

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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TALEXMEDICAL, LLC,  
Petitioner,

v.

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

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IPR2020-00030  
Patent 8,852,277 B2

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

MARSCHALL, *Administrative Patent Judge*.

Granting Institution of *Inter Partes* Review  
35 U.S.C. § 314(a)

## I. 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 (“Prelim. Resp.”). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. As such, we institute an *inter partes* review of all challenged claims on all presented challenges, and thus, institute an *inter partes* review of claims 1, 2, 9, 10, and 16 of the ’277 patent.

## II. BACKGROUND

### A. *Related Proceedings*

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). The '277 patent describes the structures of the ear that the molding device interacts with, including helix 10 having helical rim 11 on the outside of the ear, and scaphoid fossa or scapha 12 just inward from helical rim 11. *Id.* at 4:11–16, Fig. 1.

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

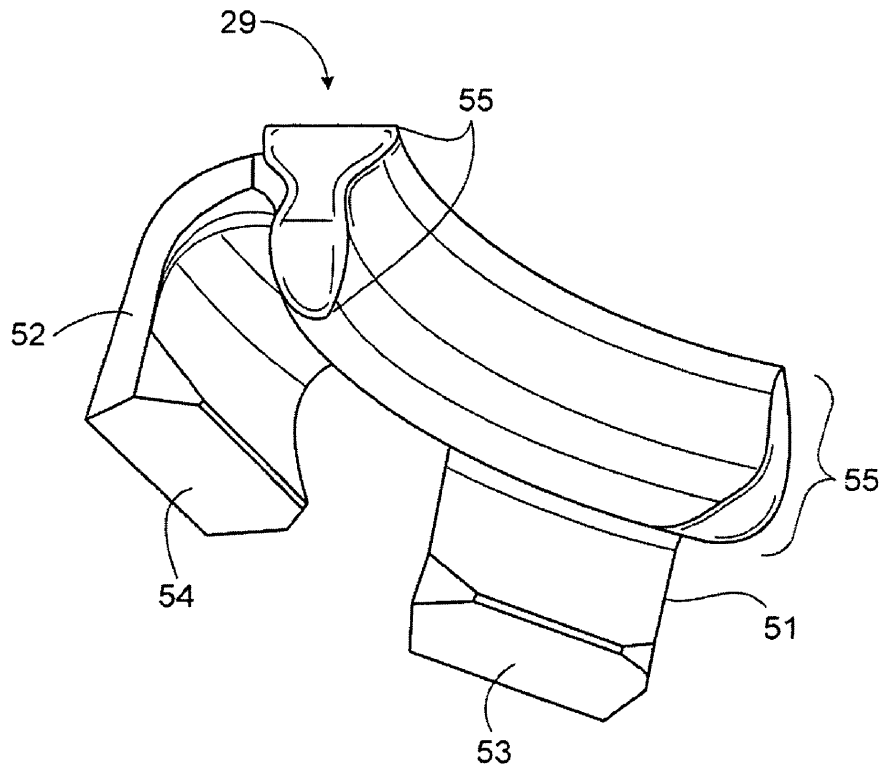


Figure 5 “is a slightly inferior and lateral view” of ear molding device 29. Ex. 1003, 3:62–63. Ear molding device 29 includes “scaphal mold 55

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 threewith configured to mold the helix and helical rim during their growth while in the ear molding device, such that the growth of the helix and helical rim conforms to a curvature defined by the space between the scaphal mold and the legs.” *Id.* at 6:49–55.

The ’277 patent also discloses cradle 20 that includes cradle base 21 and cradle cover 22. Ex. 1003, 4:42–43. 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. Illustrative Claim*

Petitioner challenges claims 1, 2, 9, 10, and 16. Pet. 1. Of those claims, claim 1 is independent and is reproduced below. Ex. 1003, 10:28–49.

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.

