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. 8,167,942
Title: Ear Molding Device for Correcting Misshaped Ears

Case No.: Not yet assigned

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,167,942

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EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 8,167,942 to Byrd et al.
1002	Excerpts from the prosecution history of U.S. Patent No. 8,167,942
1003	[Intentionally Blank]
1004	[Intentionally Blank]
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," vol. 115, no. 7, June 2005
1006	[Intentionally Blank]
1007	Dr. Hershcovitch Declaration
1008	Claim Construction Memorandum and Opinion, *Becon Medical, Ltd. et al. v. Scott P. Bartlett, M.D. et al.*, 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	[Intentionally Blank]
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	[Intentionally Blank]
1014	[Intentionally Blank]
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

Exhibit	Description
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-processionals (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 1-7 and 9 of U.S. Patent No. 8,167,942 ("the '942 patent") (Ex. 1001).

The '942 patent is directed to a splint for correcting a deformation in the ear. The '942 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. 1001 at Abstract. The '942 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. 1001 at 1:6-8.

But splints for non-surgical correction of misshaped ears predate the '942 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 '942 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 1-2. 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 10. 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 10. 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 10.

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 '942 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 '942 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. 8,852,277, 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 '942 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 '942 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 1-7 and 9 of the '942 patent, and that the PTAB determine the same to be unpatentable.

February 10, 2009, is the earliest filing date to which the '942 patent could claim priority. Pursuant to 37 C.F.R. § 42.104(b)(2), *inter partes* review of the '942 patent is requested in view of the following references, each of which is prior art to the '942 patent under 35 U.S.C. § 102 (Pre-AIA):

a. "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," vol. 115, no. 7, June 2005. ("Dancey") (Ex. 1005). Dancey was published in June 2005, and is prior art to the '942 patent under at least 35 U.S.C. § 102(b) (Pre-AIA).

b. UK Patent Application Publication GB2304579 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).

c. "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).

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

i. Claims 1-7 and 9 are rendered obvious by Dancey in view of Gault under 35 U.S.C. § 103.

ii. Claims 1 and 9 are rendered obvious by Yotsuyanagi in view of Gault under 35 U.S.C. § 103.

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 '942 Patent

The '942 patent is directed to "correcting misshaped ears using a molding device." Ex. 1001 at Abstract. The '942 patent includes a figure identifying the structure of an ear (annotated below):

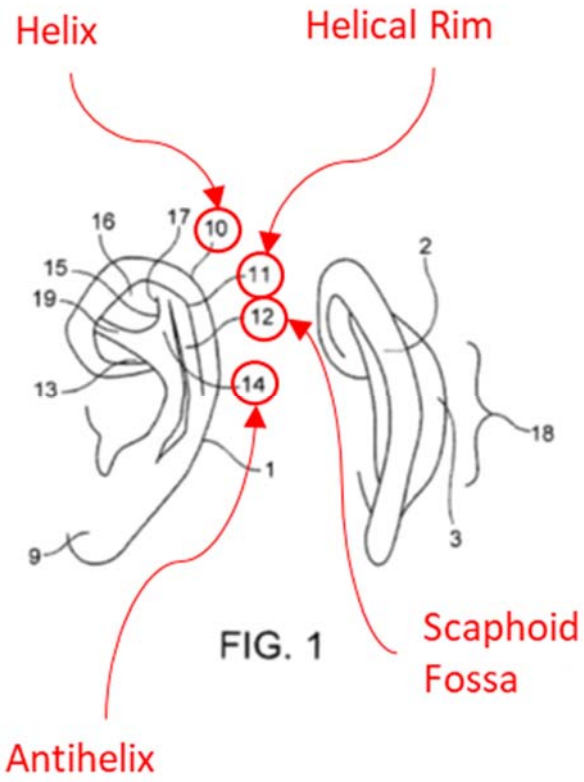


Figure 1 of the '942 Patent (annotated)

The '942 patent, describes the "structures of interest when discussing misshaped ears." Ex. 1001 at 4:2-3. 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. 1001 at 4:4-7.

The ear molding device is depicted in Figure 5 of the '942 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. 1001 at 6:41-47. The legs 51 and 52 (green) are also referred to as "braces" throughout the '942 patent. *See, e.g.*, Ex. 1001 at 6:38-39.

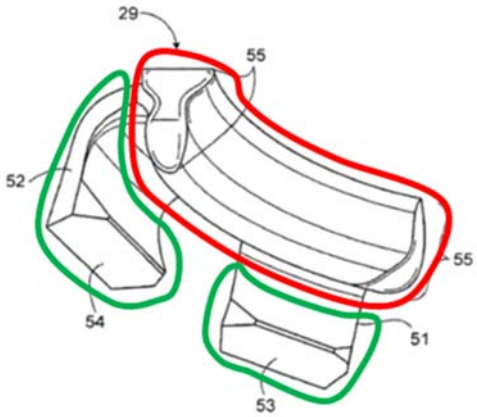


FIG. 5

Figure 5 of the '942 Patent (annotated)

While the scaphal mold (red) is illustrated in Figure 5 as including two legs (braces) (51 and 52), the '942 patent explains that "instead of two legs, the ear molding device can be a single unitary piece having one leg …." Ex. 1001 at 7:19-

20. 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. 1001 at 7:34-39.

C. Prosecution History of the '942 Patent

U.S. Patent Application No. 12/368,765 ("the '765 application"), which issued as the '942 patent, was filed on February 10, 2009.

In an Office Action dated July 14, 2011, claims 1-9 of the '765 application were rejected as anticipated by U.S. Patent No. 5,295,950 to Godley ("Godley"). Ex. 1002 at 167-72. Claim 10 was found to be allowable, if rewritten in independent form. The examiner explained that "Godley discloses a device for the human ear that is fully capable of meeting the functional language of being a 'molding device.'" Ex. 1002 at 169.

In response to the examiner's rejections, Applicants had an interview with the examiner and stated in their response that "[t]he participants agreed that modifying the phrase 'adapted to' to the amended claim language of 'constructed to' provided additional structure to the claim language." Ex. 1002 at 204. Applicant amended the pending claims to recite "constructed to" rather than "adapted to." Ex. 1002 at 197-203.

A Notice of Allowance followed. Ex. 1002 at 211-217. The examiner did not provide a statement of reasons for allowance. Ex. 1002 at 215.

D. Level of Skill in the Art

A person of ordinary skill in the art relevant to the challenged claims of the '942 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 '942 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. The only claim term from the '942 patent that was construed was the term "scaphal mold," which the Court construed to mean "mold at the end of the one or more braces that is positionable in the scaphal area." Ex. 1008 at 9-13.

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 splint, Patent Owner claimed the invention very broadly. The molding device shown in Figure 5, for instance, is claimed 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 '942 patent. The few structural elements recited in the claims provide no meaningful limitations that 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 Dancey and Yotsuyanagi, show ear splints that fall within the now broadly construed claims of the '942 patent.

VII. THERE IS A REASONABLE LIKELIHOOD THAT CLAMS 1-7 AND 9 OF THE '942 PATENT ARE UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how claims 1-7 and 9 of the '942 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 Dancey

Dancey, entitled "Acrylic Ear Splints for Treatment of Cryptotia," is directed to a splint for nonsurgically correcting cryptotia. The splint is 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 10. As shown in the figure below, "[t]he splint was made from translucent acrylic to allow regular inspection of the pinnae for pressure necrosis." Ex. 1005 at 10.

