

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of:

U.S. Patent No. 8,702,707

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Named Inventor: Gary W. Sohngen

Recorded Assignee: Advanced
Orthopaedic Solutions, Inc.

Title: Fixation Instrument for Treating
a Bone Fracture

Trial Number: To Be Assigned

Panel: To Be Assigned

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,702,707
UNDER 35 U.S.C. § 311 AND 37 C.F.R. § 42.100

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Compliance with Requirements for <i>Inter Partes</i> Review	1
A.	Mandatory Notices (37 C.F.R. § 42.8(a)(1)).....	1
a.	Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))	1
b.	Related Matters (37 C.F.R. § 42.8(b)(2))	1
c.	Designation of Lead and Backup Counsel and Service Information (37 C.F.R. §§ 42.8(b)(3)-(4)).....	2
B.	Fee for <i>Inter Partes</i> Review (37 C.F.R. § 42.103).....	2
C.	Grounds for Standing (37 C.F.R. § 42.104(a))	2
III.	Identification of Challenge (37 C.F.R. § 42.104(b))	3
IV.	Relevant Background of the '707 Patent.....	4
A.	Level of Ordinary Skill	4
B.	Description of the Alleged Invention of the '707 Patent	5
C.	Summary of the Prosecution History of the '707 Patent	5
D.	Summary of the Prosecution History of the '454 Patent	6
V.	Claim Construction.....	9
VI.	Reasonable Likelihood that Claims 1-10 Are Unpatentable	11
A.	GROUND 1: Claims 1-10 Are Anticipated By Roth Under 35 U.S.C. § 102.	11
a.	The Applicant Relied on Certain Limitations to Distinguish the '454 Patent Over Roth, But Did Not Include Those Limitations in the '707 Patent.	12
b.	Claim 1 Is Anticipated By Roth.....	13
c.	Claim 2 Is Anticipated By Roth.....	20

d.	Claim 3 Is Anticipated By Roth.....	23
e.	Claim 4 Is Anticipated By Roth.....	24
f.	Claim 5 Is Anticipated By Roth.....	25
g.	Claim 6 Is Anticipated By Roth.....	26
h.	Claim 7 Is Anticipated By Roth.....	29
i.	Claim 8 Is Anticipated By Roth.....	30
j.	Claim 9 Is Anticipated By Roth.....	32
k.	Claim 10 Is Anticipated By Roth.....	32
B.	GROUND 2: Claims 1-10 are rendered obvious by Shavit in view of Kilpela under 35 U.S.C. § 103(a).....	36
a.	Claim 1 Is Rendered Obvious by Shavit in view of Kilpela.	37
b.	Claim 2 Is Rendered Obvious By Shavit in view of Kilpela....	45
c.	Claim 3 Is Rendered Obvious By Shavit in view of Kilpela....	47
d.	Claim 4 Is Rendered Obvious By Shavit in view of Kilpela....	49
e.	Claim 5 Is Rendered Obvious By Shavit in view of Kilpela....	50
f.	Claim 6 Is Rendered Obvious By Shavit in view of Kilpela....	50
g.	Claim 7 Is Rendered Obvious By Shavit in view of Kilpela....	54
h.	Claim 8 Is Rendered Obvious By Shavit in view of Kilpela....	56
i.	Claim 9 Is Rendered Obvious By Shavit in view of Kilpela....	57
j.	Claim 10 Is Rendered Obvious By Shavit in view of Kilpela..	58
C.	Grounds 1 and 2 Are Not Cumulative.....	59
VII.	Conclusion	59

TABLES OF AUTHORITIES

Cases

<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	40
<i>KSR Int'l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007).....	41
<i>Nano-Second Tech. Co. v. Dynaflex Int'l</i> , 944 F. Supp. 2d 855 (C.D. Cal. 2013)	48, 54
<i>Nuvasive v. Warsaw Orthopedic, Inc.</i> , IPR2013-00206, Paper No. 17 (P.T.A.B. Sept. 23, 2013)	10
<i>Pharmatech Solutions, Inc., v. Lifescan Scotland</i> , IPR2013-00247, Paper No. 27 (P.T.A.B. Aug. 6, 2014).....	48, 54
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (<i>en banc</i>)	10

Statutes

35 U.S.C. § 102	4, 12, 62
35 U.S.C. § 102(a)	4
35 U.S.C. § 102(e)	4
35 U.S.C. § 103	4
35 U.S.C. § 103(a)	5, 38
35 U.S.C. § 112.....	4
35 U.S.C. § 311	1
35 U.S.C. § 315	3

Regulations

37 C.F.R. § 1.68	5
37 C.F.R. § 42.10(b)	2
37 C.F.R. § 42.100	1, 10
37 C.F.R. § 42.103	3
37 C.F.R. § 42.104(a).....	3
37 C.F.R. § 42.104(b)	4
37 C.F.R. § 42.11	34
37 C.F.R. § 42.15(a).....	3
37 C.F.R. § 42.8(a)(1)	1
37 C.F.R. § 42.8(b)(1).....	1
37 C.F.R. § 42.8(b)(2).....	1
37 C.F.R. § 42.8(b)(3).....	2
37 C.F.R. § 42.8(b)(4).....	2

I. Introduction

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, Petitioner Zimmer Biomet Holdings, Inc. (“Zimmer Biomet”) respectfully requests *inter partes* review (“IPR”) of claims 1-10 of U.S. Patent No. 8,702,707 (“the ’707 Patent”), which is attached to this Petition as Exhibit 1004.¹ The USPTO assignment records indicate that the Applicant of the ’707 Patent assigned their rights to Advanced Orthopaedic Solutions, Inc. (“AOS”). (Ex. 1009.)

II. Compliance with Requirements for *Inter Partes* Review

A. Mandatory Notices (37 C.F.R. § 42.8(a)(1))

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

a. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

Zimmer Biomet Holdings, Inc., Zimmer, Inc., and Biomet, Inc. are the real parties-in-interest. Zimmer Biomet Holdings, Inc. acquired Biomet, Inc. in June 2015.

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

The ’707 Patent is the subject of the civil action *Advanced Orthopaedic Solutions, Inc. v. Biomet Inc. et al.*, Case No. 2:14-cv-06354 ODW-(MANx), filed on August 13, 2014 in the U.S. District Court for the Central District of California.

¹ Citations throughout this Petition refer to the original page numbers of exhibits.

Biomet, Inc. was first served with a complaint alleging infringement of the '707 patent on December 2, 2014. (Ex. 1010.) This case is currently pending and may affect, or be affected by, decisions in this proceeding.

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

Lead Counsel	Backup Counsel
Eric D. Hayes (Reg. No. 53,004) eric.hayes@kirkland.com <u>Postal and Hand-Delivery Address:</u> KIRKLAND & ELLIS LLP 300 North LaSalle Street Chicago, Illinois 60654 Telephone: (312) 862-2000 Fax: (312) 862-2200	Xun (Michael) Liu (Reg. No. 68,815) michael.liu@kirkland.com <u>Postal and Hand-Delivery Address:</u> KIRKLAND & ELLIS LLP 300 North LaSalle Street Chicago, Illinois 60654 Telephone: (312) 862-2000 Fax: (312) 862-2200

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition. Please address all correspondence to lead and back-up counsel. Zimmer Biomet consents to electronic service by electronic mail.

B. Fee for *Inter Partes* Review (37 C.F.R. § 42.103)

Review of ten (10) claims is requested. Zimmer Biomet authorizes the PTO to charge Deposit Account No. 506092 for the fee set forth in 37 C.F.R. § 42.15(a) for this Petition. Zimmer Biomet also authorizes the PTO to charge to this Deposit Account for any additional fees that may be due in connection with this Petition.

C. Grounds for Standing (37 C.F.R. § 42.104(a))

Zimmer Biomet certifies that it has standing to request, and is not barred from requesting, an IPR of the '707 Patent pursuant to 35 U.S.C. § 315. Neither

Zimmer Biomet nor any privy of Zimmer Biomet has filed any civil actions challenging the validity of any claim of the '707 Patent. Neither Zimmer Biomet nor any privy of Zimmer Biomet has previously requested IPR of the '707 Patent. Zimmer Biomet further certifies that it files this petition less than one year after the date on which Zimmer Biomet or any privy of Zimmer Biomet was served with a complaint alleging infringement of the '707 Patent.

III. Identification of Challenge (37 C.F.R. § 42.104(b))

Zimmer Biomet requests institution of an IPR and cancellation of claims 1-10 of the '707 Patent based on the following prior art references:²

Roth. United States Patent 6,835,197 to Roth ("Roth") is attached as Ex. 1006. Roth was filed on October 17, 2001 and issued on December 28, 2004. Thus, Roth is at least prior art under 35 U.S.C. § 102(e). Roth was cited during the prosecution history of the '707 Patent, but was not substantively discussed.

Shavit. World International Application Publication No. WO 03/061495 to Shavit et al. ("Shavit") is attached as Ex. 1007. Shavit was filed on January 22, 2003 and published on July 31, 2003, and is prior art under at least 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e). Shavit was not cited or discussed in the prosecution history of the '707 Patent.

² References to 35 U.S.C. §§ 102, 103, and 112 throughout this Petition are to the pre-AIA versions of those provisions, which are applicable to the '707 Patent.

Kilpela. United States Patent 6,123,708 to Kilpela et al. (“Kilpela”) is attached as Ex. 1008. Kilpela issued on September 26, 2000 and is prior art under 35 U.S.C. 102 (b). Kilpela was not cited or discussed in the prosecution history of the ’707 Patent.

The Board should find claims 1-10 of the ’707 Patent unpatentable based on the following proposed statutory grounds:

- (1) Claims 1-10 are anticipated by Roth under 35 U.S.C. § 102;
- (2) Claims 1-10 are rendered obvious by Shavit in view of Kilpela under 35 U.S.C. § 103 (a).

Zimmer Biomet sets forth below the relevant background of the ’707 Patent (Section IV), how the contested claims are to be construed (Section V), and how the construed claims are unpatentable under the statutory grounds specified above (Section VI). Attached is an Appendix of Exhibits setting forth numbered exhibits supporting this Petition. Under 37 C.F.R. § 1.68, Zimmer Biomet also submits a declaration by Dr. Richard F. Kyle in support of this Petition. (Ex. 1001.)

IV. Relevant Background of the ’707 Patent

A. Level of Ordinary Skill

A person of ordinary skill in the art at the time of the alleged invention would have a bachelor’s degree in biomedical engineering, a bachelor’s degree in

mechanical engineering with coursework in biomechanics or orthopaedics, or at least 3 years of experience designing orthopaedic implants. (Ex. 1001 at ¶ 17.)

B. Description of the Alleged Invention of the '707 Patent

The '707 Patent describes “a nail and bone screw combination used to treat a fracture of the femur.” (Ex. 1004, '707 Patent, at 1:16-20.) The nail 22 has a chamber 42 in the proximal end, which contains an insert 36 to engage the bone screw 32 and a locking ring 60 that secures the insert. (*Id.* at 1:59-61.) The insert is “rotatably attached” to the locking ring, so that when “the locking ring 60 is rotated by a suitable tool, the locking ring 60 moves the insert 36 longitudinally” within the chamber. (*Id.* at 4:29-34.) As the insert moves downward, a portion of the distal end of the insert “is received in one of . . . [the] grooves [of the bone screw] to resist rotation of said bone screw.” (*Id.* at claim 1.)

C. Summary of the Prosecution History of the '707 Patent

The '707 Patent issued from U.S. Application No. 13/335,696 (“the '696 application”), filed on December 22, 2011 as a continuation to U.S. Application No. 11/078,750, which issued as U.S. Patent 8,092,454 (“the '454 Patent”), (Ex. 1005). The '707 Patent claims priority to U.S. Provisional Application No. 60/552,229, filed on March 11, 2004. (Ex. 1012.)

After receiving the filed '696 application, the Examiner imposed a restriction requirement, (Ex. 1015, 1/23/13 Action, at 2), and the Applicants

elected to continue prosecuting Figures 1-6 and claims 21-30 of the original application. (Ex. 1016, 2/4/13 Response, at 1.)

On April 5, 2013, the Examiner rejected the pending claims under § 112, § 102 (b) and § 103(a). (Ex 1017, 4/5/13 Action.) The Examiner determined various references anticipated and/or rendered obvious the pending claims. (*Id.* at 9-10, 12-14.) The Examiner indicated that claim 29 would be allowable if rewritten as an independent claim. In response to the § 102(b) rejection, the Applicant argued that each reference failed to disclose limitations directed to the locking ring. In response to the § 103(a) rejection, Applicant argued that the Examiner did not provide a reason to combine. (*Id.* at 9-11.) A notice of allowance was issued for the '696 application on December 2, 2013. (Ex. 1019, 12/2/2013 Notice.)

D. Summary of the Prosecution History of the '454 Patent

The '454 Patent issued from U.S. Application No. 11/078/750 ("the '750 application"), filed on March 11, 2005. (Ex. 1014.) The Applicant narrowed the '454 patent claims during prosecution to avoid the prior art, including Roth. As set forth in detail below, the limitations that the Applicant included to distinguish the '454 patent over Roth are not in the '707 patent claims.

