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.

IPR2020-0030
U.S. Patent No. 8,852,277

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.,

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Inter Partes Review 2020-0030

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 36) in the above-caption *inter partes* review of U.S. Patent No. 8,852,277 ("the '277 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 claim 16 is 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

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 36
Date: 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.

IPR2020-00030
Patent 8,852,277 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, 2, 9, and 10 Unpatentable
Determining Challenged Claim 16 Not Unpatentable
Denying Patent Owner's Motion to Amend
35 U.S.C. § 318(a)
Dismissing Patent Owner's Motion to Exclude
37 C.F.R. § 42.64

INTRODUCTION

TalexMedical, LLC (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of an *inter partes* review of claims 1, 2, 9, 10, and 16 of U.S. Patent No. 8,852,277 B2 (Ex. 1003, "the '277 patent"). Becon Medical Limited and Henry Stephenson Byrd, M.D. (collectively, "Patent Owner") filed a Preliminary Response. Paper 6. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of claims 1, 2, 9, 10, and 16 of the '277 patent on all presented challenges. Paper 7 ("Inst. Dec.").

After institution, Patent Owner filed a Response (Paper 13, "PO Resp."), Petitioner filed a Reply (Paper 19, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 23, "PO Sur-reply"). Patent Owner also filed a Contingent Motion to Amend (Paper 14, "PO MTA"), Petitioner filed an Opposition (Paper 18, "Pet. MTA Opp."), Patent Owner filed a Reply (Paper 24, "PO MTA Reply"), and Petitioner filed a Sur-reply (Paper 28, "Pet. MTA Sur-reply"). In addition, Patent Owner filed a Motion to Exclude (Paper 30), Petitioner filed an Opposition (Paper 33), and Patent Owner filed a Reply (Paper 34). An oral hearing in this proceeding was held on January 21, 2021, and a transcript of the hearing is included in the record (Paper 35, "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 (2019). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 9, and 10 of the '277 patent are unpatentable and that Petitioner has not shown by a preponderance of the evidence that claim 16 is unpatentable. Petitioner has also shown by a preponderance of the evidence that all of the proposed

substitute claims that are the subject of Patent Owner's Contingent Motion to Amend 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, 2.

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 '277 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 IPR2020-00028 as a related proceeding, which involves a related patent asserted by Patent Owner in the district court litigation, U.S. Patent No. 8,167,942 B2 ("the '942 patent"). Pet. 3; Paper 4, 1.

B. The '277 Patent

The '277 patent issued on October 7, 2014, from an application filed March 29, 2012. Ex. 1003, codes (22), (45). The application that led to the issuance of the '277 patent is a division of the application that led to the '942 patent that is the subject of IPR2020-00028. *Id.* code (62). The '277 patent relates to "correcting misshaped ears using a molding device." *Id.* code (57).

Petitioner's annotated version of Figure 1 of the '277 patent, reproduced below, provides a description of the parts of the ear that are relevant to this Decision. Pet. 8.

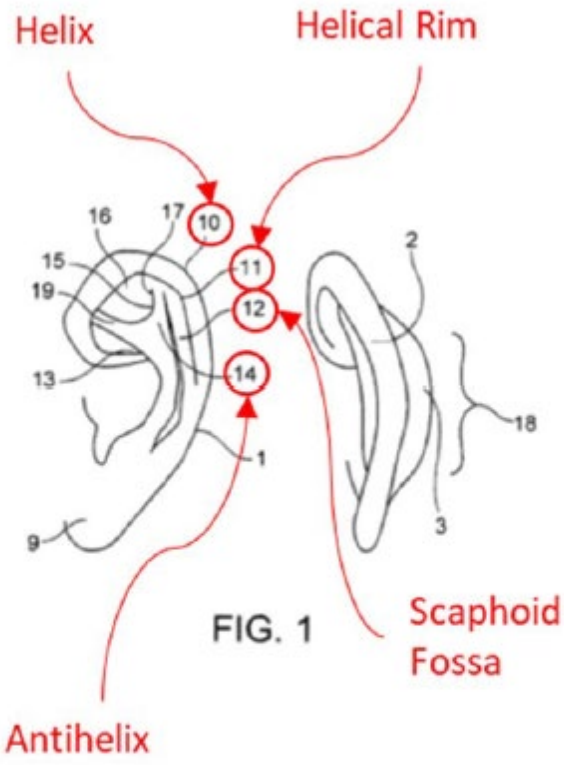


Figure 1 of the '277 Patent (annotated)

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 4:11–16, Fig. 1.

Figure 5 of the '277 patent depicts molding device 29 and is reproduced below.

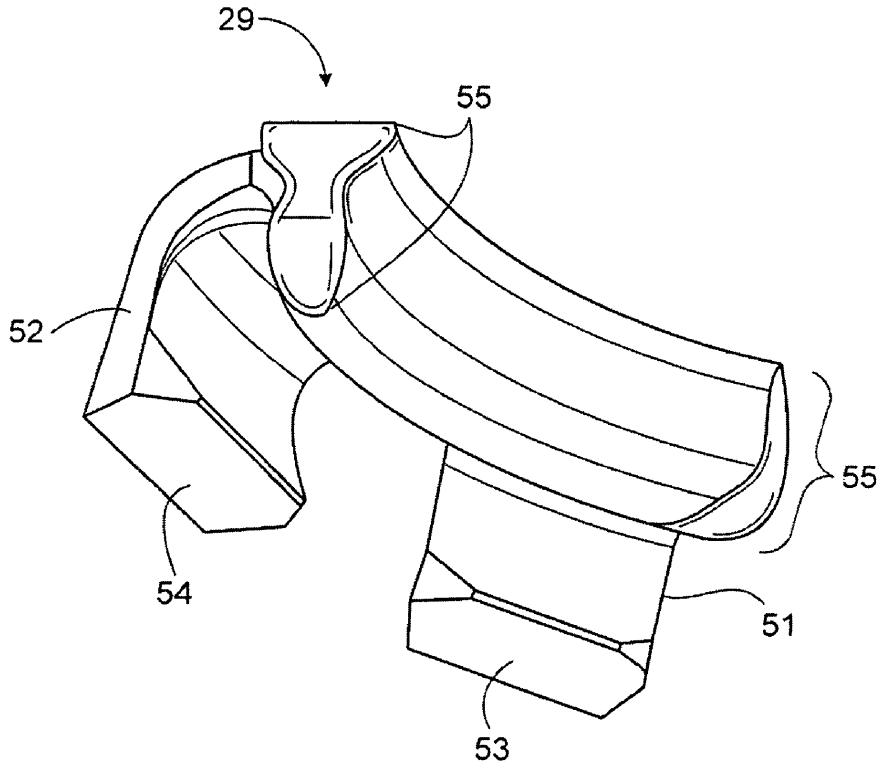


Figure 5 "is a slightly inferior and lateral view" of ear molding device 29. Ex. 1003, 3:62–63. Ear molding device 29 includes "scaphal mold 55 configured to mold the scaphoid fossa into a substantially correct anatomic shape." *Id.* at 6:38–39. The '277 patent describes scaphal mold 55 as an extension of legs or braces 51, 52. *Id.* at 6:45–47. 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 6:49–55.

The '277 patent also discloses cradle 20 that includes cradle base 21 and cradle cover 22. Ex. 1003, 4:42–43, 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 4:43–47, 5:10–12.

C. Challenged Claims

The ’277 patent has 17 claims and one independent claim, claim 1. Petitioner challenges claims 1, 2, 9, 10, and 16. Pet. 1. Claim 1 is reproduced below.

> 1. A molding system 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 system comprising:
>
> a cradle comprising:
>
> a base section defining an opening dimensioned to accommodate the passage of the ear through the opening, the base section including a posterior surface and an anterior surface;
>
> a cover releasably engageable with the base section, wherein the cover, when engaged with the base section, defines a compartment between an inner surface of the cover and an inner surface of the base section; and
>
> an ear 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 adapted to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and to maintain a substantially correct anatomical shape of the helix and the helical rim.

Ex. 1003, 10:28–49.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1, 2, 9, 10, and 16 would have been unpatentable on the following grounds (Pet. 6):

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1, 10, 16	103	Osman,[2] Yotsuyanagi,[3] Gault[4]
2, 9	103	Osman, Yotsuyanagi, Gault, Voorhees[5]

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 ("Khosla Declaration"); Ex. 2022 ("Daniali Joshi Declaration").

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) (2012); 37 C.F.R. § 42.1(d) (2018). "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

[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 '277 patent issued was filed before that date, unless otherwise stated, our citations to Title 35 are to its pre-AIA version.
[2] WO 81/02515, published September 17, 1981 (Ex. 1006) ("Osman").
[3] 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.
[4] GB 2304579 A, published March 26, 1997 (Ex. 1015) ("Gault").
[5] US 5,749,099, issued May 12, 1998 (Ex. 1013) ("Voorhees").

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 '277 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. 11. 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. 16 (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 '277 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).

Petitioner states that the district court already construed three terms at issue here. Pet. 12 (citing Ex. 1008, 16). The district court "construed the claim term 'opening' to mean 'a gap that accommodates the passage of the ear;' the term 'scaphal mold' to mean 'mold at the end of the one or more braces that is positionable in the scaphal area;' and the term 'cradle' to mean 'the base section and the cover.'" *Id.* All of these terms appear in independent claim 1. Ex. 1003, 10:32–33, 10:44. 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." Pet. 12 (citing Ex. 1008, 10–11); *see also* Pet. Reply 5–6 (arguing that district court's construction merely refers to the position of the mold, not what the scaphal mold does). Petitioner does not argue for any specific constructions of any claim terms, and applies the district court's constructions in its analysis. Pet. 12–13, 22–25.

