

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.

U.S. Patent No. 8,852,277

Title: Ear Molding Device for Correcting Misshaped Ears

Case No.: Not yet assigned

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,852,277**

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EXHIBIT LIST

Exhibit	Description
1001	[Intentionally Blank]
1002	[Intentionally Blank]
1003	U.S. Patent No. 8,852,277 to Byrd et al.
1004	Excerpts from the prosecution history of U.S. Patent No. 8,852,277
1005	“Acrylic Ear Splints for Treatment of Cryptotia,” authored by Anne Dancey, M.R.C.S., Peter Jeynes, M.I.M.P.T., and H. Nishikawa, published in “Plastic and Reconstructive Surgery,” (2005) 115(7)
1006	International Patent Application Publication to Osman, published September 17, 1981
1007	Dr. Hershcovitch Declaration
1008	Claim Construction Memorandum and Opinion, <i>Becon Medical, Ltd. et al. v. Scott P. Bartlett, M.D. et al.</i> , No. 18-4169 (E.D. Pa. Aug. 22, 2019).
1009	“Non-surgical correction of a congenital lop ear deformity by splinting with Reston foam,” authored by N. Kurozumi, S. Ono, and H. Ishida, published in “British Journal of Plastic Surgery,” (1982) 35, 181-182
1010	“Nonsurgical correction of Congenital Auricular Deformities in Children Older than Early Neonates,” authored by T. Yotsuyanagi, K. Yokoi, S. Urushidate, and Y. Sawada, published in “Plastic and Reconstructive Surgery,” (1998) 101(4), 907-914
1011	“The Use of a Thermoplastic Splint for Treating Cryptotia,” authored by T. Yotsuyanagi, K. Yokoi, M. Sakuraba, and M. Sugawara, published in “Plastic Surgery,” (1993) 36(9), 1037-1042
1012	English Translation of “The Use of a Thermoplastic Splint for Treating Cryptotia,” authored by T. Yotsuyanagi, K. Yokoi, M. Sakuraba, and M. Sugawara, published in “Plastic Surgery,” (1993) 36(9), 1037-1042
1013	U.S. Patent No. 5,749,099 to Voorhees

Exhibit	Description
1014	“Splinting Therapy for Congenital Auricular Deformities with the Use of Soft Material,” authored by P. Merlob, Y. Eshel, and N. Mor, published in “Journal of Perinatology,” (1995) 15(4), 293-296.
1015	United Kingdom Patent Application Publication GB2304579 to David Thomas Gault, publication date March 26, 1997
1016	“Early Nonsurgical Correction of Congenital Auricular Deformities,” authored by Y. Ullmann, S. Blazer, Y. Ramon, I. Blumenfeld, and I. Peled, published in “Plastic and Reconstructive Surgery,” (2002) 109(3), 907-913
1017	“Correction of Congenital Auricular Deformities by Splinting in the Neonatal Period,” authored by F. Brown, L. Colen, R. addante, and J. Graham, published in “Pediatrics,” (1986) 78(3), 406-411
1018	“Nonsurgical Correction of Congenital Auricular Deformities,” authored by K. Matsuo, R. Hayashi, M. Kiyono, T. Hirose, and Y. Netsu, published in “Clinics in Plastic Surgery,” (1990) 17(2), 383-395
1019	“Surgery of the Auricle,” authored by H. Weerda, published by Georg Thieme Verlag (2007)
1020	“Non-surgical correction for cryptotia using simple apparatus,” authored by T. Hirose, T. Tomono, and K. Yamamoto, published by Transactions of the Seventh International Congress of Plastic and Reconstructive Surgery, (1980) 353-354
1021	“Evaluation of a simple prosthesis for correction of cryptotia,” authored by H. Kamiishi, published in “Keisei geka, Plastic & Reconstructive Surgery,” (1976) 7-12
1022	“Earbuddies ear shape corrector for babies, infants, toddlers – premium kit #191145285,” http://www.worthpoint.com/worthopedia/earbuddies-ear-shape-corrector-babies-1921145285 (last visited Oct. 4, 2019)
1023	“EarBuddies™ Sales to Hospitals, Clinics & Health Professionals,” http://www.earbuddies.co.uk/pages/healthcare-professionals (last visited Oct. 4, 2019)
1024	“A simple prosthesis for correction of cryptotia,” authored by M. Muraoka, Y. Nakai, Y. Ohashi, and M. Furukawa, published in “The Laryngoscope,” (1984) 94(2) 243-248

I. INTRODUCTION

TalexMedical, LLC (“TalexMedical” or “Petitioner”) respectfully requests *inter partes* review of claims 1, 2, 9, 10, and 16 of U.S. Patent No. 8,852,277 (“the ‘277 patent”) (Ex. 1003).

The ‘277 patent is directed to a splint for correcting a deformation in the ear. The ‘277 patent describes the invention as being adapted to “retain the helix and the helical rim of a misshaped ear,” and to “maintain a substantially correct anatomical shape of the helix and helical rim.” Ex. 1003 at Abstract. The ‘277 patent describes the technical field of the invention as relating to “correcting misshaped ears, and more particularly, to non-surgical correction of misshaped ears.” Ex. 1003 at 1:14-16.

But splints for non-surgical correction of misshaped ears predate the ‘277 patent by at least 25 years. *See, e.g.*, Ex. 1009. Further, as demonstrated by various prior art references that were not before the examiner during prosecution, the structure of the splint described in the ‘277 patent—which retains the helix and the helical rim of a misshaped ear—was well-known and understood by doctors using non-surgical techniques to correct misshapen ears.

For example, Dr. Kurozumi, in his 1982 paper entitled “Non-surgical correction of a congenital lop ear deformity by splinting with Reston foam,” explains that “[t]o correct this ear deformity a piece of Reston foam (a spongy

material with adhesive on one side) was applied taking advantage of its elasticity.”

Ex. 1009 at 1. Dr. Kurozumi describes his non-surgical “technique” as follows:

After manual correction of the auricular deformity, a piece of Reston foam was applied at the bottom of the fold of the auricle

* * *

The splinting was continued for another two months and then discarded.

There has been no recurrence of the deformity for over 18 months.

Ex. 1009 at 1. The non-surgical “technique,” therefore is simply to apply a splint to retain the desired shape of the misshapen ear until it is corrected.

Similarly, in a 2005 article entitled “Acrylic Ear Splints For Treatment Of Cryptotia,” Dr. Dancey explains that “[t]he earliest report of satisfactory nonsurgical correction is from 1980,” and that the authors “claim no originality for the use of splinting in cryptotia” Ex. 1005 at 5. Dr. Dancey explains that

“various molding materials and splints have been described, including thermoplastic materials, lead-free soldering wire inserted within a suction catheter, Reston foam, temporary stopping with surgical tape, and Aluax.” Ex. 1005 at 5.

Dr. Dancey’s splint is described as “a two-part pressure splint [that] was custom made to fit over the ear and retract the upper pole into an acceptable position.”

Ex. 1005 at 5.

As described in the declaration of Dr. Meir D. Hershcovitch submitted herewith, non-surgical techniques for splinting a deformed ear were well-known in

the field far in advance of the ‘277 patent, and given the common objective of maintaining the desired form of the ear, many of the prior art splints share structural features. Ex. 1007 at ¶¶ 13-21, 41-45.

II. MANDATORY NOTICES

A. Real Party-In-Interest

TalexMedical, LLC, a Pennsylvania limited liability company, and Scott P. Bartlett, M.D. have been sued by Patent Owner for infringement of the ‘942 patent, and are the real parties-in-interest for Petitioner. BioAdvance and Children’s Hospital of Philadelphia are minority shareholders of TalexMedical, LLC.

B. Related Matters

The ‘277 patent is currently the subject of litigation in *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 September 27, 2018, and served on both defendants on October 10, 2018. [D.I. 10, 11]. No trial date has been set in that litigation.

An IPR petition for U.S. Patent No. 8,167,942, which is also asserted in the litigation, is being filed concurrently herewith.

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D. Service Information

Please direct all correspondence to lead counsel and back-up counsel at the contact information above. Petitioners consent to service by electronic mail at the email addresses set forth above.

III. GROUNDS FOR STANDING AND PROCEDURAL STATEMENT

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ‘277 patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified herein. The ‘277 patent has not been subject to a previous estoppel-based proceeding of the AIA, and the complaint served on TalexMedical and Dr. Bartlett referenced above was served within the last 12 months of the filing of this Petition.

