

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.

IPR2021-01452
Patent 9,763,716 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and
JAMIE T. WISZ, *Administrative Patent Judges*.

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, “Petitioner”) and OsteoMed LLC (“Patent Owner”). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–6, 8–13, and 16–19 (“Challenged Claims”) of U.S. Patent No. 9,763,716 B2 (“the ’716 patent,” Ex. 1001) are unpatentable.

A. Background and Summary

Petitioner filed a Petition to institute *inter partes* review of claims 1–6, 8–13, and 16–19 of the ’716 patent. Paper 2 (“Pet.” or “Petition”). Patent Owner filed a Preliminary Response. Paper 5.

Following institution, Patent Owner filed a Response to the Petition (Paper 23, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 27, “Reply”), and Patent Owner filed a Sur-Reply (Paper 33, “Sur-Reply”).

On December 15, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 42.

B. Related Matters

The Petition identifies three other patents as related to the ’716 patent. Pet. 2. Those patents are: U.S. Patent No. 8,529,608 (“the ’608 patent”); U.S. Patent No. 9,351,776 (“the ’776 patent”); and U.S. Patent No. 10,245,085 (“the ’085 patent”). *Id.* The ’608 and ’776 patents issued on grandparent

and parent applications, respectively, to the '716 patent, and the '085 patent issued on a child application to the '716 patent. Ex. 1001, code (63); IPR2021-01453 (Exhibit 1001, code (63)).

The four related patents are asserted in two pending lawsuits. Pet. 1–2; Paper 3, 1. Those lawsuits are: *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.); and *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-01621 (D. Del.). *Id.*

In addition to this IPR proceeding, other claims of the '716 patent and the related patents are challenged in other matters before the Board. Those matters include: IPR2021-01450 and IPR2022-00189 (challenging claims of the '608 patent); IPR2021-01451 and IPR2022-00190 (challenging claims of the '776 patent); IPR2021-01453 (challenging claims of the '085 patent); and IPR2022-00191 (challenging claims of the '716 patent). Pet. 2.

C. The '716 Patent

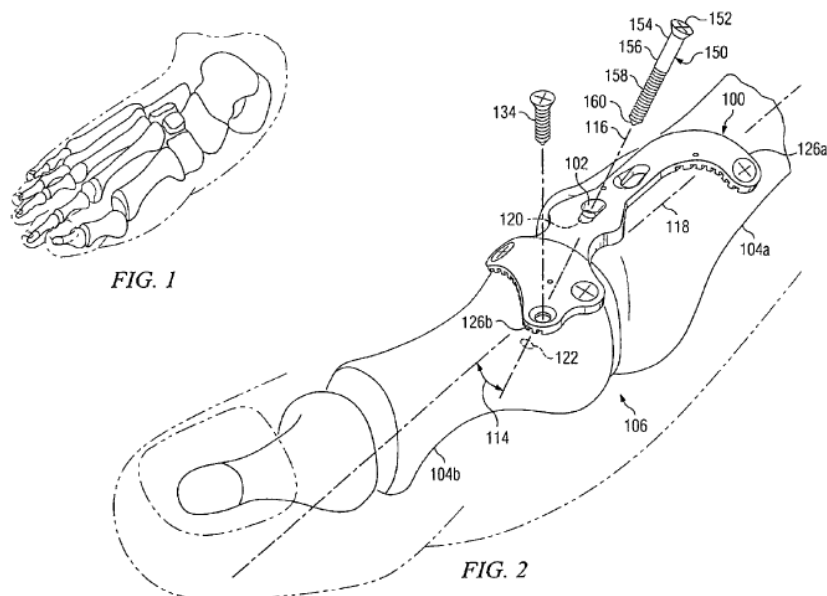
The '716 patent issued September 19, 2017, from an application filed May 5, 2016. Ex. 1001, codes (45), (22). The '716 patent claims the priority benefit of an application filed April 28, 2009. *Id.* at 1:7–13.

As background, the '716 patent explains, when reconstructing a damaged joint, “a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint,” and “[o]ne way to achieve this objective is to attach the bones of the joint to a plate that holds the bones together in alignment with one another while they fuse together.” *Id.* at 1:24–31.

The '716 patent relates to “a device for securing bones together, and more particularly, to a bone plate with a transfixation screw hole.” *Id.* at 1:18–20. The '716 patent describes a plate that includes, *inter alia*, an

elongate spine with first and second ends having attachment points for securing the plate to first and second bones on, respectively, first and second sides of a joint between the bones. *Id.* at 1:39–45. The plate’s spine also includes a “bridge portion” configured to span the joint, and a “transfixation screw hole disposed along the spine.” *Id.* at 1:45–49. The transfixation screw hole may be configured to direct a transfixation screw such that the screw extends alongside the bridge at a trajectory that passes through a first position on a first bone and a second position on a second bone when the plate is placed across a joint. *Id.* at 1:49–55.

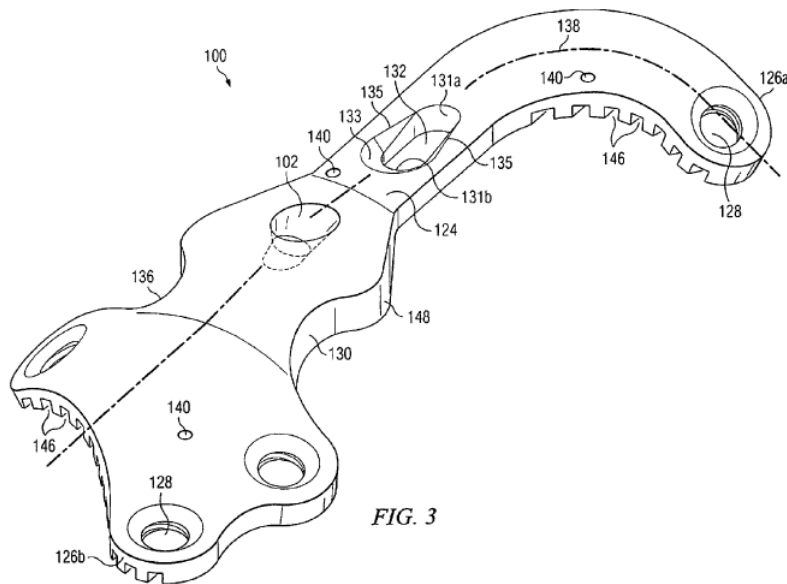
Figures 1 and 2 of the ’716 patent, reproduced below, illustrate various features of an exemplary bone plate, and the plate’s placement across a joint. Figure 1 shows a failed joint in a human foot, and Figure 2 shows a bone plate being used to repair the aforementioned joint.



Id. at Figs. 1–2. Figure 1 is a perspective view of a human foot and illustrates the bones within the foot, including a failed metatarso-phalangeal

joint of the big toe. *Id.* Figure 2 depicts a bone plate (100) being used in combination with a transfixation screw (150) to repair the joint (106) between a first bone (104a) and a second bone (104b) when the transfixation screw is screwed through the joint along a trajectory defined by the central axis (116) of transfixation screw hole (102) that crosses neutral bending axis (118) of the joint. *Id.* at 4:25–43, 6:7–11, 6:62–67.

Figure 3, reproduced below, is an enlarged isometric view of the top surface of the plate of Figure 2.



Id. at Fig. 3. Figure 3 shows plate (100) and various features, including elongate spine (124) having a first end (126a) and a second end (126b), each end with attachment points (128). *Id.* at 7:41–49. The attachment points (128) may be made to accept a bone screw (134, as depicted in Fig. 2) for attaching the first and second ends to first and second bones. *Id.* at 7:53–61. The plate includes bridge portion (130) configured to span a joint between the bones, which bridge portion includes a “thickened section 136 . . . to increase the bending strength” and minimize bending or breaking when load is applied to the joint. *Id.* at 7:48–50, 8:32–36. The plate further includes a

transfixation screw hole (102) “disposed along the center line 138 of spine 124, immediately adjacent to bridge portion 130.” *Id.* at 8:53–58.

According to the ’716 patent, the inner surface of the transfixation screw hole may direct a transfixation screw along a path that passes through a portion of first and second bones and crosses a neutral bending axis of the joint. *Id.* at 2:59–63. The patent explains that “[t]his technical advantage may create a ‘tension band’ construct 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.” *Id.* at 2:63–67; *see also id.* at 6:7–11 (“When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show[n] in FIG.2), a ‘tension band’ construct is created that puts transfixation screw 150 under tension when joint 106 flexes.”).

D. Illustrative Claims

The ’716 patent includes three independent claims (claims 1, 10, and 16), all of which are challenged here. Claim 1 is illustrative and reads:

1. A system for securing two discrete bones together across a joint between the two bones, comprising:
 - 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 an intermediate joint; and
 - a first inner surface configured to substantially conform with a geometry of the first discrete bone;
 - 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 discrete bone; and

a bridge portion disposed between the first end and the second end, at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end; and

a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends the bridge portion^[1] at a trajectory configured to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone; and

a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.

Ex. 1001, 12:24–64.

