UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC.
Petitioners,

v.

OSTEOMED LLC,
Patent Owner

_____

Case IPR2021-01450

U.S. Patent No. 8,529,608

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 8,529,608
1002	Declaration of Professor Kenneth A. Gall, Ph.D.
1003	CV of Professor Kenneth A. Gall, Ph.D.
1004	Prosecution History of U.S. Patent No. 8,529,608
1005	Slater WO 2007/131287
1006	Falkner U.S. 2005/00171544
1007	Arnauld EP 1897509
1008	Certified Translation of Arnauld EP 1897509
1009	Weaver U.S. Patent No. 6,623,486
1010	Duncan US2009/0228048
1011	Grady US2005/0010226
1012	Amended Scheduling Order, OsteoMed LLC v. Stryker Corp., No. 1:20-cv-6821(N.D. Ill. Jun. 16, 2021), ECF. No. 48.
1013	Scheduling Order, OsteoMed LLC v. Wright Medical Tech., Inc., No. 1:20-cv-01621-RGA (D. Del. Aug. 4, 2021), ECF. No. 40.
1014	Tr. of Hr'g on Mot. to Transfer, OsteoMed LLC v. Wright Medical Tech., Inc., No. 1:20-cv-01621-RGA (D. Del. Apr. 14, 2021), ECF. No. 27
1015	Strnad (US2007/0239163)
1016	U.S. Provisional Application No. 16/035,270 filed March 10, 2008 ("Duncan Provisional")
1017-1019	Not used
1020	Merriam-Webster's Medical Dictionary 51 (2006)
1021	Merriam-Webster's Medical Dictionary 557 (2006)

List of Challenged Independent Claims

Claim 1 of the 608 Patent	
1.P	A system for securing two discrete bones together across a joint between the two bones, comprising
1.1	the plate comprises: 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
1.2	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 discrete bone
1.3	a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint,
1.4	at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end
1.5	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 through the bridge portion at a trajectory configured to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone once the plate is placed across the joint
1.6	the transfixation screw comprises a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.

Claim 11 of the 608 Patent	
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.

List of Challenged Dependent Claims

Claim	Limitation
2	The system of claim 1, wherein a central axis of the inner surface of the transfixation screw hole defines the trajectory; and the trajectory is configured to cross a neutral bending axis of the joint once the plate is placed across the joint.
3	The system of claim 2, wherein the first position resides on a compression side of the joint and the second position resides on a tension side of the joint.
4	The system of claim 2, wherein the trajectory is configured to pass through the joint at a transfixation angle between about 30 degrees and about 70 degrees measured from the neutral bending axis.
5	The system of claim 2, wherein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis.
6	The system of claim 1, wherein the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw.
8	The system of claim 1, wherein each at least one attachment point comprises a threaded screw hole defined by a threaded inner surface configured to lockably engage one of a plurality of locking bone screws.
9	The system of claim 1, wherein the transfixation screw comprises a lag screw having: at a first end of the shaft adjacent to the head, an unthreaded portion configured to extend through the first bone; and at a second end of the shaft adjacent to the tip, a threaded portion configured to extend into the second bone.
10	The system of claim 1, wherein the elongate spine is configured to form an angle between the first inner surface and the second inner surface, the angle substantially conforming to a natural bend at a joint between the first bone and the second bone.
12	The plate of claim 11, wherein a central axis of the inner surface of the transfixation screw hole defines the trajectory; and the trajectory is configured to cross a neutral bending axis of the joint once the plate is placed across the joint.

Claim	Limitation
13	The plate of claim 12, wherein the first position resides on a compression side of the joint and the second position resides on a tension side of the joint.
14	The plate of claim 11, wherein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis.
17	The plate of claim 11, wherein the elongate spine is configured to form an angle between the first inner surface and the second inner surface, the angle substantially conforming to a natural bend at a joint between the first bone and the second bone.

Petitioners Stryker Corporation and Wright Medical Technology, Inc. respectfully petition for *inter partes* review of Claims 1-6, 8-14, and 17 of U.S. Patent No. 8,529,608 ("the 608 patent"), which is purportedly assigned to OsteoMed LLC.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner Wright Medical Technology, Inc. is a wholly-owned subsidiary of Petitioner Stryker Corporation. Stryker Corporation is the real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The 608 patent is one of four related patents entitled "Bone Plate with a Transfixation Screw Hole," all of which have been asserted against Petitioner Stryker in the following litigation pending in the Northern District of Illinois: *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821, filed November 17, 2020. As of the date of this petition, the litigation is in its infancy. Fact discovery opened on July 6, 2021. (EX1012). According to the current scheduling order, and assuming no extensions are granted, no claim construction hearing will take place until after April 1, 2022 at the earliest. (EX1012). Opening expert reports are due on August 5, 2022, at the earliest, depending on when the claim construction ruling is issued. (EX1012). No trial has been scheduled and dispositive motions are not expected to be filed until after November 4, 2022. (EX1012).

The same four related patents, including the 608 patent, have also been asserted against Petitioner Wright Medical in the following litigation pending in the District of Delaware: *OsteoMed LLC v. Wright Medical Technology, Inc.,* Case No. 1:20-cv-1621, filed November 27, 2020. As of the date of this petition, the litigation is also in its infancy. (EX1013). The Delaware court has indicated that this case will follow behind the Illinois case. (EX1014).

The related patents include U.S. Patent Nos. 9,351,776 ("the 776 patent"), 9,763,716 ("the 716 patent"), and 10,245,085 ("the 085 patent"), which claim priority to 608 patent. Petitioners have simultaneously petitioned for *inter partes* review of those patents on similar grounds in IPR2021-01451, IPR2021-01452, and IPR2021-01453.

C. Lead And Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

Petitioners provide the following designation of counsel.

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided in Section I.C of this Petition. Petitioners also consent to electronic service by email at: Stryker-Wright-IPR@mcandrews-ip.com.

E. Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a))

The USPTO is authorized to charge Deposit Account No. 13-0017 for fees in 37 C.F.R. § 42.15(a) and any additional fees.

F. Grounds for Standing (37 C.F.R. § 42.104(a))

The 608 patent is available for *inter partes* review and Petitioners are not barred or estopped from requesting *inter partes* review on the grounds identified in this Petition.

II. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to 35 U.S.C. §§ 311-319, Petitioners request *inter partes* review of Claims 1-6, 8-14, and 17 ("the Challenged Claims") of the 608 patent on the grounds below and request that each claim be found unpatentable. Additional support for each ground is set forth in the Declaration of Kenneth A. Gall, Ph.D. (EX1002), which demonstrates the knowledge of a person of ordinary skill in the art ("POSITA") at the time of the invention.

A. Prior Art Relied Upon

Exhibit 1005: Slater WO 2007/131287 ("Slater"), published on November 22, 2007.

Exhibit 1006: Falkner U.S. 2005/00171544 ("Falkner"), published on August 4, 2005.

Exhibit 1007 and Exhibit 1008: Arnauld EP 1897509, published on March 14, 2008, is Exhibit 1007. The certified English translation of Arnauld EP 1897509 is referenced herein as "Arnauld," Exhibit 1008.

Exhibit 1009: Weaver U.S. Patent No. 6,623,486 ("Weaver"), issued on September 23, 2003.

B. Grounds for Challenge

Petitioners request cancellation of the Challenged Claims on the following grounds:

Ground	Proposed Grounds for Rejection
1	Claims 1-5, 9-14, and 17 are anticipated by Slater
2	Claims 6 and 8 are obvious over Slater in view of Weaver
3	Claims 1-3, 6, 8-13, and 17 are anticipated by Falkner
4	Claims 4, 5, and 14 are obvious over Falkner in view of Arnauld
5	Claims 1-5, 9-14, and 17 are obvious over Arnauld in view of Slater
6	Claims 6 and 8 are obvious over Arnauld in view of Slater and Weaver

III. THE 608 PATENT

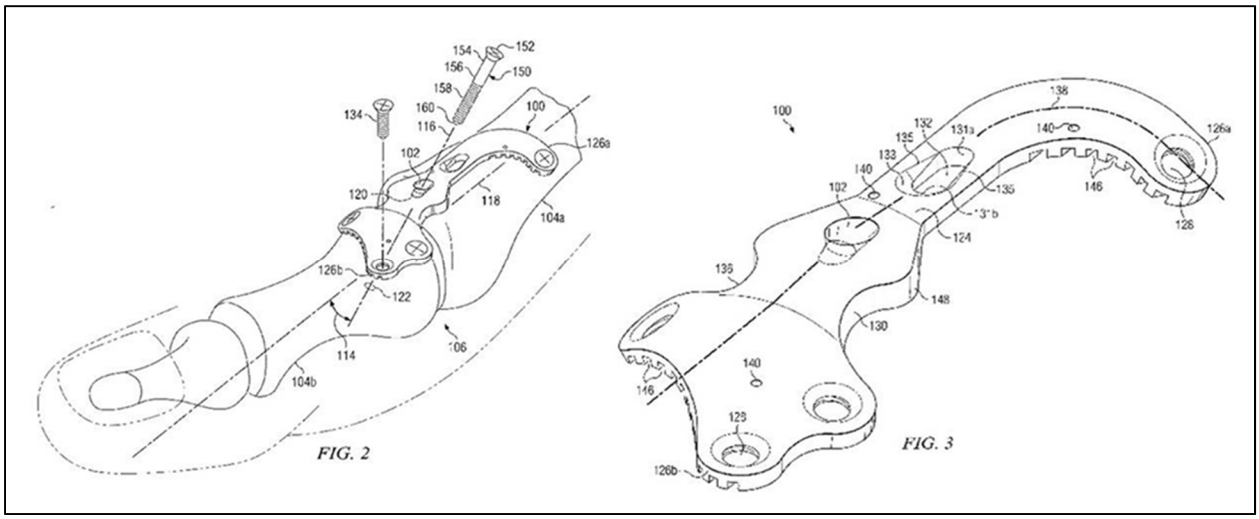
A. Priority Date of the 608 Patent

The 608 patent was filed on April 28, 2009 and published on October 28, 2010. The alleged priority date of the 608 patent is April 28, 2009.

B. Subject Matter of the 608 Patent (EX1001)

The 608 patent is directed to a bone plate used with a transfixation screw for securing the bones of a joint together. (EX1001, 1:22-25).

Figure 2 illustrates bone plate 100 being used in conjunction with a transfixation screw 150 to repair a failed metatarsophalangeal joint in the foot. (EX1001, 4:6-7). In accordance with the 608 patent, transfixation screw 150 is



inserted through transfixation screw hole 102 into a first bone 104a and a second bone 104b. (EX1001, 4:20-24). Figure 3 illustrates that the bone plate 100 includes at least one attachment point 128 for attaching first end 126a to first bone 104a, and at least one attachment point 128 for attaching second end 126b to second bone 104b.

(EX1001, 7:21-25). The bone plate 100 further includes a bridge portion disposed between the first end and the second end to span across joint 106. (EX1001, 7:25-26). "Since bridge portion 130 is configured to span across joint 106, it is typically defined by an unbroken section of spine 124 that is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130." (EX1001, 8:2-6). In the claimed embodiments, bridge portion 130 includes "a thickened section 136 of bone plate 100 to increase the bending strength of bridge portion 130." (EX1001, 8:7-9).

C. Prosecution History of the 608 Patent (EX1004)

On April 28, 2009, Patent Owner filed its application with claims generally directed to a system including a bone plate and a transfixation screw for securing two discrete bones together across a joint. (EX1004, OSTEOMED_0001591-1632.)

The Examiner rejected original application claims 1-15 under § 102(b) as anticipated by Grady US2005/0010226 (EX1011). (EX1004, OSTEOMED_0001764-65). Without amending the claims, Patent Owner attempted to distinguish Grady on the basis that "Grady discloses a bone plate dimensioned and configured for internal fixation of **two portions of a single bone**, which has been fractured" and that Grady "merely shows a screw passing through a single bone" instead of "**at a trajectory configured to pass through two bones**," as claimed. (EX1004, OSTEOMED_0001796) (emphasis in original). The Examiner

thereafter issued a Final Rejection, noting that Grady could be used with a two bone fracture. (EX1004, OSTEOMED_0001819-21).

Thereafter, Patent Owner amended the independent claims to emphasize that the first and second ends of the plate comprise inner surfaces configured to substantially conform with a geometry of a first bone and second bone. (EX1004, OSTEOMED_0001836, OSTEOMED_0001839). Patent Owner then re-argued that "Grady merely discloses a bone plate dimensioned and configured for fixing two portions of a single bone" and thus did not include the first and second inner surfaces configured to substantially conform with a geometry of a first and second bone as newly claimed. (EX1004, OSTEOMED-0001844-47).

Once again, the Examiner rejected the claims as anticipated by Grady, stating that Grady teaches a bone plate conforming to the surface of the bone. (EX1004, OSTEOMED_0001858-59).

In response, Patent Owner amended independent claim 1 to recite "at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end" and to specify that the transfixation screw extends 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 tensile load from the second discrete bone, through the screw into said head and said bridge portion."

(EX1004, OSTEOMED_0001879-80, OSTEOMED_0001886-87). Patent Owner made similar amendments to independent claim 11. (EX1004, OSTEOMED_0001881). Following these amendments, the claims were allowed without further discussion. (EX1004, OSTEOMED_0001892-99).

D. Level of Skill in the Art

A POSITA at the time of the alleged 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. (EX1002, ¶¶35-39).

IV. CLAIM CONSTRUCTION

Claim terms should generally be construed according to their ordinary and customary meaning, which is the meaning they would have to a POSITA at the time of invention, in light of the specification and file history. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). Where the construction of specific terms is not necessary to resolve the issues before the Board, the Board need not construe those terms, "leaving that question to a later forum where the issue is determinative." *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013); *see also Nidec v. Zhongshan*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that the Board need only construe terms "that are in controversy, and only to the extent necessary to resolve

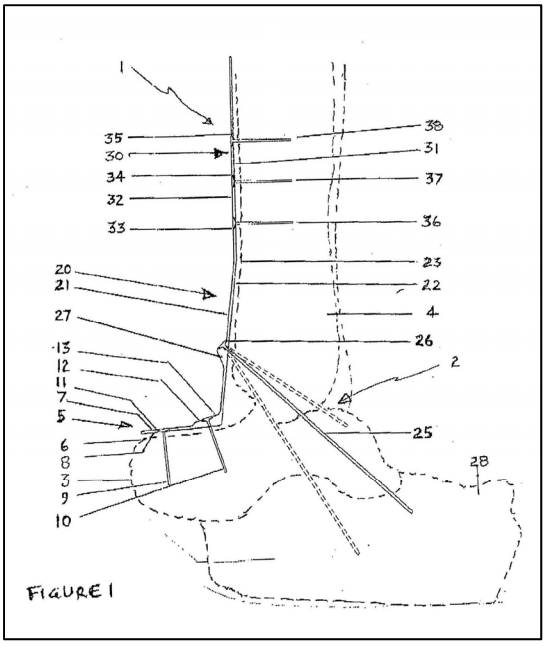
the controversy"). There are no claim terms in the Challenged Claims that require construction in order to find those claims unpatentable. Petitioners have applied the ordinary and customary meaning of each claim term throughout the Petition in light of the 608 patent specification and file history.

V. SUMMARY OF THE PRIMARY PRIOR ART REFERENCES

The 608 patent claims are directed to features well known in the art prior to its priority date of April 28, 2009. The prior art references relied upon herein are directed to the same field as the 608 patent, namely, bone plates for use in fusing bone parts in the lower extremities (feet), and thus are analogous art. (EX1002, ¶161, ¶236, ¶247). Petitioners are not aware of any secondary considerations supporting a finding of nonobviousness.

A. Slater

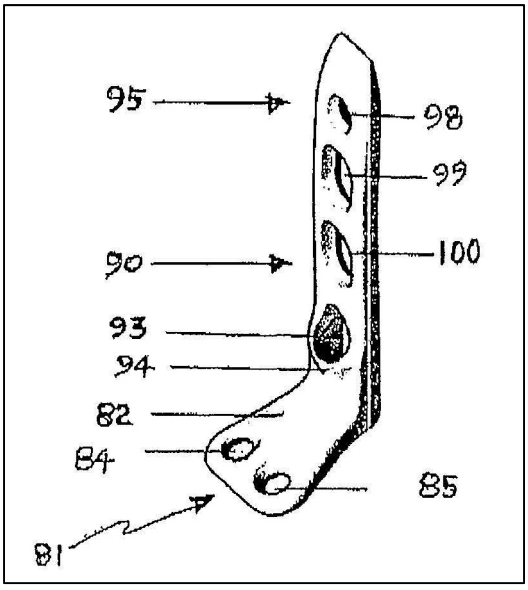
Slater, entitled "Ankle Fusion Plate," is directed to a plate for immobilizing a joint by fusion of the adjacent bones ("arthrodesis"). (EX1005, Abstract). While Slater describes a bone plate for ankle fusion, the reference specifically contemplates that its invention "may be applied to the repair/fusion of other



bones requiring axial alignment." (EX1005, 6:34-7:2).

The Slater plate includes a first end (30) and a second end (5) having inner surfaces that "conform to the typical geometry of the anatomical region." (EX1005, 9:10-12). In particular, the first end 30 comprises at least one opening (33, 34, 35) configured to allow fixation screws (36, 37, 38) to pass through to attach to the tibia 4. The second end 5 comprises at least one opening (11, 12) configured to allow fixation screws (9, 10) to pass through to attach to the talus 3. Portion 20 of the plate includes an opening 26 and a formation 27 configured to allow a screw 25 to be implanted at an angle within a predetermined allowable angular range to pass through tibia 4 and talus 3. (EX1005, 11:19-22).

Slater discloses that "the plate depth changes at different locations. Preferably, the depth at the beginning and end points of the L-shaped contour over the ankle joint in the second region will be at its maximum thickness." (EX1005, 8:31-35). "The plate will taper at at least one but preferably two different points of the plate. (EX1005, 9:3-4). As can be seen at left, the unbroken portion of the plate that spans the ankle joint is thickened.

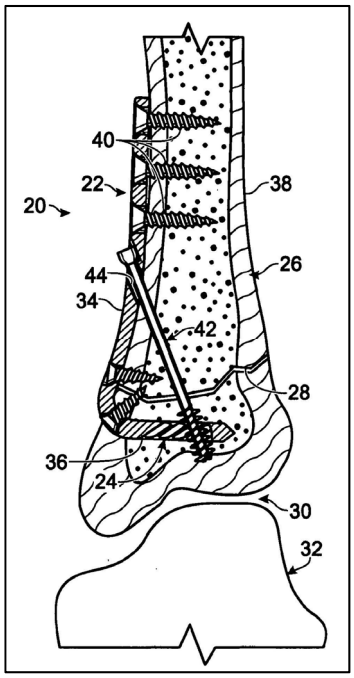


During the prosecution of the PCT application corresponding to the 608 patent, Slater was cited by the International Search Authority ("ISA") as disclosing the subject matter of original application claims 1-5, 10-14. (EX1004, OSTEOMED_0001738-41). However, the Examiner did not rely on Slater during the prosecution of the 608 patent, nor did he substantively address the international search report. The Office materially erred in failing to consider Slater as the basis for any prior art rejection, especially after Patent Owner amended its claims to require that the claimed "bridge portion" has a thickness greater than at least a portion of either or both of said first and second ends," a feature that is clearly described in Slater, as discussed above, in the context of a bone plate for use across a joint.

B. Falkner

Falkner is directed to a bone plate with toothed aperture for use in fixing bone fractures or to fuse bones across a joint. (EX1006, ¶¶21, 27-29). Falkner was not cited during the prosecution of the 608 patent, and thus was not considered by the Office.

Falkner teaches a bone plate 22 that "may be sized and shaped to conform to particular portions of a bone (or bones)." (EX1006, ¶¶33-34). Falkner further discloses that the "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." (EX1006, ¶21). The Falkner plate includes a first end (first plate portion 34) and a second end (second plate portion 36) secured to the bone(s) using bone screws that "may be placed into bone from any suitable number of openings of the bone plate." (EX1006, ¶¶23-24, 36-38). Threaded fastener 42 extends angularly through a bone fracture or a joint. (EX1006, ¶24). Falkner further recognizes that "[t]hickness may be varied within the plates," recognizing that the plate can be "thicker to increase structural stability," and that "plates may be thicker and thus stronger in regions where they may not need to be contoured…." (EX1006, ¶35).



C. Arnauld

Arnauld is directed to a bone plate for use across the joint between the first metatarsal bone and the phalanx. (EX1007, EX1008, ¶1).

As shown in Figure 1, Arnauld discloses a bone plate comprising an elongated plate body having one or more through holes at both the metatarsal part and the phalangeal part of the bone plate through which bone anchoring screws can be introduced into the metatarsal and the phalanx. (EX1008, Fig. 1). Arnauld further describes a leg of the plate that allows the plate to be attached to a dorsal-lateral surface of the epiphysis of the phalanx. (EX1008, ¶6). The leg is shaped to include a hole adapted to receive a long bone screw which extends both through the bone material of the phalanx and the bone material of the metatarsal. (EX1008, ¶6). Arnauld explains that the long bone screw extends lengthwise in a direction having an anteroposterior component so that the screw takes the bending stresses generated during the walking of the patient. (EX1008, ¶6).

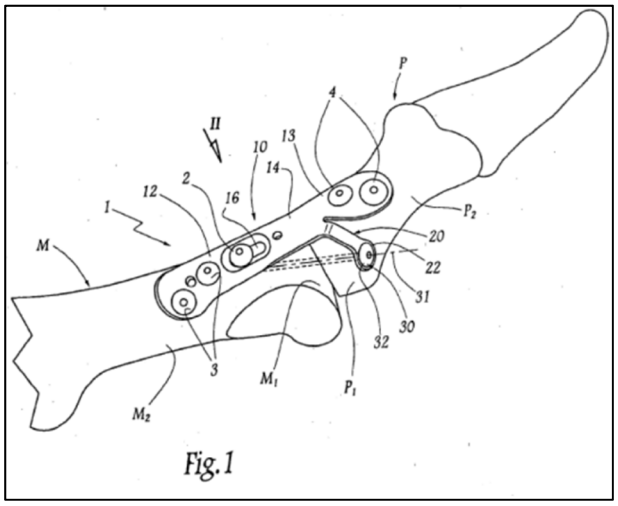


Fig.1

Arnauld was cited by the ISA during the prosecution of the PCT application corresponding to the 608 patent as disclosing the subject matter of original application claims 1-5, 10-14. (EX1004, OSTEOMED_0001738-41). However, the Office neither relied on nor substantively discussed Arnauld during prosecution of the 608 patent.

