11–12, 46–48). Petitioner also argued that Dancey's two-part custom designed "splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear." *Id.* (citing Ex. 1007 ¶¶ 82, 87, 91). According to Petitioner, the "inner surface of the brace of the Dancey splint is a vertical support that is constructed to reversibly engage

the upper surface of the posterior ear (i.e. retroauricular skin surface, which is the “second surface”) to push that area outwards, and away from the infant’s head.” *Id.* at 28–29 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 83–84). Petitioner contended that the “engagement of the vertical support of the brace with the second surface serves to stabilize the splint” and that after completion of treatment, “the splint is removed, disengaging the vertical support surface from the second surface.” *Id.* at 29 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 83–85).

In its Response, Patent Owner argued that we pointed out a potential lack of explanation as to Petitioner’s arguments regarding claim 5 in our Decision on Institution, and further argued that Petitioner’s declarant Dr. Hershcovitch provided testimony that “once again suffers from hindsight bias of arbitrarily assigning unrelated components on Dancey to the claim limitations, such as the vertical or horizontal surfaces recited in claims 5–7, without any explanation.” PO Resp. 44 (citing Paper 10, 22; Ex. 2021 ¶¶ 205–228; Ex. 2022 ¶¶ 206–229). Patent Owner also described Dr. Hershcovitch’s statements as “conclusory” and insufficient to meet Petitioner’s burden. *Id.*; *see also* PO Sur-reply 8 (arguing that Petitioner fails to identify a surface that the vertical support surface that engages).

In its Reply, Petitioner argued that the claims require vertical and horizontal support surfaces, and second and third surfaces, without specifying “what those ‘second’ and ‘third’ surfaces are.” Pet. Reply 18. Petitioner labelled a photo of Dancey’s device to identify the vertical and horizontal support surfaces and argued that Dancey describes both surfaces “that engage other surfaces to stabilize the device—and the ear retained within it—throughout the treatment.” *Id.* at 19.

In its Opening Brief on Remand, Petitioner contends that the arguments in the “Petition and supporting evidence clearly identif[y] the recited support surfaces and the second and third surfaces of Dancey that read on these limitations” and repeats those same arguments. Pet. Rem. 2–3 (citing Pet. 28–30). Petitioner also provides an annotated photograph of Dancey’s splint along with an annotated Figure 6A from the ’942 patent, which we reproduce below.



Both the annotated photograph of Dancey’s splint and the annotated Figure 6A from the ’942 patent identify alleged horizontal support surfaces in blue and alleged vertical support surfaces in green. Pet. Rem. 3; Pet. Reply 19 (showing same). Petitioner contends that it properly identified the vertical support surface required by claim 5 “as the inner surface of the brace of the Dancey splint ‘that is constructed to reversibly engage the upper surface of the posterior ear (i.e. retroauricular skin surface, which is the ‘second surface’) to push that area outwards, and away from the infant’s head.’” Pet. Rem. 4 (quoting Pet. 28). Petitioner contends that “[t]his engagement served to stabilize the splint. *Id.* (citing Pet. 29; Ex. 1007 ¶¶ 81–86; Ex. 1032 ¶¶ 7–8). Petitioner further argues that its “position is unaffected by the remanded definition of ‘reversibly engage’” because “Petitioner previously argued, and

submitted supporting evidence, that ‘once the treatment has concluded, the splint is removed and the vertical support surface disengages from the retroauricular skin surface.’” *Id.* at 5 (quoting Pet. 29) (citing Ex. 1032 ¶¶ 8–9). According to Petitioner, its “evidence of record establishes that the vertical support surface interchangeably engages with and disengages with the retroauricular skin surface.” *Id.* (citing Ex. 1032 ¶ 9).

In its Response Brief on Remand, Patent Owner argues that Petitioner and its declarant fail to address how Dancey meets the “to stabilize the device” aspect of the Federal Circuit’s construction of “reversibly engage.” PO Rem. Resp. 1. Patent Owner contends that “the patient’s ear in Dancey doesn’t stabilize the Dancey splint; it’s the other way around.” *Id.* at 1–2. Patent Owner contends that Dancey’s two-part splint pinches or clamps the ear much like a “wood shop two-part clamp,” such that the pressure exerted by the clamp on the ear holds the device on the ear; i.e., the ear does not hold the device on the ear. *Id.* at 2–3 (citing Ex. 2022 ¶¶ 84–88, 166–167). Patent Owner further contends that Dr. Hershcovitch admits that Dancey’s splint applies pressure to and holds the device on the ear and that the ear does not stabilize the device. *Id.* at 3–5 (citing Ex. 2034, 83:11–18, 129:11–131:4; Ex. 2047, 88:21–25, 91:1–5). In addition, according to Patent Owner, Dancey itself shows that the retroauricular skin on the back of the ear does not stabilize the device because the device did not maintain the ear in the correct position for the first four months of treatment. *Id.* at 5–6. Finally, Patent Owner argues that we are free to construe the claims further in this Decision, and that we should construe the “second surface” to exclude the surface of the ear. *Id.* at 6–11. Patent Owner contends that the language of claim 1 supports such an interpretation because it “already recites the

interaction between the ear molding device and the ear surface, it makes no sense for the ‘second surface’ in claim 5 to also be the surface of the ear.”

Id. at 8–9. Patent Owner also contends that the specification repeatedly identifies the second and third surfaces as surfaces not on the ear but other surfaces used to counteract the forces exerted by the ear. *Id.* at 9–11.

Finally, Patent Owner argues that Dr. Hershcovitch admits that the vertical support surface touches the ear’s helix, which cannot be the “second surface” because claim 1 already recites the helix. *Id.* at 11.