As recited above, claim 1 is to a “system.” Claims 10 and 16 are directed to a “plate” for securing two discrete bones across a joint, but otherwise include many limitations similar to claim 1 (e.g., an elongate

¹ The phrase “extends the bridge” appears to be missing language. We note that a claim correction was made for the related ’608 patent, changing the phrase “extends the bridge” to “extends through the bridge.” IPR2021-01450 (Ex. 1001, 14 (Certificate of Correction)). Claims 10 and 16 of the ’716 patent, in contrast, include the phrase “extends alongside the bridge.” Ex. 1001, 13:54, 14:40. Beyond claim 1, we find no instance of the phrase “extends the bridge” in the ’716 patent. For purposes of this Decision, we will interpret “extends the bridge” as encompassing both “extends through the bridge” and “extends alongside the bridge.”

spine, first and second ends with fixation points and that the ends conform with a geometry of the first and second bones, respectively, and a transfixation screw hole disposed along the spine). Ex. 1001, 13:34–61, 14:19–48. Unlike the “system” of claim 1, claims 10 and 16 do not require a “transfixation screw” as an affirmative claim limitation—the term appears in a functional sense in further describing the configuration of the recited “transfixation screw hole.” *Id.* Claims 10 and 16 also include “wherein” clauses that specify that “at least a portion of said bridge portion and said transfixation screw hole has a [depth] [or “thickness,” for claim 16] greater than at least a portion of said first and second ends.” *Id.*

E. Prosecution History

Starting with the ’608 patent’s prosecution history, the Examiner initially rejected “system” and “plate” claims similar to claims appearing in the ’716 patent for anticipation by Grady (Ex. 1011) and for obviousness based on Grady in view of Strnad (Ex. 1015). Ex. 1004, 173–178.² At that time, the Examiner apparently interpreted a “joint” as recited in the claims as including a “fracture” within a single bone, and also found that Grady’s system was “capable of securing two bone portions together” across a joint. *Id.* at 175. Applicant responded by arguing, *inter alia*, that Grady’s bone plate was dimensioned and configured for “fixation of ***two portions of a single bone***, which has been fractured,” and did not teach a transfixation screw hole configured to direct the screw so that it “extends ***at a trajectory configured to pass through two bones*** once the plate is placed across the joint” as claimed. *Id.* at 498.

² These page numbers refer to the page numbers added to the exhibit copy, not the original pagination, nor the Bates numbering on the exhibit.

The Examiner responded by maintaining the rejections, characterizing Applicant's arguments as based on an "intended use" of the claimed subject matter without a showing of a "structural difference" between the claims and the prior art. *Id.* at 227–234 (reiterating that Grady's plate is "capable of" performing the intended use).

Through additional back-and-forth between the Applicant and the Examiner, including multiple claim amendments, the claims were ultimately allowed. The claims were initially amended to require first and second inner surfaces of the system/plate conform with a geometry of a first and second bone. *Id.* at 246, 249. The Examiner, however, determined that such amendment did not go far enough in distinguishing the claims *structurally* over Grady. *Id.* at 267–268 (explaining that "if the applicant were to add language to recite the **structural differences** between the claimed invention and the prior art, it would overcome the rejection of record."). Applicant then amended the claims further to recite: (i) that first and second bones to which the plate/system are attached are "discrete" bones and the joint was an "intermediate" joint between them; (ii) that the bridge portion included a "thickness greater" than a portion of the first or second ends; and (iii) that the transfixation screw and screw hole are configured in such a way as to transfer tensile load from the second discrete bone through the screw and into the bridge portion. *Id.* at 289–291, 296–297 (arguing these amended features are not disclosed in Grady or Strnad). The Examiner subsequently allowed the claims without substantive comment. *Id.* at 305–309.

Prosecution of the related '776 and '716 patents included non-statutory double patenting rejections (overcome via terminal disclaimer), but no prior art rejections before allowance. *See generally* Exs. 1017 and 1018.

The prosecution of the '716 patent also included rejections for indefiniteness and written description that were overcome by minor claim amendment and cancellation of certain claims. Ex. 1017, 179, 197–198, 207.

F. Asserted Grounds

Petitioner asserts that claims 1–6, 8–13, and 16–19 are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–5, 9–13, 16–19	102(b) ³	Slater ⁴
6, 8	103(a)	Slater, Weaver ⁵
1–3, 6, 8–12, 16–18	102(b)	Falkner ⁶
4, 5, 13, 19	103(a)	Falkner, Arnauld ⁷
1–5, 9–13, 16–19	103(a)	Arnauld, Slater
6, 8	103(a)	Arnauld, Slater, Weaver

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1027) and Dr. George B. Holmes, Jr. (Ex. 1028) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

³ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Based on the putative effective filing date of the '716 patent, we apply the pre-AIA versions of §§ 102 and 103.

⁴ Slater, WO 2007/131287 A1, published Nov. 22, 2007 (Ex. 1005, “Slater”).

⁵ Weaver et al., US 6,623,486 B1, issued Sept. 23, 2003 (Ex. 1009, “Weaver”).

⁶ Falkner, US 2005/0171544 A1, published Aug. 4, 2005 (Ex. 1006, “Falkner”).

⁷ Arnauld, EP 1 897 509 B1, published Mar. 12, 2008 (Ex. 1007). Petitioner states that Exhibit 1008 is a certified English translation of Exhibit 1007 (Pet. 4) and, for purposes of this Decision, we refer to Exhibit 1008 as “Arnauld.”

G. 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. 9 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner’s proposal about the POSA’s qualifications. PO Resp. 24.

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.

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) (2020). 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 takes the position that “[t]here are no claim terms in the Challenged Claims that require construction” and that Petitioner has “applied the ordinary and customary meaning of each claim term.” Pet. 9–10 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)).

Patent Owner contends that the term “trajectory” as used in the Challenged Claims “means a fixed angle relative to the neutral bending axis of the joint.” PO Resp. 18.

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.

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) (discussing the burden of proof in *inter partes* review).

“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.⁸ *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

⁸ Patent Owner does not present any objective evidence of nonobviousness (i.e., secondary considerations) for the challenged claims.

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.

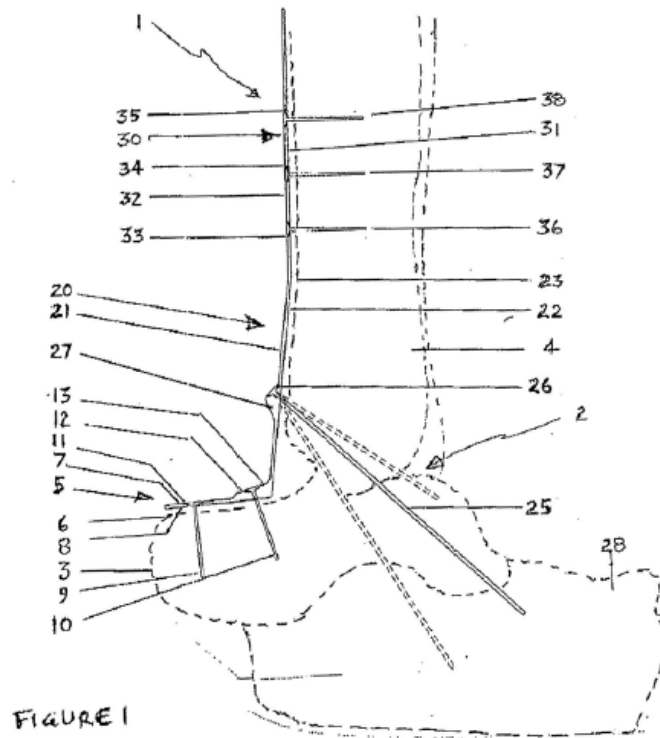
B. Overview of the Asserted Prior Art

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 2:6–7.⁹ Although Slater’s plate is “described with reference to its application to ankle fusion,” Slater discloses that “it will be appreciated by persons skilled in the art that the invention may be applied to the repair/fusion of other bones requiring axial alignment.” *Id.* at 7:34–8:2.

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

⁹ 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.



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 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).

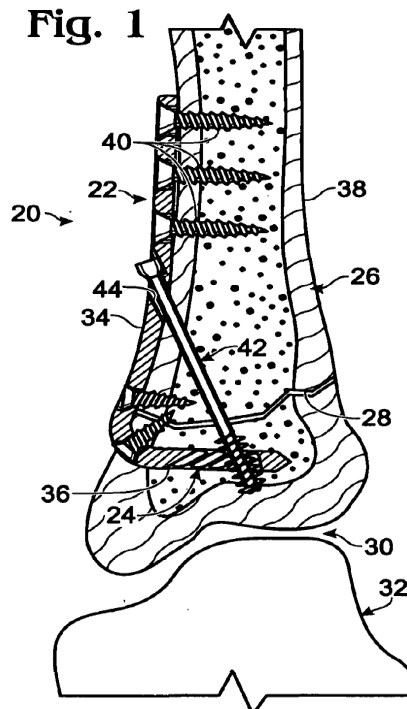
Slater discloses that “[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment.” *Id.* at 12:23–25. Continuing, Slater teaches that, “[a]s may be seen in figure 1 the screws are placed in a particular orientation 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 and [sic, and] end points of the L shaped contour over the ankle joint[] will be at its 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.* ¶ 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. *Arnauld (Ex. 1008)*

Arnauld is a European patent application that published March 12, 2008. Ex. 1008, code (43). Arnauld “relates to an arthrodesis [(i.e., fusion)] plate for a metatarso-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe.” *Id.* ¶ 1.

