UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC.
Petitioners,

v.

OSTEOMED LLC,
Patent Owner

_____

Case IPR2021-01453

U.S. Patent No. 10,245,085

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 10,245,085
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
1017	Prosecution History of U.S. Patent No. 9,351,776
1018	Prosecution History of U.S. Patent No. 9,763,716
1019	Prosecution History of U.S. Patent No. 10,245,085
1020	Merriam-Webster's Medical Dictionary 51 (2006)
1021	Merriam-Webster's Medical Dictionary 557 (2006)
1022	Geissler (U.S. Publication 2007/0270850)
1023	Chapman (U.S. Patent No. 5,190,544)

Exhibit	Description
1024	Horan (U.S. Publication 2007/0233106)

List of Challenged Independent Claim

Claim 1 of the 085 Patent	
1.P	A system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone, the system comprising:
1.1	a plate comprising: an elongate spine having a first end comprising at least one attachment point for attaching the first end to the first discrete bone on a first side of the joint,
1.2	a second end comprising at least one attachment point for attaching the second end to the second discrete bone on a second side of the joint, and
1.3	a bridge portion disposed between the first end and the second end, the bridge portion having a portion configured to span across the joint,
1.4	the bridge portion further comprising a thickened portion having a thickness greater than at least a portion of a thickness of either the first end or the second end; and
1.5	an aperture defining a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion, 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 at a trajectory configured to pass through a first position on the first discrete bone and a second position on the second discrete bone once the plate is placed across the joint.

List of Challenged Dependent Claims

Claim	Limitation
2	The system of claim 1, further comprising a transfixation screw, said transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, across the joint, and into the second discrete bone.
3	The system of claim 2, 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 discrete bone; and at a second end of the shaft adjacent to a tip of the transfixation screw, a threaded portion configured to extend into the second discrete bone.
4	The system of claim 1, wherein the inner surface of the transfixation screw hole is configured to lockably engage a head of a transfixation screw.
5	The system of claim 4, wherein the inner surface of the transfixation screw hole is threaded to provide a locking interface with a transfixation screw.
6	The system of claim 1, wherein the first position resides on a compression side of the joint and the second position resides on a tension side of the joint.
7	The system of claim 1 wherein the plate is configured to substantially conform to a geometry of the respective first and second discrete bones on which the plate is configured to be disposed.
8	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.
9	The system of claim 8 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.

Petitioners Stryker Corporation and Wright Medical Technology, Inc. respectfully petition for *inter partes* review of Claims 1-9 of U.S. Patent No. 10,245,085 ("the 085 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 085 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 085 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. 8,529,608 ("the 608 patent"), 9,351,776 ("the 776 patent"), and 9,763,716 ("the 716 patent"), all of which claim priority to the 608 patent. Petitioners have simultaneously petitioned for *inter partes* review of those patents on similar grounds in IPR2021-01450, IPR2021-01451, and IPR2021-01452.

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

Petitioners provide the following designation of counsel.

LEAD COUNSEL	**BACK-UP COUNSEL**
Sharon A. Hwang (Reg. No. 39,717) (shwang@mcandrews-ip.com) McAndrews, Held & Malloy Ltd. 500 West Madison Street, 34th Floor Chicago, IL 60661 Tel: (312) 775-8113	Robert A. Surrette (Reg. No. 52,262) (bsurrette@mcandrews-ip.com) Scott P. McBride (Reg. No. 42,853) (smcbride@mcandrews-ip.com) McAndrews, Held & Malloy Ltd. 500 West Madison Street, 34th Floor Chicago, IL 60661 Tel: (312) 775-8000

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 085 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 1-9 ("the Challenged Claims") of the 085 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 1-3 and 6-9 are anticipated by Slater
2	Claims 4 and 5 are obvious over Slater in view of Weaver
3	Claims 1-8 are anticipated by Falkner
4	Claim 9 is obvious over Falkner in view of Arnauld
5	Claims 1-3 and 6-9 are obvious over Arnauld in view of Slater
6	Claims 4 and 5 are obvious over Arnauld in view of Slater and Weaver

III. THE 085 PATENT

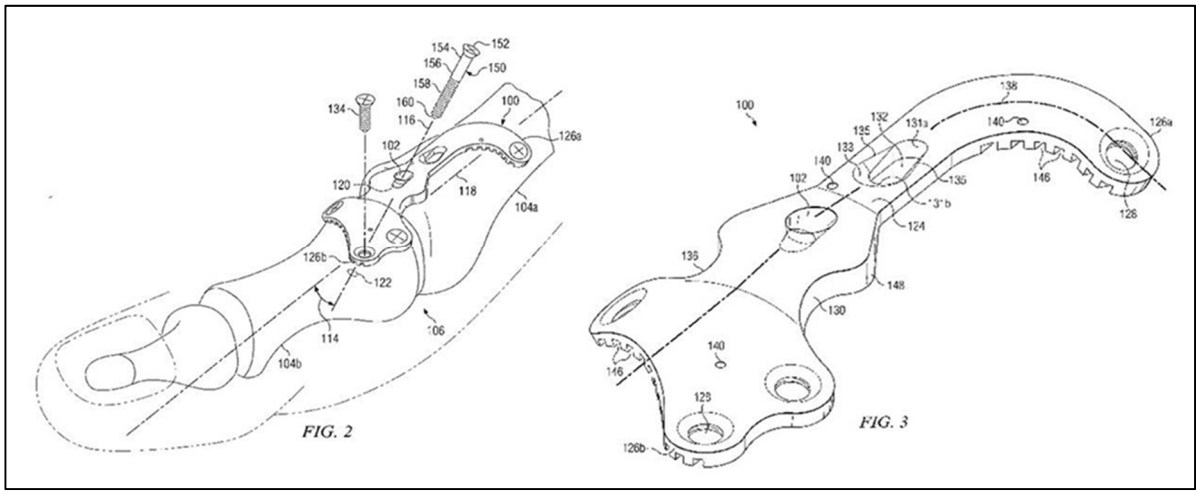
A. Priority Date of the 085 Patent

The 085 patent was filed on September 18, 2017 and is a continuation of the 716 patent, filed on May 5, 2016, which is a continuation of the 776 patent, filed on August 30, 2013, which is a continuation of the 608 patent, filed on April 28, 2009. The alleged priority date of the 085 patent is April 28, 2009.

B. Subject Matter of the 085 Patent (EX1001)

The 085 patent is directed to a bone plate used with a transfixation screw for securing the bones of a joint together. (EX1001, 1:40-42).

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, 4:28-31). In accordance with the 085 patent, transfixation screw 150 is



inserted through transfixation screw hole 102 into a first bone 104a and a second bone 104b. (EX1001, 4:43-47). 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, 7:47-53). The bone plate 100 further includes a bridge portion disposed between the first end and the second end to span across joint 106. (EX1001, 7:52-53). "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, 8:33-37). 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, 8:37-39).

C. Prosecution History of the 085 Patent (EX1004)

1. Prosecution History of the 608 Parent Patent

On April 28, 2009, Patent Owner filed its original 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).

2. Prosecution History of the 085 Patent

The continuation application that issued as the 085 patent was filed on September 18, 2017. Patent Owner submitted application claims 1-10 directed to a "system for securing bones together across a joint," all of which were rejected by the Examiner on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of the 716 patent, claims 1-15 of the 776 patent, and claims 1-17 of the 608 patent. (EX1019, OSTEOMED_0001487-0001488). In addition, the Examiner rejected claims 2, 3, and 7-9 under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Geissler (U.S. Publication 2007/0270850). (EX1019, OSTEOMED_0001489-0001490). Furthermore, the Examiner rejected original claim 4 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Geissler in view of Chapman (U.S. Patent No. 5,190,544), original claims 5 and 6 under pre-

AIA 35 U.S.C. § 103(a) as being unpatentable over Geissler in view of Horan (U.S. Publication 2007/0233106), and original claim 10 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Geissler. (EX1019, OSTEOMED_0001490-0001492).

Patent Owner thereafter requested an Examiner Interview, which was scheduled for September 20, 2018. (EX1019, OSTEOMED_0001513-0001516). Prior to the interview, Patent Owner provided an Agenda for Discussion During Interview wherein Patent Owner referenced the arguments made during the prosecution of the 608 patent in which "the Examiner [] previously recognized and appreciated the differences between plates designed to provide fixation of simple fractures involving two segments of a single bone, such as the Geissler plate [], and plates designed to provide fixation with respect to two bones separated by a joint." (EX1019 at OSTEOMED_0001521-0001522).

In the Interview Summary, the Examiner indicated that "adding language to the preamble similar to the language added in the parent case, wherein the bones are further defined as discrete first and second bones and the joint is further defined as being a joint between the bones…appeared to overcome the Geissler reference." (EX1019, OSTEOMED_0001516). Accordingly, Patent Owner cancelled the original application claims and set forth new claims that clarified that the claims are directed to "a system for securing a first discrete bone and a second discrete bone

together across a joint between the first discrete bone and the second discrete bone." (EX1019, OSTEOMED_0001535).

On October 18, 2018, the Examiner issued a Final Office Action rejecting original claims 11-19 on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of the 716 patent, claims 1-15 of the 776 patent, and claims 1-17 of the 608 patent. (EX1019, OSTEOMED_0001541-0001542). In response, Patent Owner filed a terminal disclaimer and the Examiner issued a Notice of Allowance on November 20, 2018. (EX1019, OSTEOMED_0000001563).

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 085 patent specification and file history.

V. SUMMARY OF THE PRIMARY PRIOR ART REFERENCES

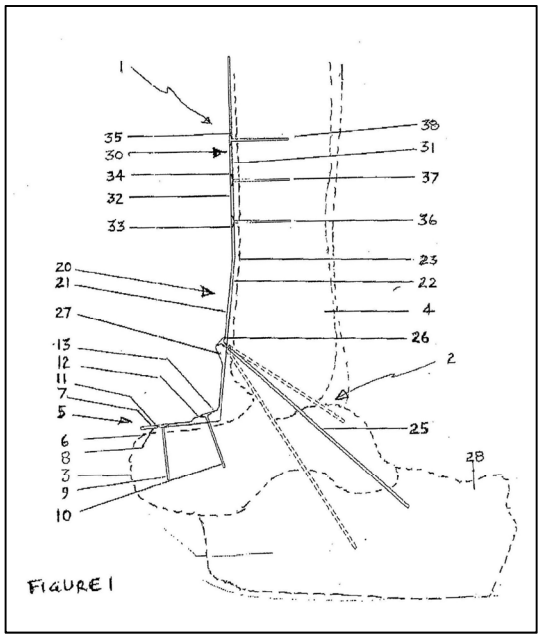
The 085 patent claims are directed to features well known in the art prior to its priority date of April 28, 2009. The prior art references relied upon herein are directed to the same field as the 085 patent, namely, bone plates for use in fusing bone parts in the lower extremities (feet), and thus are analogous art. (EX1002, ¶170, ¶224, ¶235). Petitioners are not aware of any secondary considerations supporting a finding of nonobviousness.

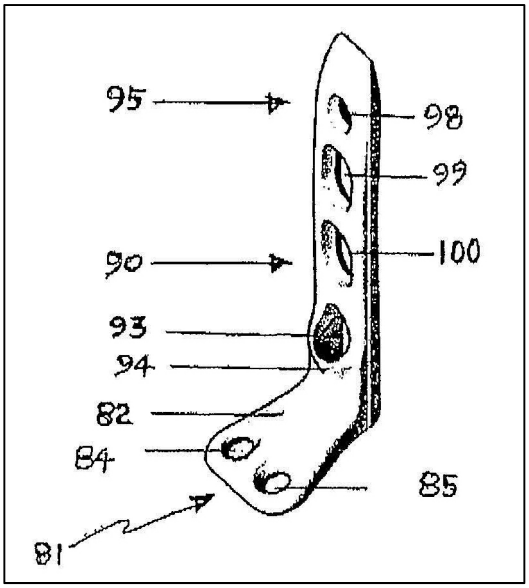
A. Slater

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.

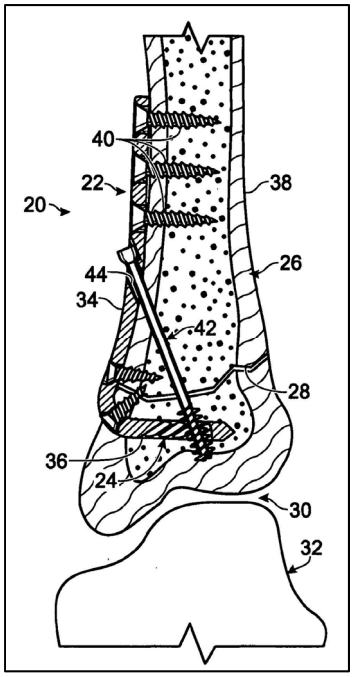
During the prosecution of the PCT application corresponding to the 608 parent patent, Slater was cited by the International Search Authority ("ISA") as disclosing the subject matter of original application claims 1-5, 10-14, and subsequently cited by Patent Owner during prosecution of the 085 patent. (EX1004, OSTEOMED_0001738-41; EX1019, OSTEOMED_0001457). However, the Examiner did not rely on Slater during the prosecution of the 085 patent or any of the prior patents in the chain, 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 608 patent 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. *See* Section III.C.1.

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 085 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).

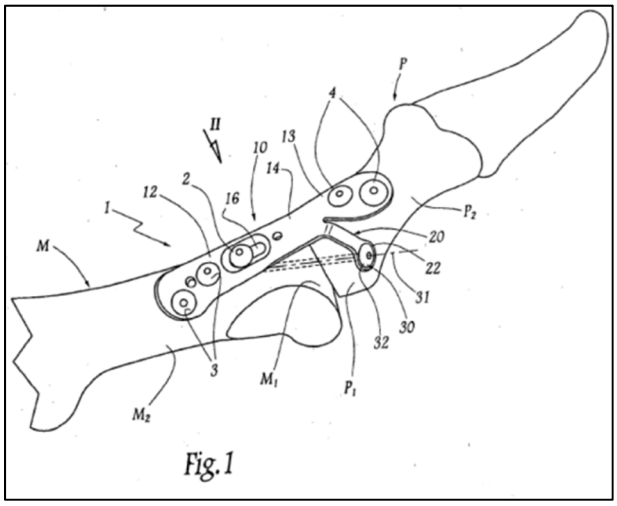


Fig.1

Arnauld was cited by the ISA during the prosecution of the PCT application corresponding to the 608 parent patent as disclosing the subject matter of original application claims 1-5, 10-14, and subsequently cited by Patent Owner during prosecution of the 085 patent. (EX1004, OSTEOMED_0001738-41; EX1019, OSTEOMED_0001495). However, the Office neither relied on nor substantively discussed Arnauld during prosecution of the 085 patent or any of the prior patents in the chain.