The Office erred in failing to consider Arnauld, particularly after Patent Owner amended the claims to specify "a first inner surface configured to substantially conform with a geometry of the first bone" and "a second inner surface configured to substantially conform with a geometry of the second bone." (EX1004, OSTEOMED_0001836-44). Arnauld expressly discloses first and second inner surfaces configured to substantially conform with the geometry of first and second bones. (EX1008, ¶¶15, 17). More significantly, unlike Grady, Arnauld expressly discloses the claimed "bone conforming" feature in the context of a system used for securing two discrete bones (metatarsal M and phalanx P) spanning an intermediate joint. (EX1008, ¶14).

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM IS UNPATENTABLE

A. Ground 1: Slater Anticipates Challenged Claims 1-5, 9-14, and 17

As shown below and in the accompanying Declaration, Slater discloses all elements of Claims 1-5, 9-14, and 17, and thus anticipates those claims under 35 U.S.C. § 102(b). (EX1002, ¶¶100-160).

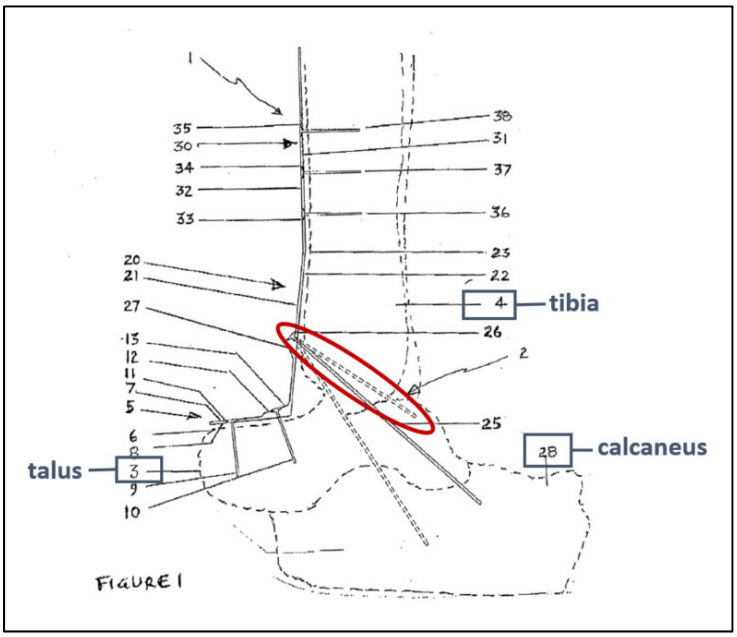
1. Independent Claim 1 is Anticipated by Slater

a. 1.P: Preamble

To the extent the preamble is limiting, Slater includes a system for securing two discrete bones together across a joint between the two bones. (EX1002, ¶102).

Slater is directed to an ankle fusion plate for arthrodesis. (EX1005, Abstract). "Arthrodesis" means "the surgical immobilization of a joint so that the bones grow solidly together." (EX1020, p. 51).

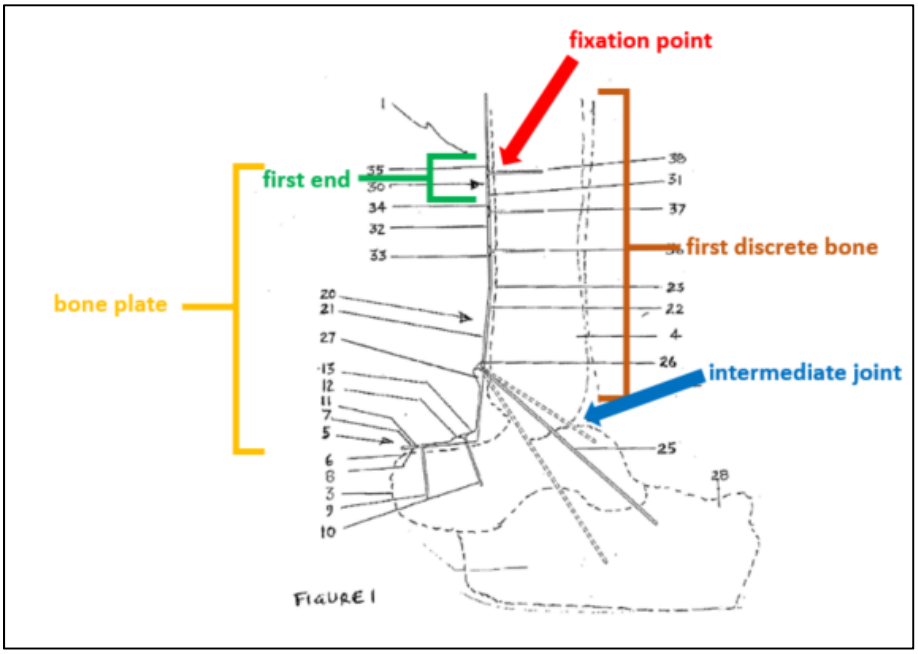
Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and calcaneous 28) across two joints and (2) an alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 2, within the oval annotated into Figure 1 immediately below) together across a single joint between the two bones. (EX1005, 12:3-4, 6:17-7:2, 8:13-28, 11:1-4, 12:3-10, 13:5-9, 14:1-8).

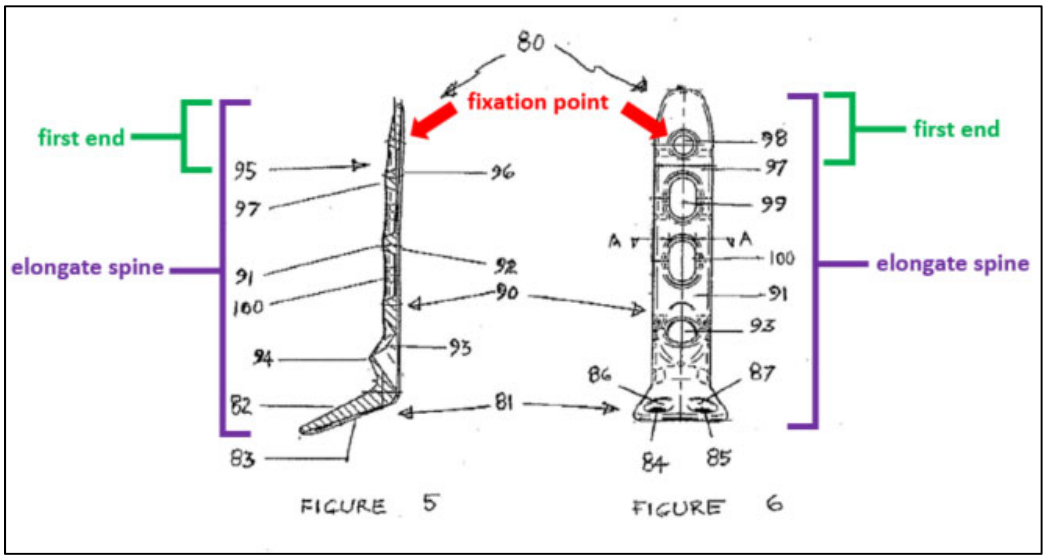


b. 1.1: "*the plate comprises: an elongate spine having: a first end comprising…*"

As shown in Figures 1, 5, and 6, Slater discloses a bone plate comprising an elongate spine having a first end (proximal end of portion 30 (of plate 1) or proximal end of portion 95 (of plate 80)) comprising at least one fixation point (fixation points 35, 34, 33 or fixation points 98, 99) for attaching the first end (proximal end of portion 30 or proximal end of portion 95) to a first discrete bone (tibia 4) on a first

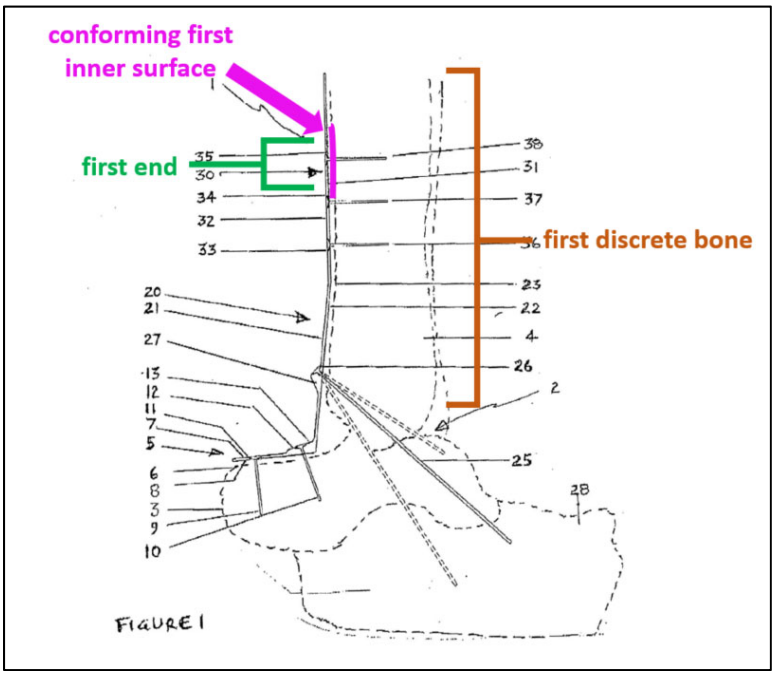
side of an intermediate joint. (EX1002, ¶¶103-105; EX1005, 12:22-23 (illustrated in Fig. 2) ("Openings 33, 34 and 35 are preformed and receive a first preferably countersunk screw type such as that shown in figure 3."), 13:28-30 (illustrated in Fig. 5) ("Portion 95 includes openings 98 and 99 which receive fastening screws each preferably in the same orientation and which engage the tibia."), Fig. 6).





(EX1005, Figs. 1, 5-6).

Moreover, as shown in Figure 1, the first inner surface (31 or 96) is configured to substantially conform with a geometry of the first discrete bone (tibia 4). (EX1002, ¶106).

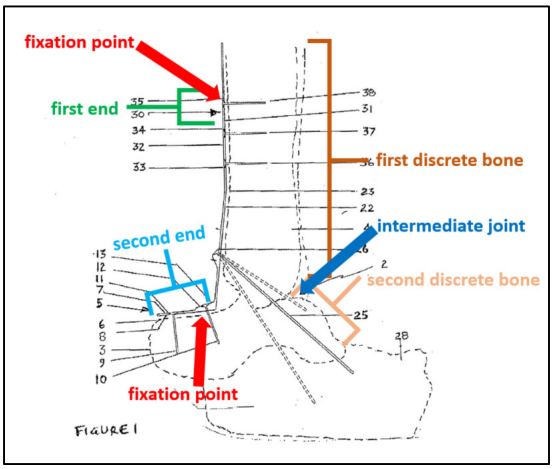


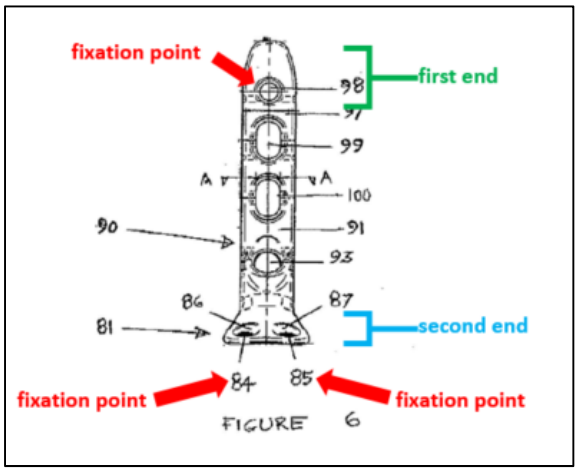
(EX1005, Fig. 1).

For example, Slater expressly discloses "the plates are configured to **generally conform to the anatomic contours** of the ankle joint." (EX1005, 9:14-15; 15:12-14, 16:32-34, 17:2-3). Slater even includes a claim that expressly recites a kit "wherein the **plate geometry** is arranged to at least partially **conform to the shape of the anatomy of bones** to which the plate is fixed." (EX1005, 23:15-17).

c. 1.2: *"a second end comprising…"*

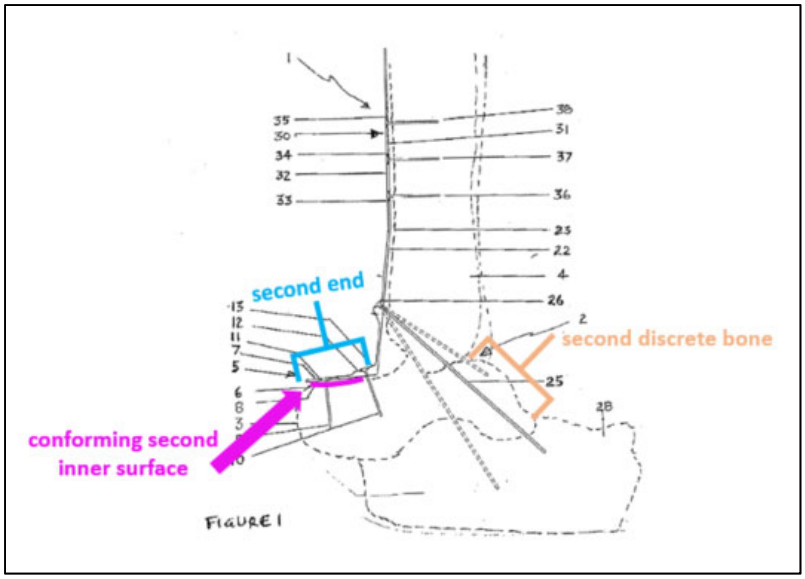
As shown in Figures 1 and 6, the second end in Slater (distal end of portion 5 or 81) includes at least one fixation point (11, 12 or 84, 85) for attaching the second end (distal end of portion 5 or 81) to a second discrete bone (talus 3) on a second side of an intermediate joint. (EX1002, ¶107; EX1005, 11:8-10, 13:10-12).





(EX1005, Figs. 1, 6).

In addition, as shown in Figure 1, the second end in Slater (distal end of portion 5 or 81) includes a second inner surface (8 or 83) configured to substantially conform with a geometry of the second discrete bone (talus 3). (EX1002, ¶108).

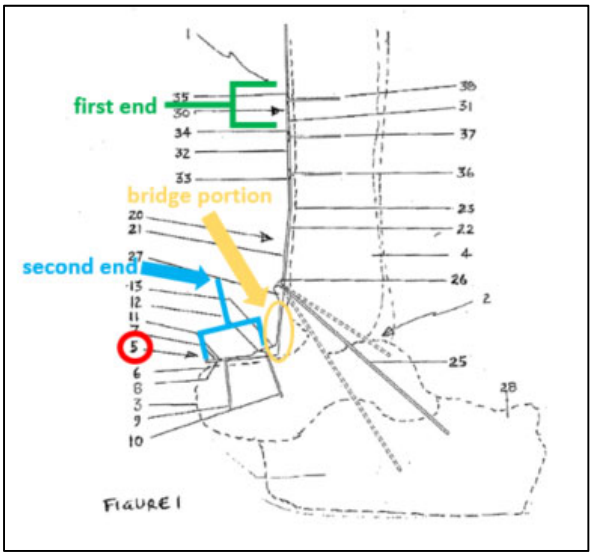


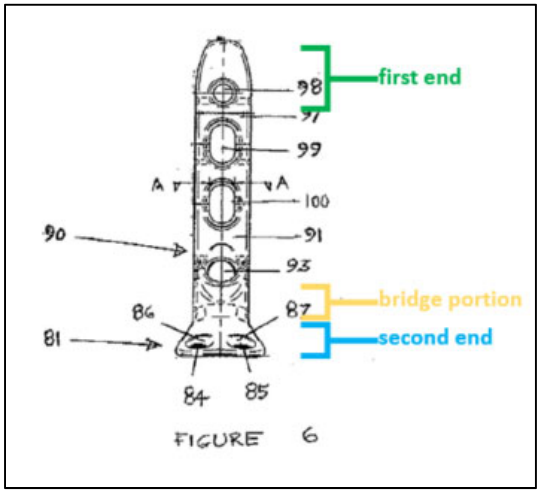
(EX1005, Fig. 1).

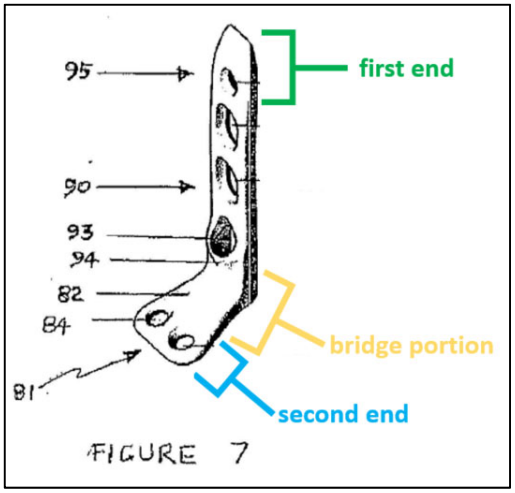
As discussed above, Slater expressly discloses that the various portions of the plate "will preferably resemble and conform to the typical geometry of the anatomical region" and that "the plates are configured to generally conform to the anatomic contours of the ankle joint." (EX1005, 9:8-15; 11:7-8, 13:9-10, 14:19-22, 16:32-34, 17:2-3; 23:15-17).

d. 1.3: "*a bridge portion disposed…*"

As shown in Figures 1, 6, and 7, Slater includes a bridge portion (portions of 5 and 20 or portions of 81 and 90) disposed between the first end (proximal end of portion 30 or portion 95) and the second end (distal end of portion 5 or portion 81). (EX1002, ¶109).

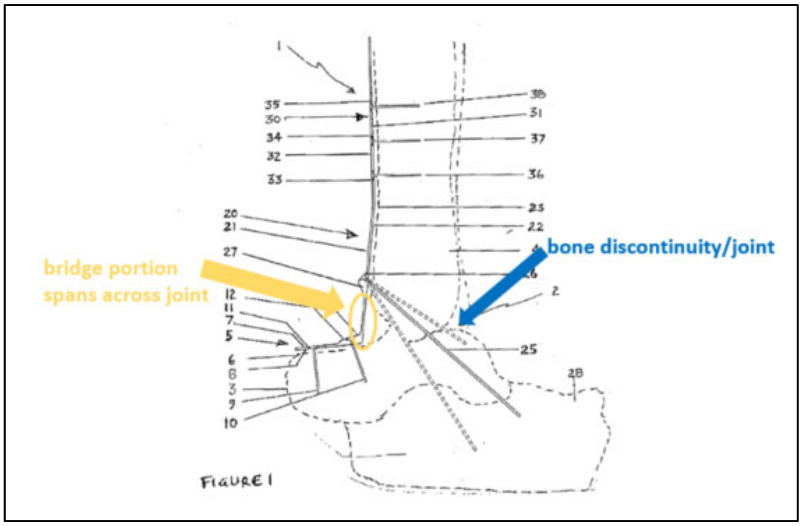






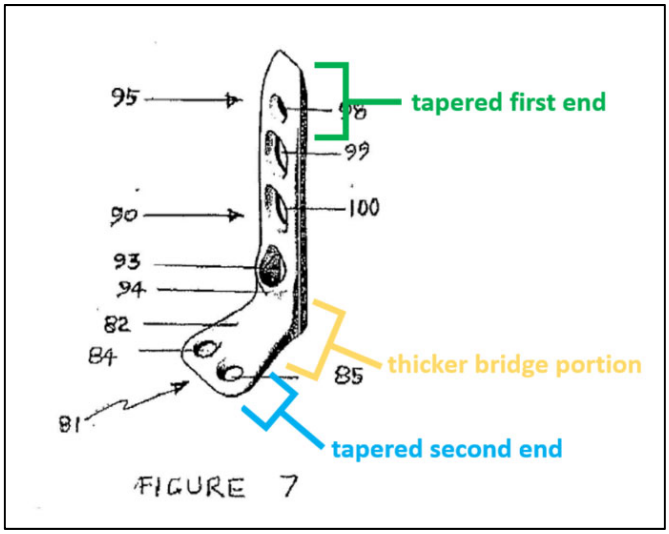
(EX1005, Figs. 1, 6, 7).

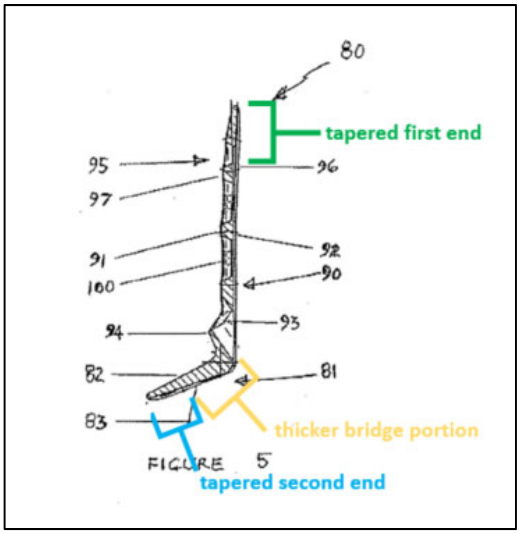
Moreover, Slater's bridge portion (portions of 5 and 20 or portions of 81 and 90) is configured to span across the joint (2). (EX1002, ¶110; EX1005, Fig. 1, 11:3-4).



e. 1.4: "*said bridge portion having a thickness…*"

As shown in Figures 5 and 7, at least a portion of Slater's bridge portion (portions of 5 and 20 or portions of 81 and 90) has a thickness greater than at least a portion of the thickness of either the first end (proximal end of portion 30 or portion 95) or the second end (distal end of portion 5 or portion 81). (EX1002, ¶111).