Arnauld describes a disadvantage with conventional plates “in the form of an elongated, generally flat body placed against the upper surfaces of the metatarsal and phalanx straddling the joint to be locked.” *Id.* ¶ 2. More specifically, Arnauld discloses that, “when the patient walks, his metatarsal-phalangeal joints are subjected to a flexion movement linked to the progressive support of his plantar arch, from the heel to the toes,” however, “[f]or the joint locked by the [conventional] plate, the bending stress is essentially absorbed by this plate which, through a cyclical repetition of this stress, weakens the bone anchorage of the screws holding the plate against the fused bones.” *Id.* ¶ 3.

Arnauld aims to remedy that disadvantage, describing a plate designed for durable fixation and that includes a “leg” structure extending laterally from the plate that “allows the plate to be attached to a lateral surface of the epiphysis of the phalanx—that is to say, in anatomical terms, to the medial surface of the phalangeal base.” *Id.* ¶¶ 5–6. According to Arnauld,

this leg is shaped so that its end hole can receive a long screw ... which will extend both through the bone material of the phalanx and into the bone material of the metatarsal ... so that this screw essentially, if not exclusively, takes up the bending stresses generated during a patient’s walking, it being noted that, due to its position, the screw works mainly by means of a traction.

Id. ¶ 6 (“Since this screw has a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone, the implantation of the plate is stable over time.”).

Arnauld’s Figure 1, reproduced below, shows an arthrodesis plate fixed to the metatarso-phalangeal joint.

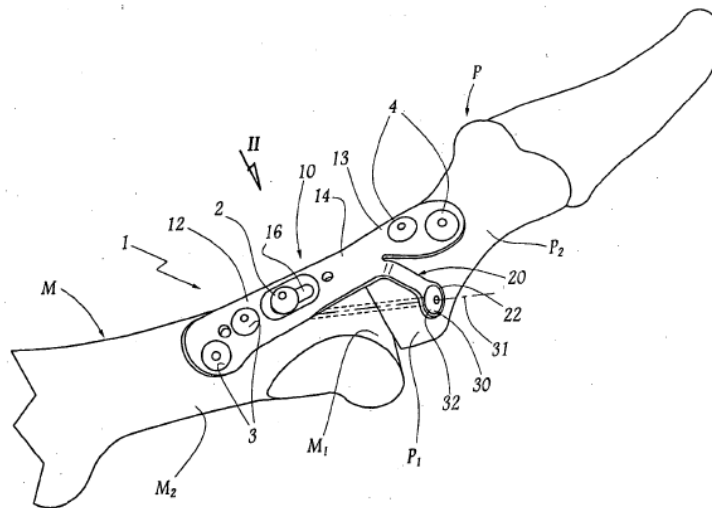


Fig.1

Id. at Fig. 1. Figure 1 of Arnauld, above, shows plate (1), having a plate body (10) that includes, in the longitudinal direction, a metatarsal portion (12) and a phalangeal portion (13) that are adapted to be fixed to the

underlying metatarsal (M) and phalanx (P) bones, and joint portion (14) between the metatarsal and phalangeal portions that is configured to overlies the joint zone. *Id.* ¶ 14; *see also id.* ¶ 21, Fig. 2 (vertical view of the plate itself without bones, and showing through-holes (e.g., 12₁ and 13₁) in the respective portions for receiving bone-anchoring screws).

Figure 1 of Arnould also shows leg (20) located on the inner longitudinal side and extending from the plate body. *Id.* ¶ 23. As Arnould explains, “leg 20 thus gives the impression of plunging downward in relation to the plate body 10, so that its end . . . is located vertically below this plate body in the configuration of implantation of the plate 1.” *Id.* Further, “the leg 20 is bent downward relative to the plate body along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13.” *Id.* ¶ 24; *see id.* at Fig. 2 (depicting bend line (23) and longitudinal direction (21)).

Arnould teaches that, at the end (22) of leg (20) is a through-hole (25) adapted to receive a screw (30). *Id.* at Figs. 1, 2; *see also id.* ¶ 26. According to Arnould, “[t]his screw 30 is a long screw in that sense that, as shown by the dotted line in Figure 1, it has sufficient length to extend from the hole 25 into both the phalangeal epiphysis P₁ and the metatarsal epiphysis M₁, and possibly also into the metatarsal diaphysis M₂.” *Id.* ¶ 26.

4. *Weaver (Ex. 1009)*

Weaver is a U.S. patent that issued September 23, 2003. Ex. 1009, code (45). Weaver relates to bone plating systems. *Id.* at Abstr. Weaver describes, among other things, locking screws that include threading on the outer surface of the head of such screws, which threading mates with corresponding threading on the surface of a hole on the plate for receiving

such screws. *Id.* at 1:49–54. Weaver teaches that such locking screws and corresponding features on the plate for receiving the screws may provide improved resistance to shear and torsional forces and reduce screw loosening. *Id.* at 1:46–48, 1:57–58, Figs. 2–4, 26.

C. Ground 1: Anticipation by Slater

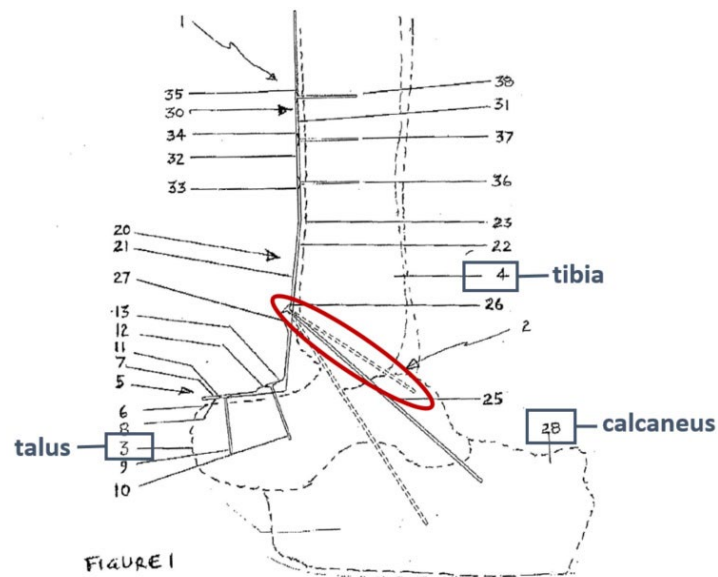
Petitioner contends that claims 1–5, 9–13, and 16–19 are anticipated by Slater. Pet. 15–36. For the independent claims, Petitioner provides a more detailed analysis on claim 1 and substantially cross-references the analysis on claim 1 when addressing claims 10 and 16. *Id.* at 16–27 (analysis for claim 1), 33–36 (combined analysis on claims 10 and 16).

Patent Owner raises multiple counterarguments. PO Resp. 25–40.

As do the parties, our discussion below focuses largely on claim 1. *See, e.g.*, Pet. 33–36 (Petitioner characterizing the elements of claims 10 and 16 as being “nearly identical” or “similar” to the elements of claim 1). Having considered the parties’ positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater. Our analysis follows.

1. Petitioner’s Contentions

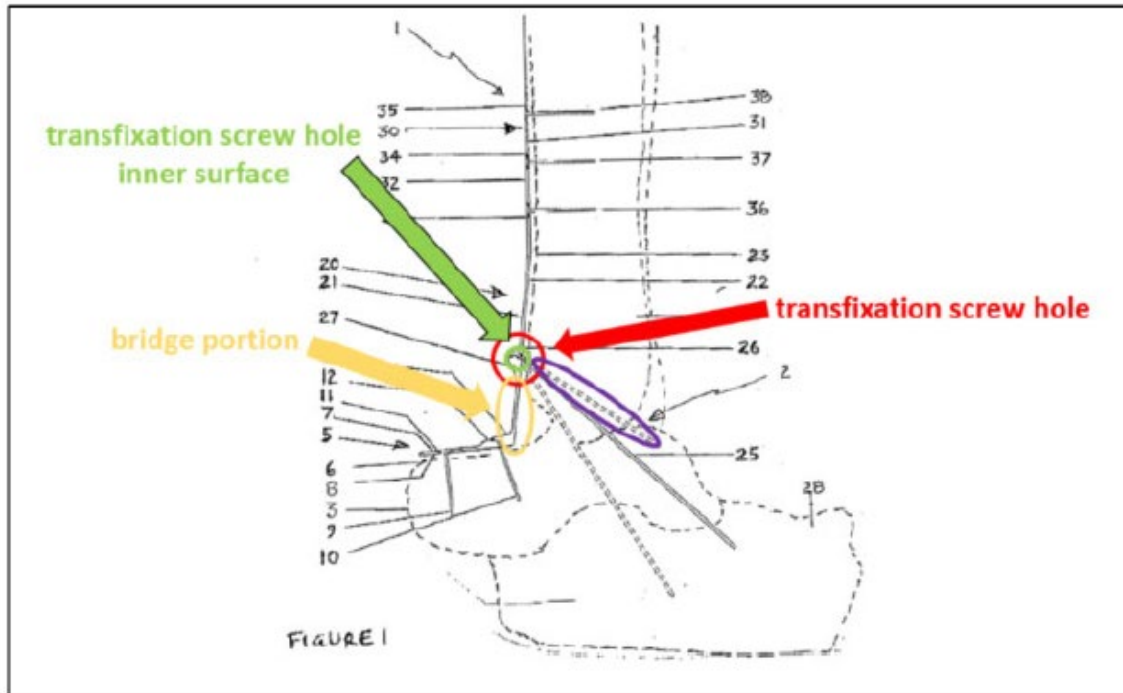
Petitioner argues that, if claim 1’s “preamble is limiting, Slater [discloses] a system for securing two discrete bones together across a joint between the two bones.” Pet. 16. In support, Petitioner provides an annotated version of Slater’s Figure 1, reproduced below.