Patent Owner argues that we should go beyond the district court constructions 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. 14. Patent Owner argues that the district court claim construction order supports its position because the district court agreed with Patent Owner that the '277 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.* (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 15–16 (citing Pet. 10–11); *see also* PO Sur-reply 7–8 (arguing that limitations require reshaping).[6]

The parties appear to agree that we should apply the district court's claim constructions for "opening," "scaphal mold," and "cradle," and we will do so in this Decision. Pet. 12–13; PO Resp. 14–16. 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

[6] Patent Owner also argues that Petitioner incorrectly argues that the functional limitations of claim 1 are merely intended use not entitled to weight. PO Sur-reply 6 (citing Pet. Reply 4–6, 8, 12, 14, 16). We do not view Petitioner's arguments as to intended use as suggesting that language in the body of claim 1 should not be given any weight; Petitioner instead argues that Patent Owner's proposed constructions amount to intended use that fail to structurally limit the claims. *See, e.g.*, Pet. Reply 4 ("PO asks the Board for a new construction of the challenged claims that does not describe a further structural distinction of the claimed device, but instead, describes the intended use of the device.").

device" or "mold" in the manner Patent Owner proposes, and the district court's references to the '277 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 7 (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. 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. Claim 1 refers to a molding device that comprises one or more braces and a scaphal mold that are "adapted to retain the helix and helical rim within a space . . . and to maintain a substantially correct anatomical shape of the helix and helical rim." Ex. 1003, 10:42–49. This language already defines the 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" the shape functions as requiring reshaping, and we see no basis to do so here.

Based on the foregoing, we construe "opening" to mean *a gap that accommodates the passage of the ear*, "scaphal mold" to mean *mold at the end of the one or more braces that is positionable in the scaphal area*, and "cradle" to mean *base section and the cover*.

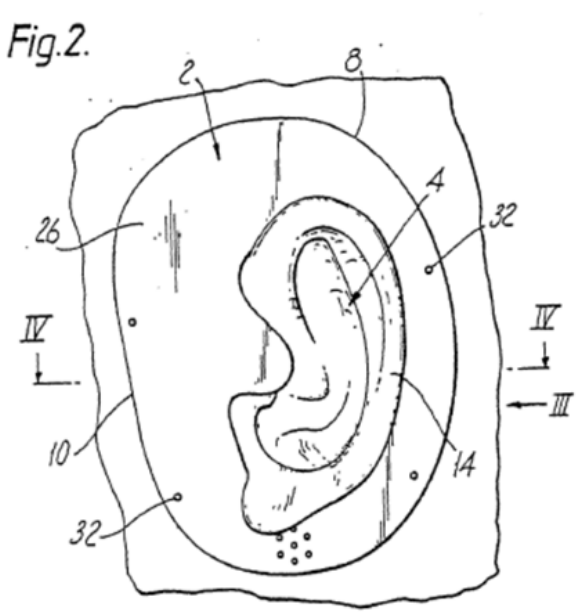
D. Challenge Under 35 U.S.C. § 103 Based on Osman, Yotsuyanagi, and Gault

Petitioner challenges claims 1, 10, and 16 under 35 U.S.C. § 103 as unpatentable over Osman, Yotsuyanagi, and Gault. Pet. 18–35. For these challenges, Petitioner cites to the asserted references and the Hershcovitch Declaration. *Id.*

1. Osman

Osman discloses "[a] device for use in protecting the human ear." Ex. 1006, code (57). Osman's device protects an ear, for example, "during care of a patient following major or minor aural surgery." *Id.* at 1:3–5.

Figures 2 and 7 of Osman are reproduced below.



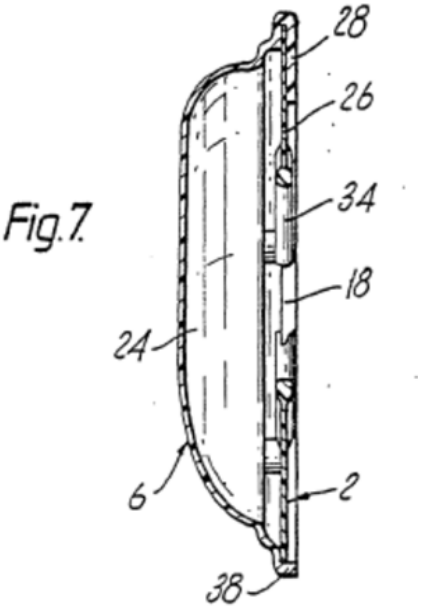
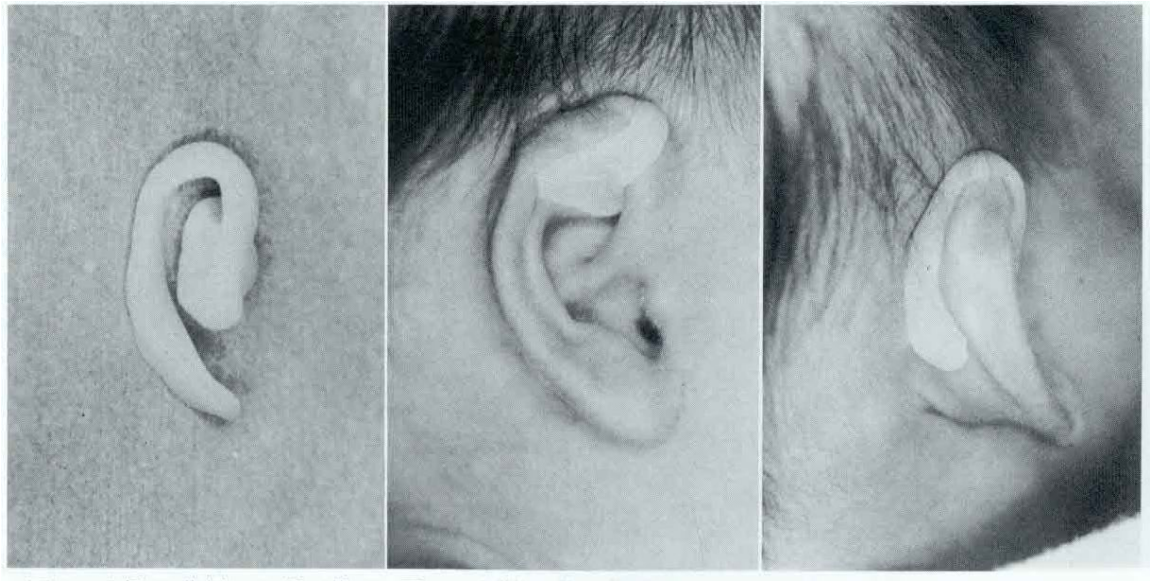


Figure 2 (above left) shows a side elevation and Figure 7 (above right) shows a vertical section of the device. Ex. 1006, 4:2–3, 4:13–14. Osman's device includes base plate 2 having opening 12 that permits helix 14 of a patient's ear to pass through opening 12. *Id.* at 4:17–18, 4:30–32. Figure 7 shows plastic cap 6 releasably attached to base plate 2, which forms space 24 that encloses the ear. *Id.* at 4:17–20, 5:11–13.

2. Yotsuyanagi

Yotsuyanagi discloses thermoplastic splints used to treat cryptotia.[7] 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

[7] According to Patent Owner, "cryptotia results when part of the auricular (i.e., the visible or outer part of the ear) is embedded under the skin. This type of malformation results when the underlying muscle is too short and pulls the ear inward." PO Resp. 3.

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.*

3. 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. Gault discloses its ear splint device in combination with a protector that fits around the ear. *Id.* at 2, 6–7, 10.

4. Discussion

We first address whether the combination of Osman, Yotsuyanagi, and Gault discloses all of the limitations of claims 1, 10, and 16. We focus on Yotsuyanagi because Patent Owner's arguments are directed to the alleged failure of Yotsuyanagi to disclose several limitations. We then address the motivation to combine the references.

a. Independent Claim 1

Petitioner asserts that the combination of Osman, Yotsuyanagi, and Gault discloses all of the limitations of claim 1. Pet. 18–27. 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 the proposed combination fails to disclose several limitations of claim 1. PO Resp. 27–30. We first address the limitations that Patent Owner does not argue are missing from the

proposed combination, and then address the limitations that Patent Owner contends are missing.

As to the preamble, Petitioner asserts that it does not limit the claim because it merely states an intended use for the claimed device. Pet. 18. In the event that the preamble limits the claim, Petitioner argues that Yotsuyanagi as well as Gault disclose the preamble's requirements. *Id.* at 18–19. As to the limitations requiring a "cradle" that comprises "a base section defining an opening" and "a cover releasably engageable with the base section," Petitioner argues that Osman discloses the limitations because it discloses base plate 2 having opening 12 to accommodate the ear, and cap 6 (i.e., the claimed "cover") releasably attached to the base plate. *Id.* at 19–22; Ex. 1003, 10:32–41 ("cradle" limitations). Patent Owner does not argue that the preamble limits claim 1 or that the combination of Osman, Yotsuyanagi, and Gault fails to disclose any of these limitations of claim 1. *See* PO Resp. 27–30. 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 Osman, Yotsuyanagi, and Gault discloses the preamble's requirements if the preamble does limit the claim, as well as all aspects of the cradle base and cradle cover limitations of claim 1. *See* Pet. 18–22.[8]

[8] We need not set forth formal findings as to the undisputed assertions by Petitioner that the references disclose these limitations of claim 1. *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.");

Claim 1 also includes "ear molding device" limitations[9] that include "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. 23–25. 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 24 (citing Ex. 1007 ¶ 147). Petitioner also relies on Gault as disclosing a device in the "scaphal area." *Id.* at 24–25 (citing Ex. 1015, 8, Figs. 1–2). The ear molding device limitations also recite "wherein the one or more braces and the scaphal mold are adapted to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and to maintain a substantially correct anatomical shape of the helix and the helical rim." Petitioner argues that Yotsuyanagi discloses a space between its brace and scaphal mold adapted to retain the helix and helical rim and maintain the correct anatomical shape of the helix and helical rim. Pet. 25–27 (citing Ex. 1007 ¶¶ 149–151; Ex. 1011, Figs. 2–13; Ex. 1012, 2–6; Ex. 1015, 7, Fig. 1).

