

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEXTREMITY SOLUTIONS, INC.,
ZIMMER BIOMET HOLDINGS, INC., and
ZIMMER INC.,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

IPR2022-00802
Patent 8,303,589 B2

Before JEFFREY N. FREDMAN, JAMES A. WORTH, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Amend
35 U.S.C. § 318(a)

I. INTRODUCTION

In response to a Petition (Paper 1, “Pet.”) filed by Petitioner Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc., and Zimmer Inc. on April 5, 2022, the Board instituted an *inter partes* review of claim 59 of U.S. Patent No. 8,303,589 B2 (Ex. 1001, “the ’589 patent”). Paper 10 (“Dec.”). Subsequently, Patent Owner Extremity Medical, LLC filed a Patent Owner Response (Paper 12, “PO Resp.”), Petitioner filed a Reply to the Patent Owner Response (Paper 15, “PO Resp.”), and Patent Owner filed a Sur-Reply (Paper 21). An oral hearing was held on May 24, 2023. A transcript of the hearing has been entered into the record. Paper 34.

Patent Owner also filed a contingent Motion to Amend proposing substitute claim 61 if we find the original claim 59 unpatentable. Paper 13 (“MTA”). Petitioner filed an opposition (Paper 16). We issued Preliminary Guidance (Paper 18) concerning the initial Motion to Amend. Following the Preliminary Guidance, Patent Owner filed a Revised Motion to Amend (Paper 22, “RMTA”), replacing the initial Motion to Amend. Petitioner filed an Opposition to the Revised Motion to Amend (Paper 24, “RMTA Opp.”), Patent Owner filed a Reply to Petitioner’s Opposition (Paper 28, “RMTA Reply”), and Petitioner filed a Sur-reply to Patent Owner’s Reply (Paper 30, “RMTA Sur-reply”).

In our Scheduling Order, we notified the parties that “any arguments not raised in the [Patent Owner] response may be deemed waived.” *See* Paper 11, 9; *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide 66 (Nov. 2019) (“The patent owner response . . . should

identify all the involved claims that are believed to be patentable and state the basis for that belief.”).¹

For the reasons that follow, on the full trial record, we conclude that Petitioner has proven by a preponderance of the evidence that claim 59 of the ’589 patent is unpatentable. We further conclude that Petitioner has proven by a preponderance of the evidence that proposed substitute claim 62 is unpatentable.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc., and Zimmer Inc. as the real parties-in-interest. Pet. 4. Patent Owner identifies Extremity Medical, LLC as the real party-in-interest. Paper 6.

III. RELATED MATTERS

The Petition states the ’589 patent is “the subject of a patent infringement lawsuit brought by the assignee of the ’589 patent, Extremity Medical, LLC. (*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).” Pet. 4.

IV. THE ’589 PATENT

The ’589 patent issued Nov. 6, 2012, from an application filed June 23, 2009. Ex. 1001, codes (45), (22). The ’589 patent claims the priority benefit of a provisional application filed June 24, 2008. *Id.*, code (60).

As background, the ’589 patent explains that: “Orthopedic implant devices . . . are often used to repair or reconstruct bones and joints affected

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

by trauma, degeneration, deformity and disease, such as Charcot arthropathy caused by diabetes in some patients.” Ex. 1001, 1:22–26. The ’589 patent teaches “Charcot arthropathy (or Charcot foot) . . . causes bony fragmentation, dislocation, and fractures that eventually progresses to foot deformity, bony prominences, ulceration and instability of the foot.” *Id.* at 1:26–31. The ’589 patent teaches “[s]urgical treatments include orthopedic fixation devices that fixate the bones in order to fuse them into a stable mass.” *Id.* at 1:38–40.

The ’589 patent teaches “[v]arious implants have been utilized for surgical treatment, including bone screws. While these devices allow fixation and promote fusion, they do not deliver restoration of the arch in a Charcot foot.” Ex. 1001, 1:43–46. The ’589 patent teaches an “object of the present invention is to provide a method for restoring the arch of the foot by delivering a fixator that can be coupled in a patient’s foot.” *Id.* at 2:11–13. Figure 1 of the ’589 patent provides “a perspective view of a fixation system according to a preferred embodiment of the present invention.” Ex. 1001, 3:7–8.

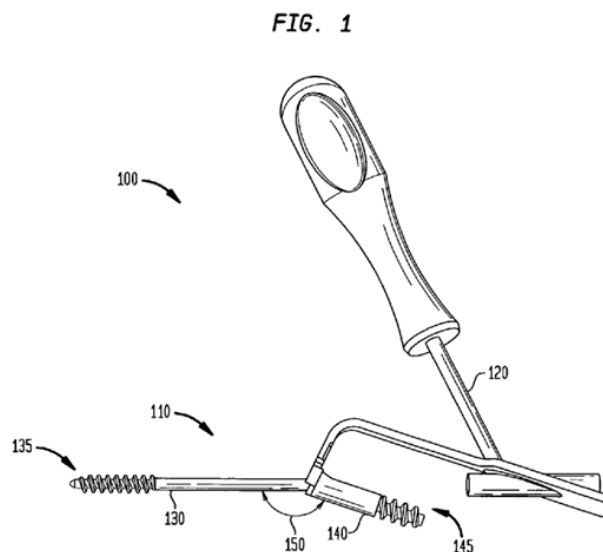


Figure 1 shows

a fixation system **100** which is made in accordance with the teachings of the preferred embodiment of the invention. As shown, the fixation system **100** includes an intramedullary fixation assembly **110**, comprising a proximal screw member **130** and a distal member **140**. Proximal screw member **130** is provided on proximal end **135** of assembly **110** and is coupled to a distal member **140** that is provided on the distal end **145** of the fixation assembly **110**. Also, proximal screw member **130** makes a fixed angle **150** with distal member **140** and this angle **150** determines the angle for arch restoration. Moreover, fixation system **100** includes instrument **120** that is utilized to couple intramedullary fixation assembly **110** to the bones, in one non-limiting example, in the mid-foot region.

Ex. 1001, 3:50–63.

Figure 3A of the '589 patent “is a perspective view of a distal member used in the fixation system.” Ex. 1001, 3:12–13.

FIG. 3A

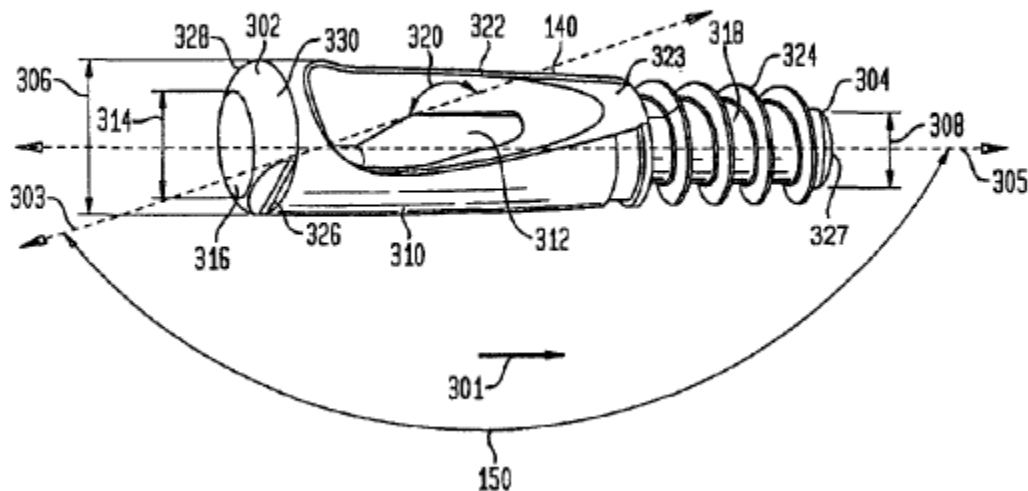


Figure 3A shows

distal member **140** of the preferred embodiment is generally tubular in shape and tapers from a first end **302** to a second end **304** . . . First end **302** has a plurality of substantially similar

grooves **326** and **328**, which form an “L-shape” with surface **330** of end **302**. Grooves **326** and **328** are provided to receive instrument **120** of fixation system **100**.

Ex. 1001, 4:49–5:5.

V. ILLUSTRATIVE CLAIM

The '589 patent includes a number of claims, but only independent claim 59 is challenged here. Claim 59 reads:

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 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.

Ex. 1001, 12:29–47.

VI. PROSECUTION HISTORY

After an election requirement (Ex. 1005, 102²), the Examiner initially rejected the claims in a non-final action on grounds of obviousness-type double patenting, of anticipation by Chang (Ex. 1006), and of obviousness

² These page numbers refer to the page numbers added to the exhibit copy, not the original pagination.

over Chang, combined with Culbert³ and Cresina.⁴ Ex. 1005, 65–81. The Examiner also identified some claims as objected for being dependent on a rejected base claim, but allowable if rewritten in independent form. *Id.* at 80. The Applicant responded by cancelling the rejected claims and rewriting the objected claims into independent form or to depend from such claims.

Id. at 58–59. The Examiner then allowed the application, stating

no reference or reasonable combination thereof could be found which disclose or suggest an instrument or method of compressing bone with a second member with first and second circumferentially spaced recesses adapted for coupling to an instrument and wherein the first and second recesses are disposed a[t] the second end of the second member.

Id. at 29.

VII. INSTITUTED GROUNDS OF UNPATENTABILITY

We instituted trial based on all asserted claims and grounds of unpatentability on the following grounds recited in the Petition:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
59	102(b)	Brumfield ⁵
59	102(b)	Marcus ⁶
59	102(b)	Chandran ⁷

Petitioner also relied on the declaration of Mike Sherman, in support of the asserted grounds. Ex. 1007. Based on the statements of qualifications and curricula vitae, we find Petitioner’s declarant Mr. Sherman qualified to

³ Culbert et. al., U.S. Patent Publication 2009/0149857, published June 11, 2009.

⁴ Cresina et al., U.S. Patent Publication 2009/0099571, published April 16, 2009.

⁵ Brumfield, D., U.S. Patent 4,827,917, issued May 9, 1989 (Ex. 1002).

⁶ Marcus, R., U.S. Patent 4,622,959, issued Nov. 18, 1986 (Ex. 1003).

⁷ Chandran, R., U.S. Patent 6,579,293 B1, issued June 17, 2003 (Ex. 1004).

provide technical opinions from the perspective of a person of ordinary skill in the art in this proceeding. *See* Ex. 1007 ¶¶ 4–11. Also based on the statements of qualifications and curricula vitae, we find Patent Owner’s declarant Dr. Drewry qualified to provide technical opinions from the perspective of a person of ordinary skill in the art in this proceeding. *See* Ex. 2001 ¶¶ 7–16.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

While the Petition itself does not address the definition of a person of ordinary skill in the art (“POSA” or “POSITA”) at the time of the invention, Petitioner’s expert, Mr. Sherman, in an accompanying declaration, states

a person of ordinary skill in the art (“POSA”) would have a bachelor’s degree in biomedical and/or mechanical engineering or similar training and would have at least five years of experience with the methods, processes and implant devices used to correct deformities in bone, stabilize fractures or fuse joints (arthrodesis).

Ex. 1007 ¶ 21.

Patent Owner did not provide a definition of a POSA in the Patent Owner Response, but in its initial Motion to Amend Patent Owner “asserts that one of ordinary skill would be a person with a Bachelor’s Degree in biomedical and/or mechanical engineering or similar training and would have at least three years of experience with implant devices used for internal fixation of bones. *See* Ex. 2001, Drewry Decl. ¶¶ 27–31.” Paper 13, 10.

Patent Owner asserts that the

Petition here fails to comply with 35 U.S.C. § 312(a)(3) because it argues that certain claim terms should be construed as they would be understood by a person of ordinary skill in the art (“POSITA”), but yet does not provide a definition or description of a POSITA in support of its argument.

PO Resp. 5.