In its Reply on Remand, Petitioner argues that it did not fail to address the “to stabilize the device” aspect of the Federal Circuit’s construction, and instead properly focused on the only aspects of its construction that changed in light of the Federal Circuit’s construction. Pet. Rem. Reply 3. Petitioner also argues that Patent Owner forfeited its arguments as to the “to stabilize the device” aspect of the construction because Patent Owner could have and should have made those arguments in response to Petitioner’s earlier proposed construction, which included the same “to stabilize the device” requirement. *Id.* at 3–4. Petitioner further contends that Patent Owner fails to offer any declarant testimony addressing the Federal Circuit’s “reversibly engage” claim construction, and that the prior testimony it relies upon lacks support because it assumes that Patent Owner’s proposed construction applies. *Id.* at 4–7. As to whether Dancey discloses the limitations of claim 5, Petitioner contends that it properly identifies a vertical support in Dancey’s device that stabilizes the device and that “Dancey makes clear that stable positioning of the device on the patient’s ear is critical.” *Id.* at 7–8 (citing Ex. 1032 ¶¶ 7–8). Petitioner also characterizes Patent Owner’s assertion that “the ear doesn’t stabilize the Dancey splint” as “unsupported

by the evidence” because when the device reversibly engages the back of the ear (corresponding to the claimed “second surface”), “the device is stabilized while another portion of the patient’s ear is subjected to treatment.” *Id.* at 8. As to whether the recited “second surface” can read on the retroauricular surface of the patient’s ear, Petitioner argues that the claimed surfaces are undefined in the specification and that we should not import surface limitations from embodiments in the specification describing a cradle for the ear molding device, given that claims 5–7 do not claim any aspects of the cradle. *Id.* at 8–10.

In its Remand Sur-reply, Patent Owner repeats its argument that Petitioner and Dr. Hershcovitch failed to address the “to stabilize the device” aspect of the claim requirement and further argues that mere engagement between the device and the ear does not necessarily stabilize the device. PO Rem. Sur-reply 1–3. Patent Owner also argues that because Petitioner “did not establish with evidence how the patient’s ear in Dancey would ‘stabilize the device,’” Patent Owner “had no burden to come forward with evidence to disprove invalidity.” *Id.* at 3. Nevertheless, according to Patent Owner, both Dancey and Dr. Hershcovitch’s testimony show that the ear does not stabilize the device. *Id.* at 3–5 (citing PO Rem. Resp. 2–6). As to Petitioner’s argument that Patent Owner forfeited its arguments about stabilization, Patent Owner argues that its declarant properly addressed this issue prior to remand, but in the context of claim 7 that includes an express limitation requiring stabilization of the device. *Id.* at 5–7 (citing Ex. 2022 ¶¶ 84–88, 166–167, 207, 209, 223–228). Patent Owner also argues that Petitioner fails to cite any intrinsic evidence in support of its argument that

the “second surface” can be any surface, including a surface of the patient’s ear. *Id.* at 8–9.

b. Discussion

We first address whether Petitioner establishes that Dancey discloses “one or more braces” that “includes a vertical support surface” as required by the first part of dependent claim 5. Petitioner argues, with declarant support, that Dancey’s two-part splint includes a part closest to the patient’s head (i.e., the brace) that includes vertical support. *See* Pet. 18 (“The brace is positioned against the patient’s head and supports the scaphal mold, which Dancey explains is ‘custom made to fit over the ear and retract the upper pole into an acceptable position.’” (citing Ex. 1005, 10; Ex. 1007 ¶¶ 58–59)), 28 (“The brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear.” (citing Ex. 1007 ¶¶ 82, 87, 91)); Pet. Reply 19 (identifying vertical support surface). As part of our prior Final Written Decision, we noted that “Patent Owner does not dispute that Dancey discloses “one or more braces” and found that Petitioner establishes sufficiently that the combination of Dancey and Gault discloses “one or more braces” as recited in claim 1, which are the same “one or more braces” required by claim 5. *See* FWD 18–19. That finding applies here. Petitioner also establishes that Dancey’s device includes a vertical support surface. *See* Pet. 28; Pet. Reply 19; Ex. 1005, 10; Ex. 1007 ¶¶ 82, 87, 91. Patent Owner disputes whether the vertical support surface Petitioner identifies meets the “reversibly engage” limitation, but does not appear to dispute that Dancey’s device includes the vertical support surface. *See* PO Resp. 44; PO Rem. Resp. 1–4. Based on the foregoing, we

find that Petitioner establishes that Dancey discloses “one or more braces” that “includes a vertical support surface” as required by the first part of dependent claim 5.

Turning to the “reversibly engage” limitation and the Federal Circuit’s construction, we first address whether Petitioner establishes that Dancey discloses a vertical support surface that “interchangeably engage[s] with and disengage[s] from” a “second surface.” *See* CAFC Dec. 16. Petitioner argues that after completion of treatment, “the splint is removed, disengaging the vertical support surface from the second surface.” Pet. 29 (citing Ex. 1007 ¶ 85); *see also* Pet. Rem. 3 (“[W]hen treatment is completed, the splint is removed from the patient’s head (the second surface) and disengaged from the top part of the Dancey splint (the third surface).” (citing Pet. 28–30)), 5 (“Petitioner previously argued, and submitted supporting evidence, that ‘once the treatment has concluded, the splint is removed and the vertical support surface disengages from the retroauricular skin surface.’” (citing Pet. 29; Ex. 1032 ¶¶ 8–9)). Notably, on remand, Patent Owner does not dispute that Dancey discloses this aspect of the Federal Circuit’s construction, and instead focuses on the “to stabilize the device” aspect of the construction, which we address below. *See* PO Rem. Resp. 1–11; PO Rem. Sur-reply 1–9. We find that Petitioner establishes that Dancey discloses a vertical support surface that interchangeably engages with and disengages from a surface on the back of the patient’s ear (i.e., the claimed “second surface”) when applying and removing Dancey’s device during treatment. *See* Pet. 29; Ex. 1007 ¶ 85; Ex. 1032 ¶¶ 8–9.