Patent Owner argues that Yotsuyanagi does not disclose the claimed "molding device" because Yotsuyanagi "only treated cryptotia," a condition that does not require "molding or shaping the ear as treatment, but rather

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Paper 8, 7 (emphasizing that "any arguments for patentability not raised in the response may be deemed waived").

[9] We refer to the "ear molding device" limitations as the language starting with "an ear molding device" through the end of claim 1. *See* Ex. 1003, 10:42–49.

requires pulling the ear away from the head to stretch underlying muscles." PO Resp. 27. According to Patent Owner, Yotsuyanagi "did not mold any part of the ear itself into the correct shape." *Id.* Patent Owner argues that Yotsuyanagi does not disclose the "scaphal mold" for essentially the same reasons. *Id.* at 27–28 (arguing that nothing in the area of Yotsuyanagi's alleged scaphal mold "molds or shapes any portion of the ear"). Patent Owner also contends that the three patient treatment cases that Yotsuyanagi describes do not show a change in shape of the ear to an anatomically correct ear shape. *Id.* at 28. As to the limitation requiring "a space defined between the one or more braces and the scaphal mold," Patent Owner relies on its previous argument that Yotsuyanagi does not disclose a scaphal mold, and therefore cannot disclose a space defined by a scaphal mold. *Id.* at 29. As to the limitation reciting "to maintain a substantially correct anatomical shape of the helix and the helical rim," Patent Owner argues that Yotsuyanagi fails to disclose the limitation because its purpose "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." *Id.* at 29.

In its Reply, Petitioner argues that Patent Owner places misplaced reliance on Yotsuyanagi's treatment of cryptotia because the claims say nothing about the deformities that can be treated with the claimed device, and Yotsuyanagi states that it not only treats cryptotia but also that "the correction of the helix or anti-helix is performed to be sure." Pet. Reply 8 (quoting Ex. 1012, 3) (citing Ex. 1007 ¶¶ 113–119); *see also id.* at 15–16. Petitioner relies on that same portion of Yotsuyanagi to argue that it discloses maintaining a substantially correct anatomical shape through

treatment and shaping the ear. *Id.* at 15 (citing Pet. 25–27; Ex. 1007 ¶¶ 149–153; Ex. 1011, Figs. 2–13; Ex. 1012, 2–6).

In its Sur-reply, Patent Owner again argues that Yotsuyanagi fails to disclose a device that reshapes the ear, and the fact that its device is positioned in the scaphal area and merely repositions the ear rather than reshapes it. PO Sur-reply 8–9. Patent Owner also argues that Petitioner incorrectly quoted Yotsuyanagi in the Petition, and failed to correct the mistake until the Reply when it relied on Yotsuyanagi's statement that "correction of the helix or anti-helix is performed to be sure" in an effort to show that Yotsuyanagi's device shaped the helix or anti-helix. *Id.* at 10–11. Patent Owner contends that the quoted sentence from Yotsuyanagi refers to correction of the *position* of the helix or anti-helix, not correction of the *shape* of the helix or anti-helix. *Id.* at 11–12 (citing Ex. 2021 ¶ 114; Ex. 2022 ¶ 115; Ex. 1027, 220:21, 221:16–19).

We find that Petitioner establishes sufficiently that Yotsuyanagi discloses the ear molding device limitations of claim 1. Because we rejected Patent Owner's attempt to further construe "molding device" or "mold" as requiring reshaping, as discussed above in the claim construction section, and Patent Owner relies on those constructions as a premise for its arguments, Petitioner's arguments employing the correct constructions are essentially unrebutted. *See* PO Resp. 27–30 (arguing that Yotsuyanagi fails to reshape or shape the helix or helical rim for each of the disputed ear molding device limitations). Patent Owner does not argue that Yotsuyanagi fails to disclose any of the ear molding device limitations if we construe "scaphal mold" to mean "mold at the end of the one or more braces that is positionable in the scaphal area," the construction we apply here.

In addition to being unrebutted under the correct claim constructions, we find Petitioner's arguments and evidence as to the ear molding device limitations persuasive. Yotsuyanagi's splint includes an arcuate portion that bends around the back of the ear (the claimed "brace") on one end and an enlarged portion on the other end of the splint positionable within the scaphal area (the claimed "scaphal mold"). Ex. 1007 ¶¶ 144–148; Ex. 1011, Figs. 2, 3, 4, 6, 9; Ex. 1015, 7–8, Figs. 1–2; Pet. 22–25. The gap formed between Yotsuyanagi's brace and scaphal mold defines a space that retains the top of the ear (i.e., the space is "adapted to retain the helix and helical rim") and maintains a substantially correct anatomical shape of the ear. Ex. 1007 ¶¶ 149–151; Ex. 1011, Figs. 2–13; Ex. 1012, 2–6; Pet. 25–27. As noted above in the claim construction analysis, Patent Owner does not set forth argument and evidence seeking a construction of "maintain" that requires reshaping the ear, and we see no reason to view maintaining a shape as requiring a change in shape or reshaping the ear.

The parties further dispute whether Yotsuyanagi discloses shaping the ear in the event that we adopt Patent Owner's construction. *See* Pet. Reply 8, 13, 15; PO Sur-reply 10. We need not reach this issue given our rejection of Patent Owner's proposed constructions. We note, however, that we would reach the same result using Patent Owner's constructions because Petitioner sufficiently establishes that Yotsuyanagi discloses a device that reshapes the ear, as discussed in more detail in the analysis of Patent Owner's Contingent Motion to Amend below.

We find that Petitioner has proven by a preponderance of the evidence that the combination of Osman, Yotsuyanagi, and Gault discloses all of the limitations of claim 1.

b. Dependent Claim 10

Claim 10 depends from claim 1 and further recites "wherein the base section and the cover include a vertical wall." Ex. 1003, 11:16–17. Petitioner argues that Osman's "cap contains vertical walls," as shown in Osman's Figure 7. Pet. 28 (citing Ex. 1006, 5:12–13, Fig. 7; Ex. 1007 ¶¶ 155–156). Patent Owner does not argue that the combination of Osman, Yotsuyanagi, and Gault fails to disclose any of these limitations of claim 10. PO Resp. 30 (arguing that claim 10 is nonobvious due to its dependency from claim 1). We are persuaded by Petitioner's arguments and evidence that the combination of Osman, Yotsuyanagi, and Gault discloses the limitations of claim 10 because Osman's cap, which corresponds to the claimed cover, includes a vertical wall. Ex. 1006, 5:12–13, Fig. 7; Ex. 1007 ¶¶ 155–156; Pet. 28.

Accordingly, we find that Petitioner has proven by a preponderance of the evidence that the combination of Osman, Yotsuyanagi, and Gault discloses all of the limitations of claim 10.

c. Dependent Claim 16

Claim 16 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 adapted to maintain a substantially correct anatomical shape of the scaphal area of the ear." Ex. 1003, 12:13–17. Petitioner argues that Yotsuyanagi's splint includes an arc-shaped semi-cylindrical extension from the brace as well as rounded edges. Pet. 29–30 (citing Ex. 1007 ¶¶ 158–160; 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

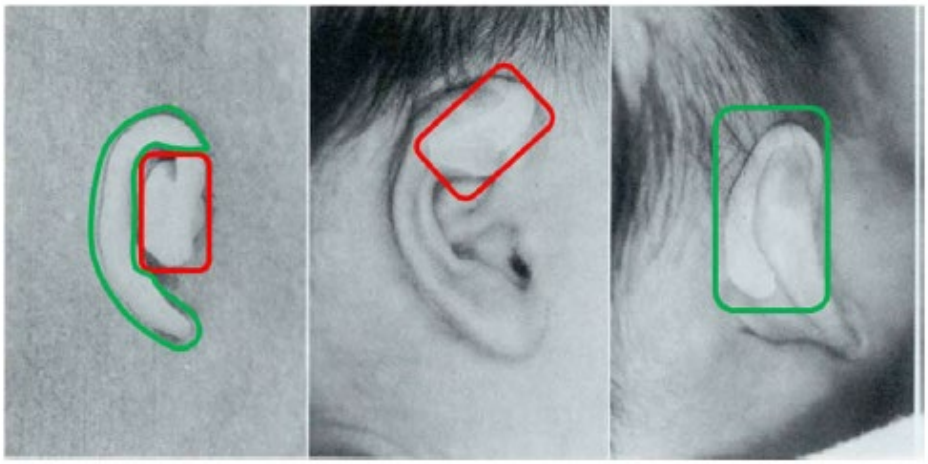
rim in an anatomically correct shape during treatment. *Id.* at 30–31 (citing Ex. 1007 ¶¶ 151, 158–161; Ex. 1011, Figs. 1, 3; Ex. 1012, 3–8).

