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Paper 6
Date: March 16, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01452
Patent 9,763,716 B2

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

MAJORS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Stryker Corporation and Wright Medical Technology, Inc. (collectively "Petitioner"), on August 30, 2021, filed a Petition to institute *inter partes* review of claims 1–6, 8–13, and 16–19 of U.S. Patent No. 9,763,716 B2 (Ex. 1001, "the '716 patent"). Paper 2 ("Pet." or "Petition"). OsteoMed LLC ("Patent Owner") filed a Preliminary Response. Paper 5 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

A decision to institute under § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). In addition, if the Board institutes trial, it will "institute on all grounds in the petition." PTAB Consolidated Trial Practice Guide, 5–6 (Nov. 2019); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Having considered the arguments and evidence presented in the Petition and the Preliminary Response, for the reasons described below, we institute *inter partes* review.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies Wright Medical Technology, Inc. as a wholly-owned subsidiary of Stryker Corporation, and states that Stryker Corporation is the real party-in-interest. Pet. 1. Patent Owner identifies itself as the real party-in-interest. Paper 3, 1.

III. 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.

IV. 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.

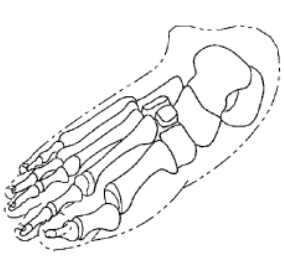


FIG. 1

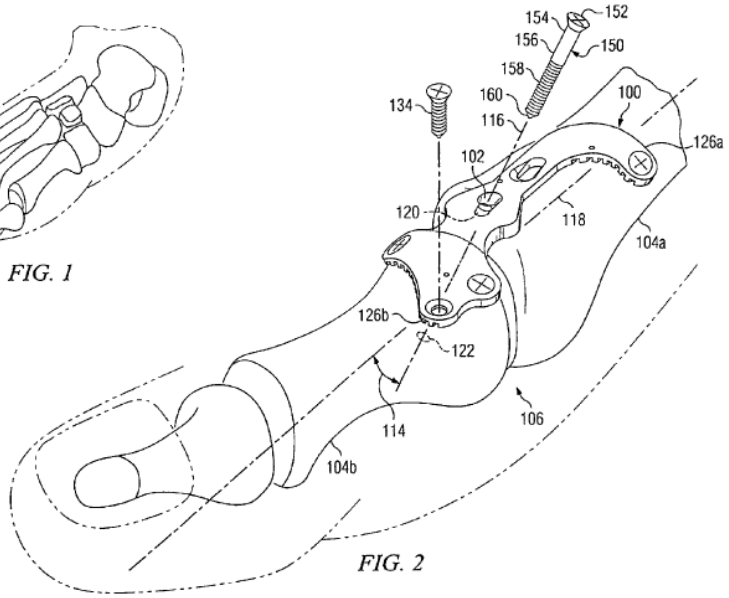


FIG. 2

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.

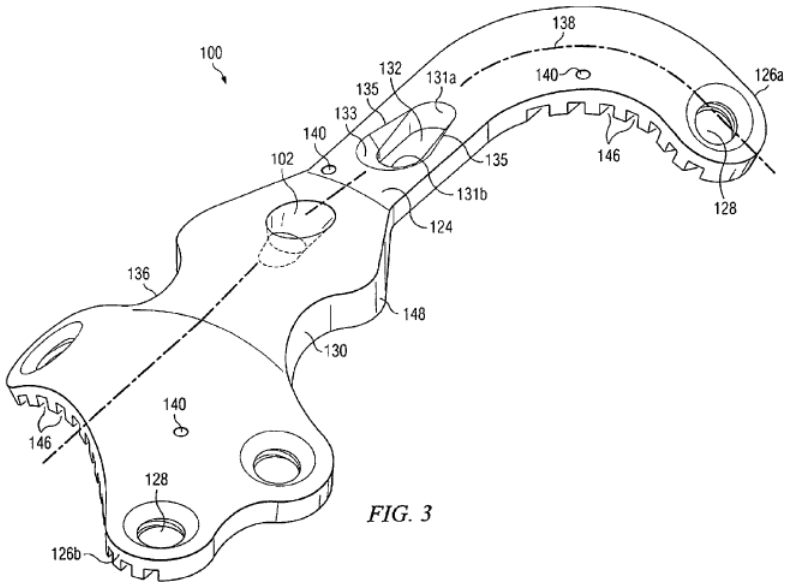


FIG. 3

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.").

V. 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 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"

[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."

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.*

VI. 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.

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

[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.

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 '776 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.

VII. 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, Arnould[7]
1–5, 9–13, 16–19	103(a)	Arnould, Slater
6, 8	103(a)	Arnould, Slater, Weaver

Petitioner also relies on the declaration of Kenneth A. Gall, Ph.D., in support of the asserted grounds. Ex. 1002. Patent Owner has not, at this time, filed rebuttal documentary or testimonial evidence.

VIII. 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

[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] Arnould, 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 "Arnould."

> 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. Prelim. Resp. 5.

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.

IX. CLAIM CONSTRUCTION

We interpret claim terms 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). Thus, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted) (en banc).

We construe only those claim terms that require analysis to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 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))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy'").

Both parties contend that the ordinary and customary meaning of the claims controls here. Pet. 9–10; Prelim. Resp. 5. And neither party proposes any special definition or express claim construction of any term at this time. Pet. 10 ("There are no claim terms . . . that require construction in

order to find those claims unpatentable."); Prelim. Resp. 5. The parties' arguments about whether certain claim limitations appear in the prior art do, however, raise potential issues of claim scope. We discuss those issues below when addressing the mapping of the claims to the prior art.

