Paper 11 Date: June 1, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC., Petitioner, v. OSTEOMED LLC, Patent Owner. IPR2022-00189 Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SNEDDEN, Administrative Patent Judge.

DECISION
Granting Institution of *Inter Partes* Review 35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

A. Background and Summary

Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claim 16 of U.S. Patent No. 8,529,608 B2 ("the '608 patent," Ex. 1001). Paper 2 ("Pet."). OsteoMed LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that claim 16 of the '608 patent is unpatentable.

B. Real Parties in Interest

Petitioner Stryker Corporation and Patent Owner OsteoMed LLC each asserts it alone is the real party in interest. Pet. 1; Paper 5, 1.

C. Related Matters

Petitioner has filed petitions for *inter partes* review in IPR2021-01451, IPR2021-01452, and IPR2021-01453 for related U.S. Patent Nos. 9,351,776; 9,763,716; and 10,245,085. Pet. 1–2; Paper 5, 1–2. The parties indicate that the '608 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed*

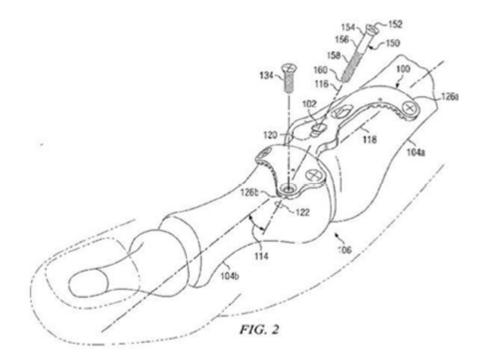
LLC v. Wright Medical Technology, Inc., Case No. 1:20-cv-1621 (D. Del.). Id. Petitioner has also filed a petition for inter partes review in IPR2021-01450 for the '608 patent challenging claims 1–6, 8–14, and 17. Pet. 2; Paper 5, 2. Patent Owner also indicates as related matters, IPR2022-00190 and IPR2022-00191 for U.S. Patent Nos. 9,351,776 and 9,763,716. Paper 5, 2.

D. The '608 patent (Ex. 1001)

The '608 patent discloses a "system for securing bones together across a joint." Ex. 1001, Abst. The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:12–16.

The '608 patent discloses that its system has "the ability to tightly couple the bones of a joint together" by including a transfixation screw that is inserted across the joint through a bone plate. *Id.* at 2:22–26. More specifically, the '608 patent discloses that the presence of the transfixation screw across the joint "may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion." *Id.* at 2:38–41. According to the '608 patent, by having the transfixation screw passing from the first bone to the second bone, a "tension band" construct is created "that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint," thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:45–52.

Figure 2, reproduced below, shows "a bone plate being used in conjunction with a transfixation screw to repair the failed metatarsophalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:1–6.



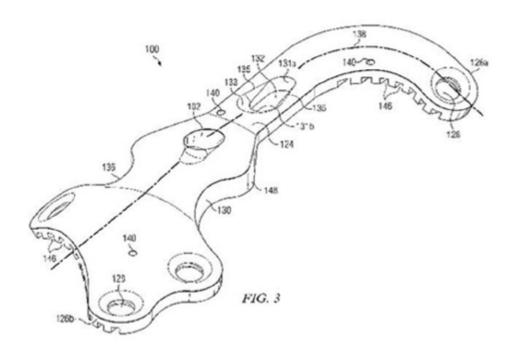


Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id.* at 4:3–8. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id.* at 4:19–25. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id.* at 7:18–26. First end 126 includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id.* The '608 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id.* at 8:2–9.

Bone plate 100 "may further include flared hips 148 adjacent to transfixation screw hole 102" in which the flared hips "may generally be defined by a widened section of bone plate 100." *Id.* at 9:64–66. Flared hips 148 "may include two generally parabolic wings extending laterally from spine 124, symmetrically opposed to one another about transfixation screw hole 102." *Id.* at 10:1–4. The '608 patent discloses that flared hips 148 helps a surgeon "precisely position the entry point for transfixation screw 150 onto a desired location on bone 104a . . . by positioning the widest portion of hips 148 directly adjacent to the desired location for transfixation screw 150 on bone 104a" so that "the surgeon may confidently position the entry point for transfixation screw 150 at the desired location, even when the entry point is out of sight." *Id.* at 10:13–23. Further, flared hips 148 "may also increase the strength of bone plate 100 around transfixation screw hole 102, lessening the chance of plate deformation or breakage." *Id.* at 10:23–25.

E. The Sole Challenged Claim

Dependent claim 16 is the only challenged claim of the '608 patent in this proceeding. Claim 16 depends from independent claim 11. Claims 11 and 16 are reproduced below.

- 11. [11.P] A plate for securing two discrete bones together across an intermediate joint, comprising:
 - [11.1] an elongate spine having:
 - a first end comprising:
 - at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and
 - a first inner surface configured to substantially con form with a geometry of the first bone;

[11.2] a second end comprising:

- at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and
- a second inner surface configured to substantially conform with a geometry of the second bone; and
- [11.3] a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and
- [11.4] a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge,
- [11.5] wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends.
- 16. [16.1] The plate of claim 11, further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate, [16.2] the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole.

Ex. 1001, 13:4–14:2, 14:20–25 (adding Petitioner's labels in brackets); Pet. 11–12.

F. Evidence

Petitioner relies upon information that includes the following.

Ex. 1005, Slater, WO 2007/131287 A1, published Nov. 22, 2007 ("Slater").

Ex. 1006, Falkner, Jr., U.S. 2005/0171544 A1, published Aug. 4, 2005 ("Falkner").

Ex. 1010, Duncan et al., U.S. 2009/0228048 A1, published Sept. 10, 2009 ("Duncan").