IV. IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.104(b) and (b)(1), Petitioner requests *inter partes* review of claims 1, 2, 9, 10, and 16 of the ‘277 patent, and that the PTAB determine the same to be unpatentable.

February 10, 2009, is the earliest filing date to which the ‘277 patent could claim priority. Pursuant to 37 C.F.R. § 42.104(b)(2), *inter partes* review of the ‘277 patent is requested in view of the following references, each of which is prior art to the ‘277 patent under 35 U.S.C. § 102 (Pre-AIA):

- a. International Patent Publication WO 81/02515 to Osman, published September 17, 1981. (“Osman”) (Ex. 1006). Osman is prior art to the ‘277 patent under at least 35 U.S.C. § 102(b) (Pre-AIA).
- b. “The Use of a Thermoplastic Splint for Treating Cryptotia,” authored by Takatoshi Yotsuyanagi, M.D., Katsunori Yokoi, M.D., Minoru Sakuraba,

M.D., and Mitsuo Sugawara, M.D., published in “Plastic Surgery 36(9): 1037-1042, 1993. (“Yotsuyanagi”) (Ex. 1011). Yotsuyanagi was published on March 29, 1993, and is prior art to the ‘942 patent under at least 35 U.S.C. § 102(b) (Pre-AIA). A certified English translation is provided herewith (Ex. 1012).

- c. U.S. Patent No. 5,749,099 to Voorhees, was published May 12, 1998. (“Voorhees”) (Ex. 1013). Voorhees is prior art to the ‘277 patent under at least 35 U.S.C. § 102(b) (Pre-AIA).
- d. UK Patent Application No. 9517764.8 to Gault, entitled “Ear splint,” published on March 26, 1997. (“Gault”) (Ex. 1015). Gault is prior art to the ‘942 patent under at least 35 U.S.C. § 102(b) (Pre-AIA).

The grounds of unpatentability presented in this petition are as follows:

- i. Claims 1, 10, and 16 are rendered obvious by Osman in view of Yotsuyanagi further in view of Gault under 35 U.S.C. § 103 (Pre-AIA).
- ii. Claims 2 and 9 are rendered obvious by Osman in view of Yotsuyanagi further in view of Gault and Voorhees under 35 U.S.C. § 103 (Pre-AIA).

V. FACTUAL BACKGROUND

A. Supporting Evidence

Pursuant to 37 C.F.R. § 42.104(b)(5), an appendix of Exhibits supporting this petition is attached. This petition is supported by the declaration of Dr. Hershcovitch (Ex. 1007), who offers his testimony with respect to the scope and content of the prior art and the combinability of the applied references.

B. Summary of the ‘277 Patent

The ‘277 patent is directed to “correcting misshaped ears using a molding device.” Ex. 1003 at Abstract. The ‘277 patent includes a figure identifying the structure of an ear (annotated below):

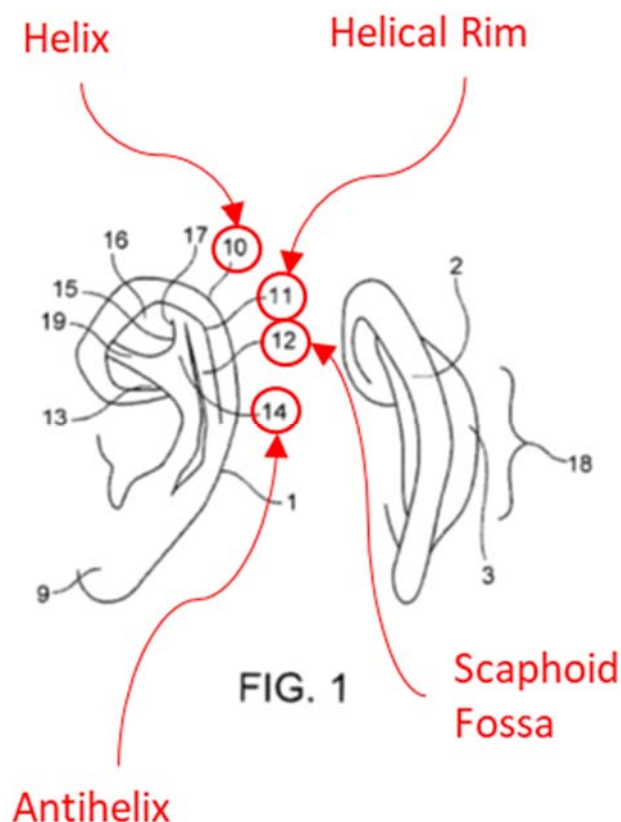


Figure 1 of the ‘277 Patent (annotated)

The ‘277 patent describes the “structures of interest when discussing misshaped ears.” Ex. 1003 at 4:11-12. Those “structures of interest” are annotated above, and include a helix 10 having a helical rim 11, a scaphoid fossa 12 is located between the helical rim 11 and an antihelix 14. Ex. 1003 at 4:14-16.

The ‘277 patent also describes a “system for correcting a misshaped ear,” which is depicted in Figure 2 (reproduced below). Ex. 1003 at 4:36-37.

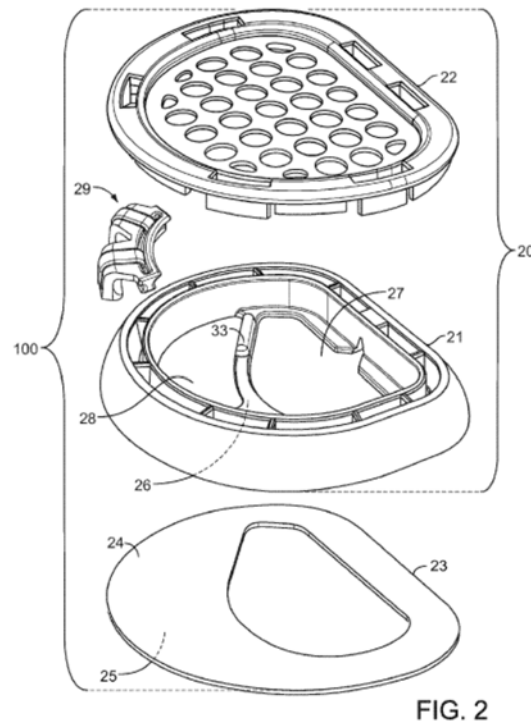


Figure 2 of the ‘277 Patent

As shown in Figure 2 of the ‘277 patent, the “system” 100 for correcting a misshaped ear includes a cradle 20 having a base 21 and a cover 22. Ex. 1003 at 4:40-43. The ear molding device 29 is positioned within the base under the cover. Ex. 1003 at 5:10-12.

The ear molding device is depicted in Figure 5 of the ‘277 patent (reproduced below), and includes a scaphal mold 55 that has an “inner curvature” that “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.” Ex. 1003

at 6:51-55. The legs 51 and 52 are also referred to as “braces” (green) throughout the ‘277 patent. *See, e.g.*, Ex. 1001 at 6:46-47.

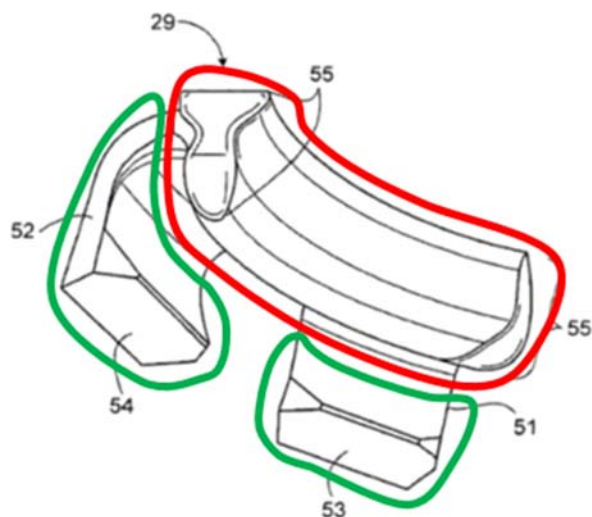


FIG. 5

Figure 5 of the ‘277 Patent (annotated)

While the scaphal mold (red) is illustrated in Figure 5 as including two legs (braces) (51 and 52), the ‘277 patent explains that “instead of two legs, the ear molding device can be a single unitary piece having one leg” Ex. 1003 at 7:26-28. The braces include “feet” (53, 54), which are flat surfaces that “can be placed in any location ... such that the scaphal mold 55 of the ear molding device 29 is placed in an area of the scaphoid fossa to maintain and mold the scaphoid fossa, helical rim, and helix in a substantially correct anatomic shape.” Ex. 1003 at 7:42-47.

