

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

TALEXMEDICAL, LLC,
Appellant

v.

**BECON MEDICAL LIMITED, HENRY
STEPHENSON BYRD, M.D.,**
Cross-Appellants

2021-2069, 2021-2071, 2021-2109, 2021-2110

Appeals from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in Nos. IPR2020-
00028, IPR2020-00030.

Decided: July 22, 2022

ARTHUR ROBERT WEAVER, The Brickell IP Group,
PLLC, Miami, FL, argued for appellant. Also represented
by RICHARD GUERRA, JAVIER SOBRADO.

DAVID BOGDAN CUPAR, McDonald Hopkins LLC, Cleve-
land, OH, argued for cross-appellants. Also represented by
MATTHEW JOHN CAVANAGH; ERIN RACHAEL CONWAY,
NICHOLAS A. KURK, Chicago, IL.

Before LOURIE, SCHALL, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

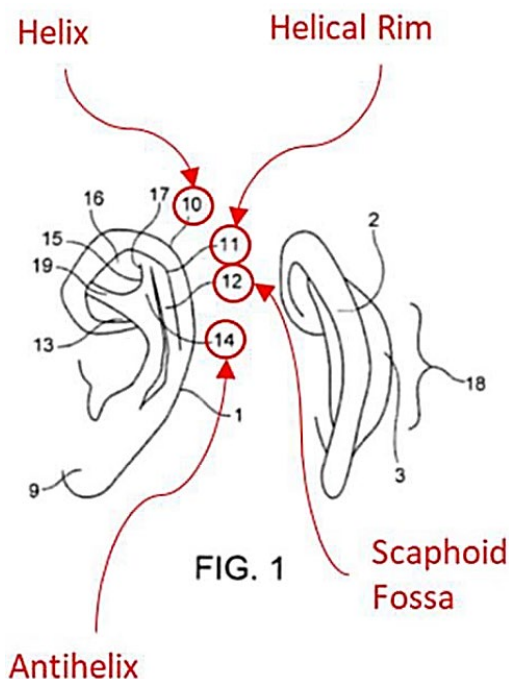
TalexMedical, LLC appeals from two decisions of the U.S. Patent and Trademark Office Patent Trial and Appeal Board (the “Board”) holding that claims 4–7 of U.S. Patent 8,167,942 (the “’942 patent”) and claim 16 of U.S. Patent 8,853,277 (the “’277 patent”) are not unpatentable as obvious. *See TalexMedical, LLC v. Becon Med. Ltd.*, IPR2020-00028, 2021 WL 1433251 (P.T.A.B. Apr. 15, 2021) (“’942 Decision”) and *TalexMedical, LLC v. Becon Med. Ltd.*, IPR2020-00030, 2021 WL 1433255 (P.T.A.B. Apr. 15, 2021) (“’277 Decision”).¹ Becon Medical Limited and Henry Stephenson Byrd (collectively, “Becon”) cross-appeal from the Board’s decisions holding that claims 1–3 and 9 of the ’942 patent and claims 1–2 and 9–10 of the ’277 patent would have been obvious over prior art. *See id.*

For the reasons provided below, we *affirm* the judgment of invalidity for claims 1–3 and 9 of the ’942 patent and claims 1–2 and 9–10 of the ’277 patent. We also *affirm* the judgment of no invalidity for claim 4 of the ’942 patent and claim 16 of the ’277 patent. We finally hold that the Board erred in its construction of the “reversibly engage” claim limitation, *vacate* the judgment of no invalidity for claims 5–7 of the ’942 patent, and *remand* for further proceedings consistent with this opinion.

¹ Because the ’942 Decision and the ’277 Decision address overlapping issues, all citations are to the ’942 Decision unless otherwise noted.

BACKGROUND

Becon owns the '942 and '277 patents, which describe “correcting misshaped ears using a molding device.”² '942 patent at Abstract. A molding device includes one or more braces and a scaphal mold. *Id.* Talex’s annotated version of Figure 1 of the '942 patent, below, depicts the relevant portions of an ear. *See '942 Decision*, 2021 WL 1433251, at *1.



