

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2022-00189
Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and
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 claim 16 (“Challenged Claim”) of U.S. Patent No. 8,529,608 B2 (“the ’608 patent,” Ex. 1001) is unpatentable.

A. *Background and Summary*

Petitioner filed a Petition requesting an *inter partes* review of claim 16 of the ’608 patent. Paper 2 (“Pet.”). Patent Owner filed a Preliminary Response to the Petition. Paper 6.

Following institution, Patent Owner filed a Response to the Petition (Paper 17, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 20, “Reply”), and Patent Owner filed a Sur-reply (Paper 23, “Sur-reply”).

On March 1, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 33.

B. *Related Matters*

Petitioner filed another petition for *inter partes* review in IPR2021-01450 that challenged claims 1–6, 8–14, and 17 in the ’608 patent. Pet. 2; Paper 8, 2. Petitioner has filed petitions for *inter partes* review in IPR2021-01451 and IPR2022-00190 for related U.S. Patent No. 9,351,776; IPR2021-01452 and IPR2022-00191 for related U.S. Patent No. 9,763,716; and IPR2021-01453 for related U.S. Patent No. 10,245,085. Pet. 2–3; Paper 5,

1–2. The parties indicate that the ’608 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-1621 (D. Del.). *Id.*

C. The ’608 patent (Ex. 1001)

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

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

Figure 2, reproduced below, shows “a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-

phalangeal joint” and immediately below it is Figure 3, which shows “a more detailed isometric view of the bone plate.” *Id.* at 3:1–6.

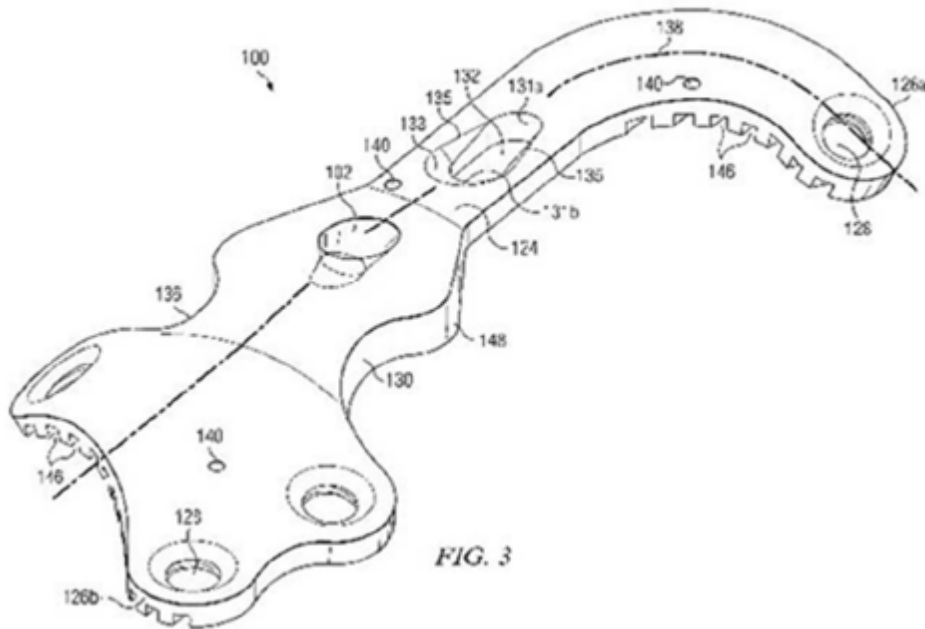
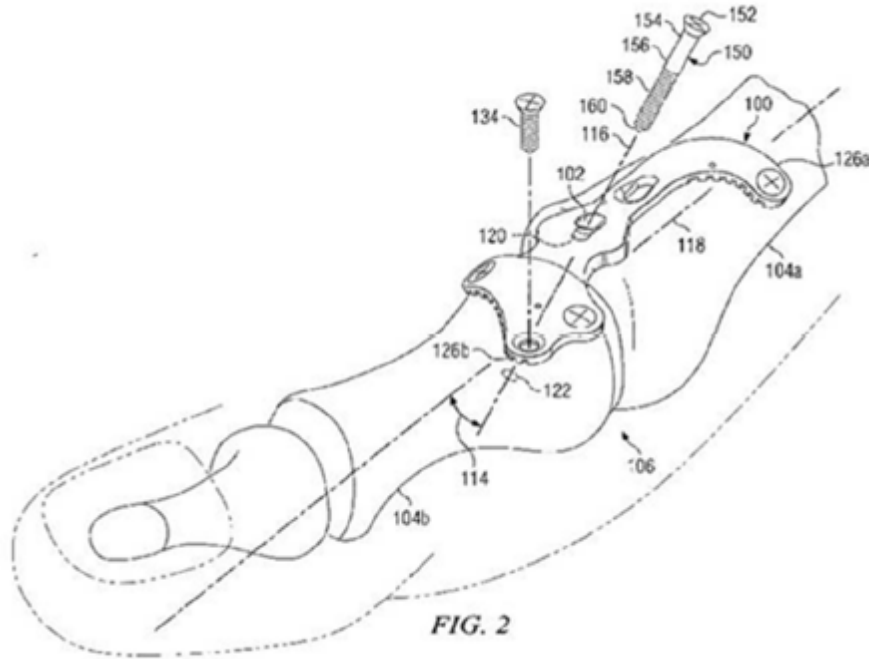


Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id.* at 4:3–8. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b “in order to fuse joint 106.” *Id.* at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

D. The Sole Challenged Claim

Dependent claim 16, reproduced below, is the only challenged claim of the ’608 patent in this proceeding. Claim 16 depends from independent claim 11, which is also reproduced below.

11. [11.P] A plate for securing two discrete bones together across an intermediate joint, comprising:

[11.1] an elongate spine having:

a first end comprising:

at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and

a first inner surface configured to substantially conform with a geometry of the first bone;

[11.2] a second end comprising:

at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

a second inner surface configured to substantially conform with a geometry of the second bone; and

[11.3] a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and

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

[11.5] wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends.

16. The plate of claim 11, [16.1] further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate, [16.2] the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole.

Ex. 1001, 13:4–14:2, 14:20–25 with Petitioner’s numbering added (*see* Pet. 11–12).

E. Evidence

Petitioner relies upon information that includes the following.

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

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

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

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1028) and Dr. George B. Holmes, Jr. (Ex. 1029) to support its contentions.