C. Prosecution History of the ‘277 Patent

U.S. Patent Application No. 13/434,465 (“the ‘465 application”), which issued as the ‘277 patent, was filed on March 29, 2012, and claims priority, as a divisional application, to U.S. Patent Application No. 12/368,765 (now U.S. Patent No. 8,167,942), which was filed on February 10, 2009. Ex. 1003 at 1.

There was no substantive prosecution in the ‘465 application. On June 6, 2014, the Office issued a first-action Notice of Allowance. Ex. 1004 at 62-68. In the Notice of Allowance, the examiner provided the following reasons for allowance: “The prior art fails to disclose or fairly teach or suggest a molding system comprising a cradle having a base section to accommodate the human ear and a cover releasably engageable with the base section in combination with an ear molding device having one or more braces and a scaphal mold to retain the helix and helical rim.” Ex. 1004 at 67.

D. Level of Skill in the Art

A person of ordinary skill in the art relevant to the challenged claims of the ‘277 patent would have advanced medical education and knowledge of nonsurgical ear molding devices.

VI. CLAIM CONSTRUCTION

Pursuant to 37 C.F.R. § 42.104(b)(3), the claims are to be given their ordinary and customary meaning, or “the meaning that the term would have to a

person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc).

In the co-pending litigation in which Patent Owner asserted the ‘277 patent, the U.S. District Court for the Eastern District of Pennsylvania has issued an Order construing certain of the disputed claim terms of the patents-in-suit. Ex. 1008.

In that Order, the 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.” Ex. 1008 at 16.

As explained by the district court, Petitioner had argued that the term “scaphal mold” means “mold for scaphal or scaphoid fossa (scapha).” Ex. 1008 at 9. But Patent Owner sought a much broader construction, namely that “the term ‘scaphal’ refers to *where* the scaphal mold is placed—the scaphal area of the ear.” Ex. 1008 at 10-11 (emphasis added). That is, Patent Owner argued that the term “scaphal mold” is broad enough to cover any mold so long as it is positioned in the scaphal area of the ear. Ex. 1008 at 10-11. The district court adopted Patent Owner’s positional argument as the argument that “best describes the way ‘scaphal mold’ is used in the Patents.” Ex. 1008 at 12.

* * *

Despite disclosing a specific structure that functions as a system for splinting an ear, Patent Owner claimed the invention very broadly. The molding device shown in Figure 5, for instance, is claimed simply as a “scaphal mold” supported by a “brace” in the claims, with few other structural limitations. Even the term “scaphal mold”—as construed by the district court—does not provide any specific structure or function of the mold but rather, only refers generally to where the mold can be positioned.

This, ultimately, is the downfall of the ‘277 patent. The few structural elements recited in the claims provide no meaningful limitations to distinguish the claims from other known splints that provide the same function, in this case, splinting an ear. As shown in this Petition, various prior art disclosures, including Osman and Yotsuyanagi, show ear splints and “systems” for protecting an ear that fall within the now broadly construed claims of the ‘277 patent.

VII. THERE IS A REASONABLE LIKELIHOOD THAT CLAIMS 1, 2, 9, 10, AND 16 OF THE ‘277 PATENT ARE UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how claims 1, 2, 9, 10, and 16 of the ‘277 patent are unpatentable, including where each claim feature is found in the prior art and the motivation to combine the prior art is set forth below.

A. Brief Overview of the Prior Art

1. Overview of Yotsuyanagi

Yotsuyanagi, entitled “Cryptotia Correction using Thermoplastic Splint,” is directed to thermoplastic splints “that conform to the complex shape of the auricle.” Ex. 1012 at 6; Ex. 1011 at Figures 2, 3, and 4. As shown in the figures below, the Yotsuyanagi splint is a simple plastic device that is applied to the ear, including the scaphal area of the ear. Ex. 1011 at Figures 2, 3, and 4.



Figures 2, 3, and 4 of Yotsuyanagi

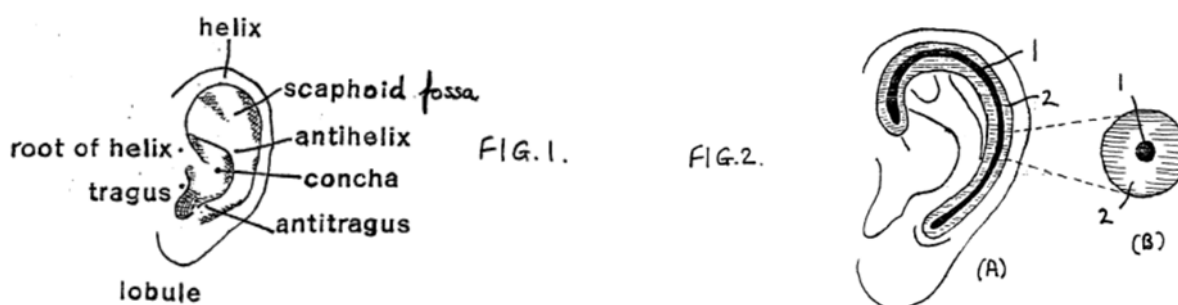
Yotsuyanagi’s study concluded that “we achieved a positive result by adapting to the complex shape of the auricle. . . .” Ex. 1012 at 8.

2. Overview of Gault

Gault, entitled “Ear splint,” is directed to “an ear splint for use in holding an ear in a desired position or shape.” Ex. 1015 at 5. The splint “can be formed into a desired shape and fitted into the auricle of the ear.” Ex. 1015 at 6. Gault also

describes a protective means that can cover the splint during treatment “for protecting the ear from pressure from the splint when the head is laid down on the ear.” Ex. 1015 at 6-7, 10-11.

As shown in the figures below, Gault describes fitting the splint “into the scaphoid fossa of the abnormal ear so as to hold the ear in the desired curved shape.” Ex. 1015 at 8.



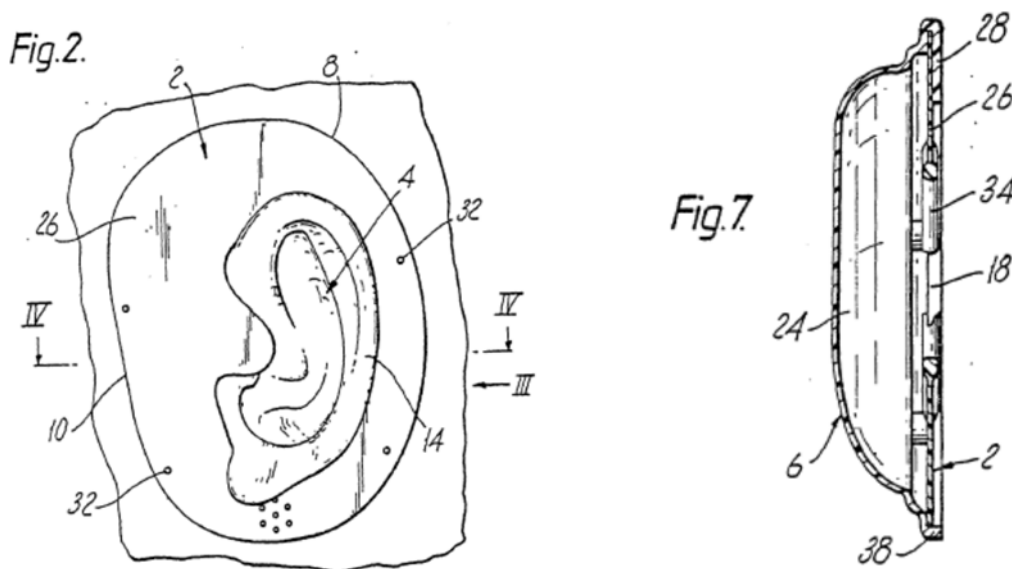
Figures 1 and 2 of Gault

Gault explains that the use of the ear splint “is extremely simple and inexpensive. An ear splint may be applied by a doctor or surgeon but the technique is so simple that parents may be able to install a splint on their own children.” Ex. 1015 at 12.

3. Overview of Osman

International Patent Application Publication WO 81/02515, entitled “Devices for Protection of Human Ears,” invented by Mohammad Fekry Osman, is directed to a device for protecting an ear, for example, “during care of a patient following major or minor aural surgery.” Ex. 1006 at 1:3-5.