On October 26, 2006, the Examiner issued an office action that rejected all pending claims based on various prior art references, including U.S. Publication

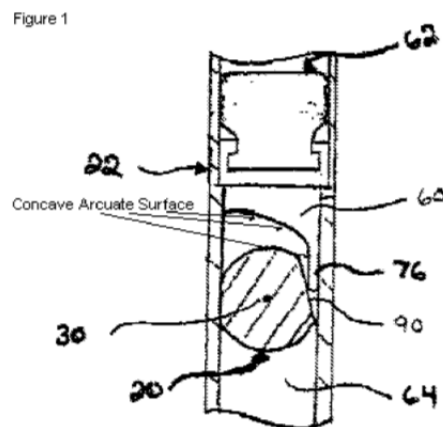
2003/0074000 (“Roth Publication,” which issued as Roth). (Ex. 1020, 10/26/06 Action, at 1, 3-7, 8-10.) To overcome the rejections, the Applicant added new limitations and redrafted several dependent claims into independent form. (Ex. 1021, 3/26/07 Resp., at 3-10.) Among the changes, the Applicant amended claim 6 to recite an insert with “a lower surface [that] ... includes a locking projection wherein the lower surface is operative to contact a bone screw.” (*Id.* at 12.)

In the second office action, the Examiner continued to reject claims based on various references. (Ex. 1022, 6/13/07 Action, at 2-11.) And in a third office action, the Examiner found several claims obvious in view of various references including U.S. Patent 7,306,600 (“Roth II”).³ (Ex. 1024, 2/4/08 Action at 7.) The Applicant then further amended the claims. (Ex. 1025, 5/29/2008 Resp., at 2-9.) For example, the Applicant amended claim 6 to recite a bone screw with “longitudinal extending grooves ... wherein said locking projection is located in one of said grooves when said lower surface contacts said bone screw.” (*Id.*)

In a final office action on August 18, 2008, the Examiner rejected every claim except for 15, 16 and 20. (Ex. 1026, 8/18/08 Action, at 1.) In response, the Applicant filed a Request for Continued Examination (“RCE”), (Ex. 1027,

³ Roth II issued from a divisional application of U.S. App. No. 09/978,002, which later issued as U.S. Patent 6,835,197 (Roth). Roth and Roth II contain the same disclosure.

12/18/08 RCE, at 11), along with amended claims. (Ex. 1028, 12/18/08 Resp., at 11.) The Examiner then issued another final rejection. (Ex. 1029, 3/9/09 Action.) The Applicant filed a pre-appeal brief request, (Ex. 1030, 06/09/2009 Req.), and the Patent Office reopened prosecution. (Ex. 1031, 7/27/09 Notice.) In the next office action, the Examiner found that the Roth Publication anticipated claims 6-12, 14, and 17-21. (Ex. 1032, 10/26/09 Action, at 4-5.) In particular, the Examiner stated that the Roth Publication disclosed a lower surface “having at least one locking projection [76] . . . that engages the groove (90) of the bone screw,” (*id.* at 4), and identified a concave lower surface as follows.



(*Id.* at 5.) Applicant responded that “Claim 6 requires [] as an element thereof that the insert have a lower surface with the lower surface operative to contact a bone screw . . . Claim 6 further requires a locking projection located on the lower surface of the insert. *Applicant submits that these elements are not shown in Roth.*” (Ex. 1033, 3/26/10 Resp., at 14 (emphasis added).)

Unpersuaded, the Examiner issued a final rejection, (Ex. 1034, 4/27/10 Action), and the Applicant filed another pre-appeal brief. (Ex. 1035, 8/27/10 Request.) This time, the Applicant argued “*Claim 6 requires as an element thereof that the insert have a lower surface with the lower surface operative to contact a bone screw Claim 6 further requires a locking projection located on the lower surface of the insert. Applicant submits that these separate elements are not shown in Roth.*” (*Id.* at 3-4 (emphasis added).) Further, the Applicant stated that “Claim 14 includes ... a lower surface ... engaging a bone screw ... [and] Applicant submits that *Roth as set forth above does not include a lower surface that engages the bone screw.*” (*Id.*)

In response, the Patent Office reopened prosecution, (Ex. 1036, 11/26/2010 Notice), and allowed the claims based on the Applicant’s arguments. (Ex. 1037, 02/01/11 Action; Ex. 1038, 06/30/11 Resp.) A Notice of Allowability was mailed on September 6, 2011. (Ex. 1039, 9/6/11 Notice.)

V. Claim Construction

Zimmer Biomet submits, for purposes of this IPR, that the term “a plurality of longitudinally extending grooves,” as recited in the ’707 Patent, should be construed as “a plurality of longitudinally extending cuts or depressions.” A claim in IPR is given the broadest reasonable interpretation (“BRI”). 37 C.F.R. § 42.100(b). Under the BRI standard, claim terms are given their “ordinary and

customary meaning as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure.” *Nuvasive, Inc. v. Warsaw Orthopedic, Inc.*, IPR2013-00206, Paper No. 17 at 6 (PTAB Sept. 23, 2013).

In view of the intrinsic evidence, a person of ordinary skill in the art would understand that “grooves” refers to cuts or depressions on the bone screw. (Ex. 1001 at ¶¶ 34-35.) The ’707 Patent does not expressly define this term, nor limit “groove” to any particular geometry. Rather, the specification explains that the grooves are of “a size and shape that are complementary to the locking projection located on the lower surface 52 of the insert 36.” (Ex. 1004 at 3:32-34.) And “the purpose of the locking projections 54 is to engage the grooves 56.” (*Id.* at 3:38-39.) Based on this description, a person of ordinary skill in the art would interpret “grooves” as cuts or depressions to fit a locking projection or insert.

The purpose of the groove also supports such an interpretation. Longitudinal grooves help prevent the bone screw from rotating, but allow longitudinal movement. (Ex. 1001 at ¶¶ 24-25.) This facilitates healing by allowing the femur to contract and reduces the risk that the bone screw will “cut-out” of the femoral head as the bone contracts. (*Id.*) Hence, a person of ordinary skill would understand that “grooves” refers to cuts or depressions that form a space for positioning an insert. (*Id.*) This interpretation is consistent with the plain and ordinary meaning of the term. (*See e.g.* Ex. 1044, Oxford Dictionary at 2

(defining groove as “a channel or hollow, cut by artificial means, in metal, wood, etc.”).)

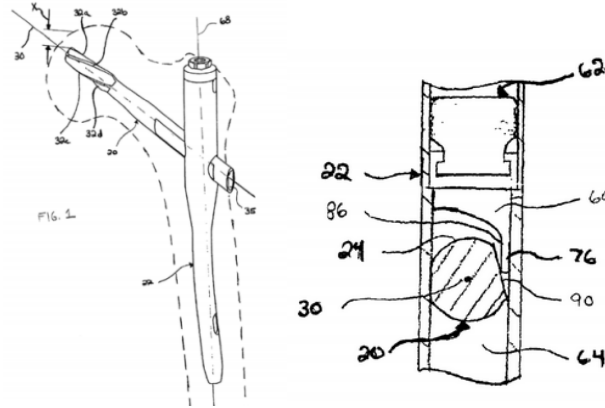
Zimmer Biomet submits, for purposes of this IPR, that the remaining terms be given their plain and ordinary meaning in accordance with the BRI standard.

VI. Reasonable Likelihood that Claims 1-10 Are Unpatentable

A. GROUND 1: Claims 1-10 Are Anticipated By Roth Under 35 U.S.C. § 102.

Roth discloses a device for the “internal fixation of a long bone, such as a femur.” (*See e.g.*, Ex. 1006 at 1:13-17; Ex. 1001 at ¶ 46.) The device includes an intramedullary nail, a bone screw, and components to couple the bone screw in the intramedullary nail. (*See e.g.*, Ex. 1006 at 2:29-47; Ex. 1001 at ¶¶ 37-38). Figure 1 shows the device implanted in a femur. (Ex. 1006 at 3:45-49.)

The proximal portion of the intramedullary nail includes a chamber that contains a coupling mechanism to secure the bone screw against rotation. (Ex. 1006 at 6:29-47.) The coupling mechanism includes a locking ring (62) and insert (60). (Ex. 1001 at ¶¶ 37-38.) As the locking ring (62) is screwed in or out of the chamber, it pushes or pulls the attached insert (60). (Ex. 1006 at 7:31-37.) The insert (60) itself is constrained against rotation so it will not become misaligned as it engages the bone screw (20). (*Id.* at 7:7-10.)



(Ex. 1006 at Figs. 1, 12A.)

a. The Applicant Relied on Certain Limitations to Distinguish the '454 Patent Over Roth, But Did Not Include Those Limitations in the '707 Patent.

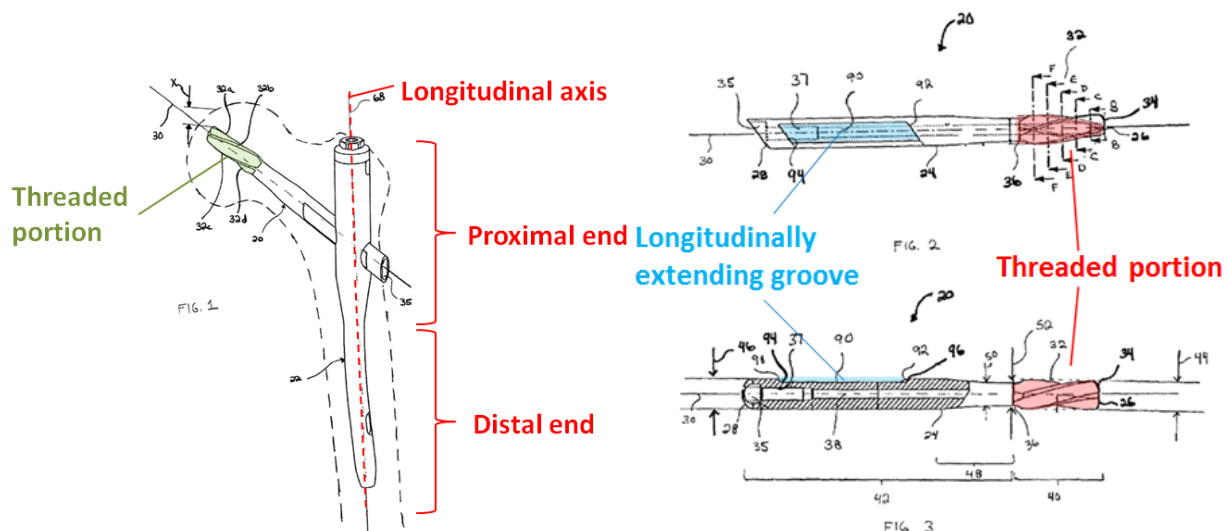
Applicant narrowed the scope of the '454 Patent claims to avoid Roth, but did not include the distinguishing limitations in the '707 Patent. The '454 Patent includes five independent claims: 1, 6, 13, 16 and 19, each of which include distinguishing limitations that are not present in the '707 Patent. Claims 1 and 16 require the insert to have “a concave lower surface” to engage “a convex surface of said bone screw.” During the prosecution of the '454 Patent, Applicant argued that Roth does not disclose this limitation. (Ex. 1025, 5/29/2008 Resp., at 11-12.) There is no mention of a concave lower surface to engage a convex surface of the bone screw in any of the '707 Patent claims.

Claim 6 of the '454 Patent requires the insert to have “a lower surface operative to contact a bone screw ... [and] a locking projection located on said lower surface of the insert.” From this language, Applicant argued the lower

surface and the locking projection must be “separate elements,” and the lower surface must be operative to contact the bone screw. (Ex. 1035, 8/27/10 Request at 3-4.) Applicant argued “these elements are not shown in Roth.” (Ex. 1033, 3/26/10 Resp., at 14.) Unlike the ’454 Patent, the ’707 Patent claims do not require “a lower surface operative to contact the bone screw.” Nor do the claims require “a locking projection located on said lower surface of the insert.” Likewise, claims 13 and 19 of the ’454 Patent recite limitations, such as an aperture through the insert, not found in the ’707 Patent claims.

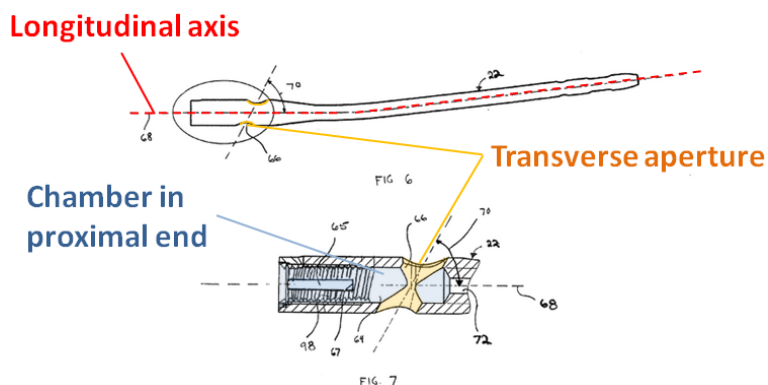
b. Claim 1 Is Anticipated By Roth.

Preamble. Roth discloses the preamble “[a] fixation instrument for treating a bone fracture.” For example, Roth describes that a “fracture fixation implant 20 according to one embodiment of the present invention is shown implanted in a femur and coupled to a second fracture fixation implant.” (Ex. 1006 at 3:45-49; Fig. 1; *see also* Ex. 1001 at ¶ 46.)



(Ex. 1006 at Figs. 1-3 (annotated).)

Limitation [A]. Roth discloses “a nail member, having a longitudinal axis, a distal end and a proximal end, said proximal end having a transverse aperture extending therethrough and said nail member having a chamber located in said proximal end.” Roth states, for example, that “[i]ntramedullary nail 22 defines a longitudinal axis 68.” (Ex. 1006 at 6:33-37.) The nail member of Roth also has a distal end and a proximal end, as shown in, for example, Figure 1. (*Id.* at Fig. 1; Ex. 1001 at ¶ 48.)