*Id.*

#### *D. Asserted Grounds*

Petitioner challenges claims 1, 2, 9, 10, and 16 on two grounds. Petitioner challenges (1) claims 1, 10, and 16 under 35 U.S.C. § 103(a) as unpatentable over Osman,<sup>1</sup> Yotsuyanagi,<sup>2</sup> and Gault;<sup>3</sup> and (2) claims 2 and 9 under 35 U.S.C. § 103 as unpatentable over Osman, Yotsuyanagi, Gault, and Voorhees.<sup>4</sup> Pet. 6. Petitioner also relies on the Declaration of Dr. Meir D. Hershcovitch. Ex. 1007 (“Hershcovitch Declaration”).

### III. ANALYSIS

#### *A. Denial under 35 U.S.C. § 325(d)*

Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution because the Examiner already considered the substance of the three references at issue here during prosecution. Prelim. Resp. 25–28.

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<sup>1</sup> WO 81/02515, published September 17, 1981 (Ex. 1006) (“Osman”).

<sup>2</sup> 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.

<sup>3</sup> GB 2304579 A, published March 26, 1997 (Ex. 1015) (“Gault”).

<sup>4</sup> US 5,749,099, issued May 12, 1998 (Ex. 1013) (“Voorhees”).

*1. Legal Background*

Section 325(d) provides that, in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office;
- and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

*Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential).

In applying the two-part framework, we consider several non-exclusive factors, including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Becton*,

*Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph). If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 10.

For the reasons set forth below, under the facts presented and arguments made, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny instituting trial.

## 2. *The Prosecution History and the Parties’ Positions*

There was no substantive prosecution of the application that led to the issuance of the ’277 patent. On June 6, 2014, the Office issued a first-action Notice of Allowance. Ex. 1004 at 62–68. The Examiner provided reasons for allowing the claims that generally tracked the language of claim 1. *See id.* at 67. None of the four references at issue here—Osman, Yotsuyanagi, Gault, and Voorhees—were before the Patent Office during prosecution of the ’277 patent.

Patent Owner argues that the Examiner already considered the substance of Yotsuyanagi and Gault during prosecution. Prelim. Resp. 26–27 (addressing *Becton, Dickinson* factors). Patent Owner argues that several *Becton, Dickinson* factors favor denial of institution, including the fact that “Yotsuyanagi is cumulative over the prior art considered by the Patent Office” during prosecution and “Petitioner concedes that Gault is cumulative.” *Id.* at 26. As to Yotsuyanagi, Patent Owner contends that a

later 2004 Yotsuyanagi<sup>5</sup> reference considered during prosecution renders Yotsuyanagi cumulative. *Id.* at 26–27. As to Gault, Patent Owner argues that it discloses a device known as “EarBuddies,” and that several “EarBuddies” references were considered during prosecution. *Id.* at 14. Patent Owner also argues that there are no “errors that warrant reconsidering” the allegedly cumulative prior art. *Id.* at 28.

Petitioner argues that “none of the *Becton Dickinson* factors weigh in favor of denying institution.” Pet. 41. As to Yotsuyanagi, Petitioner argues that it differs from, and is not cumulative of, the 2004 Yotsuyanagi reference that appeared in an Information Disclosure Statement during prosecution because the 2004 Yotsuyanagi reference did not contain any pictures showing how its splint was applied to a patient. *Id.* Petitioner argues that Osman and Voorhees were not considered during prosecution, and does not address the Gault reference. *Id.*

### 3. Discussion

We first consider “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.” *Advanced Bionics*, Paper 6 at 8. Patent Owner’s arguments explicitly or implicitly concede three key points. First, none of the references Petitioner relies on in the Petition were considered by the Examiner during prosecution. Second, none of the references Petitioner relies on in the Petition are cumulative of any reference applied by the Examiner during prosecution, because the

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<sup>5</sup> Yotsuyanagi, *Nonsurgical Correction of Congenital Auricular Deformities in Children Older than Early Neonates*, *Congenital Auricular Deformities*, Vol. 114, No. 1, 190–91 (2004) (Ex. 2017) (“2004 Yotsuyanagi”).



