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 Owners.

IPR2020-00028
U.S. Patent No. 8,167,942

PETITIONER'S FILING OF PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner's counsel of record in the above identified *inter partes* review proceeding hereby files a true and correct copy of Petitioner's Notice of Appeal to the United States Court of Appeals for the Federal Circuit in compliance with 37 C.F.R. §§ 42.6(e) and 90.2(a).

Dated: June 16, 2021

Respectfully submitted,

/ Thomas J. Fisher /

Thomas J. Fisher
Registration No. 44,681
COZEN O'CONNOR
1200 19th Street, N.W.
Washington, D.C. 20036
Tel. (202) 471-3430

Lead Counsel for Petitioner
TalexMedical, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

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Becon Medical Limited and
Henry Stephenson Byrd, M.D.,

Patent Owner.

Inter Partes Review 2020-0028

PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE is hereby given, pursuant to 35 U.S.C. §§ 141(c), 142, 319; 37 C.F.R. §§ 90.2(a), 90.3(a); and Federal Circuit Rule 15(a)(1), that Petitioner TalexMedical, LLC ("Petitioner" or "TalexMedical") appeals to the United States Court of Appeals for the Federal Circuit from the Patent Trial and Appeal Board's Final Written Decision entered on April 15, 2021 (Paper 30) in the above-caption *inter partes* review of U.S. Patent No. 8,167,942 ("the '942 Patent"). This notice is timely filed within 63 days of the issuance of the Board's Final Written Decision. 37 C.F.R. § 90.3(b)(1).

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner states that the issues on appeal include the following: (1) whether the Board erred in holding that claims 4-7 are not unpatentable; (2) whether the Board's subsidiary findings supporting or relating to the Board's holding were unsupported by substantial evidence and rested on legal error; and (3) all other issues decided adversely to Petitioner, including any orders, decision, rulings and/or opinions in the IPR proceeding.

Simultaneously with this submission, Petitioner is filing a true and correct copy of this Notice of Appeal with the Director of the U.S. Patent and Trademark Office and filing one copy of this Notice of Appeal, along with the required docketing fees, with the Clerk of the U.S. Court of Appeals for the Federal Circuit as set forth in the accompanying Certificate of Service and Filing.

Dated: June 16, 2021

/A. Robert Weaver/
Arthur Robert Weaver
Registration No. 63,123
rweaver@brickellip.com

The Brickell IP Group, PLLC
1101 Brickell Avenue,
South Tower, Suite 800
Miami, FL 33131
(305) 728-8831 (telephone)
rweaver@brickellip.com

Attorneys for Petitioner/Appellant
TalexMedical, LLC

CERTIFICATE OF SERVICE AND FILING

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), the undersigned certifies that on this 16th day of June, 2021, I caused a copy of the above PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT to be served by electronic mail on the following counsel of record in the *inter partes* review proceeding:

Thomas Fischer, tfisher@cozen.com
James A. Gale, jgale@cozen.com
Jeffrey Townes, jtownes@cozen.com
Keri Schaubert, kschaubert@cozen.com
COZEN 'O CONNOR
Counsel for Petitioner

David Cupar, dcupar@mcdonaldhopkins.com
Matthew Cavanagh, mcavanagh@mcdonaldhopkins.com
Erin R. Conway, econway@mcdonaldhopkins.com
MCDONALD HOPKINS LLC
Counsel for Patent Owner

The undersigned hereby also certifies that the above PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT was electronically filed on this 16th day of June, 2021, with the Patent Trial and Appeal Board via PTAB E2E as well as with the Clerk of the United States Court of Appeals for the Federal Circuit via CM/ECF.

The undersigned hereby further certifies that the above PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT was filed on this 16th day of June, 2021 with the

Director of the United States Patent and Trademark Office c/o the Office of

General via hand delivery to the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
United States Patent and Trademark Office
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314

Dated: June 16, 2021

/A. Robert Weaver/
Arthur Robert Weaver

Exhibit
Decision Appealed

Trials@uspto.gov
571.272.7822

Paper 30
Filed: April 15, 2021

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
Determining Challenged Claims 1–3 and 9 Unpatentable
Determining Challenged Claims 4–7 Not Unpatentable
35 U.S.C. § 318(a)

INTRODUCTION

TalexMedical, LLC (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of an *inter partes* review of claims 1–7 and 9 of U.S. Patent No. 8,167,942 B2 (Ex. 1001, "the '942 patent"). 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"). An oral hearing in this proceeding was held on January 21, 2021, and a transcript of the hearing is included in the record (Paper 29, "Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 9 of the '942 patent are unpatentable and that Petitioner has not shown by a preponderance of the evidence that claims 4–7 are unpatentable.

BACKGROUND

A. Real Parties-in-Interest and Related Matters

Petitioner states that its real parties-in-interest are Petitioner and Scott P. Bartlett, M.D. Pet. 3. Patent Owner states that it is the sole real party-in-interest for Patent Owner. Paper 4, 1.

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.

B. 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.

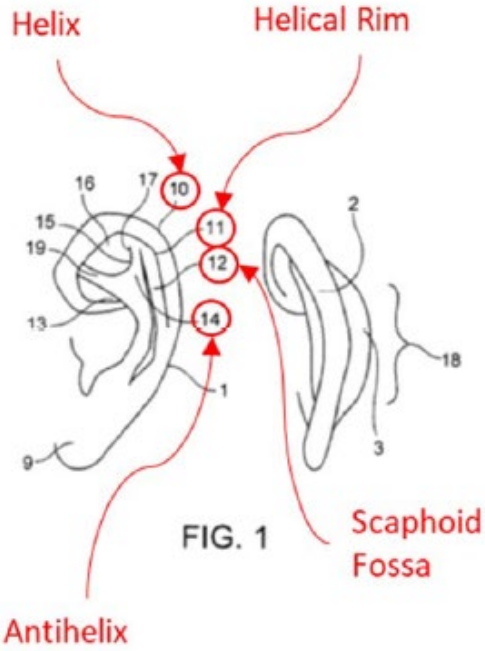

Figure 1 of the '942 Patent (annotated)

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.

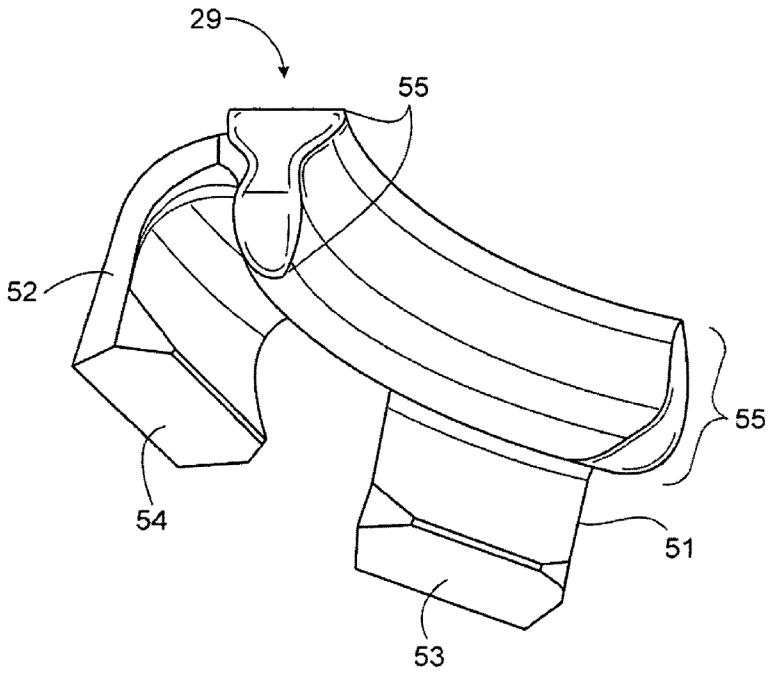

Figure 5 “is a slightly inferior and lateral view” of ear molding device 29. Ex. 1001, 3:53–54. Ear molding device 29 includes “scaphal mold 55 configured to mold the scaphoid fossa into a substantially correct anatomic shape.” *Id.* at 6:29–31. The ’942 patent describes scaphal mold 55 as an extension 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 threwith 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.

C. Illustrative Claim

Petitioner challenges claims 1–7 and 9. Pet. 1. Of those claims, claim 1 is independent, and is reproduced below. Ex. 1001, 10:19–34.

> 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.

Id.

D. Asserted Grounds

Petitioner asserts that claims 1–7 and 9 would have been unpatentable on the following grounds (Pet. 6).

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

Petitioner also relies on the Declaration of Dr. Meir D. Hershcovitch. Ex. 1007 ("Hershcovitch Declaration"). Patent Owner relies on Declarations of Rohit K. Khosla, M.D. and Lily N. Daniali, M.D. *See* Ex. 2021; Ex. 2022.

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

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[1] 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.

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

[3] GB 2304579 A, published March 26, 1997 (Ex. 1015) ("Gault").

[4] Yotsuyanagi, *Cryptotia Correction using Thermoplastic Splint*, Plastic Surgery 36(9):1037–1042 (1993) (Exs. 1011, 1012) ("Yotsuyanagi"). We refer to the photos of the original Yotsuyanagi at Exhibit 1011, and we refer to the translated text of Yotsuyanagi at Exhibit 1012 for all other citations.

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. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). "The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art" at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational

level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

Petitioner contends that a person having ordinary skill in the art "would have advanced medical education and knowledge of nonsurgical ear molding devices." Pet. 10. Patent Owner does not explicitly address Petitioner's proposed level of ordinary skill in the art as set forth in the Petition, and instead "accepts" the proposed definition set forth by Petitioner's declarant, Dr. Hershcovitch. PO Resp. 18 (citing Ex. 1007 ¶ 35). Dr. Hershcovitch's proposed definition includes Petitioner's proposal as set forth in the Petition (underlined below), and expands upon it:

> In view of the simplicity of an ear molding splint, in my opinion, a person of ordinary skill in the art relevant to the '942 and '277 patents would have an advanced medical education and knowledge of nonsurgical ear molding devices. More specifically, a person of ordinary skill in the art relevant to the '942 patent would have an understanding of how basic splints are used to correct misshapen human ears, and would be aware of the techniques available at the time.