(Ex. 1006 at Fig. 7 (annotated).) The proximal end, in turn, has a transverse aperture extending therethrough, which Roth calls the “bore.” (Ex. 1001 at ¶ 49.) For example, Roth states that “referring to FIGS. 6 and 7, bore 66 [transverse aperture] extends through intramedullary nail 22 and intersects with channel 64 [chamber].” (Ex. 1006 at 6:46-49.) The nail member also has a chamber located in said proximal end, which Roth calls the “channel.” (*Id.* at 6:37-41; Ex. 1001 at ¶

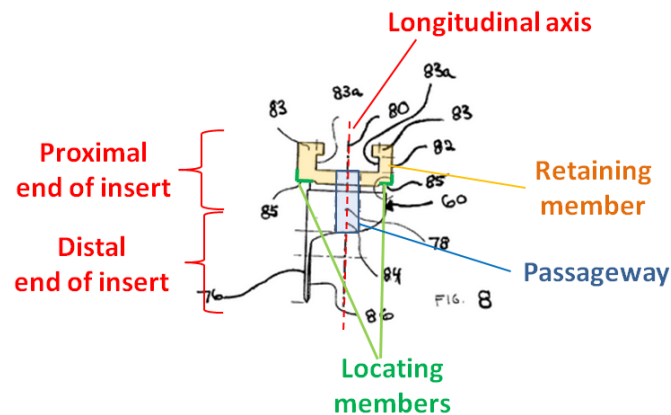
50.) Roth states, for example, that “channel 64 [chamber] extends substantially along longitudinal axis 68, and is dimensioned and configured to receive body member 60 [insert] and drive member 62 [locking ring].” (Ex. 1006 at 6:37-41.)

Limitation [B]. Roth discloses “a bone screw, having a threaded portion, said bone screw extending through said aperture.” The fixation instrument disclosed in Roth has a bone screw with a threaded portion. (Ex. 1001 at ¶ 51.) For example, Roth explains that “implant 20 [bone screw] includes a bladed portion 40 [threaded portion], upon which blades 32 [threads] are disposed.” (Ex. 1006 at 5:42-44; *see also* Ex. 1001 at ¶ 51.) As Figure 1 of Roth shows, the bone screw extends through the aperture.

Limitation [C]. Roth discloses “an insert having a longitudinal axis, a distal end, a proximal end and a passageway extending longitudinally through said insert from said proximal end to said distal end, said insert having a retaining member located on said proximal end of said insert, said insert positioned and constrained against rotation about said longitudinal axis of said insert within said chamber.”

Roth discloses an insert, which it calls a “body member.” (*See e.g.*, Ex. 1006 at 6:21-32, Figs. 8-10; *see also* Ex. 1001 at ¶ 53.) Roth describes the insert as “includ[ing] a substantially cylindrical portion 78 that defines a longitudinal axis 80 of the body member 60 [insert], and a prong 76 [locking projection] extending from cylindrical portion 78.” (Ex. 1006 at 6:66-7:3.) Figure 8 shows the insert of

Roth includes a longitudinal axis, a distal end, and a proximal end. (Ex. 1006 at Fig. 8; Ex. 1001 at ¶ 54.)

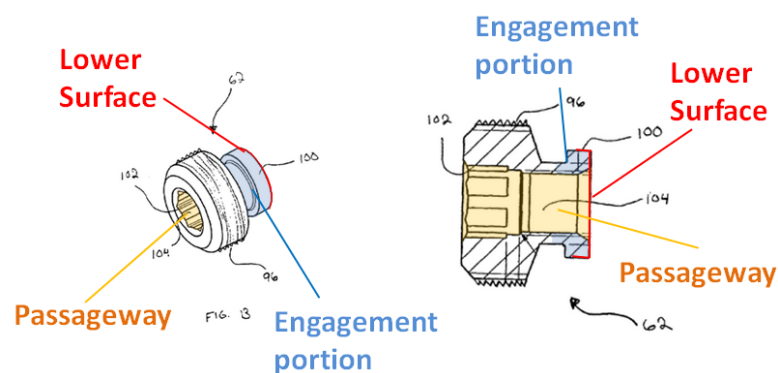


(Ex. 1006 at Fig. 8 (annotated).) Additionally, “[a] cannulation 84 [passageway] may optionally be provided through body member 60 [insert] in substantial coaxial alignment with longitudinal axis 80 to permit insertion of a guide wire.” (*Id.* at 7:37-40.) This insert also includes an “attachment portion 82 [retaining member], which is configured and dimensioned to rotatably couple body member 60 [insert] to drive member 62 [bone screw].” (*Id.* at 7:31-34; *see also* Ex. 1001 at ¶ 56.)

This insert is positioned and constrained against rotation about the longitudinal axis. (Ex. 1001 at ¶¶ 57-58.) According to Roth, “[a] pair of alignment tabs 85 . . . may extend from cylindrical portion 78 [of the insert]. . . . Cooperation between tabs 85 and grooves 65 [on the nail member] substantially limits rotation of body member 60 [insert] within channel 64 [chamber] of intramedullary nail 22.” (Ex. 1006 at 7:7-11.)

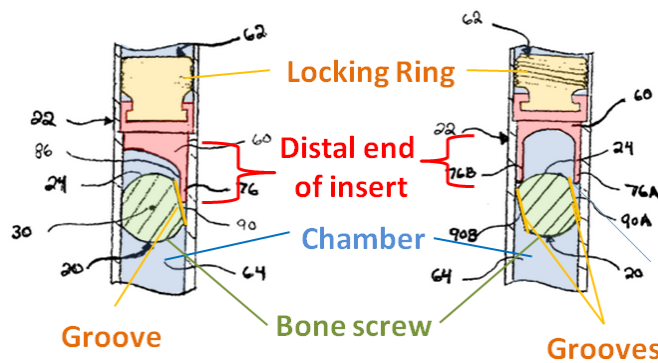
Limitation [D]. Roth discloses “a locking ring, having a longitudinal passageway extending therethrough, said locking ring including a lower surface having an engagement portion, said locking ring received in said chamber and said engagement portion engaging said retaining member of said insert to attach said locking ring to said insert, said locking ring operative to secure said insert within said chamber.”

Roth discloses a locking ring, which it calls the “drive member.” (Ex. 1006 at 9:26-60; *see also* Ex. 1001 at ¶ 60.) The locking ring of Roth includes a longitudinal passageway extending therethrough. (Ex. 1001 at ¶ 61.) For example, Roth notes that “[a] cannulation 104 may optionally extend substantially axially through drive member 62 to permit insertion of a guide wire (not shown) therethrough.” (Ex. 1006. at 9:58-60; *see also* Fig. 14.)



(Ex. 1006 at Figs. 13-14 (annotated).) Roth also explains that this locking ring is received in the chamber in the proximal end of the nail member, which Roth calls the “channel 64.” (Ex. 1006 at 6:37-41; Ex. 1001 at ¶ 60.)

The locking ring in Roth includes a lower surface having an engagement portion, which Roth calls an “attachment portion,” that engages the retaining member of the insert. (Ex. 1006 at 9:34-38; Ex. 1001 at ¶ 62.) For example, Roth states that “[d]rive member 62 [locking ring] also includes an attachment portion 100 [engagement portion] which is configured and dimensioned to rotatably couple drive member 62 [locking ring] to body member 60 [insert], such that drive member 62 [locking ring] may freely rotate with respect to body member 60 [insert].” (Ex. 1006 at 9:34-38.)

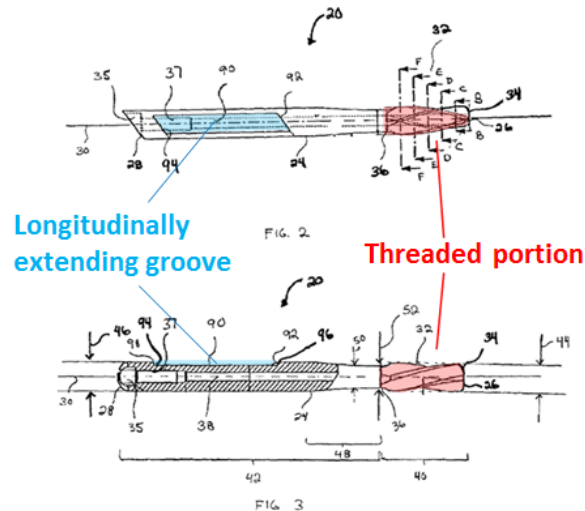


(Ex. 1006 at Fig. 12 (annotated).) The locking ring disclosed in Roth is operative to secure said insert within the chamber in the proximal end of the nail member. (Ex. 1001 at ¶ 63.) For example, Roth explains that “[d]rive member 62 is configured and dimensioned to engage channel 64 to selectively hold body member 60 in position. (Ex. 1006 at 9:27-29.)

Limitation [E]. Roth discloses “said bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending

substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is received in one of said grooves to resist rotation of said bone screw within said aperture.”

Roth discloses a bone screw, which it calls an “implant,” with a plurality of longitudinally extending grooves, which it calls “engagement surfaces.” (Ex. 1006 at 7:41-8:51; *see also id.* at Fig. 2; Ex. 1001 at ¶¶ 66-68.) Roth, for example, explains that the bone screw includes an “engagement surface 90 [groove] is recessed into shaft 24 of implant [bone screw] 20, and stops 92, 94 are formed at the boundaries of the recessed surface.” (Ex. 1006 at 8:2-5.) Hence, the bone screw includes “a plurality of longitudinally extending cuts or depressions.” (Ex. 1001 at ¶ 66-67.) Likewise, Roth explains that the bone screw may include multiple grooves, stating that “[t]he two-pronged embodiment [of the insert] may be used, for example, with an implant 20 [bone screw] having two diametrically opposed engagement surfaces [grooves]. Alternatively, a single-pronged embodiment [of the insert] may be used with an implant 20 having two or more engagement surfaces [grooves].” (Ex. 1006 at 7:58-62; Ex. 1001 at ¶ 68.) The grooves in Roth extend substantially parallel to the longitudinal axis of the bone screw. (Ex. 1006 at Figs. 2 and 3; Ex. 1001 at ¶¶ 66-67.)



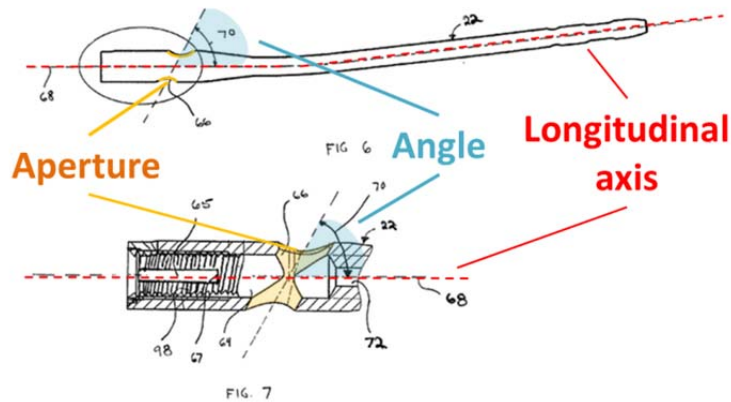
(Ex. 1006 at Figs. 2-3 (annotated).)

Roth discloses an insert and bone screw wherein at least a portion of said distal end of said insert is received in one of said grooves to resist rotation of said bone screw within said aperture. (Ex. 1006 at 7:46-51; Ex. 1001 at ¶ 69.) According to Roth, “prong 76 [a portion of the distal end of the insert] may be provided with a first engagement surface 86 that contacts a second engagement surface 90 [groove] formed on implant 20 [bone screw] to substantially prevent rotation of implant 20 [bone screw] and limit sliding of implant 20 [bone screw].” (Ex. 1006 at 7:45-51.)

c. Claim 2 Is Anticipated By Roth.

Preamble. Roth discloses “[a] fixation instrument for treating a bone fracture as set forth in claim 1,” as described above with respect to claim 1.

Limitation [A]. Roth discloses “said aperture extending at an angle through the proximal end of the nail member.”

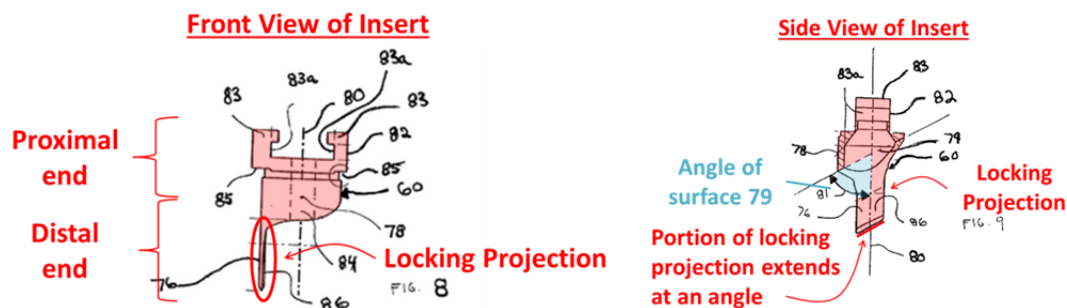


(Ex. 1006 at Fig. 7 (annotated).) Roth teaches an aperture extending at an angle through the nail member, and states that “bore 66 [aperture] is disposed at an angle 70 with respect to the longitudinal axis 68 [of the nail member].” (*Id.* at 6:53-54.)

Limitation [B]. Roth discloses “said distal end of said insert includes a locking projection, said locking projection having a portion thereof that extends at an angle substantially the same as the angle of said aperture, wherein said portion of said locking projection that extends at an angle substantially the same as the angle of said aperture extends into and is located in one of said grooves of said bone screw.”