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

F. Asserted Grounds of Unpatentability

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

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

II. ANALYSIS

A. 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 states that it has “applied the ordinary and customary meaning of each claim term throughout the Petition in light of the ’608 patent specification and file history.” Pet. 13

Patent Owner contends that preamble of claim 11 “is limiting, and requires a plate for securing two discrete bones together across a joint between the two bones.” PO Resp. 15. Patent Owner also contends that the

term “trajectory” as used in the Challenged Claim “means a fixed angle relative to the neutral bending axis of the joint.” *Id.* at 16. Patent Owner’s proposed construction is relevant to Ground 1 and our discussion below regarding whether Slater is anticipatory.

Petitioner replies that “Patent Owner fails to demonstrate that the preamble of claim 11 is limiting,” because the limitation “a plate *for* securing two discrete bones together across a joint” is “an intended use,” and “is not a limitation that describes a fundamental characteristic of the claimed invention.” Reply 1 (citing *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (affirming that preamble phrase “for rehabilitation of unilateral hearing loss” is non-limiting)).

In response, Patent Owner reiterates that the preamble is limiting and that “the limiting language in the preamble was added during prosecution in response to a rejection to limit the claims.” Sur-reply 2 (citing Ex. 1004, 267–268, 289, 291, 296).

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.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner proposes that a person of ordinary skill in the art (“POSA” or “POSITA”) at the time of the invention

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

Pet. 12 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner’s proposal about the POSA’s qualifications. PO Resp. 22.

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.

C. Summary of Cited Prior Art

1. Summary of Slater (Ex. 1005)

Slater is an international patent application published on November 22, 2007. Ex. 1005, code (43). Slater relates to an ankle fusion plate for fusion of the anterior ankle. *Id.* at 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3. According to Slater, internal fixation techniques require “the fracture be stable axially, torsionally and rotationally.” *Id.* at 3:19–25; 7:1–2. To achieve such objectives, Slater discloses a fixation screw and plate design in which “the plate depth changes at different locations” so that “the depth at

the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness.” *Id.* at 8:27–34. Slater further discloses that “[t]he plate will taper at least one but preferably two different points of the plate” and that “[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region.” *Id.* at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws “to an abbreviated ankle joint (dotted lines).” *Id.* at 9:28–30.

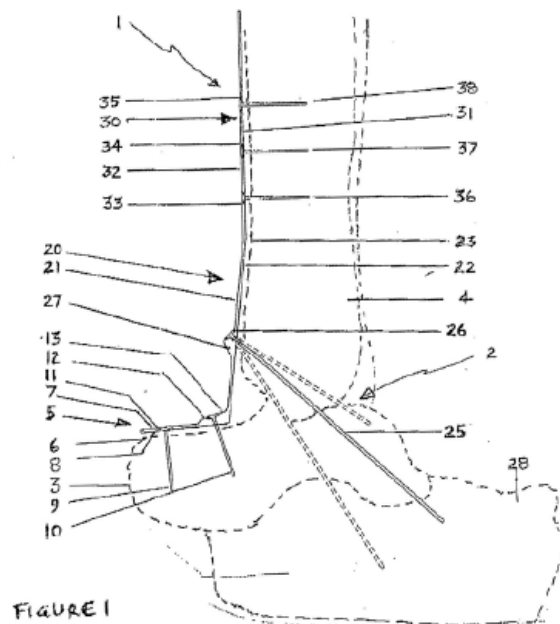


Figure 1 shows plate (1) attached to an ankle joint (2) opposing the talus bone (3) and the tibial bone (4). *Id.* at 12:2–4. Figure 1 depicts plate (1) having inner (22) and outer (21) surfaces, with inner surface (22) opposing the anterior surface (23) of the tibia (4). *Id.* at 12:18–19. Portion (30) 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 [sic] maximum thickness." *Id.* at 9:31–34; *see also id.* at 10:3–6 ("The plate will taper 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

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. *Summary of Duncan (Ex. 1010)*

Duncan is a U.S. patent application filed March 9, 2009, which published on September 10, 2009. Ex. 1010, codes (22), (43). Duncan relates to a joint fixation system (i.e., plate), especially for the joints of the hand. *Id.* at code (57). Figure 2 of Duncan is reproduced below.

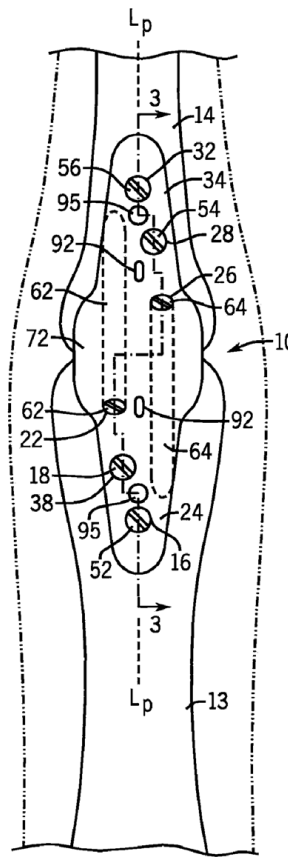


FIG. 2

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

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

D. Ground 1: Anticipation of Claim 16 by Slater

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

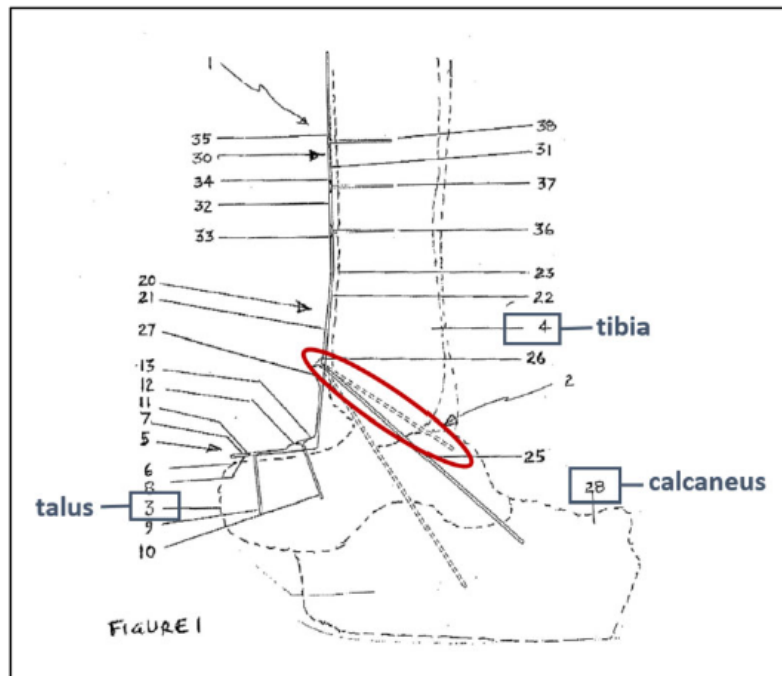
and then addresses the limitations added by dependent claim 16, the sole challenged claim (*id.* at 28–30). Patent Owner raises multiple counterarguments. PO Resp. 22–39.