Ex. 1007 ¶ 35. We view this proposal as consistent with Petitioner's proposal in the Petition, and the parties therefore agree as to the substance of the proposed level of ordinary skill in the art.

We adopt Petitioner's asserted level of ordinary skill as set forth by its declarant Dr. Hershcovitch because it is consistent with the problems identified and solutions provided in the '942 patent and the prior art.

C. Claim Construction

In *inter partes* reviews, we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) (setting forth claim construction approach in district court cases). Under that

standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1313–14. Although extrinsic evidence, when available, may also be useful when construing claim terms under this standard, extrinsic evidence is generally "less reliable" than the intrinsic record. *See id.* at 1318–19. Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

1. "scaphal mold" / "molding device" / "mold"

Petitioner states that the district court already construed the term "scaphal mold" in claim 1 to mean "mold at the end of the one or more braces that is positionable in the scaphal area." Pet. 10 (citing Ex. 1008, 9–13). Petitioner argues that the district court adopted Patent Owner's broad construction of "scaphal mold" in a manner that covers any mold "positioned in the scaphal area of the ear." *Id.* at 11 (citing Ex. 1008, 10–11). Petitioner does not argue for any specific constructions of any claim terms, and applies the district court's constructions in its analysis. Pet. 10–11, 16–19. Patent Owner agrees that aspect of the district court's construction. PO Resp. 15.

Patent Owner also argues that we should go beyond the district court's construction and construe "molding device" in claim 1 to mean a "device that reshapes" and construe "mold" in "scaphal mold" in claim 1 to mean "a component that reshapes." PO Resp. 15. Patent Owner argues that the district court claim construction order supports its position because the

district court agreed with Patent Owner that the '942 patent emphasizes correction of the "shape of the helix, helical rim and/or scaphoid fossa" and emphasizes reshaping of those portions of the ear. *Id.* at 15–16 (quoting Ex. 1008, 11). According to Patent Owner, because the district court's analysis repeatedly refers to the mold reshaping portions of the ear, Petitioner incorrectly argues that the district court broadly construed "mold" to cover "non-molding components in the prior art." *Id.* at 16–17 (citing Pet. 10–11); *see also* PO Sur-reply 15–18 (arguing that limitations require reshaping).

Because the parties agree on the district court's construction of "scaphal mold," we will apply this construction in this Decision. As to Patent Owner's argument that we should further construe or interpret the district court's claim construction such that "molding device" and "mold" require a device or component that "reshapes," we decline to adopt such a construction. Patent Owner relies almost exclusively on the district court claim construction order, but the district court did not construe "molding device" or "mold" in the manner Patent Owner proposes, and the district court's references to the '942 patent do not, standing alone, support Patent Owner's construction here. *See* Ex. 1008, 11. The district court merely referred to aspects of the specification to support its rejection of Petitioner's proposed construction without relying on those portions of the specification to construe any claim terms to require reshaping. *See id.* We do not view that analysis as support for Patent Owner's constructions or as a basis to read those statements into the district court's construction as Patent Owner suggests. *See* PO Sur-reply 16–17 (arguing that scaphal mold components in prior art do not reshape "as required by the court's claim construction that the parties agreed to"). In addition, the district court's statement that

reshaping of the scapha, helix, and helical rim requires "*both* the 'scaphal mold' and the 'one or more braces' *together*—not the scaphal mold alone," undermines Patent Owner's position that the scaphal mold alone reshapes the helix and helical rim because every appearance of "mold" in claim 1 requires reshaping. Ex. 1008, 11 (citing Ex. 1003, 10:45–49).

Our review of the pertinent language from claim 1 further supports our decision not to limit "molding device" and "mold" to reshaping. First, "molding device" appears only in the preamble of claim 1, and Patent Owner sets forth no argument in its Response to support its implicit position that the preamble limits the claim. *See* PO Resp. 15–17. Second, claim 1 refers to a molding device that comprises one or more braces and a scaphal mold that are "constructed to retain the helix and helical rim within a space," "maintain a substantially correct anatomical shape of the helix and helical rim," and "mold the helix and helical rim during their growth." Ex. 1001, 10:24–34. This language already defines functional aspects of the disputed limitations without referring to reshaping, suggesting that we should not read further requirements into the claim. Patent Owner does not directly address this language or argue that we should construe the "retain" and "maintain" functions as requiring reshaping, and we see no basis to do so here.

Based on the foregoing, we construe "scaphal mold" to mean *mold at the end of the one or more braces that is positionable in the scaphal area*.

2. *"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"*

Patent Owner argues that we should construe this language at the end of claim 1 to mean "the space in the scaphal mold and brace allows the helix

and helical rim to grow and conform to that space to reshape them into the correct anatomical shape." PO Resp. 17–18 (citing Ex. 1003, 6:41–47, 7:40–43; Ex. 1008, 9–13). Patent Owner provides no argument, analysis or support for this proposed construction, other than a citation to the '942 patent specification and the district court's claim construction order, which did not construe this limitation. Patent Owner's undeveloped claim construction argument is not entitled to weight, and we decline to adopt Patent Owner's proposed construction. We apply the ordinary meaning to this language.

Although we decline to adopt Patent Owner's proposed construction, we disagree with Petitioner's position to the extent it suggests that the ordinary meaning of the limitations added by the proposed amendment amount to mere intended use that fail to limit the claims in any way. *See* Pet. Reply 6–7. Petitioner argues that the limitation does not limit the claims because "is directed to the intended use of the device, not its structure." *Id.* at 6. The limitation requires that "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," which denotes that the space formed by the scaphal mold and one or more braces must be sufficient to mold the helix and helical rim during their growth. These limitations do not describe a mere "intended use" that fails to limit scope of the claim at all as Petitioner suggests, because the added limitations require specific structure "constructed to" perform certain functions. These limitations may be functional and broad, but do not fail to limit the claims. We, therefore,

disagree with Petitioner's position to the extent it suggests that the added limitations do not limit the claim in any way.

3. "reversibly engage"

The parties dispute the construction of "reversibly engage" in dependent claims 5 and 6. *See* Ex. 1001, 10:46–51. Claim 5 requires a surface of the one or more braces that includes "a vertical support surface constructed to reversibly engage a second surface," while claim 6 requires "a horizontal support surface to constructed to reversibly engage a third surface." *Id.*

Patent Owner argues that we should construe the limitation to mean "to engage a surface on a reverse side facing away from the ear." PO Resp. 17 (citing E. 1001, 8:6–13, Fig. 5; Ex. 2021 ¶¶26–33; Ex. 2022 ¶¶ 27–34). Petitioner argues that we should construe the limitation "to mean simply to engage, or contact, to stabilize the device." Pet. Reply 6. According to Petitioner, 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. *Id.* at 5–6 (citing Ex. 1027, 125:3–7).

We agree with Patent Owner's proposed construction because it more accurately tracks the claim language and specification. The language of claims 5 and 6 suggests a particular engagement with these other surfaces. The '942 patent specification describes the engagement of vertical supports 65, 66 with cradle wall 34. *Id.* at 8:6–13. The specification also describes engagement of horizontal supports 63, 64 with cradle cover 22 by stating that supports 63, 64 "can reversibly engage or contact the cover when the cover is engaged with the cradle base." *Id.* at 7:57–63. In both contexts, the

supports engage the other surfaces on the side facing away from the ear; the other side of the supports face the brace and the ear. *See id.* at Figs. 2, 3, 6A, 7. Patent Owner's proposed construction more clearly captures this form of engagement, and gives meaning to the term "reversibly" in the claims. Petitioner's proposal fails to provide meaning to the term "reversibly" by encompassing any engagement that stabilizes the device, which could include any engagement or contact with any other surface. In addition, Petitioner did not give proper weight to the most pertinent portions of the specification addressing reversible engagement, and instead relied on a different embodiment, not covered by claims 5 and 6, that addresses reversible attachment. *See* Pet. Reply 5 (citing Ex. 1001, 5:22–27).

Based on the foregoing, we construe "reversibly engage" to mean *to engage a surface on a reverse side facing away from the ear*.

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

Petitioner challenges claims 1–7 and 9 under 35 U.S.C. § 103 based on Dancey and Gault. Pet. 15–22. For these challenges, Petitioner cites to the asserted references and the Hershcovitch Declaration. *Id.*

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 is reproduced below.

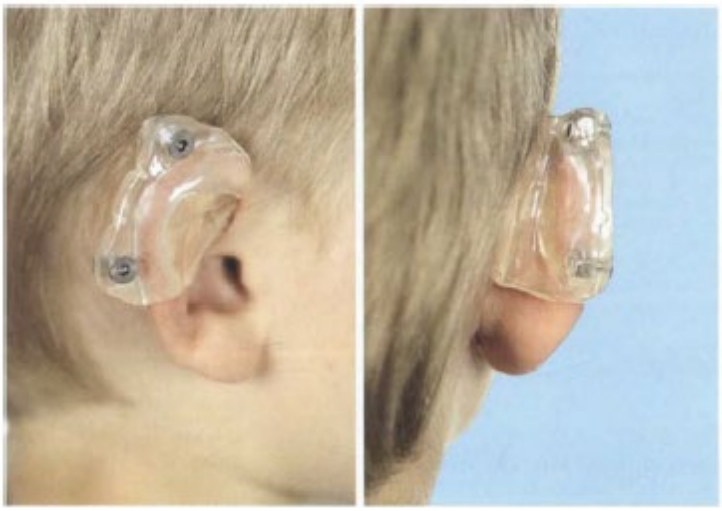

Figure 1 depicts a lateral (on the left) and posterior (on the right) view of Dancey's device on a patient. Ex. 1005, Fig. 1. Dancey describes the splint as "made from translucent acrylic to allow regular inspection" of the ear to note any "pressure necrosis" during treatment. *Id.* at 10. "The splint 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. Gault

Gault discloses an ear splint having a wire core enclosed in a cover. Ex. 1015, codes (54), (57), Figs. 2(A), 2(B). Gault also discloses, in Figure 1, a diagram of the ear that identifies the various parts of the ear by name, including the helix and scaphoid fossa. *Id.* at 3, Fig. 1.