The molding device interacts with the helix and the helical rim “to maintain a substantially correct anatomical shape of the helix and the helical rim,” '942 patent at Abstract, or “the scaphal area of the ear,” *id.* at col. 2 l. 67–col. 3 l. 2; *see also id.* at col. 6 ll. 37–41 (“the scaphal area

² Because the '942 and '277 patents share a substantially similar specification, all citations are to the '942 patent unless otherwise noted. *See '942 Decision*, 2021 WL 1433251, at *1.

12"). As shown in Figure 5, below, a molding device "is generally a semi-cylindrical extension from legs (or braces) 51 and 52 having rounded edges." *Id.* at col. 6 ll. 37–41. "[T]he inner curvature of the scaphal mold 55 facing the legs 51 and 52 cooperates with inner surface of legs 51 and 52 to form a space therewith configured to mold the helix and helical rim during their growth while in the ear molding device, such that the growth of the helix and helical rim conforms to a curvature defined by the space between the scaphal mold and the legs." *Id.* at col. 6 ll. 41–47.

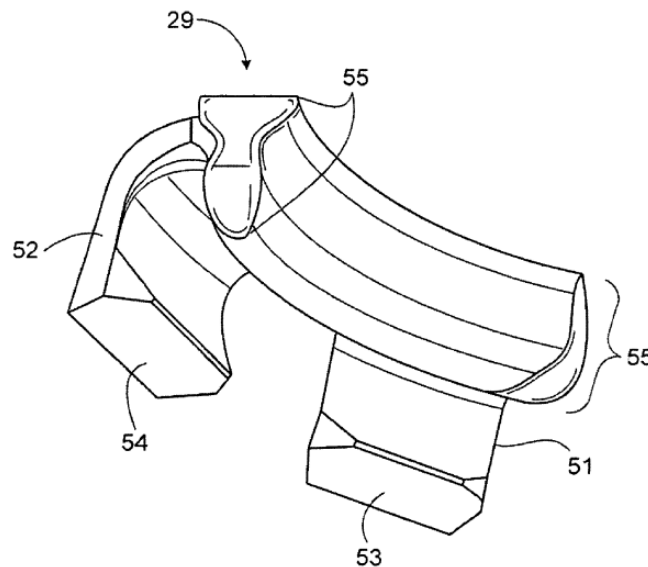


FIG. 5

The '942 patent claims a molding device for a human ear. Claim 1, the only independent claim at issue on appeal, recites:

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

one or more braces; and

a scaphal mold supported by the one or more braces, wherein the one or more braces and the scaphal mold are constructed to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and further constructed to maintain a substantially correct anatomical shape of the helix and the helical rim, wherein the scaphal mold and one or more braces are constructed to mold the helix and helical rim during their growth such that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces.

Id. at col. 10 ll. 19–34.

Claim 4 further requires that “a foot member positioned at an end of the brace distal to the scaphal mold” “includes a broad flat surface adapted for securing the ear molding device to a first surface.” *Id.* at col. 10 ll. 35–39; col. 10 ll. 43–45. Claims 5–7 recite that the “one or more braces includes a vertical support surface constructed to reversibly engage a second surface” and/or “a horizontal support surface constructed to reversibly engage a third surface.” *Id.* at col. 10 ll. 43–55.

The '277 patent claims a molding system for a human ear. The system includes a molding device and a cradle. The cradle includes a base section and a cover. '277 patent, col. 2 ll. 21–22. The molding device is configured to be positioned within the compartment defined by the cradle base and cover. *See id.* at col. 5 ll. 10–12; fig. 2. Claim 1, the only independent claim at issue on appeal, recites:

1. A molding system for a human ear, wherein the ear includes an antihelix, a superior limb of the triangular fossa, a helix, a helical rim, a base, a

concha, and a scaphal area, the molding system comprising:

a cradle comprising:

a base section defining an opening dimensioned to accommodate the passage of the ear through the opening, the base section including a posterior surface and an anterior surface;

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

an ear molding device comprising:

one or more braces; and

a scaphal mold supported by the one or more braces, wherein the one or more braces and the scaphal mold are adapted to retain the helix and helical rim within a space defined between the one or more braces and the scaphal mold, and to maintain a substantially correct anatomical shape of the helix and the helical rim.

Id. at col. 10 ll. 28–49.

Claim 9 of the '942 patent and claim 16 of the '277 patent further require that the “scaphal mold includes a generally arc-shaped semi-cylindrical extension from the one or more braces having rounded edges.” *Id.* at col. 12 ll. 12–16; '942 patent, col. 10 ll. 59–63.