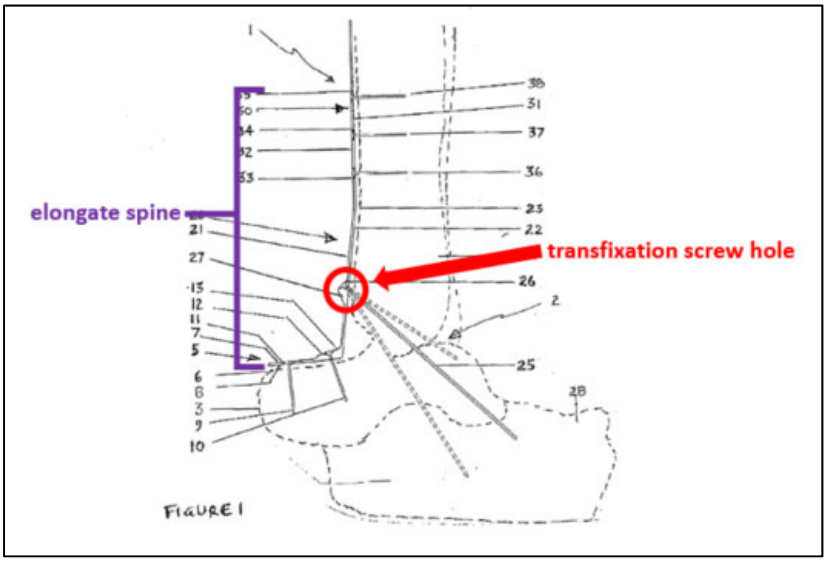


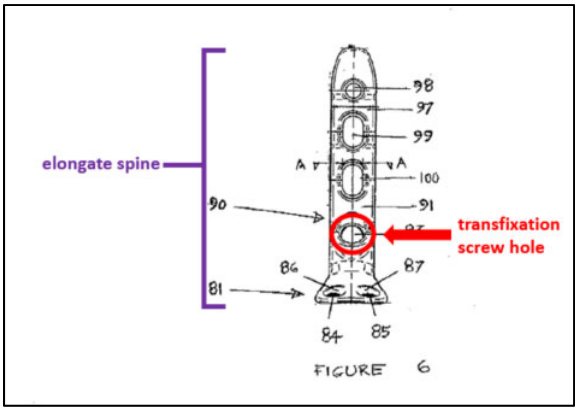
(EX1005, Figs. 5, 7).

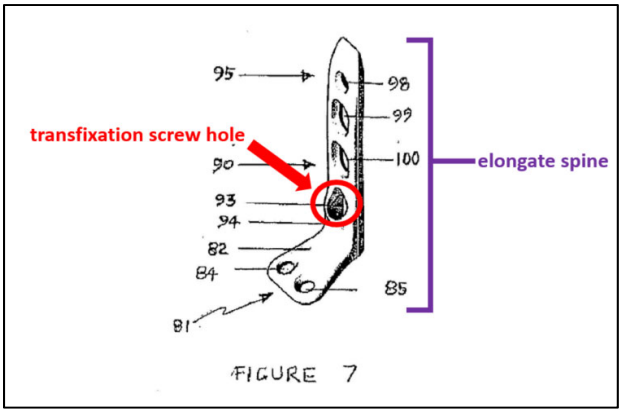
Slater specifically discloses that the portion of the plate adjacent the ankle joint will preferably be the thickest part of the plate, while the portions towards the ends of the plate may be thinner. (EX1005, 8:25-26, 8:32-9:6). Slater recognizes that the plate should be at its "maximum thickness" at the "region that the highest loading will occur in normal use." (EX1005, 14:19-23). Dependent claim 29 expressly recites a kit "wherein the plate thickness varies at different locations and wherein the portion of the plate which lays over the ankle joint has maximum thickness." (EX1005, 34:17-19).

f. 1.5: "*a transfixation screw hole disposed…*"

As shown in Figures 1, 6 and 7, Slater includes a transfixation screw hole (opening 26 or 93) disposed along the spine. (EX1002, ¶112).





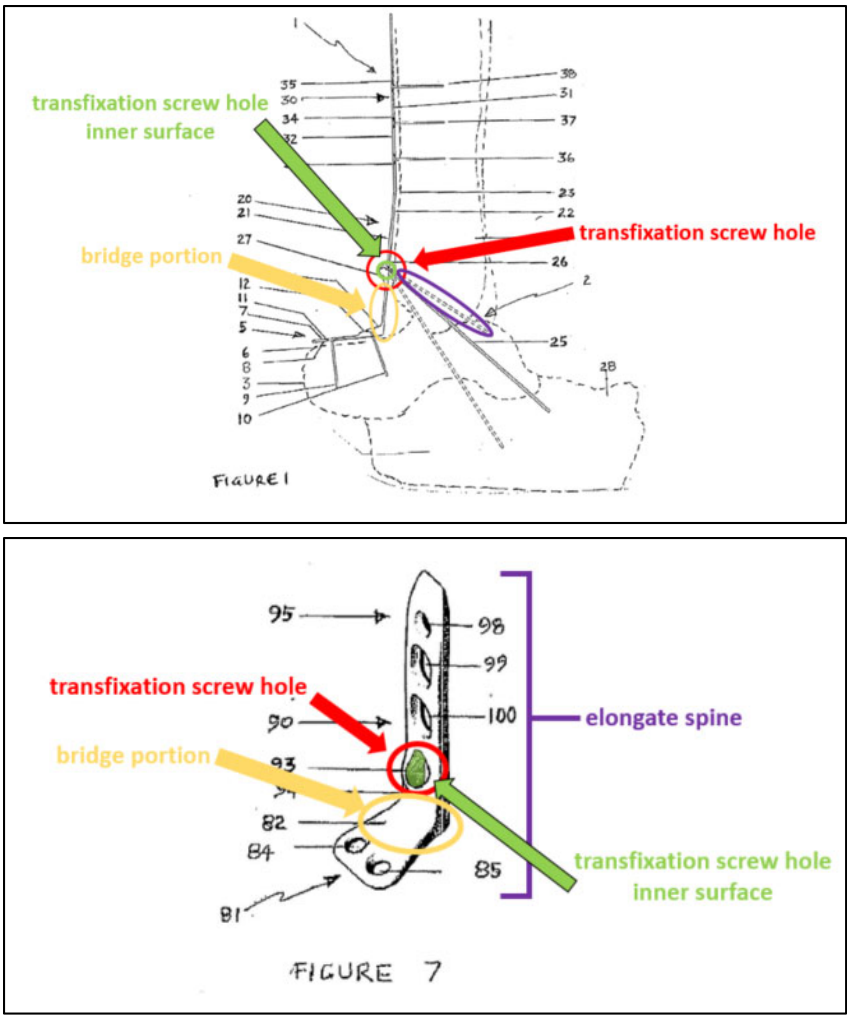


(EX1005, Figs. 1, 6, 7).

While Slater does not explicitly identify openings 26 and 93 as "transfixation screw holes," Slater's disclosure makes it clear that openings 26 and 93 each receive a fixation screw that passes through those openings so that the screw is implanted at an angle. (EX1005, 11:19-21, 13:21-24).

As shown in Figures 1 and 7, Slater includes a transfixation screw hole (26 or 93) that comprises an inner surface (unnumbered in Slater's drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends through the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of the joint (2), and a second position on the second discrete bone (talus 3) once the plate (1 or 80) is placed across the joint. (EX1002, ¶113; EX1005, 11:19-25, 13:21-25). Figure 1 shows three separate exemplary angles for the transfixation screw 25, including one example where the

screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3). (EX1002, ¶113).

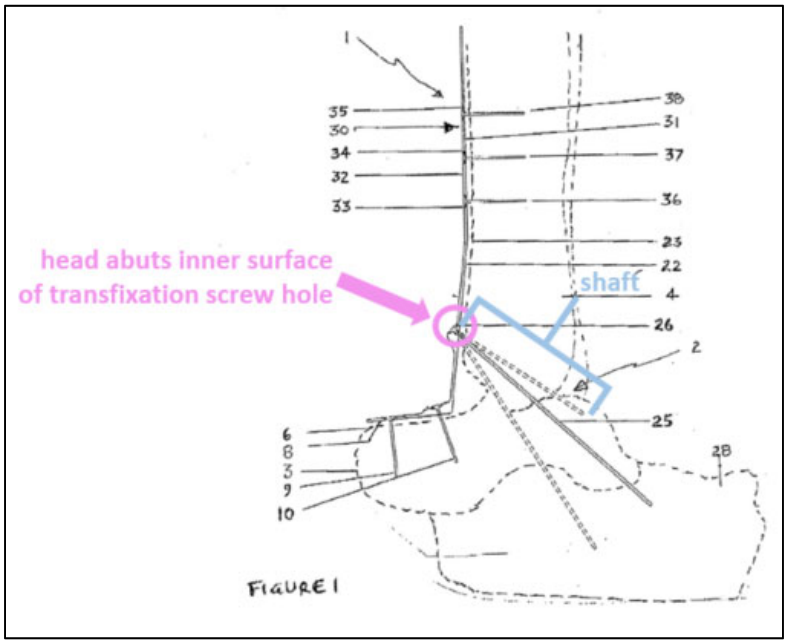


(EX1005, Figs. 1, 7).

g. 1.6: "*the transfixation screw comprises…*"

As shown in Figure 1, Slater includes a transfixation screw (25) comprising a head configured to abut the inner surface of the transfixation screw hole (unnumbered in Slater's drawings) and a shaft configured to contiguously extend

through the first discrete bone (tibia 4), through the joint (2), and into the second discrete bone (talus 3). (EX1002, ¶114).



(EX1005, Fig. 1, 11:19-25, 13:21-24).

In Slater, when the fixation screw (25) advances through the opening (26) and into the second discrete bone (talus 3), the second discrete bone (talus 3) is loaded relative to the first discrete bone (tibia 4), and tensile load is transferred from the second discrete bone (talus 3), through the screw (25) into the screw head (proximal end of screw 25) and into the bridge portion (portions of 5 and 20 or portions of 81 and 90) of the plate. (EX1002, ¶114). This 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. (EX1002, ¶114; EX1005, 12:32-13:3).

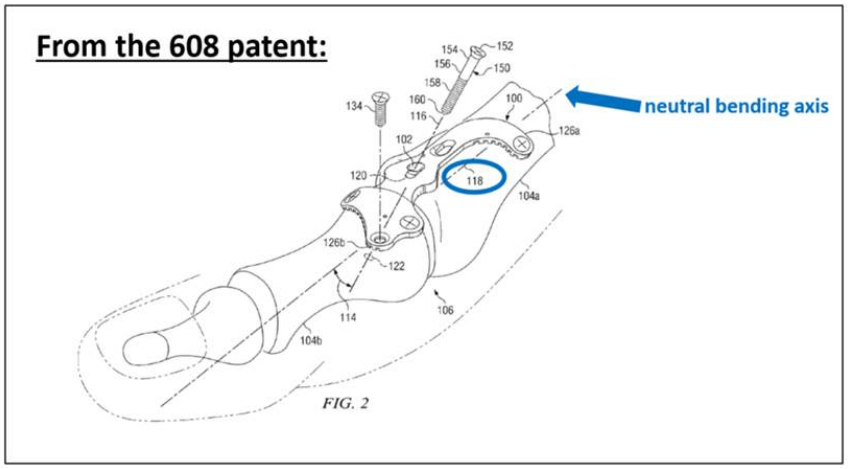
2. Dependent Claims 2-5 and 9-10 are Anticipated by Slater

As discussed above, Slater anticipates independent claim 1. For the reasons set forth below, Slater also anticipates dependent claims 2-5 and 9-10.

a. Dependent Claim 2

Slater discloses that the central axis of the inner surface of the transfixation screw hole (26 or 93) defines a trajectory configured to cross a neutral bending axis of the joint once the plate is placed across the joint. (EX1002, ¶¶115-120).

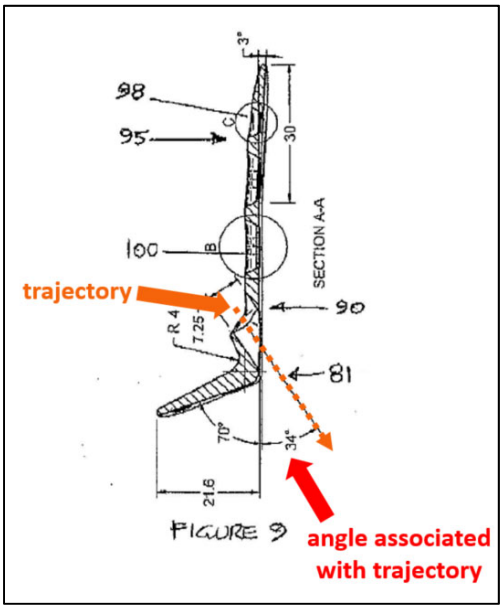
The term "neutral bending axis" is defined by the 608 patent as "[t]he line about which the force on joint 106 transitions from tension to compression….In other words, neutral bending axis 118 defines the boundary line that separates the tension side of joint 106 from the compression side of joint 106." (EX1001, 5:47-52). Figure 2 of the 608 patent illustrates neutral bending axis 118 in connection with the metatarsophalangeal joint. (EX1001, Fig. 2).



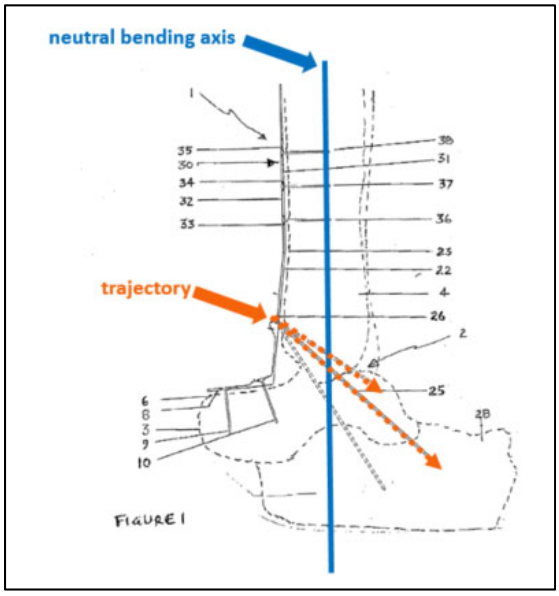
A POSITA would understand that "the neutral bending axis" of a given joint would fall approximately down the center of the adjacent bones, for each bone,

depending on the cortical thickness on opposing surfaces. (EX1002, ¶¶117-118). In Slater, the axis of the bone plate approximates the direction of the neutral bending axis of the joint between the tibia 4 and talus 3. (*Id.*).

In Figure 9, Slater discloses a central axis of the transfixation screw hole (26 or 93) that defines a trajectory and even identifies an angle associated with that trajectory relative to the axis of the bone plate. (EX1002, ¶119; EX1005, Fig. 9).



Similarly, as shown in Figure 1, when the Slater plate is placed across the joint, the trajectory defined by the central axis of the inner surface of the transfixation hole crosses the neutral bending axis of the joint. (EX1002, ¶120).



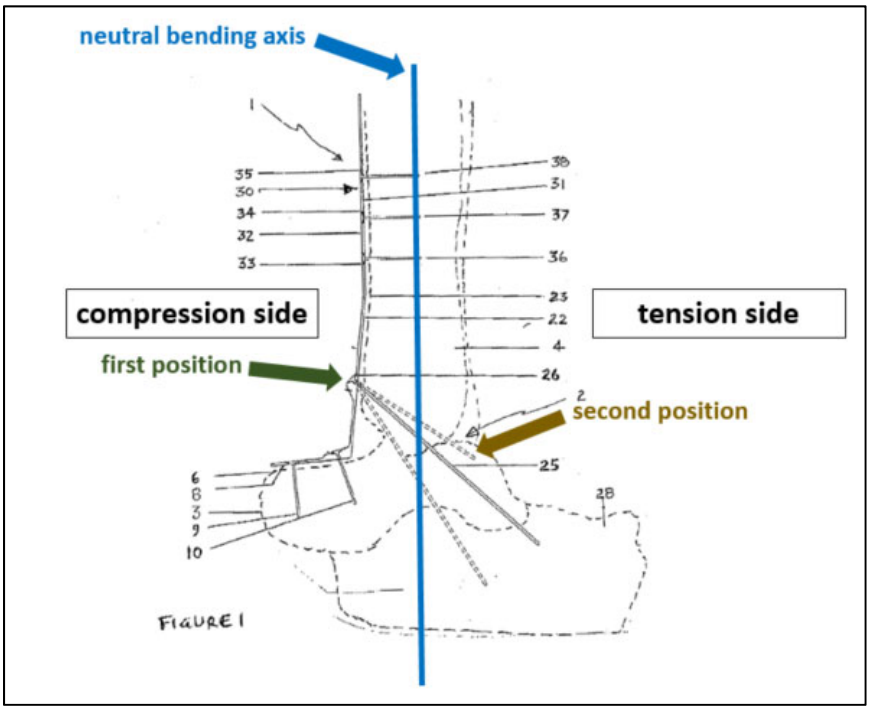
(EX1005, Fig. 1; 11:19-27, 12:3-4, 12:32-13:3, 13:20-25).

b. Dependent Claim 3

Slater discloses that the first position resides on a compression side of the joint and the second position resides on a tension side of the joint. (EX1002, ¶¶121-127).

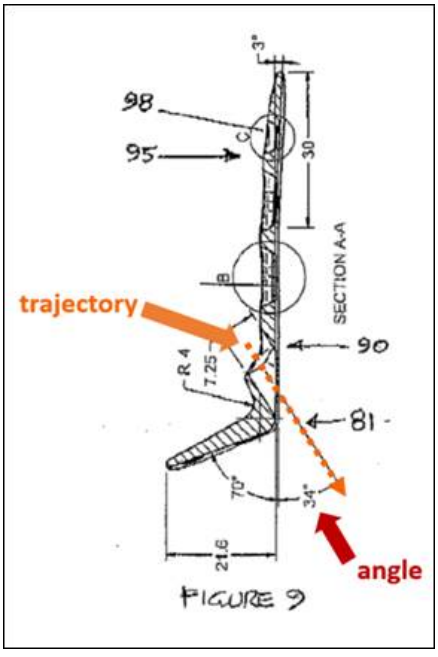
As discussed above, the "neutral bending axis 118 defines the boundary line that separates the tension side of joint 106 from the compression side of joint 106." (EX1001, Fig. 2; 5:50-52). Moreover, a POSITA would understand that having a screw cross the joint at the midpoint of the joint would maximize the compressive forces applied across the joint and would cross from the compression side to the tension side of the joint. (EX1002, ¶¶123-126; EX1010, ¶49; EX1016, ¶35).

In the context of Slater and as labeled in Figure 1, a force in the posterior direction on the foot would place both the tibia and ankle joint in compression on the posterior side of the joint. (EX1002, ¶127; EX1005, Fig. 1). A POSITA would recognize that, when walking, the first position in Slater on the first bone (tibia 4) will, at some point during the gait cycle, reside on a compression side of the joint and the second position in Slater on the second bone (talus 3) will reside on a tension side of the joint. (EX1002, ¶127).



(EX1005, Fig. 1).

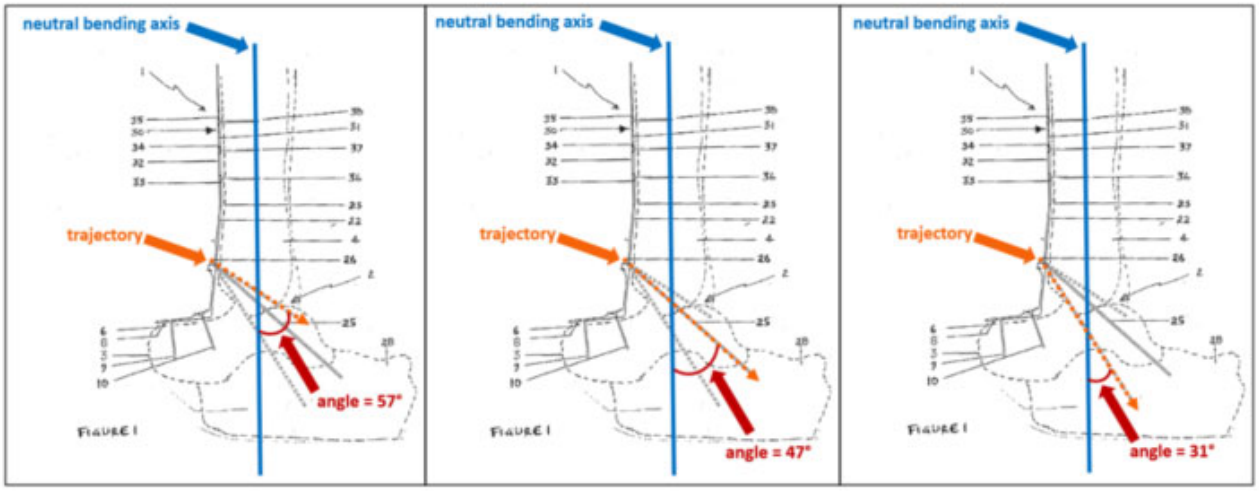
c. Dependent claims 4 and 5



As shown in Figure 9, Slater discloses an embodiment where the central axis of the transfixation hole defines a trajectory that is configured to pass through the joint at a transfixation angle of 34° measured from the axis of the bone plate, which approximates the direction of the neutral bending axis. (EX1002, ¶130; EX1005, 15:23-25, Fig. 9). A transfixation angle of 34 degrees is

"between about 30 degrees and about 70 degrees," and thus discloses the claim element set forth in dependent claim 4. (EX1002, ¶¶130-133).

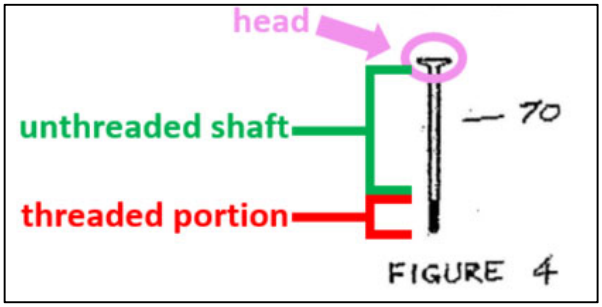
In addition, in Figure 1, Slater discloses three different transfixation angles for screw 25: 31°, 47° and 57°, all of which fall within the claim 4 range of between about 30 and 70 degrees measured from the neutral bending axis of the joint. (EX1002, ¶131). The 47° angle is a transfixation angle of "about 50 degrees," as recited in claim 5.