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. 30–31 (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 31–32 (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 17 (citing Pet. 28–31; Ex. 1007 ¶¶ 157–161; 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 16 requires. PO Sur-reply 15 (citing Pet. Reply 17; Ex. 1007 ¶¶ 145–146, 159–161).

Petitioner relies on two portions of Yotsuyanagi's splint with respect to claim 16, 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. 29–30 (citing Ex. 1007 ¶¶ 158–160; 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 15.

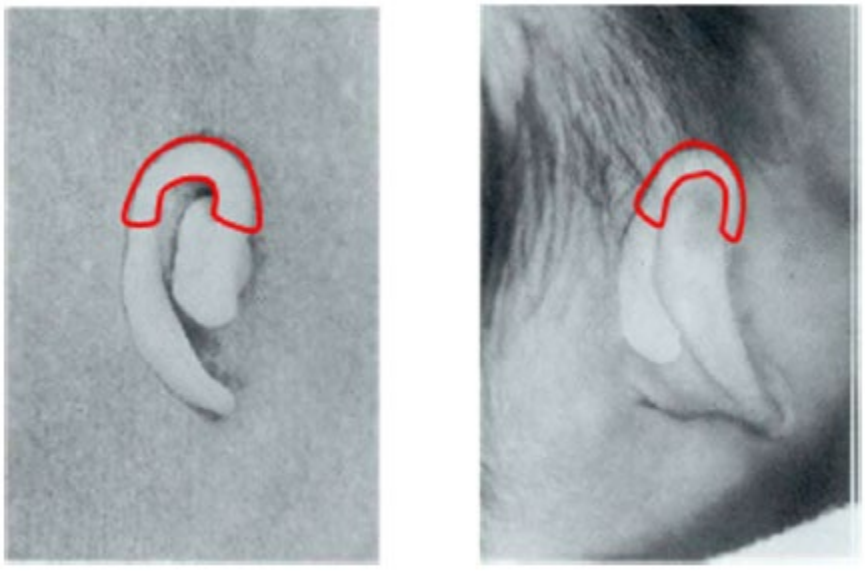
An annotated version of Yotsuyanagi's Figures 2–4 taken from the Petition is reproduced below (Pet. 24).



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. 23 (citing Ex. 1007 ¶ 145; Ex. 1011, Figs. 2–3).

An annotated version of Yotsuyanagi's Figures 2 and 4 taken from the Petition is reproduced below (Pet. 30).



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. 29–30 (citing Ex. 1011, Figs. 2, 4; Ex. 1007 ¶ 160).

Claim 16 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. 31–32; Pet. Reply 17.

Because claim 16 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 16 are disclosed by the combination of Osman, Yotsuyanagi, and Gault.

d. Motivation to Combine References

As to the motivation to combine Osman, Yotsuyanagi, and Gault, Petitioner contends that one of ordinary skill in the art would have understood the advantages in protecting splints on an ear, such as Yotsuyanagi's device, using Osman's protective cover. Pet. 31–32 (citing Ex. 1007 ¶¶ 162–163). According to Petitioner, Gault's use of a protective cover and Yotsuyanagi's reference to the difficulty in patient compliance

further support the motivation to use Osman's cover in combination with Yotsuyanagi's device. *Id.* at 32–33 (citing Ex. 1007 ¶ 163; Ex. 1012, 6; Ex. 1015, 16). Petitioner also contends that one of ordinary skill in the art would have a reasonable expectation of success in making the proposed combination. *Id.* at 34–35 (citing Ex. 1005, 5; Ex. 1007 ¶ 167; Ex. 1015, 7, 10, 16).

Patent Owner argues that Yotsuyanagi and Gault disclose two very different systems, with Yotsuyanagi treating cryptotia and Gault treating cartilage deformation, and one of ordinary skill in the art would not combine the two to achieve the claimed ear molding device. PO Resp. 33 (citing Ex. 2021 ¶¶ 357–362; 2022 ¶¶ 358–363). Patent Owner also contends that one of ordinary skill in the art would not have been motivated to combine Osman's cradle with Yotsuyanagi and Gault, as evidenced by Yotsuyanagi's statement that its splint was in use for 18 years without applying a cradle from Osman. *Id.* (citing Ex. 1012, 5); *see also* PO Sur-reply 16.

Petitioner establishes sufficiently that one of ordinary skill in the art would have been motivated to combine Osman's protective cover with Yotsuyanagi's splint, and use Gault's teachings to understand further Yotsuyanagi's disclosure and the use of protective covers. Petitioner sets forth persuasive articulated reasoning for the combination, including the advantages in protecting ear splints such as Yotsuyanagi's with Osman's protective cover, and the likelihood of success in making the combination. Pet. 31–35; 1007 ¶¶ 162–163, 167; Ex. 1012, 6; Ex. 1015, 6; Pet. Reply 18. Patent Owner does not directly address Petitioner's arguments and evidence on these points. In addition, Patent Owner's argument that Yotsuyanagi and Gault were directed to different patient treatments does not undermine

Petitioner's point that the combination would have yielded advantages even if the references, considered separately, address different patient concerns. In addition, Patent Owner's argument that Yotsuyanagi undermines a combination with Osman because Yotsuyanagi did not see the need to apply Osman's cover for a long period of time also fails to directly address or undermine Petitioner's arguments in favor of the combination. Further, that one person in the field such as Yotsuyanagi, who may or may not have been aware of Osman, chose not to use Osman's cover does not suggest that one of ordinary skill in the art presumed to be aware of all pertinent art would not have found it obvious to employ Osman's cover with Yotsuyanagi's splint. *See Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.").

We find that Petitioner has proven by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, and Gault for the reasons provided by Petitioner.

e. 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. 35–53. 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 37–38. Patent Owner also contends that Petitioner used the EarWell device as a guide when designing Petitioner's competing "InfantEar" product. *Id.* at 39–42. 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 43–44. 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 41 (citing Ex. 2021 ¶¶ 381–412; Ex. 2022 ¶¶ 382–413); *see also id.* at 47–48 (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 46–47 (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 48–49 (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 50 (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 51–52.

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. 53 (citing Ex. 2004).

Petitioner argues that Patent Owner "makes no showing" that its EarWell device "practices the claims of the '277 patent, or that there is a nexus between any of its purported objective indicia 'evidence' and the claims of the '277 patent." Pet. Reply 21. As to copying, Petitioner argues that its InfantEar device differs from the EarWell device "in a number of ways." *Id.* at 23. 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.* 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 24. 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 22. 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 25–26.

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., 4). As to copying, Patent Owner 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. 41 (citing Ex. 2021 ¶¶ 381–412; Ex. 2022 ¶¶ 382–413); *see also id.* at 47–48 (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. 41, 48. 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., 4). 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 ¶¶ 69–72; Ex. 2022 ¶¶ 70–73. Patent Owner also

cites to its Patent Owner Response for support (at page 4), 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. 4. 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.[10]

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. 38 (citing Exs. 2008, 2009). Petitioner correctly notes that other, unclaimed, features of the devices differ, including the shape of the scaphal mold and use of gel in the product. *See* Pet. Reply 23–24. That evidence tends to show that the

[10] 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.").

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. 48–49. 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. 50–52 (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 25–26. 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. 53 (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.

5. Conclusion as to Claims 1, 10, and 16

"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 Osman, Yotsuyanagi, and Gault discloses all the limitations of claims 1 and 10, but not claim 16; (3) one of ordinary skill in the art would have been motivated to combine Osman, 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 claims 1 and 10 of the '277 patent are unpatentable over the combination of Osman, 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 claims 1 and 10 stronger than the objective indicia, and would still conclude that claims 1 and 10 are unpatentable as

obvious. A preponderance of the evidence does not persuade us that claim 16 of the '277 patent is unpatentable.

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

Petitioner challenges dependent claims 2 and 9 under 35 U.S.C. § 103 as unpatentable over Osman, Yotsuyanagi, Gault, and Voorhees. Pet. 35–40. For these challenges, Petitioner cites to the asserted references and the Hershcovitch Declaration. *Id.* We first address Voorhees, the only reference not already discussed above, and then discuss the parties' positions.

1. Voorhees

Voorhees discloses a protective ear enclosure with an opening for the ear. Ex. 1013, code (57). Voorhees discloses use of an adhesive material that surrounds the opening for the ear, enabling attachment of the ear enclosure to the skin surrounding the base of the ear. *Id.* at 1:12–15. The adhesive layer may include an adhesive on both sides, with one side adhered to a plastic surface on the enclosure and the other to the patient. *Id.* at 4:8–12.

2. Discussion

Petitioner asserts that the combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses all of the limitations of claims 2 and 9. Pet. 35–40. Petitioner provides analysis of each limitation in claims 2 and 9, 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).

Claim 2 depends from claim 1 and further requires "an adhesive backing" with various additional limitations. Ex. 1003, 10:50–56. Petitioner relies on Voorhees as disclosing the "adhesive backing" required by claim 2. Pet. 35–37 (citing Ex. 1007 ¶¶ 169–172; Ex. 1013, 3:67–4:12, Fig. 1). Petitioner also argues that one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, Gault, and Voorhees because securing the protective cover of Osman using the adhesive as shown in Voorhees would help ensure the cap remains in place to protect the splint during treatment. Pet. 39 (citing Ex. 1007 ¶ 178). Petitioner also argues that one of ordinary skill in the art would have had a reasonable expectation of success in applying double sided tape around Osman's opening to secure the device to the patient. *Id.* at 40 (citing Ex. 1007 ¶ 179). With the exception of arguments made in the context of claim 1 that we addressed above, Patent Owner does not argue that the combination of Osman, Yotsuyanagi, Gault, and Voorhees fails to disclose any of the limitations of claim 2 or that one of ordinary skill in the art would not have been motivated to combine the references. PO Resp. 34 (arguing that claim 2 is nonobvious due to its dependency from claim 1). Based on our review of the record, we are persuaded by Petitioner's arguments and evidence that the combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses the limitations of claim 2. Ex. 1007 ¶¶ 169–172; Ex. 1013, 3:67–4:12, Fig. 1. We are also persuaded that one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, Gault, and Voorhees for the reasons stated by Petitioner. Ex. 1007 ¶¶ 178–179.