As shown in the figure below, the device includes a base plate 8, which is a flat member having an opening 12 of a size to permit the helix 14 of the ear to pass through. Ex. 1006 at 4:30-32.



Figures 2 and 7 of Osman

The Osman device also includes a plastic cap 6 that can be releasably attached to the base plate 8 to enclose the ear. Ex. 1006 at 4:17-20.

4. Overview of Voorhees

United States Patent No. 5,749,099, entitled “Draining Disposable Fluid-Tight Ear Protector,” invented by Donna Sue Voorhees, is directed to a device for protecting an ear, for example, “for persons having a medical condition that requires them to prevent water or other foreign matter from coming in contact with the pinna, or external ear, or from entering the auditory canal.” Ex. 1013 at 1:5-9.

The device includes an “opening being lined by a layer of adhesive material to affix the ear enclosure to the skin surrounding the base of the ear, where the ear joins the skull.” Ex. 1013 at 1:12-15.

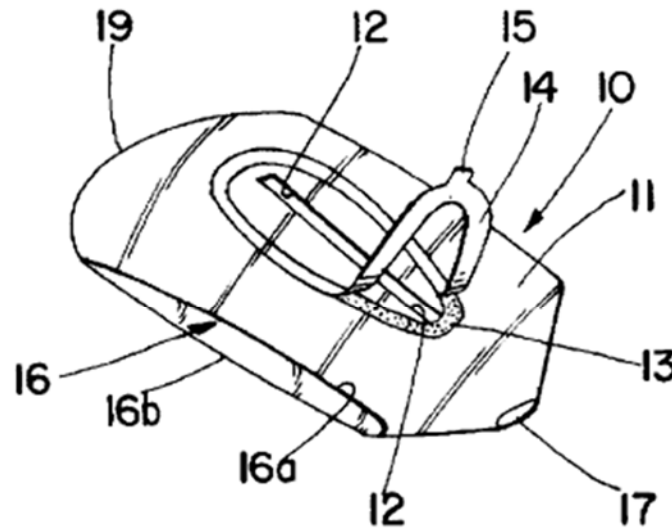


Figure 1 of Voorhees

As shown above, Voorhees discloses an “area surrounding the rim of this opening is provided with a layer or strip of pressure sensitive adhesive 13 of a type well known in the adhesive art as non-reactive with or harmful to the skin.”

Ex. 1013 at 3:67-4:3. “This adhesive is firmly adherent to plastic 11 and is preferably protected until application to the skin by a masking cover 14 readily peelable from layer 13 at the time of use.” Ex. 1013 at 4:8-12. The Voorhees device therefore uses an adhesive backing to adhere the ear enclosure to the skin around the ear.

B. Unpatentability of the Challenged Claims

1. Ground I: Claims 1, 10, and 16 are Obvious Over Osman In View of Yotsuyanagi and Further In View of Gault

a) Independent Claim 1

(1) Preamble: “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 device comprising:”

The preamble to claim 1 of the ‘277 patent is not a claim limitation. The preamble merely recites an intended use of the molding device for a human ear. Instead, the body of claim 1 recites the structural limitations of an ear molding device. If a claim sets forth all of the limitations of the claimed invention, and the preamble merely states the intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *see also Rowe v. Dror*, 112 F.3d 473, 478, (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”).

To the extent that the Board finds that the preamble to claim 1 is a limitation, the preamble is rendered obvious by Osman in view of Yotsuyanagi and further in view of Gault because Yotsuyanagi, Gault, and claim 1 of the ‘277

patent all teach “a molding system for a human ear.” Yotsuyanagi and Gault also include illustrations of the ear molding system secured to a human ear for shape correction. Ex. 1001 at Abstract; Ex. 1011 at Figures 1, 3, 5-13; Ex. 1015 at 3.

The anatomy of the human ear, as described in Yotsuyanagi and Gault, contains an antihelix, a superior limb of the triangular fossa, a helix, a helical rim, a base, a concha, and a scaphal area. Ex. 1011 at Figures 1, 3, 5-13; Ex. 1015 at 3; Ex. 1007 at ¶ 137.

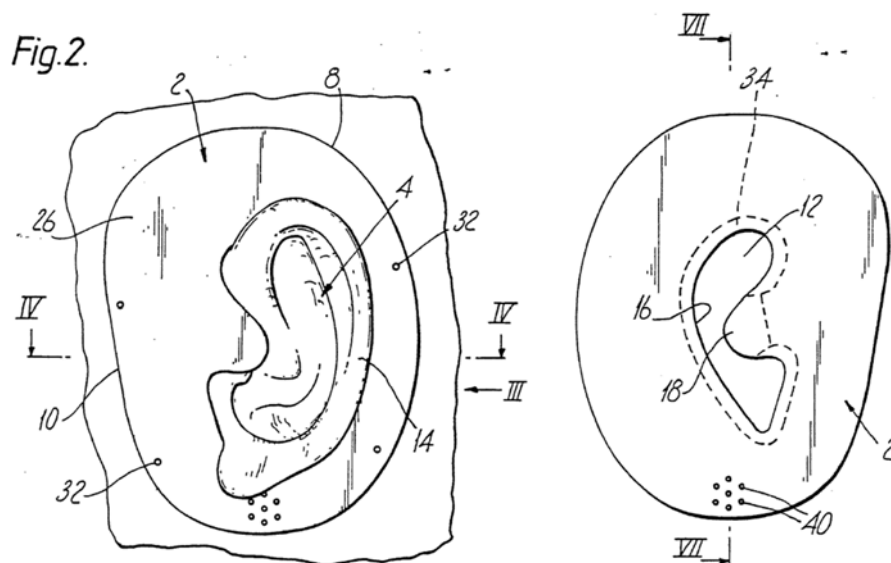
(2) *Element 1.1: “a cradle comprising:”*

(a) *“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;”*

Element 1.1(a) is rendered obvious by Osman.

As shown below, Osman discloses a base plate 2. Ex. 1006 at 4:17-20.

Osman further discloses that “[t]hrough the central part of the base plate there is an opening 12 of a size to permit the helix 14 of the auricle to pass through the opening.” Ex. 1006 at 4:30-32; Ex. 1007 at ¶ 138.



Figures 2 and 5 of Osman

Osman also discloses that the “base plate can be supported on the auricle ... with the posterior part of the base plate lying between the auricle 14 and the adjacent surface 22 of the head (Figure 4).” Ex. 1006 at 5:1-5. A person of ordinary skill in the art would have understood that the “posterior part of the base plate” is a “posterior surface” as recited in claim 1 of the ‘277 patent. Ex. 1007 at ¶ 139.

Fig. 4.

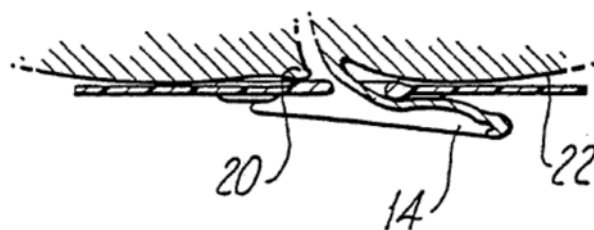


Figure 4 of Osman

Osman discloses: “face 26 of the base plate, that being the face which, when the base plate is supported on the auricle, is outwards.” Ex. 1006 at 5:13-15, Figure 2, Figure 7. A person of ordinary skill in the art would have understood that face 26 is an “anterior surface” as recited in claim 1 of the ‘277 patent. Ex. 1007 at ¶ 140.

Thus, Osman discloses a cradle having a base section defining an opening to accommodate the passage of the ear, the base section having a posterior surface and an anterior surface. Osman therefore renders obvious each limitation recited in element 1.1(a) of claim 1 of the ‘277 patent. Ex. 1007 at ¶¶ 138-141.

(b) “a cover releasably engageable with the base section, wherein the cover, when engaged with the base section, defines a compartment between the inner surface of the cover and an inner surface of the base section; and”

Element 1.1(b) is rendered obvious by Osman.

Osman teaches a “cover in the form of a cap.” Ex. 1006 at 3:16-17. “[C]ap 6 [is] intended to be releasably attached to the base plate.” Ex. 1006 at 4:19-20. As shown below, Osman also discloses that “when the cap is attached to the base plate, it encloses a space 24 adjacent to the face 26 of the base plate.” Ex. 1006 at 5:12-13, Figure 7. The space 24 represents a “compartment between the inner surface of the cover and the inner surface of the base section.” Ex. 1007 at ¶ 142.