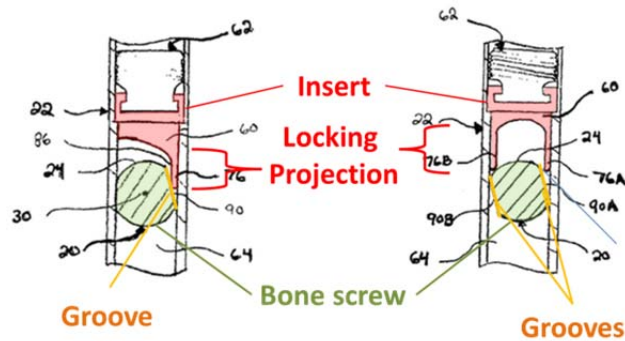
Roth teaches an insert with a locking projection on its distal end. (Ex. 1001 at ¶¶ 74-75.) For example, the insert in Roth is “receivable in the first implant [nail member] and including a single prong [locking projection] extending from the body [insert] for contacting a surface of the second implant [bone screw].” (Ex. 1006 at 2:31-34.) A portion of this locking projection extends at an angle substantially the same as the angle of the aperture. For example, in Figure 9,

annotated below, the distal portion of the locking projection extends at an angle substantially the same as the angle of surface 79. (*Id.* at Fig. 9; Ex. 1001 at ¶ 76.) The angle of surface 79 is, in turn, “substantially equal to angle 70 [the angle of the aperture].” (Ex. 1006 at 7:24-27.) Hence, the locking projection has a portion that extends at an angle substantially the same as the angle of the aperture.



(Ex. 1006 at Fig. 8 (left), Fig. 9 (right) (annotated).)

Roth teaches that this portion of the locking projection extends into and is located in one of the bone screw grooves. (Ex. 1001 at ¶¶ 77-78.) For example, Roth explains that “movement of body member 60 [insert] toward implant 20 [bone screw] causes prong 76 [locking projection] to slide along second engagement surface 90 [groove].” (Ex. 1006 at 8:66-9:1.) The locking projection serves “to influence implant 20 [bone screw] to rotate about longitudinal axis 30 until first and second engagement surfaces 86, 90 [locking projection and groove] are flush with one another and moreover, are engaged.” (*Id.* at 8:62–9:5.) In Roth, the locking projection is located in one of the bone screw grooves “to substantially prevent rotation of implant 20 [bone screw].” (*Id.*)



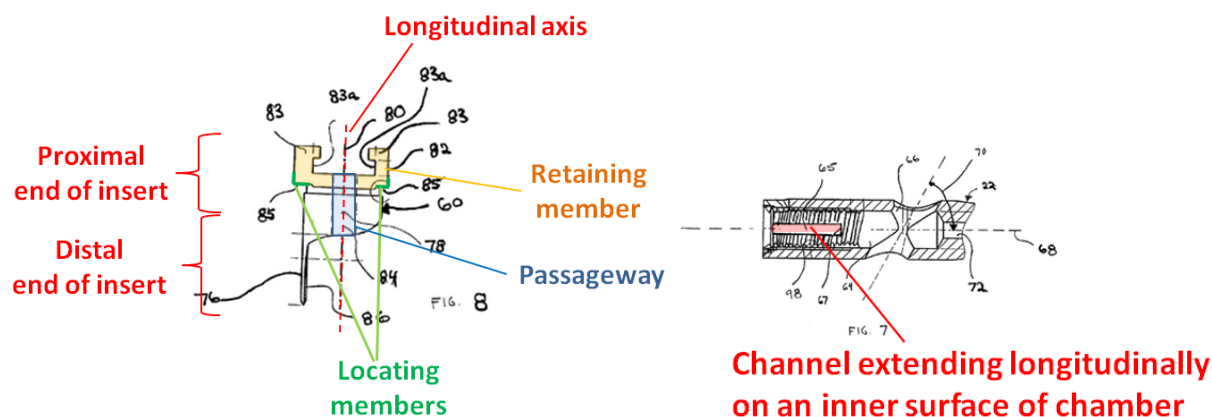
(Ex. 1006 at Fig. 12 (annotated).)

d. Claim 3 Is Anticipated By Roth.

Claim 3 recites “[a] fixation instrument for treating a bone fracture as set forth in claim 1 including said insert having a locating member configured to be received by a corresponding channel extending longitudinally on an inner surface of chamber, said locating member operative to constrain said insert from rotation within said chamber.” Roth describes a fixation instrument for treating a bone fracture as set forth in claim 1, as discussed above with respect to claim 1.

The insert in Roth has locating members, which Roth calls “alignment tabs.” (Ex. 1001 at ¶ 81.) For example, Roth states that “[a] pair of alignment tabs 85 [locating members] (shown in FIGS. 8 and 11) may extend from cylindrical portion 78” of the insert. (Ex. 1006 at 7:7-11.) The locating members are received by a corresponding channel, which extends longitudinally on an inner surface of the chamber. For example, Roth states “tabs 85 [locating members] may be received in grooves 65 [channel].” (*Id.* at 7:7-11.) Roth also discloses a locating member operative to constrain an insert from rotation within the chamber. (Ex.

1001 at ¶¶ 82-83.) For example, Roth states that “[c]ooperation between tabs 85 [locating member] and grooves 65 [channel] substantially limits rotation of body member 60 within channel 64 of intramedullary nail 22.” (Ex. 1006 at 7:11-13.)



(Ex. 1006 at Figs. 7, 8 (annotated).)

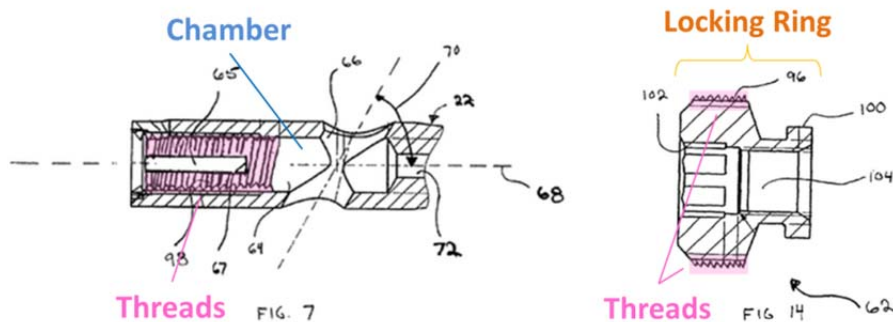
e. Claim 4 Is Anticipated By Roth.

Preamble. As described above with respect to claim 1, Roth discloses “[a] fixation instrument for treating a bone fracture as set forth in claim 1.”

Limitation [A]. Roth discloses “said chamber having an inner surface and a plurality of threads located on said inner surface.” (Ex. 1001 at ¶ 85.) Roth teaches a chamber with threads on the inner surface. For example, Roth states that “[a] series of threads 98 may be disposed on channel 64 [chamber].” (Ex. 1006 at 6:41-43.) Roth also depicts the chamber threads in Figure 7.

Limitation [B]. Roth discloses “said locking ring having an outer surface and a plurality of threads located on said outer surface, wherein said threads located on said locking ring engage said threads on said inner surface of said

chamber.” Roth teaches that the locking ring threads engage the threads on the inner surface of the chamber. (Ex. 1001 at ¶¶ 86-87.) For example, Roth explains the locking ring threads “mate with a series of threads 98 formed in channel 64 [chamber].” (Ex. 1006 at 9:29-34.)



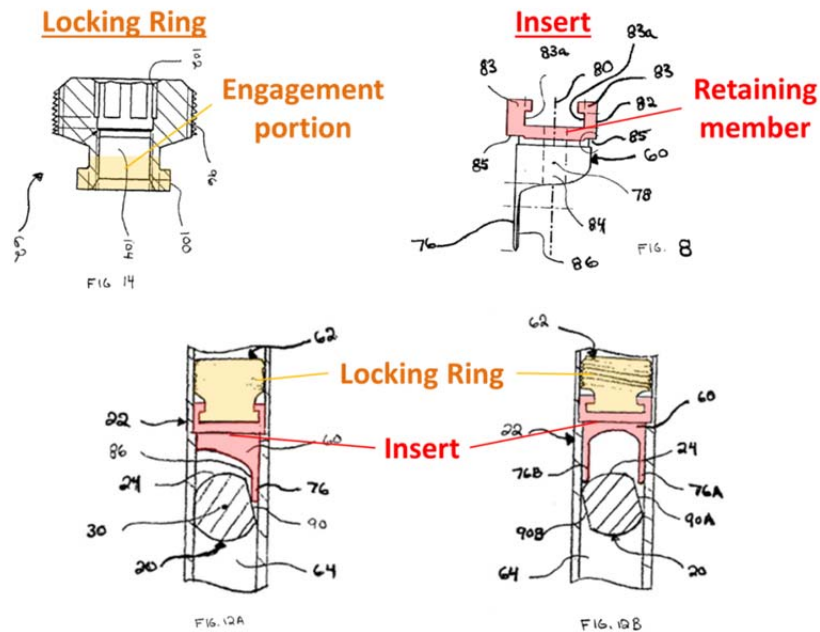
(Ex. 1006 at Figs. 7, 14 (annotated).)

f. Claim 5 Is Anticipated By Roth.

Claim 5 recites “[a] fixation instrument for treating a bone fracture as set forth in claim 1 including said engagement portion and said retaining member configured such that when said engagement portion engages said retaining member said locking ring may rotate about said longitudinal axis of said insert while remaining attached to said insert.”

Roth teaches an engagement portion engaging a retaining member to allow the locking ring to rotate while remaining attached to the insert. According to Roth, the locking ring includes an engagement portion “which is configured and dimensioned to rotatably couple drive member 62 [locking ring] to body member

60 [insert], such that drive member 62 [locking ring] may freely rotate with respect to body member 60 [insert].” (Ex. 1006 at 9:34-38; *see also* Ex. 1001 at ¶¶ 89-90.)



(Ex. 1006 at Figs. 8, 12, 14 (annotated).)

g. Claim 6 Is Anticipated By Roth.

Independent Claim 6 recites many of the same limitations as Claim 1, and each limitation is addressed below in turn.

Preamble. Roth discloses “[a] fixation instrument for treating a bone fracture” as described above with respect to Claim 1.

Limitation [A]. Roth discloses “a nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough at an angle with respect to said longitudinal axis of said nail member, said nail member having a chamber located in said proximal end, said chamber

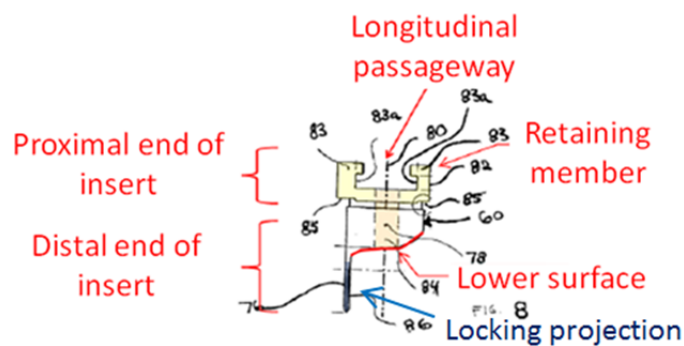
having an inner surface and a plurality of threads located on said inner surface.” This limitation is similar to limitation [A] of claim 1, except that it also requires the aperture to be “at an angle with respect to said longitudinal axis of said nail member,” and the chamber to have “an inner surface and a plurality of threads located on said inner surface.” Roth teaches an aperture at an angle with respect to the longitudinal axis and a chamber including a plurality of threads, as discussed with respect to claims 2 and 4, above.

Limitation [B]. Roth discloses “a bone screw having a threaded portion, said bone screw extending through said aperture,” as discussed above with respect to claim 1.

Limitation [C]. Roth discloses “an insert, said insert having a longitudinal axis, a distal end, a proximal end and a passageway extending longitudinally through said insert from said proximal end to said distal end, said insert having a lower surface, said insert positioned within said chamber.” As discussed with respect to claim 1 above, Roth teaches an insert having “a longitudinal axis, a distal end, a proximal end and a passageway ... said insert positioned within said chamber.”

Roth also discloses an insert having a lower surface. (Ex. 1001 at ¶¶ 104-05.) During the prosecution of the parent application, the patent owners stated that the locking “projection is separate from the lower surface.” (Ex. 1035, 8/27/10

Request, at 3.) Assuming this holds true for the '707 patent as well, Roth discloses a lower surface that is separate from the locking projection, as seen below in Figure 8. (Ex. 1001 at ¶ 104.) Again, unlike the claims of the parent application, '707 patent claim 6 does not require the lower surface to contact a bone screw. Hence, the surface identified below is a “lower surface.” (*Id.*)



(Ex. 1006 at Fig. 8 (annotated).)

Limitation [D]. Roth discloses “a locking ring having a longitudinal passageway extending therethrough and an outer surface, a plurality of threads located on said outer surface, wherein said threads located on said outer surface of said locking ring engage said threads on said inner surface of said chamber, said locking ring rotatably connected to said insert.” Roth discloses a locking ring with a longitudinal passageway as discussed above with regards to claim 1. Likewise, Roth also discloses a locking ring with threads on an outer surface that engage the inner surface of the chamber, as discussed above with regards to claim 4. This locking ring “may freely rotate with respect to body member 60 [insert].” (Ex. 1006 at 9:34-38.)