If the parties believe that further responsive argument on claim interpretation is needed to resolve disputed issues, they may provide such argument in briefing permitted in trial.

X. 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 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).

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

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.

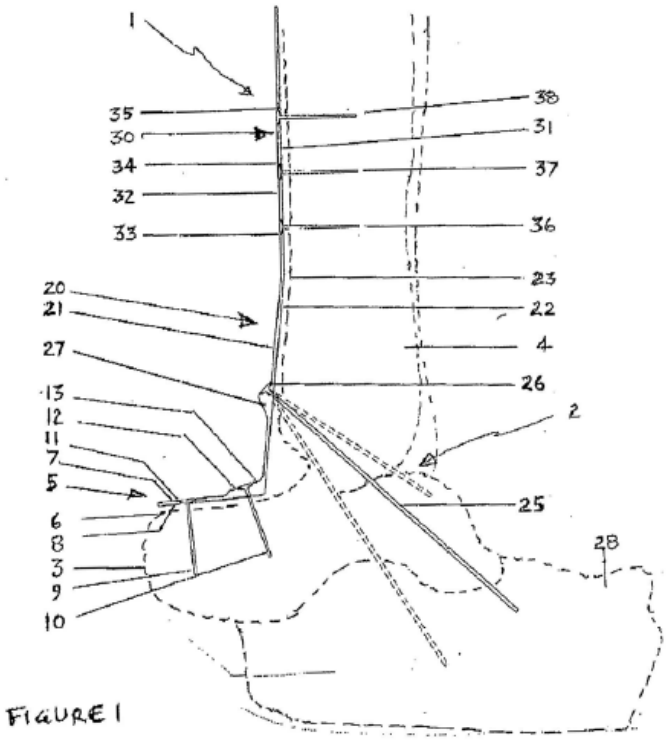
B. Overview of the Asserted Prior Art

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).

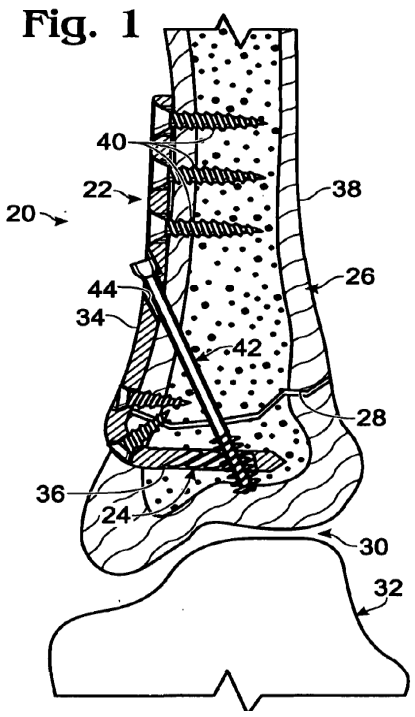
Slater discloses that "[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment." *Id.* at 12:23–25. Continuing, Slater teaches that, "[a]s may be seen in figure 1 the screws are placed in a particular orientation 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 arid [*sic*, and] end points of the L shaped contour over the ankle joint . . . will be at it's [*sic*] maximum thickness." *Id.* at 9:31–34; *see also id.* at 10:3–6 ("The plate will taper at at least one but preferably two different points of the plate . . . [and] [t]he desired effect is for the plate to taper in and decrease in thickness proximally."). Slater further teaches that the plate "will preferably resemble and conform to the typical geometry of the anatomical region. . . . Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint." *Id.* at 10:11–15.

2. *Falkner (Ex. 1006)*

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

Falkner's Figure 1, reproduced below, is a cross-sectional view of an example bone plate including a toothed aperture with the plate secured to a fractured bone. *Id.* ¶ 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. *Arnould (Ex. 1008)*

Arnould is a European patent application that published March 12, 2008. Ex. 1008, code (43). Arnould "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.

Arnould 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, Arnould 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.

Arnould 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 Arnould,

> 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.").

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

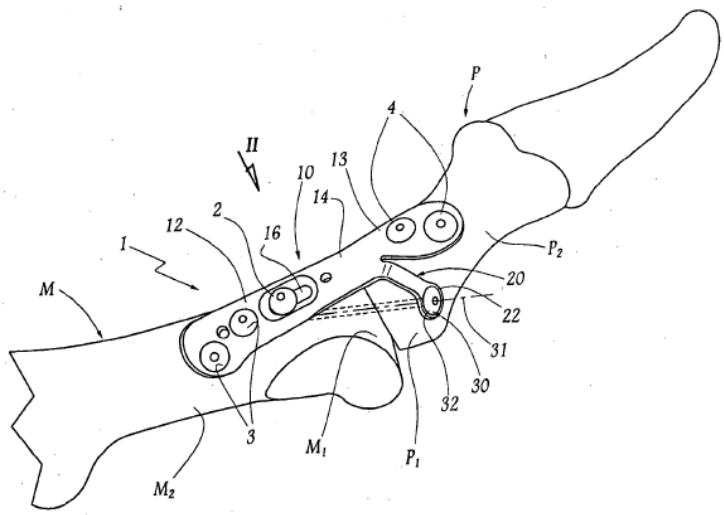


Fig.1

Id. at Fig. 1. Figure 1 of Arnould, 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 overlie 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., 12_1 and 13_1) 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 P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2." *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.