Talex petitioned for *inter partes* review of claims 1–7 and 9 of the '942 patent and claims 1–2, 9–10, and 16 of the '277 patent. J.A. 544; J.A. 1065. Talex asserted that each of the challenged claims would have been obvious over a combination of prior art references including Dancey,³ Gault,⁴ and Yotsuyanagi.⁵ J.A. 544; J.A. 1065. After the petition was instituted, Becon filed a contingent motion to amend the '277 patent to add substitute claims 18–34 in the event the Board found original claims 1–17 unpatentable. J.A. 1261. The proposed substitute claims modified the claims to further specify that “the scaphal mold and one or more braces are constructed to mold the helix and helical rim during their growth such that the growth of the helix and helical rim conforms to the space between the scaphal mold and the one or more braces.” J.A. 1285. Talex opposed Becon’s motion to amend the claims and advanced similar obviousness arguments for the substitute claims. J.A. 1315.

Dancey discloses an acrylic ear splint for non-surgical treatment of cryptotia, a congenital deformity of the ear. Dancey’s device is a two-part pressure splint that is custom made to fit an ear and move the upper portion of the ear into an anatomically correct position. *See '942 Decision*, 2021 WL 1433251, at *6 (citing J.A. 1818–19). Gault discloses an ear splint with a wire core enclosed in a cover. *See id.* (citing J.A. 1978, 1980). Yotsuyanagi discloses thermoplastic splints that conform to the outside of an ear to

³ Anne Dancey, et al., *Acrylic Ear Splints for Treatment of Cryptotia*, 115 *Plastic and Reconstructive Surgery* 2150–52 (2005).

⁴ David Thomas Gault, GB 2304579 A, published Mar. 26, 1997.

⁵ Takatoshi Yotsuyanagi, et al., *Cryptotia Correction Using Thermoplastic Splint*, 36 *Plastic Surgery* 1037–42 (1993).

treat cryptotia. *See id.* at *15–16 (citing J.A. 1953, 1958–59).

Regarding the '942 patent, the Board held that claims 1–3 and 9 would have been obvious over Dancey and Gault and that claim 1 would have also been obvious over Yotsuyanagi and Gault. *Id.* at *20. Regarding the '277 patent, the Board held that claims 1–2 and 9–10 would have been obvious over two combinations of prior art, both combinations including Yotsuyanagi and Gault, but not Dancey. '277 *Decision*, 2021 WL 1433255, at *25–26. The Board also held that Talex failed to show that claims 4–7 of the '942 patent and claim 16 of the '277 patent would have been obvious.

Several additional aspects of the Board's decisions are particularly relevant to the parties' arguments on appeal. First, the Board declined Becon's request to construe "mold" and "molding device" to require reshaping an ear. The Board construed "scaphal mold" to mean "mold at the end of the one or more braces that is positionable in the scaphal area." '942 *Decision*, 2021 WL 1433251, at *3–5. The Board then found that Dancey and Yotsuyanagi each independently disclose an ear molding device as recited in the '942 patent claims and the '277 patent claims, respectively. *Id.* at *7; '277 *Decision*, 2021 WL 1433255, at *8. Next, the Board found that Dancey, but not Yotsuyanagi, discloses the "semi-cylindrical extension" limitation. '942 *Decision*, 2021 WL 1433251, at *11; '277 *Decision*, 2021 WL 1433255, at *9. The Board then found that Talex failed to show that Dancey's foot member includes a "broad flat surface." '942 *Decision*, 2021 WL 1433251, at *11. Additionally, the Board construed the "reversibly engage" limitation to mean "to engage a surface on a reverse side facing away from the ear." *Id.* at *12. Applying its construction, the Board found that Dancey fails to disclose that limitation. *Id.*

Furthermore, the Board concluded that Becon failed to establish that it was entitled to a nexus between secondary considerations and the asserted claims, or a presumption of a nexus, for any of the challenged claims. The Board explained that “[Becon’s] briefing and cited evidence lack sufficient specificity.” *Id.* at *14–15. The Board also determined that, even if Becon had established a nexus, the Board would have found the strength of the obviousness allegations greater than the indicia of nonobviousness (e.g., copying and industry praise). *Id.*

Finally, the Board denied Becon’s motion to amend the ’277 patent claims. ’277 *Decision*, 2021 WL 1433255, at *16. The Board determined that, even under Becon’s interpretation of the meaning of the substitute claims, Talex proved that Becon’s substitute claims would have been obvious. *Id.* at *22.