Patent Owner asserts “there is no support in the Petition for Petitioner’s argument that a POSITA would have understood the claim terms as Petitioner proposes.” PO Resp. 6. Patent Owner acknowledges that “Mr. Sherman’s declaration includes a proposed definition for a POSITA (*see* Exhibit 1007 at ¶¶ 13-21).” PO Resp. 6.

We find this argument unpersuasive. As Patent Owner notes, Petitioner’s expert provides a definition of POSITA that is very similar to that recited by Patent Owner in its Motion to Amend, substantively differing only in the number of years of experience of the engineer at issue. This congruity supports the conclusion that the level of ordinary skill in the art may be recognized in the prior art itself. *Okajima*, 261 F.3d at 1355 (“the absence of specific findings on the level of skill in the art does not give rise to reversible error ‘where the prior art itself reflects an appropriate level and a need for testimony is not shown’”).

We think the *Okajima* logic is applicable to the current case, where the Petition relied solely upon anticipatory prior art. Unlike obviousness, which is viewed through the lens of the person of ordinary skill in the art, anticipation asks whether the claimed structure is the same as the prior art without regard for any intended use. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). That is because “the question [of] whether a reference is analogous art is irrelevant to whether that reference anticipates.” *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997).

Therefore, to the extent that the level of ordinary skill in the art is an issue in this proceeding, we adopt the level provided by Patent Owner in its Motion to Amend. Paper 16, 10. However, we are not persuaded that the failure to recite a level of ordinary skill in the art in the original Petition, where Petitioner's expert provided a definition, where the grounds in the original Petition were entirely based on anticipation, and where no claim interpretation was identified as required by either party supports a determination that the original Petition is fatally flawed.

IX. CLAIM CONSTRUCTION

We interpret claim terms 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).” 37 C.F.R. § 42.100(b) (2020). Thus, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted) (en banc).

Here, we construe only those claim terms that require analysis to determine whether Petitioner has met its burden to prove unpatentability by a preponderance of the evidence. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”).

Patent Owner does not identify any disagreement on claim construction issues with respect to claim 59. *See, e.g.*, PO Resp. 5–7; PO RMTA 12. Rather, Patent Owner’s arguments, which we found unpersuasive as discussed above, pertain to the level of ordinary skill in the art.

Petitioner asserts that the terms “screw member,” “bore,” “recesses,” and “coupling” “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.” Pet. 24–25.

In our Institution Decision, we agreed with Petitioner that the “portion of the preamble reciting ‘for compressing bone’ is not limiting to the claim” and found that other terms did not require construction. Dec. 8–9. We agreed with Petitioner that “[t]he phrase ‘for compressing bone’ merely identifies an intended use.” Pet. 20; Dec. 9. Patent Owner does not dispute this interpretation. *See generally* PO Resp. We agree with Petitioner that “the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Therefore, having considered the entire record developed during trial, we adhere to the preliminary construction that the limitation “for compressing bone” does not impose a structural limitation on claim 59 and that the other terms do not require construction.

X. ANALYSIS

A. Introduction

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is

unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

“Determining whether claims are anticipated involves a two-step analysis. The first step involves construction of the claims of the patent at issue. Claim construction is a question of law reviewed de novo.” *In re Aoyama*, 656 F.3d 1293, 1296 (Fed. Cir. 2011). “The second step [of an anticipation analysis] involves comparing the claims to the prior art. Anticipation is a question of fact reviewed for substantial evidence.” *Id.* “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation.” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012). A reference may anticipate inherently if a claim limitation that is not expressly disclosed “is necessarily present, or inherent, in the single anticipating reference.” *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a preponderance of evidence showing unpatentability of claim 59.

B. Overview of the Asserted Prior Art

1. Brumfield (Ex. 1002)

Brumfield is a U.S. patent that teaches devices for treating femoral fractures, specifically teaching “[i]f there is a femoral neck fracture the

compression of lag screw **50** functions like a compression screw assembly to reduce the fracture.” Ex. 1002, 6:57–59. Figure 6 of Brumfield teaches lag screw **50** shown below:

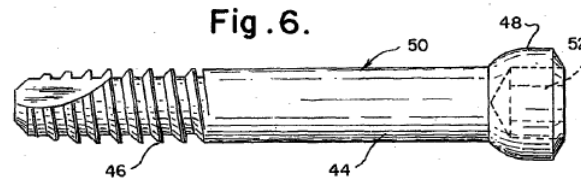
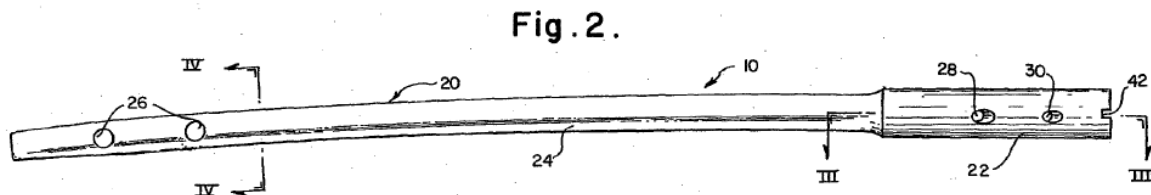


Figure 6 shows that “the lag screw **50** includes a smooth portion **44**, a self-tapping threaded end **46** and a beveled head portion **48**.” Ex. 1002, 20–22. Brumfield teaches that “lag screw **50** is inserted through the distal pair of holes **28** in head **22** of rod **20**.” Ex. 1002, 5:33–35.

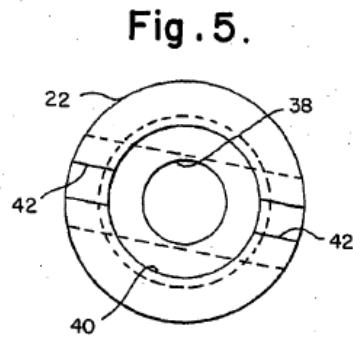
Figure 2 of Brumfield depicts an elevation view of rod **20** shown below:



Intramedullary rod **20** includes a proximal head **22**, a stem **24** distal to the head **22** and a longitudinal bore **32**. . . . the longitudinal axis of rod **20** curves through one plane along the stem **24** to align the rod along the length of the marrow canal of the femur. The head **22** includes at least two pairs of holes, a proximal pair of holes **30** and a distal pair of holes **28**. . . . the holes of a pair are coaxially arranged on a common axis extending through bore **32** in an angled direction relative to the longitudinal axis of rod **20**.

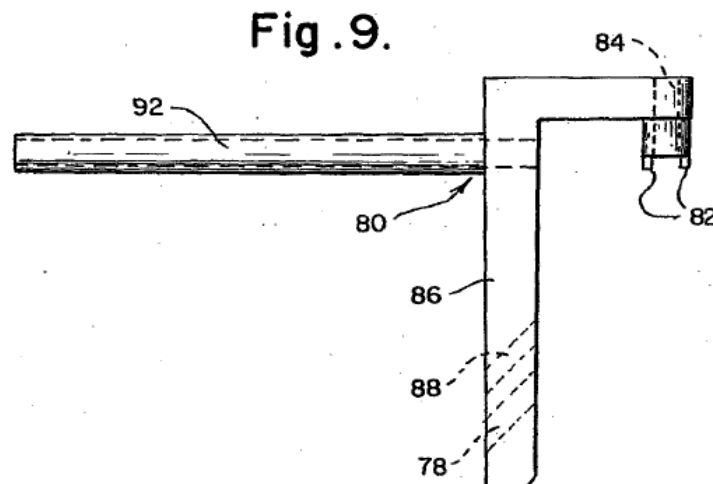
Ex. 1002, 4:29–39.

Figure 5 of Brumfield depicts a top end view of rod **20** shown in Figure 2 of Brumfield.



Brumfield teaches that, as shown in Figure 5, a “threaded counterbore **40** with slots **42** is provided at the end of head **22** to receive the set screw **60** and prongs **82** of tool **80**, respectively. The axis of slots **42** is parallel in one plane with the common axes of holes **28** and **30** to insure alignment with tool **80**.” Ex. 1002, 47–52.

Brumfield teaches a tool **80** shown in Figure 9, reproduced below, to help align the parts of femoral fracture device **10** during insertion into a patient’s bone.



Brumfield explains Figure 9 as showing that

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 tool **80** to rod **20** for driving and 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. 1002, 5:45–55.

In Figure 1, Brumfield shows the rod 20 inserted within a bone with the lag screw 50 coupled at an angle, demonstrating the final disposition of these elements after alignment using tool 80, as reproduced below:

Fig. 1.

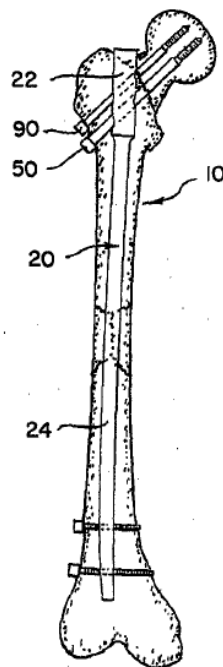


Figure 1 “is a view of the intramedullary rod of the present invention in place in a femur.” Ex. 1002, 5–657.

2. *Marcus (Ex. 1003)*

Marcus is a U.S. patent that teaches “an all-purpose or multi-use femoral intramedullary nail for use in fractures of the femur from the femoral neck to the supracondylar region.” Ex. 1003, 1:6–9. Figure 1 of

Marcus depicts “an intramedullary nail according to the invention, within a right femur (shown in phantom lines) and also showing fixation and femoral neck screws insertable into the nail.” Ex. 1003, 4:6–9.

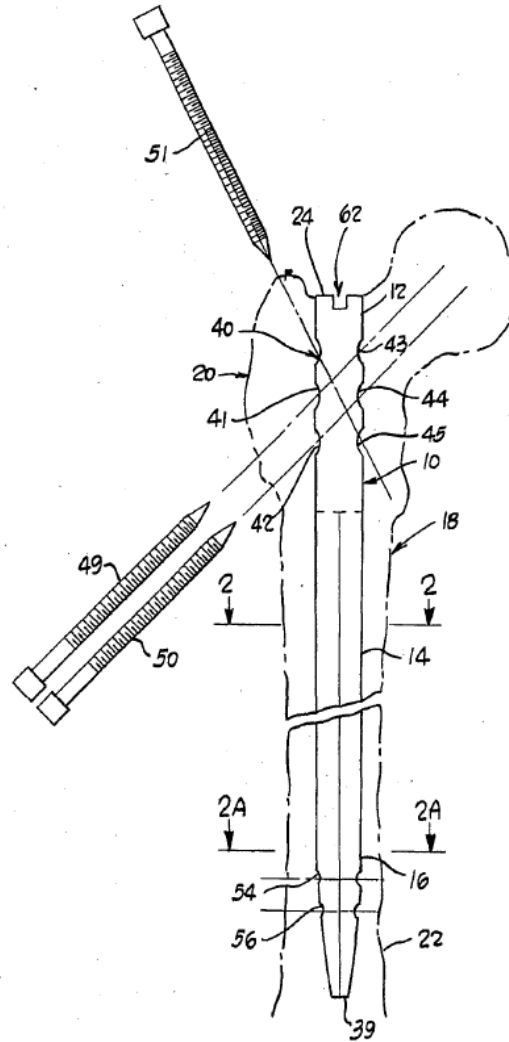


Fig. 1

Figure 1 of Marcus shows

nail **10** is advantageously driven into the femur to a position in which the top end of head **12** is adjacent to and preferably flush with the entry opening formed in the femoral tip. Formed in the sidewall of head **12** are several screw receiving openings **40-45**. . . . opening **40** is diametrically opposed to opening **43**, opening **41** is diametrically opposed to opening **44**, and opening **42** is diametrically opposed to opening **45**. A line **46** extending

through the centers of openings **40** and **45** makes an angle A of about 30° with the axis of the nail.

Ex. 1003, 5:32–43.