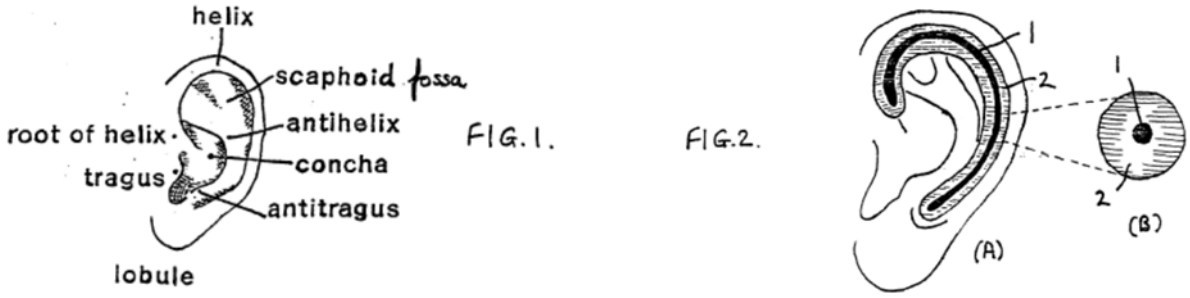
Figure 1 of Dancey

Dancey's splint is supported against the patient's head, and maintains the helix in an "acceptable position." Ex. 1005 at 10. Dancey explains that the "splint was worn continuously for 1 year and then intermittently for 9 months. The patient now has a satisfactory cosmetic result, with an essentially normal-looking ear." Ex. 1005 at 10. As noted by the authors—even in 2005—they "claim no originality for the use of splinting in cryptotia," but rather, that their "custom-made acrylic splint is a simple and effective method of nonsurgical intervention." Ex. 1005 at 10.

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 to the auricle of the ear." Ex. 1015 at 6. Gault also describes a protector 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.

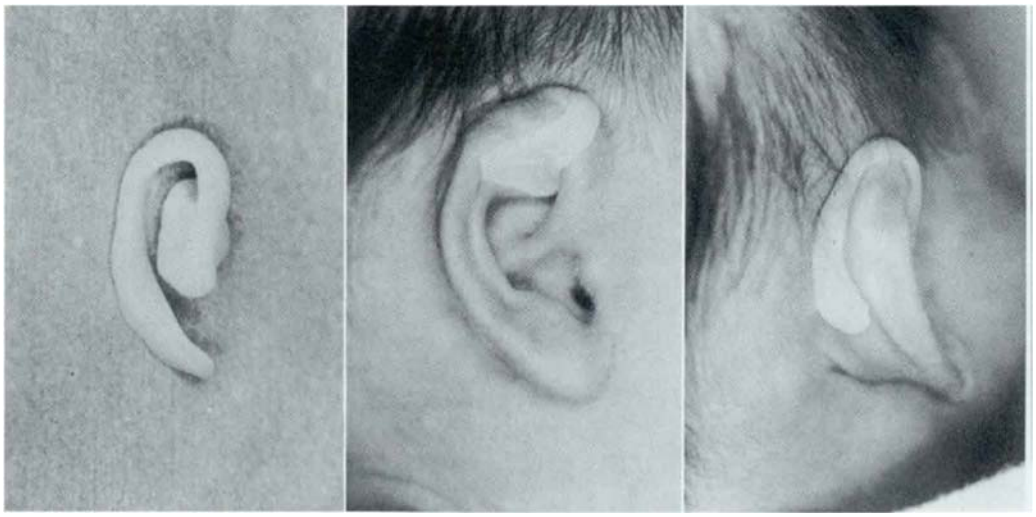


Figures 1 and 2 of Gault

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 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.

B. Unpatentability of the Challenged Claims

1. Ground I: Claims 1-7 and 9 are Obvious Over Dancey In View of Gault

a) Independent Claim 1

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

The preamble to claim 1 of the '942 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 Dancey in view of Gault because both Dancey, Gault, and claim 1 of the '942 patent all teach "a molding device for a human ear." Dancey and Gault also include illustrations of the ear molding device secured to a human ear for shape correction. Ex. 1001 at Abstract; Ex. 1005 at 10; Ex. 1015 at 3. The anatomy of the human ear as shown in Dancey and described in 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. 1005 at 10; Ex. 1015 at 3; Ex. 1007 at ¶ 55.

(2) Element 1.1: "one or more braces; and a scaphal mold supported by the one or more braces"

Element 1.1 is rendered obvious by Dancey in view of Gault.

In the district court litigation where Patent Owner asserted the '942 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 '942 patent, annotated below. Ex. 1007 at ¶ 57.

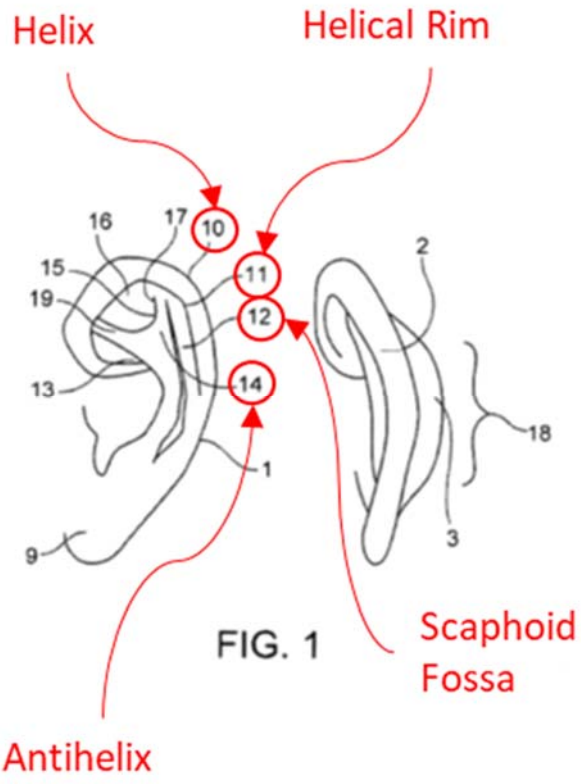


Figure 1 of the '942 Patent (annotated)

Dancey teaches an ear molding device that is positioned in the scaphal area, as shown below. Ex. 1005 at 10; Ex. 1007 at ¶¶ 58-60.