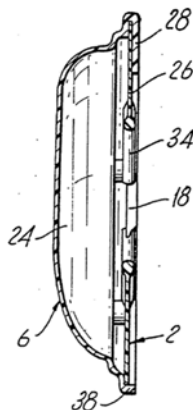


Figure 7 of Osman

Thus, Osman discloses a cradle having a cover that is releasably engageable with the base section, and which defines a compartment between the cover and the base section. Osman therefore renders obvious each limitation recited in element 1.1(b) of claim 1 of the ‘277 patent. Ex. 1007 at ¶¶ 142-143.

(3) *Element 1.2: “an ear molding device comprising:”*

(a) *“one or more braces; and a scaphal mold supported by the one or more braces,”*

Element 1.2(a) is rendered obvious by Yotsuyanagi in view of Gault.

In the district court litigation where Patent Owner asserted the ‘277 patent, the Court construed the claim term “scaphal mold” to mean a “mold at the end of the one or more braces that is *positionable* in the scaphal area.” Ex. 1008 at 12 (emphasis added). In doing so, the Court rejected Petitioners’ argument that “scaphal mold” should mean a “mold for scapha or scaphoid fossa (scapha),” instead finding that under the proper construction, the term “scaphal” “refers to

which side of the ear the scaphal mold is placed—in the scaphal area.” Ex. 1008 at 13.

The “scaphal area” is the upper portion of the ear that includes the scaphoid fossa 12, helix 10, and helical rim 11 as shown in Figure 1 of the ‘277 patent. Ex. 1007 at ¶ 144.

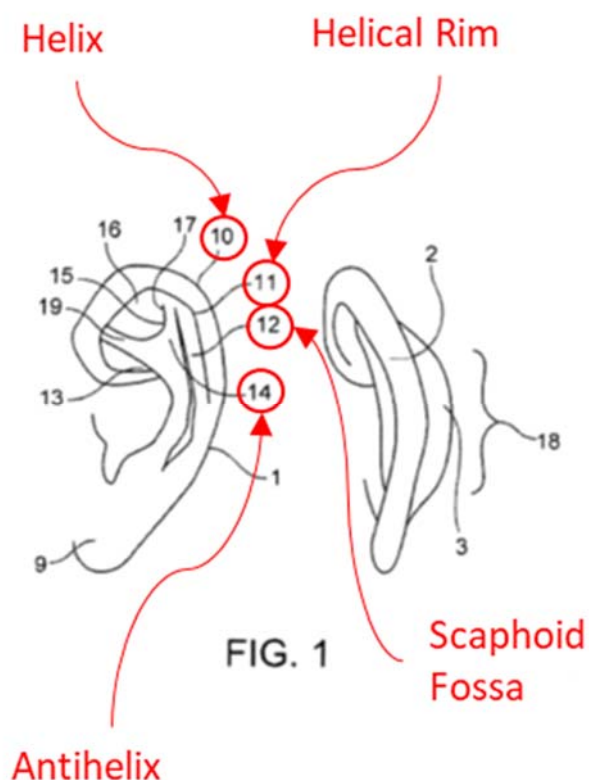
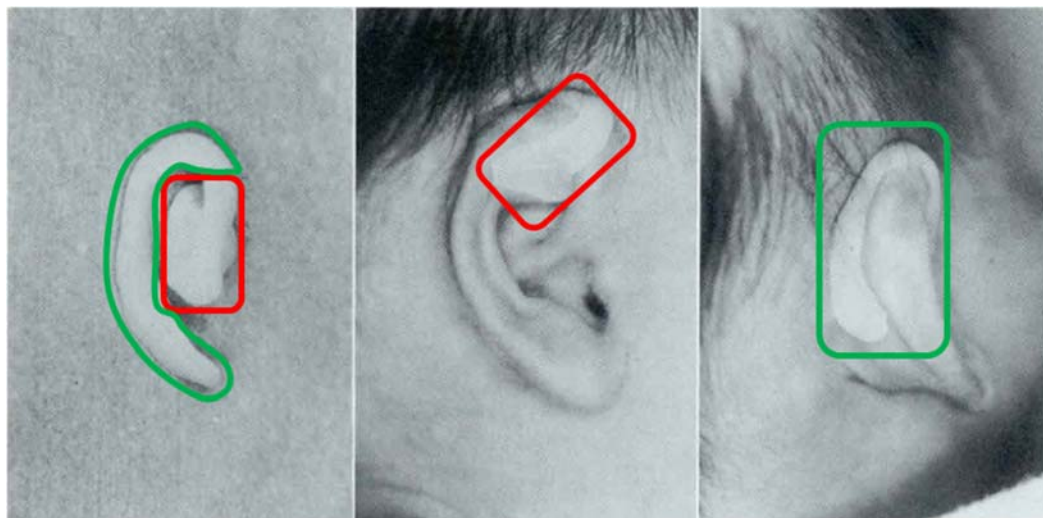


Figure 1 of the ‘277 Patent (annotated)

Yotsuyanagi teaches an ear molding device that is positioned in the scaphal area, as shown below. Ex. 1011 at Figures 2, 3, 6, 9; Ex. 1007 at ¶ 145.

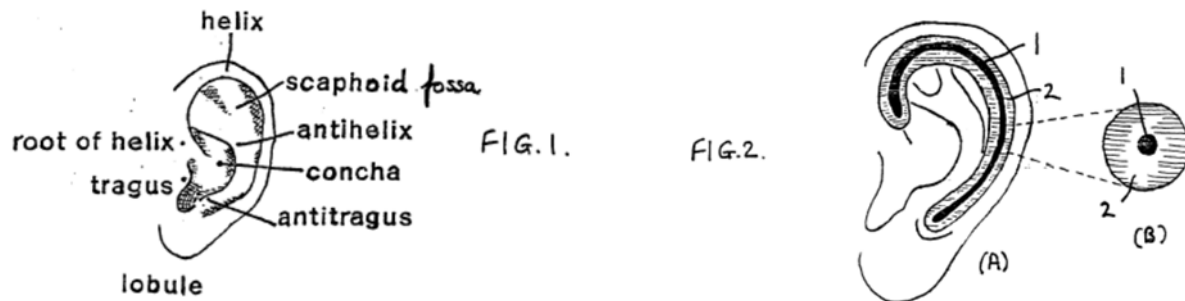


Figures 2, 3, and 4 of Yotsuyanagi (annotated)

As evidenced by annotated figures from Yotsuyanagi, the Yotsuyanagi splint includes a scaphal mold (red) positioned in the scaphal area that is supported by a brace (green), as required by claim 1 of the ‘277 patent. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶¶ 145. The position of the scaphal mold in the Yotsuyanagi splint on the ear is identical to the placement of the scaphal mold in the ‘277 patent. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶ 146. The brace is designed to fit on the posterior portion of the ear in a way that supports the scaphal mold. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶ 145.

While 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. Ex. 1007 at ¶ 147. Gault describes the “scaphoid fossa [as] the narrow curved depression between the helix and the antihelix.” Ex. 1015 at 7. Like Yotsuyanagi, Gault uses a splint positioned

in “the scaphal area (scaphoid fossa), and explains that the splint is “fitted into the scaphoid fossa of the abnormal ear so as to hold the ear in the desired curved shape.” Ex. 1015 at 8.



Figures 1 and 2 of Gault

Thus, in view of the disclosure in Gault, a person of ordinary skill in the art would understand Yotsuyanagi’s splint to be a scaphal mold placed in the scaphal area, consistent with the district court’s construction of this claim term. Ex. 1008 at 13; Ex. 1007 at ¶¶ 144-148.

Yotsuyanagi in view of Gault therefore renders obvious each limitation of element 1.2(a) of claim 1 of the ‘277 patent.

(b) “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.”

Element 1.2(b) is rendered obvious by Yotsuyanagi in view of Gault.

Yotsuyanagi discloses that the brace and scaphal mold of the splint are adapted to retain the helix and helical rim. Ex. 1011 Figures 2-13; Ex. 1012 at 2-6;

Ex. 1007 at ¶¶ 149-151. Gault identifies the “helix (or helical rim) [as] the curved, prominent rim of the ear, which extends around its periphery.” Ex. 1015 at 7.

