UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00487
U.S. PATENT NO. 9,078,713

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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MANDATORY NOTICES (37 C.F.R. §42.8(b))

A. Real Parties-In-Interest

The following are real parties-in-interest pursuant to 37 C.F.R. §42.8(b)(1):

- OsteoMed LLC
- Acumed LLC
- Colson Medical, LLC

Without conceding that the following would be determined to be real parties-in-interest under the governing legal standard, but for the purposes of identifying potential conflicts and analysis under 35 U.S.C. §315(b)[12], Petitioner identifies the following additional parties that may be relevant to the determinations:

- Marmon Holdings, Inc.
- Berkshire Hathaway Inc.

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[1] *See Proppant Express Investments, LLC v. Oren Techs., LLC*, Case IPR2017-01917, Paper 86 at 14-15 (Feb. 13, 2019) (precedential).

[2] None of these identified parties are subject to any time bar for the filing of an *inter partes* review petition, such that a determination as to their actual status as a real party-in-interest is not necessary. Nevertheless Petitioner has listed them out of an abundance of caution.

B. Related Matters

Patent Owner, Stryker European Operations Holdings LLC, along with its exclusive licensee, Howmedica Osteonics Corp., and parent corporation, Stryker Corp., asserted U.S. Patent No. 9,078,713 ("the '713 Patent") in the following litigation:

- *OsteoMed LLC v. Stryker Corp. et al.*, Case No. 1:20-cv-06821 (N.D. Illinois) ("NDIL Action").

The following patents are being asserted by Patent Owner in the NDIL Action:

- U.S. Patent No. 9,168,074; and
- U.S. Patent No. 10,993,751 (related to the '713 Patent).

Petitions for *Inter Partes* Review have been filed for the above-referenced patents in the following matters (collectively with this proceeding, the "OsteoMed IPRs"):

- IPR2022-00486; and
- IPR2022-00488.

The following related patent applications are currently pending before the United States Patent and Trademark Office ("USPTO"):

- Ser. No. 16/429,834.

C. Lead and Backup Counsel and Service (37 C.F.R. §42.8(b)(3)-(4))

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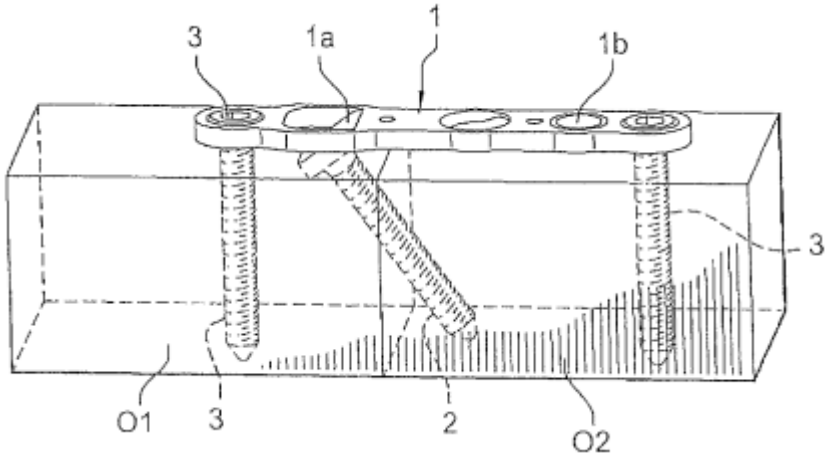
Petitioner consents to electronic service by email.

I. INTRODUCTION

Petitioner requests institution of *Inter Partes* Review ("IPR") of claims 32-39 ("Challenged Claims") of the '713 Patent (Ex. 1001) and subsequent cancellation of the same, in view of the Grounds described below. This Petition is supported by the declaration of Michael Sherman, an expert in the field of the '713 Patent and the prior art. (Ex. 1002).

II. '713 PATENT OVERVIEW

The '713 Patent was filed on September 9, 2013, and issued on July 14, 2015. (Ex. 1001, Cover). The '713 Patent describes and claims a method for performing arthrodesis or the surgical procedure of fusing a bone joint with a bone plate. (*Id.*, Abstract, cl. 32). Specifically, the '713 Patent claims a "method of fusing a joint … spanning first and second bones separated by a joint with a bone plate, … wherein the third fixation member is the only fixation member extending across the joint." (Ex. 1001, cl. 32). Figure 3 shows an exemplary application of a bone plate 1 that spans across the joint between a first bone O1 and second bone O2, fused by a third fixation member 2 that is the only fixation member that extends across the joint:



(Ex. 1001, FIG. 3; *see also* 2:8-17; 5:1-19).

As set forth in this Petition, the '713 Patent fails to add anything to the then-existing state of the art, and merely describes known techniques for securing a compression bone plate and fusing the joint between two bones. (Ex. 1002, ¶¶34-40, 49-54).

A. Prosecution History of the '713 Patent

The application leading to the '713 Patent, Application No. 14/041,706, was filed September 9, 2013, claiming the priority to foreign application FR0856694A, that was filed on October 2, 2008. During the prosecution of the '713 Patent, the Examiner rejected independent claim 32 under §102 in a Non-Final Office Action prior to allowing the application. (Ex. 1003, 132-33). Specifically, the Non-Final Office Action rejected claims 33 and 35 (allowed claims 32 and 34) under §102 as being anticipated by Aikins (U.S. Pat. Application Pub. No. US 2003/0040748) (Ex. 1009) and claims 34 and 36-40 (allowed claims 33 and 35-39) under §103 as obvious

over Aikins in view of U.S. Pat No. 4,988,350. (Ex. 1003, 133-38).

Following the Non-Final Office Action, Applicants requested an Examiner Interview and proposed claim amendments. (Ex. 1003, 190). The proposed amendment included changes to independent claim 33 (allowed claim 32) to add the claim element "so that a free end of the third fixation member, ***not attached to any portion of the plate***, resides in the second bone and a head of the third fixation member is seated in the third hole." (Ex. 1003, 204).[3] The proposed amendment was designed to differentiate the '713 Patent from a portion of Aikins:

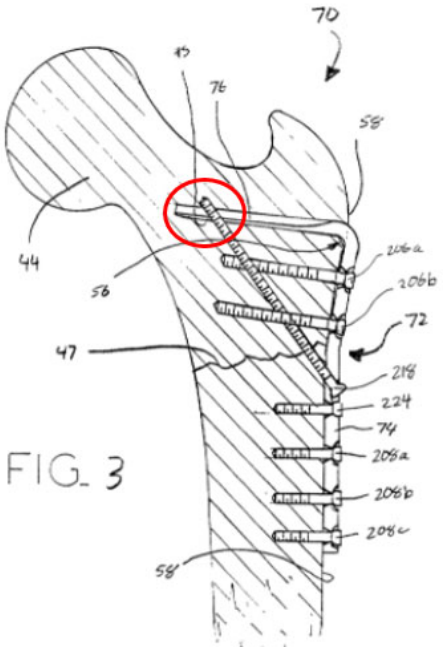


FIG. 3

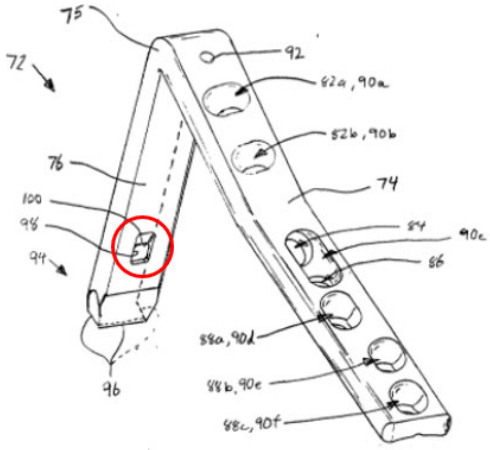


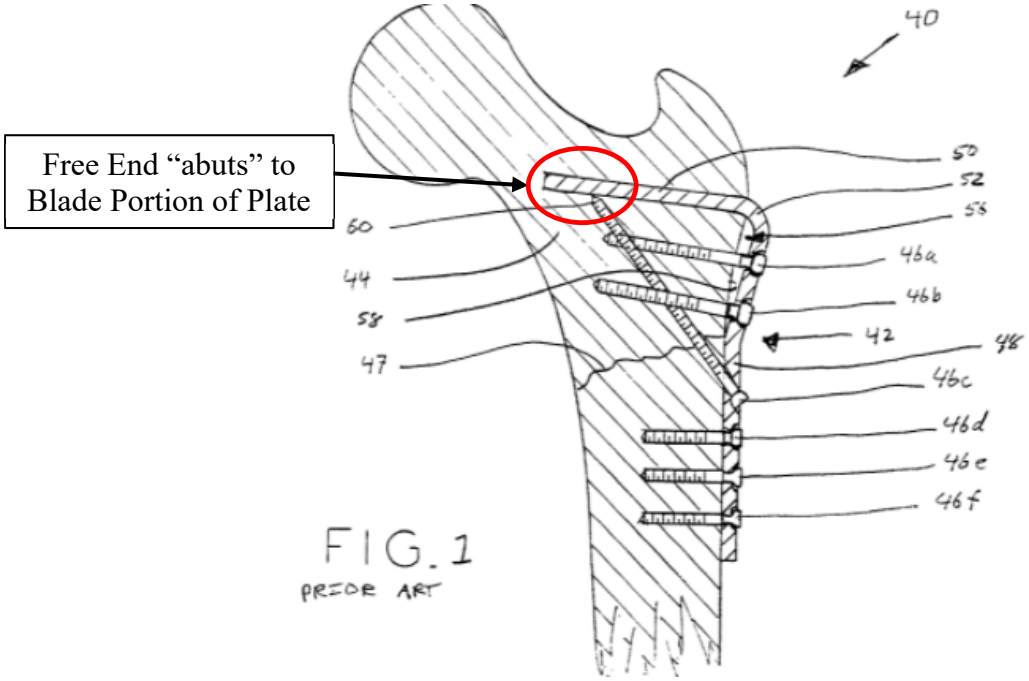
FIG. 4

(Ex. 1009, FIGS. 3 and 4; *see also* ¶¶61-63). Specifically, the free end of the fixation member 218 (strut screw) in Aikins 100 engages ledge 100 of blade hole 98 in bone

[3] All emphasis added unless otherwise indicated.

plate 76 (blade portion of blade plate 72). (*Id.*; *see also* ¶84, FIG. 25).

Based on the proposed amendment, Applicant and Examiner reached an agreement on allowable subject matter, and claims 32-39 were allowed. (Ex. 1003, 212). However, it should be noted that Figure 1 of Aikin discloses a prior art embodiment that still reads on the amended language—wherein the free end 60 of trans-fixation member 46c abuts, but is not attached, to the blade portion 50 of the plate assembly 40:



(Ex. 1009, FIG. 1 (annotated); *see also* ¶60).

B. '713 Patent Priority

The '713 Patent claims priority to foreign application FR0856694A, through intervening Application Nos. 12/918,071 and PCT/FR2009/051879. (Ex. 1001,

Cover). Application No. 12/918,071 was filed on October 29, 2010, now U.S. Pat No. 8,556,946, as a continuation application of National Stage application PCT/FR2009/051879. The National Stage application PCT/FR2009/051879 was filed on October 2, 2009, which in turn claimed prior to foreign application FR0856694A, which was filed on October 2, 2008. However, for the purposes of this Petition, no determination as to intervening priority need be made; all of the prior art relied upon herein is prior art to the earliest U.S. filing date of October 2, 2009. (Ex. 1003, 37). All references herein to 35 U.S.C. §§102-103 are to the pre-AIA versions thereof which apply to the Challenged Claims.

III. GROUNDS FOR STANDING (37 C.F.R. §42.104(a))

Petitioner certifies that (1) the ’713 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting an IPR on the Grounds identified herein; and (3) Petitioner has not filed a complaint relating to the ’713 Patent.

IV. PAYMENT OF FEES (37 C.F.R. §§42.15 and 42.103)

Petitioner authorizes the USPTO to charge any required fees to Deposit Account 02-1818.

V. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to know the relevant prior art and has ordinary creativity when

interpreting and combining prior art. *In re Coutts*, 726 F. App'x 791, 796 (Fed. Cir. 2018); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007).

With respect to the '713 Patent, a POSITA as of October of 2009, had, among other attributes, a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and had approximately three years of experience with orthopedic implant design. (Ex. 1002, ¶¶55-56). Such a POSITA would have had knowledge of design considerations known in the industry and would have been familiar with then-existing products and solutions. (Ex. 1002, ¶34-40, 57). A POSITA would have been familiar with orthopedic implants, bone plates, and intramedullary implants. (*Id.*).

VI. CLAIM CONSTRUCTION

For purposes of this proceeding, Petitioner believes no terms need to be construed as the prior art utilizes substantially the same language such that, under any construction of the terms of the Challenged Claims, the claims are unpatentable. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Petitioner reserves its right to respond to any unforeseeable claim constructions Patent Owner may advance.

VII. STATEMENT OF PRECISE RELIEF REQUEST AND REASONS THEREFORE

Petitioner requests the institution of IPR and the cancellation of the Challenged Claims on the following Grounds:

Ground	Basis	Reference(s)	Claim(s)
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater (Ex. 1004)	32, 33, 36, 37
2	§103	Slater and U.S. Pat. Pub. No. 2006/0241608 to Myerson et al. ("Myerson") (Ex. 1008)	34, 35, 39
3	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	32, 33, 38
4	§103	E.P. Patent 1897509 to Arnould ("Arnould") (Ex. 1005) and Zahiri	32, 33, 36-39
5	§103	Arnould, Zahiri, and Myerson	34, 35

A. The Petition Should Not Be Discretionarily Denied

1. *Becton, Dickinson*

The claims of the '713 Patent have not been considered in view of any of the prior art relied upon in the asserted grounds of this Petition. Accordingly, the present Petition should not be discretionarily denied under 35 U.S.C. §325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

2. *Fintiv*

The Board should not deny this Petition in view of 35 U.S.C. §314(a). *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020), sets forth six factors to consider in a discretionary denial under 35 U.S.C. §314(a). When assessed holistically, these six factors do not warrant discretionary denial.

First, Petitioner is going to file a motion to stay the NDIL Action in view of and as it relates to the OsteoMed IPRs. The motion to stay will be filed before the deadline set forth in Northern District of Illinois Local Patent Rule 3.5(b). And the Northern District of Illinois has granted, at least in part, approximately 73 percent of motions to stay in view of *inter partes* AIA proceedings. (Ex. 1012, 1-2). Thus, factor 1 favors not exercising discretionary denial.

Second, there is no trial date presently set for any litigation involving the '751 Patent. Thus, factor 2 favors not exercising discretionary denial.

Third, the parties have made some investment in the district court litigation, but discovery is still open and the claim construction hearing is not yet scheduled and likely will not occur until after an institution decision comes out. Thus, factor 3 weighs in favor of institution.

Fourth, the merits of the arguments presented to the Board here strongly warrant consideration, thus weighing factor 6 in favor of institution.

The remaining factors (4 - overlap of issues, and 5 - same parties) are seemingly neutral and do not outweigh the benefits of instituting.

Balancing these factors holistically, the Board should not exercise its discretion to deny this Petition.

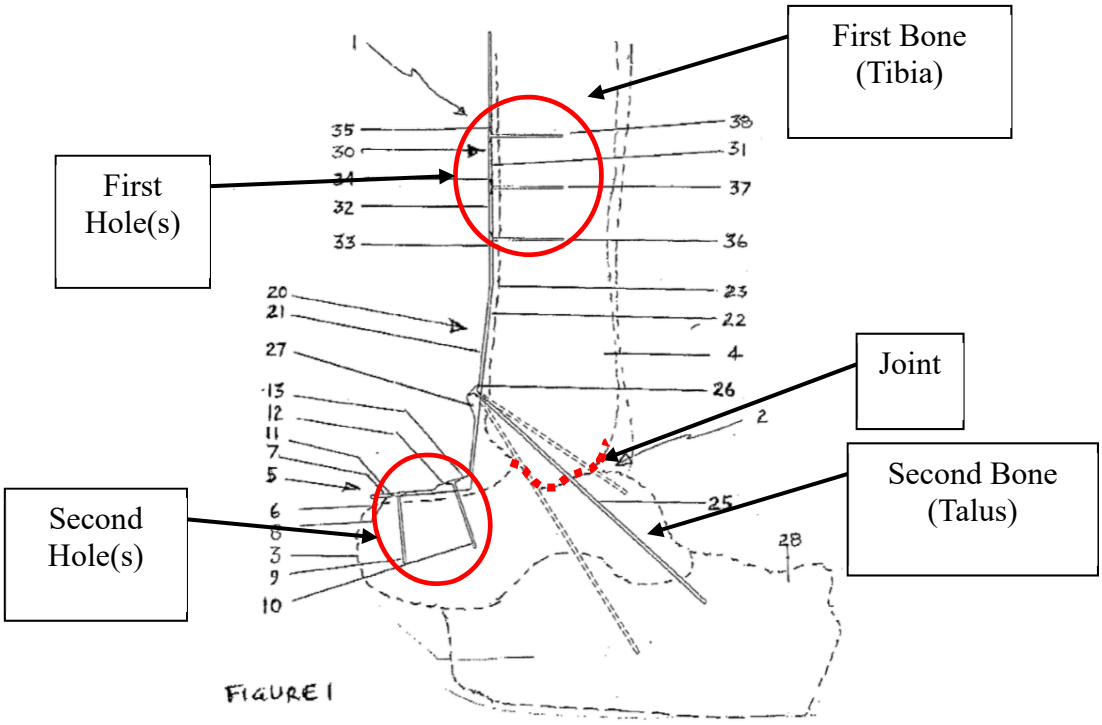
B. Overview of Prior Art

The Challenged Claims merely represent a collection of known components modified or combined according to known methods to yield predictable results, and are therefore obvious under 35 U.S.C. §103. (*See, e.g.*, Ex. 1002, ¶¶84, 145, 168, 197, 248).

1. Slater (Ex. 1004)

Slater is a WIPO patent application that published on November 22, 2007. (Ex. 1004, Cover). Slater qualifies as prior art under §102(b) as it is a printed publication more than one year prior to October 2, 2009, the date of the application for the ’713 Patent in the United States.

Slater discloses a fusion plate for arthrodesis of the joint between the tibia and the talus bone. (Ex. 1004, 11:1-16). Slater’s bone plate comprises a first portion that attaches to the tibia, a second portion that attaches to the talus, and an angled fixation screw that compresses the joint, as shown in Figure 1:



(Ex. 1004, FIG. 1 (annotated); *see also* Ex. 1002, ¶¶58-60).

2. Arnould (Ex. 1005, Ex. 1006)

Arnould published on March 12, 2008. (Ex. 1005, cover). Arnould qualifies as prior art under §102(b) as it is a printed publication more than one year prior to October 2, 2009, the date of the application for the '713 Patent in the United States. Arnould was originally filed in French (*see* Ex. 1005) and a certified translation to English is provided with this Petition (*see* Ex. 1006).

Arnould discloses the arthrodesis of the metatarsal-phalangeal (MTP) joint through the use of a bone plate that straddles the joint and permanently locks the joint in place. (Ex. 1006, ¶¶1-2). A bone plate implanted in the foot is subject to frequent stress from walking and may weaken over time. (Ex. 1006, ¶6). To mitigate

this effect, a screw is positioned through a tab (extension) of the plate and across the joint. (Ex. 1006, ¶26). The screw "has a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone," thus providing a more stable plate over time. (Ex. 1002, ¶¶61-65; Ex. 1006, ¶6).

3. Zahiri (Ex. 1007)

Zahiri is a U.S. patent that issued on May 29, 2012 from an application filed September 26, 2006. (Ex. 1007, Cover). Zahiri qualifies as prior art under §102(e).

Zahiri discloses a bone plate 14 configured to fuse a bone fracture 6 with a lag screw 20 that crosses the fracture line 6 at an angle of 90°, 150°, 160° (20°, 30°, or 90°), as illustrated in Figure 1:

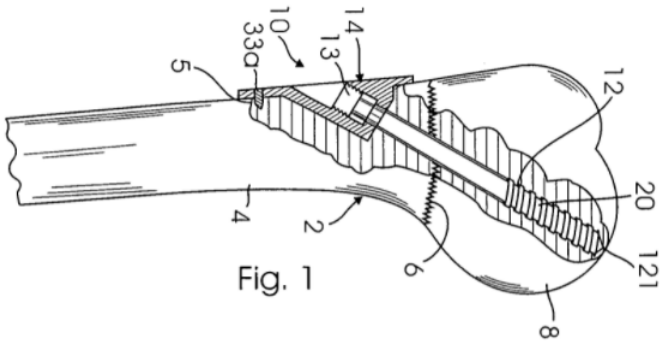


Fig. 1

(Ex. 1007, FIG. 1; *see also* 3:59-67). The bone plate further comprises a plurality of pins that are designed to temporarily lock into the holes of the plate and partially penetrate into the bone segment. (Ex. 1007, 3:11-18). The temporary locking design for the pins provides a user-friendly condition that allows a surgeon to place the device. (Ex. 1002, ¶¶66-70; Ex. 1007, 3:11-18).

4. Myerson (Ex. 1008)

Myerson is a U.S. patent application that published on October 26, 2006. (Ex. 1008, Cover). Myerson qualifies as prior art under §102(b).

Myerson discloses a bone plate for joint fusion of the metatarso-phalangeal (MTP) joint in the foot. (Ex. 1008, FIG. 1; ¶2). The bone plate is contoured to follow the anatomy of metatarsal bone and phalanx and engage with the curved surfaces of the bone. (Ex. 1008, ¶10; Ex. 1002, ¶¶71-74).

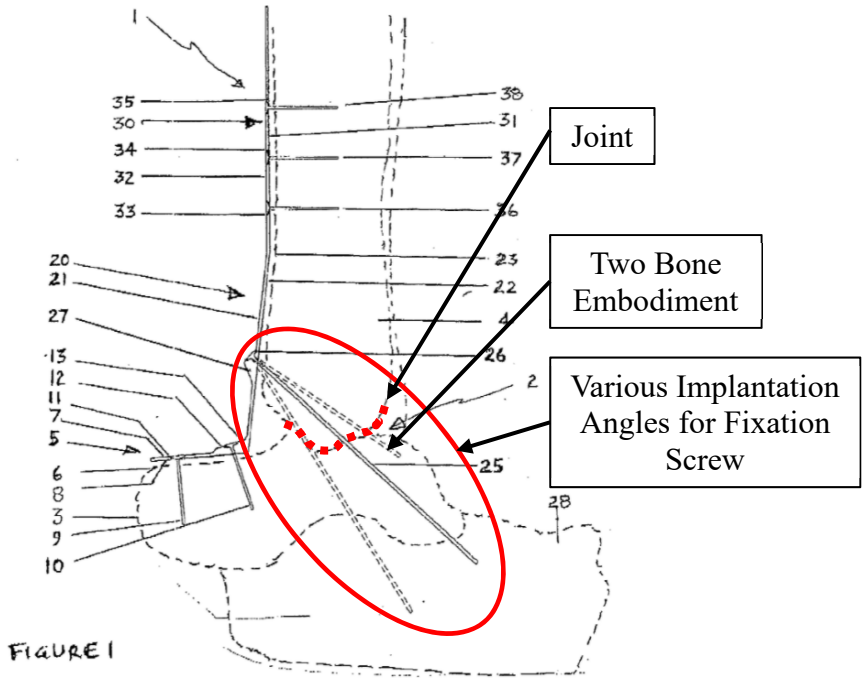
C. Ground 1: Claims 32, 33, 36 and 37 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Slater

Independent claim 32 and dependent claims 33, 36 and 37 are obvious in view of Slater. (Ex. 1002, ¶¶78-84).

