

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,303,589**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the Inter Partes Review of U.S. Patent No. 8,303,589

Trial No.: Not Yet Assigned

Issued: November 6, 2012

Filed: June 23, 2009

Inventors: Jeff Tyber, *et al.*

Assignee: Extremity Medical, LLC

Title: FIXATION SYSTEM, AN INTERMEDULLARY FIXATION  
ASSEMBLY AND METHOD OF USE

**MAIL STOP PATENT BOARD**

Patent Trial and Appeal Board

United States Patent & Trademark Office

P.O. Box 1450

Alexandria, Virginia 22313-1450

**PETITION FOR INTER PARTES REVIEW OF**  
**UNITED STATES PATENT NO. 8,303,589**  
**PURSUANT TO 35 U.S.C. § 311 AND 37 C.F.R. §42.304**

On behalf of Nextremity Solutions, Inc. (“Nextremity” or “Petitioner”) and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.304, *inter partes* review is respectfully requested for claim 59 of U.S. Patent No. 8,303,589 (“the ‘589 Patent”), attached hereto as Exhibit (“Ex.”) 1001.

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**I. Mandatory Notices Pursuant to 37 C.F.R. § 42.8(a)(1)**

Pursuant to 37 C.F.R. § 42.8(a)(1), the mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

**A. 37 C.F.R. § 421.8(b)(1): Real Parties-In-Interest**

Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc. and Zimmer, Inc. are the real Parties-In-Interest for this Petition.

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

The ‘589 Patent is currently the subject of a patent infringement lawsuit brought by the assignee of the ‘589 patent, Extremity Medical, LLC. (herein referred to as “Patentee”) (*See Extremity Medical, LLC v. Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc. and Zimmer, Inc.*, U.S. District Court for the District of Delaware, Civil Action No. 1:22-cv-00239-VAC). Patentee served Nextremity et al. with the complaint on February 25, 2022. This judicial matter may affect decisions made in this proceeding.

**C. 37 C.F.R. § 42.8(b)(3) and (4): Lead and Back-up Counsel and Service Information**

Nextremity provides the following designation of counsel:

<b>Lead Counsel</b>	<b>Back-up Counsel</b>
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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition. Please address all correspondence to lead and back-up counsel at the addresses above. Nextremity also consents to electronic service by email at the email addresses listed above.

**II. Ground for Standing Pursuant to 37 C.F.R. §42.104(a)**

Petitioner certifies that the ‘589 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging Claim 59 of the ‘589 Patent on the grounds identified herein.

**III. Relief Requested**

Petitioner respectfully asks that the Board review the accompanying prior art and analysis, institute a trial for *inter partes* review of claim 59 of the ‘589 patent, and find claim 59 invalid.

**IV. The Reasons for Requested Relief**

The full statement of the reasons for relief requested is as follows:

**A. Summary of Reasons**

The ‘589 patent relates to an orthopedic implant device. In general, the ‘589 Patent describes a fixation system used for internal fixation of angled joints, bones

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and deformity correction. The fixation system disclosed utilizes an instrument to couple a first screw member at an angle through an angled bore of a second member. The second member has two circumferentially spaced recesses adapted for coupling to the instrument.

These features were all well known in the prior art in 2008 when the provisional application that issued as the '589 Patent was filed on June 24, 2008. For example, U.S. Patent No. 4,827,917 to Brumfield (Ex. 1002) ("Brumfield"), U.S. Patent No. 4,622,959 to Marcus (Ex. 1003) ("Marcus"), and U.S. Patent No. 6,579,293 to Chandran (Ex. 1004) ("Chandran") each disclose each and every limitation recited in claim 59 of the '589 Patent. Neither Brumfield, Marcus, nor Chandran was considered by the Patent Office during prosecution of the application that issued into the '589 Patent.

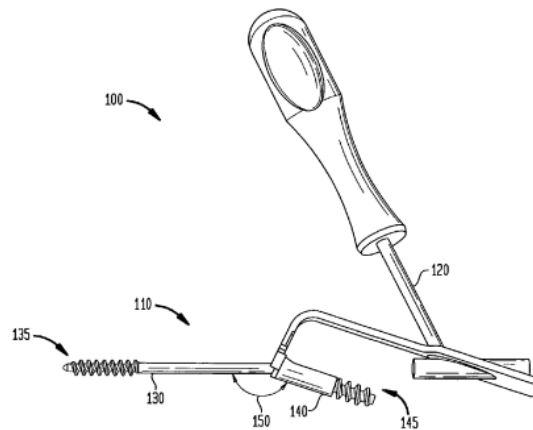
Consequently, this petition demonstrates that claim 59 simply claims a fixation system that was well known in the prior art and is anticipated by the prior art references presented in this Petition.

### **B. The '589 Patent**

#### **1. Overview**

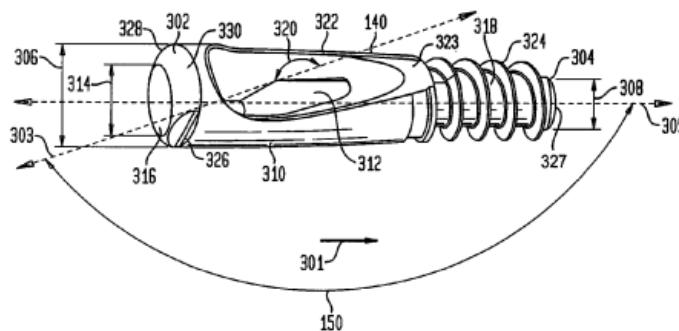
The '589 patent describes a fixation system, including a fixation assembly and an instrument for coupling the fixation assembly to bones. (Ex. 1001 at Abst.).

FIG. 1



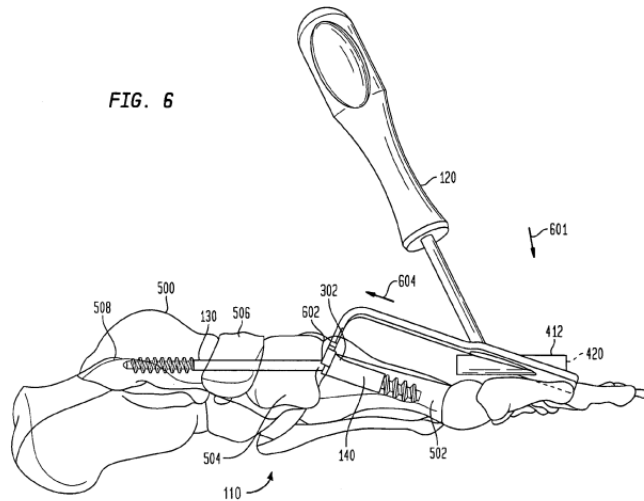
As shown above in Figure 1 of the '589 Patent, the fixation assembly includes a screw member 130 coupled to a distal member 140 at a fixed angle. *Id.* The instrument 100 is removably coupled to the distal member 140 by slidably coupling the instrument to grooves or recesses 326 and 328 formed at an end of the distal member 140 (as shown in Fig. 3A below). *Id.* at Abst., 5:2-8, 5:51-54.

FIG. 3A



As illustrated in Figure 6, below, the fixation assembly 100 may, for example, be inserted into any of the bones of a foot such as, but not limited to, the

metatarsal, cuneiform, calcaneus, cuboid, talus and navicular bones. (Ex. 1001 at 7:1-6).



## **2. Prosecution History**

The '589 patent was filed on June 23, 2009. (Ex. 1001 at front page). The initial application, as filed, included 113 claims. Patentee filed a Preliminary Amendment dated November 17, 2010 cancelling claims 1-113 and adding new claims 114-203. (Ex. 1005 at pp. 107-123). In response to a Restriction Requirement of May 18, 2011 dated June 20, 2011, Patentee elected to pursue claims 114-182. For purposes of this Petition, independent claim 158 and dependent claim 170 added by the Preliminary Amendment recited:

158. A fixation system for compressing bone, comprising:

a proximal screw member comprising a head portion and a first shaft extending along a first longitudinal axis;



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a distal member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis; and

an instrument adapted for coupling said proximal screw member to said distal member;

wherein said second longitudinal axis and said bore axis define an angle,

wherein said proximal screw member is adapted for coupling to said distal member at said angle,

wherein each of said proximal screw member and said distal member is adapted for residing substantially within at least one bone

170. The fixation system of claim 158, wherein said distal member comprises first and second circumferentially spaced recessed adapted for coupling to said instrument.

In a first substantive Office Action dated September 23, 2011 that addressed the patentability of the pending claims, claims 114-125, 128, 132, 134-148, 151, 155, 157-169, 172, 176 and 178-182 were rejected based on being anticipated or obvious over the prior art. In this Office Action, claims 126-127, 129-131, 133, 149-150, 152-154, 156, 170-171, 173-175 and 177 were indicated to contain allowable subject matter if rewritten in independent form including all of the

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limitations of the base claim and any intervening claims. (Ex. 1005 at pp. 63-81).

In this Office Action, independent claim 158, from which dependent claim 170 depended, was rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent Application Publication No. 2009/0240252 to Chang (“Chang”). *Id.* at pp. 70-71. As recognized by the Office Action, Chang disclosed an intramedullary fixation assembly including

a proximal screw member (11) comprising a head portion (112) and a first shaft (Fig 4) extending along a first longitudinal axis; a distal member (10) comprising a second shaft (313) extending along a second longitudinal axis and a bore (101) extending therethrough along a bore axis; where said second longitudinal axis and said bore axis define an angle, wherein said proximal screw member is adapted for coupling to said distal member at said angle, and wherein each of said proximal screw member and said distal screw member is adapted for residing substantially within at least one bone. The proximal member is coupled to the bore by penetration and, as pictured the angle is approximately 90 degrees. Both the proximal and distal members are capable/adapted for residing in bone.

(Ex. 1005 at 70-71; Ex. 1006 at Fig. 1, 3 and 5).

Chang discloses a nail retention member, one or more locking cortical screws and a targeting apparatus to couple the locking screws to the nail retention member for the correction and fixation of femur deformity of a child. (Ex. 1006 at Abst., ¶[0016]-[0019]). Chang did not explicitly discuss use of its invention for compressing bone. However, Patentee did not argue or contest that Chang did not disclose a fixation system for compressing bone.

In response to this Office Action, Patentee amended certain claims into

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independent form to overcome the anticipation and obvious rejections. (Ex. 1005 at pp. 31-62). For purposes of this Petition, Patentee amended dependent claim 170 by rewriting it into independent form to overcome the anticipation rejection of independent claim 158 from which it depended. *Id.* at p. 50. This newly amended independent claim 170 issued as independent claim 59 of the ‘589 Patent, the claim at issue in this Petition.

In this response, Patentee accepted the rejection of independent claim 158 based on Chang and rewrote dependent claim 170 into independent form to overcome this rejection and “in an effort to remove all remaining issues.” (Ex. 1005 at pp. 58-59). Thus, based on the amendment to the claims and lack of arguments in this response, Patentee conceded that the invention recited in claim 59 (or amended independent claim 170) is disclosed in Chang with the exception of the features in dependent claim 170, namely, “first and second circumferentially spaced recesses” in the second member for coupling to the instrument.

### **C. The State of the Art**

As recognized by the inventors in the “Background of the Invention” of the ‘589 patent, “[o]rthopaedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct bones and joints affected by trauma, degeneration, deformity and disease.” (Ex. 1001 at 1:21-25). “Surgical treatments include orthopedic fixation devices that fixate the bones in order to fuse

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them into a stable mass. These orthopedic implant devices realign bone segments and hold them together in compression until healing occurs, resulting in a stable mass.” *Id.* at 1:38-42.

And, as recognized and conceded by the Patentee during the prosecution of the ‘589 Patent, a fixation assembly that includes a first screw member having a head portion and a first shaft extending along a first longitudinal axis, a second member or nail having a second shaft extending along a second longitudinal axis and a bore extending therethrough along a bore axis, where the second longitudinal axis and the bore axis define an angle, where the first screw member is adapted for coupling to the second member or nail at the angle, and where each of the first screw member and the second member or nail reside substantially within at least one bone (e.g. the limitations recited in independent claim 158 during prosecution), was known in the art, is disclosed in Chang, and existed at the time of filing of the ‘589 Patent application.

During prosecution, Patentee never argued or contested that Chang does not disclose a fixation system for compressing bone or that Chang was not analogous art to the ‘589 Patent. Patentee also never argued that Chang did not disclose any of the claim limitations recited in independent claim 158. Instead, Patentee accepted the rejection of independent claim 158 based on Chang and rewrote dependent claim 170 into independent form to overcome this rejection and “in an

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effort to remove all remaining issues.” (Ex. 1005 at pp. 58-59). By conceding to the rejection of independent claim 158 based on Chang during prosecution of the ‘589 Patent, Patentee admitted that the combination of all of those recited features were not novel.

