

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER BIOMET HOLDINGS, INC., ZIMMER INC., and
BIOMET INC.,
Petitioners,

v.

ADVANCED ORTHOPAEDIC SOLUTIONS, INC.,
Patent Owner.

Case IPR2016-00236
Patent 8,702,707 B2

Before LORA M. GREEN, SCOTT A. DANIELS, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Zimmer Biomet Holdings, Inc., Zimmer Inc., and Biomet Inc. (collectively “Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–10 of U.S. Patent No. 8,702,707 B2 (Ex. 1004, “the ’707 patent”). Paper 1 (“Pet.”). Advanced Orthopaedic Solutions, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 5 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–10. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner notes that “[t]he ’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.” Pet. 1.

We note further that Petitioner filed a second IPR, IPR2016-00311, which challenges related U.S. Pat. No. 8,092,454 B2.

B. The ’707 Patent (Ex. 1004)

The ’707 patent issued on April 22, 2014, with Gary W. Sohngen as the listed inventor. Ex. 1004. The ’707 patent is a continuation of application No. 11/078,750, filed on March 11, 2005, now U.S. Pat. No. 8,092,454 B2. *Id.*

The '707 patent is drawn to “a fixation instrument for treating bone fractures,” and “[m]ore specifically, a nail and bone screw combination used to treat a fracture of the femur.” *Id.* at 1:16–18. “The bone nail extends within the shaft portion of a bone such as a femur,” and an “opening in the head or proximal end of the nail receives a bone screw that, in the case of a femoral neck fracture, extends into the femoral head.” *Id.* at 1:55–58. “[A] locking insert disposed within the nail engages the bone screw and prevents rotation thereof.” *Id.* at 1:59–61.

Figure 1 of the '707 patent is reproduced below:

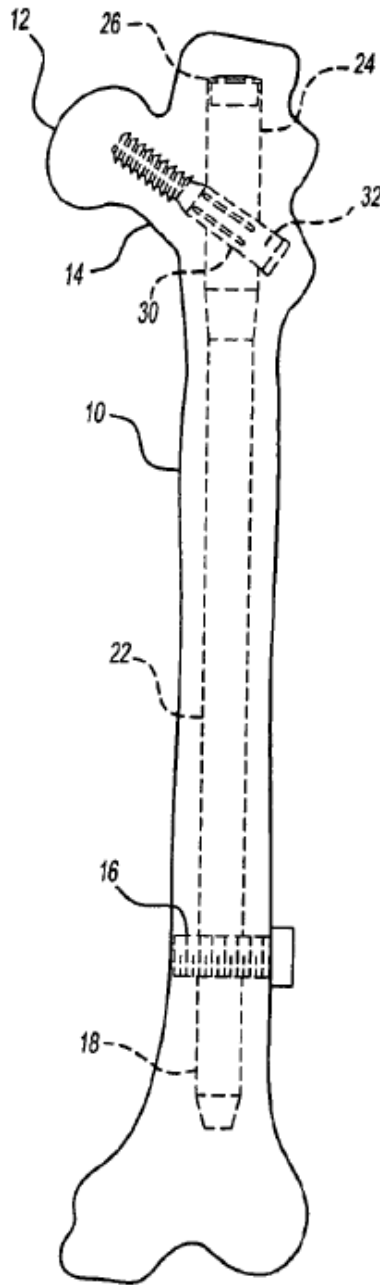


Fig-1

Figure 1 “is a diagrammatic front view of a fixation instrument . . . shown implanted within a femur.” *Id.* at 2:3–5. As can be seen in Figure 1, the

fixation instrument includes nail member 22 that has distal end 18 and proximal end 24. *Id.* at 2:50–52.