Talex appealed, and Becon cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board’s legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board’s factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Obviousness is a question of law that “lends itself to several basic factual inquiries,” including the scope and content of the prior art, the level of ordinary skill in the art, differences between the prior art and the claimed invention, and any relevant secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (citing *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 155 (1950)). “What the prior art teaches, whether a

person of ordinary skill in the art would have been motivated to combine references, and whether a reference teaches away from the claimed invention are questions of fact.” *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (first citing *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047–48 (Fed. Cir. 2016) (en banc), then citing *In re Mouttet*, 686 F.3d 1322, 1330 (Fed. Cir. 2012)).

A. Talex’s Appeal

Talex raises three arguments on appeal. Specifically, Talex argues that (1) the Board’s finding that Yotsuyanagi fails to disclose the “semi-cylindrical extension” limitation was unsupported by substantial evidence, (2) the Board’s finding that Dancey fails to disclose the “broad flat surface” limitation was unsupported by substantial evidence, and (3) the Board erred in construing the “reversibly engage” limitation. We address each argument in turn.

I. Semi-Cylindrical Extension

Claim 16 of the ’277 patent requires that the “scaphal mold includes a generally arc-shaped semi-cylindrical extension.” The Board determined that Talex failed to show that the portion of Yotsuyanagi’s device characterized as the “scaphal mold” is the portion that includes the claimed extension.

As noted above, what prior art teaches presents a question of fact that is reviewed for substantial evidence. *See, e.g., In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1332 (Fed. Cir. 2016). Talex argues that it demonstrated that Yotsuyanagi discloses the “semi-cylindrical extension” limitation. Talex accuses the Board of failing to consider an annotated version of Yotsuyanagi’s figure 6, in which Talex allegedly identified a “semi-cylindrical extension” as part of Yotsuyanagi’s scaphal mold. Becon counters that the Board correctly found that what Talex identified as the “semi-circular extension” overlaps with portions of the same structure that Talex relied on as the brace. Becon

also notes that Talex declined to clarify its argument in its reply before the Board.

We agree with Becon that the Board's determination was supported by substantial evidence. Some of Talex's annotated figures indeed identified an extension as part of Yotsuyanagi's brace. In view of Talex's conflicting annotations, the Board could not discern whether any portion of Yotsuyanagi's device identified as the claimed extension is part of the scaphal mold, and if so, whether any such portion can be considered semi-cylindrical. Talex did not use the opportunity to address its confusing annotations in its reply before the Board.

We disagree with Talex that the Board failed to consider Talex's annotated version of Yotsuyanagi's figure 6. As Becon points out, the Board cited this figure and the portions of Talex's expert's declaration that discuss the annotated version. *See '277 Decision*, 2021 WL 1433255, at *9 (citing J.A. 1953–54 (Yotsuyanagi's "Figs. 2–4, 6, 9"); J.A. 1908–09 (Talex's expert's declaration at ¶¶ 158–60)). In the declaration, an annotated version of "Figure 6" is incorrectly labeled as "Figure 3." *See* J.A. 1088 (displaying a correctly labeled version of annotated figure 6 in Talex's petition); *see also* J.A. 1953 (displaying the original versions of figures 3 and 6 in Yotsuyanagi). The Board did not fail to consider Talex's annotated version of figure 6 merely because this figure was mislabeled as figure 3 in Talex's expert's declaration. Furthermore, Talex's annotated version of figure 6 does not correct the inconsistencies in its argument concerning the "semi-cylindrical extension" limitation.

We therefore affirm the portion of the Board's decision holding that Talex failed to prove by a preponderance of the evidence that all of the limitations of claim 16 of the '277 patent are disclosed by the cited prior art.