Having considered the parties’ positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 16 is anticipated by Slater. Our analysis follows.

1. Petitioner’s Contentions

Petitioner first contends that, if claim 11’s preamble is limiting, Slater discloses a plate for securing two discrete bones together across an intermediate joint between the bones. Pet. 18–19.¹ In support, Petitioner directs our attention to its annotated Figure 1, reproduced below, which shows “a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines).” *Id.*; Ex. 1005, 9:28–30.

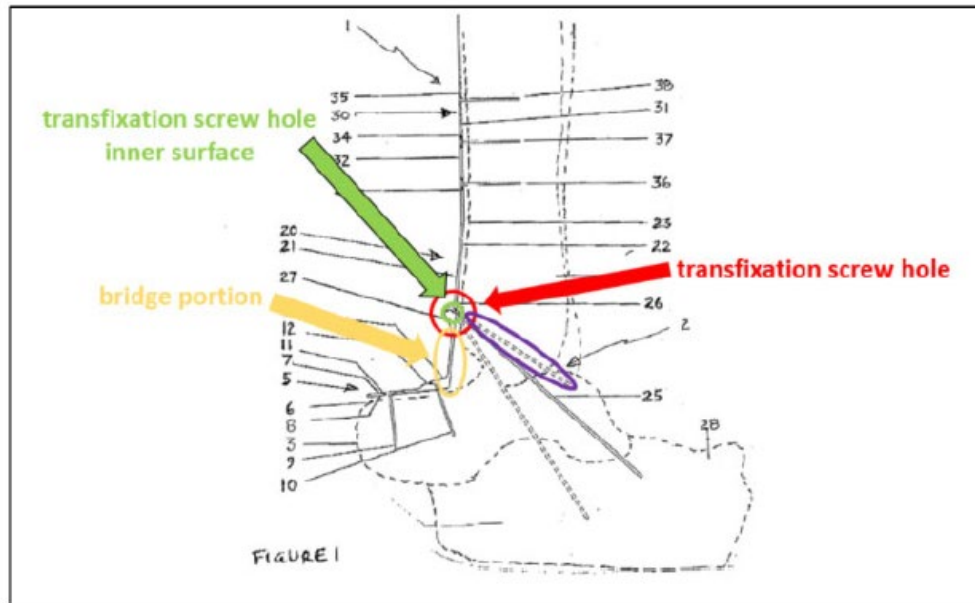
¹ We need not decide whether the preamble is limiting because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 11 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.



Pet. 19. 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. *Id.* at 18 (citing Ex. 1002 ¶ 89).

Petitioner further contends that Slater discloses claim 11’s elongate spine and first and second ends, as well as a bridge portion between the ends as claimed (labeled by Petitioner as claim limitations 11.1, 11.2, and 11.3). Pet. 19–23 (citing Ex. 1002 ¶¶ 90-94). 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 11's recited transfixation screw hole and related functionality, labeled limitation 11.4 by Petitioner. Pet. 24–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



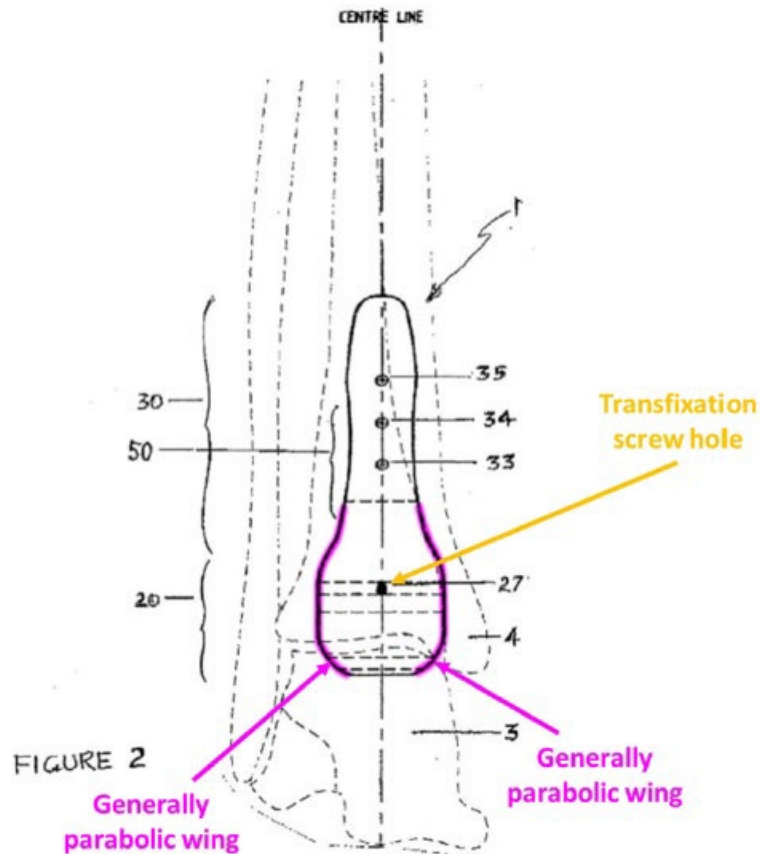
Id. at 26. Petitioner's annotation to Figure 1 identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶ 98). 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.* at 25–26 ; Ex. 1005, Fig. 1.

According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the

talus through the screw into the screw head and plate's bridge portion as claimed. Pet. 26–27. Petitioner explains that “[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between.” *Id.* at 27. Petitioner cites Dr. Gall's testimony to support this understanding of Slater's plate and its functionality when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 100).

Petitioner next addresses claim 11's recitation of “wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends,” which Petitioner labels as limitation 11.5. Pet. 27–28. With reference to Figures 5 and 7 of Slater, Petitioner contends that Slater discloses limitation 11.5. *Id.* (citing Ex. 1005, Figs. 5, 7; Ex. 1002 ¶ 100). In particular, Petitioner contends that “the first and second ends of the Slater bone plate are tapered [, and a]s such, both the bridge portion and the portions of the plate surrounding the transfixation screw hole are thicker than “at least a portion of” the tapered ends.” *Id.* (citing Ex. 1002 ¶ 100; Ex. 1005, 8:25–26, 8:32–9:6, 14:19–23, 24:17–19).