At the time of filing of the ‘589 patent application, there were also numerous other examples, in addition to Chang, of orthopedic implant systems for compressing bone that used a nail, an angled screw coupled to the nail at an angle, and an instrument for coupling the angled screw to the nail, with the nail and angled screw residing entirely within at least one bone. (Ex. 1007 at ¶27). In addition to Chang, some other examples of such fixation systems were disclosed in, for example, Brumfield, Marcus, Chandran, U.S. Patent No. 5,779,705 to Matthews (“Matthews”) and U.S. Patent No. 5,032,125 to Durham (“Durham”). (Ex. 1007 at ¶¶28-30; x. 1008-1009). Therefore, it was well known to one of ordinary skill in the art at the time of filing of the ‘589 patent application that orthopedic implant devices and system, such as those disclosed in, for example, Brumfield, Marcus, Chandran, Matthews, and Durham, included a nail, an angled screw coupled to the nail at an angle, and an instrument for coupling the angled screw to the nail, with the nail and angled screw residing entirely within at least one bone. (Ex. 1007 at ¶¶28-30, 64, 66-182).

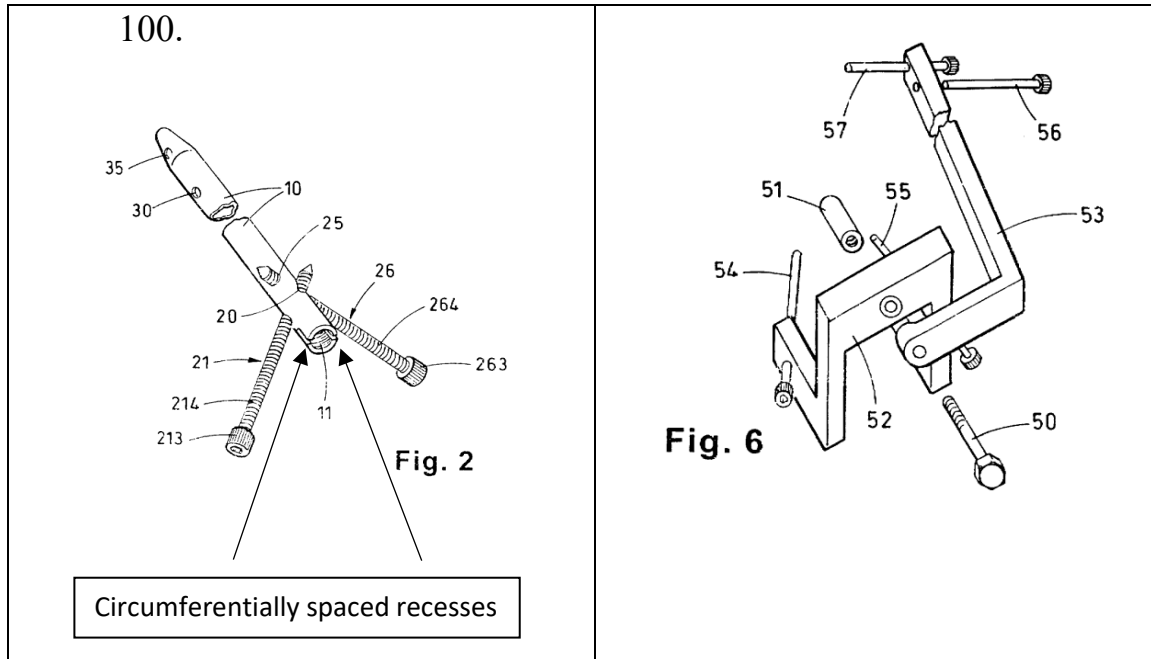
Thus, based on the amendment to the claims and lack of arguments during

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prosecution, Patentee conceded that the invention recited in claim 59 (or amended independent claim 170) was disclosed in Chang, with the exception of the features in dependent claim 170, namely, “first and second circumferentially spaced recesses” in the second member for coupling to the instrument.

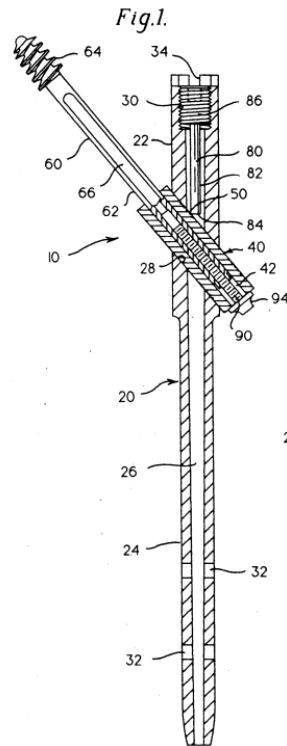
However, this feature was not novel either at the time of filing the ‘589 Patent application. (Ex. 1007 at ¶¶27-31, 98-104, 136-142, 176-181). The use of first and second circumferentially spaced recesses in a second member or nail for coupling to an instrument that is adapted for coupling the first screw member to the second member was also well known at that time. *Id.* For example, Brumfield, Marcus, Chandran, Matthews, and Durham all teach a second member or nail comprising first and second circumferentially spaced recesses adapted for coupling to an instrument. *Id.* Brumfield, Marcus, and Chandran are discussed in more detailed below.

Matthews discloses a fixation system including an intramedullary nail 10, screws 21 and 26 extending through “predrilled holes” in nail 10 at angles, and a jig, as shown below in Figures 2 and 6 of Matthews.



In Matthews, nail 10 includes circumferentially spaced slots at a distal end of nail for secure attachment to the jig. (Ex. 1007 at ¶¶28-29; Ex. 1008 at 3:36-39). The jig is attached to nail 10 in the appropriate position to align the cross screws 21 and 26 with respect to the angled predrilled holes in the nail 10. (Ex. 1007 at ¶29; Ex. 1008 at 2:58-67, 3:1-34).

Durham discloses an intramedullary rod 20 having a lag screw 60 extending through the rod 20 at an angle. (Ex. 1007 at ¶30; Ex. 1009 at Fig. 1, 3:17-23). For convenience, Figure 1 of Durham is reproduced below for convenience.



(Ex. 1009 at Fig. 1). Durham also teaches that “[r]od 20 also includes an internally threaded counter bore 30 with slots 34 at the opening for receiving threaded set screw 80 and the prongs of a tool for aligning rod 20 within the femur.” (Ex. 1007 at ¶30; Ex. 1009 at 3:36-39). Durham further teaches that when the rod 20 is properly oriented, the lag screw 60 is aligned with passage 28 by a suitable known tool. (Ex. 1007 at ¶30; Ex. 1009 at 4:58-59).

Therefore, it was well known to one of ordinary skill in the art at the time of filing of the ‘589 patent application that orthopedic implant devices and system, such as, for example, those disclosed in Brumfield, Marcus, Chandran, Matthews, and Durham, included a second member or nail comprising first and second



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circumferentially spaced recesses adapted for coupling to an instrument.

Therefore, this feature is not novel either.

## **D. Identification of Challenge Pursuant to 37 C.F.R. §42.104(b)**

Pursuant to 37 C.F.R. §§ 42.104(b) and (b)(1), Petitioner requests *inter partes* review of claim 59 of the '589 patent and respectfully requests that the Patent Trial and Appeal Board cancel that claim.

### **1. Challenged Claim**

Pursuant to 37 C.F.R. §42.104(b)(1), *inter partes* review is requested for claim 59 of the '589 patent.

### **2. Statutory Grounds for Challenges**

Pursuant to 37 C.F.R. §42.104(b)(2), *inter partes* review is requested in view of the following prior art references:

- U.S. Patent No. 4,827,917 to Brumfield (“Brumfield”). Brumfield was filed on December 30, 1986 and issued on May 9, 1989, and is prior art to the '589 patent under at least 35 U.S.C. §102(b), pre-AIA. Brumfield was not considered during the original prosecution of the '589 patent, nor is it cumulative of any prior art considered by the Patent Office.
- U.S. Patent No. 4,622,959 to Marcus (“Marcus”). Marcus was filed on March 5, 1985 and issued on November 18, 1986, and is prior art

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to the '589 patent under at least 35 U.S.C. §102(b), pre-AIA. Marcus was not considered during the original prosecution of the '589 patent, nor is it cumulative of any prior art considered by the Patent Office.

- U.S. Patent No. 6,579,293 to Chandran (“Chandran”). Chandran was filed on August 2, 2000 and issued on June 17, 2003, and is prior art to the '589 patent under at least 35 U.S.C. §102(b), pre-AIA.

Chandran was not considered during the original prosecution of the '589 patent, nor is it cumulative of any prior art considered by the Patent Office.

The specific statutory grounds on which the challenge to the claim is based on the prior art relied upon for each ground are as follows:

- Claim 59 is anticipated under 35 U.S.C. §102(b), pre-AIA, based on Brumfield;
- Claim 59 is anticipated under 35 U.S.C. §102(b), pre-AIA, based on Marcus; and
- Claim 59 is anticipated under 35 U.S.C. §102(b), pre-AIA, based on Chandran.

### **3. Claim Construction**

This Petition presents claim analysis in a manner that is consistent with 37 C.F.R. § 42.100(b). Specifically, the terms appearing in the patent claims were

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interpreted using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. §282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art in light of the specification and the prosecution history pertaining to the patent. Claim terms are given their ordinary and accustomed meaning as would be understood by one of ordinary skill in the art, unless, the inventors, as lexicographers, has set forth a special meaning for a term.

Claim 59 of the '589 patent recites:

59. A fixation system for compressing bone, comprising:

a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis;

a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis; and an instrument adapted for coupling said first screw member to said second member;

wherein said second longitudinal axis and said bore axis define an angle, wherein said first screw member is adapted for coupling to said second member at said angle,

wherein each of said first screw member and said second member is

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adapted for residing substantially within at least one bone, and  
wherein said second member comprises first and second  
circumferentially spaced recesses adapted for coupling to said instrument.

In the '589 Patent, the inventors did not act as lexicographers and did not provide a special meaning for any of the claim terms recited in claim 59.

Accordingly, using the above-referenced standard, the claim terms should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art.

**i. The Preamble Phrase “For Compressing Bone” Is Not Limiting**

The preamble of Claim 59 recites “[a] fixation assembly for compressing bone.” The portion of the preamble reciting “for compressing bone” is not limiting to the claim. The phrase “for compressing bone” merely identifies an intended use for the fixation assembly.

Generally, the preamble does not limit the claims. *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir. 2002). A preamble may be limiting if: (1) “it recites essential structure or steps”; (2) claims “depend[] on a particular disputed preamble phase for antecedent basis”; (3) the preamble “is essential to understand limitations or terms in the claim body”; (4) the preamble “recit[es] additional structure or steps underscored as important by the

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specification” or there was “clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.” *Id.* However, “preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant.” *Id.* at 809.

The phrase “for compressing bone” does not recite an essential structure or step of claim 59. The body of claim 59 describes a structurally complete invention. The Federal Circuit has long held that “a preamble is not limiting where a Patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use of the invention.” *Arctic Cat Inc. v. GEP Power Products, Inc.*, 919 F.3d 1320, 1329-30 (Fed.Cir. 2019) (preamble term of generic non-inventive structure, with body defining inventive structure). The preamble language “for compressing bone” does not identify any structure for the fixation assembly claimed. The body of claim 59 contains the only descriptions of the structure for the fixation assembly, with no additional structure furnished by the preamble phrase “for compressing bone.” In fact, deletion of this phrase from the preamble would not affect the structural definition or operation of the invention itself. *Catalina*, 289 F.3d at 810; *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015) (preamble considered intended use)..

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The phrase “for compressing bone” also is not necessary to provide antecedent basis for the body of the claims. Although the body of claim 59 does recite “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone,” this limitation is separate from, and does not refer back to, the phrase “for compressing bone” in the preamble. Therefore, this phrase in the preamble does not provide the antecedent basis for any structure within the body of claim 59.

The preamble language “for compressing bone” is also not essential to understand limitations or terms in the body of Claim 59. Each of the limitations recited in the body of Claim 59 are understandable and stand on their own separate from the phrase “for compressing bone.”

Finally, the Patentee of the ‘589 Patent did not rely on this language in the specification or during prosecution to overcome any cited prior art. Nothing in the specification or prosecution history states, or even suggests, that the Patentee of the ‘589 Patent intended to exclude use of technology that was structurally identical to its claimed fixation assembly in Claim 59 but that was installed or used in a manner that would not compress bone. *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1236 (Fed. Cir. 2017). In fact, the Patentee of the ‘589 Patent never attempted to distinguish Chang (e.g. directed to a femur) during prosecution of the ‘589 Patent in response to the rejection of independent claim 158 on the

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basis of a limitation “for compressing bone” in the preamble. Chang discloses use of a nail retention member, one or more locking cortical screws and a targeting apparatus to couple the locking screws to the nail retention member for the correction and fixation of femur deformity of a child. (Ex. 1007 at ¶27; Ex. 1006 at [0016]-[0019]). The words “compress” and “compression” do not appear anywhere in Chang. However, to overcome the rejection of independent claim 158 based on Chang, the Patentee of the ‘589 Patent rewrote dependent claim 170 in independent form to incorporate the limitations of independent claim 158. (See Section IV.B.2 above). Therefore, the Patentee of the ‘589 Patent either conceded that the intended use “for compressing bone” was (as part of the claim preamble) not patentably significantly feature or an essential or limiting feature of the invention recited therein, or that the invention disclosed in Chang could be used for compressing bone despite not mentioning the word compression and being directed to a femur deformity.