II. Broad Flat Surface

Talex next argues that it demonstrated that Dancey discloses a foot with a “broad flat surface,” as required by claim 4 of the ’942 patent. Talex explains that Dancey’s foot is designed to press against a patient’s skin for at least a year, so a person of ordinary skill in the art would understand that the bottom of Dancey’s foot would necessarily be broad and flat to avoid injury. Becon counters that the Board correctly found that Talex failed to show that the portion of Dancey’s foot adjacent to the patient’s head is broad or flat. Instead, as the Board found, Dancey’s foot appears thin rather than broad and curved rather than flat.

We agree with Becon that the Board’s determination was supported by substantial evidence. The Board considered Talex’s argument and expert testimony but found it unpersuasive. *See ’942 Decision*, 2021 WL 1433251, at *11 (citing J.A. 1876–77 (Talex’s expert’s declaration at ¶¶ 77–79)). Becon provided opposing expert testimony on this issue. *See* J.A. 3404–06 (Khosla’s expert declaration at ¶¶ 200–03); *see also* J.A. 3611–13 (Daniali’s expert declaration at ¶¶ 201–04). Although the Board did not cite those sections of Becon’s declarations with reference to its determination regarding the “broad flat surface” limitation, the Board cited Becon’s Patent Owner Response, which expressly relied on these declarations in opposition to Talex’s argument. *See ’942 Decision*, 2021 WL 1433251, at *11 (citing J.A. 734). Furthermore, “this court has said on multiple occasions that failure to explicitly discuss every issue or every piece of evidence does not alone establish that the tribunal did not consider it.” *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1328 (Fed. Cir. 2017) (citations omitted).

We therefore affirm the portion of the Board’s decision holding that Talex failed to prove by a preponderance of the evidence that the structure it identifies as the foot member

includes a “broad flat surface,” as required by claim 4 of the ’942 patent.

III. Reversibly Engage

Talex argues that the Board erred in construing the “reversibly engage” limitation in claims 5–7 of the ’942 patent to mean “to engage a surface on a reverse side facing away from the ear.” See *’942 Decision*, 2021 WL 1433251, at *6.

A claim term is generally given its plain and ordinary meaning as understood by a skilled artisan. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). “To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Id.* (internal quotation marks omitted). Embodiments cannot limit the scope of the claims absent the patentee’s “words or expressions of manifest exclusion or restriction.” *Id.* at 1372 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)). We review claim construction *de novo* except for subsidiary factual findings based on extrinsic evidence, which we review for substantial evidence. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331–33 (2015).

Talex asserts that the proper meaning of the “reversibly engage” limitation is “to simply engage, or contact, to stabilize the device.” Appellant’s Opening Br. 31. Talex contends that the Board’s adopted construction is inconsistent with the ’942 patent’s specification and adds unnecessary structural limitations concerning a surface’s orientation relative to a patient’s ear. Becon counters by

pointing to embodiments in the '942 patent's specification that are covered by claims 5–7 when using the construction of the “reversibly engage” limitation adopted by the Board. Becon also argues that Talex's proposed construction impermissibly reads the term “reversibly” out of the claims.

We agree with Talex that the Board erred in adopting Becon's proposal when construing the “reversibly engage” limitation, but we do not adopt Talex's proposed construction. The Board correctly determined that “[Talex's] proposal fails to provide meaning to the term ‘reversibly’ by encompassing any engagement that stabilizes the device, which could include any engagement or contact with any other surface.” *See '942 Decision*, 2021 WL 1433251, at *6. The Board agreed with Becon's proposed construction because “it more accurately tracks the claim language and specification.” *See id.* By focusing solely on which of the parties' two proposed constructions “more clearly captures this form of engagement, and gives meaning to the term ‘reversibly,’” the Board failed to consider the possibility that both constructions are inconsistent with the intrinsic evidence. *See id.*

Neither Talex nor Becon offered the Board a plausible construction of the “reversibly engage” limitation. Although Talex now correctly asserts that “the specification considers ‘reversibly engage’ to be interchangeable ‘contact,’” Appellant's Opening Br. 31, Talex failed to propose a sufficiently narrow construction to the Board. This strategic choice led the Board down the wrong path.

The Board's construction improperly narrowed the scope of the claims by importing a directional limitation based on embodiments described in the specification. Absent limiting language, we do not import aspects from the written description into the claims. *See Hill-Rom*, 755 F.3d at 1372–73; *see also Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against

confining the claims to those embodiments.”). The Board did not rely on any limiting language from the intrinsic evidence in restricting a claimed surface’s orientation relative to an ear. Becon did not point to any evidence of disclaimer but instead merely argued that the claims, as construed, cover embodiments described in the specification.