1. Basis for Obviousness in view of Slater

The scope and content of the prior art includes Slater and the technical expertise of a POSITA, which collectively disclose all of the elements of claims 32, 33, 36, and 37. There are no differences between the subject matter of these claims and the combination of Slater and the technical expertise of a POSITA.

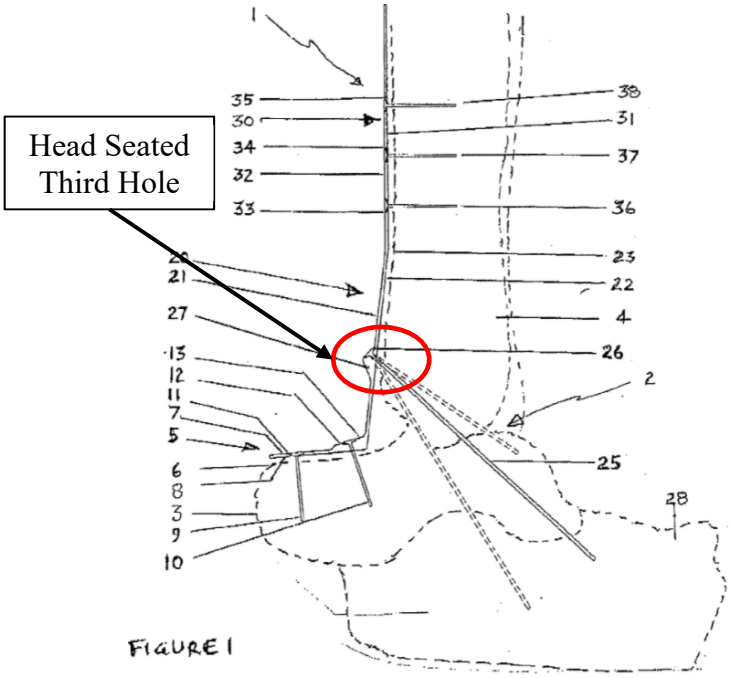
Slater discloses a bone plate comprising a fixation screw that is placed at an angle so that it compresses the ankle joint and intersects the tibia, talus, and potentially the calcaneus:



(Ex. 1004, FIG. 1 (annotated); *see also* 6:14-28, 11:18-27). Slater's bone plate comprises a predetermined allowable angle range of the fixation screw 25, as depicted by the three possible angles in Figure 1, and discloses that a key advantage of the bone plate is the ability for the fixation screw to be configured at multiple angles and "incorporate more joints into the arthrodesis as required." (Ex. 1004, 16:25-17:12). Therefore, a POSITA would understand that Slater discloses an embodiment where the fixation screw 25 configured to intersect a joint through two discrete bones. (Ex. 1002, ¶¶79-84).

A POSITA would recognize that fixation screw 25 is configured to develop compression across the joint intended to be fused, and that the head of the fixation screw 25 is seated in the third opening 26 in formation 27. (*See* Ex. 1004, 6:14-21;

see also 12:23-25 ("Opening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation."); Ex. 1002, ¶82). Figure 1 depicts the fixation screw 25 in a recessed position in opening 26, and that it enters the bone plate through opening 26 in formation 27 and anchors into the bone within a predetermined range of angles:



(Ex. 1004, FIG. 1 (annotated); ¶¶57, 63; Ex. 1002, ¶83). Thus, a POSITA would understand that the fixation screw 25 (third fixation member) is seated in the third hole (opening 26), crosses a joint between two bones, is the only fixation element in the second bone and does not contact the bone plate. (Ex. 1002, ¶83).

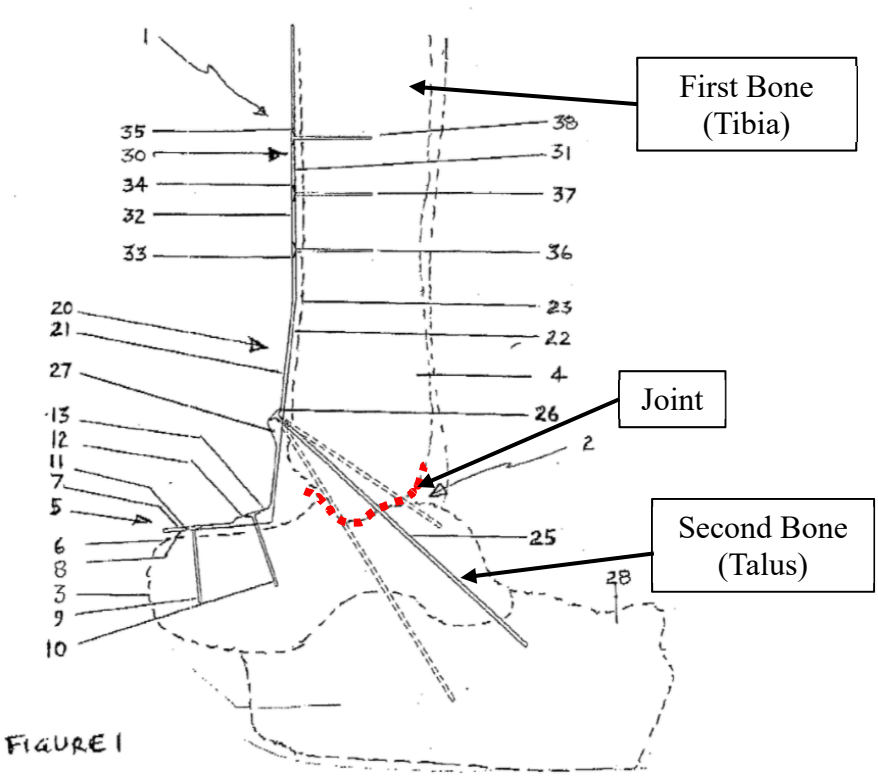
Accordingly, based on the teachings of Slater and knowledge of the art, a POSITA would find claims 32, 33, 36, and 37 obvious. (Ex. 1002, ¶84).

2. Claims 32, 33, 36 and 37 are Obvious in view of Slater

a. *Independent Claim 32*

i. [32Pre] A method of fusing a joint, the method comprising:

Slater discloses an arthrodesis fusion plate to fuse the anterior ankle joint between the tibia (first discrete bone) and the talus (second discrete bone), as shown in Figure 1:



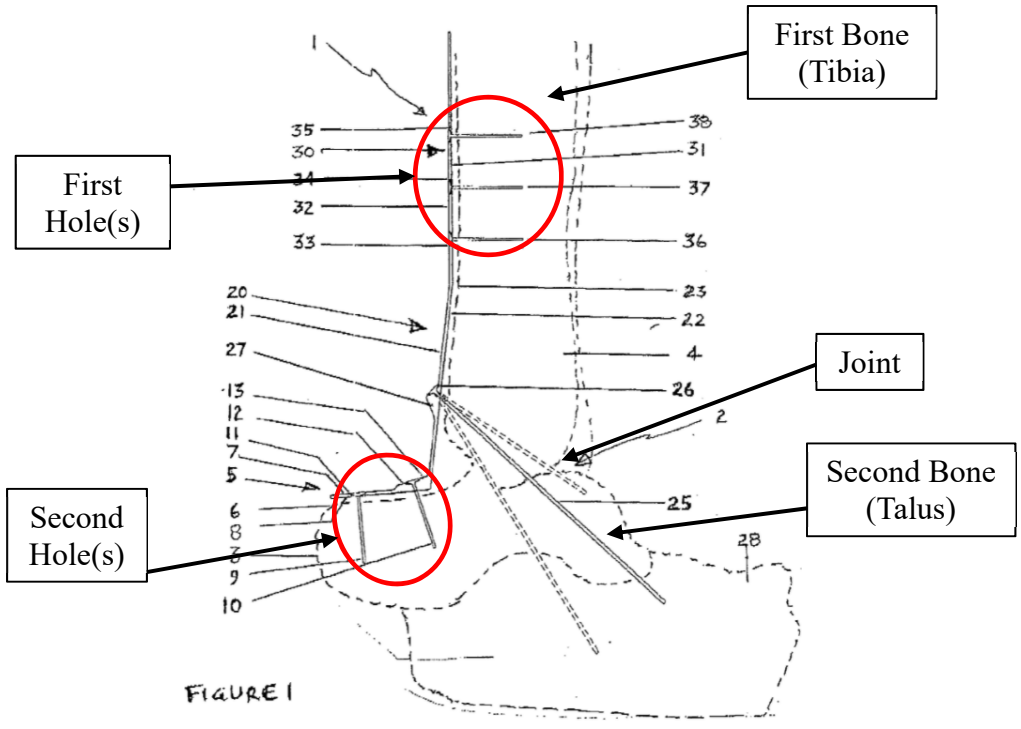
(Ex. 1004, FIG. 1 (annotated); *see also* 1:6-7 ("The present invention relates to prosthetic devices and more particularly relates to an ankle fusion plate for fusion of the anterior ankle."); 6:14-28; 8:13-24).

Thus, Slater discloses a plate that is used to perform the claimed method of

joint fusion. (Ex. 1002, ¶¶85-89).

ii. [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

Slater's bone plate is configured to fuse the joint between the tibia (first bone) and the talus (second bone) and comprises a first portion 30 and third portion 5, where the first portion 30 attaches to the anterior surface 23 of the tibia (via a screw through a first hole) and the third portion 5 attaches to the anterior surface 6 of the talus (via a screw through a second hole):

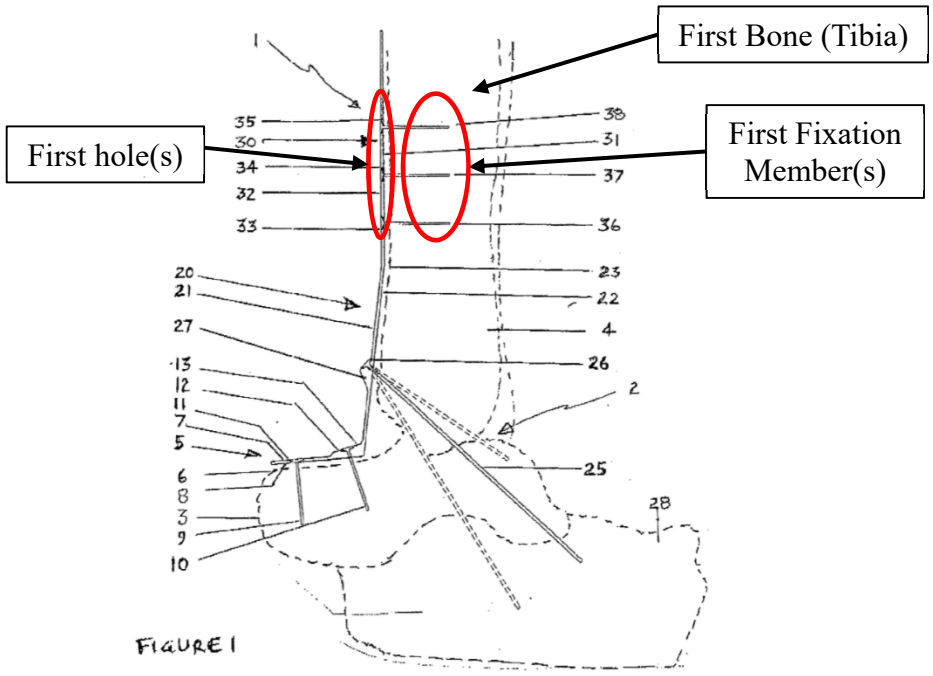


(Ex. 1004, FIG. 1 (annotated); *see also* 6:14-28, 8:13-24, 11:5-10, 11:18-19, 13:5-18).

Thus, Slater discloses this element. (Ex. 1002, ¶¶90-92).

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

Slater's bone plate is configured to receive one or more screws (first fixation member) at an opening (first hole) in the first portion 30 of the plate into the first bone (tibia) of the joint:



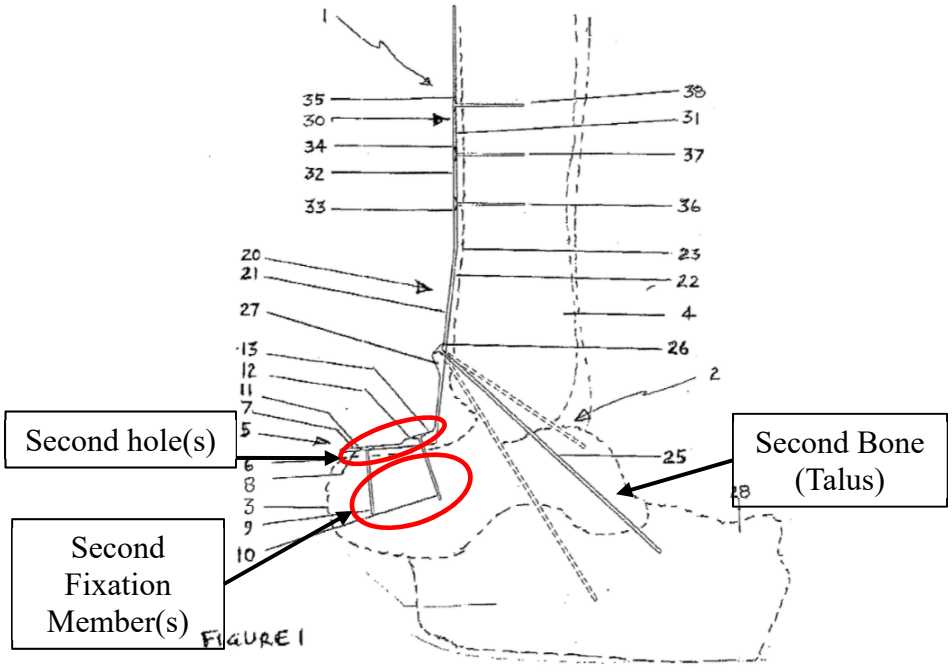
(Ex. 1004, FIG. 1 (annotated); *see also* 8:13-24 ("The first portion includes at least one opening including a formation which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region.")). Portion 30 aligns with the anterior surface 23 of the tibia (first

bone). (Ex. 1004, 11:18-19, 11:28-12:2; *see also* 8:13-24 ("Preferably the inner surface of the first portion of the plate opposes the anterior tibia.")).

Thus, Slater discloses this element. (Ex. 1002, ¶¶93-95).

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

Slater's bone plate is configured to receive one or more screws at the third portion 5 of the plate through an opening (second hole) into the second bone (talus) of the joint:



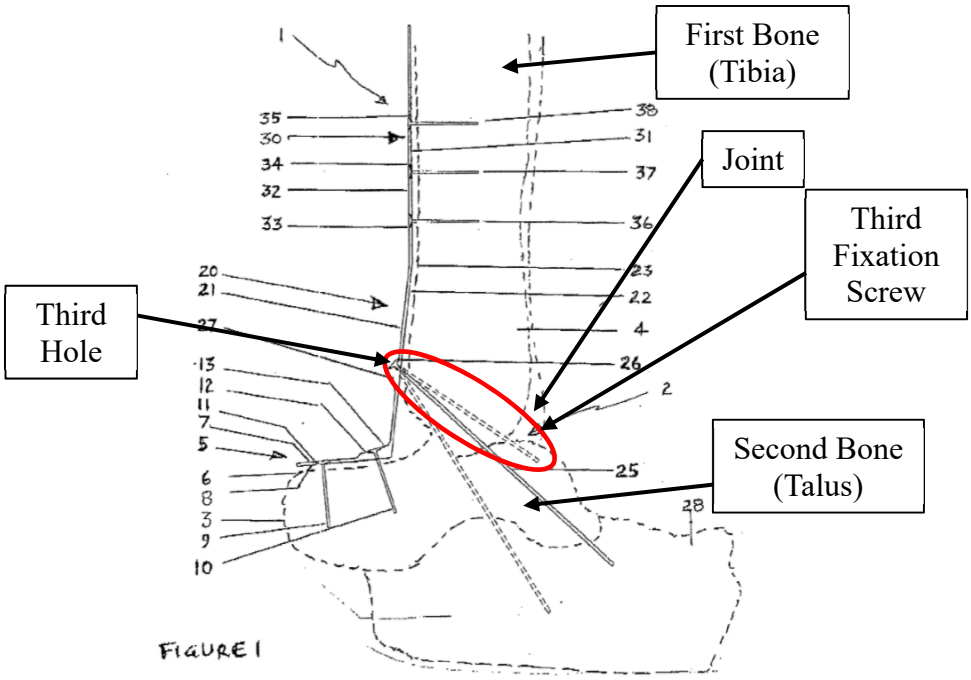
(Ex. 1004, FIG. 1 (annotated); *see also* 8:13-24 ("The third portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the Talus.")). The opening at portion 30 allows the bone screw

(second fixation member) to implant into the talus (second bone). (Ex. 1004, 8:13-24, 11:1-16).

Thus, Slater discloses this element. (Ex. 1002, ¶¶96-98).

v. [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and

Slater's bone plate comprises opening 26 (third hole) configured to receive fixation screw 25 (third fixation member) and engage with the tibia and the talus at a predefined angle according to formation 27:



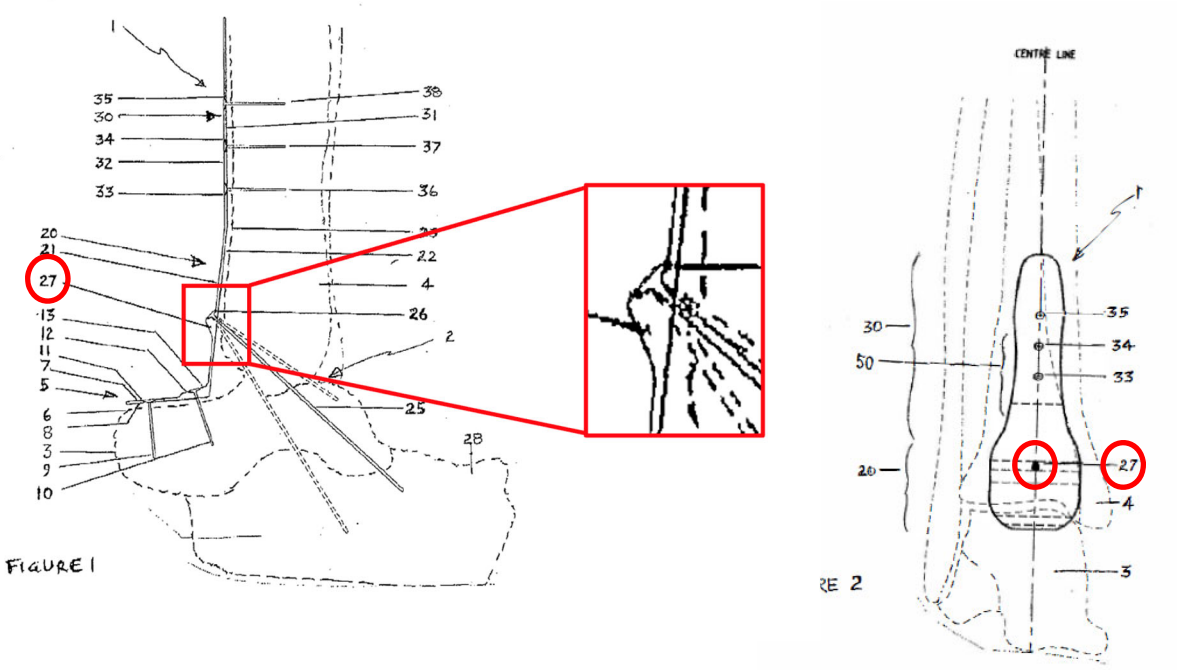
(Ex. 1004, FIG. 1 (annotated); *see also* 11:18-27 ("Disposed in portion 20 is fixation screw 25 which passes through opening 26 in formation 27. Formation 27 is

configured so that screw 25 is implanted at an angle within a predetermined allowable angular range. The allowable range will preferably be within a 40 degree arc. Screw 25 engages tibia 4, talus 3, and calcaneus 28 effectively providing three points of fixation according to this embodiment."). Thus, if the fixation screw 25 (third fixation member) is inserted into opening 26 (third hole) at the angle circled in red in the above image of Figure 1, it would pass through the tibia (first bone), the joint, and into the talus (second bone), such that fixation screw 25 resides in the second bone and the free end does not attach to any portion of the plate. (Ex. 1002, ¶¶100-01). Moreover, while Slater discloses three specific angles and two discrete lengths of screws in Figure 1, a POSITA would know that surgeons are typically provided with a variety of screw lengths when preparing to implant a plate such as Slater's, and that because of the variability of angles permitted by the disclosed plate, a shorter screw that only passes through two bones would be used for fusing one joint, and that the free end would not engage any portion of the plate. (Ex. 1002, ¶102).