In contrast, the preamble language “for compressing bone” merely states a purpose or intended use for the recited invention. The preamble’s recitation of “for compressing bone” is merely a statement of intended use of the fixation assembly, and not an essential structure or feature of the invention. *Cochlear Bone Anchored Solutions AB v. Oticon Medical AB*, 958 F.3d 1348, 1354–55 (Fed.Cir. 2020) (preamble statement “for rehabilitation of unilateral hearing loss considered

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intended use); *Georgetown*, 867 F.3d at 1236 (preamble phrase referring to intended use).

Therefore, the phrase “for compressing bone” states only an intended use, adds no structural element to the fixation assembly, and provides no antecedent basis for the bone of the claims. Accordingly, the phrase “for compressing bone” in the preamble is not limiting to Claim 59.

### ii. Claim Construction of Certain Terms

In accordance with the above standard for claim construction, Petitioner submits, solely for purposes of this *inter partes* review proceeding, that the following claim terms of Claim 59 warrant construction based on their ordinary and customary meaning to a person of ordinary skill in the art and in light of the specification and prosecution history. For the purposes of this petition, Nextremity adopts and applies the construction of the following terms:

- “screw member”: A “screw member” is “a threaded device used in bone surgery for fixation of parts (as fragments of fractured bones).” (Ex. 1007 at ¶¶44-46)
- “bore”: A “bore” is “a hole made by or as if by boring.” This may include an aperture. (Ex. 1007 at ¶¶34-43).
- “recesses”: A “recess” is “an indentation, cleft, and this includes a groove.” (Ex. 1007 at 47-52).



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- “coupling”: “Coupling” is “the act of bringing or coming together: pairing.” (Ex. 1007 at ¶¶53-60). Any interpretation of the term “coupling” to require permanent fixation would be improper because, for example, the ‘589 Patent discusses the recited structures being “slidably coupled” and the fact that, for example, the recited instrument must be removed from the second member after the surgery is completed. (Ex. 1007 at ¶58).

### **iii. The Remaining Claim Terms Should Be Construed Based on Their Ordinary Meaning**

All claimed terms not specifically addressed below have been construed in accordance with their ordinary and customary meaning as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. (ex. 1007 at ¶33). For example, claim 59 does not specifically identify any specific bones in which the first screw member and the second member substantially reside. Therefore, the term “bone” should be interpreted to be any bone in the body, not specifically limited to the foot as the embodiments described in the ‘589 patent are directed. In fact, Patentee conceded that the invention in claim 59 of the ‘589 Patent could be used in a femur since it did not distinguish over Chang, which was directed to use of a fixation assembly in a femur, during prosecution. (See Section IV.B.2 above; Ex. 1006 at Abst.).

Petitioner reserves the right to advocate a different claim interpretation in

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district court or any other forum in accordance with the claim construction standard applied in such forum.

## **4. Supporting Evidence**

Pursuant to 37 C.F.R. § 42.204(b)(5), the appendix numbers of the supporting evidence relied upon to support the challenges and the relevance of the evidence to the challenges raised, including identifying the specific portions of the evidence that support the challenges are provided below. This Petition is supported by the Declaration of Mike Sherman of MB Innovations, Inc. (attached as Exhibit 1007) (“Sherman Declaration”). Mr. Sherman offers his opinion with respect to the content of the ‘589 Patent, the state of the prior art, claim construction, and the factual comparison between the claim limitations of claim 59 of the ‘589 Patent and the prior art references discussed herein.

## **5. Identification of How Claim 59 is Unpatentable and Supporting Evidence Relied upon to Support the Challenge**

Claim 59 is anticipated under 35 U.S.C. § 102(b), pre-AIA, based on Brumfield and, separately, based on Marcus and, separately, based on Chandran. Brumfield, Marcus, and Chandran, separately addressed below, each disclose and teach each and every limitation recited in claim 59 of the ‘589 patent to anticipate the claimed subject matter. For the reasons set forth below and the supporting evidence, Petitioner is reasonably likely to prevail in challenging claim 59 of the

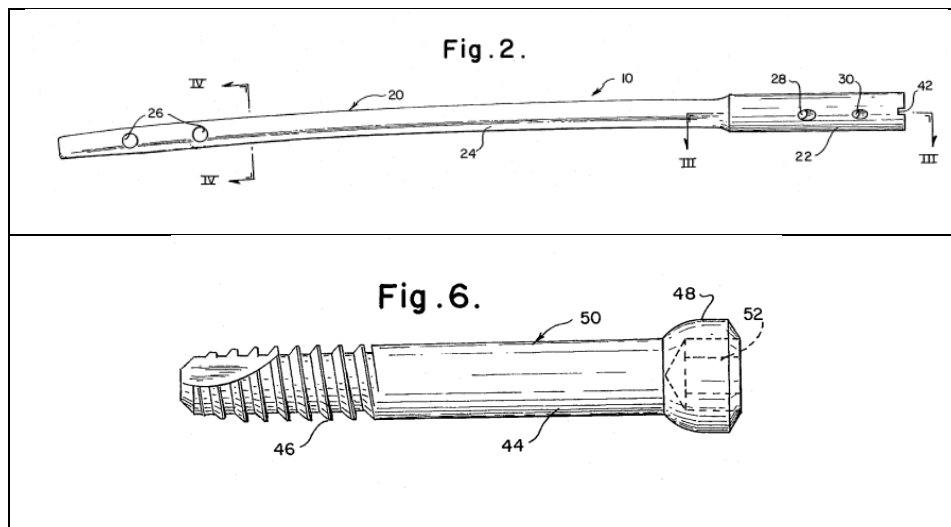
‘589 patent based on anticipation by Brumfield, Marcus, and/or Chandran.

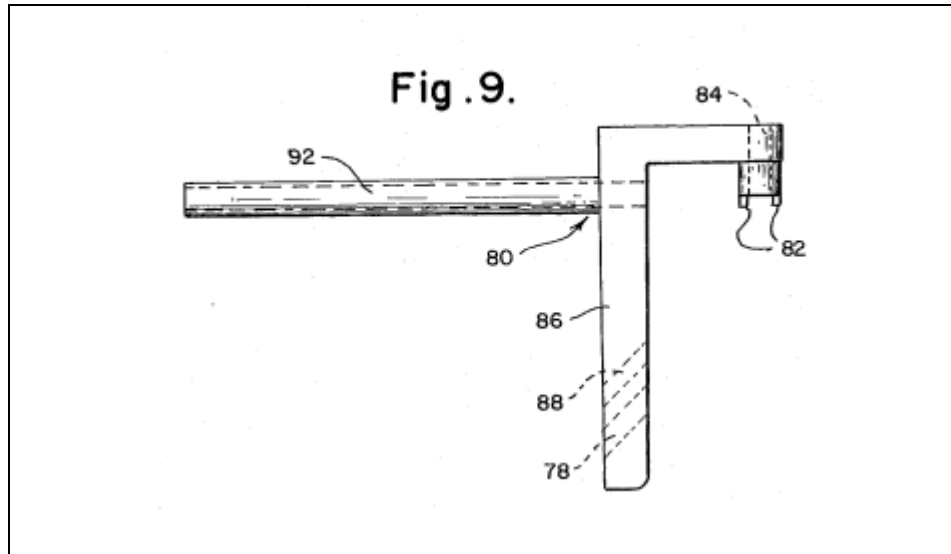
**i. Claim 59 Is Anticipated by Brumfield**

Petitioner is reasonably likely to prevail in challenging claim 59 of the ‘589 patent based on anticipation by Brumfield. Pursuant to 35 U.S.C. § 102(b), pre-AIA, Brumfield discloses each and every limitation of claim 59, as set forth in, for example, the Sherman Declaration, including the claim charts provided therewith, and the following arguments.

*Preamble: “A fixation system for compressing bone, comprising”.*

Brumfield discloses a fixation system for compressing bone. (Ex. 1007 at ¶¶67-70; Ex. 1002 at Figs. 2, 6 and 9). For convenience, Figures 2, 6 and 9 of Brumfield illustrating the fixation assembly are provided below.





(Ex. 1002 at Figs. 2, 6 and 9).

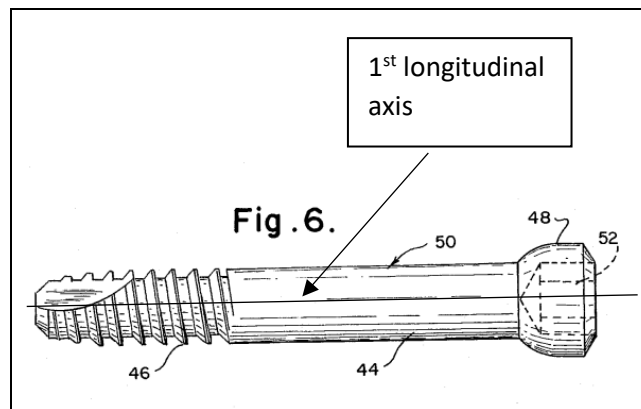
As set forth *supra*, the preamble of claim 59 recites an intended use only and thus is not a limitation of the claim. (see Section IV.D.3). Nevertheless, to the extent that the portion of the preamble “for compressing bone” of claim 59 is limiting, Brumfield teaches a fixation system for compressing bone. Brumfield teaches that “[t]he surface of rod 20 which defines the holes 28 and 30 is smooth to permit sliding contact with lag screw 50 and optional additional anchoring means 90 for sliding compression of a femoral neck or intertrochanteric fracture.” (Ex. 1007 at ¶69; Ex. 1002 at 4:43-48). Brumfield also teaches the preparation of the hole formed in the femoral head and neck for allowing “lag screwing the femoral head and thus sliding compression of a femoral neck fracture.” (Ex. 1007 at ¶69; Ex. 1002 at 6:47-49). Finally, Brumfield teaches that “[i]f there is a femoral neck fracture the compression of lag screw 50 functions like a compression screw

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assembly to reduce the fracture.” (Ex. 1007 at ¶¶69; Ex. 1002 at 6:57-59).

Therefore, Brumfield teaches a “fixation system for compressing bone”, as recited in claim 59

*Element 1: “a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis”.* Brumfield discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶71-74). The first screw member recited in this claim element is lag screw 50 shown in Figure 6. (Ex. 1007 at ¶72; Ex. 1002 at Fig. 6; 5:20-22). For convenience, annotated Figure 6 of Brumfield showing a first screw member 50 having a head 48, a shaft 44, 46 and a longitudinal axis (noted below) is provided below.

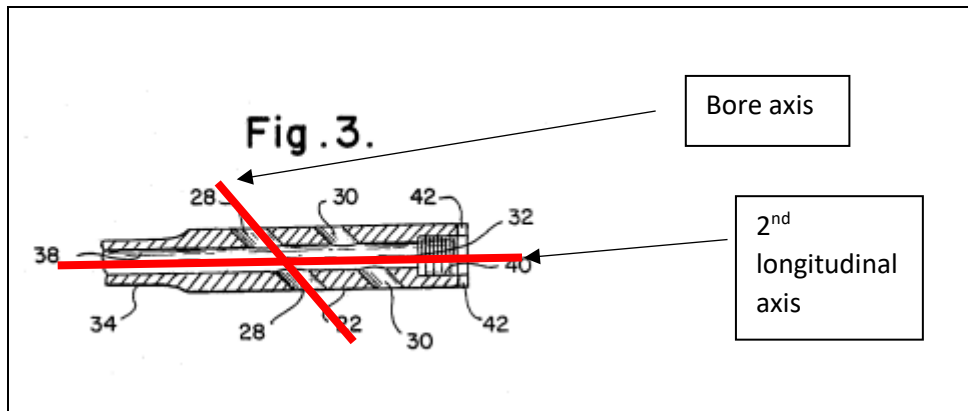


(Ex. 1002 at Fig. 6, annotated).

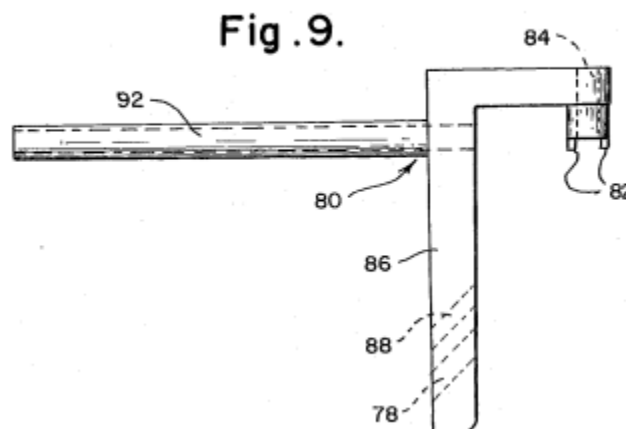
*Element 2: “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a*



bore extending through said second shaft along a bore axis is provided below.