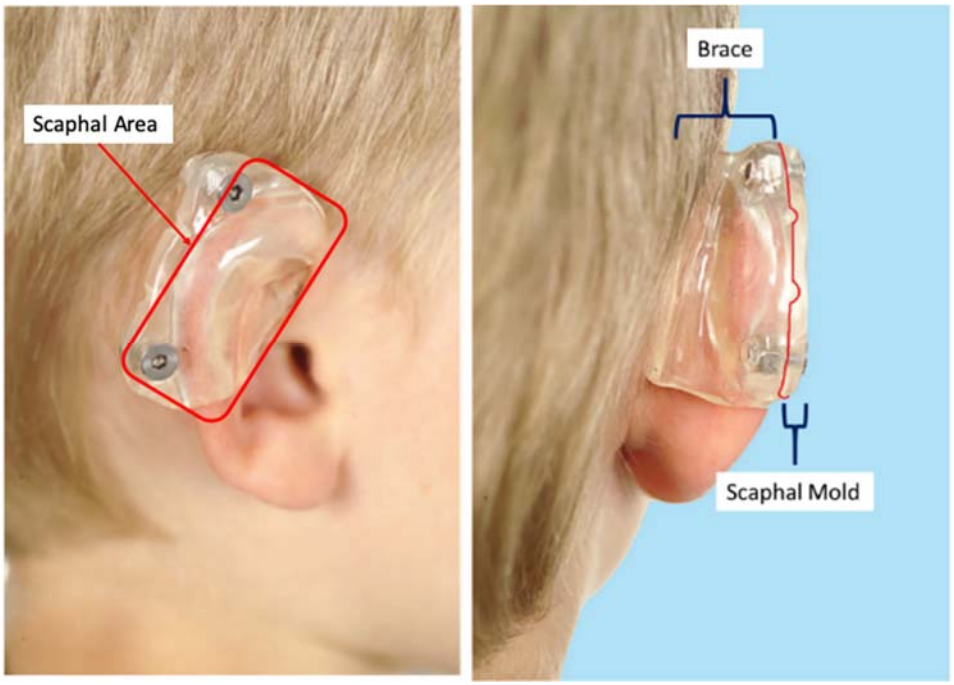


Figure 1 of Dancey (annotated)

Dancey's ear molding device includes a scaphal mold positioned in the scaphal area that is supported by a brace, as shown in the annotations added to Figure 1 above, as required by claim 1. The brace is positioned against the patient's head and supports the scaphal mold, which Dancey explains is "custom made to fit over the ear and retract the upper pole into an acceptable position." Ex. 1005 at 10; Ex. 1007 at ¶¶ 58-59. Dancey's positioning of the scaphal mold is identical to placement of the scaphal mold in the '942 patent.

While Dancey does not expressly disclose that the splint is placed in the "scaphal area," those skilled in the art would have understood that the scaphal area

includes the region between the helix and the antihelix. Gault describes the "scaphoid fossa [as] the narrow curved depression between the helix and the antihelix." Ex. 1015 at 7. Like Dancey, 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.

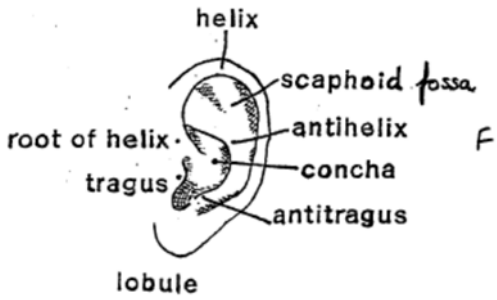
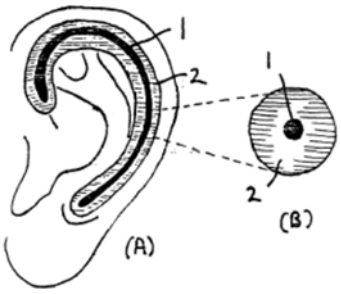


FIG. 1.

FIG. 2.



Figures 1 and 2 of Gault

Thus, in view of the disclosure in Gault, a person of ordinary skill in the art would understand Dancey's splint to be a scaphal mold placed in the scaphal area, consistent with the district court's construction of this claim term. Ex. 1008 at 13; Ex. 1007 at ¶¶ 60-61.

Dancey in view of Gault therefore renders obvious each limitation of element 1.1 of claim 1 of the '942 patent.

(3) Element 1.2: "wherein the one or more braces and the scaphal mold are constructed to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and"

Element 1.2 is rendered obvious by Dancey in view of Gault.

Dancey discloses positioning the splint in the scaphal area, which includes the helix and helical rim. Ex. 1005 at 10. Gault identifies the "helix (or helical rim) [as] the curved, prominent rim of the ear, which extends around its periphery." Ex. 1015 at 7.

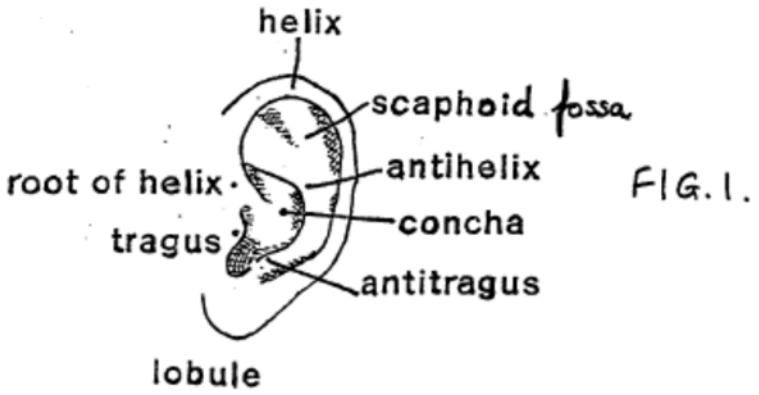


Figure 1 of Gault

Dancey discloses that the "pressure splint was custom made to fit over the ear and retract the upper pole into an acceptable position." Ex. 1005 at 10. The translucent splint shows that the scaphal mold is supported by the brace and constructed to retain the helix and helical rim within a space defined between the brace and the scaphal mold. Ex. 1005 at 10; Ex. 1007 at ¶ 62.

Dancey in view of Gault therefore renders obvious each limitation of element 1.2 of claim 1 of the '942 patent.

(4) Element 1.3: "further constructed to maintain a substantially correct anatomical shape of the helix and the helical rim,"

Dancey teaches "a two-part pressure splint custom designed to fit over the ear and retract the upper pole into an acceptable position" to provide "a satisfactory cosmetic result, with an essentially normal-looking ear." Ex. 1005 at 10; Ex. 1007 at ¶¶ 63-64. The translucent splint shows that scaphal mold maintains a substantially correct anatomical shape of the helix and helical rim. Ex. 1005 at 10; Ex. 1015 at Figure 1; Ex. 1007 at ¶ 64.

Dancey in view of Gault therefore renders obvious each limitation of element 1.3 of claim 1 of the '942 patent.

(5) Element 1.4: "wherein the scaphal mold and one or more braces are constructed to mold the helix and helical rim during their growth such that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces."

Element 1.4 is rendered obvious by Dancey in view of Gault.

As discussed above, the Dancey splint is custom made to mold the helix and helical rim. Ex. 1007 at ¶ 66. Dancey explains that the splint was "worn continuously for 1 year and then intermittently for 9 months," resulting in "a satisfactory cosmetic result, with an essentially normal-looking ear." Ex. 1005 at 10; Ex. 1007 at ¶ 66. A person of ordinary skill in the art would have understood that the helix and helical rim of the ear would have grown to conform to the space

between brace and scaphal mold after wearing the mold for the time period disclosed in Dancey. Ex. 1007 at ¶¶ 66-67. As discussed above, Gault identifies the structure of the helix and helical rim of the ear. Ex. 1015 at Figure 1.