Petitioner also relies upon the Declaration of Dr. Kenneth A. Gall (Ex. 1002) to support its contentions.

G. Asserted Ground of Unpatentability

Petitioner asserts that claim 16 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	16	102	Slater
2	16	103	Falkner, Duncan

H. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id*.

Petitioner states that it has "applied the ordinary and customary meaning of each claim term throughout the Petition in light of the '608 patent specification and file history" in which the "claim term 'flared hips' from claim 16 means 'a widened section of the bone plate." Pet. 13 (citing Ex. 1001, 9:66–67). Patent Owner does not take issue with Petitioner's position. Prelim. Resp. 4. Having considered the parties' positions and evidence of record, we determine that no express construction of any claim

term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

I. Level of Ordinary Skill in the Art

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Petitioner proposes that a person of ordinary skill in the art ("POSA" or "POSITA") at the time of the invention

would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon.

Pet. 12 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner's proposal about the POSA's qualifications. Prelim. Resp. 4.

For this Decision, we adopt and apply Petitioner's proposal for the POSA level, which does not appear to be inconsistent with the level of skill reflected in the asserted prior art.

II. ANALYSIS

A. Introduction

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015). Moreover, a petitioner should not "place the burden on [the Board] to sift through information presented by the Petitioners, determine where each element [of the challenged claims] is found in [the cited references], and identify any differences between the claimed subject matter and the teachings of [the cited references.]" Google Inc. v. EveryMD.com LLC, IPR2014-00347, Paper 9 at 25 (PTAB May 22, 2014).

Anticipation is a question of fact, as is the question of what a prior art reference teaches. *In re NTP, Inc.*, 654 F.3d 1279, 1297 (Fed. Cir. 2011). "Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Whether a reference anticipates a claim is assessed from the skilled artisan's perspective. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329

F.3d 1358, 1368 (Fed. Cir. 2003) ("[T]he dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching that every claim element was disclosed in that single reference." (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991))).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

The obviousness inquiry also typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). A petitioner cannot prove obviousness with "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Rather, a petitioner must articulate a sufficient reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of success at trial.

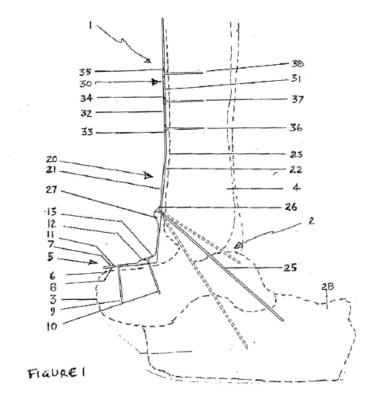
¹ Patent Owner does not present any objective evidence of nonobviousness (i.e., secondary considerations) for the challenged claims.

B. Summary of Cited Prior Art

1. Slater (Ex. 1005)

Slater is an international patent application published on November 22, 2007. Ex. 1005, code (43). Slater relates to "prosthetic devices and more particularly relates to an ankle fusion plate for fusion of the anterior ankle." *Id.* at 2:6–7.²

Figure 1 of Slater, reproduced below, shows a side elevation of an example plate attached via fixation screws to an abbreviated ankle joint.



Id. at Fig. 1. Slater's Figure 1, above, shows plate (1) attached to an ankle joint (2) opposing the talus bone (3) and the tibial bone (4). *Id.* at 12:2–4. Figure 1 depicts plate (1) having inner (22) and outer (21) surfaces, with

² These page number citations in Slater are to the page numbers added to the exhibit copy, and the applicable line numbers on those pages. For other asserted prior art, however, we may cite to the numbered paragraphs within the reference, or to the column and line numbers.

inner surface (22) opposing the anterior surface (23) of the tibia (4). *Id.* at 12:18–19. Portion (30) of the plate includes openings (33, 34, 35) for receiving fastening screws (36, 37, 38), which engage tibia (4). *Id.* at 12:28–31. Portion (5) of the plate has inner (8) and outer (7) surfaces that oppose surface (6) of the talus bone (3) for fixation thereto by screws (9, 10), which pass through openings (11, 12) and into the talus. *Id.* at 12:5–10.

In addition, portion (20) of Figure 1's plate resides between portions (5) and (30), and includes opening (26) in formation (27), for receiving fixation screw (25). *Id.* at 12:18–22. According to Slater, "[f]ormation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range . . . preferably within a 40 degree arc." *Id.* at 12:21–23; *see also id.* at Fig. 2 (front elevation view of plate 1, showing another view of plate portions (20, 30), openings (33, 34, 35) and formation (27) relative to the underlying anterior tibia (4) and talus (3) to which the plate is attached).

Slater discloses that "[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment." *Id.* at 12:23–25. Continuing, Slater teaches that, "[a]s may be seen in figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis," and "[t]his is also necessary to achieve maximal compression of the fusion site/s." *Id.* at 13:3–5.

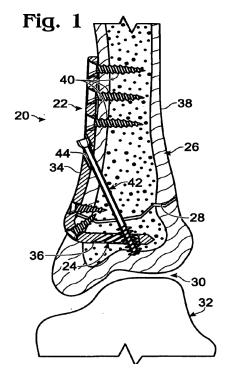
In summarizing features of its invention, Slater discloses that the plate's depth may change at different locations and "[p]referably, the depth at the beginning arid [sic, and] end points of the L shaped contour over the ankle joint . . . will be at it's [sic] maximum thickness." *Id.* at 9:31–34; see

also id. at 10:3–6 ("The plate will taper at at least one but preferably two different points of the plate . . . [and] [t]he desired effect is for the plate to taper in and decrease in thickness proximally."). Slater further teaches that the plate "will preferably resemble and conform to the typical geometry of the anatomical region. . . . Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint." *Id.* at 10:11–15.