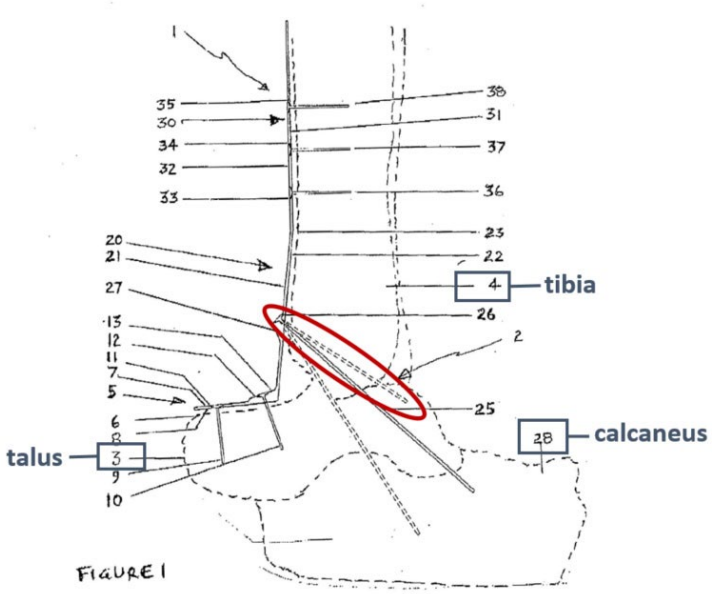
C. Ground 1: Anticipation by Slater

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).

Our discussion below focuses largely on claim 1. We begin with Petitioner's contentions on claim 1, and then move to our analysis, which addresses Patent Owner's counterarguments. We note that Patent Owner has not, at this time, provided separate argument on the patentability of the challenged dependent claims.

1. *Analysis of Claim 1*

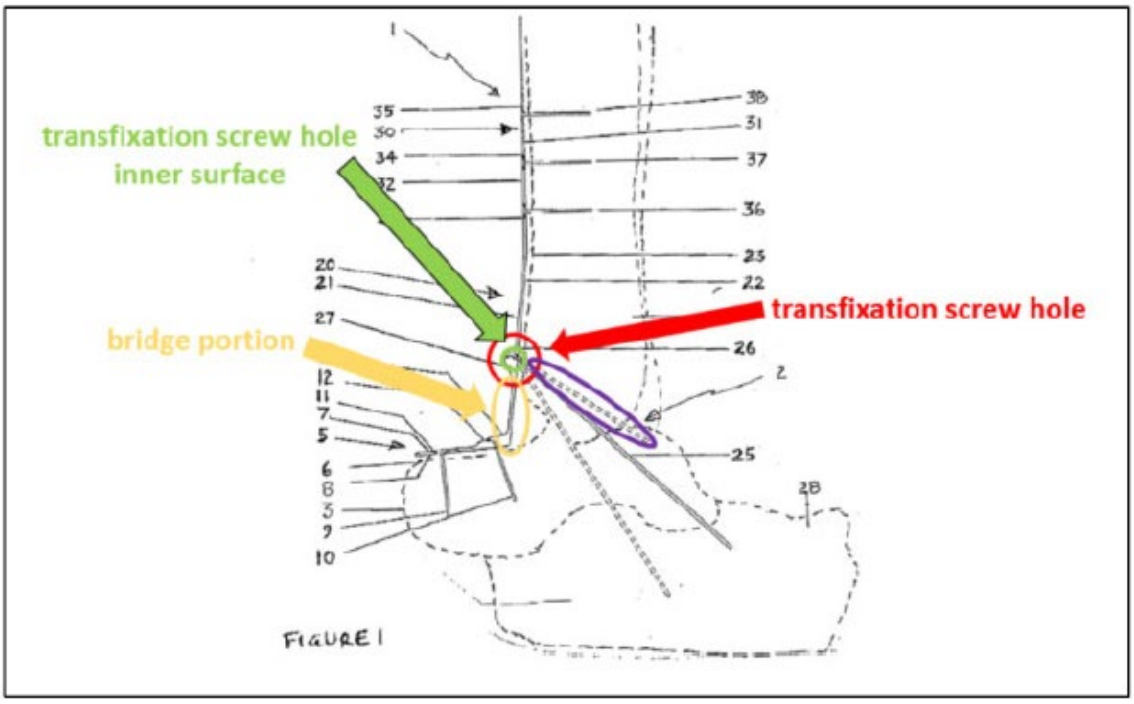
Petitioner argues that, if claim 1's preamble is limiting, Slater discloses a system for securing two discrete bones together across a joint between the two bones. Pet. 16. In support, Petitioner provides an annotated version of Slater's Figure 1, reproduced below.



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.* And Patent Owner does not, at this stage, contest that Slater discloses a bone plate with those recited features meeting the limitations of claim 1. *See generally* Prelim. Resp. 8–18.

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).

Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing the claim 1 is anticipated by Slater. Petitioner argues, with documentary and testimonial support, that Slater's Figure 1 describes a bone plate with an elongate spine having respective first and second ends with respective fixation points for attaching the plate to two bones (tibia and talus) across a joint. Pet. 17–20 (citing, Ex. 1002 ¶¶ 122–127 (identifying corresponding features on Slater's plate)). Petitioner also supports its position that Slater's plate includes ends with inner surfaces configured to substantially conform to the geometry of the first and second discrete bones to which those ends are attached. *Id.* Petitioner further identifies a thickened bridge portion in Slater's plate as required by claim 1. *Id.* at 20–22 (*see, e.g.*, Ex. 1005; Figs. 1, 6, 7); Ex. 1002 ¶¶ 127–28. Patent Owner does not dispute that Slater teaches those limitations. And, although Patent

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

Notwithstanding the above, Patent Owner argues that Slater does not disclose claim 1's preamble (a "system for securing two discrete bones together across a joint between the two bones"),[10] nor the "transferring the tensile load" limitation of the claim. Prelim. Resp. 11–18. For reasons discussed below, Patent Owner's argument does not avoid institution on this record.