3. Discussion

a. Independent Claim 1

Petitioner asserts that the combination of Dancey and Gault discloses all of the limitations of claim 1. Pet. 15–22. Petitioner provides analysis of each limitation in claim 1, with citations to the references that correspond to each of the claim limitations. *Id.* Petitioner also cites to the relevant

declarant testimony. *Id.* (citing various portions of Ex. 1007). Patent Owner argues that Dancey fails to disclose several limitations in claim 1, but does not dispute Petitioner's arguments in support of the combination of Dancey and Gault. *See* PO Resp. 36–40. We first address the limitations of claim 1, and then Petitioner's arguments in support of the motivation to combine Dancey and Gault.

Claim 1's preamble states: "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." Petitioner asserts that the preamble is not a limitation because it merely states an intended use for the claimed device. Pet. 15–16. Patent Owner does not explicitly argue that the preamble limits the claim in its Response, and addresses the issue for the first time in its Sur-reply. PO Resp. 15–18; PO Sur-reply 17. We do not consider Patent Owner's arguments raised for the first time in its Sur-reply. *See* Paper 11, 7 (emphasizing that "any arguments for patentability not raised in the response may be deemed waived").[5] We agree with Petitioner that the preamble does not limit the claim. The preamble sets forth an intended use, "molding device for a human ear," and the parts of the ear that provide context for the claimed device. The body of the claim sets forth a structurally complete

[5] Even if we considered Patent Owner's arguments, they are limited to arguing that "molding device" in the preamble of claim 1 here must limit the claim because "molding device" in the body of claim 1 of the related '277 patent and limits that claim. *See* PO Sur-reply 17. We are not persuaded by Patent Owner's argument. The presence of a claim term in the body of a claim in one patent does not mean that same term must limit claims in related patents when the term only appears in the preamble.

device, without the need to rely on any of the parts of the ear or the "molding device" to limit the claim.

Petitioner further contends that if the preamble does limit the claim, both Dancey and Gault disclose molding devices for the human ear and include illustrations that show the parts of the ear identified in the preamble. *See* Pet. 16 (citing Ex. 1001, Abstract; Ex. 1005, 10; Ex. 1007 ¶ 55; Ex. 1015, 3). Patent Owner argues that Dancey does not disclose a "molding device" because Dancey states that the treated ear is "normal" so that the acrylic splint in Dancey cannot be molding the shape of the ear in any way. PO Resp. 37 (citing Ex. 2021 ¶¶ 147–163; Ex. 2022 ¶¶ 148–164). According to Patent Owner, "Dancey treats cryptotia only, which a POSITA readily knows it not a medical condition that requires molding or shaping the ear as treatment, but rather requires pulling the ear away from the head." *Id.*; *see also* PO Sur-reply 17–18. Patent Owner also argues that the patient in Dancey was 10 months old, and therefore Dancey's splint could not mold the child's ear "because a child's cartilage hardens for molding purposes within the first 6 months." PO Resp. 37. Petitioner responds by arguing that Patent Owner improperly focuses on unclaimed aspects of the claim, such as "which deformities might be treated with the device, the ages of the patients, and what might happen to an ear when placed in the device," which fails to address the claimed structure of the device. Pet. Reply 15.

We find that Petitioner establishes sufficiently that all of the limitations of the preamble are disclosed by the combination of Dancey and Gault even if the preamble limits the claim. Pet. 16; Ex. 1007 ¶ 55; Ex. 1015, 3. Patent Owner does not address the majority of terms in the

preamble,[6] and we disagree with Patent Owner's arguments as to the "molding device." First, Patent Owner implicitly assumes that its proposed construction for "molding device" applies, and does not argue that Dancey fails to disclose a molding device if we decline to adopt Patent Owner's construction. Second, the ordinary meaning of the term "molding device" does not require any specific type of molding on any specific part of the ear, such that even molding an ear to move it away from the head when treating cryptotia constitutes a molding device. Third, Petitioner correctly points out that the claims are not limited to treating a specific type of deformity such as cryptotia, or a specific age of a patient, or achieving a specific treatment result. *See* Pet. Reply 15.

Claim 1 further requires "one or more braces; and a scaphal mold supported by the one or more braces." Petitioner argues that Dancey discloses "an ear molding device that is positioned in the scaphal area," consistent with the construction for "scaphal mold" adopted in the district court litigation. Pet. 16 (citing Ex. 1008, 12), 18 (citing Ex. 1005, 10, Fig. 1; Ex. 1007 ¶¶ 58–60). Petitioner points to specific areas of the device between the back of the ear and the head as the brace, and a portion of the

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[6] We need not set forth formal findings as to the undisputed assertions by Petitioner. *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) ("Although the Board did not make findings as to whether any of the other claim limitations (such as fusion apertures or anti-migration teeth) are disclosed in the prior art, it did not have to: NuVasive did not present arguments about those limitations to the Board. . . . The Board, having found the only disputed limitations together in one reference, was not required to address undisputed matters."); Paper 8, 7 (emphasizing that "any arguments for patentability not raised in the response may be deemed waived").

device adjacent the helical rim as in the "scaphal area." *Id.* at 18. Petitioner contends that although "Dancey does not expressly disclose that the splint is placed in the 'scaphal area,' those skilled in the art would have understood that the scaphal area includes the region between the helix and the antihelix." *Id.* at 18–19. Petitioner also relies on Gault as disclosing a device in the "scaphal area." *Id.* at 19 (citing Ex. 1015, 8, Figs. 1–2). Petitioner argues that "in view of the disclosure in Gault, a person of ordinary skill in the art would understand Dancey's splint to be a scaphal mold placed in the scaphal area, consistent with the district court's construction of this claim term." *Id.* (citing Ex. 1007 ¶¶ 60–61; Ex. 1008, 13); *see also* Pet. Reply 14, 16.

Patent Owner does not dispute that Dancey discloses "one or more braces," but does argue that Dancey fails to disclose the "scaphal mold." PO Resp. 37–38. Patent Owner contends that Dancey's alleged scaphal mold fails to mold or shape any portion of the ear, much less the helix or helical rim. *Id.* (citing Ex. 1021 ¶¶ 172–176; Ex. 2022 ¶¶ 173–177). According to Patent Owner, "[t]he components Petitioner identifies in Dancey and Yotsuyanagi as the 'scaphal mold' are not 'reshaping' the helix or helical rim as required by the court's claim construction that the parties agreed to." PO Sur-reply 16–17.

We find that Petitioner establishes sufficiently that the combination of Dancey and Gault discloses "one or more braces; and a scaphal mold supported by the one or more braces." *See* Pet. 16–18; Ex. 1005, 10, Fig. 1; Ex. 1007 ¶¶ 58–60; Ex. 1008, 8, 12, Figs. 1–2. As to the "scaphal mold," Dancey discloses a mold at the end of the one or more braces that is positionable in the scaphal area. *See id.* Patent Owner bases its arguments

on its proposed construction for "scaphal mold," which we decline to adopt. *See* PO Resp. 37–38; PO Sur-reply 16–17. Because Patent Owner does not argue that Dancey fails to disclose a molding device if we decline to adopt Patent Owner's construction and apply the district court's claim construction to the term, Petitioner's argument and evidence as to "scaphal mold" are undisputed.

The remainder of claim 1 includes "wherein" clauses that require the claimed braces and scaphal mold to be "constructed to" perform certain functions. For example, claim 1 requires "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." Petitioner argues that Dancey in view of Gault discloses these limitations because Dancey discloses its acrylic splint fitted over the ear, which retains the helix and helical rim of the ear within a space defined between the brace and scaphal mold, and maintains a substantially correct shape. Pet. 19–21 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 62–64; Ex. 1015, 7, Fig. 1). Claim 1 further requires "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." Petitioner argues that because Dancey discloses a splint made to mold the helix and helical rim, which was worn continuously for one year and intermittently for another 9 months,

> [a] person of ordinary skill in the art would have understood that the helix and helical rim of the ear would have grown to

> conform to the space between [the] brace and scaphal mold after wearing the mold for the time period disclosed in Dancey.

Pet. 21–22 (citing Ex. 1007 ¶¶ 66–67).

Patent Owner argues that Dancey does not disclose a device "constructed to maintain a substantially correct anatomical shape of the helix and the helical rim," because "the purpose of the Dancey splint is to pull the 'normal' ear away from the head to treat cryptotia—*not* to 'correct' the anatomical shape of the helix or helical rim." PO Resp. 38. Patent Owner also argues that Dancey does not disclose "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." *Id.* at 39 (citing Ex. 2021 ¶¶ 185–187; Ex. 2022 ¶¶ 186–188). According to Patent Owner, Dancey cannot be "constructed to mold" an ear that Dancey describes as "normal" and cannot mold "during their growth" because Dancey's patient is 10 months old. *Id.*; *see also* PO Sur-reply 19–20. Patent Owner also argues that Dancey fails to disclose "that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces," but does not elaborate on its reasoning beyond reasserting that Dancey fails to disclose the "scaphal mold." PO Resp. 39 (citing Ex. 2021 ¶¶ 185–187; Ex. 2022 ¶¶ 186–188). In its Sur-reply, Patent Owner reiterates its position that "the claims *require* molding or reshaping the helix or helical rim," and argues that Petitioner fails to take into account that Dancey does not disclose a space that would mold the helix during growth or a device that accommodates any growth at all. PO Sur-reply 16, 19.

