UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00488
U.S. PATENT NO. 10,993,751

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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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)[1][2], 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. 10,993,751 ("'751 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. 9,078,713 (related to the '751 Patent); and
- U.S. Patent No. 9,168,074.

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
- IPR2022-00487.

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))

Lead Counsel	Backup Counsel
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Petitioner consents to electronic service by email.

I. INTRODUCTION

Petitioner requests institution of *Inter Partes* Review ("IPR") of claims 1-3 and 6-18 ("Challenged Claims") of the '751 Patent (Ex. 1001) and cancellation of the Challenged Claims in view of the Grounds described below. This Petition is supported by the declaration of Michael Sherman, an expert in the field of the '751 Patent and the prior art. (Ex. 1002; Ex. 1002, ¶¶1-20).

II. '751 PATENT OVERVIEW

The '751 Patent issued on May 4, 2021. (Ex. 1001, Cover). It describes a bone plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of the plate. (*Id.*, Abstract; Ex. 1002, ¶44). It claims a "system for fusing a first discrete bone and a second discrete bone separated by a joint, … and a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in the second discrete bone." (Ex. 1001, cl. 1; Ex. 1002, ¶45). Figure 3 is exemplary:

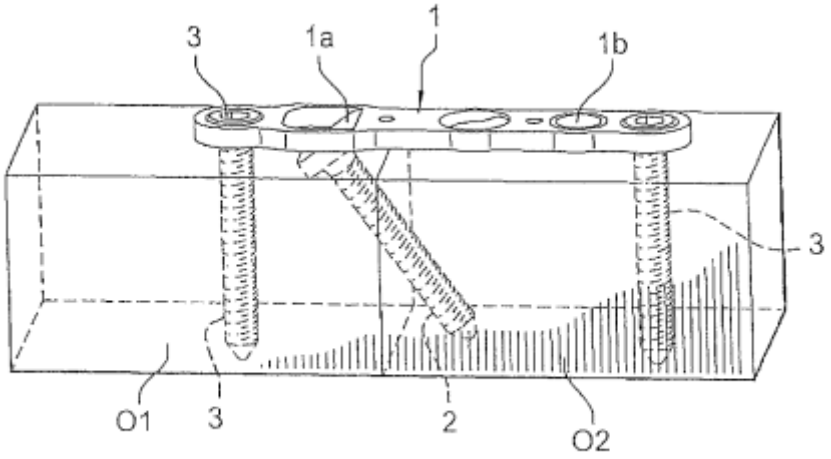


Fig. 3

(Ex. 1001, Fig. 3; cl. 1, 2:20-29).

The '751 Patent fails to add anything to the then-existing state of the art, and describes known techniques for securing a compression bone plate and fusing the joint between two bones. (Ex. 1002, ¶¶34-40, 44-47).

A. Prosecution History of the '751 Patent

Application No. 17/143,709 was granted following amendments made after a Non-Final Office Action. (Ex. 1003, 11-12; Ex. 1002, 48-49). The Examiner rejected the claims under §102 in view of U.S. Pub. No. 2002/0128653, and §103 in view of U.S. Pub. No. 2002/0128653 and U.S. Pub. No. 2009/0210011. Applicant proposed amended claims in an Examiner Interview. (Ex. 1003, 160-61). Independent claims 2, 12, and 18 (allowed claims 1, 11, and 17) were then allowed. (Ex. 1003, 169).

Claim 2 (allowed claim 1) was allowed for reciting, " a first discrete bone and second discrete bone separated by a joint"; claim 12 (allowed claim 11) was allowed

for reciting, "a third hole and a fourth located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area", and "the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area"; and claim 18 (allowed claim 17) was allowed for reciting, "said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate." (Ex. 1003, 153-56).

B. '751 Patent Priority

The '751 Patent claims priority to foreign application FR0856694A, through intervening Application Nos. PCT/FR2009/051879; 12/918,071; 14/041,706; 14/734,676; 15/130,147; and 16/429,834. (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 priority to FR0856694A, filed on October 2, 2008. (Ex. 1002, ¶¶41-42). No determination as to intervening priority need be made here as the references relied upon herein are prior art to the earliest U.S. filing date of October 2, 2009. (Ex. 1003, 7; Ex. 1002, ¶43). All references to §§102-103 are pre-AIA, which apply to the Challenged Claims.

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

Petitioner certifies that (1) the '751 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 '751 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 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 '751 Patent, a POSITA as of October of 2009, had at least a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and approximately three years of experience with orthopedic implant design. (Ex. 1002, ¶51). 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. (*Id.*). A POSITA would have been familiar with orthopedic implants, bone plates, and intramedullary implants. (*Id.*; Ex. 1002, ¶¶50-52).

VI. CLAIM CONSTRUCTION

For purposes of this proceeding, no terms need to be construed as the prior art because 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. (Ex. 1002, ¶¶22-26).

VII. STATEMENT OF PRECISE RELIEF REQUEST AND REASONS THEREFORE

Petitioner requests the institution of IPR and cancellation of the Challenged Claims as follows:

Ground	Basis	Relied-On References	Claim(s)
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater ("Slater") (Ex. 1004)	1, 2, 7, 8
2	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	1-2, 7-18
3	§103	Slater, Zahiri, and U.S. Pat. Pub. No. 2006/0241592 to Myerson ("Myerson") (Ex. 1010)	6
4	§103	E.P. Patent No. 1,897,509 to Arnould ("Arnould") (Ex. 1005-1006) and Zahiri	1-3, 7-18
5	§103	Arnould, Zahiri, and Myerson	6

A. The Petition Should Not Be Discretionarily Denied

1. *Becton, Dickinson*

'751 Patent claims have not been considered in view of the prior art relied upon in this Petition. The 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.

Petitioner plans to seek a stay of the NDIL Action. The motion to stay will be filed before the local patent rule deadline. And approximately 73 percent of motions to stay in view of IPRs have been granted in the district. (Ex. 1012, 1-2). There is no trial date presently set for any litigation involving the '751 Patent. The parties have made some investment in the litigation, but discovery is open and the *Markman* hearing is not yet scheduled and likely will not occur until after an institution decision comes out. The merits of the Petition's arguments strongly warrant consideration. The remaining factors are seemingly neutral. Balancing these factors, the Board should not exercise its discretion to deny this Petition.

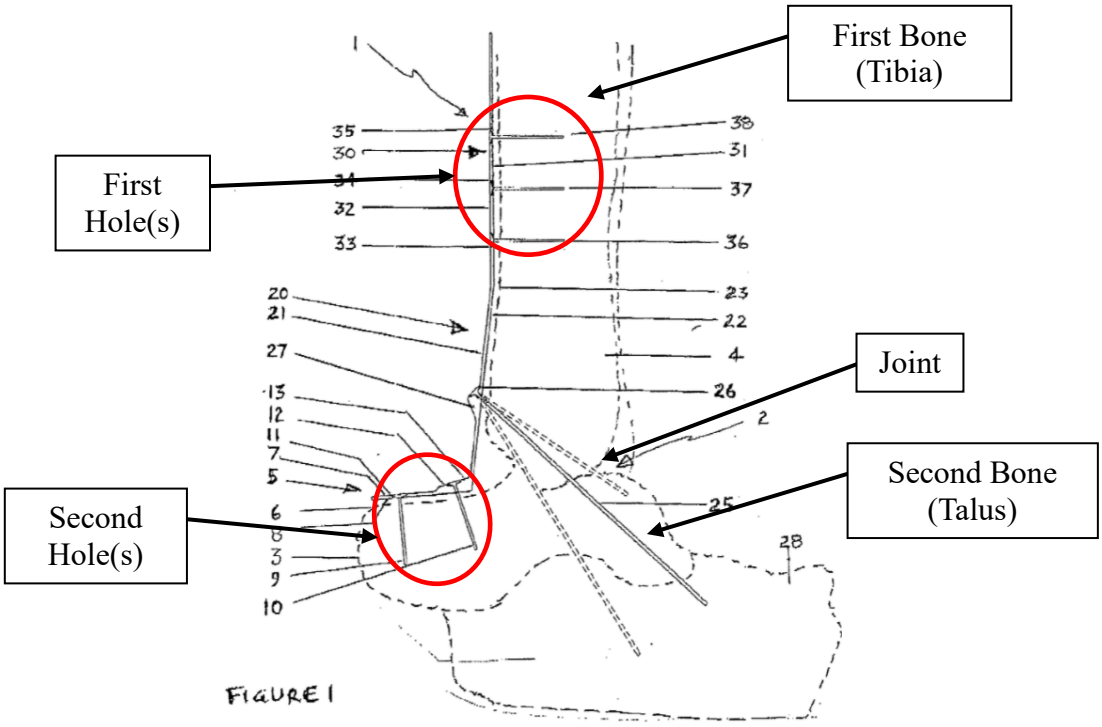
B. Overview of Prior Art

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. (*, e.g.*, Ex. 1002, ¶¶27-40).

1. Slater

Slater is a WIPO application published on November 22, 2007. (Ex. 1004, Cover). Slater qualifies as prior art under §102(b) as a printed publication more than one year prior to October 2, 2009, the earliest U.S. filing date of the ’751 Patent.

Slater discloses a fusion plate for arthrodesis of the joint between the tibia and the talus bone. (Ex. 1004, 11:1-16). Slater’s 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); Ex. 1002, 53-55).

2. Arnould

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 earliest U.S. filing date of the '751 Patent. Arnould was originally filed in French (Ex. 1005) and a certified English translation is provided. (Ex. 1006; Ex. 1002, ¶56).

Arnould discloses the arthrodesis of the metatarsal-phalangeal (MTP) joint through the use of a plate across the joint and permanently locks the joint in place. (Ex. 1006, ¶¶1-2; Ex. 1002, ¶57). A plate implanted in the foot is subject to frequent stress from walking and may weaken over time. (Ex. 1006, ¶6; Ex. 1002, ¶58). To

mitigate this effect, a screw is positioned through a tab of the plate and across the joint. (Ex. 1006, ¶26; Ex. 1002, ¶58). The screw "has a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone," providing a more stable plate. (Ex. 1006, ¶6; Ex. 1002, ¶¶59-60).

3. Zahiri

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 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:

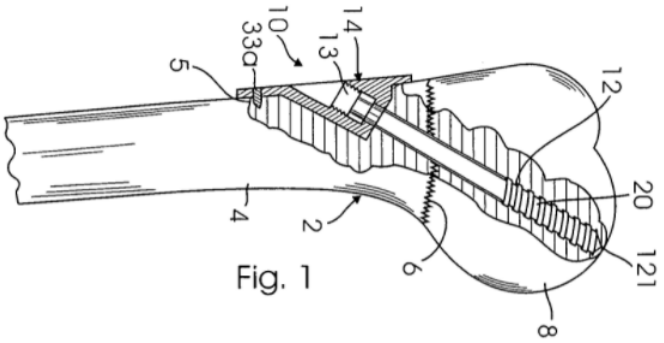


Fig. 1

(Ex. 1007, FIG. 1; 3:59-67). The plate further comprises pins 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 allows a surgeon to place the device. (*Id.*; Ex. 1002, ¶¶61-65).

4. Myerson

Myerson is a U.S. patent application that published on October 26, 2006. (Ex. 1010, Cover). Myerson qualifies as prior art under §102(b).

Myerson discloses a plate configured for joint fusion "between the first and second metatarsals and the middle and/or internal cuneiforms." (Ex. 1010, FIG. 1; ¶¶5, 10). The plate is contoured to follow the anatomy of the mid-foot bones and especially across the metatarsal joints. (Ex. 1010, ¶¶21-22; Ex. 1002, ¶¶66-69).

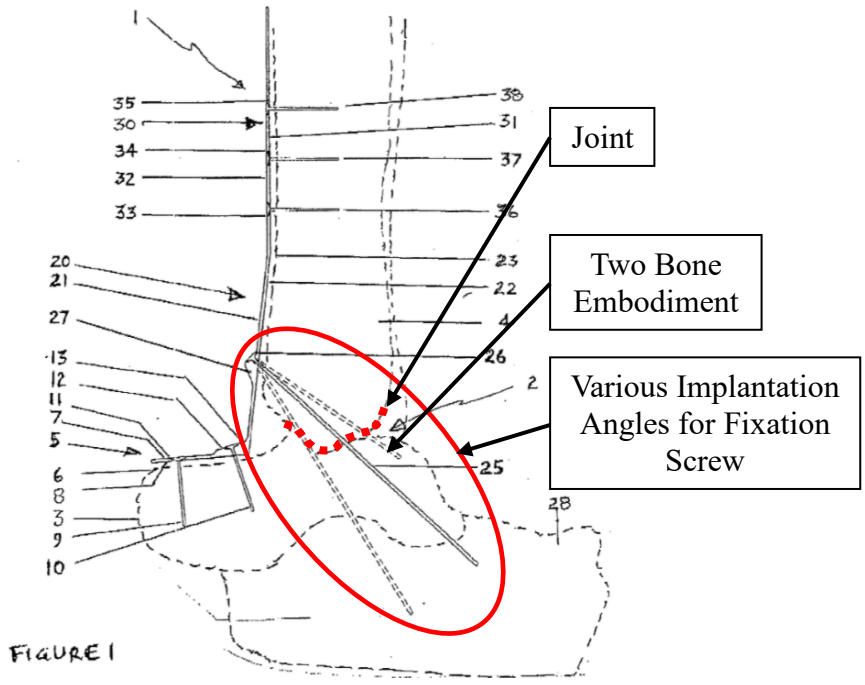
C. Ground 1: Claims 1, 2, 7, and 8 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Slater

Independent claim 1 and dependent claims 2, 7, and 8 are obvious in view of Slater. (Ex. 1002, ¶73)

1. Basis for Combination

The scope and content of the prior art includes Slater and the technical expertise of a POSITA, which collectively discloses all of the elements of claims 1, 2, 7, and 8. There are no differences between the subject matter of these claims and the combination of Slater and the technical expertise of a POSITA.

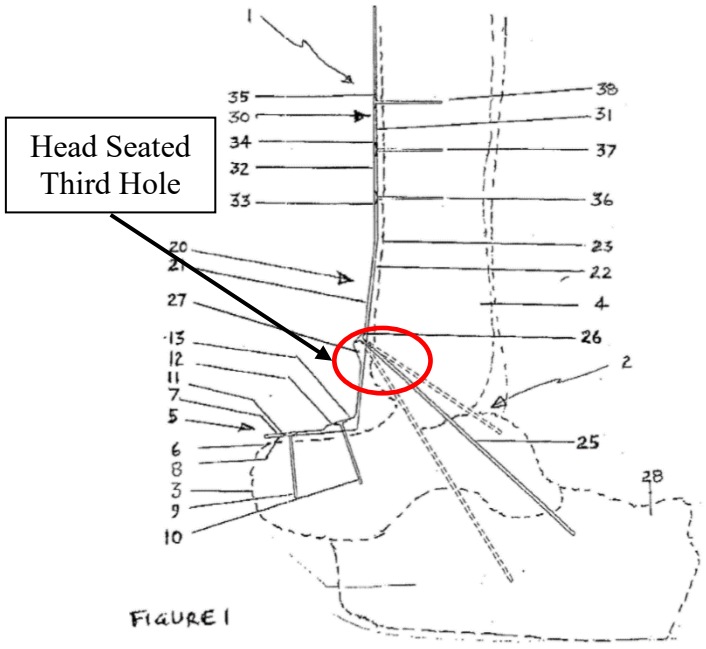
Slater discloses a plate comprising a fixation screw that is placed at an angle so that it compresses the ankle joint and intersects the tibia, talus, and potentially the calcaneus:



(Ex. 1004, FIG. 1 (annotated); 6:14-28, 11:18-27). Slater's 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 plate is that the fixation screw can be configured at multiple angles and "incorporate more joints into the arthrodesis as required." (Ex. 1004, 16:25-17:12; Ex. 1002, ¶¶74-75). Therefore, a POSITA would understand that Slater discloses an embodiment of the fixation screw 25 configured to intersect a joint through two discrete bones. (Ex. 1002, ¶76).

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

21; 12:23-25 ("Opening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation."); Ex. 1002, ¶77). Slater's fixation screw 25 enters the plate through opening 26 in formation 27 and anchors into the bone within a predetermined range of angles:



(Ex. 1004, FIG. 1 (annotated); 11:18-27). Additionally, Slater depicts the fixation screw 25 in a recessed position in opening 26. A POSITA would understand that the fixation screw 25 (third fixation member) is seated in the third hole (opening 26). (Ex. 1002, ¶¶78-79).

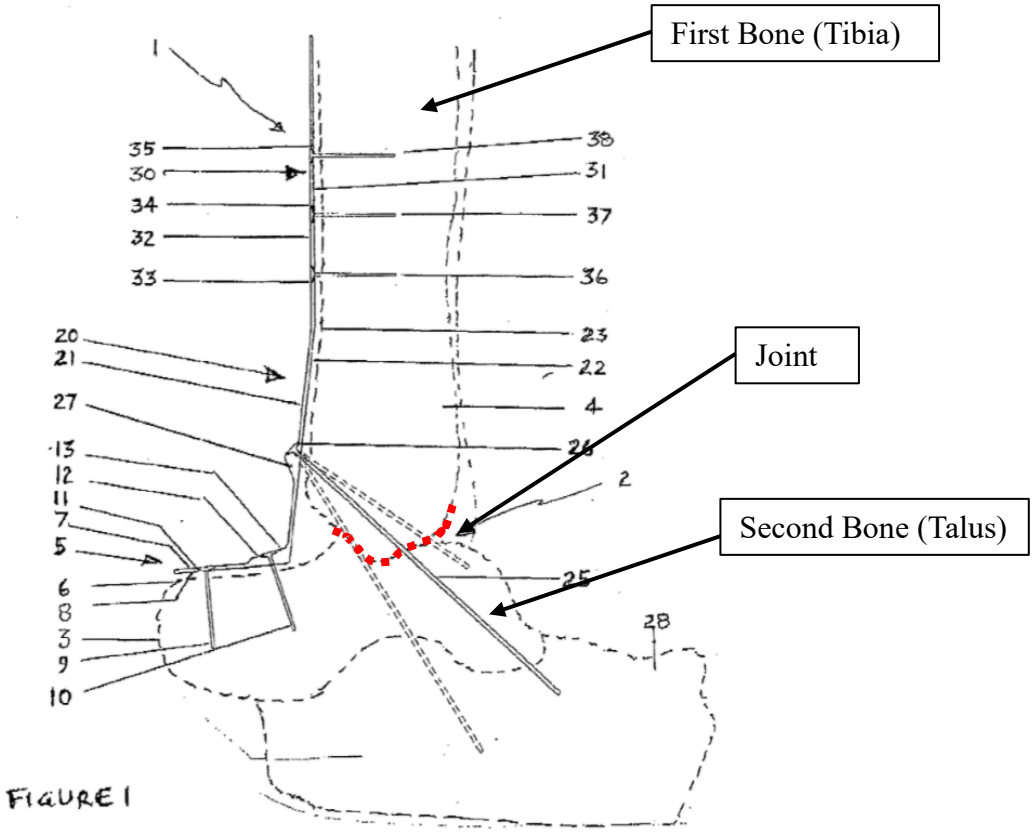
Based on the teachings of Slater and knowledge of the art, a POSITA would find claims 1, 2, 7, and 8 obvious. (Ex. 1002, ¶79).

2. Claims 1, 2, 7, and 8 would have been Obvious

a. *Independent Claim 1*

i. [1Pre] A system for fusing…[3]

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); 1:6-7 ("The present invention relates to prosthetic devices and more particularly relates to an ankle fusion plate for fusion of the

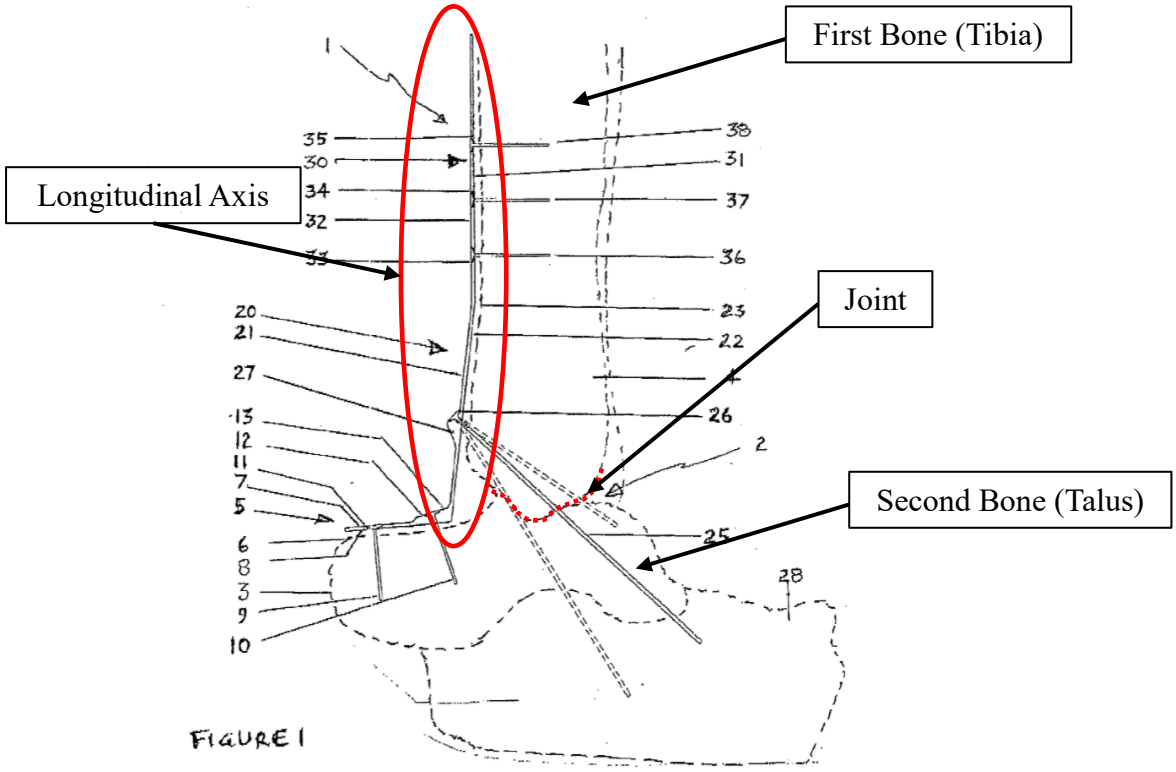
[3] The full language of each claim element is listed in the Claim Appendix, below.

anterior ankle."); 6:14-28; 8:13-24; Ex. 1002, ¶¶82-83).