Thus, a POSITA would find this element disclosed by Slater. (Ex. 1002, ¶99-103).

vi. [32e] a head of the third fixation member is seated in the third hole,

Slater's bone plate discloses the need to maintain the integrity of the screw bone interface, through the cooperation of the fixation screws and the screw insertion hole. (*See* Ex. 1004, 5:28-31 ("Proper plate fixation relies on the integrity of the screw bone interface, screw insertion angle, screw tightness and effective co operation between screw head and the screw insertion hole."); *see also* 6:3-9). Figures 1 and 2 show depth to opening 26 in formation 27 to allow for the screw head to be countersunk, or seated below the plate:



(Ex. 1004, FIGS. 1, 2 (annotated)). Slater specifically describes that "[o]pening 27 which is also preformed, receives a countersink screw which is allowed adjustable

orientation." (Ex. 1004, 12:23-25). In addition, Figures 5 and 7 show there is depth to formation 94 such that the head of a fixation screw is seated in the plate:

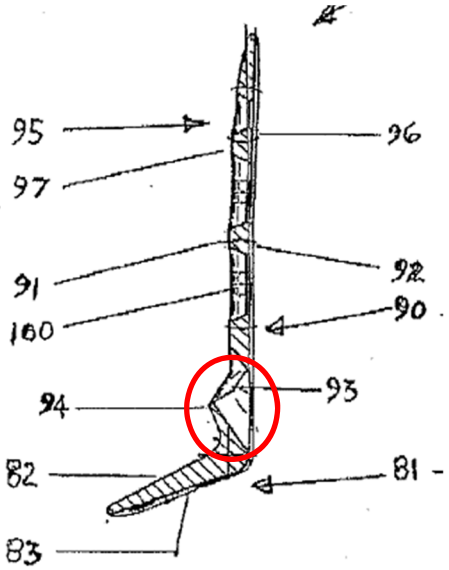


FIGURE 5

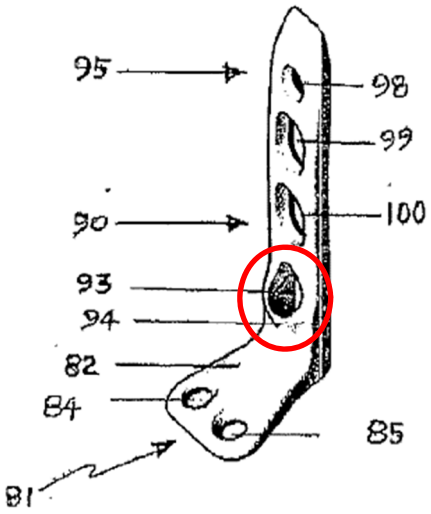


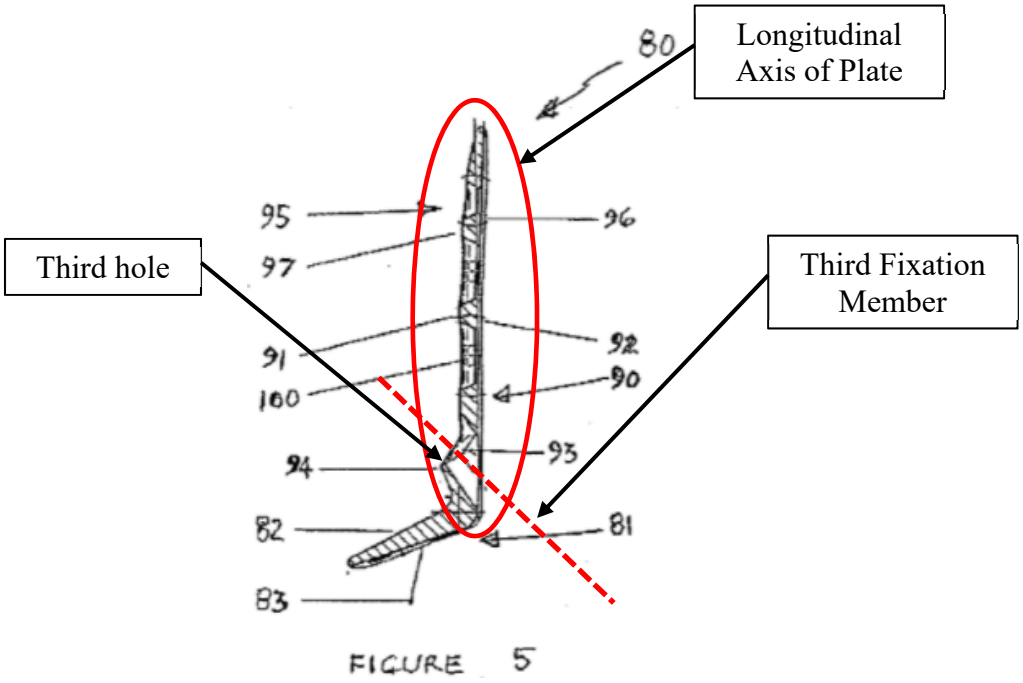
FIGURE 7

(Ex. 1004, FIGS. 5, 7 (annotated); *see also* 13:21-24 ("Disposed in portion 90 is a fixation screw which passes through opening 93 in formation 94. Formation 94 is configured so that a fixation screw is directed at an angle within a predetermined allowable angular range.").

Thus, a POSITA would find this element disclosed by Slater. (Ex. 1002, ¶¶104-09).

vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

Slater discloses an angled fixation screw 25 (third fixation member) configured to pass through opening 93 (third hole) in formation 94, such that the fixation screw is directed at a predetermined allowable angle range:



(Ex. 1004, FIG. 5 (annotated); *see also* FIG. 1, 13:20-25). Figure 5 shows a longitudinal cross section of the bone plate relative to angle formation 94. (Ex. 1004, FIG. 5). A POSITA would understand that the opening 93 is a third hole that is angled relative to a longitudinal axis of the plate and the third fixation member passes through the plate through opening 93. (Ex. 1002, ¶¶110-11).

Additionally, the section of the plate that contains opening 93 is thicker than the rest of the plate:

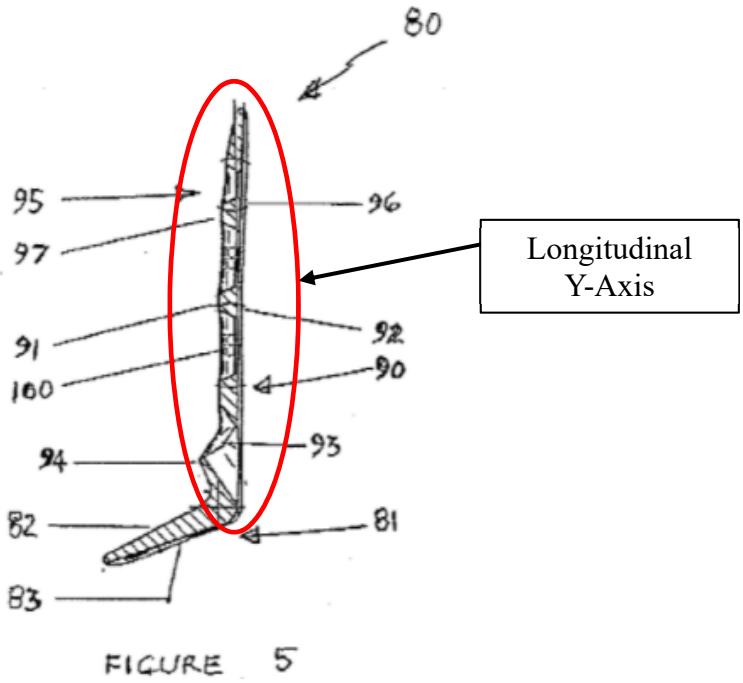


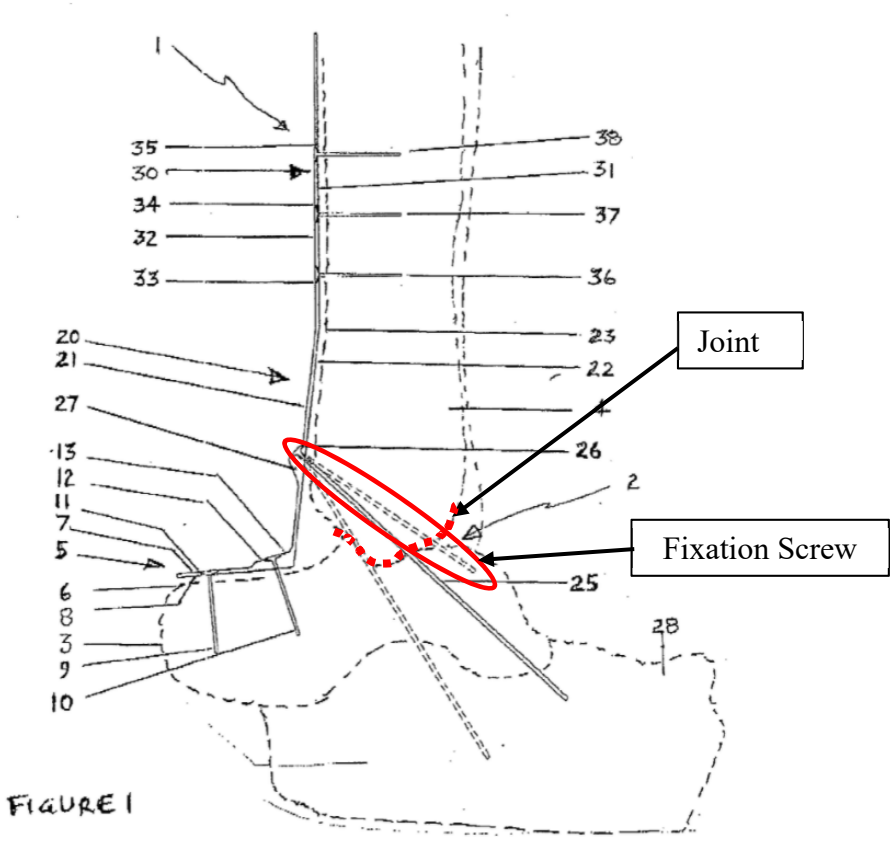
FIGURE 5

(Ex. 1004, FIG. 5 (annotated); *see also* 8:25-9:19 ("the plate depth changes at different locations. Preferably, the depth at the beginning arid end points of the L shaped contour over the ankle joint in the second region will be at it's maximum thickness."). Slater explains further that "[t]he depth and the beginning and end points of the generally L shaped contour over the ankle joint formed by portions 81 and 90 will be the maximum thickness as it is at this region that the highest loading will occur in normal use," indicating that the thickness is in the middle. (Ex. 1004, 14:19-22; Ex. 1002, ¶¶112-13).

Thus, a POSITA would find this element disclosed by Slater. (Ex. 1002, ¶¶114-15).

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

Figure 1 of Slater shows formation 27 configured to receive angle fixation screw 25 at an angle range such that fixation screw 25 is the only screw that passes through the joint between the tibia and the talus:



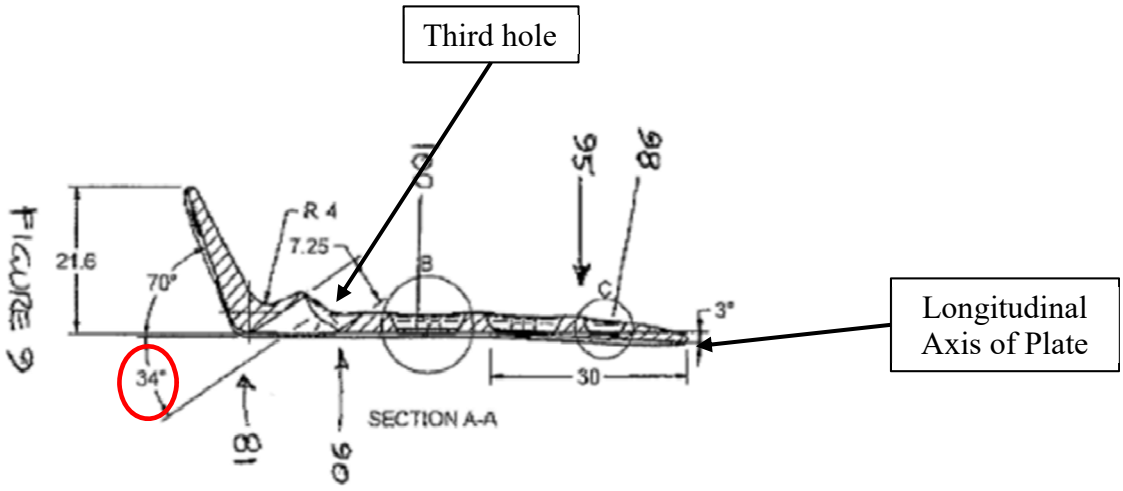
(Ex. 1004, FIG. 1 (annotated); *see also* 11:18-27).

Thus, Slater discloses this element. (Ex. 1002, ¶¶116-18).

b. *Dependent Claims 33, 36 and 37*

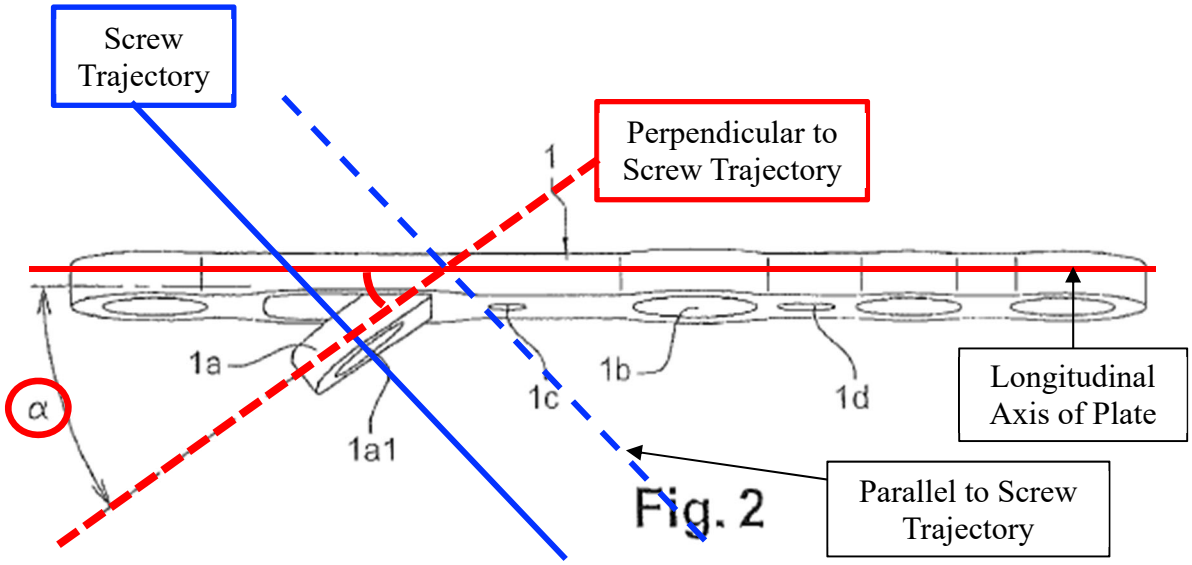
i. Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

Slater's bone plate comprises a formation 94 that has an angled opening 93 (shown as 34°) such that a fixation screw 25 is angled in relation to the axis of hole 93:

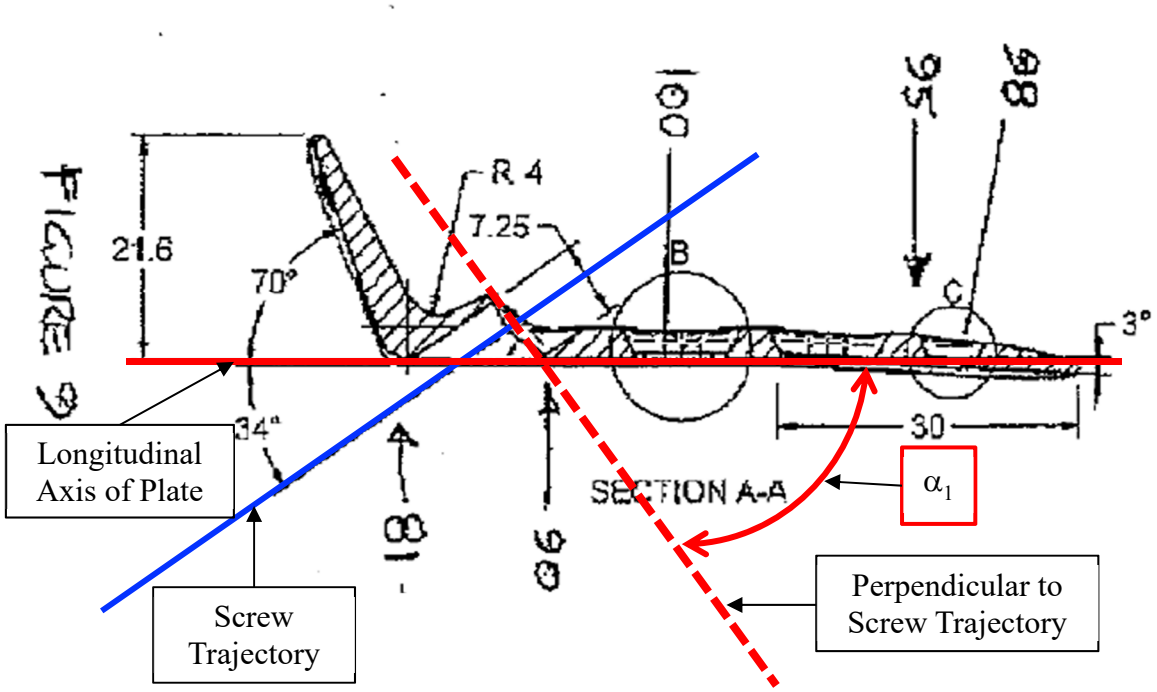


(Ex. 1004, FIGS. 9 (annotated); *see also* 11:18-27 ("Formation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range. The allowable range will preferably be within a 40 degree arc.")). A POSITA would understand that the disclosed angle in Slater would need to be converted into an analogous format so it may be compared directly to the claimed angle "α" disclosed by the '713 Patent. (Ex. 1002, ¶¶119-20). In the '713 Patent, α is defined

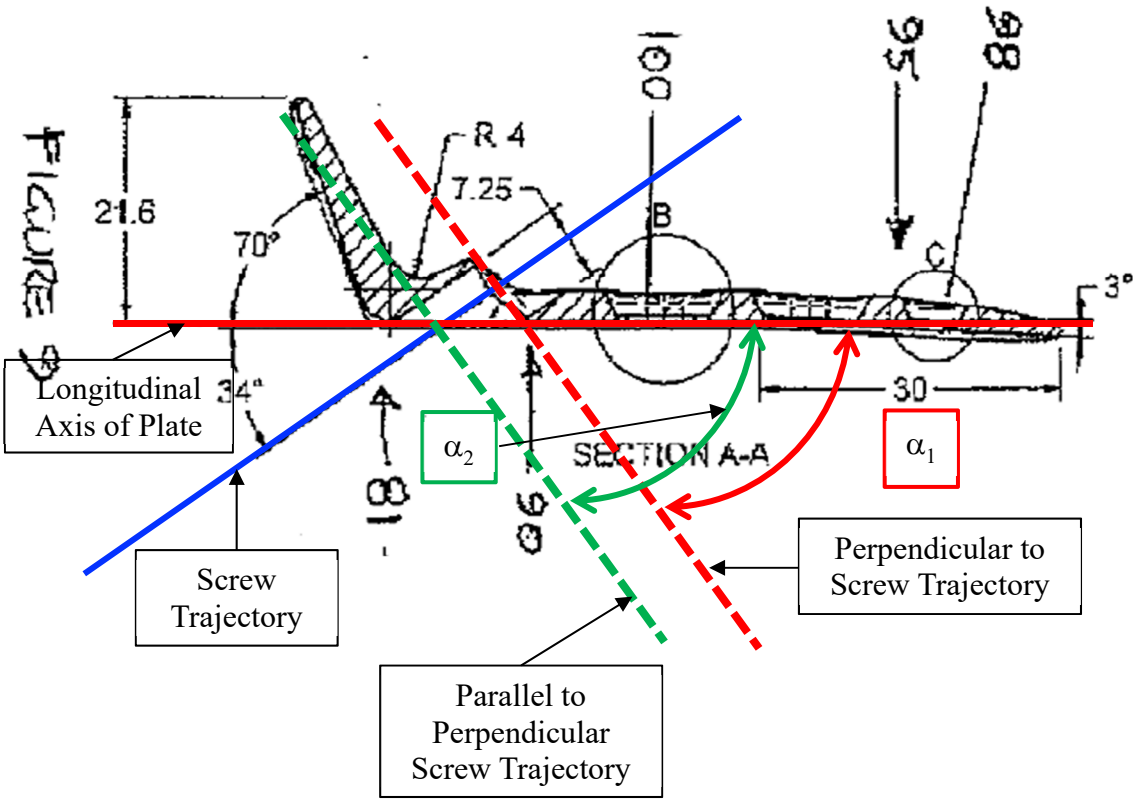
as the acute angle between the longitudinal axis of the plate and the plane that is perpendicular to the screw trajectory:



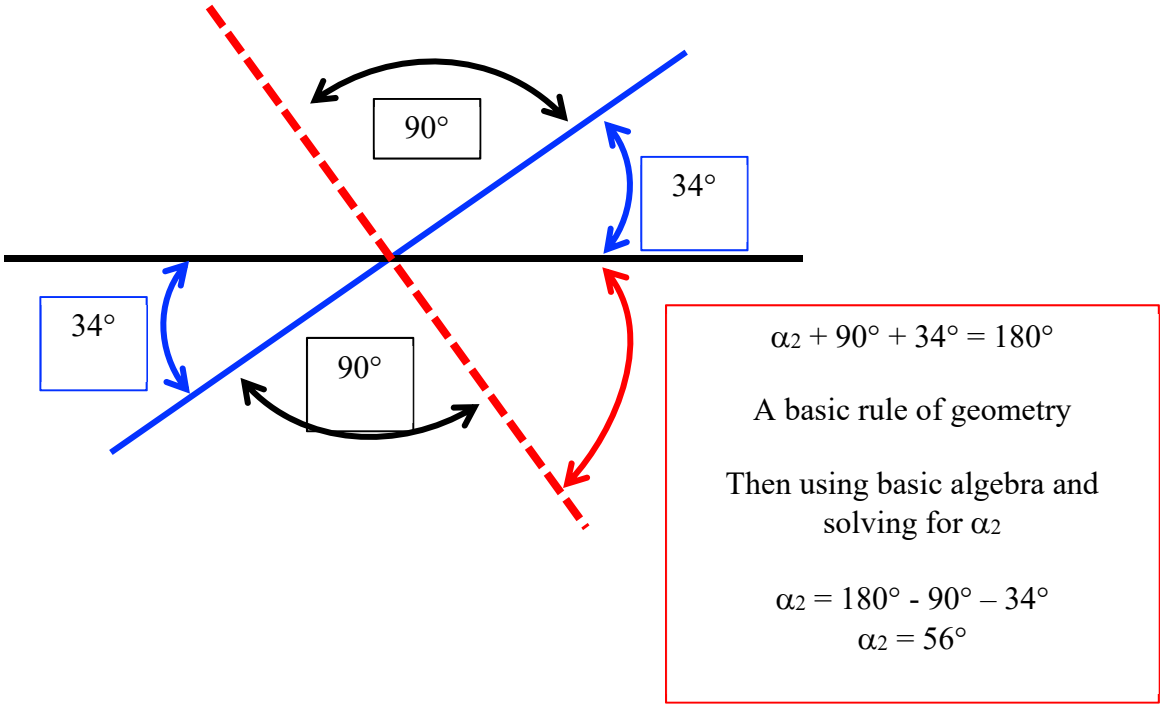
(Ex. 1001, FIG. 2 (annotated); *see also* Ex. 1002, ¶121). A POSITA would understand that the blue dashed line in the figure above is parallel to the screw trajectory and would intersect the longitudinal axis of the plate at the same angle as α. (Ex. 1002, ¶122). A POSITA further would understand that in order to use the angles disclosed by Slater to solve for the angle equivalent to α in the '713 Patent, the measurements must be oriented relative to the longitudinal axis of the plate:



(Ex. 1004, FIG. 9 (annotated); *see also* Ex. 1002, ¶121-22). The angle in Slater that is equivalent to that of α in the '713 Patent is shown in the figure above as α_1. (Ex. 1002, ¶123). In order to solve for α_1 using the values given in Slater, a line (shown below in green dashed line) is drawn parallel to the perpendicular screw trajectory (red dashed line):



(Ex. 1004, FIG. 9 (annotated); *see also* Ex. 1002, ¶123). A POSITA would understand that α_2 is equivalent to α_1 because the green dashed line and red dashed line are parallel and both intersect the longitudinal axis at the same angle. (Ex. 1002, ¶123). Moreover, a POSITA would know that $\alpha_2 = 90° – 34° = 56°$:



(Ex. 1002, ¶124). Accordingly, $\alpha_2 = \alpha_1 = 56°$, and is within the claimed 30° to 60° angle range for the third hole. (*Id.*).