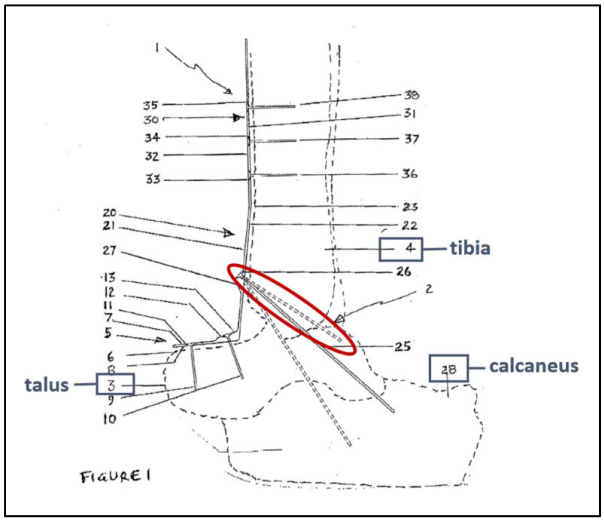


(EX1005, Fig. 1).

d. Dependent claim 9

Figure 4 of Slater depicts a lag screw 70 with a "longer shank" and "an abbreviated threaded portion." (EX1002, ¶135; EX1005, Fig. 4; 12:32-13:3). As shown in Figure 1, when inserted into the transfixation hole, screw type 70 has a first end of the shaft adjacent to the head and an unthreaded portion configured to extend through the first bone (tibia 4) and, at the second end of the shaft adjacent to the tip, a threaded portion configured to extend into the second bone (talus 3). (EX1002, ¶¶134-136).

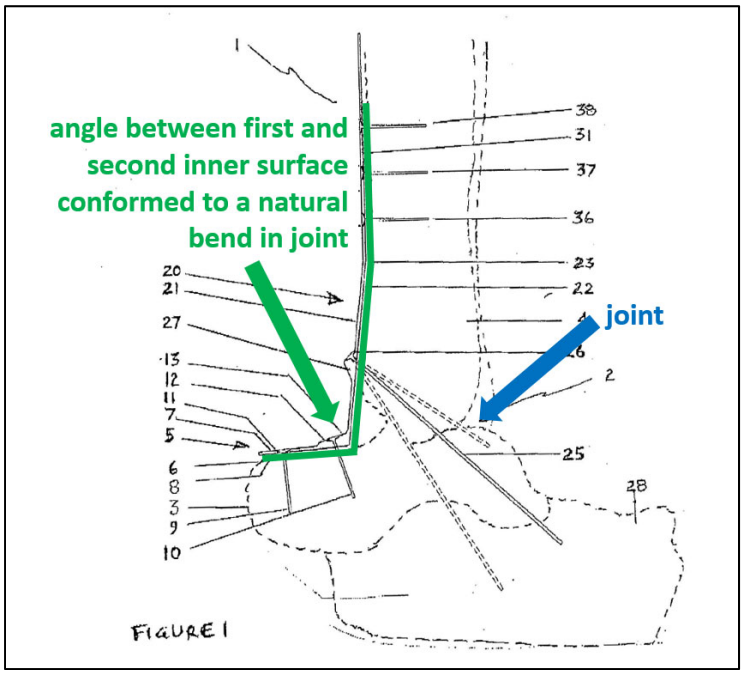




e. Dependent claim 10

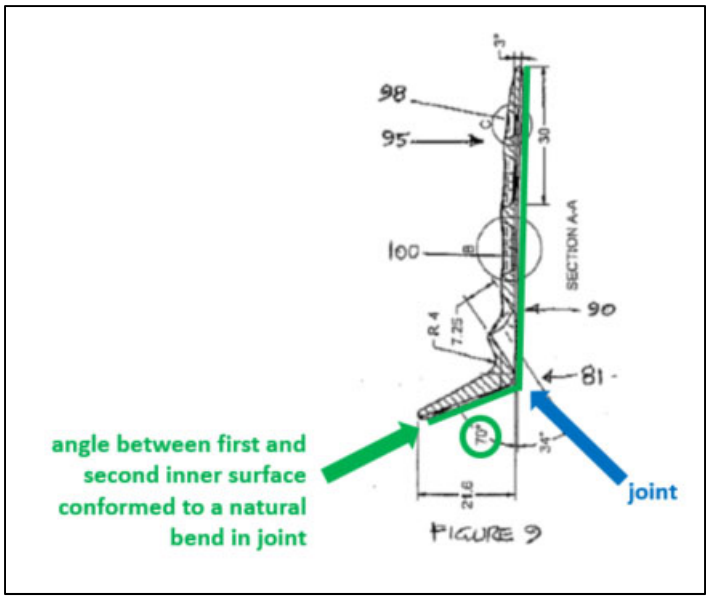
Slater discloses a system wherein the elongate spine is configured to form an angle between the first inner surface (31 or 96) and the second inner surface (8 or 83), the angle substantially conforming to a natural bend at a joint between the first bone (tibia 4) and the second bone (talus 3). (EX1002, ¶¶137-141). For example, Figure 1 illustrates how an angle is formed between a first and second inner surface, substantially conforming to a natural bend at a joint between the first bone (tibia 4)

and the second bone (talus 3). (EX1002, ¶139; EX1005, Fig. 1, 9:15-19, 11:5-8, 11:25-29, 12:6-10).



(EX1005, Fig. 1).

Similarly, an angle is formed between first inner surface (96) and second inner surface (83) in the Figure 9 embodiment. (EX1005, 15:19-25; 13:20-28). As discussed with respect to claim elements 1.1 and 1.2, Slater repeatedly explains that the bone plate is configured to generally conform to the anatomic contours of the ankle joint.



3. Independent Claim 11 is Anticipated by Slater

a. 11.P: Preamble

The preamble of claim 11 is nearly identical to the preamble of claim 1 except that it recites a "plate" rather than a "system," and recites "across an intermediate joint" rather than "across a joint between the two bones." For the same reasons discussed with respect to claim element 1.P, Slater discloses claim element 11.P. (EX1002, ¶144).

b. 11.1: "*an elongate spine having: a first end comprising…*"

Claim elements 11.1 and 1.1 are identical except for a minor wording change ("an intermediate joint" versus "a joint"). For the same reasons discussed with respect to claim element 1.1, Slater discloses claim element 11.1. (EX1002, ¶¶145-147).

c. 11.2: "*a second end comprising…*"

Claim elements 11.2 and 1.2 are identical except for a minor wording change ("geometry of the second discrete bone" versus "geometry of the second bone"). For the same reasons discussed with respect to claim element 1.2, Slater discloses claim element 11.2. (EX1002, ¶¶148-149).

d. 11.3: "*a bridge portion disposed…*"

Claim elements 11.3 and 1.3 are identical. For the same reasons discussed with respect to claim element 1.3, Slater discloses claim element 11.3. (EX1002, ¶¶150-151).

e. 11.4: "*a transfixation screw hole disposed…*"

Claim elements 11.4 and 1.5 are similar except: 11.4 recites that the transfixation screw extends "alongside" the bridge portion instead of "through" the bridge portion;" 1.5 expressly specifies that the trajectory of the transfixation screw is configured to pass through "a portion of the joint" whereas 11.4 does not; and the second portion of claim element 11.4 recites "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" whereas the second portion of 1.6 recites "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." These minor wording changes do not affect how Slater reads on the claim. For the same reasons discussed with respect to claim elements 1.5 and 1.6, Slater discloses claim element 11.4. (EX1002, ¶¶152-154).

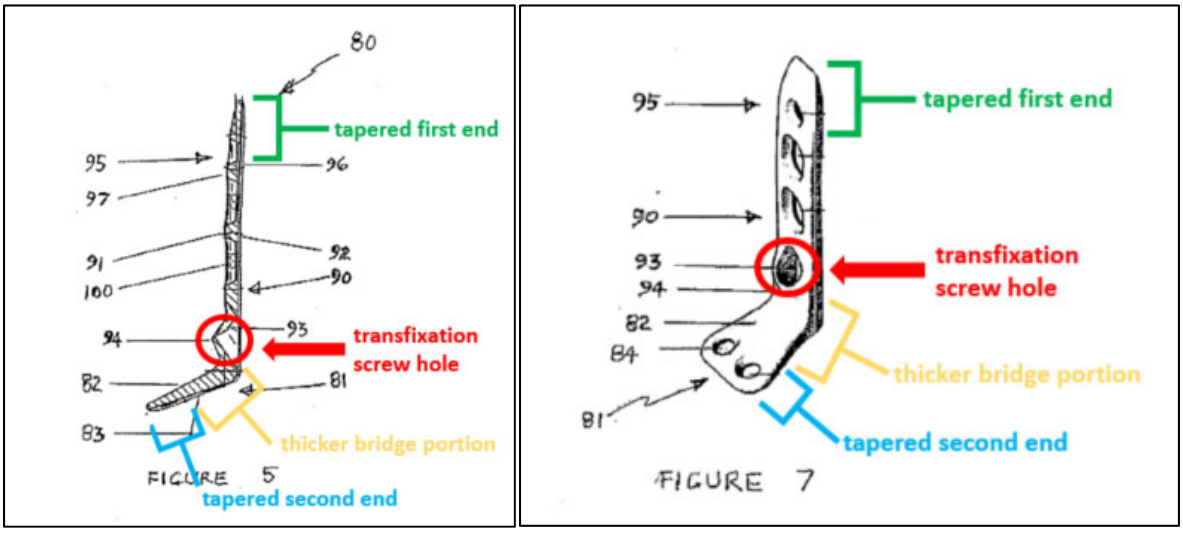
f. 11.5: "*wherein…said bridge portion and said transfixation screw hole has a thickness….*"

Claim elements 11.5 and 1.4 are similar except that 11.5 recites "at least a portion of said bridge portion and said transfixation screw hole" have a thickness greater than "at least a portion of said first and second ends."

As discussed in Section III.C., during the prosecution of the 608 patent, Patent Owner amended claim 1 to include the language of claim element 1.4 and amended claim 11 to include the language of claim element 11.5. (EX1004, OSTEOMED_0001879, OSTEOMED_0001881). Patent Owner represented that "the amended claims further recite that at least a portion of the bridge portion has a thickness greater than at least the portion of the thicknesses of either the first or second end," thus confirming that the amended claims were intended to have the same scope, at least with respect to the comparison of thicknesses between the bridge portion and either the first or second end. (EX1004, OSTEOMED_0001886). Thus, for the same reasons as discussed with respect to claim element 1.4, Slater discloses claim element 11.5. (EX1002, ¶155).

Further, as shown in Figures 5 and 7, at least a portion of Slater's bridge portion (portions of 5 and 20 or portions of 81 and 90) and the portion of the plate including the transfixation screw hole (26 or 93) have a thickness greater than at least a portion of the thickness of the first and second ends (proximal end of portion 30 or 95, distal end of portion 5 or 81). (EX1002, ¶155). Indeed, the first and second

ends of the Slater bone plate are tapered. As 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. (EX1002, ¶155; EX1005, Figs. 5, 7, 8:25-26, 8:32-9:6, 14:19-23, 24:17-19).



(EX1005, Figs. 5, 7).

4. Dependent Claims 12-14 and 17 are Anticipated by Slater

As discussed in Section VI.A.3., Slater anticipates independent claim 11. Moreover, dependent claims 12-14 and 17 mirror the language in dependent claims 2-3, 5, and 10 described above. Thus, for the same reasons described with respect to dependent claims 2-3, 5, and 10, Slater anticipates claims 12-14 and 17. (EX1002, ¶¶156-160).

B. Ground 2: Claims 6 and 8 are Obvious Over Slater in View of Weaver

As discussed above, Slater anticipates independent claim 1. Moreover, Weaver discloses every additional element described in dependent claims 6 and 8, which recite that the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw (claim 6) and that at least one attachment point comprises a threaded screw hole to lockably engage a locking bone screw (claim 8). As discussed below, dependent claims 6 and 8 are rendered obvious by Slater in view of Weaver. (EX1002, ¶¶161-169).

Weaver is directed to a bone plate having plate holes for both locking and non-locking screws. (EX1009, 1:10-13). Weaver explains that "[a] locking screw has threading on an outer surface of its head that mates with corresponding threading on the surface of the plate hole to lock the screw to the plate. Bone plates having threaded holes for accommodating locking screws are known." (EX1009, 1:49-54). Weaver explains that locking screws "provide a high resistance to shear or torsional forces" and reduce the incidence of screw loosening. (EX1009, 1:46-48, 1:57-58).

In Figures 3 and 26, Weaver discloses a bone plate having both threaded holes 36, 86 and non-threaded holes 38, 88. Figure 4 shows a threaded hole 36 including

thread 40 that mates with a thread on the head of a locking screw (Figure 2). (EX1009, 4:48-51, 5:1-5).

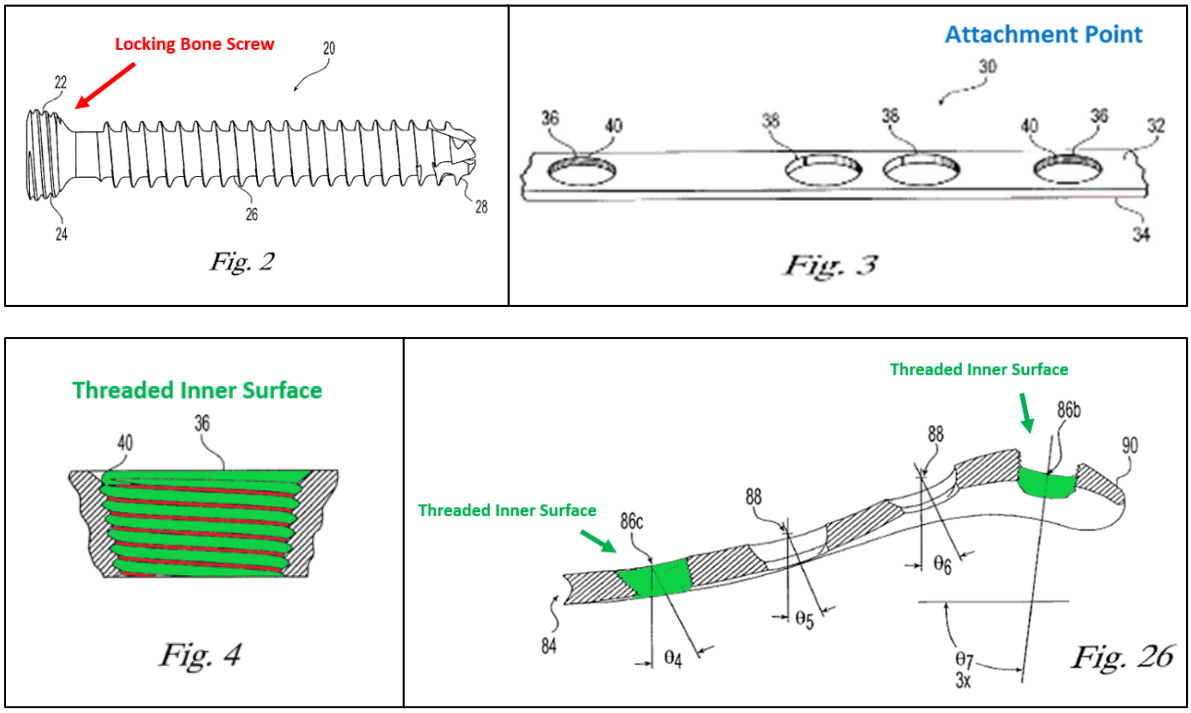


Fig. 2 Fig. 3 Fig. 4 Fig. 26

(EX1009, Figs. 2-4, 26).

In April 2009, it was known that bone plates used for lower extremities are particularly prone to screws loosening or backing-out of plates because of the repeated loads and stresses placed upon the ankles and feet during typical human activities such as walking. (EX1002, ¶164; EX1005, 1:24-2:14, 3:24-25). Since the Slater plate is used to fuse the ankle and is subject to repeated loads and stresses, a POSITA would have been motivated to include at least one threaded screw hole to lockably engage with a locking bone screw to help provide a more secure fixation. (EX1002, ¶¶164-165, ¶¶167-169). This modification would have involved nothing

more than combining a known prior art element in a known way, with no change in function to yield a predictable result. (EX1002, ¶165, ¶169); *see also Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1375 (Fed. Cir. 2013). Moreover, a POSITA would have had a reasonable expectation of success in combining Slater and Weaver because locking screws with threaded heads that mate with threaded plate holes were common at the time. (EX1002, ¶165; EX1005, 8:35-9:1).

Weaver discloses the use of at least one plate hole (36 in Fig. 3) defined by a threaded inner surface (40 in Fig. 4; 86b and 86c in Fig. 26) configured to lockably engage with a locking bone screw (20 in Fig. 2). (EX1009, Figs. 2-4, 26; 1:52-54, 1:60-2:3-6, 3:9-17, 4:41-67, 5:13, 5:66-6:1-2, 6:44-45, 7:32-33). Configuring Slater's transfixation screw hole (claim 6) or at least one of Slater's attachment points (claim 8) as a threaded screw hole to lockably engage the head of a locking screw would have been an obvious design choice. (EX1002, ¶¶166-169). Such design choice would have been made because locking screws "provide a high resistance to shear or torsional forces" and reduce the incidence of screw loosening. (EX1009, 1:46-48, 1:57-58; EX1002, ¶¶162-163).

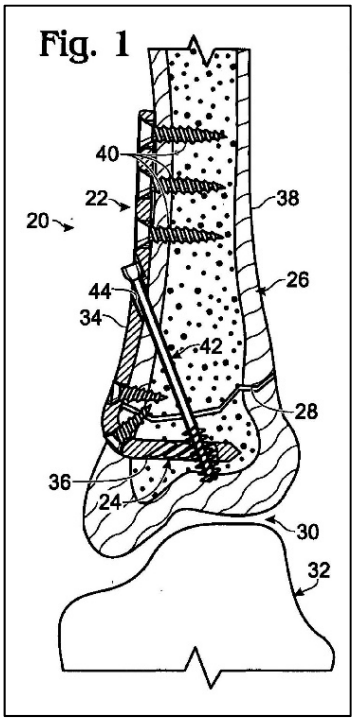
C. Ground 3: Falkner Anticipates Claims 1-3, 6, 8-13, and 17

As shown below and in the accompanying Declaration, Falkner discloses all elements of claims 1-3, 6, 8-13, and 17, and thus anticipates those claims under 35 U.S.C. § 102(b). (EX1002, ¶¶170-233).

1. Independent Claim 1 is Anticipated by Falkner

a. 1.P: Preamble

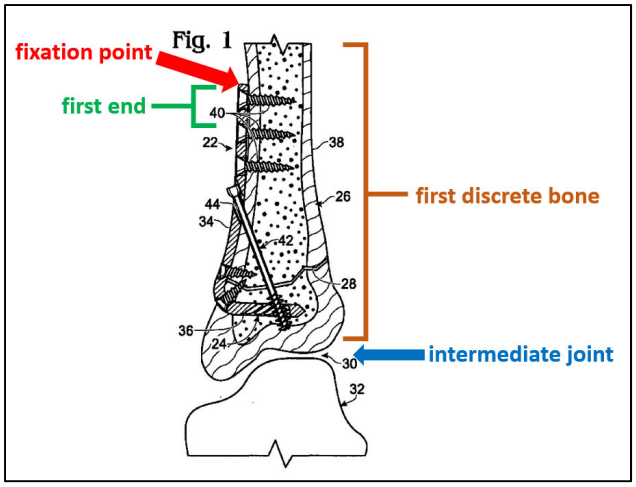
To the extent the preamble is limiting, Falkner discloses a system 20 for securing two discrete bones (tibia 26 and talus 32) together across a joint 30 between the tibia 26 and talus 32. (EX1002, ¶172).

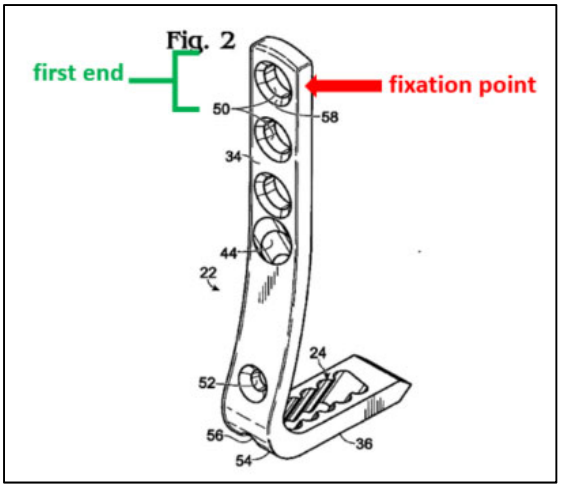


While Figure 1 of Falkner shows an exemplary system for fixing bones, the Falkner disclosure expressly contemplates that "the bone plate may be positioned on and/or in any suitable **bone(s)** to span any natural or artificial discontinuity within a bone or between bones. In the present illustration, plate 22 is secured to a distal end (metaphyseal) region of a tibia bone 26 and spans fracture 28. **In other examples, plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among them.**" (EX1006, ¶21) (emphasis added); (EX1006, ¶¶27-29, 62).

b. 1.1: "*the plate comprises: an elongate spine having: a first end comprising…*"

As shown in Figures 1 and 2, Falkner discloses a bone plate 22 comprising an elongate spine (22) having a first end comprising at least one fixation point (50) for attaching the first end to a first discrete bone (tibia 26) on a first side of an intermediate joint (30). (EX1002, ¶¶173-175).



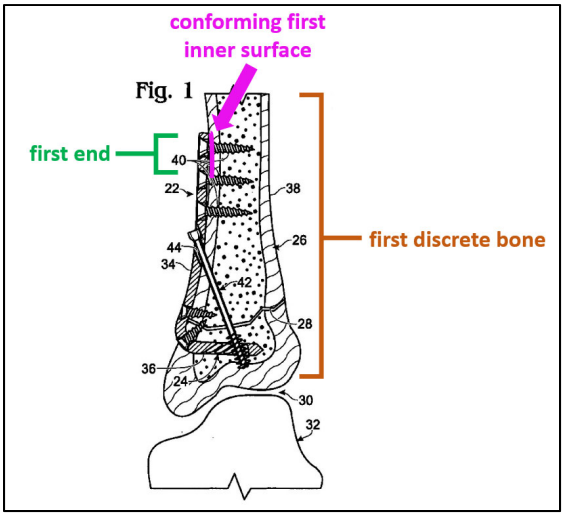


(EX1006, Figs. 1, 2).