On remand, the parties dispute whether Dancey’s vertical support surface interchangeably engages with and disengages from a surface on the

back of the patient's ear *to stabilize the device* as the Federal Circuit's claim construction requires. *See* CAFC Dec. 16. Petitioner argues that Dancey's two-part custom designed "splint includes both a vertical support and a horizontal support that work in tandem *to stabilize the splint* and the vertical and horizontal forces exerted by the scaphal mold on the ear." Pet. 28 (citing Ex. 1007 ¶¶ 82, 87, 91) (emphasis added). According to Petitioner, the "engagement of the vertical support of the brace with the second surface serves to stabilize the splint." *Id.* at 29 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 83–84). Petitioner goes on to contend that "[t]hose skilled in the art recognize that stabilization of the device is fundamental to non-surgical splinting treatments." Pet. Reply 19 (citing Pet. 28–31; Ex. 1007 ¶¶ 81–93); Pet. Rem. 4 ("This engagement served to stabilize the splint." (citing Pet. 29; Ex. 1032 ¶¶ 7–8)); Pet. Rem. Reply 7–8.

We find Petitioner's arguments, and the supporting declarant testimony, persuasive. Petitioner sufficiently shows that the engagement of the vertical support of the brace with the upper surface of the posterior ear (i.e. retroauricular skin surface (the second surface)) helps stabilize the device. Dancey itself supports the argument by stressing the importance of "maintaining a splint in the correct position" because the splint did not maintain that correct position on the 6-month-old patient's ear during the initial four months of treatment. Ex. 1005, 10. After that time period, the "splint was worn continuously for 1 year and then intermittently for 9 months," with "a satisfactory cosmetic result"—i.e., with sufficient stability to maintain the correct position. *See id.* Accordingly, Dr. Hershcovitch's testimony that Dancey's vertical support surface stabilizes the device finds ample support in Dancey, and we find that testimony credible and

persuasive. *See* Ex. 1007 ¶ 82 (“Dancey addressed stabilizing the device from movement in the vertical direction” (citing Ex. 1005, 10)), ¶ 83 (“The vertical support surface engages the retroauricular skin surface, which is the ‘second surface,’ and provides a supporting counter force to secure the device and impede vertical movement away or toward the temporal skin surface.”).

We have considered Patent Owner’s arguments, but they do not undermine Petitioner’s persuasive showing on this issue. *See* PO Rem. Resp. 1–11; PO Rem. Sur-reply 1–9. The overarching theme of Patent Owner’s arguments hinges on its assertion that the “ear does not stabilize” Dancey’s device. *See* PO Rem. Resp. 1–6.⁵ For example, Patent Owner argues that Dr. Hershcovitch admits that if one places only one part of Dancey’s splint on an ear, the device will not be stable, which allegedly supports Patent Owner’s argument that the ear does not stabilize the device. *See id.* at 4–5 (citing Ex. 2047, 88:21–25, 91:1–5). These arguments miss the mark for two reasons. First, they suggest that the ear alone must somehow stabilize Dancey’s device or keep it in place. *See id.* at 1 (“[T]he patient’s ear in Dancey doesn’t stabilize the Dancey splint.”), 2 (acknowledging that pressure caused by clamping Dancey’s splint on the

⁵ Petitioner argues that Patent Owner forfeited all of its “to stabilize the device” arguments because it never made them prior to the remand. *See* Pet. Rem. Reply 3–4. We disagree. Prior to the remand, Patent Owner argued that Dancey’s surfaces failed to stabilize the device. *See* PO Sur-reply 9. Although this argument addresses the limitation in claim 7 that expressly requires the second and third surfaces to “stabilize the ear molding device,” we find Patent Owner’s argument sufficient to put Petitioner on notice of Patent Owner’s position and to preserve the argument on remand.

ear, which necessarily includes contact on the back of the ear, stabilizes the device). Nothing in the claim language or the Federal Circuit’s construction supports such an interpretation. The claim requires “a vertical support surface constructed to reversibly engage a second surface” and the Federal Circuit’s construed “reversibly engage” to mean “interchangeably engage with and disengage from, to stabilize the device.” CAFC Dec. 16. Read together, the claim requires a vertical support surface constructed to interchangeably engage with and disengage from the second surface, to stabilize the device. The claim does not require the second surface (Dancey’s ear) alone to stabilize the device—the stabilization stems from the engagement of the vertical support surface with the ear.

Second, Patent Owner’s arguments do not account for the possibility that other surfaces may also help stabilize the device. Claim 5 focuses on the engagement of one part of the device, the vertical support surface, with a second surface, but other claims focus on other interactions. For example, claim 6, which depends from claim 5, requires “a horizontal support surface constructed to reversibly engage a third surface,” which under the Federal Circuit’s construction of “reversibly engage” requires that the horizontal support and the third surface also stabilize the device. Thus, claim 5 does not foreclose the possibility that a horizontal support surface reversibly engaging a third surface also helps to stabilize the device, thereby undermining Patent Owner’s implicit argument that the back of the ear (the “second surface” of claim 5) must alone stabilize the device. As the Petition put it, the two support surfaces “work in tandem to stabilize the splint.” Pet. 28 (citing Ex. 1007 ¶¶ 82, 87, 91). Patent Owner’s arguments fail to establish, with adequate argument and supporting evidence, that the ear

alone, or the engagement of the vertical support surface with the back of the ear, standing alone, must stabilize the device. We do not read the claim so narrowly, and instead view the “reversibly engage” limitation in claim 5 as met even if other engagements with other surfaces also help to stabilize the device.