Slater discloses this element. (Ex. 1002, ¶84).

ii. [1a] a bone plate having…

Slater's bone plate comprises regions 30 and regions 20 that extend along the length of the tibia (first bone) to the talus (second bone), such that the bone plate is configure to isolate, span and fuse the joint along the x and y axes:

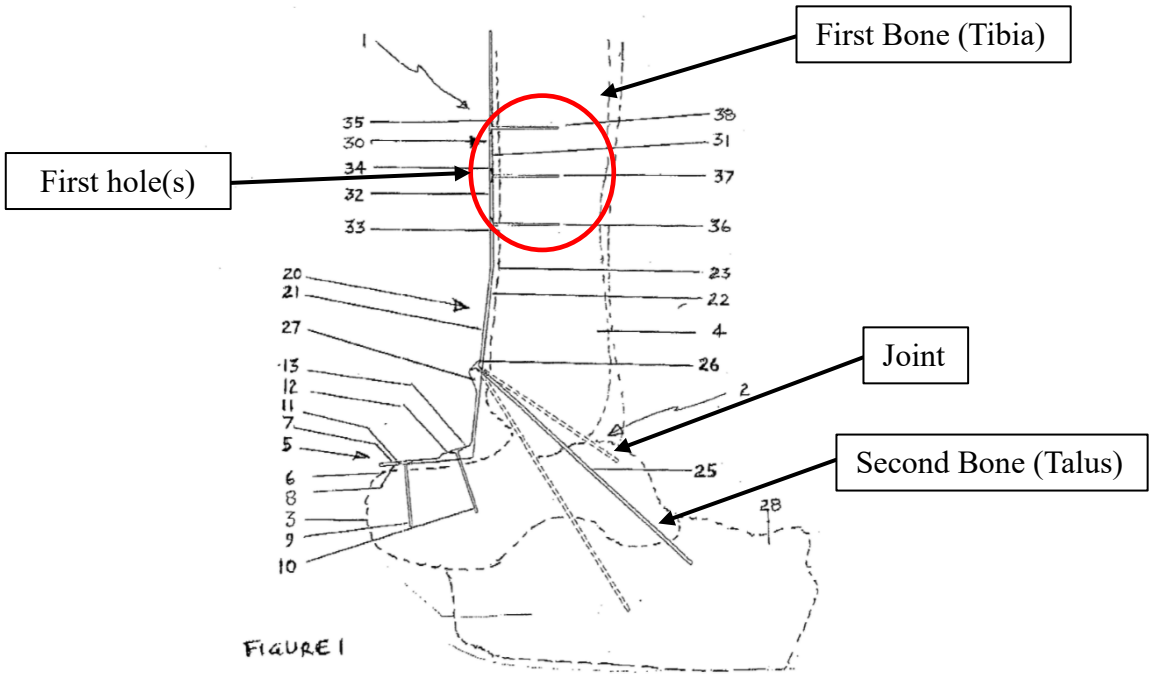


(Ex. 1004, FIG. 1 (annotated); 12:12-27, 13:5-18). A POSITA would understand that the bone plate comprises a longitudinal axis that spans from the first bone to the second bone with a sufficient length to encompass the joint between the first bone and second bone. (Ex. 1002, ¶¶85-86).

A POSITA would find Slater discloses this element. (Ex. 1002, ¶87).

iii. [1b] said bone plate defining…

Slater's bone plate is configured to fuse the joint between the Tibia (first discrete bone) and the Talus (second discrete bone) and comprises a first portion 30 (first end) that attaches to the anterior surface 23 of the tibia at openings 33-35 (first hole(s)):



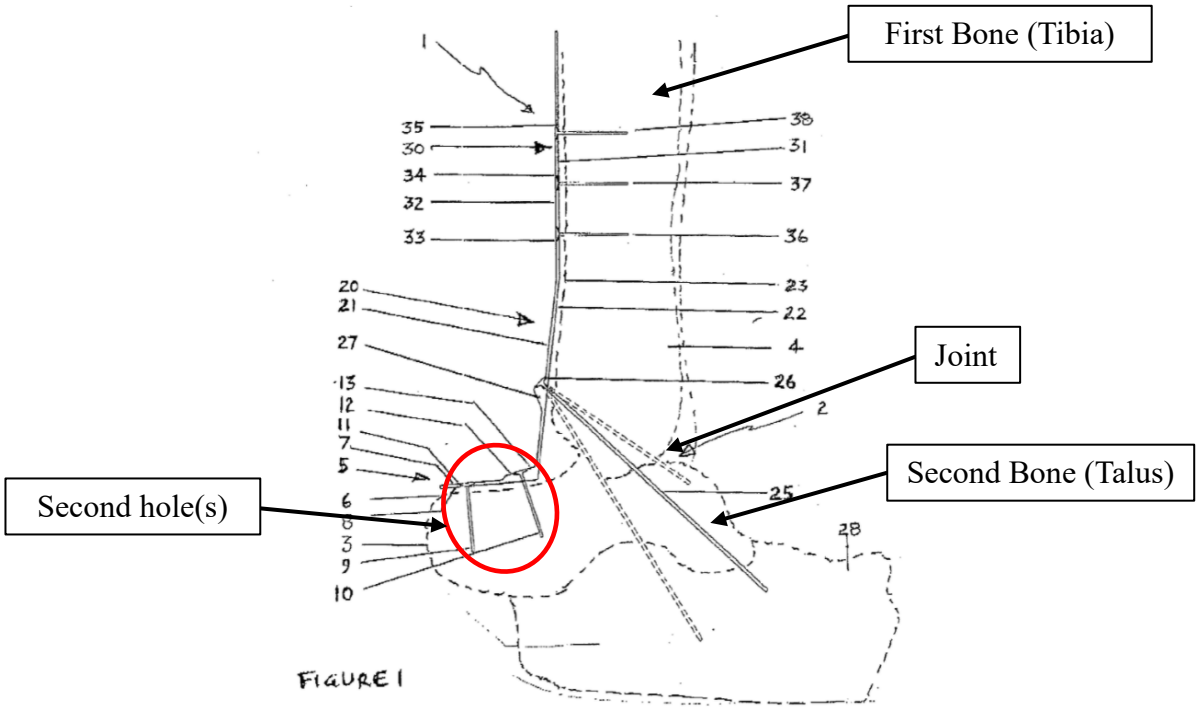
(Ex. 1004, FIG. 1 (annotated); 8:15-19 ("The first portion includes at least one opening including a formation which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region."); 13:6-9 ("Plate 80 which is attachable to an ankle joint opposing the Talus bone and Tibial bone, comprises a portion 81 disposed in a first plane which

generally aligns with an anterior surface of the talus."); 13:20-21 ("Portion 90 of plate 80 has an outer surface 91 and inner surface 92 which opposes an anterior surface of tibia for fixation thereto."); 11:18-19; Ex. 1002, ¶¶88-90). Portion 30 aligns with the anterior surface of the tibia (first bone). (Ex. 1004, 11:28-31; 8:13-14 ("Preferably the inner surface of the first portion of the plate opposes the anterior tibia.")).

Slater discloses this element. (Ex. 1002, ¶91).

iv. [1c] a second hole…

Slater's bone plate is configured to fuse the joint between the Tibia (first discrete bone) and the Talus (second discrete bone) and comprises a third portion 5 (second end) that attaches to the anterior surface 6 of the talus at openings 11-12 (second hole(s)):

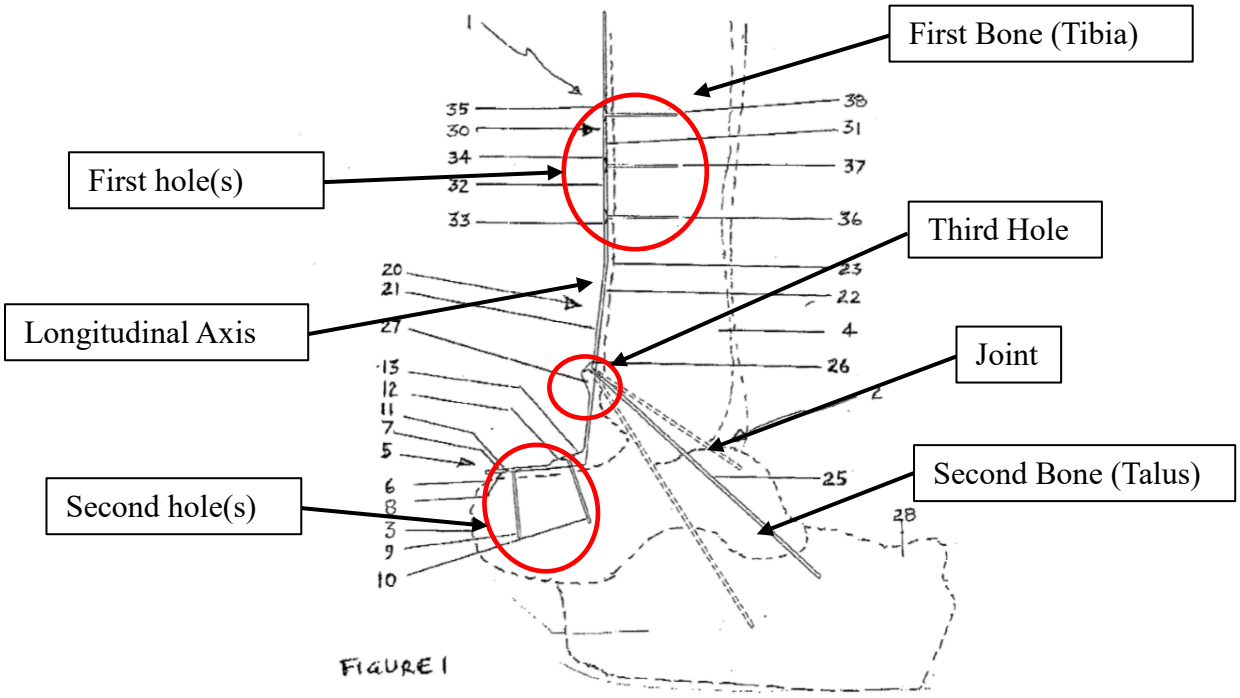


(Ex. 1004, FIG. 1 (annotated); 8:22-24 ("The third portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the Talus."); 13:6-12 ("Plate 80 which is attachable to an ankle joint opposing the Talus bone and Tibial bone, comprises a portion 81 disposed in a first plane which generally aligns with an anterior surface of the talus. Portion 81 has an outer surface 82 and inner surface 83 which opposes a talus for fixation thereto. 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."); 11:5-10; Ex. 1002, ¶¶92-94). The opening at portion 30 allows the bone screw (second fixation member) to implant into the talus (second bone). (Ex. 1004, 8:13-24, 11:5-16).

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

v. [1d] a third hole…

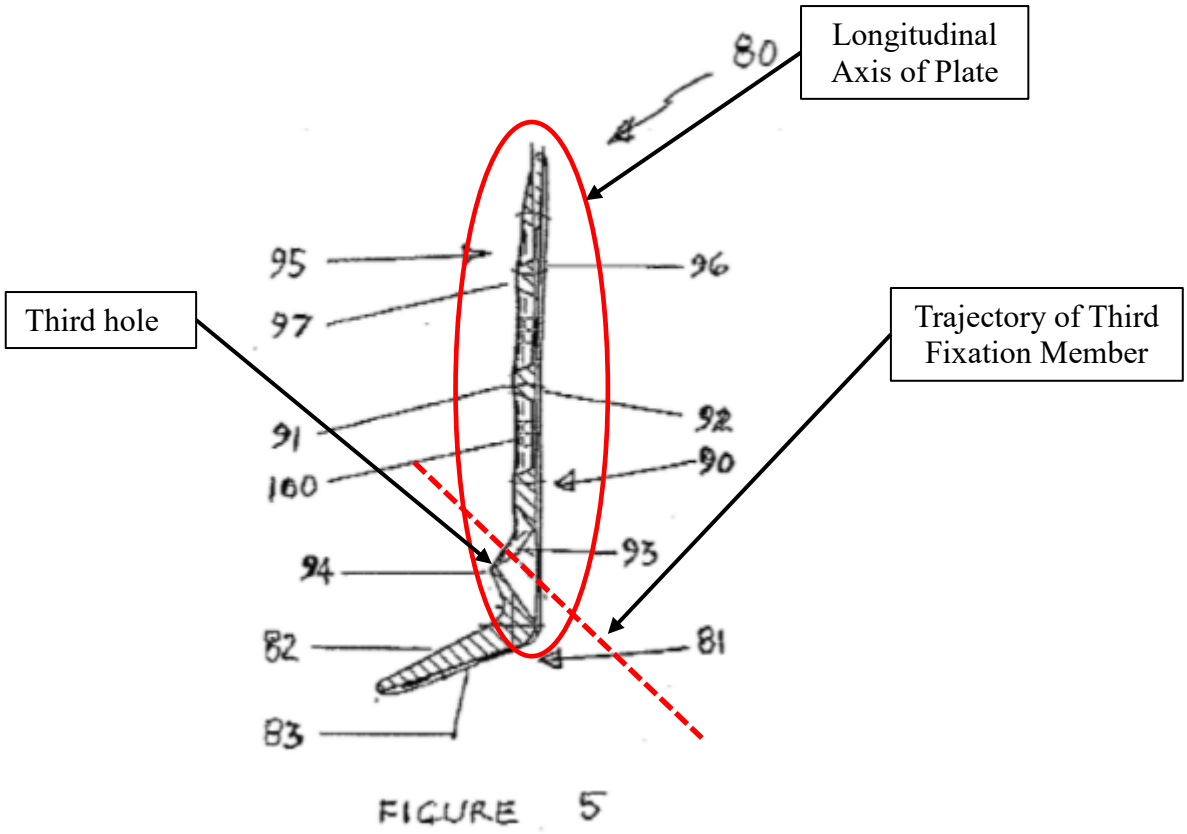
Slater's bone plate comprises a formation 27 for opening 26, where opening 26 is located between openings 33-35 (first hole(s)) and openings 11-12 (second hole(s)):



(Ex. 1004, FIG. 1 (annotated); 11:19-25 ("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."); 11:5-16, 11:28-12:2). Formation 27 is configured so that screw 25 is implanted into the tibia at a predetermined angle. (*Id.*).

A POSITA would understand that the opening 26 (third hole) is configured at an angle relative to the longitudinal axis of the bone plate. (Ex. 1002, ¶¶96-97).

Figure 5 shows a longitudinal cross section of the bone plate relative to angle formation 94:

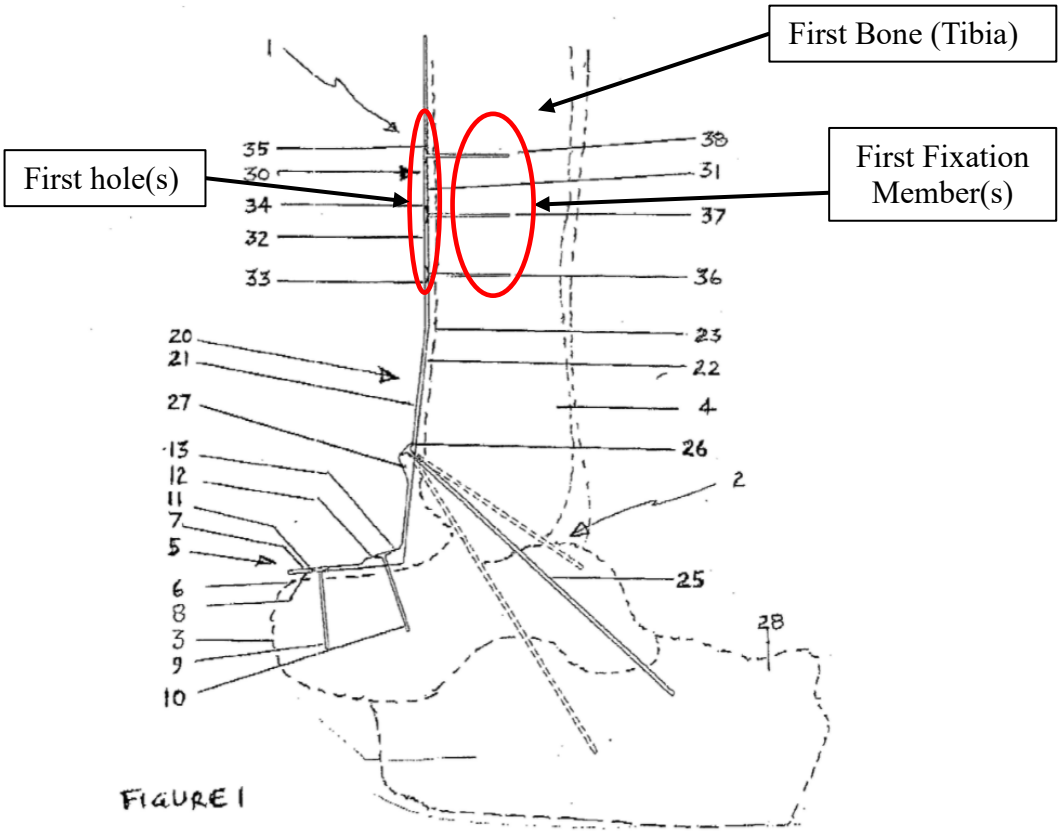


(Ex. 1004, FIG. 5 (annotated); FIG. 9). A POSITA would understand that the opening 93 is a third hole that is angled relative to a longitudinal axis of the plate. (Ex. 1002, ¶98).

A POSITA would find Slater discloses this element. (Ex. 1002, ¶99).

vi. [1e] a first fixation member…

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 discrete bone (tibia) of the joint:



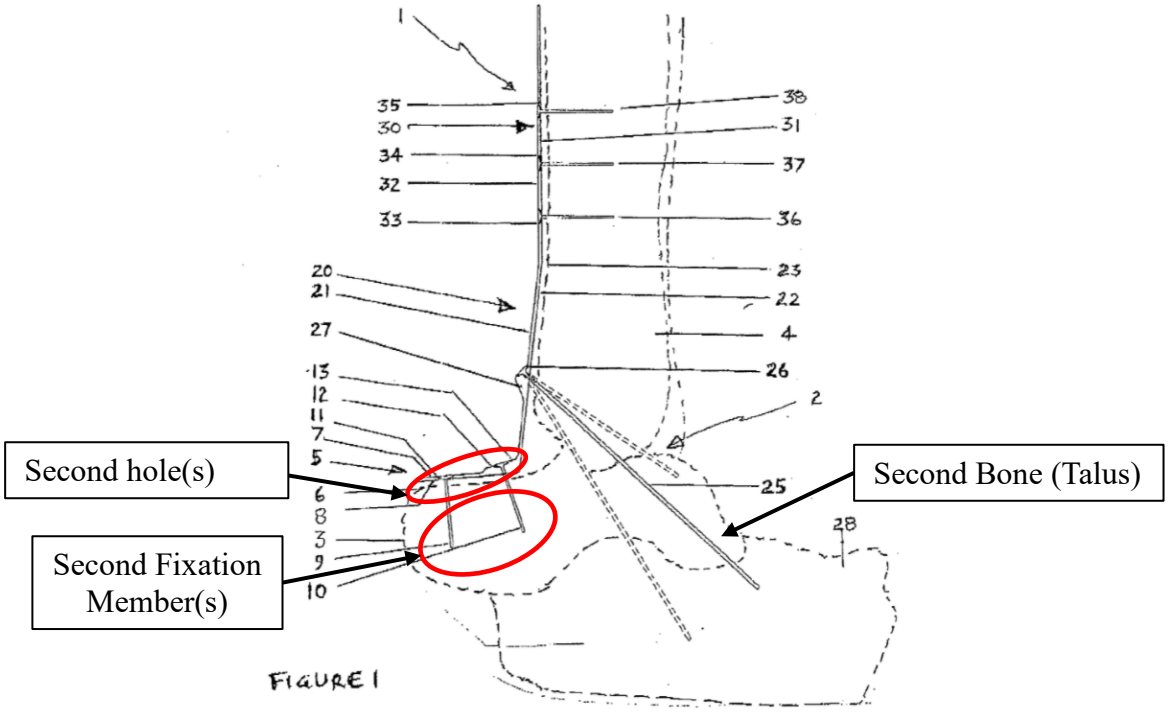
(Ex. 1004, FIG. 1 (annotated); 8:16-19 ("The first portion includes at least one opening including a formation which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region."); Ex. 1002, ¶¶100-101). Portion 30 aligns with the anterior surface 23 of the tibia (first bone) and the opening allows the bone screw (first fixation

member) to implant into the tibia (first bone). (Ex. 1004, 11:28-31; 8:13-14 ("Preferably the inner surface of the first portion of the plate opposes the anterior tibia."); 11:18-19).