2. Falkner (Ex. 1006)

Falkner is a U.S. patent application that published August 4, 2005. Ex. 1006, code (43). Falkner relates to systems for fixing bones using bone plates having toothed apertures for retaining fasteners. *Id.* ¶ 7.

Falkner's Figure 1, reproduced below, is a cross-sectional view of an example bone plate including a toothed aperture with the plate secured to a fractured bone. *Id.* \P 8.



Id. at Fig. 1. Falkner's Figure 1 shows bone plate (22) with toothed aperture (24) attached to the tibia (26) and spanning fracture (28). *Id.* ¶ 21. As

illustrated, external plate portion (34) is secured to the tibia with a suitable fastener, such as bone screw (40), and internal plate portion (36) is disposed substantially interior to the tibia. *Id.* ¶¶ 23–24. The internal plate portion (36) defines a toothed aperture (24) configured to receive threaded fastener or screw (42) inserted through opening (44). *Id.* ¶ 24. According to Falkner, "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region . . . into/through the aperture applies a tension to the plate." *Id.* ¶ 71; *see also id.* at Fig. 2 (showing a more detailed view of toothed aperture (24)).

Although the above embodiment is shown attached to a single bone and spanning a fracture in that bone, Falkner discloses that a plate may be used to span other bone discontinuities—including discontinuities between more than one bone. *Id.* ¶¶ 27–28 (disclosing that discontinuities include fractures (breaks in bones) and joints). Falkner discloses that "[i]n other examples, plate 22 may span a joint, such as a joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21.

Falkner teaches that the inner and outer surfaces of a bone plate "may be generally complementary in contour to the bone surface." *Id.* ¶ 34. Moreover, Falkner discloses, "[t]he thickness of the plates may vary between plates and/or within plates, according to the intended use." *Id.* ¶ 35.

3. Duncan (Ex. 1010)

Duncan is a U.S. patent application filed March 9, 2009, which published on September 10, 2009. Ex. 1010, codes (22), (43). Duncan relates to a joint fixation system (i.e., plate), especially for the joints of the hand. *Id.* at Abstr. Figure 2 of Duncan is reproduced below.

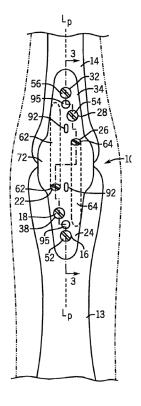


FIG. 2

Id. at Fig. 2. Figure 2, above, is an antero-posterior view of fixation system (10) secured to the proximal interphalangeal joint of a finger. Id. \P 32.

As shown above, Duncan teaches a joint fixation plate that is widened at an intermediate section (72). Id. ¶ 45. This intermediate section is located between the plate's proximal section (24) and distal section (34), and is designed such that screws (64, 62) do not interfere with each other when the screws are inserted, respectively, into proximal phalanx (13) and intermediate phalanx (14). Id.

C. Ground 1: Anticipation by Slater

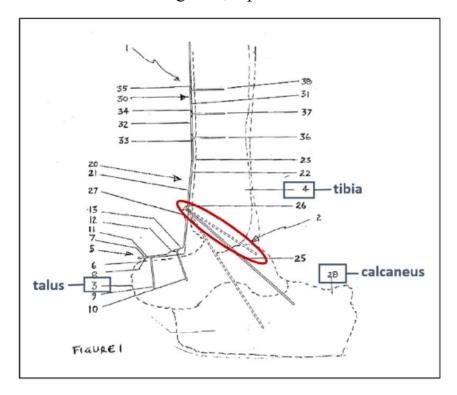
1. Parties' Contentions

Petitioner contends that claim 16 is anticipated by Slater. Pet. 18–30. Petitioner begins with its analysis of independent claim 11 (*id.* at 18–28),

and then addresses the limitations added by dependent claim 16 (*id.* at 28–30).

Our discussion begins with Petitioner's contentions on claims 11 and 16, and then move to our analysis, which addresses Patent Owner's counterarguments.

Petitioner argues that, if claim 11's preamble is limiting, Slater discloses a plate for securing two discrete bones together across an intermediate joint between the bones. Pet. 18–19. Petitioner provides an annotated version of Slater's Figure 1, reproduced below.

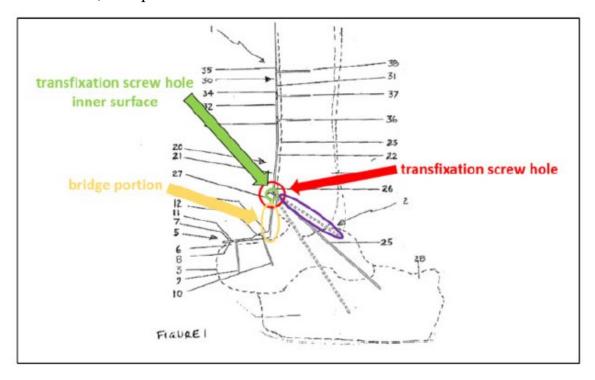


Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* Petitioner contends that Figure 1 shows an embodiment where the fusion plate is secured to three discrete bones (tibia, talus, and calcaneus) across two joints between those bones, and also an embodiment where the plate is secured to only two bones

(tibia and talus) across one joint between those bones—the latter evidenced by the screw path in the red oval noted above. *Id.* Petitioner supports this interpretation of Slater with Dr. Gall's testimony. Ex. 1002 ¶ 89.

Petitioner further contends that Slater discloses claim 11's elongate spine and first and second ends, as well as a bridge portion between the ends as claimed (labeled by Petitioner as claim limitations 11.1, 11.2, and 11.3). Pet. 21–26 (citing Ex. 1002 ¶¶ 90–96). Petitioner contends that those limitations are disclosed in, for example, Slater's Figure 1 and the features depicted therein. *Id.* Patent Owner does not, at this stage, contest that Slater discloses a bone plate with those recited features meeting the corresponding limitations of claim 11. *See generally* Prelim. Resp. 7–16.