For example, Falkner explains that "[e]ach bone plate portion may define one or more openings for receiving fasteners, such as bone screws, that secure the plate portions to bone." (EX1006, ¶19). Falkner further explains with respect to Figure 2 that external portion 34 "**may include a first set of one or more openings 50**, a second set of one or more openings 52, and an oblique opening 44 disposed between the first and second sets." (EX1006, ¶68; ¶¶23, 36, 39).

As discussed in Section VI.C.1.a., Falkner specifically contemplates that "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32." (EX1006, ¶21). In that situation, the plate 22 would be placed across the 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. (EX1002, ¶175).

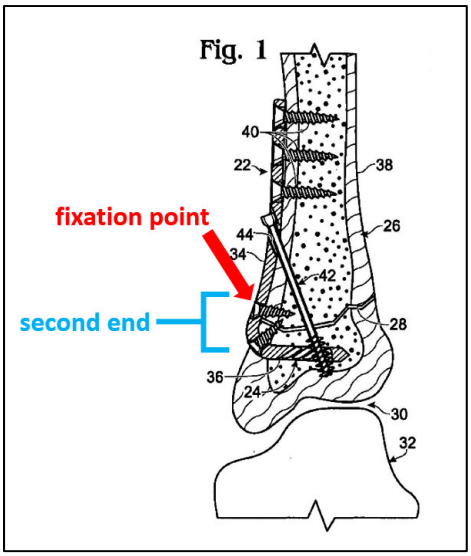
As shown in Figure 1, the first end of Falkner includes a first inner surface configured to substantially conform with a geometry of the first discrete bone (tibia 26). (EX1002, ¶176; EX1006 at Fig. 1).

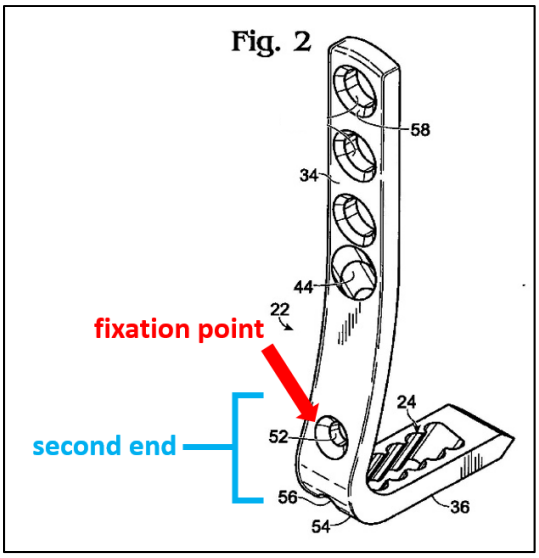


Falkner specifically discloses that "[t]he external plate portion may be contoured to follow an exterior surface of the bone." (EX1006, ¶23). Falkner further explains that "[t]he bone plates (or exterior plate portions, see Section II) may include inner (bone-facing) and outer (bone-opposing) surfaces. **One or both of these surfaces may be contoured generally to follow an exterior surface of a target bone (or bones) for which a bone plate is intended**, so that the bone plate maintains a low profile and fits onto the bone(s). For example, the inner surface of a plate (or of an exterior plate portion) may be generally complementary in contour to the bone surface." (EX1006, ¶34). To the extent that the Falkner plate 22 spans joint 30, the first inner surface would be configured to substantially conform with a geometry of the first discrete bone (tibia 26). (EX1002, ¶176). Of course, if the plate 22 was used to span a different joint, Falkner teaches that the first inner surface would substantially conform with a geometry of the first discrete bone of that particular joint "so that the bone plate maintains a low profile and fits onto the bone(s)." (EX1006, ¶34).

c. 1.2: *"a second end comprising…"*

As shown in Figures 1 and 2, Falkner discloses a bone plate 22 comprising an elongate spine having a second end comprising at least one fixation point (52, seen in Fig. 2) for attaching the second end to a second discrete bone (talus 32) on a second side of the joint 30. (EX1002, ¶177).

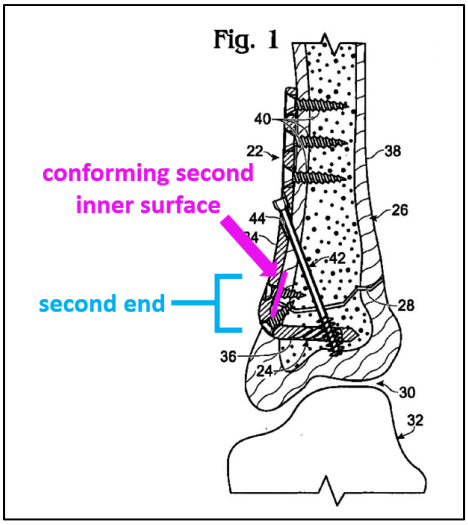




(EX1006, Figs. 1-2).

Similar to the discussion above relating to the first end, Falkner explains that external portion 34 "may include a first set of one or more openings 50, **a second set of one or more openings 52**, and an oblique opening 44 disposed between the first and second sets." (EX1006, ¶68). If the Falkner plate was used to span a joint between tibia 26 and talus 32 (as specifically contemplated at ¶¶21, 27-29, 62), the plate 22 would be placed across the 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

and a bone screw 40 may be placed into second discrete bone (talus 32) through the opening 52 at the second end of the plate 22. (EX1002, ¶177).

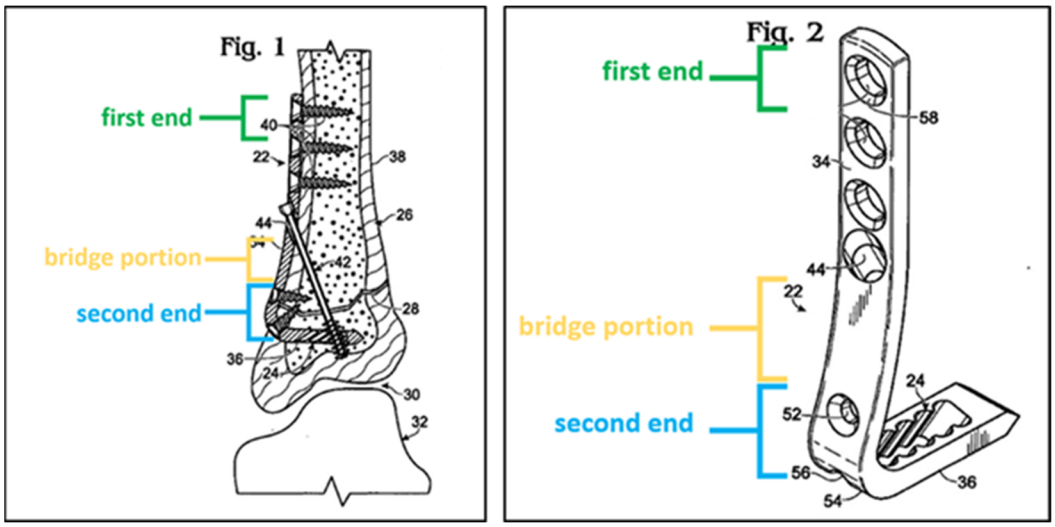


Falkner discloses that its second end comprises a second inner surface configured to substantially conform with a geometry of the second discrete bone (talus 32) when the plate is used to span a joint. (EX1002, ¶178; EX1006, Fig. 1).

Falkner expressly contemplates that "[t]he external plate portion may be contoured to follow an exterior surface of the bone." (EX1006, ¶23; ¶¶34, 42). When Falkner is configured to span a joint between two discrete bones, the plate would be placed across the joint and the second inner surface would be configured to substantially conform with a geometry of the second discrete bone (talus 32). (EX1002, ¶178).

d. 1.3: "*a bridge portion disposed…*"

As shown in Figures 1 and 2, Falkner includes a bridge portion disposed between the first end and the second end, the bridge portion configured to span across a joint. (EX1002, ¶¶179-180).



(EX1006, Figs. 1-2).

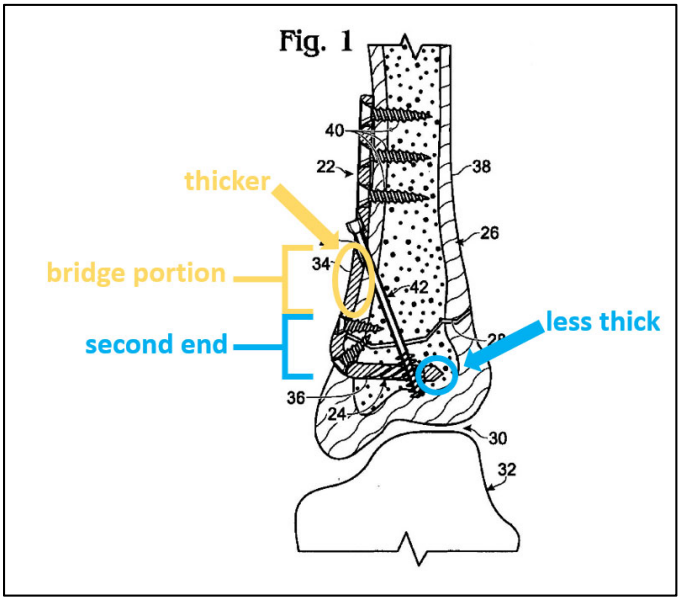
The exemplary system 20 illustrated in Falkner depicts a bone plate 22 having first and second plate portions 34, 36 "disposed so that they are, respectively, external to (on) and internal to (in) tibia 26." (EX1006, ¶22). Falkner refers to the junction of the external and internal plate portions as a "bridge region" or "bridge portion 54 and recognizes that "[t]he bridge portion may be configured to span a bone discontinuity." (EX1006, ¶¶35, 45, 68, 69). Thus, if the Falkner plate was used to span a joint, the bridge portion disposed between the first end and the second end would be configured to span across the joint. (EX1002, ¶180).

e. 1.4: "*said bridge portion having a thickness…*"

At least a portion of the Falkner bridge portion has a thickness greater than at least a portion of the thickness of either the first end or the second end. (EX1002, ¶181). According to Falkner, "[t]he thickness of the bone plates may be defined by

the distance between the inner and outer surfaces of the plates. The thickness of the plates may vary between plates and/or within the plates, according to the intended use." (EX1006, ¶35). Falkner expressly recognizes that "[t]hickness may be varied within the plates" and that "the plates may become thinner as they extend over protrusions (such as processes, condyles, tuberosities, and/or the like), reducing their profile and/or rigidity, among others" or "thicker to increase structural stability." (EX1006, ¶35). "In this way, the plates may be thicker and thus stronger in regions where they may not need to be contoured, such as along the shaft of the bone." (EX1006, ¶35).

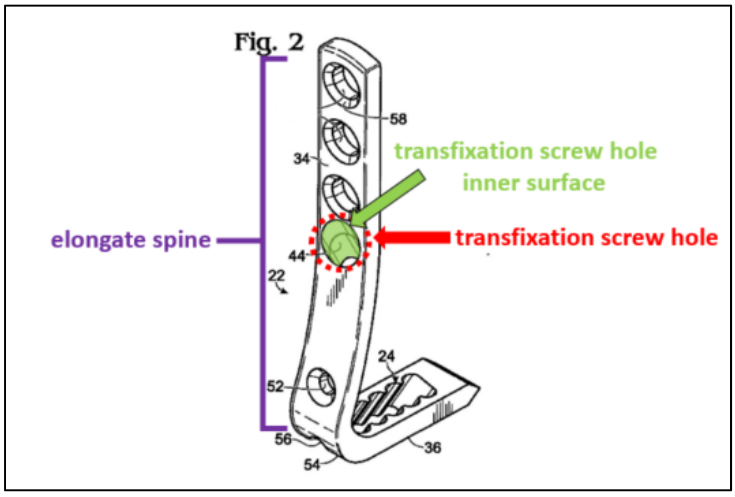
As can be seen in Figure 1, at least a portion of the bridge portion has a thickness greater than at least a portion of the thickness of the second end. (EX1002, ¶181). In particular, the second end is described as an "internal portion" that is thinner at the end to facilitate insertion into the bone and becomes thicker towards the bridge portion to increase structural stability. (EX1006, ¶35; EX1006, Fig. 1).



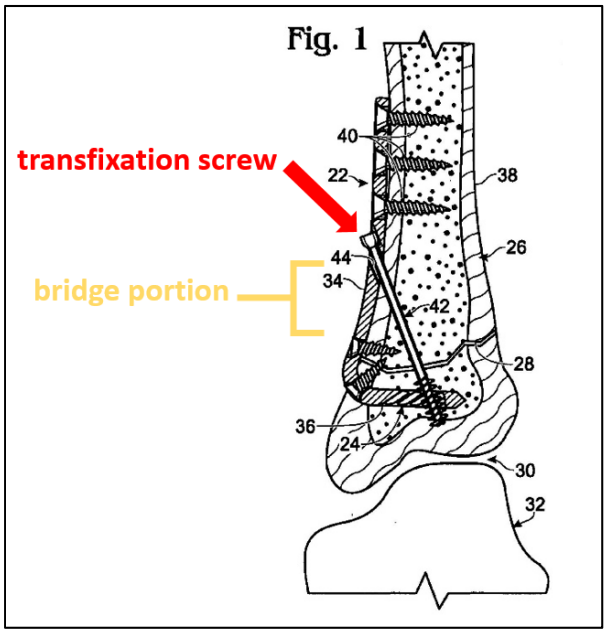
As such, Falkner teaches that at least a portion of the claimed bridge portion has a thickness greater than at least a portion of the thickness of either the first end or the second end. (EX1002, ¶181).

f. 1.5: "*a transfixation screw hole disposed…*"

As shown in Figure 2, Falkner discloses a transfixation screw hole (44) disposed along the spine (22), the transfixation screw hole comprising an inner surface configured to direct a transfixation screw (42) through the screw hole (44). (EX1002, ¶¶182-183; EX1006, Fig. 2, ¶¶68, 71-72, 78).



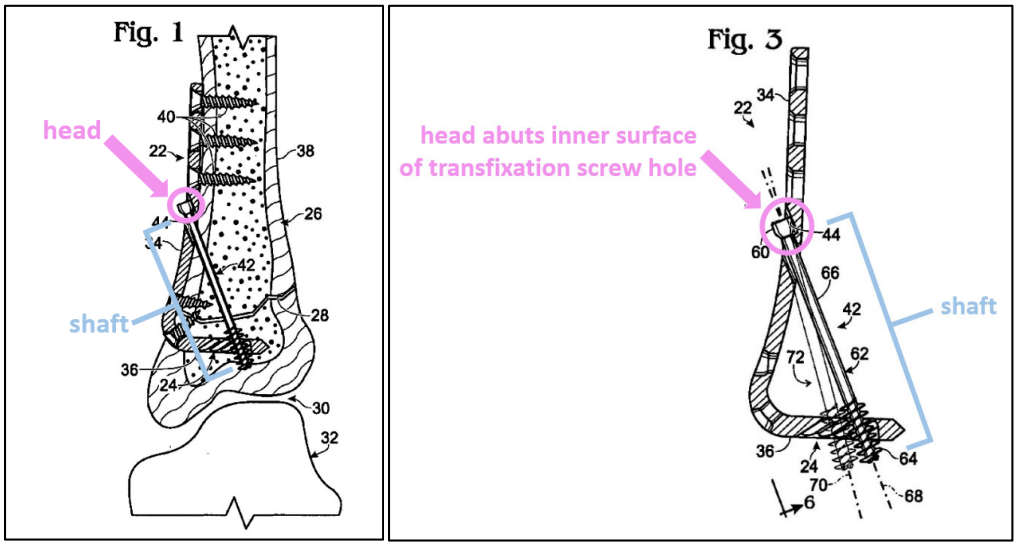
As discussed above, when the Falkner bone plate is configured to span a joint 30 such as tibia 26 and talus 32, then the oblique opening 44 is a transfixation screw hole comprising an inner surface configured to direct a transfixation screw 42 through the oblique opening 44 such that the transfixation screw 42 extends through the bridge portion at a trajectory configured to pass through a first position on the first discrete bone (tibia 26), a portion of the joint 30, and a second position on the second discrete bone (talus 32) once the plate is placed across the joint 30. (EX1002, ¶183).



g. 1.6: "*the transfixation screw comprises…*"

As shown in Figure 1, Falkner teaches a transfixation screw (42) comprising a head configured to abut the inner surface of the transfixation screw hole (44) and a shaft configured to contiguously extend through both sides of fractured tibia 26. (EX1002, ¶184; EX1006, ¶70). As discussed above, when the Falkner plate is configured to span a joint between tibia 26 and talus 32 (EX1006, ¶¶21, 27-29, 62), the plate 22 would be placed across the joint 30 and threaded fastener 42 would

extend through the first discrete bone (tibia 26), through the joint (30), and into the second discrete bone (talus 32). (EX1002, ¶184).



(EX1006, Figs. 1, 3).

In that configuration, when the second discrete bone (talus 32) is loaded relative to the first discrete bone (tibia 26), tensile load is transferred from the second discrete bone (talus 32) through the screw into the head and the bridge portion of the plate. (EX1002, ¶184). For example, Falkner explains 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." (EX1006, ¶71).

2. Dependent Claims 2-3, 6, and 8-10 are Anticipated by Falkner

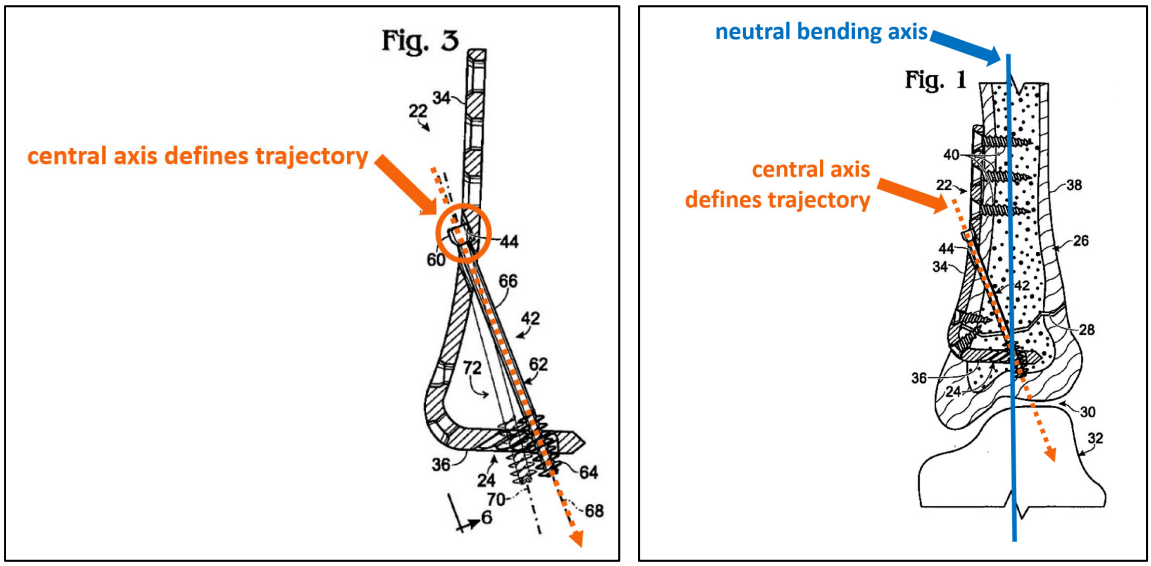
As discussed above, Falkner anticipates independent claim 1. For the reasons set forth below, Falkner discloses every element of dependent claims 2-3, 6, and 8-10 and therefore anticipates those claims.

a. Dependent Claim 2

The central axis of the inner surface of the Falkner transfixation screw hole (44) defines a trajectory configured to cross a neutral bending axis of the joint 30 once the plate is placed across the joint. (EX1002, ¶¶186-192).

As discussed above in Ground 1, a POSITA would understand that the neutral bending axis of a joint would fall approximately down the center of the adjacent bones, for each bone, depending on the cortical thickness on opposing surfaces. (EX1002, ¶189). In Falkner, the axis of the bone plate approximates the direction of the neutral bending axis of the joint. (*Id.*).

In Figure 3, Falkner discloses a central axis (68 or, alternatively, 70) of the inner surface of the transfixation screw hole (44) defining a trajectory. (EX1006, ¶72; Fig. 3). In an embodiment contemplated by Falkner to span joint 30 instead of a fracture 28 (EX1006, ¶¶21, 27-29), the trajectory would cross a neutral bending axis of joint 30 once the plate is placed across the joint. (EX1002, ¶¶190-192).

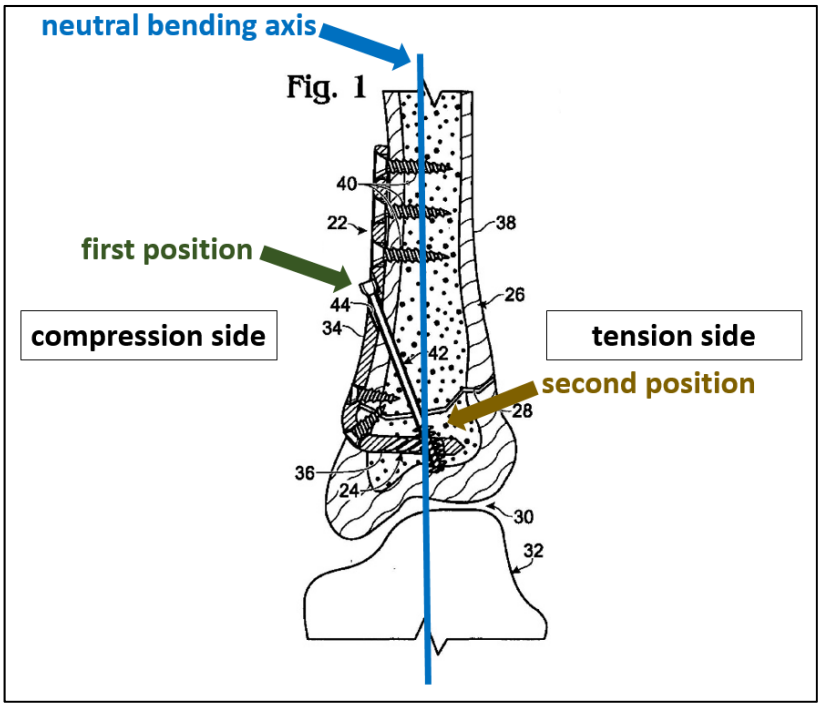


(EX1006, Figs. 1, 3).

b. Dependent Claim 3

Falkner discloses that the first position on the first discrete bone resides on a compression side of the joint and the second position on the second discrete bone resides on a tension side of the joint. (EX1002, ¶¶193-198).