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



Id. at 29. Figure 2, above, is a front elevation view of Slater's plate (the plate as otherwise depicted in a side elevation in Figure 1) and shows the plate oriented for placement on the underlying tibia (4) and talus (3); Petitioner's annotation shows "Generally parabolic wing[s]" (labeled with purple arrows and highlighting) on the lower left and right sides of the plate, extending laterally on opposite sides of the transfixation screw hole (indicated by yellow arrow). *Id.*; Ex. 1002 ¶ 106.

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. 35. 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.* at 36. 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 35–36 (citing Ex. 2002 ¶¶ 106–107; 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 36–37 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶¶ 109–110). 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 transfixation screw was affixed or loaded, or how many bones it penetrated. *Id.* at 37–38 (citing Ex. 1002 ¶ 99; Ex. 2002 ¶¶ 111–116; 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. Reply 13–14 (citing Ex. 1002 ¶ 99; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 121–123; Ex. 1028 ¶¶ 33–42; Ex. 1031, 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 '608 patent in the same manner that Dr. Gall describes Slater transfers

tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶ 99; Ex. 1028 ¶¶ 33–43; Ex. 1031, 74:9–13, 90:24–91:23). 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. 1028 ¶¶ 44–45). 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. 1028 ¶¶ 45–46; Ex. 1031, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 11 recites

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

Ex. 1001, 13:22–31 (emphasis added). We will refer to this limitations collectively as the “transfer of tensile load” limitation. The parties dispute whether Slater expressly or inherently discloses this limitations.

We first address Petitioner’s argument that Slater discloses a “vise” 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 (citing Ex. 1002 ¶ 99; Ex. 1005, 11:19–25, 12:32–13:3, 13:21–24); Reply 13–15 (citing Ex. 1002 ¶ 99; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex.

1027 ¶¶ 121–123; Ex. 1028 ¶¶ 33–42; Ex. 1031, 67:23–68:7, 68:17–70:3, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22, 106:19–107:17; Ex. 2003, 46:23–48:4, 90:24–91:23). 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. 26–27; Ex. 1002 ¶ 99 (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

wise-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. 26–27, *with* Reply 15. 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 “wise” configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 13. (relying on “wise” 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 “wise” 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 to 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 ¶ 99; Ex. 2002 ¶¶ 111–116; Ex. 2003, 92:24–93:7). 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 limitation in claims 11.

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 ¶ 99; Ex. 1027 ¶¶ 33–42. 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 ¶¶ 57–58 (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), 81–83, 108–120 (opining that Slater fails to disclose the transfer of tensile load limitations).²

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claim 11 and therefore does not prove, by a preponderance of the evidence, that Slater discloses each element of independent claim 11. Petitioner’s challenge to dependent claim 16 as anticipated by Slater is substantially similar to its analysis of independent claim 11, which relies on Petitioner’s predicate analysis on the independent claim. Pet. 28–29. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 16 is anticipated by Slater.

E. Ground 2: Obviousness of Claim 16 over Falkner and Duncan

Petitioner argues that dependent claim 16 would have been obvious over Falkner and Duncan. Pet. 30–45. As with Ground 1, Petitioner begins with an analysis of independent claim 11 before moving to the challenged dependent claim 16. *Id.* To support its contention, Petitioner directs our attention to the various disclosures of Falkner and provides a detailed claim analysis addressing how each element of claim 11 is disclosed by Falkner.

² We are also unpersuaded by Petitioner’s arguments based on the alleged similarity between the description Mr. Sommers provides of how the ’608 patent shows the transfer of tensile load and Dr. Gall’s description of how Slater transfers tensile load. See Reply 14–15. 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.

Pet. 28–36 (citing Ex. 1002 ¶¶ 106–120). Petitioner then directs our attention to the various disclosures of Duncan and provides a detailed claim analysis addressing how each element of claim 16 is disclosed by Duncan, and explains why a person of ordinary skill in the art would have been motivated to modify Faulkner in view of the teachings of Duncan. Pet. 30–45 (citing Ex. 1002 ¶¶ 107–120). Patent Owner raises multiple counterarguments. PO Resp. 39–52.

Having considered the parties’ positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 16 would have been obvious over Falkner and Duncan. Our analysis follows.

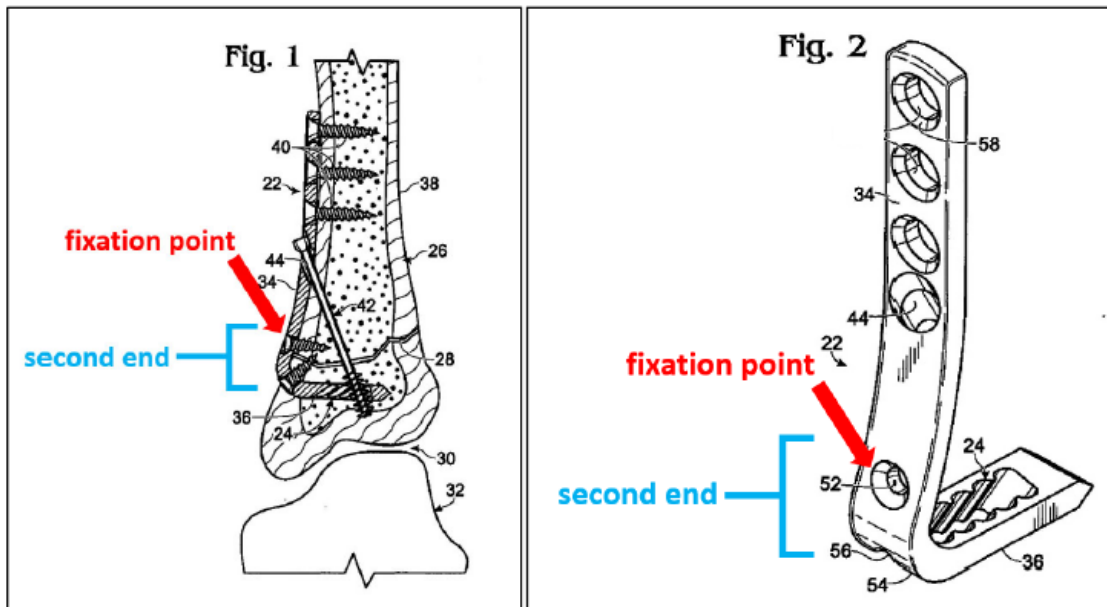
1. Petitioner’s Contentions

We begin our analysis with Petitioner’s contentions with regard to claim 11. Petitioner contends that Falkner discloses the preamble and every other element of claim 11. Pet. 31. According to Petitioner, although Falkner’s Figure 1 shows a plate for fixing a single fractured bone, Falkner discloses that its bone plates may be used for any suitable “bone(s)” to fix fractures or other bone discontinuities. Ex. 1006 ¶¶ 21, 28. Petitioner cites Falkner’s disclosure that, “[i]n other examples, plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others.” *Id.* ¶ 21 (emphasis omitted).