Petitioner also contends that Slater discloses claim 11's recited transfixation screw hole and related functionality, labeled limitation 11.4 by Petitioner. Pet. 24–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



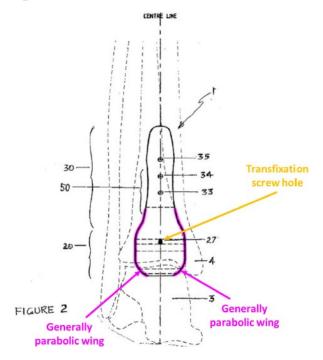
Id. at 26. Petitioner's annotation to Figure 1, above, identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). Id. (citing Ex. $1002 \, \P \, 98$). According to Petitioner, "Figure 1 shows three separate exemplary angles for the transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." Id. at 25-26; Ex. 1005, Fig. 1.

According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the talus through the screw into the screw head and plate's bridge portion as claimed. Pet. 26–27. Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* at 27. Petitioner cites Dr. Gall's testimony to support this understanding of Slater's plate and its functionality when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 99).

Petitioner next addresses claim 11's recitation of "wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends," which Petitioner labels as limitation 11.5. Pet. 27–28. With reference to Figures 5 and 7 of Slater, Petitioner contends that discloses limitation 11.5. *Id.* (citing Ex. 1005, Figs. 5, 7; Ex. 1002 ¶100). In particular, Petitioner contends that

"the first and second ends of the Slater bone plate are tapered[, and a]s such, both the bridge portion and the portions of the plate surrounding the transfixation screw hole are thicker than "at least a portion of" the tapered ends." *Id.* (citing (Ex. 1005, 8:25–26, 8:32–9:6, 14:19–23, 24:17–19).

Altogether, Petitioner argues that Slater discloses every limitation of claim 11, and Petitioner then turns to dependent claim 16. Pet. 28–30. According to Petitioner, Slater also describes a bone plate with flared hips comprising two generally parabolic wings as claimed (labeled limitations 16.1 and 16.2 by Petitioner). *Id.* Petitioner provides an annotated version of Slater's Figure 2, reproduced below.



Id. at 30. Figure 2, above, is a front elevation view of Slater's plate (the plate as otherwise depicted in a side elevation in Figure 1) and shows the plate oriented for placement on the underlying tibia (4) and talus (3); Petitioner's annotation shows "Generally parabolic wing[s]" (labeled with purple arrows and highlighting) on the lower left and right sides of the plate, extending laterally on opposite sides of the transfixation screw hole

(indicated by yellow arrow). *Id.*; Ex. 1002 ¶ 106. Patent Owner does not presently dispute that Slater discloses a plate with flared hips comprising generally parabolic wings as claimed. Prelim. Resp. 16–17.

2. Discussion

Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claim 16 is anticipated by Slater. We discuss below.

Petitioner argues, with documentary and testimonial support, that Slater's Figure 1 describes a bone plate with an elongate spine having respective first and second ends with respective fixation points for attaching the plate to two bones (tibia and talus) across an intermediate joint. Pet. 18–19; Ex. 1002 ¶¶ 89 (identifying corresponding features on Slater's plate). Petitioner also supports its position that Slater's plate includes ends with inner surfaces configured to substantially conform to the geometry of the first and second discrete bones to which those ends are attached. Pet. 19–24. Based on the present record, we also agree that Slater describes a bridge portion and transfixation screw hole that are thickened relative to end portions of the plate. *Id.* at 24–27 (*see, e.g.*, Ex. 1005; Figs. 1, 6, 7); Ex. 1002 ¶¶ 114, 118. Patent Owner does not dispute that Slater teaches those limitations (labeled elements 11.1, 11.2, 11.3, and 11.5).

Although Patent Owner questions the level of detail in Slater, Patent Owner does not dispute that Slater describes a transfixation screw hole and a transfixation screw disposed at an angle through that hole to engage either two or three bones of the ankle, crossing either one or two joints between the bones. *See* Prelim. Resp. 8–10 (highlighting an "alternative two-bone embodiment" in Patent Owner's annotated version of Slater, Fig. 1). Patent

Owner, nevertheless, argues that Slater does not disclose claim 11's preamble (a "plate for securing two discrete bones together across an intermediate joint"),³ or the alleged "transferring the tensile load" limitation. *Id.* at 10–16. For reasons discussed below, Patent Owner's arguments do not avoid institution on this record.

Patent Owner argues that Slater fails to disclose a single embodiment that meets all the limitations of claim 11. *Id.* at 8–10. More specifically, Patent Owner contends that Petitioner is picking features from "alternative" embodiments in Slater to combine and modify to arrive at the claimed subject matter. Id. Patent Owner contends that "Slater fails to describe th[e] alternative [two-bone] embodiment in detail, only briefly acknowledging that it may be an option" and, thus, Petitioner is allegedly "forced to rely on expert testimony to fill the gaps regarding how the three-bone embodiment would be modified for a two bone application." *Id.* at 9; see also id. at 11 ("Dr. Gall relies on one embodiment securing three bones . . . and another distinct embodiment of Slater using a different screw configuration for securing two bones across a single joint."), 12 (asserting that "only three [disclosures in Slater] refer to using the plate across fewer than two joints, and the reference to such a plate is only made in passing as a mere alternative"). Accordingly, Patent Owner argues that at least claim 11's preamble is not disclosed in Slater. *Id.* at 11–13.