Patent Owner raises several other arguments that we find unpersuasive. First, Patent Owner repeatedly argues that Petitioner fails to address the “to stabilize the device” aspect of claim 5. Not so. Prior to remand, Petitioner and Dr. Hershcovitch repeatedly argued that the vertical support surface’s engagement with the back of the ear stabilizes Dancey’s device when addressing the limitations of claim 5. *See* Pet. 28–31; Pet. Reply 19; Ex. 1007 ¶¶ 82, 91. After remand, Petitioner and Dr. Hershcovitch again argue that the same engagement stabilizes the device. *See* Pet. Rem. 4, 6–7; Pet. Rem. Reply 7–8; Ex. 1032 ¶¶ 8, 18. Petitioner did not fail to address adequately the “to stabilize the device” aspect of claim 5’s “reversibly engage” limitation.

Second, Patent Owner argues that we should credit the testimony of its declarant, Dr. Daniali, who opined that “Dancey’s device is held onto the ear by that clamping force [of Dancey’s two-part splint] and not by any other surfaces.” PO Rem. Resp. 3 (citing Ex. 2022 ¶¶ 84–88, 166–167, 227; Ex. 2034, 129:11–131:4). Petitioner argues that we should disregard this testimony as “fatally tainted” because Dr. Daniali based it on Patent Owner’s now-rejected claim construction. *See* Pet. Rem. Reply 5–7. Patent Owner argues that it did not forfeit the argument because the testimony as to stabilization did not depend on Patent Owner’s construction, and Petitioner failed to address all of Dr. Daniali’s testimony. PO Rem. Sur-reply 5–7

(citing Ex. 2022 ¶¶ 84–88, 166–167, 207, 209, 223–228). We agree with Patent Owner that we should not disregard all of Dr. Daniali’s testimony simply because it accepts Patent Owner’s now-rejected claim construction as a starting point for the analysis. Nevertheless, we find the testimony unpersuasive. Several of the cited paragraphs from Dr. Daniali do not mention stability at all. *See* Ex. 2022 ¶¶ 84–88. Others arguably support Petitioner’s position by noting that “Dancey’s pressure splint applies a clamping force on the auricle so that the splint is not dislodged,” with clamping an ear by engaging it on both sides to prevent the device from being dislodged arguably showing how the engagement of the ear promotes stability of the device. *See id.* ¶ 166; *see also id.* ¶ 227 (“It is this pinching force that clamps Dancey’s two-part pressure splint to the ear.”). As noted above, the claim requires engagement between the vertical support surface and the back of the ear to help stabilize the device, not the ear alone. Even if some of these passages can be read as supportive of Patent Owner’s position, we view Petitioner’s argument and supporting testimony from Dr. Hershcovitch addressing the stability issue as more credible. *See* Pet. 28–29; Ex. 1007 ¶¶ 82–84.

Third, Patent Owner argues that the fact that Dancey’s device was not used on the 6-month-old patient for the first four months of treatment “due to technical difficulties in maintaining a splint in the correct position” indicates that the skin on the back of the ear does not stabilize the device. PO Rem. Resp. 5–6 (citing Ex. 1005, 10). Even if the device lacked stability for these first four months of treatment, however, Patent Owner ignores the fact that the device worked as intended “continuously for 1 year and then intermittently for 9 months.” Ex. 1005, 10. When read in full, Dancey’s

successful treatment for one year and nine months after initial difficulties suggests that Dancey's device was stabilized during that later time period. *See id.* At a minimum, this aspect of Darcey does not suggest that its device was incapable of stabilization as Patent Owner suggests.

Fourth, Patent Owner argues that the claimed "second surface" cannot read on the skin on the back of a patient's ear as in Dancey, and urges us to adopt a new claim construction to that effect in this Decision. *See* PO Rem. Resp. 6–11; PO Rem. Sur-reply 8–9. In our Institution Decision, we noted that Petitioner may need to more fully address whether the claimed surfaces can read on surfaces on the patient, and invited the parties to address the issue further during trial. Paper 10, 22. Patent Owner noted this aspect of our Institution Decision in its Patent Owner Response, but did not argue that we should construe the "second surface" or any other surfaces as not covering surfaces on the patient, as it does now. *See* PO Resp. 44; PO Sur-reply 8.⁶ Patent Owner could have and should have raised its claim construction argument in the Patent Owner Response. *See* Paper 11, 7 ("Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived."). Patent Owner fails to identify any aspect of the Federal Circuit's construction that would open the door to such an argument for the first time on remand. *See* PO Rem. Resp. 6–11. Under these circumstances, Patent Owner forfeited the right to make the argument when it did not raise the argument prior to remand, given that the

⁶ Petitioner briefly addressed the issue prior to remand in its Reply when it argued that "[t]he claims do not specify what those 'second' and 'third' surfaces are." Pet. Reply 18.

argument was equally applicable then and our Institution Decision invited the parties to address the issue during the trial.

Even if we consider the substance of Patent Owner's new claim construction argument, we are unpersuaded that we should construe "second surface" in claim 5 to exclude a patient's skin. The claim language itself does not limit the surface to a surface on the device or another non-human surface, and, as Petitioner points out, the specification does not define the terms in that manner. *See* Pet. Rem. Reply 8–9. The specification does describe the claimed support surfaces as part of a cradle that cooperates with the claimed ear molding device, but the claims at issue here cover the ear molding device, and unlike claims in Patent Owner's related patent, these claims do not refer to the cradle or its surfaces in any way. *See id.* at 9 (citing Ex. 1001, 2:4–26; Ex. 1003, claim 1). Patent Owner has the unenviable task of arguing that the claims are not so narrow that the "second surface" is part of the claimed ear molding device (because the specification does not support that reading), and not so narrow that the "second surface" must be a part of the cradle (because the cradle is unclaimed), but yet narrow enough to exclude the patient's skin from the scope of the limitation. We do not view the specification's reference to non-patient surfaces corresponding to the claimed "second surface," without any disavowal of claim scope, as sufficient to thread that needle. Doing so would require improperly reading in a limitation from the specification that the specification only implicitly suggests.