Claim 9 depends from claim 2 and further requires "a kit containing one or more cradles, one or more ear molding devices, and one or more

adhesive backings." Ex. 1003, 11:13–15. Petitioner argues that those of ordinary skill in the art "recognize that it was common practice to package ear molding devices as kits for commercial sale" and "would therefore have understood that it would have been obvious to package the necessary parts for the ear splinting treatment as a kit." Pet. 38 (citing Ex. 1007 ¶¶ 174–175). Petitioner contends that packaging a splint with a protective cover as a kit "would have been common sense" here. *Id.* Petitioner also argues that Gault "teaches providing a kit including an ear molding device" and other components. *Id.* at 38–39 (citing Ex. 1015, 16).

Patent Owner argues that Petitioner's declarant fails to establish that the commercial product evidencing the "common practice" of providing kits was prior art. PO Resp. 34 (citing Ex. 1007 ¶¶ 174–175; Ex. 2034, 181:10–183:17). Patent Owner also argues that Gault makes no mention of a "kit." *Id.* at 35.

In its Reply, Petitioner argues that the '277 patent specification only mentions the "kit" once as containing one or more cradles, ear molding devices, and adhesive backings. Pet. Reply 19 (citing Ex. 1003, 3:45–46). Petitioner argues that such kits were commonplace in the art, as evidenced by Gault's EarBuddies product that was marketed as a kit for more than 25 years. *Id.* (citing Ex. 1007 ¶¶ 173–177); Ex. 1022. Petitioner also contends that Gault itself includes claims directed to combining the ear molding device with a protector means. *Id.* (citing Ex. 1015, 16).

In its Sur-reply, Patent Owner argues that Gault does not disclose providing items described in the '277 patent as part of a "kit." PO Sur-reply 13–14. Patent Owner also argues that Gault's commercial EarBuddies

product was not part of the grounds instituted, and therefore "Petitioner's reliance on it is improper." *Id.* at 14.

We are persuaded by Petitioner's argument and evidence as to claim 9. The combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses the one or more cradles (Osman), ear molding devices (Yotsuyanagi), and adhesive backings (Voorhees) required by claim 9. The remaining issue is whether it would have been obvious to provide these items in a kit. Petitioner's argument and evidence persuades us that it would have been obvious to provide such items in a kit for the reasons provided by Petitioner. *See* Pet. 37–39; Pet. Reply 19–20. For example, Petitioner's declarant explains that providing components for a medical procedure as part of a kid was common practice in the art. Ex. 1007 ¶¶ 173–177. These opinions are backed up by reference to Gault's commercial product marketed as a kit for over 25 years as well as Gault itself, which claims a combination of ear molding device and protector means. Ex. 1007 ¶ 174; Ex. 1022 (depicting EarBuddies kit); Ex. 1015, 16.

Patent Owner's arguments do not persuade us that Petitioner failed to meet its burden here. The fact that the EarBuddies website itself was not dated prior to the '277 patent or that it was not part of the invalidity ground does not require us to ignore it entirely, and we view the statement that the EarBuddies product was in use for over 25 years as generally supportive of the declarant testimony that use of such kits was common practice. *See* PO Resp. 34–35. Further, the fact that Gault itself does not use the term "kit" or describe all of the contents of the kit required by claim 9 does not render the reference irrelevant *See id.* at 35. Instead, the reference to a combination of ear molding device and protector means generally supports the declarant's

testimony that such combinations, when sold together, would constitute a kit.

Based on the foregoing, we find that Petitioner has proven by a preponderance of evidence the combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses all of the limitations of claims 9. As noted above, Petitioner provides a rationale for the combination of Osman, Yotsuyanagi, Gault, and Voorhees that Patent Owner does not address beyond the arguments addressed above in the context of claim 1. We find that Petitioner has proven by a preponderance of evidence that one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, Gault, and Voorhees.

3. Conclusion as to Claims 2 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 Osman, Yotsuyanagi, Gault, and Voorhees discloses all the limitations of claims 2 and 9; (3) one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, Gault, and Voorhees 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 2 and 9 of the '277 patent are unpatentable over the combination of Osman, Yotsuyanagi, Gault, and Voorhees. 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 claims 2 and 9 stronger than the objective indicia, and would still conclude that claims 2 and 9 are unpatentable as obvious.

F. Patent Owner's Contingent Motion to Amend

Pursuant to 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 42.121(a), Patent Owner moved to replace claims 1–17 of the '277 patent with proposed substitute claims 18–34, contingent on our determination that challenged claim 1 is unpatentable. PO MTA 1–2.[11] Patent Owner also requested preliminary guidance in accordance with the Pilot Program. *Id.* at 1. We issued our non-binding Preliminary Guidance, advising Patent Owner that, on the contingent motion to amend record, Patent Owner demonstrated a reasonable likelihood that it had satisfied the procedural requirements imposed by 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121(a) for its Motion. Paper 20 ("Prelim. Guidance") 3–6. We further advised Patent Owner that, on the contingent motion to amend record, Petitioner demonstrated a reasonable likelihood that proposed substitute claims were unpatentable as obvious. *Id.* at 7–9. As discussed above, we determine that original claims 1, 2, 9 and 10 of the '277 patent have been shown to be unpatentable by a preponderance of the evidence. Therefore, we proceed to address Patent Owner's Contingent Motion to Amend and proposed substitute claims 18, 19, 26, and 27, which correspond to original claims 1, 2, 9, and 10, respectively. For the reasons provided below, we determine that Petitioner has proven that the proposed substitute claims would have been obvious, and for that reason, we deny Patent Owner's Contingent Motion to Amend.

[11] Although Patent Owner numbers the pages of its Motion to Amend and its Reply "A1, A2, . . .," we will drop the "A" designation when referring to the pages of Patent Owner's Motion and Reply. We retain the "A" designation when referring to the List of Proposed Substitute Claims in Appendix A, which also contains pages numbered "A1, A2, ..."

1. Applicable Law

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). The Board must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential) ("*Lectrosonics*"). Subsequent to the issuance of *Aqua Products*, the Federal Circuit issued a decision in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017) ("*Bosch*"), as well as a follow-up Order amending that decision on rehearing. *See Bosch Auto. Serv. Sols., LLC v. Iancu*, No. 2015-1928 (Fed. Cir. Mar. 15, 2018) (Order on Petition for Panel Rehearing).

In accordance with *Aqua Products*, *Bosch*, and *Lectrosonics*, a patent owner does not bear the burden of persuasion to demonstrate the patentability of the substitute claims presented in the motion to amend. Rather, ordinarily, "the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the evidence." *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *see Lectrosonics*, Paper 15 at 3–4; 37 C.F.R. § 42.121(d)(2). In determining whether a petitioner has proven unpatentability of the substitute claims, the Board focuses on "arguments and theories raised by the petitioner in its petition or opposition to the motion to amend." *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020).

2. Proposed Substitute Claims

Patent Owner submitted substitute claims 18–34 in the Motion to Amend. Only proposed substitute claim 18 contains substantive amendments, with the amendments to the remaining claims only changing claim dependencies. *See* PO MTA A5–A9. Substitute claim 18 is reproduced below with proposed added limitations underlined (as compared to claim 1):

> 18. (Proposed Substitute for Claim 1) A molding system 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 system comprising:
>
> a cradle comprising:
>
> a base section defining an opening dimensioned to accommodate the passage of the ear through the opening, the base section including a posterior surface and an anterior surface;
>
> a cover releasably engageable with the base section, wherein the cover, when engaged with the base section, defines a compartment between an inner surface of the cover and an inner surface of the base section; and
>
> an ear 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 adapted to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and to maintain a substantially correct anatomical shape of the helix and the helical rim;
>
> <u>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</u>

helical rim conforms to the space between the scaphal mold and the one or more braces.

PO MTA A5–A6.

3. Procedural Requirements

"Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121." *See Lectrosonics*, Paper 15 at 4.

First, we consider whether the motion to amend proposes a reasonable number of substitute claims. 35 U.S.C. § 316(d)(1)(B) (2018). "There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim." *Lectrosonics*, Paper 15 at 4–5 (citing 37 C.F.R. § 42.121(a)(3)).

Patent Owner proposes 17 substitute claims (18–34) whereas the Petition challenges only five claims (claims 1, 2, 9, 10, and 16). Specifically, Patent Owner proposes to substitute claims 20–25, 28–32, and 34 for unchallenged original claims 3–8, 11–15, and 17, respectively. PO MTA A6–A9; Pet. 1. In its Opposition, Petitioner only addresses substitute claims that correspond to the challenged claims, because 35 U.S.C. § 316(d) provides for proposing substitute claims for each challenged claim. Pet. MTA Opp. 12. n.1. We agree with Petitioner that Section 316(d) does not permit Patent Owner to cancel or propose substitutes for non-challenged claims. 35 U.S.C. § 316(d)(1)(B) (motion to amend may "[f]or each challenged claim, propose a reasonable number of substitute claims"); Pet. Reply n.1 (agreeing to proceed only on substitute claims that correspond to challenged claims). We, therefore, do not consider proposed substitute

claims 20–25, 28–32, and 34 that correspond to unchallenged claims 3–8, 11–15, and 17, respectively. We also do not consider proposed substitute claim 33 because it corresponds to original claim 16, and we conclude that Petitioner has not shown that claim 16 is unpatentable. *See* PO MTA A8. Accordingly, we limit our consideration to proposed substitute claims 18, 19, 26, and 27.