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 ¶ 121.

Petitioner further contends that Slater discloses claim 1’s elongate spine and first and second ends, as well as a bridge portion between the ends that has a depth (or thickness) greater than the first and/or second end portions. Pet. 17–23 (citing Ex. 1002 ¶¶ 122–128). Petitioner contends that those limitations are disclosed in, for example, Slater’s Figure 1 and the features depicted therein. *Id.*

Petitioner also contends that Slater discloses claim 1's transfixation screw hole and transfixation screw limitations. Pet. 23–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



Id. at 24–25. 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 ¶ 130). According to Petitioner, "Figure 1 shows three separate exemplary angles for 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.*; Ex. 1005, Fig. 1.

Petitioner contends that Slater discloses a transfixation screw with a head and shaft as claimed. Pet. 25–26. Again, referencing Slater's Figure 1, Petitioner contends that Slater discloses a screw configured to contiguously

extend through a first bone (tibia 4), through a joint (2), and into a second bone (talus 3). *Id.* at 26 (citing Ex. 1005, Fig. 1, 11:19–25, 13:21–24). For claim 1’s recitation about the screw being configured “so as to absorb tensile load” and “transferring the tensile load” from the second bone through the screw into the head and bridge, Petitioner contends that Slater satisfies those elements as well. *Id.* at 26–27. 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. *Id.* 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.* Petitioner provides testimony from Dr. Gall to support this understanding of Slater’s teachings and the functionality of Slater’s plate when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 131).

2. Patent Owner’s Response

Patent Owner contends that “nothing in Slater expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate.” PO Resp. 37. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a “vise” configuration to transfer tensile load from the second bone, through the screw and into the bridge portion. *See id.* According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall’s assumption depends on the assumption that the threads of Slater’s screw 70 would only engage the second bone (the talus) in Slater’s two-bone

embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 36–37 (citing Ex. 2002 ¶ 107; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner’s “vise” construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 40–41 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶ 109). Patent Owner further contends that Dr. Gall’s opinion lacks citations of support to Slater, and any reliance on Slater’s finite element analysis lacks support because the test data does not state how the transfixion screw was affixed or loaded, or how many bones it penetrated. *Id.* at 41–42 (citing Ex. 1002 ¶¶ 125, 154; Ex. 2002 ¶¶ 117–119; Ex. 2003, 92:24–93:7).

3. *Petitioner’s Reply*

Petitioner responds that Slater discloses the “vise” configuration because it uses a lag screw “through an angled formation in the bone plate to cross a joint or joints where the screw head is in ‘cooperation’ with the screw hole,” creating a well-known “lag effect” to compress bone parts and absorb tensile load. Pet. Reply 13–14 (citing Ex. 1002 ¶¶ 131, 151–153, 165, 182; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 34–45; Ex. 1030, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the ’716 patent in the same manner that Dr. Gall describes Slater transfers tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶¶ 131, 165, 182; Ex. 1027 ¶¶ 42–43; Ex. 1030, 67:23–68:7, 74:6–25, 77:14–22). Petitioner also argues that “Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate.” *Id.* at 15

(citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1027 ¶ 44).

According to Petitioner, Slater’s testing simulated in vivo loading conditions and show that “at least some tensile load is necessarily distributed from the angled screw formation to the bridge portion.” *Id.* (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1027 ¶¶ 44–45; Ex. 1030, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 1 recites

a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone *so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.*

Ex. 1001, 12:56–64 (emphasis added). Independent claim 10 recites

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, *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 13:50–59 (emphasis added). Independent claim 16 recites

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, 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 14:36–45 (emphasis added). We will refer to these limitations collectively as the “transfer of tensile load” limitations. The parties dispute whether Slater expressly or inherently discloses these limitations.

We first address Petitioner’s argument that Slater discloses a “wise” configuration, which relies on Petitioner’s argument that Slater uses a lag screw with threads on its end that only engage the second bone in Slater’s two-bone configuration. *See* Pet. 26–27; Reply 12–15. We are not persuaded by Petitioner’s argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater’s Figure 4 “shows an elevation view of a second screw type 70” having “a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone.” Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the “majority of the shank” as “slid[ing] through” holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner’s position that the threads of screw type 70 only engage the second bone in Slater’s *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 16; Ex. 1002 ¶ 121 (arguing that Slater’s Figure 1 shows

two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a vise-like configuration that transfers tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Reply 13–15. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 26 with Reply 15; Sur-Reply 6–7. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a “vise” configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 12–13 (relying on “vise” argument), 15 (“Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate.”). Petitioner does not appear to argue that even if we find that Slater does not disclose the “vise” configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. Reply 15. Accordingly, we do not find the testing argument persuasive due its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 37–38 (citing Ex. 1002 ¶¶ 131, 165; Ex. 2002 ¶¶ 106–107; Ex. 2003, 44:21–45:15). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate on a patient in either the three-bone or two-bone embodiments. Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and “anticipated loadings” of the plate). Slater also emphasizes that the simulations only apply to “a plate of the particular type and geometry tested” and that “plates with different geometry and dimension . . . may result in different measured loadings and plate response” and “will be likely to have different load capacity results.” *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1, 10 and 16.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 131; Ex. 1027 ¶¶ 37–46. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art,

when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See* Ex. 2002 ¶¶ 81–82 (opining that Slater “does not describe whether there would also be threads” in the second of the three bones in the three-bone embodiment, in practice the threads may engage multiple bones, and Slater does not illustrate or describe how the screw would be used on a two-bone configuration), 75, 105–117 (opining that Slater fails to disclose the transfer of tensile load limitations).¹⁰

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1, 10 and 16, and, therefore does not prove, by a preponderance of the evidence, that Slater anticipates either of claim 1, 10 or 16.

Petitioner's challenge to dependent claims 2–5, 9, 11–13, and 17–19 as anticipated by Slater is substantially similar to its analysis of independent claims 1, 10 and 16, which relies on Petitioner's predicate analysis on the independent claims. Pet. 27–32, 36. That analysis suffers from at least the same shortcomings discussed above for independent claims 1, 10 and 16.

¹⁰ We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '716 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 16–17. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater.

D. Ground 2: Obviousness over Slater and Weaver

Petitioner contends that claims 6 and 8 are unpatentable for obviousness over Slater and Weaver. Pet. 36–39. Claims 6 and 8 depend from claim 1 and add, respectively, that transfixation screw hole or at least one attachment point includes features that lockably engage the transfixation screw head or locking bone screws. Ex. 1001, cl. 6, cl. 8. Petitioner alleges that those locking features are disclosed in Weaver and it would have been obvious to add them to Slater’s plate to provide a more secure fixation between the screws and the plate. Pet. 37–38; Ex. 1002 ¶¶ 191–192, 194–196. Petitioner otherwise relies on its anticipation analysis for claim 1 discussed above. *Id.* at 36.

We have considered Petitioner’s arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Slater and Weaver.

E. Ground 3: Anticipation by Falkner

Petitioner contends that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner. Pet. 39–58. As with Slater and Ground 1, Petitioner provides its analysis on claim 1 and largely cross-references that analysis for claims 10 and 16. *Id.* at 39–49 (claim 1), 55–57 (combined analysis on

claims 10 and 16). Patent Owner raises multiple counterarguments. PO Resp. 45–54.

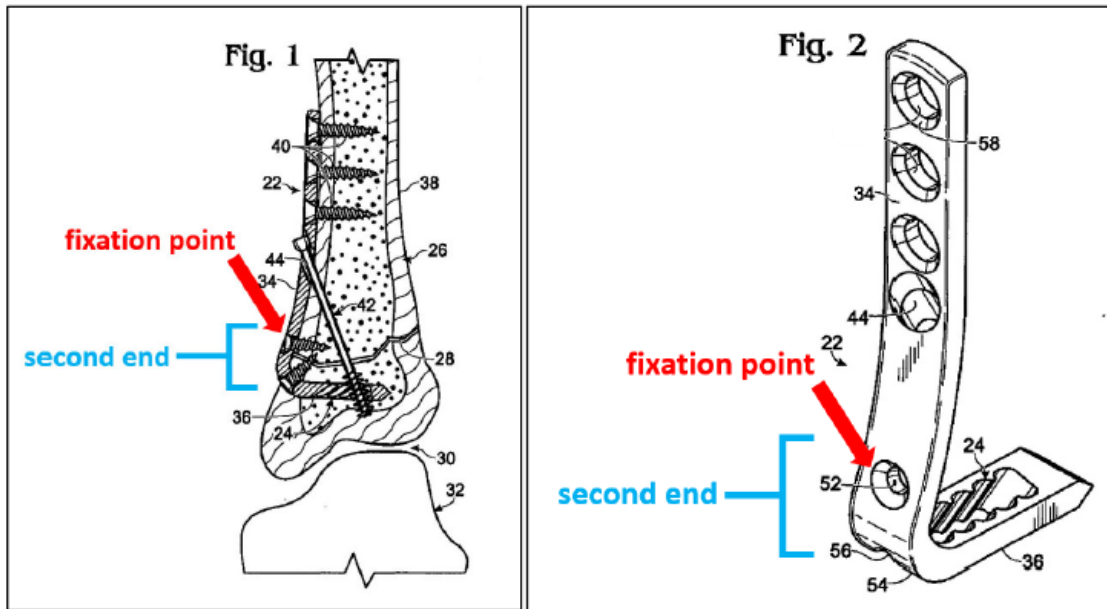
Having considered the parties’ positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner. Our analysis follows.