Figure 2 of the '707 patent is reproduced below:

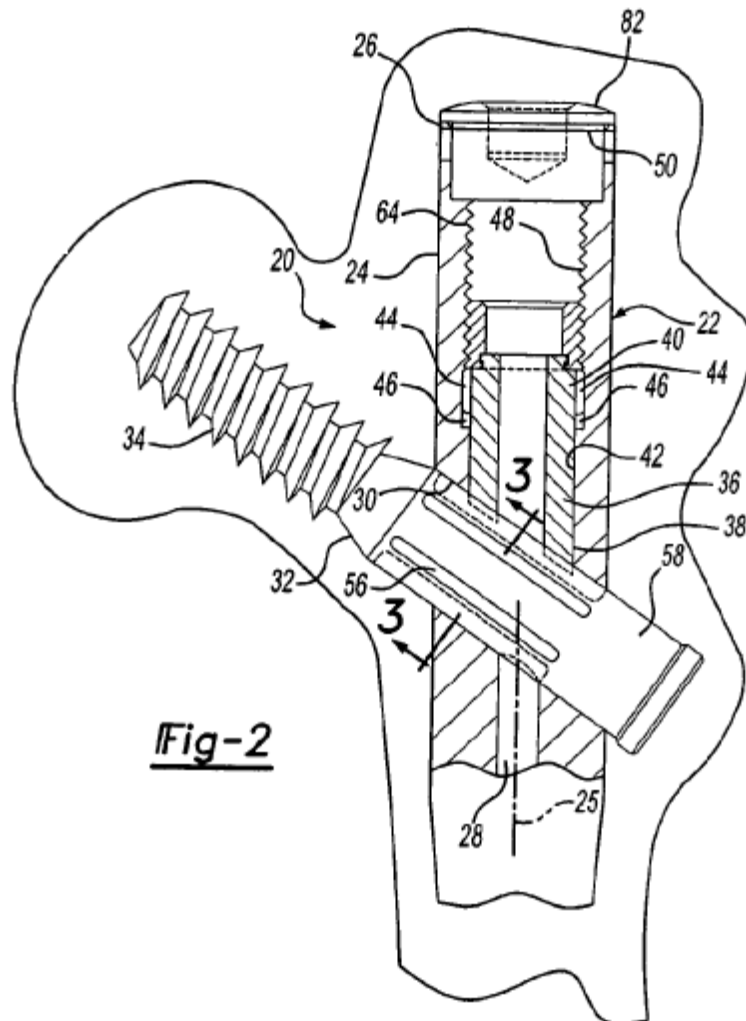


Figure 2 “is an enlarged front view of the proximal end of the fixation instrument according to the present invention with portions removed for clarity and illustration.” *Id.* at 2:6–8.

As shown in Figure 2, passageway 28 extends through the nail longitudinally between the proximal and distal ends. *Id.* at 2:57–59. The

passageway may receive a guide wire that may be used to position the nail member 22 into the bone 10. *Id.* at 2:59–62.

The bone screw 32, which is received in nail 22, includes a plurality of longitudinally extending grooves 56, which are “of a size and shape that are complementary to the locking projections 54 located on the lower surface 52 of the insert 36.” *Id.* at 3:30–45 (emphasis omitted). “Once properly aligned, the insert 36 is driven further within or into the chamber 42 until the lower surface 52 of the insert 36 engages the outer surface 58 of the bone screw 32 and the locking projections 54 of the insert 36 extend into the grooves 56 of the bone screw 32.” *Id.* at 3:42–47 (emphasis omitted).

Figure 3 of the '707 patent is reproduced below:

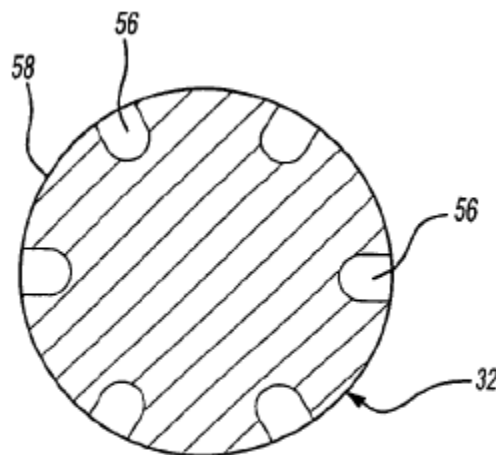


Fig-3

Figure 3 is “a cross-sectional view of the bone screw shown in FIG. 2 taken along lines 3-3.” *Id.* at 2:9–10 (emphasis omitted). Shown is a cross-sectional view of the longitudinally extending grooves located on the outer surface 58 of bone screw 32. *Id.* at 3:30–32.

The '707 patent notes that “[i]t should be understood that the detailed description and specific examples, while indicating the preferred

embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.” *Id.* at 1:63–67.