*Element 3: “an instrument adapted for coupling said first screw member to said second member”.* Brumfield discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶81-85). The instrument recited in this claim element is the tool 80 shown in Figure 9 of Brumfield. (Ex. 1007 at ¶82; Ex. 1002 at Fig. 9; 5:43-55). For convenience, Figure 9 of Brumfield showing tool 80 adapted for coupling lag screw 50 to rod 20 is provided below.

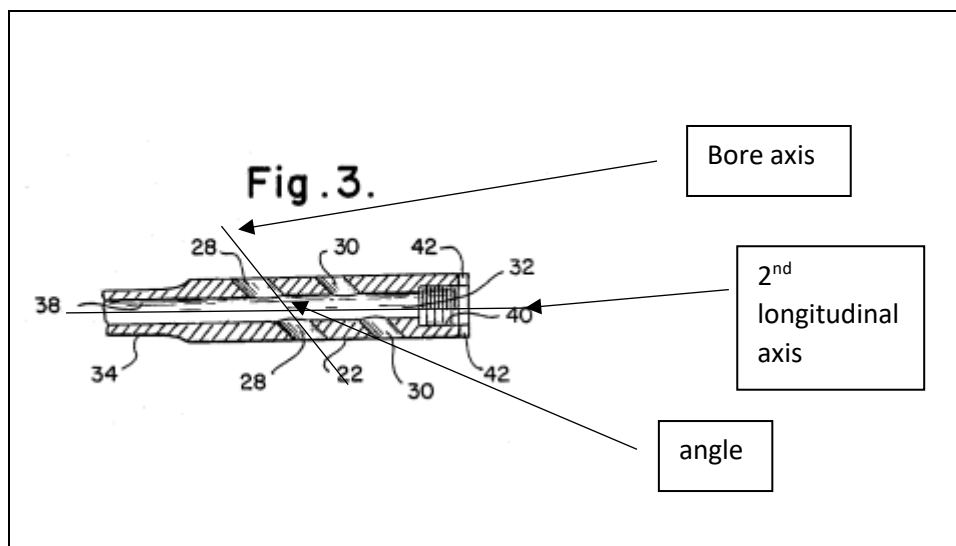


(Ex. 1002 at Fig. 6). Brumfield teaches that “[l]ag screw 50 and the optional

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additional anchoring means can be inserted through the appropriate holes in rod 20 by means of tool 80.” (Ex. 1007 at ¶84; Ex. 1002 at 5:50-55). Thus, tool 80 brings together or pairs lag screw 50 and rod 20. (Ex. 1007 at ¶84). Therefore, Brumfield discloses an instrument adapted for coupling said first screw member to said second member, as required by this claim element.

*Element 4: “wherein said second longitudinal axis and said bore axis define an angle”.* Brumfield discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶86-89; Ex. 1002 at Fig. 3, 4:36-39). This angle can clearly be seen in annotated Figure 3 of Brumfield provided below for convenience.



(Ex. 1002 at Fig. 3, annotated). Brumfield teaches that “[t]he holes of a pair [including holes 28, 30] are coaxially arranged on a common axis extending through bore 32 in an angled direction relative to the longitudinal axis of rod 20.”

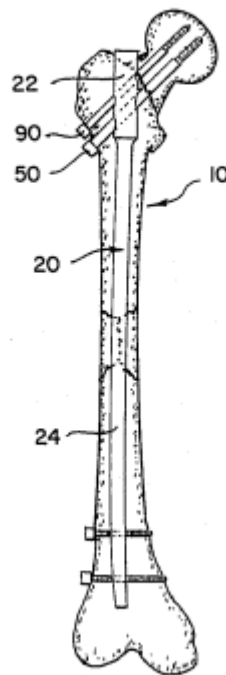


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(Ex. 1007 at ¶88; Ex. 1002 at 4:36-39. Therefore, Brumfield discloses that the second longitudinal axis and the bore axis define an angle, as required by this claim element.

*Element 5: “wherein said first screw member is adapted for coupling to said second member at said angle”*. Brumfield discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶90-93; Ex. 1002 at Fig. 1, 5:50-55). For convenience, Figure 1 of Brumfield shows lag screw 50 being adapted for coupling to rod 20 at the angle defined by the bore axis through rod 20 is provided below.

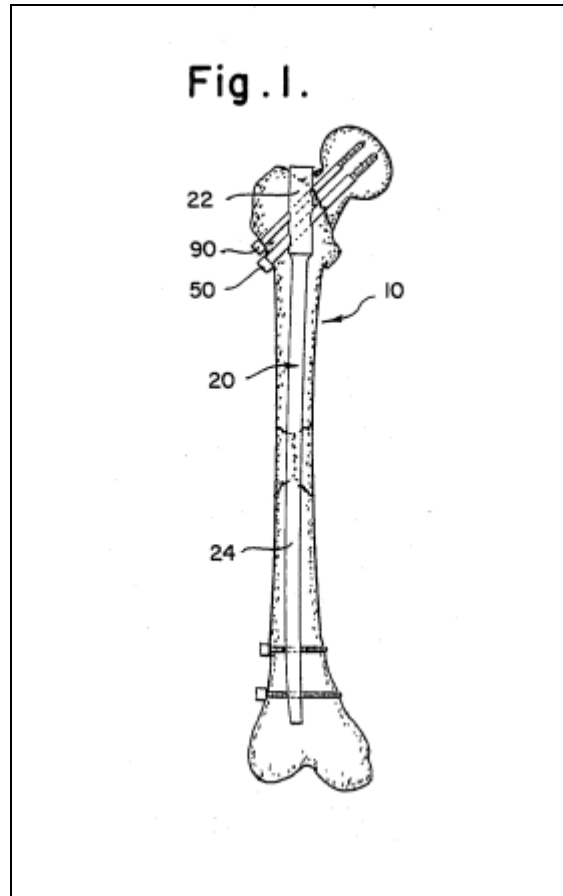
**Fig. 1.**



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(Ex. 1002 at Fig. 2). Brumfield teaches “[l]ag screw 50 and the optional additional anchoring means can be inserted through the appropriate holes in rod 20 by means of tool 80.” (Ex. 1007 at ¶92; Ex. 1002 at 5:50-55). Therefore, Brumfield discloses the first screw member is adapted for coupling to the second member at said angle, as required by this claim element.

*Element 6: “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone”.* Brumfield discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶94-97; at Ex. 1002 at Figs. 1, 3, 5, 4:31-33; 6:28-29, 41-47). For convenience, Figure 1 of Brumfield showing rod 20 and lag screw 50 residing substantially within the femur once installed is provided below.



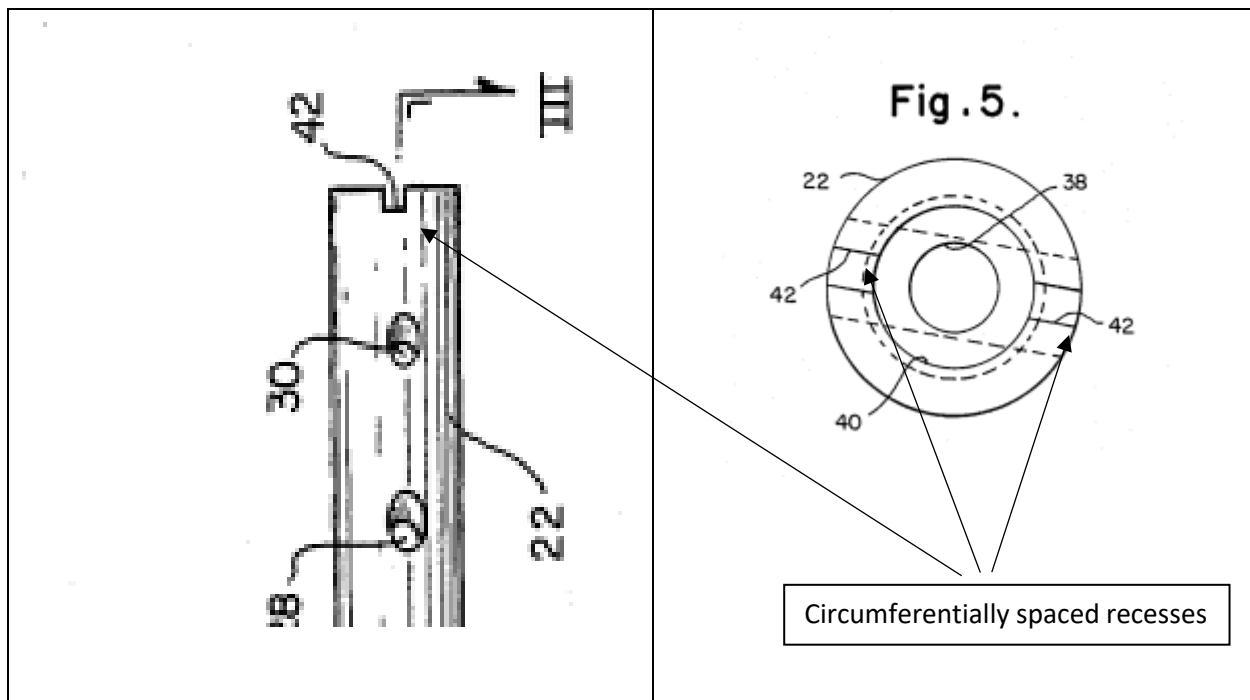
(Ex. 1002 at Fig. 1). Brumfield teaches rod 20 and lag screw 50 being positioned in the femur, including the femoral neck. Ex. 1007 at ¶¶95-96; Ex. 1002 at 4:31-33; 6:28-29, 41-47). Therefore, Brumfield discloses that each of said first screw and said second member is adapted for residing substantially within at least one bone, as required by this claim element.

*Element 7: “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument”.*

Brumfield discloses the second member comprising first and second

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circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶98-104). The first and second circumferentially spaced recesses recited in this claim element are the slots 42 shown in Figures 2 and 5 of Brumfield. (Ex. 1007 at ¶¶99-102; Ex. 1002 at Figs. 2 and 5, 5:51-54). For convenience, annotated Figures 2 and 5 of Brumfield showing slots for secure attachment of rod 20 to the tool 80 is provided below.



(Ex. 1002 at Fig. 2, annotated). Brumfield discloses that slots 42 of rod 20 are adapted for coupling to the tool 80 shown in Figure 9. (Ex.1007 at ¶103). For example, Brumfield teaches that “[t]he tool 80 includes prongs 82 to engage slots 42 of head 22 to align bore 84 with bore 32 for insertion of a (temporary) cannulated locking bolt therethrough to secure to tool 80 to rod 20 for driving and

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for precise alignment of drilling instruments and lag screws. By placing prongs 82 in slots 42, bores 88 and 78 of arm 86 of tool 80 align with the proximal and distal pairs of holes 30 and 28, respectively of head 22. Lag screw 50 and the optional additional anchoring means can be inserted through the appropriate holes in rod 20 by means of tool 80.” (Ex. 1007 at ¶103; Ex. 1002 at 5:45-55). Therefore, Brumfield discloses the second member comprises first and second circumferentially spaced recesses adapted for coupling to the instrument, as required by this claim element.

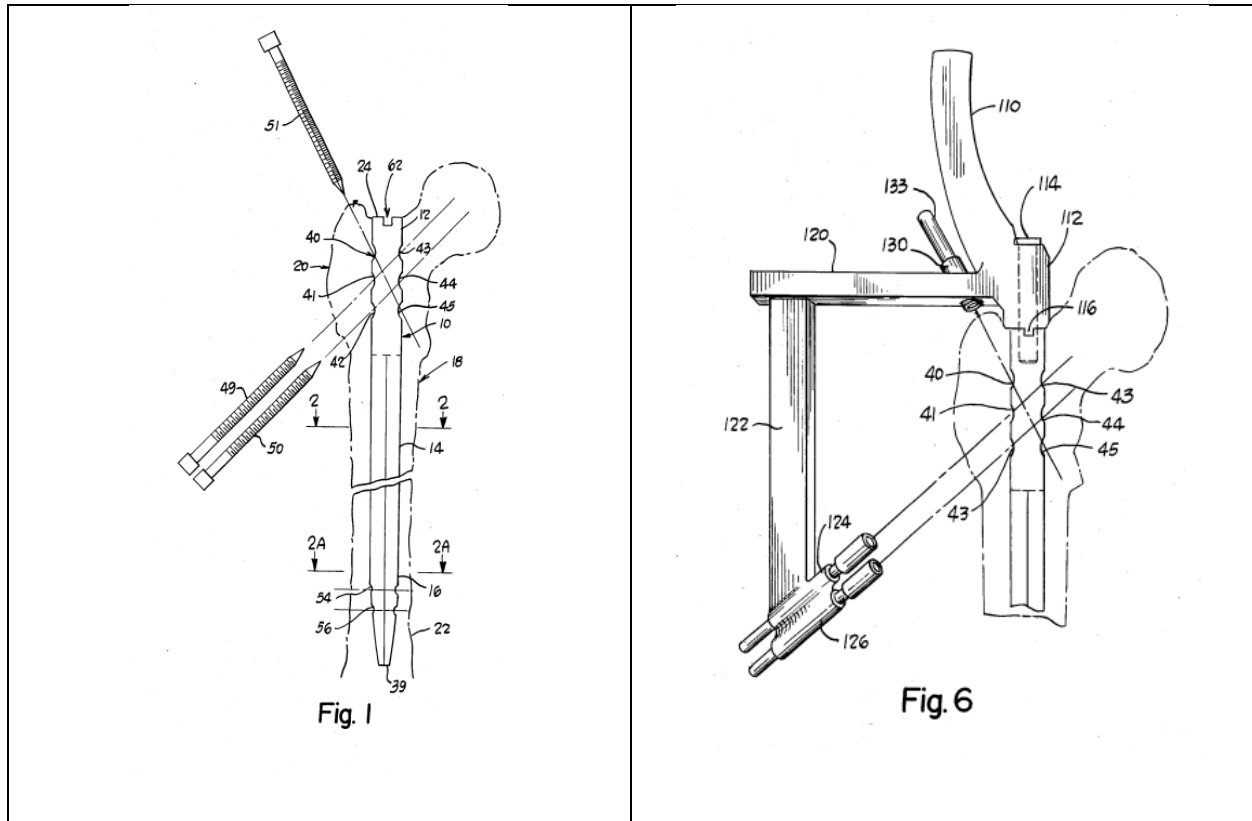
Accordingly, each and every limitation of claim 59 is disclosed in Brumfield.