1. Petitioner’s Contentions

Petitioner alleges that Falkner discloses claim 1’s preamble. Pet. 39–40. According to Petitioner, although Falkner’s Figure 1 shows a plating system for fixing a single bone having a fracture, Falkner discloses that its bone plates may be used for any suitable “bone(s)” to fix fractures or other bone discontinuities. Ex. 1006 ¶¶ 21, 28. Petitioner also cites Falkner’s disclosure that, in other examples, “plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others.” *Id.* ¶ 21.

In a scenario where Falkner’s plate spans the ankle joint, Petitioner contends that “plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22.” Pet. 41 (citing Ex. 1002 ¶ 201). And, Petitioner argues, “the inner surface [of the plate] would be configured to substantially conform with a geometry of the first discrete bone (tibia 26).” *Id.* at 42 (citing Ex. 1006 ¶¶ 23, 34; Ex. 1002 ¶ 202). According to Petitioner, this configuration would meet claim 1’s “elongate spine” and “first end” limitations. *Id.* at 40–43.

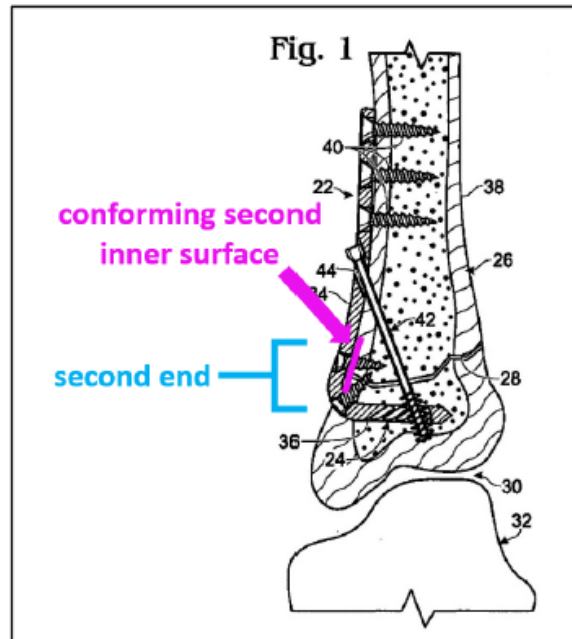
For claim 1’s “second end” limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.



Pet. 43 (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 . . . bone screw 40 may be placed into the second discrete bone . . . (talus) through the opening 52 at the second end of the plate 22.” *Id.* at 44 (citing Ex. 1002 ¶

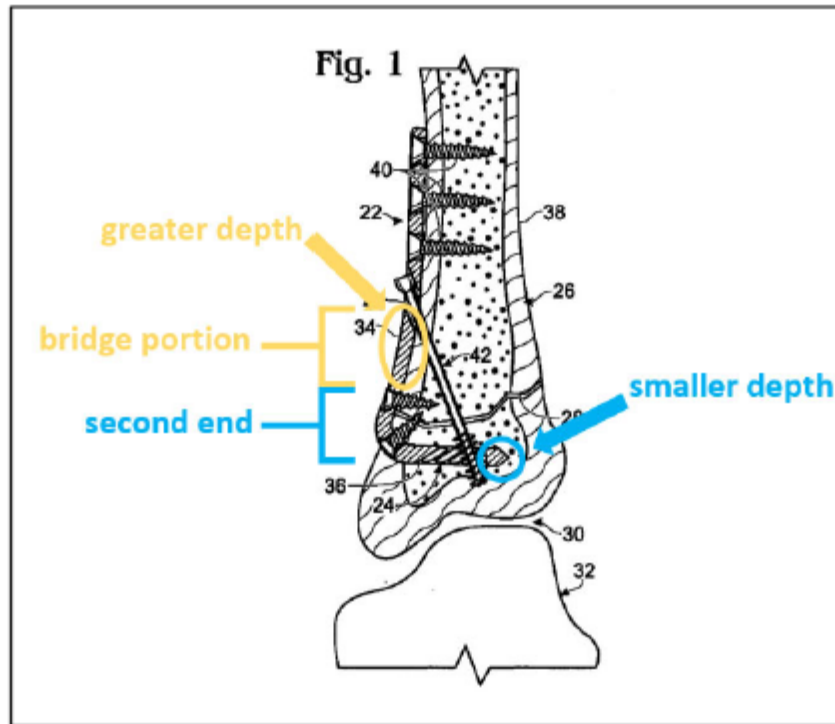
203). And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that “the second inner surface would be configured to substantially conform with a geometry of the second discrete bone (talus 32).” *Id.* at 44–45 (citing Ex. 1002 ¶ 204).



Id. at 44; 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. 44. 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.* at 44–45.

Turning to claim 1’s bridge portion and the requirement that the bridge portion have a depth or thickness greater than a portion of the first or

second ends, Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 45–46. This annotated figure is reproduced below.



Id. at 46; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, 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. 46. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "greater depth." *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 having a "smaller depth," which Petitioner highlights with a blue circle, arrow, and text. *Id.* From this, Petitioner argues that "at least a portion of the bridge

portion has a depth (i.e., thickness) greater than at least a portion of the depth of the second end.” *Id.* (citing Ex. 1002 ¶ 206).

For the transfixation screw hole and transfixation screw limitations of claim 1, Petitioner cites Falkner’s oblique opening (44) in external plate portion (34), and threaded faster (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate’s internal plate portion (36). Pet. 47–49. According to Petitioner, in a configuration where Falkner’s plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* at 48. And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 49 (citing Ex. 1002 ¶ 209). 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.” Pet. 49 (quoting Ex. 1006 ¶ 71).

2. *Patent Owner’s Response*

Patent Owner makes three main arguments with regard to independent claims 1, 10, and 16. PO Resp. 40–54. For purposes of this decision, especially given the parties’ overlapping arguments, we focus on claim 1.

First, Patent Owner argues that Falkner fails to disclose a system for securing two discrete bones together across a joint between the two bones. *Id.* at 46–48. Patent Owner contends that Falkner’s plate is not designed to secure the two discrete bones across a joint and further contends that “[t]o

make a Falkner-type plate that crosses a joint would require extensive modification.” *Id.* at 46–47.

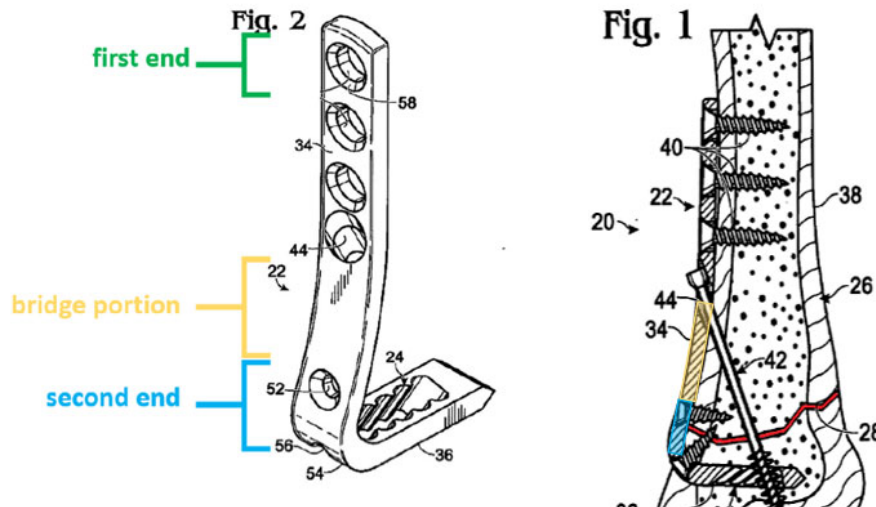
Second, Patent Owner argues that Falkner fails to disclose a “second end” that includes a “fixation point” and an “inner surface configured to substantially conform with a geometry of the second discrete bone” as required by the claims. *Id.* at 48–50. Patent Owner argues that what Petitioner identifies as the “second end” of Falkner’s plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 50. Patent Owner further contends that,

With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that “the plate 22 would have been placed across the joint 30 and the second inner surface would have been configured to substantially conform with a geometry of the second discrete bone (talus 32).” (Ex. 1002, ¶ 204 (emphasis added)). That something “would have been configured” is the hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003 86:11–15). Therefore, Falkner fails to disclose a second end configured to “substantially conform with a geometry of the second discrete bone.”

PO Resp. 50–51.

Third, Patent Owner contends that Petitioner’s modified version of Falkner’s plate does not have any portion configured to span across the bridge portion. *Id.* at 52–54. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the “second end”, not the bridge portion. *See id.* at 52 (“the *Falkner* blade-plate ‘bridge portion’ that Petitioners rely upon would not cross the joint at all”). To illustrate that point, Patent Owner references and compares Dr. Gall’s

annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.