Finally, as to Patent Owner's argument that Dr. Hershcovitch admits that the vertical support surface touches the ear's helix, which cannot be the "second surface" because claim 1 already recites the helix, we are

unpersuaded that this testimony undermines any of Petitioner’s arguments. *See* PO Rem. Resp. 11. Petitioner does not rely on contact with the helix as satisfying any limitations in claim 5. *See* Pet. 28–29. Instead, Petitioner relies on engagement with “the upper surface of the posterior ear (i.e. retroauricular skin surface, which is the ‘second surface’).” *Id.* at 28. Even if the vertical support surface also engages the helix, Petitioner does not rely on that engagement in the context of claim 5 and therefore does not rely on the same structures to satisfy two distinct claim limitations, as Patent Owner suggests.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that the combination of Dancey and Gault⁷ discloses all of the limitations of claim 5.

c. Conclusion

“Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1361 (Fed. Cir. 2017). Above, based on the full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art; and (4) objective indicia of nonobviousness.

In particular, we find that (1) Petitioner’s proposed level of ordinary skill in the art is consistent with the art of record; (2) the combination of

⁷ Petitioner relies on Gault in the context of claim 1, from which claim 5 depends. *See* Paper 30, 15–24.

Dancey and Gault discloses all the limitations of claim 5; (3) one of ordinary skill in the art would have been motivated to combine Dancey and Gault in the manner Petitioner proposes; and (4) Patent Owner fails to establish a nexus and therefore fails to establish that the objective indicia support a finding of nonobviousness. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claim 5 of the '942 patent is unpatentable over the combination of Dancey and Gault.

3. *Claim 6*

a. The Parties' Positions

Petitioner argues that Dancey discloses the additional limitations in claim 6 requiring “horizontal support surface constructed to reversibly engage a third surface.” Pet. 29–30. Similar to its arguments in the context of claim 5, Petitioner argues that the “brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear.” *Id.* at 30 (citing Ex. 1007 ¶¶ 82, 87, 91–92). Petitioner identifies the horizontal support surface as the “top surface of the brace of the Dancey splint (the portion that is axial to the vertical support of the brace)” that reversibly engages “the bottom surface of the top part of the Dancey splint, which is the ‘third surface.’” *Id.* (citing Ex. 1005, 10; Ex. 1007 ¶ 88). According to Petitioner, the “engagement of the horizontal support of the brace with the third surface serves to stabilize the splint, including the scaphal mold, and to form the shape of the helix and helical rim during treatment.” *Id.* (citing Ex. 1005, 10; Ex. 1007 ¶ 88). Petitioner also contends that “[w]hen treatment is completed, the splint is removed, disengaging the horizontal support surface from the third surface.” *Id.*

(citing Ex. 1007 ¶ 88); *see also* Pet. Reply 19 (identifying horizontal support surface in annotated photograph of Dancey’s device).

In its Sur-reply, Patent Owner argues that Petitioner improperly identifies the horizontal support surface because it coincides with the scaphal mold Petitioner relies on in the context of claim 1. *See* PO Sur-reply 8–9. Patent Owner also argues that the alleged horizontal support surface “doesn’t engage anything, let alone a ‘third surface.’” *Id.*

In its Opening Brief on Remand, Petitioner repeats its argument from the Petition and Reply and posits that its “position is unaffected by the remanded definition of ‘reversibly engage.’” Pet. Rem. 5. According to Petitioner, as it stated in the Petition, the horizontal support surface (i.e., the top surface of the splint) disengages from the third surface (i.e., the bottom surface of the top part of the splint), and the pair of removable screws in Dancey’s device underscore how the two surfaces are disengageable from one another. *Id.* at 5–6.

Petitioner’s Opening Brief on Remand also presents an alternative mapping of the “horizontal support surface” and the “third surface” to Dancey. *Id.* at 3–4, 6. In particular, Petitioner sets forth an alternative argument relying on the end of Dancey’s brace (the alternative “horizontal support surface”) abutting the skin on the patient’s head (the alternative “third surface”). *Id.* at 6 (citing Ex. 1032 ¶¶ 13–15). Petitioner contends that the Federal Circuit’s new construction supports this alternative argument because these two surfaces (the end of the device and patient’s head) satisfy the Federal Circuit’s construction. *Id.*

In its Response Brief on Remand, Patent Owner argues that claim 6 is patentable due to its dependency from claim 5. PO Rem. Resp. 11. As to

Petitioner’s primary argument, Patent Owner argues that the “scaphal mold” cannot be the claimed “third surface” because Petitioner and Dr. Hershcovitch already rely on the scaphal mold in Dancey’s device to satisfy the “scaphal mold” limitation in claim 1. *Id.* at 12–13 (citing Ex. 1007 ¶ 59; Ex. 1032 ¶ 10; Ex. 2047, 30:3–14; 24:17–23, 25:14–26:2).⁸ More specifically, Patent Owner argues that the blue line Petitioner identifies as the horizontal support surface coincides with a red line defining where the braces support the scaphal mold in Dancey’s device—i.e., Patent Owner argues that the same lines improperly identify two different claim elements. *See id.* at 13 (citing Ex. 1032 ¶ 10). In addition, Patent Owner argues that the claimed “third surface” cannot be a surface on the ear molding device because “[i]t makes no sense whatsoever that the second or third surfaces would also be on the ear molding device.” *Id.* According to Patent Owner, the “‘device’ is the brace and scaphal mold as recited in claim 1” and the “‘third surface’ cannot be the scaphal mold; otherwise, [Petitioner] is literally arguing that the ear molding device reversibly engages the ear molding device to stabilize the device.” *Id.* As to Petitioner’s alternative