The Office erred in failing to consider Arnauld, particularly after Patent Owner amended the 608 patent 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 1-3and 6-9

As shown below and in the accompanying Declaration, Slater discloses all elements of Claims 1-3 and 6-9, and thus anticipates those claims under 35 U.S.C. § 102(b). (EX1002, ¶¶132-169).

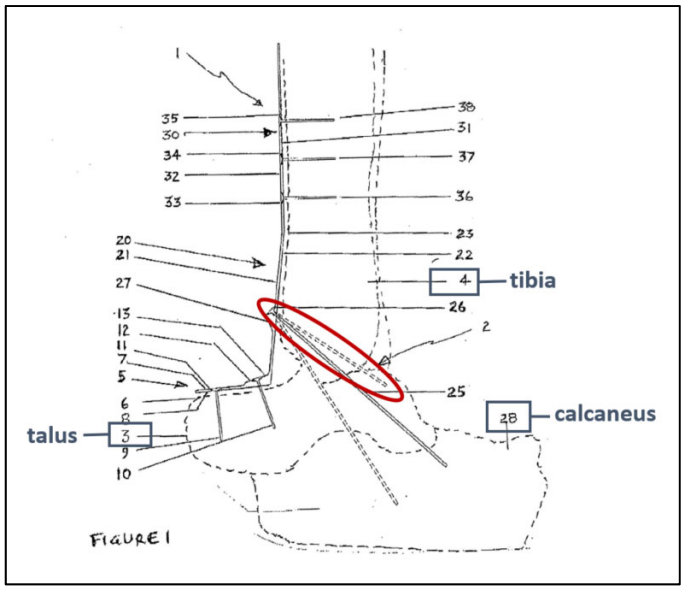
1. Independent Claim 1 is Anticipated by Slater

a. 1.P: Preamble

To the extent the preamble is limiting, Slater includes a system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone. (EX1002, ¶133).

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).

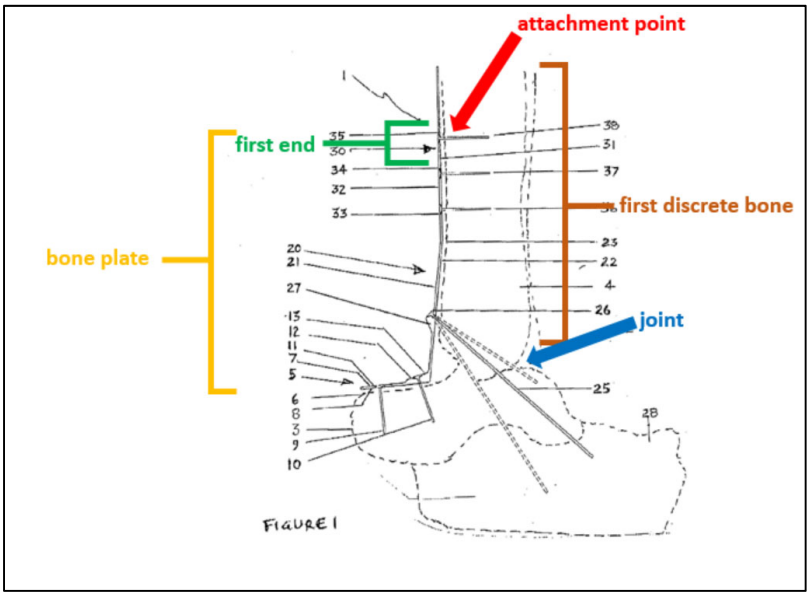
Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and calcaneous 28) across two joints and (2) an alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 2, within the oval annotated into Figure 1 immediately below) together across a single joint between the two bones. (EX1002, ¶133; EX1005, 12:3-4, 6:17-7:2, 8:13-28, 11:1-4, 12:3-10, 13:5-9, 14:1-8).

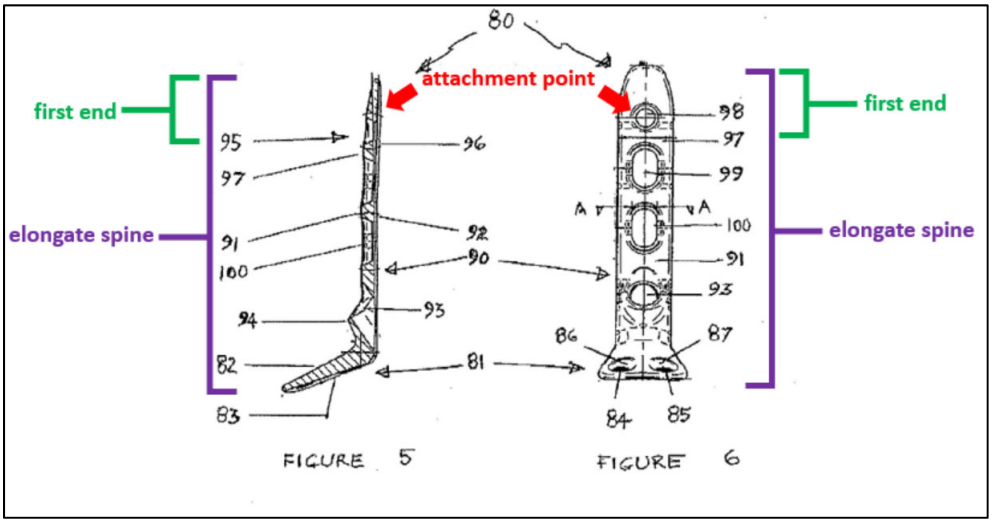


b. 1.1: "*a plate comprising: an elongate spine having a first end comprising…*"

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 attachment point (attachment points 35, 34, 33 or attachment points 98, 99) for attaching the first end (proximal end of portion 30 or proximal end of portion 95) to the first discrete bone (tibia 4) on a first side of the joint. (EX1002, ¶¶134-136; 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).

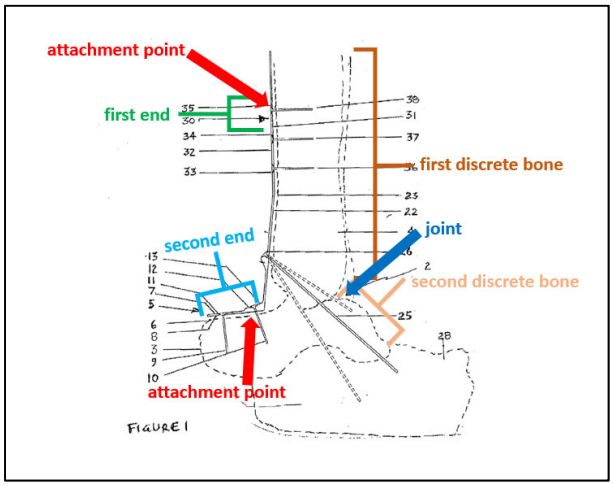


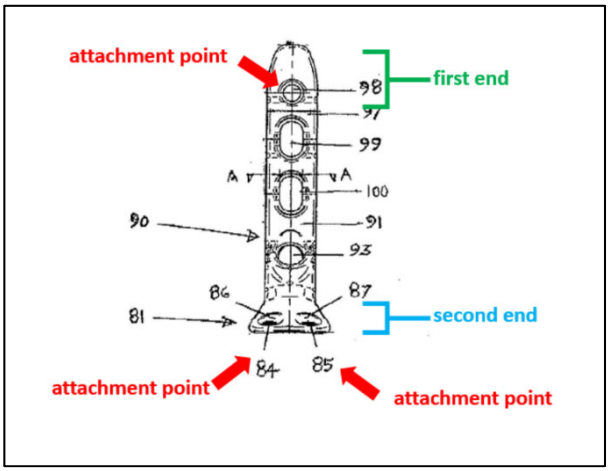


(EX1005, Figs. 1, 5-6).

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 attachment point (11, 12 or 84, 85) for attaching the second end (distal end of portion 5 or 81) to the second discrete bone (talus 3) on a second side of the joint. (EX1002, ¶137; EX1005, 11:8-10, 13:10-12).

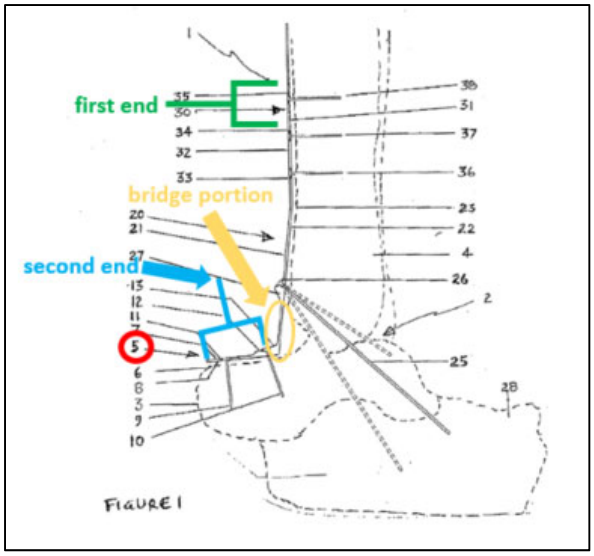


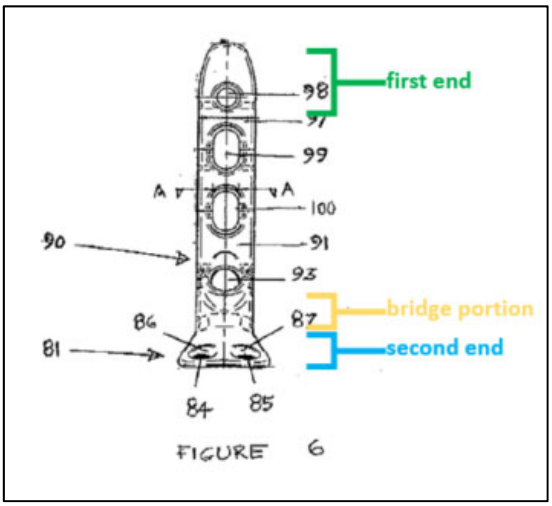


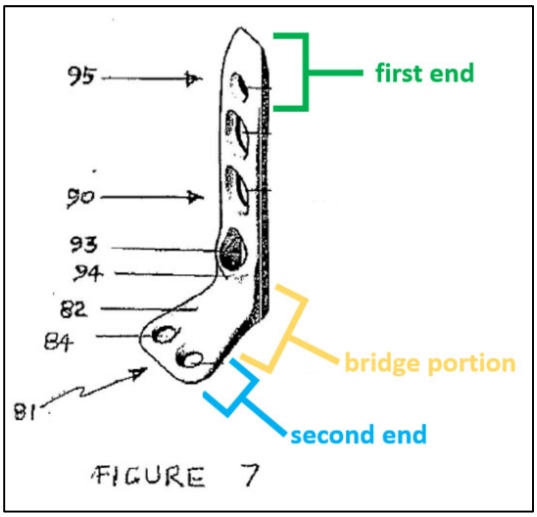
(EX1005, Figs. 1, 6).

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

As shown below 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, ¶138).

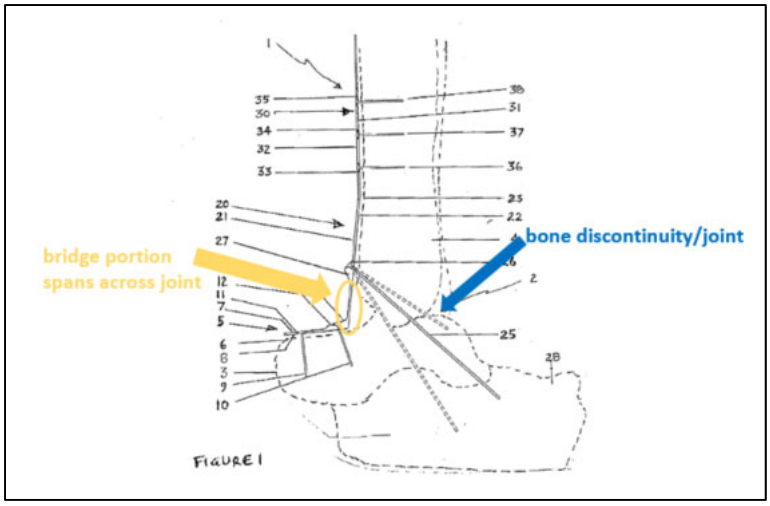






(EX1005, Figs. 1, 6, 7).

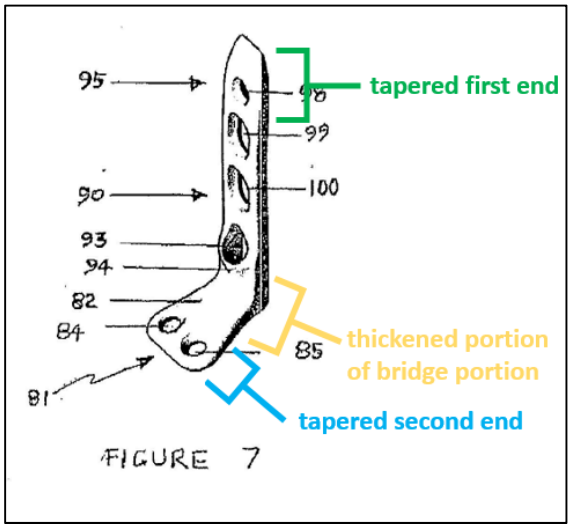
Moreover, a portion of Slater's bridge portion (portions of 5 and 20 or portions of 81 and 90) is configured to span across the joint (2). (EX1002, ¶139; EX1005 at 11:3-4).

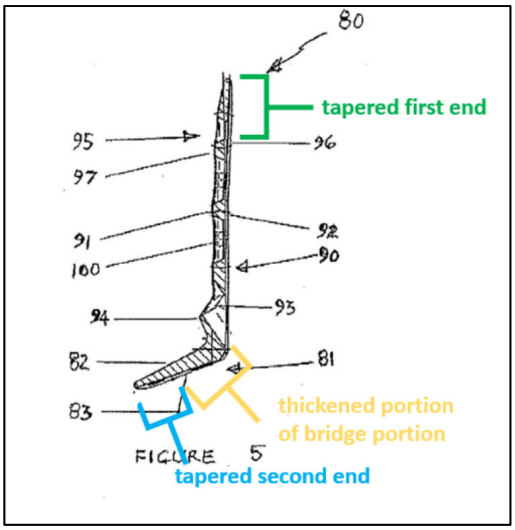


(EX1005, Fig. 1).

e. 1.4: "*the bridge portion further comprising a thickened portion…*"

As shown below in Figures 5 and 7, Slater's bridge portion further comprises as thickened portion (portions of 5 and 20 or portions of 81 and 90) having a thickness greater than at least a portion of a 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, ¶140).