Dancey in view of Gault therefore renders obvious each limitation of element 1.4 of claim 1 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 1 of the '942 patent.

b) Dependent Claim 2

Claim 2 depends from claim 1, and adds two limitations: (1) "[t]he ear molding device of claim 1, wherein each of the one or more braces includes a foot member positioned at an end of the brace distal to the scaphal mold," and (2) "the foot member constructed to facilitate maintaining the substantially correct anatomical shape of the helix." Dancey teaches both of these limitations and, thus, dependent claim 2 is rendered obvious by Dancey in view of Gault.

(1) Element 2.1: "2. The ear molding device of claim 1, wherein each of the one or more braces includes a foot member positioned at an end of the brace distal to the scaphal mold,"

Claim 2 recites a "foot member positioned at an end of the brace distal to the scaphal mold." Ex. 1001 at 10:36-37. At the end of the Dancey brace, and distal to the Dancey scaphal mold, is an additional support component of the brace that engages the infant's head to maintain its position. Figure 1 of Dancey, reproduced

below, depicts this additional support component as fitted against the infant's head and at the end of the portion of the brace. Ex. 1005 at 10; Ex. 1007 at ¶ 69.

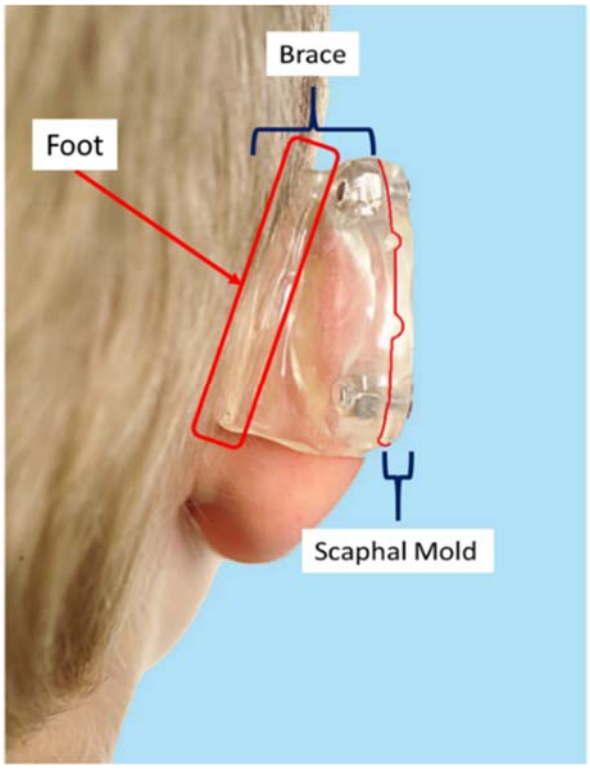


Figure 1 of Dancey (annotated)

Dancey teaches element 2.1 of claim 2 of the '942 patent.

(2) Element 2.2: "the foot member constructed to facilitate maintaining the substantially correct anatomical shape of the helix."

Dancey teaches a splint to maintain the substantially correct anatomical shape of the helix. Ex. 1005 at 10; Ex. 1007 at ¶¶ 71-72. Cryptotia is a malformity where the upper portion of the ear appears buried within skin-folds on the side of an infant's head. Ex. 1007 at ¶ 71. The Dancey splint was designed to treat a patient having cryptotia. Ex. 1005 at 10. The splint includes a foot member at the

end of the brace that serves to stabilize the device to maintain the splinted ear in a correct position so that the splint can form "an essentially normal-looking ear." Ex. 1005 at 10; Ex. 1007 at ¶¶ 71-72.

Forming a normal-looking ear on a child suffering from cryptotia involves reshaping the malformity and then maintaining the correct anatomical shape of the helix. Ex. 1007 at ¶ 71. By keeping the splint at the correct position for the Dancey splint to be effective, the foot member in the Dancey brace facilitates maintaining the correct anatomical shape of the ear's helix. Ex. 1007 at ¶¶ 71-72.

Dancey teaches element 2.2 of claim 2 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 2 of the '942 patent.

c) Dependent Claim 3

(1) Element 3.1: "a surface of the one or more braces facing the scaphal mold defines a substantially correct anatomic curvature for the helix."

Claim 3 depends from claim 2, and adds the limitation "wherein a surface of the one or more braces facing the scaphal mold defines a substantially correct anatomic curvature for the helix." Ex. 1001 at 10:40-42. Dancey teaches this limitation and thus, dependent claim 3 is rendered obvious by Dancey in view of Gault.

As discussed above and shown below, Dancey teaches "a two-part pressure splint custom designed to fit over the ear and retract the upper pole into an acceptable position." Ex. 1005 at 10; Ex. 1007 at ¶ 75. The inner space between the scaphal mold and brace of the Dancey splint are custom made to define the contours of a substantially correct anatomic curvature for the helix of the ear. Ex. 1007 at ¶ 75. Accordingly, the surface of the Dancey brace that is facing the scaphal mold defines the substantially correct anatomic curvature of the ear's helix. Ex. 1005 at 10; Ex. 1015 at Figure 1; Ex. 1007 at ¶¶ 75-76.

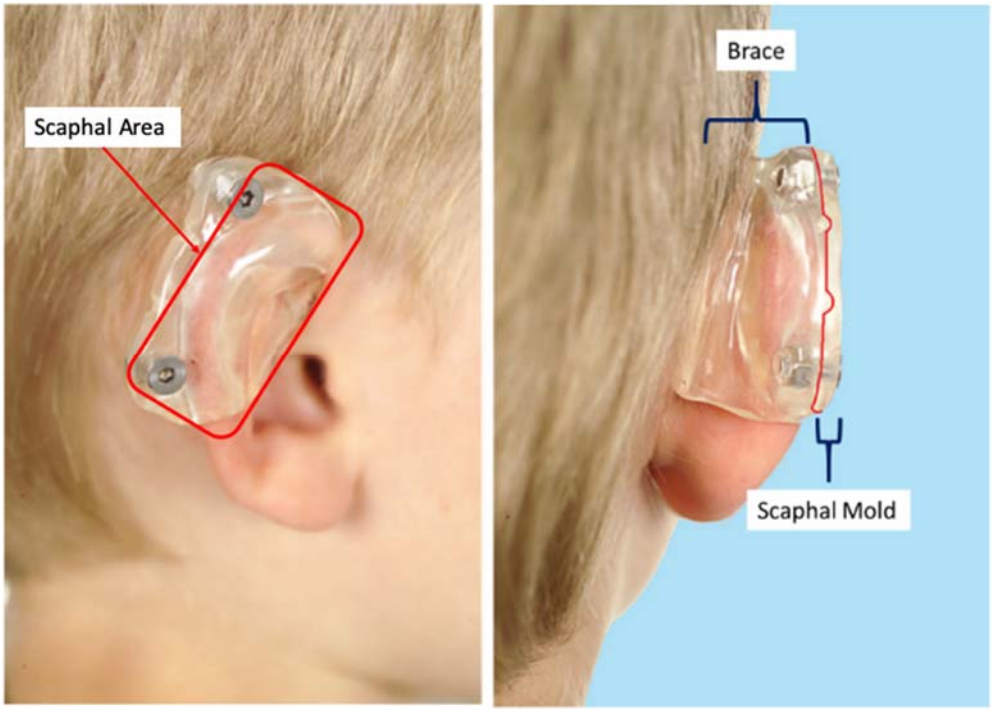


Figure 1 of Dancey (annotated)

Dancey teaches element 3.1 of claim 3 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 3 of the '942 patent.

d) Dependent Claim 4

(1) Element 4.1: "the foot includes a broad flat surface adapted for securing the ear molding device to a first surface."