We find that Petitioner establishes sufficiently that the combination of Dancey and Gault discloses all of the limitations in the "wherein" clauses at

the end of claim 1. *See* Ex. 1001, 10:25–34; Pet. 19–22; Ex. 1005, 10; Ex. 1007 ¶¶ 62–67; Ex. 1015, 7, Fig. 1. Patent Owner again bases its arguments on its own proposed constructions that we did not adopt, or implicit constructions that lack support. *See* PO Resp. 38–39; PO Sur-reply 16–20. For example, Patent Owner argues that Dancey fails to disclose a device "constructed to maintain a substantially correct anatomical shape of the helix and the helical rim," by assuming that the maintaining function requires correction of a misshapen helix. PO Resp. 38–39. We do not view the claim language as so limiting, and Patent Owner fails to support the argument with an appropriate claim construction. *See id.* Similarly, Patent Owner argues that Petitioner fails to take into account the need for growth during treatment, and that Dancey fails to allow for any growth, and that children's ears do not allow for molding by age 10 months. PO Sur-reply 19–20. Nothing in the claim language supports reading in a specific growth requirement, or a specific size of the space between the brace and scaphal mold to allow a specified amount of growth, and Patent Owner does not support its argument with an appropriate claim construction argument. *See id.*

In addition, Patent Owner places undue emphasis throughout its briefing on the need to correct a patient's deformity and the age of the patient.[7] Claim 1 is a "device" claim that defines certain structure without

[7] Patent Owner's counsel seemed to confirm this approach's corrective aspects at oral argument in the context of claim 1. *See* Tr. 48:24–49:6 (stating in general that "the way the claims work is that there's a misshapen helix and helical rim and what it does is shape it or reshape it in a way to make it anatomically correct"), 54:13–18 (arguing that the point of Yotsuyanagi "is not to reshape a deformed cartilage").

any affirmative steps that must be performed such as reshaping a malformed ear, treating a specific condition, or measuring a certain amount of ear growth with patients in a specific age range. *See also* Pet. Reply 8–14 (arguing that such devices are used to successfully treat deformities other than cryptotia in children up to 9 years old). Whether the limitations of claim 1 are met does not depend on these issues, and can be established by examining the structure of the prior art such as Dancey without showing reshaping of a malformed helix into an anatomically correct shape.

Petitioner's arguments and evidence are not only undisputed because they are based on proper claim constructions, but also supported by credible declarant testimony. *See* Ex. 1007 ¶¶ 57–67. For example, Dr. Hershcovitch credibly opines that Dancey's translucent device makes "it readily apparent to me that the helix and helical rim are retained in the space between the brace and scaphal mold" and that "a person of ordinary skill in the art would have understood that nonsurgical methods of ear shape correction entailed maintaining a malformed infant ear in a correct anatomical position for a period of time to allow the cartilage in the infant's ear to grow and harden into a correctly shaped ear." Ex. ¶¶ 62–63 (citing Ex. 1005, 10). Petitioner and Dr. Hershcovitch support the position with reference to Dancey's figure showing the "space" that forms between the brace and scaphal mold that captures the helix and helical rim, and states that the device provides satisfactory cosmetic results. Pet. 19–21; Ex. 1005, 10, Fig. 1; Ex. 1007 ¶¶ 62–67. The successful cosmetic results also undermine Patent Owner's argument that Dancey's device provides no room at all for growth during the nearly two years of treatment. Ex. 1012, 10. We view Petitioner's argument and evidence as more credible on these issues.

See Pet. 21–22; Pet. Reply 15–16; Ex. 1007 ¶¶ 66–67. Based on our review of the record, Petitioner has established sufficiently that the combination of Dancey and Gault discloses all of the limitations of claim 1.

As to the motivation to combine Dancey and Gault, Petitioner contends that both references "serve the same purpose to solve the same problem" and that "[d]octors working in the field of nonsurgical techniques for splinting deformed ears at the time of the '942 patent would have turned to earlier references such as Gault to better understand and interpret the treatment described in Dancey." Pet. 34–36. Patent Owner does not address Petitioner's arguments and evidence as to motivation to combine. Based on our review of the record, Petitioner establishes sufficiently that one of ordinary skill in the art would have been motivated to incorporate Gault's teachings into Dancey's device, and use Gault to understand further Dancey's disclosure.

b. Dependent Claims 2, 3, and 9

Claim 2 depends from claim 1 and further recites "wherein each of the one or more braces includes a foot member positioned at an end of the brace distal to the scaphal mold, the foot member constructed to facilitate maintaining the substantially correct anatomical shape of the helix." Ex. 1001, 10:35–39. Petitioner argues that Dancey discloses these limitations. Pet. 22–24. Petitioner relies on Dancey's "support component" adjacent the infant's head for the claimed "foot member" and contends that by keeping the splint in the correct position during treatment, the foot member facilitates maintaining the correct anatomical position of the helix. *Id.* (citing Ex. 1007 ¶¶ 69, 71–72). Patent Owner argues that Dancey does not disclose a foot member because Dancey does not mention the edge of its device, relied on

by Petitioner, or suggest it has any importance. PO Resp. 40 (citing Ex. 2021 ¶¶ 188–194; Ex. 2022 ¶¶ 189–195). Patent Owner also argues that the alleged foot member does not "facilitate maintaining the substantially correct anatomical shape of the helix" because it touches the head and has nothing to do with providing the helix of the ear itself with a "substantially correct anatomical shape." *Id.* at 40–41; *see also* PO Sur-reply 11–12. In response, Petitioner argues that the '942 patent describes the foot as "nothing more than a surface 'positioned at an end of the brace distal to the scaphal mold'" and the claim does not specify that the foot must touch a certain surface. Pet. Reply 16–17 (citing Ex. 1001, 10:36–37; Pet. 22–24; Ex. 1007 ¶¶ 68–72). Petitioner also argues that Dancey's foot member serves the same stabilization purpose as the foot the '942 patent describes. *Id.* at 17 (citing Ex. 1007 ¶¶ 71–73; Ex. 1027, 75:19–23; Ex. 1028, 37:15–24).

We find that Petitioner establishes sufficiently that Dancey and Gault disclose all of the limitations of claim 2. Pet. 22–24; Pet. Reply 16–17; Ex. 1007 ¶¶ 68–72. As a matter of claim construction, Petitioner correctly points out that claim 2 does not require the foot member to engage or interact with any other surface of the device, and therefore Patent Owner's argument that it merely engages the head does not undermine Petitioner's position. Petitioner relies on a structure "at an end of the brace distal to the scaphal mold," which is all that the claim requires. *See* Pet. 22–23; Pet. Reply 16–17; Ex. 1007 ¶ 69. As to the "constructed to facilitate maintaining the substantially correct anatomical shape of the helix" issue, the claims merely require the foot member to *facilitate* maintaining the correct shape; they do not require any direct interaction with the helix as Patent Owner

suggests. Petitioner and its declarant persuasively reason that the structure identified as Dancey's foot member stabilizes the device during treatment, which facilitates maintaining the correct shape as claimed. Pet. 23–24; Pet. Reply 17; Ex. 1007 ¶¶ 71–72.

Claim 3 depends from claim 2 and further recites "wherein a surface of the one or more braces facing the scaphal mold defines a substantially correct anatomic curvature for the helix." Ex. 1001, 10:40–42. Petitioner argues that Dancey discloses these limitations because "[t]he inner space between the scaphal mold and brace of the Dancey splint are custom made to define the contours of a substantially correct anatomic curvature for the helix of the ear." Pet. 25 (citing Ex. 1007 ¶ 75). Patent Owner argues that Dancey fails to disclose this limitation because it is Dancey's "outer piece," the alleged scaphal mold, that defines the curvature of the helix, not the "inner piece," or brace. PO Resp. 42 (citing Ex. 2021 ¶¶ 195–199; Ex. 2022 ¶¶ 196–200). In response, Petitioner argues Patent Owner admits that the space between the scaphal mold and brace define a "normal" ear, and therefore, both pieces of Dancey's splint define an anatomically correct curvature of the helix. Pet. Reply 17 (citing PO Resp. 27).

We find that Petitioner establishes sufficiently that Dancey and Gault disclose all of the limitations of claim 3. As Petitioner points out, the parties seem to agree that both sides of Dancey's splint conform to the shape of a normal ear, and therefore are anatomically correct. *See* PO Resp. 27. The dispute appears to be whether the surface of the brace sufficiently defines the curvature of the helix. Patent Owner argues that only the surface of the scaphal mold defines the curvature of the helix. We disagree, and find Petitioner's argument persuasive because the '942 patent broadly defines the

claimed surface. For example, the '942 patent refers to legs 51, 52 (i.e., the braces) and feet 53, 54 of the braces as forming inner surfaces that are "configured to mold the helix." Ex. 1001, 7:40–44. As shown in the figures, feet 53, 54 are not on the top of the ear or toward the helical rim adjacent the scaphal area, but instead wrap around to the back of the ear. *See id.* at Figs. 6A, 7. Accordingly, structures on the back of the ear, near the top of the ear but not on top of the ear, fall within the scope of brace surfaces that are "configured to mold the helix." As such, Petitioner's reliance on Dancey's brace for the claimed surface, which extends to the top of the ear, falls within the scope of claim 3. *See* Pet. 25 (depicting annotated Fig. 1 of Dancey); Ex. 1007 ¶¶ 75–76; Ex. 1015, Fig. 1.