Thus, a POSITA would find this claim disclosed by Slater. (Ex. 1002, ¶125).

ii. Claim 36: The method of claim 32, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

Slater's bone plate comprises a triangularly shaped opening orientation, where opening 98 attaches to the tibia (first bone) and openings 84 and 85 attach to the talus (second bone):

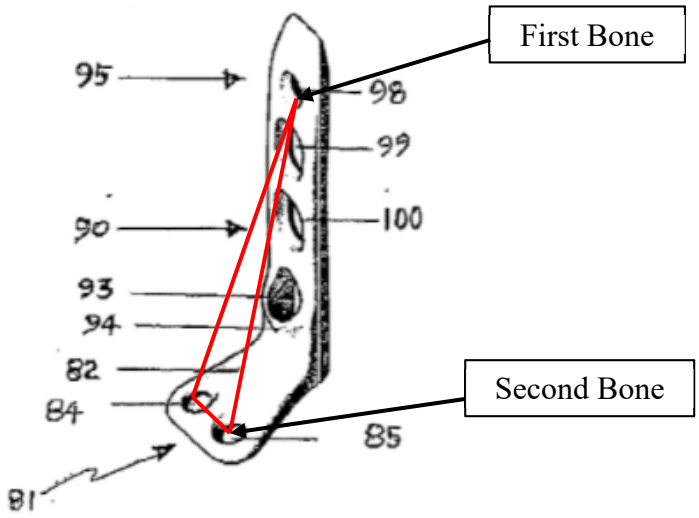


FIGURE 7

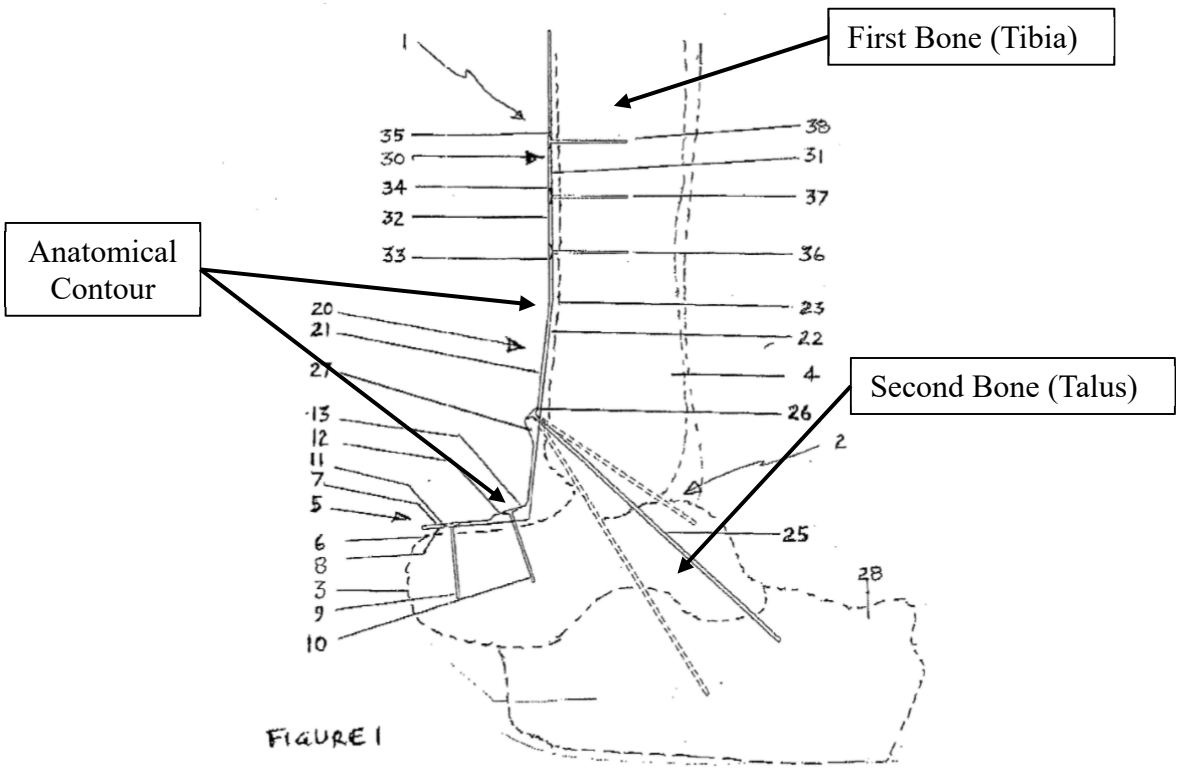
(Ex. 1004, FIG. 7 (annotated); *see also* 13:10-12 ("Disposed in portion 81 are fixation screws (not shown) which pass through openings 84 and 85 of portion 81 engaging the talus at selected orientations."); 13:28-30 ("Portion 95 includes openings 98 and 99 which receive fastening screws each preferably in the same orientation and which engage the tibia.")). A POSITA, looking at the plate in Slater,

would recognize that the plate openings (holes) were arranged in a triangle shape and that fixation members would be used in these holes to secure the plate to the first and second bones as taught by Slater. (Ex. 1002, ¶¶126-28).

Thus, a POSITA would find this claim obvious in view of Slater. (Ex. 1002, ¶¶128-29).

iii. Claim 37[a]: The method of claim 36, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and

Slater's bone plate is configured to conform to the anatomical contours of the tibia and the ankle joint between the tibia and the talus:



(Ex. 1004, FIG. 1 (annotated); *see also* 8:25-9:19 ("Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint."); 12:12-27; Ex. 1002, ¶¶130-31).

Additionally, Slater defines an angle as well as a radius of curvature to the plate permitting it to better conform to the anterior surfaces of the ankle joint:

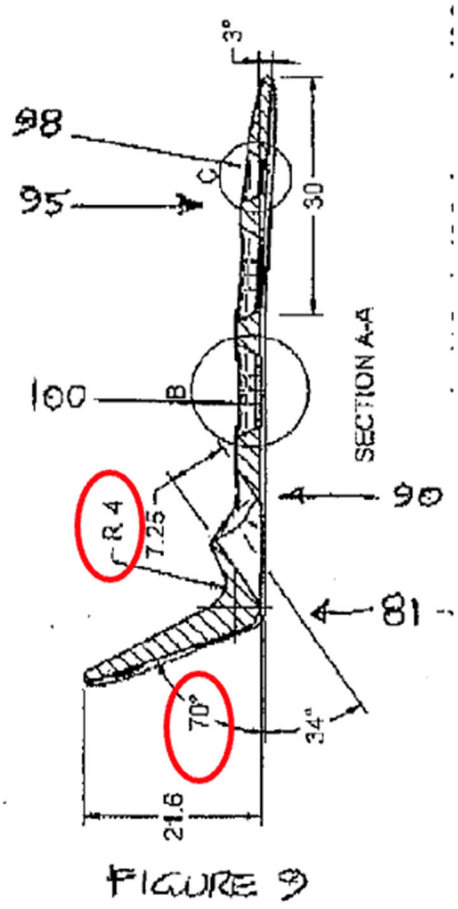


FIGURE 9

(Ex. 1004, FIG. 9 (annotated)). Slater also defines the radius of curvature on the underside (bone facing side) of the plate:

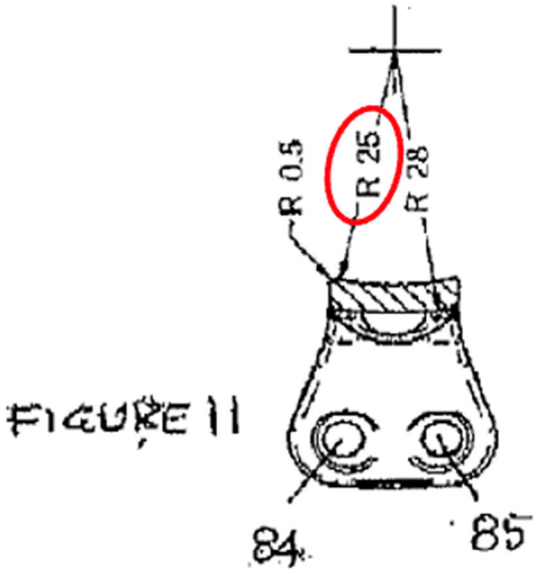


FIGURE 11

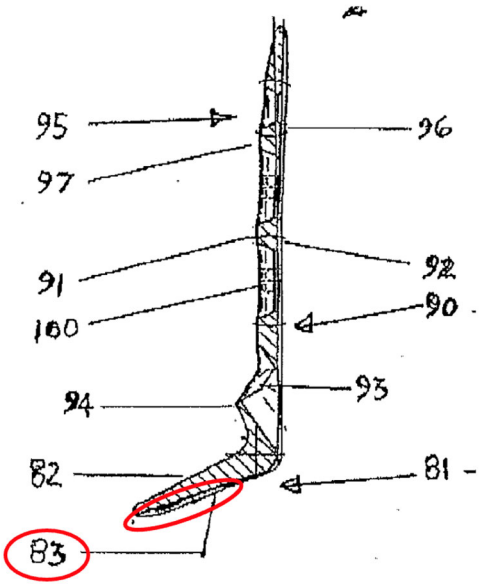


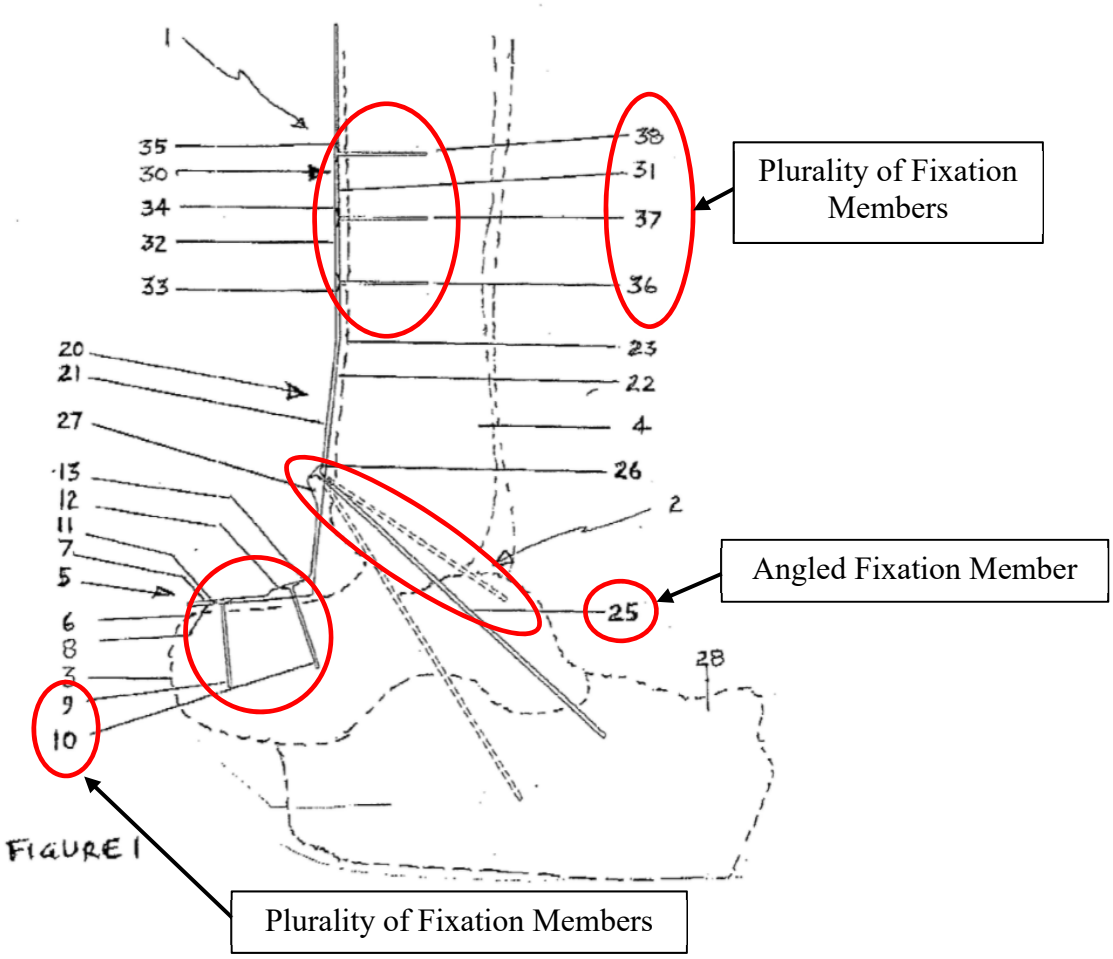
FIGURE 5

(Ex. 1004, FIGS. 5, 11 (annotated)). A POSITA would know that this radius of curvature (R25), is intended to ensure the plate properly and intimately conforms to the surface of the first bone (tibia). (Ex. 1002, ¶¶132-34). A POSITA would also appreciate the subtle but clearly present contouring of surface 83 depicted in the cross section of Figure 5 and know that this rounded surface is intended to fit on the anterior surface 6 of the talus (second bone). (Ex. 1002, ¶134).

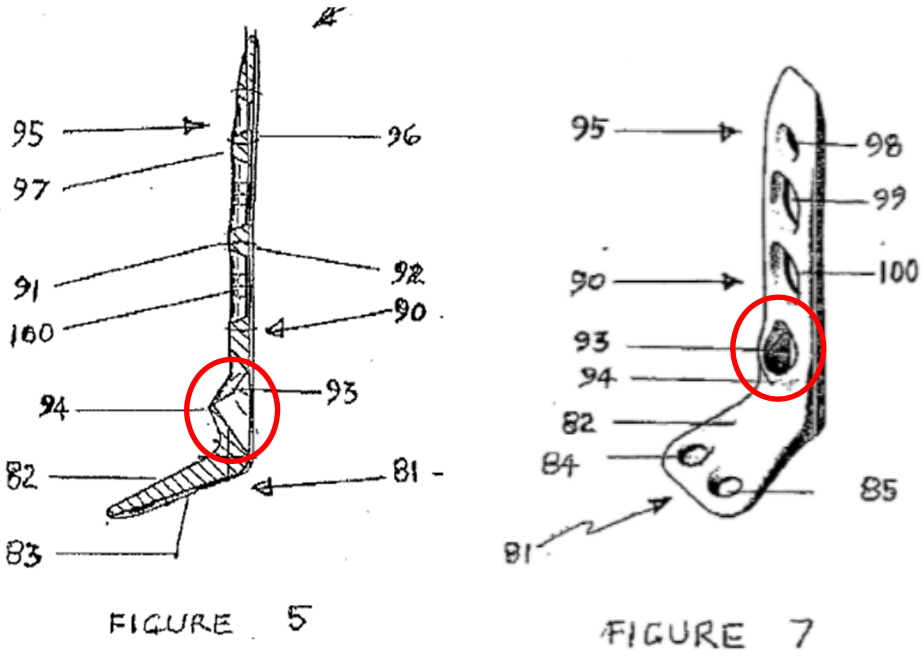
Thus, a POSITA would understand that this element is taught by Slater. (Ex. 1002, ¶¶130-35).

iv. Claim 37[b]: the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

Slater further discloses a plurality of screws 36, 37, 38 that engage with the tibia and fixation screw 25 that is implanted at an angle:



(Ex. 1004, FIG. 1 (annotated); *see also* 11:18-12:2). Slater describes how "[f]ormation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range." (Ex. 1004, 11:18-27). Slater also states that "[d]isposed in portion 90 is a fixation screw which passes through opening 93 in formation 94. Formation 94 is configured so that a fixation screw is directed at an angle within a predetermined allowable angular range. Portion 90 is angled relative to portion 81 at a non-limiting angle of about 100 degrees." (Ex. 1004, 13:21-25). As can be seen in Figures 5 and 7 below, formation 94 is angled with respect to portions 90 and 81:



(Ex. 1004, FIGS. 5, 7 (annotated)).

Therefore, A POSITA would understand that this element is taught by Slater. (Ex. 1002, ¶¶136-39).

D. Ground 2: Claims 34, 35 and 39 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over the combination of Slater and Myerson

Dependent claims 34, 35 and 39 are obvious in view of the combination of Slater and Myerson. (Ex. 1002, ¶140).

1. Basis for the Combination of Slater and Myerson

Slater does not expressly disclose using a locking screw for the first and second screws, but guides a POSITA to incorporate known prior art methods for immobilizing bones by using locking mechanisms: "[a] screw blocking or locking mechanism is provided in the plate to block the screws in the fastening position once the screws have been passed through the plate and screwed into the bone pieces, for preventing the screws from unscrewing from the bone pieces and moving out of the fixation plate once and after the fixation plate and the screws have been firmly installed in the bones." (Ex. 1004, 2:9-14).

In looking to improve fixation of Slater's plate, a POSITA would look to Myerson, which discloses the advantages of using locking screws and threaded holes to prevent the screws from backing out and a method of implementing them. (Ex. 1008, ¶4; *see also* ¶22 ("the screw holes are designed to receive locking screws, such as by the incorporation of locking threads (not shown) within the screw hole. . . In a

specific embodiment, the locking screws may be at 0.5 mm pitch, with a 4.0 mm major diameter and a 3.6mm minor diameter.")). While Slater discloses how the prior art uses a screw locking mechanism in the plate, it lacks detail as to how this locking mechanism is configured. (Ex. 1002, ¶141). Thus, a POSITA would be motivated to look to locking mechanisms known in the art. (Ex. 1002, ¶142).

In analogous art, Myerson discloses a bone plate configured to receive locking screws into locking threaded holes to lock the fixation screws in place. (Ex. 1008, ¶22; Ex. 1002, ¶142). Thus, the use of locking screws with locking threaded holes to prevent the screws from backing out is a known element to obtain a predictable result in the art. (Ex. 1002, ¶143). Therefore, incorporating locking screws with locking threaded holes into Slater's bone plate would provide a known advantage and accomplish a predictable result. (*Id*.). A POSITA would be motivated to implement the locking screws with locking threaded holes disclosed in Myerson to modify Slater's bone plate. (*Id*.).

Slater's bone plate is configured for arthrodesis of the ankle joint by fusing bones of the leg and the foot. (Ex. 1004, 6:14-28). Although Slater's bone plate anchors to a bone or multiple bones in the foot, it may be argued that the ankle joint itself is not a joint in the foot. A POSITA would understand that internal fixation bone plates are often reconfigured for different applications, and in most cases, are not limited to a single specific bone or a single specific indication. (Ex. 1002, ¶144).

However, it should be noted that while the Slater plate is designed to fuse the tibia to the talus (which is commonly considered the ankle joint), when long screws are used, the plate can also fuse the talus to the calcaneus. (Ex. 1004, 11:18-27; *see also* Ex. 1002, ¶144). This latter joint is the also known as the subtalar joint and is a joint in the foot. (Ex. 1002, ¶144).

Additionally, Slater discloses that an advantage of the plate is the presence of pliable regions to allow the plate to be bent to conform to the anatomy of different bones. (Ex. 1004, 17:2-3; Ex. 1002, ¶144). Indeed, claim 1 of Slater generally claims "[a] fusion plate for arthrodesis" and is not limited to any bone. (Ex. 1004, 21:7-20). Therefore, due to the close proximity of joints exclusively in the foot, and the pliability of the bone plate, a POSITA would understand that Slater's bone plate could be configured to fuse joints in the foot. (Ex. 1002, ¶144). A POSITA would understand that reconfiguring the bone plate for a different joint would be obvious to try, and could be done in a predictable manner. (Ex. 1002, ¶¶144-45).

Myerson further describes a bone plate configured for arthrodesis of the metatarsal-phalangeal (MTP) joint in the foot. (Ex. 1008, ¶20). A POSITA would understand that the fixation screw disclosed by Slater could intersect the MTP joint and provide a similar advantage by compressing the joint. (Ex. 1002, ¶145). Thus, the combination of Slater and Myerson yields predictable improvements and a

POSITA would be motivated to apply the teachings of Myerson and modify Slater's bone plate. (Ex. 1002, ¶¶143-45).

2. Claims 34, 35 and 39 are Obvious in view of the Combination of Slater and Myerson

a. *Independent Claim 32*

Independent claim 32, from which claims 34, 35, and 39 depend, is obvious in view of Slater (Ground 1). (*See* Section VII.C.2.a.i-viii; Ex. 1002, ¶¶85-118, 146).

b. *Dependent Claims 34, 35 and 39*

i. Claim 34: The method of claim 32, wherein the first and second holes are locking holes.

Myerson's bone plate comprises screw holes 22 (first hole) and 32, 36 (second hole) configured to receive locking screws with the plate having locking threads within the screw holes:

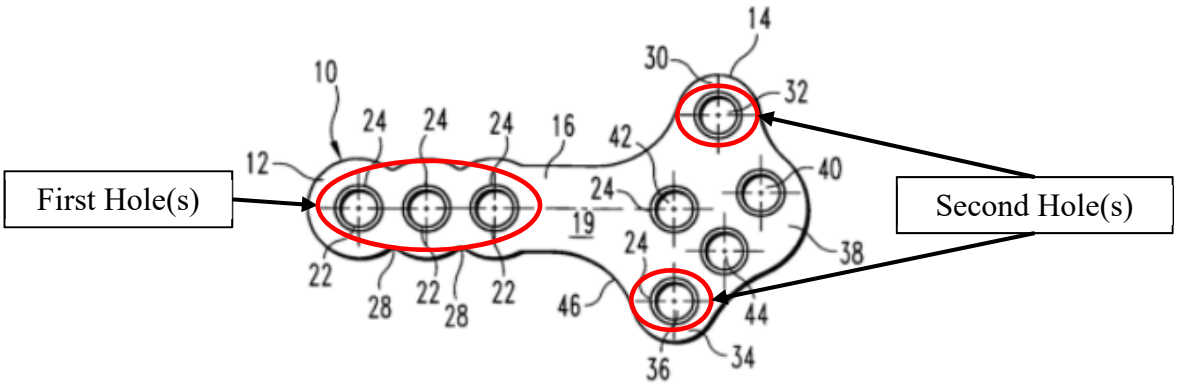


Fig. 2

(Ex. 1008, FIG. 2 (annotated); *see also* ¶22 ("the screw holes are designed to receive locking screws, such as by the incorporation of locking threads (not shown) within

the screw hole."); ¶25). The use of locking screws with locking threaded holes, as described in Myerson, with Slater's plate, provides a solution and a predictable result in the field of bone plates, to the known problem of screws loosening and backing out over time, something explicitly recognized by Slater. (Ex. 1004, 2:9-14; *see also* Ex. 1002, ¶147). Myerson identifies a known method for securing screws and preventing screws from backing out: use of locking screws with locking threaded holes. (Ex. 1008, ¶22). Thus, a POSITA would have been motivated to combine this teaching from Myerson with Slater's plate because the use of locking screws with locking threaded holes are a known technique to prevent the screws from backing out. (Ex. 1002, ¶148).