Claim 4 depends from claim 2, and includes the limitation that "the foot includes a broad flat surface adapted for securing the ear molding device to a first surface." Ex. 1001 at 10:43-42. Dancey teaches this limitation and thus, dependent claim 4 is rendered obvious by Dancey in view of Gault.

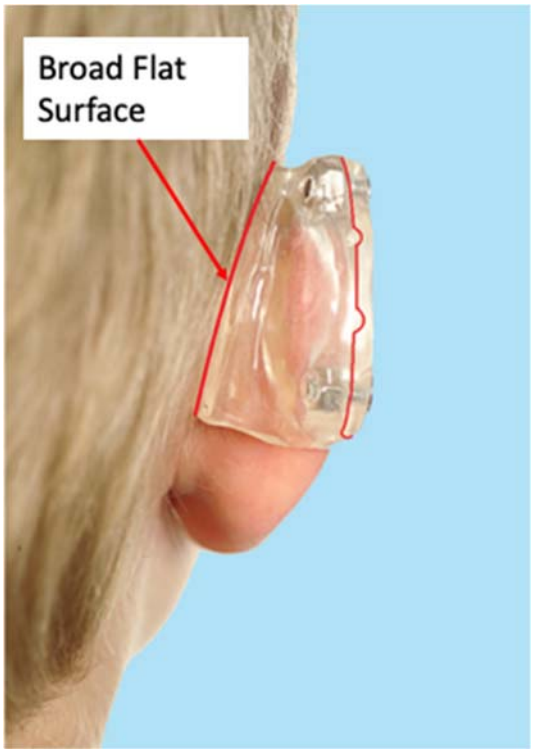


Figure 1 of Dancey (annotated)

The Dancey splint was constructed to be worn by an infant continuously for 1 year, then intermittently for 9 months. Ex. 1005 at 10. Dancey explains that the splint alleviated "technical difficulties of maintaining a splint in the correct position." Ex. 1005 at 10. The Dancey splint does so by having a broad flat surface on the foot of the brace that secures the splint against the patient's head ("first surface"). Ex. 1007 at ¶¶ 77-78. The splint is designed to be stable so that the ear can conform to the shape of the splint to obtain "an essentially normal-looking ear." Ex. 1005 at 10; Ex. 1007 at ¶¶ 77-79.

Dancey teaches element 4.1 of claim 4 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 4 of the '942 patent.

e) Dependent Claim 5

(1) Element 5.1: "the one or more braces includes a vertical support surface constructed to reversibly engage a second surface."

Claim 5 depends from claim 1, and further recites that "the one or more braces includes a vertical support surface constructed to reversibly engage a second surface." Ex. 1001 at 10:46-48. Dancey teaches this limitation and thus, dependent claim 5 is rendered obvious by Dancey in view of Gault.

Dancey discloses a splint for treating cryptotia. Ex. 1005 at 10; Ex. 1007 at ¶¶ 46-48. Cryptotia is an ear deformity where the upper pole of the ear appears buried within the skin of an infant's head. Ex. 1007 at ¶¶ 11-12. As a non-surgical solution, Dancey teaches "a two-part pressure splint custom designed to fit over the ear and retract the upper pole into an acceptable position." Ex. 1005 at 10.

The brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear. Ex. 1007 at ¶¶ 82, 87, 91. The inner surface of the brace of the Dancey splint is a vertical support that is constructed to reversibly engage the upper surface of the posterior ear (i.e. retroauricular skin surface, which is the "second surface") to push that area

outwards, and away from the infant's head. Ex. 1005 at 10; Ex. 1007 at ¶¶ 83-84. The engagement of the vertical support of the brace with the second surface serves to stabilize the splint, and to form the shape of the posterior ear during treatment. Ex. 1005 at 10; Ex. 1007 at ¶¶ 83-84.When treatment is completed, the splint is removed, disengaging the vertical support surface from the second surface. Ex. 1007 at ¶ 85.

Dancey teaches element 5.1 of claim 5 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 5 of the '942 patent.

f) Dependent Claim 6

(1) Element 6.1: "the one or more braces include a horizontal support surface constructed to reversibly engage a third surface."

Claim 6 depends from claim 5 and further recites that "the one or more braces include a horizontal support surface constructed to reversibly engage a third surface." Ex. 1001 at 10:49-51. Dancey teaches this limitation and thus, dependent claim 6 is rendered obvious by Dancey in view of Gault.

Dancey discloses a splint for treating cryptotia. Ex. 1005 at 10; Ex. 1007 at ¶¶ 46-48. Cryptotia is an ear deformity where the upper pole of the ear appears buried within the skin of an infant's head. Ex. 1007 at ¶¶ 11-12. As a non-surgical

solution, Dancey teaches "a two-part pressure splint custom designed to fit over the ear and retract the upper pole into an acceptable position." Ex. 1005 at 10.

The brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear. Ex. 1007 at ¶¶ 82, 87, 91. The top surface of the brace of the Dancey splint (the portion that is axial to the vertical support of the brace) is a horizontal support that is constructed to reversibly engage the bottom surface of the top part of the Dancey splint, which is the "third surface." Ex. 1005 at 10; Ex. 1007 at ¶ 88. The engagement of the horizontal support of the brace with the third surface serves to stabilize the splint, including the scaphal mold, and to form the shape of the helix and helical rim during treatment. Ex. 1005 at 10; Ex. 1007 at ¶ 88. When treatment is completed, the splint is removed, disengaging the horizontal support surface from the third surface. Ex. 1007 at ¶ 88.

Dancey teaches element 6.1 of claim 6 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 6 of the '942 patent.

g) Dependent Claim 7

(1) Element 7.1: "the vertical and horizontal support surfaces when engaged to the second and third surfaces, respectively, stabilize the ear molding device."

Claim 7 depends from claim 6, and further recites that "the vertical and horizontal support surfaces when engaged to the second and third surfaces, respectively, stabilize the ear molding device." Ex. 1001 at 10:52-55. Dancey teaches this limitation and thus, dependent claim 7 is rendered obvious by Dancey in view of Gault.

As discussed above in the context of claims 5 and 6, the brace of the Dancey splint includes both a vertical support and a horizontal support that work in tandem to stabilize the splint and the vertical and horizontal forces exerted by the scaphal mold on the ear. Ex. 1007 at ¶¶ 82, 87,91-92. The vertical support reversibly engages the surface of the posterior ear, which is the "second surface"; and the horizontal support reversibly engages the bottom surface of the top part of the two-part pressure splint, which is the "third surface." Ex. 1005 at 10; Ex. 1007 at ¶¶ 91-92.