Claim 9 depends from claim 1 and further recites "wherein the scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges, and the extension is constructed to maintain a substantially correct anatomical shape of the scaphal area of the ear." Ex. 1001, 10:59–63. Petitioner argues that Dancey's splint covering the scaphal area extends from the brace and includes rounded edges and "an arc-shaped conformation that mimics an anatomically correct shape of an ear so that the deformed ear can be splinted at an acceptable position." Pet. 33 (citing Ex. 1005, 10; Ex. 1007 ¶ 95). Petitioner also argues that the "interior shape of the scaphal mold is generally semi-cylindrical in order to properly house and splint the helix and helical rim." *Id.* Petitioner also contends that Dancey's custom-designed splint is constructed to maintain a substantially anatomically correct shape of the scaphal area with the goal of retracting "the upper pole into an acceptable position." *Id.* at 34 (quoting Ex. 1005, 10). Patent Owner argues

that Petitioner's declarant improperly identifies a semi-cylindrical *space* rather than a semi-cylindrical *extension*, and that the declarant was unable to identify the claimed features at his deposition. PO Resp. 45–46 (citing Ex. 2021 ¶¶ 229–235; Ex. 2022 ¶¶ 230–236; Ex. 2034, 150:24–152:9); *see also* PO Sur-reply 13–14.

We find that Petitioner establishes sufficiently that Dancey and Gault disclose all of the limitations of claim 9. Pet. 32–34; Ex. 1005, 10, Fig. 1; Ex. 1007 ¶¶ 58, 95–96. Petitioner persuasively identifies structure that forms part of Dancey's scaphal mold that is both generally arc-shaped and generally semi-cylindrical. Pet. 32–33; Ex. 1007 95. The claims do not require a perfect semi-cylindrical shape, or solid semi-cylinder rather than a hollow one defining a space. *See* Ex. 1001, Fig. 5 (depicting an oblong shape for the claimed "extension"). Petitioner also persuasively identifies structure in Dancey's scaphal mold within the scaphal area that forces that area to conform to an anatomically correct shape. Pet. 34; Ex. 1007 ¶ 98. Patent Owner does not directly address the language in the Petition, and instead takes issue with the use of the word "space" by Petitioner's declarant in one of the cited paragraphs. PO Resp. 45–46. While the language of the declaration does not mirror the language in the Petition, we do not view the mismatch as so pronounced that the declaration does not support Petitioner's position. For example, the Petition refers to the "interior shape" formed by the scaphal mold as "generally semi-cylindrical," while the declarant refers to this interior shape as a "space," which is largely the same thing. Pet. 33; Ex. 1007 ¶ 95. Patent Owner further argues that it must be the extension, i.e., a part of the "scaphal mold," that has the generally semi-cylindrical shape, but we interpret Petitioner's argument, and supporting declaration

testimony, as stating that the semi-cylindrical interior shape or space is defined by the semi-cylindrical extension of the scaphal mold. *See* Pet. 32–33; Ex. 1007 ¶ 95. We also do not view the declarant's deposition testimony as contradicting this interpretation. *See* PO Resp. 46. We find that this evidence adequately supports Petitioner's position as to claim 9.

Based on our review of Petitioner's arguments and evidence for these claims, we determine that Petitioner has proven by a preponderance of the evidence that the combination of Dancey and Gault discloses all of the limitations of claims 2, 3, and 9.

c. Claims 4–7

Claim 4 depends from claim 2, which requires "a foot member," and further requires "wherein the foot includes a broad flat surface adapted for securing the ear molding device to a first surface." Petitioner relies on Dancey's Figure 1 as disclosing the "broad flat surface" and the patient's head as the "first surface." Pet. 26–27 (citing Ex. 1005, 10; Ex. 1007 ¶¶ 77–79). Patent Owner argues that Petitioner fails to establish that its alleged foot member includes a "broad flat surface." PO Resp. 43.

We agree with Patent Owner that Petitioner fails to prove by a preponderance of the evidence that the structure it identifies as the foot member includes a broad flat surface as required by claim 4. *See* Pet. 27; Ex. 1007 ¶¶ 77–78. The portion of the foot member adjacent the head appears thin rather than broad, and the portion adjacent the back of the ear appears curved rather than flat. *See id.* We do not view either surface as both broad and flat.

Claim 5 depends from claim 1 and further requires "the one or more braces includes a vertical support surface constructed to reversibly engage a

second surface." Petitioner contends that Dancey's brace includes a vertical surface and that skin on the back of the patient's ear in Dancey discloses the "second surface." Pet. 28–29 (citing Ex. 1007 ¶¶ 82, 87, 91). Patent Owner argues that the vertical support surface Petitioner identifies in Dancey's splint fails to "reversibly engage" the back of the ear because the claim requires engagement on the side of the support facing away from the ear. PO Resp. 44; PO Sur-reply 7.

We agree with Patent Owner. As noted above in the claim construction section, we construe "reversibly engage" to mean "to engage a surface on a reverse side facing away from the ear." 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 that claim construction. *See* Pet. 28–29. Because 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. Because 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.

d. Objective Indicia of Nonobviousness

i. The Parties' Positions

Patent Owner argues that extensive objective indicia illustrate the nonobviousness of the challenged claims, including copying of Patent Owner's commercial product by Petitioner, long-felt but unresolved need, industry praise, and licensing. PO Resp. 53–71. As to copying, Patent Owner alleges that Petitioner's founder was a former purchaser of Patent

Owner's commercial product, the "EarWell" device, who founded a new company with the goal of providing a duplicate of the EarWell device at a lower price. *Id.* at 55–56. Patent Owner also contends that Petitioner used the EarWell device as a guide when designing Petitioner's competing "InfantEar" product. *Id.* at 56–58. Patent Owner also argues that Petitioner received an opinion that its product infringed Patent Owner's patents and that Patent Owner would be unlikely to sue, and that Petitioner moved forward with its InfantEar device without an invalidity defense. *Id.* at 61. Patent Owner asserts that a nexus exists because Petitioner's InfantEar device is a copy of Patent Owner's "patented EarWell device" and that Patent Owner is entitled to a presumption of nexus. *Id.* at 59 (citing Ex. 2021 ¶¶ 381–412; Ex. 2022 ¶¶ 382–413); *see also id.* at 65–66 (citing Ex. 2021 ¶¶ 401–422; Ex. 2022 ¶¶ 402–423) (arguing that Dr. Bartlett article shows "nexus between resolving long-felt need and the patented EarWell device providing a solution").

As to long-felt need, Patent Owner alleges that Dr. Bartlett admitted to the long-felt need in a 2017 paper that described the unresolved "need for the patented ear molding device . . . for over 30 years." PO Resp. at 65 (citing Ex. 2015; Ex. 2021 ¶¶ 401–422; Ex. 2022 ¶¶ 402–423). Patent Owner further contends that Yotsuyanagi's 1993, 1998, and 2004 research papers demonstrate long-felt need that Yotsuyanagi could not resolve. *Id.* at 66–67 (citing Exs. 1010–1012, 2017).

As to industry praise, Patent Owner asserts that its "EarWell device has received prominent praise from medical professionals in the industry," including three articles from an industry journal. PO Resp. at 68 (citing Ex. 2021 ¶¶ 416–429; Ex. 2022 ¶¶ 417–430; Ex. 2039; Ex. 2042; Ex. 2043).

Patent Owner also relies on a conference program and Dr. Bartlett's own 2017 research paper as further evidence of industry praise. *Id.* at 68–71.

As to licensing, Patent Owner argues that Petitioner considered taking a license from Patent Owner in 2017 when Petitioner received advice that it may be infringing Patent Owner's patents. PO Resp. 71 (citing Ex. 2004).

Petitioner argues that Patent Owner "makes no showing" that its EarWell device "practices the claims of the '942 patent, or that there is a nexus between any of its purported objective indicia 'evidence' and the claims" of the '942 patent. Pet. Reply 24. As to copying, Petitioner argues that its InfantEar device differs from the EarWell device "in a number of ways." *Id.* at 25–26. For example, Petitioner contends that its InfantEar lacks a scaphal mold with a flat bottom, unlike the EarWell device that includes a scaphal mold with a semi-cylindrical extension as claimed in claim 16. *Id.* at 25. Petitioner also contends that Patent Owner successfully sought a claim construction of "scaphal mold" in the district court litigation to cover the InfantEar's scaphal mold, and Patent Owner now seeks to avoid the consequences of that broad construction. *Id.* Petitioner also argues that the InfantEar device, unlike the EarWell device, "is a different system" that "is encased in a curable gel to stabilize the device" to overcome some of the disadvantages of the EarWell device. *Id.* at 26–27. As to long-felt need, Petitioner argues that Dr. Bartlett's 2017 article cannot establish long-felt need for the EarWell device because it describes the device as suboptimal, which led to the creation of the InfantEar device. *Id.* at 25. As to industry praise, Petitioner argues that the articles relied on by Patent Owner are not remarkable because they are consistent with a body of literature describing the use of such devices for many years. *Id.* at 28.

In its Sur-reply, Patent Owner argues that its declarants provided analysis of how the challenged claims cover the EarWell product, Patent Owner is entitled to a presumption of nexus, and Petitioner failed to rebut that presumption. PO Sur-reply 1–2 (citing Ex. 2021 ¶¶ 63–72, 380–412; Ex. 2022 ¶¶ 64–73, 381–413; PO Resp. 3). As to copying, Patent asserts that the use of gel in the InfantEar does not suggest that it is not a copy of the EarWell device because InfantEar "is a copy of the *claimed* portions from EarWell, and the gel isn't in the claims." *Id.* at 3–4. As to long-felt need based on the 2017 Dr. Bartlett article, Patent Owner argues that the positive efficacy results touted in the article are based on the EarWell device, undermining Petitioner's argument that the article did not include positive statements as to the EarWell device. *Id.* at 3. As to industry praise, Patent Owner contends that Petitioner selectively quoted from the articles to suggest that the EarWell device merely amounts to the same type of devices in use for centuries, when in fact the article describes the EarWell device as an "innovation." *Id.* at 4–5 (quoting Ex. 2038, 1).

ii. Discussion

We first address the nexus between the claimed invention and Patent Owner's objective indicia of nonobviousness and then the strength of Patent Owner's objective indicia evidence.