Thus, a POSITA would find that the combination of Slater and Myerson teaches the first and second holes are locking holes. (Ex. 1002, ¶¶147-50).

ii. Claim 35: The method of claim 34, wherein the first and second holes are threaded.

For the same reasons given with respect to claim 34 and explained in Section VII.D.2.b.i, Myerson's explicit description of locking threaded holes guides a POSITA to combine locking threaded holes of Myerson with Slater's first and second holes to ensure that the screws do back out. (*See* Ex. 1008, FIG. 2, ¶¶22, 25; Ex. 1002, ¶¶147-51).

iii. Claim 39: The method of claim 32, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

Myerson's bone plate is configured to fuse the MTP joint in the foot and contour to the phalanx:

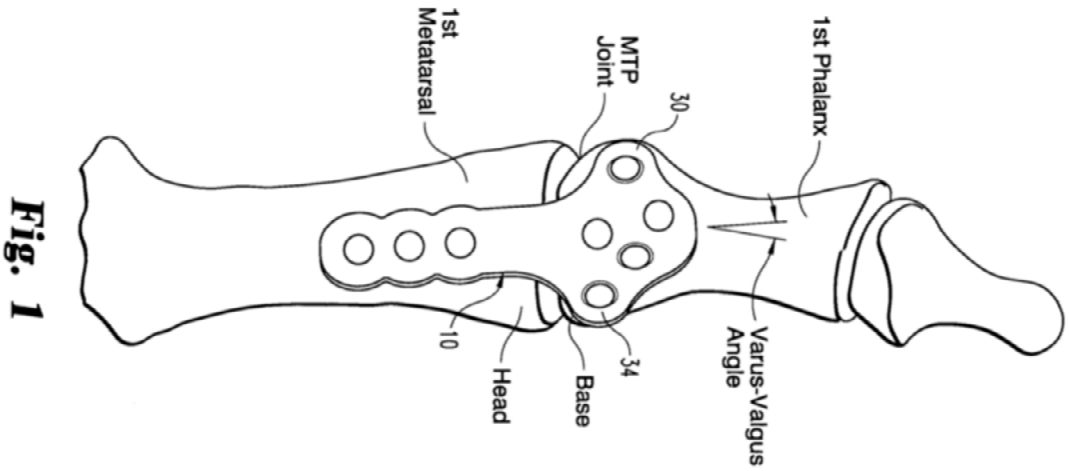


Fig. 1

(Ex. 1008, FIG. 1; *see also* ¶10 ("In a further aspect of the invention, the entire plate is curved to provide a curved bone engaging surface that generally follows the contour of the metatarsal bone and phalanx."); ¶20 ("In particular, the toe includes a first metatarsal bone, a first phalanx bone and a metatarsal phalangeal (MTP) joint therebetween. A fixation plate 10 according to one embodiment of the present invention spans the MTP joint and is configured to be fixed to both bones of the joint."); ¶31 ("In a further feature of the fixation plate 10, the bone engaging surface 18 of the plate may be contoured at a radius approximating the surface of the bone, as shown in FIGS. 3 and 5.")).

As discussed previously, Slater describes a bone plate configured to fuse the joint between the tibia and talus that anatomically contours to the ankle joint, as well as the joint between the calcaneus and the talus. (*See* Section VII.C.2.b.vi (citing Ex. 1004, FIG. 1, 8:25-9:19, 10:14-16)). Thus, a POSITA would understand that Slater's bone plate is configured to contour to the fused bones and could be contoured to the phalanx as described in Myerson. (Ex. 1002, ¶¶152-53).

Thus, a POSITA would find this claim obvious in view of the combination of Slater and Myerson. (Ex. 1002, ¶¶152-56).

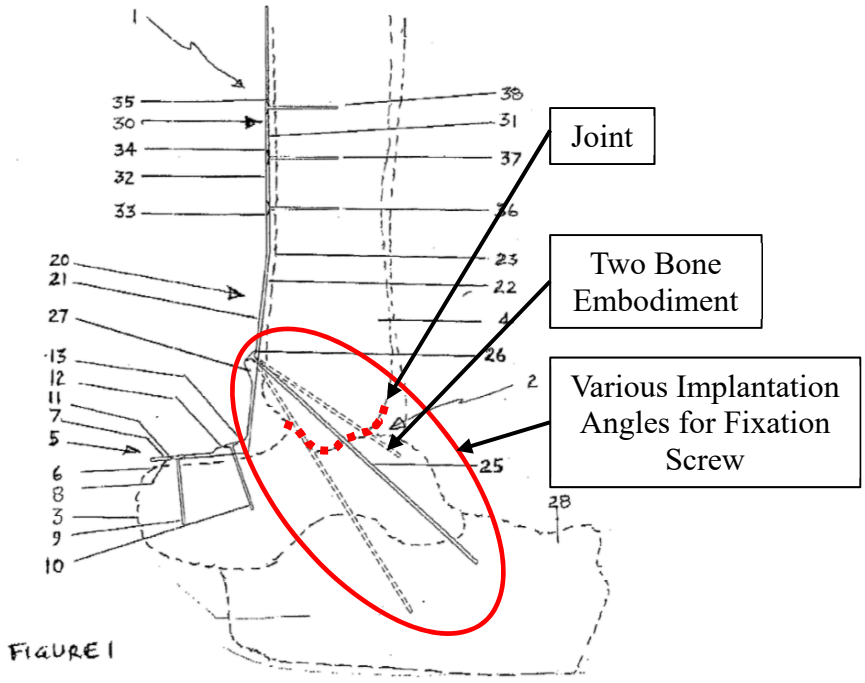
E. Ground 3: Claims 32, 33 and 38 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over the combination of Slater and Zahiri

Independent claim 32 and dependent claims 33 and 38 are obvious in view of the combination of Slater and Zahiri. (Ex. 1002, ¶¶157-188).

1. Basis for the Combination of Slater and Zahiri

The scope and content of the prior art includes Slater and Zahiri, which collectively disclose all of the elements of claims 32, 33 and 38. There are no differences between the subject matter of these claims and the combination of Slater and Zahiri and they are analogous art. (Ex. 1002, ¶158).

Slater discloses a bone plate comprising a fixation screw that is placed at an angle so that it compresses the ankle joint and intersects the tibia, talus, and potentially the calcaneus:



(Ex. 1004, FIG. 1 (annotated); *see also* 6:14-28, 11:18-27). Slater's bone plate comprises a predetermined allowable angle range of the fixation screw 25, as depicted by the three possible angles in Figure 1. (*Id.*). Slater further discloses that a key advantage of the bone plate is the ability to for the fixation screw to be configured at multiple angles and "incorporate more joints into the arthrodesis as required." (Ex. 1004, 16:25-17:12). Therefore, a POSITA would understand that Slater discloses an embodiment where the fixation screw 25 configured to intersect a joint through two discrete bones. (Ex. 1002, ¶¶159-62).

However, at the very least, Slater's disclose would guide a POSITA to incorporate the teachings of Zahiri, and position the fixation screw 25 at an angle that contacts only two bones. (Ex. 1002, ¶¶163). Zahiri discloses a bone plate

configured to fuse a first and second bone part with an angled fixation member and compress the bone fracture:

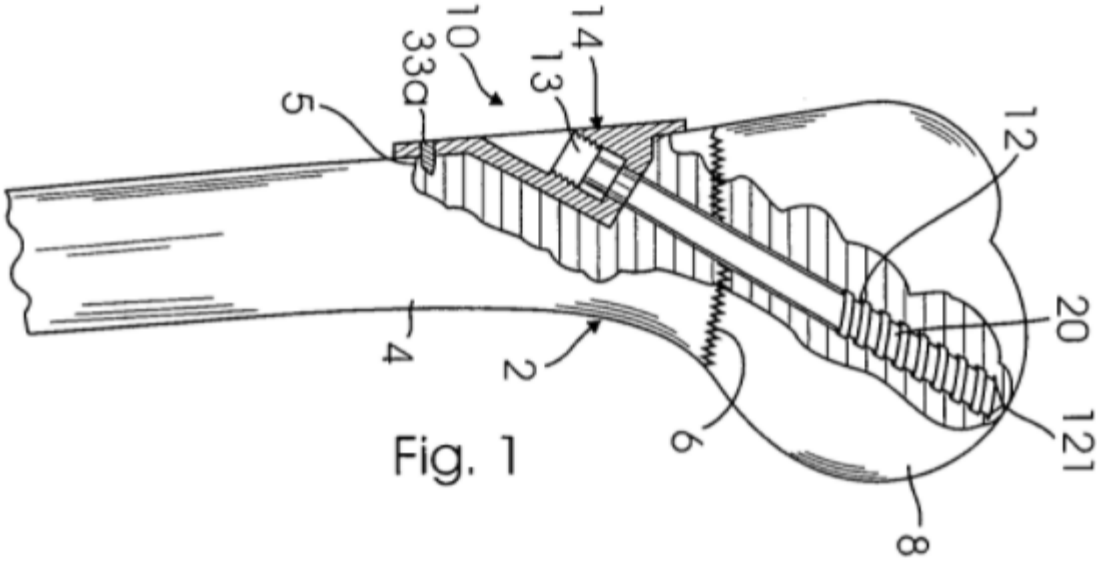
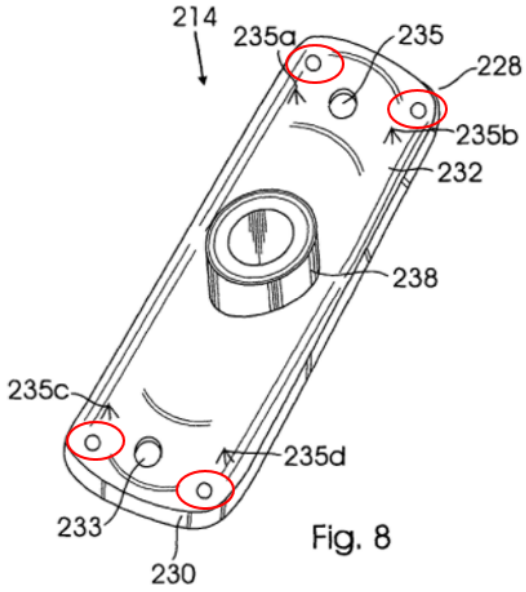


Fig. 1

(Ex. 1007, FIG. 1; *see also* 2:45-48). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11). A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. (Ex. 1002, ¶¶163-64). A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. (Ex. 1002, ¶164). Therefore, a POSITA would look to Zahiri when making improvements to Slater's bone plate. (*Id.*).

Slater contemplates the importance of proper bone plate alignment and would guide a POSITA to incorporate the temporary pin holes disclosed by Zahiri into

Slater. (Ex. 1004, 4:17-5:9; Ex. 1002, ¶165). Slater specifically discloses that "[i]f an arthrodesis or ankle replacement is not properly aligned, significant gait abnormalities may result." (Ex. 1004, 4:23-25). Additionally, Zahiri discloses four small holes in the corner of the bone plate intended for used with pins to temporarily hold the bone plate in place during implantation, as shown in Figure 8:



(Ex. 1007, FIG. 8 (annotated); *see also* 3:10-18 ("[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.")). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (*Id.*). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (*Id.*).

Thus, a POSITA would understand that the temporary pin holes, as disclosed in Zahiri, could be implemented into Slater's bone plate to guide the plate alignment during implantation. (Ex. 1002, ¶¶166-67). A POSITA would further recognize that the implantation techniques from Zahiri would support Slater's goal of reducing the risk of complications and improving the likelihood of painless, normal walking by the patient. (Ex. 1004, 5:2-3; Ex. 1002, ¶167). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, *Id.*).

Thus, a POSITA would be motivated to combine the teachings of Slater and Zahiri, to utilize a known prior art technique for improving the implantation of a bone plate (similar device), and obtain a similar and predictable improvement. (Ex. 1002, ¶168).

2. Claims 32, 33 and 38 are Obvious in view of the Combination of Slater and Zahiri

a. *Independent Claim 32*

i. [32Pre] A method of fusing a joint, the method comprising:

Slater discloses a bone plate configured to perform the claimed method of joint fusion, as explained above in Section VII.C.2.a.i. (*See* Ex. 1004, FIG. 1, 6:14-28, 8:13-24; Ex. 1002, ¶169).

ii. [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

Slater discloses a bone plate configured to fuse a joint between a first and second bone, wherein a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint, as explained above in Section VII.C.2.a.ii. (*See* Ex. 1004, FIG. 1, 6:14-28, 8:13-24, 13:5-18; Ex. 1002, ¶170).

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

Slater discloses a bone plate configured for inserting a first fixation member through the first hole of the plate and into the first bone of the joint, as explained above in Section VII.C.2.a.iii. (*See* Ex. 1004, FIG. 1, 8:13-24, 11:28-12:2; Ex. 1002, ¶171).

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

Slater discloses a bone plate configured for inserting a second fixation member through the second hole of the plate and into the second bone of the joint, as explained above in Section VII.C.2.a.iv. (*See* Ex. 1004, FIG. 1, 8:13-24, 11:1-16; Ex. 1002, ¶172).

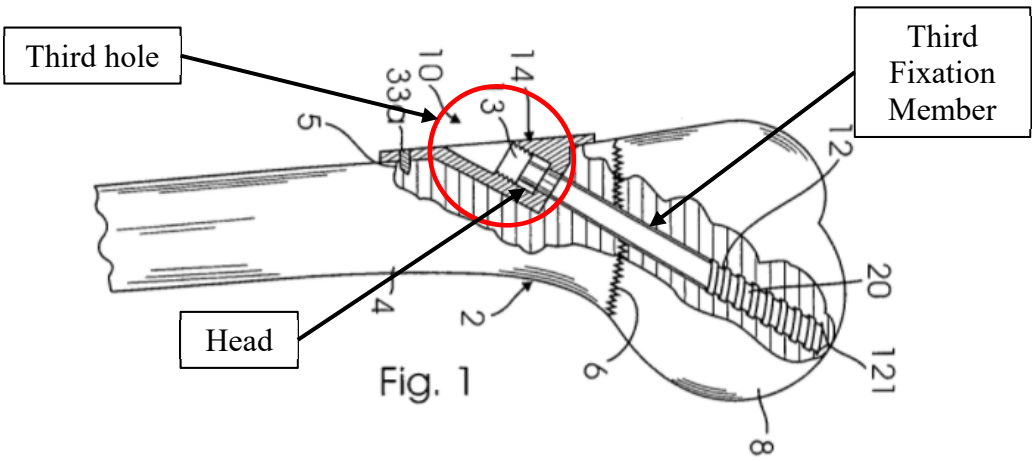
v. [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and

A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone, as explained above in Section VII.C.2.a.v. (*See* Ex. 1004, FIG. 1, 11:18-27; Ex. 1002, ¶173).

vi. [32e] a head of the third fixation member is seated in the third hole,

A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member wherein a head of the third fixation member is seated in the third hole, as explained above in Section VII.C.2.a.vi. (*See* Ex. 1004, 5:28-31, 6:3-9, FIGS. 5, 7, 13:21-24; Ex. 1002, ¶174).

To the extent that Slater is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶175). Zahiri discloses a threaded portion 37 in the short barrel portion 38 (third hole), which provides a press fit engagement with the head 22 of the lag screw 12 (third fixation member):



(Ex. 1007, FIG. 1 (annotated); *see also* 7:31-38). Thus, in order to achieve the stated goal from Slater of maintaining the integrity of the third fixation member, it would be obvious to a POSITA to use the seated head of the lag screw from Zahiri to ensure the third fixation member is seated securely in the third hole. (Ex. 1002, ¶¶175-76).

Thus, a POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶177).

vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member through a third hole wherein the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate, as explained above in Section VII.C.2.a.vii. (*See* Ex. 1004, FIGS. 5, 1, 7, 13:20-25, 8:25-9:19; Ex. 1002, ¶178).

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

Slater discloses a bone plate configured for inserting a third fixation member through a third hole wherein the third fixation member is the only fixation member extending across the joint, as explained above in Section VII.C.2.a.viii. (*See* Ex. 1004, FIG. 1, 11:18-27; Ex. 1002, ¶179).

b. *Dependent Claims 33 and 38*

i. Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

A POSITA would find a bone plate configured for inserting a third fixation member through a third hole wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate obvious in view of Slater, as explained above in Section VII.C.2.b.i. (*See* Ex. 1004, FIGS. 9, 2, 11:18-27; Ex. 1002, ¶180).

Additionally, Zahiri further discloses an incidence angle of a locking screw "A" that is preferably 90°, 150° or 160° from the guide plate but "in the range of from 90° to 170°." (Ex. 1007, 3:59-67). The incidence angle "A" is measured as the obtuse angle between the guide plate and the locking screw trajectory:

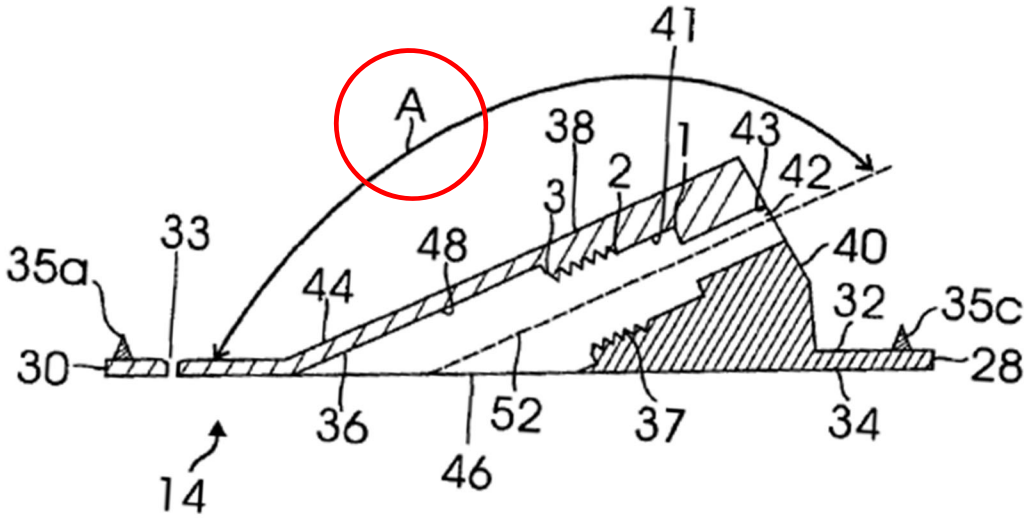
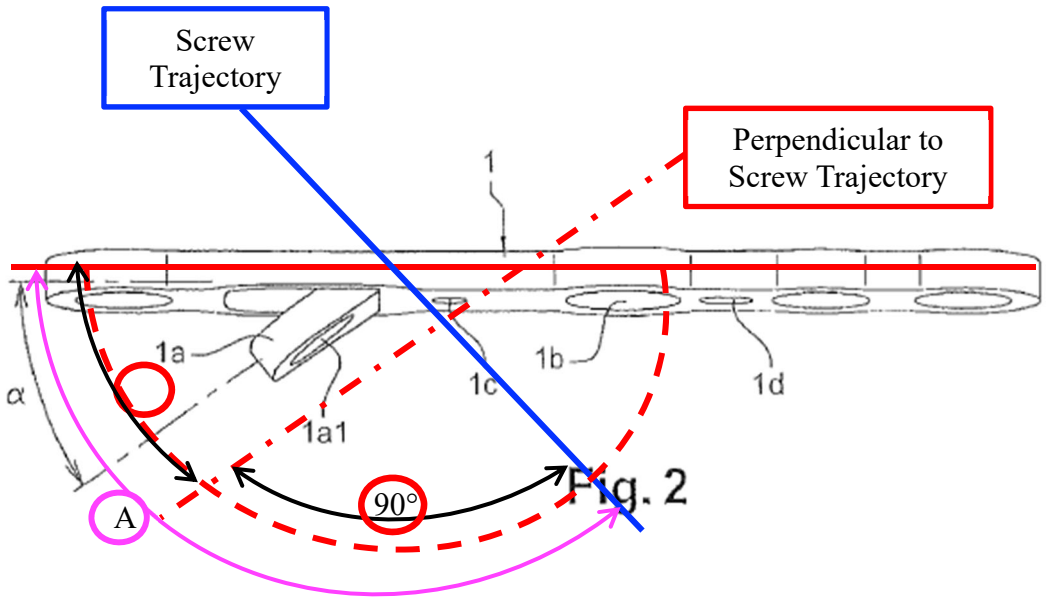


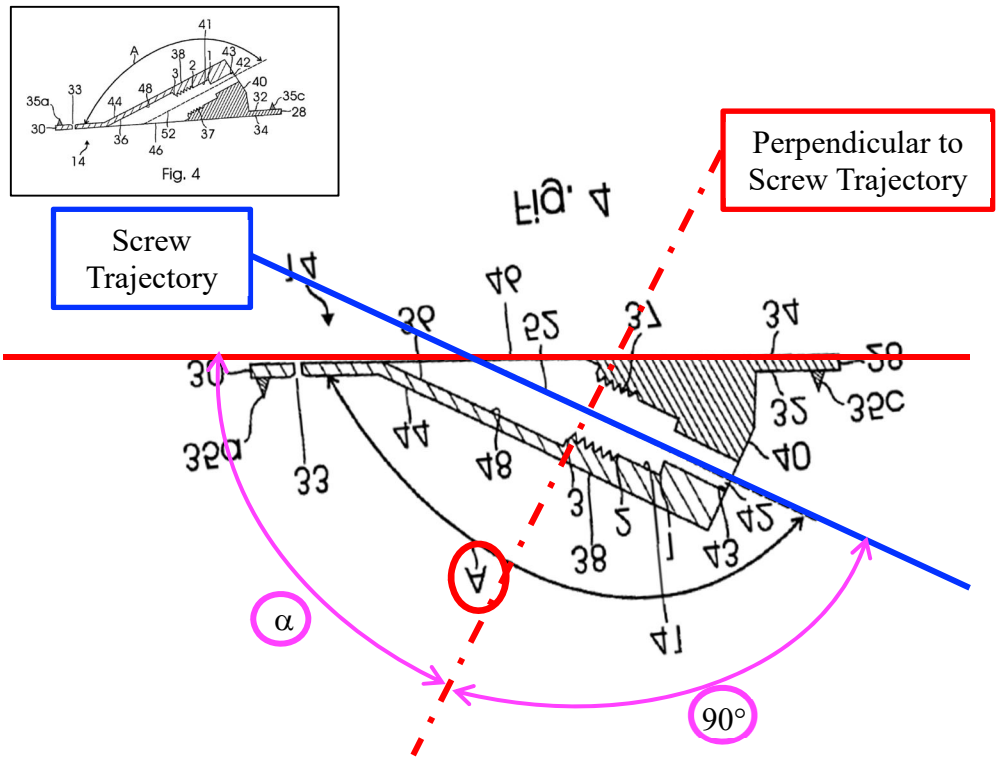
Fig. 4

(Ex. 1007, FIG. 4 (annotated); Ex. 1002, ¶181). In contrast, the '713 Patent refers to angled tab by the angle "α," which is the acute angle between the plate and the tab in Figure 2:



Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°

(Ex. 1001, FIG. 2 (annotated); *see also* Ex. 1002, ¶182). To be comparable to angle "A" in Zahiri, 90° has to be added to "α":



Zahiri's Screw Incidence Angle = "A"
Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°
For example, if Zahiri says that "A" can be 90° - 170°;
then '713 Patent α can be 0° - 80°
But Zahiri prefers "A" = 150° or 160°,
which equates to α in the '713 Patent equaling 60° - 70°

(Ex. 1007, FIG. 4 (annotated); *see also* Ex. 1002, ¶182). Therefore, the angle of the hole opening "α," is determined by subtracting 90° from A (hole opening "α," = A - 90°). (Ex. 1002, ¶183). Accordingly, Zahiri teaches a hole-opening angle "α," at 0° to 80° with respect to the longitudinal surface of the guide plate. (Ex. 1002, ¶183-84).