Figure 4 of Marcus depicts top plan view of “the head of the nail” **10** and is reproduced below:

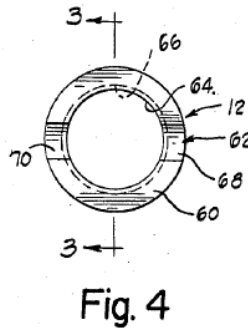


Figure 4 of Marcus shows that:

Slot **62** has a width somewhat less than the diameter of the opening **64** in head **12**. Opening **64** has internal threads **66** for threadedly securing various tools to the head of the nail both before and after insertion of the nail in the femur. As can be seen at FIG. 4, the slot **62** provides locating grooves **68** and **70** at opposite sides of opening **64**.

Ex. 1003, 6:13–19.

Figure 6 of Marcus depicts “a first jig, in accordance with the invention, for use in drilling and/or inserting screws in the proximal region of the femur in alignment with openings in an inserted nail.” Ex. 1003, 4:25–28.

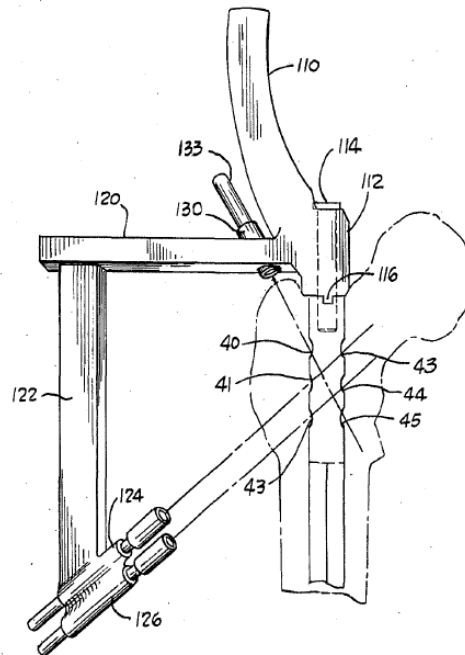


Fig. 6

The jig of Figure 6 above shows a

securing head **112**, the lower end of which has a configuration identical to seat **76** of the driver-extractor. Extending through head **112** is a fastening screw having threads to mate with the internal threads **66** in the head **12** of the nail. The lugs **116** at the bottom of head **112** enter the respective grooves in the upper end of the nail head to accurately align the jig circumferentially as well as axially of the inserted nail, when the screw **114** is fully tightened.

Ex. 1003, 6:64 to 7:4.

3. Chandran (Ex. 1004)

Chandran is a U.S. patent that teaches a “surgical rod-and-screw kit . . . for use in ankle arthrodesis. . . . When this screw is tightened, it compresses the lower end of the tibia bone against the talus and/or calcaneum, which improves the stability of the ankle fixation.” Ex. 1004, code (57). Figure 4 of Chandran is reproduced below:

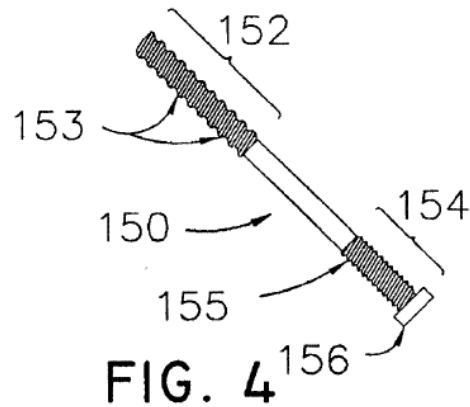
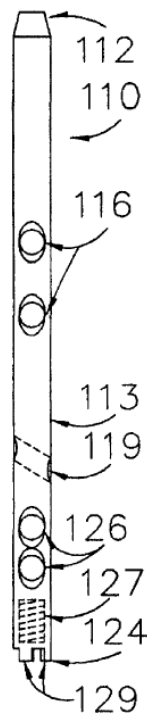


Figure 4 of Chandran, reproduced above, depicts “an oblique screw having a threaded tip that will enter a tibial bone, and a base having optional additional threads with a slightly different pitch which will become set in the calcaneal bone.” Ex. 1004, 4:32–35. Figure 3 of Chandran is a side view of a vertical rod, having a slanted hole which accommodates the oblique screw shown above and is reproduced below:



Vertical rod **110** has a tip **112**, a shaft **113**, and a base **124**, with various holes and slots described below. During a surgical operation to insert rod-and-screw assembly **100** into a damaged, diseased, or otherwise defective ankle joint, the tip **112** will be pushed through a hole that has been drilled through the bottom of calcaneal bone **92**, in the heel. This preferably should be done with the aid of a “jig” **230** (also called a guide, template, etc.).

Chandran teaches “the oblique screw **130** [of Figure 4] must pass through an accommodating slanted hole **119** in vertical rod **110** [of Figure 3].” Ex. 1004, 5:51–53. Chandran also teaches that rod “base **124** is also provided with four slots **129** in a ‘cruciate’ (orthogonal) arrangement When slots **129** interact with alignment fins **270** on the jig coupling bolt, it allows the alignment jig **230** to be rotated around an axis established by the vertical rod **110**.”

FIG. 6

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Chandran teaches that, as shown in Figure 6,

the jig can be rotated in increments of 90 degrees, so that the alignment fins **270** will reengage the accommodating slots inside the shaft of rod **110**. This will position the oblique arm **234** and vertical arm **236** on the posterior surface of the patient's heel, and it will cause the hole **235** in oblique arm **234** to be aligned with the oblique hole **119** which passes through vertical rod **110**.

Ex. 1004, 10:30–37. Figure 2 of Chandran is reproduced below:

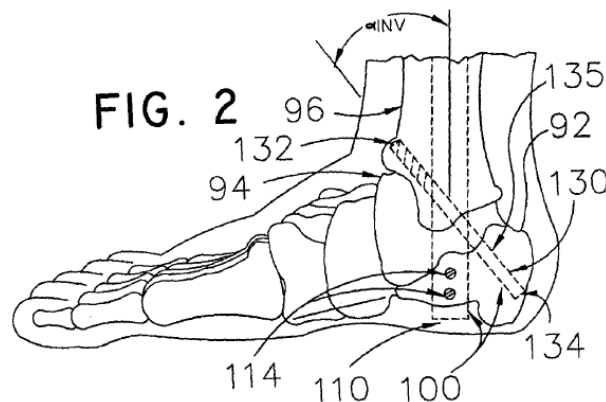


Figure 2 shows “the rod-and-screw assembly of this invention, showing vertical rod and oblique screw inside the major bones of an ankle joint.”

Ex. 1004, Pet. 25–27.

C. Ground 1: Anticipation over Brumfield

Petitioner contends that claim 59 is anticipated by Brumfield. Pet. 27–37. We note that Patent Owner does not provided specific arguments challenging Petitioner’s position regarding the patentability of the challenged claim. *See generally* PO Resp.

1. Analysis of Claim 59

Petitioner asserts, regarding the preamble, that “Brumfield discloses a fixation system for compressing bone. (Ex. 1007 at ¶¶67-70; Ex. 1002 at Figs. 2, 6 and 9).” Pet. 27. Petitioner asserts “Brumfield teaches that “[i]f

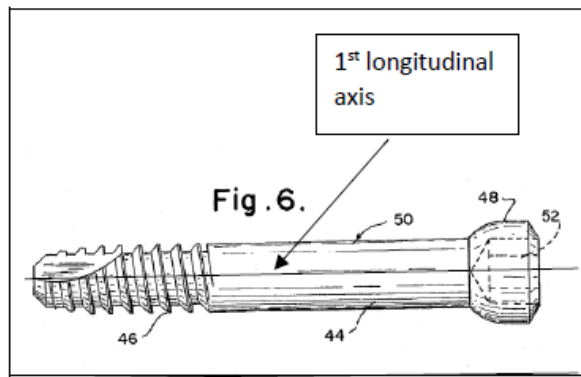
there is a femoral neck fracture the compression of lag screw 50 functions like a compression screw assembly to reduce the fracture.’ (Ex. 1007 at ¶¶69; Ex. 1002 at 6:57-59).” Pet. 28–29.

Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that

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).

Pet. 29.

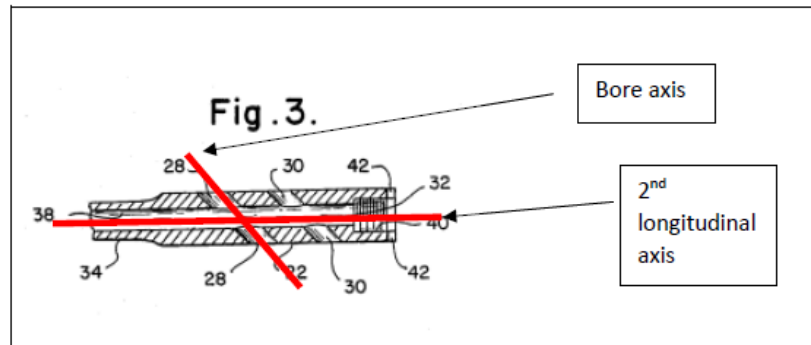
Petitioner’s annotated figure 6 of Brumfield is reproduced below:



Petitioner provides an “annotated Figure 6 of Brumfield showing a first screw member 50 having a head 48, a shaft 44, 46 and a longitudinal axis” Pet. 29 (citing Ex. 1002, Fig. 6).

Petitioner asserts, as to the recitation in claim 59 of “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,” that “Brumfield 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 ¶¶75-80; Ex. 1002 at Figs. 2-3, 4:29-39).” Pet. 30.

Petitioner provides an annotation of Figure 3 of Brumfield, reproduced below:



Petitioner asserts annotated Figure 3 shows “intramedullary rod 20 including a bore (holes 28, 30) extending through a shaft (22) along a bore axis that extends in an ‘angled direction relative to the longitudinal axis of rod 20.’ (Ex. 1007 at ¶¶77-79; Ex. 1002 at 4:36-39[)].” Pet. 30.

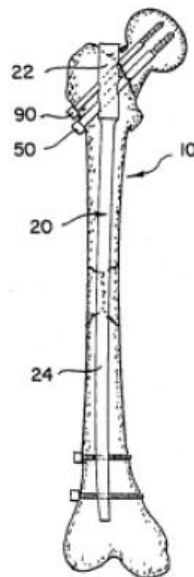
Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member,” that “Brumfield discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶81-85). The instrument recited in this claim element is the tool 80 shown in Figure 9 of Brumfield. (Ex. 1007 at ¶82; Ex. 1002 at Fig. 9; 5:43-55).” Pet. 31.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “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).” Pet. 32. As shown in the annotated figure 3 reproduced above, Petitioner asserts “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.’ (Ex. 1007 at ¶88; Ex. 1002 at 4:36-39[)].” Pet. 32–33.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle,” that “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).” Pet. 33. Petitioner reproduces figure 1, shown below:

Fig. 1.



Petitioner asserts “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.” Pet. 33. Petitioner asserts that “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).” Pet. 34.