We disagree on this record that Petitioner is improperly picking from and combining unrelated disclosures in Slater to arrive at the claimed subject

³ We need not decide whether the preamble is limiting at this stage because a plate for securing two bones across an intermediate joint is disclosed in Slater. Moreover, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.

matter. It is prohibited, when anticipation is the issue, to pick and choose from "various disclosures not directly related to each other by the teachings of the cited reference." In re Arkley, 455 F.2d 586, 587 (CCPA 1972) (emphasis added). But here, the disclosures of Slater relied upon by Petitioner are sufficiently related to each other as evidenced by at least Figure 1 itself, and related written description in Slater. The two-bone embodiment appears to be an "alternate" embodiment only insofar as it reflects another angled pathway for the screw so it anchors in a second and not a third bone. This is not wholly distinct, however, from the three-bone embodiment. Both the two-bone and three-bone embodiments are depicted as alternatives within the plate of Figure 1 itself. Thus, Figure 1, with the two-bone pathway, is arranged in a manner that meets the preamble of claim 1, and we are persuaded on this record that a POSA would understand Slater that way. Indeed, the fact that related text in Slater about Figure 1 indicates that one or multiple joints may be fused supports Petitioner's and Dr. Gall's interpretation of Slater. See, e.g., Ex. 1005, 13:3-5 ("As may be seen from figure 1, the screws are placed in a particular orientation and required angle to the *joint/s* required for arthrodesis.") (emphasis added).

Patent Owner criticizes Dr. Gall's analysis "of a single cursory embodiment" on whether Slater discloses a plate for securing two bones across a single joint. Prelim. Resp. 11. That criticism is, however, unavailing because "[e]xpert testimony may shed light on what a skilled artisan would reasonably understand or infer from a prior art reference." *Acoustic Tech., Inc. v. Itron Networked Solutions, Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). Patent Owner also points out that Slater's disclosure mostly concerns securing three bones across two joints, and that Slater

purportedly teaches that adding "more joints" in the fusion is advantageous. Prelim. Resp. 12 (citing, e.g., Ex. 1005, 16:28–30). Even if that aptly characterizes Slater's disclosure, that does not negate anticipation. Unpreferred—even disfavored—embodiments may still anticipate a claim. Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998) ("A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it."). We recognize counsel's argument that "Dr. Gall's opinion of Slater does not represent a fair reading" of the reference, yet Patent Owner provides no testimonial evidence to support a competing interpretation of Slater. Prelim. Resp. 12. Nor does Patent Owner provide argument or evidence that Slater fails to enable the two-bone embodiment that Patent Owner admits is disclosed in Slater. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003) (noting a "presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled"); In re Antor Media Corp., 689 F.3d 1282, 1288 (Fed. Cir. 2012) (extending presumption to prior art printed publications).⁴

Patent Owner also argues that Slater does not disclose claim 11's "transferring the tensile load" limitation. Prelim. Resp. 13. As a threshold matter, claim 11 is for a bone "plate" and the specific phrase "transferring the tensile load" does not appear in the claim. Nor is a "transfixation screw" required structure in claim 11. *Compare* Ex. 1001, claim 11, *with id.* at 12:23–32 (claim 1, reciting a "system" and affirmatively requiring a "transfixation screw" among other structural features). The "transfixation

⁴ Although *Antor Media* addressed the presumption in the context of patent examination, the Federal Circuit has since held that it applies equally to AIA trial proceedings. *Apple, Inc. v. Corephotonics, Ltd.*, 861 F. App'x 443, 449–50 (Fed. Cir. 2021).

screw" and "tensile load" language, to the extent recited in claim 11, appears in a longer claim phrase about how the structurally-required "transfixation screw hole" is configured:

a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge.

Id. at 13:21–31. The question, thus, would seem to be whether Slater's plate and its transfixation screw hole includes an inner surface configured to direct a hypothetical transfixation screw to enable and permit the functionality about tensile load absorption and transfer. It is not otherwise apparent that the recitation about a transfixation screw and tensile load impart any specific structural requirements within claim 11. Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device is, not what a device does." (emphasis omitted)).

In any event, Patent Owner argues that Dr. Gall's testimony on this portion of claim 11 is conclusory and should be disregarded. Prelim. Resp. 13–14. Patent Owner contends that Dr. Gall improperly relies on the three-bone embodiment where the screw extends through the tibia and talus before finally anchoring in the calcaneus, with no adequate explanation how anchoring in the calcaneus would shift tensile load from the talus (or the second bone) to the screw head and plate. *Id.* at 15 (arguing there are "no threads in the second bone" in Slater's three-bone embodiment). Moreover, Patent Owner argues, the "loading" that Dr. Gall is describing is "not the

type of tensile load" in claim 11, which allegedly relates to the biomechanics of the joint during normal activity, not the forces upon insertion. *Id.* at 15–16 (citing, e.g., Ex. 1001, 5:41–46, 560–6:3).

Whether Slater's bone plate ultimately satisfies limitation 11.4, including the "tensile load" language, is best resolved on a full record through trial. At present, however, Petitioner provides evidence comprising at least Dr. Gall's testimony that a skilled artisan would understand limitation 11.4 as met with Slater's plate where the screw is angled through the screw hole to cross a joint's neutral bending axis and anchors, not in the calcaneus, but in the talus as shown in the two-bone embodiment as discussed above. While Dr. Gall supports his opinion by relying, in part, on Slater's disclosure about a screw and threaded shank anchoring in the calcaneus (heel bone), Patent Owner provides no evidence to undermine Dr. Gall's opinion that, where only the tibia and talus are involved (as also shown in Figure 1), a POSA would recognize that the threads of the screw will engage the talus—securing the second bone (talus) to the plate via the screw with the tibia held between. Ex. 1002 ¶¶ 98–99. We do not agree with Patent Owner that Dr. Gall's opinion is so lacking in reasoning or support that the Petition should be denied as a result.