Patent Owner argues that Slater fails to disclose an embodiment that meets all the limitations of claim 1. *Id.* at 8–11. More specifically, Patent Owner contends that Petitioner is picking-and-choosing features from among "alternative" embodiments in Slater to combine and modify to arrive at the claimed subject matter. *Id.* at 9–13. Patent Owner contends that "Slater fails to describe th[e] alternative [two-bone] embodiment in detail, only briefly acknowledging that it may be an option" and, thus, Petitioner is allegedly "forced to rely on expert testimony to fill the gaps regarding how the three-bone embodiment would be modified for a two bone application." *Id.* at 10–12 ("Dr. Gall relies on one embodiment securing three bones . . .

[10] We need not decide whether the preamble is limiting at this stage because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 1 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.

and another distinct embodiment of Slater using a different screw configuration for securing two bones across a single joint."), 13 (asserting that "only three [disclosures in Slater] refer to using the plate across fewer than two joints, and the reference to such plate is only made in passing as a mere alternative"). Accordingly, Patent Owner argues that at least claim 1's preamble is not disclosed in Slater.

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

Patent Owner criticizes Dr. Gall's analysis "of a single cursory embodiment" on whether Slater discloses a system for fusing two bones across a single joint. Prelim. Resp. 13. That criticism is, however, unavailing because "[e]xpert testimony may shed light on what a skilled artisan would reasonably understand or infer from a prior art reference." *Acoustic Tech., Inc. v. Itron Networked Solutions, Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). Patent Owner also points out that Slater's disclosure mostly concerns securing three bones across two joints, and that Slater purportedly teaches that adding "more joints" in the fusion is advantageous. Prelim. Resp. 13 (citing, e.g., Ex. 1005, 16:20–30). Even if that aptly characterizes Slater's disclosure, that does not negate anticipation. Un-preferred—even disfavored—embodiments may still anticipate a claim. *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) ("A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it."). We also recognize counsel's argument that "Dr. Gall's opinion of Slater does not represent a fair reading" of the reference, yet Patent Owner provides no testimonial evidence to support a competing interpretation of Slater. Prelim. Resp. 14.

For claim 1's recitation of "transferring the tensile load," Patent Owner argues that Slater includes no such disclosure. Prelim. Resp. 15. Patent Owner argues that Dr. Gall's testimony on that limitation is conclusory and should be disregarded. *Id.* at 15–16. Here, Patent Owner contends, Dr. Gall improperly relies on the three-bone embodiment where the screw extends through the tibia and talus before finally anchoring in the calcaneus, with no adequate explanation how anchoring in the calcaneus would shift tensile load from the talus (or the second bone) to the screw head and plate. *Id.* at 17 (arguing there are "no threads in the second bone" in

Slater's three-bone embodiment). Moreover, Patent Owner argues, the "loading" that Dr. Gall is describing is "not the type of tensile load" in claim 1, which allegedly relates to the biomechanics of the foot or joint during normal activity, not the forces upon insertion of the plate. *Id.* at 17–18 (citing, e.g., Ex. 1001, 5:61–67, 6:30–40).

Patent Owner's position about whether Slater discloses "transferring the tensile load" as in claim 1 may have merit. We determine, however, that this question is better resolved on a full record through trial. At present, Petitioner provides evidence comprising at least Dr. Gall's testimony that a skilled artisan would understand this feature as met in Slater where the screw is angled to cross a joint's neutral bending axis and anchors, not in the calcaneus, but in the talus according to the two-bone embodiment as discussed above. While Dr. Gall supports his opinion by relying, in part, on Slater's express disclosure about a screw and threaded shank anchoring in the calcaneus (heel bone), Patent Owner provides no evidence to undermine Petitioner's showing and Dr. Gall's opinion that, where only the tibia and talus are involved (as also shown in Figure 1), a POSA would recognize that the threads of the screw must engage the talus—securing the second bone (talus) to the plate via the screw with the tibia held between. Ex. 1002 ¶ 131. We do not agree that Dr. Gall's opinion is so lacking in reasoning or support that the Petition should be denied as a result.

On whether the load in claim 1 differs from the load and load transfer provided by Slater's plate when the tibia is held in a vise-like arrangement between the plate and talus as explained by Petitioner, this too would benefit from further argument and evidence before final resolution. From the '716 patent, it appears that transferring of tensile load as claimed depends at least somewhat on the biomechanics of the foot (or other hinge-type joint)

when the joint is subjected to conditions in which it would otherwise flex. *See, e.g.*, Ex. 1001, 5:56–6:6. On the other hand, the patent explains, a "'tension band' construct" that allows load to be transferred arises when the plate is attached and the fixation screw crosses the joint's neutral bending axis (which axis separates a tension and compression side of the joint) and anchors in a second bone. *See id.* at 6:7–40 ("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 . . . a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes."). This "tension-band" construct in the '716 patent, thus, appears consistent with how Slater's plate would work when fixed to the tibia and talus in the manner identified by Petitioner. Lending support for this tension band construct in Slater is Petitioner's analysis of dependent claims 2 and 3, which provides further detail on the trajectory of Slater's fixation screw and the biomechanics of the ankle joint. There, Petitioner explains that Slater's screw extends at a trajectory that traverses a portion of the tibia (first position), a neutral bending axis of the joint, and a portion of the talus (second position) so that, at least periodically during the gait/walking cycle, the first position will reside on compression side of the joint and the second position on the tension side of the joint.[11] Pet. 27–30; Ex. 1002 ¶¶ 133–144.