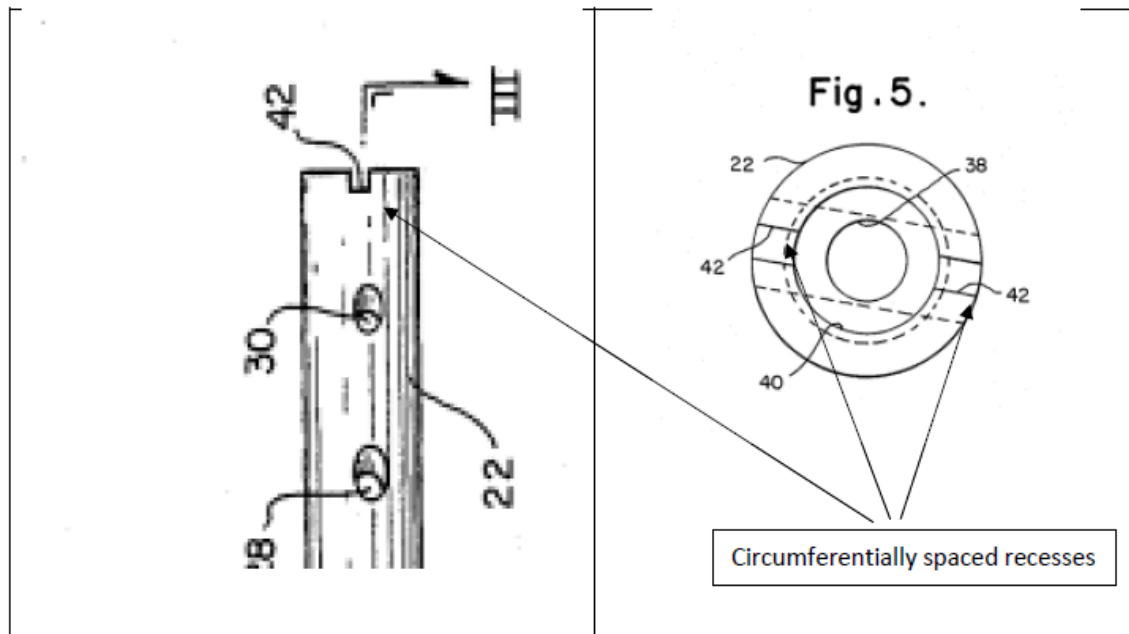
Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially

within at least one bone,” that “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).” Pet. 34. Petitioner points to Figure 1, shown above, and asserts “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).” Pet. 35.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument,” that

Brumfield discloses the second member comprising first and second 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).

Pet. 36. Petitioner reproduces annotated Figures 2 and 5 of Brumfield, shown below:



Petitioner asserts

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 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).

Pet. 36–37.

Patent Owner disputes the Petition generally but Patent Owner does not identify any error in Petitioner’s foregoing arguments. Accordingly, we adopt the factual statements regarding the specific teachings of the references as findings of fact. *See generally In re NuVasive*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art). We have reviewed Petitioner’s analysis and the underlying evidence cited in support and conclude that Petitioner has shown, by a preponderance of the evidence, that the limitations of claim 59 are disclosed by Brumfield.

D. Ground 2: Anticipation over Marcus

Petitioner contends that claim 59 is anticipated by Marcus. Pet. 37–50. We note that Patent Owner does not provide specific arguments challenging Petitioner’s position regarding the patentability of the challenged claim. *See generally* PO Resp.

1. *Analysis of Claim 59*

Petitioner asserts, regarding the preamble, that Petitioner asserts, regarding the preamble, that

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).

Pet. 38. Petitioner asserts “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).” Pet. 39.

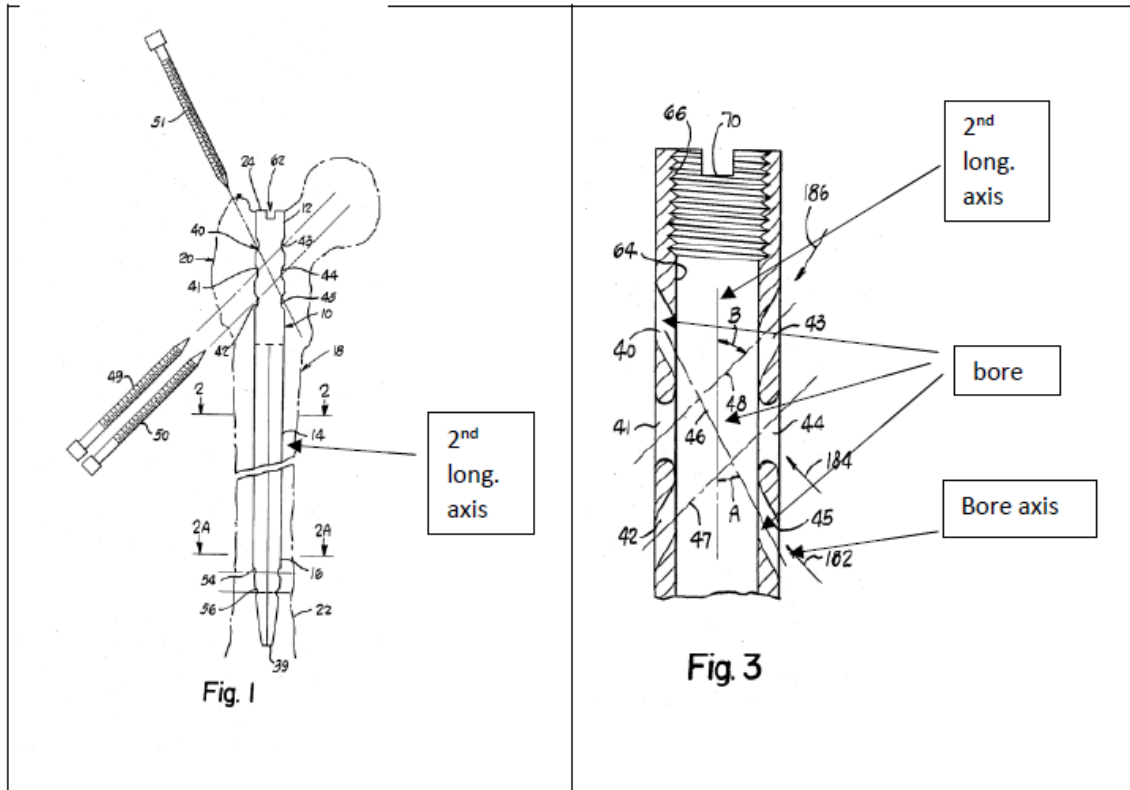
Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that “Marcus discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶110-112; Ex. 1003 at Fig. 1, 5:48-51).” Pet. 39. Petitioner provides “an annotated portion of Figure 1 of Marcus showing a first screw member 51” that is discussed in the next recitation. *Id.*

Petitioner asserts, as to the recitation in claim 59 of “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,” that:

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).

Pet. 40.

Petitioner provides an annotation of Figures 1 and 3 of Marcus, reproduced below:



Petitioner asserts annotated Figure 3 shows “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).” Pet. 41.

Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member,” that “Marcus discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶119-123).” Pet. 42.

Petitioner reproduces Figure 6 of Marcus, as shown below:

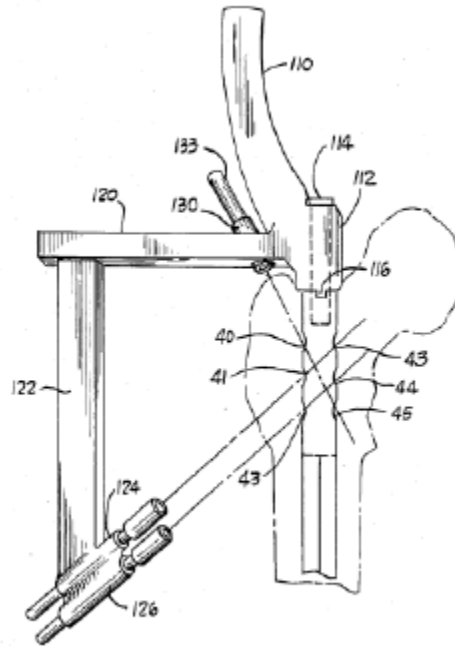


Fig. 6

Petitioner asserts

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).

Pet. 42–43.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “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).” Pet. 43. As shown in the annotated Figure 3 reproduced above, Petitioner asserts “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).” Pet. 44.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle,” that “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).” Pet. 45. Petitioner asserts, based on Figures 1 and 3 of Marcus reproduced above, that

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).

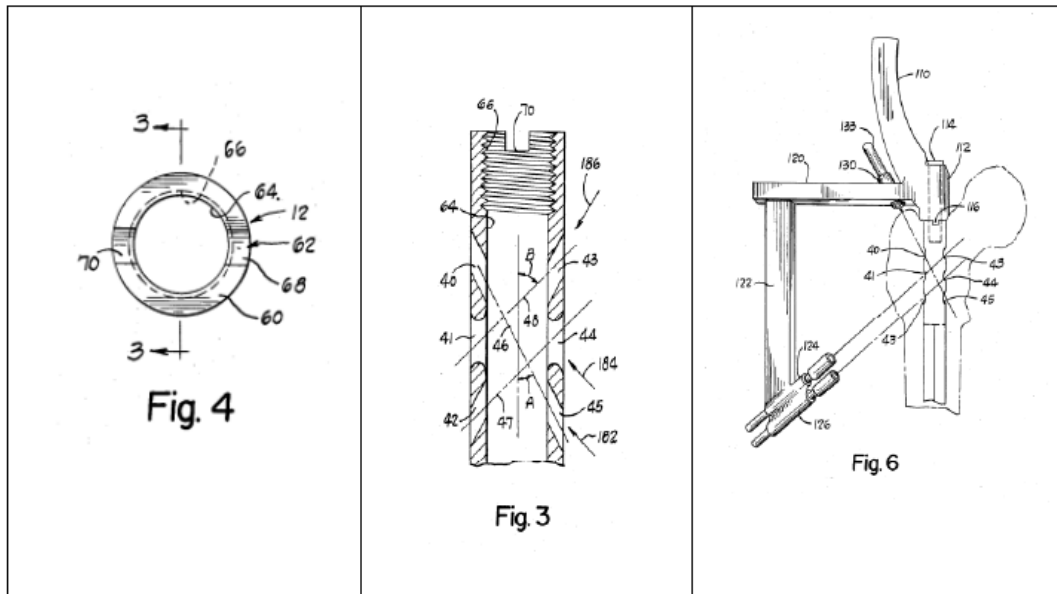
Pet. 46.

Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone,” that “Marcus discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶132-135; Ex. 1003 at Fig. 1, 4:40-44, 5:48-51).” Pet. 47. Petitioner points to Figure 1, shown above, and asserts 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).” Pet. 48.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument,” that

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[)].

Pet. 49. Petitioner points to Figures 3, 4, and 6 of Marcus, reproduced below.



Petitioner asserts

Marcus teaches that lugs 116 at the bottom of the 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).

Pet. 49–50.

Patent Owner does not dispute Petitioner's foregoing arguments or identify specific errors in these findings of fact. Accordingly, we adopt them as findings of fact. *See generally In re NuVasive*, 841 F.3d 966, 974

(Fed. Cir. 2016). We have reviewed Petitioner’s analysis and the underlying evidence cited in support and conclude that Petitioner has shown, by a preponderance of the evidence, that the limitations of claim 59 are disclosed by Marcus.

E. Ground 3: Anticipation over Chandran

Petitioner contends that claim 59 is anticipated by Chandran. Pet. 50–59. We note that Patent Owner does not provided specific arguments challenging Petitioner’s position regarding the patentability of the challenged claim. *See generally* PO Resp.