Examiner did not issue any rejections of the claims or discuss any specific prior art. Third, Patent Owner does not assert that the *arguments* presented in the Petition are substantially the same as the arguments considered during prosecution, because there were no substantive arguments made during prosecution of the '277 patent. With that background in hand, we consider whether the references Petitioner relies on in the Petition are substantially the same as those before the Examiner, but never applied or discussed by the Examiner during prosecution.

As to Yotsuyanagi, Patent Owner relies on text from the 2004 Yotsuyanagi reference that describes thermoplastic splints that “sandwich the ear from both sides, along a broad area.” Prelim. Resp. 27 (quoting Ex. 2017, 1). We do not agree with Patent Owner’s argument that this phrase renders Yotsuyanagi cumulative. Yotsuyanagi includes 13 photographs that show the device and the results it obtains, while the 2004 Yotsuyanagi reference contains no photographs or figures. Ex. 1011, 2–4; Ex. 2017, 1–2. Yotsuyanagi also describes, in more detail than the 2004 Yotsuyanagi reference, how the device fits in a patient’s ear. *See* Ex. 1012, 2 (referring to a “splint that matches the complex shape of the auricle”), 3 (“Thanks to the material, the deformed cartilage’s correction conforms to the complex shape of the auricle as the splint is inserted throughout the auricle.”). We do not view Yotsuyanagi as substantially the same as the 2004 Yotsuyanagi reference before the Patent Office during prosecution.

Patent Owner does not address Osman or Voorhees, and apparently concedes that neither reference is cumulative of any references considered during prosecution of the '277 patent. *See* Prelim. Resp. 26–28. Petitioner relies on Osman as teaching several limitations in claim 1; thus, Osman is a

necessary reference in each challenge in the Petition. *See* Pet. 6, 19–22. Petitioner relies on Voorhees for certain limitations in claim 2 related to an adhesive backing. *See id.* at 6, 35–37.

As to Gault, neither party provides substantive analysis of Gault in comparison to the allegedly similar references before the Examiner. We need not reach whether Gault is substantially the same as other references before the Examiner, or whether the Examiner erred with respect to those disclosures, given the limited role Gault plays in the Petition. For claim 1, Petitioner relies on Gault as a secondary reference that teaches the parts of the ear, a disclosure arguably inherently disclosed by Osman and Yotsuyanagi. *See* Pet. 14, 16, 19–20, 23–24.

Having determined that the first part of the framework set forth in *Advanced Bionics* is not met, we need not reach “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics* at 8–9.

#### 4. Conclusion

After considering the framework set forth in *Advanced Bionics* and the appropriate *Becton, Dickinson* factors, the particular circumstances of this case do not indicate that we should exercise our discretion under § 325(d) to deny institution.

#### B. Denial under 35 U.S.C. § 314(a) Based on District Court Litigation

Institution of an *inter partes* review under 35 U.S.C. § 314(a) is discretionary. *See* 35 U.S.C. § 314(a) (stating “[t]he Director *may not* authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition . . . shows that there

is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” (emphasis added)); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). The Board will consider the advanced state of a district court proceeding as a “factor that weighs in favor of denying the Petition under § 314(a).” *NHK Spring Co. v. Intrix-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential).

Patent Owner, relying on *NHK*, argues that we should deny institution based on the advanced stage of the district court litigation. Prelim. Resp. 24–25. Patent Owner contends that Petitioner’s motion to stay the district court litigation based on this proceeding was denied based on the advanced stage of the litigation. *Id.* at 24. Patent Owner further contends that “[a]ll that is left in the litigation is expert discovery, dispositive motions, and trial,” such that the “case will likely be complete well before the Board would issue a final decision.” *Id.* Patent Owner also argues that Petitioner knew of the prior art relied on in the Petition “for years” and knew of Patent Owner’s infringement contentions since February, 2019, yet improperly waited until after substantial work on the district court litigation was complete before filing the Petition. *Id.* at 24–25.

In *NHK*, the trial in the district court proceeding was set to conclude six months before a final Board decision would be due. *See NHK*, Paper 8 at 20. Here, however, as acknowledged by Patent Owner, the trial date in the related district court proceeding has not yet been set, and will not occur until after expert discovery and consideration of dispositive motions. Prelim. Resp. 24. Patent Owner does not offer any further evidence to support a

conclusion that the trial date will be set before this proceeding is complete. *Id.* at 24–25.