⁸ Patent Owner’s argument here differs from its argument in its Sur-reply prior to remand. Prior to remand, Patent Owner argued that Petitioner improperly identified a portion of the scaphal mold as the “horizontal support surface,” while post-remand, Patent Owner argues that Petitioner improperly identifies a portion of the scaphal mold as the “third surface.” *Compare* PO Sur-reply 8–9, *with* PO Rem. Resp. 12–13. We address Patent Owner’s current argument on remand in this Decision because it is more recent and more consistent with Petitioner’s arguments in the Petition. *See* Pet. 30 (relying on the top surface of the brace as the “horizontal support surface” and bottom surface of the top part of Dancey’s splint (the scaphal mold) as the “third surface”).

argument, Patent Owner argues that Petitioner cannot rely on the end of the device as the horizontal support surface because Petitioner relies on that same structure as the “foot” required by claim 2. *Id.* at 14 (citing Ex. 1007 ¶ 71; Ex. 1032 ¶ 13).

In its Remand Reply, Petitioner contends that its argument as to the scope of the claimed surfaces covering the patient’s skin applies to claim 6’s “third surface” the same way it applies to claim 5’s “second surface.” Pet. Rem. Reply 8–10. Petitioner also argues that its alternative argument does not conflict with its argument as to the “foot” in claim 2 because claims 5–7 ultimately depend from claim 1, not claim 2, and the claims have different requirements. *Id.* at 10. Petitioner also argues that we already found that the surface at the foot of Dancey’s device “served to stabilize” the device. *Id.* (citing FWD 25).

In its Remand Sur-reply, Patent Owner argues that Petitioner fails to dispute several of its arguments. PO Rem. Sur-reply 9–10 (arguing that Petitioner does not dispute that (1) Dr. Hershcovitch identifies the same interaction of parts to satisfy different limitations; (2) Dr. Hershcovitch relied on a figure from attorney argument he “never read”; (3) the third surface cannot be a surface on the ear molding device; and (4) Petitioner shifts its identification of claimed structures in Dancey). Patent Owner also argues that Petitioner’s argument as to the scope of the claimed surfaces covering the patient’s skin lacks merit. *See id.* at 10.

b. Discussion

Because several of the parties’ arguments track their arguments for claim 5, our analysis generally follows the analysis above. We first address whether Petitioner establishes that Dancey discloses “one or more braces”

that “includes a horizontal support surface” as required by the first part of dependent claim 6. As we noted above, Petitioner establishes that Dancey’s two-part splint includes a part closest to the patient’s head that meets the “brace” limitation of claim 5, and that finding applies to the brace limitation of claim 6 as well. *See* Pet. 18 (“The brace is positioned against the patient’s head and supports the scaphal mold, which Dancey explains is ‘custom made to fit over the ear and retract the upper pole into an acceptable position.’” (citing Ex. 1005, 10; Ex. 1007 ¶¶ 58–59)). Petitioner also argues that Dancey’s brace includes a horizontal support surface at the “top surface of the brace of the Dancey splint (the portion that is axial to the vertical support of the brace).” Pet. 30 (citing Ex. 1005, 10; Ex. 1007 ¶ 88).⁹ On remand, Patent Owner disputes whether Dancey’s scaphal mold can meet the “third surface” limitation because the two coincide with one another, an issue we address below, but does not dispute that Dancey discloses the horizontal support surface Petitioner identifies. *See* PO Rem. Resp. 11–14. Based on the foregoing, we find that Petitioner establishes that Dancey discloses “one or more braces” that “includes a horizontal support surface” (the top surface of the brace axial to the vertical support of the brace) as required by the first part of dependent claim 6. *See* Pet. 30; Pet. Reply 19; Ex. 1005, 10; Ex. 1007 ¶¶ 58–59.

Turning to the “reversibly engage” limitation and the Federal Circuit’s construction, we first address whether Petitioner establishes that Dancey discloses a horizontal support surface that “interchangeably engage[s] with

⁹ We address Petitioner’s primary argument here, and address its alternative argument below.

and disengage[s] from” a “third surface.” *See* CAFC Dec. 16. Petitioner contends that “[w]hen treatment is completed, the splint is removed, disengaging the horizontal support surface from the third surface.” Pet. 30 (citing Ex. 1007 ¶ 88); *see also* Pet. Rem. 3 (“[W]hen treatment is completed, the splint is removed from the patient’s head (the second surface) and disengaged from the top part of the Dancey splint (the third surface).” (citing Pet. 28–30)), 5–6. On remand, Patent Owner does not dispute that Dancey discloses the horizontal support surface that interchangeably engages and disengages from another surface, although Patent Owner disputes whether that surface meets the “third surface” limitation in the claims. *See* PO Rem. Resp. 11–14. We find that Petitioner establishes that Dancey discloses a horizontal support surface that interchangeably engages with and disengages from the surface Petitioner identifies as the “third surface” (the top part of Dancey’s splint) when applying and removing Dancey’s device during treatment. *See* Pet. 30; Ex. 1007 ¶ 88; Ex. 1032 ¶¶ 11–12.