Id. at 53 (citing Ex. 1006, Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 205); Ex. 2002 ¶ 145 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as it would be applied to a bone. Ex. 1001, 3:16–17. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* at 2:17–21. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioner identifies as the "second end." PO Resp. 53–54. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified highlighted in blue just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* (citing Ex. 2002 ¶ 146). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. *Petitioner's Reply*

In its Reply, Petitioner responds that “Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification ‘may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.’” Reply 17–18 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1028. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes’ testimony who believes that “Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***.” Reply 18–19 (citing Ex. 1028, ¶¶ 19–20, 25–36). Instead, Petitioner cites to Dr. Holmes who describes a procedure whereby:

surgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus” to help create a biomechanically stable joint for fusion. (Ex.1028, ¶¶31–32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 19. Petitioner contends that Falkner “expressly contemplates and enables a POSITA to use its bone plate for joint fusion, and teaches all of the structural limitations set forth in the challenged claims.” *Id.* at 20.

4. *Patent Owner's Sur-Reply*

In its Sur-Reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes’ testimony on how the

plate could have been modified. Sur-Reply 17. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that the theory of anticipation raised in the Petition is obviousness in disguise." *Id.* at 18. Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-Reply 18–22 ("the extensive modifications required for Falkner's plate to be used across a joint, go beyond what reasonably could be anticipation")

5. *Analysis*

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 45–54 of the Patent Owner Response and pages 18–22 of the Sur-Reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. PO Resp. 45–46; 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 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 as claimed would apparently require at least some level of redesign or modification. Those might be simple, even arguably obvious, changes for the person of ordinary skill in the art in light of Falkner and its overall teachings, but Petitioner's challenge is based on anticipation. Indeed, Petitioner's and Dr. Gall's repeated invocation of how Falkner's plate, if

used in the hypothetical joint-spanning context, “would have been” configured rings of obviousness, not anticipation. *See, e.g.*, Ex. 1002 ¶¶ 202–204.

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate’s actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge portion relative to the ends). The person of ordinary skill in the art might, for example, decide to conform some or multiple portions of the hypothetical bone plate to the exterior geometries of multiple bones, such as the tibia and talus. Such a design is even arguably suggested elsewhere in Falkner, where it discloses that bone plates “may be sized and shaped to conform to particular portions of a bone (or bones)” or “may be contoured generally to follow an exterior surface of a target bone (or bones)” (Ex. 1006 ¶¶ 33–34). But, here again, our concern is that such a theory drifts from anticipation—a doctrine still rooted in “strict identity”¹¹—to obviousness.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner’s plate

¹¹ *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

that appears to be close to the middle of the plate and characterizes that portion as a “second end.” Pet. 43. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* at 46. Petitioner’s position on what constitutes the “second end” of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position, while purporting to modify other portions of that embodiment (e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones.¹² Such picking and choosing is indicative of obviousness.

Regarding independent claim 10, Petitioner acknowledges that many of the limitations recited in independent claims 1, 10, and 16 are “nearly identical” with exceptions accounted for in its analysis set forth in the Petition. Pet. 54–56. Those differences between claim 1 and 10 identified by Petitioner do not cure the deficiencies discussed above with regard to claim 1. Thus, for at least the same reasons as discussed with respect to

¹² As a further example, Petitioner identifies opening (52) in Falkner’s plate in Figure 1 as the alleged fixation point on a second end of the plate as claimed. Pet. 43. But, as described in Falkner, opening (52) and its corresponding bone screw is fixed on the *same side* of the bone discontinuity (fracture) as the plate portion Petitioner identifies as the plate’s first end. Ex. 1006, Fig. 1. Inasmuch as a joint is simply another bone discontinuity in Falkner, Petitioner asserts, with minimal explanation, that a screw would have been placed through opening (52) to secure a second bone (e.g., talus) on the *opposite side* of the joint relative to the plate’s first end when the plate is modified for use in this different context. *Id.* at 44; Ex. 1002 ¶ 202.

claim 1, we are not persuaded on the current record that Falkner anticipates claim 11.

Petitioner's challenge to dependent claims 2–3, 6, 8–9, 11–12, and 17–18 as anticipated by Falkner relies on Petitioner's predicate analysis on the independent claims. Pet. 49–54, 57. That analysis suffers from at least the same shortcomings discussed above for independent claims 1, 10, and 16.

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner.

F. Ground 4: Obviousness over Falkner and Arnauld

Petitioner argues that dependent claims 4, 5, 13, and 19 would have been obvious over Falkner and Arnauld. Pet. 58–61. Petitioner's argument under Ground 4 relies on Petitioner's predicate anticipation challenge under Ground 3 for those claims from which claims 4, 5, 13, and 19 depend. *Id.* Petitioner relies on Arnauld under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claims 4, 5, 13, and 19.

We determine that Ground 4 suffers from at least the same shortcomings as discussed above for Ground 3. Also, Petitioner contends a person of ordinary skill in the art would have been motivated to modify Falkner's bone plate to provide a plate specifically for use with a metatarsophalangeal joint and, in so doing, select the transfixation angles disclosed in Arnauld. Pet. 58–61. Petitioner's anticipation analysis of Falkner, however, focused on the plate of Falkner's Figure 1, allegedly designed to render it suitable for use with the tibia and talus. Petitioner provides no sufficient explanation as to how this plate would be now

designed and configured for an entirely different set of bones and joint—the metatarsophalangeal joint—and still meet all the claim limitations of the underlying independent claims. *Id.* Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Falkner and Arnould.

G. Ground 5: Obviousness over Arnould and Slater

Petitioner argues that claims 1–5, 9–13, and 16–19 would have been obvious over Arnould and Slater. Pet. 61–77. For independent claims 1, 10, and 16, like Petitioner, our analysis focuses on claim 1. *Id.* at 74–76 (relying substantially on analysis for claim 1 for claims 10 and 16). Petitioner also contends that a person of ordinary skill in the art “would have been motivated to modify the bone plate of Arnould with the thickened bridge portion of [] Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint.” Pet. 67.

Patent Owner raises multiple counterarguments. PO Resp. 56–60. In particular, Patent Owner contends that thickening the portion of the Arnould plate Petitioner identifies as the bridge portion, “junction zone 14,” would be contrary to the purpose of Arnould’s disclosure. PO Resp. 57. Patent Owner further contends that Arnould in view of Slater fails to teach the elements of “a transfixation screw hole disposed along the spine.” *Id.* at 59–61.

Having considered the parties’ positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious by the combination of Arnould and Slater. Our analysis follows. For independent claims 1, 10, and 16, like Petitioner, our analysis focuses on claim 1.

Pet. 74–76 (relying substantially on analysis of claim 1 for claims 10 and 16).

1. Independent Claim 1

a) Whether there is Motivation to Combine Arnould and Slater

Petitioner contends that “Arnould discloses each and every element of independent claim 1 except” the element “which recites ‘at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end.’” Pet. 61–62; Ex. 1002 ¶ 282. For that missing limitation, Petitioner turns to Slater, which Petitioner argues discloses a thicker bridge portion. Pet. 62. Petitioner argues that a person of ordinary skill in the art “would have been motivated to modify the bone plate of Arnould with the thickened bridge portion [] of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint.” *Id.* at 67 (citing Ex. 1002 ¶ 290); *see also* Reply 25 (there is motivation to combine Arnould and Slater “to strengthen the plate in the area that experiences the highest stress—the portion near the MTP joint.”) (citing Ex. 1002 ¶¶ 290, 333, 351; Ex. 1027 ¶¶ 52–54).

Petitioner also explains that “[w]ith the use of a plate bender, a surgeon can adjust even a thickened portion of an MTP plate to conform to the variable anatomy of the metatarsophalangeal joint.” Reply 25 (citing Ex. 1028 ¶ 34). Moreover, Petitioner contends that

Arnould expressly contemplates a surgeon modifying the angle between the metatarsal and phalangeal parts of the bone plate to accommodate varying degrees of dorsiflexion. Bending the plate at the bend line weakens the plate, so thickening the plate at the bend line would improve the strength of the *Arnould* plate.

Id. (citing Ex. 1008 ¶¶ 20, 38; Ex. 1027 ¶ 56).

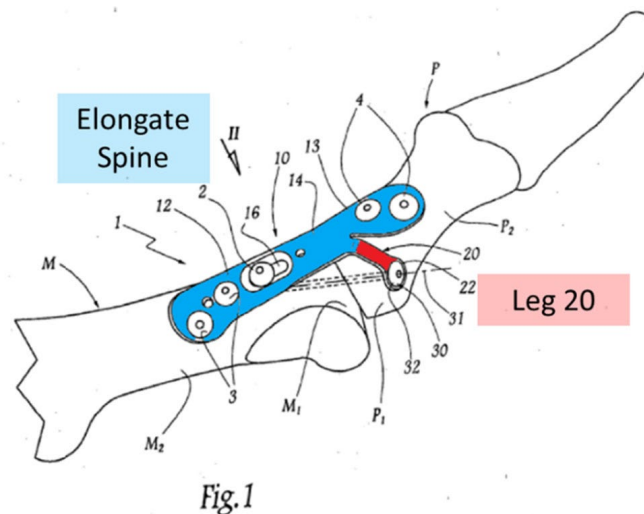
We have considered Petitioner’s arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that the proposed motivation is contrary to the disclosure of Arnould for two reasons. PO Resp. 56–58. First, thickening the specified portion in Arnould “would be contrary to the purpose of Arnould’s disclosure” because “it is designed in a specific manner to allow a surgeon to bend the plate at that junction zone to conform the plate in situ to a patient’s bone anatomy.” PO Resp. 57–58; Ex. 1008 ¶ 38; Ex. 2002 ¶¶ 155–157; *see also* Ex. 2002 ¶ 157 (Arnould’s “junction zone 14” is “purposely not strengthened to allow for bending by the surgeon at time of implantation.”) (citing Ex. 1008 ¶ 38).