Slater discloses this element. (Ex. 1002, ¶102).

vii. [1f] a second fixation member…

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 discrete bone (talus) of the joint:



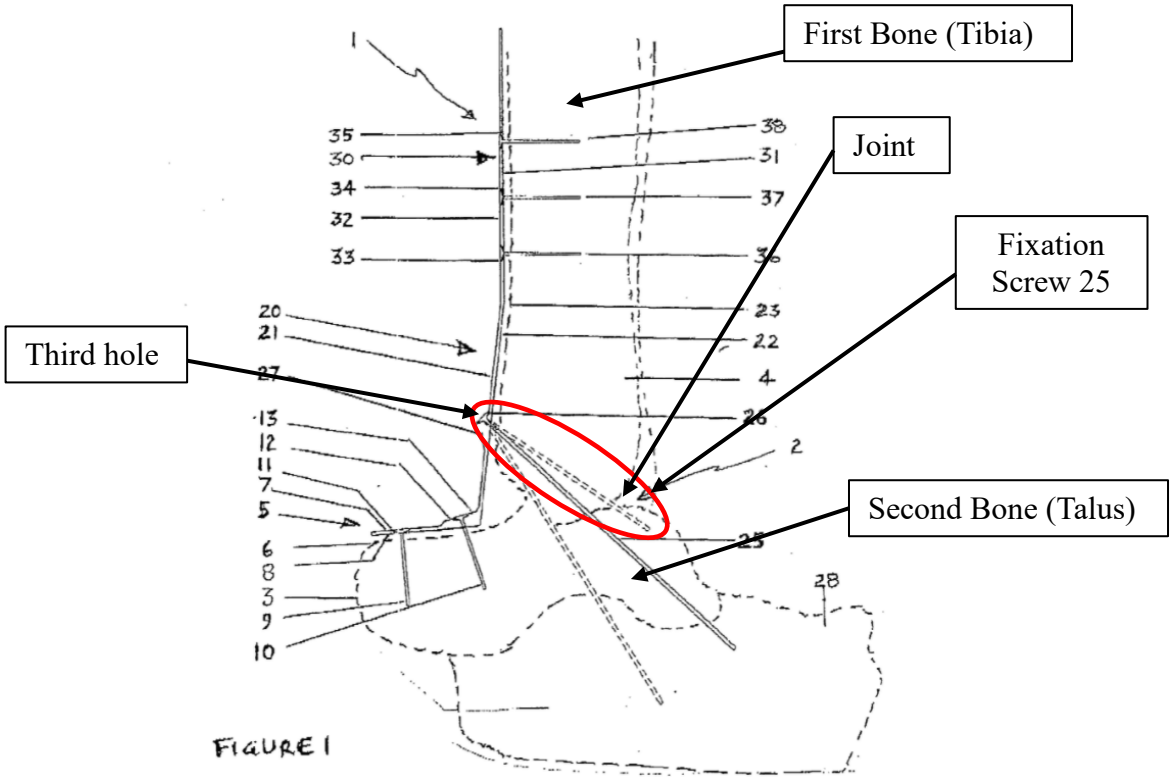
(Ex. 1004, FIG. 1 (annotated); 8:22-24 ("The third portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the Talus."); Ex. 1002, ¶¶103-104). The opening at portion 30 allows the bone

screw (second fixation member) to implant into the talus (second bone). (Ex. 1004, 8:13-24, 11:5-16).

Slater discloses this element. (Ex. 1002, ¶¶105).

viii. [1g] a third fixation member…

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:



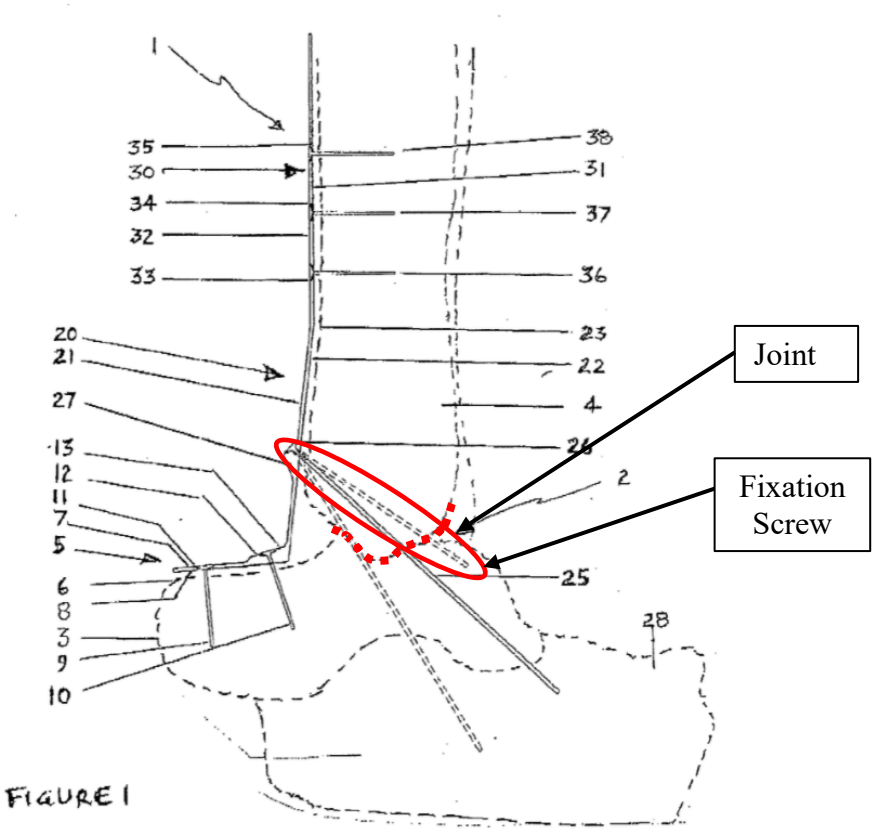
(Ex. 1004, FIG. 1 (annotated); 11:19-25 ("Disposed in portion 20 is fixation screw 25 which passes through opening 26 in formation 27. Formation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular

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."); Ex. 1002, ¶¶106-107). A POSITA would understand that the fixation screw 25, if inserted at the angle highlighted in the above image of Figure 1, would pass through the first bone (tibia), through the joint, and into the second bone (talus), such that fixation screw 25 resides in the second bone and the free end does not attach to the plate. (Ex. 1002, ¶¶108-109).

A POSITA would find Slater discloses this element. (Ex. 1002, ¶110).

ix. [1h] wherein said third fixation member…

Slater shows formation 27 configured to 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:



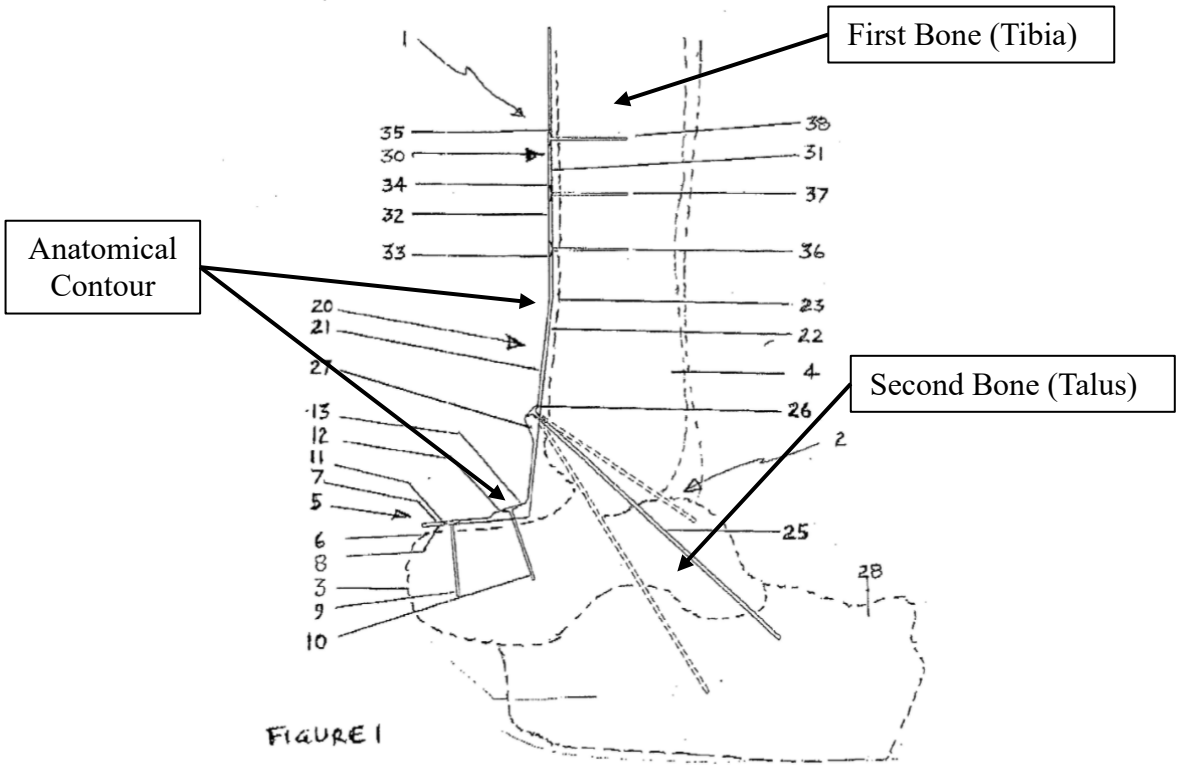
(Ex. 1004, FIG. 1 (annotated); 11:18-27).

Slater discloses this element. (Ex. 1002, ¶¶111-112).

b. *Dependent Claims 2, 7, and 8*

i. Claim 2: The system of claim 1 wherein said bone plate…

Slater describes a bone plate configured to fuse the joint between the tibia and talus and optionally the joint between the talus and the calcaneus. Together these joints represent the ankle joint. The bone plate of Slater anatomically contours to this ankle joint:



(Ex. 1004, FIG. 1 (annotated); 8:25-9:19 ("Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint."); 11:2-4 ("Plate 1 is attached to an ankle joint 2 opposing the Talus bone 3 and Tibial bone 4."); 11:23-24 ("Screw 25 engages tibia 4, talus 3, and calcaneus 28…")). A POSITA would understand that the talus and calcaneus are bones in the foot and the ankle is an anatomical joint of the foot. (Ex. 1002, ¶¶113-115).

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:

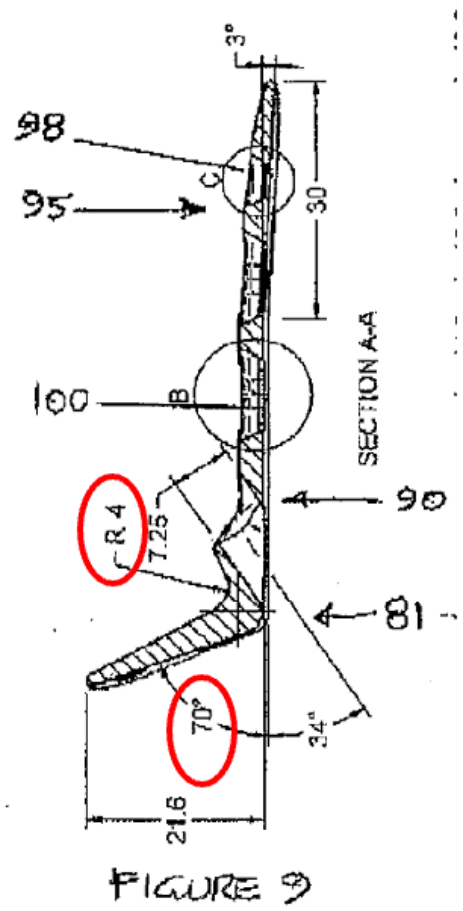


FIGURE 9

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

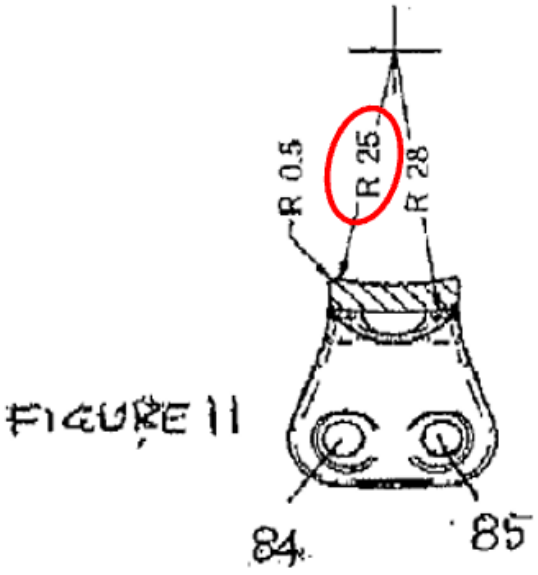


FIGURE 11

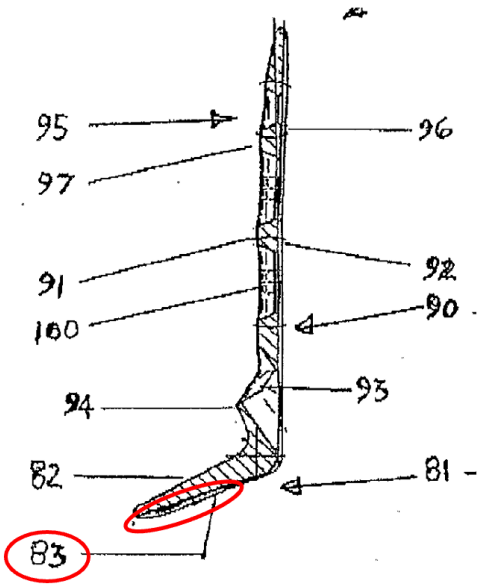


FIGURE 5

(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, ¶¶116-118). 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 of the talus, a bone in the foot. (Ex. 1002, ¶118).

A POSITA would find Slater discloses this claim. (Ex. 1002, ¶119).

ii. Claim 7: The system of claim 1 wherein said third fixation member…

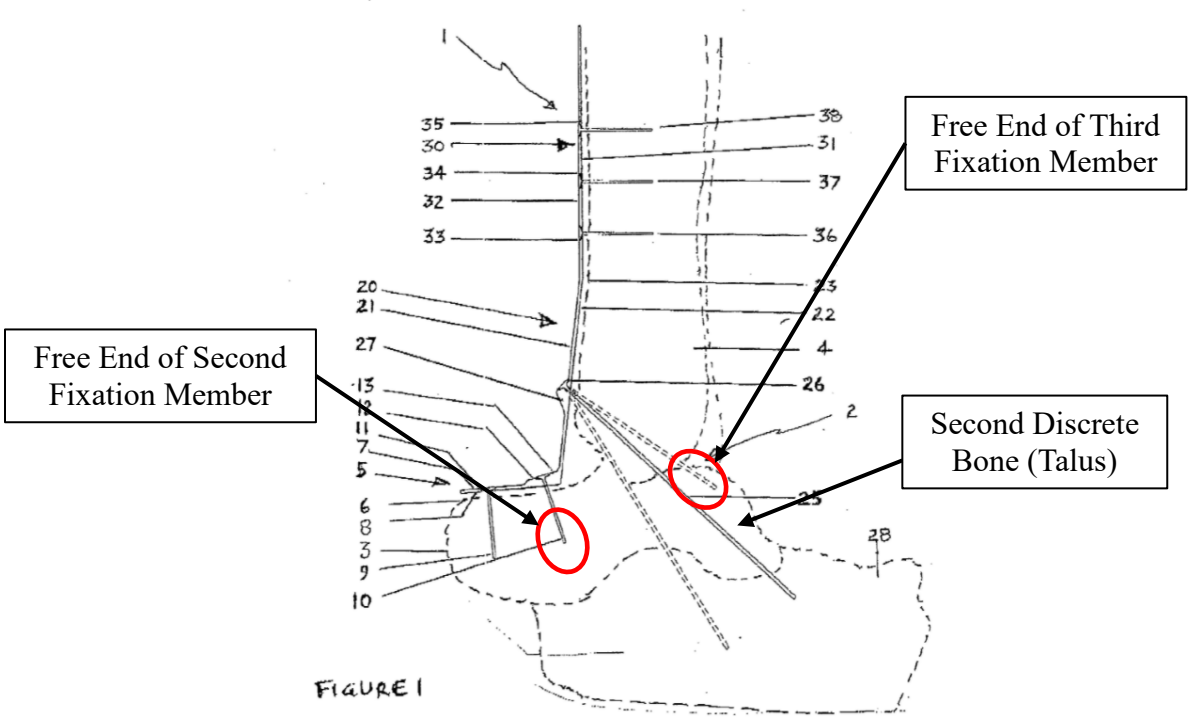
Slater discloses a fixation screw that is inserted into the bone plate at an appropriate angle to achieve an optimal amount of compression on to perform the joint fusion. (Ex. 1004, 6:17-21 ("The present invention provides an improved

arthrodesis fusion plate for fusion of the anterior ankle. More particularly the invention provides an ankle plate in which openings in the plate receive fixation screws allowing compression of bones being fused and orientation of the fixation screws to optimise accommodation of bone loading for efficient and effective fusion.")). While the '751 Patent does not explicitly define lag effect, a POSITA would understand that it is referring to the typical function of a lag screw, which is to compress one member against another. (Ex 1001, 1:40-44 and 2:15-19). In Slater, two or three bones are compressed against one another to increase stability. (Ex. 1002, ¶¶120-122). This can be achieved by using a lag screw or by using fully threaded screws and selectively over drilling the near hole. (Ex. 1002, ¶122).

A POSITA would find Slater discloses this claim. (Ex. 1002, ¶123).

iii. Claim 8: The system of claim 1 wherein the free end …

Slater's bone plate comprises screw 10 (second fixation member) and screw 25 (third fixation member), configured to engage with the talus:



(Ex. 1004, FIG. 1 (annotated); 11:5-27). A POSITA would understand that Figure 1 depicts embodiments of screw 25 (third fixation member) at various angles and lengths, where one embodiment shows the free end adjacent to the free end of the second fixation member. (Ex. 1002, ¶¶124-125).

A POSITA would find Slater discloses this claim. (Ex. 1002, ¶126).

D. Ground 2: Claims 1-2 and 7-18 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Slater and Zahiri

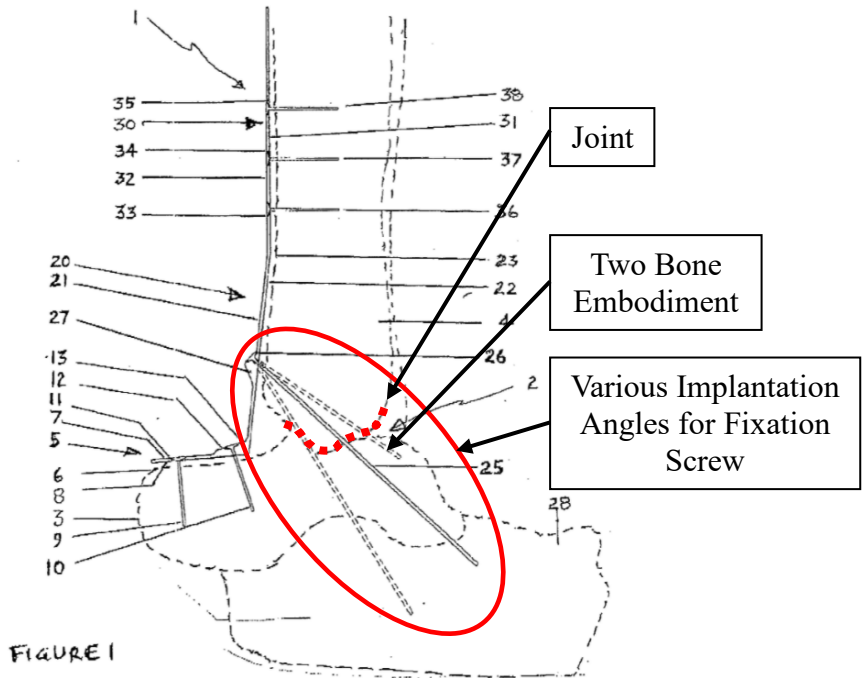
Independent claims 1, 11, and 17, and dependent claims 2, 7-10, 12-16, and 18, are obvious in view of the combination of Slater and Zahiri. (Ex. 1002, ¶127)

1. Basis for Combination

The scope and content of the prior art includes Slater and Zahiri, which

collectively disclose all of the elements of claims 1-2 and 7-18. 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, ¶128).

Slater discloses a 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); 6:14-28, 11:18-27). Slater's plate comprises a predetermined allowable angle range of the fixation screw 25, as depicted by the three possible angles and multiple lengths in Figure 1. (*Id.*). Slater further discloses that a key advantage of the 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). A POSITA would understand that Slater's bone plate discloses an embodiment of the fixation screw 25 configured to intersect a joint between two discrete bones. (Ex. 1002, ¶¶129-131).