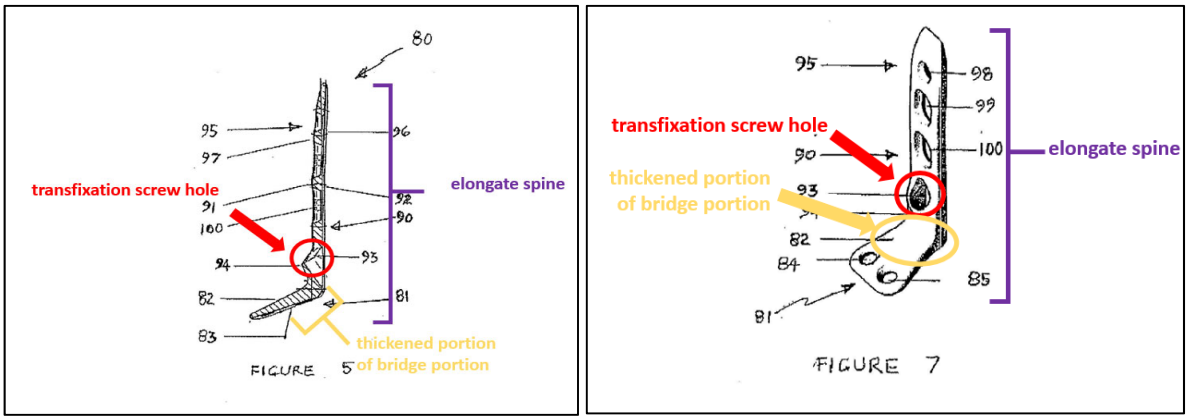


(EX1005, Figs. 5, 7).

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: "*an aperture defining a transfixation screw hole disposed…*"

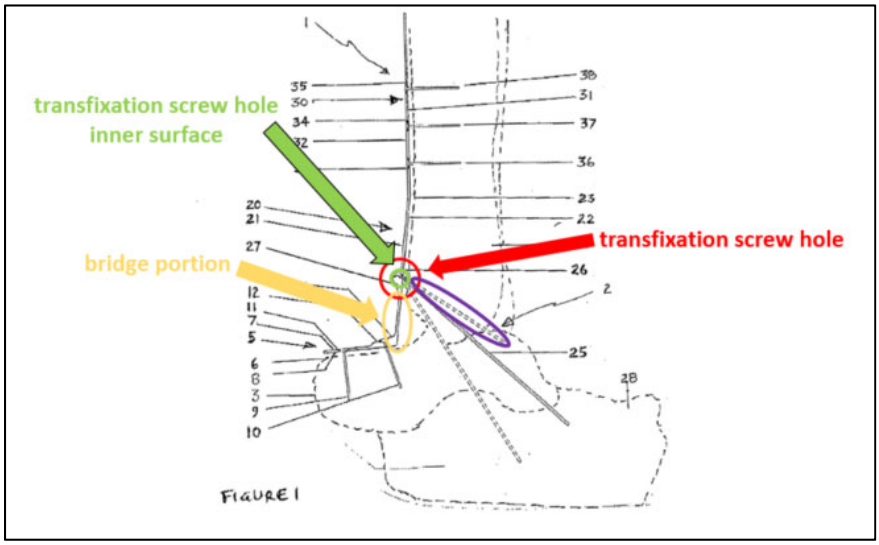
As shown below in Figures 5 and 7, Slater includes an aperture defining a transfixation screw hole (opening 26 or 93) disposed along the spine at the thickened portion of the bridge portion. (EX1002, ¶141); EX1005, Figs. 5, 7).

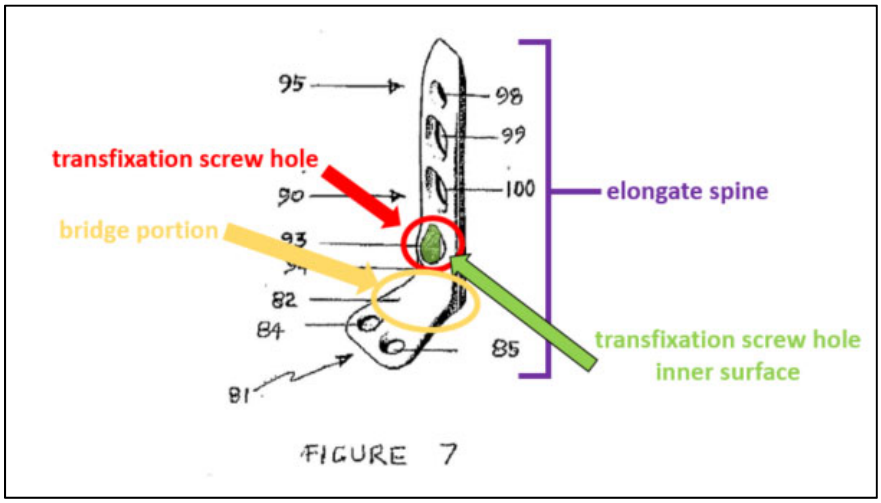


While Slater does not explicitly identify openings 26 and 93 as "transfixation screw holes," Slater's disclosure makes it clear that openings 26 and 93 each receive a fixation screw that passes through those openings so that the screw is implanted at an angle. (EX1005, 11:19-21, 13:21-24).

As shown below 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 at a trajectory configured to pass through a first position on the first discrete bone (tibia 4) and a second position on the second

discrete bone (talus 3) once the plate (1 or 80) is placed across the joint. (EX1002, ¶142; 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, ¶142).





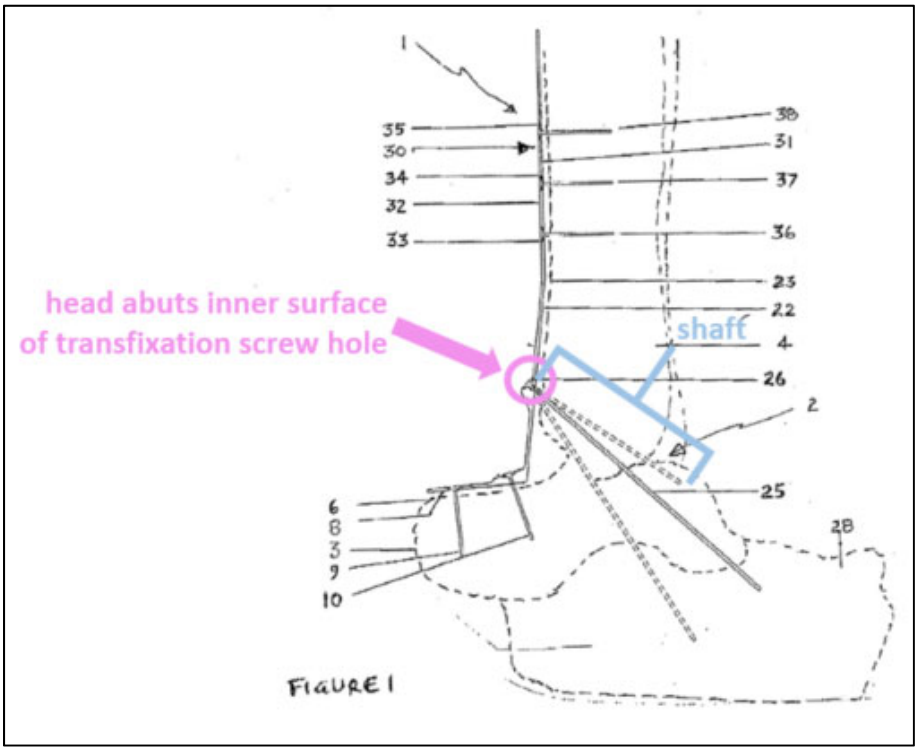
(EX1005, Figs. 1, 7)

2. Dependent Claims 2-3 and 6-9 are Anticipated by Slater

As discussed above, Slater anticipates independent claim 1. For the reasons set forth below, Slater also anticipates dependent claims 2-3 and 6-9. (EX1002, ¶¶143-169).

a. Dependent Claim 2

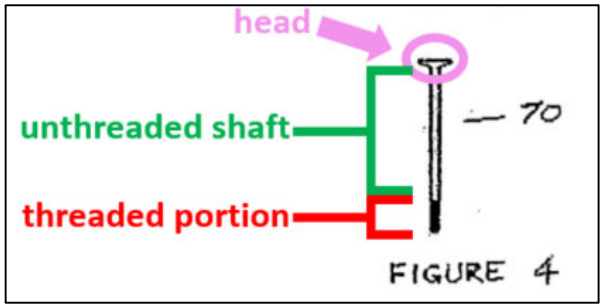
As shown in Figure 1 below, Slater includes a transfixation screw (screw 25) comprising a head configured to abut the inner surface of the transfixation screw hole (unnumbered in Slater's drawings) and a shaft configured to contiguously extend through the first discrete bone (tibia 4), across the joint (2), and into the second discrete bone (talus 3). (EX1002, ¶¶144-145).

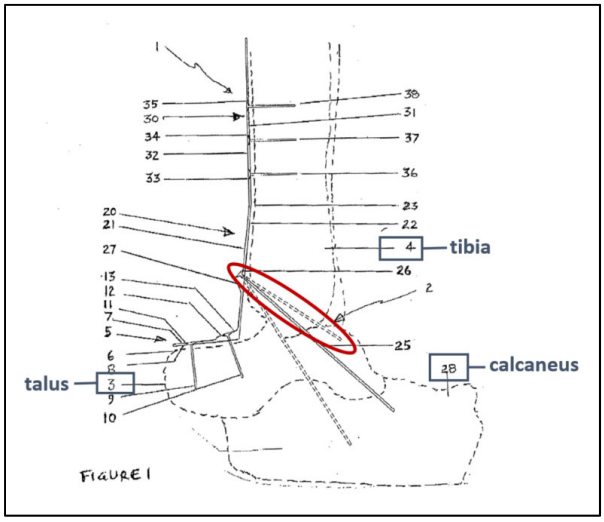


(EX1005, Fig. 1, 11:19-25, 13:21-24).

b. Dependent Claim 3

Figure 4 of Slater depicts a lag screw 70 with a "longer shank" and "an abbreviated threaded portion." (EX1002, ¶147; 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 discrete bone (tibia 4) and, at the second end of the shaft adjacent to the tip, a threaded portion configured to extend into the second discrete bone (talus 3). (EX1002, ¶¶146-148).





(EX1005, Figs. 4, 1)

c. Dependent Claim 6

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, ¶¶149-157).

The term "neutral bending axis" is defined by the 085 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, 6:4-10). Figure 2 of the 085 patent illustrates neutral bending axis 118 in connection with the metatarsophalangeal joint. (EX1001, Fig. 2).

From the 085 patent:

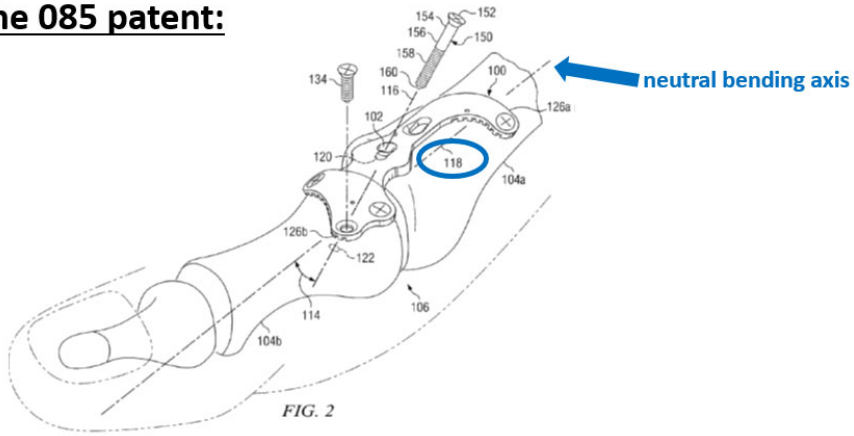
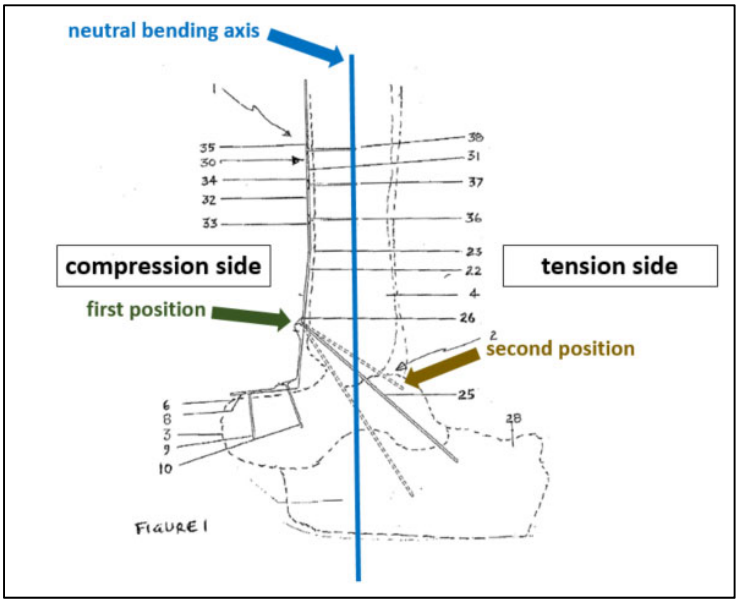


FIG. 2

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, ¶152). 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. (EX1002, ¶152). 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, ¶¶153-156; EX1010, ¶49; EX1016, ¶35).