In a scenario where Falkner’s plate spans the ankle joint, Petitioner contends that “plate 22 would be placed across 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. 32 (citing Ex. 1002 ¶ 111). And, Petitioner argues, “the first inner surface [of the plate] would be configured

to substantially conform with a geometry of the first bone (tibia 26).” *Id.* at 33 (citing Ex. 1002 ¶ 112; and Ex 1006 ¶¶ 23, 34 (disclosures in Falkner that one or multiple surfaces of the bone plate may be contoured to follow the exterior surface of a bone or bones, which helps to provide a low profile to the plate)). According to Petitioner, this configuration would meet claim 11’s “elongate spine” and “first end” limitations, of element [11.1]. *Id.*

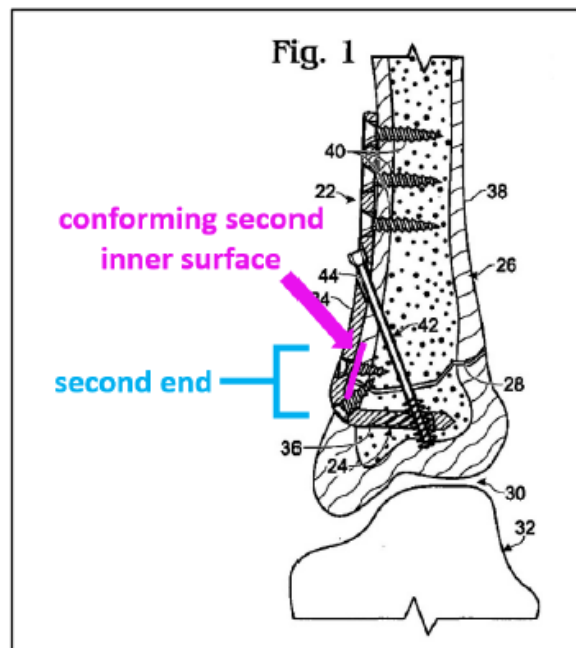
For claim 11’s “second end” limitations (labeled element [11.2] by Petitioner), Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.



Pet. 34 (citing Ex. 1006, Figs. 1–2). Petitioner’s annotated version of Falkner’s Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia’s external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner’s annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate’s general “L” shape. *Id.* In both figures, Petitioner adds a

blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which 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.*

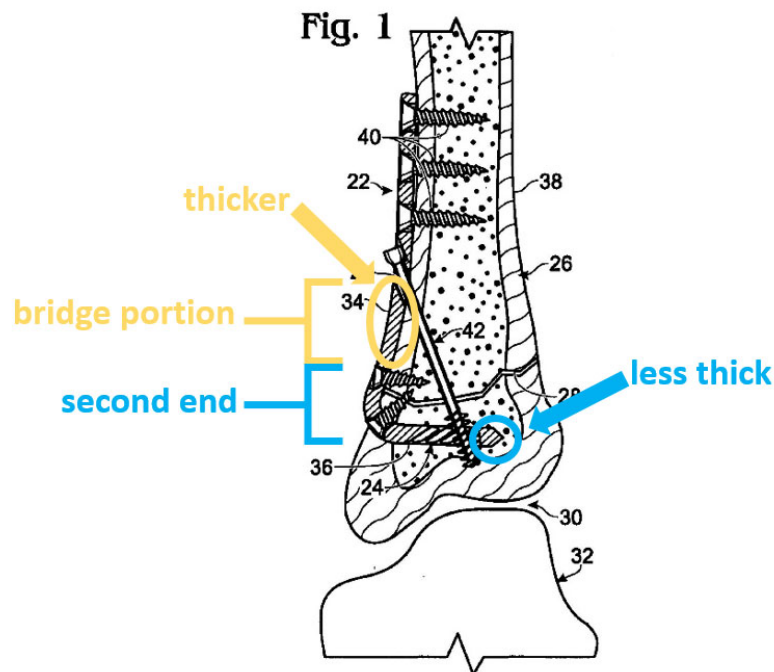
With that context in mind, Petitioner then argues that, “[i]f the Falkner plate was used to span a joint between tibia 26 and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22.” *Id.* at 34–35 (citing Ex. 1002 ¶ 113). 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 bone (talus 32).” *Id.* at 35 (citing Ex. 1002 ¶ 114).



Id. at 35; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner’s plate attached to the tibia, including Petitioner’s blue bracket designating the same alleged “second end,” but here, Petitioner

annotates (with purple arrow, line, and text) an alleged conforming “second inner surface.” Pet. 35. Petitioner’s position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.*

Turning to claim 11’s bridge portion and the requirement that a portion of the bridge and transfixation screw hole have a thickness greater than a portion of the first or second ends (elements 11.3 and 11.5), Petitioner provides another annotation to Falkner’s Figure 1. *Id.* at 35–36. This annotated figure is reproduced below.



Id. at 39; 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. 39. Petitioner also indicates (with yellow arrow and text) that this

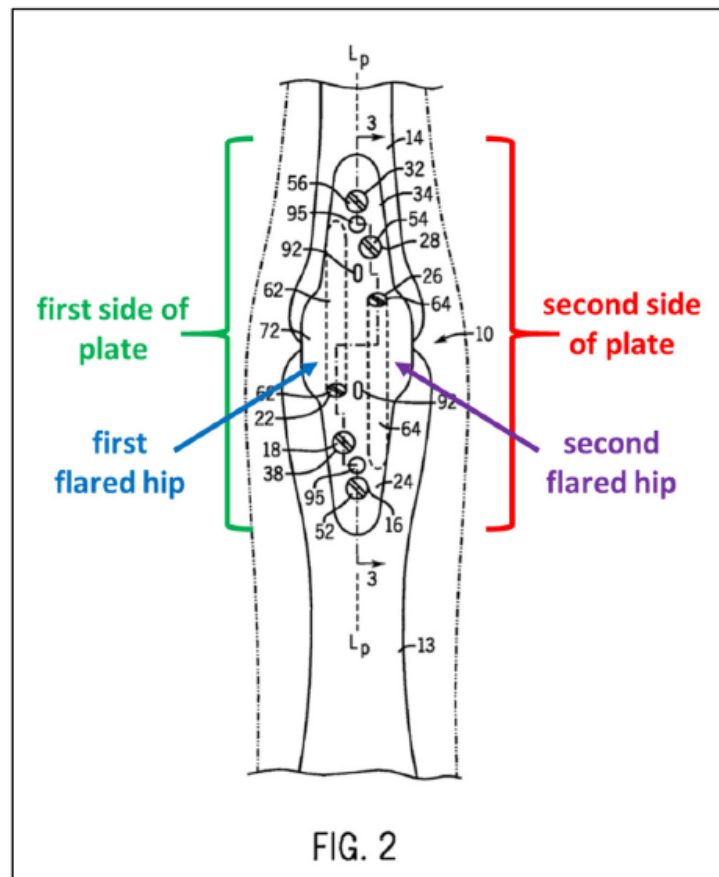
alleged “bridge portion” is thicker.” *Id.* This alleged bridge portion or section is immediately above the blue-bracketed “second end” as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as being less thick,” which Petitioner highlights with a blue circle, arrow, and text. *Id.*