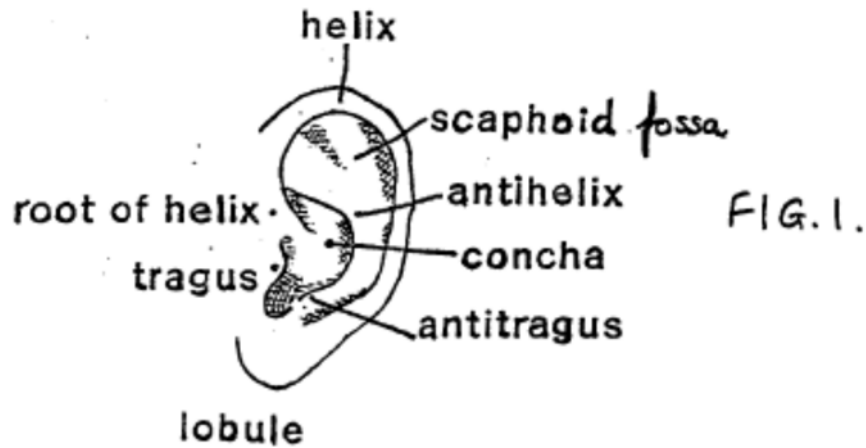
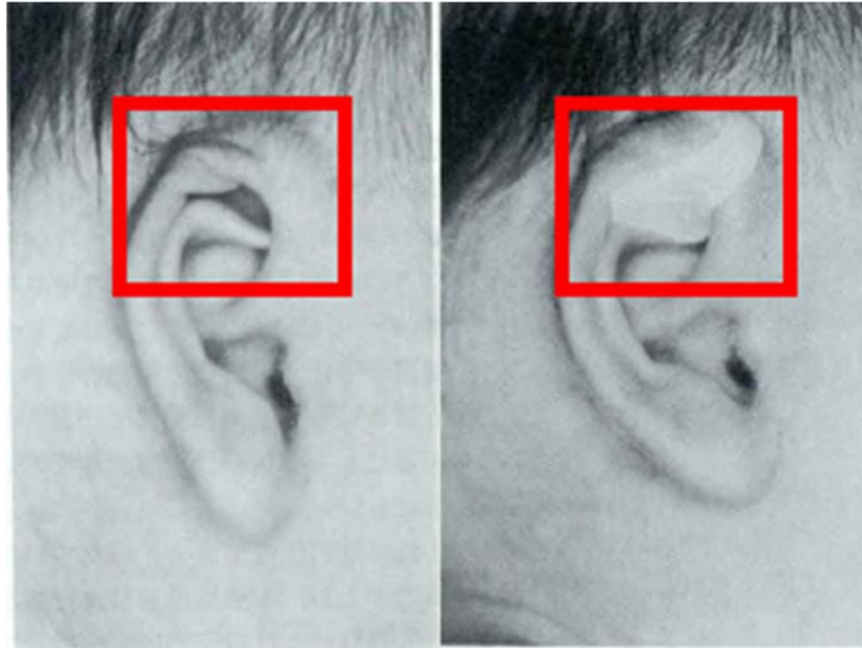


Figure 1 of Gault

Yotsuyanagi discloses that the splint is applied to correct “the helix and antihelix in order to gradually approach the proper ear shape.” Ex. 1012 at 2. A person of ordinary skill in the art would have understood that the “proper ear shape” is the substantially correct anatomical shape of the helix and helical rim. Ex. 1007 at ¶¶ 149-151.

As shown in the annotated figure below, the Yotsuyanagi splint maintains the helix and helical rim in an anatomically correct position in the space between the brace and scaphal mold. Ex. 1011 at Figures 1 and 3; Ex. 1007 at ¶¶ 149-151.



Figures 1 and 3 of Yotsuyanagi (annotated)

Yotsuyanagi discloses the brace and scaphal mold are adapted to retain the helix and helical rim within a space to maintain a substantially correct anatomical shape of the ear. Yotsuyanagi in view of Gault therefore renders obvious each limitation of element 1.2(b) of claim 1 of the ‘277 patent. Ex. 1007 at ¶¶ 149-151.

Accordingly, the combination of Osman, Yotsuyanagi, and Gault renders obvious each limitation recited in claim 1 of the ‘277 patent.

b) Dependent Claim 10

Claim 10 depends from claim 1 and adds the limitation that “the base section and the cover include a vertical wall.” Osman in view of Yotsuyanagi and further in view of Gault renders obvious this limitation.

As shown below, Osman refers to Figure 7 and discloses that “when the cap is attached to the base plate, it encloses a space 24 adjacent to the face 26 of the base plate” Ex. 1006 at 5:12-13.

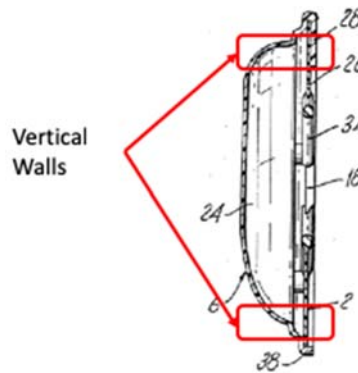


Figure 7 of Osman (annotated)

A person of ordinary skill in the art would have understood that the Osman cap contains vertical walls, as shown in Annotated Figure 7 above, and that the vertical walls create space 24 between cap 6 and base plate 2. Ex. 1007 at ¶¶ 156.

Thus, Osman discloses a base section and a cover including a vertical wall. For the reasons discussed here and above concerning claim 1, the combination of Osman, Yotsuyanagi, and Gault renders obvious each limitation recited in claim 10 of the ‘277 patent. Ex. 1007 at ¶¶ 155-156.

c) Dependent Claim 16

Claim 16 depends from claim 1 and adds the limitation that “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

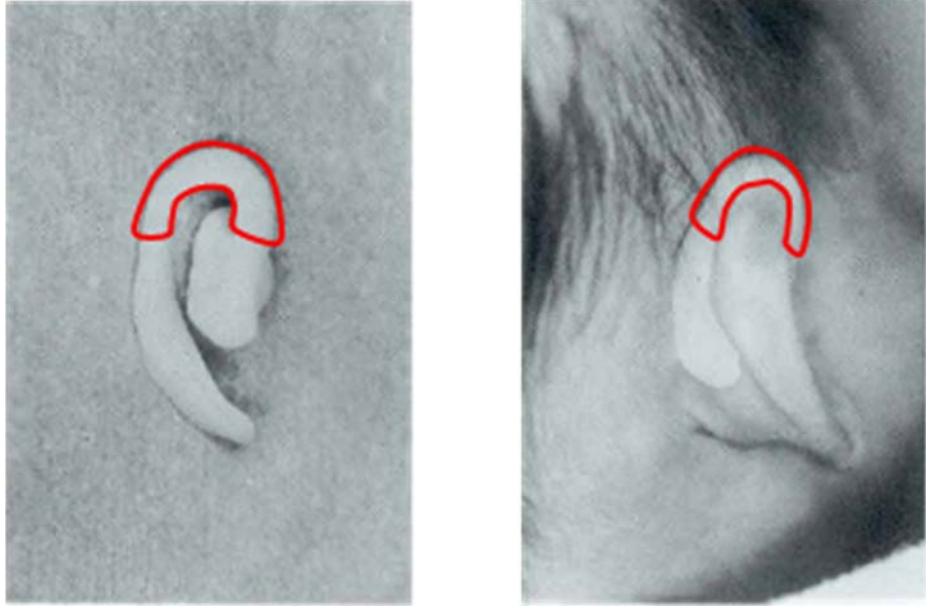
substantially correct anatomical shape of the scaphal area of the ear.” Osman in view of Yotsuyanagi, and further in view of Gault renders obvious this limitation.

Yotsuyanagi discloses a splint that is adapted to correct the shape of a malformed ear. Ex. 1011 at Figures 3, 6, 9; Ex. 1007 at ¶ 158. As shown below, the scaphal mold of the Yotsuyanagi splint forms an arc-shaped extension from the brace. Ex. 1011 at Figure 3; Ex. 1007 at ¶¶ 158-159.