While Figure 1 illustrates an embodiment wherein the bone plate is placed across a fracture, the Falkner disclosure specifically contemplates that the bone plate can be placed across a joint. *See* Section VI.C.1.a. As discussed above, the "neutral bending axis 118 defines the boundary line that separates the tension side of joint 106 from the compression side of joint 106." (EX1001, Fig. 2; 5:50-52). Moreover, a POSITA would understand that a transfixation screw crossing the joint at the midpoint of the joint would maximize the compressive forces applied across the joint and would cross from the compression side to the tension side of the joint. (EX1002, ¶196; EX1010, ¶49; EX1016, ¶35).



Assuming that Falkner Figure 1 shows an anterior view of the left foot, inversion would result in compression on the medial side and tension on the lateral side of the ankle joint. (EX1002, ¶197). In such loading, the first position resides on a compression side of the joint and the second position resides on a tension side of the joint. (*Id.*). Thus, in an embodiment contemplated by Falkner to span a joint

instead of a fracture, the first position of the transfixation screw 42 would reside on a compression side of joint 30 and, due to the angle of the screw and the length of the screw, the second position of the transfixation screw 42 would reside on a tension side of joint 30. (EX1002, ¶198).

c. Dependent Claim 6

Falkner discloses that the inner surface of the transfixation screw hole (44) may be configured to lockably engage the head of the transfixation screw (42). (EX1002, ¶¶199-200).

For example, Falkner states that the head 60 of the transfixation screw 42 "may be nonthreaded (as shown here) or may include a thread configured to lock the head to the plate." (EX1006, ¶70). Falkner further teaches that "[e]xternal and internal portions 34, 36 may include a plurality of openings…Each opening may be threaded or nonthreaded…" (EX1006, ¶68). A POSITA would understand that Falkner's disclosure of a threaded screw head configured to lock the head to the plate together with threaded openings teaches that the inner surface of the transfixation screw hole may be configured to lockably engage the head of the transfixation screw. (EX1002, ¶200).

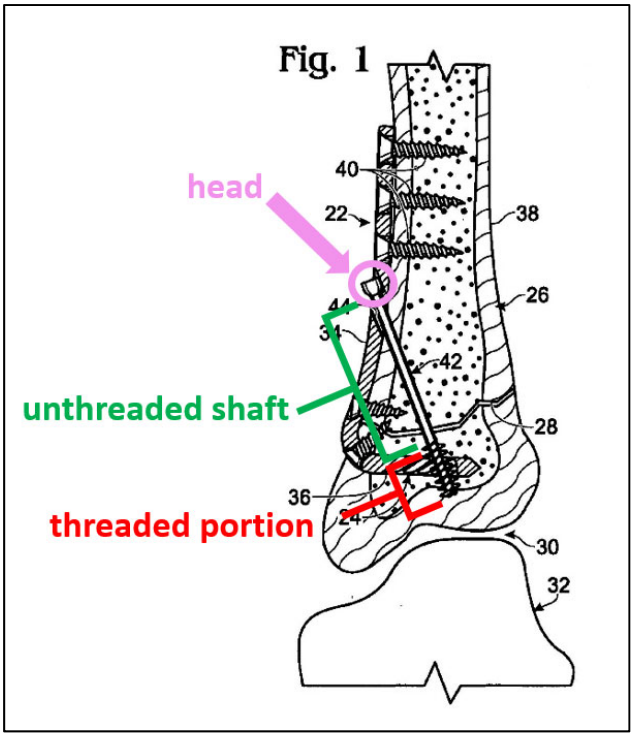
d. Dependent Claim 8

Falkner discloses a system wherein each at least one attachment point (50, 52) comprises a threaded screw hole defined by a threaded inner surface configured to

lockably engage one of a plurality of locking bone screws 40. (EX1002, ¶¶201-205). As discussed with respect to claim 6, Falkner teaches that "t[h]e bone plates generally include a plurality of openings" and that "[t]he openings may be threaded or nonthreaded, and each bone plate may include one or more threaded and/or nonthreaded openings." (EX1006, ¶¶36, 38, 68). Falkner further recognizes that bone screws may have threaded or nonthreaded heads for locking or nonlocking engagement, respectively, with threaded openings. (EX1006, ¶¶70, 80).

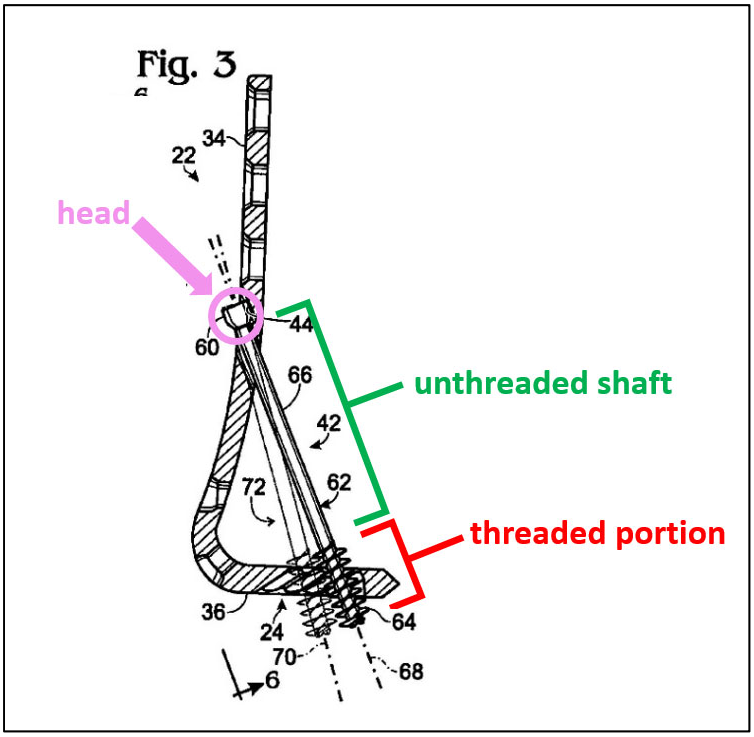
e. Dependent Claim 9

As shown in Figures 1 and 3, Falkner discloses a transfixation screw (42) comprising a lag screw having an unthreaded portion configured to extend through the first bone (located at a first end of the shaft adjacent to the head) and a threaded portion configured to extend into the second bone (located at a second end of the shaft adjacent to the tip). (EX1002, ¶¶206-209).



Moreover, Falkner expressly discloses that "[i]n some examples, the bone screws may include a shaft that includes a distal threaded region and a proximal nonthreaded region. This

arrangement of threaded and nonthreaded regions may permit the screw to function as a compression screw that spans plate portions and applies an adjustable tension between the plate portions." (EX1006, ¶39). Referring to Figure 3, Falkner further teaches that bone screw 42 "may include a head 60 and a shank 62. The shank may be a threaded shank that includes a distal threaded region 64 and a proximal nonthreaded region 66…." (EX1006, ¶70).



f. Dependent Claim 10

Falkner discloses a system wherein the elongate spine 22 is configured to form an angle between the first inner surface and the second inner surface, the angle substantially conforming to a natural bend at a joint between the first bone and the second bone. (EX1002, ¶¶210-215).

Falkner repeatedly confirms that the disclosed system may be used to secure two bones together across a joint. (EX1002, ¶213). As discussed in Sections VI.C.1.b-c, Falkner further discloses that "[t]he bone plates described herein may be

sized and shaped to conform to particular portions of a bone (or bones)." (EX1006, ¶33; ¶¶23, 31, 34). Since Falkner teaches that the inner surface of the bone plate may be contoured to follow an exterior surface of a target bone or bones for which the plate is intended, it necessarily follows that when Falkner's plate is used to fuse a joint, the plate is configured to form an angle between the first inner surface and the second inner surface, the angle substantially conforming to a natural bend at a joint between the first bone and the second bone. (EX1002, ¶215).

3. Independent Claim 11 is Anticipated by Falkner

a. 11.P: Preamble

As explained above for Ground 1, the preamble of claims 1 and 11 are nearly identical. For the same reasons discussed with respect to claim element 1.P, Falkner discloses claim element 11.P. (EX1002, ¶218).

b. 11.1: "*an elongate spine having: a first end comprising…*"

As explained above for Ground 1, claim elements 1.1 and 11.1 are nearly identical. For the same reasons as discussed with respect to claim element 1.1, Falkner discloses claim element 11.1. (EX1002, ¶¶219-221).

c. 11.2: "*a second end comprising…*"

As explained above for Ground 1, claim elements 1.2 and 11.2 are nearly identical. For the same reasons as discussed with respect to claim element 1.2, Falkner discloses claim element 11.2. (EX1002, ¶¶222-223).

d. 11.3: "*a bridge portion disposed…*"

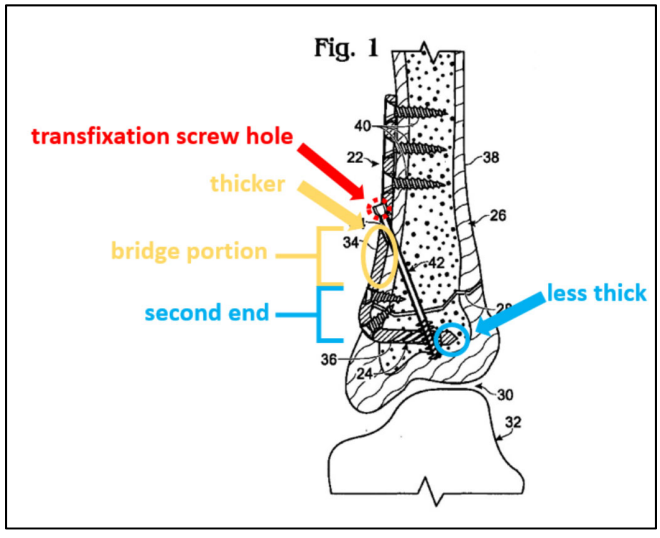
For the same reasons as discussed with respect to claim element 1.3, Falkner discloses claim element 11.3. (EX1002, ¶¶224-225).

e. 11.4: "*a transfixation screw hole disposed…*"

As explained above for Ground 1, the first portion of claim element 11.4 is similar to claim element 1.5, and the second portion of claim element 11.4 is similar to the second portion of claim element 1.6. The minor wording changes do not affect how Falkner reads on the claim. For the same reasons discussed with respect to claim elements 1.5 and 1.6, Falkner discloses claim element 11.4. (EX1002, ¶¶226-228).

f. 11.5: "*wherein…said bridge portion and said transfixation screw hole has a thickness….*"

As explained above for Ground 1, claim elements 1.4 and 11.5 are nearly identical. For at least the same reasons as discussed with respect to claim element 1.4, Falkner discloses claim element 11.5. (EX1002, ¶229). In addition, at least a portion of the Falkner bridge portion and transfixation screw hole has a thickness greater than at least a portion of the thickness of the first and second ends. (EX1002, ¶229).



Falkner expressly contemplates that the thickness of the bone plates may be varied such that portions of the plate may be thicker in regions that require increased structural stability. (EX1006, ¶35). As can be seen in Figure 1, at least a portion of the bridge portion and the transfixation screw hole (44) has a thickness greater than at least a portion of the thickness of the first and second ends. (EX1006, Fig. 1). In particular, the second end is described in the specification as an "internal portion" and is thinner at the end to facilitate insertion into the bone and becomes thicker towards the bridge portion to increase structural stability. (EX1006, ¶35). Similarly, the portions of the plate surrounding the transfixation screw hole have a thickness greater than at least a portion of the thickness of the second end. (EX1002, ¶229).

4. Dependent Claims 12-13 and 17 are Anticipated by Falkner

As discussed in Section VI.C.3., Falkner anticipates independent claim 11. Moreover, dependent claims 12-13 and 17 mirror the language in dependent claims 2-3 and 10. Thus, for the same reasons described with respect to claims 2-3 and 10, Falkner contains all of the elements of claims 12-13 and 17 and therefore anticipates those claims. (EX1002, ¶¶230-233).

D. Ground 4: Falkner in View of Arnauld Renders Obvious Dependent Claims 4, 5, and 14

As discussed above, Falkner anticipates dependent claim 2 and independent claim 11. Arnauld, an arthrodesis plate for a metatarsophalangeal joint, discloses the additional limitations recited in dependent claims 4-5 and 14, all of which pertain

to the angle of the trajectory of the transfixation screw. (EX1002, ¶¶234-246). For the reasons described below, dependent claims 4-5 and 14 are obvious in view of Falkner and Arnauld.

1. A POSITA Would Have Been Motivated to Combine Falkner with Arnauld

While Falkner provides an exemplary transfixation angle for use in a fractured tibia (EX1006, ¶78), Falkner does not expressly provide a suggested transfixation angle for use across a joint, even though such configuration is contemplated. (EX1006, ¶21). Since Falkner does not expressly disclose a transfixation angle for a joint, a POSITA would look to other bone plates for use with a particular joint when determining the transfixation angle to use to ensure proper fixation of both bones of the joint. (EX1002, ¶241).

As discussed in Section V.C., Arnauld describes an arthrodesis plate for use with a metatarsophalangeal joint. (EX1007, Figs. 1, 2).

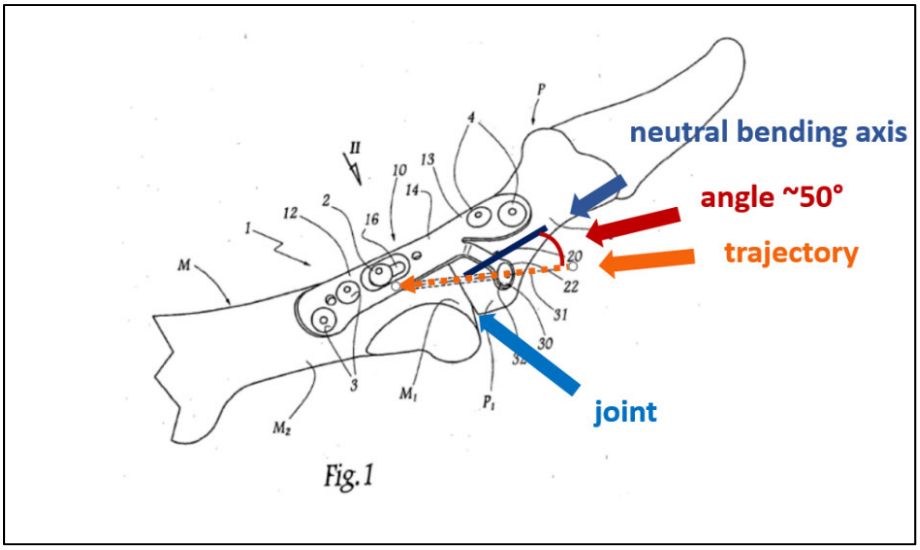


Fig.1

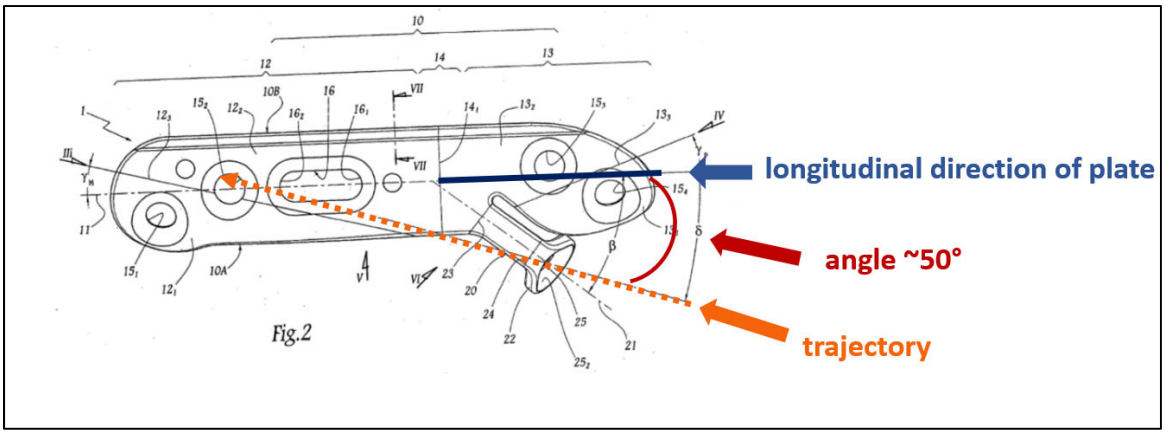


Fig.2

As shown in Figures 1 and 2, the Arnauld bone plate includes a leg 20 bent downward at an angle between 20° and 60°. (EX1008, ¶¶23-25). The leg 20 includes a through-hole 25 adapted to receive a screw 30 that is further angled such that, when the plate is placed across the metatarsophalangeal joint, the screw successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1. (EX1008, ¶¶27, 32).

Arnauld explains that the longitudinal axis 31 of screw 30 forms a non-zero angle δ with the longitudinal direction 11 of the plate body 10. (EX1008, ¶27). A

POSITA would understand that direction 11 of Arnauld is approximately the same as the direction of the neutral bending axis as described in the 608 patent. (EX1002, ¶243). In selecting the transfixation angle of the screw, Arnauld states that "[f]or anatomical reasons, the **angle δ is** advantageously chosen to be less than **45°**." (EX1008, ¶28).

At the time of the invention, a POSITA would have been motivated to modify the Falkner bone plate, which is generically described as spanning any suitable bone discontinuity, to include the teachings of Arnauld in order to provide a bone plate specifically for use with a metatarsophalangeal joint. (EX1002, ¶¶244-245). In doing so, a POSITA would have selected a transfixation angle of "less than 45°" ("about 50°") for a Falkner-type plate configured for use with a metatarsophalangeal joint in order to ensure penetration of the transfixation screw in the metatarsal. (EX1002, ¶240, ¶¶243-244; EX1008, ¶28, ¶32; EX1010, ¶49; EX1016, ¶35; Section VI.C.2.b). By obtaining superior positioning of the bones to be fused, a successful fusion or immobilization can result. (EX1002, ¶244).

In any event, the Federal Circuit and its predecessors have long recognized that "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). Here, the claimed ranges do not "produce a new and unexpected result" but rather appear to be based on patient anatomy at the metatarsophalangeal joint. (EX1002 at ¶240). As such,

the claimed ranges are obvious. *See, e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1368-69 (Fed. Cir. 2007).

2. Dependent Claims 4 and 5

As discussed above, at the time of the invention, a POSITA seeking to use a Falkner-type bone-plate to fuse a first phalanx and first metatarsal across a metatarsophalangeal joint would have been motivated to combine Arnauld with Falkner to select a transfixation angle of "less than 45°," which renders obvious a transfixation angle of "about 50°" as required by dependent claim 5 and "between about 30° and about 70°" as required by dependent claim 4, measured from the neutral bending axis. (EX1002, ¶240, ¶¶244-245). As such, Falkner in view of Arnauld renders obvious dependent claims 4 and 5. (EX1002, ¶¶234-245).

3. Dependent Claim 14

The claim language for claim 14 is identical to claim 5 except that claim 14 depends from independent claim 11. For the same reasons described above with respect to dependent claim 5, claim 14 is rendered obvious by Falkner in view of Arnauld. (EX1002, ¶¶235-246).

E. Ground 5: Arnauld in View of Slater Renders Obvious Claims 1-5, 9-14, and 17

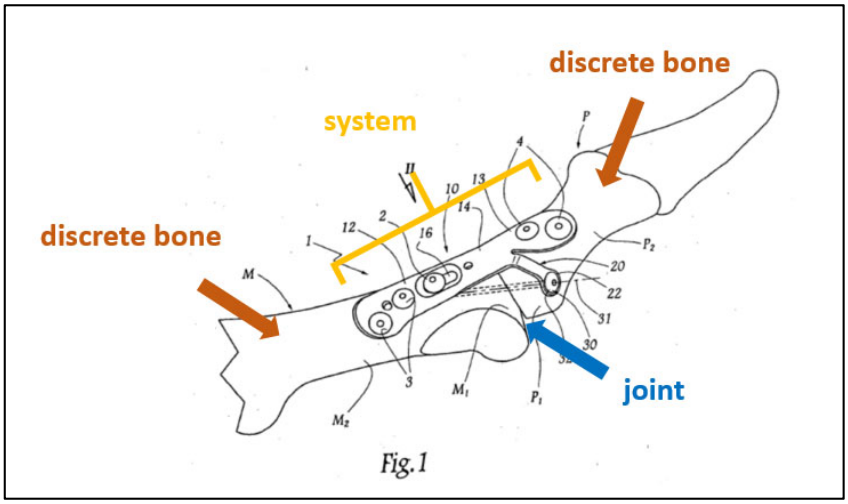
As shown below and in the accompanying Declaration, Claims 1-5, 9-14 and 17 are rendered obvious by Arnauld in view of Slater under 35 U.S.C. § 103. (EX1002, ¶¶247-309).

1. Independent Claim 1 is Rendered Obvious by Arnauld in View of Slater

Arnauld discloses each and every element of independent claim 1 except claim element 1.4, which recites "at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end." (EX1002, ¶¶248). However, as discussed in Sections VI.A.1.e., Slater discloses a bone plate where at least a portion of the bridge portion has a thickness greater than at least a portion of the thickness of either the first end or the second end. As discussed below, a POSITA would have been motivated to include the thickened bridge portions of Slater in the Arnauld bone plates.