In addition, further developments in the district court litigation since the filing of Patent Owner’s Preliminary Response indicate that the district court litigation has been further delayed. Petitioner filed a second motion to stay the district court litigation to allow the parties to attend a mediation on May 20, 2020. *See* IPR2020-00028, Ex. 1025. In its motion to stay, Petitioner asserted that our Decision in this matter and the related IPR proceeding could aid the parties’ settlement discussions. *Id.* ¶¶ 10–11. The district court granted Petitioner’s motion and stayed the case at least until the mediation takes place on May 20, 2020. *See* IPR2020-00028, Ex. 1026. This stay, although limited in duration for the time being, undermines Patent Owner’s assertion that the district court litigation will proceed to trial so soon that we should deny institution on that basis.

Patent Owner also raises an argument of unexplained delay by Petitioner. Petitioner’s delay, standing alone, does not support denial of institution here. As noted above, the delay has not resulted in our making this Decision in the face of a looming trial date. Further, Patent Owner provides no evidence that the delay provides Petitioner with an unfair advantage based on the filing of any previous petitions challenging the ’277 patent. Prelim. Resp. 24–25.

Based on the foregoing, we decline to exercise our discretion to deny institution under 35 U.S.C. § 314(a).

*C. Level of Ordinary Skill in the Art*

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 address this issue in the Preliminary Response.

We preliminarily adopt Petitioner’s asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition.

*D. Claim Construction*

For petitions such as this one that are filed after November 13, 2018, we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b) “including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b) (2019). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

Petitioner points out that the claim terms “opening” and “scaphal mold” were already construed in the district court litigation to mean “a gap that accommodates the passage of the ear” and “mold at the end of the one or more braces that is positionable in the scaphal area,” respectively. Pet. 12 (quoting Ex. 1008, 16). Petitioner acknowledges that, in the district court, it proposed a construction that the court rejected, instead adopting Patent Owner’s construction. *Id.* at 12. Petitioner appears to apply the district court’s construction in the Petition. *Id.* at 13. Patent Owner takes issue with

Petitioner’s characterization of what the “scaphal mold” construction means, but does not argue for a different construction in this proceeding. *See* Prelim. Resp. 15–16. Patent Owner also contends that the term “cradle” was construed in the district court litigation to mean “base section and the cover.” *Id.* at 16 (citing Ex. 1008, 7–8, 13–17).

We need not construe the terms “opening,” “scaphal mold,” and “cradle” for purposes of this Decision, where the parties apparently agree that we should apply the district court’s constructions and do not dispute that the prior art relevant here discloses these limitations. *See* Pet. 19–25; Prelim Resp. 16–18 (focusing argument as to claim 1 on the “space” limitation). Accordingly, for purposes of this Decision, “opening” means *a gap that accommodates the passage of the ear*, “scaphal mold” means *mold at the end of the one or more braces that is positionable in the scaphal area*, and “cradle” means *base section and the cover*. The parties may address these issues further during trial, if necessary.

*E. 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.*

For the reasons discussed below, Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least independent claim 1.

*1. Legal Standard*

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).