At the very least, Slater's disclosure guides a POSITA to incorporate the teachings of Zahiri, and position the fixation screw 25 at an angle that contacts only two bone fragments. (Ex. 1002, ¶132). Zahiri discloses a bone plate configured to fuse a first and second bone part with an angled fixation member oriented to compress the bone fracture:

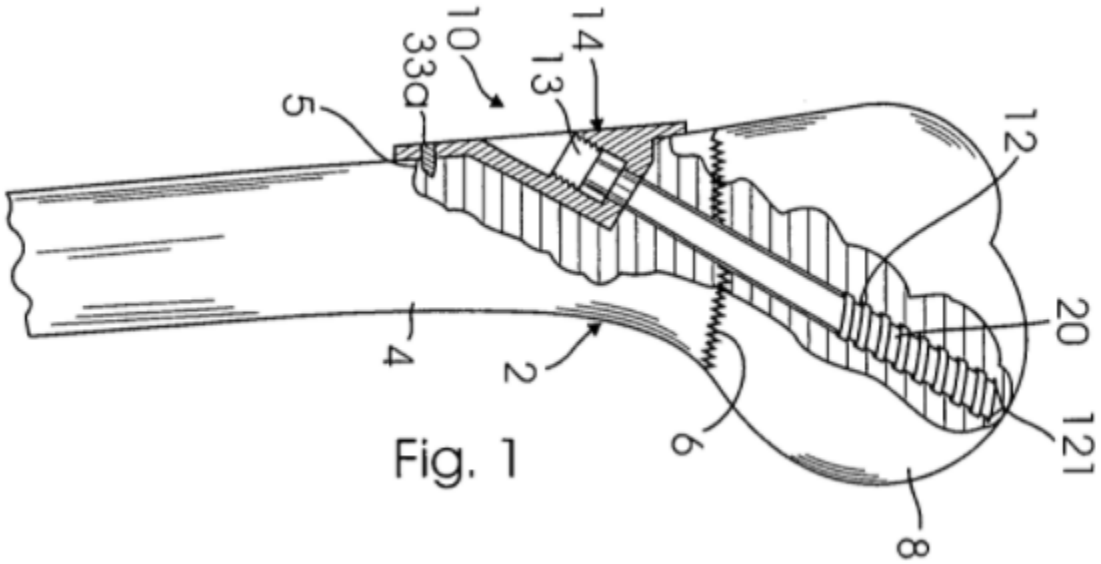
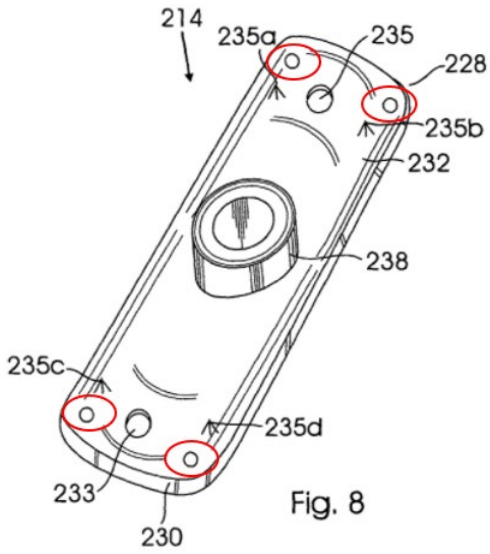


Fig. 1

(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; Ex. 1002, ¶133). A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. (Ex. 1002, ¶134). A POSITA

would know that plates configured for arthrodesis and plates to fuse bone fractures have been used interchangeably for decades. (*Id.*). A POSITA would look to Zahiri to improve Slater's bone plate. (*Id.*).

Slater contemplates the importance of proper bone plate alignment and guides a POSITA to incorporate the temporary pin holes disclosed by Zahiri into Slater. (Ex. 1004, 4:17-5:9; Ex. 1002, ¶135). 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 that temporarily hold the bone plate in place during implantation, as shown in Figure 8:



(Ex. 1007, FIG. 8 (annotated); 3:11-18 ("[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."); Ex. 1002, ¶136). 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. (*Id.*; Ex. 1002, ¶137).

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. (Ex. 1002, ¶138). 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, ¶138). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, ¶138).

A POSITA would be motivated to combine the teachings of Slater and Zahiri to utilize known techniques for improving the implantation of a bone plate, and obtain a similar and predictable improvement. (Ex. 1002, ¶139).

2. Claims 1-2 and 7-18 would have been Obvious

a. *Independent Claim 1*

i. [1Pre]

Slater discloses this element, as explained above in Section VII.C.2.a.i. (Ex. 1004, FIG. 1, 1:6-7, 6:14-28, 8:13-24; Ex. 1002, ¶140).

ii. [1a]

A POSITA would find Slater discloses this element, as explained in Section VII.C.2.a.ii. (Ex. 1004, FIG. 1, 12:12-27, 13:5-18; Ex. 1002, ¶141).

iii. [1b]

Slater discloses this element, as explained in Section VII.C.2.a.iii. (Ex. 1004, FIG. 1, 8:15-19, 13:6-9, 13:20-21, 11:28-31, 11:18-19, 8:13-14; Ex. 1002, ¶142).

iv. [1c]

Slater discloses this element, as explained in Section VII.C.2.a.iv. (Ex. 1004, FIG. 1, 8:22-24, 13:6-12, 8:13-24, 11:5-16; Ex. 1002, ¶143).

v. [1d]

A POSITA would find Slater discloses this element, as explained in Section VII.C.2.a.v. (Ex. 1004, FIGS. 1, 5, 11:19-25, 11:5-16, 11:28-12:2; Ex. 1002, ¶144).

vi. [1e]

Slater discloses this element, as explained in Section VII.C.2.a.vi. (Ex. 1004, FIG. 1, 8:16-19, 11:28-31, 8:13-14; Ex. 1002, ¶145).

vii. [1f]

Slater discloses this element, as explained in Section VII.C.2.a.vii. (Ex. 1004, FIG. 1, 8:13-24, 11:5-16; Ex. 1002, ¶146).

viii. [1g]

A POSITA would find Slater discloses this element, as explained in Section

VII.C.2.a.viii. (Ex. 1004, FIG. 1, 11:19-25; Ex. 1002, ¶147).

ix. [1h]

Slater discloses this element, as explained in Section VII.C.2.a.ix. (Ex. 1004, FIG. 1, 11:18-27; Ex. 1002, ¶148).

b. *Independent Claim 11*

i. [11Pre] A system for fusing…

For at least the reasons in Section VII.C.2.a.i, Slater discloses this element.[4] (Ex. 1004, FIG. 1, 1:6-7, 6:14-28, 8:13-24; Ex. 1002, ¶150).

ii. [11a] a bone plate having…

For at least the reasons in Section VII.C.2.a.ii, a POSITA would find Slater discloses this element. (Ex. 1004, FIG. 1, 12:12-27, 13:5-18; Ex. 1002, ¶151).

iii. [11b] a first hole…

For at least the reasons in Section VII.C.2.a.iii, Slater discloses this element.

[4] Certain elements of claim 11 are identical to elements of claim 1 except that claim 1 is directed to a system for fusing two discrete bones whereas claim 11 is directed to a system for fusing two bone parts. A POSITA would find there is no difference with respect to a bone plate used for fusing two discrete bones verses bone parts. (Ex. 1002, ¶149). For those elements, the Petition refers back to the arguments made with respect to claim 1.

(Ex. 1004, FIG. 1, 8:15-19, 13:6-9, 13:20-21, 11:28-31, 11:18-19, 8:13-14; Ex. 1002, ¶152).

iv. [11c] a second hole…

For at least the reasons in Section VII.C.2.a.iv, Slater discloses this element. (Ex. 1004, FIG. 1, 8:22-24, 13:6-12, 8:13-24, 11:5-16; Ex. 1002, ¶153).

v. [11d] a third hole…

This element appears to be present in Slater (*, e.g.*, Ex. 1004, FIGS. 1, 7), but Slater lacks sufficient disclosure regarding the full dimensions of the opening 26 in formation 27 or hole 93. (Ex. 1002, ¶154). A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (*Id.*).

Zahiri's bone plate comprises a barrel portion 38 with a third hole defined by an inner side wall 48 extending from an opening 46 and a third point 3 and a fourth hole that is defined by an opening side wall 43 that extends from a first point 1 to an opening 42:

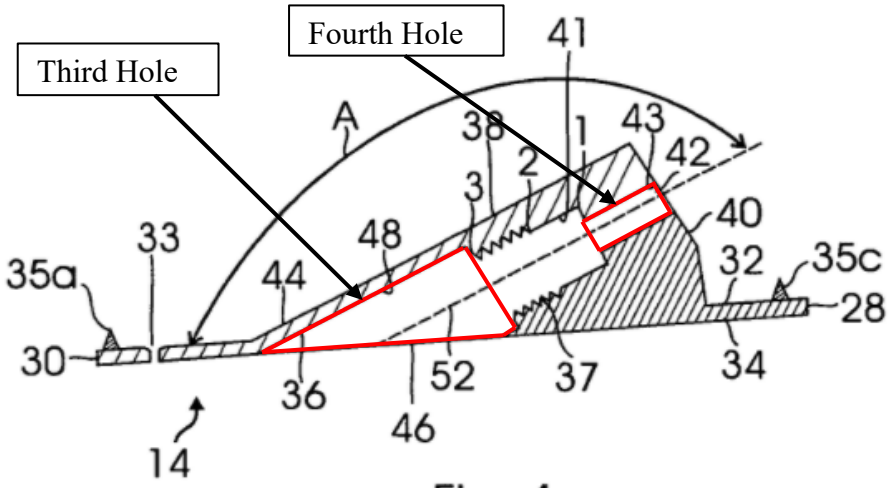


Fig. 4

(Ex. 1007, FIG. 4 (annotated); 6:12-35). The inner side wall 48 of the third hole has a larger diameter than opening side wall 43 of the fourth hole. (*Id.*). A POSITA would understand that the area defined by the third hole is larger than the area defined by the fourth hole, as shown by annotated Figure 4. (Ex. 1002, ¶¶155-156). Looking to improve the integrity of the angled fixation screw of Slater, a POSITA would have readily looked to the disclosure of Zahiri. (*Id.*).

Additionally, the barrel portion of Zahiri's bone plate further discloses an axis, as shown by the dotted line in Figure 4. (Ex. 1007, FIG. 4, 6:12-35). A POSITA would understand that the lag screw passes through the third hole and then through the fourth hole along the axis, as shown by Figure 4 above. (Ex. 1002, ¶157).

Finally, the barrel portion 238 of Zahiri's bone plate, comprising the third hole and the fourth hole, is located between identical holes 233 and 235 that are located at opposite ends of the plate along a center line:

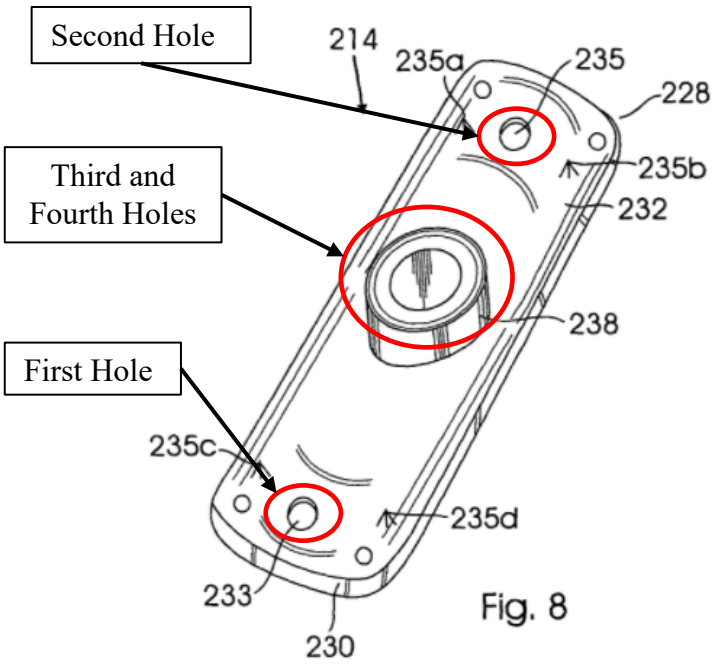


Fig. 8

(Ex. 1007, FIG. 8 (annotated); 8:34-44). A POSITA would understand that the third and fourth holes are located in the center of the bone plated, between holes 233 and 235, as shown by Figure 8 of Zahiri, just as opening 26 in formation 27 of Slater is located between the first hole (e.g., opening 33) and the second hole (e.g., opening 12) of Slater. (Ex. 1002, ¶¶158-159).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶160).

vi. [11e] a fifth hole…

The purpose of the fifth hole (as discussed below with respect to element 11k) is to receive a temporary fixation member. As previously mentioned, Slater is silent regarding the use of temporary fixation members, and a POSITA would look to

improve the disclosure of Slater through the use of temporary alignment techniques as taught by Zahiri. (Ex. 1002, ¶161).

Zahiri discloses four small holes 31a-d in the respective corners of the bone plate, located adjacent to medium size holes:

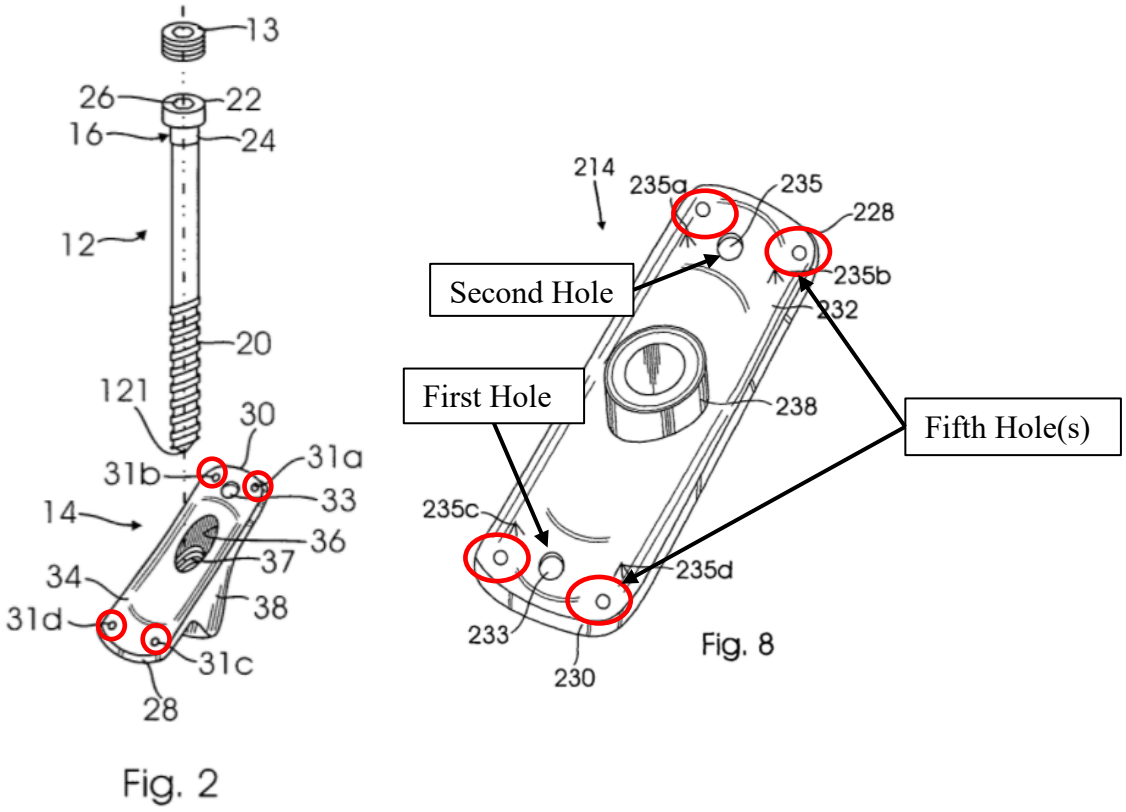


Fig. 2

Fig. 8

(Ex. 1007, FIGS. 2 and 8 (annotated); 5:47-64). Zahiri discloses that these holes are used for "pins 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, 3:11-18). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw

is inserted. (Ex. 1007, 7:19-24, 7:63-64). The guide pins ensure proper alignment during implantation and prevent discomfort and abnormalities. (*Id.*; Ex. 1002, ¶162-163).

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, ¶164). Zahiri discloses a known technique for improving plate alignment. (*Id.*). A POSITA would be motivated to combine the teachings of Slater and Zahiri, to utilize a known technique for improving the implantation of a bone plate. (*Id.*). A POSITA would further understand that holes 31a-d are analogous to the claimed fifth hole, adjacent to the first and second holes, and smaller in diameter than the first and second holes. (*Id.*).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶165).

vii. [11f] a first fixation member…

For at least the reasons in Section VII.C.2.a.vi, Slater discloses this element. (Ex. 1004, FIG. 1, 8:16-19, 11:28-31, 8:13-14; Ex. 1002, ¶166).

viii. [11g] a second fixation member…

For at least the reasons in Section VII.C.2.a.vii, Slater discloses this element. (Ex. 1004, FIG. 1, 8:13-24, 11:5-16; Ex. 1002, ¶167).

ix. [11h] a third fixation member…

While Slater discloses the use of a third fixation member that is angled into the first bone (tibia), across the joint, and into the second bone (talus) (Section VII.C.2.a.ix (citing Ex. 1004, FIG. 1, 11:18-27)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶168). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*) Zahiri's bone plate comprises a lag screw (third fixation member) that is inserted through the three different diameter portions of the barrel portion of the bone plate and settles into the depth of the epiphysis portion of the bone:

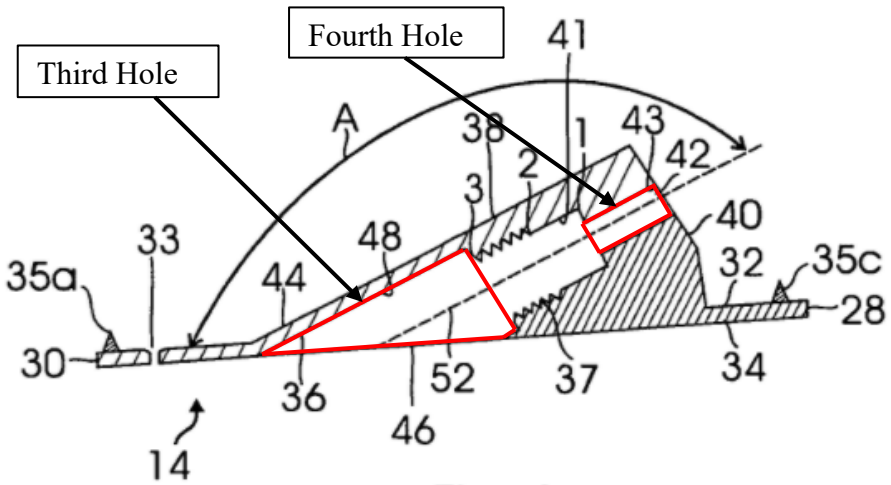
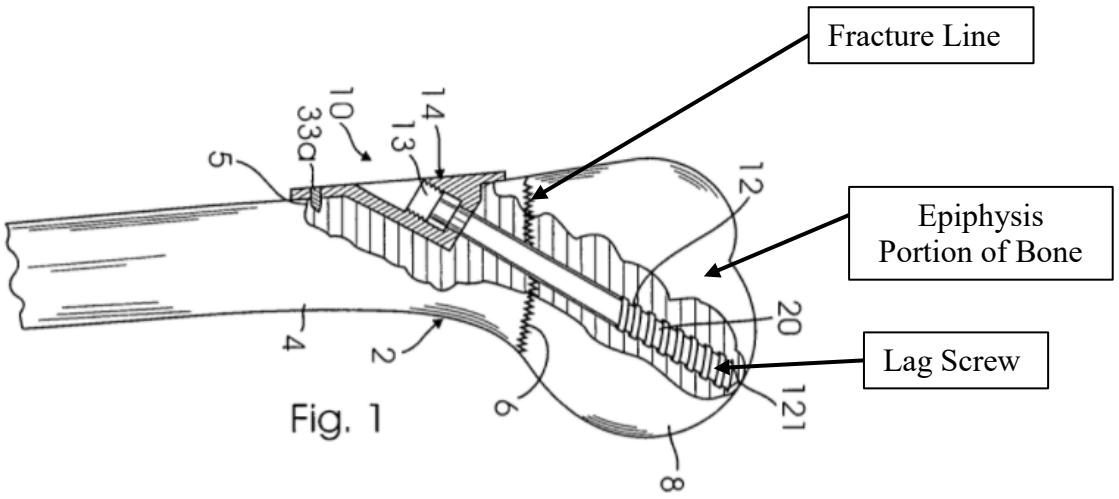


Fig. 4

(Ex. 1007, FIG. 4 (annotated); 6:12-35). The barrel portion comprises a third hole defined by an inner side wall 48 extends from an opening 46 and a third point 3 and

a fourth hole that is defined by an opening side wall 43 that extends from a first point 1 to an opening 42. (*Id.*; Ex. 1002, ¶169). Zahiri discloses the lag screw advances/traverses across the fracture line at an angle and settles into the depth of the epiphysis of the bone:



(Ex. 1007, FIG. 1 (annotated); 2:23-28; Ex. 1002, ¶170). A POSITA would readily combine the disclosure of the lag screw from Zahiri, which utilizes the third and fourth holes, into the plate of Slater, to further improve the integrity of the angled fixation screw of Slater's bone plate. (Ex. 1002, ¶¶171-172).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶173).

x. [11i] wherein a free end…

While Slater discloses the use of a third fixation member that has a free end not attached to any portion of the bone plate and resides in the second discrete bone

(Section VII.C.2.a.viii (citing Ex. 1004, FIG. 1, 11:19-25)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶174). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*). Zahiri's bone plate comprises a lag screw that is inserted through barrel portion of the bone plate and settles into the depth of the epiphysis portion of the bone:

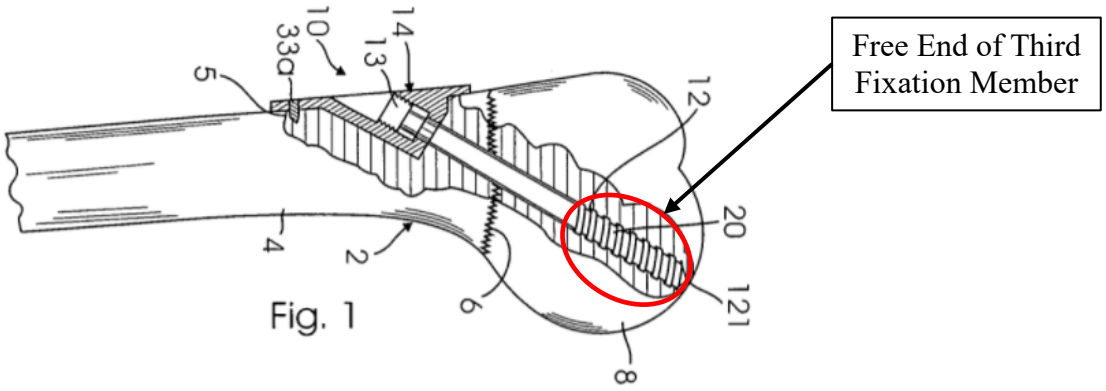


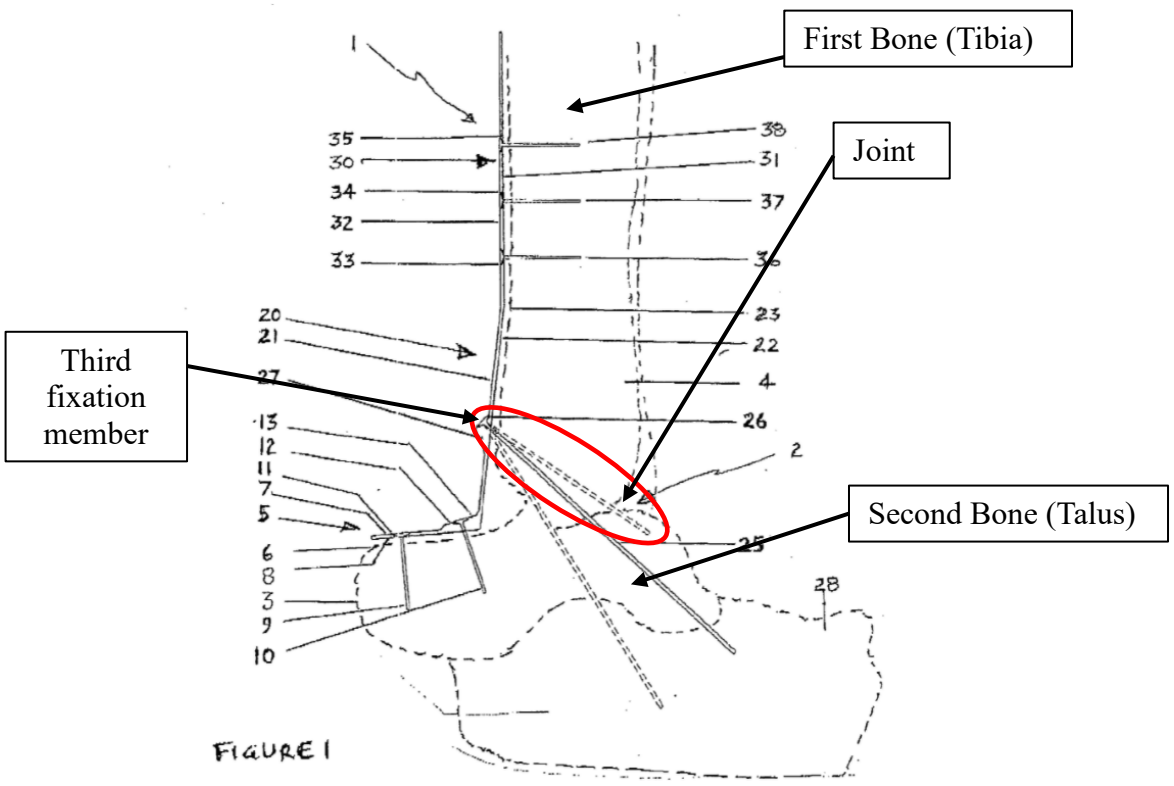
Fig. 1

(Ex. 1007, FIG. 1 (annotated); 2:23-28, 5:5-8). A POSITA would understand that the distal threaded position 20 of the lag screw 12 does not attach to any portion of the bone plate. (Ex. 1002, ¶¶175-176). As with element [11h], a POSITA would have been motivated to combine the teachings of Zahiri regarding the third fixation member with Slater's bone plate. (Section VII.D.2.b.ix).

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

xi. [11j] and wherein the third fixation member…

Slater discloses the use of a third fixation member that is the only fixation member extending across the joint:



(Ex. 1004, FIG. 1 (annotated); 11:19-25). While it appears there is depth to opening 26 in formation 27 to allow for the screw head (third fixation member) to be countersunk, or seated below the plate (, *e.g.*, Ex. 1004, FIG. 1, 12:23-25), Slater lacks sufficient disclosure of the full dimensions of the third fixation member. (Ex. 1002, ¶¶178-179). A POSITA would look to prior art like Zahiri for disclosure of a fixation member with a fixation head defining a head area, the head area being greater than the second area and less than the first area. (*Id.*).

Zahiri discloses a lag screw that traverses across the fracture line at an angle and settles into the epiphysis of the bone:

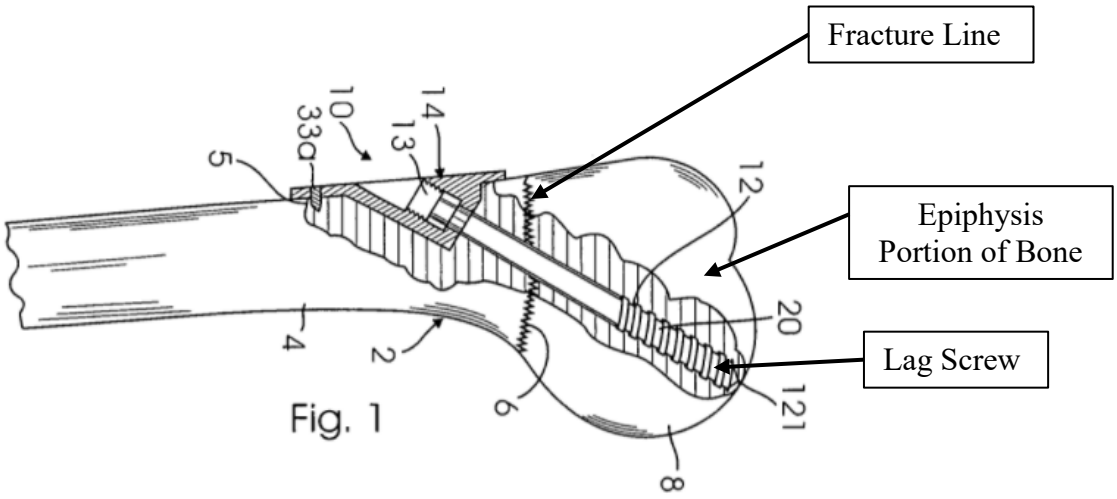


Fig. 1

(Ex. 1007, FIG. 1 (annotated); 2:23-28). A POSITA would understand that the fixation member anchors to the epiphyseal zone of the second bone and teaches the limitations of the third fixation member. (Ex. 1002, ¶¶180). It would be obvious to a POSITA that Slater depicts a free end of bone screw 25 configured to reside deep within the talus (the second bone). (*Id.*). As with element [11h], a POSITA would have been motivated to combine the teachings of Zahiri regarding the third fixation member with Slater's bone plate. (Section VII.D.2.b.ix; Ex. 1002, ¶181).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶182).

xii. [11k] and a temporary fixation member…

The purpose of the fifth hole is to receive a temporary fixation member. Slater

is silent regarding the use of temporary fixation members, but describes the need of proper alignment. (Ex. 1004, 4:23-25). A POSITA would look to improve the disclosure of Slater through the use of temporary alignment techniques as taught by Zahiri. (Ex. 1002, ¶183).

The small holes 31a-d of Zahiri's bone plate are used with "pins 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, 3:11-18). 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, 7:63-66). A POSITA would understand that the additional pins are temporary fixation members that are inserted through the small holes (fifth hole). (Ex. 1002, ¶¶184-185). As with element [11e], a POSITA would have been motivated to combine the teachings of Zahiri regarding the four small holes that are used with temporary guide pins with Slater's bone plate. (Section VII.D.2.b.vi; Ex. 1002, ¶186).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶187).

c. *Independent Claim 17*

i. [17Pre] An orthopedic implant comprising;

For at least the reasons in Section VII.C.2.a.i, Slater discloses this element.[5] (Ex. 1004, FIG. 1, 1:6-7, 6:14-28, 8:13-24; Ex. 1002, ¶190).

ii. [17a] a bone plate…

Slater's bone plate comprises "an outer surface 21 and an inner surface 22 with is opposes anterior surface 23 of tibia 4." (Ex. 1004, 11:18-19; FIG. 1).

Slater discloses this element. (Ex. 1002, ¶¶190-191).

iii. [17b] said bone plate having…

For at least the reasons in Section VII.C.2.a.ii, a POSITA would find that Slater discloses this element. (Ex. 1004, FIG. 1, 12:12-27, 13:5-18; Ex. 1002, ¶193).

[5] Certain elements of claim 17 are identical to elements of claim 1 except that claim 1 is directed to a system for fusing two discrete bones whereas claim 17 is directed to an implant positionable alongside first and second bone parts straddling the fracture or joint. A POSITA would find there is no difference with respect to a bone plate used for fusing two discrete bones verses one that is used across two bone parts. (Ex. 1002, ¶188). As such, for those elements, the Petition refers back to the arguments made with respect to claim 1.

iv. [17c] said bone plate having a first hole…

For at least the reasons in Sections VII.C.2.a.iii and VII.C.2.a.vi, Slater discloses this element. (Ex. 1004, FIG. 1, 8:13-19, 13:6-9, 13:20-21, 11:28-31; 11:18-19; Ex. 1002, ¶194).

v. [17d] a second hole…

For at least the reasons in Sections VII.C.2.a.iv and VII.C.2.a.vii, Slater discloses this element. (Ex. 1004, FIG. 1, 8:13-24, 13:6-12, 11:5-16; Ex. 1002, ¶195).

vi. [17e] a third hole…

For at least the reasons in Section VII.C.2.a.v, a POSITA would find that Slater discloses this element. (Ex. 1004, FIG. 1, 11:19-25, 11:5-16, 11:28-12:2; Ex. 1002, ¶196).

vii. [17f] said third hole sized…

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, 11:19-21 ("Disposed in portion 20 is fixation screw 25 which passes through opening 26 in formation 27"); 12:23-25 ("Opening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation."); 22:16-19). A POSITA would understand that the formation 27 must be slightly larger than the diameter of

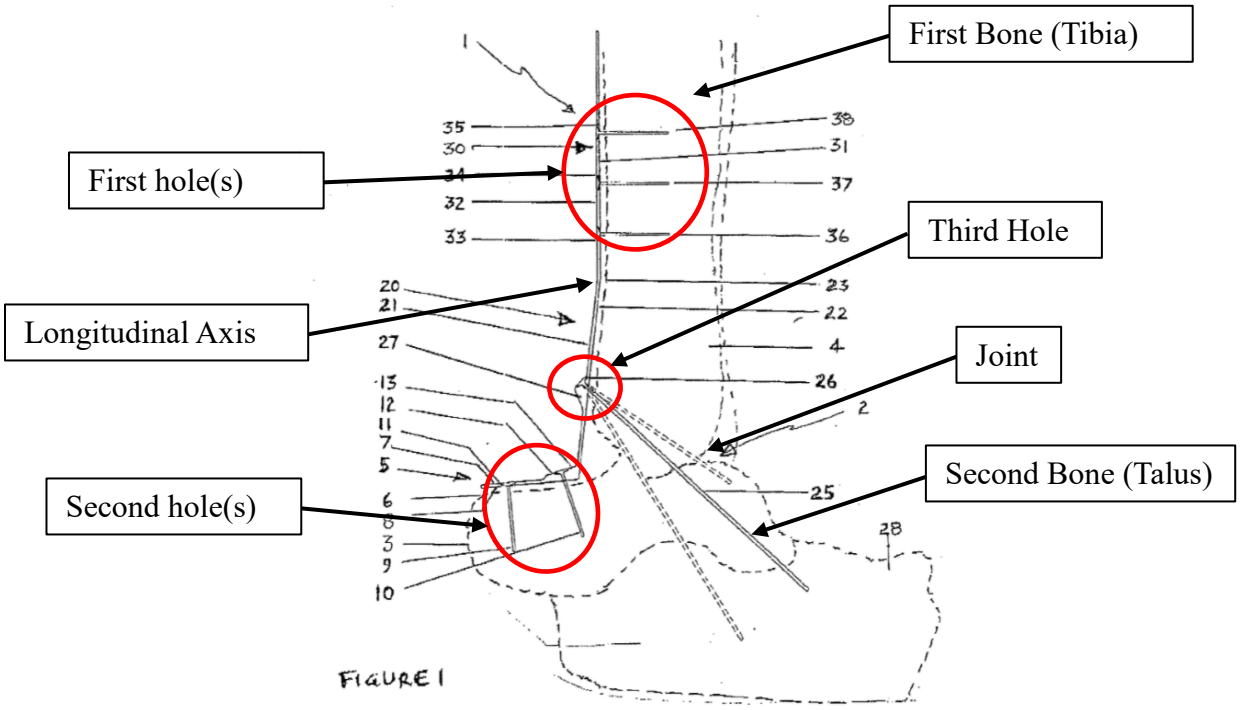
the head of screw 25 so that it can receive the screw head in a countersunk recess. (Ex. 1002, ¶¶197-198). A POSITA would understand that the third hole accepts the third screw and is sized to accept the third screw head. (*Id.*).

A POSITA would also have looked to Zahiri to improve the integrity of the angled fixation screw. (Ex. 1002, ¶199). Zahiri's lag screw comprises a head that is slightly less than the diameter of the barrel portion, and provides a mechanical advantages so that the surgeon may precisely set the desired level of compression. (Ex. 1007, 7:35-41). A POSITA would be motivated to combine Zahiri's improvement into Slater's formation 27, to provide a surgeon with a mechanical advantage when they are tightening and compressing screw 25. (Ex. 1002, ¶199).

A POSITA would find this element disclosed by Slater and Zahiri. (Ex. 1002, ¶200).

viii. [17g] said third hole being angled…

Slater's bone plate comprises an opening 26 (third hole) configured for screw 25 (third bone screw) to implant into the tibia at a predetermined allowable angular range and continue into the talus:



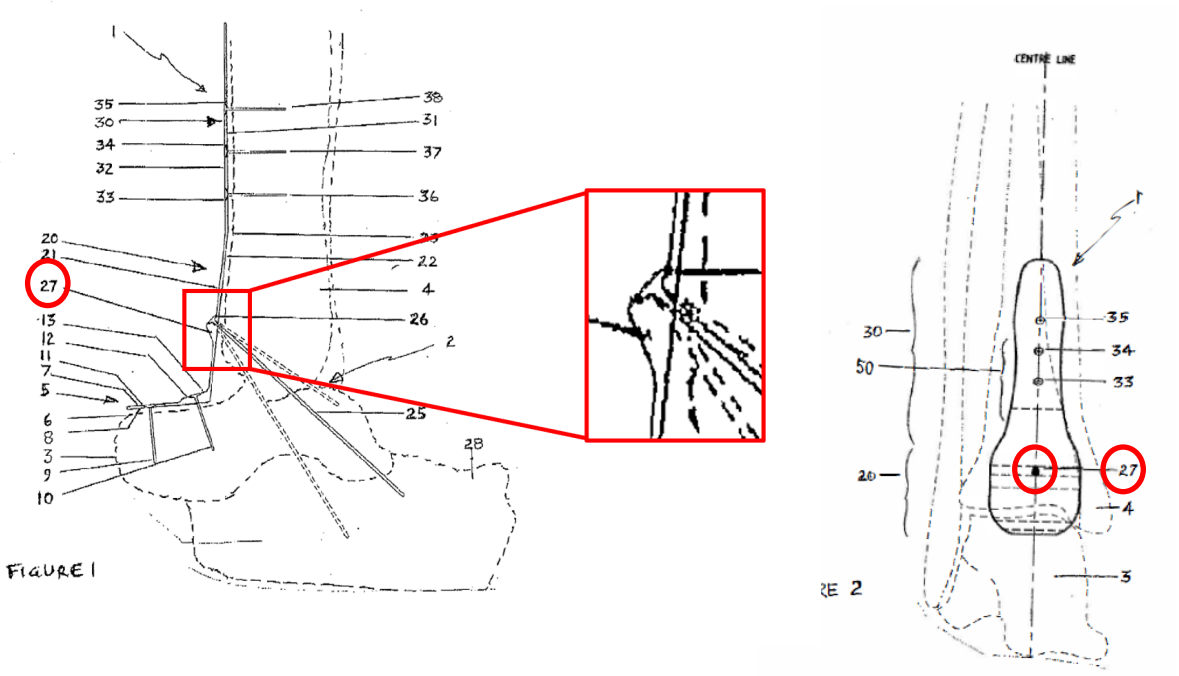
(Ex. 1004, FIG. 1 (annotated); 11:5-27). A POSITA would understand that the opening 26 (third hole) is configured at an angle relative to the bone plate such that the screw crosses the joint. (Ex. 1002, ¶¶201-202).

A POSITA would find this element disclosed by Slater. (Ex. 1002, ¶203).

ix. [17h] said third hole being configured…

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. (Ex. 1004, FIG 1; 5:28-30 ("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."); 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 describes that "[o]pening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation." (Ex. 1004, 12:23-25). Figures 5 and 7 also show depth to formation 94 such that the head of a fixation screw is seated below the proximal surface of the bone plate:

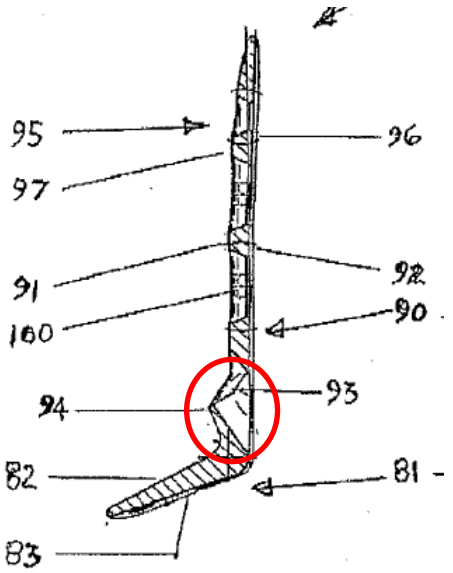


FIGURE 5

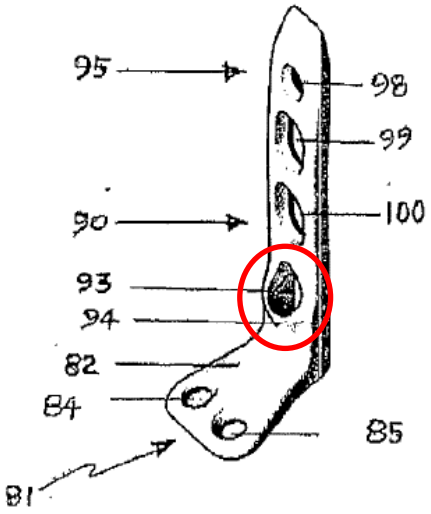


FIGURE 7

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

A POSITA would find this element disclosed by Slater. (Ex. 1002, ¶204-208).

A POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶209). Zahiri discloses a lag screw 20 that crosses a fracture line with a head that engages with the threaded wall of the short barrel portion 38 of the bone plate 14:

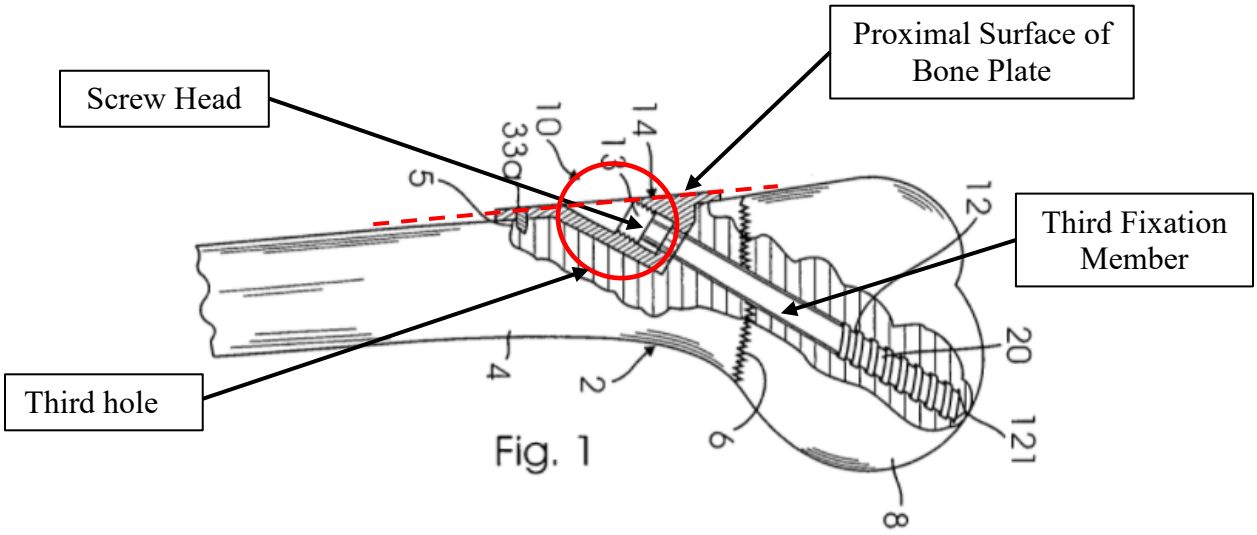


Fig. 1

(Ex. 1007, FIG. 1 (annotated); 2:23-36, 7:31-38). Zahiri further show that inner cylinder wall 41 "has a length defined between the first point 1 and the second point 2, which is the same as the height of the proximal head of 22 of the lag screw":

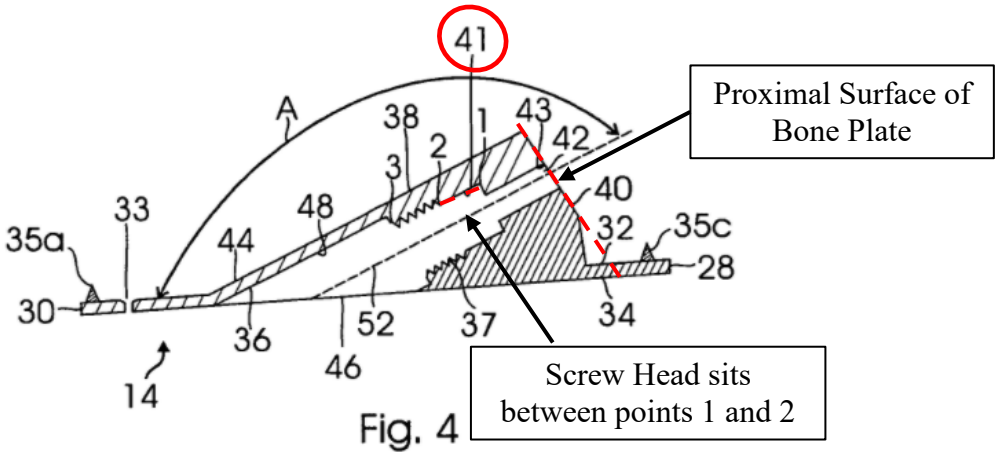


Fig. 4

(Ex. 1007, FIG. 4 (annotated), 6:21-24). Since the screw head sits between points 1 and 2, which are below the surface of the bone plate, Zahiri expressly contemplates this limitation.

To achieve the goal from Slater of "facilitating integrity of the screw bone interface … and effective co operation between the screw head and the insertion hole," it would be obvious 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. 1004, 5:28-30; Ex. 1002, ¶¶209-212).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶213).

x. [17i] a pin hole located…

For at least the reasons in Section VII.D.2.b.vi, a POSITA would be motivated to combine Slater and Zahiri, and would find the combination teaches this element.[6] (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:19-24, 7:63-64; Ex. 1002, ¶214).

xi. [17j] said pin hole extending…

For at least the reasons in Section VII.D.2.b.xii, a POSITA would be motivated to combine Slater and Zahiri, and would find the combination teaches this element. (Ex. 1007, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶215).

[6] Certain elements of claim 17 are identical to elements of claim 11. As such, for those elements, the Petition refers back to the arguments made with respect to claim 11. (Ex. 1002, 189).

d. *Dependent Claims 2, 7-10, 12-16, and 18*

i. Claim 2

A POSITA would find Slater teaches this claim, as explained in Section VII.C.2.b.i. (Ex. 1004, FIG. 1, 8:25-9:19, 11:1-4, 11:23-24; Ex. 1002, ¶216).

ii. Claim 7

A POSITA would find Slater teaches this claim, as explained in Section VII.C.2.b.ii. (Ex. 1004, 6:17-21; Ex. 1002, ¶217).

A POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶218). Zahiri's bone plate comprises a lag screw that compresses the diaphyseal cortex (bone) as it is advanced deeper in the epiphysis (bone end). (Ex. 1007, 7:55-62). A POSITA would understand that compression at the fracture site is predominantly developed by the lag screw. (Ex. 1007, 2:45-48; Ex. 1002, ¶219).

A POSITA would find this claim obvious in view of Slater and Zahiri. (Ex. 1002, ¶220).

iii. Claim 8

A POSITA would find Slater teaches this claim, as explained in Section VII.C.2.b.iii. (Ex. 1004, FIG. 1, 11:5-27; Ex. 1002, ¶221).

iv. Claim 9: The system of claim 1 wherein said bone plate includes…

For at least the reasons in Sections VII.D.2.b.vi and VII.D.2.b.xii, a POSITA would be motivated to combine Slater and Zahiri, and find the combination teaches this claim. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶222).

v. Claim 10: The system of claim 1 wherein said bone plate includes…

For at least the reasons in Sections VII.D.2.b.vi and VII.D.2.b.xii, a POSITA would be motivated to combine Slater and Zahiri, and find the combination teaches this claim. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶223).

vi. Claim 12: The system of claim 11 wherein the bone plate is contoured…

A POSITA would find Slater teaches this claim, as explained in Section VII.C.2.b.i. (Ex. 1004, FIG. 1, 8:25-9:19, 11:1-4; Ex. 1002, ¶224).

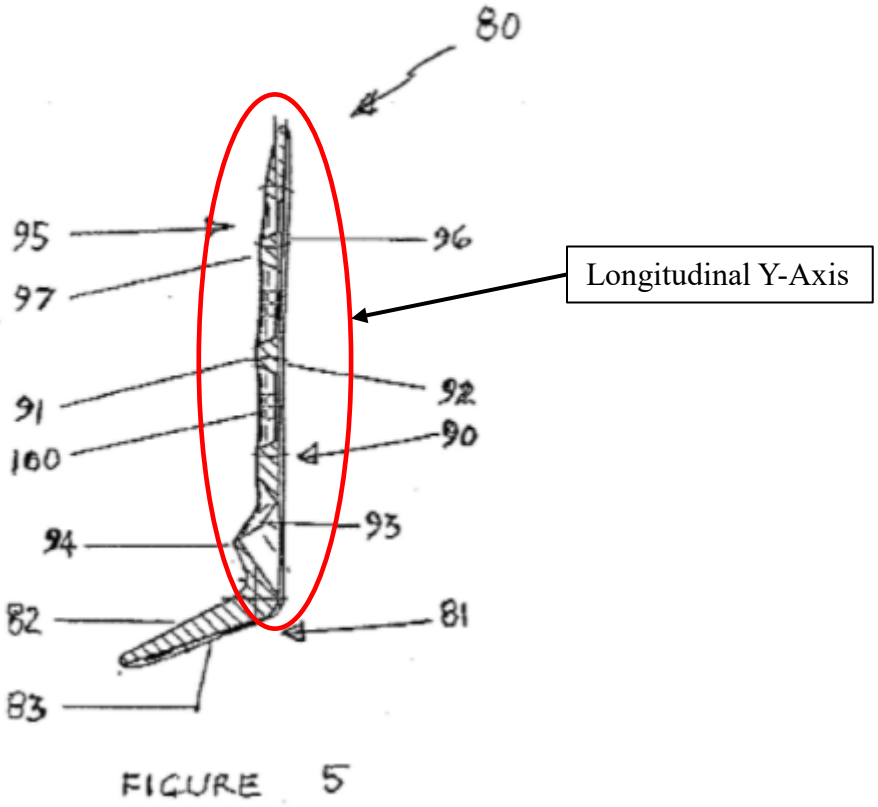
vii. Claim 13: The system of claim 11 wherein the free end…

A POSITA would find Slater teaches this claim, as explained in Section VII.C.2.b.iii. (Ex. 1004, FIG. 1, 11:5-27; Ex. 1002, ¶225).

viii. Claim 14: The system of claim 11 wherein the bone plate…

Slater's bone plate is configured with a substantial portion of the plate

disposed along the Y-axis:



(Ex. 1004, FIG. 5 (annotated)). Slater discloses that "[a]n ideal tibial length of the plate would be approximately 80mm. The contour of geometry over the distal aspect of the tibia will be incorporated into the design of the plate. The length from the L point out to the phalanges would be about 25mm in length." (Ex. 1004, 15:12-15).

Slater discloses this claim. (Ex. 1002, ¶226-228).

ix. Claim 15: The system of claim 11 wherein the fifth hole…

For at least the reasons in Section VII.D.2.b.vi, a POSITA would be motivated to combine Slater and Zahiri, and find the combination teaches this claim. (Ex. 1007, FIGS. 2, 8, 5:47-64, 7:19-24, 7:63-66, 3:11-18; Ex. 1002, ¶229).

x. Claim 16: The system of claim 11 wherein the temporary fixation member…

For at least the reasons in Section VII.D.2.b.xii, a POSITA would be motivated to combine Slater and Zahiri, and find the combination teaches this claim. (Ex. 1007, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶230).

xi. Claim 18: The orthopedic implant of claim 17 wherein the temporary fixation…

For at least the reasons in Section VII.D.2.b.xii, a POSITA would be motivated to combine Slater and Zahiri, and find the combination teaches this claim. (Ex. 1007, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶231).

E. Ground 3: Claim 6 is Unpatentable Under 35 U.S.C. §103(a) as Obvious over Slater, Zahiri, and Myerson

Dependent claim 6 is obvious in view of Slater, Zahiri, and Myerson. (Ex. 1002, ¶232).

1. Basis for Combination

A POSITA would be motivated to combine Slater and Zahiri for at least the reasons in Section VII.D.1. (Ex. 1002, ¶233).

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 is not a foot joint. A POSITA would understand that internal fixation bone plates are often reconfigured for different applications, and typically not limited to a single specific bone. (Ex. 1002, ¶¶234-235). 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. 1002, ¶¶235). This latter joint is the also known as the subtalar joint, which is a foot joint. (*Id.*). Slater discloses that an advantage of its plate is the pliable regions permitting conformance to different bone anatomy. (Ex. 1004, 17:2-3). Slater claims "[a] fusion plate for arthrodesis," not limited to any bone. (Ex. 1004, 21:7-20). 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, ¶236). 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. (*Id.*).

Myerson describes a bone plate configured for joint fusion "between the first and second metatarsals and the middle and/or internal cuneiforms." (Ex. 1010, ¶5; FIG. 1, ¶10). A POSITA would understand that the ankle fusion plate disclosed by

Slater could be extended in to cover additional bones in the foot. (Ex. 1002, ¶237). 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. (*Id.*).

Myerson teaches that "the plate 10 is configured to be positioned anywhere in the mid-foot." (Ex. 1010, ¶21). Myerson guides a POSITA to substitute differently contoured plates in order for the plate to be positioned across the cuboid bone. (Ex. 1010, ¶¶21-22; Ex. 1002, ¶238). A POSITA would understand that if a joint in the mid-foot needed to be fused, Slater's bone plate would be modified to conform to the bones in the mid-foot. (Ex. 1002, ¶238).

2. Claim 6: The system of claim 1 wherein said joint…

Slater discloses a bone plate configured to conform to the anatomical contours of the tibia and the ankle joint between the tibia and the talus. (Ex. 1004, FIG. 1, 8:31-9:19, 12:12-27). While neither of these joints are a tarsometatarsal joint, a POSITA would understand that internal fixation bone plates are often reconfigured for different indications and specific bones. (Ex. 1002, ¶239). A POSITA would look to prior art like Myerson for disclosure of known plates for other joints. (*Id.*).

Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones in the mid-foot, "especially across the metatarsal joints."

(Ex. 1010, ¶¶21-22). Myerson illustrates a bone plate fixed across the tarsometatarsal joint:

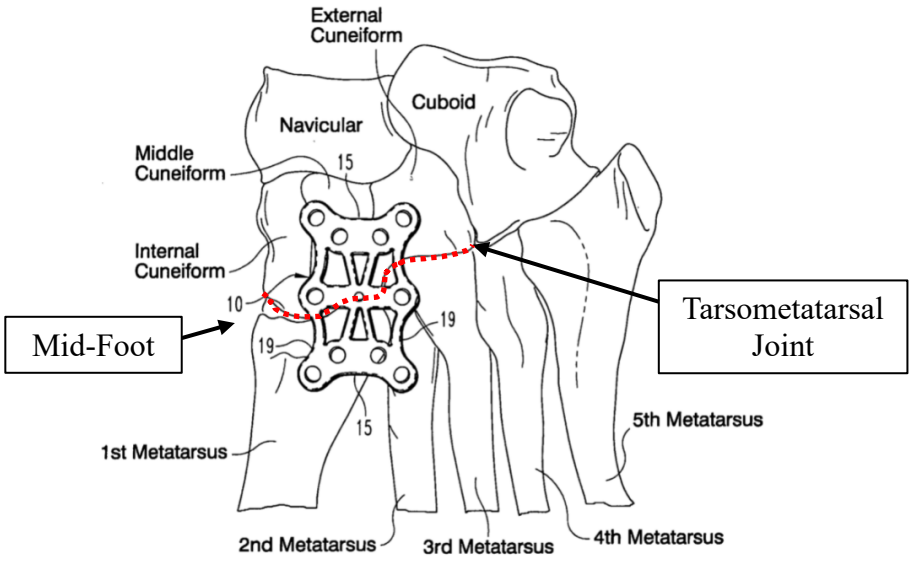


Fig. 1

(Ex. 1010, FIG. 1 (annotated). A POSITA would understand that Myerson's bone plate is configured to fuse the tarsometatarsal joint. (Ex. 1002, ¶¶240-241). A POSITA would understand that Slater's bone plate could be configured to extend to the bones in the mid-foot and fuse the tarsometatarsal joint. (*Id.*).

It would be obvious to a POSITA to extend and contour Slater's bone plate to the bones in the mid-foot by modifying the length or shape of the plate, and would obtain a predictable result. (Ex. 1002, ¶242).

F. Ground 4: Claims 1-3 and 7-18 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Arnould and Zahiri

Independent claims 1, 11, and 17, and dependent claims 2-3, 7-10, 12-16, and 18, are obvious in view of the combination of Arnould and Zahiri. (Ex. 1002, ¶243).

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 1-3 and 7-18. There are no differences between the subject matter of these claims and the combination of Arnould and Zahiri. (Ex. 1002, ¶244).

Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone, in analogous fields of invention. (Ex. 1006, ¶6; Ex. 1007, 2:20-31). 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 (also known as the phalanges). (Ex. 1006, ¶31). Arnould explains that "the screw works mainly by means of traction." (Ex. 1006, ¶6). A POSITA knows that screws positioned across an interface, "working in traction" are providing compression at the interface. (Ex. 1002, ¶¶245-246). 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). Arnould teaches that 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, ¶247). It may be argued 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 at least guides 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, ¶248). Zahiri's bone plate fuses a first and second bone part with an angled fixation member and compresses the bone fracture:

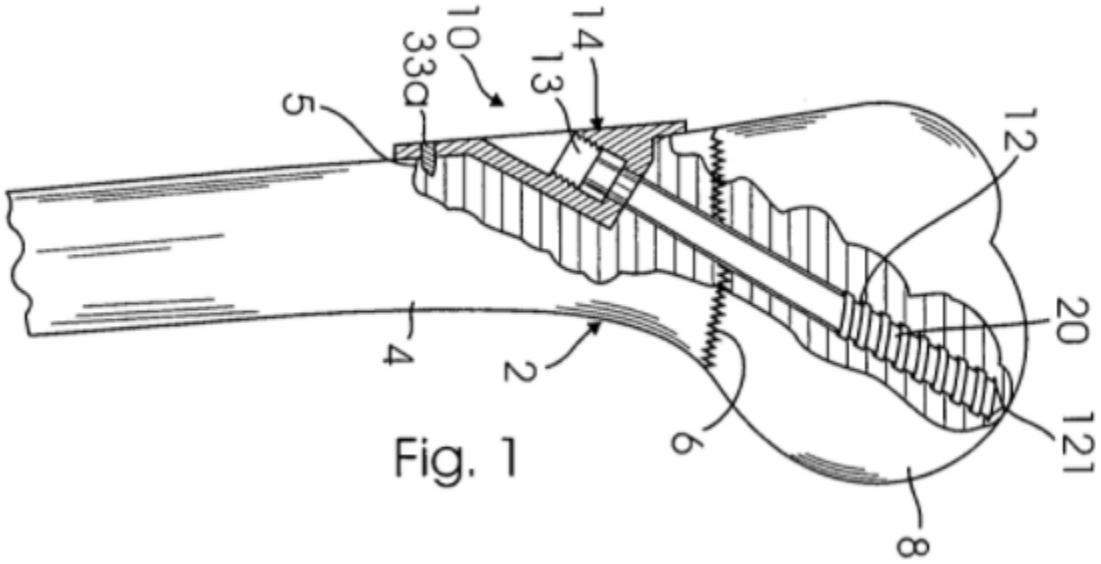


Fig. 1

(Ex. 1007, FIG. 1; 2:23-28). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bones while dissipating the force along the plate so it does not damage the bones. (Ex. 1007, 5:65-6-11). A POSITA would understand that there are no practical differences between stabilizing

a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose fusing a bone fracture. (Ex. 1002, ¶249). A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. (*Id.*). A POSITA would look to Zahiri when making improvements to the plate disclosed in Arnould. (*Id.*).

Arnould discloses a method for partially affixing the bone plate to the bone by partially immobilizing the plate using a screw that is not tightened fully in an oblong hole so that the surgeon can correctly position and align the plate. (Ex. 1006, ¶31; Ex. 1002, ¶250). 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). A POSITA would understand that Figure 2 of Arnould illustrates temporary guide holes (circled in red below) that are used to temporarily secure the plate during the implantation process:

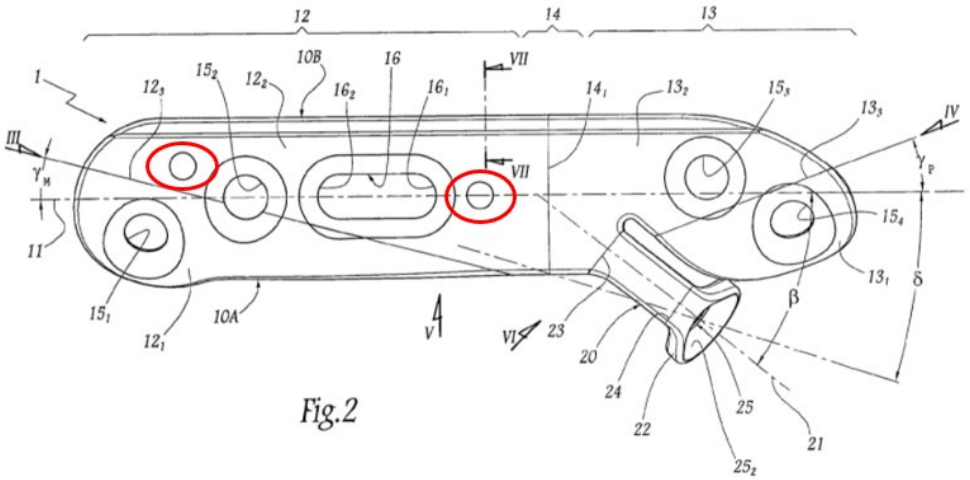
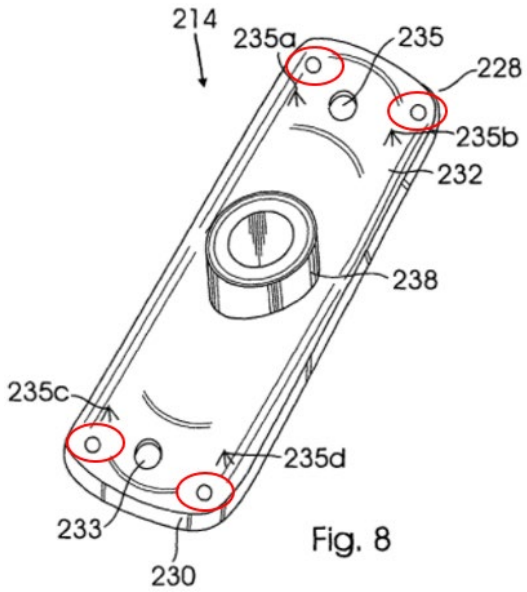


Fig.2

(Ex. 1006, FIG. 2 (annotated); ¶31; Ex. 1002, ¶251). While the figures of Arnould show such temporary guide holes, Arnould lacks sufficient disclosure regarding temporary fixation members in the guide holes. (Ex. 1002, ¶252). A POSITA would look to prior art in the relevant field, like Zahiri, for this disclosure. (*Id.*).