Both Slater and Zahiri teach a third hole configured at an angle with respect to the longitudinal axis of the plate and that angle encompasses the claimed range.

Thus, it would also be obvious to a POSITA that a fixation member configured to diagonally secure a joint would be angled between 30° and 60° with respect to the longitudinal axis of the plate. (Ex. 1002, ¶184).

Thus, a POSITA would find this claim obvious in view of Slater and Zahiri. (Ex. 1002, ¶185).

ii. Claim 38: The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

Zahiri discloses additional pins that "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). Figure 8 shows the location of these pin holes:

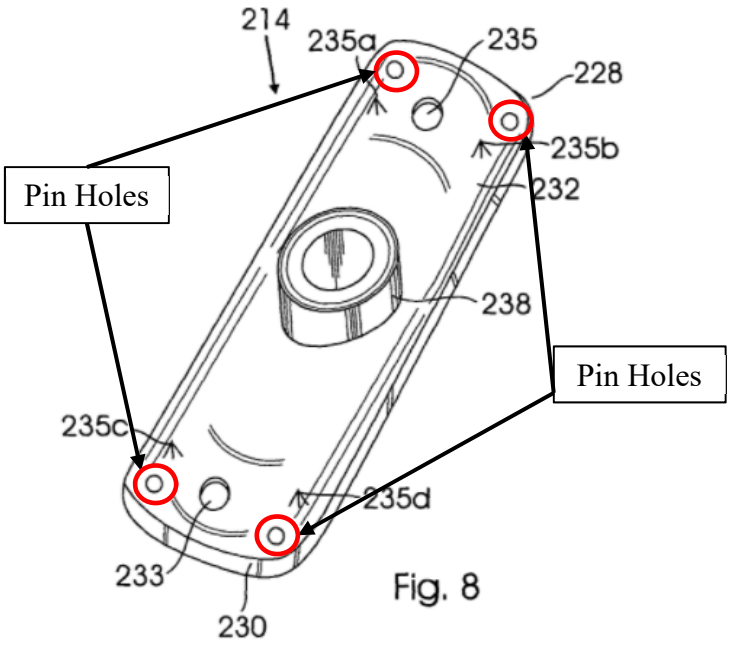


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* Ex. 1002, ¶186). Additionally, after "the lag screw 12 is settled inside of the epiphysis 8 the four pins are pulled out, and a medium size screw 33a is pressed and turned through the hole [2]33 of the plate [2]14 and into the bone diaphyseal segment." (Ex. 1007, 7:63-8:11). Since Slater describes a goal of reducing the risk of complications and improving the likelihood of painless, normal walking by the patient, a POSITA would be motivated to utilize the pin holes in Zahiri to ensure proper placement and alignment of the plate during implantation. (Ex. 1002, ¶187). Use of temporary fixation pins was common at the time of invention, and would have been readily utilized by a POSITA given the explicit disclosure in Zahiri and the desire to improve the placement and alignment Slater's plate. (*Id.*).

Thus, a POSITA would find this claim obvious in view of Slater and Zahiri. (Ex. 1002, ¶¶186-188).

F. Ground 4: Claims 32, 33 and 36-39 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over the combination of Arnould and Zahiri

Independent claim 32 and dependent claims 33 and 36-39 are obvious in view of the combination of Arnould and Zahiri. (Ex. 1002, ¶189).

1. Basis for the Combination of Arnould and Zahiri

The scope and content of the prior art includes Arnould and Zahiri, which collectively disclose all of the elements of claims 32-33 and 36-39. There are no differences between the subject matter of these claims and the combination of Arnould and Zahiri.

Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone or across a fracture. (Ex. 1006, ¶6; Ex. 1007, 2:20-31). A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture, and therefor Arnould and Zahiri are in analogous fields of art. (Ex. 1002, ¶190-91). Arnould's bone plate comprises a hole 25 that determines the relative position of a screw 30 that passes through and fuses the joint between the metatarsal and phalanx. (Ex. 1006, ¶31). Arnould explains that "the screw works mainly in traction," and that "[w]ith a single action consisting of screwing in this

long screw, the surgeon automatically brings the two bones to be fused closer to each other." (Ex. 1006, ¶6).

A POSITA knows that screws positioned across an interface, "working in traction" are providing compression at the interface. (Ex. 1002, ¶191). Arnould further discloses a variable fixation angle between the longitudinal axis of the plate body, selected by the surgeon to fuse the metatarsal and phalanx. (Ex. 1006, ¶¶27, 32). In other words, the surgeon "has the possibility of modifying the angle α," indicating the surgeon can choose the angle at which the fixation member is inserted to achieve an optimal interface between the screw and the bone. (Ex. 1006, ¶38; Ex. 1002, ¶192).

While a POSITA may find that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate, Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri, and position the third hole at an angle relative to the longitudinal thickness of the bone plate. (Ex. 1002, ¶193). Zahiri discloses a bone plate configured to fuse a first and second bone part with an angle fixation member and compress the bone fracture:

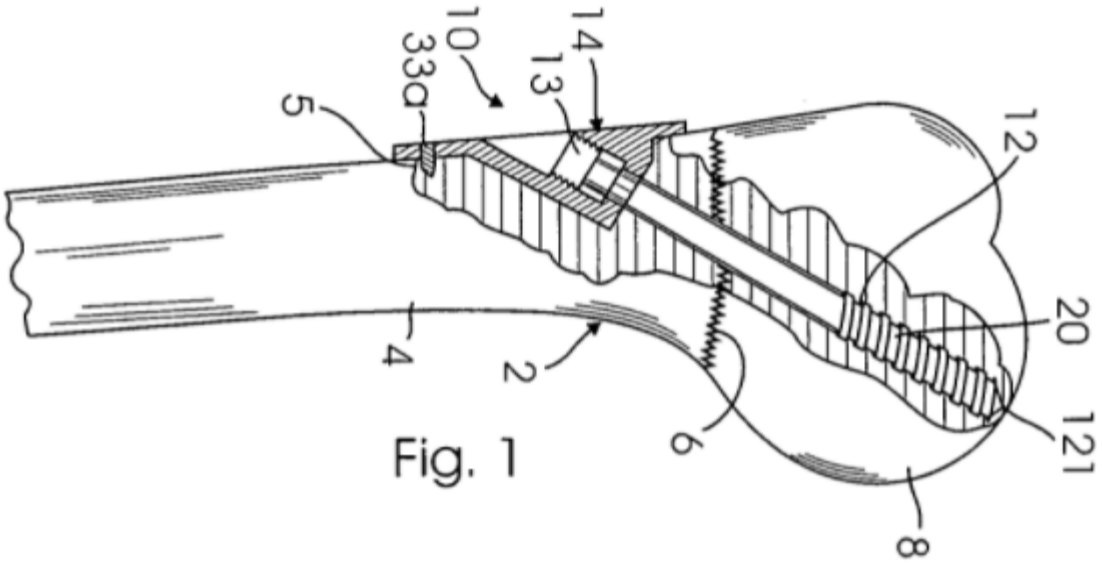


Fig. 1

(Ex. 1007, FIG. 1; 2:45-48). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11). Moreover, there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture, and thus a POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures would be used interchangeably, as they have for decades. (Ex. 1002, ¶193). Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate. (*Id.*).

While Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted, the figures show pin holes that are intended to be used to temporarily secure the plate with k-wires during the implantation process:

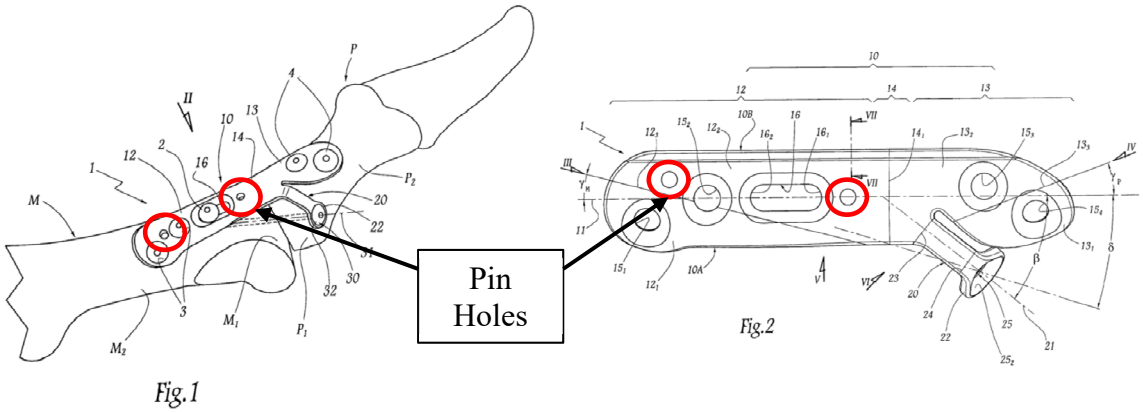


Fig.1 Fig.2

(Ex. 1006, FIGS. 1, 2 (annotated); Ex. 1002, ¶194). K-wires are commonly used for temporary placement, alignment and immobilization of bone plates so that the surgeon can correctly position and align a plate. (Ex. 1002, ¶194). Arnould discusses the difficultly of proper plate alignment faced by the surgeon during implantation and the importance that proper placement has on patients' comfort. (Ex. 1006, ¶3). Zahiri further discusses the importance of plate alignment and specifically discloses the use of temporary locking pins to temporarily secure the bone plate to the bone during implantation. (Ex. 1007, 3:10-18). As this would be done before the plate is permanently affixed, a POSITA would look to incorporate the use of temporary pins disclosed by Zahiri into Arnould to ensure correct placement. (*See* Ex. 1006, ¶¶3, 31; *see also* Ex. 1002, ¶194).

Similarly, Zahiri discloses four small holes in the corner of the bone plate that are used with pins to temporarily hold the bone plate in place during implantation:

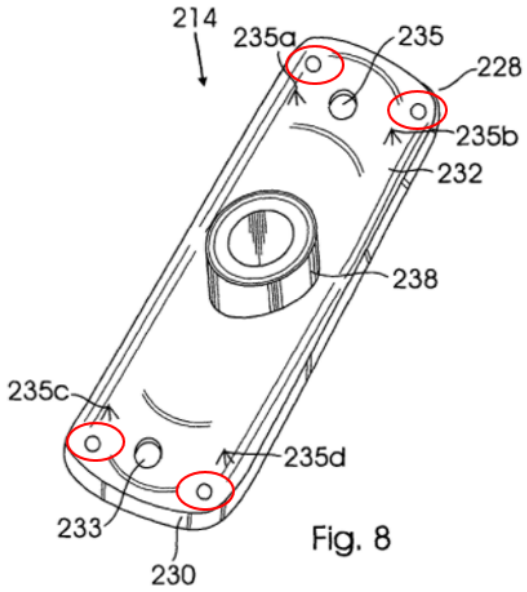


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* 3:10-18 ("[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.")). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (*Id.*). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (*Id.*).

Thus, a POSITA would understand that the temporary pin holes, as disclosed in Zahiri, could be implemented into Arnould's bone plate to temporarily maintain plate alignment during implantation. (Ex. 1002, ¶¶195-96). A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins and would render the incorporation of Zahiri's guide holes

obvious. (Ex. 1006, FIG. 1; Ex. 1002, ¶196). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, ¶196).

Thus, a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement. (Ex. 1002, ¶197).

2. Claims 32, 33 and 36-39 are Obvious in view of the Combination of Arnould and Zahiri

a. *Independent Claim 32*

i. [32Pre] A method of fusing a joint, the method comprising:

Arnould discloses a bone plate configured for arthrodesis of a joint between the first metatarsal and the first phalanx. (Ex. 1006, ¶11 ("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.")).

Thus, Arnould discloses a plate that is used to perform the claimed method. (Ex. 1002, ¶¶198-200).

ii. [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

Arnould's bone plate comprises four screw holes 15_1-15_4 configured to anchor the plate body to the phalanx (first bone) through holes 15_3-15_4 (first holes), and to the metatarsal (second bone) through holes 15_1-15_2 (second holes):

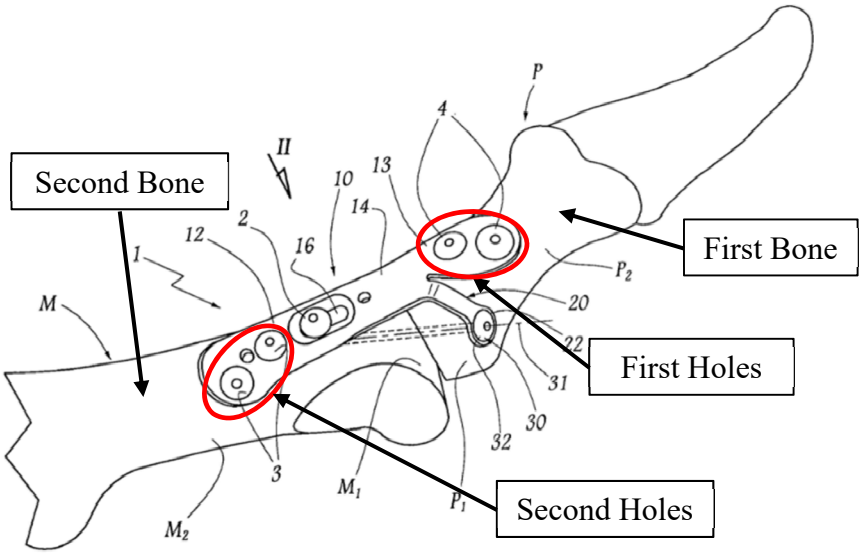


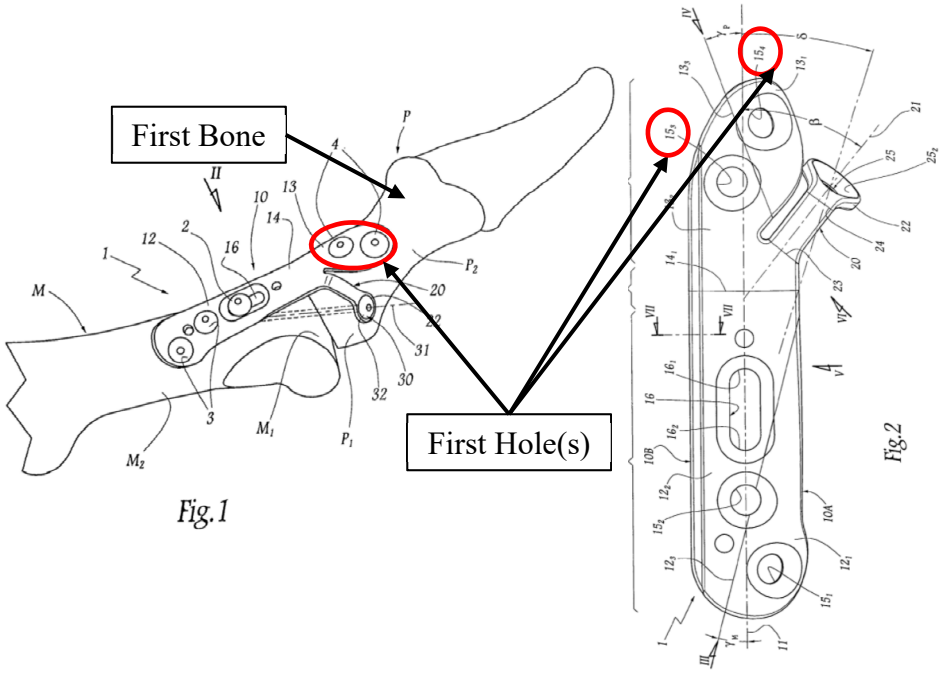
Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* FIG.2; ¶33 ("The screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2."); ¶34 ("Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.")).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶201-03).

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

Arnould discloses the steps of inserting screws 4 into holes 15_3 and 15_4, and attaching to the phalanx (first bone):



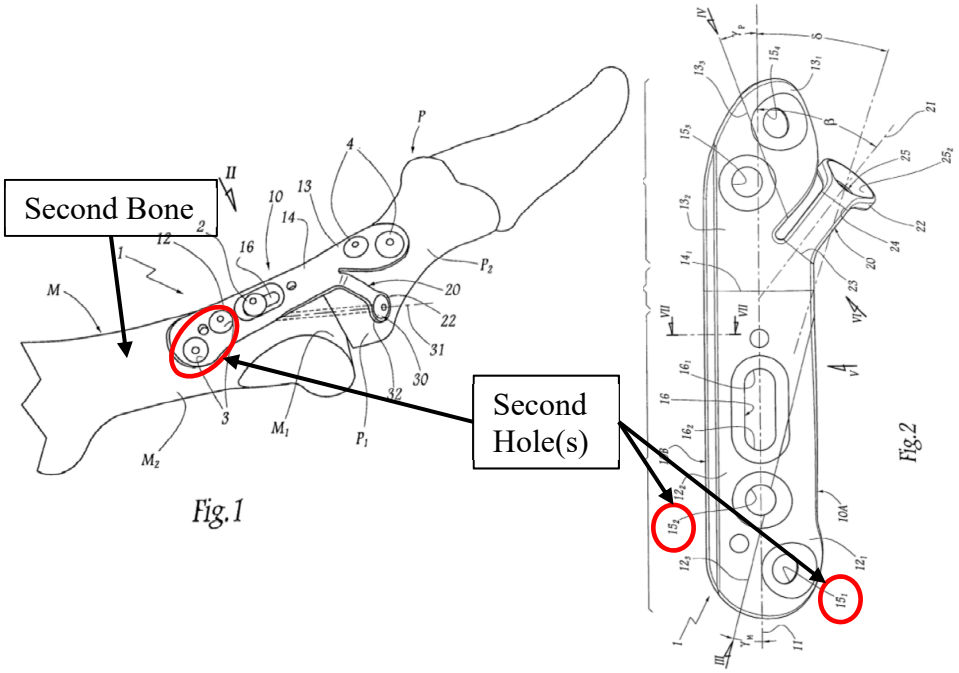
(Ex. 1006, FIGS. 1, 2 (annotated); *see also* ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶34 ("Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into

the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.")).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶204-07).

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

Arnould discloses the steps of inserting screws 3 into holes 15_1 and 15_2, and attaching to the metatarsal (second bone):



(Ex. 1006, FIGS. 1, 2 (annotated); ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶33 ("The screw 2 is then

completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2.")).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶208-11).

v. [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and

Arnould discloses a screw 30 configured to be inserted into hole 25 that is configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

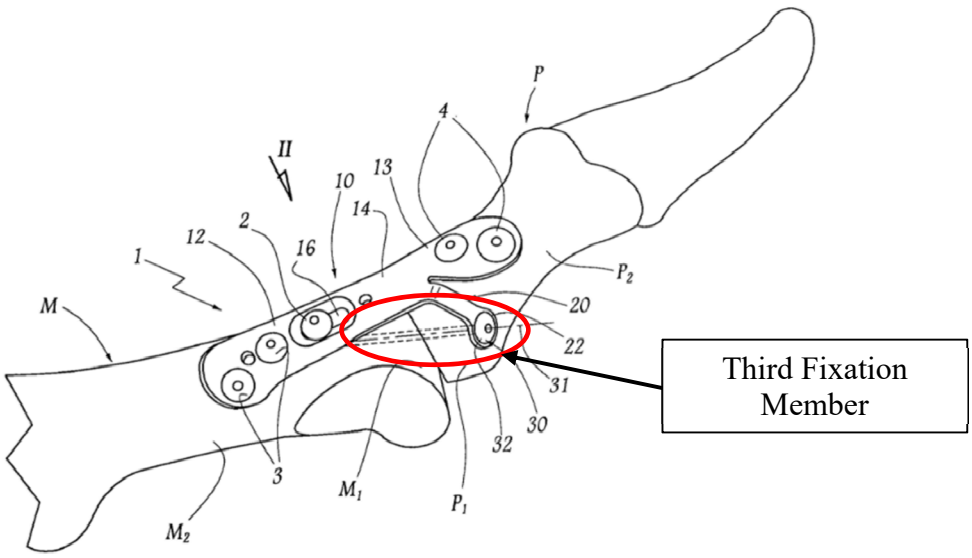


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶32 ("The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above."); Ex. 1002, ¶212). A POSITA would understand that the free end of screw 30 resides in the second bone and does not attach to any portion of the bone plate. (Ex. 1002, ¶213).