Limitation [E]. Roth discloses “said bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is located in one of said grooves to resist rotation of said bone screw within said aperture.” This limitation is similar to the corresponding limitation in claim 1. Claim 6, however, requires a portion of the distal end of the insert to be “located in one of said grooves,” whereas claim 1 requires a portion of the distal end of the insert to be “received in one of said grooves.” The ’707 Patent does not disclose any differences between “located in” and “received in.”

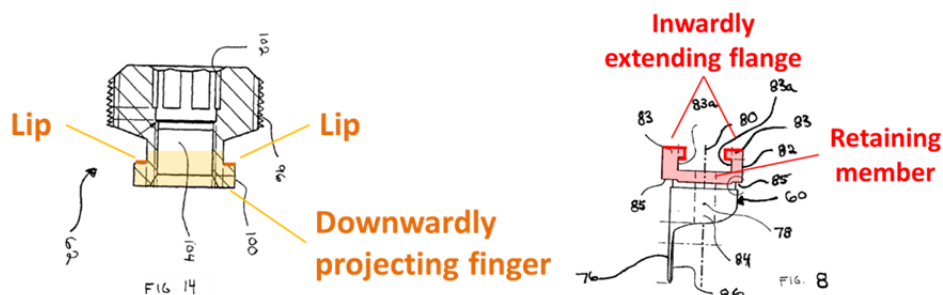
The insert in Roth includes a distal end that is located in one of the grooves. (Ex. 1001 at ¶¶ 118-19.) Roth explains that “prong 76 [a portion of the distal end of the insert] may be provided with a first engagement surface 86 that contacts a second engagement surface 90 [groove] formed on implant 20 [bone screw].” (Ex. 1006 at 7:45-51.) And Figure 12A, for example, shows a portion of the distal end of the insert located in the groove. (*Id.* at Fig. 12A.)

h. Claim 7 Is Anticipated By Roth.

Preamble. Roth discloses “[a] fixation instrument for treating a bone fracture as set forth in claim 6,” as described above with respect to claim 6.

Limitation [A]. Roth discloses “said locking ring having a downwardly projecting finger having a lip.” Roth depicts a locking ring with a downwardly projecting finger having a lip, as shown in Figure 14. (Ex. 1006 at Fig. 14; Ex. 1001 at ¶¶ 122-23.)

Limitation [B]. Roth discloses “said insert having an inwardly extending flange whereby said flange cooperates with said lip to rotatably secure the locking ring to the insert.” The insert of Roth has “a pair of upward-extending arms 83 [inwardly extending flange] that define a pair of opposed channels 83 for receiving a portion of drive member 62 [locking ring] therein.” (Ex. 1006 at 7:34-38.)



(Ex. 1006 at Fig. 14 (left), Fig. 8 (right) (annotated).)

i. Claim 8 Is Anticipated By Roth.

Preamble. Roth discloses “[a] fixation instrument for treating a bone fracture as set forth in claim 7,” as discussed above with respect to claim 7.

Limitation [A]. Roth discloses “said chamber having a groove extending along a side wall of said chamber.” Roth teaches a chamber having a groove. (Ex. 1001 at ¶ 129.) For example, Roth states that “a pair of grooves 65 may be formed

on channel 64 [chamber], and are preferably diametrically opposed from one another.” (Ex 1006 at 6:43-45.) As shown in Figure 7, a groove extends along a side wall of the chamber. (*Id.* at Fig. 7.)

Limitation [B]. Roth discloses “said insert including a locating member extending radially outward from a body of said insert, said locating member cooperating with said groove whereby said insert moves in said chamber in a longitudinal direction and is constrained against rotation by the locating member.”

Roth states, for example, that “[a] pair of alignment tabs 85 [locating members] (shown in Figs. 8 and 11) may extend from cylindrical portion 78” of the insert. (Ex. 1006 at 7:7-11.) Roth also teaches that a locating member cooperates with a groove, (Ex. 1001 at ¶¶ 131-32.) explaining, for example, that the “tabs 85 [locating members] may be received in grooves 65.” (Ex. 1006 at 7:7-11.) Roth further teaches that this configuration constrains the insert against rotation, but allows the insert to move in the longitudinal direction of the chamber. (Ex. 1001 at ¶ 132.) For example, Roth states that “[c]ooperation between tabs 85 and grooves 65 substantially limits rotation of body member 60 within channel 64 [chamber].” (Ex. 1006 at 7:7-11.) The insert may, however, “move in channel 64 [chamber] at least partially along longitudinal axis 68.” (*Id.* at 6:38-42.)

j. Claim 9 Is Anticipated By Roth.

Claim 9 recites “A fixation instrument for treating a bone fracture as set forth in claim 8 including said insert having an overall outer diameter less than an inner diameter of said chamber formed by said threads on said inner surface of said chamber.”

Roth teaches an insert having an overall outer diameter less than the inner diameter of the chamber formed by the threads. As shown in Figure 7, the chamber “is dimensioned and configured to receive body member 60 [insert] and drive member 62 [locking ring], such that the two parts may move in channel 64 [chamber] at least partially along longitudinal axis 68.” (*Id.* at 6:38-43.) Further, Roth discloses that the insert “may have any shape that permits body member 60 [insert] to move within channel 64 [chamber] of intramedullary nail 22.” (*Id.* at 7:3-7.) In order for the insert to move along the longitudinal axis, it must have an overall outer diameter less than the inner diameter of the chamber formed by the threads. (Ex. 1001 at ¶ 134.)

k. Claim 10 Is Anticipated By Roth.

Claim 10 recites “a fixation instrument for treating a bone fracture as set forth in claim 8 wherein said portion of said lower surface engaging said grooves

in said locking screw extends at an angle substantially the same as the angle of said aperture.”⁴

As a preliminary matter, the term “said portion of said lower surface,” does not appear in any other claim. By reciting “said portion,” claim 10 appears to reference an earlier description of a specific section of the lower surface. Although claim 6 recites an “insert having a lower surface,” neither the claims nor the specification describe any particular portion of this lower surface. Moreover, claim 10 recites “said locking screw,” which is a term that cannot be found anywhere in the specification. Nonetheless, in the co-pending district court litigation, the patent owner identifies the same component as the “bone screw” and “locking screw,” apparently suggesting the two terms are interchangeable. (Ex. 1040, AOS Contentions.) For the purpose of this petition only, and in no way agreeing with the patent owner’s interpretation and/or application, Zimmer Biomet will rely on the patent owner’s infringement contentions and read “locking screw” as “bone screw.”

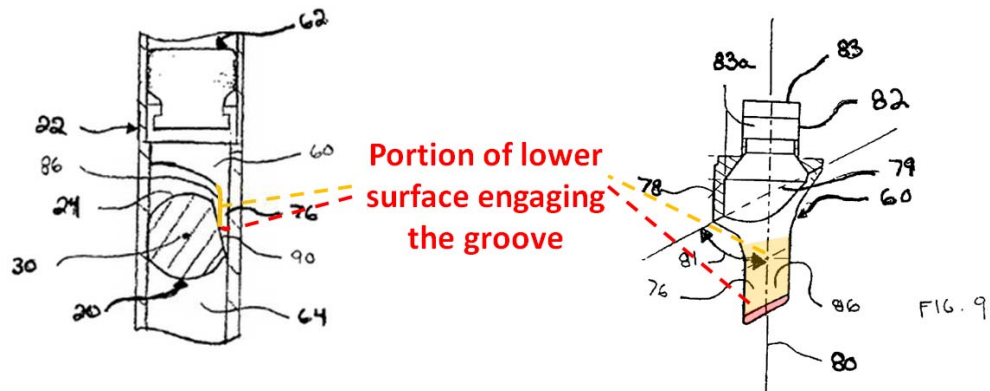
⁴ Zimmer Biomet contends in the co-pending district court litigation that claim 10 is indefinite and/or lacks written description. Zimmer Biomet, however, does not base this petition on 35 U.S.C. § 112 and discloses the potential indefiniteness and/or written description issues to the PTO pursuant to its duty of candor. 37 C.F.R. § 42.11.

Even so, the language of claim 10 remains at odds with the prosecution history of the parent application of the '707 patent. During the prosecution of the parent application, the Applicant stated that “lower surface” and “locking projection” are separate structures. (Ex. 1035, 8/27/10 Request, at 3.) And the '707 patent specification further explains that the locking projection—not the lower surface—engages the grooves on the bone screw. (Ex. 1006 at 3:30-47, Figs. 2, 4A). Claim 10, however, recites “said portion of said lower surface engaging said grooves.” In other words, the lower surface cannot be separate from the locking projection and simultaneously engage the groove. Even if one could imagine such geometry, the '707 patent does not disclose this embodiment.

For claim 10 to make sense, “portion of said lower surface engaging said grooves” must include the locking projection. If so, the insert disclosed by Roth includes a “portion of said lower surface engaging said grooves” on the bone screw. (Ex. 1001 at ¶¶ 137-39.) In particular, the “portion of said lower surface” annotated below engages the grooves on the bone screw. (*Id.* at ¶ 137.)

The “portion of said lower surface” at the end of the insert (shown in red below) engages the groove as the insert secures the bone screw. (*Id.* at ¶¶ 138-39.) Roth explains that “movement of body member 60 [insert] toward implant 20 [bone screw] causes prong 76 [which includes “portion of said lower surface”] to slide along second engagement surface 90 [groove] to influence implant 20 [bone

screw] to rotate about longitudinal axis 30” until the bone screw is correctly oriented to receive the locking projection. (Ex. 1007 at 8:62-9:5.) In other words, the “portion of said lower surface” “engages” with the groove to rotate and align the bone screw. (Ex. 1001 at ¶¶ 138-39.)

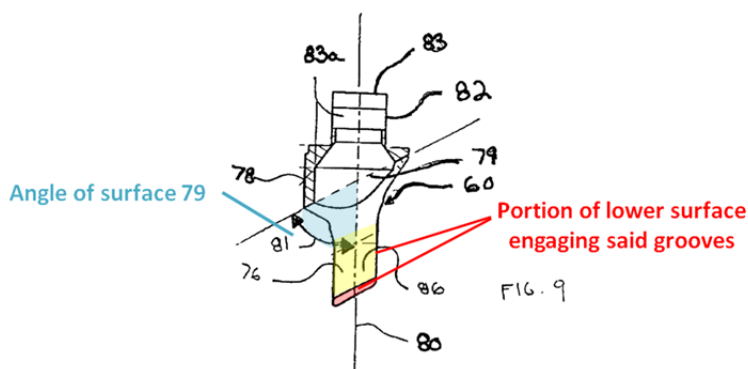


(Ex. 1006 at Fig. 12 (left), Fig. 9 (right) (annotated).)

Once the “portion of said lower surface” is received in the groove, the “portion of said lower surface” (annotated in yellow) engages the grooves on the bone screw to prevent the bone screw from further rotation. (Ex. 1001 at ¶ 137.) Roth explains that “prong 76 [locking projection] may be provided with a first engagement surface 86 [lower surface] that contacts a second engagement surface 90 [groove] formed on implant 20 [bone screw] to substantially prevent rotation of implant 20 [bone screw] and limit sliding of implant 20 [bone screw].” (Ex. 1006 at 7:46-51.) “In this configuration, implant 20 [bone screw] is substantially prevented from rotation about its longitudinal axis 30 due to abutment of

substantially flat first and second engagement surfaces 86, 90 [lower surface and groove].” (*Id.* at 8:22-25.)

Further, “said portion of said lower surface engaging said groove” extends at an angle substantially the same as the angle of surface 79. (*Id.* at Fig. 9; Ex. 1001 at ¶ 140.) The angle of surface 79 is, in turn, “substantially equal to angle 70 [the angle of the aperture].” (Ex. 1006 at 7:24-27.) Therefore, “said portion of said lower surface” extends at an angle substantially the same as the angle of the aperture.



(Ex. 1006 at Fig. 9 (annotated).)

B. GROUND 2: Claims 1-10 are rendered obvious by Shavit in view of Kilpela under 35 U.S.C. § 103(a).

Shavit discloses a device “used to repair bone fractures, in particular intramedullary nails used for fractures of the proximal femur.” (Ex. 1007 at 1:3-4.) The device includes an intramedullary nail, bone screws, and a locking mechanism for the bone screws. (*Id.* at 7:29-33; Ex. 1001 at ¶ 40.) The locking mechanism includes a locking ring attached to an insert inside of the bone nail. (Ex. 1007 at

9:1-18.) As the locking ring moves downward, it pushes the attached insert towards the bone screw. (*Id.* at 9:3-9.) The locking ring is tightened until a locking projection on the insert engages a groove on the bone screw, thereby securing the bone screw. (*Id.* at 8:7-16.)

Similarly, Kilpela discloses an intramedullary nail and bone screws that are connected with a set screw in the proximal end of the nail. (Ex. 1008 at 4:1-44.) Kilpela explains that the set screw may be preloaded in the nail, and is preferably cannulated so the nail can be implanted over a guide wire. (*Id.* at 3:13-27.)