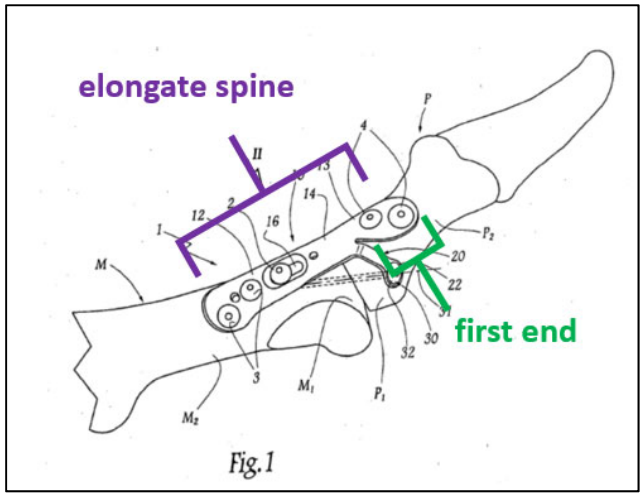
a. 1.P: Preamble

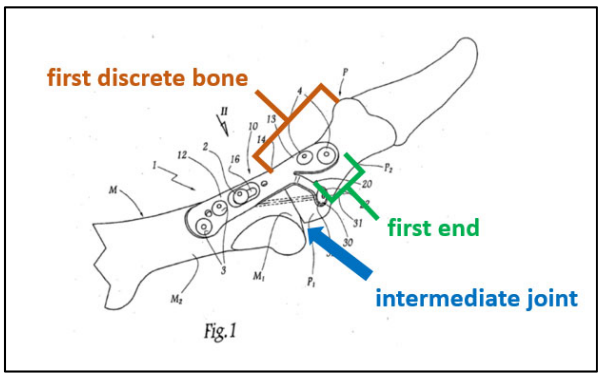
To the extent the preamble is limiting, Arnauld (entitled "Arthrodesis Plate for a Metatarsal Phalangeal Joint") discloses a system for securing two discrete bones together across a joint between the two bones. (EX1002, ¶249). Arnauld explains that "Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." (EX1008, ¶11; Fig. 1).

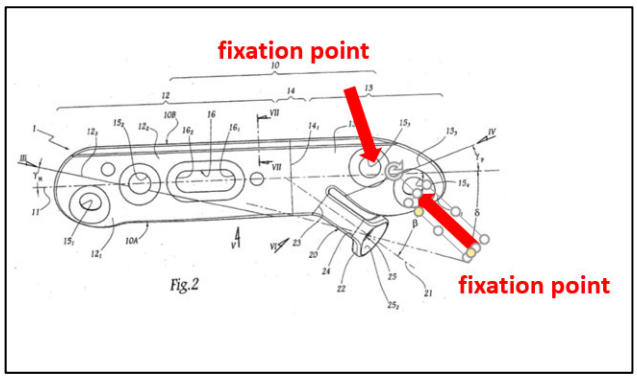


b. 1.1: "*the plate comprises: an elongate spine having: a first end comprising…*"

As shown in Figure 1, Arnauld discloses a bone plate comprising an elongate spine (elongated plate body 10) having a first end (phalangeal part 13). (EX1002, ¶¶250-251; EX1008, ¶¶8, 13-14, 17, 34; claims 1, 5; Figs. 2, 5-6). In particular, Arnauld describes an arthrodesis plate "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" having a first end (phalangeal portion 13) and a second end (metatarsal portion 12). (EX1008, ¶¶2, 14; Fig. 1).





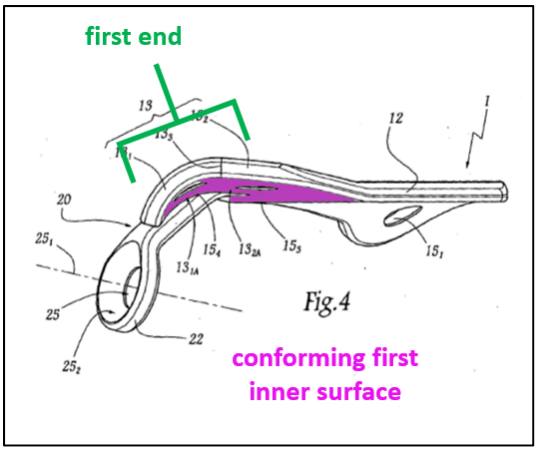


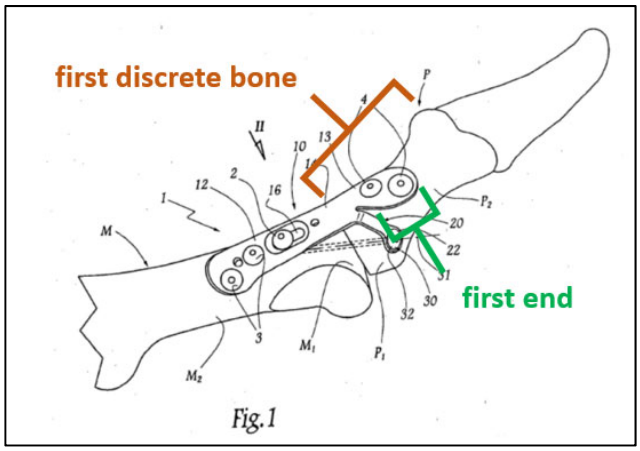
(EX1008, Figs. 1-2).

Moreover, the first end (13) includes at least one fixation point (fixation points 15_3 and 15_4) for attaching the first end (13) to a first discrete bone (phalanx P) on a

first side of an intermediate joint. (EX1008 Figs. 1-2, ¶21, ¶34, claim 5; EX1002, ¶252).

In addition, as shown in Figures 1 and 4, the first end in Arnauld (13) includes a first inner surface (13_{1A} and 13_{2A}) configured to substantially conform with a geometry of the first discrete bone (phalanx P). (EX1002, ¶253; EX1008, claim 9). For example, Arnauld explains that "the concave lower surface 13_{1A} of the bent section 13_1, which is clearly visible in Figure 4, is sized to fit the bulging medial surface of the phalangeal diaphysis P_2, while the lower surface 13_{2A} of the section 13_2 covers the dorsal surface of this diaphysis and, above all, the phalangeal epiphysis P_1, as represented in Figure 1." (EX1008, ¶17).



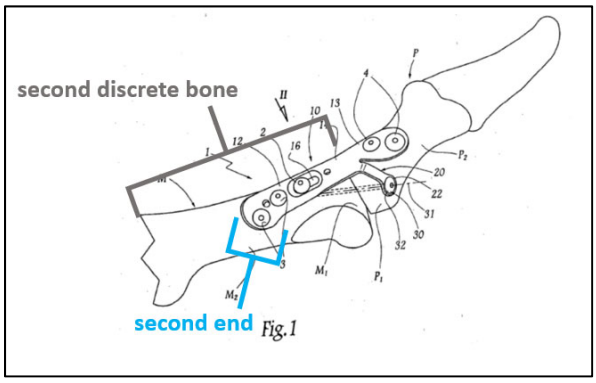


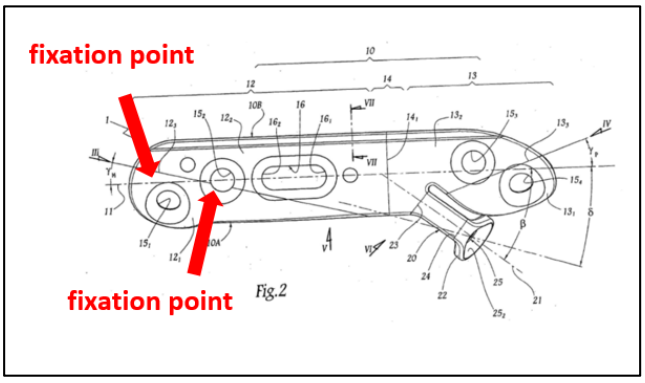
(EX1008, Figs. 1, 4).

c. 1.2: "*a second end comprising…*"

As shown in Figure 1, Arnauld discloses an elongate spine (elongated plate body 10) having a second end (metatarsal portion 12). (EX1002, ¶¶254-255). As

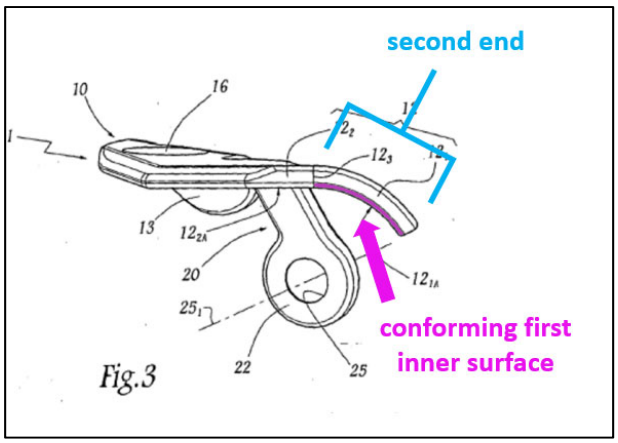
shown in Figure 2, the second end of the plate (12) includes at least one fixation point (fixation points 15_1 and 15_2) for attaching the second end (12) to a second discrete bone (metatarsal M) on a second side of the joint. (EX1008 at ¶¶21, 33; claim 5).





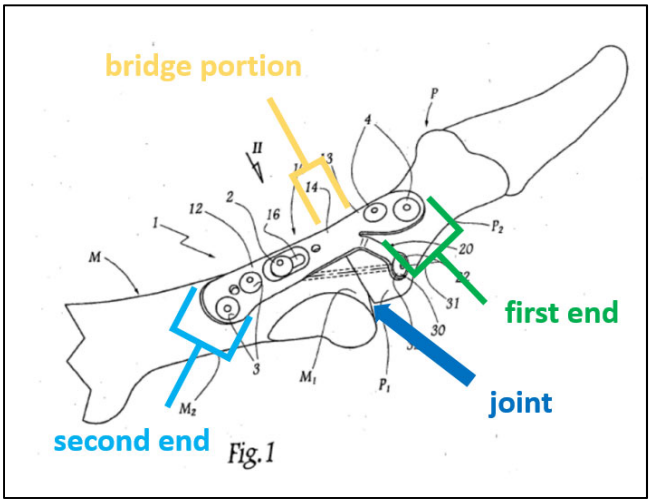
(EX1008, Figs. 1-2).

In addition, as shown in Figure 3, the second end of the Arnauld plate (12) includes a second inner surface (12_{1A} in Fig. 3) configured to substantially conform with a geometry of the second discrete bone. (EX1002, ¶255; EX1008, ¶16; claim 7). Arnauld explains that "surface 12_{2A} is intended to be placed against a generally flat surface zone of the upper surface of the metatarsal M, while surface 12_{1A} covers a domed metatarsal zone." (EX1008, ¶15).



d. 1.3: "*a bridge portion disposed…*"

As shown in Figure 1, Arnauld includes a bridge portion (junction zone 14, also referred to as joint zone 14) disposed between the first end (13) and the second end (12), the bridge portion (14) configured to span across the joint. (EX1002, ¶256). For example, Arnauld explains that the "joint zone 14 between parts 12 and 13 is provided to overlie the joint zone between the facing epiphyseal ends M_1 and P_1 of the metatarsal M and phalanx P so that the plate body 10 straddles the metatarsal-phalangeal joint along direction 11." (EX1008, ¶14).



e. 1.4: "*said bridge portion having a thickness…*"

For the reasons discussed in Section VI.A.1.e., Slater discloses claim element 1.4. (EX1002, ¶257). A POSITA would have been motivated to modify the bone plate of Arnauld with the thickened bridge portion of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint.

As described in Section V.C., Arnauld discloses an arthrodesis plate that "straddles" a metatarsophalangeal joint. (EX1008, ¶14). Metatarsophalangeal joints are subject to a flexion movement when a patient walks. (EX1008, ¶3). Arnauld

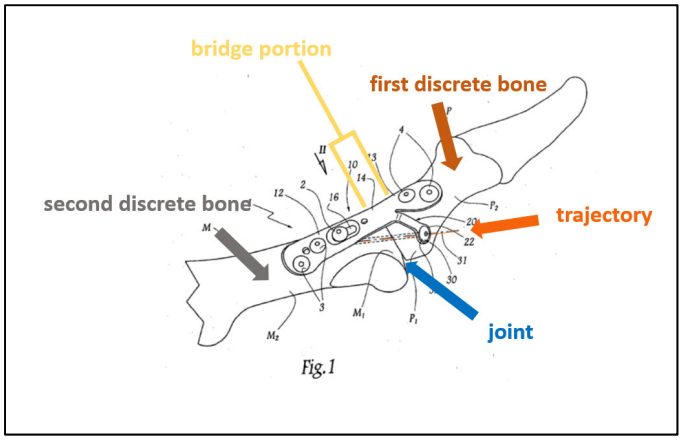
explains that an arthrodesis plate for fusing a metatarsophalangeal joint absorbs the bending stress and that "cyclical repetition of this stress [] weakens the bone anchorage of the screws holding the plate against the fused bones." (*Id.*) The stated purpose of Arnauld is to remedy these disadvantages by providing an arthrodesis plate with a simple and durable fixation. (EX1008, ¶4).

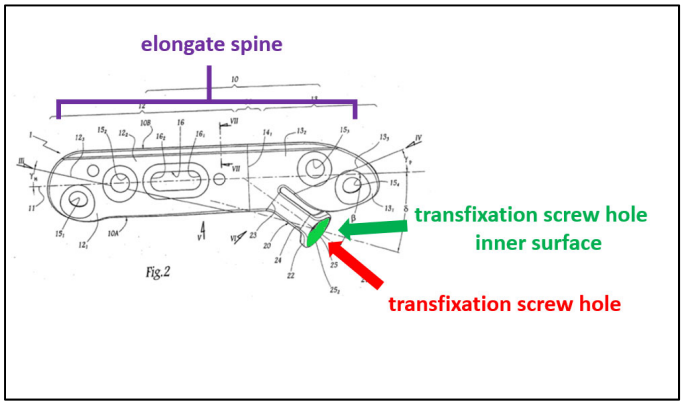
As set forth in Section V.A. and VI.A.1.e., Slater discloses an ankle fusion plate wherein at least a portion of the bridge portion (portions of 5 and 20 or portions of 81 and 90) has a thickness greater than at least a portion of the thickness of either the first end (proximal end of portion 95) or the second end (distal end of portion 81). (EX1002, ¶257; EX1005, 8:25-26; 8:31-9:1; 9:5-6; 12:19-21; 14:19-23; 24:17-19). Slater contemplates that "[a]lthough the invention will be described with reference to its application to ankle fusion 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." (EX1005, 6:35-7:2).

At the time of the invention, a POSITA would have been motivated to use a thickened bridge portion as in Slater (which acknowledges that the plate should be at the maximum thickness at the joint region where the highest loading will occur in normal use) across the portion of the Arnauld plate where the highest loading will occur, *e.g.*, in the bridge portion that spans the metatarsophalangeal joint. (EX1002, ¶257; EX1005, 14:19-23, 16:32-34). A POSITA would have a reasonable

expectation that combining Arnauld and Slater would result in strengthening the Arnauld bone plate and thus providing a stronger or more durable system for securing two discrete bones together across a metatarsophalangeal joint. (EX1002, ¶257). As such, Arnauld in view of Slater renders obvious claim element 1.4.

f. 1.5: "*a transfixation screw hole disposed…*"

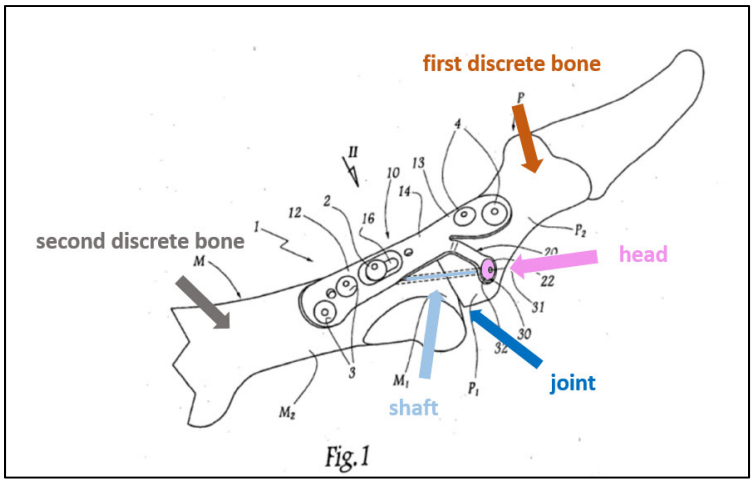




As shown below in Figures 1 and 2, Arnauld includes a transfixation screw hole (through-hole 25) disposed along the spine (10), the transfixation screw hole (25) comprising an inner surface (edge 25_2) configured to direct the transfixation screw (30) through the transfixation screw hole (25) such that the transfixation screw extends through the bridge portion (14) at a trajectory (longitudinal axis 31) configured to pass through a first position on the first discrete bone (phalanx P), a portion of the joint, and a second position on the second discrete bone (metatarsal M) once the plate is placed across the joint. (EX1002, ¶46, ¶¶258-260; EX1008, ¶¶6, 8, 23, 26-27, 32; claims 1, 3; Figs. 1-2, 5).

g. 1.6: "*the transfixation screw comprises…*"

As shown in Figure 1, Arnauld discloses a transfixation screw (30) comprising a head (32) configured to abut the inner surface (25_2) of the transfixation screw hole (25) and a shaft (broken lines of 30 shown in Fig. 1) configured to contiguously extend through the first discrete bone (phalanx P in Fig. 1), through the joint, and into the second discrete bone (metatarsal M in Fig. 1) so as to absorb tensile load when the second discrete bone (metatarsal M) is loaded relative to the first discrete bone (phalanx P) thereby transferring the tensile load from the second discrete bone (metatarsal M), through the screw (30) into said head (32) and said bridge portion (14). (EX1002, ¶¶261-262; EX1008, ¶¶6, 8-9, 26, 27, 32; claims 1, 3). As discussed above in Section VI.A.1.g., Slater also discloses this claim element.



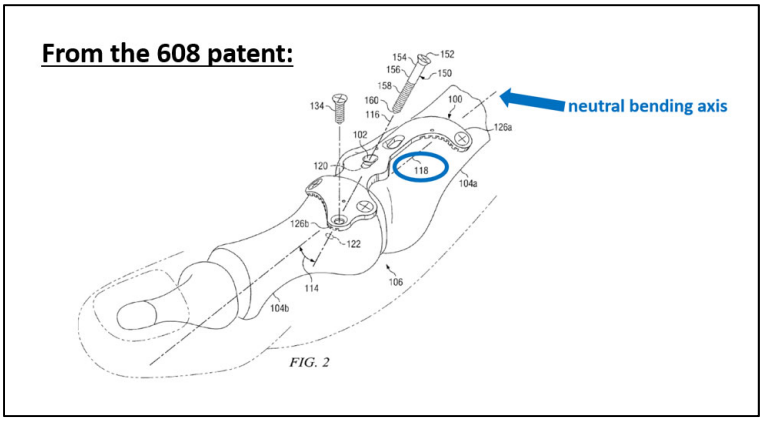
2. Dependent Claims 2-5 and 9-10 are Rendered Obvious by Arnauld in View of Slater

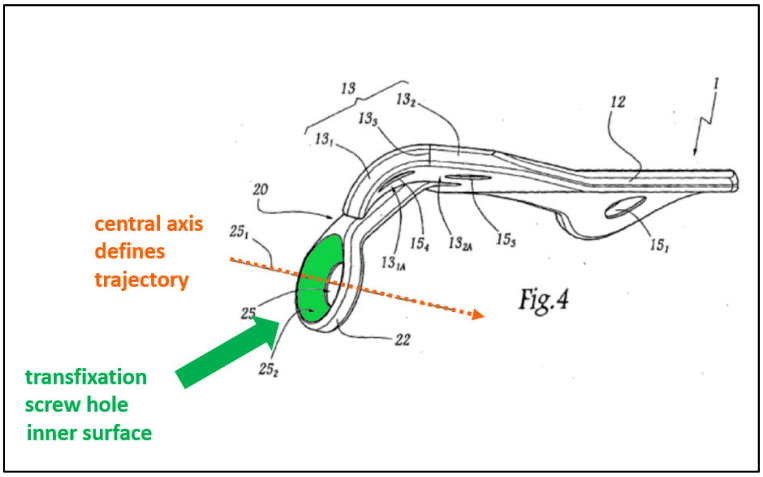
As discussed above, independent claim 1 is rendered obvious by Arnauld in view of Slater. Moreover, Arnauld alone discloses every additional element described in dependent claims 2-5 and 10, while Slater discloses dependent claim 9.

For the reasons set forth below, dependent claims 2-5 and 9-10 are rendered obvious by Arnauld in view of Slater.

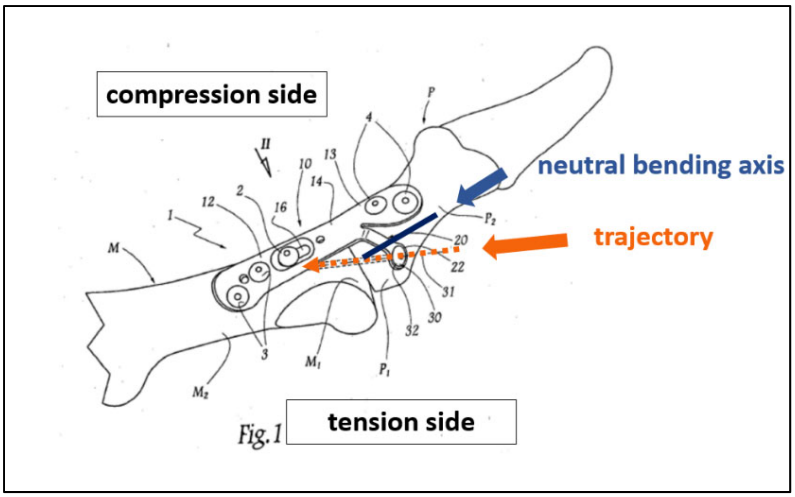
a. Dependent Claim 2

Arnauld includes a central axis (25_1) of the inner surface of the transfixation screw hole (through-hole edge 25_2) defining the trajectory; and the trajectory is configured to cross a neutral bending axis of the joint once the plate is placed across the joint. (EX1002, ¶¶264-269). Since Arnauld discloses a bone plate for use with the same metatarsophalangeal joint as pictured in Figure 2 of the 608 patent, a POSITA would understand that the neutral bending axis in the Arnauld figures would be the same as that depicted in Figure 2 of the 608 patent. (EX1002, ¶268; EX1001, Fig. 2; 5:47-52).