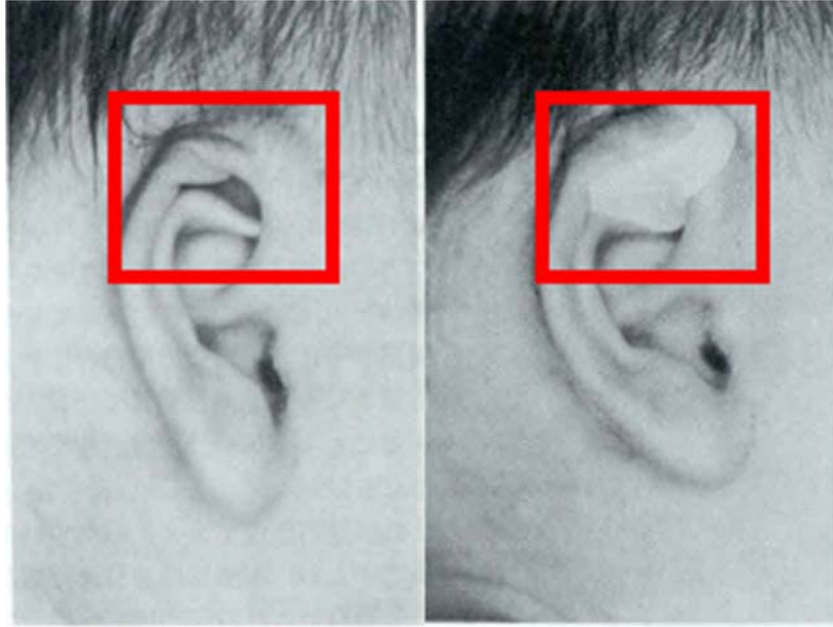
Figure 6 of Yotsuyanagi (annotated)

The Yotsuyanagi splint also has a semi-cylindrical extension from the brace having rounded edges, as shown below. Ex. 1011 at Figures 2, 4; Ex. 1007 at ¶ 160.



Figures 2 and 4 of Yotsuyanagi (annotated)

As discussed above concerning claim 1, Yotsuyanagi discloses that the brace and scaphal mold of the splint are adapted to maintain the helix and helical rim in an anatomically correct shape. *See* Ex. 1012 at 3-8; Ex. 1007 at ¶¶ 158-161. The use of the splint to maintain the correct anatomically correct shape of the scaphal region of the ear is depicted below in annotated Figures 1 and 3 from Yotsuyanagi. Ex. 1007 at ¶¶ 151, 158-161.



Figures 1 and 3 of Yotsuyanagi (annotated)

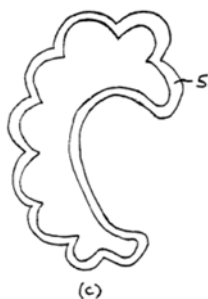
Thus, Yotsuyanagi discloses a scaphal mold having an arc-shaped semi-cylindrical extension adapted to maintain a substantially correct anatomical shape of the scaphal region of the ear. For the reasons discussed here and above concerning claim 1, the combination of Osman, Yotsuyanagi and Gault renders obvious each limitation recited in claim 16 of the '277 patent. Ex. 1007 at ¶¶ 157-161.

d) Motivation to Combine Osman, Yotsuyanagi, and Gault

A person of ordinary skill in the art would have known, at the time of the '277 patent, that an important aspect of nonsurgical treatment of a deformed ear using a splint is maintaining the splint in its desired position. Ex. 1007 at ¶¶ 162-163. It was further understood that this treatment was typically provided to infants

or small children, whose ears had not yet fully formed. Ex. 1007 at ¶¶ 162.

Accordingly, doctors recognized that it was desirable to protect the splint so that the child could not displace the stint throughout the duration of the treatment, which could be weeks or longer. Ex. 1007 at ¶¶ 162-163. To that end, those skilled in the art would have been motivated to combine the protective cover of Osman with the splint of Yotsuyanagi in order to protect the installation of the splint and ensure success of the treatment. Ex. 1007 at ¶¶ 162-163. In fact, Gault teaches including a protective cover for that very same purpose. As depicted below in an excerpt of Figure 4 of Gault, Gault discloses a “protector means for fitting around the ear for protecting the ear from pressure from the splint when the head is laid down on the ear.” Ex. 1015 at 16; Ex. 1007 at ¶ 163.



Excerpt of Figure 4 of Gault

Yotsuyanagi itself reports that “[t]here’s also the problem of patient compliance, with patients 5 months and older removing the apparatus, and since it is difficult to keep the apparatus in place on patients up to 4 years of age, some recommend waiting until 5 years of age or older to resume treatment.” Ex. 1012 at

6; Ex. 1007 at ¶ 162. A person of ordinary skill in the art would therefore have looked for ways to cover the splint and protect the splint from an infant's interference—exactly the purpose of the Osman and Gault protective covers.

Ex. 1007 at ¶¶ 162-165. Osman discloses a device for protecting human ears. Ex. 1006 at Title, Abstract. Osman notes that its protective cover “may be desirable during care of a patient following major or minor aural surgery.” Ex. 1006 at 1:4-5. Osman further discloses that the device is sized for the needs of children, who are the desired patients for the Yotsuyanagi splinting treatment. Ex. 1006 at 6:16-20; Ex. 1007 at ¶ 164. Moreover, the size of the device opening in the Osman protective cover to secure the device around the ear “is such that the device will not become shaken off, nor be accidentally dislodged by slight pressure or impact.” Ex. 1006 at 1:65-2:2.

Accordingly, a person of ordinary skill in the art at the time of the '277 patent would have been motivated to use the Osman protective cover to impede an infant from displacing the Yotsuyanagi splint during the treatment period.

Ex. 1007 at ¶¶ 162-165.

Yotsuyanagi and Gault are both directed to nonsurgical techniques for splinting a deformed ear to correct the deformity, so the inventions serve the same purpose to solve the same problem. Ex. 1007 at ¶ 166. The Gault reference

includes further details on the background of the art and the terminology used by those skilled in the art. Ex. 1007 at ¶ 166.

A person skilled in the art would have been motivated to further combine Yotsuyanagi and Gault at the time of the ‘277 patent because both references are directed to the very same purpose of providing nonsurgical splinting techniques for treating a deformed ear. Ex. 1007 at ¶ 166. “A motivation to combine may be found explicitly or implicitly in market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common sense of the person of ordinary skill.” *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1274 (Fed. Cir. 2019) (internal quotations and citations omitted). Doctors working in the field of nonsurgical techniques for splinting deformed ears at the time of the ‘277 patent would have turned to earlier references such as Gault to better understand and interpret the treatment being sought. *Id.*

e) Reasonable Expectation of Success When Combining the Osman Protective Cover with the Yotsuyanagi Splint

As explained by Dancey in 2005, there is no originality for the use of splinting an ear to correct a deformity, which dates back to decades before the ‘277 patent. Ex. 1005 at 5. A person of ordinary skill in the art at the time of the ‘277

patent would have also found that the protective cover disclosed in Osman is a simple device with a well understood purpose. Ex 1007 at ¶ 167. Indeed, as discussed above, Gault discloses the use of a protective cover for its splint. Ex. 1015 at 7, 10, 16. A doctor providing the nonsurgical treatment described in Yotsuyanagi would have reasonably understood that using the Osman protective cover would simply involve maneuvering the infant's ear through the opening of the base plate, applying the Yotsuyanagi splint, and then attaching the protective cap onto the base plate. Ex. 1007 at ¶ 167. The splinted infant ear would remain in the space defined under the protective cap, and the splint would be protected from the infant's hands. Ex. 1007 at ¶¶ 167.

Therefore, one skilled in the art would have had a reasonable expectation that combining the Yotsuyanagi splint with the Osman protective cover would have been successful for the purpose of protecting the splint.

2. Ground II: Claims 2 and 9 are Obvious Over Osman In View of Yotsuyanagi And Gault, And Further In View of Voorhees

a) Dependent Claim 2

Claim 2 depends from claim 1 and adds the following limitation:

an adhesive backing dimensioned to fit the posterior surface of the base section and defining an opening corresponding to the opening in the base section, wherein the adhesive backing includes an anterior adhesive surface adapted to adhere to the posterior surface of the base section, and a posterior adhesive surface adapted to adhere to periauricular skin surface.

As discussed above in the section concerning claim 1, the combination of Osman, Yotsuyanagi, and Gault renders obvious each limitation recited in claim 1 of the ‘277 patent. Osman in view of Yotsuyanagi and Gault, and further in view of Voorhees, renders obvious this limitation of claim 2. Ex. 1007 at ¶¶ 169-172.

Voorhees discloses an ear protection device that includes an “ear receiving opening.” Ex. 1013 at 3:67. Voorhees further discloses that an:

area surrounding the rim of this opening is provided with a layer or strip of pressure sensitive adhesive 13 of a type well known in the adhesive art as non-reactive with or harmful to the skin.