To be sure, how Slater's system is capable of "transferring the tensile load" could have been better explained in the Petition. Proceeding on this

[11] It appears that what Petitioner has identified as the "posterior side of the joint" is the anterior side based on the heel bone's prominence to the lower right of Slater's Figure 1. Pet. 30; Ex. 1002 ¶ 144. In any event, the anterior and posterior sides of the ankle joint will seemingly transition back-and-forth from compression to tension during walking as the joint flexes.

record is a close call and, we emphasize, Patent Owner may well prevail on this or other issues at trial. But, based on the existing evidence including Dr. Gall's testimony that a POSA would understand that Slater's system is configured as claimed, we determine that Petitioner is at least reasonably likely to prevail in showing that Slater anticipates claim 1.

2. *Analysis of Remaining Claims*

Petitioner's challenge to independent claims 10 and 16 as anticipated by Slater is substantially similar to its challenge on claim 1. Pet. 33–36 (cross-referencing analysis on claim 1); Ex. 1002 ¶¶ 154–166 (claim 10), 171–183 (claim 16). Patent Owner raises the same arguments on claims 10 and 16 as it raised on claim 1. Considering the argument and evidence on claims 10 and 16 at this stage, we determine that Petitioner is reasonably likely to prevail in establishing that those claims are anticipated by Slater for substantially the same reasons as discussed above.

Petitioner also argues that dependent claims 2–5, 9, 11–13, and 17–19 are anticipated by Slater. Pet. 27–32, 36. Petitioner cites documentary and testimonial support for its argument and Patent Owner does not provide any separate rebuttal argument on the challenged dependent claims. *Id.*; *see generally* Prelim. Resp. 19 (merely noting that "the remaining claims all depend from [allegedly patentable] claims 1, 10, and 16"). Patent Owner's argument on claims 1, 10, and 16 is unavailing as noted above and, on this record, Petitioner is reasonably likely to prevail in showing that one or more of the challenged dependent claims are unpatentable. Also, if trial is instituted, we will institute on all challenged claims and grounds. *SAS*, 138 S. Ct. at 1354; *PGS Geophysical,* 891 F.3d at 1360.

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, 13:14–16, 13:22–25. 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.

Patent Owner's only counterargument to Ground 2 at this stage is its argument for claim 1 and Ground 1. Patent Owner's argument on Ground 1 is addressed above. On this record, Petitioner has met its institution burden on Ground 2 and, as we are instituting trial on other claims and grounds, we must institute trial on all challenged claims and grounds.

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).

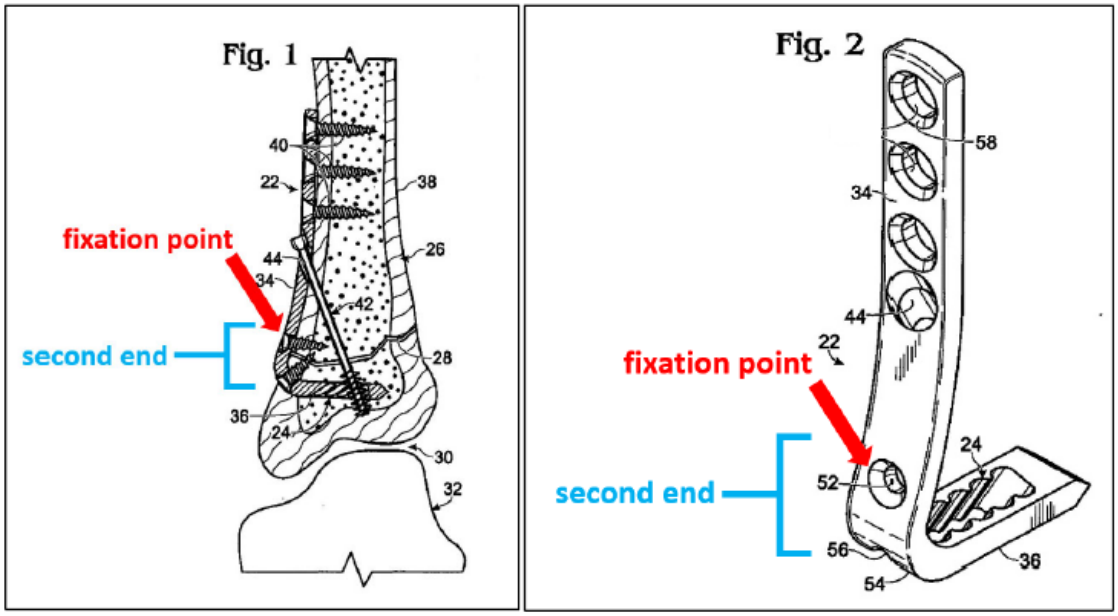
1. *Analysis of Claim 1*

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.* ¶ 28.

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 and Ex. 1002 ¶ 202). According to Petitioner, this configuration would meet claim 1's "elongate spine" and "first end" limitations. *Id.* at 40–43.