The Board considered the following portions of the ’942 patent’s specification while evaluating the meaning of the “reversibly engage” limitation. *See ’942 Decision*, 2021 WL 1433251, at *6.

Horizontal support 63 and 64 have an outer surface that is configured to be contacted by the cradle cover 22 when the cover is engaged with the cradle base 21. The horizontal supports 63 and 64 can **reversibly engage or contact the cover when the cover is engaged with the cradle base**, and when the cover is removed from the cradle base the horizontal support structures **disengage** from the cover.

’942 patent, col. 7 ll. 57–63 (emphases added).

As discussed above, ear molding device 29 can also contact the cradle wall 34, if desired. Vertical supports 65 and 66 have an outer surface that is configured to be contacted by the cradle wall 34. When the outer surfaces of vertical supports 65 and 66 are placed in contact with the cradle wall 34, **adhesive strip 35 can be used to adhere the surfaces 65 and 66 to the cradle wall 34**, with or without the use of shims depending on the size of the ear being corrected.

Id. at col. 8 ll. 6–13 (emphasis added).

Consistent with the claim language, the ’942 patent’s specification describes the horizontal and vertical supports adapted to reversibly engage with respective surfaces. In

describing reversible engagement, the specification describes supports that engage and disengage. The specification explains that this engagement may be facilitated by the use of adhesive, which further implies disengagement as well as engagement. *See, e.g., id.* at col. 3 ll. 24–37. And, finally, there is the plain meaning of the word “reversibly,” which clearly implies a two-way direction for engagement.

We conclude that the meaning of the “reversibly engage” limitation is “interchangeably engage with and disengage from, to stabilize the device.” Accordingly, we vacate the Board’s construction of the “reversibly engage” limitation, vacate its judgment of no invalidity for claims 5–7 of the ’942 patent, and remand the ’942 *Decision* for the limited purpose of having the Board apply the correct claim construction.

B. Becon’s Cross-Appeal

Becon raises three arguments on cross-appeal. Becon argues that (1) the Board erred in construing the “mold” limitation in all of the claims at issue and the Board’s finding that Dancey and Yotsuyanagi each disclose the “mold” limitation was unsupported by substantial evidence, (2) the Board erred in weighing Becon’s secondary considerations evidence, and (3) the Board abused its discretion in denying Becon’s motion to amend. We address each argument in turn.

I. Mold / Molding Device

As indicated, all of the challenged claims include a “mold” and/or a “molding device.” Becon refers to these limitations together as “the claimed ‘mold’ term.” *See Cross-Appellants’ Opening Br.* 3. Becon first argues that the Board erred in construing the “mold” limitation. Becon argues that the intrinsic evidence demonstrates that the claimed “mold” requires reshaping. Becon also argues that the Board incorrectly found that Dancey and Yotsuyanagi each disclose the “mold” limitation.

Although the patent specifications describe reshaping by a molding device, the Board was correct in concluding that the “mold” limitation does not **require** reshaping. First, as the Board noted, the claims already include functional language. *'942 Decision*, 2021 WL 1433251, at *4. Additionally, the specifications describe embodiments in which a mold alone is not necessarily sufficient to reshape an ear. Some examples describe a mold used in combination with another component or multiple components to alter a portion of an ear. *See id.*

Becon argues that the Board’s findings regarding Dancey and Yotsuyanagi were unsupported because the findings were based on an incorrect construction of the “mold” limitation. Becon’s arguments regarding application of the “mold” limitation are thus limited to arguments based on Becon’s proposed construction. In view of our decision to affirm the Board’s construction of the “mold” limitation, we do not need to address Becon’s challenge to the Board’s application of the construction.

We therefore affirm the portions of the Board’s decisions declining to construe the “mold” limitation to require reshaping and finding that Dancey and Yotsuyanagi each teach the “mold” limitation.

II. Secondary Considerations

Becon argues that the Board erred in determining that Becon’s evidence of secondary considerations did not establish nonobviousness of the challenged claims of the ’942 and ’277 patents. Becon argues that (1) the Board incorrectly concluded that Becon was not entitled to a presumption of a nexus, (2) the Board incorrectly concluded that Becon did not demonstrate a long-felt but unresolved need, and (3) the Board failed to give proper weight to Becon’s evidence.