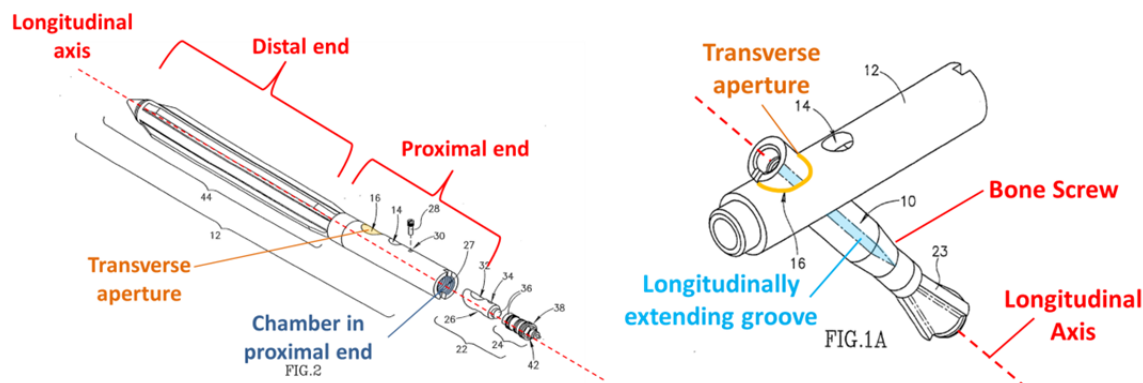
a. Claim 1 Is Rendered Obvious by Shavit in view of Kilpela.

Preamble. Shavit discloses “[a] fixation instrument for treating a bone fracture.” For example, Shavit describes an intramedullary nail “used for fractures of the proximal femur.” (Ex. 1007 at 1:4; Ex. 1001 at ¶ 143.)

Limitation [A]. Shavit discloses “a nail member, having a longitudinal axis, a distal end and a proximal end, said proximal end having a transverse aperture extending therethrough and said nail member having a chamber located in said proximal end.”

Shavit discloses a nail member with a transverse aperture extending through the proximal end. (Ex. 1001 at ¶ 145.) Shavit states, for example, that “the proximal portion of nail 12 ... [includes] smaller hole 14, closer to the proximal end, and larger hole 16 [transverse aperture] further from the proximal end.” (Ex.

1007 at 8:3-4.) The nail member in Shavit also includes a longitudinal axis and distal end. (*Id.* at Fig. 3A; Ex. 1001 at ¶ 145.)



(Ex. 1007 at Figs. 2, 1A (annotated).) The nail member of Shavit has a chamber located in the proximal end. (Ex. 1001 at ¶ 145.) For example, Shavit depicts “a cross-sectional view of locking mechanism 22 assembled inside the nail,” and the chamber in which the locking mechanism is located. (Ex. 1007 at 9:26-27.)

Limitation [B]. Shavit discloses “a bone screw, having a threaded portion, said bone screw extending through said aperture.” For example, Shavit describes a bone screw, called a “hip peg,” and explains that “screw threads or any other anchoring mechanism is used to anchor hip peg 10 [bone screw] in the bone.” (Ex. 1007 at 8:30-31.) Further, the bone screw in Shavit extends through the aperture. (*Id.* at Fig. 1A; Ex. 1001 at ¶ 146.)

Limitation [C]. Shavit in view of Kilpela renders obvious “an insert having a longitudinal axis, a distal end, a proximal end and a passageway extending longitudinally through said insert from said proximal end to said distal end, said

insert having a retaining member located on said proximal end of said insert, said insert positioned and constrained against rotation about said longitudinal axis of said insert within said chamber.”

Shavit discloses an insert, and states that “[l]ocking mechanism 22 comprises a linear adapter 24 [locking ring] and a stem 26 [insert].” (Ex. 1007 at 9:1-2; Ex. 1001 at ¶ 149.) The insert has a longitudinal axis, a distal end, and a proximal end. (Ex. 1007 at Fig. 4; Ex. 1001 at ¶ 149.) Likewise, there is a retaining member on the proximal end of the insert, which is part of the “coupling mechanism.” (Ex. 1001 at ¶ 149.) Shavit explains that “[a]dapter 24 [locking ring] connects to stem 26 [insert], using coupling mechanism 36. The coupling mechanism allows adapter 24 [locking ring] to rotate freely with respect to stem 26 [insert] while it is coupled.” (Ex. 1007 at 9:5-7; *see also id.* Figs. 2, 4.)

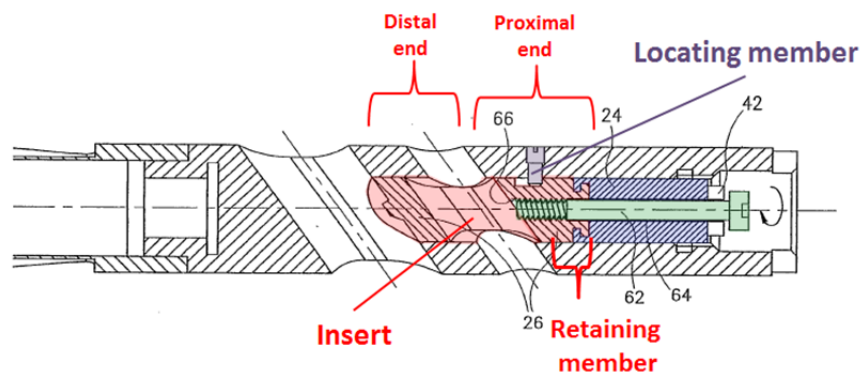


FIG. 4

(Ex. 1007 at Fig. 4 (annotated).)

The insert in Shavit is positioned and constrained against rotation about said longitudinal axis of said insert within said chamber. (Ex. 1001 at ¶ 157.) Shavit

discloses a locating member, which it calls a “nail-stopping screw.” (*Id.*) For example, Shavit explains “[t]here is a nail-stopping screw 28 [locating member], which goes through a hole 30 in the nail [member], and engages in a slot 34 in stem 26 [insert].” (Ex. 1007 at 12:19-20.) The “[n]ail-stopping screw 28 ... prevents stem 26 [insert] from accidentally turning and becoming misaligned” (*Id.*) As such, the insert is positioned and constrained against rotation about the longitudinal axis. (Ex. 1001 at ¶ 157.)

Shavit in view of Kilpela renders obvious an insert with a passageway extending longitudinally through said insert from said proximal end to said distal end. (*Id.* at ¶ 156.) Obviousness depends on the scope and content of the prior art, any differences between the claimed invention and the prior art, and the level of ordinary skill. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Here, Shavit teaches that the locking mechanism, which includes the locking ring and insert, is preferably preloaded into the bone nail. (Ex. 1007 at 12:28-13:2; Ex. 1001 at ¶ 154.) Kilpela also discloses a locking mechanism, in the form of a set screw, which is preloaded in the bone nail, and explains that the set screw includes a passageway so a guide wire can extend through the nail “despite the presence of the set screw.” (Ex. 1008 at 3:14-22; Ex. 1001 at ¶ 155.) In view of Kilpela, a person of ordinary skill in the art would have found it obvious to provide a passageway in the insert of Shavit so the bone nail (with the preloaded insert) can

be implanted over a guide wire. *See e.g. KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007) (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious ...”).

A person of ordinary skill in the art would have reason to combine Kilpela and Shavit. (Ex. 1001 at ¶ 156.) Implanting a bone nail over a guide wire was a well-known and widely adopted surgical technique at the time of the alleged invention. (Ex. 1008 at 3:14-22; Ex. 1001 at ¶¶ 28-30, 152-53.) Because guide wires are easier to manipulate than bone nails, surgeons use them to align bone fragments and direct surgical devices across fracture sites. (*Id.* at ¶¶ 28-29, 151.) During the implant operation, the surgeon first extends the guide wire into the distal fragment of the bone, and then introduces the bone nail over the wire. (*Id.* at ¶¶ 28, 151.) This way, the guide wire directs the nail across the fracture and into the distal bone fragment, thus preventing the nail from straying into the surrounding soft tissue during insertion. (Ex. 1001 at ¶ 151.)

For this procedure to work, the bone nail and any components must have a passageway for the wire. (*Id.* at ¶ 151.) Hence, a person of ordinary skill would have had reason and been motivated to follow the teachings of Kilpela to include a longitudinal passageway in the insert of Shavit. (*Id.* at ¶ 156.) This passageway would allow a bone nail with a preloaded insert to be implanted over a guide wire.

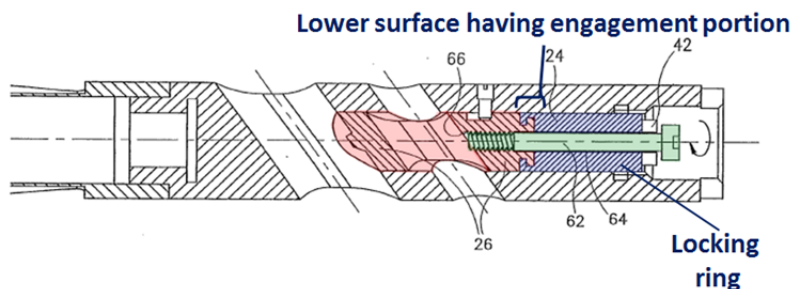
(Ex. 1001 at ¶¶ 153-54.) Both Shavit and Kilpela teach that an insert or set screw is used to lock the bone screw against rotation, and the insert should be preloaded in the nail member. Kilpela further explains the preloaded set screw should include an “axial aperture, to permit a guide wire to extend completely through the central bore despite the presence of the set screw.” (Ex. 1008 at 3:14-22.) A person of ordinary skill in the art would have recognized that such a passageway would also allow the implant of Shavit to be implanted over a guide wire. Hence, a person of ordinary skill in the art, in view of Kilpela, would have reason and been motivated to include a longitudinal passageway in the insert of Shavit. (Ex. 1001 at ¶ 156.)

Further, Shavit does not teach away from the use of a guide wire. (Ex. 1001 at ¶ 154.) In particular, Shavit discloses designs for a fixation device without valves or channels for fluid. (Ex. 1007 at 14:10-11.) Nothing in the bone nail would preclude cannulation for a guide wire, and the passageway described in Kilpela could be readily implemented in these devices. (Ex. 1001 at ¶ 154.)

Limitation [D]. Shavit discloses “a locking ring, having a longitudinal passageway extending therethrough, said locking ring including a lower surface having an engagement portion, said locking ring received in said chamber and said engagement portion engaging said retaining member of said insert to attach said

locking ring to said insert, said locking ring operative to secure said insert within said chamber.”

Shavit discloses a locking ring, which it calls an “adapter,” that is received in the proximal chamber. (*Id.* at ¶ 159.) For example, Shavit states that “[l]ocking mechanism 22 comprises a linear adapter 24 [locking ring] and a stem 26 [insert]. There is an opening 27 [chamber] at the proximal end of the nail. Adapter 24 [locking ring] has threads 38 which match threads inside opening 27 [chamber].” (Ex. 1007 at 9:1-3.) Further, there is a “[h]ole 64 [longitudinal passageway] [that] extends all the way through adapter 24 [locking ring].” (*Id.* at 13:32-33.)



(Ex. 1007 at Fig. 4 (annotated).) The locking ring in Shavit includes a lower surface having an engagement portion, said locking ring received in said chamber and said engagement portion engaging said retaining member of said insert to attach said locking ring to said insert. (Ex. 1001 at ¶ 159.) For example, Shavit states that “[a]dapter 24 [locking ring] connects to stem 26 [insert], using coupling mechanism 36.” (Ex. 1007 at 9:5-6.) Accordingly, “[t]he coupling mechanism allows adapter 24 [locking ring] to rotate freely with respect to stem 26 [insert]

while it is coupled.” (*Id.*) This mechanism “allows adapter 24 [locking ring] to push or pull stem 26 [insert] axially, without requiring stem 26 [insert] to rotate ...” (*Id.* at 9:7-9.) Because the locking ring is coupled to the chamber with threads, it prevents the insert from backing out of the chamber. (Ex. 1001 at ¶ 160.) Thus, the locking ring is operative to secure an insert within a chamber in the proximal end of the nail member. (*Id.*)

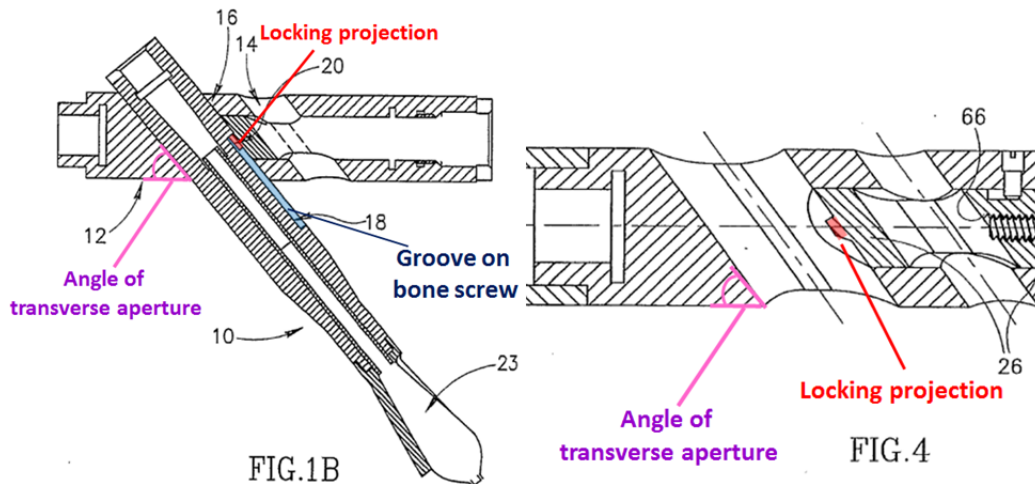
Limitation [E]. Shavit discloses “said bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is received in one of said grooves to resist rotation of said bone screw within said aperture.”

Shavit discloses a bone screw, which it calls a hip peg, having a longitudinal axis and a plurality of longitudinally extending grooves, called “slots.” (Ex. 1001 at ¶ 162; Ex. 1007 at 8:7-8.) This bone screw can include more than one groove. For example, Shavit explains that “[o]ptionally, there is a second slot [a second groove] in hip peg 10 [bone screw]” and that “[a]lternatively, the second slot [second groove] is separate from slot 18 [first groove].” (Ex. 1007 at 8:16-20.) These “slots” form “a plurality of longitudinally extending cuts or depressions.” As seen in figures 1A and 1B, the grooves in Shavit extend substantially parallel to

“intramedullary nail . . . a first hole going through the nail at an angle to the axis, and a second hole going through said nail at the same or a different angle to the axis.” (Ex. 1007 at 3:12-14.)