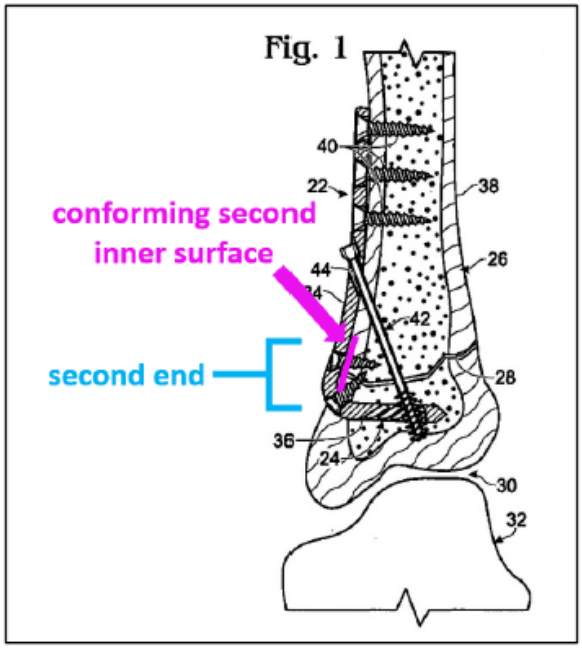
For claim 1's "second end" limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.



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

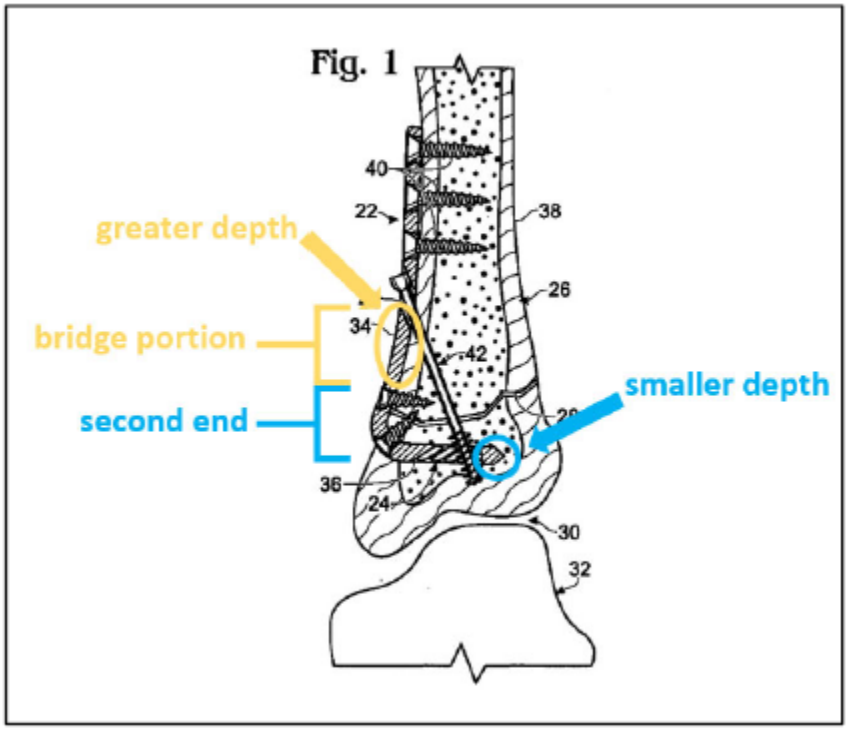
to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner 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 and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 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).

Patent Owner raises multiple counterarguments. Prelim. Resp. 20–32. According to Patent Owner, "Falkner is entirely focused on a bone plate for fixing a bone fracture (i.e., a break in a single bone)" and "there is no disclosure in Falkner explaining how spanning a joint would be achieved or when such an application would be desired." *Id.* at 20–21. Patent Owner contends that Falkner does not disclose a single embodiment that meets all the limitations of claim 1, so Petitioner "relies on a smattering of paragraphs" in Falkner in an attempt to stretch Falkner's single-bone embodiment to explain how Falkner's plate would have been configured in a different context to reach the claimed subject matter. *Id.* at 20–25, 32. This, Patent Owner contends, is not a theory supportive of anticipation. *Id.*

Patent Owner also contends that Falkner's cited plate does not include a second end with an inner surface configured to substantially conform with a geometry of a second bone as claimed. *Id.* at 29–32. According to Patent

Owner, what Petitioner identifies as the "second end" of Falkner's plate is not, in fact, a "second end." *Id.* at 29 ("The end of the plate is [as] described and claimed, not some portion before the end."). To the contrary, Patent Owner argues that the "second end of the plate of Falkner is inside the bone, and does not conform to the geometry of the second bone" and further, that this internal end portion includes an aperture for receiving the threaded fastener so any attempt to modify its geometry to conform to a second bone would run counter to the design and purpose of Falkner's plate. *Id.* at 32.

Moreover, Patent Owner argues that Falkner fails to disclose "transferring the tensile load" as recited in claim 1. *Id.* at 26–29. Patent Owner contends that Dr. Gall's testimony on this topic is conclusory, that Dr. Gall fails to appreciate differences between compressive forces (as allegedly recited in Falkner's ¶ 71) and tension forces as claimed, and that because Falkner's screw is not being anchored in the second bone but instead in a second (internal) portion of the plate, Dr. Gall's opinion that Falkner's plate transfers tensile forces as claimed is "contrary to the purpose of the screw in Falkner." *Id.*

Based on the present record, we are doubtful that Petitioner will prevail in showing that Falkner anticipates claim 1. Manifestly, Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second 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 POSA 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 ¶ 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 POSA 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 POSA 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"[12]—to obviousness.

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

The parties' dispute about what is or is not a "second end" in Falkner may turn on claim construction, for which the parties have provided no briefing. Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that portion as a "second end." 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. Moreover, 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.[13] Such picking and choosing is indicative of a theory based on obviousness.