Insofar as Patent Owner contends there is a difference between the "loading" addressed by Dr. Gall and a "transfer of tensile load" as recited in claim 11, this too is a subject best resolved on a full record. From the '608 patent, it appears a transfer of tensile load depends at least somewhat on the biomechanics of the foot (or other hinge-type joint) when the joint is subjected to conditions in which it would flex. *See, e.g.*, Ex. 1001, 5:36–52. On the other hand, the patent explains, a "tension band' construct" that

permits load to be transferred arises when the plate is attached and the fixation screw crosses the joint's neutral bending axis (which axis separates a tension and compression side of the joint) and anchors in a second bone. See id. at 5:53–57 ("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 . . . a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes."). This "tension-band" construct in the '608 patent, thus, appears consistent with how Slater's plate would work when fixed to the tibia and talus in the manner identified by Petitioner.

3. Conclusion

Although Patent Owner may ultimately prevail at trial based on a fully-developed record, on the present evidence, we find that Petitioner has shown to a reasonable likelihood that Slater discloses the plate of claim 11. At this stage, Petitioner also shows, and Patent Owner does not dispute, that Slater describes a plate with "flared hips" comprising opposing "generally parabolic wings" as recited in dependent claim 16. Pet. 28–30; Ex. 1005, Fig. 5; Ex. 1002 ¶ 106; Prelim. Resp. 16–17. We, thus, find that Petitioner is reasonably likely to prevail in establishing that Slater discloses all the limitations of, and anticipates, claim 16.

D. Ground 2: Obviousness over Falkner and Duncan

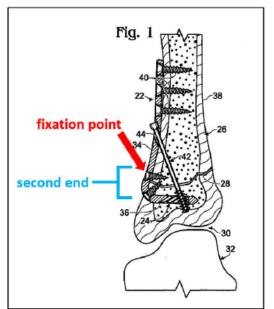
Petitioner contends that dependent claim 16 would have been obvious over the combination of Falkner and Duncan. Pet. 30–45. As with Ground 1, Petitioner begins with an analysis of independent claim 11 before moving to the challenged dependent claim 16. *Id*.

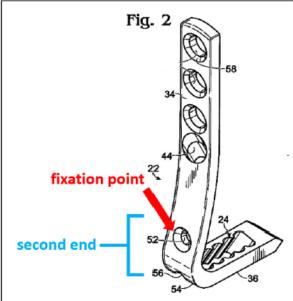
Petitioner contends that Faulkner discloses the preamble and every other element of claim 11. *Id.* at 30. According to Petitioner, although

Falkner's Figure 1 shows a plate for fixing a single fractured bone, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. Ex. $1006 \, \P \, 21, \, 28$. Petitioner cites Falkner's disclosure that, "[i]n other examples, plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21 (emphasis omitted).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across the joint 30 and bone screws 40 may be placed into the first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 32 (citing Ex. 1002 ¶ 111). Also, Petitioner argues, "the first inner surface [of the plate] would be configured to substantially conform with a geometry of the first bone (tibia 26)." *Id.* at 33 (citing Ex. 1006 ¶¶ 23, 34 (disclosures in Falkner that one or multiple surfaces of the bone plate may be contoured to follow the exterior surface of a bone or bones, which helps to provide a low profile to the plate); Ex. 1002 ¶ 112). According to Petitioner, this configuration would meet element 11.1 of claim 11. *Id.* at 31–33.

For claim 11's "second end" limitations (labeled element 11.2 by Petitioner), Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as reproduced below.

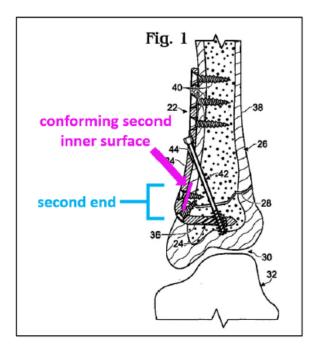




Pet. 34 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which bracketed segment Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia 26 and talus 32 . . . the plate 22 would be placed across the joint 30 . . . and a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 34–35 (citing Ex. 1002 ¶ 113). Referencing

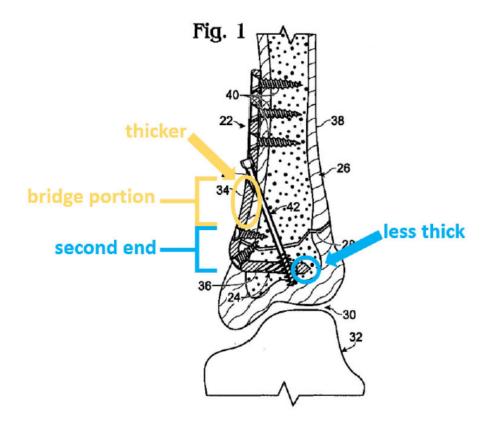
another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second bone (talus 32)." *Id.* at 35 (citing Ex. 1002 ¶ 114).



Id. at 35; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here Petitioner annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 35. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. Id.

Turning to claim 11's bridge portion and the requirement that a portion of the bridge and transfixation screw hole have a depth (thickness) greater than a portion of the first and second ends (elements 11.3 and 11.5),

Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 38–39, 42. This annotated figure is reproduced below.



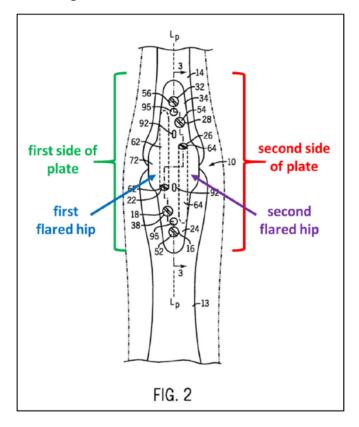
Id. at 42; Ex. 1006, Fig. 1. This annotated version of Figure 1, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 42. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" is "thicker." Id. This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as being "less thick," which Petitioner highlights with a blue circle, arrow, and text. Id.