Patent Owner bears the burden of establishing a nexus. *See Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). "[A] patentee is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim if the patentee shows that the asserted evidence is tied to a specific product and that the product '*is* the invention disclosed and claimed.'" *Id.* (quoting

Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988)).

Patent Owner fails to meet its burden of establishing a nexus. Patent Owner seems to rely entirely on a presumption of nexus based on the assumption that the challenged claims cover the "patented EarWell product." PO Resp. 59 (citing Ex. 2021 ¶¶ 381–412; Ex. 2022 ¶¶ 382–413); *see also id.* at 65–66 (citing Ex. 2021 ¶¶ 401–422; Ex. 2022 ¶¶ 402–423); PO Sur-reply 2. The Patent Owner Response, however, contains no analysis to support that contention, or any analysis of the challenged claims with respect to the EarWell device. *See* PO Resp. 59, 65–66. The Patent Owner Response cites to 41 paragraphs of declarant testimony in two different reports for direct support of its presumption of nexus argument, but those paragraphs cover Patent Owner's copying, long-felt need, and praise by others allegations. *See* Ex. 2021 ¶¶ 381–422; Ex. 2022 ¶¶ 382–413. Only a single sentence of that testimony appears pertinent to whether the EarWell device is covered by the challenged claims, and that sentence merely states that the declarant believes Petitioner's InfantEar device "is a copy of the patented EarWell ear molding device that is recited in claims 1–7 and 9 of the '942 Patent, as well as claims 1, 2, 9, 10, and 16 of the '277 Patent." Ex. 2021 ¶ 388; Ex. 2022 ¶ 389.

Patent Owner's Sur-reply does not contain any additional substantive analysis as to the presumption of nexus issue. PO Sur-reply 1–2 (citing Ex. 2021 ¶¶ 63–72, 380–412; Ex. 2022 ¶¶ 64–73, 381–413; PO Resp. 3). In addition, the testimony cited by Patent Owner does not contain a claim-by-claim or limitation-by-limitation analysis of the challenged claims, and merely summarily concludes that certain limitations are present while

providing unlabeled photographs of the EarWell device and patient photographs. Ex. 2021 ¶¶ 63–65; Ex. 2022 ¶¶ 64–66. Patent Owner also cites to its Patent Owner Response for support (at page 3), but that page merely shows a labelled photo of the EarWell device in an effort to support Patent Owner's copying allegation, without any assertion that the device shown is covered by the challenged claims, much less any claim-by-claim or limitation-by-limitation analysis. *See* PO Resp. 3. Because Patent Owner's briefing and cited evidence lack sufficient specificity, we conclude that Patent Owner fails to establish that it is entitled to a presumption of nexus.[8]

For the sake of completeness, we address Patent Owner's allegations relating to objective indicia based on the assumption that Patent Owner established a nexus. As to copying, Patent Owner persuasively argues that at least the limitations in challenged claim 1 were copied by Petitioner during development of its competing InfantEar device. As a customer using the EarWell device, Petitioner was well aware of its design and the evidence supports Patent Owner's position that Petitioner attempted to duplicate the EarWell device with a lower cost device. *See* PO Resp. 56 (citing Exs. 2008, 2009). Petitioner correctly notes that other, unclaimed, features of the

[8] In addition to failing to establish that the challenged claims cover the EarWell device, Patent Owner does not address whether any of the claims are "coextensive" with the EarWell device. Merely establishing that the claims broadly cover the EarWell device does not entitle Patent Owner to a presumption of nexus. *See Fox Factory*, 944 F.3d at 1373 (noting that Federal Circuit has "reaffirmed the importance of the 'coextensiveness' requirement"); *see also id.* at 1377 ("We reject [Patent Owner's] attempt to reduce the coextensiveness requirement to an inquiry into whether the patent claims broadly cover the product that is the subject of the evidence of secondary considerations.").

devices differ, including the shape of the scaphal mold and use of gel in the product. *See* Pet. Reply 25–26. That evidence tends to show that the InfantEar device was not a slavish copy of the EarWell device, and that such differences may have led to an effort to avoid infringement of claim 1 and may impact the performance of the InfantEar device in comparison to the EarWell device. Nevertheless, viewed as a whole, we deem the evidence of copying as relatively strong.

As to long-felt but unresolved need, and in particular the 2017 Dr. Bartlett article, we view the evidence as relatively weak. When referencing the EarWell device, the article describes "mixed" results and a number of problems, including "a tendency for early device separation" and "inability to adjust the ear shape beyond" the two sizes provided. Ex. 2015, 7. The article goes on to tout its own device that allegedly improves upon the EarWell by using Velcro and a clear gel matrix material that "is less rigid and henceforth more resistant to dislodging," and provides "far greater flexibility to shape the ear." *Id.* The fact that the "conformers" used as part of the improved device in the article were the EarWell device, as Patent Owner alleges, does mean that the conformers alone satisfied a long-felt but unresolved need, especially given the specific discussion of the EarWell device and its limitations. *See* PO Sur-reply 3. Because the 2017 Dr. Bartlett article mildly disparages the EarWell device and discloses a device that allegedly improves upon the EarWell device, we do not view the article as a whole as supporting Patent Owner's position that it shows a long-felt but unresolved need satisfied by the EarWell device. As to the Yotsuyanagi articles relied on by Patent Owner, even if those articles show ongoing needs in the field, Patent Owner does not show how the articles support its position

that the claimed device or the EarWell device satisfied those needs. *See* PO Resp. 66–67. We view the evidence of long-felt but unresolved need as weak.

As to industry praise, Patent Owner persuasively relies on several papers touting the success of the EarWell device. PO Resp. 68–70 (discussing Exs. 2039, 2042, 2043). These articles generally describe improved results and high success rates using the EarWell device. *Id.* Petitioner attempts to cast the articles as unremarkable because corrections of ear shape have been done for many years, but Petitioner's generalized statements do not rebut the specific successes of the EarWell device Patent Owner relies upon. *See* Pet. Reply 28. In addition, Patent Owner persuasively argues that the article noting that ear molding has been taking place for centuries goes on to praise the EarWell device in comparison to prior techniques. PO Sur-reply 4–5 (citing Ex. 2038, 2). Assuming that a nexus was established by Patent Owner, we view the evidence of industry praise as relatively strong.

As to licensing, Patent Owner presents only one potential licensee, Petitioner. PO Resp. 71 (citing Ex. 2004). That evidence consists of a single remark that a license may be possible, but the record does not reveal that any license was ever sought by Petitioner, that Patent Owner offered a license, or that any license terms were ever considered by either party. We do not view a single, general remark that a license was at one point considered by Petitioner as persuasive evidence that third parties were willing to obtain a license to the patented technology.

Based on the foregoing, we find that Patent Owner fails to establish a nexus and therefore fails to establish that the objective indicia support a

finding of nonobviousness. However, had Patent Owner established a nexus, the evidence of copying and industry praise are relatively strong.

4. Conclusion as to Claims 1–7 and 9 Based on Dancey and Gault

"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 Dancey and Gault discloses all the limitations of claims 1–3 and 9, but not claims 4–7; (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 claims 1–3 and 9 of the '942 patent are unpatentable over the combination of Dancey and Gault. Even if Patent Owner establishes a nexus to the relatively strong evidence of copying and industry praise, we find the strength of the prior art in light of the breadth of the claims 1–3 and 9 stronger than the objective indicia, and would still conclude that claims 1–3 and 9 are unpatentable as obvious. A preponderance of the evidence does not persuade us that claims 4–7 of the '942 patent are unpatentable.

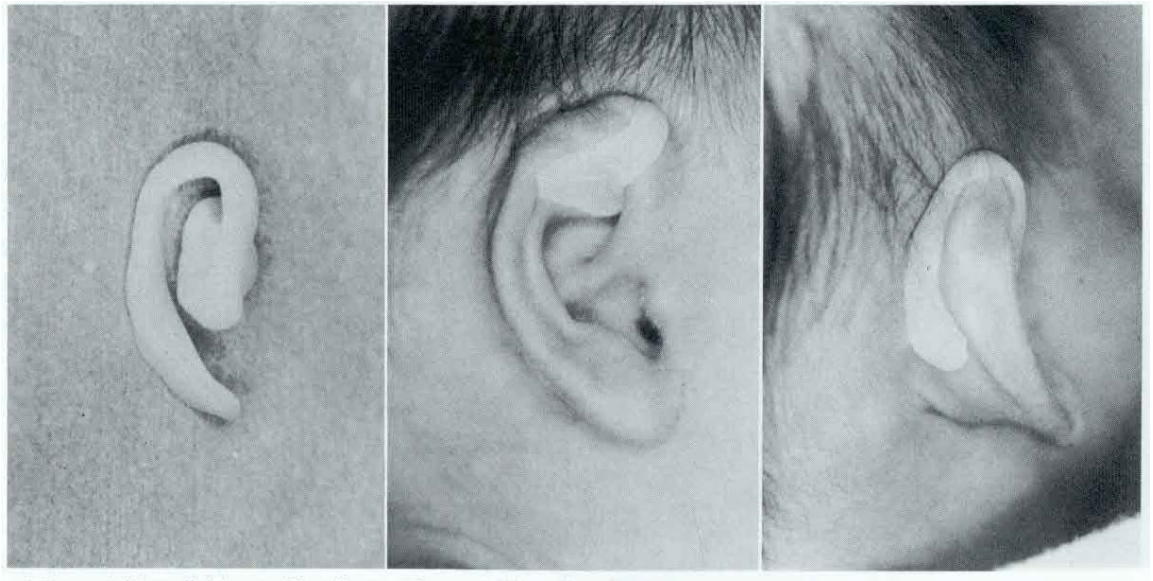
E. Challenge Under 35 U.S.C. § 103 Based on Yotsuyanagi and Gault

Petitioner challenges claims 1 and 9 under 35 U.S.C. § 103 based on Yotsuyanagi and Gault. Pet. 36–47. For these challenges, Petitioner cites to the asserted references and the Hershcovitch Declaration. *Id.*

1. Yotsuyanagi (Ex. 1012)

Yotsuyanagi discloses thermoplastic splints used to treat cryptotia. Ex. 1012, 2. The thermoplastic material allows the device to conform to the complex shape of the ear's auricle—the outside of the ear. *Id.* at 2–3.