### ii. **Claim 59 Is Anticipated by Marcus**

Petitioner is reasonably likely to prevail in challenging claim 59 of the ‘589 patent based on anticipation by Marcus. Pursuant to 35 U.S.C. § 102(b), pre-AIA, Marcus discloses each and every limitation of claim 59, as set forth in, for example, the Sherman Declaration, including the claim charts provided therewith, and the following arguments.

*Preamble: “A fixation system for compressing bone, comprising”.* Marcus discloses a fixation system for compressing bone. (Ex. 1007 at ¶¶107-109). For convenience, Figures 1 and 6 of Marcus showing the disclosed fixation system including a first screw member 51, a second member 10 and an instrument 120 are

provided below.



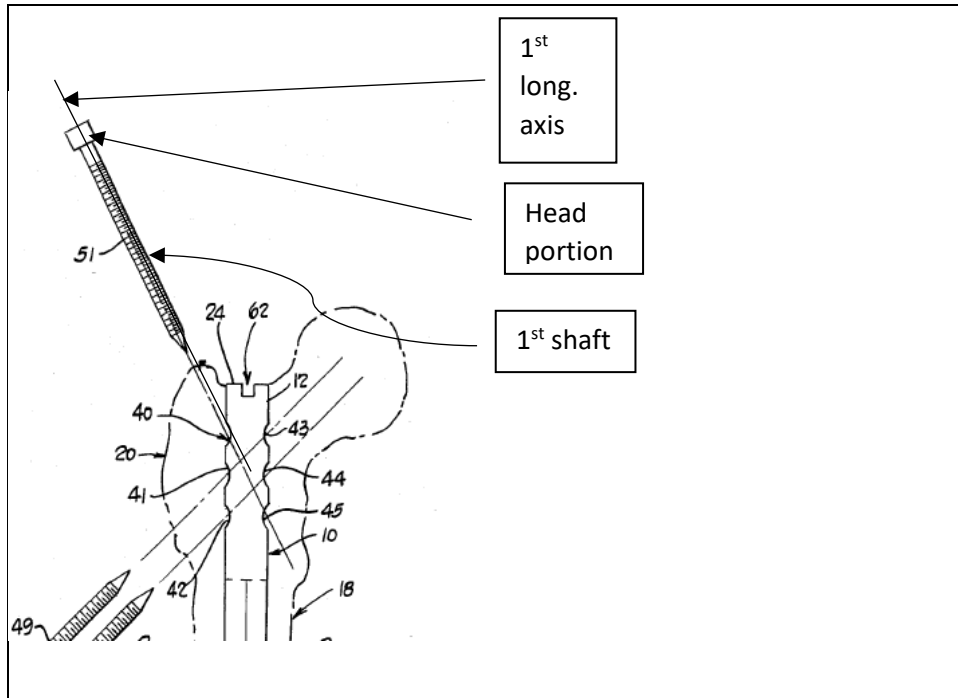
(Ex. 1003 at Fig. 1 and 6).

As set forth *supra*, the preamble of claim 59 recites an intended use only and thus is not a limitation of the claim. (see Section IV.D.3). Nevertheless, to the extent that the portion of the preamble “for compressing bone” of claim 59 is limiting, Marcus discloses the use of an intramedullary nail with angled screws and a jig for use in fractures of the left or right femur. (Ex. 1007 at ¶107; Ex. 1003 at 1:5-9, 2:50-51; 4:59-68, 6:1-7:21). As conceded by the Patentee during the prosecution of the ‘589 Patent, this type of fixation assembly can be used for compressing bone based on the failure to distinguish over Chang during the

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prosecution of the '589 Patent. See Section IV(D)(3)(i) above. Also, use of threaded screws to secure bone to bone, by their nature, cause the closing together of bone pieces and thus compression of bone. (Ex. 1007 at ¶108).

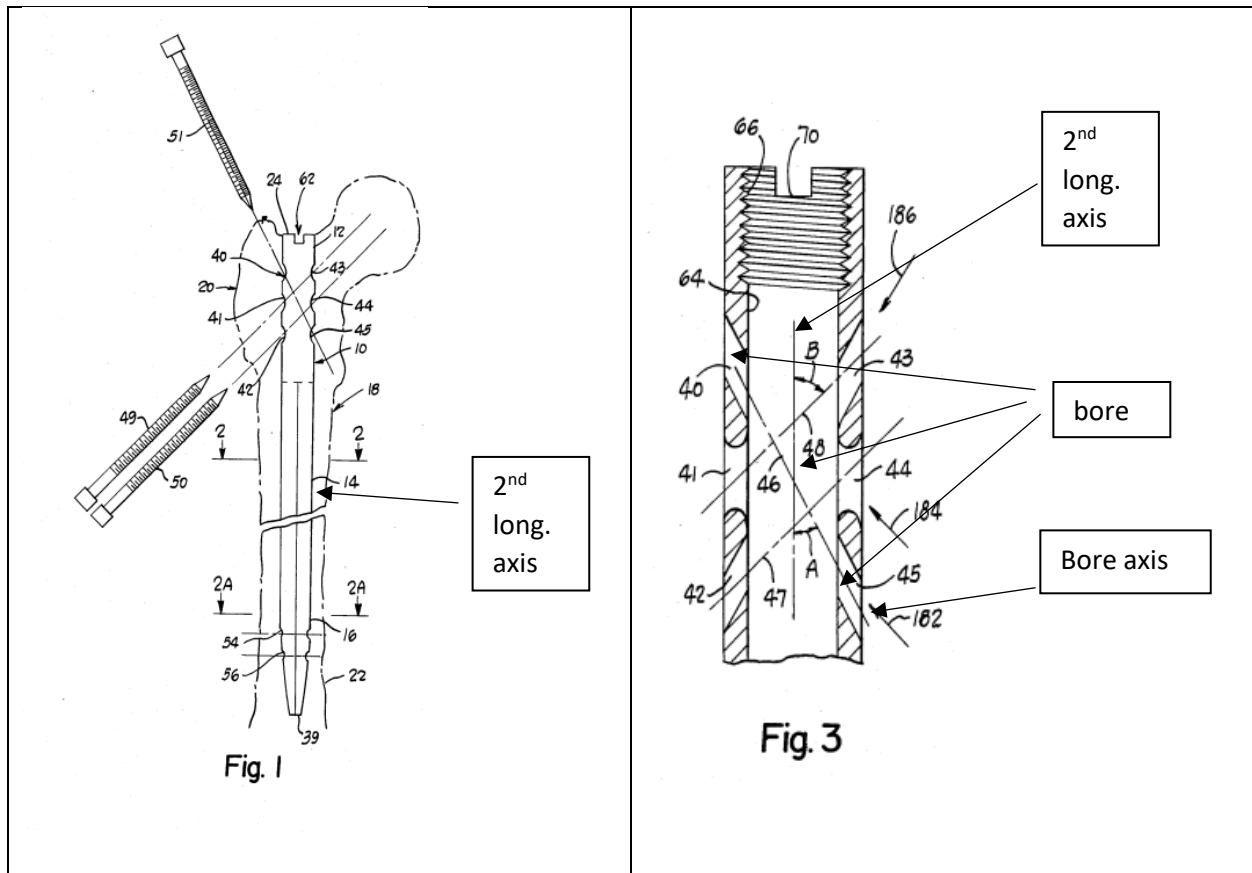
*Element 1: “a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis”.* Marcus discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶110-112; Ex. 1003 at Fig. 1, 5:48-51). The first screw member recited in this claim element is screw 51. (Ex. 1007 at ¶111). For convenience, an annotated portion of Figure 1 of Marcus showing a first screw member 51 including a head portion (as noted below) and a first shaft (as noted below) extending along a first longitudinal axis (as noted below) is provided below. (Ex. 1003 at Fig. 1, annotated).



*Element 2: “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis”.* Marcus discloses a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through the second shaft along a bore axis. (Ex. 1007 at ¶¶113-118). In Marcus, nail 10 is the second member, the “bore” is the hole which is bored or reamed (and thus is made by or as if by boring) that forms openings 40 and 45 during creation of the nail 10, and the “bore axis” is line 46. (Ex. 1007 at ¶¶114-115; Ex. 1003 at Figs. 1 and 3, 4:36-39; 5:51-53, 8:6-9). For convenience, annotated Figures 1 and 3 of Marcus showing a second member 10 including a second shaft (12, 14, 16) extending along a second longitudinal axis (as noted below) and a bore (as noted below) extending



through the second shaft along a bore axis (line 46) are provided below.



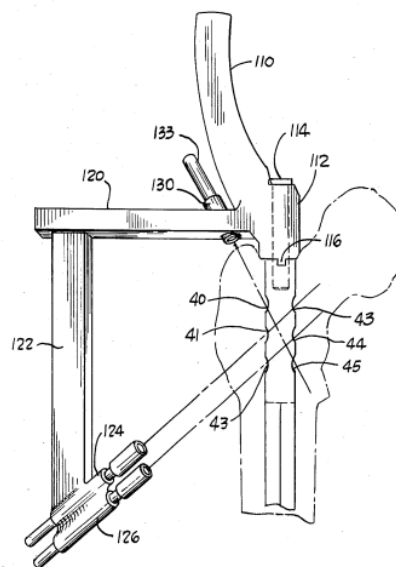
(Ex. 1003 at Figs. 1 and 3, annotated). Marcus specifically teaches that the pair of openings 40, 45 are “bored (or reamed) along an axis 46 at an angle A which is about 30°” when the nail is made. (Ex. 1007 at ¶114; Ex. 1003 at 8:6-9).

Therefore, the path along line 46 in which screw 51 takes through opening 40 extending through the shaft of nail 10 through opening 45 is a “bore”, as this term is properly construed. (Ex. 1007 at ¶¶116-117). Marcus teaches that openings 40, 45 are “bored (or reamed)”, which is consistent with the definition of the term “bore” as “a hole made by or as if by boring.” *Id.*

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Marcus also teaches that this “bore” is made “along an axis 46”, which would be considered the “bore axis” recited in this claim limitation. (Ex. 1007 at ¶117; Ex. 1003 at 8:6-11). Therefore, Marcus discloses a “bore” extending through the shaft of nail 10 along “bore axis” or line 46 extending from opening 40 to opening 45, as required by this claim limitation.