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

For the transfixation screw hole and transfixation screw limitations of claim 11.4, Petitioner identifies Falkner’s Figures 1 and 2. As shown in those figures, Petitioner cites Falkner’s oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate’s internal plate portion (36). Pet. 37–38. According to Petitioner, Falkner’s oblique opening is a “transfixation screw hole” as claimed, and, in a configuration where Falkner’s plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener (i.e., screw) would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* 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 38 (citing Ex. 1002 ¶ 119). In support, Petitioner cites Falkner’s teaching that “[w]ith the head of the screw engaged with the external plate portion, further

rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate.” Pet. 38 (quoting Ex. 1006 ¶ 71).

Having cited disclosure in Falkner that allegedly meets all the limitations of claim 11, Petitioner moves to claim 16 and the recited “flared hip[s].” *Id.* at 40–45. Petitioner cites Duncan’s Figure 2, reproduced below with Petitioner’s annotations, as teaching the flared hips comprising generally parabolic wings as recited in claim 16.



Id. at 41 (citing Ex. 1016, Fig. 2). Duncan’s Figure 2, above, depicts a bone plate (10) attached to two bones (13 and 14) of a finger; Petitioner’s annotation highlights the alleged first and second sides of the plate with, respectively, green and red brackets. *Id.* at 41–42. Petitioner identifies, with

blue and purple arrows, the alleged first and second flared hips of the plate on the respective first and second sides of the plate. *Id.* (citing Ex. 1002 ¶¶ 127–131 (testimony that the hips are symmetrically opposed as parabolic wings)).

Petitioner contends it would have been obvious to modify Falkner's plate to include the symmetrically flared hips of Duncan. *Id.* at 42–43. According to Petitioner, a person of ordinary skill in the art would understand that bone plates can be strengthened by making certain portions thicker and wider to counteract higher stress that occurs in those portions. *Id.* (citing Ex. 1002 ¶ 129–130). Petitioner alleges that a person of ordinary skill in the art would understand that including an angled screw hole, such as Falkner's oblique opening (44), results in more plate material being hollowed out such that the plate may require additional strength in those areas. *Id.* at 46 (Ex. 1002 ¶ 128). Petitioner argues that, in addition to thickening the area around the angled screw hole, a POSA would understand that widening the plate around the screw hole will provide added support, and that the need for such support would have motivated a POSA to include flared hips on the plate, such as disclosed in Duncan, particularly if Falkner's plate is designed for use on the medial side of the ankle. *Id.* at 43–44 (citing Ex. 1002 ¶¶ 129–130). Petitioner further contends that a parabolic shape to the hips around the screw hole would help surgeons properly position the plate over the joint. *Id.* at 44 (citing Ex. 1002 ¶ 131). Petitioner argues these changes would have been made with a reasonable expectation of success, predictably adding strength to the plate and adding visual cues to help position the strongest part of the plate over the joint. *Id.*

2. *Patent Owner's Response*

Patent Owner raise multiple counterarguments to Petitioner's Ground 2 and challenges Petitioner's reasoning for combining Falkner and Duncan. *See generally* PO Resp. 39–51.

First, Patent Owner argues that Ground 2 is treated as an “anticipation analysis” with respect to the underlying analysis of independent claim 11 from which challenged claim 16 depends. *Id.* at 39 n.4. But, according to Patent Owner, Falkner “fails to disclose each and every element of [claim 11], arranged as in the claim.” *Id.*

Second, Patent Owner argues that “*Falkner's* plate is not designed to secure ‘two discrete bones together across an intermediate joint,’” as seen in “Figure 1 itself, which shows a blade-plate solely on the tibia bone with the talus bone untouched. PO Resp.40 (citing Ex. 2002 ¶ 120). According to Patent Owner, although “*Falkner* explains that this type of blade-plate may be configured to cross a joint rather than a bone fracture, *Falkner* includes ‘a dearth of detail about such a hypothetical plate’s design.’” *Id.* at 41 (citing Paper 11, 38; Ex. 2002 ¶ 121). Patent Owner contends that Falkner does not disclose a single embodiment that meets all the limitations of claim 11, so Petitioner and Dr. Gall's testimony “far exceeds what is described in the ‘four corners of that document [] either expressly or inherently,’” 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 42.