## 2. 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.

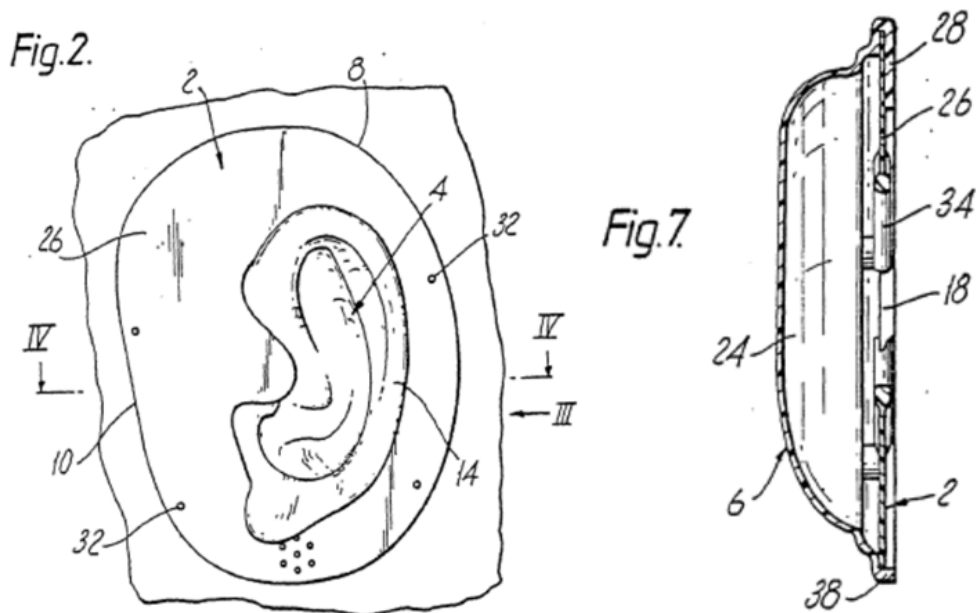


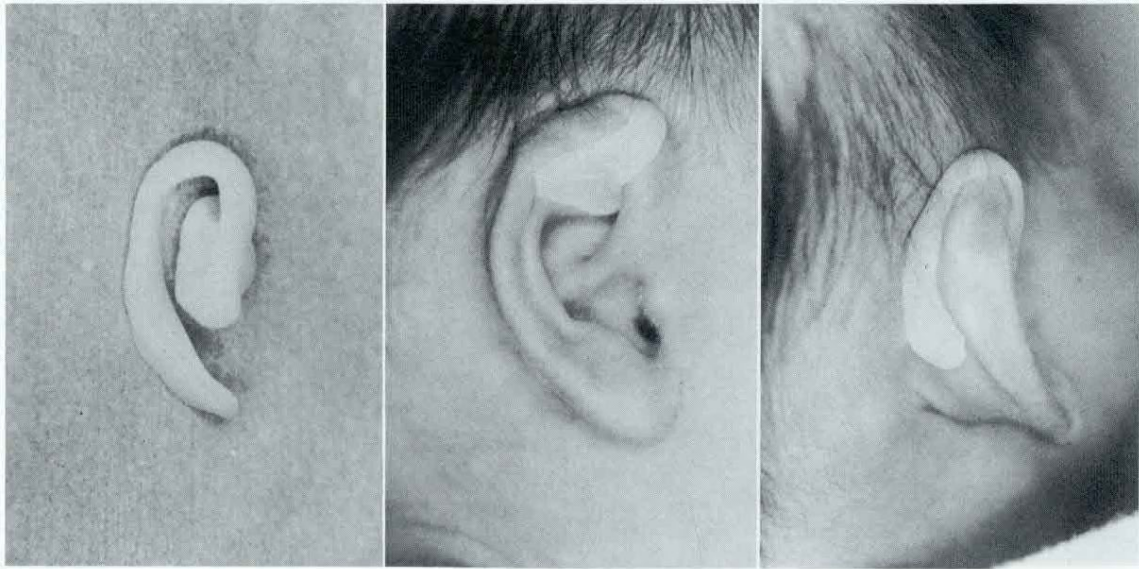
Figure 2 (above left) shows a side elevation and Figure 7 (above right) shows a vertical section of the device. Ex. 1006, 4:2–3, 4:13–14. Osman’s

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.

### 3. *Yotsuyanagi*

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

Photographs 2–4 of Yotsuyanagi are reproduced below.



Ex. 1011, 3. Photograph 2, shown on the left above, depicts Yotsuyanagi's device alone. *Id.* Photographs 3 and 4, shown in the middle and on the right above, 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.*



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

#### 5. *Discussion*

##### 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 only addresses Petitioner’s argument and evidence as to the “space” limitation, discussed further below. Prelim. Resp. 16–18.