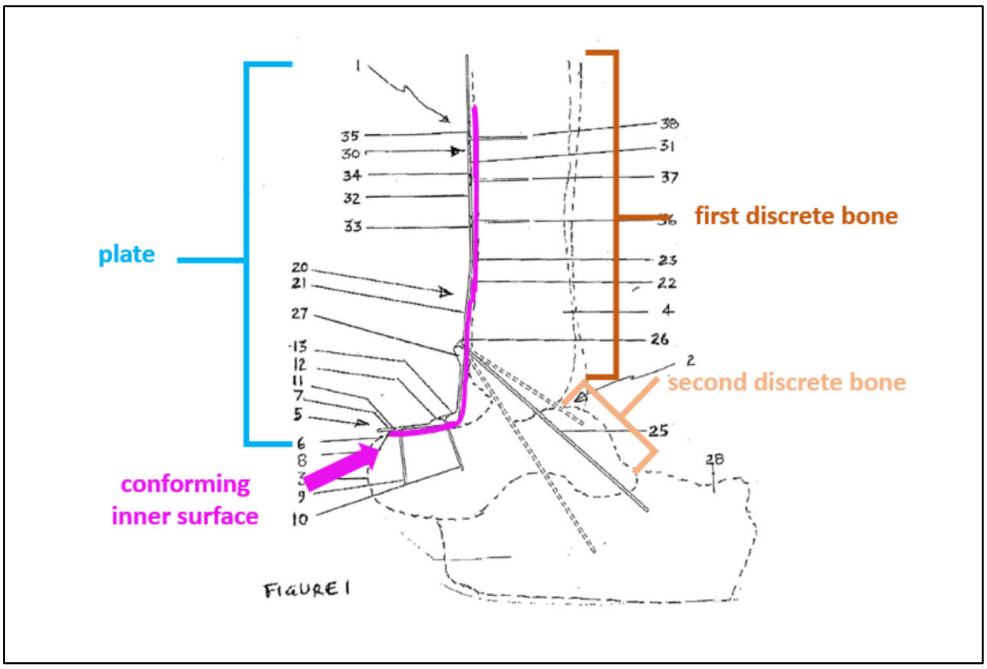


In the context of Slater and as labeled in Figure 1, a force in the posterior direction on the foot would place both the tibia and ankle joint in compression on the posterior side of the joint. (EX1002, ¶157; EX1005, Fig. 1). A POSITA would recognize that, when walking, the first position in Slater on 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, ¶157).

d. Dependent Claim 7

As shown in Figure 1 below, Slater discloses a plate configured to substantially conform to a geometry of the respective first (tibia 4) and second (talus

3) discrete bones on which the plate is configured to be disposed. (EX1002, ¶¶158-159).



(EX 1005, 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). Moreover, 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

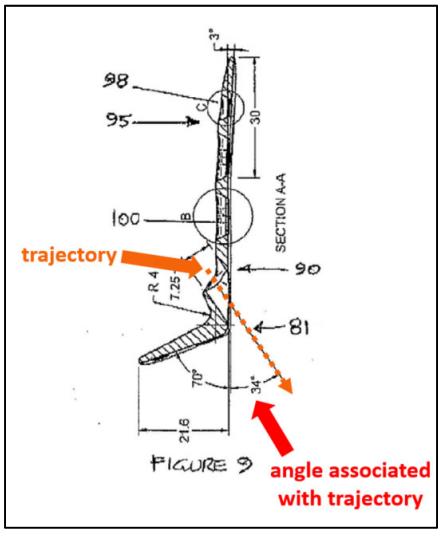
the ankle joint." (EX1005, 9:8-15; 11:7-8, 13:9-10, 14:19-22, 16:32-34, 17:2-3; 23:15-17).

e. Dependent Claim 8

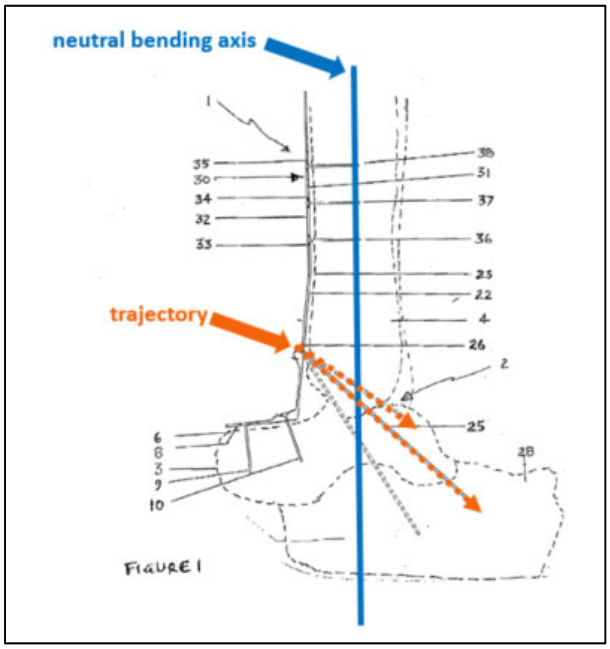
Slater discloses that the central axis of the inner surface of the transfixation screw hole (26 or 93) defines a trajectory configured to cross a neutral bending axis of the joint once the plate is placed across the joint. (EX1002, ¶¶160-163).

As discussed above, "the neutral bending axis 118 defines the boundary line that separates the tension side of the joint 106 from the compression side of the joint 106." (EX 1001, Fig. 2; 6:7-10). Further, as discussed above, 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, ¶161). 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. (EX1002, ¶161).

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, ¶162; EX1005, Fig. 9).

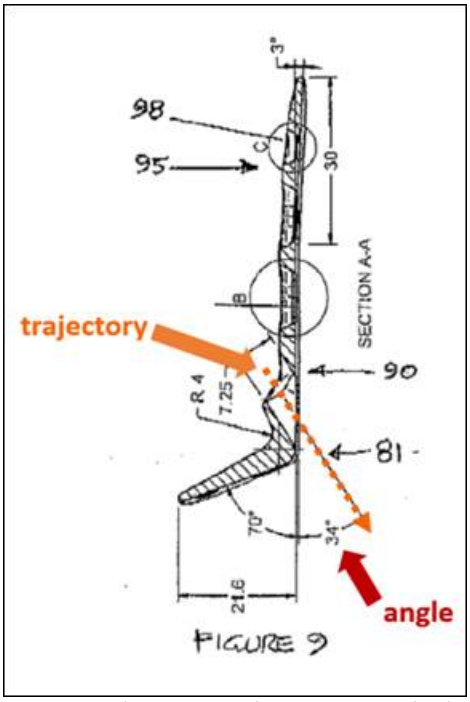


Similarly, as shown below in Figure 1, when the Slater plate is placed across the joint, the trajectory defined by the central axis of the inner surface of the transfixation hole crosses the neutral bending axis of the joint. (EX1002, ¶163).



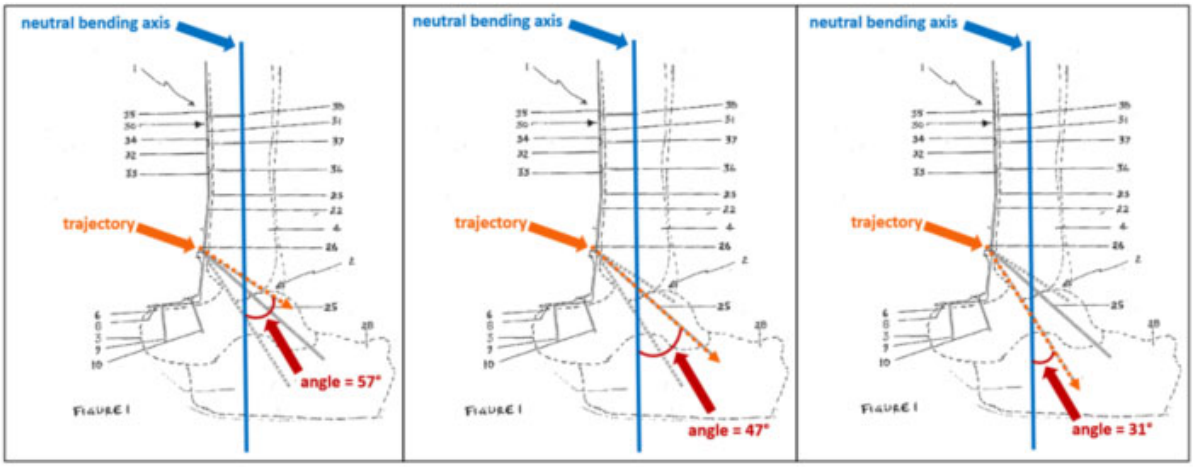
(EX1005, Fig. 1; 11:19-27, 12:3-4, 12:32-13:3, 13:20-25).

f. Dependent Claim 9



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 of the joint. (EX1002, ¶¶165-166__; 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 9. (EX1002, ¶¶165-166__).

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 9 range of between about 30 and 70 degrees measured from the neutral bending axis of the joint. (EX1002, ¶¶167-169).



(EX1005, Fig. 1).

B. Ground 2: Claims 4 and 5 are Obvious Over Slater in View of Weaver

As discussed above, independent claim 1 is anticipated by Slater. Moreover, Weaver discloses each and every additional element described in dependent claims 4 and 5, which recite that the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw (claim 4) and threaded to provide a locking interface with a transfixation screw (claim 5). As discussed below, dependent claims 4 and 5 are rendered obvious by Slater in view of Weaver. (EX1002, ¶¶170-178).

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 details of an example 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).

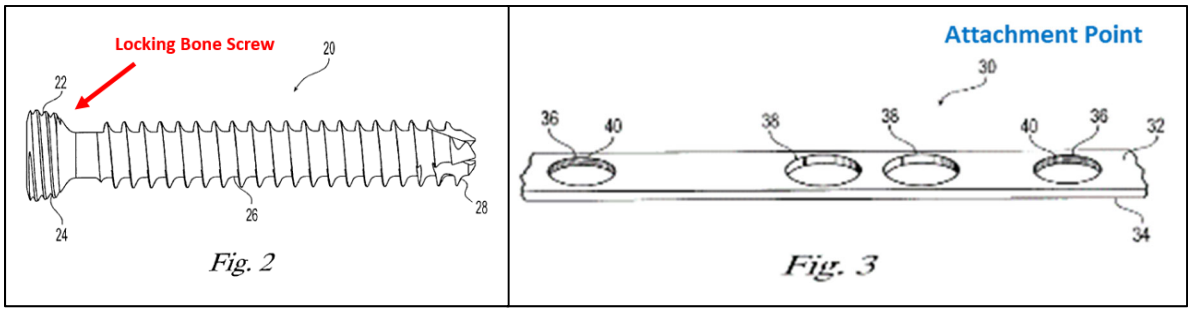


Fig. 2 *Fig. 3*

(EX1009, Figs. 2-3).

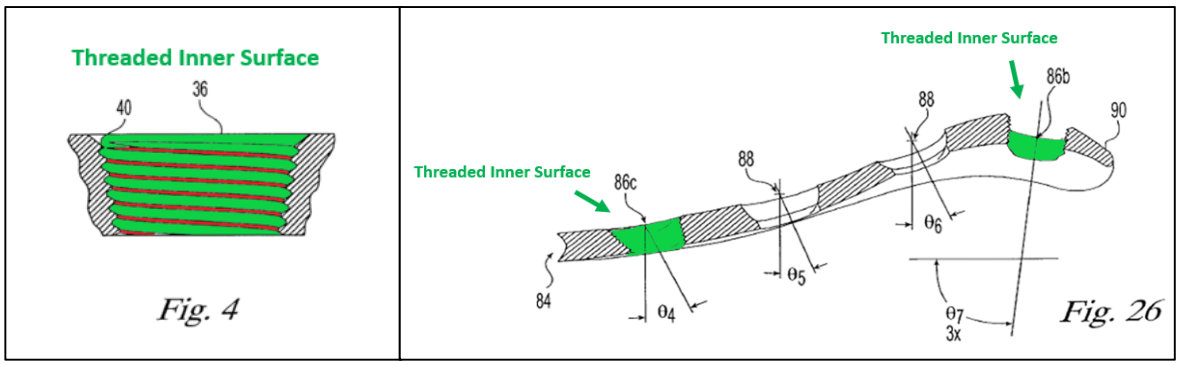


Fig. 4 *Fig. 26*

(EX1009, Figs. 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, ¶173; 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 thread the inner surface of the transfixation screw hole to lockably engage with the head of a transfixation screw to help provide a more secure fixation. (EX1002, ¶¶173-174, ¶¶176-177,). 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, ¶174, ¶178); *see 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 given that locking screws with threaded heads that mated with threads in the plate holes were common at the time. (EX1002, ¶174, ¶178; 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, 3, 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 4) to lockably engage a head of a

transfixation screw would have been an obvious design choice. (EX1002, ¶¶173-178). So too would it have been an obvious design choice to configure the inner surface of Slater's transfixation screw hole (claim 5) as a threaded screw hole to provide a locking interface with a transfixation screw. (EX 1002, ¶¶173-178). Such design choice would have been made, for example, 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, ¶¶173-175, ¶¶176-178).

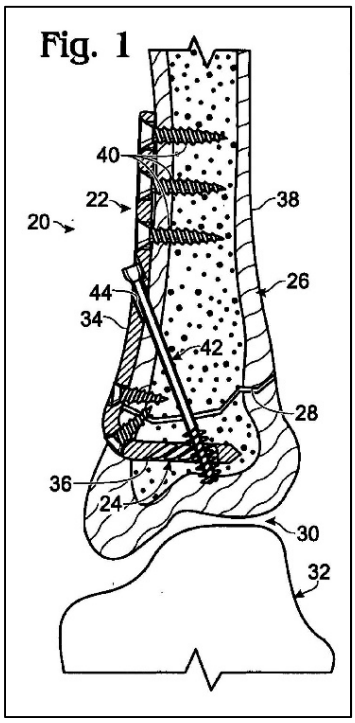
C. Ground 3: Falkner Anticipates Claims 1-8

As shown below and in the accompanying Declaration, Falkner discloses all elements of claims 1-8, and thus anticipates those claims under 35 U.S.C. § 102(b). (EX1002, ¶¶179-222).

1. Independent Claim 1 is Anticipated by Falkner

a. 1.P: Preamble

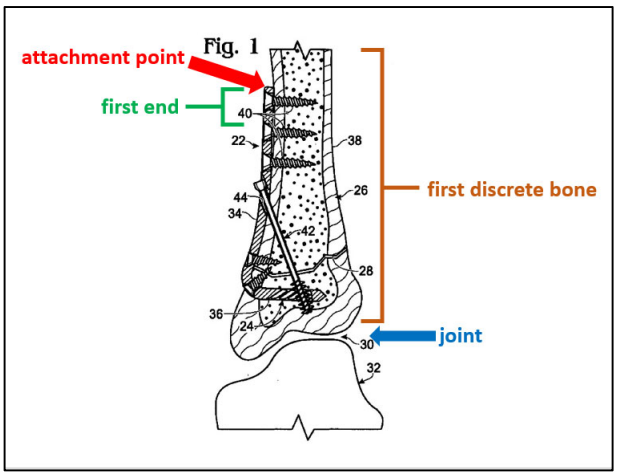
To the extent the preamble is limiting, Falkner discloses a system 20 for securing a first discrete bone (tibia 26) and a second discrete bone (talus 32) together across a joint 30 between the first discrete bone (tibia 26) and the second discrete bone (talus 32). (EX1002, ¶181).