Petitioner argues that, "[a]s can be seen in Figure 1, at least a portion of the bridge portion and the transfixation screw hole (44) has a thickness greater than at least a portion of the first and second ends." *Id.* at 39. According to Petitioner, the alleged "second end" is "thinner at the end" to aid insertion into the bone and becomes thicker toward the bridge to add stability. *Id.* (citing Ex. $1006 \, \P \, 35$).

For element 11.4, Petitioner identifies Falkner's Figures 1 and 2. As shown in those figures, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Id. at 37-38. According to Petitioner, Falkner's oblique opening is a "transfixation screw hole" as claimed, and, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener (i.e., screw) would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* In that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred through the screw and into the bridge portion. *Id.* at 38 (citing Ex. 1002) ¶ 119). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." *Id.* (quoting Ex. $1006 \, \P \, 71$).

Having cited disclosure in Falkner that allegedly meets all the limitations of claim 11, Petitioner moves to claim 16 and the recited "flared hip[s]." *Id.* at 40–45. Petitioner cites Duncan's Figure 2, reproduced below

with Petitioner's annotations, as teaching the flared hips comprising generally parabolic wings as recited in claim 16.



Id. at 41 (citing Ex. 1016, Fig. 2). Duncan's Figure 2, above, depicts a bone plate (10) attached to two bones (13 and 14) of a finger; Petitioner's annotation highlights the alleged first and second sides of the plate with, respectively, green and red brackets. Id. at 41–42. Petitioner identifies, with blue and purple arrows, the alleged first and second flared hips of the plate on the respective first and second sides of the plate. Id. (citing Ex. 1002 ¶ 125 (testimony that the hips are symmetrically opposed as parabolic wings)).

Petitioner contends it would have been obvious to modify Falkner's plate to include the symmetrically flared hips of Duncan. *Id.* at 42–43. According to Petitioner, a POSA would understand that bone plates can be

strengthened by making certain portions thicker and wider to counteract higher stress that occurs in those portions. *Id.* (citing Ex. $1002 \, \P \, 127$). Petitioner alleges that a POSA would understand that including an angled screw hole, such as Falkner's oblique opening (44), results in more plate material being hollowed out such that the plate may require additional strength in those areas. *Id.* at 43 (Ex. 1002 ¶ 128). Petitioner argues that, in addition to thickening the area around the angled screw hole, a POSA would understand that widening the plate around the screw hole will provide added support, and that the need for such support would have motivated a POSA to include flared hips on the plate, such as disclosed in Duncan, particularly if Falkner's plate is designed for use on the medial side of the ankle. *Id.* at 43– 44 (citing Ex. 1002 ¶¶ 129–130). Petitioner further contends that a parabolic shape to the hips around the screw hole would help surgeons properly position the plate over the joint. *Id.* at 44 (citing Ex. 1002 ¶ 131). Petitioner argues these changes would have been made with a reasonable expectation of success, predictably adding strength to the plate and adding visual cues to help position the strongest part of the plate over the joint. *Id.*

Patent Owner does not contest that the combination of Falkner and Duncan teaches or suggests a bone plate with the flared hips of claim 16, nor does Patent Owner challenge Petitioner's reasoning for combining Falkner and Duncan. *See generally* Prelim. Resp. 17–30.⁵ Patent Owner does,

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⁵ We disagree with Patent Owner's contention that "the Petition strictly relies on Duncan as an anticipatory reference that discloses every element of dependent claim 16." Prelim. Resp. 17. Although the Petition does cite Duncan's teachings relevant to the flared hips limitations of claim 16, Petitioner advances an obviousness rationale based on the modification of Falkner in view of Duncan's teachings as discussed above.

however, raise multiple counterarguments to Petitioner's Ground 2. *Id.* We discuss below.

Patent Owner argues that Ground 2 "is treated as an anticipation challenge" with respect to the underlying analysis of independent claim 11 from which challenged claim 16 depends. *Id.* at 18. According to Patent Owner, "Falkner therefore must . . . disclose each and every element of claim 11, arranged as in the claim." *Id.*

There is some basis for Patent Owner's argument. In the related and recently-instituted proceeding, Petitioner expressly challenged claim 11 as anticipated by Falkner. IPR2021-01450, Paper 6 at 24–33 (addressing Petitioner's anticipation arguments and noting the absence of a challenge based on obviousness over Falkner alone). Now, Petitioner cites approvingly to its filing in that related proceeding as allegedly supporting its challenge here. Pet. 30 ("As an initial matter and as shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1450, Falkner discloses every element of Claim 11 of the 608 patent"). Moreover, to the extent Petitioner's challenge purports to modify Falkner's single-bone embodiment (e.g., as shown in Figures 1 and 2) by citing various other teachings in Falkner, we see minimal analysis that explains why the POSA would have been motivated to make those modifications with a reasonable expectation of success to arrive at claim 11's subject matter. Even when only one reference is involved, the mere fact that each claim limitation might be found in such reference's disclosure does not necessarily prove

⁶ To be clear, however, Petitioner is not permitted to incorporate-by-reference its argument from a separate proceeding, even if related. 37 C.F.R. § 42.6(a)(3).

obviousness without analysis that explains why the skilled artisan would have combined those teachings to arrive at the claimed subject matter. *In re Stepan Co.*, 868 F.3d 1342, 1345–46 n.1 (Fed. Cir. 2017) ("Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, *there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful*, otherwise a skilled artisan would not arrive at the claimed combination.") (emphasis added).