1. Analysis of Claim 59

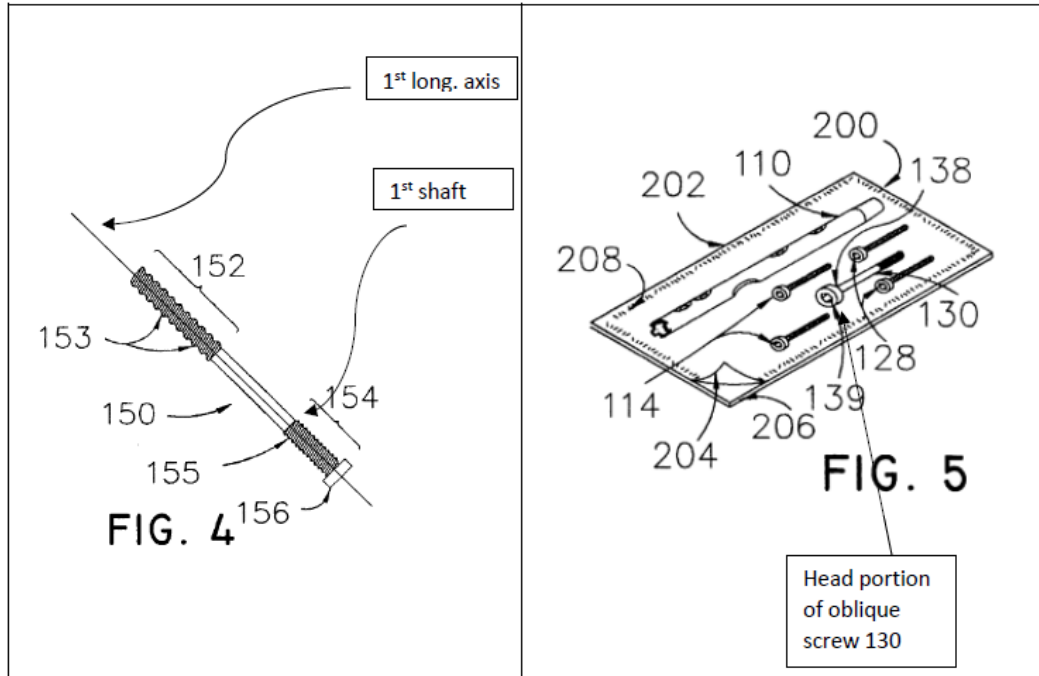
Petitioner asserts, regarding the preamble, that “to the extent that the portion of the preamble ‘for compressing bone’ of claim 59 is limiting, Chandran also teaches that the disclosed fixation assembly may be used for compressing bone. (Ex. 1007 at ¶¶146-148; Ex. 1004 at Abst., 7:24-30, 10:43-48).” Pet. 51.

Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that

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).

Pet. 52.

Petitioner provides an annotated Figure 4 of Chandran that is reproduced below:

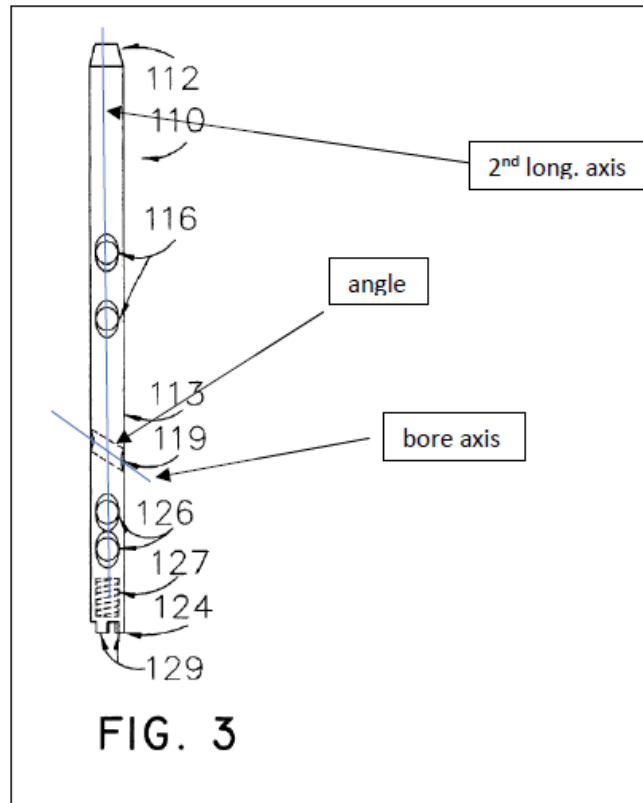


“[A]nnotated Figure 4 of Chandran showing oblique screw 150 (or 130 in Fig. 5) including a head portion 156 and a first shaft extending along a first longitudinal axis.” Pet. 52 (citing Ex. 1004, Figs. 4, 5).

Petitioner asserts, as to the recitation in claim 59 of “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,” that

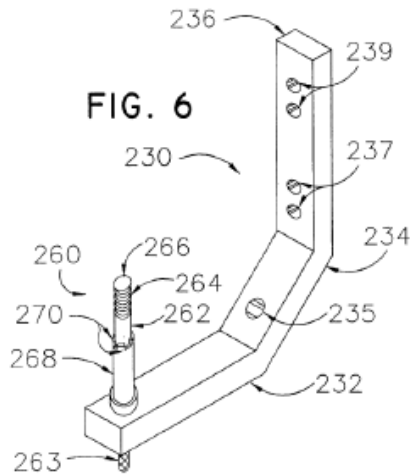
Chandran discloses a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through the second shaft along a bore axis. (Ex. 1007 at ¶¶154-158). The second member recited in this claim element is vertical rod 110. (Ex. 1007 at ¶¶155-156; Ex. 1004 at 5:15-16). Pet. 52–53.

Petitioner provides an annotation of Figure 3 of Chandran, reproduced below:



Petitioner asserts annotated Figure 3 shows “Chandran discloses a ‘slanted hole 119’ having a slanted bore axis. (Ex. 1007 at ¶157; Ex. 1004 at Fig. 3).” Pet. 53, 55.

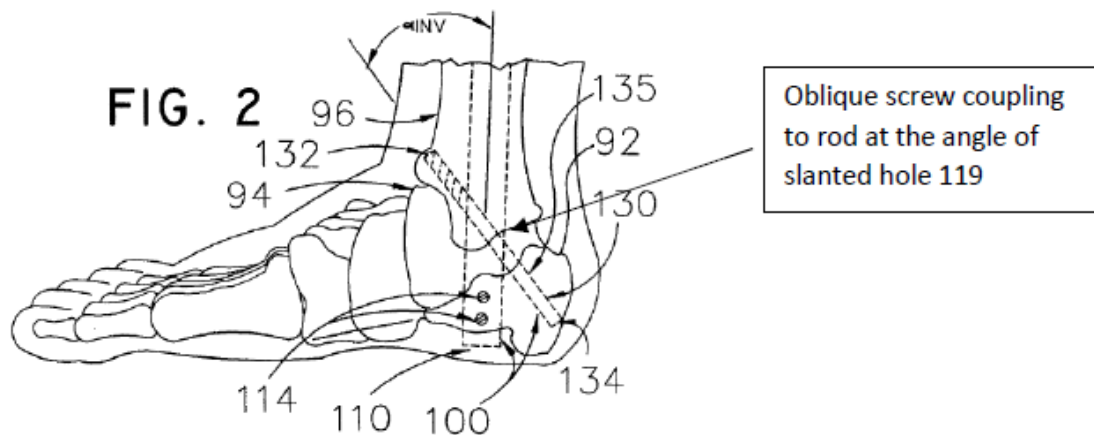
Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member,” that “Chandran discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶159-163; Ex. 1004 at Fig. 6; 9:7-10, 24-40, 49-55).” Pet. 54. Petitioner reproduces Figure 6 of Chandran, as shown below:



Petitioner asserts “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).” Pet. 54.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “Chandran discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶164-166; Ex. 1004 at Fig. 3).” Pet. 55. As shown in the annotated Figure 3 reproduced above, Petitioner asserts “Chandran teaches a ‘slanted hole 119’ formed in 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.” Pet. 32–33.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle,” that “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).” Pet. 56. Petitioner reproduces Figure 2, shown below:



Petitioner asserts “Figure 2 of Chandran clearly show[s] oblique screw being adapted for coupling to nail 110 at the angle defined by the bore axis of slanted hole 119 through nail 110.” Pet. 56. Petitioner asserts that “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 110.’ (Ex. 1007 at ¶169; Ex. 1004 at 6:24-26).” Pet. 56–57.

Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone,” that “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).” Pet. 57. Petitioner points to Figure 2, shown above, and asserts Chandran shows “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).” Pet. 57.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument,” that

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).

Pet. 58. Petitioner points to Figure 3 of Chandran, reproduced above.

Petitioner asserts

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).

Pet. 59.

Patent Owner does not dispute Petitioner’s foregoing arguments or identify error in these findings of facts. Accordingly, we adopt them as findings of fact. *See generally In re NuVasive*, 841 F.3d 966, 974 (Fed. Cir. 2016). We have reviewed Petitioner’s analysis and the underlying evidence cited in support and conclude that Petitioner has shown, by a preponderance of the evidence, that the limitations of claim 59 are disclosed by Chandran.

XI. PATENT OWNER’S REVISED MOTION TO AMEND

Pursuant to 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 42.121(a), Patent Owner filed a Contingent Motion to Amend stating that if Claim 59 is found unpatentable, Patent Owner “requests that the Board grant this Revised MTA and issue the corresponding substitute Claim 62.” RMTA, 1. Having determined that Petitioner has shown by a preponderance of the evidence that original claim 59 of the ’589 patent is unpatentable, we proceed to address Patent Owner’s Motion. Patent Owner proposes substitute claim 62

to replace challenged patent claim 59. *Id.* A copy of proposed substitute claim 62 is provided by Patent Owner in the Claims Appendix of the Motion.

For the reasons discussed below, Patent Owner has shown that proposed substitute claim 62 meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. For the reasons discussed below, however, Petitioner has proven by a preponderance of the evidence that proposed substitute claim 62 is unpatentable over prior art. Therefore, we *deny* Patent Owner’s Revised Motion to Amend.

A. *Principles of Law*

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend claims. 35 U.S.C. § 316(d). Ordinarily, the petitioner “bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable.” 37 C.F.R. § 42.121(d)(2); *Lectrosonics, Inc. v. Zaxcon, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential).

But before considering the patentability of the substitute claim, we first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. *Lectrosonics*, Paper 15 at 4. In that regard, Patent Owner bears the burden of persuasion to show that: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial; (3) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; and (4) the original disclosure sets forth written description support

for each proposed substitute claim. *Id.*; 35 U.S.C. § 316(d); 37 C.F.R. § 42.121(d)(1).

B. The Proposed Substitute Claim

Patent Owner proposes to amend the '589 patent by adding new claim 62 as a substitute for original claim 59. *See* RMTA 1, Claims App. Claim 62 is reproduced below. Underlined language reflects subject matter added to original claim 59, and strike-through indicates deletion.

~~59.~~62. A fixation system for compressing bone, comprising:

a first screw member comprising a head portion at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end;

a second member comprising a second shaft extending from a first end to a second end along a second straight, 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 the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft,

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 adapted for residing substantially within at least one bone in the mid-foot region, and

wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument.

RMTA Claims App., 24–25.

C. Statutory and Regulatory Requirements

1. Reasonable number of substitute claims

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see also* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see also* 37 C.F.R. § 42.121(a)(3). Patent Owner proposes one substitute claim for the challenged claim. RMTA 2, Claims App. Petitioner does not contend that Patent Owner proposes more than a reasonable number of substitute claims. *See generally* RMTA Opp. We determine that Patent Owner proposes a reasonable number of substitute claims.

2. Responsive to ground of unpatentability

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i). The Petition asserts that claim 59 is unpatentable over prior art. As shown above, through the Revised Motion to Amend, Patent Owner has sought to change the substantive features of challenged independent claim 59 by substituting claim 62 for claim 59. “A revised MTA includes one or more new proposed substitute claims in place of previously presented substitute claims, and may provide new arguments and/or evidence as to why the revised MTA meets statutory and regulatory requirements for an MTA.” Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings

under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497, 9,501 (Mar. 15, 2019). Although Petitioner contends that the amendments are unrelated to issues raised in the Preliminary Guidance or Opposition (*see* RMTA Opp. 25), Petitioner does not contend that the proposed amendments fail to respond to a ground of unpatentability in this trial. *See generally* RMTA Opp. Patent Owner asserts,

[t]he amendment reciting that “the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft” distinguishes the fixation system recited in Claim 62 over Jellicoe, as well as the other references cited in Petitioner’s Opposition as allegedly invalidating original Claim 59 and Claim 61 proposed in Patent Owner’s Motion to Amend.

RMTA 4.

Because the amendments attempt to distinguish over at least Jellicoe (Ex. 1013), we determine that the proposed amendments are responsive to a ground of unpatentability involved in this trial.