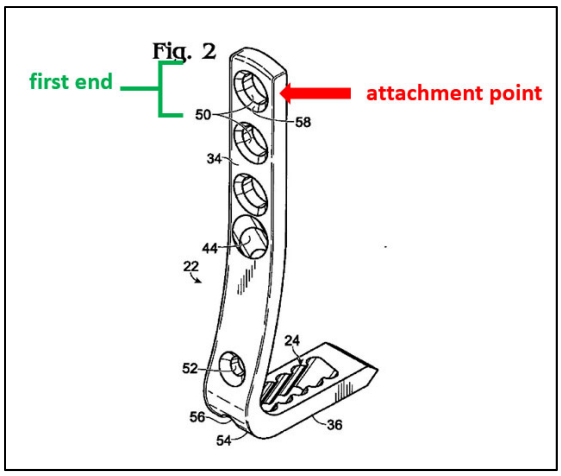


While Figure 1 of Falkner shows an exemplary system for fixing bones, the Falkner disclosure expressly contemplates that "the bone plate may be positioned on and/or in any suitable **bone(s)** to span any natural or artificial discontinuity within a bone or between bones. In the present illustration, 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: "*a plate comprising: an elongate spine having a first end comprising…*"

As shown in Figures 1 and 2 below, Falkner discloses a bone plate 22 comprising an elongate spine (22) having a first end comprising at least one attachment point (50) for attaching the first end to the first discrete bone (*e.g.*, tibia 26) on a first side of the joint (30). (EX1002, ¶¶182-184).





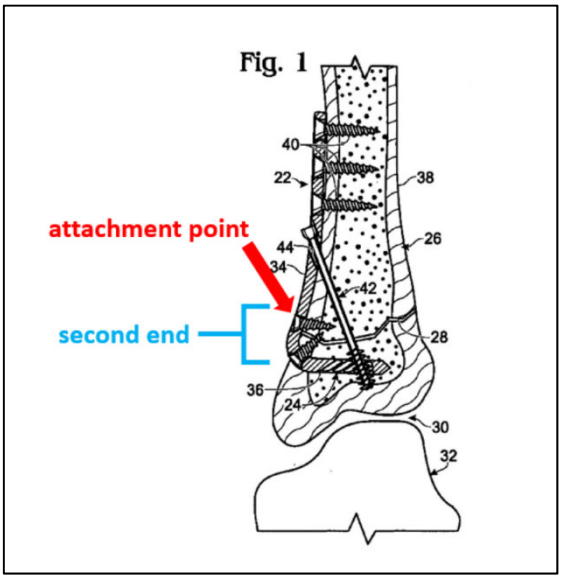
(EX1006, Figs. 1, 2).

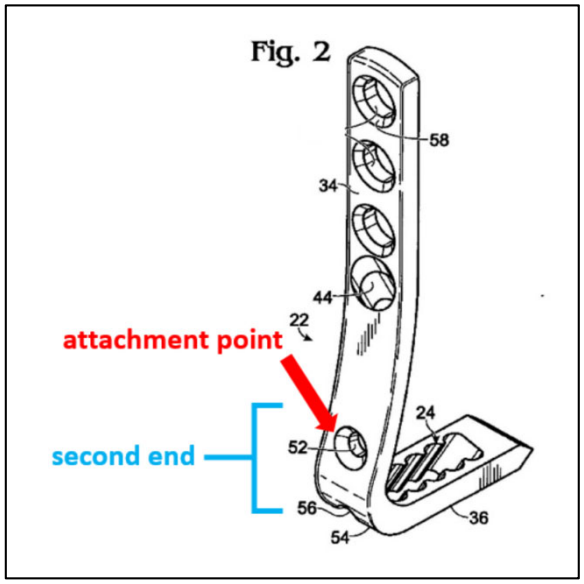
For example, Falkner explains that "[e]ach bone plate portion may define one or more openings for receiving fasteners, such as bone screws, that secure the plate portions to bone." (EX1006, ¶19). Falkner further explains with respect to Figure 2 that external portion 34 "**may include a first set of 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 above 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, ¶184).

c. 1.2: "*a second end comprising…*"

As shown below in Figures 1 and 2, Falkner discloses a bone plate 22 comprising an elongate spine having a second end comprising at least one attachment point (52, seen in Fig. 2) for attaching the second end to the second discrete bone (talus 32) on a second side of the joint 30. (EX1002, ¶185).





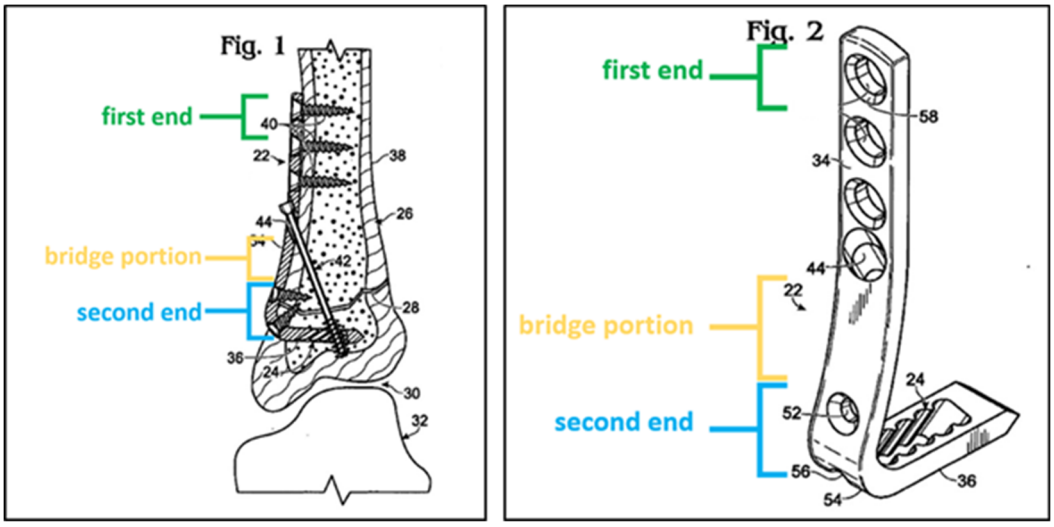
(EX1006, Figs. 1 and 2).

Similar to the discussion above in Section VI.C.1.b. 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, ¶185).

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

As shown below in Figures 1 and 2, Falkner includes a bridge portion disposed between the first end and the second end, the bridge portion having a portion configured to span across the joint. (EX1002, ¶¶186-187).



(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

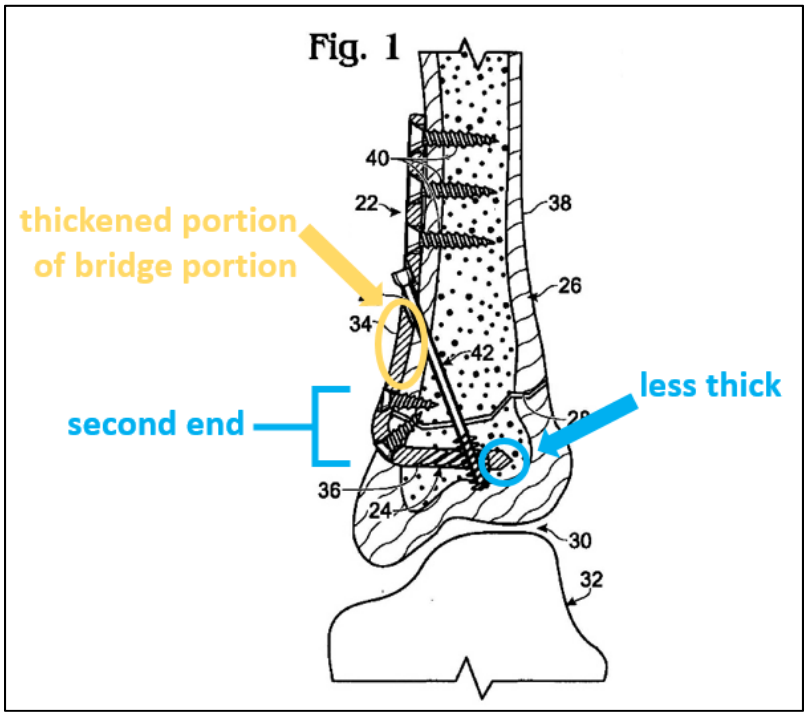
used to span a joint, a portion of the bridge portion disposed between the first end and the second end would be configured to span across the joint. (EX1002, ¶187).

e. 1.4: "*the bridge portion further comprising a thickened portion…*"

The Falkner bridge portion further comprises a thickened portion having a thickness greater than at least a portion of a thickness of either the first end or the second end. (EX1002, ¶188). 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 below in Figure 1, a thickened portion of the bridge portion has a thickness greater than at least a portion of the thickness of the second end. (EX1002, ¶188). 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).



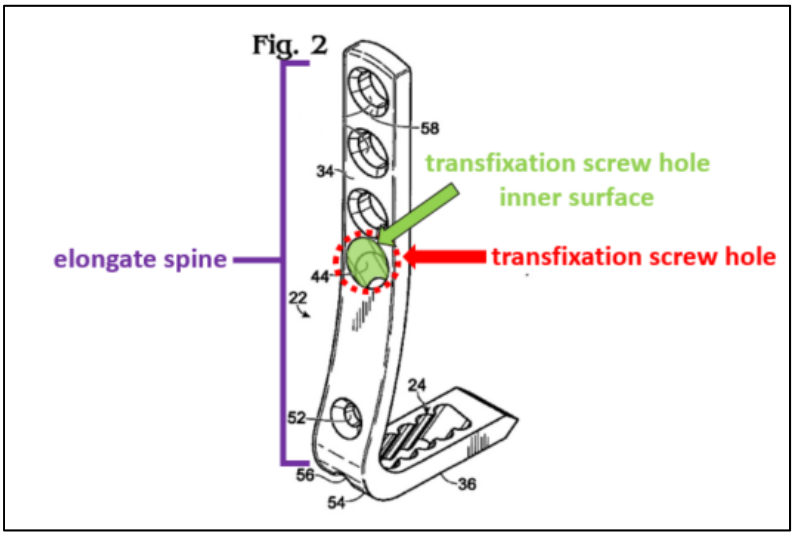
(EX1006, Fig. 1).

As such, Falkner teaches that a thickened portion of the claimed bridge portion has a thickness greater than at least a portion of a thickness of either the first end or the second end. (EX1002, ¶188).

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

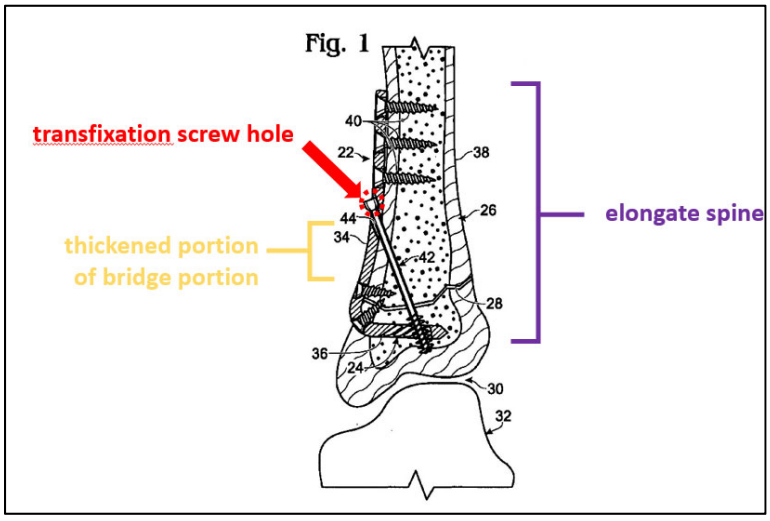
As shown in Figure 2 below, Falkner discloses an aperture defining a transfixation screw hole (oblique opening 44) disposed along the spine (22) at the thickened portion of the bridge portion, the transfixation screw hole (oblique opening 44) comprising an inner surface configured to direct a transfixation screw

(threaded fastener 42) through the screw hole (oblique opening 44). (EX1002, ¶189).



(EX1006, Fig. 2; EX1006, ¶¶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 (threaded fastener 42) through the oblique opening 44 such that the transfixation screw 42 extends at a trajectory configured to pass through a first position on the first discrete



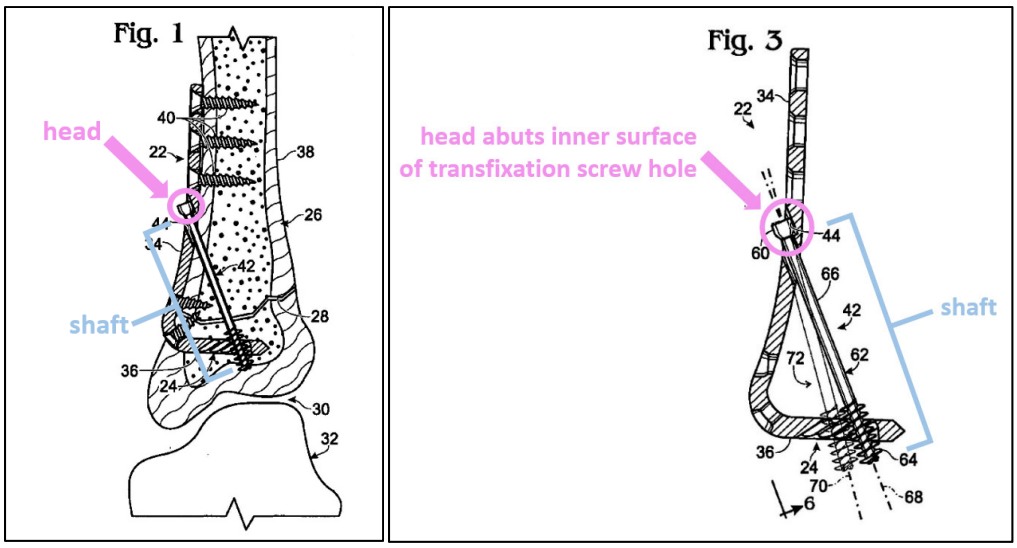
bone (tibia 26) and a second position on the second discrete bone (talus 32) once the plate is placed across the joint 30. (EX1002, ¶190; EX1006, Fig. 2).