Zahiri discusses the importance of plate alignment and discloses an improvement that uses temporary locking pins to temporarily secure the bone plate to the bone. (Ex. 1007, 3:11-18). Zahiri discloses four small holes in the corner of the bone plate that temporarily hold the bone plate in place during implantation:



(Ex. 1007, FIG. 8 (annotated); 3:11-18 ("[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. (Ex. 1007, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶¶253-254).

As the use of these temporary guide pins would be before the plate is permanently affixed, a POSITA would look to incorporate these improvements disclosed by Zahiri into Arnould to ensure correct placement. (Ex. 1006, ¶¶3, 31; Ex. 1002, ¶¶255). A POSITA would understand that the temporary guide pins used with pin holes, as disclosed in Zahiri, could be implemented with Arnould's bone plate to temporarily secure the plate alignment during implantation. (Ex. 1002, ¶255). A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins, rendering the incorporation of Zahiri's temporary guide pins obvious. (Ex. 1006, FIG. 1; Ex. 1002, ¶255). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, ¶255).

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, ¶256).

2. Claims 1-3, 7-10, 12-18 are Obvious

a. *Independent Claim 1*

i. [1Pre]

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.")).

Arnould discloses this element. (Ex. 1002, ¶257).

ii. [1a]

Arnould's bone plate 1 comprises a plate body 10 that "includes, along its longitudinal direction 11, a metatarsal portion 12 [a second end] and a phalangeal portion 13 [a first end] which are respectively adapted to be placed and fixed on the metatarsal M and the phalanx P." (Ex. 1006, ¶14).

Arnould discloses this element. (Ex. 1002, ¶¶258).

iii. [1b]

Arnould's bone plate comprises holes 15_3 and 15_4 (first hole(s)) configured to attach to the phalangeal portion 13 (first end) of the plate 1 to the phalanx (first bone):

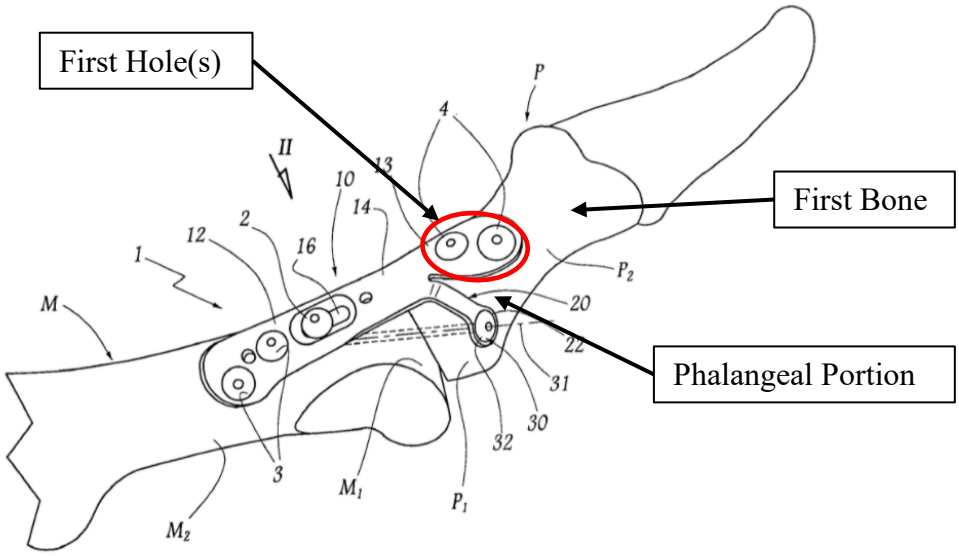


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶21, 34).

Arnould discloses this element. (Ex. 1002, ¶¶259-260).

iv. [1c]

Arnould's bone plate comprises holes 15_1 and 15_2 (second hole(s)) configured to attach to the metatarsal portion 12 (second end) of the plate 1 to the metatarsal (second bone):

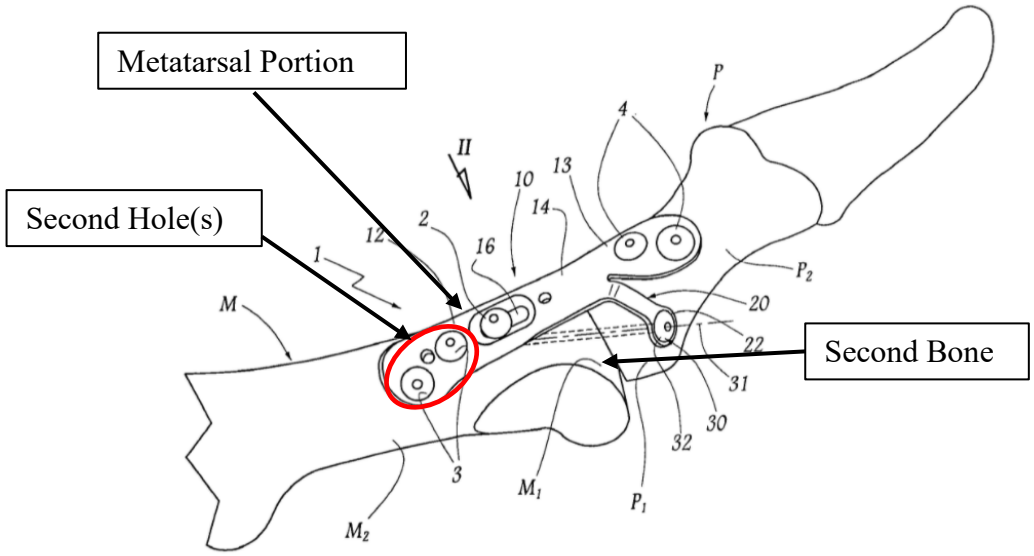


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶21, 33).

Arnould discloses this element. (Ex. 1002, ¶¶261-262).

v. [1d]

Arnould discloses a screw 30 configured to be inserted into hole 25 at an angle δ selected by the surgeon:

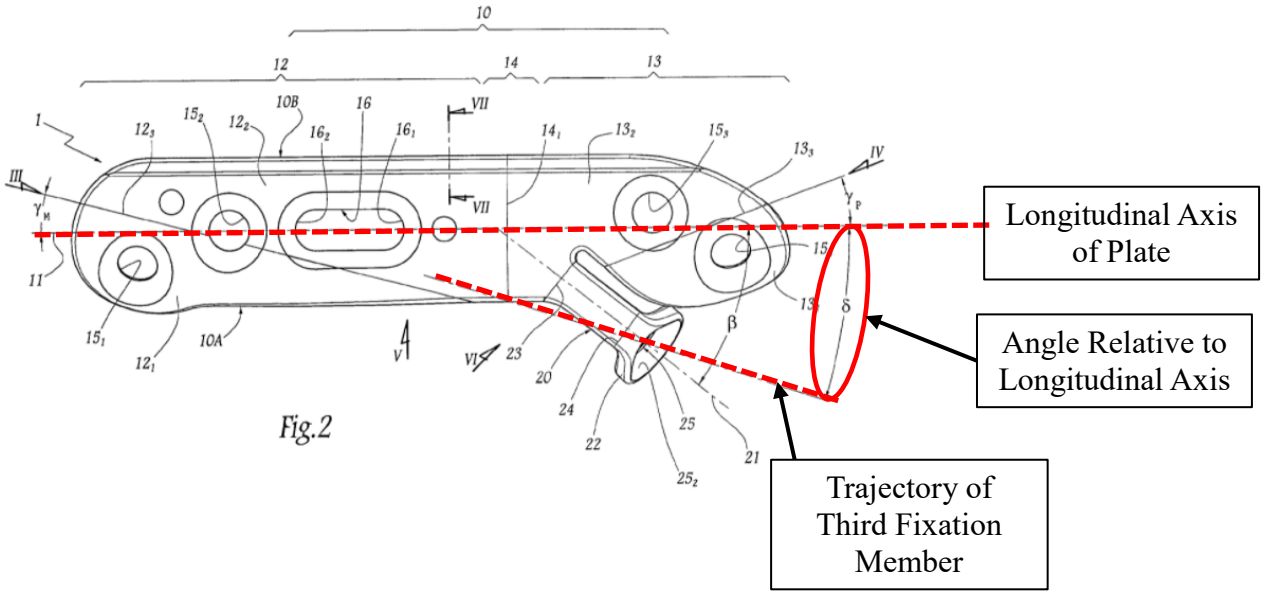


Fig.2

(Ex. 1006, FIG. 2 (annotated); ¶32). The trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate (δ). (Ex. 1006, FIG. 2, ¶27; Ex. 1002, ¶263). 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). A POSITA would understand that the hole 25 is a third hole that is offset at angle β relative to a longitudinal axis of the plate. (Ex. 1006, ¶25; Ex. 1002, ¶¶263-264).

A POSITA would also have looked to Zahiri for a way to provide better compression across the joint because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. (Ex. 1002, ¶265). Zahiri's bone plate comprises a barrel portion 38 with a third hole defined by an inner side wall 48 that extends from an opening 46 and a third point 3:

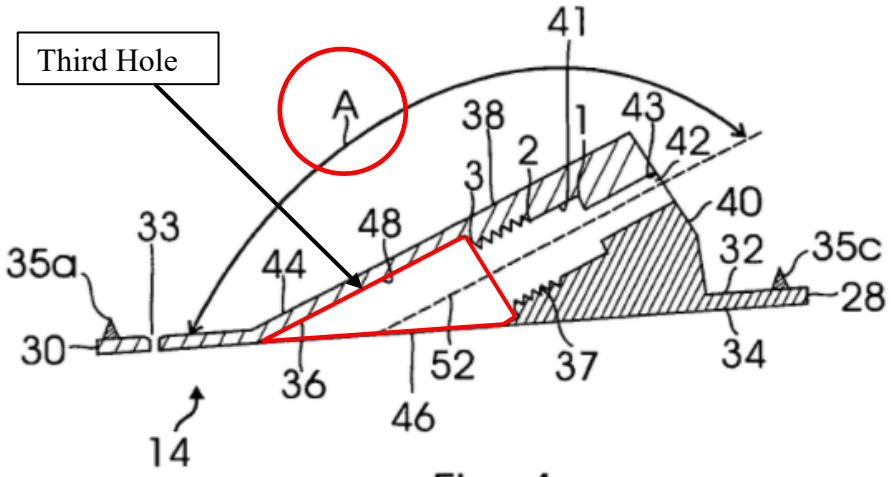


Fig. 4

(Ex. 1007, FIG. 4 (annotated); 6:12-35). The third hole is angle at an incline "A" relative to the central longitudinal line of the plate. (Ex. 1007, FIG. 4, 6:30-35, 6:50-56).

Zahiri further shows the barrel portion 238 (third hole) located between the first hole 233 and the second hole 235:

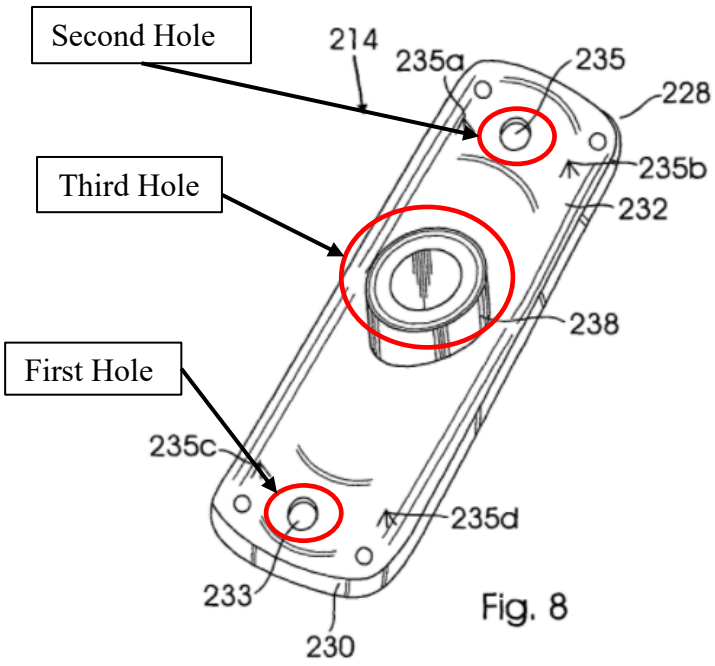


Fig. 8

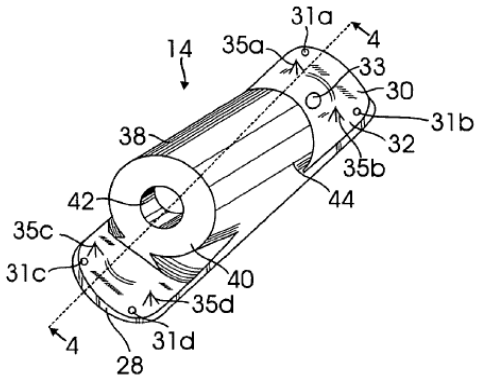


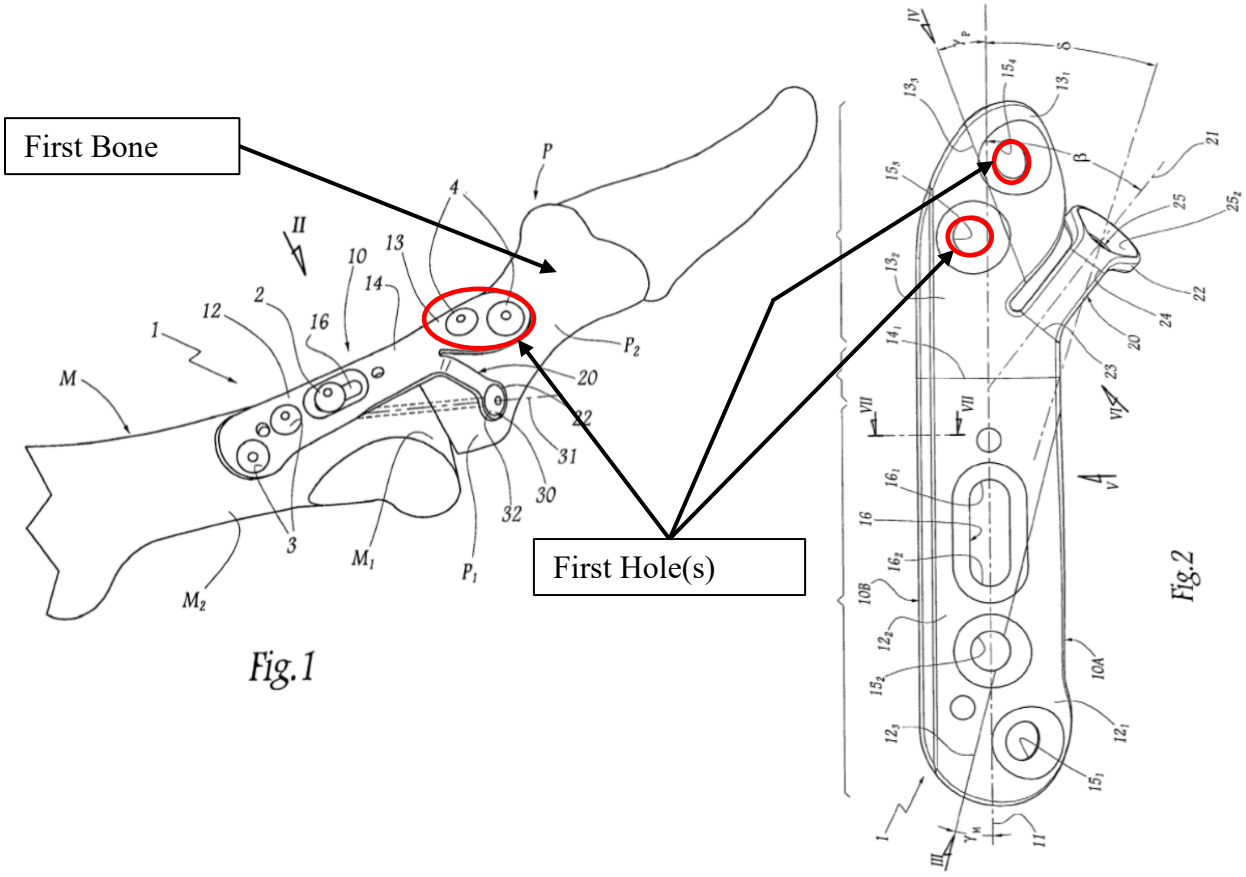
Fig. 3

(Ex. 1007, FIG. 3, 8 (annotated); 8:34-41). A POSITA would understand that the opening 238 is a third hole that is angled relative to a longitudinal axis of the plate and such a location would be easily implemented on the plate of Arnould to increase compressive forces. (Ex. 1002, ¶¶263-268).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶269).

vi. [1e]

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

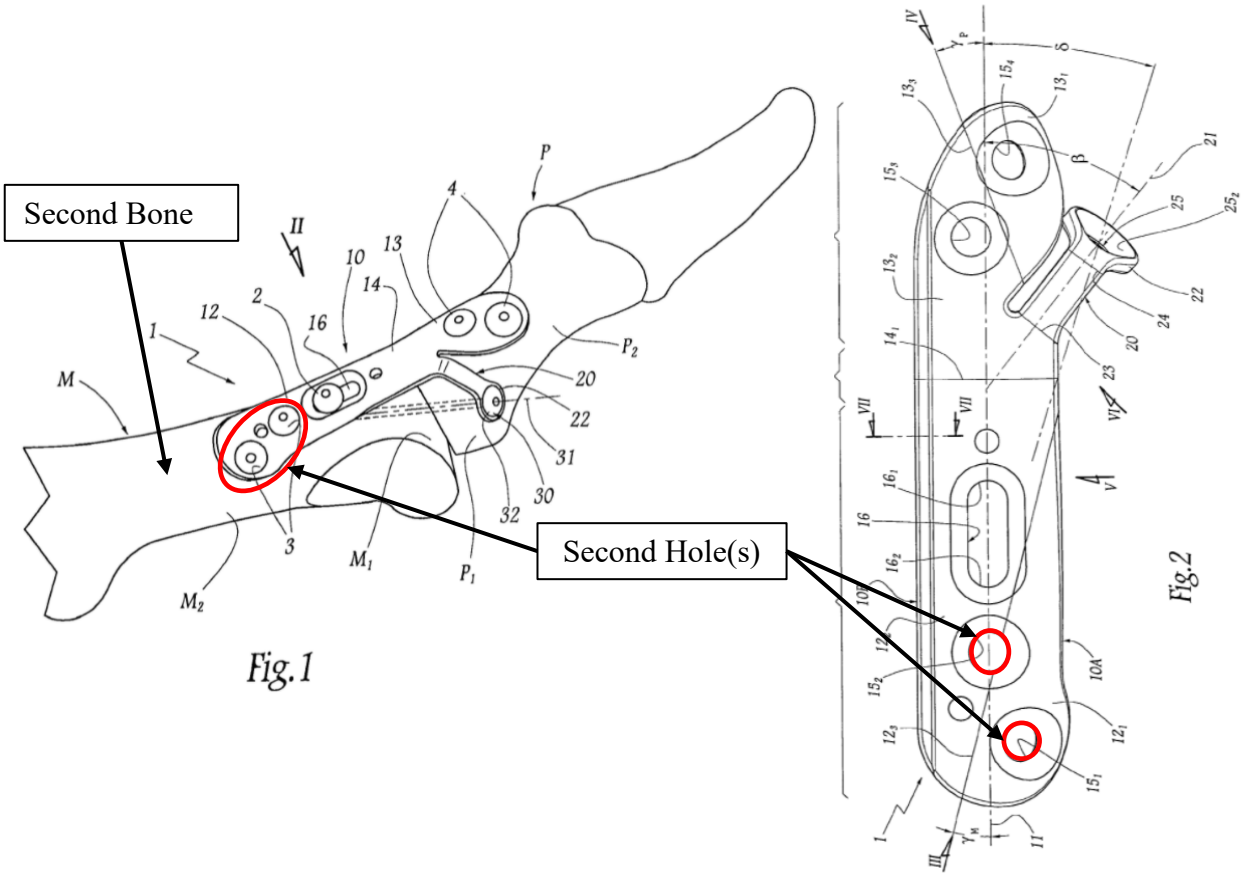


(Ex. 1006, FIGS. 1, 2 (annotated); ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶34 ("Before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

Arnould discloses this element. (Ex. 1002, ¶¶270-272).

vii. [1f]

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.")).

Arnould discloses this element. (Ex. 1002, ¶¶273-275).

viii. [1g]

Arnould discloses a screw 30 configured to be inserted into hole 25 at an angle δ selected by the surgeon. (Ex. 1006, ¶32). Screw 30 is further configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone). (Ex. 1006, ¶¶6, 32). 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, ¶276).