Second, there is no motivation to modify the plate in Arnould “[b]ecause the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest.” PO Resp. 58. Rather, Arnould discloses that “the highest loading occurs in the cross-joint screw itself: ‘this screw essentially, **if not exclusively**, takes up the bending stress generated during the patient’s walking.’” *Id.* (quoting Ex. 1008 ¶ 6; citing Ex. 2002 ¶¶ 70, 165). “Because the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest, there would be no reason to modify that portion of the plate to accommodate additional stress as taught in Slater.” *Id.*

b) Whether Arnould in view of Slater Fails to Teach a Transfixation Screw Hole Disposed Along the Spine

Claims 1, 10 and 16 of the ’716 patent specify that the “transfixation screw hole [is] disposed along the spine” of the plate. Ex. 1001, cl. 1, 10, 16. The Petition relies solely on Arnould for this element. Pet. 67.

We have considered Petitioner’s arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that Arnould in view of Slater fails to teach or suggest a transfixation screw hole to be deposited along the spine. PO Resp. 57–59. The alleged transfixation screw hole of Arnould is a “through-hole 25 (at the end of leg 20[]) . . . [and] is not disposed on the spine, but part of a separate leg piece that extends off the spine.” *Id.* at 59. The following annotated version of Arnould’s Figure 1 illustrates that point.



Id. at 59; Ex. 1008, Fig. 1. The annotated version of Arnould’s Figure 1, above, shows plate (1) having a plate body (10) attached to the metatarso-phalangeal bones and joint, and Patent Owner has highlighted in blue the plate’s longitudinal body, which Patent Owner calls the “Elongate Spine.” PO Resp. 59. In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate’s midsection. *Id.*

Arnould discloses that leg (20) is meant to wrap around the bone and is located vertically below the plate body, which is evident with reference to

Figure 1 above. Ex. 1008 ¶ 23; Ex. 2002 ¶¶ 161, 172. Furthermore, as noted by Patent Owner:

Arnould fails to disclose or suggest disposing screw 30 along the spine; and there is no reason in view of Arnould to locate a transfixation screw hole along the spine as required by the claims of the '716 patent because the explicit advantage of Arnould is that the leg and screw were moved off the spine to generate “a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone.”

PO Resp. 60 (citing Ex. 1008 ¶ 6 (emphasis added); Ex. 2002 ¶ 162).

We have considered but are not persuaded by Petitioner’s Reply argument that

Patent Owner incorrectly re-writes “disposed along the spine” as “disposed on the spine,” and improperly narrows the term “spine” to mean the center line of the plate. (POR, 59). The claim language nowhere equates the “elongate spine” with the center line of the plate.

Reply 26. Rather, we agree with Patent Owner that

Something cannot be both along the body (or in the case of the claims, the spine) and below it. Petitioners also ignore the rest of claim 1, which requires that “the bridge portion [of the elongate spine] [be] configured to span across the joint,” and that “a transfixation screw hole [is] disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends through the bridge portion at a trajectory . . . [.]” (Ex. 1001, cl. 1). *Given that leg 20 is located below the body of the plate and does not cross the joint, it cannot be the claimed bridge portion.*

Sur-Reply 24 (emphasis removed; emphasis added).

c) Analysis of Remaining Claims

Petitioner’s analysis of independent claim 10 as obvious over Arnould and Slater is essentially the same as its analysis of claim 1. Pet. 77–78. That

analysis suffers from at least the same shortcomings discussed above for claim 1. The same is true of Petitioner's analysis of dependent claims 2–5, 9, 11, 12, and 13, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 69–73, 75–76.

2. Conclusion

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious over Arnould and Slater.

H. Ground 6: Obviousness of Claims 6 and 8 over Arnould, Slater, and Weaver

Petitioner argues that claims 6 and 8 would have been obvious over Arnould and Slater, in further view of Weaver. Pet. 76–77. Petitioner's reliance on Weaver here is substantially the same as for Ground 2—citing Weaver's screw locking features and reasons to add them. *Id.* Claim 6 and 8 depend, however, from claim 1 and Petitioner's challenge under Ground 6 presumes Petitioner's predicate success on Ground 5. *Id.* (asserting that “independent claim 1 is rendered obvious by Arnould in view of Slater” before turning to claims 6 and 8).

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to the combination of Arnould and Slater with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Arnould, Slater, and Weaver.

III. CONCLUSION

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 9–13, 16–19	102	Slater		1–5, 9–13, 16–19
6, 8	103	Slater, Weaver		6, 8
1–3, 6, 8–12, 16–18	102	Falkner		1–3, 6, 8–12, 16–18
4, 5, 13, 19	103	Falkner, Arnould		4, 5, 13, 19
1–5, 9–13, 16–19	103	Arnould, Slater		1–5, 9–13, 16–19
6, 8	103	Arnould, Slater, Weaver		6, 8
Overall Outcome				1–6, 8–13, 16–19

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6, 8–13, and 16–19 of the '716 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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.

IPR2021-01452
Patent 9,763,716 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and
JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, concurring.

I concur that Slater does not anticipate claims 1–6, 8–13, and 16–19,
and reach that result for the following additional reason.

Independent claim 1 recites a “transfixation screw hole comprising *an inner surface configured to direct the transfixation screw* through the transfixation screw hole *such that* the transfixation screw extends the bridge portion *at a trajectory configured* to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone once the plate is placed across the joint.” Independent claims

10 and 16 recite a substantially similar element. A dispute between the parties is whether the claim recitation for “an inner surface configured to direct the transfixation screw . . . at a trajectory” is taught by Slater.

To that point, Petitioner contends that Slater identifies openings 26 and 93 that “each receive a fixation screw that passes through those openings so that the screw is implanted at an angle.” Pet. 24 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1, 7). More specifically, Petitioner contends that Slater’s “transfixation screw hole (26 or 93) . . . comprises an inner surface (unnumbered in Slater’s drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends through the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of the joint (2), and a second position on the second discrete bone (talus 3)” once the plate (1 or 80) is placed across the joint. *Id.* (citing Ex. 1002 ¶¶ 129–130; Ex. 1005, 11:19–25, 13:21–25).

In its Response, Patent Owner directs our attention to Figure 1 of Slater, and contends that this Figure “depicts, in phantom, the use of a screw that passes through the tibia and terminates in the talus.” PO Resp. 10 (citing Ex. 2002 ¶ 55). “The hole that the screw 25 passes through is constructed in a manner that allows the angle of the screw to be modified as the plate is affixed to the ankle joint.” *Id.* at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). “This hole is described as ‘slotted,’ meaning that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles.” *Id.* (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8); *see also* Ex. 1005, 16:28–30 (“One significant advantage of the plate described is the oblique

screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required.”), Fig. 1.

Furthermore, Patent Owner notes that Slater “provides no detail regarding the structure of the inner surface of the hole” because a surgeon using Slater’s plate “determines the path in situ with a range of options available.” PO Resp. 35 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 97). That is, “Slater describes a plate that intentionally allows for varied angles through the same hole.” *Id.* at 35–36 (citing Ex. 1005, 16:28–30 (“[o]ne significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required”); Ex. 2002 ¶ 103)). Patent Owner contends that, because the hole identified by Petitioner as Slater’s transfixation screw hole allows for varied angles through the same hole, Slater fails to disclose a transfixation screw hole having “an inner surface configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory,” where “trajectory” is properly interpreted to mean an “allowable fixed angle relative to at least the neutral bending axis of the joint.” PO Resp. 18–21, 34–36.

In its Reply, Petitioner contends that Patent Owner’s suggestion that trajectory limits the challenged claims to a single, fixed angle is “unsupported by the intrinsic evidence.” Reply 4. Specifically, Petitioner contends that

The claims recite only that the claimed “trajectory” is the transfixation screw trajectory, and that such trajectory is configured to pass through “a first position on the first [discrete] bone[, a portion of the joint,] and a second position on the second [discrete] bone” once the plate is placed across the joint. (EX1001, cls. 1, 11). *There is a wide range of angles at which*

this can be achieved, not just one fixed angle. (EX1001, cl. 4; EX1027, ¶11)).

Reply 2–3 (emphasis added). Petitioner further contends that “the inner surface of the transfixation screw hole does not, alone, determine the precise angle of the trajectory,” as “the size, shape, and geometry of the screw also determine what angles the trajectory may have.” *Id.* at 3 (citing Ex. 1027 ¶¶ 12–13).

Moreover, Petitioner contends that “Patent Owner’s reliance on the ‘neutral bending axis’ as a point of reference for ‘trajectory’ is nonsensical” because “the neutral bending axis of a particular joint may shift depending on the position of the bone plate and the loads exerted on that joint” and, thus, “the ‘trajectory’ cannot be known by analyzing a bone plate or system alone.” *Id.* (citing Ex. 2002 ¶ 39).