2. Dependent Claims 2-8 are Anticipated by Falkner

As discussed above, Falkner anticipates independent claim 1. For the reasons set forth below, Falkner discloses each and every element of dependent claims 2- 8 and therefore anticipates those claims. (EX1002, ¶¶191-222).

a. Dependent Claim 2

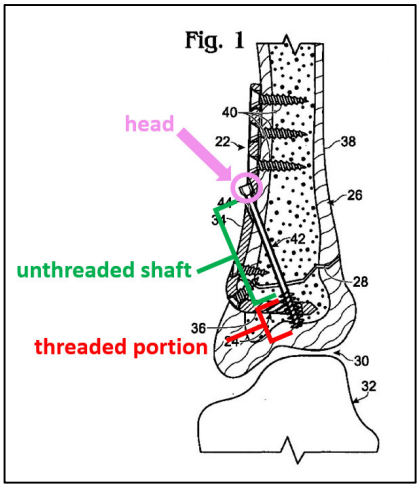
As shown in Figure 1, Falkner teaches a transfixation screw (threaded fastener 42) comprising a head configured to abut the inner surface of the transfixation screw hole (oblique opening 44) and a shaft configured to contiguously extend through both sides of fractured tibia 26. (EX1002, ¶¶192-194; EX1006, ¶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) across the joint (30) and into the second discrete bone (talus 32). (EX1002, ¶193).

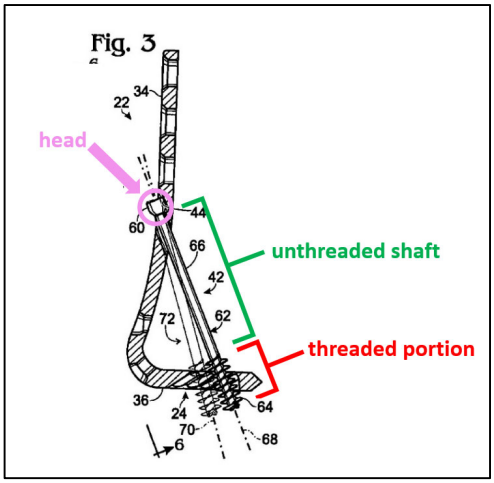


(EX1006, Figs. 1, 3).

b. Dependent Claim 3

As shown in Figures 1 and 3 below, Falkner discloses a transfixation screw (threaded fastener 42) comprising a lag screw having an unthreaded portion configured to extend through the first discrete bone (located at a first end of the shaft adjacent to the head) and a threaded portion configured to extend into the second discrete bone (located at a second end of the shaft adjacent to the tip). (EX1002, ¶¶195-198).





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).

c. Dependent Claims 4 and 5

Falkner discloses that the inner surface of the transfixation screw hole (oblique opening 44) may be configured to lockably engage a head of a transfixation screw (threaded fastener 42) (claim 4). (EX1002, ¶¶199-200). Furthermore, Falkner discloses that the inner surface of the transfixation screw hole (oblique opening 44)

is threaded to provide a locking interface with a transfixation screw (threaded fastener 42) (claim 5). (EX1002, ¶201-205).

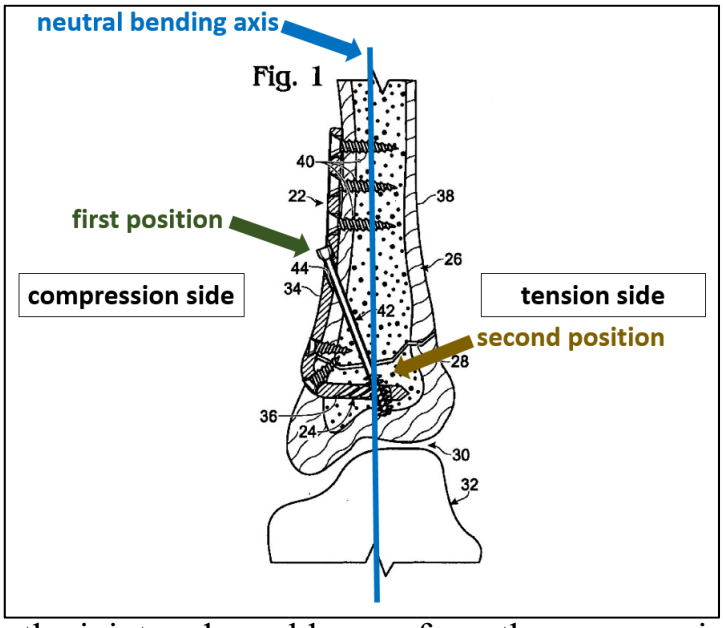
For example, Falkner states that the head 60 of the transfixation screw 42 "may be nonthreaded (as shown here) or may include a thread configured to lock the head to the plate." (EX1006, ¶70). Falkner further teaches that "[e]xternal and internal portions 34, 36 may include a plurality of openings…Each opening may be threaded or nonthreaded…" (EX1006, ¶68). A POSITA would understand that Falkner's disclosure of a threaded screw head 60 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 a head of a transfixation screw and to provide a locking interface with a transfixation screw. (EX1002, ¶200, ¶202).

d. Dependent Claim 6

Falkner 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, ¶¶206--213).

While Figure 1 illustrates an embodiment wherein the bone plate is placed across a fracture, as discussed above, the Falkner disclosure specifically contemplates that the bone plate can be placed across joint 30. *See* Section VI.C.1.a. As discussed above, the "neutral bending axis 118 defines the boundary line that

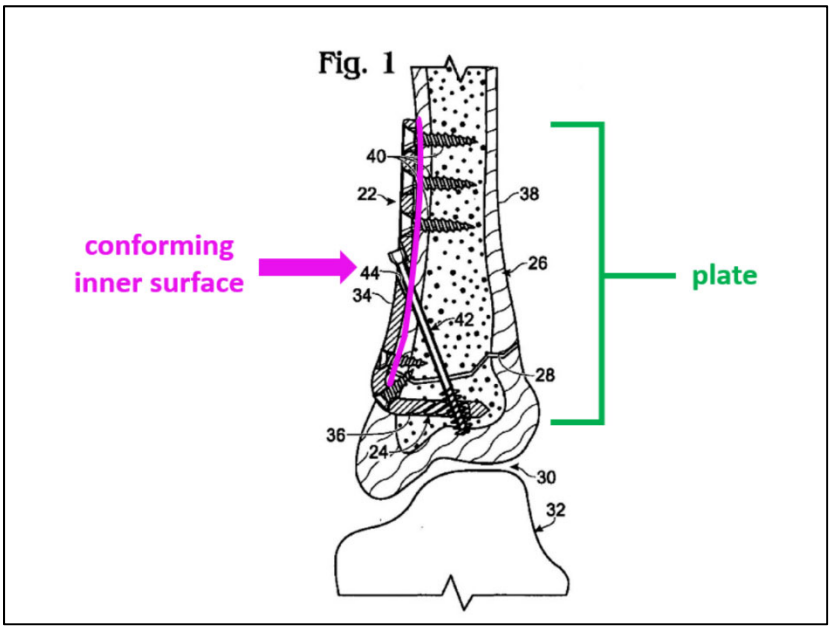
separates the tension side of joint 106 from the compression side of joint 106." (EX1001, Fig. 2; 6:4-10). Moreover, as explained in Section VI.A.2.c, a POSITA would understand that a transfixation screw crossing the joint at the midpoint of the joint would maximize the compressive forces applied across the joint and would cross from the compression side to the tension side of the joint. (EX1002, ¶212; EX1010, ¶49; EX1016, ¶35).



For example, assuming that Figure 1 is 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, ¶212). In such loading, the first position in Falkner resides on a compression side of the joint and the second position resides on a tension side of the joint. (EX1002, ¶212). Thus, in an embodiment contemplated by Falkner to span a joint 30 instead of a fracture 28, 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, ¶213).

e. Dependent Claim 7

As shown below in Figure 1, Falkner discloses a plate configured to substantially conform to a geometry of the respective first (tibia 26) and second (talus 32) discrete bones on which the plate is configured to be disposed. (EX1002, ¶¶214-216).



(EX1006, Fig. 1).

For example, Falkner specifically discloses that "[t]he external plate portion may be contoured to follow an exterior surface of the bone." (EX1006, ¶23; ¶¶34, 42, 62). 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 plate would be configured to substantially conform to a geometry of the first discrete bone (tibia 26). (EX1002, ¶216). Of course, if the plate 22 was used to span a different joint, Falkner teaches that the plate would substantially conform to 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). Similarly, when Falkner is configured to span a joint between two discrete bones, the plate 22 would be placed across the joint 30 and would be configured to substantially conform to a geometry of the second discrete bone (**talus 32)**. (EX1002, ¶216).

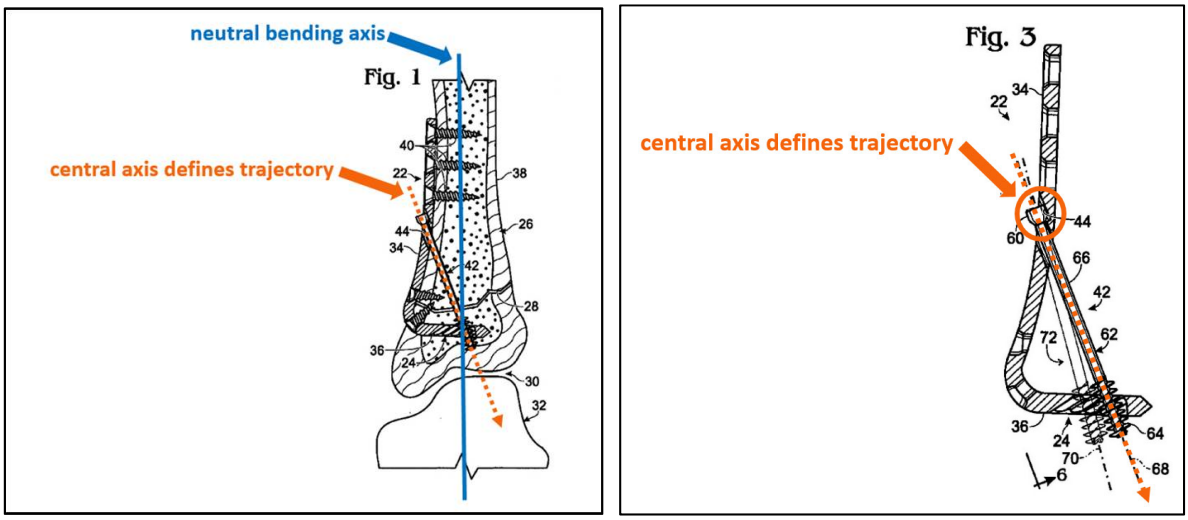
f. Dependent Claim 8

The central axis of the inner surface of the Falkner transfixation screw hole (oblique opening 44) defines a trajectory configured to cross a neutral bending axis of the joint 30 once the plate is placed across the joint. (EX1002, ¶¶217-222).

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, ¶219). In Falkner, the axis of the bone plate approximates the direction of the neutral bending axis of the joint. (EX1002, ¶219).

In Figure 3, Falkner discloses a central axis (68 or, alternatively, 70) of the inner surface of the transfixation screw hole (oblique opening 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, ¶222; EX1006, Fig. 1).



(EX1006, Figs. 1, 3).

D. Ground 4: Falkner in View of Arnauld Renders Obvious Dependent Claim 9

As discussed above, Falkner anticipates dependent claims 2-8 and independent claim 1. Arnauld, an arthrodesis plate for a metatarsophalangeal joint, discloses the "transfixation angle between about 30 degrees and about 70 degrees measured from the neutral bending axis" of dependent claim 9. (EX1002, ¶¶223-233). A POSITA would have been motivated to combine the transfixation angle taught by Arnauld with the Falkner plate. (EX1002, ¶¶224-233).

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, ¶229).

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

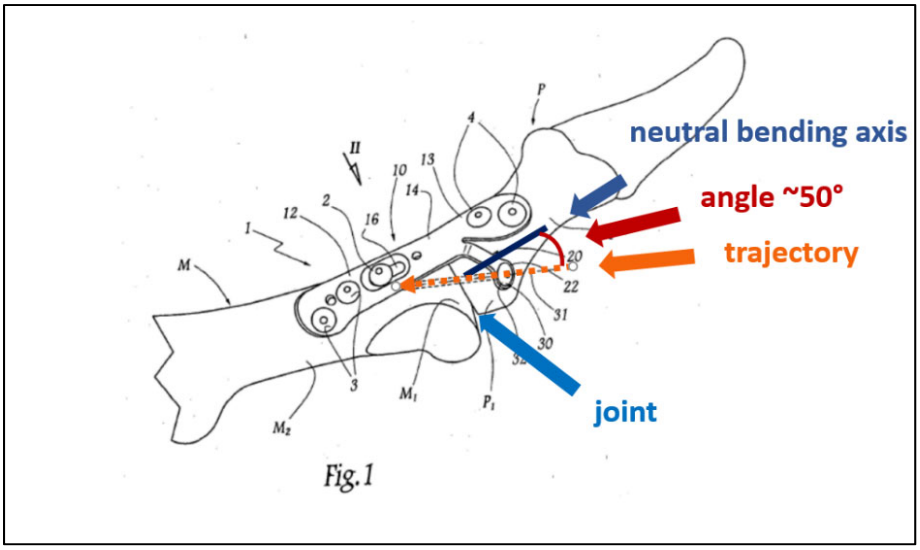


Fig.1

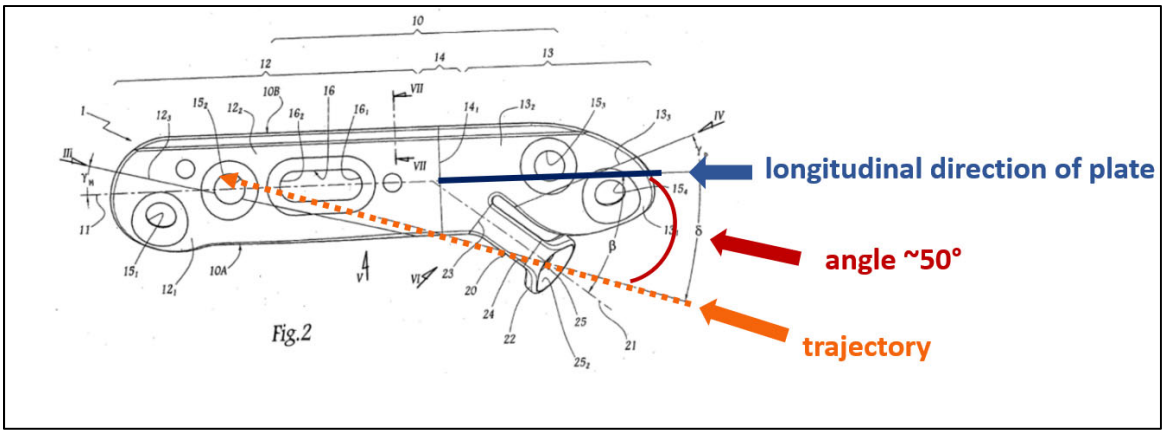


Fig.2

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 085 patent. (EX1002, ¶231). 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, ¶¶232-233). In doing so, a POSITA would have selected a transfixation angle of "less than 45°" 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, ¶228, ¶¶232-233; EX1008, ¶28). Selecting a transfixation angle of "less than 45°" renders obvious a transfixation angle "between about 30 degrees and about 70 degrees," measured from the neutral bending axis. (EX1002, ¶231; EX1008, ¶32; EX1010, ¶49; EX1016, ¶35; Section VI.C.2.d). By obtaining superior positioning of the bones to be fused, a successful fusion or immobilization can result. (EX1002, ¶232). As such, Falkner in view of Arnauld renders obvious a dependent claim 9. (EX1002, ¶233).