*Element 3: “an instrument adapted for coupling said first screw member to said second member”.* Marcus discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶119-123). The instrument recited in this claim element is the screw guide and drilling jig shown in Figure 6. (Ex. 1007 at ¶120; Ex. 1003 at Fig. 6, 7:10-14). For convenience, Figure 6 of Marcus showing a screw guide and drilling jig coupled to nail 10 is provided below

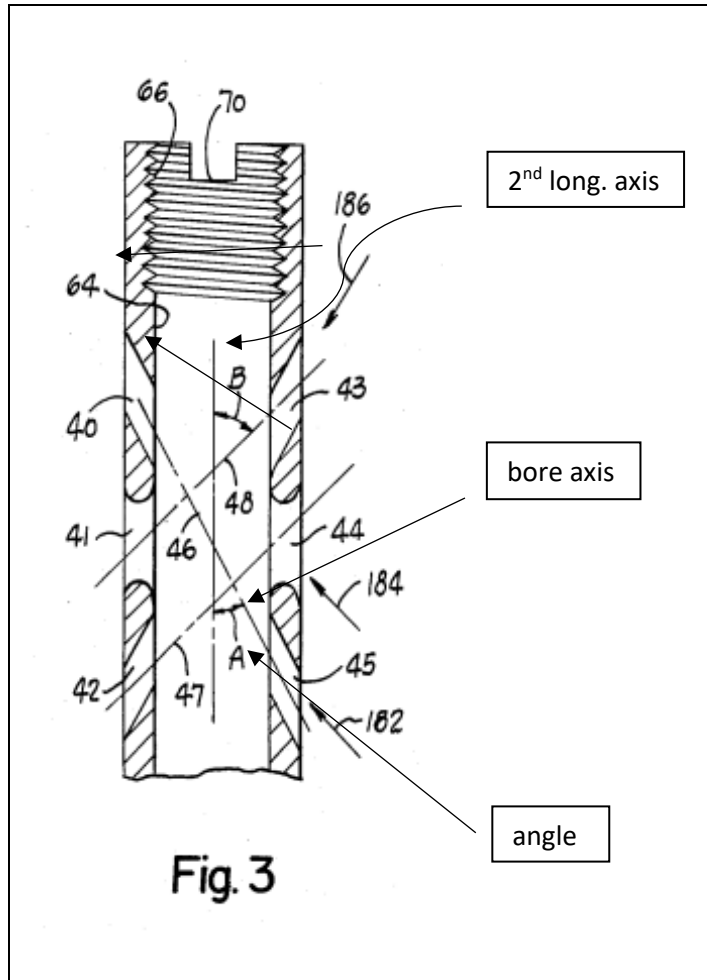


**Fig. 6**

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(Ex. 1003 at Fig. 6). Marcus discloses that the screw guide and drilling jig is adapted for coupling screw 51 to nail 10. Marcus discloses that the screw guide and drilling jig shown in Figure 6 includes guide sleeve 130 “which is in precise alignment with the centers of openings 40, 45 in the inserted nail, when the jig is secured to the nail. An extension bushing 133 slidable through sleeve 130 can also be provided for more accurate guiding of either a drill for forming the opening of the femur, or for guiding the screw during insertion.” (Ex. 1007 at ¶121; Ex. 1003 at Fig. 6, 7:15-21) (emphasis added). Therefore, Marcus discloses the jig illustrated in Figure 6 adapted for coupling screw member 51 to the nail 10, as required by this claim element.

*Element 4: “wherein said second longitudinal axis and said bore axis define an angle”.* Marcus discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶124-127; Ex. 1003 at Fig.3, 5:41-43, 8:6-9, 26-29). For convenience, annotated Figure 3 of Marcus showing the second longitudinal axis (as noted below) and the bore axis (46) defining an angle is provided below.



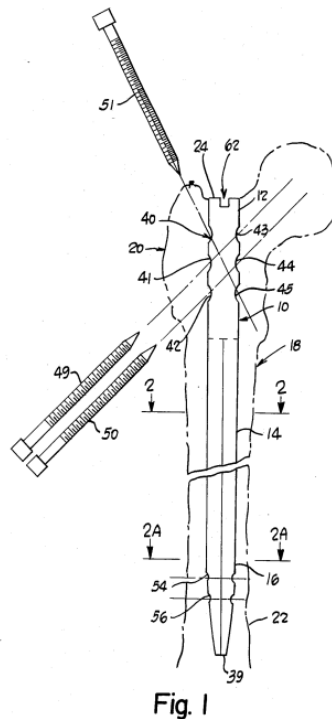
Marcus teaches that the second longitudinal axis defined by nail 10 and the bore axis or line 46 define an angle. (Ex. 1007 at ¶125; Ex. 1003 at 6-11). Figure 3 of Marcus showing the second longitudinal axis of the second member 10 and the bore axis 46 defining an angle A is provided above with annotations. (Ex. 1007 at ¶125; Ex. 1003 at Fig. 3, 8:6-9, 26-29). Marcus also teaches that bore axis or line 46 extending through the centers of openings 40, 45 makes an angle A of about 30° with the axis of the nail (e.g. longitudinal axis of second member). (Ex. 1007 at ¶126; Ex. 1003 at 8:6-9). The same angle can also be clearly seen in FIG.

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1 of Marcus as well. (see p. 40).

Therefore, Marcus disclosed the second longitudinal axis and said bore axis defining an angle, as required by this claim element.

*Element 5: “wherein said first screw member is adapted for coupling to said second member at said angle”.* Marcus discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶128-131; Ex. 1003 at Figs. 1 and 3, 5:51-54, 8:6-9). For convenience, Figure 1 of Marcus shows screw 51 being adapted for coupling to nail 10 at the angle defined by bore axis 46 through nail 10 is provided below.

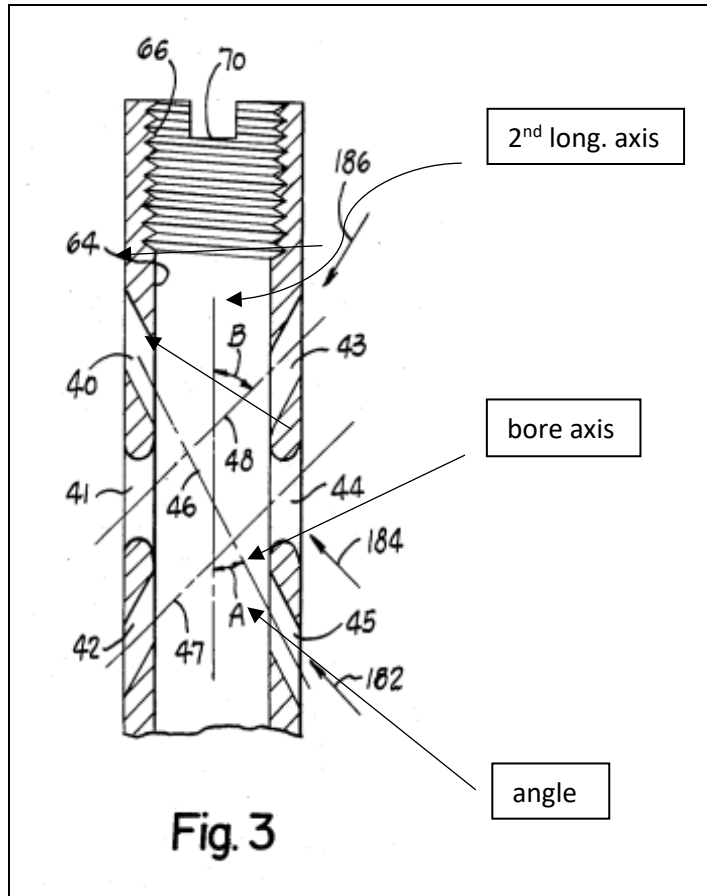


(Ex. 1003 at Fig. 1). Marcus teaches that the screw 51 is adapted for coupling to

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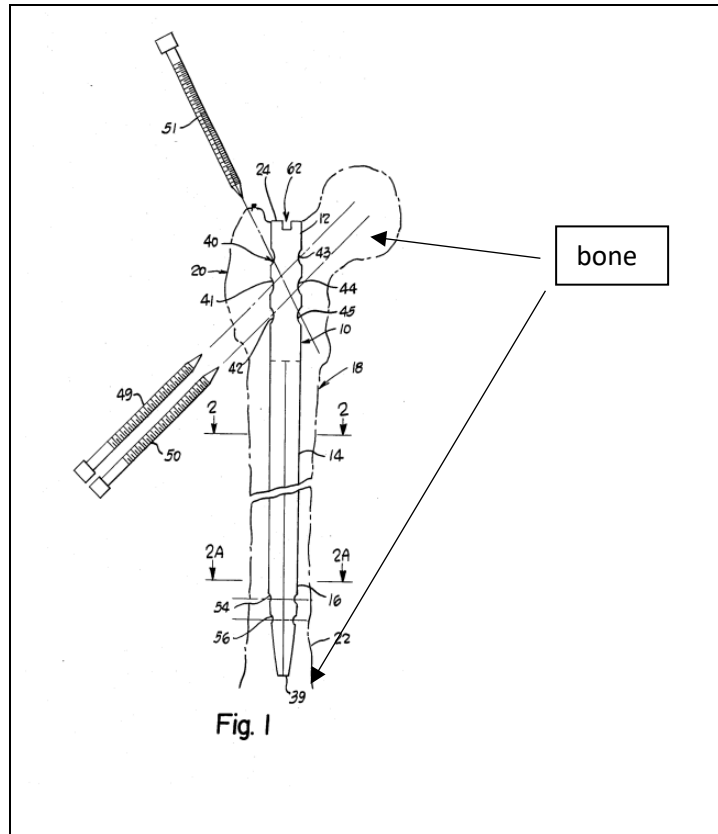
nail 10 at the angle defined by second longitudinal axis defined by nail 10 and the bore axis or line 46. (Ex. 1007 at ¶129; Ex. 1003 at 8:6-9). For example, Figure 1 of Marcus, provided above, shows screw 51 being adapted for coupling to nail 10 at the angle defined by bore axis 46 extending through nail 10 and the vertical or main axis of nail 10. (Ex. 1007 at ¶129; Ex. 1003 at Figs. 1 and 3, 5:51-54).

Marcus also teaches that “[f]or locking the nail in the intertrochanteric region of the right femur a screw, such as screw 51, is inserted downwardly through the openings 40, 45” ... “along axis 46 at an angle A which is about 30°.” (Ex. 1007 at ¶130; Ex. 1003 at Figs. 1 and 3, 5:41-43, 8:6-9, 8:26-29). For convenience, annotated Figure 3 showing angle A is provided below.



Therefore, Marcus teaches the first screw member is adapted for coupling to the second member at the angle, as required by this element of claim 59.

*Element 6: “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone”.* Marcus discloses that each of the first screw and the second member is adapted for residing substantially within at least one bone. (Ex. 1007 at ¶¶132-135; Ex. 1003 at Fig. 1, 4:40-44, 5:48-51). For convenience, Figure 1 of Marcus showing nail 10 and screw 51 residing substantially within the femur once installed is provided below.



(Ex. 1002 at Fig. 1, annotated). Marcus teaches nail 10 being inserted into the medullary canal of a femur to a position in which the nail head 12 is in the intertrochanteric region 20 of the femur and the distal tip 16 is in the distal femur region. (Ex. 1007 at ¶134; Ex. 1003 at 4:40-44). Marcus also teaches that “[f]or locking the nail in the intertrochanteric region of the right femur a screw, such as screw 51, is inserted downwardly through the openings 40, 45.” (Ex. 1007 at ¶134; Ex. 1003 at 5:51-53). As shown in Figure 1 above, openings 40, 45 are deep within the femur.

Therefore, Marcus teaches that “said first screw and said second member is adapted for residing substantially within at least one bone”, as required by this



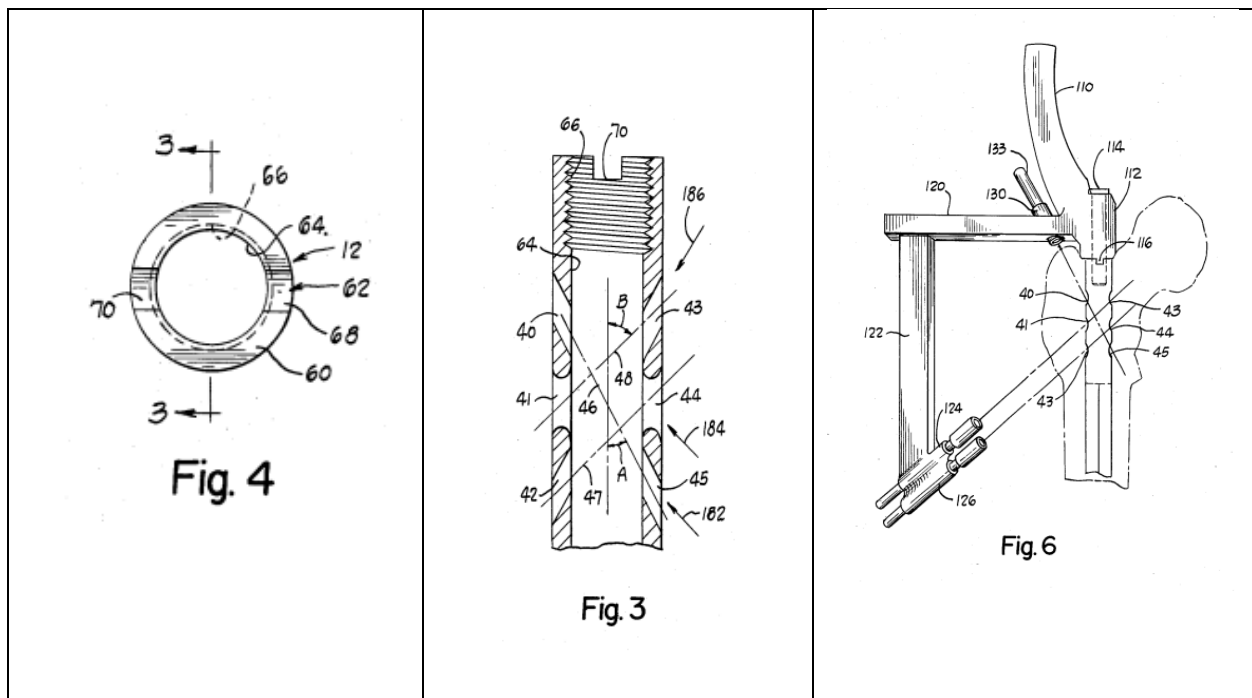
claim element.