Dancey teaches element 7.1 of claim 7 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 7 of the '942 patent.

h) Dependent Claim 9

Claim 9 depends from claim 1, and adds two limitations: (1) the scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges," and (2) "the extension is constructed to maintain a substantially correct anatomical shape of the scaphal area of the ear." Dancey teaches both of these limitations and, thus, dependent claim 9 is rendered obvious by Dancey in view of Gault.

(1) Element 9.1: "the scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges, and"

As discussed above, the scaphal mold of the Dancey splint covering the scaphal area extends from the brace, which is positioned behind the ear. Ex. 1005 at 10; Ex. 1007 at ¶ 58.

Figure 1 of Dancey (annotated)

The scaphal mold has an arc-shaped conformation that mimics an anatomically correct shape of an ear so that the deformed ear can be splinted at an acceptable position. Ex. 1005 at 10; Ex. 1007 at ¶ 95. The interior shape of the scaphal mold is generally semi-cylindrical in order to properly house and splint the helix and helical rim into a correct position that would promote "a satisfactory cosmetic result, with an essentially normal-looking ear." Ex. 1005 at 10; Ex. 1007 at ¶ 95. The annotated figure above shows that the edges of the scaphal mold contacting the patient's skin surface are rounded, which is identical to the description in the '942 patent. Ex. 1001 at 6:53-55 ("The scaphal mold 55

generally has a rounded edge for contacting the skin in the scaphoid fossa 12."); Ex. 1007 ¶ 96.

Dancey teaches element 9.1 of claim 9 of the '942 patent.

(2) Element 9.2: "the extension is constructed to maintain a substantially correct anatomical shape of the scaphal area of the ear."

As discussed above for elements 9.1 and 1.1, the scaphal mold in the Dancey splint is custom designed such that applying the device to the scaphal area of the patient's ear forces the ear to assume the conformation of an anatomically correct shaped ear. Ex. 1005 at 10; Ex. 1007 at ¶ 98. Specifically, Dancey teaches "a two-part pressure splint custom designed to fit over the ear and retract the upper pole into an acceptable position" to provide "a satisfactory cosmetic result, with an essentially normal-looking ear." Ex. 1005 at 10.

Dancey teaches element 9.2 of claim 9 of the '942 patent.

Accordingly, the combination of Dancey and Gault renders obvious each limitation recited in claim 9 of the '942 patent.

i) Motivation to Combine Dancey and Gault

A person of ordinary skill in the art would have known, at the time of the '942 patent, that there are a variety of nonsurgical techniques for splinting a deformed ear. Ex. 1007 at ¶¶ 13-21, 100. Dancey, published in 2005, provides one such technique that teaches all of the elements set forth in the challenged

claims of the '942 patent, as set forth above. Gault, published in 1997—some 8 years before Dancey—is another technique.

Both Dancey and Gault are 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. *In Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004) (finding a motivation to combine because the two references address the same problem); Ex. 1007 at ¶ 99. The earlier Gault reference serves to enlighten as to the state of the art at the time of Dancey's publication and includes further details on the background of the art and the terminology used by those skilled in the art.

A person skilled in the art would have been motivated to combine Dancey and Gault at the time of the '942 patent because both references are directed to the same purpose of providing nonsurgical splinting techniques for treating a deformed ear. Ex. 1007 at ¶ 99. "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, 1374 (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 '942 patent would have turned to earlier references such as Gault to better understand and interpret the treatment described in Dancey. *Id.*

2. Ground II: Claims 1 and 9 are Obvious Over Yotsuyanagi In View of Gault

a) Independent Claim 1

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

The preamble to claim 1 of the '942 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 Yotsuyanagi in view of Gault

because Yotsuyanagi, Gault, and claim 1 of the '942 patent all teach "a molding device for a human ear." Yotsuyanagi and Gault also include illustrations of the ear molding device secured to a human ear for shape correction. Ex. 1001 at Abstract; Ex. 1011 at Figures 2, 3, 4; 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. 1005 at 10; Ex. 1015 at 3; Ex. 1011 at 1013; Ex. 1007 at ¶ 107.

(2) Element 1.1: "one or more braces; and a scaphal mold supported by the one or more braces"

Element 1.1 is rendered obvious by Yotsuyanagi in view of Gault.

In the district court litigation where Patent Owner asserted the '942 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 '942 patent. Ex. 1007 at ¶ 108.

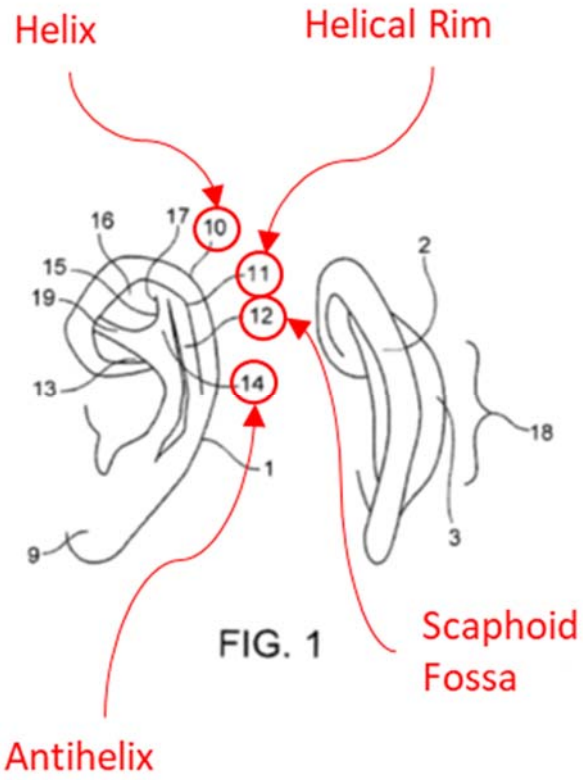
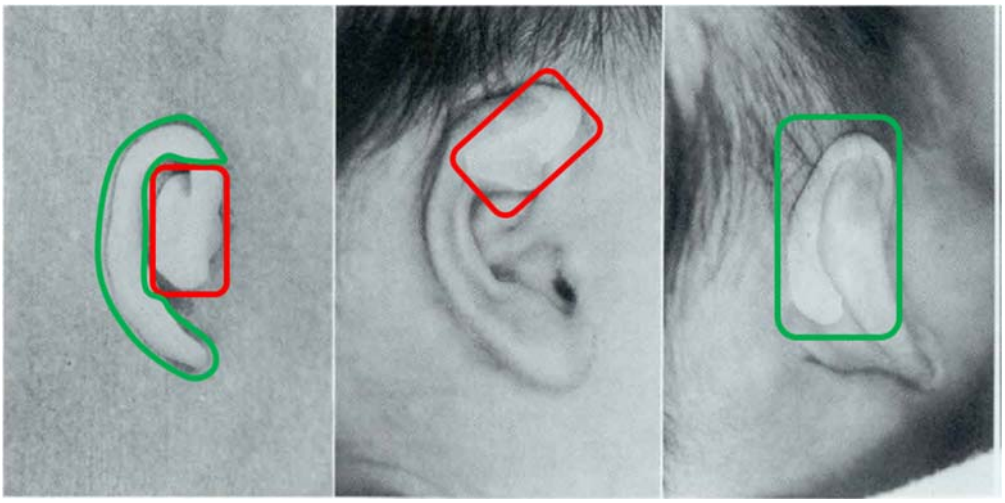


Figure 1 of the '942 Patent (annotated)

Yotsuyanagi teaches an ear molding device that is positioned in the scaphal area, as shown below. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶¶ 109-110.

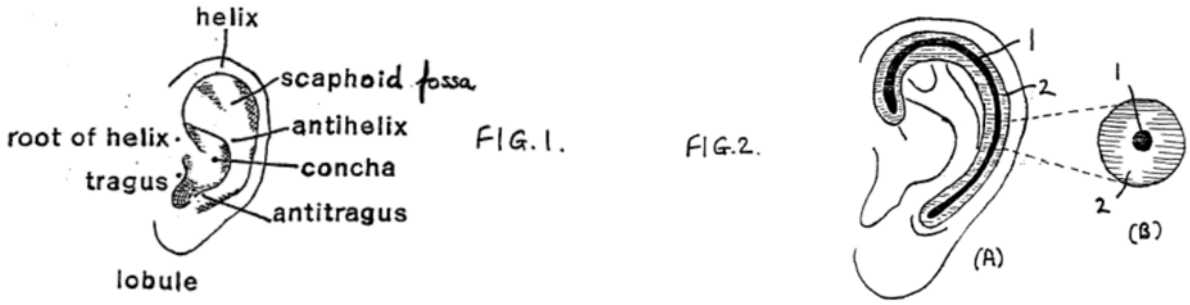


Figures 2, 3, and 4 of Yotsuyanagi (annotated)

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 '942 patent. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶¶ 109-110. The position of the scaphal mold in the Yotsuyanagi splint on the ear is identical to the placement of the scaphal mold in the '942 patent. Ex. 1011 at Figures 2, 3, 4; Ex. 1007 at ¶ 110. 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 ¶ 109.

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 ¶ 111 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 ¶¶ 109-112.

Yotsuyanagi in view of Gault therefore renders obvious each limitation of element 1.1 of claim 1 of the '942 patent.

(3) Element 1.2: "wherein the one or more braces and the scaphal mold are constructed to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and further constructed to maintain a substantially correct anatomical shape of the helix and the helical rim,"

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

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

2-6; Ex. 1007 at ¶¶ 113-114. Gault identifies the "helix (or helical rim) [as] the curved, prominent rim of the ear, which extends around its periphery." Ex. 1015 at 7.

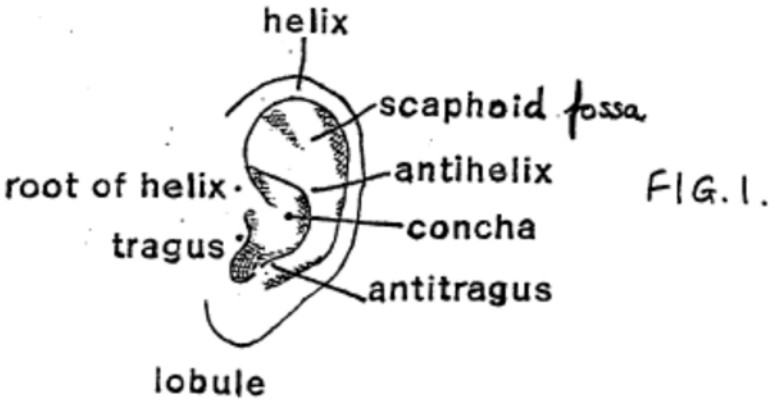
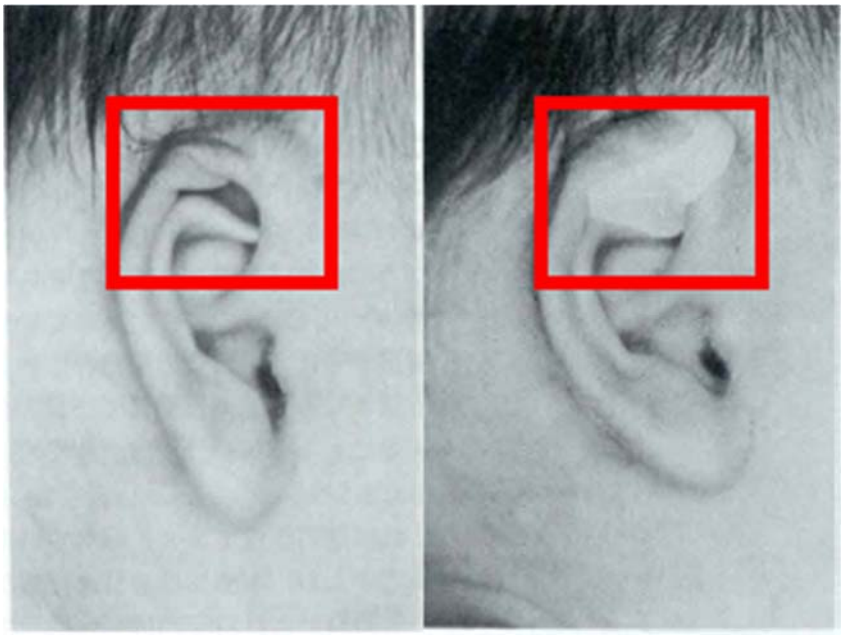


Figure 1 of Gault

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 3. 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 ¶¶ 113-115.

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, 3; Ex. 1007 at ¶¶ 113-115.



Figures 1 and 3 of Yotsuyanagi (annotated)

Yotsuyanagi discloses the brace and scaphal mold are constructed 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 of claim 1 of the '942 patent. Ex. 1007 at ¶¶ 113-115.

(4) Element 1.3: "wherein the scaphal mold and one or more braces are constructed to mold the helix and helical rim during their growth such that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces."

Element 1.3 is rendered obvious by Yotsuyanagi in view of Gault.

As discussed above, the Yotsuyanagi splint is a thermoplastic material that is wrapped around the ear, sandwiching it on both sides. Ex. 1007 at ¶¶ *See* Ex. 1012

at 3; Ex. 1011 at Figures 3, 6. Yotsuyanagi explains that "the deformed cartilage's correction conforms to the complex shape of the auricle as the splint is inserted throughout the auricle" and that the ear "get[s] to a normal shape over time." Ex. 1012 at 3; Ex. 1007 at ¶¶ 117-118. A person of ordinary skill in the art would have understood that the scaphal mold and brace in the Yotsuyanagi splint cover both the helix and helical rim. Ex. 1007 at ¶ 117. A person of ordinary skill in the art would have further understood that the ear would have grown to conform to the space between brace and scaphal mold after wearing the mold for the time period disclosed in Yotsuyanagi (treatment for 1-5 weeks, followed by 13-26 months monitoring). Ex. 1012 at 4 (Table 1); Ex. 1007 at ¶ 118. As discussed above, Gault identifies the structure of the helix and helical rim of the ear. Ex. 1015 at 3.

Yotsuyanagi in view of Gault therefore renders obvious each limitation of element 1.3 of claim 1 of the '942 patent.