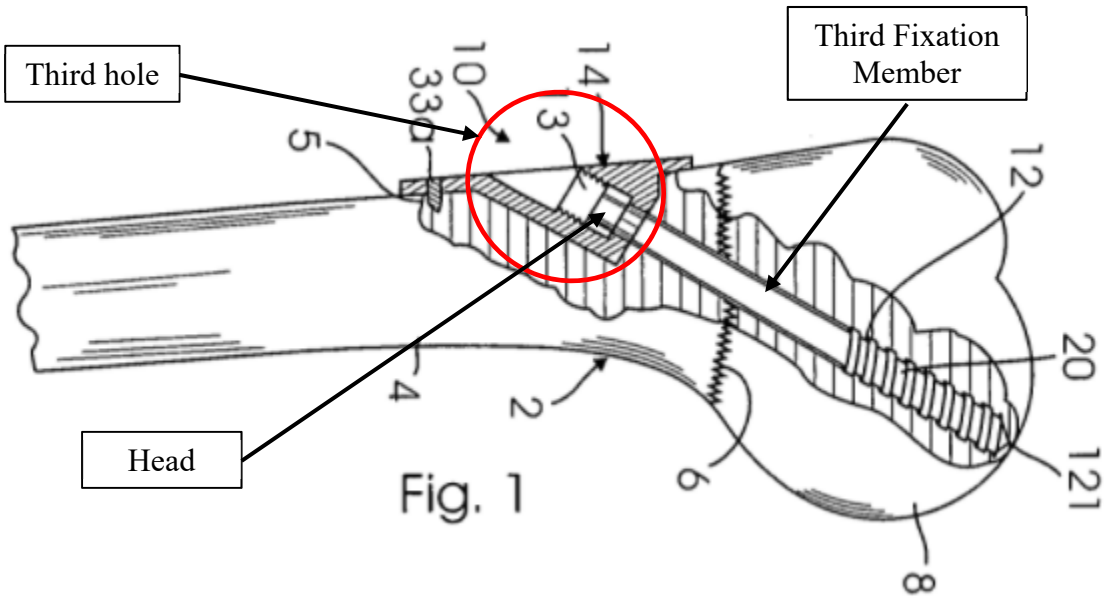
Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶¶212-13).

vi. [32e] a head of the third fixation member is seated in the third hole,

Arnould's bone plate comprises screw 30 configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone). (Ex. 1006, ¶32). Screw 30 is tightened until the head 32 is abutted against the edge of hole 25. (*Id.*). In order for screw 30 to lock in place, hole 25 comprises a concave surface that is substantially complementary with head 32 of screw 30. (Ex. 1006, ¶27). Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶¶214-15).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the placement of

the angled fixation screw. (Ex. 1002, ¶216). Zahiri discloses a threaded portion 37 in the short barrel portion 38 (third hole), which provides a press fit engagement with the head 22 of the lag screw 12 (third fixation member):

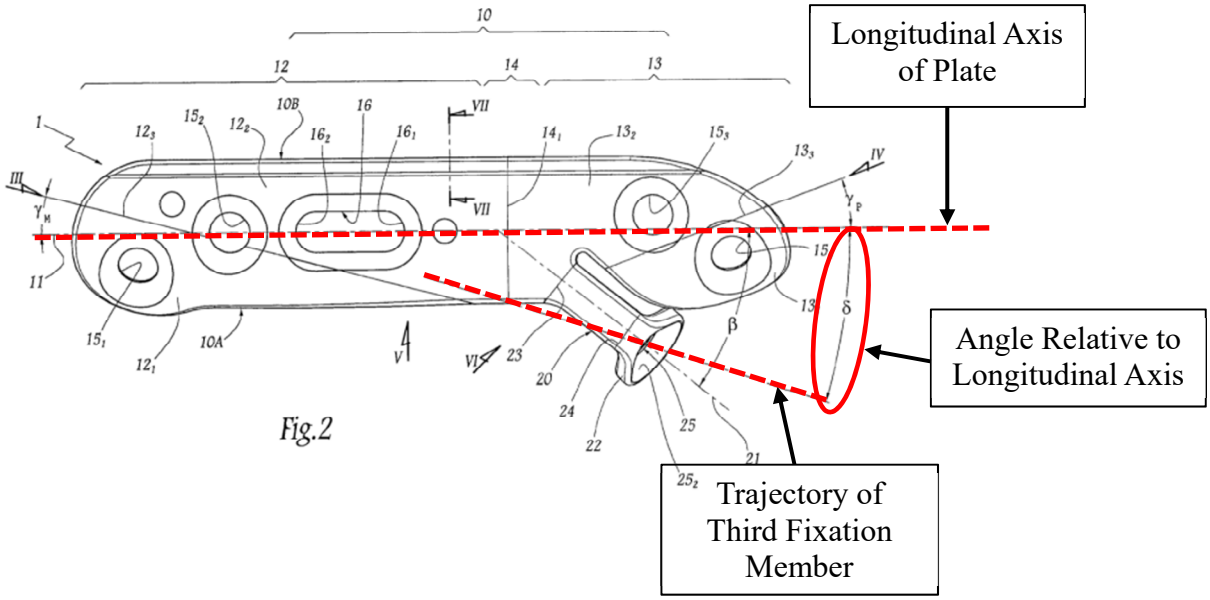


(Ex. 1007, FIG. 1 (annotated); *see also* 7:31-38). Thus, in order to achieve the stated goal from Arnould of locking screw 30 by the head 32, it would be obvious to a POSITA to use the seated head of the lag screw from Zahiri to ensure the third fixation member is seated in the third hole. (Ex. 1002, ¶216).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶217).

vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

Arnould describes a screw hole 25 (third hole) configured such that the screw 30 forms a non-zero angle in relation to the longitudinal axis of the plate body:



(Ex. 1006, FIG. 2 (annotated); *see also* ¶27 ("The hole 25 is provided to receive the screw 30 so that, depending on the direction of observation corresponding to arrow II, the longitudinal axis 31 of this screw can be inclined in relation to the longitudinal direction 11 of the plate body 10, forming a non-zero angle δ with this direction 11."); Ex. 1002, ¶218). Thus, the trajectory of the third fixation member, and therefore the third hole, is angled relative to the longitudinal axis of the plate. (Ex. 1002, ¶218).

Arnould further shows how there is a thickness to the plate where screw 30 is inserted into hole 25:

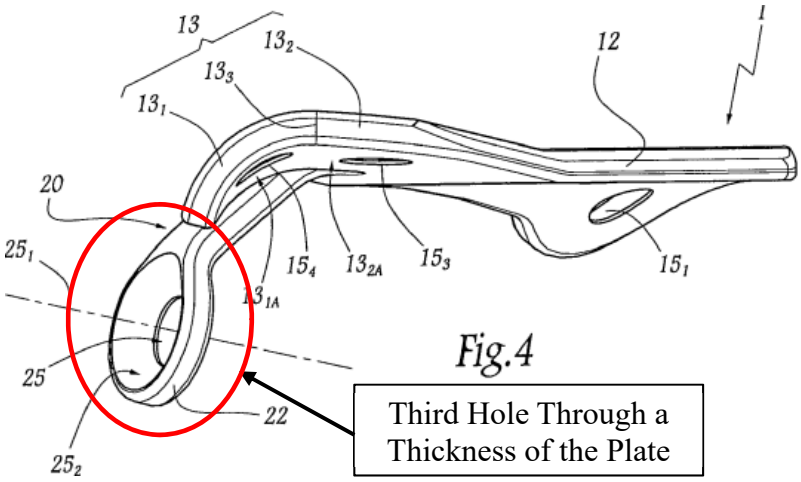
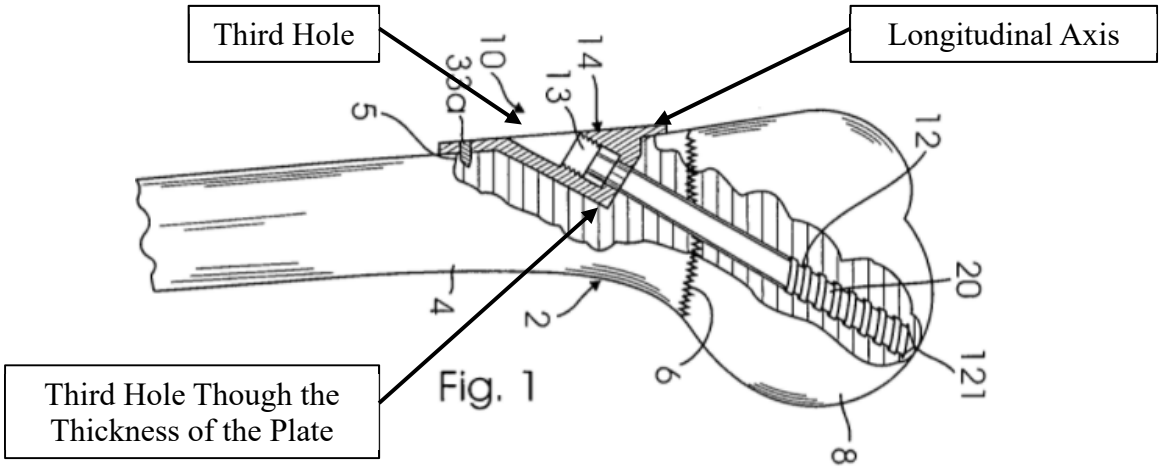


Fig.4

(Ex. 1006, FIG. 4 (annotated); Ex. 1002, ¶219).

Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶220).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw, which includes putting the screw through a thickness of the plate:



(Ex. 1007, FIG. 1 (annotated), *see also* 7:63-8:11; Ex. 1002, ¶221).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶222).

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

Arnould depicts a bone plate comprising one hole 25 configured to receive an angled screw 30 that passes through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

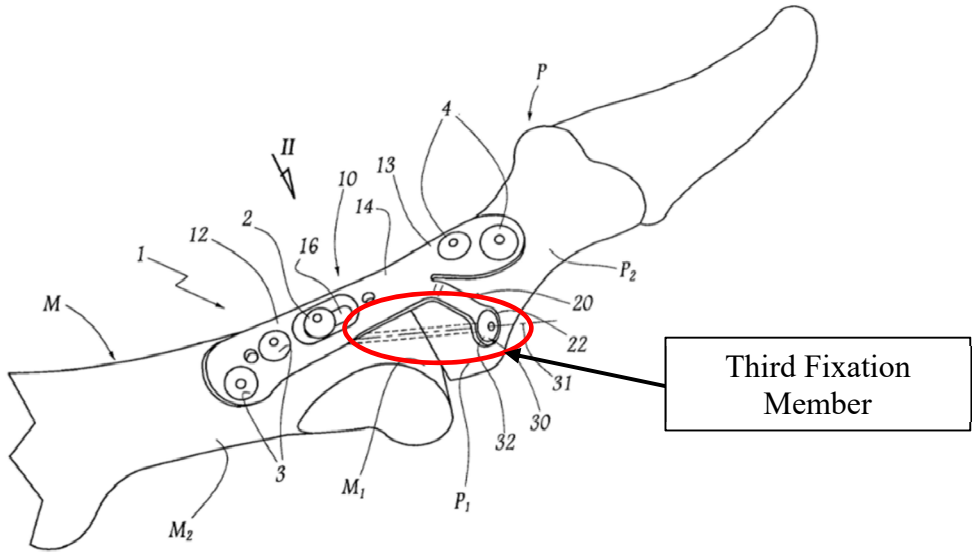


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶32 ("The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above.")).

Additionally, Zahiri depicts a bone plate comprising a guide hole through a barrel portion configured to angle a lag screw through a first bone and into a second bone. (Ex. 1007, 2:23-36). Figure 1 of Zahiri shows that the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone fragment and the second bone fragment:

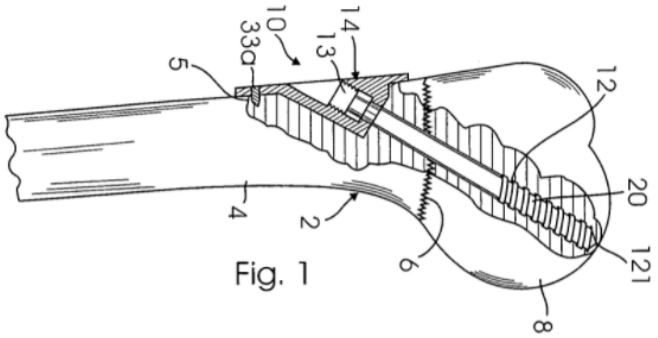


Fig. 1

(Ex. 1007, FIG. 1; *see also* 2:23-36). Therefore, a POSITA would understand that both Arnould's bone plate and Zahiri's bone plate are configured for only one compression screw to intersect the joint and/or fracture line. (Ex. 1002, ¶¶223-24).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶225).

b. *Dependent Claims 33, 36-39*

i. Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

Arnould discloses the trajectory of screw 30, and therefore hole 25, forms a non-zero angle relative to the plate body in the longitudinal direction at angle δ, where angle δ is less than 45°:

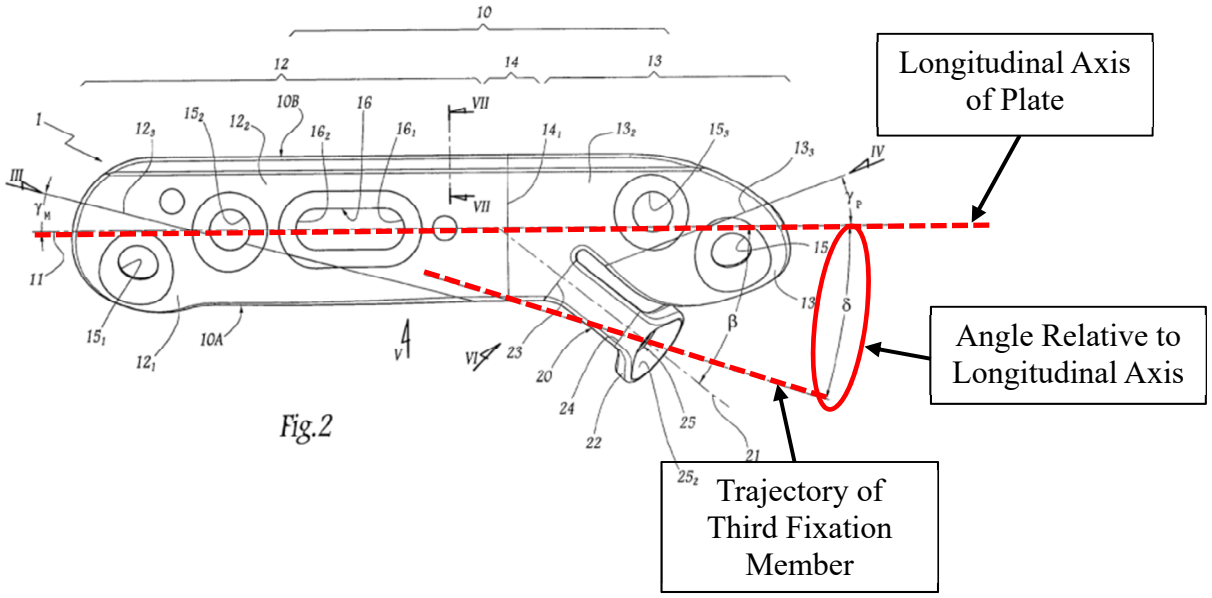


Fig.2

(Ex. 1006, FIG. 2 (annotated); *see also* ¶27 ("For anatomical reasons, the angle δ is advantageously chosen to be less than 45.")). Hole 25 is further connected to leg 20, where leg 20 is offset at angle β with respect to the longitudinal axis of the plate. (Ex. 1006, ¶25). Thus, a POSITA would understand that the disclosed angle range of Arnould would fall within the claimed angle range. (Ex. 1002, ¶226).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶227). Additionally, if the specific application did not allow the leg 20 to wrap around the side of the bone, as shown in Figure 1 of Arnould, a POSITA would look for other plates, such as Zahiri, that are equally applicable to the application. (*Id.*). Give that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone

parts for the purpose of fusing a bone fracture, a POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures would be used interchangeably, as they have for decades. (Ex. 1002, ¶228). Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate. (*Id.*).

Zahiri further discloses an incidence angle of a locking screw "A" that is preferably 90°, 150° or 160° from the guide plate but "in the range of from 90° to 170°." (Ex. 1007, 3:59-67). The incidence angle "A" is measured as the obtuse angle between the guide plate and the locking screw trajectory:

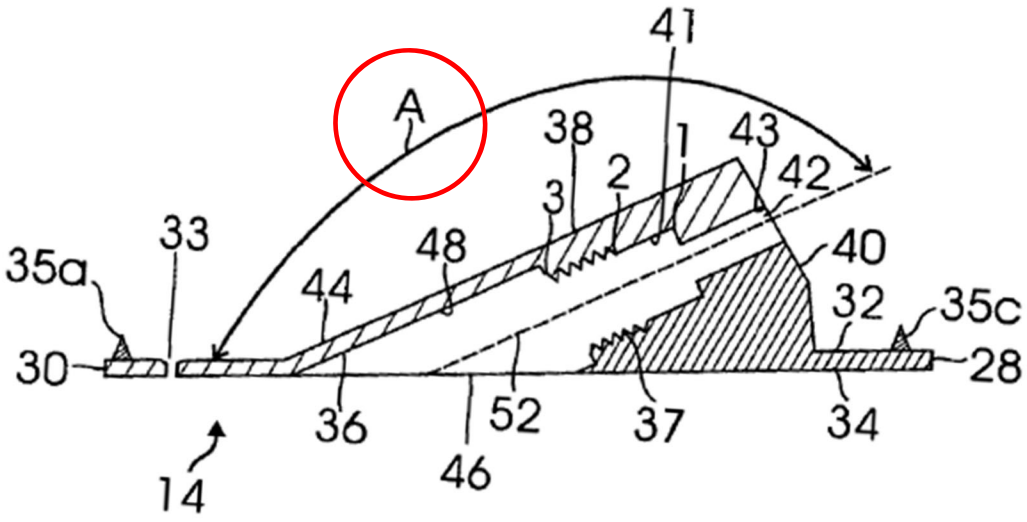
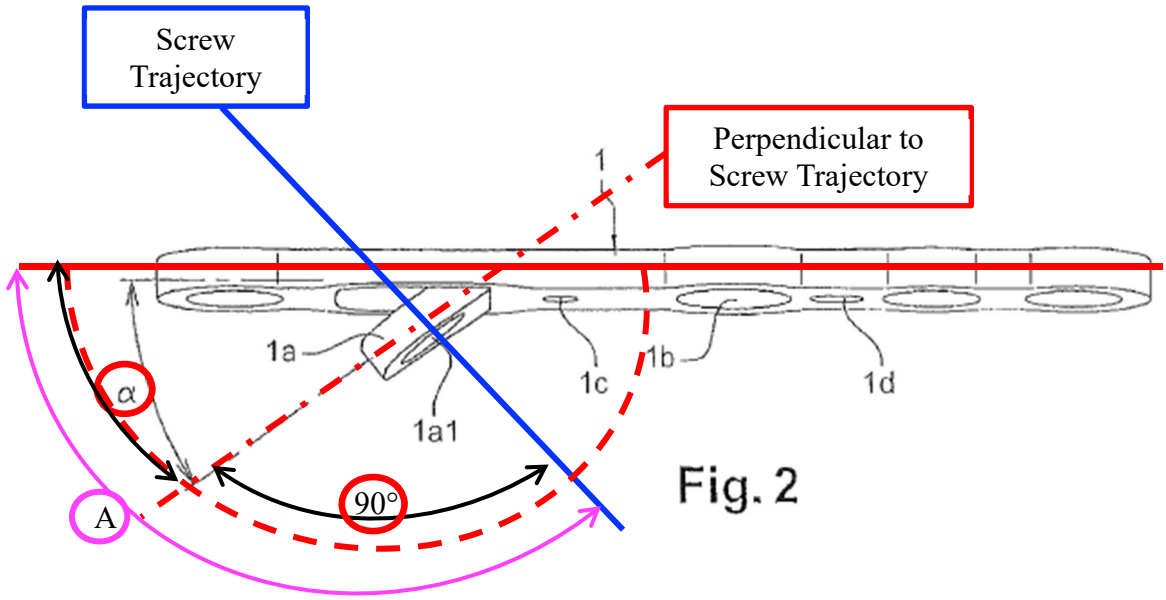


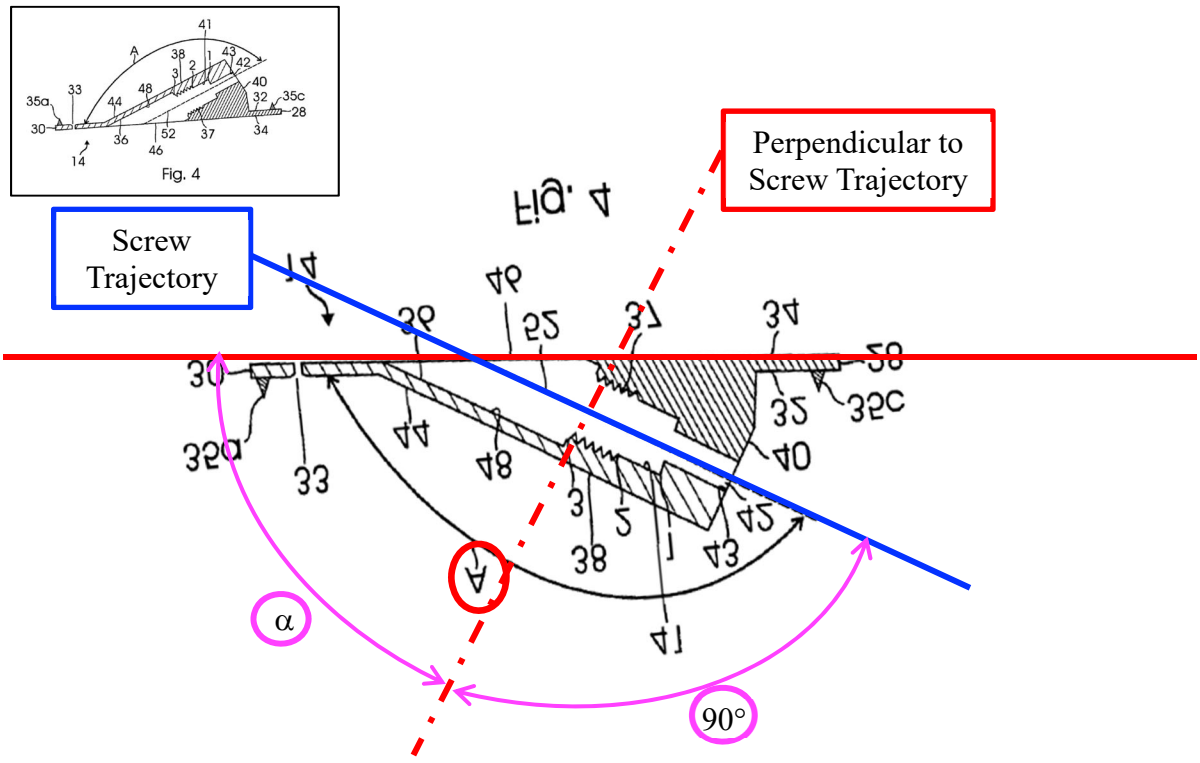
Fig. 4

(Ex. 1007, FIG. 4 (annotated); Ex. 1002, ¶229). In contrast, the '713 Patent refers to angled tab by the angle "α," which is the acute angle between the plate and the tab in Figure 2:



Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°

(Ex. 1001, FIG. 2 (annotated); *see also* Ex. 1002, ¶229). To be comparable to angle "A" in Zahiri, 90° has to be added to "α":



Zahiri's Screw Incidence Angle = "A"
Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°
For example, if Zahiri says that "A" can be 90° - 170°; then '713 Patent α can be 0° - 80°
But Zahiri prefers "A" = 150° or 160°, which equates to α in the '713 Patent equaling 60° - 70°

(Ex. 1007, FIG. 4 (annotated); *see also* Ex. 1002, ¶229). Therefore, the angle of the hole opening "α," is determined by subtracting 90° from A (hole opening "α," = A - 90°). (Ex. 1002, ¶229). Accordingly, Zahiri teaches a hole-opening angle "α," at 0° to 80° with respect to the longitudinal surface of the guide plate. (Ex. 1002, ¶230).

Both Arnould and Zahiri teach a third hole configured at an angle with respect to the longitudinal axis of the plate and that angle encompasses the claimed range. Thus, it would also be obvious to a POSITA that a fixation member configured to

diagonally secure a joint would be angled between 30° and 60° with respect to the longitudinal axis of the plate. (Ex. 1002, ¶230-31).