Photographs 2–4 of Yotsuyanagi are reproduced below.



Ex. 1011, 3. Photograph 2, shown on the left above, depicts Yotsuyanagi's device alone. *Id.* Photographs 3 and 4, shown in the middle and on the right above, respectively, depict the device placed on a patient's ear. *Id.* An enlarged end of the device fits within the ear adjacent the helical rim and connects to a more slender portion of the device that wraps around the top of the ear and sits between the ear and the patient's head. *Id.*

2. Discussion

a. Independent Claim 1

Petitioner asserts that the combination of Yotsuyanagi and Gault discloses all of the limitations of claim 1. Pet. 36–43. Petitioner provides analysis of each limitation in claim 1, with citations to the references that correspond to each of the claim limitations. *Id.* Petitioner also cites to the relevant declarant testimony. *Id.* (citing various portions of Ex. 1007). Patent Owner argues that Yotsuyanagi fails to disclose several limitations in claim 1, but does not dispute Petitioner's arguments in support of the combination of Yotsuyanagi and Gault. *See* PO Resp. 46–50. We first address the limitations of claim 1, and then Petitioner's arguments in support of the motivation to combine Yotsuyanagi and Gault.

The parties' positions as to the preamble of claim 1 mirrors those discussed above in the context of the analysis based on Dancey and Gault. Petitioner argues that the preamble does not limit the claim, but if it does, Yotsuyanagi and Gault disclose the preamble's requirements. Pet. 36–37. Patent Owner argues that Yotsuyanagi fails to disclose an ear "molding device," but that term only appears in the preamble and Patent Owner does not argue that the preamble limits claim 1 in its Patent Owner Response. *See* PO Resp. 46–47. In addition, Patent Owner's argument as to "molding device" appears to be premised on Patent Owner's proposed construction for that term, which requires a "device that reshapes." *Id.* at 15, 46 ("[T]he Yotsuyanagi thermoplastic only treated cryptotia and did not *mold* any part of the ear itself *into the correct shape*." (emphasis added)). We find Patent Owner's arguments unpersuasive for the same reasons we provided above in the context of the ground based on Dancey and Gault. We agree with

Petitioner that the preamble does not limit the claim. In addition, we are persuaded by Petitioner's arguments and evidence that the combination of Yotsuyanagi and Gault discloses the preamble's requirements if the preamble does limit the claim. *See* Pet. 36–37; Ex. 1007 ¶ 107; Ex. 1011, Figs. 2–4; Ex. 1015, 3.

Claim 1 further requires "one or more braces; and a scaphal mold supported by the one or more braces." Petitioner argues that the slender portion of Yotsuyanagi's device discloses the claimed "brace" and the enlarged end discloses the claimed "scaphal mold" supported by the brace. Pet. 37–39 (citing Ex. 1001, Fig. 1; Ex. 1007 ¶¶ 108–110; Ex. 1011, Figs. 2–4). Petitioner contends that although "Yotsuyanagi does not expressly disclose that the splint is placed in the 'scaphal area,' those skilled in the art would have understood that the scaphal area includes the region between the helix and the antihelix." *Id.* at 39 (citing Ex. 1007 ¶ 111). Petitioner also relies on Gault as disclosing a device in the "scaphal area." *Id.* at 39–40 (citing Ex. 1015, 8, Figs. 1–2). Petitioner argues that "in view of the disclosure in Gault, a person of ordinary skill in the art would understand Yotsuyanagi's splint to be a scaphal mold placed in the scaphal area, consistent with the district court's construction of this claim term." *Id.* at 40 (citing Ex. 1007 ¶¶ 109–112; Ex. 1008, 13); *see also* Pet. Reply 14, 16.

Patent Owner does not dispute that Yotsuyanagi discloses "one or more braces," but does argue that Yotsuyanagi fails to disclose the "scaphal mold." PO Resp. 47. Patent Owner contends that Yotsuyanagi's alleged scaphal mold fails to mold or shape any portion of the ear, much less the helix or helical rim. *Id.* (citing Ex. 1021 ¶¶ 172–176; Ex. 2022 ¶¶ 173–177). According to Patent Owner, "[t]he components Petitioner identifies in

Dancey and Yotsuyanagi as the 'scaphal mold' are not 'reshaping' the helix or helical rim as required by the court's claim construction that the parties agreed to." PO Sur-reply 16–17.

We find that Petitioner establishes sufficiently that the combination of Yotsuyanagi and Gault discloses "one or more braces; and a scaphal mold supported by the one or more braces." *See* Pet. 37–39; Ex. 1007 ¶¶ 108–110; Ex. 1011, Figs. 2–4. As to the "scaphal mold," Yotsuyanagi discloses a mold at the end of the one or more braces that is positionable in the scaphal area. *See id.* Patent Owner bases its arguments on its proposed construction for "scaphal mold," which we decline to adopt. *See* PO Resp. 47–48; PO Sur-reply 16–17. Because Patent Owner does not argue that Yotsuyanagi fails to disclose a molding device if we decline to adopt Patent Owner's construction and apply the district court's claim construction to the term, Petitioner's argument and evidence as to "scaphal mold" are undisputed.

The remainder of claim 1 includes "wherein" clauses that require the claimed braces and scaphal mold to be "constructed to" perform certain functions. Petitioner argues that Yotsuyanagi in view of Gault discloses these limitations because Yotsuyanagi's device retains the helix and helical rim of the ear within a space defined between the brace and scaphal mold, and maintains a substantially correct shape. Pet. 41–42; Ex. 1007 ¶¶ 113–115. Petitioner also argues that Yotsuyanagi discloses treatment with its device in an effort to get "closer to a normal shape over time." *Id.* at 43 (quoting Ex. 1012, 3) (citing Ex. 1007 ¶¶ 117–118). According to Petitioner,

> [a] person of ordinary skill in the art would have understood that the ear would have grown to conform to the space between [the] brace and scaphal mold after wearing the mold for the

> time period disclosed in Yotsuyanagi (treatment for 1–5 weeks, followed by 13–26 months monitoring).

Pet. 43 (citing Ex. 1012, 4 (Table 1); Ex. 1007 ¶ 118).

Patent Owner argues that Yotsuyanagi does not disclose a device "constructed to maintain a substantially correct anatomical shape of the helix and the helical rim," because "the purpose of the Yotsuyanagi splint is to pull the 'normal' ear away from the head to treat cryptotia—*not* to 'correct' the anatomical shape of the helix or helical rim." PO Resp. 48. Patent Owner also argues that Yotsuyanagi does not disclose "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." *Id.* at 49 (citing Ex. 2021 ¶¶ 281–285; Ex. 2022 ¶¶ 282–286). According to Patent Owner, Yotsuyanagi cannot be "constructed to mold" when the three patient cases described in Yotsuyanagi fail to show a change in shape of the helix or helical rim. *Id.*; *see also* PO Sur-reply 21. Patent Owner also argues that Yotsuyanagi fails to disclose "during their growth" and "that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces," again due to the lack of reshaping of the ears in the treatments Yotsuyanagi treated. PO Resp. 49–50. In its Sur-reply, Patent Owner reiterates its position that "the claims *require* molding or reshaping the helix or helical rim," and argues that Yotsuyanagi does not disclose reshaping. PO Sur-reply 16, 20–21.

We find that Petitioner establishes sufficiently that the combination of Dancey and Gault discloses all of the limitations in the "wherein" clauses at the end of claim 1. *See* Ex. 1001, 10:25–34; Pet. 41–43; Ex. 1005, 10; Ex. 1007 ¶¶ 113–118; Ex. 1011, Figs. 2–13; Ex. 1012, 3–6; Ex. 1015, 7, Fig. 1.

Throughout its briefing, Patent Owner bases its arguments on its own proposed constructions that we did not adopt, or implicit constructions that lack support. *See* PO Resp. 49–50; PO Sur-reply 16–17, 20–21. Because we decline to adopt Patent Owner's proposed construction, Petitioner's arguments as to these limitations using the correct constructions and ordinary meaning are unrebutted.

In addition, as noted above, Patent Owner places undue emphasis throughout its briefing on the need to correct a patient's deformity, the age of the patient, and the specific results obtained by the treatment. Whether the limitations of claim 1 are met does not require proof that Yotsuyanagi's device performed these acts and reshaped a malformed helix of a patient.

Based on our review of the record, Petitioner has established sufficiently that the combination of Yotsuyanagi and Gault discloses all of the limitations of claim 1.