Accordingly, the combination of Yotsuyanagi and Gault renders obvious each limitation recited in claim 1 of the '942 patent.

b) Dependent Claim 9

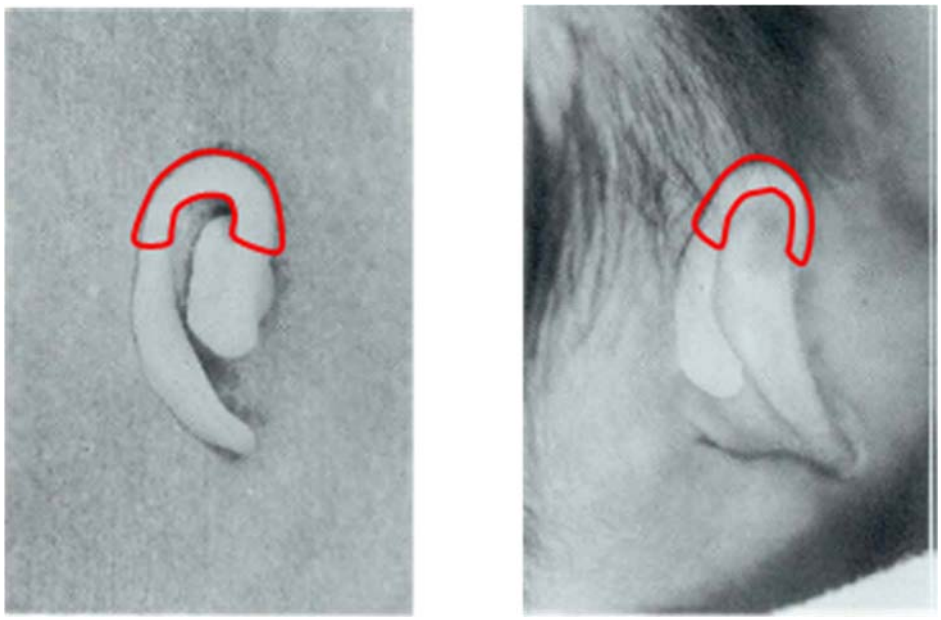
Claim 9 depends from claim 1, and adds two limitations: (1) the scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges," and (2) "the extension is constructed to maintain a substantially correct anatomical shape of the scaphal area of the ear."

Yotsuyanagi in view of Gault teaches both of these limitations and, thus, dependent claim 9 is rendered obvious by Yotsuyanagi in view of Gault.

Yotsuyanagi discloses a splint that is constructed to correct the shape of a malformed ear. Ex. 1011 at Figures 3, 6, 9; Ex. 1007 at ¶¶ 121-124. "[T]he deformed cartilage's correction conforms to the complex shape of the auricle as the splint is inserted throughout the auricle" Ex. 1012 at 3. 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 ¶ 122.

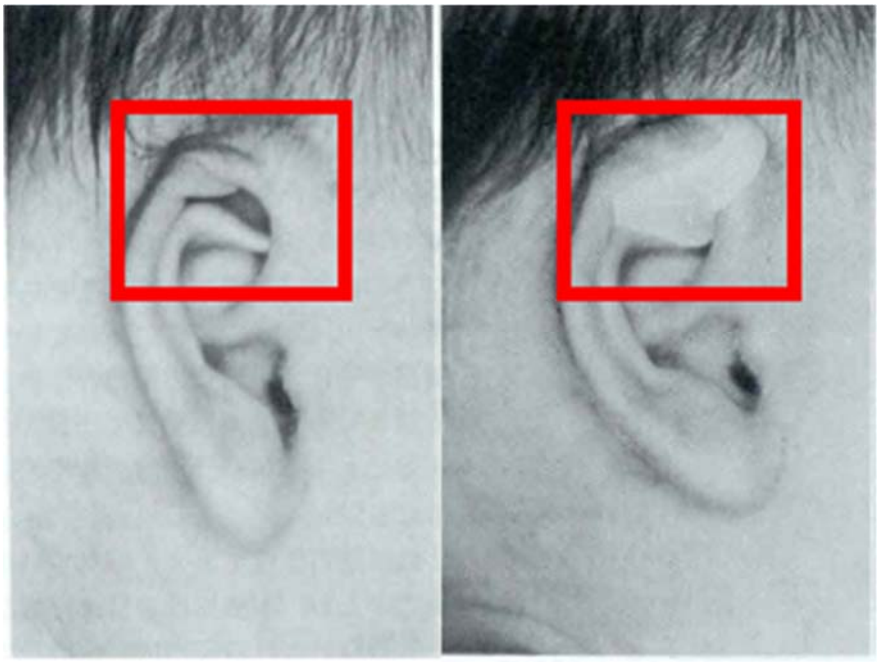
Figure 6 of Yotsuyanagi (annotated)

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 ¶ 123.



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 constructed to maintain the helix and helical rim in an anatomically correct shape. *See* Ex. 1012 at 3-8; Ex. 1007 at ¶¶ 121-124. 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 ¶¶ 115, 121-124.



Figures 1 and 3 of Yotsuyanagi (annotated)

Thus, Yotsuyanagi discloses a scaphal mold having an arc-shaped semi-cylindrical extension constructed 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 Yotsuyanagi and Gault renders obvious each limitation recited in claim 9 of the '942 patent. Ex. 1007 at ¶¶ 120-124.

c) Motivation to Combine Yotsuyanagi and Gault

A person of ordinary skill in the art would have known, at the time of the '942 patent, that there are a variety of nonsurgical techniques for splinting a deformed ear. Ex. 1007 at ¶¶ 13-21, 100. Yotsuyanagi, published in 1993, provides one such technique that teaches all of the elements set forth in the claims

1 and 9 of the '942 patent, as set forth above. Gault, published in 1997 is another technique.

Both Yotsuyanagi and Gault are 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. *In Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004) (finding a motivation to combine because the two references address the same problem); Ex. 1007 at ¶¶ 125. The earlier Gault reference serves to enlighten as to the state of the art at the time of the '942 patent and includes further details on the background of the art and the terminology used by those skilled in the art.

A person skilled in the art would have been motivated to combine Yotsuyanagi and Gault at the time of the '942 patent because both references are directed to the same purpose of providing nonsurgical splinting techniques for treating a deformed ear. Ex. 1007 at ¶¶ 125. Doctors working in the field of nonsurgical techniques for splinting deformed ears at the time of the '942 patent would have turned to earlier references such as Gault to better understand and interpret the treatment described in Yotsuyanagi.

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.

Dancey was not considered by the PTO during prosecution of the '942 Patent. The only prior art reference applied by the examiner was Godley, a reference that Applicants characterized as disclosing a "pressure dressing" and

distinguished over by amending the claims to modify the recited phrase "adapted to" to "constructed to." Dancey is therefore not cumulative to Godley.

Yotsuyanagi also was not considered by the PTO during prosecution of the '942 Patent. 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
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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 8,738 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.

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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.

Date of service:	October 9, 2019
Manner of service:	Priority Overnight Federal Express Mail
Documents served	Petition for *Inter Partes* Review Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104; Petitioner's Exhibit List; Exhibits 1001-1002, 1005, 1007-1009, 1011-1012, 1015-1024; and Power of Attorney
Persons Served	FISH & RICHARDSON P.C. P.O. Box 1022 Minneapolis, MN 55440-1022
Persons Served	Chief Executive Officer Becon Medical Limited 2307 Brinmore Court Naperville, Illinois 60540
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