Thus, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1002, ¶231).

ii. Claim 36: The method of claim 32, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

Arnould's bone plate comprises four holes 15_1-15_4 configured in a quadrilateral orientation and receive screws 3 and 4:

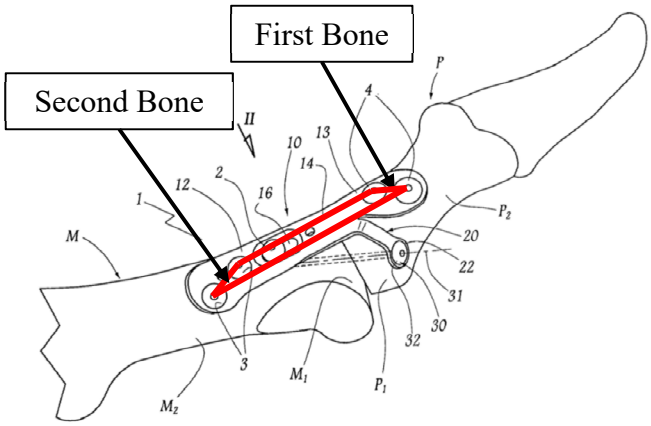


Fig.1

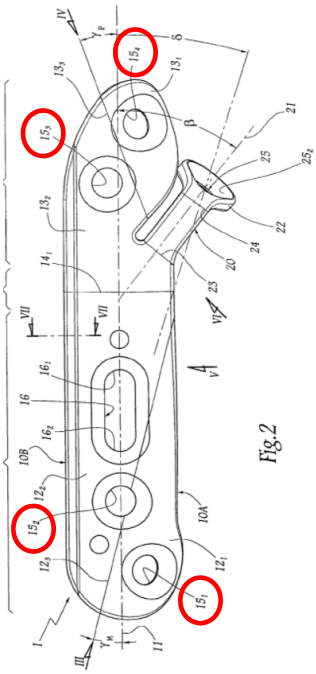


Fig.2

(Ex. 1006, FIGS. 1, 2 (annotated); *see also* ¶21). Holes 15_1 and 15_2 are configured to receive screws 3 and attach to the metatarsal (second bone), and holes 15_3 and 15_4 are configured to receive screws 4 and attach to the phalanx (first bone). (*Id.*).

Additionally, Zahiri's bone plate comprises four holes 31a-d in a rectangular (i.e., quadrilateral) orientation, where the holes are intended for anchoring the plate to the bone:

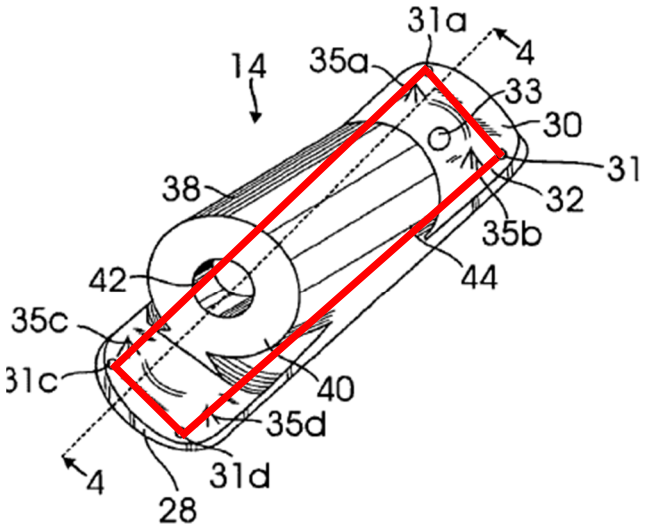


Fig. 3

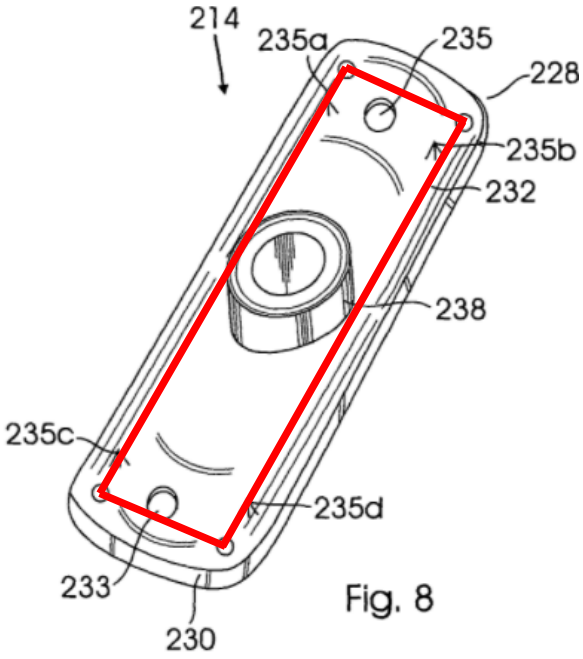


Fig. 8

(Ex. 1007, FIGS. 3, 8 (annotated); *see also* 5:47-49 ("Referring to FIGS. 2 and 3, there is illustrated the guide plate 14 having four small holes 31a, 31b, 31c, and 31d respectively located at each corner of the rectangular plate")). A POSITA looking at Zahiri's plate would recognize that these holes were arranged in a quadrilateral shape and that fixation members would be used in these holes to secure the plate to the

bone. (Ex. 1002, ¶¶232-33). Combining these holes and fixation members from Zahiri with Arnould's plate would result in securing the plate to the first and second bones. (Ex. 1002, ¶233).

Thus, a POSITA would understand that this claim is taught by Arnould and Zahiri. (Ex. 1002, ¶234).

iii. Claim 37[a]: The method of claim 36, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and

Arnould discloses a bone plate comprising predetermined contours necessary to secure to the metatarsal and phalangeal and to conform to the upper surface of the diaphyseal portion of the metatarsal:

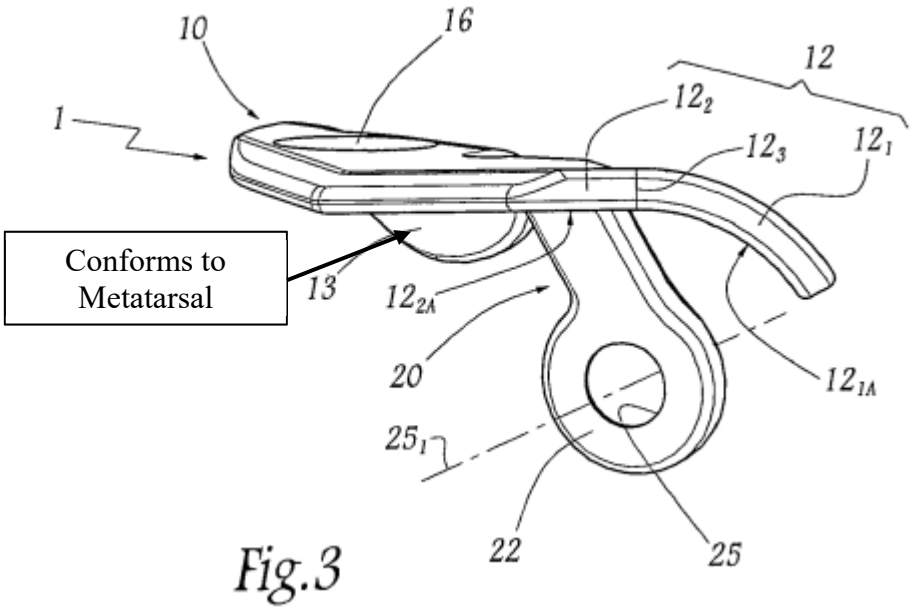


Fig.3

(Ex. 1006, FIG. 3 (annotated); *see also* FIGS. 4, 5, 6; ¶15 ("The concave lower surface 12_{1A} of the bent section 12_1, which is clearly visible in Figure 3, is shaped to

conform to the upper surface of the diaphyseal portion M_2 of the metatarsal M – that is to say, to come into contact with this diaphysis while partially covering it in a fitted manner, as shown in Figure 1."); ¶39 ("This plate is, in a first step, cut in accordance with predetermined contours in order to secure the metatarsal 12 and phalangeal 13 parts, as well as the leg 20.")).

Thus, a POSITA would find this element is taught by Arnould. (Ex. 1002, ¶¶235-37).

iv. Claim 37[b]: the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

Arnould describes a bone plate comprising screw 30 that is angularly inserted into hole 25 relative to the plate body:

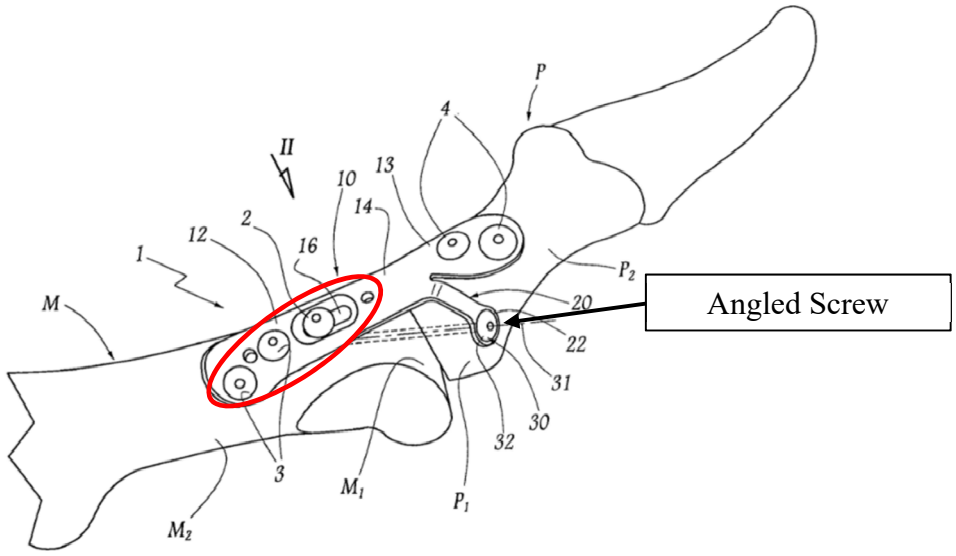


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶¶32-34). Screws 3 and 4 are inserted into respective holes 15_1-15_4, and are configured to secure the plate body to the metatarsal and phalanx. (Ex. 1006, ¶¶32-34). A POSITA looking at Figure 1 would understand that screw 30 is angled relative to screws 3 and 4. (Ex. 1002, ¶238).

Thus, a POSITA would find this element is taught by Arnould. (Ex. 1002, ¶239).

v. Claim 38: The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

Arnould discloses partially affixing the bone plate so that surgeon can correctly place the plate before the plate is permanently affixed. (Ex. 1006, ¶31). While Arnould does not explicitly describe the use of k-wires to temporarily hold

the plate in place while the screws are inserted, the figures show pin holes that are used to temporarily secure the plate with k-wires during the implantation process:

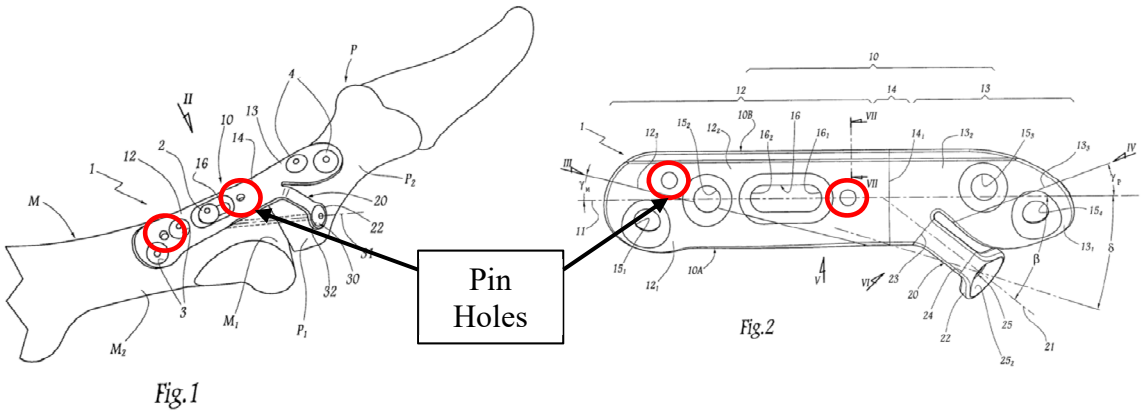


Fig.1

Fig.2

(Ex. 1006, FIGS. 1, 2 (annotated); Ex. 1002, ¶240). K-wires are commonly used for temporary placement and immobilization of bone plates so that the surgeon can correctly position and align a plate. (Ex. 1002, ¶240).

Thus, a POSITA would find this claim obvious in view of Arnould. (Ex. 1002, ¶241).

To the extent that Arnould does not render this element obvious, a POSITA would have readily looked to Zahiri. (Ex. 1002, ¶242). Zahiri explicitly discloses additional pins that "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). Figure 8 shows the location of these pin holes:

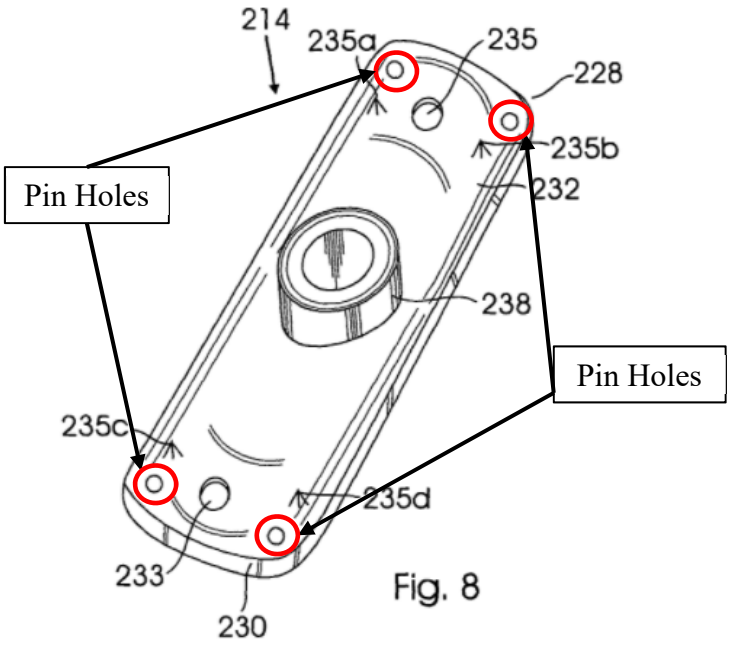


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* Ex. 1002, ¶242). Additionally, after "the lag screw 12 is settled inside of the epiphysis 8 the four pins are pulled out, and a medium size screw 33a is pressed and turned through the hole [2]33 of the plate [2]14 and into the bone diaphyseal segment." (Ex. 1007, 7:63-8:11). Since Arnould describes temporarily securing the plate, a POSITA would be motivated to utilize the pin holes in Zahiri to ensure proper placement and alignment of the plate during implantation. (Ex. 1002, ¶242). Use of temporary fixation pins was common at the time of invention, and would have been readily utilized by a POSITA given the explicit disclosure in Zahiri and the desire to temporarily secure Arnold's plate. (*Id.*).

Thus, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1002, ¶243).

vi. Claim 39: The method of claim 32, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

Arnould discloses a bone plate for arthrodesis of the metatarsophalangeal joint which is a joint within the foot:

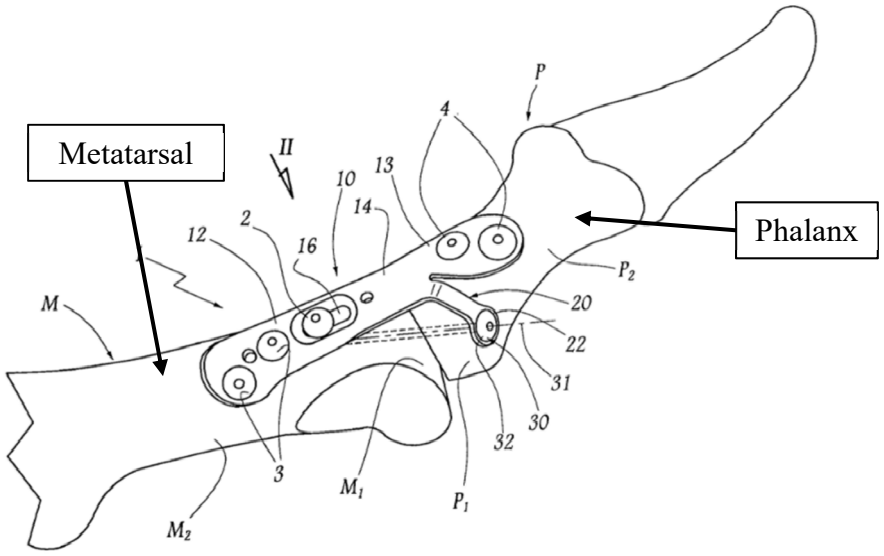


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶5). Arnould specifically states 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." (Ex. 1006, ¶11). A POSITA would understand that the metatarsal and phalanx are bones in the foot. (Ex. 1002, ¶244).

Thus, a POSITA would find that this claim is taught by Arnould. (Ex. 1002, ¶245).

G. Ground 5: Claims 34 and 35 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over the Combination of Arnould, Zahiri and Myerson

Dependent claims 34 and 35 are obvious in view of the combination of Arnould, Zahiri, and Myerson.

1. Basis for Combination of Arnould, Zahiri and Myerson

A POSITA would be motivated to combine Arnould and Zahiri for at least the reasons set forth in Section VII.F.1. Additionally, Arnould describes the desire to completely secure the plate to the bone using the screws. (Ex. 1006, ¶¶33-34). In analogous art, Myerson discloses a bone plate for fusion of the MTP joint as well as for receiving a locking screw in combination with threaded holes to lock the fixation screws in place. (Ex. 1008, ¶22).

Thus, the use of locking screws or threaded holes to prevent the screws from backing out is a well-known element of the prior art to obtain a predictable result. (Ex. 1002, ¶248). Therefore, incorporating locking screws or threaded holes into Arnould's bone plate can be accomplished through a simple substitution to provide a known advantage and accomplish a predictable result. (*Id.*). A POSITA would be motivated to apply the teachings of Myerson and modify Arnould's bone plate. (Ex. 1002, ¶¶247-48).

2. Claims 34 and 35 are Obvious in view of the Combination of Arnould, Zahiri and Myerson

a. *Independent Claim 32*

Independent claim 32, from which claims 34, and 35 depend, is obvious in view of Arnould and Zahiri (Ground 4). (*See* Section VII.F.2.a.i-viii; Ex. 1002, ¶¶198-225, 249).

b. *Dependent Claims 34 and 35*

i. Claim 34: The method of claim 32, wherein the first and second holes are locking holes.

Myerson's bone plate comprises screw holes 22 (first hole) and 32, 36 (second hole) configured to receive locking screws with the plate having locking threads within the screw holes:

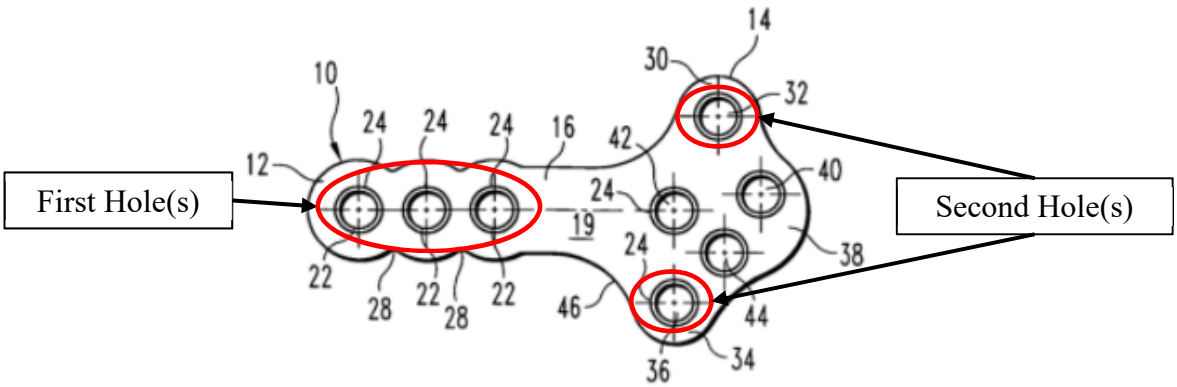


Fig. 2

(Ex. 1008, FIG. 2 (annotated); *see also* ¶22 ("the screw holes are designed to receive locking screws, such as by the incorporation of locking threads (not shown) within the screw hole."); ¶25). Myerson provides an explicit description of the locking

thread: "In a specific embodiment, the locking screws may be at 0.5 mm pitch, with a 4.0 mm major diameter and a 3.6mm minor diameter." (Ex. 1008, ¶22),

The use of locking screws with locking threaded holes, as described in Myerson, with Arnould's plate, provides a solution and a predictable result in the field of bone plates, to the known problem of screws loosening and backing out over time. (Ex. 1002, ¶250). Myerson identifies a known method for securing screws and preventing screws from backing out: use of locking screws with locking threaded holes. (Ex. 1008, ¶22). Thus, a POSITA would have been motivated to combine this teaching from Myerson with Arnould's plate, which was already modified by Zahiri as discussed with respect to claim 32, because the use of locking screws with locking threaded holes are a known technique to prevent the screws from backing out. (Ex. 1002, ¶¶251-52).

Thus, a POSITA would find that the combination of Arnould, Zahiri and Myerson teaches the first and second holes are locking holes. (Ex. 1002, ¶253).

ii. Claim 35: The method of claim 34, wherein the first and second holes are threaded.

For the same reasons given with respect to claim 34 and explained in Section VII.G.2.b.i, a POSITA would find that the combination of Arnould, Zahiri and Myerson teaches the first and second holes are locking threaded holes. (*See* Ex. 1008, FIG. 2, ¶¶22, 25; Ex. 1002, ¶254).

VIII. CONCLUSION

The Petition demonstrates a reasonable likelihood that at least one claim is unpatentable. Accordingly, all grounds in the Petition should be instituted. *SAS Institute Inc. v. Iancu*, 138 S.Ct. 1348, 1359-60 (2018).

Respectfully submitted by

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IX. CLAIM APPENDIX OF THE CHALLENGED CLAIMS

[32pre] A method of fusing a joint, the method comprising:

[32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

[32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

[32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

[32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and

[32e] a head of the third fixation member is seated in the third hole,

[32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

[32g] wherein the third fixation member is the only fixation member extending across the joint.

[33] The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

[34] The method of claim 32, wherein the first and second holes are locking holes.

[35] The method of claim 34, wherein the first and second holes are threaded.

[36a] The method of claim 32, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral,

[36b] and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

[37a] The method of claim 36, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and

[37b] the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

[38] The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

[39] The method of claim 32, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

Certification of Service Under 37 C.F.R. §42.6(e)(4)

A copy of this Petition for *Inter Partes* Review and supporting materials has been served at the following correspondence address of record for the subject patent via Federal Express Priority Overnight® on this 28th day of January, 2022:

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Certification of Word Count Under 37 C.F.R. §42.24(d)

The undersigned hereby certifies that the foregoing Petition for *Inter Partes* Review contains 13,528 words, not including a table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits or appendix of claim listing as specified by 37 C.F.R. §42.24, according to the word count feature of the word-processing software used to prepare the Petition.

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