As to whether Dancey’s horizontal support surface interchangeably engages with and disengages from a surface on the back of the patient’s ear *to stabilize the device* as the Federal Circuit’s claim construction requires, Petitioner argues that the “engagement of the horizontal support of the brace with the third surface serves to stabilize the splint, including the scaphal mold, and to form the shape of the helix and helical rim during treatment.” Pet. 30 (citing Ex. 1005, 10; Ex. 1007 ¶ 88); Pet. Reply 19. On remand, Patent Owner does not dispute that Dancey discloses the horizontal support surface that interchangeably engages and disengages from another surface in a manner that stabilizes Dancey’s device, although Patent Owner disputes

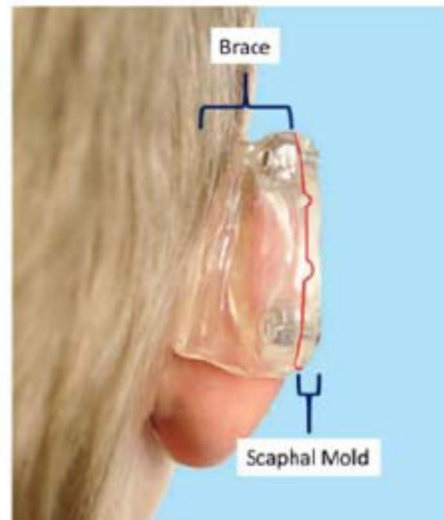
whether that surface meets the “third surface” limitation in the claims. *See* PO Rem. Resp. 11–14. We find that Petitioner establishes that Dancey discloses a horizontal support surface that interchangeably engages with and disengages from the surface Petitioner identifies as the “third surface” “to stabilize the device” as the Federal Circuit’s construction of “reversibly engage” requires. *See* Pet. 30; Ex. 1007 ¶¶ 87–88.

The parties dispute whether the surface Petitioner identifies at the end of Dancey’s scaphal mold can meet the “third surface” limitation in claim 6. Petitioner relies on the engagement between the horizontal support surface at one end of the brace and “the bottom surface of the top part of the Dancey splint.” Pet. 30; Reply 19. We agree with Petitioner that the horizontal support surface engages the claimed “third surface” at the top part of the Dancey splint. Petitioner supports its argument with sufficient explanation, an annotated photograph of Dancey’s splint, and credible declarant testimony. Pet. 30; Reply 19; Ex. 1007 ¶ 88.

Patent Owner raises two arguments against Petitioner’s reliance on the “third surface” in Dancey’s device, but neither argument persuades us that Petitioner fails to meet its burden here. First, Patent Owner argues that Petitioner improperly relies on part of the “scaphal mold” as the “third surface,” which Petitioner already relies on to satisfy the “scaphal mold” limitation in claim 1. PO Rem. Resp. at 12–13 (citing Ex. 1007 ¶ 59; Ex. 1032 ¶ 10; Ex. 2047, 30:3–14; 24:17–23, 25:14–26:2); *see also* PO Sur-reply 8–9; PO Rem. Sur-reply 9–10. Patent Owner illustrates its argument by reproducing annotated photographs of Dancey’s device from Petitioner’s filings, which we reproduce below (*see* PO Sur-reply 9).



Dancey



The annotated photograph on the left shows a blue line indicating the location of a “horizontal support surface,” while the annotated photograph on the right identifies a part of Dancey’s device as a brace and another part as a scaphal mold, with a red line indicated where the parts meet. *See* PO Sur-reply 9. Patent Owner argues that the blue line identified as the horizontal support surface coincides with a red line defining where the braces support the scaphal mold in Dancey’s device. *See* PO Rem. Resp. 13 (citing Ex. 1032 ¶ 10).

We do not view Petitioner’s reliance on these structures in the context of its allegations as to claims 1 and 6 as problematic. Claim 1 requires “a scaphal mold supported by the one or more braces” and Petitioner argues that “Dancey’s ear molding device includes a scaphal mold positioned in the scaphal area that is supported by a brace” and uses the annotated photograph shown on the right above to illustrate where the brace supports the scaphal mold in Dancey’s device. *See* Pet. 16–18. Claim 1 does not refer to any surfaces of the brace or scaphal mold in this context, and Petitioner’s red line showing where the brace and scaphal mold meet does not refer to any

surfaces. *See id.* Claim 6, on the other hand, requires a specific surface on the brace to engage another specific “third surface,” and Petitioner’s identification of the third surface on one end of the scaphal mold does not conflict with any of its contentions with respect to claim 1 because Petitioner does not rely on that surface to disclose any limitations in claim 1. *See id.* at 30.

Second, Patent Owner argues that the claimed “third surface” cannot be a surface on the ear molding device because “[i]t makes no sense whatsoever that the second or third surfaces would also be on the ear molding device.” PO Rem. Resp. 13; *see also* PO Rem. Sur-reply 9–10. We disagree. Claim 6 refers to a “third surface” without restricting the location of that surface and without indicating that it cannot be located on the ear molding device. Patent Owner equates Petitioner’s identification of the “third surface” with the “scaphal mold,” but the surface at the end of the scaphal mold is not the same as the entire upper part of Dancey’s device, which Petitioner identifies as the “scaphal mold.” *See* Pet. 16–19, 30; PO Rem. Resp. 13. Again, we see no conflict in Petitioner’s reliance on an entire half of Dancey’s splint as the “scaphal mold” in the context of claim 1 and the end surface of that same structure as the “third surface” in the context of claim 6. Petitioner’s arguments rely on two different aspects of Dancey’s device to address two different claim limitations.

We next turn to Petitioner’s alternative argument, which asserts that the end of Dancey’s brace abutting the patient’s head discloses the “horizontal support surface” and the surface of the patient’s head discloses the “third surface.” *See* Pet. Rem. 6 (citing Ex. 1032 ¶¶ 13–16). Petitioner contends that “[t]hese two surfaces meet the remanded definition of

‘reversibly engage’ because once treatment is concluded, the splint is removed and this alternative horizontal support surface disengages from the patient’s temporal skin.” *Id.* (citing Ex. 1032 ¶ 16). Although Patent Owner raises an argument as to Petitioner’s identification of the horizontal support surface that we address below, Patent Owner does not argue that the identified horizontal support surface fails to “reversibly engage” the identified “third surface” on the patient’s head as required by the Federal Circuit’s construction. *See* PO Rem. Resp. 14; PO Rem. Sur-reply 9–10. Based on our review of the arguments and evidence, we find that Petitioner’s alternative argument establishes that Dancey discloses a horizontal support surface that interchangeably engages with and disengages from the surface Petitioner identifies as the “third surface” “to stabilize the device” as the Federal Circuit’s construction of “reversibly engage” requires. *See* Pet. Rem. 6; Pet. Rem. Reply 10; Ex. 1032 ¶¶ 13–16.