For at least the above reasons, we are skeptical that Petitioner will prevail in establishing that claim 1 is anticipated by Falkner. Nevertheless,

[13] 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 ¶ 203.

consistent with precedents and Board guidance, if we institute, we must include all challenged claims and grounds.

2. *Analysis of Remaining Claims*

Petitioner's analysis on independent claims 10 and 16 as anticipated by Falkner is substantially similar to its analysis of claim 1. Pet. 55–57. 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, 3, 6, 8, 9, 11, 17, and 18, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 49–54, 57. All challenged claims and grounds must, however, be included in trial when institution is granted.

F. Ground 4: Obviousness over Falkner and Arnould

Petitioner argues that dependent claims 4, 5, 13, and 19 would have been obvious over Falkner and Arnould. 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 Arnould under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claims 4, 5, 13, and 19.

Patent Owner argues that Petitioner's challenge under Ground 4 should be rejected for the same reasons as Ground 3. Prelim. Resp. 33. We determine, at this stage, that Ground 4 suffers from at least the same shortcomings as discussed above for Ground 3 because Ground 4 relies on Petitioner's threshold success on Ground 3's anticipation challenge. Also, Petitioner contends a POSA 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 Arnould. Pet. 60. 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 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.* The conclusory testimony of Dr. Gall on this issue is likewise deficient. Ex. 1002 ¶¶ 277–278. Nevertheless, we include all challenged claims and grounds in trial.

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 of claim 1 for claims 10 and 16).

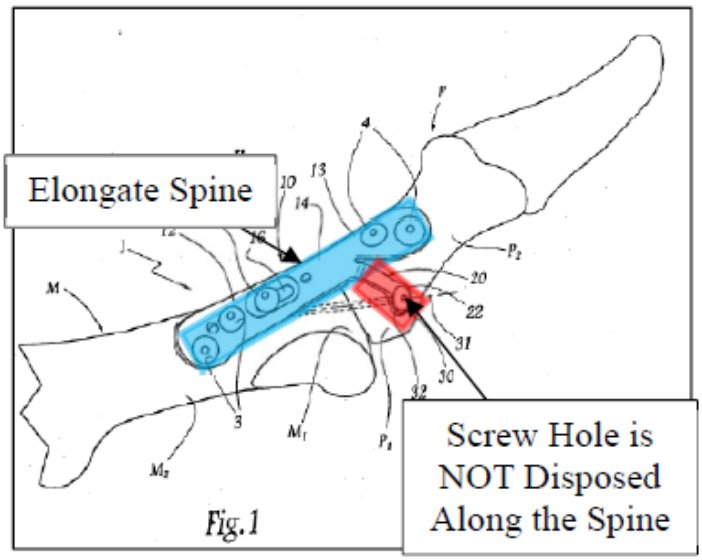
1. *Analysis of Claim 1*

Petitioner contends that "Arnauld 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 POSA "would have been motivated to modify the bone plate of Arnauld with the thickened bridge portion (bridge portion having greater depth) of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." *Id.* at 67–68 (citing Ex. 1002 ¶ 290; Ex. 1005, 15:19–23, 17:32–33).

Patent Owner does not, at this time, dispute that Arnould discloses most of claim 1's limitations. *See generally* Prelim. Resp. 34–38. Nor does

Patent Owner challenge Petitioner's proposed rationale for combining Arnould and Slater. *Id.* Patent Owner, instead, raises two arguments.

First, Patent Owner contends that Petitioner's modified version of Arnould and Slater does not disclose a transfixation screw hole "disposed along the [elongate] spine" as recited in each of claims 1, 10, and 16. *Id.* at 34–37. According to Patent Owner, 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 at all, but is rather part of a separate arm piece that extends off the spine." *Id.* at 34. Patent Owner provides the following annotated version of Arnould's Figure 1 in support of its argument.



Id. at 35; 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." Prelim. Resp. 35. In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate's midsection. *Id.* Patent Owner explains, with citation to related disclosure in

Arnould, that leg (20) "is meant to wrap around the bone and is located vertically below the plate body." *Id.* (citing Ex. 1008 ¶ 23). In the figure above, Patent Owner adds an arrow identifying a screw hole at the end of the leg (20), which Patent Owner adds "is NOT Disposed Along the Spine." *Id.*

Based on the present record, we tend to agree with Patent Owner. Indeed, it appears that Arnould's leg extends in a different plane, down and away from the main or central elongate body of Arnould's plate. This is evident from Patent Owner's annotation, and Arnould's figures and related teachings. *See, e.g.*, Ex. 1008 ¶¶ 23–24, Figs. 1–2; *see supra* Section X.B.3 (summarizing Arnould). As Patent Owner explains, the leg's end (22) (where the alleged transfixation screw hole resides) is located vertically below the plate body, and the leg itself is bent downward relative to the plate body, including a distinct bend line (23) and "junction" between the leg and the phalangeal portion of the plate body (13). Prelim. Resp. 35–36; Ex. 1008 ¶ 24. The parties may consider briefing the issue further at trial, but insofar as the alleged transfixation screw hole of Arnould is located away from the main body of the plate, at the end of a seemingly distinct leg structure, we are skeptical that such screw hole in Arnould is, under a supportable interpretation, "disposed along the [elongate] spine" of the bone plate as in claims 1, 10, and 16.[14]

[14] The parties may, for example, consider addressing the patent's disclosure that appears to distinguish screw holes located on flanges that laterally extend from an elongate spine versus screw holes "disposed along [the] spine." Ex. 1001, 11:19–29. Although the claims may not require a transfixation screw hole be disposed precisely at the spine's centerline, the patent appears to generally define the spine as the plate's "central portion" spanning its length. Ex. 1001, 8:21–22. In that light, we are doubtful that a screw hole located at the end of a leg structure that extends down and away