Because Patent Owner's Motion (as limited above) proposes a single substitute claim for each challenged claim, we determine that Patent Owner has proposed a reasonable number of substitute claims. *See* Prelim. Guidance 3–4 (taking same approach in preliminary guidance in finding that Patent Owner proposes a reasonable number of substitute claims).

Second, we consider whether the proposed substitute claims respond to a ground of unpatentability involved in this trial. *Lectrosonics*, Paper 15 at 5–6. In the Motion, Patent Owner argues that the proposed substitute claims responded to each of the trial grounds set forth in our Institution Decision. PO MTA 13–14. Patent Owner's Motion also contains arguments and evidence addressing the grounds of unpatentability. *Id.* at 15–21. Petitioner does not argue that Patent Owner's Motion fails to respond to a ground of unpatentability. We agree with Patent Owner that the proposed substitute claims respond to a ground of unpatentability involved in this trial.

Third, we consider the breadth of the substitute claims. "A motion to amend may not present substitute claims that enlarge the scope of the claims of the challenged patent or introduce new subject matter." *Lectrosonics*, Paper 15 at 6–8 (citing 35 U.S.C. § 316(d)(3); 37 C.F.R. § 41.121(a)(2)(ii)). As to the requirement that the amendments may not enlarge the scope of the original claims, Patent Owner argues that its proposed substitute claim 18

includes narrowing limitations. PO MTA 4–5, A5–A6. Petitioner argues that the proposed amendment does not add a structural limitation because the new wherein clause merely intended use, and that the "proposed substitute claims are improper for failing to narrow the original apparatus claims." Pet. MTA Opp. 4, 7. Even if true, "failing to narrow the original claims" does not suggest that the amendments "enlarge" the scope of the claims and that Patent Owner fails to comply with § 316(d)(3). In addition, as we discuss further below in the obviousness analysis, the added limitation includes functional language requiring certain functionality of the claimed structure. PO MTA A6. We determine that the language added by the proposed amendment narrows the claim and does not enlarge the scope of the claim.

As to the requirement that the amendments not introduce "new matter," Patent Owner provides citations to the application from which the '277 patent issued to demonstrate written description support for each limitation in the proposed substitute claims. PO MTA 5–13. Petitioner does not argue that Patent Owner's Motion fails to meet the "no new matter" requirement, but Petitioner does argue that the proposed claims lack written description support. *See* Pet. MTA Opp. 10–11. A portion of the language Patent Owner seeks to add to proposed substitute claim 18 recites "the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces." PO MTA A6. Petitioner argues that "the original disclosure never describes how much space is necessary such that growth of the helix and helical rim conforms to the recited 'space.'" Pet. MTA Opp. 10. In its Motion, Patent Owner contends that this proposed amendment is supported by Figures 2, 3, and 7 and the original

disclosure, which states that "the inner curvature of the scaphal mold 55 facing the legs 51 and 52 cooperates with inner surface of legs 51 and 52 to form a space therewith 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." PO MTA 7–8. We agree with Patent Owner that the original disclosure supports the proposed amendment because the pertinent language in the proposed amendment tracks the language in the original disclosure. Although the proposed amendment requires "the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces," the proposed amendment does not recite a particular amount of space between the mold and one or more braces. Accordingly, the original disclosure need not disclose a particular amount or size of "space" in order to adequately describe the limitation. We determine that the proposed substitute claims do not introduce new subject matter.

Finally, the Contingent Motion includes a claim listing, as required by 37 C.F.R. § 42.121(b). PO MTA A1–A9; *see Lectrosonics*, Paper 15 at 8.

In view of the above, we determine Patent Owner's Contingent Motion meets the statutory and regulatory requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

4. Claim Construction

For the proposed substitute claims, Patent Owner states that in its Patent Owner Response, Patent Owner "requests that the Board construe the terms 'molding device,' and 'mold' in scaphal mold." PO MTA 15. Although Patent Owner does not formally seek those same claim constructions as part of its Motion to Amend, even if it did so, for the

reasons provided above in our claim construction section addressing the original claims, we decline to adopt Patent Owner's proposed constructions for those terms. Instead, we apply the same claim constructions discussed above to Patent Owner's Contingent Motion to Amend.

Patent Owner also argues that we should construe the language added by amendment to proposed substitute claim 18 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 MTA 15 (citing Ex. 1003, 6:49–55, 7:48–52). Patent Owner provides no argument, analysis or support for this proposed construction, other than a citation to the '277 patent specification. Petitioner argues that (1) Patent Owner failed to support the proposed construction; (2) the construction amounts to mere intended use and fails to limit the structure of the claim; and (3) we should apply the plain and ordinary meaning to the limitations added by the proposed amendment. Pet. MTA Opp. 3. We agree with Petitioner that 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 of the language added by amendment.

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 amounts to mere intended use that fail to limit the claims in any way. *See* Pet. MTA Opp. 3–7. Petitioner argues that the proposed amendment does not limit the claims because "the added language is directed to the *intended use/result* of the scaphal mold and one or more braces of the claimed

molding system, not a further structural distinction thereof" and that "by only claiming the intended use/result of the ear molding device, PO has also failed to distinguish the art of record." *Id.* at 4, 7. The proposed amendment 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. PO MTA A6. These limitations do not describe a mere "intended use" that fails to limit scope of the claim at all as Petitioner argues, because the added limitations require specific structure "constructed to" perform certain functions. These limitations may be functional and broad, but do not fail to further 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.

5. Challenges to Patentability Based on Obviousness

Petitioner argues that the proposed substitute claims are unpatentable as obvious based on the same combinations of references set forth in the Petition for the corresponding original claims. Pet. MTA Opp. 12. The chart below summarizes the challenges to the proposed substitute claims.

Proposed Substitute Claims Challenged	35 U.S.C. §	Reference(s)/Basis
18, 27	103	Osman, Yotsuyanagi, Gault
19, 26	103	Osman, Yotsuyanagi, Gault, Voorhees

Because we have determined already that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 2, 9, and 10 of the '277 patent are unpatentable, we rely on our analysis from above with respect to the limitations in the original claims and we focus our analysis on the new limitations in the proposed substitute claims.

6. Obviousness of Proposed Substitute Claims 18 and 27 Based on Osman, Yotsuyanagi, and Gault

a. The Parties' Positions

The parties dispute whether Yotsuyanagi discloses the limitations added to proposed substitute claim 18 by Patent Owner's proposed amendment. Because proposed substitute claim 27 (corresponding to original claim 10) does not contain any substantive amendments, the parties do not address it separately in their briefing. Patent Owner argues that "[n]one of the prior art of record or otherwise known to [Patent Owner] teach or suggest the additional feature of the substitute claims and, thus it is not rendered obvious by the prior art." PO MTA 15–16. Patent Owner argues that Yotsuyanagi fails to disclose the added limitations for several reasons. *Id.* at 17–18. For example, Patent Owner argues that Yotsuyanagi's three cases showed "no molding of the helix or helical rim whatsoever," and the children treated in two of the cases were six years old, "so that the ears are hardened and there is no further 'growth' as there would be in a newborn." *Id.* Patent Owner also argues that Yotsuyanagi fails to disclose "molding during the growth of the helix or helical rim" or "conforming the helix or helical rim to the space that would allow them to

mold and grow." *Id.* at 18.[12] Patent Owner does not argue that any other limitations are not disclosed by the proposed combination, or that one of ordinary skill in the art would not have been motivated to combine the references. *See id.* at 16–19.

Petitioner responds that Yotsuyanagi discloses the language added by the proposed amendment. Pet. MTA Opp. 16–17. Petitioner argues that the "Yotsuyanagi splint is constructed to retain the helix and helical rim within a space defined between the scaphal mold portion and the brace portion of the splint" and "maintain the helix and helical rim in a substantially correct anatomical shape throughout the treatment." *Id.* at 16–17 (citing Ex. 1007 ¶¶ 107–119; Ex. 1011, Figs. 2–13; Ex. 1012, 2–6; Ex. 1028, 63:22–64:2). Petitioner also relies on Yotsuyanagi's statement that "[t]he correction of the helix or anti-helix is performed to be sure." *Id.* at 17 (quoting Ex. 1012, 3). According to Petitioner, "[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 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)." *Id.* (citing Ex. 1007 ¶¶ 66–67; Ex. 1012, 4 (Table 1)).

In its Reply, Patent Owner argues that none of the three treatments Yotsuyanagi discloses employs splints "constructed to mold the helix or helical rim" as required by the proposed substitute claims. PO MTA

[12] Patent Owner also alleges, as it did with respect to claim 1, that Yotsuyanagi fails to disclose a "scaphal mold." PO MTA 18. Because Patent Owner bases this argument on a claim construction that we do not adopt, we find the argument equally unavailing in the context of Patent Owner's Motion to Amend.