Secondary considerations, also referred to as objective indicia of non-obviousness, may be used to establish that

an invention appearing to have been obvious in light of the prior art was not. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983). Secondary considerations include commercial success enjoyed by embodiments of the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unmet need for the invention. *See Apple*, 839 F.3d at 1052–53; *see also Graham*, 383 U.S. at 17–18.

Evidence of objective indicia of nonobviousness must have a nexus to the claims, i.e., “there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). “The patentee bears the burden of showing that a nexus exists” *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999) (citing *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed. Cir. 1985)). “To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the claim scope.” *Henny Penny*, 938 F.3d at 1332. The presence of a nexus is a factual question that we review for substantial evidence. *See Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015).

“[A] patentee is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim if the patentee shows that the asserted evidence is tied to a specific product and that the product ‘is the invention disclosed and claimed.’” *Fox Factory v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (emphasis added) (quoting *Demaco*, 851 F.2d at 1392). The presumption applies “when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown &*

Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000)). “Conversely, ‘[w]hen the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process,’ the patentee is not entitled to a presumption of nexus.” *Fox Factory*, 944 F.3d at 1373 (quoting *Demaco*, 851 F.2d at 1392).

The Board determined that Becon failed to establish a nexus between purported objective indicia relating to its EarWell product and the challenged claims of the ’942 and ’277 patents. Specifically, it found that Becon failed to show that the EarWell product is the claimed invention. The Board explained that Becon relied on a presumption of nexus argument that assumed that the challenged claims cover the EarWell product. But the Board found that Becon provided no analysis of the claims with respect to the device. The Board also found that, in addition to failing to establish that the challenged claims cover the EarWell device, Becon did not address whether any of the claims are coextensive with the EarWell device. The Board noted that Becon’s arguments relating to copying, long-felt need, and praise by others did not go to show that those considerations applied to a patented device. Overall, the Board concluded that Becon failed to establish a nexus and hence failed to show that the objective indicia supported nonobviousness.

Becon argues that the Board improperly concluded that Becon was not entitled to a presumption of a nexus. Becon accuses the Board of ignoring sections of Becon’s expert declarations contending that Becon’s EarWell product embodies each of the challenged patent claims. *See* Cross-Appellants’ Opening Br. 70 (citing expert reports at J.A. 3323; J.A. 3338–44; J.A. 3529–30; J.A. 3546–51). Becon also argues that the Board ignored an annotated photo of the EarWell device. *See id.* at 72 (citing the Patent Owners’ Response at J.A. 1200). Becon finally argues that the

Board imposed a heightened burden on Becon by requiring a claim chart, a claim-by-claim analysis, or a limitation-by-limitation analysis.

Talex counters that the Board was correct in determining that Becon's threadbare evidence failed to meet its burden to demonstrate that it was entitled to a nexus. Talex argues that Becon relied on a sentence that "merely states that [Becon] believes [Talex's] device 'is a copy of the patented EarWell ear molding device that is recited in [the challenged claims].'" '942 *Decision*, 2021 WL 1433251, at *14. In response to Becon's arguments that the Board overlooked evidence, Talex points out that the Board cited and discussed Becon's expert declarations. Talex also contends that the Board did not ignore the annotated photo of the EarWell device. The Board instead stated that the photo "merely shows a labelled photo of the EarWell device in an effort to support [Talex's] copying allegation, without any assertion that the device shown is covered by the challenged claims." *Id.*

We conclude that the Board conducted a thorough review of Becon's evidence in search of substantive analysis concerning a potential nexus or presumption of a nexus. Contrary to Becon's allegations, the Board did consider Becon's expert declarations and the annotated photo from Becon's Patent Owners' Response. *See id.* Notably, the labeled photo of the EarWell device lacks mention of several claim limitations that are at issue on appeal and also appears to be attorney argument. Becon essentially disagrees with the Board's characterization of its evidence but fails to show that the Board committed reversible error.

Furthermore, the Board did not impose an improperly heightened burden on Becon. The Board noted that Becon did not provide a claim-by-claim or limitation-by-limitation analysis, but this was not error. The Board did not improperly require that Becon's evidence be presented in a particular format. *See id.* (stating that the "Patent Owner also

cites to its Patent Owner Response for support . . . **without any assertion** that the device shown is covered by the challenged claims, **much less** any claim-by-claim or limitation-by-limitation analysis.” (emphases added)).