A POSITA would find this element obvious in view of Arnould. (Ex. 1002, ¶277).

ix. [1h]

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):

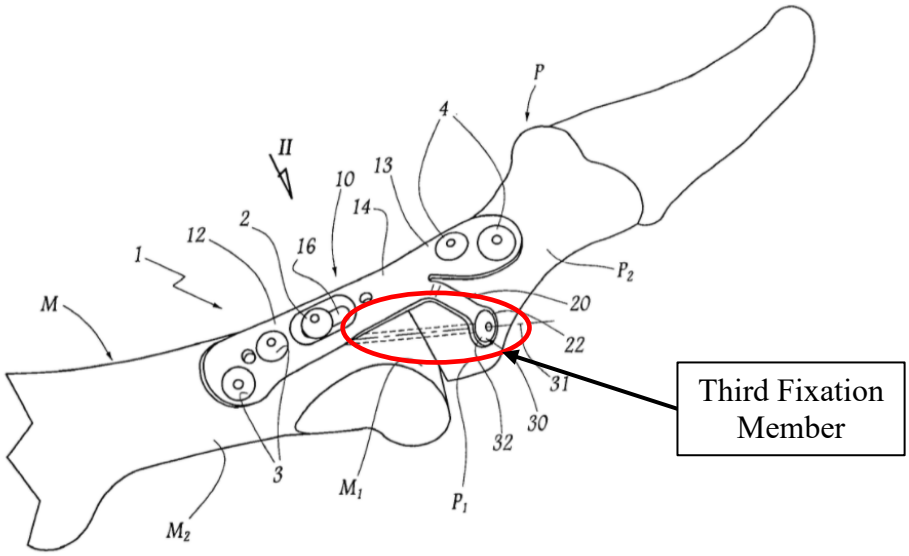


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶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.")). Thus, Arnould discloses that the third fixation member is the only fixation member extending across said joint. (Ex. 1002, ¶¶278-279).

A POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶280). 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). Zahiri shows that

the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone and the second bone:

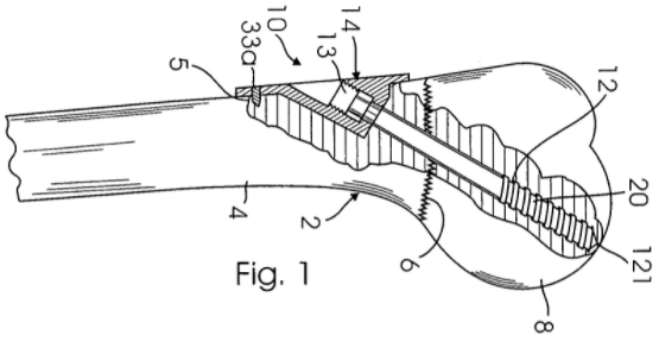


Fig. 1

(Ex. 1007, FIG. 1; 2:23-36). A POSITA would understand that the Arnould and Zahiri bone plates are configured for only one compression screw to intersect the joint and/or fracture line. (Ex. 1002, ¶280).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶281).

b. *Independent Claim 11*

i. [11Pre]

For at least the reasons in Section VII.F.2.a.i, Arnould discloses this element. (Ex. 1006, ¶11; Ex. 1002, ¶282).

ii. [11a]

For at least the reasons in Section VII.F.2.a.ii, Arnould discloses this element. (Ex. 1006, ¶14; Ex. 1002, ¶283).

iii. [11b]

For at least the reasons in Section VII.F.2.a.iii, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 34; Ex. 1002, ¶284).

iv. [11c]

For at least the reasons in Section VII.F.2.a.iv, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 33; Ex. 1002, ¶285).

v. [11d]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶286).

As discussed in Section VII.D.2.b.v, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 4, 8, 6:12-35, 8:34-44; Ex. 1002, ¶287). Looking for a way to improve the integrity of the angled fixation screw of Arnould's bone plate, a POSITA would consider the disclosure of Zahiri to implement this improvement. (Ex. 1002, ¶287).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶288).

vi. [11e]

The purpose of the fifth hole (as discussed below with respect to element 11k) is to receive a temporary fixation member. Arnould is silent regarding the use of

temporary fixation members with the guide holes shown in its figures. (Ex. 1002, ¶289). A POSITA would look to relevant prior art like Zahiri for disclosure of known temporary fixation members. (*Id.*).

As discussed in Section VII.D.2.b.vi, a POSITA would find Zahiri discloses this element. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18; Ex. 1002, ¶290). 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 improve Arnould's plate to guide the plate alignment during implantation. (Ex. 1002, ¶290).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶291).

vii. [11f]

For at least the reasons in Section VII.F.2.a.vi, Arnould discloses this element. (Ex. 1006, FIGS. 1, 2, ¶¶21, 34; Ex. 1002, ¶292).

viii. [11g]

For at least the reasons in Section VII.F.2.a.vii, Arnould discloses this element. (Ex. 1006, FIGS. 1, 2, ¶¶21, 33; Ex. 1002, ¶293).

ix. [11h]

While Arnould discloses the use of a third fixation member that is angled into the first bone, across the joint, and into the second bone (Section VII.F.2.a.vii (citing

Ex. 1006, FIGS. 1, 2, ¶¶21, 33)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶294). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*).

As discussed in Section VII.D.2.b.ix, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 1, 4, 6:12-35, 2:23-28; Ex. 1002, ¶295). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to improve the integrity of the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶295).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶296).

x. [11i]

While Arnould discloses the use of a third fixation member that has a free end not attached to any portion of the bone plate and resides in the second discrete bone (Section VII.F.2.a.viii (citing Ex. 1006, ¶¶6, 32)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶297). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*).

As discussed in Section VII.D.2.b.x, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIG. 1, 2:23-28, 5:5-8; Ex. 1002, ¶298). A

POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the angled fixation screw of Arnould's plate with Zahiri's lag screw. (Ex. 1002, ¶298).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶299).

xi. [11j]

Arnould lacks sufficient disclosure of the full dimensions of the third fixation member. (Ex. 1002, ¶300). A POSITA would look to prior art like Zahiri for disclosure of a fixation member with a fixation head defining a head area, the head area being greater than the second area and less than the first area. (*Id.*).

As discussed in Section VII.D.2.b.xi, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIG. 1, 2:23-28; Ex. 1002, ¶301). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶301).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶302).

xii. [11k]

The purpose of the fifth hole is to receive a temporary fixation member. Arnould is silent regarding the use of temporary fixation members with the guide

holes shown in its figures. (Ex. 1002, ¶303). A POSITA would look to prior art like Zahiri for disclosure of known temporary fixation members. (*Id.*).

As discussed in Section VII.D.2.b.xii, a POSITA would find that Zahiri discloses this element. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶304). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve Arnould's plate to temporarily place the plate during implantation using Zahiri's pins. (Ex. 1002, ¶304).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶305).

c. *Independent Claim 17*

i. [17Pre]

For at least the reasons in Section VII.F.2.a.i, Arnould discloses this element. (Ex. 1006, ¶11; Ex. 1002, ¶306).

ii. [17a]

Arnould's plate comprise an outer longitudinal side 10B that faces outward and an inner longitudinal side 10B that presses against the surface of the bones. (Ex. 1006, ¶¶29, 23).

Arnould discloses this element. (Ex. 1002, ¶307).

iii. [17b]

For at least the reasons in Section VII.F.2.a.ii, Arnould discloses this element. (Ex. 1006, ¶14; Ex. 1002, ¶308).

iv. [17c]

For at least the reasons in Section VII.F.2.a.iii, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 34; Ex. 1002, ¶309).

v. [17d]

For at least the reasons in Section VII.F.2.a.iv, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 33; Ex. 1002, ¶310).

vi. [17e]

For at least the reasons in Section VII.F.2.a.v, Arnould discloses this element. (Ex. 1006, FIG. 2, ¶32; Ex. 1002, ¶311).

vii. [17f]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶312).

As discussed in Section VII.D.2.c.vii, a POSITA would find that Zahiri discloses this element. (Ex. 1007, 7:35-41; Ex. 1002, ¶313). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the

integrity of the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶313).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶314).

viii. [17g]

Arnould describes a screw hole 25 (third hole) configured such that the screw 30 (third bone screw) forms a non-zero angle in relation to the longitudinal direction of the plate body, and screw 30 passes through hole 25 and enters the phalanx and the metatarsal bone:

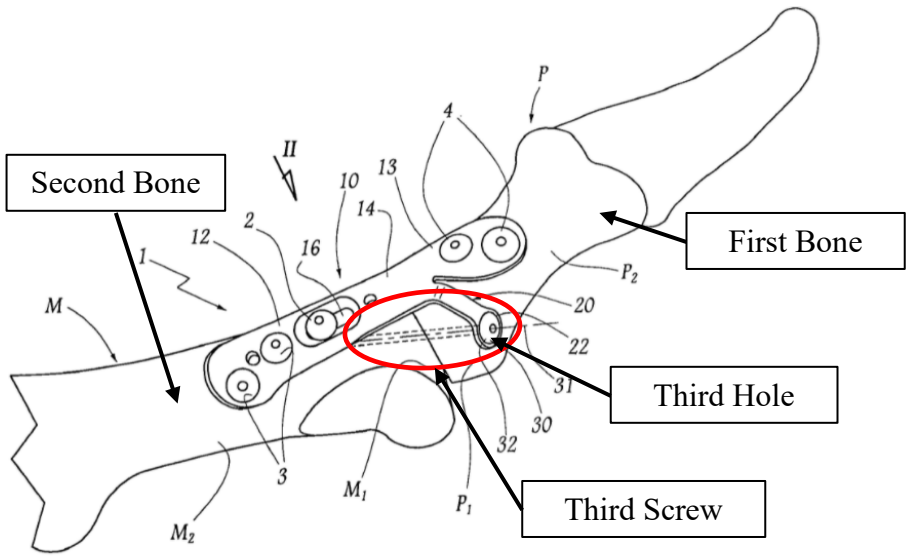


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶26-27). A POSITA would understand that screw 30 passes through the joint between the phalanx and the metatarsal. (Ex. 1002, ¶¶315-316).

A POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶317).

ix. [17h]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶318).

As discussed in Section VII.D.2.c.ix, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 1, 4, 2:23-36, 7:31-38, 6:18-24; Ex. 1002, ¶319). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the integrity of the angled fixation screw of Arnould's plate by utilizing the seated head of the lag screw from Zahiri to ensure the third fixation member is seated securely in the third hole. (Ex. 1002, ¶319).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶320).

x. [17i]

For at least the reasons in Section VII.F.2.b.vi, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18; Ex. 1002, ¶321).

xi. [17j]

For at least the reasons in Section VII.F.2.b.xii, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶322).

d. *Dependent Claims 2-3, 7-10, 12-16, and 18*

i. Claim 2

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, which are both bones in the human foot. (Ex. 1006, ¶¶1, 15, 39; Ex. 1002, ¶323).

Arnould discloses this element. (Ex. 1002, ¶324).

ii. Claim 3: The system of claim 1 wherein said joint…

Arnould's arthrodesis bone plate is configured "for the joint between the first metatarsal and the first phalanx of the big toe," and to be "placed and fixed on the metarsal-phalangeal joint locked by the plate." (Ex. 1006, FIG. 1, ¶¶1, 10).

Arnould discloses this element. (Ex. 1002, ¶¶325-326).

iii. Claim 7

Arnould discloses a fixation screw 30 that is configured to be tightened such that the metatarsal and the phalanx are substantially contiguous. (Ex. 1006, ¶32). Zahiri's bone plate comprises a lag screw configured to compress the diaphyseal

cortex (bone) as it is advanced deeper in the epiphysis (bone end). (Ex. 1007, 7:55-62). A POSITA would understand that screw 30 passes through the joint between the metatarsal and the phalanx and compresses the joint. (Ex. 1002, ¶327). A POSITA would understand that one way compression at the fixation site is developed is by the lag screw. (Ex. 1007, 2:45-48; Ex. 1002, ¶327).

A POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1002, ¶328).

iv. Claim 8

Arnould's bone plate is configured such that the free end of screw 30 (third fixation member) and the free end of screws 3 (Second fixation member) anchor into the metatarsal (second discrete bone):

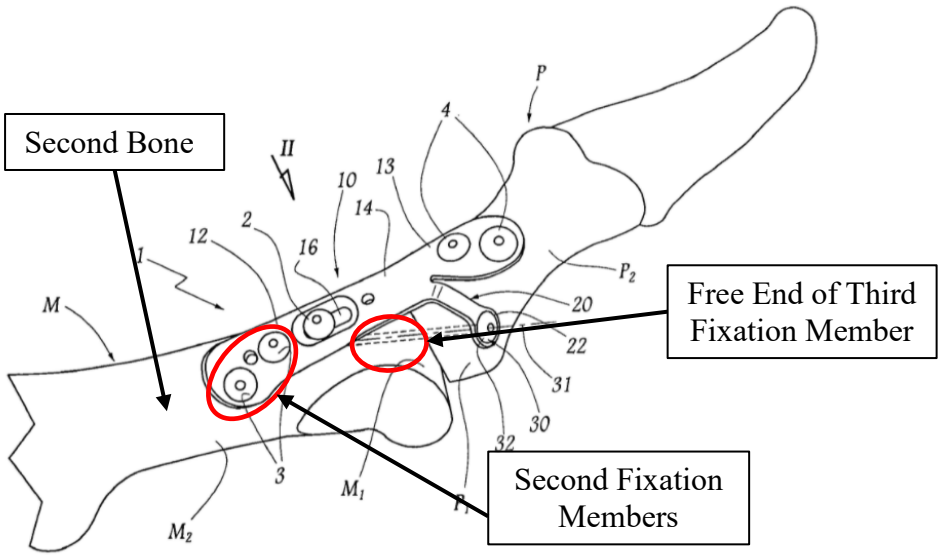


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶32-33). A POSITA would understand that the free end of screw 30 and screws 3 would reside adjacent to each other in the metatarsal. (Ex. 1002, ¶¶329-330).

A POSITA would find this element obvious in view of Arnould. (Ex. 1002, ¶331).

v. Claim 9

For at least the reasons in Sections VII.F.2.b.vi and VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:63-7:66; Ex. 1002, ¶332).

vi. Claim 10

For at least the reasons in Sections VII.F.2.b.vi and VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:63-7:66; Ex. 1002, ¶333).

vii. Claim 12

For at least the reasons in Section VII.F.2.d.i, a POSITA would find that this claim is taught by Arnould. (Ex. 1006, ¶15, 39; Ex. 1002, ¶334).

viii. Claim 13

For at least the reasons in Section VII.F.2.d.iv, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1006, ¶32; Ex. 1002, ¶335).

ix. Claim 14

Arnould's bone plate comprises a metatarsal portion 12 and a phalangeal portion 13 that are connected at a junction zone 14. (Ex. 1006, ¶¶15, 17). The metatarsal portion 12 and the phalangeal portion 13 are defined by "substantially planar section[s]." (*Id.*). Therefore, a POSITA would understand that Arnould's bone plate is substantially planar. (Ex. 1002, ¶336)

A POSITA would find that this claim is taught by Arnould. (Ex. 1002, ¶337).

x. Claim 15

For at least the reasons in Section VII.F.2.b.vi, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18; Ex. 1002, ¶338).

xi. Claim 16

For at least the reasons in Section VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶339).

xii. Claim 18

For at least the reasons in Section VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶340).

G. Ground 5: Claim 6 is Unpatentable Under 35 U.S.C. §103(a) as Obvious over Arnould, Zahiri, and Myerson

Dependent claim 6 is obvious in view of Arnould, Zahiri, and Myerson. (Ex. 1002, ¶341).

1. Basis for Combination of Arnould, Zahiri, and Myerson

A POSITA would be motivated to combine Arnould and Zahiri for at least the reasons in Section VII.E.1.

Myerson teaches that "the plate 10 is configured to be positioned anywhere in the mid-foot." (Ex. 1010, ¶21). Myerson guides a POSITA to substitute differently contoured plates in order for the plate to be positioned across the cuboid bone. (Ex. 1010, ¶¶21-22; Ex. 1002, ¶¶342-343). A POSITA would understand, that if a joint in the mid-foot needed to be fused, Arnould's bone plate would be modified to conform to the bones in the mid-foot. (Ex. 1002, ¶¶344).

2. Claim 6

Arnould discloses a bone plate is configured to conform to the anatomical contours of the domed metatarsal zone. (Ex. 1006, ¶15). In analogous art, Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones "anywhere along the mid-foot," "especially across the metatarsal joints." (Ex. 1010, ¶¶21-22). Myerson illustrates a bone plate fixed across the tarsometatarsal joint:

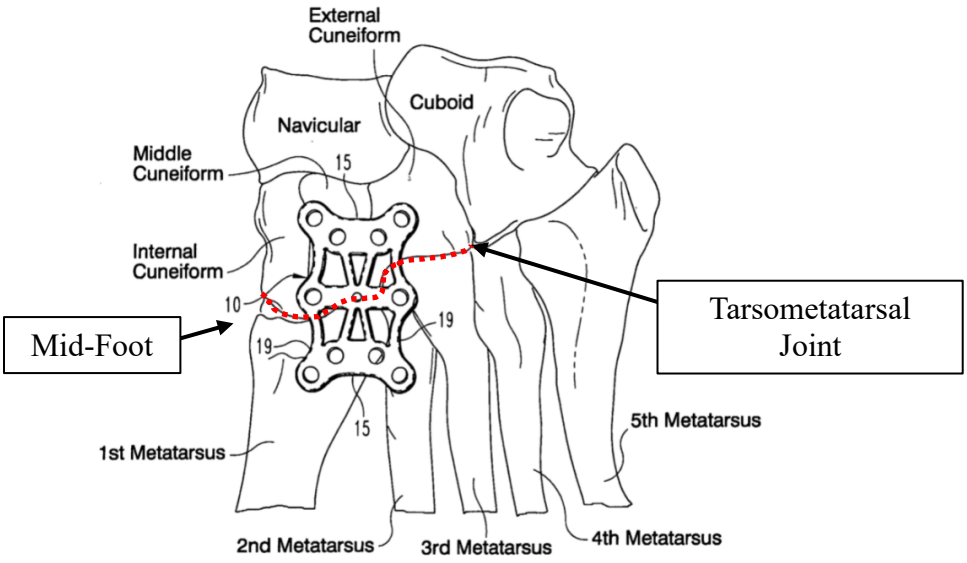


Fig. 1

(Ex. 1010, FIG. 1 (annotated)). A POSITA would understand that Myerson's bone plate is configured to fuse the tarsometatarsal joint. (Ex. 1002, ¶¶345-346). A POSITA would understand that Arnould's bone plate would easily be configured to contour to the bones in the mid-foot and fuse the tarsometatarsal joint. (*Id.*).

It would be obvious to a POSITA to contour Arnould's bone plate to the bones in the mid-foot through a simple substitution to obtain a predictable result. (Ex. 1002, ¶347).

VIII. CONCLUSION

The Petition demonstrates a reasonable likelihood that at least one claim is unpatentable. 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

[1pre] A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:

[1a] a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:

[1b] a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint;

[1c] a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and

[1d] a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate;

[1e] a first fixation member configured to be inserted through the first hole of the bone plate and into the first discrete bone of the joint;

[1f] a second fixation member configured to inserted through said second hole of said bone plate and into the second discrete bone of said joint; and

[1g] a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in the second discrete bone,

[1h] wherein said third fixation member is the only fixation member extending across said joint from the first side of the joint to the second side of the joint.

[2] The system of claim 1 wherein said bone plate is contoured to anatomically fit bones in a human foot.

[3] The system of claim 1 wherein said joint is a metatarsophalangeal joint.

[6] The system of claim 1 wherein said joint is a tarsometatarsal joint.

[7] The system of claim 1 wherein said third fixation member is configured to develop compression across said joint with lag effect when said third fixation member is tightened.

[8] The system of claim 1 wherein the free end of said third fixation member and a free end of said second fixation member are configured to reside adjacent each other within said second discrete bone.

[9] The system of claim 1 wherein said bone plate includes at least one pin hole adjacent said first hole, said pin hole configured to receive a temporary fixation member.

[10] The system of claim 1 wherein said bone plate includes at least one pin hole adjacent said second hole, said pin hole configured to receive a temporary fixation member.

[11pre] A system for fusing first and second bone parts, said system comprising:

[11a] a bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint, said bone plate having;

[11b] a first hole configured to align with the first bone part,

[11c] a second hole configured to align with the second bone part,

[11d] a third hole and a fourth located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area, and

[11e] a fifth hole located adjacent either the first hole or the second hole, said fifth hole being smaller in area than said first hole or said second hole;

[11f] a first fixation member configured to be inserted through the first hole of said bone plate and into the first bone part;

[11g] a second fixation member configured to be inserted through the second hole of said bone plate and into the second bone part;

[11h] a third fixation member configured to be inserted through the third and fourth hole in the bone plate, into the first bone part, across the fracture or joint, and into the second bone part, wherein a free end of said third fixation member does not attach to any portion of the bone plate and wherein the third fixation member is the only fixation member extending across the fracture or joint, the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area; and

[11i] a temporary fixation member configured to be inserted through the fifth hole in the bone plate.

[12] The system of claim 11 wherein the bone plate is contoured to anatomically fit bones in a human foot.

[13] The system of claim 11 wherein the free end of the third fixation member and a free end of the second fixation member are configured to reside adjacent each other within said second bone part.

[14] The system of claim 11 wherein the bone plate is substantially planar.

[15] The system of claim 11 wherein the fifth hole is a pin hole.

[16] The system of claim 11 wherein the temporary fixation member is a guide pin.

[17Pre] An orthopedic implant comprising;

[17a] a bone plate having a proximal surface and an opposite distal bone contacting surface, said bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint,

[17b] said bone plate having a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw,

[17c] a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw,

[17d] a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate, and

[17e] a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member.

[18] The orthopedic implant of claim 17 wherein the temporary fixation is a guide pin.

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 **13,963** 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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