*Element 7: “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument”.*

Marcus discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶136-142).

The first and second circumferentially spaced recesses recited in this claim element are grooves 62 and 70. (Ex. 1007 at ¶137; Ex. 1003 at Figs. 3, 4 and 6, 6:17-19

For convenience, Figures 3, 4 and 6 of Marcus showing circumferentially spaced indentations or grooves 62 and 70 (Figures 3, 4) that couple to lugs 116 of the jig (Figure 6) are provided below.



(Ex. 1003 at Figs. 3, 4 and 6). Marcus teaches that lugs 116 at the bottom of the

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head 112 of the screw guide and drilling jig shown in Figure 6 enter the respective grooves 68 and 70 in the upper end of the nail head to accurately align the jig circumferentially as well as axially of the inserted nail. (Ex. 1007 at ¶¶137-141; Ex. 1003 at Fig. 6, 6:68-7:4). In Figure 6 of Marcus, shown above, the instrument 122 is shown as coupled, namely, paired with, the second member (i.e.. nail 10). (Ex. 1007 at ¶141). Therefore, Marcus discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument, as required by this claim element.

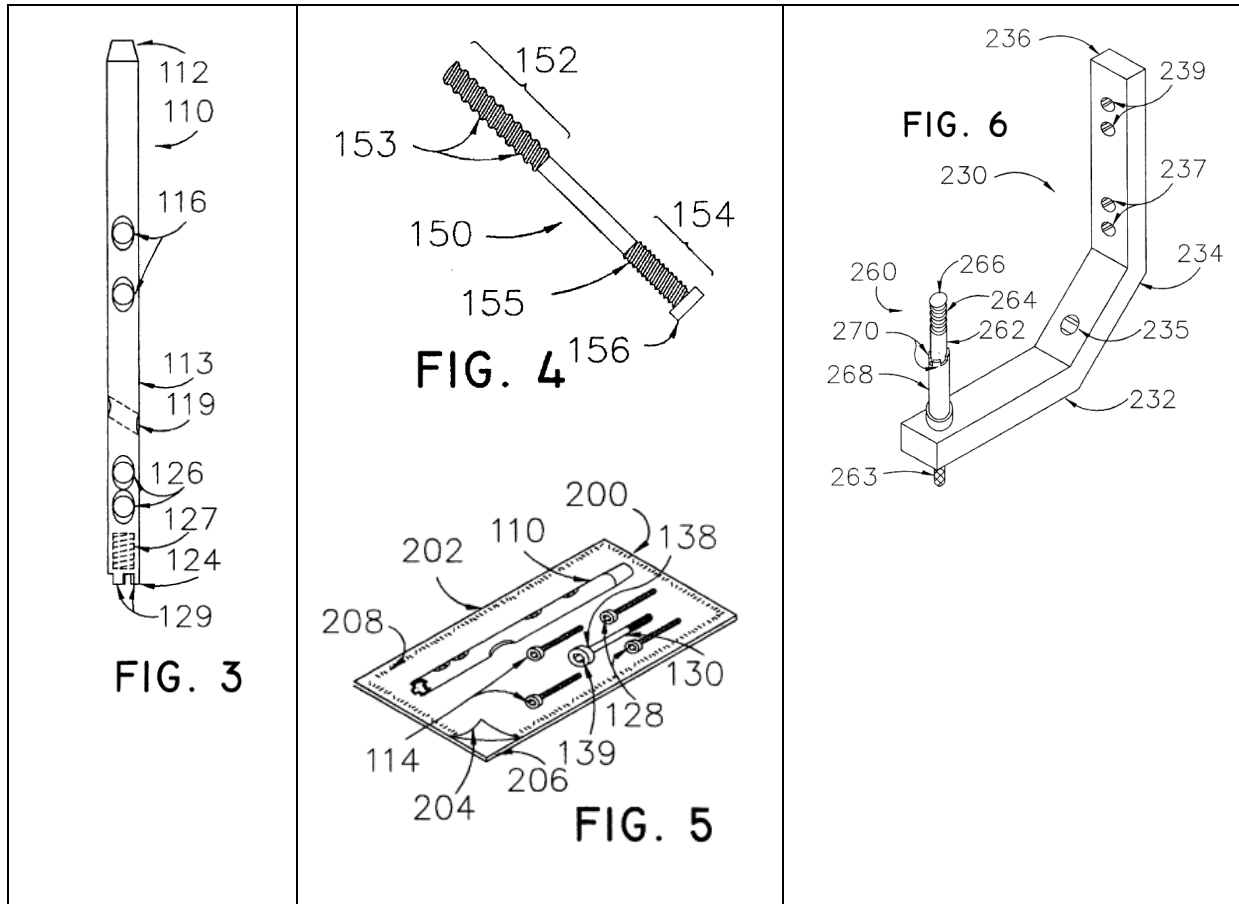
Accordingly, each and every limitation of claim 59 is disclosed in Marcus.

### **iii. Claim 59 Is Anticipated by Chandran**

Petitioner is reasonably likely to prevail in challenging claim 59 of the '589 patent based on anticipation by Chandran. Pursuant to 35 U.S.C. § 102(b), pre-AIA, Chandran discloses each and every limitation of claim 59, as set forth in the technological summary above, the Sherman Declaration, including the claim charts provided therewith, and the following argument.

*Preamble: "A fixation system for compressing bone, comprising".*

Chandran discloses a fixation system for compressing bone. (Ex. 1007 at ¶¶145-148; Ex. 1004 at Figs. 3, 4 and 6). Below are Figures 3-6 of Chandran showing the fixation system:

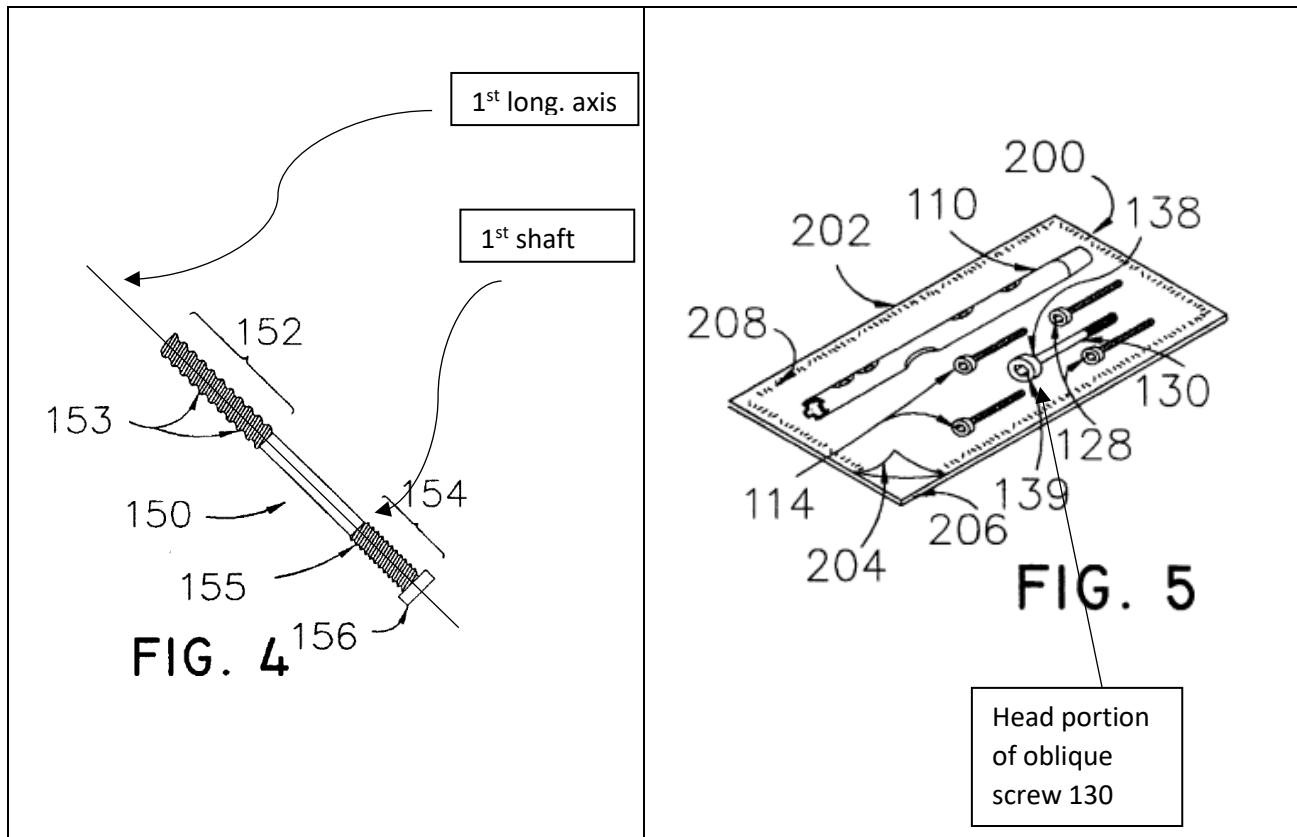


(Ex. 1004 at Figs. 3, 4 and 6).

As set forth *supra*, the preamble of claim 59 recites an intended use only and thus is not a limitation of the claim. (see Section IV.D.3). Nevertheless, to the extent that the portion of the preamble “for compressing bone” of claim 59 is limiting, Chandran also teaches that the disclosed fixation assembly may be used for compressing bone. (Ex. 1007 at ¶¶146-148; Ex. 1004 at Abst., 7:24-30, 10:43-48).

*Element 1: “a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis”.* Chandran discloses a first screw

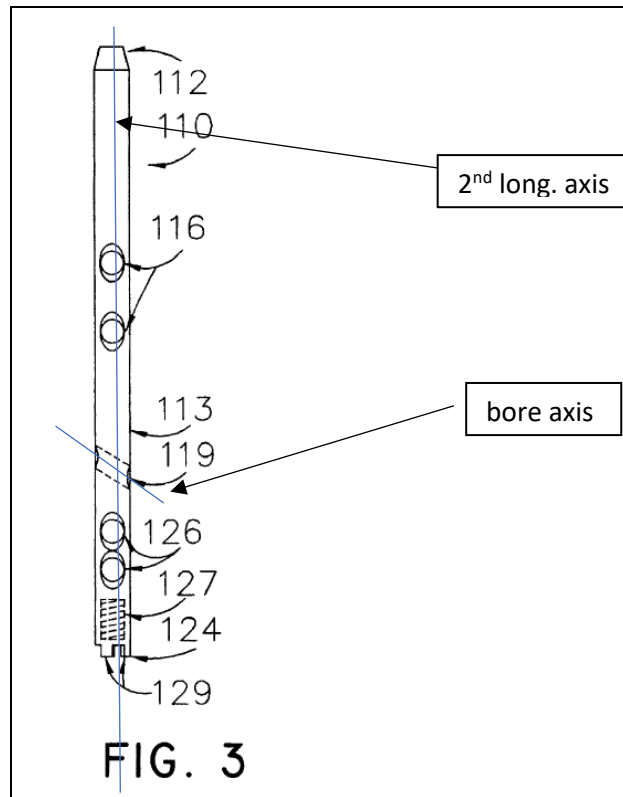
member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶149-153). The first screw member recited in this claim element is oblique screw 130 or 150 illustrated in Figure 4 of Chandran. (Ex. 1007 at ¶150; Ex. 1004 at 7:51-56). For convenience, annotated Figure 4 of Chandran showing oblique screw 150 (or 130 in Fig. 5) including a head portion 156 and a first shaft extending along a first longitudinal axis is provided below.



(Ex. 1004 at Figs. 4 and 5, annotated).

*Element 2: “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis”.* Chandran discloses a second member comprising a second shaft

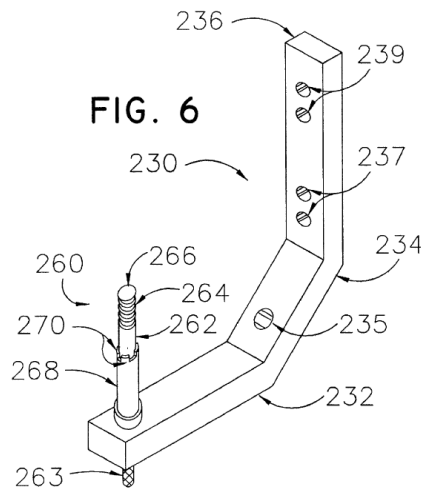
extending along a second longitudinal axis and a bore extending through the second shaft along a bore axis. (Ex. 1007 at ¶¶154-158). The second member recited in this claim element is vertical rod 110. (Ex. 1007 at ¶¶155-156; Ex. 1004 at 5:15-16). For convenience, annotated Figure 3 of Chandran showing a vertical rod 110 having a shaft 113, a longitudinal axis (noted below) and a slanted hole 119 is provided below.