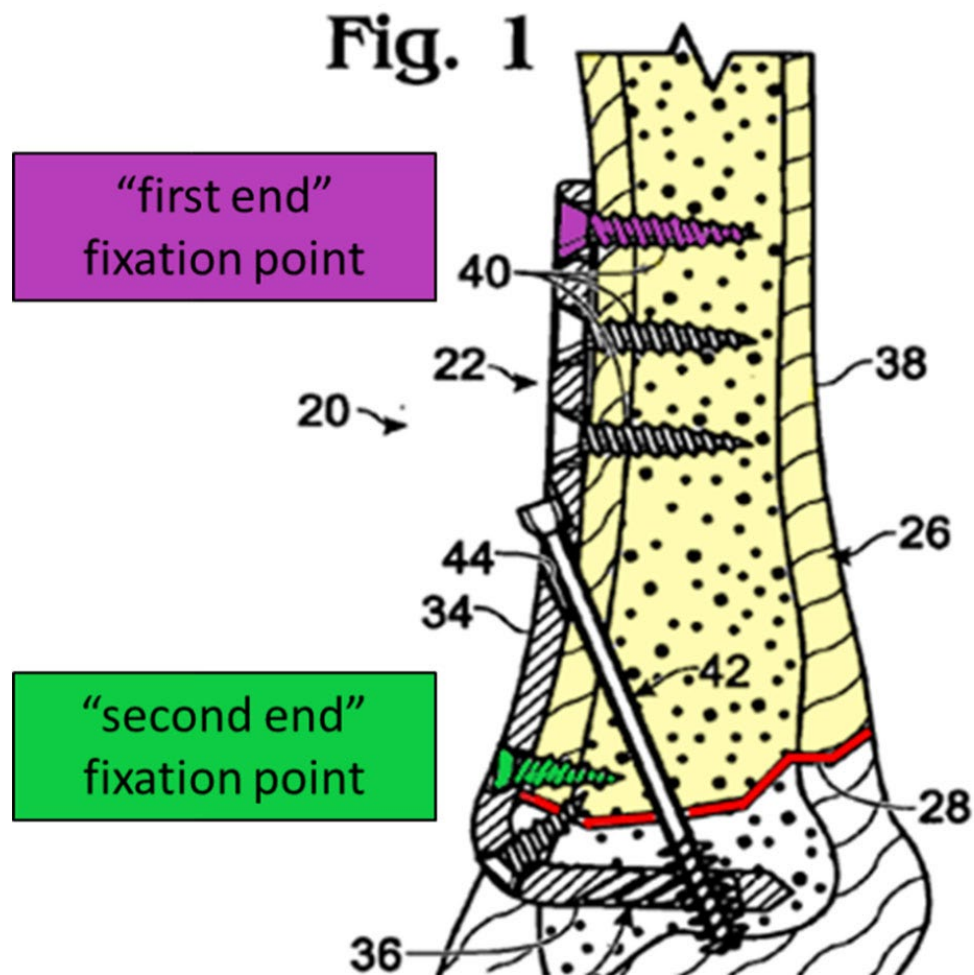
Next, Patent Owner argues that Falkner fails to disclose a “second end” that includes a “fixation point” and an “inner surface configured to substantially conform with a geometry of the second bone” as required by

claim 11. *Id.* at 43–47. 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 45. 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, ¶ 114 (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. 45–46. Patent Owner asserts that although Petitioner also identifies another portion of the blade-plate as the “second end,” Petitioner’s “identified fixation point is not on the second bone (or on the second part of the fractured bone) at all.” *Id.* at 46 (citing Ex. 2002 ¶¶124–125).

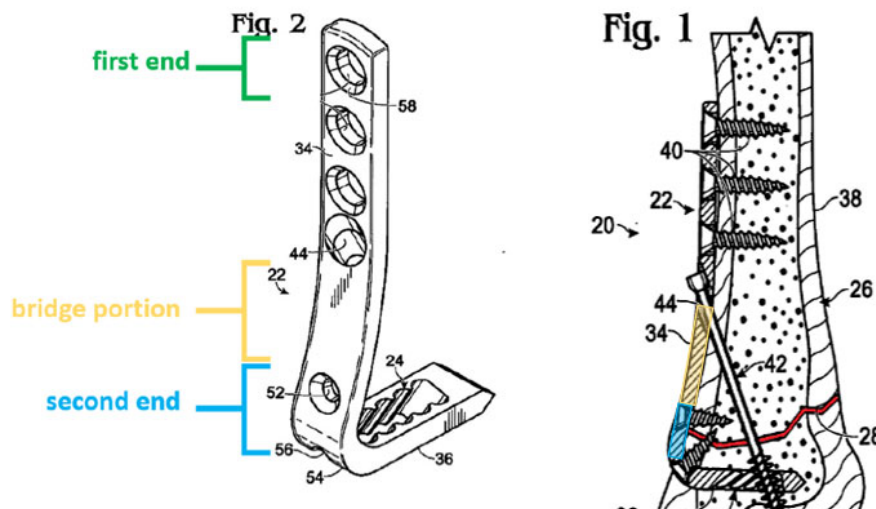
According to Patent Owner, “Petitioners rely upon a second end fixation point (green) that is on the same side of the bone discontinuity as the first end fixation point (purple), as shown in the annotated image below. *Id.* (citing Ex. 2002 ¶ 125).



PO Resp. 46 (citing Ex. 1006, Fig. 1). Falkner’s Figure 1, above, depicts a bone plate 22 attached to tibia 26; Patent Owner’s annotation highlights the alleged first and second fixation points with, respectively, purple and green screws with correspondingly colored label boxes adjacent the screws. *Id.* Patent Owner asserts “[i]f the *Falkner* blade-plate were modified to span a joint rather than a fracture, a POSITA would try to position the plate such that the joint would be in the same location as the fracture shown in Figure 1

to preserve the design intent of the *Falkner* concept.” *Id.* (citing Ex. 2002 ¶ 126). Thus, according to Patent Owner, even under this additional “second end” of Falkner, “Falkner fails to meet the “second end” limitations of claim 10. *Id.* (citing Ex. 2002 ¶ 127).

Lastly, Patent Owner contends that Petitioner’s modified version of Falkner’s plate does not have any portion configured to span across the bridge portion. PO Resp. at 48–50. 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 48 (“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 48–49 (citing Ex. 1006 Fig. 1 (Dr. Gall’s annotations from Ex. 1002 ¶ 115); Ex. 2002 ¶ 137 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as in would be applied to a bone. Ex. 1001 ¶ 8. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* ¶¶ 9, 67.

Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioners identify as the "second end." PO Resp. 48. 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.* at 49 (citing Ex. 2002 ¶ 138). 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 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1029. 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 (citing Ex. 1029 ¶¶ 19–20, 25–36). Instead, Petitioner cites to Dr. Holmes who describes a procedure whereby:

[S]urgeons 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. 1029, ¶¶ 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 18. Petitioner contends that Falkner “expressly enables a [person of ordinary skill in the art] to use its bone plate for joint fusion, and teaches all of the **structural** limitations set forth in the challenged claims.” *Id.* at 19.

4. *Patent Owner’s Sur-reply*

In its Sur-reply, Patent Owner responds that Falkner does not disclose the modifications required to teach all elements of the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes’ testimony on how the plate could have been modified. Sur-reply 11. 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 *Falkner’s* passing reference to a two-bone embodiment is insufficient to anticipate Claim 11 and insufficient to render the [Claim 16] obvious in view of *Falkner* and *Duncan*.” *Id.* at 16–17 (citing, Inst. Dec., 38–39). Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-reply 16–20 (“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 39–50 of the Patent Owner Response and pages 16–20 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. 40–41; 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. Yet, Petitioner cites approvingly to its filing in related IPR2021-01450 as allegedly supporting its challenge here. Pet. 30 (“As an initial matter and as shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1450, *Falkner discloses every element of Claim 11 of the 608 patent*”) (emphasis added).