We have held that a nexus between asserted objective indicia relating to a product and the claims of a patent is needed to ensure that these indicia truly correspond to what is claimed rather than to something else. *See, e.g., Henny Penny*, 938 F.3d at 1332–33. Thus, objective indicia relating to a multi-component product are not necessarily attributed to a smaller portion of the product that is the subject of the claims. And objective indicia relating to a product consisting of components that are not part of asserted claims do not necessarily show that what is patented is non-obvious. Arguments asserting nexus therefore must connect the indicia with the claims. It is that connection that the Board here found inadequate. Industry praise and copying may indicate non-obviousness when connected to the claims, but not when they do not.

These are findings of fact that we are not free to ignore, unless they are clearly erroneous, and we do not consider that they are here. The Board used terms such as “no analysis,” lack of “limitation-by-limitation analysis,” and lack of “sufficient specificity.” *’942 Decision*, 2021 WL 1433251, at *14. Moreover, the Board found that, even if a nexus had been established, the strength of the prior art in light of the breadth of claim 1 overcame the objective indicia. *Id.* at *15. That is because one might envision a spectrum balancing objective indicia and the prior art. If the indicia are especially strong, they might overwhelm close prior art, as what might have seemed to be obvious at the time of an invention may be shown by indicia not to have been obvious. Similarly, weak, ambiguous, or debatable indicia may be found not to overcome strong prior art. Again, such determinations are for the Board to make, and we do not find their conclusions here to be reversible. Ultimately, the

question is whether what is claimed has been shown to be not obvious over the prior art.

We therefore affirm the Board's conclusion that the asserted objective indicia do not support a conclusion of non-obviousness for lack of nexus. Given our affirmance of the Board's finding that Becon failed to demonstrate a nexus, we need not review the Board's evaluation of other objective indicia of nonobviousness.

III. Motion to Amend

We finally consider whether the Board erred in denying Becon's motion to amend. As discussed above, the substitute claims would have added the following new limitation: "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." The Board stated that this additional limitation imposes a requirement that "specific structure" be "constructed to' perform certain functions." *'277 Decision*, 2021 WL 1433255, at *19.

The Board found that Yotsuyanagi discloses the additional limitation recited in substitute claim 18 because "Yotsuyanagi seeks to mold the helix and helical rim during their growth by changing the shape of the ear" and "discloses successfully treating patients by altering and improving the shape of the helix." *Id.* at *22–23. The Board also found Talex's arguments and evidence on this issue more credible than Becon's. The Board thus determined that granting the motion to amend would not have rendered the claims allowable.

Becon argues for patentability of the substitute claims by referencing its arguments regarding its construction proposal for the "mold" term. Becon explains that if this court determines that "mold the helix and helical rim" distinguishes the substitute claims from the prior art, the

substitute claims should be found patentable and the Board's denial of its motion should be reversed. Talex counters that the Board correctly determined that Yotsuyanagi discloses reshaping of the helix and helical rim.

We agree with Talex that the Board fairly weighed the parties' evidence regarding Yotsuyanagi's teachings. Granting a motion to amend is a matter within the Board's discretion, and substantial evidence supports the Board's determination that Yotsuyanagi discloses the limitation added by the substitute claims. The Board cited statements from Yotsuyanagi that describe correcting the shape of a helix. The Board also cited three clinical cases discussed in Yotsuyanagi that resulted in reshaped patient ears. *Id.* at *22–23. Since substantial evidence supported the Board's finding, the Board did not abuse its discretion in denying Becon's motion to amend. Accordingly, we affirm the Board's determinations regarding Becon's motion to amend.

CONCLUSION

We have considered the parties' remaining arguments, but we find them unpersuasive. We *affirm* the Board's determination that claims 1–3 and 9 of the '942 patent and claims 1–2 and 9–10 of the '277 patent were shown to be unpatentable. We also *affirm* the Board's determination that claim 4 of the '942 patent and claim 16 of the '277 patent were not shown to be unpatentable. We *vacate* the Board's determination that claims 5–7 of the '942 patent were not shown to be unpatentable and *remand* for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

No costs.