3. *Does not enlarge the scope of the claims*

An amendment may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). Patent Owner asserts that proposed substitute claim 62 does not enlarge the scope of the challenged claim because it adds only narrowing features. RMTA 2–3. Petitioner does not contend that proposed substitute claim 62 enlarges the scope of challenged patent claim 59. *See generally* RMTA Opp. We determine that proposed substitute claim 62 includes narrowing limitations and does not violate the statutory and regulatory prohibition of enlarging the scope of patent claims.

4. *New Matter*

An amendment may not introduce new matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). New subject matter is any addition to the claims that lacks sufficient support in the subject patent's original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When [an] applicant adds a claim . . . , the new claim[] must find support in the original specification."). Patent Owner also is required to show written description support in "the original disclosure of the patent for each claim that is . . . amended," and in "an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought." 37 C.F.R. § 42.121(b).

Having considered Petitioner's contrary position, we find Patent Owner has sufficiently set forth adequate written description support for proposed substitute claim 62 in the '589 patent.

Petitioner asserts that the added limitation of "'wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft' lacks written description," because the "[d]isclosure only supports a taper with a width that increases, not decreases, 'from the end of the first member' to the shaft." RMTA Opp. 4. Petitioner asserts that the ordinary artisan would understand that "the term 'end' is 'the extreme or last part lengthwise.'" *Id.* Petitioner asserts the "'head portion' does not start tapering with a decreasing width in Fig. 2 of the Original Disclosure at the extreme end, but rather at some undefined location spaced from the extreme end." *Id.* at 5.

We are not persuaded. Patent Owner identifies support for the taper language in the disclosure that "bulbous portion 202 has a taper, such as a

Morse taper, with a width that decreases from end 211 to end 212.” RMTA 9 (citing Ex. 2004, 9:14–20). Given that this language comes directly from the original disclosure and given that Figure 2 does not depict end 211 at the extreme end, Petitioner does not persuasively explain why a dictionary definition supersedes the explicit written and depicted definition of “end” as this term is used in the ’589 patent. Based on this disclosure, coupled with Figure 2 depicting a taper from end 211 to end 212 (at the shaft), we find that the limitation “wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft” has adequate written description support.

For these reasons, we determine that proposed substitute claim 62 is supported by the ’589 patent and does not introduce new matter.

Accordingly, we determine that Patent Owner has shown that proposed substitute claim 62 meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

D. Petitioner’s Assertions of Unpatentability

Petitioner contends that proposed substitute claim 62 is unpatentable under 35 U.S.C. § 102 as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as unpatentable over, Russell (Ex. 1021); and is unpatentable under 35 U.S.C. § 102 as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as unpatentable over, Czartoski (Ex. 1022). Petitioner also contends that claim 62 is “disclosed or rendered obvious by” Brumfield (Ex. 1002), Marcus (Ex. 1003), and Chandran (Ex. 1004). RMTA Opp. 11–25. Petitioner additionally challenges proposed substitute claim 62 as being indefinite and as failing to comply with the written description requirement. *Id.* at 3–5. We begin our analysis

with Petitioner's indefiniteness challenge, then turn to the written description challenge, and then address the prior art challenges.

1. *Indefiniteness*

Petitioner asserts that amended claim 62 is indefinite because “there is no antecedent basis for ‘the end’, ‘the first member’, ‘the shaft’ and ‘the mid-foot region’.” RMTA Opp. 3–4.

The Supreme Court interprets the definiteness requirement of 35 U.S.C. § 112(b) “to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014); USPTO Memorandum on the Approach to Indefiniteness Under 35 U.S.C. § 112 in AIA Post-Grant Proceedings (Jan. 6, 2021), *available at* <https://www.uspto.gov/sites/default/files/documents/IndefinitenessMemo.pdf>. “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing, LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (emphasis added).

According to Petitioner, based on the lack of antecedence, “a POSITA cannot determine what ‘end’ of what ‘member’ is being referred to in Claim 62.” RMTA Opp. 3. We disagree that the meaning of these terms is unclear. Three of these terms are recited in the following phrase, “wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft.” RMTA, Claims App. 24. Given that claim 62 previously recites, “a first screw member comprising a head portion at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end,” an ordinary artisan would

understand that “the first member” refers to the first screw member, because that is the only recited member that includes a head portion. Indeed, there are only two members recited, and the claimed “second member” is never referred to as a screw member. Thus, it is clear and definite to which member “the first member” refers.

Similarly, because the first shaft extends along a first longitudinal axis from the head portion to a second end, the recited taper “with a width that decreases from the end of the first member to the shaft” can only be interpreted as referring to the first end because that is the end associated with the head portion. An ordinary artisan would understand that an end does not decrease from itself, so the use of the word “end” in the phrase in claim 62 must refer to the first end. Likewise, because the limitation at issue is further defining the first screw member, one of ordinary skill in the art would understand that “the shaft” refers to the first shaft of the first screw member.

As to the recited “the mid-foot region,” every foot inherently has a mid-foot region. Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. *See Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359 (Fed. Cir. 2001). Because a person of ordinary skill in the art would know that the foot has a mid-foot region, a person of ordinary skill in the art would know with reasonable certainty where the claimed fixation system is intended to reside. Thus, “the mid-foot region” is not unclear, because an ordinary artisan would know to which region this refers.

We find that Petitioner has not proven, by a preponderance of the evidence, that proposed substitute claim 62 is unpatentable as indefinite under 35 U.S.C. § 112.

2. *Asserted Lack of Written Description*

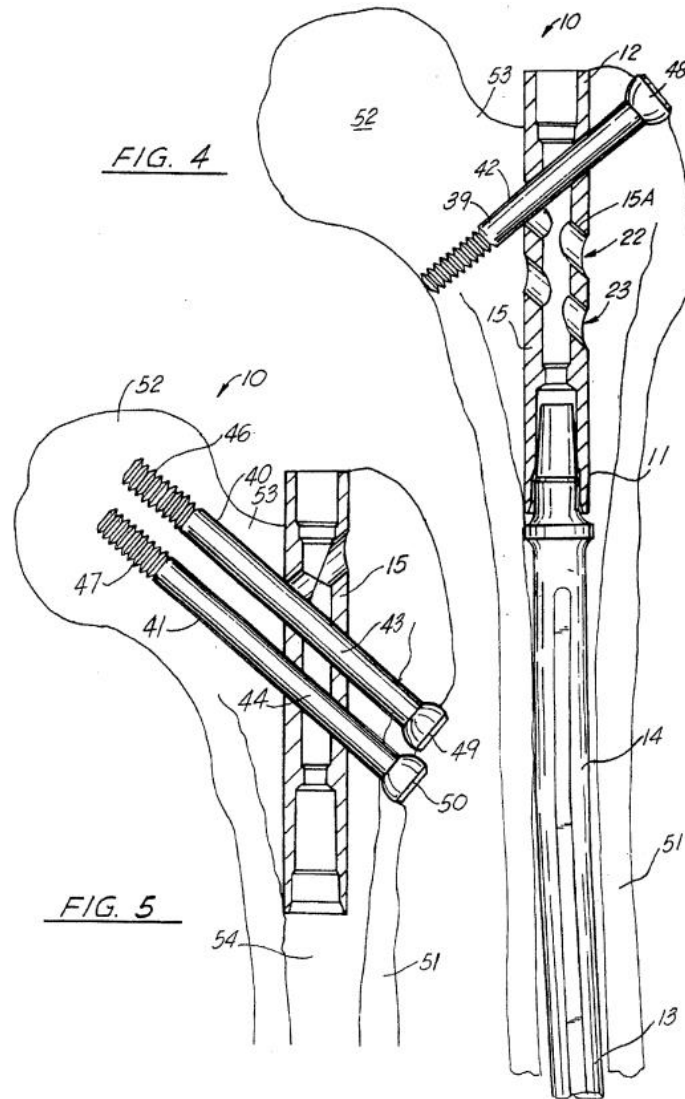
Petitioner contends that proposed substitute claim 62 fails to comply with the written description requirement for the same reasons discussed above that the proposed substitute claim allegedly seeks to add new subject matter. RMTA Opp. 4–5.

We find that the original disclosure of the '589 patent provides sufficient written description support for the added limitation “wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft,” as recited in proposed substitute claim 62, for the same reasons previously described in Section I.C.4 of this Decision.

We find that Petitioner has not proven, by a preponderance of the evidence, that proposed substitute claim 62 is unpatentable as lacking sufficient written description support under 35 U.S.C. § 112.

3. *Russell (Ex. 1021)*

Russell is a U.S. Patent drawn to treatments of femoral fractures using intramedullary rods and nails. Ex 1021, 1:6–8. Figures 4 and 5 of Russell, below, show the femoral mode and recon mode illustrated with respect to a patient's femur 51, femoral head 52, femoral neck 53, and intramedullary canal 54.



In FIG. 4, bone screw 39 has been placed through the passageway defined by opening 21 and cylindrically shaped section 29 of opening 25. Bone screw 39 has an unthreaded smooth cylindrically shaped section 42 with an outer surface that conforms to the inside wall 33 of opening 21 and the inside wall 37 of cylindrical section 29. In FIG. 5, the recon mode is shown with bone screws 40, 41 being positioned respectively through openings 22 and 23. The bone screw 40 extends along axis 27 through the passageway defined by opening 22 and cylindrical section 30 of opening 25. The bone screw 41 extends along axis 26 through the passageway defined by opening 23 and opening 24.

Ex. 1021, 5:44–57.

Figure 6 of Russell is reproduced below

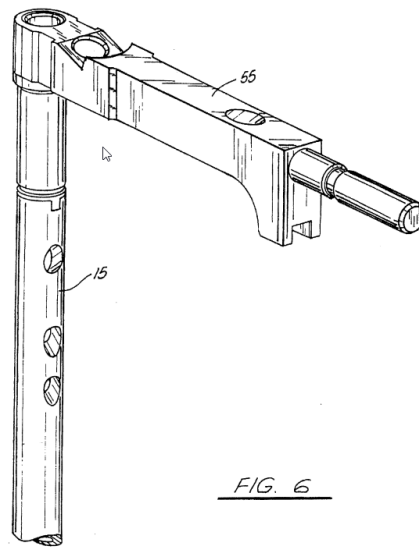


Figure 6 shows a drill guide for the bone apparatus attached to the device.
Ex. 1021, 4:50–52.

4. *Czartoski (Ex. 1022)*

Czartoski is a U.S. patent publication drawn “to a device for securing a prosthetic component to bone for use in orthopaedic trauma or orthopaedic joint products.” Ex. 1022, ¶ 2. Figures 2 and 3 of Czartoski are reproduced below.

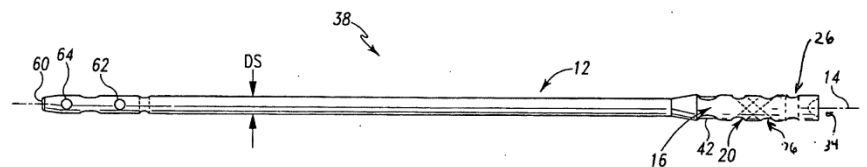


Fig. 2

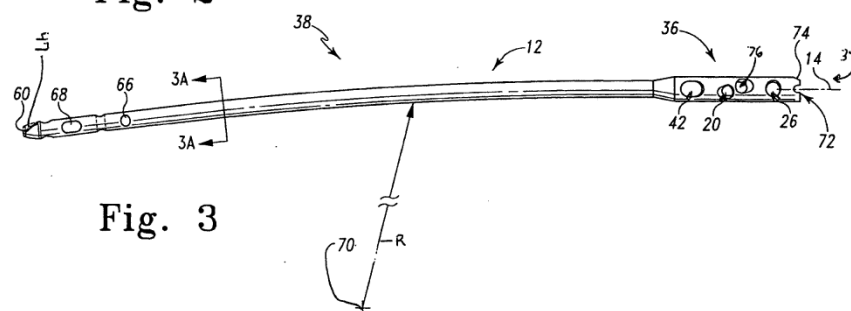


Fig. 3

The distal portion as shown in FIG. 2 is cylindrical and defined by diameter DS. The anterior/posterior view of the nail 12 of FIG. 2 is straight and extends along longitudinal axis 14. The nail 12 includes a series of holes or openings adjacent distal end 60 of the nail 12. As can be seen in FIGS. 2 and 3, the end 60 has a generally tapered shape to assist in the insertion of the nail 12 into the medullary canal. The distal portion 38 of the nail 12 near the end 60 includes a plurality of holes or openings for securing the distal portion 38 of the nail 12 in the long bone or femur 4. For example, and as shown in FIGS. 2 and 3, the anterior/posterior view of the nail 12 of FIG. 2 shows a first distal opening 62 and a second distal opening 64. The distal openings 62 and 64 as shown in FIG. 2 are transverse or perpendicular to longitudinal axis 14. Referring now to FIG. 3, the distal end 38 of the nail 12 may include additional holes near the end 60 of the nail 12. For example, and as shown in FIG. 3 the nail 12 includes a third distal opening 66 which is transverse to the longitudinal axis 14 of the nail 12 and a fourth distal opening 68 which is also transverse or perpendicular to the longitudinal axis 14 of the nail 12.