Moreover, to the extent Petitioner’s challenge purports to modify Falkner’s single-bone embodiment (e.g., as shown in Figures 1 and 2) by citing various other teachings in Falkner, we see minimal analysis that explains why the POSA would have been motivated to make those modifications with a reasonable expectation of success to arrive at claim 11’s subject matter. Even when only one reference is involved, the mere fact that each claim limitation might be found in such reference’s disclosure does not necessarily prove obviousness without analysis that explains why the skilled artisan would have combined those teachings to arrive at the claimed subject matter. *In re Stepan Co.*, 868 F.3d 1342, 1345–46 n.1 (Fed. Cir. 2017) (“Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, *there must be a motivation to make the combination and a reasonable*

expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.”) (emphasis added).

Falkner’s cited plate in Figures 1 and 2 is not arranged as claimed. Ex. 1006, Fig. 1. It is not configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second discrete bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured would seemingly require redesign or modifications. Those might be simple design changes for a POSA based on their knowledge and Falkner’s overall teachings. Petitioner’s obviousness analysis on claim 11 is, however, wanting for detail as noted above (e.g., minimal explanation why the POSA would have modified the Falkner plate with a reasonable expectation of success).

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones, including the ankle joint. *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 and screw hole portion relative to the ends)., and Petitioner also provides

minimal argument and evidentiary support to explain why all the claimed features would be included. Petitioner argues, for example, that Falkner's Figure 1 shows a portion of a transfixation screw hole that has a thickness greater than a portion of the plate's first and second ends. Pet. 38–40. Neither the identified bridge portion nor screw hole itself appears to have a thickness greater than the plate's first end—claim 11 recites that the thickness be greater than a portion of the *first and second ends*. Petitioner briefly remarks that Falkner “contemplates reducing the [plate] thickness of the bone plate to minimize irritation of soft tissue in regions such as the ‘first end’ of the plate.” *Id.* at 39 (citing Ex. 1002 ¶ 120, Ex. 1006 ¶¶ 32, 35). But, on this record, whether Falkner's cited disclosures teach or suggest that the plate's first end, in particular, should be made thinner than the bridge and screw hole portions lacks clarity; and Petitioner does very little to explain why a person of ordinary skill in the art would have been motivated to decrease the thickness at that specific part of the plate.

Moreover, we note that 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. 39. 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.* 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 with respect to claim 11, 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. Such picking and choosing is indicative of obviousness, which as noted above is lacking explanation why the person or ordinary skill in the art would have modified the Falkner plate with a reasonable expectation of success.

Petitioner relies on Duncan principally for its teaching related to the “flared hips” feature (elements 16.1/16.2) of the challenged claim. *Id.* at 40–45. Petitioner’s reliance on Duncan and reasoning for adding the flared hips, does not remedy the concerns noted above with Petitioner’s showing on the subject matter recited in claim 11.

Accordingly, Petitioner fails to demonstrate by a preponderance of evidence that claim 16 would have been obvious over Falkner and Duncan.

III. CONCLUSION

In summary:

Claim	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
16	102	Slater		16
16	103	Falkner, Duncan		16
Overall Outcome				16

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 16 of the ’608 patent is 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.

IPR2022-00189
Patent 8,529,608 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 claim 16, and reach that result for the following additional reason.

Independent claim 11 recites a “transfixation screw hole comprising *an inner surface configured to direct a transfixation screw* through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion *at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is*

placed across the joint.” Ex. 1001, 13:22–27 (emphasis added). 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. Pet. 25.

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. 25 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1 and 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 alongside 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 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 ¶ 98; 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.* (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. 33 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 96). That is, “*Slater* describes a plate that intentionally allows for varied angles through **the same hole.**” *Id.* at 33–34 (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 ¶ 102)). 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 the neutral bending axis of the joint.” PO Resp. 16–19, 33–35.

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 bone and a second position on the second 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; EX1028, ¶11)).

Reply 2 (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. 1028 ¶ 12).

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.* at 2–3 (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 a configuration that achieves a screw hole that directs a screw at a particular angle (or “trajectory”), where that angle may be configured within a certain range. PO Resp. 18 (citing Ex. 2002 ¶ 95; Ex. 1001, 6:25–30). 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 ¶ 89 (“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 ¶ 102 (“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 “trajectory” as used in the challenged claims means an “allowable fixed angle relative to at least the neutral bending axis of the joint.” PO Resp. 16–19. 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 bone and a second position on the second bone.” Ex. 1001, 13:25–26, claim 11.

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, 1:46–49 (“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: 42–46 (“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 5:53–57 (“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.”). 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 ¶ 128; Ex. 2002 ¶ 93. Furthermore, certain 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, claim 14 (“wherein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis.”). However, with regard to independent claim 11, I again find that the express recitation of “once the plate is placed across the joint” provides adequate basis for determining how a trajectory is defined, especially in view of Dr. Gall’s and Mr. Sommer’s testimony, summarized above.³ Ex. 1001, 13:26–27, claim 11; Ex. 1002 ¶ 128; Ex. 2002 ¶ 93.

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. 24; 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

³ I also note that our express determination of whether a trajectory should be measured from an elongate axis, neutral bending axis of the joint, or otherwise, 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))).

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, 95, 97; PO Resp. 17–18. 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, 8:47–52 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:46–47; 6:19–33. 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 8:53–9:26. 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 6:19–33. 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. Ex. 1001, 12:32–36; *see also id.* at 14:3–7 (claim 12). 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 oblique⁴ and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* (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, ¶ 98); *see also* Ex. 2002 ¶ 97 (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 the '608 patent, I agree with Patent Owner that a person of ordinary skill in

⁴It 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. 10 (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 ¶ 102; Ex. 1005, 16:28–30.

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. 18 (Ex. 2002 ¶ 95; *see also* Ex. 1001, 6:25–30). 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 ¶ 95; 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.” Ex. 1001, 12, ll. 49–51; *see also id.* at claim 14. 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. *Id.* at 12, ll. 52–54. Thus, each of dependent claims 2–6, 12, and 14 further limit independent claims 1 and 11 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 and 11, 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 the 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 2–3. In other words, we agree with Patent Owner that "[a person of ordinary skill in the art] reading [claim 11] 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." PO Resp. 17; Ex. 2002 ¶ 94.

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 claim 16 as anticipated by Slater is substantially similar to its analysis of independent claim 11, which relies on Petitioner's predicate analysis on claim 11. *See generally* Pet. That analysis suffers from at least the same shortcomings discussed here for independent claim 11.

In view of the above, I determine that Slater does not disclose "the transfixation screw hole comprising an inner surface configured to direct the

transfixation screw . . . at a trajectory.” 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 claim 16 is anticipated by Slater.

IPR2022-00189
Patent 8,529,608 B2

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