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

E. Ground 5: Arnauld in View of Slater Renders Obvious Claims 1-3 and 6-9

As shown below and in the accompanying Declaration, Claims 1-3 and 6-9 are rendered obvious by Arnauld in view of Slater under 35 U.S.C. § 103. (EX1002, ¶¶234-275).

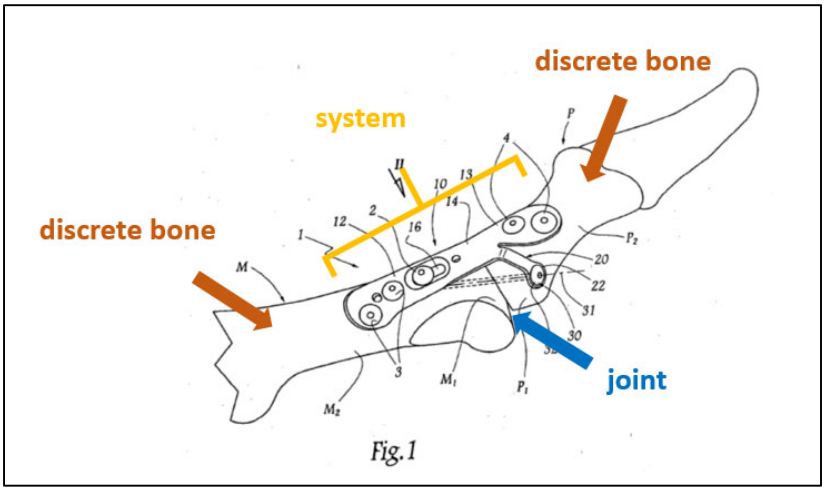
1. Independent Claim 1 is Rendered Obvious by Arnauld in View of Slater

Arnauld discloses each and every element of independent claim 1 except claim element 1.4, which recites "the bridge portion further comprising a thickened portion having a thickness greater than at least a portion of a thickness of either the first end or the second end." (EX1002, ¶235). However, as discussed above in Section VI.A.1.e, Slater discloses a bone plate where the bridge portion further comprises a thickened portion having a thickness greater than at least a portion of a 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.

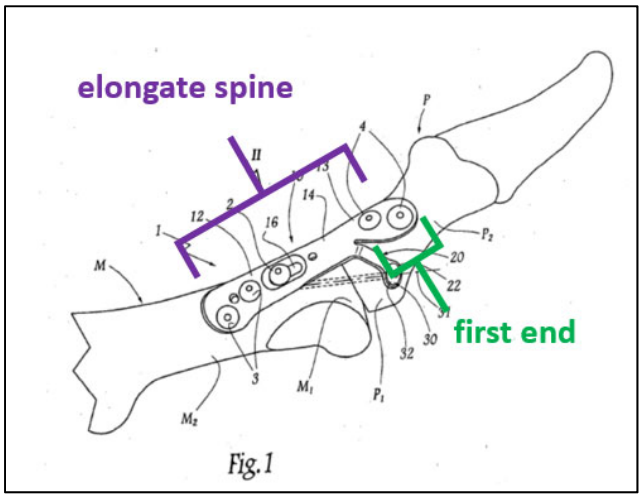
a. 1.P: Preamble

To the extent the preamble is limiting, Arnauld (entitled "Arthrodesis Plate for a Metatarsal Phalangeal Joint") discloses a system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone. (EX1002, ¶236). 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).

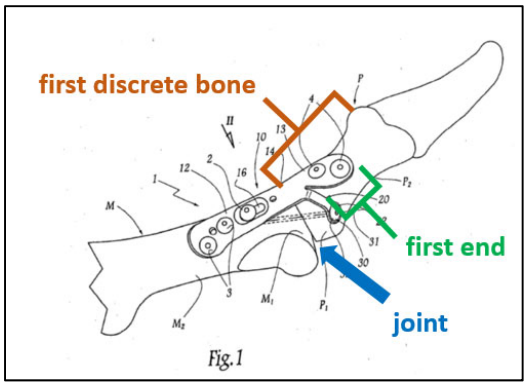


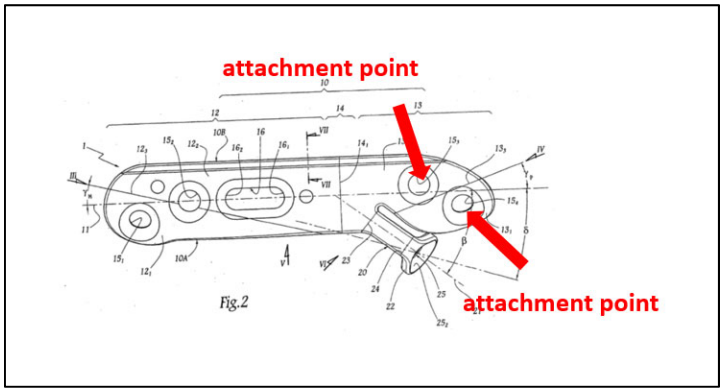
b. 1.1: "*a plate comprising: an elongate spine having a first end comprising…*"

As shown below in Figure 1, Arnauld discloses bone plate 10 comprising an elongate spine (elongated plate body 10) having a first end (phalangeal part 13). (EX1002, ¶¶237-238; 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).



Moreover, the first end (phalangeal portion 13) includes at least one attachment point (attachment points 15_3 and 15_4) for attaching the first end (phalangeal portion 13) to the first discrete bone (phalanx P) on a first side of the joint. (EX1008 Figs. 1-2, ¶21, ¶34, claim 5; EX1002, ¶239).

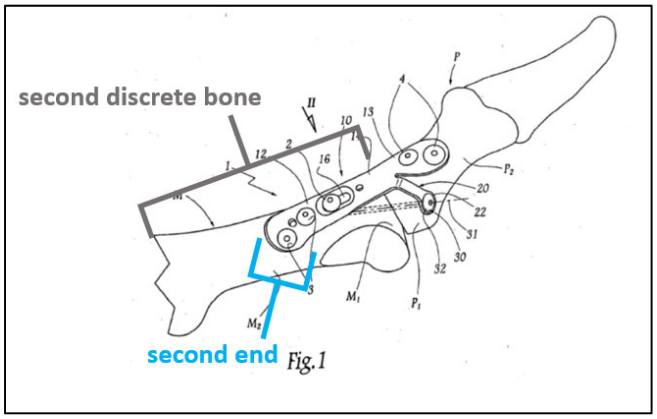


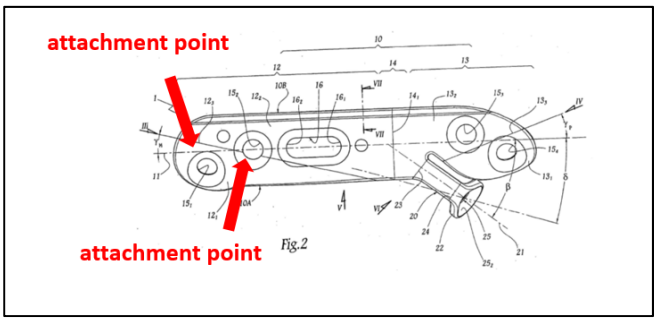


(EX1008 Figs. 1-2).

c. 1.2: "*a second end comprising…*"

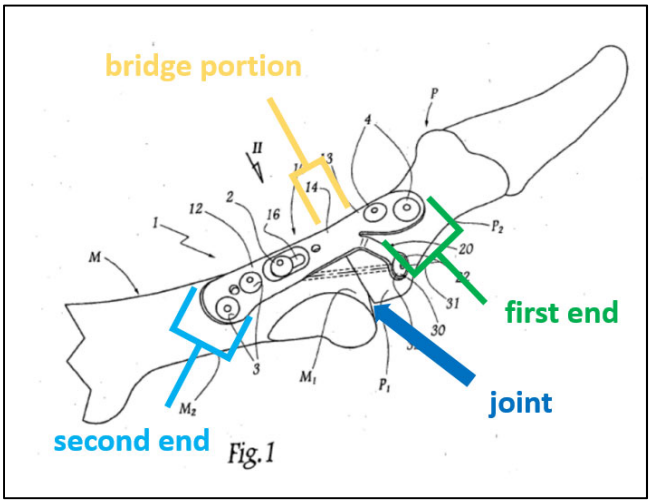
As shown in Figure 1, Arnauld discloses an elongate spine (elongated plate body 10) having a second end (metatarsal portion 12). (EX1002, ¶240). As shown in Figure 2, the second end of the plate (metatarsal portion 12) includes at least one attachment point (attachment points 15_1 and 15_2) for attaching the second end (metatarsal portion 12) to the second discrete bone (metatarsal M) on a second side of the joint. (EX1008 at ¶¶21, 33; claim 5).





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

As shown in Figure 1, Arnauld includes a bridge portion (junction zone 14) disposed between the first end (phalangeal portion 13) and the second end (metatarsal portion 12), the bridge portion having a portion (junction zone 14, also referred to as joint zone 14) configured to span across the joint. (EX1002, ¶241). 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: "*the bridge portion further comprising a thickened portion…*"

For the reasons discussed in Sections VI.A.1.e, Slater discloses claim element 1.4. (EX1002, ¶242). 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).

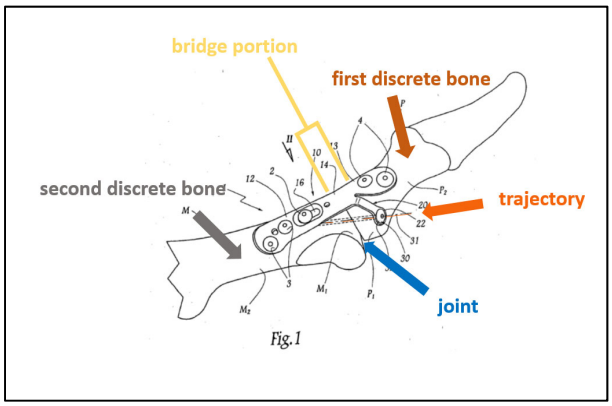
As set forth in Section V.A. and VI.A.1.e., Slater discloses an ankle fusion plate wherein the bridge portion further comprises a thickened portion (portions of 5 and 20 or portions of 81 and 90) having a thickness greater than at least a portion of a thickness of either the first end (proximal end of portion 95) or the second end (distal end of portion 81). (EX1002, ¶242; 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).

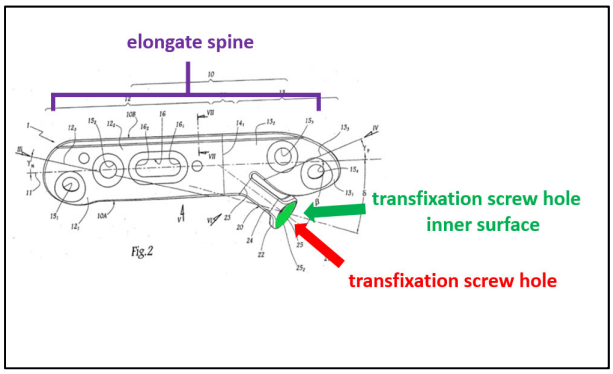
At the time of the invention, a POSITA would have been motivated to use a thickened bridge portion as in Slater (which acknowledges that the plate should be at the maximum thickness at the joint region where the highest loading will occur in normal use) across the portion of the Arnauld plate where the highest loading will occur, *e.g.*, in the bridge portion that spans the metatarsophalangeal joint. (EX1002, ¶242; 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, ¶242). As such, Arnauld in view of Slater renders obvious claim element 1.4.

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

As shown below in Figures 1 and 2, Arnauld includes an aperture defining a transfixation screw hole (through-hole 25) disposed along the spine (plate body 10) at the thickened portion of the bridge portion (as modified by Slater), the transfixation screw hole (through-hole 25) comprising an inner surface (through-hole edge 25_2) configured to direct the transfixation screw (screw 30) through the transfixation screw hole (through-hole 25) such that the transfixation screw extends at a trajectory (longitudinal axis 31) configured to pass through a first position on the first discrete bone (phalanx P)and a second position on the second discrete bone (metatarsal M) once the plate is placed across the joint. (EX1002, ¶¶243-244; EX1008, ¶¶6, 8, 23, 26, 27, 32; claims 1, 3; Figs. 1, 2, 5).