Patent Owner also argues that "Falkner is entirely focused on a bone plate for fixing a bone fracture (i.e., a break in a single bone)" and "there is no disclosure in Falkner explaining how spanning a joint would be achieved or when such an application would be desired." Prelim. Resp. 19. Patent Owner contends that Falkner does not disclose a single embodiment that meets all the limitations of claim 11, so Petitioner and Dr. Gall "rel[y] on a smattering of paragraphs" to stretch Falkner's single-bone embodiment to explain how Falkner's plate would have been configured in a different context to reach the claimed subject matter. *Id.* at 21–22.

Patent Owner contends that Falkner's cited plate does not include a second end with an inner surface configured to substantially conform with a geometry of a second bone as claimed. *Id.* at 25–28. According to Patent Owner, what Petitioner identifies as the "second end" of Falkner's plate is not, in fact, a "second end." *Id.* at 25 ("The end of the plate is [as] described and claimed, not some portion before the end."). To the contrary, Patent Owner argues that the "second end of the plate of Falkner is *inside* the bone, and does not conform to the geometry of the second bone" and further, that

this internal end portion includes an aperture for receiving the threaded fastener so modifying its geometry to conform to a second bone would run counter to the design and purpose of Falkner's plate. *Id.* at 27–28.

Patent Owner also contends that Falkner fails to disclose "transferring the tensile load" as allegedly recited in claim 11. *Id.* at 22–25. Patent Owner contends that Dr. Gall fails to appreciate differences between compressive forces (as allegedly recited in Falkner's ¶ 71) and tensile forces, and that, because Falkner's screw is not being anchored in the second bone but instead in a second (internal) portion of the plate, Dr. Gall's opinion that Falkner's plate transfers tensile forces is "contrary to the actual disclosures in Falkner regarding the Falkner screw that is designed to be anchored in the end of the second end of the plate in order to provide tension between the two ends of the plate." *Id.* at 24 (citing Ex. 1006 ¶ 6 ("An 'interlocking' bone screw has been used to secure the blade portion, when inside bone, to an end region of a fractured bone. The interlocking screw may span the anchor and blade portions (and the fracture) to 'interlock' and tension these portions.")).

Based on the present record, we are doubtful that Petitioner will prevail on Ground 2. Falkner's cited plate in Figures 1 and 2 is not arranged as claimed. Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second discrete bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured would seemingly require redesign or modifications. Those might

be simple design changes for a POSA based on their knowledge and Falkner's overall teachings. Petitioner's obviousness analysis on claim 11 is, however, wanting for detail as noted above (e.g. minimal explanation why the POSA would have modified the Falkner plate with a reasonable expectation of success).

Falkner does disclose that its plates may be designed to traverse a joint between bones, including the ankle joint. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. Yet there is a dearth of detail about such a hypothetical plate's design. On this record, making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, span a joint between the tibia and talus would likely require the POSA to make distinct design choices beyond what is exemplified in Falkner.⁷ Even then, it is not a foregone conclusion that all claim 11's limitations would be met (e.g., thicker bridge and screw hole portions relative to the first and second ends), and Petitioner provides minimal argument and evidentiary support to explain why all the claimed features would be included. Petitioner argues, for example, that Falkner's Figure 1 shows a portion of a transfixation screw hole that has a thickness greater than a portion of the plate's first and second ends. Pet. 38–40. Neither the identified bridge portion nor screw hole itself appears to have a thickness greater than the plate's first end—claim 11 recites that the

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⁷ If we read Petitioner's analysis as essentially an anticipation theory, we are mindful that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) ("It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.")).

thickness be greater than a portion of the first and second ends.⁸ Petitioner briefly remarks that Falkner "contemplates reducing the [plate] thickness of the bone plate to minimize irritation of soft tissue in regions such as the 'first end' of the plate." *Id.* at 39 (citing Ex. 1006 ¶¶ 32, 35; Ex. 1002 ¶ 120). But, on this record, whether Falkner's cited disclosures teach or suggest that the plate's first end, in particular, should be made thinner than the bridge and screw hole portions lacks clarity; and Petitioner does very little to explain why a POSA would have been motivated to decrease the thickness at that specific part of the plate.

The parties' dispute about what is or is not a "second end" in Falkner may turn on claim construction, for which the parties have provided no briefing. Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that portion as a "second end." Id. at 39. Yet, when wanting to show that the second end of the plate is thinner than portions of the bridge and transfixation screw hole, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id*. On this record, Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency.

Petitioner relies on Duncan principally for its teaching related to the "flared hips" feature (elements 16.1/16.2) of the challenged claim. *Id.* at 40– 44. It is not apparent at present that Petitioner's reliance on Duncan and

⁸ By comparison, claim 1 of the '608 patent recites that a portion of the bridge has "a thickness greater than at least a portion of the thickness of either the first end or the second end." Ex. 1001, 12:42–46.

reasoning for adding the flared hips remedies the concerns noted above with Petitioner's threshold showing on the subject matter recited in claim 11.

For at least the above reasons, we are skeptical that Petitioner will prevail in establishing that claim 16 would have been obvious over Falkner and Duncan. If we institute, we must nevertheless include all grounds. *SAS*, 138 S. Ct. at 1359–60.

III. CONCLUSION

Petitioner has, at this stage, established a reasonable likelihood of prevailing in showing that at least one of the challenged claims is unpatentable. This determination is, however, based on a preliminary record. We will make a final determination on the patentability of the challenged claims, as necessary and applying the preponderance of the evidence standard, based on a fully developed record through trial. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting in the context of an *inter partes* review that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

Any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. *See In re NuVasive*, 842 F.3d at 1380–81 (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response). In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board's Rules.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a) an *inter partes* review of claim 16 of the '608 patent is hereby instituted on the grounds set forth in the Petition, commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial will be conducted in accordance with a separately issued Scheduling Order.

IPR2022-00189 Patent 8,529,608 B2

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