I begin this analysis by clarifying that I understand Patent Owner’s position to be that the “inner surface of the transfixation screw hole” is not a hole configured to allow a screw to be inserted into a bone at a plurality of angles, but that the language of the claim requires the configuration of a trajectory at a particular angle where that angle may be configured within a certain range. PO Resp. 20 (citing Ex. 2002 ¶ 96; Ex. 1001, 6:48–53). Thus, the dispute between the parties is whether a singular “inner surface of the transfixation screw hole” may be configured to operate so as to accommodate a range of angles, for example, in the same manner that Slater’s oblique screw portal allows for screws to be inserted at varied angles through the same hole. *Id.*; Ex. 1002 ¶ 121 (“One significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required.”) (quoting Ex. 1005, 16:28–30); Ex. 2002 ¶ 103 (“I

agree with Dr. Gall that *Slater* teaches a screw hole that allows a screw to be inserted at a wide range of angles”).

With that important distinction in mind, I consider Patent Owner’s contention that the term “a trajectory” as used in the challenged claims means an allowable “fixed angle relative to the neutral bending axis of the joint.” PO Resp. 18–20, 35–36. Here, I note that the challenged claims themselves define what angles are “allowable.” That is, an allowable angle for the transfixation screw is an angle that directs the screw “through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone.” Ex. 1001, cl. 1; *see also id.* at cl. 10 (“through a first position on the first bone and a second position on the second bone”); *id.* at cl. 16 (“through a first position on the first bone and a second position on the second bone”).

Regarding Patent Owner’s inclusion of the phrase “relative to the neutral bending axis of the joint” in its proposed construction of “trajectory,” I recognize that the specification makes constant reference to the “neutral bending axis” and its relationship to the trajectory is defined by the disclosed transfixation screw hole. *See e.g.* Ex. 1001, 1:62–63 (“the trajectory may be configured to cross a neutral bending axis of the joint once the plate is placed across the joint”); *id.* at 2:59–63 (“the inner surface of the transfixation screw hole in the plate may direct the transfixation screw along a trajectory that crosses a neutral bending axis of the joint”); *id.* at 6:7–11 (“When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show in FIG. 2), a ‘tension band’ construct is created that puts transfixation screw 150 under tension when joint 106 flexes.”). Furthermore, later dependent claims, when accounting for the precise angles recited by those claims, expressly recite angles

measured from the neutral bending axis of the joint. *See, e.g.*, Ex. 1001, cl. 5 (“herein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis.”). I also recognize Dr. Gall’s and Mr. Sommer’s statements explaining that the axis of a bone plate may generally approximate the direction of the neutral bending axis of the joint. Ex. 1002 ¶ 135 (“When a bone has a reasonable degree of symmetry, the axis of the bone plate approximates the direction of the neutral bending axis of the joint.”); Ex. 2002 ¶ 95. Given the guidance set forth in the specification, summarized above, and the apparent agreement between the expert testimony, the trajectory of the recited screw could be measured “relative to both the elongate axis of the plate and the neutral bending axis of the joint.” PO Resp. 20. Nonetheless, I also note that our express determination of whether a trajectory should be measured from an elongate axis or neutral bending axis of the joint is unnecessary as such a determination would not affect the outcome of our decision. *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))).

The dispositive question is whether the recited transfixation screw hole is configured to direct the transfixation screw on a trajectory that is a fixed angle or is configured to allow for “adjustable orientation” based on “a predetermined allowable angular range” such as opening 26 of Slater, identified by Petitioner as the transfixation screw hole. Pet. 11; Ex. 1005, 12:23–25, 11:21–22. Here, I first note the specification does not describe a plate having a hole identified as a transfixation screw hole that would

accommodate insertion of a screw at a plurality of angles through the same hole. Rather, the specification repeatedly describes the disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:26–45, 2:8–14, 2:42–46; Ex. 2002 ¶¶ 50, 94, 96; PO Resp. 18–21. For example, the specification describes how “increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100.” Ex. 1001, 9:8–12 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:60–61; 6:41–67. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132 and serves the purpose of tightening bones so as to “to press together at the interface of joint 106.” *Id.* at 9:12–9:46. Taken together, the specification, when read as a whole, describes plates with a transfixation screw hole configured at a single trajectory selected to achieve the functional objectives of the plate, namely, joint fusion, where that single trajectory is preferably between 30 and 70 degrees, and more preferably, 50 degrees. *Id.* at 6:41–55. Petitioner fails to direct us to any example or other disclosure to support its alternative interpretation, namely, a plate configured with a transfixation screw hole 102 configured to permit the placement of a screw at a plurality of trajectories or angles.

Second, other dependent claims support the interpretation of a trajectory configured at a fixed angle. Claim 2, for example, recites that the “central axis of the inner surface of the transfixation screw hole defines the trajectory,” a distinguishing feature as compared to the device in Slater that I will discuss here by way of comparison. Figure 1 of Slater depicts, in phantom, the use of screw 25 that passes through the tibia and terminates in the talus. PO Resp. 10 (citing Ex. 2002 ¶ 55). The hole that screw 25 passes through is oblique¹³ and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). In other words, the oblong hole of Slater is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002 ¶ 124); *see also* Ex. 2002 ¶ 98 (Figure 1 of Slater “does not detail anything at all regarding the structure of [the ‘inner surface’ of the transfixation screw hole], much less demonstrate the hole has an ‘inner surface configured to direct the transfixation screw . . . at a trajectory.’”)

Claim 4 includes an allowable range between 30 and 70 degrees for the trajectory. Claim 4, however, depends from claim 2, and therefore requires the central axis of the screw hole to define the trajectory of the screw between 30 and 70 degrees. Upon review of this claim structure for

¹³ It is undisputed that the hole identified by Petitioner as the transfixation screw hole is oblong. As noted by Patent Owner, this hole is described as “slotted,” which means “that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles.” PO Resp. 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8). Likewise, Dr. Gall recognizes the same hole as the transfixation screw hole of Slater and describes it as an “oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required.” Ex. 1002 ¶ 114; Ex. 1005, 16:28–30.

the '716 patent, I agree with Patent Owner that a person of ordinary skill in the art would understand that, in the context of the intrinsic record, this means that any given plate is configured at a single trajectory or single fixed angle, and that different plates could have a different fixed angle, with plates having single fixed angles in the range between 30 and 70 degrees. PO Resp. 20 (Ex. 2002 ¶ 96; *see also* Ex. 1001, 6:41–55). Here, I also credit Mr. Sommer's explanation that a person of ordinary skill in the art would understand that to mean that a surgeon would be provided with a kit that includes multiple plates, each one with a single fixed angle of, for example, 50, 55, 60, 65 and 70 degrees. Ex. 2002 ¶ 96; Sur-Reply, 4. Moreover, claim 5 further limits the trajectory of claim 4 to "a transfixation angle of about 50 degrees measured from the neutral bending axis." Claim 6 further limits claim 1 and requires that "the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw," and that engagement of the screw head and screw hole would inherently constrain the configuration of the screw hole to a particular angle. Thus, each of dependent claims 2–6 further limit claim 1 along the lines of a single "trajectory" and are more specifically directed to plates configured with a screw hole that defines a single trajectory.

Finally, while the term "trajectory" used in isolation may not necessarily connote a fixed angle, the assessment here is whether the recitation of an inner surface of a screw configured to direct a screw *at a trajectory* is describing a fixed angle, and more specifically, describing a screw hole configured to direct a screw at a single trajectory. In view of the claim structure of independent claims 1, 10, and 16, the content of the specification, and testimony of Mr. Sommer's, summarized above, I determine it does. The claims expressly require a transfixation screw hole

that itself is “configured to direct the transfixation screw through [a] transfixation screw hole . . . *at a trajectory*,” which in context indicates that a screw hole directs the trajectory of the screw, even if other factors may also influence the trajectory. *Cf.* Reply 3–4. In other words, we agree with Patent Owner that “a POSITA reading [claim 1] in light of the intrinsic record would understand that [the claim language describing the recited screw hole] means that the shape of the inner surface of the transfixation screw hole is such that it guides the screw at a fixed angle relative to both the elongate axis of the plate and the neutral bending axis of the joint.” PO Resp. 20; Ex. 2002 ¶ 95.

I recognize Petitioner’s argument that “[w]hile Slater’s transfixation screw hole allows the transfixation screw to be positioned within a predetermined range, once the screw is threaded into the bone, the screw trajectory, and thus the angle, is fixed,” however, I am not persuaded. Reply 12. Petitioner insufficiently explains how the fixation of the angle of the screw trajectory by virtue of being inserted into a bone equates to the claim requirement that the inner surface of the transfixation screw hole directs the screw at a trajectory.

Petitioner’s challenge to dependent claims 2–5, 9, 11–13, and 17–19 as anticipated by Slater is substantially similar to its analysis of independent claims 1, 10 and 16, which relies on Petitioner’s predicate analysis on the independent claims. Pet. 27–32, 36. That analysis suffers from at least the same shortcomings discussed here for independent claims 1, 10 and 16.

In view of the above, I determine that Slater does not disclose “the transfixation screw hole comprising an inner surface configured to direct [a] transfixation screw . . . *at a trajectory*” as required by the claims. Slater’s opening 26 is meant to be a variable angle hole and not an opening

configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 (“an angle within a predetermined allowable angular range”); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26). Accordingly, for this additional reason, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater.

For PETITIONER:

Sharon Hwang
Robert Surrette
Scott McBride
MCANDREWS, HELD & MALLOY LTD
shwang@mcandrews-ip.com
bsurrette@mcandrews-ip.com
smcbride@mcandrews-ip.com

For PATENT OWNER:

Jason Engel
Katherine Allor
Devon C. Beane
K&L GATES LLP
jason.engel.ptab@klgates.com
katy.allor@klgates.com
devon.beane@klgates.com