Reply 6. Patent Owner contends that Yotsuyanagi's first case treated an infant with cryptotia, but that "the shape of the helix remain[ed]" the same. *Id.* at 6 (quoting Ex. 1011, Figs. 1–7; Ex. 1012, 4–5 (emphasis omitted); Ex. 2021 ¶¶ 116–123; Ex. 2022 ¶¶ 117–124). As to Yotsuyanagi's second case, Patent Owner argues that the patient's ear had a "slight" "deformation of the auricle cartilage" prior to treatment, but that after treatment "this 'deformation' remained unchanged." *Id.* at 6–7 (citing Ex. 1011, Figs. 8–10; Ex. 1012, 5; Ex. 2021 ¶¶ 124–128; Ex. 2022 ¶¶ 125–129). As to Yotsuyanagi's third case, Patent Owner argues that the splint "caused the antihelix to be 'very deformed,' 'crushed throughout,' and 'crooked.'" *Id.* at 7 (citing Ex. 1011, Figs. 11–12; Ex. 1012, 5–6; Ex. 2021 ¶¶ 124–128; Ex. 2022 ¶¶ 125–129). Patent Owner also contends that Dr. Hershcovitch failed to address critical aspects of each of these cases. *See id.* at 6–7. Patent Owner also argues that both Dr. Hershcovitch and Yotsuyanagi acknowledge the difference between merely repositioning an ear away from the head and "molding or reshaping the helix or helical rim." *Id.* at 7–8 (citing Ex. 1007 ¶¶ 113, 117; Ex. 1012, 5). As to Yotsuyanagi's statement that "[t]he correction of the helix or anti-helix is performed to be sure," Patent Owner argues that Petitioner failed to properly quote the passage in the Petition and that deposition testimony of Patent Owner's declarants confirms that the passage indicates that the position of the helix or antihelix is corrected, not its shape. *Id.* at 8–10 (citing Pet. 26; Pet. MTA Opp. 16; Ex. 1007 ¶¶ 149–151; Ex. 1027, 220:21, 221:16–19; Ex. 1028, 88:12–16, 89:1–5; Ex. 2021 ¶ 114; Ex. 2022 ¶ 115).

In its Sur-reply, Petitioner argues that Patent Owner's argument that treating children older than newborns would not work lacks adequate

support. Pet. MTA Sur-reply 3. Petitioner also contends that Yotsuyanagi as well as a later Yotsuyanagi article confirms that deformities in children up to nine years old can be treated "even if the patient is not young." *Id.* at 3–4 (citing Ex. 1012, 2; Ex. 2017, 1). Petitioner also argues that in each of Yotsuyanagi's three cases, "the 'shape' of the helix or anti-helix is corrected." *Id.* at 4. As to the first case, Petitioner argues that Patent Owner improperly quotes the results mid-treatment that suggests the shape remained the same, but fails to acknowledge that the splint was adjusted and successful results were achieved after three additional weeks of treatment. *Id.* at 4–5 (citing Ex. 1011, Figs. 1, 5–7; Ex. 1012, 4–5). As to the second and third cases, according to Petitioner the final results of the treatment were described as "good" (case 2) or "favorable" (case 3) when assessing the shape of the ear. *Id.* at 5–6 (citing Ex. 1012, 5–6). As to the improper quotation of Yotsuyanagi, Petitioner acknowledges the error and explains that it was based on an uncertified translation. *Id.* at 6–7.

b. Discussion

We first address the scope of the proposed amendment because it bears on Patent Owner's arguments. As noted above, we decline to adopt Patent Owner's proposed construction because Patent Owner provides no substantive analysis or argument in support of its position. *See* PO MTA 15. Patent Owner's proposed construction does away with the claim language reciting a "scaphal mold and one or more braces are *constructed to* mold the helix and helical rim during their growth . . ." and replaces it with "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*." *Id.* (emphasis altered) (citation omitted). Patent Owner appears to apply that

construction in its analysis of Yotsuyanagi, and suggests that Yotsuyanagi must show that it actually reshaped a malformed helix and helical rim into a correct anatomical shape in order to disclose the "constructed to mold" limitation. *See* PO MTA Reply 6 (arguing that Yotsuyanagi's first case did not disclose the "constructed to mold" requirement because the shape of the helix did not change), 7 (referring to failure to "reshape the helix or helical rim" in context of second case and failure "to mold the helix or helical rim to a correct anatomical shape" in context of third case) (citing Ex. 2021 ¶¶ 124–125, 127; Ex. 2022 ¶¶ 125–126, 128).[13] Accordingly, when assessing whether Petitioner met its burden to show unpatentability, we view Petitioner's assertion that Yotsuyanagi discloses the limitations in the proposed amendment as unrebutted when using the district court's construction and the plain and ordinary meaning of those terms, without adopting any aspects of Patent Owner's proposed construction.

In our analysis below, we do not view the claims as requiring a space that "reshapes" the helix and helical rim into the correct anatomical shape. Proposed substitute claim 18 claims a "molding system" without any affirmative steps that must be performed, and instead requires a structure "constructed to" perform certain functions, which can be established by examining the structure of the prior art without showing reshaping of a malformed helix into an anatomically correct shape. Nevertheless, because

[13] Patent Owner's counsel seemed to confirm this approach at oral argument in the context of claim 1. 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").

we determine that Petitioner has shown that Yotsuyanagi discloses such reshaping, we would arrive at the same result even if we applied Patent Owner's construction throughout our analysis.

Turning to the disputes as to Yotsuyanagi, we first note that, in the context of claim 1, we already found that Yotsuyanagi discloses a scaphal mold and brace "adapted to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and to maintain a substantially correct anatomical shape of the helix and the helical rim." The remaining issue is whether those structures "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." PO MTA A6. We are persuaded by Petitioner's argument and evidence and find that Yotsuyanagi discloses the limitations added by the proposed amendment to substitute claim 18. *See* Pet. MTA Opp. 16–17; Pet. MTA Sur-reply 2–8.

First, Petitioner establishes sufficiently that Yotsuyanagi seeks to mold the helix and helical rim during their growth by changing the shape of the ear rather than merely repositioning the ear to treat cryptotia as Patent Owner alleges. *See* Pet. MTA Opp. 17; Pet. MTA Sur-reply 4–8. Yotsuyanagi itself directly supports this position by stating that its treatment involves multiple "steps" to "get closer to a *normal shape* over time. The correction of the helix and anti-helix is performed to be sure." Ex. 1012, 3 (emphasis added). Yotsuyanagi then states that the steps can be easily repeated. *Id.* These references to taking multiple steps toward a normal shape, and references to correcting the helix, support Petitioner's position that Yotsuyanagi's devices is constructed to improve the shape of the helix,

not merely its position. *See* Pet. MTA Sur-reply 7–8.[14] In addition, Yotsuyanagi discusses treating the shape of the helix when discussing the three patient cases. Ex. 1012, 5 (referring to treatment of "shape of the helix" in case 1 and addressing the "crooked deformity of the helix" in case 3). In light of these references to treating the shape of the helix, some of which Patent Owner does not directly address in its briefs, we find Petitioner's arguments and evidence more credible than Patent Owner's arguments and evidence suggesting that Yotsuyanagi is devoted *solely* to repositioning the ear. *See* Pet. MTA Opp. 17; Pet. MTA Sur-reply 2–8; PO MTA 17–18; PO MTA Reply 6–7, 9–10; Ex. 1007 ¶¶ 107–119, 149–151.

Second, Petitioner establishes that Yotsuyanagi discloses successfully treating patients by altering and improving the shape of the helix, further supporting Petitioner's position that Yotsuyanagi's devices were constructed to mold the helix and helical rim during growth and that the helix and helical rim conforms to the space between the scaphal mold and brace. Pet. MTA Sur-reply 4–7. As to the first case, Yotsuyanagi states that after just one week of treatment, the "auricle is further pulled out of the cranial side, but the shape of the helix remains," and the misshapen helix can be seen in the accompanying Figure 5. Ex. 1011, Fig. 5; Ex. 1012, 5. The splint was then "fine-tuned" and after three weeks of treatment "the same appearance as

[14] Patent Owner argues at one point that "Yotsuyanagi itself distinguishes successfully repositioning the ear away from the head" from "molding or shaping the helix or helical rim." PO MTA Reply 8 (citing Ex. 1012, 5). That argument supports Petitioner's position, as references to changing "shape" in Yotsuyanagi suggest that the shape of the ear, including the helix, changes, rather than its position. *See, e.g.*, Ex. 1012, 3 (discussing taking steps to "get closer to a normal shape over time" in the context of "correction of the helix").

opposite side ear was achieved," with the change in shape of the helix shown in the accompanying Figure 7. Ex. 1011, Fig. 7; Ex. 1012, 5. Patent Owner attempts to capitalize on the mid-treatment statement that "the shape of the helix remains" the same, but ignores that there were problems with the "shape of the helix" after one week that were then resolved after three weeks of treatment. *See* PO MTA 17–18; PO MTA Reply 6 Ex. 1011, Figs. 5, 7; Ex. 1012, 5.