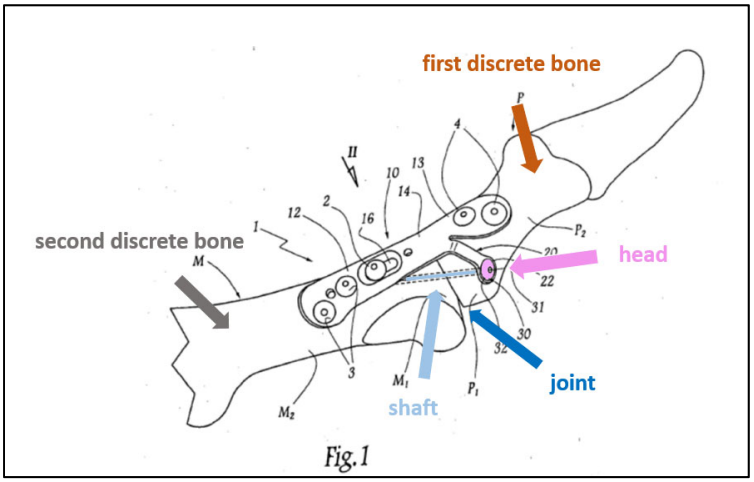


2. Dependent Claims 2-3 and 6-9 are Rendered Obvious by Arnauld in View of Slater

As discussed above, independent claim 1 is rendered obvious by Arnauld in view of Slater. Moreover, Arnauld alone discloses each and every additional element described in dependent claims 2-3 and 6-9, while Slater discloses dependent claim 3. For the reasons set forth below, dependent claims 2-3 and 6-9 are rendered obvious by Arnauld in view of Slater. (EX1002, ¶¶246-274).

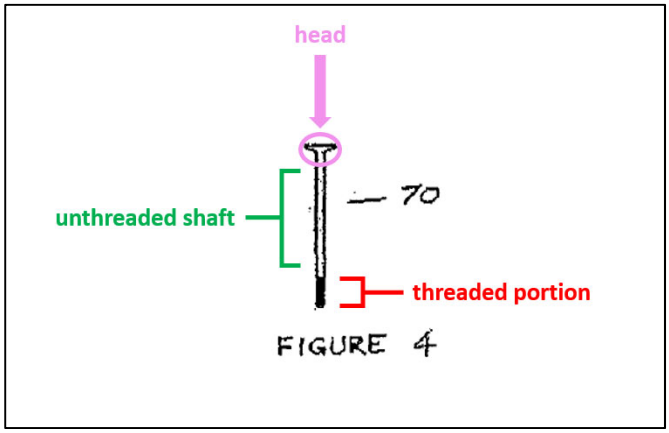
a. Dependent Claim 2

As shown in Figure 1, Arnauld discloses a transfixation screw (screw 30) comprising a head (head 32) configured to abut the inner surface (25_2) of the transfixation screw hole (through-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), across the joint, and into the second discrete bone (metatarsal M in Fig. 1). (EX1002, ¶247; EX1008, ¶¶6, 8, 9, 26, 27, 32; claims 1, 3).



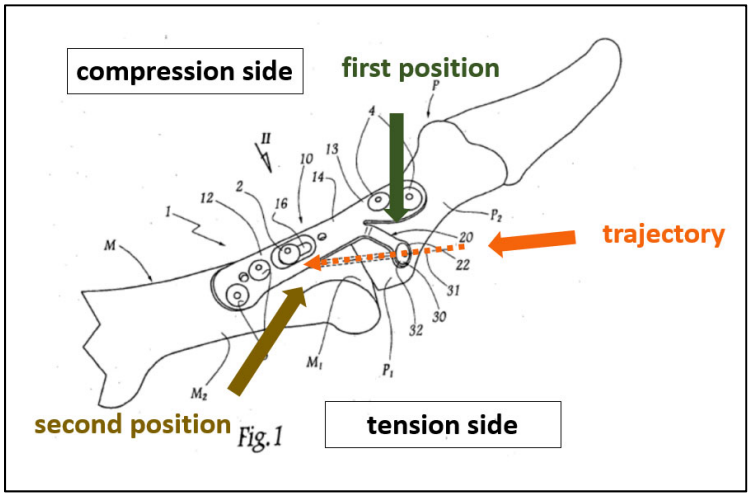
b. Dependent Claim 3

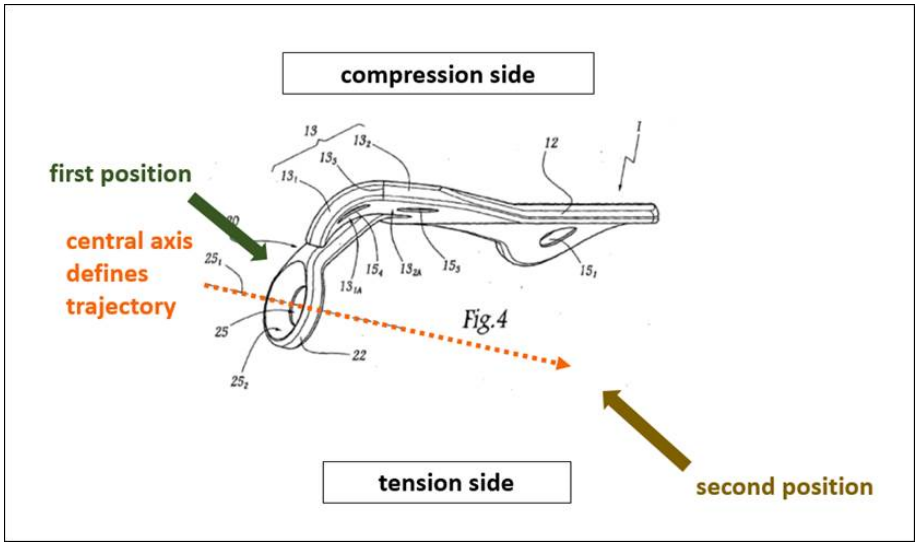
While Arnauld does not disclose details regarding the characteristics of transfixation screw 30, as shown in Figure 4, Slater discloses a transfixation screw with an unthreaded portion at a first end and threaded portion at a second end. (Section VI.A.2.b; EX1005, Fig. 4; 12:34-13:1-4). As explained by Professor Gall, at the time of the invention, it would have been obvious to a POSITA to substitute the Slater transfixation screw for Arnauld's transfixation screw 30 to provide improved compression between the bones. (EX1002, ¶¶248-252; EX1006, ¶39).



c. Dependent Claim 6

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, ¶¶253-260__). As discussed above, Arnauld discloses that the transfixation screw (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).





(EX1008, Figs. 1, 4).

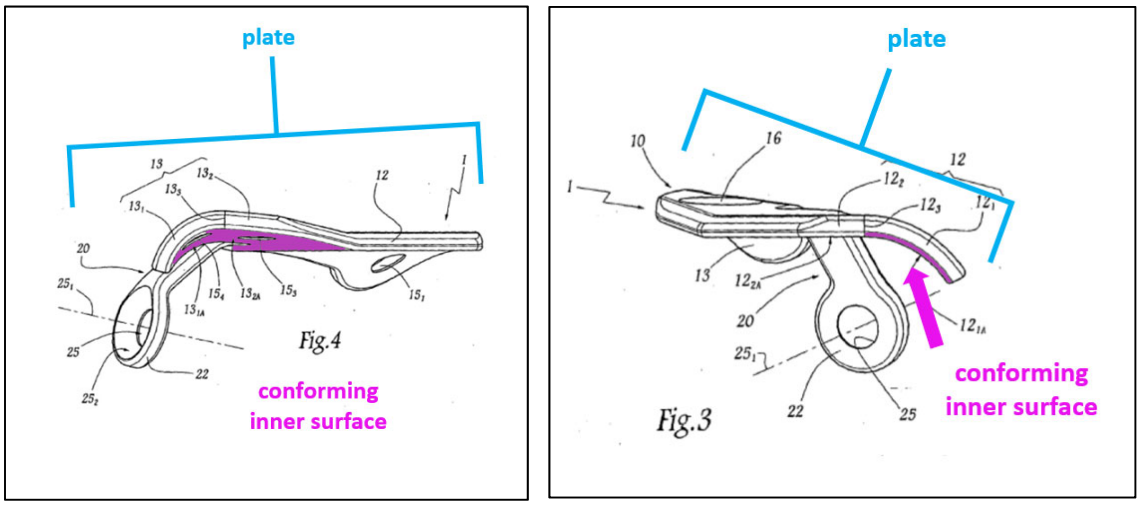
Arnauld explains that a non-zero angle δ is formed by the longitudinal axis 31 of the screw 30 and the longitudinal direction 11 of the plate body 10, and that "[f]or anatomical reasons, the angle δ is advantageously chosen to be less than 45°." (EX1008, ¶¶27, 28).

As discussed above in Section VI.C.2.d, 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, ¶260). 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, ¶260).

d. Dependent Claim 7

As shown in Figures 3 and 4 below, the plate in Arnauld (10) is configured to substantially conform to a geometry of the respective first (phalanx P) and second (metatarsal M) discrete bones on which the plate is configured to be disposed. (EX1002, ¶¶261-262; EX1008, ¶16, claim 7, claim 9).

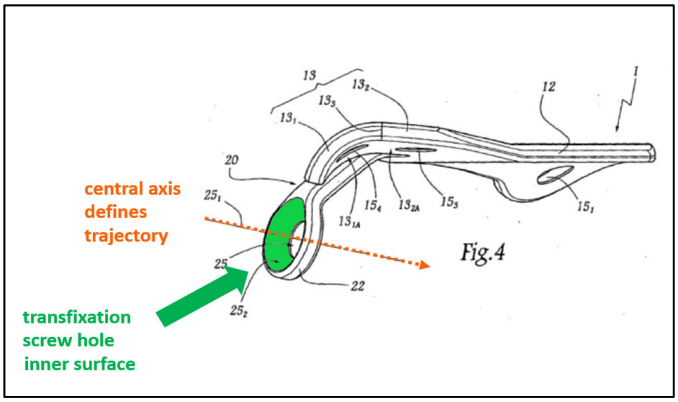


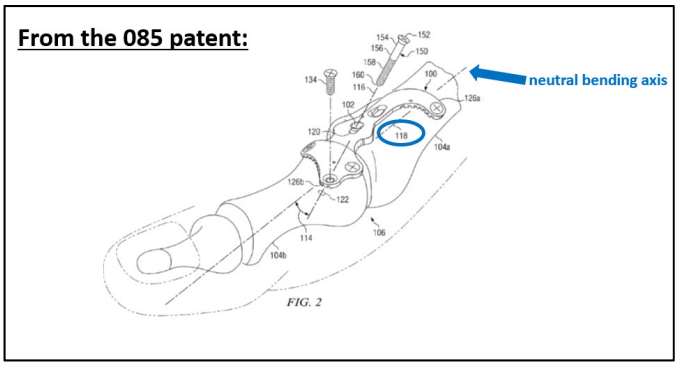
(EX1008 at Figs. 3, 4).

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). Arnauld also 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).

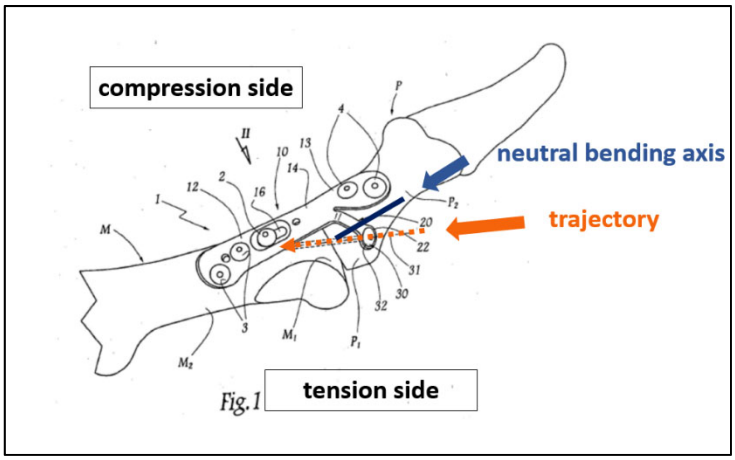
e. Dependent Claim 8

Arnauld includes a central axis (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, ¶¶263-268). Since Arnauld discloses a bone plate for use with the same metatarsophalangeal joint as pictured in Figure 2 of the 085 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 085 patent. (EX1002, ¶267; EX1001, Fig. 2; 6:4-10).





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, ¶268; EX1008, ¶¶26, 27; Figs. 1, 4).



(EX1008, Fig. 1).

f. Dependent Claim 9

As discussed in Section VI.D., Arnauld discloses a trajectory (axis 25_1) of transfixation hole (through-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 9. (EX1002, ¶¶269-274).

F. Ground 6: Dependent Claims 4 and 5 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 4 and 5, which recite that the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw (claim 4) and threaded to provide a locking interface with a transfixation screw (claim 5). For the reasons set forth below, dependent claims 4 and 5 are rendered obvious by Arnauld in view of Slater and Weaver. (EX1002, ¶¶275-283).

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 Section VI.B. 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. 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, ¶¶277-283; 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 4), as modified by Slater, to lockably engage a head of a transfixation screw as described in Weaver to ensure stability and to prevent screw back-out. (Ex. 1002, ¶282). For the same reason, it would have been obvious to a POSITA to thread the inner surface of the Arnauld transfixation screw hole (claim 5), as modified by Slater, to provide a locking interface with a transfixation screw as described in Weaver to ensure stability and to prevent screw back-out. (Ex. 1002, ¶283).

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 of the parent application, 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 085 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 in the parent application 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). Patent Owner filed a Terminal Disclaimer in the continuation application that issued as the 085 patent, and no further substantive review took place regarding the prior art. It appears that the Office was simply unaware that Slater and Arnauld disclose the limitations added by amendment in the parent application and carried over to the continuation

application, and had no opportunity to consider Falkner, which also discloses those limitations. (EX1006, ¶¶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 085 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 085 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. *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

[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).

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 1-9 of the 085 patent.

Respectfully submitted,

Dated: August 30, 2021

By: /s/ Sharon A. Hwang
Sharon A. Hwang (No. 39,717)
McANDREWS, HELD & MALLOY, LTD.
500 West Madison St., Suite 3500
Chicago, IL 60661
Telephone: (312) 775-8000

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 11,947, less than 14,000 words, as measured by Microsoft Word™.

Dated: August 30, 2021

/s/ Sharon A. Hwang
Sharon A. Hwang
Registration No. 39,717

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 10,245,085 (IPR2021-01453) 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
P.O. Box 1135
Chicago, IL 60690

An electronic courtesy copy was sent via email to:

Alan L. Barry
K&L Gates LLP
70 W. Madison Street, Suite 3100
Chicago, Illinois 60602
alan.barry@klgates.com

Counsel for OsteoMed in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821, and *OsteoMed LLC v. Wright Medical Technology, Inc.,* Case No. 1:20-cv-1621.

/s/ Sharon A. Hwang
Sharon A. Hwang
Registration No. 39,717