As shown in Figure 1, Arnauld discloses that the central axis 25_1 is configured to cross the neutral bending axis once the plate is placed across the metatarsophalangeal joint. (EX1002, ¶269; EX1008, ¶¶26, 27; Figs. 1, 4).



(EX1008, Fig. 1).

b. Dependent Claim 3

Arnauld discloses that the first position resides on a compression side of the joint (plantar aspect of P in Fig. 1) and the second position resides on a tension side of the joint (dorsal aspect of M in Fig. 1). (EX1002, ¶¶270-274). As discussed above, Arnauld discloses that the transfixation screw (30) passes through a first position on the phalangeal side of the joint (phalanx P) and a second position on the metatarsal side of the joint (metatarsal M). (EX1008, ¶¶6, 8, 14, 26, 32; claim 1; Figs. 1, 4).

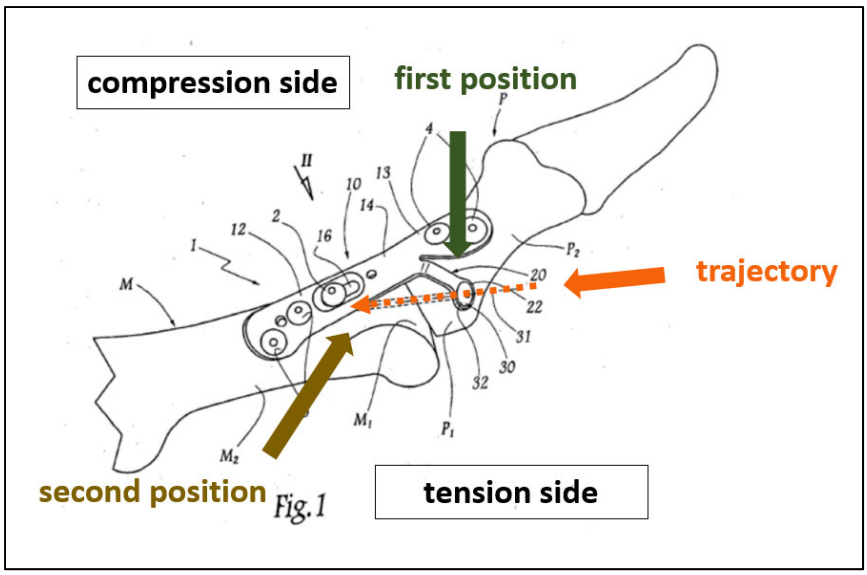


Fig.1

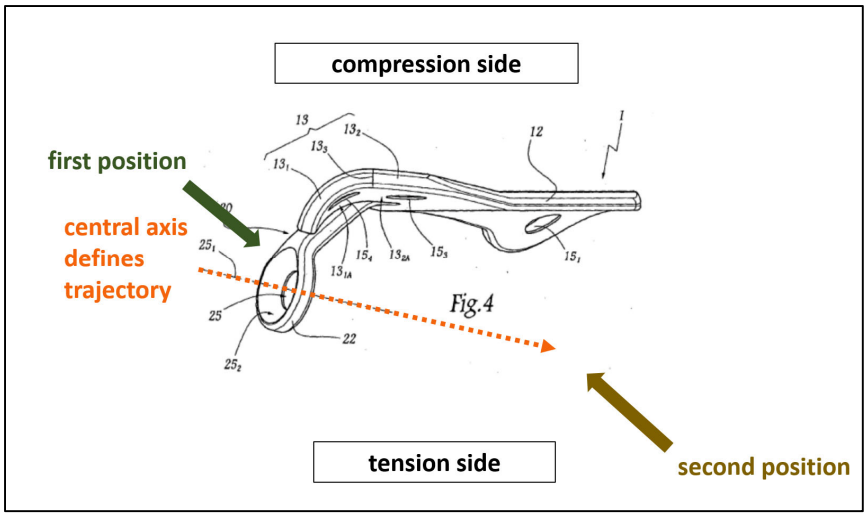


Fig.4

(EX1008, Figs. 1, 4).

Arnauld explains that a non-zero angle δ is formed by the longitudinal axis 31 of the screw 30 and the longitudinal direction 11 of the plate body 10, and that "[f]or anatomical reasons, the angle δ is advantageously chosen to be less than 45°." (EX1008, ¶¶27-28).

As discussed above, a POSITA would understand that a screw crossing the joint at the midpoint in a manner that maximizes compressive forces would cross

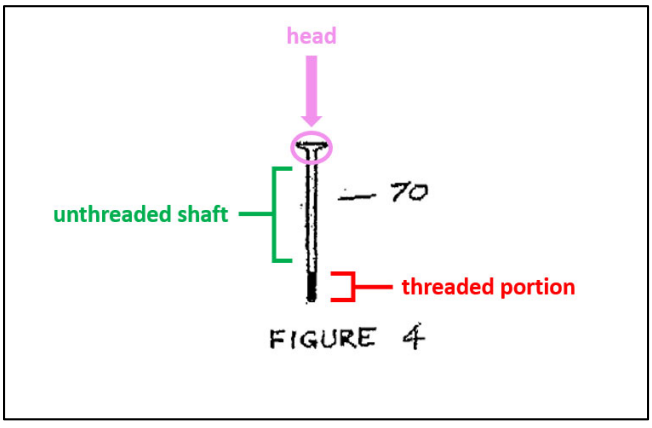
from the compression side to the tension side of the joint. (EX1002, ¶274). Thus, when the Arnauld screw 30 is angled in a dorsal to plantar direction and has a length suitable to cross the joint, the first position of the screw 30 will be on the compression side of the joint and the second position of the screw 30 will be on the tension side of the joint. (EX1002, ¶274).

c. Dependent Claims 4 and 5

As discussed in Section VI.D.1-VI.D.2, Arnauld discloses a trajectory (axis 25_1) of transfixation hole (25) that is configured to pass through the joint at a transfixation angle between about 30 degrees and about 70 degrees measured from the neutral bending axis, as set forth in dependent claim 4. In addition, Arnauld discloses a trajectory of "about 50 degrees," as set forth in dependent claim 5. (EX1002, ¶¶275-281).

d. Dependent Claim 9

While Arnauld does not disclose details regarding the characteristics of transfixation screw 30, as shown in Figure 4, Slater discloses a transfixation screw with an unthreaded portion at a first end and threaded portion at a second end.

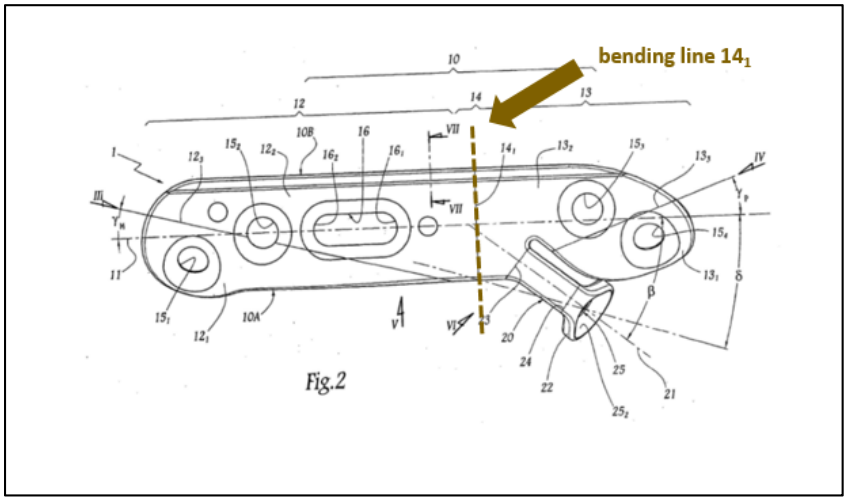


(Section VI.A.2.d.; EX1005, Fig. 4; 12:34-13:1-4). At the time of the invention, a

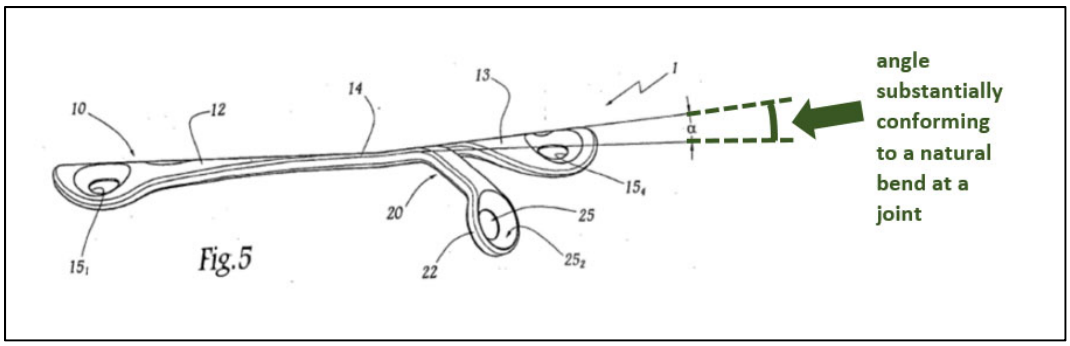
POSITA would have been motivated to substitute the Slater screw for Arnauld's transfixation screw 30 to provide improved compression between the bones. (EX1002, ¶¶282-286; EX1006, ¶39).

e. Dependent Claim 10

Arnauld further discloses that elongate spine (10) is configured to form an angle (bending line 14_1) between the first inner surface (13_{1A}) and the second inner surface (12_{1A}), the angle substantially conforming to a natural bend at a joint between the first bone (phalanx P) and the second bone (metatarsal M). (EX1002, ¶¶287-290). For example, Arnauld explains that the metatarsal 12_2 and phalangeal 13_2 planar sections "form a non-zero angle, noted as α in Figure 5… which guarantees a better adaptation of the plate body 10 to the anatomy of the metatarsal-phalangeal joint when it is locked." (EX1008, ¶20). Figure 2 shows the bending line 14_1 between the metatarsal 12 and phalangeal 13 parts. (EX1002, ¶290). Figure 5 shows the non-zero angle formed between the metatarsal 12 and phalangeal 13 parts. (EX1002, ¶290). Arnauld explains that "[t]he joint zone 14 between parts 12 and 13 is provided to overlie the joint zone between the facing



epiphyseal ends M_1 and P_1 of the metatarsal M and phalanx P so that the plate body 10 straddles the metatarsal-phalangeal joint along direction 11." (EX1008, ¶14).



(EX1008, Fig. 5).

3. Independent Claim 11 is Rendered Obvious by Arnauld in View of Slater

Arnauld discloses each and every element of independent claim 11 except claim element 11.5. However, as discussed in Section VI.A.3.f., Slater discloses bone plates where at least a portion of the respective bridge portions and transfixation screw hole have a thickness greater than at least a portion of the first and second ends. As discussed *supra* and *infra*, claim 11 is rendered obvious by Arnauld in view of Slater.

a. 11.P: Preamble

As explained above for Ground 1, the preamble of claims 1 and 11 are nearly identical. For the same reasons discussed with respect to claim element 1.P, Arnauld includes a plate for securing two discrete bones together across an intermediate joint. (EX1002, ¶293).

b. 11.1: "*an elongate spine having: a first end comprising…*"

As explained above for Ground 1, claim elements 1.1 and 11.1 are nearly identical. For the same reasons discussed with respect to claim element 1.1, Arnauld discloses claim element 11.1. (EX1002, ¶¶294-296).

c. 11.2: "*a second end comprising…*"

As explained above for Ground 1, claim elements 1.2 and 11.2 are nearly identical. For the same reasons discussed with respect to claim element 1.2, Arnauld discloses claim element 11.2. (EX1002, ¶¶297-298).

d. 11.3: "*a bridge portion disposed…*"

As explained above for Ground 1, claim elements 1.3 and 11.3 are identical. For the same reasons discussed with respect to claim element 1.3, Arnauld discloses claim element 11.3. (EX1002, ¶229).

e. 11.4: "*a transfixation screw hole disposed…*"

As explained above for Ground 1, the first portion of claim element 11.4 is similar to claim element 1.5, and the second portion of claim element 11.4 is similar to the second portion of claim element 1.6. For the same reasons discussed with respect to claim elements 1.5 and 1.6, Arnauld discloses claim element 11.4. (EX1002, ¶¶300-303).

f. 11.5: "*wherein…said bridge portion and said transfixation screw hole has a thickness….*"

As explained above for Ground 1, claim elements 1.4 and 11.5 are nearly identical. For the same reasons discussed in Ground 1, Slater discloses claim element 11.5. Moreover, as discussed in Section VI.E.1.e., at the time of the invention, a POSITA would have been motivated to combine the thickness of the bridge portion and transfixation hole of Slater (which acknowledges that the plate should be at its maximum thickness at the joint region where the highest loading will occur in normal use) with the bridge portion (14) of Arnauld. (EX1002, ¶304).

4. Dependent Claims 12, 13, 14, and 17 are Rendered Obvious by Arnauld in View of Slater

As discussed in Section VI.E.3, independent claim 11 is rendered obvious by Arnauld in view of Slater. Moreover, dependent claims 12-14 and 17 mirror the language in dependent claims 2-3, 5, and 10 described above. Thus, for the same reasons described above with respect to dependent claims 2-3, 5, and 10, Arnauld in view of Slater renders obvious claims 12-14 and 17. (EX1002, ¶¶305-309).

F. Ground 6: Dependent Claims 6 and 8 are Obvious Over Arnauld in View of Slater and Weaver

As discussed above, independent claim 1 is rendered obvious by Arnauld in view of Slater, and Weaver discloses the additional limitations recited in dependent claims 6 and 8. For the reasons set forth below, dependent claims 6 and 8 are rendered obvious by Arnauld in view of Slater and Weaver.

Arnauld is directed to an arthrodesis plate for use in the lower extremities and specifically recognizes that bone plates used for the lower extremities are particularly prone to screw back-out due to loading conditions and constant use of the foot. (EX1008, ¶3) (repetition of bending stress "weakens the bone anchorage of the screws holding the plate against the fused bones"). Thus, for the same reasons set forth in Ground 2 with respect to Slater and Weaver, at the time of the invention, a POSITA would have been motivated to include Weaver's threaded screw holes in the Arnauld plate as modified by Slater to include a thickened bridge portion and a thickened portion surrounding the transfixation screw hole. (EX1002, ¶¶312-318). Moreover, a POSITA would have had a reasonable expectation of success in combining Arnauld, Slater and Weaver given that locking screws with threaded heads that mated with threads in the plate holes were common at the time. (EX1002, ¶318; EX1005, 8:35-9:1). It would have been obvious to a POSITA to configure the inner surface of the Arnauld transfixation screw hole (claim 6) and the inner surface of at least one of the Arnauld attachment points (claim 8), as modified by Slater, to lockably engage the head of a locking screw as described in Weaver to ensure stability and to prevent screw back-out. (Ex. 1002, ¶317).

VII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. 35 U.S.C. § 325(d) Does Not Favor Denial of Institution

The Board applies a two-part framework in considering whether to exercise its discretion to deny institution under § 325(d). *Advanced Bionics, LLC v, Med-El Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Fed. 13, 2020) (precedential). Section 325(d) does not apply here because the same or substantially the same prior art and arguments presented in this Petition were not previously presented to the Office.

For example, while Slater and Arnauld were buried among the almost 200 prior art references presented to the Office during prosecution, they were not substantively addressed by the Office or discussed by Patent Owner. *See* Sections V.A, V.C. Falkner was not before the Office during prosecution of the 608 patent. Under these circumstances, the Board has declined to exercise its discretion to deny institution. *See, e.g., Cellco Partnership v. Huawei Device Co.*, IPR2020-01117, Paper 10 at 13 (P.T.A.B. Feb. 3, 2021) ("[T]he fact that Wen was not the basis of rejection weighs strongly against exercising our discretion to deny institution under 35 U.S.C. § 325(d)."); *Apple Inc. v. Qualcomm Inc.*, IPR2018-01315, Paper 7 at 25 (P.T.A.B. Jan. 18, 2019) ("The fact that neither AAPA nor Majcherczak was the basis of rejection weighs strongly against exercising our discretion to deny under 35 U.S.C. § 325(d)"). *See also Oticon Medical AB v. Cochlear Limited*, IPR2019-

00975, Paper 15 at 20 (P.T.A.B. Oct. 16, 2019) (precedential) (declining to exercise institution where one prior art reference was new and noncumulative).

As discussed in Sections V.A. and V.C., the Office erred by failing to consider Slater and Arnauld, particularly after Patent Owner amended its claims to distinguish over Grady to add limitations directed to the thickness of the bone plate (Slater) and conforming the inner surfaces of the bone plate to the outer surfaces of discrete bones (Arnauld). It appears that the Office was simply unaware that Slater and Arnauld disclose the limitations added by amendment, and had no opportunity to consider Falkner, which also discloses those limitations. (Ex. 1006, ¶¶21, 27-29, 33, 35). Since the Petition presents different prior art than the Office was aware of, a discretionary denial of institution is inappropriate here. *See, e.g.*, *Oticon Medical AB*, IPR2019-00975, Paper 15 at 20.

B. 35 U.S.C. § 314(a) Does Not Favor Denial of Institution

The decision whether to exercise discretion to deny institution under Section 314(a) is based on "a balanced assessment of all relevant circumstances in the case, including the merits." PTAB Consolidated Trial Practice Guide at 58 (Nov. 2019). This case does not involve follow-on petitions, as the present Petition is the only petition for IPR that Petitioners have ever filed relating to the 608 patent.

While there is co-pending litigation in Illinois and Delaware, both cases are in their infancy such that a final written decision would issue long before any trial

takes place. (EX1012, EX1013). An examination of the *Fintiv* factors weighs strongly against discretionary denial of institution under 35 U.S.C. § 314(a). *See, e.g., Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential).

1. Likelihood of a Stay

None of the parties to the district court proceedings has requested a stay. As such, this factor is neutral. *See, Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (P.T.A.B. May 13, 2020) (informative) ("*Fintiv II*").

2. Proximity of Trial Date

No trial date has been set in either case. (EX1012; EX1013). As such, this factor weighs against discretionary denial. *See Google LLC v. Uniloc 2017 LLC*, IPR2020-00441, Paper 13 at 35 (PTAB July 17, 2020).

3. Investment in the Parallel Proceeding

The two litigation matters are in their infancy such that any investment in them has been minimal. As discussed in Section I.B., discovery only recently began on July 6, 2021 in both cases, and no claim construction hearing is expected to take place in Illinois until April 2022, at the earliest. (EX1012). The Delaware court indicated that the Illinois case will go first and that Delaware is "completely jammed with cases, and it's been aggravated by the pandemic. And you know, this case is going to sit" because of the enormous backlog of cases in that district. (EX1014,

17:10-12, 32:7-10). To date, no substantive orders have been issued in either case relating to the 608 patent. This fact weighs against discretionary denial. *See Nvidia Corp. v. Invensas Corp.*, IPR2020-00602, Paper 11 at 27 (P.T.A.B. Sept. 3, 2020).

Moreover, Petitioners diligently filed the present Petition within six weeks of being served infringement contentions in the Illinois case (July 20, 2021) and weeks before being served infringement contentions in the Delaware case. This fact weighs against discretionary denial. *Cellco Partnership*, IPR2020-01117, Paper 10 at 22.

4. Overlap in Issues

While Petitioner Stryker's recently-served invalidity contentions include the prior art addressed in the Petition, Petitioners agree that, upon institution, neither they nor related co-defendant Howmedica Osteonics Corp. will pursue the invalidity grounds in the litigation that are included in this Petition and upon which trial is instituted.[1] Such agreement mitigates any "concerns of inefficiency and the possibility of conflicting decisions," and thus weighs against discretionary denial.

[1] Petitioner Wright Medical has not yet served invalidity contentions in Delaware. Both Petitioners expressly reserve the right to pursue other grounds of invalidity as consistent with 35 U.S.C. § 315 and the relevant case law. *E.g.*, *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 11 (P.T.A.B. June 16, 2020) (informative).

See, e.g., *Sand Revolution II*, Paper 24 at 11; *Peloton Interactive, Inc. v. Icon Health & Fitness, Inc.*, IPR2021-00342, Paper 14 at 14-16 (P.T.A.B. Jul. 7, 2021).

5. Petitioner and Defendant Same Party

Patent Owner OsteoMed is the plaintiff in the parallel district court proceedings. Petitioner Wright Medical is the defendant in the Delaware case. Petitioner Stryker is the defendant in the Illinois case, along with wholly owned subsidiary Howmedica Osteonics Corp. Because the Office is likely to reach the merits before either district court case, this factor weighs against discretionary denial. *See, e.g.*, *Nvidia Corp. v. Tessera Advanced Techs., Inc.*, IPR2020-00708, Paper 9 at 17 (P.T.A.B. Sept. 2, 2020).

6. Other Circumstances

Petitioners diligently filed the present Petition well within the 1-year window and within six weeks of learning which claims OsteoMed is asserting against Petitioner Stryker. Moreover, Petitioners have established a reasonable likelihood that they will prevail with respect to the challenged claims, with multiple references anticipating or rendering obvious the challenged claims. Where, as here, the merits of the challenges presented in the Petition are strong, this factor favors institution. *Cellco Partnership*, IPR2020-01117, Paper 10 at 26-27.

Five of the *Fintiv* factors (2-6) weigh against the exercise of discretion to deny institution, while one factor (1) is neutral. Here, the nascent state of the parallel

district court proceedings combined with the strength of Petitioners' showing of unpatentability strongly favor institution of *inter partes* review. *Id.*, Paper 10 at 27.

VIII. CONCLUSION

Petitioners respectfully request institution of *inter partes* review of Claims 1-6, 8-14, and 17 of the 608 patent.

Respectfully submitted,

Dated: August 30, 2021

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CERTIFICATE OF WORD COUNT

I hereby certify that this Petition complies with the word count limit of 37 CFR § 42.24. The argument sections of this Petition (Introduction, Section I.F. (Grounds for Standing), and Sections II-VIII) have a total of 13,967, less than 14,000 words, as measured by Microsoft Word™.

Dated: August 30, 2021

/s/ Sharon A. Hwang
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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,529,608 (IPR2021-01450) was served on August 30, 2021, via pre-paid, overnight Express Mail to the correspondence address of record for the subject patent pursuant to 37 C.F.R. §42.105:

K&L Gates LLP – Chicago
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