Limitation [B]. Shavit discloses “said distal end of said insert includes a locking projection, said locking projection having a portion thereof that extends at an angle substantially the same as the angle of said aperture, wherein said portion of said locking projection that extends at an angle substantially the same as the angle of said aperture extends into and is located in one of said grooves of said bone screw.”

The insert disclosed in Shavit includes a locking projection, called a “tab.” (*Id.* at ¶¶ 169-70.) For example, Shavit states that “[t]he hip peg [bone screw] has a slot 18 [groove], and there is a tab 20 [locking projection], at the end of locking mechanism 22, which fits into slot 18 [groove].” (Ex. 1007 at 8:7-8.) This locking projection includes a portion that extends at an angle substantially the same as the angle of said aperture, as shown in Figure 1B and 4. (Ex. 1001 at ¶ 169.) And this portion of the locking projection also extends into and is located in one of the grooves on the bone screw. (*Id.* at ¶ 170.) Shavit states, for example, “there is a tab 20 [locking projection], at the end of locking mechanism 22, which fits into slot 18 [groove].” (Ex. 1007 at 8:7-8.)



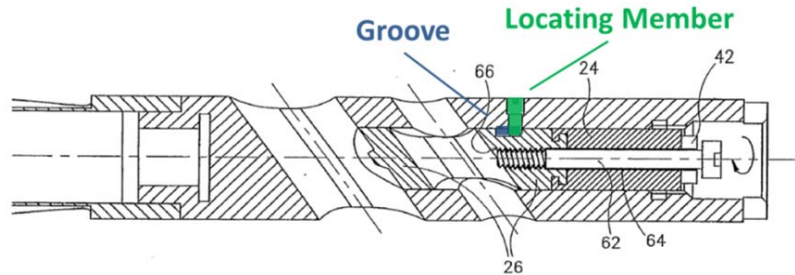
(Ex. 1007 at Figs 1B, 4 (annotated).)

c. Claim 3 Is Rendered Obvious By Shavit in view of Kilpela.

Claim 3 recites “[a] fixation instrument for treating a bone fracture as set forth in claim 1 including said insert having a locating member configured to be received by a corresponding channel extending longitudinally on an inner surface of chamber, said locating member operative to constrain said insert from rotation within said chamber.”

Shavit in combination with Kilpela renders claim 3 obvious as a matter of design choice. Shavit discloses a locating member and the corresponding channel. (*Id.* at ¶¶ 173-74; Ex. 1007 at 12:19-28.) For example, Shavit states that “a nail-stopping screw 28 [locating member] ... goes through a hole 30 in the nail, and engages in a slot 34 [channel] in stem 26 [insert].” (Ex. 1007 at 12:19-20.) Shavit also explains that “[o]ptionally a peg or a projection of some kind is used instead of a screw.” (*Id.* at 12:20-21.) The locating member “prevents stem 26 [insert]

from accidentally turning and becoming misaligned, before the hip pin has been inserted into hole 14.” (*Id.* at 12:26-28.)



(Ex. 1007 at Fig. 4 (annotated).)

In claim 3, the locating member extends from the insert and the corresponding channel is on the inner surface of the nail. In Shavit, the locating member extends from the inner surface of the nail member, and the corresponding channel is on the insert. In short, Claim 3 of the '707 Patent reverses the position of the locating members and channel as disclosed in Shavit. A claim, however, is obvious if it merely arranges “old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement.” *KSR*, 550 U.S. at 417 (2007). Moving existing elements to different locations, without achieving any novel or unexpected results, is “a matter of design choice.” *Pharmatech Solutions, Inc., v. Lifescan Scotland*, IPR2013-00247, Paper No. 27, at 19 (PTAB Aug. 6, 2014); *see also, Nano-Second Tech. Co. v. Dynaflex Int'l*, 944 F. Supp. 2d 855, 863-64 (C.D. Cal. 2013), *appeal dismissed* (July 22, 2013).

Here, Shavit discloses a locating member with a corresponding channel. (Ex. 1007 at 12:19-28.) The interaction between these two components prevents the insert from rotating. (Ex. 1001 at ¶ 175.) Neither this interaction, nor its result, is changed by reversing the location of the locating member and channel. (*Id.*) A person of ordinary skill would understand the locating member can be positioned on the nail or insert, so long as it still interacts with a corresponding groove to prevent rotation. (*Id.*) Hence, claim 3 is obvious because it rearranges elements disclosed by Shavit to perform the same function.

d. Claim 4 Is Rendered Obvious By Shavit in view of Kilpela.

Preamble. Shavit and Kilpela disclose “[a] fixation instrument for treating a bone fracture as set forth in claim 1,” as described above with respect to claim 1.

Limitation [A]. Shavit discloses “said chamber having an inner surface and a plurality of threads located on said inner surface.” Shavit states that “[t]here is an opening 27 [chamber] at the proximal end of the nail. Adapter 24 [locking ring] has threads 38 which match threads inside opening 27 [chamber]. (Ex. 1007 at 9:2-3.) Likewise, Figure 2 depicts “threads inside opening 27 [chamber].” (*Id.* at Fig. 2; 8:32-9:3.)

Limitation [B]. Shavit discloses “said locking ring having an outer surface and a plurality of threads located on said outer surface, wherein said threads located on said locking ring engage said threads on said inner surface of said

chamber.” Shavit explains that “[a]dapter 24 [locking ring] has threads 38 which match threads inside opening 27 [chamber].” (*Id.* at 9:2-3.)

e. Claim 5 Is Rendered Obvious By Shavit in view of Kilpela.

Claim 5 recites “A fixation instrument for treating a bone fracture as set forth in claim 1 including said engagement portion and said retaining member configured such that when said engagement portion engages said retaining member said locking ring may rotate about said longitudinal axis of said insert while remaining attached to said insert.”

As described above in relation to claim 1, Shavit discloses an insert (referred to as a “stem”) with a retaining member and a locking ring (“referred to as an “adapter”) with an engagement portion. This configuration allows the locking ring to rotate about said longitudinal axis of the insert while remaining attached to the insert. (Ex. 1001 at ¶¶ 182-83.) For example, Shavit states “[a]dapter 24 [locking ring] connects to stem 26 [insert], using coupling mechanism 36. The coupling mechanism allows adapter 24 [locking ring] to rotate freely with respect to stem 26 [insert] while it is coupled.” (Ex. 1007 at 9:6-7.)

f. Claim 6 Is Rendered Obvious By Shavit in view of Kilpela.

Independent Claim 6 recites many of the same limitations as Claim 1, and each limitation is addressed in turn below:

Preamble. Shavit and Kilpela disclose “[a] fixation instrument for treating a bone fracture” as described above with respect to Claim 1.

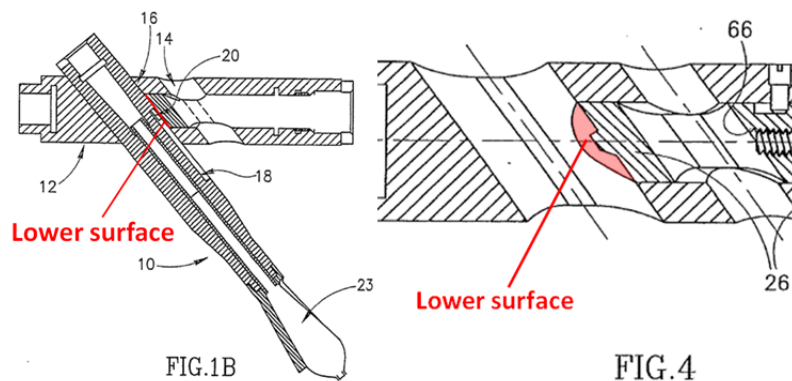
Limitation [A]. Shavit discloses “a nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough at an angle with respect to said longitudinal axis of said nail member, said nail member having a chamber located in said proximal end, said chamber having an inner surface and a plurality of threads located on said inner surface.” This limitation is similar to limitation [A] of claim 1, except that it also requires the aperture to extend at an angle with respect to the longitudinal axis of the nail, and the chamber to have an inner surface with a plurality of threads.

As described above, Shavit discloses limitation [A] of claim 1. Shavit also discloses an aperture extending therethrough at an angle with respect to said longitudinal axis of said nail member, as discussed with respect to claim 2. Further, Shavit provides a chamber having an inner surface and a plurality of threads located on said inner surface, as discussed with respect to claim 4.

Limitation [B]. Shavit discloses “a bone screw having a threaded portion, said bone screw extending through said aperture,” as discussed above with respect to claim 1.

Limitation [C]. Shavit and Kilpela discloses “an insert, said insert having a longitudinal axis, a distal end, a proximal end and a passageway extending

longitudinally through said insert from said proximal end to said distal end, said insert having a lower surface, said insert positioned within said chamber.” As described with respect to claim 1, Shavit in view of Kilpela renders obvious an insert with a longitudinal axis, distal end, proximal end and a passageway. The insert of Shavit includes a lower surface and is positioned within the chamber. (Ex. 1007 at Figs. 1B, 4; *see also* Ex. 1001 at ¶¶ 194-95.) This lower surface, as annotated below, is separate from the locking projection.



(Ex. 1007 at Figs. 1B, 4 (annotated).)

Limitation [D]. Shavit discloses “a locking ring having a longitudinal passageway extending therethrough and an outer surface, a plurality of threads located on said outer surface, wherein said threads located on said outer surface of said locking ring engage said threads on said inner surface of said chamber, said locking ring rotatably connected to said insert.” As described above with respect to claim 1, Shavit discloses a locking ring having a longitudinal passageway extending therethrough. Likewise, as described with respect to claim 4, the

locking ring has a plurality of threads on the outer surface that engage the threads on the inner surface. (Ex. 1001 at ¶ 206.)

The locking ring is rotatably connected to the insert. (Ex. 1001 at ¶ 207-08.) For example, Shavit explains that the “adapter 24 [locking ring] . . . [can] rotate freely with respect to stem 26 [insert] while it is coupled. In particular, the coupling mechanism allows adapter 24 [locking ring] to push or pull stem 26 axially, without requiring stem 26 [insert] to rotate” (Ex. 1007 at 9:8-9.)

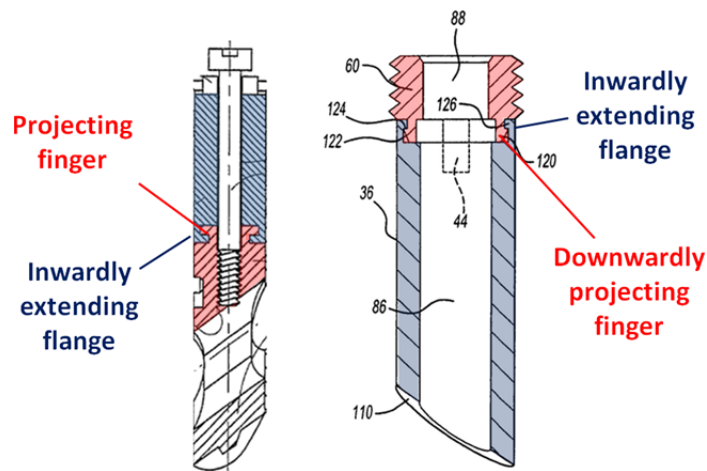
Limitation [E]. Shavit discloses “bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is located in one of said grooves to resist rotation of said bone screw within said aperture.” As discussed with respect to claim 1, Shavit discloses a bone screw with longitudinal axis and longitudinally extending grooves.

Shavit discloses an insert and bone screw, wherein at least a portion of said distal end of the insert is located in one of said grooves to resist rotation of said bone screw within said aperture. (Ex. 1001 at ¶ 211.) For example, “[t]he hip peg [bone screw] has a slot 18 [groove], and there is a tab 20, at the end of locking mechanism 22 [distal end of insert], which fits into slot 18 [groove].” (Ex. 1007 at 8:7-8.) This configuration resists rotation of the bone screw within the aperture.

g. Claim 7 Is Rendered Obvious By Shavit in view of Kilpela.

Preamble. Shavit and Kilpela disclose “[a] fixation instrument for treating a bone fracture as set forth in claim 6,” as described above.

Limitation [A]. Shavit renders obvious, as matter of design choice, “said locking ring having a downwardly projecting finger having a lip.” In claim 7, the projecting finger and lip are located on the locking ring. In Shavit, the projecting finger and lip are located on the insert. Structurally and functionally, the projecting finger in Shavit (left) is the same as the projecting finger claimed in the ’707 Patent (right). The location is merely flipped.



(Ex. 1007, Shavit, at Fig 4; Ex. 1004, ’707 Patent, at Fig. 8A (annotated).)

Moving the projecting finger to the locking ring would have been obvious as a matter of design choice to a person of ordinary skill in the art. (Ex. 1001 at ¶ 214.) Again, a claim is not patentable if it only moves existing elements without achieving any novel or unexpected result. *Pharmatech*, IPR2013-00247, Paper 27

at 19; *Nano-Second Tech.*, 944 F. Supp. 2d at 863-64. In this case, the '707 Patent moved a prior art projecting finger from the insert to the locking ring. The projecting finger performs the same function, and the interaction between the locking ring and the inserts remains unchanged. (Ex. 1001 at ¶ 213-14.) As such, it would have been obvious to a person of ordinary skill in the art as a matter of design choice based on Shavit to change the location of the projecting finger.