(Ex. 1004 at Fig. 3, annotated). As shown above, Chandran discloses a “slanted hole 119” having a slanted bore axis. (Ex. 1007 at ¶157; Ex. 1004 at Fig. 3). Therefore, Chandran discloses a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said

second shaft along a bore axis, as required by this claim element.

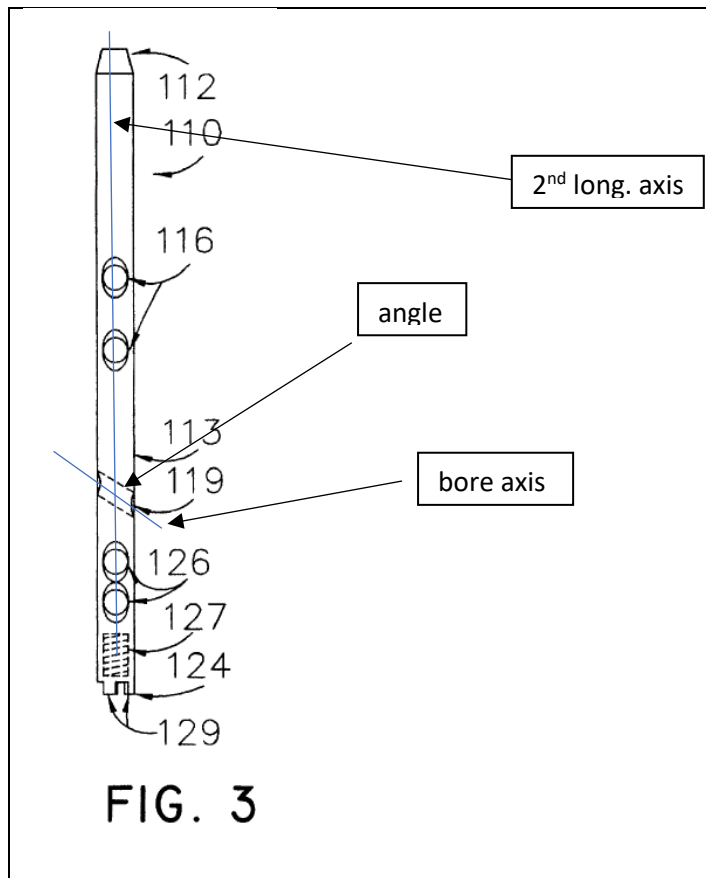
*Element 3: “an instrument adapted for coupling said first screw member to said second member”.* Chandran discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶159-163; Ex. 1004 at Fig. 6; 9:7-10, 24-40, 49-55). For convenience, Figure 6 of Chandran showing a jig that is adapted for coupling the oblique screw to nail 110 is provided below.



(Ex. 1004 at Fig. 6). Chandran teaches use of the jig shown in Figure 6 to serve as an alignment guide for drilling oblique hole 119 and for inserting of the screws into vertical rod 110. (Ex. 1007 at ¶161; Ex. 1004 at 10:28-55). Specifically, Chandran teaches the positioning of the jig so that oblique hole 119 is drilled into the patient’s calcaneal bone and then setting and securing the oblique screw. (Ex. 1007 at ¶¶161-162; Ex. 1004 at 10:28-55). According to Chandran, the jig is not moved until “after the oblique hole has been drilled and the oblique screw has been

set and secure.” *Id.* Therefore, Chandran discloses an instrument adapted for coupling said first screw member to said second member, as required by this claim element.

*Element 4: “wherein said second longitudinal axis and said bore axis define an angle”.* Chandran discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶164-166; Ex. 1004 at Fig. 3). For convenience, annotated Figure 3 of Chandran showing the second longitudinal axis and the bore axis defining an angle is provided below.

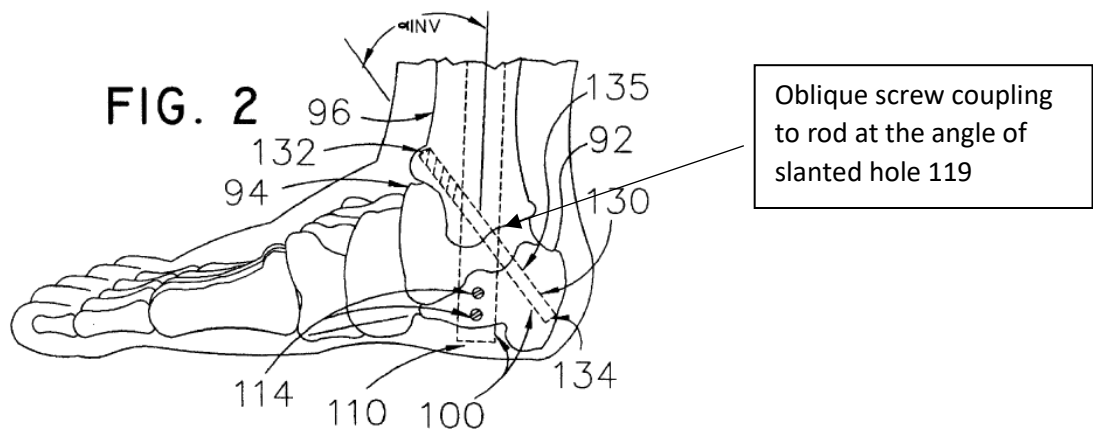


(Ex. 1004 at Fig. 3, annotated). Chandran teaches a “slanted hole 119” formed in

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nail 110. (Ex. 1007 at ¶¶165-166; Ex. 1004 at 5:53-54). The axis of this slanted hole 119 is clearly at an angle to the second longitudinal axis. Therefore, Chandran discloses the second longitudinal axis and the bore axis define an angle, as required by this claim element.

*Element 5: “wherein said first screw member is adapted for coupling to said second member at said angle”.* Chandran discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶167-171; Ex. 1004 at 6:24-26, 31-35). For convenience, Figure 2 of Chandran clearly showing oblique screw being adapted for coupling to nail 110 at the angle defined by the bore axis of slanted hole 119 through nail 110 is provided below.



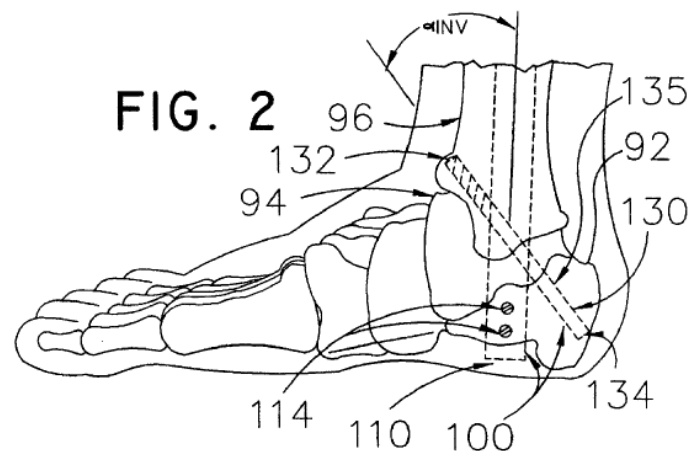
(Ex. 1004 at Fig. 2, annotated). Chandran refers to the first screw member or screw 130 or 150 as “oblique” and defines the term “oblique” to indicate that the screw “is positioned at a slanted angle with respect to the main axis of the rod



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110.” (Ex. 1007 at ¶169; Ex. 1004 at 6:24-26). Therefore, Chandran discloses the first screw member is adapted for coupling to the second member at the angle, as required by this claim element.

*Element 6: “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone”.* Chandran discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶172-175; Ex. 1004 at 5:16-20, 39-44, 6:20-23). For convenience, Figure 2 of Chandran showing nail 110 and oblique screw residing substantially within the bones of the rear foot and ankle once installed is provided below.



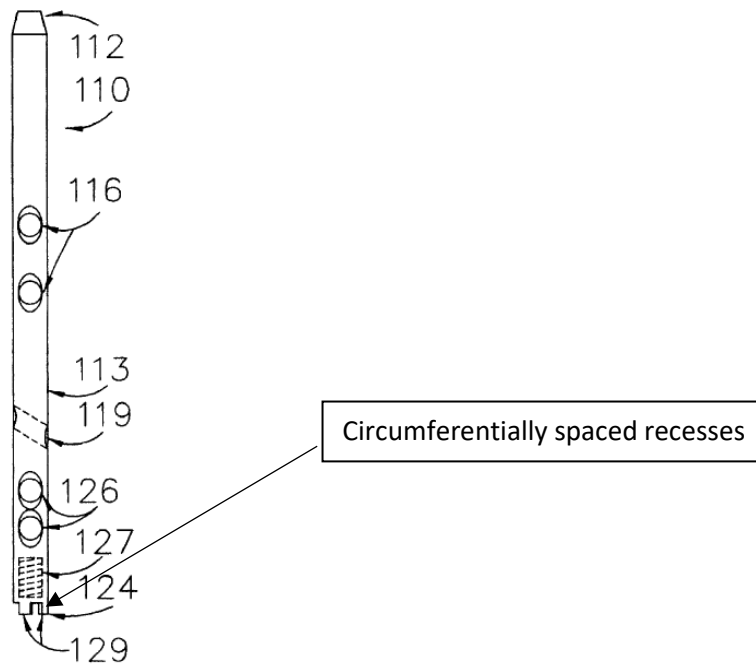
(Ex. 1004 at Fig. 2). Chandran teaches that vertical rod 110 may pass through a portion of the talus bone with the upper end being driven into the lower end of the tibial bone and the upper portion being securely and permanently affixed in the

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tibial bone. (Ex. 1007 at ¶174; Ex. 1004 at 5:16-20, 39-44). Chandran also teaches the oblique screw being pushed into the posterior surface of the calcaneum. (Ex. 1007 at ¶174; Ex. 1004 at 6:20-23). Therefore, Chandran discloses each of the first screw and the second member is adapted for residing substantially within at least one bone, as required by this claim element.

*Element 7: “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument”.*

Chandran discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶176-181). The first and second circumferentially spaced recesses recited in this claim element are the slots 129 illustrated in Figure 3 of Chandran. (Ex. 1007 at ¶177; Ex. 1004 at 6:2-10). For convenience, annotated Figures 3 of Chandran showing slots 129 for secure attachment of nail 110 to the jig 230 is provided below.



**FIG. 3**

(Ex. 1004 at Fig. 3, annotated). Chandran teaches that slots 129 “will accommodate alignment fins 270 [of jig 230].” (Ex. 1007 at ¶179; Ex. 1004 at 6:2-10). Chandran also teaches that “[w]hen the slots interact with alignment fins 270 on the jig coupling bolt, it allows the alignment jig 230 to be rotated around an axis established by vertical rod 110, after the rod has been inserted into the tibial bone.” (Ex. 1007 at ¶180; Ex. 1004 at 6:2-10). Therefore, Chandran discloses the second member comprises first and second circumferentially spaced recesses adapted for coupling to the instrument, as required by this claim element.

Accordingly, each and every limitation of claim 59 is disclosed in Chandran.

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**V. Payment of Fees**

The undersigned representative of Petitioner authorizes the Patent Office to charge the *Inter partes* review fees – Up to 20 claims, along with any additional fees, to Deposit Account 08-1935, reference no.: 3768.123.

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**VI. PETITIONER'S EXHIBIT LIST**

EXHIBIT 1001	U.S. Patent No. 8,303,589
EXHIBIT 1002	U.S. Patent No. 4,827,917 to Brumfield
EXHIBIT 1003	U.S. Patent No. 4,622,959 To Marcus
EXHIBIT 1004	U.S. Patent No. 6,579,293 to Chandran
EXHIBIT 1005	Relevant portions of the Prosecution History of U.S. Patent No. 8,303,589
EXHIBIT 1006	U.S. Patent Application Publication No. 2009/0240252 to Chang
EXHIBIT 1007	Declaration of Mike Sherman
EXHIBIT 1008	U.S. Patent No. 5,779,705 to Matthews
EXHIBIT 1009	U.S. Patent No. 5,032,125 to Durham
EXHIBIT 1010	Merriam-Webster's Collegiate Dictionary, 10 <sup>th</sup> Edition, 1993, relevant pages containing definitions for the words "aperture", "bore", "recess", "coupling" and "slot"
EXHIBIT 1011	Webster's Medical Desk Dictionary, 1986, relevant page containing definition for the word "screw"

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**VII. Conclusion**

Petitioner therefore requests that the Patent Office order an *inter partes* review trial and then proceed to cancel claim 59 of the '589 patent.

Dated: April 1, 2022

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT UNDER 37 C.F.R. § 42.24(a)**

I, the undersigned, do hereby certify that the attached Petition, including footnotes, contain 10,319 words, as measured by the Word Count function of Microsoft Word. This is less than the limit of 14,000 words as specified by 37 C.F.R. § 42.24(a)(i).

Respectfully submitted,

April 1, 2022

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