Patent Owner's second argument is that "Arnould fails to disclose transferring tensile load from a second bone to the plate using screw 30 when the second bone is loaded relative to the first." Prelim. Resp. 37. Because, in Patent Owner's view, Arnould's through-hole (25) is not disposed along the spine or bridge but, instead, in a separate leg vertically below the plate, "tensile load is not transferred into the bridge . . . it is transferred into the through-hole at the end of the leg." *Id.*

Patent Owner's second argument appears to have potential merit as well. Petitioner tells but does not endeavor to show how tensile load from a second bone in Arnould is allegedly transferred from the screw to the bridge. Pet. 70. Arnould suggests that a load or bending stress is transferred to the long screw (30) that is accepted by through-hole (25). Ex. 1008 ¶ 6 ("[T]his screw essentially, if not exclusively, takes up the bending stresses generated during the patient's walking."), Fig. 1. And we might surmise that some such stress is transferred to the screw hole or perhaps even some portion of the leg. But, on this record, it is a leap to conclude that tensile load is transferred from the screw to the "bridge portion (junction zone 14)" of the plate's main body as asserted by Petitioner. Pet. 70. Petitioner's and Dr. Gall's conclusory assertions on this issue are wanting for evidentiary support and, thus, unpersuasive. *Id.*; Ex. 1002 ¶ 295. Furthermore, it seems the primary purpose of Arnould plate design, with its distinct leg and screw structure is to *take bending stresses off the plate* body. *Compare* Ex. 1008 ¶¶ 3–4 (explaining disadvantages with prior systems where "bending stress is essentially absorbed by [the] plate"), *with* ¶ 6 (describing the screw at the

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from a central portion of Arnould's plate would be interpreted as being "disposed along the [elongate] spine."

end of the leg as taking up the bending stresses owing to the screw's higher capacity to resist bending stresses so the plate is stable over time). The transfer of load from the second bone, to the screw, screw head, and into the bridge portion of the plate as proposed by Petitioner appears, therefore, to run counter to Arnould's design and purpose.[15]

For at least the reasons above, we are doubtful that Petitioner can prevail on its challenge to claim 1 as obvious over Arnould and Slater. All challenged claims and grounds must, however, be included in trial when institution is granted.

2. *Analysis of Remaining Claims*

Petitioner's analysis on independent claims 10 and 16 as obvious over Arnould and Slater is essentially the same as its analysis of claim 1. Pet. 74–76. 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, 11–13, and 17–19, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 70–74, 77. All challenged claims and grounds must, however, be included in trial when institution is granted.

H. Ground 6: Obviousness 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. 77–78. 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.*

[15] Petitioner makes a final passing statement that "Slater also discloses this claim element" about transferring tensile load. Pet. 70. This is not a developed argument and we give it no weight. The only express change to Arnould's design under Ground 5 that Petitioner proposes for claim 1 is to make the alleged bridge portion thicker as allegedly taught by Slater.

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). Because we doubt that Petitioner can prevail on Ground 5, we doubt that it will prevail on Ground 6. Nevertheless, all challenged claims and grounds must be included in trial when institution is granted.

I. Incorporation-by-Reference

Patent Owner argues that the Petition cites to numerous paragraphs in Dr. Gall's declaration that include "arguments and analysis not included in the Petition." Prelim. Resp. 39–40 (citing, *e.g.*, Ex. 1002 ¶¶ 121–131). According to Patent Owner, this tactic amounts to improper incorporation-by-reference of subject matter that should have been included in the Petition itself and reveals Petitioner's attempt to circumvent the controlling word limits. *Id.* Patent Owner requests that the Petition be denied as a result.

We disagree that the Petition should be denied on the basis of Petitioner's citations to Dr. Gall's testimony. Patent Owner contends that Dr. Gall's cited testimony includes argument and analysis not provided in the Petition, but Patent Owner does not identify any such argument or analysis nor explain how Dr. Gall's testimony departs materially from what is argued in the Petition. Although some sections of Dr. Gall's testimony are longer—in pages or words—than corresponding sections of the Petition, much of what's in the declaration contributing to that length is simply text from the cited portions of the references that has been written out (i.e., quoted) by Dr. Gall in support of major premises that certain claimed subject matter is disclosed in the asserted art. *See, e.g.*, Ex. 1002 ¶ 121.

Again, Patent Owner does not direct us to any specific argument in the declaration that is new or materially different from what is in the Petition. Moreover, it is often appropriate for a declarant to elaborate on the argument or evidence in the Petition—otherwise the Petition and the declaration simply mirror each other, which the Board has discouraged. *InfoBionic, Inc. v. Braemer Mfg., LLC*, IPR2015-01704, Paper 11 at 6 (PTAB Feb. 16, 2016) (finding declaration unpersuasive when it "repeats the Petitioner's arguments and offers little or no elaboration"). The line between permissible and improper reliance on expert testimony to support positions taken in the Petition is not always easy to draw. But we are not persuaded that Petitioner crossed it under the circumstances here.

XI. CONCLUSION

Petitioner has, at this stage, established a reasonable likelihood of prevailing in showing that at least one of the challenged claims is unpatentable. This determination is, however, based on a preliminary record. We will make a final determination on the patentability of the challenged claims, as necessary and applying the preponderance of the evidence standard, based on a fully developed record through trial.

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

XII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a) an *inter partes* review of claims 1–6, 8–13, and 16–19 of the '716 patent is hereby instituted on the grounds set forth in the Petition, commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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

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