Claim 1’s preamble states: “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.” Petitioner asserts that the preamble is not a limitation because it merely states an intended use for the claimed device. Pet. 18. We agree, based on the current record, that the preamble does not limit the claim. The preamble sets forth an intended use, “molding system for a human ear,” and the parts of the ear that provide context for the claimed device. The body of the claim sets forth a structurally complete device, without the need to rely on any of the parts of the ear to limit the claim. Petitioner further contends

that if the preamble does limit the claim, both Yotsuyanagi and Gault disclose molding devices for the human ear and include illustrations that show the parts of the ear identified in the preamble. *See id.* at 18–19 (citing Ex. 1003,<sup>6</sup> Abstract; Ex. 1007 ¶ 137; Ex. 1011, Figs. 1, 3, 5–13; Ex. 1015, 3). Petitioner establishes sufficiently, based on the current record, that both Yotsuyanagi and Gault disclose the limitations in the preamble, to the extent that the preamble limits claim 1.

Claim 1 requires “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.” Petitioner argues that Osman’s base plate 2 having opening 12 to accommodate an ear discloses “a cradle” having “a base section defining an opening dimensioned to accommodate the passage of the ear” as required by claim 1. Pet. 19–21 (citing Ex. 1006, 4:17–20, 4:30–32, 5:1–5, 5:13–15, Figs. 2, 7; Ex. 1007 ¶¶ 138–141). Claim 1’s cradle also comprises “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.” Petitioner argues that Osman’s “cover in the form of a cap,” releasably engaged with Osman’s base plate 2, discloses the claimed cover. *Id.* at 21–22 (citing Ex. 1006, 3:16–17, 4:19–20, 5:12–13, Fig. 7; Ex. 1007 ¶¶ 142–143). Petitioner establishes sufficiently, based on the current record, that Osman discloses

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<sup>6</sup> Although Petitioner cites to Exhibit 1001, we understand this to be a typographical error with the intended citation being to Exhibit 1003.

the claimed “cradle” having a “base section” and “cover” as required by claim 1.

Claim 1 also requires “an ear molding device” that includes “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). Petitioner establishes sufficiently, based on the current record, that Yotsuyanagi discloses the claimed “ear molding device” having “one or more braces” and a “scaphal mold” as required by claim 1.

The final limitation of claim 1 recites “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 maintain the correct anatomical shape of the helix and helical rim, to maintain a substantially correct shape of the helix and helical rim. Pet. 25–27 (citing in part Ex. 1007 ¶¶ 149–151; Ex. 1011, Figs. 2–13; Ex. 1012, 2–6; Ex. 1015, 7, Fig. 1). Patent Owner argues that Yotsuyanagi fails to disclose these limitations because it merely discloses a “pinching splint” that applies “pressure to the ears of older children” and

does not provide “space for the ears to grow.” Prelim. Resp. 17–18 (citing Ex. 2015, 5). Patent Owner also contends that Yotsuyanagi “requires repeated adjustments to the pinching pressure to avoid blisters.” *Id.* at 18.

Petitioner establishes sufficiently, based on the current record, that Yotsuyanagi discloses a device with a space between its brace and scaphal mold “adapted to retain the helix and helical rim” and “maintain a substantially correct anatomical shape of the helix and the helical rim.” Petitioner supports its position with reference to Yotsuyanagi’s photographs showing the “space” that forms between the brace and scaphal mold that captures the helix and helical rim, and states that the device provides satisfactory cosmetic results. *See* Pet. 25–27; Ex. 1011, Figs. 2–13; Ex. 1012, 7 (touting advantages and successful results of the splint, including “matching the complex shape of the auricle,” making excess pressure on the ear less likely). Petitioner also supports its reasoning and interpretation of Yotsuyanagi with declarant testimony. *See* Ex. 1007 ¶¶ 149–151. Patent Owner’s argument seems to presume, based on a deposition in the district court litigation, that the claim requires a specific amount of space that allows the ear to grow, but Patent Owner does not support that position with a claim construction argument or declarant testimony in this proceeding, and we decline to adopt such a construction at this time. *See* Prelim. Resp. 17–18. We note that the claim language merely requires a device “adapted to retain the helix and helical rim” and “maintain a substantially correct anatomical shape,” without mentioning growth during treatment.