Limitation [B]. Shavit renders obvious, as a matter of design choice, “said insert having an inwardly extending flange whereby said flange cooperates with said lip to rotatably secure the locking ring to the insert.” Shavit describes an inwardly extending flange that secures the insert to the locking ring. (Ex. 1007 at 9:5-15.) In claim 7, the inwardly extending flange is located on the insert. In Shavit, the inwardly extending flange is located on the locking ring. (*See e.g.* Ex. 1007 at Fig. 4.) As described above, a person of ordinary skill in the art would have recognized, as a matter of design choice, that the flange could be located on either the locking ring or the insert. (Ex. 1001 at ¶ 214.) As such, it would have been obvious to a person of ordinary skill in the art based on Shavit to include the inwardly extending flange on the insert instead of the locking ring.

Shavit also explains that the inwardly extending flange cooperates with the lip to rotatably secure the locking ring to the insert. (*Id.* at ¶¶ 213-14.) For example, Shavit explains the locking ring can “rotate freely with respect to stem 26

[insert] while it is coupled. In particular, the coupling mechanism allows adapter 24 [locking ring] to push or pull stem 26 [insert] axially, without requiring stem 26 to rotate” (Ex. 1007 at 9:7-9.)

h. Claim 8 Is Rendered Obvious By Shavit in view of Kilpela.

Preamble. Shavit and Kilpela disclose “[a] fixation instrument for treating a bone fracture as set forth in claim 7,” as described with respect to claim 7.

Limitation [A]. Shavit renders obvious, as a matter of design choice, “said chamber having a groove extending along a side wall of said chamber.” As discussed with respect to claim 3, Shavit discloses a channel, or groove, for a locating member. The purpose of the groove is to “prevent[] stem 26 [insert] from accidentally turning and becoming misaligned.” (*Id.* at 12:26-28.)

In Shavit, the groove for the locating member is located on the insert. But for the reasons discussed with respect to claim 3, repositioning the groove to the side wall of the chamber is a matter of design choice that would have been obvious in view of Shavit to a person of ordinary skill in the art. (*See also* Ex. 1001 at ¶¶ 220-21.)

Limitation [B]. Shavit renders obvious, as a matter of design choice, “said insert including a locating member extending radially outward from a body of said insert, said locating member cooperating with said groove whereby said insert moves in said chamber in a longitudinal direction and is constrained against

rotation by the locating member.” As discussed with respect to claim 3, Shavit discloses a locating member to prevent rotation of the insert, but positions the locating member on a side wall of the chamber. Similarly, the corresponding groove in Shavit is located on the insert. Although claim 8 of the ’707 reverses the position of the locating member and groove, this change was a design choice obvious to a person of ordinary skill in view of Shavit for the reasons discussed with respect to claim 3.

The locating member in Shavit cooperates with the groove to allow the insert to move in a longitudinal direction, but is constrained against rotation. (*Id.* at ¶ 225.) In particular, the groove “is long enough axially so that, when nail-stopping screw 28 engages slot 34 [groove], stem 26 [insert] is free to move axially.” (Ex. 1007 at 12:22-26.) Also, the locating member prevents the insert from “accidentally turning and becoming misaligned.” (*Id.* at 27-29.)

i. Claim 9 Is Rendered Obvious By Shavit in view of Kilpela.

Claim 9 recites “A fixation instrument for treating a bone fracture as set forth in claim 8 including said insert having an overall outer diameter less than an inner diameter of said chamber formed by said threads on said inner surface of said chamber.” Shavit discloses an insert having an overall outer diameter less than an inner diameter of said chamber formed by said threads on said inner surface of said chamber, as depicted, for example, in Figure 4. (*See also* Ex. 1001 at ¶¶ 226-27.)

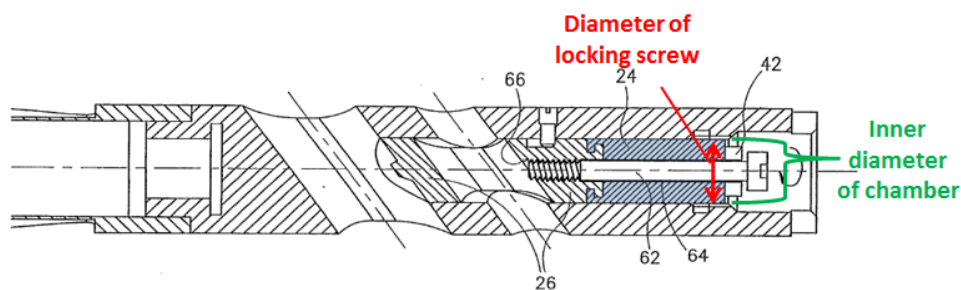


FIG. 4

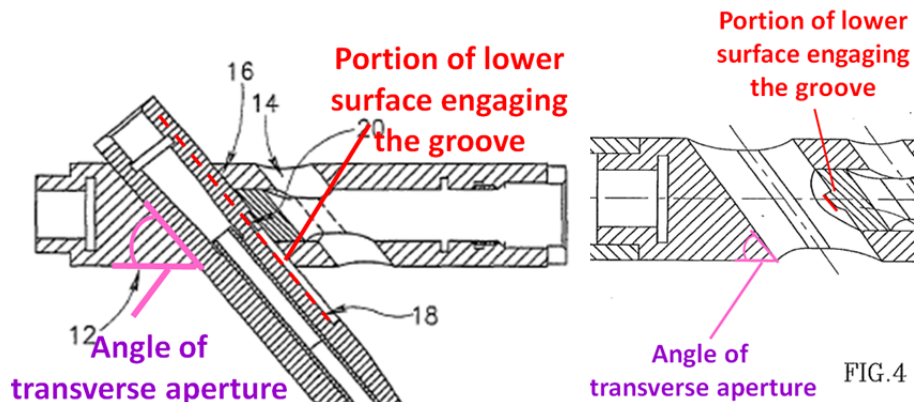
(Ex. 1007 at Fig. 4 (annotated).)

j. Claim 10 Is Rendered Obvious By Shavit in view of Kilpela.

Claim 10 recites “a fixation instrument for treating a bone fracture as set forth in claim 8 wherein said portion of said lower surface engaging said grooves in said locking screw extends at an angle substantially the same as the angle of said aperture.”

For the reasons discussed with respect to claim 10 in view of Roth above, “portion of said lower surface engaging said grooves” lacks antecedent basis and is inconsistent with the ’707 patent specification and prosecution history. Nonetheless, if “said portion of said lower surface” includes the locking projection, Shavit in view of Kilpela discloses an insert wherein “said portion of said lower surface” engages said grooves in said locking screw and extends at an angle substantially the same as the angle of said aperture. (Ex. 1001 at ¶ 230.) Shavit describes an insert with a lower surface that extends at an angle substantially the same as the angle of the transverse aperture, as seen in Figures 1B and 4. (Ex. 1007 at Figs. 1B, 4; Ex. 1001 at ¶ 231.) A portion of this lower surface “fits into

slot 18 [groove], preventing hip peg 10 [bone screw] from coming out of hole 16 [transverse aperture].” (Ex. 1007 at 8:7-8.) This portion extends at the same angle as the aperture. (*Id.* at Figs. 1B, 4.)



(Ex. 1007 at Figs. 1B, 4 (annotated).)

C. Grounds 1 and 2 Are Not Cumulative

Although Grounds 1 and 2 independently invalidate every claim of the '707 patent, the Board should institute trial on both grounds because each one presents distinct issues. For example, Roth and Shavit disclose different geometries for the longitudinal grooves and locking projections. (*Compare* Ex. 1006 at Fig. 8 *with* Ex. 1007 at Fig. 1B.) Thus, there is variation in how each reference discloses the claims. Further, Ground 1 relies only on 35 U.S.C. § 102, which is narrower than the obviousness inquiry of Ground 2.

VII. Conclusion

As explained herein, there is a reasonable likelihood that Zimmer Biomet will prevail in establishing each of the claims challenged in this Petition as

unpatentable. Zimmer Biomet requests that a trial on Grounds I and II be instituted and that claims 1-10 of U.S. Patent 8,702,707 be cancelled.

Date: November 23, 2015

Respectfully submitted,

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APPENDIX OF EXHIBITS

Exhibit No.	Description
1001	Declaration of Richard F. Kyle, M.D. Under 37 C.F.R. § 1.68 in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,702,707
1002	Appendix A to Exhibit 1001: Richard F. Kyle Curriculum Vitae
1003	Appendix B to Exhibit 1001: Richard F. Kyle Materials Considered
1004	U.S. Patent 8,702,707 (“’707 patent”)
1005	U.S. Patent 8,092,454 (“’454 patent”)
1006	United States Patent 6,835,197 (“Roth”)
1007	World International Application Publication No. WO 03/061495 to Shavit et al. (“Shavit”)
1008	United States Patent 6,123,708 to Kilpela et al. (“Kilpela”)
1009	USPTO Assignments on the Web for ’707 Patent
1010	December 2, 2014 Service of Process Notice
1011	Amended Answer And Counterclaims, <i>Advanced Orthopaedic Solutions, Inc. v. Biomet, Inc. et al.</i> , Case No. 2:14-cv-06354-ODWMAN
1012	U.S. Provisional Application No. 60/552,229

Exhibit No.	Description
1013	U.S. Application No. 13/335,696 (“the ’696 application”)
1014	U.S. Application No. 11/078,750 (“the ’750 application”)
1015	Excerpt from the File History of the ’696 Application: January 23, 2013 Restriction Requirement (“1/23/13 Action”)
1016	Excerpt from the File History of the ’696 Application: February 4, 2013 Response to Restriction Requirement (“2/4/13 Resp.”)
1017	Excerpt from the File History of the ’696 Application: April 5, 2013 Office Action (“4/5/13 Action”)
1018	Excerpt from the File History of the ’696 Application: October 25, 2013 Applicant Response (“10/25/13 Resp.”)
1019	Excerpt from the File History of the ’696 Application: December 4, 2013 Notice of Allowance (“12/4/2014 Notice”)
1020	Excerpt from the File History of the ’750 Application: October 26, 2006 Non-Final Office Action (“10/26/06 Action”)
1021	Excerpt from the File History of the ’750 Application: March 26, 2007 Applicant Response (“3/26/07 Resp.”)
1022	Excerpt from the File History of the ’750 Application: June 13, 2007 Non-Final Office Action (“6/13/07 Action”)
1023	Excerpt from the File History of the ’750 Application: November 13, 2007 Applicant Response (“11/13/07 Resp.”)
1024	Excerpt from the File History of the ’750 Application: February 4, 2008 Non-Final Rejection (“2/4/08 Action”)

Exhibit No.	Description
1025	Excerpt from the File History of the '750 Application: May 29, 2008 Applicant Response ("5/29/2008 Resp.")
1026	Excerpt from the File History of the '750 Application: August 18, 2008 Final Office Action ("8/18/08 Action")
1027	Excerpt from the File History of the '750 Application: December 18, 2008 Request for Continued Examination ("12/18/08 RCE")
1028	Excerpt from the File History of the '750 Application: December 18, Applicant Response ("12/18/08 Resp.")
1029	Excerpt from the File History of the '750 Application: March 9, 2009 Final Office Action ("3/9/09 Action")
1030	Excerpt from the File History of the '750 Application: June 9, 2009 Pre-Appeal Brief Request ("06/09/2009 Req.")
1031	Excerpt from the File History of the '750 Application: July 27, 2009 Notice of Panel Decision from Pre-Appeal Brief Review ("7/27/09 Notice")
1032	Excerpt from the File History of the '750 Application: October 26, 2009 Non-Final Office Action ("10/26/2009 Action")
1033	Excerpt from the File History of the '750 Application: March 26, 2010 Applicant Response ("3/26/2010 Resp.")
1034	Excerpt from the File History of the '750 Application: April 27, 2010 Final Office Action ("4/27/2010 Action")

Exhibit No.	Description
1035	Excerpt from the File History of the '750 Application: August 27, 2010 Pre-Appeal Brief Request 8/27/10 Request ("8/27/10 Request")
1036	Excerpt from the File History of the '750 Application: November 26, 2010 Notice of Panel Decision from Pre-Appeal Brief Review ("11/26/10 Notice")
1037	Excerpt from the File History of the '750 Application: February 1, 2011 Non-Final Office Action ("02/01/11 Action")
1038	Excerpt from the File History of the '750 Application: June 30, 2011 Applicant Response ("06/30/2011 Resp.")
1039	Excerpt from the File History of the '750 Application: September 6, 2011 Notice of Allowance ("9/6/11 Notice")
1040	September 2, 2015 Advanced Orthopaedic Solutions Amended Infringement Contentions ("AOS Contentions")
1041	Bruce D. Browner & Charles C. Edwards, The Science and Practice of Intramedullary Nailing (Lea & Febiger 1987) ("Browner")
1042	T.R.C. Davis et al., Intertrochanteric Femoral Fractures , 72 Bone & Joint J. No. 1. (1990) ("Davis et al.")
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,702,707 UNDER 35 U.S.C. § 311 AND 37 C.F.R. § 42.100, along with all exhibits and other supporting documents, were served on November 23, 2015, by USPS Express Mail directed to the attorney of record for the patent at the following address:

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A courtesy copy was also served by electronic mail on the attorneys of record for the following related matter:

Advanced Orthopaedic Solutions, Inc. v. Biomet Inc. et al., Case No. 2:14-cv-06354 ODW-(MANx) (C.D. Cal.)

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