Figure 7 is reproduced below.

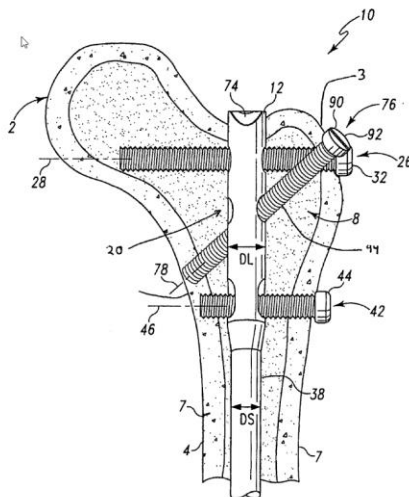


Fig. 7

In Figure 7,

the nail assembly 10 is shown installed in a left femur. The nail assembly 10 includes the nail 12 as well as second screw 32 which is positioned in second opening 26 and third screw 44 which is positioned in third opening 42. The nail assembly 10 as shown in FIG. 7, further includes fourth screw 90 which is positioned in fourth opening 76 and positioned along fourth opening centerline 78.

Ex. 1022, ¶¶ 112–113.

Figure 12A is reproduced below.



Fig. 12A

Figure 12A shows a cortical screw 96 which “may be fitted into any of the first opening 62, second opening 64, third opening 66 and fourth opening 68 of distal portion 38 of the nail 12 . . . [and] may include a head 98 for engagement with the outer cortical wall of the femur.” Ex. 1022, ¶ 126.

5. Asserted Anticipation/Obviousness of Claim 62 based on Russell

Petitioner asserts, regarding the preamble language of claim 62 to “*Preamble: ‘A fixation system for compressing bone,’*” that Russell satisfies the preamble because “Russell discloses a fixation system for compressing bone comprising nail 10, screw 39 and drill guide 55.” RMTA Opp. 11 (citing Ex. 1020 ¶ 67; Ex. 1021, Figs. 4, 6).

Petitioner contends, as to the recitation in claim 62 of “*Element 1: ‘a first screw member comprising a head portion at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end, ’*” that “Russell discloses first screw member 39 comprising a head portion 48 at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end.” RMTA Opp. 11–12 (citing Ex. 1020 ¶ 68; Ex. 1021, 5:61–63, Fig. 4).

Petitioner contends, as to the recitation in claim 62 of “*Element 2: ‘a second member comprising a second shaft extending from a first end to a second end along a second, straight longitudinal axis and a bore extending through said second shaft along a bore axis, ’*” that “Russell discloses a second member (nail 10) comprising a second shaft (nail body 12) extending from a first end to a second end along a longitudinal, straight axis 20 and a bore (29, 21-25) extending through shaft along a bore axis 28.” RMTA Opp. 12 (citing Ex. 1020 ¶ 69; Ex. 1021, 4:58–59, 5:14–17, 23–32, Fig. 1).

Petitioner contends, as to the recitation in claim 62 of “*Element 3: ‘an instrument adapted for coupling said first screw member to said second member, ’*” that “Russell discloses a drill guide 55 illustrated in Figure 6 that is attached to an open top of nail 10 and adapted for coupling the first screw member to the second member.” RMTA Opp. 12–13 (citing Ex. 1020 ¶ 70; Ex. 1021, 5:9–12, Fig. 6).

Petitioner contends, as to the recitation in claim 62 “*Element 4: ‘wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft, ’*” that “Russell discloses the head portion 48 of the first member 39 is tapered with a width that decreases from the end of the first member to the shaft.” RMTA Opp. 13 (citing Ex. 1020 ¶¶ 71–72; Ex. 1021, 5:62–63, Fig. 4).

Petitioner contends, as to the recitation in claim 62 “*Element 5: ‘wherein said second longitudinal axis and said bore axis define an angle,’*” that “Russell discloses the second longitudinal axis 20 and the bore axis 28 defining an angle, as shown in annotated Figure 1 [in the Opposition].” RMTA Opp. 13–14 (citing Ex. 1020 ¶ 73; Ex. 1021 at Fig. 4, 5:23–26.)

Petitioner contends, as to the recitation in claim 62 “*Element 6: wherein said first screw member is adapted for coupling to said second member at said angle,’*” that “Russell discloses screw 39 being adapted for coupling to nail 10 at the angle defined by the bore axis 28 through nail 10, as disclosed in the portion of Figure 4 shown [in the Opposition].” RMTA Opp. 14 (citing Ex. 1020 ¶ 74; Ex. 1021 at Fig. 1, 4, 5:32–34.)

Petitioner contends, as to the recitation in claim 62 “*Element 7: ‘wherein each of said first screw and said second members is adapted for residing substantially within at least one bone in the midfoot region,’*” that “Russell discloses this limitation. See Section III.B.(2) [of the Opposition].” RMTA Opp. 14 (citing Ex. 1020 ¶ 75–77, 112–116)

Petitioner contends, as to the recitation in claim 62 “*Element 8: ‘wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling said instrument,’*” that “Russell discloses nail body 12 having first and second circumferentially spaced recesses (shown below) adapted for coupling guide 55, as shown in annotated Figures 1 and 6.” RMTA Opp. 14–15 (citing Ex. 1020 ¶ 78; Ex. 1021 at Figs. 1, 6).

We have reviewed the evidence and we agree that Russell discloses each of the limitations for the reasons stated by Petitioner and in particular, we find that the cited record provides evidentiary support showing Russell’s

disclosure of the limitations at issue. Ex. 1020 ¶¶ 67–78, 112–116 ; Ex. 1021, 4:58–59, 5: 5:9–12, 14–17, 23–34, 61–63; Ex. 1021, Figs. 1, 4, 6.

We address Patent Owner’s responsive arguments below.

Patent Owner contends that Russell’s second member (nail 10) does not extend along a straight line, because “Petitioner’s expert [conceded] that shaft is curved.” RMTA Reply 6. (citing Ex. 1021, Fig. 4; Ex. 2007, 19:1–18).

Russell discloses that “[i]ntramedullary nail 10 provides a central longitudinal bore” including bore 17 extending below head 15 and bore 18 in head 15. Ex. 1021, 5:3–6. Russell further discloses that “bores 17, 18 have a common central longitudinal axis 20.” *Id.* at 5:7. Based on this disclosure, a preponderance of the evidence supports Petitioner’s assertion that Russell discloses a second member, i.e., nail 10, that extends along a straight line of common central axis 20. That Patent Owner points to a second embodiment not relied upon by Petitioner does not affect whether Russell teaches this limitation. *See* RMTA Sur-reply 9–10. Simply because one embodiment of Russell teaches the limitation and one does not “is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.” *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976). Preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971).

Patent Owner contends that Russell’s drill guide 55 is not “‘an instrument adapted for coupling said first screw member to said second member,’ as recited in Claim 62.” RMTA Reply 6. According to Patent Owner, Russell’s “head (15) [merely] provides a place for the attachment of drill guide (55).” *Id.* at 6–7 (citing Ex. 1021, 5:9–12).

Petitioner's expert opines that drill guide 55 is adapted for coupling the first screw member and the second member, because "[t]he hole in drill guide 55 aligns with opening 21 for use of a drill and insertion of screw 39 during use." Ex. 1020 ¶ 70 (citing Ex. 1021, 5:9–12, Fig. 6). We agree. Russell discloses that "[a] drill guide which can be inserted in the proximal end of the extension provides a convenient tool for predrilling the femur at the proper places and at the proper angles." Ex. 1021, 2:11–14. Given that Figure 4 of Russell depicts screw 39 in a hole in the femur, and that screw 39 is aligned with opening 21 in head 15 of nail 10, it logically follows that drill guide 55 was used to make the hole. Because Petitioner relies on screw 39 as a first member and relies on nail 10 as a second member, we agree with Petitioner's expert that drill guide 55 is adapted for coupling the first screw member with the second member, because it is used for aligning the holes and openings for coupling the first screw member and the second member.

Patent Owner argues that Russell "states explicitly that it is directed to devices for treating fractures of the femur, the upper bone of the leg and the longest bone in the body," and does not suggest "using the disclosed devices in the mid-foot region." RMTA Reply 8. According to Patent Owner, adapting Russell's nail "so that it fits within the bones in the mid-foot region would require the nail to be scaled so that it is comically thin as compared to those bones." *Id.* at 8–9. Thus, Patent Owner asserts that "Russell cannot be credibly seen to disclose a first screw member and second member adapted for residing substantially within the mid-foot region. Nor would it have been obvious, or 'a simple matter' as [Mr.] Sherman puts it, to adapt Russell to be used in the mid-foot region." *Id.* at 9.

We are not persuaded. The added limitation of "adapted for residing

substantially within at least one bone *in the mid-foot region*” is an intended use type recitation in a product claim. Patent Owner has not identified, nor do we see, differences in structure that the Specification teaches are necessary to adapt the device. *See In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Circ. 1997) (“the burden shifted to Schreiber to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus.”).⁸ Claim 62 does not impose specific size constraints that would differentiate between the femur and mid-foot region, and the femur of a child might well be smaller than the mid-foot region of a large individual.

Moreover, we need not shift the burden to Patent Owner in this case, but rather can note that the Specification of the ’589 patent itself discloses that the invention relates “to an intramedullary fixation assembly used for internal fixation of angled joints, bones and deformity correction,” that “may be utilized to treat *any* bones in human body.” Ex. 1001, 1:15–17, 2:2–3 (emphasis added). Consequently, the ordinary artisan would reasonably expect the device of Russell to function in other bones just as the device recited in claim 62.

Patent Owner asserts, and we adopted above, that one of ordinary skill would be a person with a Bachelor’s Degree in biomedical and/or mechanical engineering or similar training and would have at least three years of experience with implant devices used for internal fixation of bones. RMTA 12 (citing Ex. 2006 ¶¶ 27–31). Patent Owner does not assert that

⁸ When asked at oral argument about the meaning of the term “adapted [to be used in] the mid-foot . . .” [which occurs in proposed substitute claim 62], counsel for Patent Owner responded that the term means “straight.” Paper 34 (Tr.), 29:16–25, 36:19–26.

one of ordinary skill has experience with only one type of bone. Thus, it appears that one of ordinary skill would be experienced in treating many types of bones and would know what needs to be modified or adjusted to adapt a device for a particular bone. Because Patent Owner has not identified structure that is necessary to adapt the device for the mid-foot region, absent evidence that adapting Russell's device for a mid-foot region would have been beyond the capabilities of one of ordinary skill in the art, we find persuasive the opinion of Petitioner's expert that a person of ordinary skill would have had sufficient skill to adapt Russell's fixation system to reside within a bone in the mid-foot region. *See* Ex. 1020 ¶¶ 75–77 (“[A] POSITA would be aware of the requirements for a navicular cuneiform joint fusion, including the appropriate size of the nail body, screws and angles, forces, etc., and would be able to apply the teachings from Russell to adapt the fixation system in Russell by taking the local anatomy and joint specific requirements into consideration.”).