We also find the statements in Yotsuyanagi that Patent Owner refers to, which suggest a need to avoid pressure on the ear, do not suggest a

failure to provide the claimed “space.” *See* Prelim. Resp. 18 (“pressure from their splints can create a blister or ulcer”). The ’277 patent describes a similar approach and suggests that avoiding pressure points appears common in this field, and Yotsuyanagi describes its results as successful, suggesting that use of its device did not cause problems in this area. *See* Ex. 1003, 6:41–45 (describing desire to avoid pressure necrosis); Ex. 1012, 7 (describing ability to avoid unwanted pressure).

Moreover, the deposition testimony Patent Owner relies on from the district court litigation does not constitute a declaration in this proceeding, and even if the testimony were in declaration form, any genuine issues of material fact would be resolved in favor of Petitioner at this stage. *See* 37 C.F.R. § 42.108(c). Patent Owner will have the opportunity to provide declarant testimony during trial.

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 does not address these issues. *See* Prelim. Resp. 18. Based on the current record, 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.

Patent Owner further argues that certain objective indicia support its position that claim 1 is not obvious. *See* Prelim. Resp. 18–21. For example, Patent Owner asserts that Petitioner's own documents establish long felt and unmet need in the industry, failure of others to achieve results, industry acceptance, copying, and strong evidence of willfulness. *Id.* at 19–21. We do not reach the merits of Patent Owner's assertions as to objective indicia of nonobviousness. Petitioner has not had a chance to address Patent Owner's arguments, and it would be best to allow the parties to address the arguments more fully during the trial before coming to any conclusions on the merits of Patent Owner's arguments.

Based on our review of the current record, Petitioner has established sufficiently that the combination of Osman, Yotsuyanagi, and Gault discloses all of the limitations of claim 1, and that one of ordinary skill in the art would have been motivated to combine the teachings of Osman, Yotsuyanagi, and Gault to arrive at the claimed subject matter. Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to independent claim 1.

*b. Claims 10 and 16*

We have also reviewed Petitioner's challenge of claims 10 and 16. Pet. 37–31. Based on our review of Petitioner's arguments and evidence for these claims, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claims 10 and 16 are

unpatentable under 35 U.S.C. § 103 based on Osman, Yotsuyanagi, and Gault.

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

Petitioner challenges 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.*

For the reasons discussed below, Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at claims 2 and 9.

*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). Patent Owner only addresses Petitioner’s

argument and evidence as to the “space” limitation as it relates to Yotsuyanagi, which we already addressed above. *See* Prelim. Resp. 16–18.

Claim 2 depends from claim 1, and claim 9 depends from claim 2. Petitioner’s arguments and evidence as to dependent claims 2 and 9 rely on the arguments and evidence it sets forth with respect to claim 1. *See* Pet. 36. Petitioner relies on Voorhees as disclosing the “adhesive backing” required by claim 2. *Id.* at 36–37 (citing Ex. 1007 ¶¶ 169–172; Ex. 1013, 3:67–4:12, Fig. 1). Petitioner relies on expert testimony and Gault in arguing that it would have been obvious to package the splint and protective together as a “kit” required by claim 9. *See id.* at 37–39 (citing Ex. 1007 ¶¶ 174–177; Ex. 1015, 16). Petitioner argues that one of ordinary skill in the art would have been motivated to combine Voorhees with the existing combination to secure a protective cap to a patient, and that there would have been a reasonable expectation of success in making the combination. *Id.* at 39–40 (citing Ex. 1007 ¶ 178–179). Patent Owner does not address Petitioner’s additional contentions as to claims 2 and 9.

Based on our review of Petitioner’s arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to claims 2 and 9.

#### IV. CONCLUSION

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, we institute an *inter partes* review of all challenged claims on all presented challenges.



At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 2, 9, 10, and 16 of U.S. Patent No. 8,852,277 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,852,277 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2020-00030  
Patent 8,852,277 B2

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