Patent Owner casts Petitioner’s alternative argument as “new” (it is), but does not argue that Petitioner’s arguments should not be considered. *See* PO Rem. Resp. 14. We consider the argument because Petitioner correctly points out that it is responsive to the Federal Circuit’s construction on appeal. *See* Pet. Rem. 6. As to the substance of the argument, Patent Owner argues that the “third surface” cannot be the patient’s skin, the same argument Patent Owner raises with respect to claim 5. *See* PO Rem. Resp. 6–11. For the reasons set forth above, we find that Patent Owner forfeited the argument by not raising it prior to the remand, and we find the substance of the argument unpersuasive.

Patent Owner also argues that Petitioner improperly relies on the same structure at the end of Dancey’s brace abutting the patient’s head as the

“foot” required by claim 2 and the “horizontal support surface” required by claim 6. *See id.* at 14. We disagree. Claim 2 depends from claim 1 and requires a brace that includes a “foot member,” while claim 6 depends from claim 5, which depends from claim 1, and requires a brace that includes a “horizontal support member.” Ex. 1001, 10:36, 10:50. We see no conflict in Petitioner’s reliance on the same brace surface as satisfying two different claim limitations in two different claims in this situation, where the claim terms are not in the same claim or in claims that depend from one another. *See* Pet. Rem. Reply 10 (“[C]laims 5–7 are separate and distinct from claim 2.”). Moreover, Patent Owner cites no authority to support its argument. *See* PO Rem. Resp. 14; PO Rem. Sur-reply 9–10. Patent Owner also argues that under Petitioner’s rationale “the first surface is now a third surface,” apparently in reference to Petitioner’s reliance on the surface of the head as the “first surface” in the context of claim 4. *See* PO Rem. Resp. 14; Sur-reply 9–10. Claim 4, like claim 2, depends directly from claim 1 and we see no conflict in Petitioner relying on the surface of the patient’s head as meeting the “first surface” limitation in one set of claims and the “third surface” requirement in a different set of claims. As before, Patent Owner provides insufficiently developed argument and evidence, or persuasive authority, that would persuade us that Petitioner improperly relies on these surfaces in its contentions. Patent Owner’s arguments do not persuade us that Petitioner’s alternative argument fails to show that Dancey discloses the limitations of claim 6.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that the combination of Dancey and Gault discloses all of the limitations of claim 6.

c. Conclusion

We find that (1) Petitioner’s proposed level of ordinary skill in the art is consistent with the art of record; (2) the combination of Dancey and Gault discloses all the limitations of claim 6; (3) one of ordinary skill in the art would have been motivated to combine Dancey and Gault in the manner Petitioner proposes; and (4) Patent Owner fails to establish a nexus and therefore fails to establish that the objective indicia support a finding of nonobviousness. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claim 6 of the ’942 patent is unpatentable over the combination of Dancey and Gault.

4. Claim 7

Claim 7 depends from claim 6 and requires a wherein clause that largely repeats the requirements of claims 5 and 6: “wherein the vertical and horizontal support surfaces when engaged to the second and third surfaces, respectively, stabilize the ear molding device.” Ex. 1001, 10:52–55. For claim 7, Petitioner relies on its arguments for claims 5 and 6 and argues that “the brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear.” Pet. 31 (citing Ex. 1007 ¶¶ 82, 87, 91–92). Petitioner also argues that the “vertical support reversibly engages the surface of the posterior ear, which is the ‘second surface’; and the horizontal support reversibly engages the bottom surface of the top part of the two-part pressure splint, which is the ‘third surface.’” *Id.* (citing Ex. 1005, 10; Ex. 1007 ¶¶ 91–92). In the remaining briefing both before and after remand, the parties rely on same the arguments made in the context of claims 5 and 6. *See* PO Resp. 44; Pet.

Reply 18–20; PO Sur-reply 8–9; Pet. Rem. 6–7 (citing Ex. 1032 ¶¶ 18–19); PO Rem. Resp. 14–15 (recounting arguments made with respect to claims 5 and 6 that also apply to claim 7); PO Rem. Sur-reply 10.

Based on our review of the arguments and evidence, and in light of the findings we made above in the context of the same claim limitations addressed in claims 5 and 6, we find that Petitioner establishes that Dancey discloses both vertical and horizontal support surfaces that, when engaged with respective second and third surfaces, stabilize Dancey’s ear molding device. *See* Pet. 31; Ex. 1007 ¶¶ 82, 87, 91–92; Pet. Rem. 6–7; Ex. 1032 ¶¶ 18–19. Patent Owner argues that “claim 7 includes at least four limitations Dancey doesn’t disclose,” but all four of those arguments have been addressed above in the context of claims 5 and 6. *See* PO Rem. Resp. 14–15.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that the combination of Dancey and Gault discloses all of the limitations of claim 7.

We find that (1) Petitioner’s proposed level of ordinary skill in the art is consistent with the art of record; (2) the combination of Dancey and Gault discloses all the limitations of claim 7; (3) one of ordinary skill in the art would have been motivated to combine Dancey and Gault in the manner Petitioner proposes; and (4) Patent Owner fails to establish a nexus and therefore fails to establish that the objective indicia support a finding of nonobviousness. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claim 7 of the ’942 patent is unpatentable over the combination of Dancey and Gault.

CONCLUSION¹⁰

A summary of our conclusions appears in the chart below:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
5–7	103	Dancey, Gault	5–7	
Overall Outcome			5–7	

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 5–7 of U.S. Patent 8,167,942 B2 have been shown, by a preponderance of the evidence, to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the 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.

¹⁰ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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