Accordingly, for the foregoing reasons, we conclude that Petitioner has shown, by a preponderance of the evidence, that the limitations of proposed substitute claim 62 are anticipated under 35 U.S.C. § 102 and are rendered obvious under 35 U.S.C. § 103 by Russell.

6. *Asserted Anticipation/Obviousness of Claim 62 Based on Czartoski*

Petitioner asserts, regarding the preamble language of claim 62 to “*Preamble: ‘A fixation system for compressing bone,’*” that “Czartoski discloses a fixation system for compressing bone comprising nail, screws and instrument to engage the screws to lock the screws in position in the nail.” RMTA Opp. 15–16 (citing Ex. 1020 ¶ 83; Ex. 1022 ¶¶ 86–87, 108, 121, 164, Figs. 1, 2, 11).

Petitioner contends, as to the recitation in claim 62 of “*Element 1: ‘a first screw member comprising a head portion at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end,’*” that “Czartoski discloses screws (e.g. 44, 96) comprising a head portion at a first end and a first shaft extending along a first longitudinal axis from the head portion to a second end.” RMTA Opp. 16 (citing Ex. 1020 ¶ 84; Ex. 1022 ¶¶ 121, 126, 164, Figs. 11, 12A, 28).

Petitioner contends, as to the recitation in claim 62 of “*Element 2: ‘a second member comprising a second shaft extending from a first end to a second end along a second, straight longitudinal axis and a bore extending through said second shaft along a bore axis,’*” that “Czartoski discloses a nail 12 (2nd member) comprising a proximal shaft portion 36 (2nd shaft) for use within a bone.” RMTA Opp. 16–17 (citing Ex. 1020 ¶ 85; Ex. 1022 ¶¶ 86, 98, Fig. 2–5).

Petitioner contends, as to the recitation in claim 62 of “*Element 3: ‘an instrument adapted for coupling said first screw member to said second member,’*” that “Czartoski discloses a ‘threaded fastener’ that is threadably attached to a threaded counterbore 86 of nail 12 (*see* Fig. 5) that ‘engage[s] the screws to lock the screws in position in the nail.’” RMTA Opp. 17 (citing Ex. 1020 ¶¶ 86–87; Ex. 1022 ¶ 108).

Petitioner contends, as to the recitation in claim 62 “*Element 4: ‘wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft,’*” that “Czartoski discloses a tapered head portion of the first member with a width that decreases from the end of the first member to the shaft.” RMTA Opp. 18 (citing Ex. 1020 ¶¶ 88–89, Ex. 1022, Figs. 11, 12A, 28).

Petitioner contends, as to the recitation in claim 62 “*Element 5: ‘wherein said second longitudinal axis and said bore axis define an angle,’*” that “Czartoski discloses a second longitudinal axis and bore axis defining an angle.” RMTA Opp. 18 (citing Ex. 1020 ¶¶ 90–91; Ex. 1022 ¶ 116, Figs. 5, 7).

Petitioner contends, as to the recitation in claim 62 “*Element 6: wherein said first screw member is adapted for coupling to said second member at said angle,’*” that “Czartoski discloses screw being adapted for coupling to nail at the angle defined by the bore axis through nail.” RMTA Opp. 14 (citing Ex. 1020 ¶ 91; Ex. 1022 ¶ 116, Figure 7.)

Petitioner contends, as to the recitation in claim 62 “*Element 7: ‘wherein each of said first screw and said second members is adapted for residing substantially within at least one bone in the midfoot region,’*” that Czartoski discloses this limitation. RMTA Opp. 19 (citing Ex. 1020 ¶ 92–95, 112–116).

Petitioner contends, as to the recitation in claim 62 “*Element 8: ‘wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling said instrument,’*” that “Czartoski discloses proximal portion 36 of the nail 12 having first and second circumferentially spaced recesses (notch 72 in Fig. 3).” RMTA Opp. 19–20 (citing Ex. 1020 ¶ 96; Ex. 1022 ¶ 103, Figs. 3, 10).

We have reviewed the evidence and we agree that Czartoski discloses each of the limitations for the reasons stated by Petitioner and in particular, we find that the cited record provides evidentiary support showing Czartoski’s disclosure of the limitations at issue. Ex. 1020 ¶¶ 83–96; Ex. 1022 ¶¶ 86–87, 98, 103, 108, 116, 121, 126, 164, Figs. 1–5, 7, 10, 11, 12A, 28.

Patent Owner contends that Czartoski's "shaft (38) is curved and does [not] extend along a straight, longitudinal axis as recited in Claim 62." RMTA Reply 9 (citing Ex. 1022 ¶¶ 95–96, 102 ("The medial/lateral plane of the femur is curved and, as such, the nail 12 is curved in the distal portion 38.")). According to Patent Owner, Czartoski's disclosure that "nail 12 may have any 'shape'" refers to the cross-sectional shape, because "the cited paragraph makes clear that the nail must be shaped to fit a femur (i.e., curved)." *Id.*

We do not agree. Petitioner's expert notes that "Czartoski discloses a nail 12 (second member) comprising a proximal portion 36 (second shaft) for use within a long bone." Ex. 1020 ¶ 85. Although we appreciate that the femur may be curved, Czartoski discloses that "long bones include the femur, fibula, tibia, humerus, radius and ulna." Ex. 1022 ¶ 3. We find persuasive Petitioner's expert's testimony that "'nail 12 may have any suitable shape,' which would include straight." Ex. 1020 ¶ 85 (citing Ex. 1022 ¶ 87).

Patent Owner asserts, Czartoski does not disclose "an instrument adapted for coupling a first screw member to a second member, as recited in Claim 62," and "Petitioner failed to show that an instrument adapted for coupling the first screw member to the second member would have been obvious in view of Czartoski and any of the other cited references." RMTA Reply 10–11. We disagree.

Czartoski discloses that "internal threads 88 may cooperate with a threaded fastener (not shown), which may engage the screws to lock the screws in position in the nail." Ex. 1022 ¶ 108. Given that the threads are in the nail (second member), and engage the screws (first member), we

understand the “threaded fastener (not shown)” is an instrument that couples the screw member to the nail (second member) by “lock[ing] the screws in position in the nail.” We are persuaded by Petitioner’s unrebutted expert testimony that based on this disclosure, “Czartoski explicitly teaches an instrument adapted for coupling the first screw member to the second member.” RMTA Sur-reply 12.

We also are unpersuaded by Patent Owner’s argument that “Czartoski refers to ‘long bones,’ but does not refer to any bones of the foot.” RMTA Reply 11. For the same reasons discussed above, because Patent Owner has not identified structure that is necessary to adapt the device for the mid-foot region, absent evidence that adapting Czartoski’s device for a mid-foot region would have been beyond the capabilities of one of ordinary skill in the art, we find persuasive the opinion of Petitioner’s expert that a person of ordinary skill could, and would have had reason to, adapt Czartoski’s fixation system to reside within a bone in the mid-foot region. *See* Ex. 1020 ¶¶ 92–95 (“A POSITA would understand the anatomy of the foot bones and the pathology required to adapt the fixation system disclosed in Czartoski to the mid-foot region bones.”).

Having considered Patent Owner’s contrary assertions, Petitioner has shown by a preponderance of the evidence that the limitations of proposed substitute claim 62 are anticipated under 35 U.S.C. § 102 and rendered obvious under 35 U.S.C. § 103 by Czartoski.

7. *Asserted Obviousness of claim 62 Based on Brumfield, Marcus, and/or Chandran*

Petitioner asserts that the limitations added to claim 62 “are disclosed or rendered obvious by Brumfield, Marcus and/or Chandran.” RMTA Opp. 20–21. In particular Petitioner asserts that these references “disclose a

‘first screw member’ comprising a head portion ‘at a first end’ and a first shaft extending along a first longitudinal axis ‘from the head portion to a second end.’” RMTA Opp. 21 (citing Ex. 1020 ¶¶ 101, 108; Ex. 1002, Fig. 6; Ex. 1003, Fig. 1; Ex. 1004, Fig. 4). Petitioner asserts that these references also disclose a second member comprising a second shaft “extending from a first end to a second end along a second straight, longitudinal axis.” RMTA Opp. 21–22 (citing Ex. 1020 ¶¶ 102, 109–110; Ex. 1002, Fig. 2; Ex. 1003, Fig. 1; Ex. 1004, Fig. 3). Petitioner asserts that the references “also disclose ‘wherein the head portion of the first member is tapered with a width that decreases from the end of the first member to the shaft,’” in particular Brumfield’s “‘beveled head 48.’” RMTA Opp. 23 (citing Ex. 1002, 5:20–22; Ex. 1020 ¶¶ 104, 110). As to the recited “in the mid-foot region,” Petitioner asserts that this limitation is disclosed or rendered obvious by each reference. RMTA Opp. 25 (citing RMTA Opp. 8–10).

Patent Owner asserts that Petitioner improperly incorporates by reference Petitioner’s arguments regarding “the limitations of Claim 62 which Patent Owner did not amend.” RMTA Reply 11.

Although we appreciate that Petitioner cannot incorporate findings by reference, “the Board determines whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner.” *Lectrosonics*, Paper 15 at 4. Petitioner has already established, by a preponderance of the evidence, that the limitations of proposed substitute claim 62, present in original claim 59 and which Patent Owner did not amend, are disclosed by each of Brumfield, Marcus, and Chandran. *See supra* Sections X.C.1., X.D.1., X.E.1.

Patent Owner reiterates that Brumfield, Marcus, and Chandran do not disclose “apparatuses adapted for residing in the rear-foot region.” RMTA Reply 12 (citing RMTA 16–19). According to Patent Owner, these references do “not disclose a first screw member and second member adapted for residing substantially within the mid-foot region. Nor would it have been obvious, or as [Mr.] Sherman puts it a simple matter, to adapt the devices disclosed in [Brumfield, Marcus, and Chandran] to be used in the mid-foot region.” *Id.*

For the reasons discussed above, because claim 62 does not have any identified structure that is necessary to adapt the device for the mid-foot region, absent evidence that adapting Brumfield, Marcus, and Chandran’s device for a mid-foot region would not have been obvious to one of ordinary skill in the art, we find persuasive the opinion of Petitioner’s expert that a person of ordinary skill would have been able, and had reason, to adapt Brumfield, Marcus, and Chandran’s fixation systems to reside within a bone in the mid-foot region. *See* Ex. 1020 ¶¶ 99–100 (“A POSITA prior to the filing of the ‘589 Patent would understand the anatomy of the bones of the human body including the mid-foot and the design modifications required to adapt the fixation assemblies disclosed in Brumfield, Marcus or Chandran to substantially reside in the bones of the mid-foot.”).

Accordingly, for the foregoing reasons, we conclude that Petitioner has shown, by a preponderance of the evidence, that the limitations of proposed substitute claim 62 are rendered obvious under 35 U.S.C. § 103 by Brumfield, Marcus, and Chandran.

XII. CONCLUSION⁹

After considering the evidence and arguments presently before us in the complete trial record, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 59 is unpatentable. We further conclude that Petitioner has also shown, by a preponderance of the evidence, that proposed substitute claim 62 is unpatentable. In summary,

Claim	35 U.S.C. §	Reference(s)/Basis	Claim Shown Unpatentable	Claims Not Shown Unpatentable
59	102	Brumfield	59	
59	102	Marcus	59	
59	102	Chandran	59	
Overall Outcome			59	

Motion to Amend Outcome	Claim
Original Claims Cancelled by Amendment	
Substitute Claim Proposed in the Amendment	62
Substitute Claim: Motion to Amend Granted	
Substitute Claim: Motion to Amend Denied	62
Substitute Claims: Not Reached	

⁹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

XIII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 59 of the '589 patent is determined to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend is denied as to the request to add proposed substitute claim 62 to the '589 patent; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2022-00802
Patent 8,303,589 B2

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