* * *

This adhesive is firmly adherent to plastic 11 and is preferably protected until application to the skin by a masking cover 14 readily peelable from layer 13 at the time of use.

Ex. 1013 at 3:67-4:12. As shown below, the double-sided tape disclosed in Voorhees is shown to have an anterior adhesive surface that adheres to the posterior base of the Voorhees device at plastic 11, and further includes a posterior adhesive surface adapted to adhere to a patient’s skin surface behind the ear, exactly as set forth in claim 2 of the ‘277 patent.

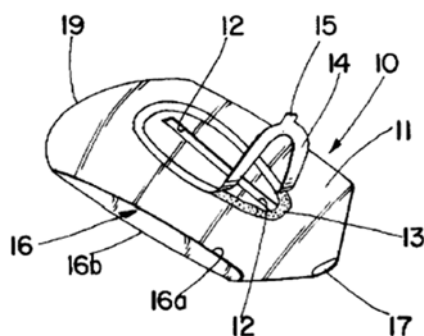


Figure 1 of Voorhees

Thus, Voorhees discloses the use of a double-sided adhesive to adhere a plastic protective ear cover to a patient's skin surface behind the ear. For the reasons discussed here and above concerning claim 1, the combination of Osman, Yotsuyanagi, Gault, and Voorhees renders obvious each limitation recited in claim 2 of the '277 patent. Ex. 1007 at ¶¶ 169-172.

b) Dependent Claim 9

Claim 9 depends from claim 2 and adds the limitation that the molding system is a "kit containing one or more cradles, one or more ear molding devices, and one or more adhesive backings."

As discussed above in the sections concerning claims 1 and 2, the combination of Osman, Yotsuyanagi, Gault, and Voorhees renders obvious each limitation recited in claims 1 and 2 of the '277 patent. Osman in view of Yotsuyanagi and Gault, and further in view of Voorhees, renders obvious this limitation of claim 9. Ex. 1007 at ¶¶ 174-177.

Those skilled in the art at the time of the ‘277 patent recognize that it was common practice to package ear molding devices as kits for commercial sale. Ex. 1007 at ¶¶ 174-175; This practice was common not only for ear molding kits, but also for other surgical and nonsurgical treatments where a number of parts were necessary to complete the treatment. Ex. 1007 at ¶¶ 174-175. A person of ordinary skill in the art would therefore have understood that it would have been obvious to package the necessary parts for the ear splinting treatment as a kit. Ex. 1007 at ¶¶ 174-175. *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016) (“A claimed invention may be obvious even when the prior art does not teach each claim limitation, so long as the record contains some reason why one of skill in the art would modify the prior art to obtain the claimed invention.”). This is particularly the case here where it would have been common sense to those skilled in the art to package the splint with the protective cover as a kit for commercial sale. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1309 (Fed. Cir. 2006) (“we do not think that the single package limitation makes the device of the ‘611 patent claims patentably distinct ... in the light of the well-known practice of packaging items in the manner most convenient to the purchaser.”).

Gault, for instance, teaches providing a kit including an ear molding device and its associated components, such as a protective cover. Gault states that “[a]ccording to another aspect of the invention there is provided an ear splint [] in

combination with protector means for fitting around the ear for protecting the ear from pressure from the splint when the head is laid down on the ear.” Ex. 1015 at 16. In fact, Gault even claims such a combination in claim 24: “An ear splint as claimed in any of Claims 1 to 19 in combination with protector means” Ex. 1015 at 16.

For the reasons discussed here and above concerning claims 1 and 2, the combination of Osman, Yotsuyanagi, Gault, and Voorhees renders obvious each limitation of claim 9 of the ‘277 patent.

c) Motivation to Combine Osman, Yotsuyanagi, Gault, and Voorhees

As discussed above, a person of ordinary skill in the art at the time of the ‘277 patent would have been motivated to combine the protective cover of Osman with the splints described in Yotsuyanagi and Gault in order to protect the Yotsuyanagi splint from the infant in order to successfully carry out the nonsurgical treatment of a deformed ear. A person of ordinary skill in the art would have been further motivated to secure such a protective cap to the patient’s skin using an adhesive, as described in Voorhees. Ex. 1007 at ¶¶ 178. Securing the protective cover to the patient’s skin would further ensure that the protective cap remains in place to protect the splint for the duration of the treatment. Ex. 1007 at ¶¶ 178.

d) Reasonable Expectation of Success When Combining the Osman Protective Cover with the Yotsuyanagi and Gault Splints and the Voorhees Adhesive

There is a reasonable expectation that, for a person of ordinary skill in the art at the time of the ‘277 patent, placing double-sided tape around opening of the Osman protective cover to secure the device to a patient’s head around the ear would have been successful in further securing the protective cover in place for the duration of the treatment. Ex. 1007 at ¶¶ 179.

VIII. THIS PETITION SHOULD NOT BE DENIED UNDER 35 U.S.C. §§ 314(a) or 315(b)

Section 314(a) provides the Director with the discretion to deny a petition. In *General Plastic Co., Ltd. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) (precedential), the PTAB set forth a number of non-exclusive factors it may consider when exercising its discretion to deny institution. None of those factors weigh in favor of denying institution here. This is Petitioner’s first petition directed to the ‘942 patent, and it is timely filed within the one year statutory bar set forth in 35 U.S.C. § 315(b). The district court proceeding in which Patent Owner asserted the ‘942 patent is not in its final stages, and no trial date has been set.

IX. THIS PETITION SHOULD NOT BE DENIED UNDER 35 U.S.C. § 325(d)

Under 35 U.S.C. § 325(d), the Director, in determining whether to institute an IPR proceeding, may take into account whether the petition relies on the same

or substantially the same prior art or arguments previously presented to the Office.

In *Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586

(PTAB Dec. 15, 2017) (Paper 8) (precedential), the PTAB set forth six non-exclusive factors for deciding whether to deny institution on the basis of § 325(d).

In this case, none of the *Becton Dickinson* factors weigh in favor of denying institution.

Neither Osman, nor Yotsuyanagi, nor Voorhees were considered by the PTO during prosecution of the ‘277 patent. The examiner did not apply a single prior art reference against the claimed invention, issuing a first-action Notice of Allowance. A different Yotsuyanagi reference, published in 2004, was provided by Applicants in an IDS. However, there are notable differences between the 2004 Yotsuyanagi reference and the 1993 Yotsuyanagi reference relied upon in this Petition, notably that the 2004 Yotsuyanagi reference did not contain any pictures or explanation of how the splint is applied. The 1993 Yotsuyanagi reference is therefore not cumulative to the 2004 Yotsuyanagi reference.

Accordingly, this Petition should not be denied institution under § 325(d).

X. CONCLUSION

For the reasons set forth above, the challenged claims are unpatentable. Accordingly, Petitioners respectfully request that the Board grant this Petition for *inter partes* review and institute trial.

Dated: October 9, 2019

Respectfully submitted,

/s/ Thomas J. Fisher

Thomas J. Fisher
Counsel for Petitioner
Registration No. 44,681

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this Petition for *Inter Partes* Review complies with the type-volume limitations of 37 C.F.R. § 42.24. As calculated by the word count feature of Microsoft Word®, it contains 7,176 words, excluding any table of contents, table of authorities, mandatory notices under § 42.8, certificate of service or word count, or appendix of exhibits or claim listing.

/s/ Thomas J. Fisher/
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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. §§ 42.6(e)(4) and 42.105, that service was made on the Patent Owner as detailed below.

<i>Date of service:</i>	October 9, 2019
<i>Manner of service:</i>	Priority Overnight Federal Express Mail
<i>Documents served</i>	Petition for <i>Inter Partes</i> Review Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104; Petitioner's Exhibit List; Exhibits 1003-1024; and Power of Attorney
<i>Persons Served</i>	FISH & RICHARDSON P.C. P.O. Box 1022 Minneapolis, MN 55440-1022
<i>Persons Served</i>	Chief Executive Officer Becon Medical Limited 2307 Brinmore Court Naperville, Illinois 60540
<i>Persons Served</i>	Dr. Henry Stephenson Byrd 10074 County Road 357 Terrell, Texas 75161

Petition for *Inter Partes* Review of U.S. Patent No. 8,852,277

A further courtesy electronic copy was also provided to litigation counsel for

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