Yotsuyanagi's successful results with its first case alone support Petitioner's positions, but the second and third cases also show successful results noted in the text and figures of Yotsuyanagi. *See* Ex. 1011 Figs. 8–10 (second case), Figs. 11–13 (third case); Ex. 1012, 5–6 (describing deformation as "slight" in second case but "shape is good" after two weeks of treatment; describing third case as "achiev[ing] favorable shape 5 weeks after beginning treatment (image 13)"). Patent Owner argues that the second and third cases involved six-year-olds having "hardened" ears with "no further 'growth' as there would be in a newborn," but those statements lack support and ignore the positive results noted in the text and figures of Yotsuyanagi and Yotsuyanagi's statement that "results are positive among older children" as old as six. *See* PO MTA 18 (citing Ex. 2020 ¶¶ 281–285; Ex. 2021 ¶¶ 282–286; Ex. 1012, 2, 4 (Table 1); *see also* Ex. 2017, 1–2, Tables I–II (1998 Yotsuyanagi article) (stating that deformities in children up to nine-years-old may be corrected). To the extent Patent Owner suggests that six-year-olds have harder ears and less growth when compared to newborns, that fact does not suggest that six-year-old patients have ears with deformities that cannot be treated at all or that no growth occurs after several weeks of treatment. *See* Pet. MTA Sur-reply 2–4; Ex. 1012, 4

(Table I) (showing successful treatment spanned several weeks); Ex. 1007 ¶ 118. The proposed amendment does not require a particular amount of molding or growth and Patent Owner does not argue for any claim construction that would require any specific amount of molding or growth; any amount will satisfy the claim language. Given the breadth of the claim, we agree with Petitioner's statement that "[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 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. MTA Opp. 17 (citing Ex. 1007 ¶¶ 66–67; Ex. 1012, 4 (Table 1)).

Patent Owner's argument that Petitioner improperly quotes a sentence from Yotsuyanagi in the Petition, while true, does not suggest that Yotsuyanagi fails to disclose the limitations in the proposed amendment. *See* PO MTA Reply 8–10 (stating that "[t]he correction of the helix or anti-helix is performed to be sure" does not appear in the Petition or Dr. Hershcovitch's report, but does appear in the certified translation). Petitioner acknowledges that the incorrect quote came from an uncertified translation of Yotsuyanagi, but Petitioner relies solely on the certified translation (Ex. 1012), which was of record throughout this proceeding. Tr. 15:4–6 ("To be clear, Petitioner is only relying on Exhibit 1011 and the certified translation in Exhibit 1012 in these proceedings.").

Based on the foregoing, Petitioner has proven by a preponderance of the evidence that Osman, Yotsuyanagi, and Gault disclose all of the limitations of proposed substitute claims 18 and 27. Petitioner also argues that one of ordinary skill in the art would have been motivated to combine

Osman, Yotsuyanagi, and Gault, relying on many of the same rationales as Petitioner advanced with respect to claim 1. *See* Pet. MTA Opp. 19–20. Patent Owner does not address Petitioner's arguments, or argue in the context of proposed substitute claim 18 that one of ordinary skill in the art would not have been motivated to combine the references. *See* PO MTA 16–19. We find that Petitioner has proven by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, and Gault, for the reasons provided by Petitioner. *See* Pet. MTA Opp. 19–20.

c. Objective Indicia of Nonobviousness

Patent Owner argues that "[t]here is a substantial amount of secondary indicia evidence showing that the Substitute Claims are nonobvious as described in" Patent Owner's Response addressing the original claims. PO MTA 20–21. Petitioner argues that Patent Owner improperly incorporates by reference its entire analysis from the Patent Owner Response. Pet. MTA Opp. 25. In its Reply, Patent Owner argues that it is entitled to a presumption of nexus. PO MTA Reply 2 (citing Ex. 2021 ¶¶ 63–72, 380–412; Ex. 2022 ¶¶ 64–73, 381–413; Ex. 2030). Patent Owner also argues, as it did in its Patent Owner Response, that evidence of copying, long-felt need, industry praise, and licensing all establish nonobviousness of the proposed substitute claims. *Id.* at 2–5. In its Sur-reply, Petitioner argues that Patent Owner's one sentence assertion that it is entitled to presumption of nexus "is conclusory, not supported by a cogent explanation, and insufficient to meet PO's burden." PO MTA Sur-reply 8–9. As to the remaining objective indicia issues, Petitioner raises arguments against Patent Owner's assertions that largely mirror its arguments in Petitioner's Reply.

See id. at 8–12.

Because the parties raise the same substantive arguments as they did with respect to the original claims, we come to the same conclusions as we did in the analysis above in the context of the original claims. First, Patent Owner fails to establish a presumption of a nexus because it fails to (1) develop any argument or evidence in support of its assertion in its briefing; (2) address whether the proposed substitute claims are coextensive with the EarWell device; and (3) provide sufficient analysis to establish that any of the proposed substitute claims cover the EarWell device. *See* PO MTA Reply 2 (citing Ex. 2021 ¶¶ 63–72, 380–412; Ex. 2022 ¶¶ 64–73, 381–413; Ex. 2030). For example, the most pertinent cited support for Patent Owner's presumption argument does not contain a claim-by-claim or limitation-by-limitation analysis of the proposed substitute claims, and merely summarily concludes that certain limitations are present while providing unlabeled photographs of the EarWell device and patient photographs. *See* Ex. 2021 ¶¶ 69–72; Ex. 2022 ¶¶ 70–73. Second, assuming a nexus was shown, Patent Owner presents relatively strong evidence of both copying and industry praise. *See* PO MTA Reply 2–5. Patent Owner's evidence of long-felt need and licensing are both weak. *See id.* at 3–5.

d. Conclusion as to Proposed Substitute Claims 18 and 27

We find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the art of record;[15] (2) the combination of Osman,

[15] We apply the same level of ordinary skill in the art as we applied above in the context of the challenges to the original claims.

Yotsuyanagi, and Gault discloses all the limitations of proposed substitute claims 18 and 27; (3) one of ordinary skill in the art would have been motivated to combine Osman, 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 proposed substitute claims 18 and 27 of the '277 patent are unpatentable over the combination of Osman, Yotsuyanagi, 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 proposed substitute claims 18 and 27 stronger than the objective indicia, and would still conclude that proposed substitute claims 18 and 27 are unpatentable as obvious.

7. Obviousness of Proposed Substitute Claims 19 and 26 Based on Osman, Yotsuyanagi, Gault, and Voorhees

Patent Owner argues that proposed substitute claims 19 and 26 (replacing original claims 2 and 9, respectively) are not obvious over Osman, Yotsuyanagi, Gault, and Voorhees because none of those references disclose the additional limitations found in the proposed amendment to proposed substitute claim 18. PO MTA 19–20. Both claims ultimately depend from proposed substitute claim 18. *Id.* at A6–A7. Petitioner argues that the combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses all of the limitations of proposed substitute claims 19 and 26, and that one of ordinary skill in the art would have been motivated to combine the references for a number of reasons. Pet. MTA Opp. 21–25. Patent Owner does not address or dispute these assertions in its Reply. *See* PO MTA

Reply 1 n.2. Based on our review of the record, we find that Petitioner establishes by a preponderance of the evidence that the combination of Osman, Yotsuyanagi, Gault, and Voorhees discloses all of the limitations of proposed substitute claims 19 and 26, and that one of ordinary skill in the art would have been motivated to combine the references for the reasons provided by Petitioner. Pet. MTA Opp. 21–25

In summary, 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 Osman, Yotsuyanagi, Gault, and Voorhees discloses all of the limitations of proposed substitute claims 19 and 26; (3) one of ordinary skill in the art would have been motivated to combine Osman, Yotsuyanagi, Gault, and Voorhees 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 proposed substitute claims 19 and 26 of the '277 patent are unpatentable over the combination of Osman, Yotsuyanagi, Gault, and Voorhees. 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 proposed substitute claims 18 and 27 stronger than the objective indicia, and would still conclude that proposed substitute claims 19 and 26 are unpatentable as obvious.

8. Challenges to Patentability Based on 35 U.S.C. § 112

Petitioner argues that proposed substitute claims are unpatentable under 35 U.S.C. §112 due to indefiniteness, lack of written description

support, and lack of enablement. Pet. MTA Opp. 7–12. Patent Owner disagrees. PO MTA Reply 12.

Because we have already determined that all of the proposed substitute claims are unpatentable based on Petitioner's obviousness challenges, we need not determine whether they are also unpatentable due to their alleged failure to meet the requirements of § 112.[16]

G. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Exhibit 1030 and any reference to, or reliance upon, this exhibit. Paper 30, 1. Exhibit 1030 is an uncertified translation of Yotsuyanagi that Petitioner filed in an effort to explain why it had included an incorrect quote of Yotsuyanagi in the Petition. *Id.* at 2–3. Petitioner opposes the Motion, but acknowledges that it is only relying on the certified translation of Yotsuyanagi (Exhibit 1012) in these proceedings. Paper 33; Tr. 15:4–6.

We do not rely on Exhibit 1030 in any way in our Decision, or on any substantive assessment of Exhibit 1030 by either of the parties. We, therefore, dismiss Patent Owner's Motion to Exclude as moot.

CONCLUSION[17]

A summary of our conclusions appears in the chart below:

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[16] The potential indefiniteness concerns raised by Petitioner are not of the type that prevents us from applying the prior art to the claims. *See* Pet. MTA Opp. 7–10. Petitioner bases its argument on the alleged failure of the claims to identify how much "growth" or "space" is necessary to satisfy the language added by amendment. *Id.* at 8. As noted above in our obviousness analysis, any growth or space satisfies these claim requirements.

[17] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 10, 16	103	Osman, Yotsuyanagi, Gault	1, 10	16
2, 9	103	Osman, Yotsuyanagi, Gault, Voorhees	2, 9	
Overall Outcome			1, 2, 9, 10	16

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	18–34
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	18, 19, 26, 27
Substitute Claims: Not Reached	20–25, 28–34

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).

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 2, 9, 10 of U.S. Patent 8,852,277 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that claim 16 of U.S. Patent 8,852,277 B2 has not been shown, by a preponderance of the evidence, to be unpatentable;

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

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*; 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.

For PETITIONER:

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

For PATENT OWNER:

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