As to the motivation to combine Yotsuyanagi and Gault, Petitioner contends that both references "serve the same purpose to solve the same problem" and that "[d]octors working in the field of nonsurgical techniques for splinting deformed ears at the time of the '942 patent would have turned to earlier references such as Gault to better understand and interpret the treatment described in Yotsuyanagi." Pet. 47 (citing Ex. 1007 ¶ 125). Patent Owner does not address Petitioner's arguments and evidence as to motivation to combine. Based on our review of the record, Petitioner establishes sufficiently that one of ordinary skill in the art would have been motivated to incorporate Gault's teachings into Yotsuyanagi's device, and use Gault to understand further Yotsuyanagi's disclosure.

b. Dependent Claim 9

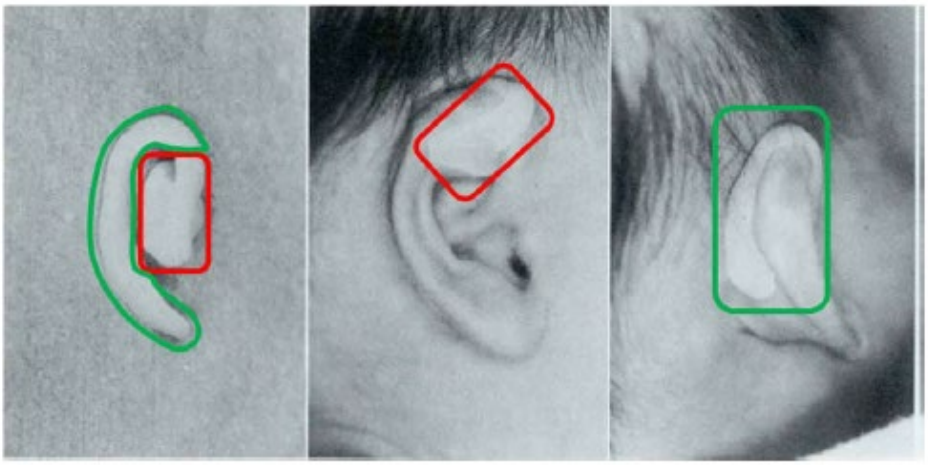
Claim 9 depends from claim 1 and further recites "wherein the scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges, and the extension is constructed to maintain a substantially correct anatomical shape of the scaphal area of the ear." Ex. 1001, 10:59–63. Petitioner argues that Yotsuyanagi's splint includes an arc-shaped semi-cylindrical extension from the brace as well as rounded edges. Pet. 44–45 (citing Ex. 1007 ¶¶ 121–124; Ex. 1011, Figs. 2–4, 6, 9). Petitioner also contends, relying on its arguments with respect to claim 1, that Yotsuyanagi's device maintains the helix and helical rim in an anatomically correct shape during treatment. *Id.* at 45–46 (citing Ex. 1007 ¶¶ 151, 121–124; Ex. 1011, Figs. 1, 3; Ex. 1012, 3–8).

Patent Owner argues that Dr. Hershcovitch (Petitioner's declarant) fails to identify anything on Yotsuyanagi's alleged scaphal mold that "is 'arc-shaped' or semi-cylindrical." PO Resp. 51 (citing Ex. 1011, Figs. 2–4). Patent Owner also argues that Dr. Hershcovitch inconsistently identifies the portions of Yotsuyanagi's brace and the extension of the scaphal mold such that the brace, rather than the scaphal mold, encompasses the alleged extension. *Id.* at 51–52 (citing Ex. 1007 ¶¶ 109–110, 121–124).

In its Reply, Petitioner argues that Patent Owner's arguments are based on its improper claim construction arguments. Pet. Reply 23 (citing Pet. 43–46; Ex. 1007 ¶¶ 120–124; Ex. 1011, Figs. 1–4, 6; Ex. 1012, 3–8; Ex. 2034, 168:18–21). In its Sur-reply, Patent Owner again states that Petitioner improperly identifies the claimed "extension" as part of the brace rather than the scaphal mold, as claim 9 requires. PO Sur-reply 14–15 (citing Pet. Reply 23; Ex. 1007 ¶¶ 109–110, 121–124).

Petitioner relies on two portions of Yotsuyanagi's splint with respect to claim 9, an allegedly "arc-shaped" first portion on the underside of the helical rim, and an allegedly semi-cylindrical second portion wrapping around the top of the ear. Pet. 44–45 (citing Ex. 1007 ¶¶ 121–124; Ex. 1011, Figs. 2–4, 6, 9). We agree with Patent Owner that Petitioner's identification of the allegedly semi-cylindrical structure fails to identify clearly an extension that is part of the scaphal mold rather than the brace. *See* PO Sur-reply 14–15.

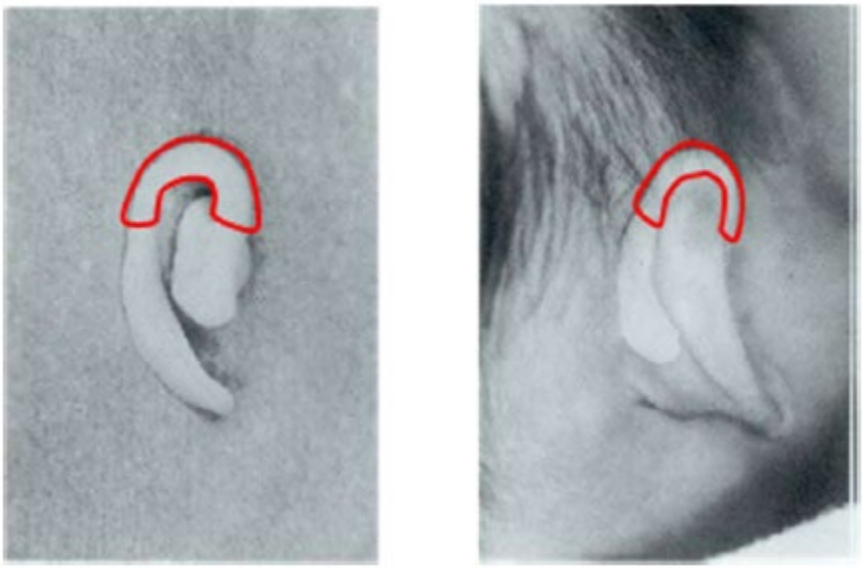
An annotated version of Yotsuyanagi's Figures 2–4 taken from the Petition is reproduced below (Pet. 39).



Figures 2, 3, and 4 of Yotsuyanagi (annotated)

The annotated figures depict Yotsuyanagi's splint in three different views, with Petitioner's identification of the claimed brace shown in green and the scaphal mold shown in red. Pet. 39 (citing Ex. 1007 ¶¶ 109–110; Ex. 1011, Figs. 2–4).

An annotated version of Yotsuyanagi's Figures 2 and 4 taken from the Petition is reproduced below (Pet. 45).



Figures 2 and 4 of Yotsuyanagi (annotated)

The annotated Figures 2 and 4 shown above depict Yotsuyanagi's device, with Petitioner's identification of the claimed "semi-cylindrical extension from the brace" shown in red. Pet. 44–45 (citing Ex. 1011, Figs. 2, 4; Ex. 1007 ¶ 123).

Claim 9 requires the *scaphal mold* to include a generally "semi-cylindrical extension," not the brace. Petitioner's identification of the semi-cylindrical extension, however, overlaps significant portions of the same structure that Petitioner relies on for the brace, shown in green above. We cannot discern from Petitioner's annotations whether any portion it identifies as the claimed extension is part of the scaphal mold, and if so, whether any such portion can be considered generally semi-cylindrical. Petitioner had an opportunity to clarify the issue in its Reply after Patent Owner raised the issue in its Response, but Petitioner declined to do so. *See* PO Resp. 51–52; Pet. Reply 23.

Because claim 9 requires a generally semi-cylindrical extension that is part of the *scaphal mold*, and Petitioner identifies such an extension as part

of the *brace*, Petitioner has not proven by a preponderance of the evidence that all of the limitations of claim 9 are disclosed by the combination of Yotsuyanagi and Gault.

3. Conclusion as to Claims 1 and 9

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 Yotsuyanagi and Gault discloses all the limitations of claim 1, but not claim 9; (3) one of ordinary skill in the art would have been motivated to combine Yotsuyanagi 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 1 of the '942 patent is unpatentable over the combination of Yotsuyanagi and Gault. Even if Patent Owner established a nexus to the relatively strong evidence of copying and industry praise, we find the strength of the prior art in light of the breadth of the claim 1 stronger than the objective indicia, and would still conclude that claim 1 are unpatentable as obvious. A preponderance of the evidence does not persuade us that claim 9 of the '942 patent would have been obvious based on Yotsuyanagi and Gault.

CONCLUSION[9]

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
1–7, 9	103	Dancey, Gault	1–3, 9	4–7
1, 9	103	Yotsuyanagi, Gault	1	9
Overall Outcome			1–3, 9	4–7

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3 and 9 of U.S. Patent 8,167,942 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that claims 4–7 of U.S. Patent 8,167,942 B2 have not 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.

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[9] 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).

For PETITIONER:

Thomas Fisher
James Gale
Jeffrey Townes
Keri L. Schaubert
COZEN O'CONNOR
tfisher@cozen.com
jgale@cozen.com
jtownes@cozen.com
kschaubert@cozen.com

PATENT OWNER:

David Cupar
Matthew Cavanagh
Erin R. Conway
MCDONALD HOPKINS LLC
dcupar@mcdonaldhopkins.com
mcavanagh@mcdonaldhopkins.com
econway@mcdonaldhopkins.com

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that on June 16, 2021, a copy of the foregoing PETITIONER'S FILING OF PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT was served on counsel of record for Patent Owner by filing this document through the PTAB E2E System as well as delivering a copy via email as follows:

David B. Cupar
Matthew J. Cavanagh
MCDONALD HOPKINS LLC
600 Superior Avenue, East, Ste. 2100
Cleveland, OH 44114
dcupar@mcdonaldhopkins.com
mcavanagh@mcdonaldhopkins.com

Erin Conway
MCDONALD HOPKINS LLC
300 N. LaSalle St., Ste. 1400
Chicago, IL 60654
econway@mcdonaldhopkins.com

Dated: June 16, 2021

Respectfully submitted,

/ Thomas J. Fisher /
Thomas J. Fisher
Registration No. 44,681

Lead Counsel for Petitioner
TalexMedical, LLC