C. Illustrative Claim

Petitioner challenges claims 1–10 of the ’707 patent. Claims 1 and 6 are independent. Claim 1 is illustrative of the challenged claims, and is reproduced below:

1. A fixation instrument for treating a bone fracture comprising:

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;

a bone screw, having a threaded portion, said bone screw extending through said aperture;

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;

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; and

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.

Claim 6 requires many of the same limitation as claim 1. It differs, in part, from claim 1 in that it requires that the nail member have “an aperture extending therethrough at an angle with respect to said longitudinal axis of said nail member.”

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–10 of the ’707 patent on the following grounds (Pet. 4):

References	Basis	Claims Challenged
Roth ¹	§ 102	1–10
Shavit ² and Kilpela ³	§ 103(a)	1–10

Petitioner relies also on the Declaration of Richard F. Kyle, M.D. Ex. 1001.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable constructions in light of the Specification of the patent in which they appear. *See* 37 C.F.R. §42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed.

¹ Roth et al., U.S. Patent No. 6,835,197 B2, issued Dec. 28, 2004 (Ex. 1006) (“Roth”).

² Shavit et al., WO 03/061495 A2, published Jul. 31, 2003 (Ex. 1007) (“Shavit”).

³ Kilpela et al., US Patent No. 6,123,708, issued Sep. 26, 2000 (Ex. 1008) (“Kilpela”).

Cir. 2015) (“Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA,” and “the standard was properly adopted by PTO regulation.”), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (2016) (mem.) (No. 15-446). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

“[T]he specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.’” *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1149 (Fed. Cir. 2012) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed.Cir.2005) (en banc)). The Court of Appeals for the Federal Circuit has cautioned, however, “[t]here is a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims.” *Retractable Techs., Inc. v. Becton, Dickinson, and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011), *reh’g and reh’g en banc denied*, 659 F.3d 1369 (Fed. Cir. 2011), *cert. Denied*, 133 S.Ct. 833 (2013). Thus, “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014).

i. “A Plurality of Longitudinally Extending Grooves”

Petitioner contends “that the term ‘a plurality of longitudinally extending grooves’ . . . should be construed as ‘a plurality of longitudinally

extending cuts or depressions.’” Pet. 9. In support of that proposed construction, Petitioner contends:

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.

Pet. 10.

Patent Owner responds that that the “term ‘longitudinally extending grooves’ is clear and does not need construction.” Prelim. Resp. 4. Specifically, referencing Figures 2 and 3 of the Specification, Patent Owner argues that grooves “are long, narrow furrows, cuts, or indentations” in the outer surface of the bone screw. *Id.* at 5.

Patent Owner argues that Petitioner’s construction is based on the testimony of Dr. Kyle, contending, however, that Dr. Kyle testifies as to his opinion, and not as the person of ordinary skill in the art. *Id.* at 7 (citing Ex. 1001 ¶¶ 33–35. Patent Owner asserts that “Dr. Kyle does not explain or provide specifics regarding why a person of ordinary skill in the art would construe the term in the manner he proposes,” and, therefore, his testimony is entitled to little weight. *Id.* (citing 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”))).

For purposes of this decision, we adopt Petitioner’s proposed construction of “longitudinally extending grooves,” that is, as “a plurality of longitudinally extending cuts or depressions.” We have considered Patent

Owner's contention that "longitudinally extending grooves" should be construed as "long, narrow furrows, cuts, or indentations," but Patent Owner does not point us to where the disclosure restricts the term "grooves" to that construction. Although Patent Owner points us to Figures 2 and 3 of the Specification, limitations from the Specification, even when only a single embodiment is disclosed, are not to be imported into the claims absent "a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Hill-Rom Services*, 755 F.3d at 1372 (citations omitted).

ii. *Other Claim Terms*

We determine that, for purposes of this Decision, none of the remaining terms in the challenged claims require express construction at this time. *See, e.g. Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (noting that only claim terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy).

B. *Anticipation by Roth (Ex. 1006)*

Petitioner contends that claims 1–10 are anticipated by Roth. Pet. 13–36. Patent Owner disagrees. Prelim. Resp. 10–14.

i. *Overview of Roth (Ex. 1006)*

Roth discloses "a bone implant and locking apparatus for internal fixation of a long bone, such as a femur." Ex. 1006, 1:15–17.

Figure 1 of Roth is reproduced below:

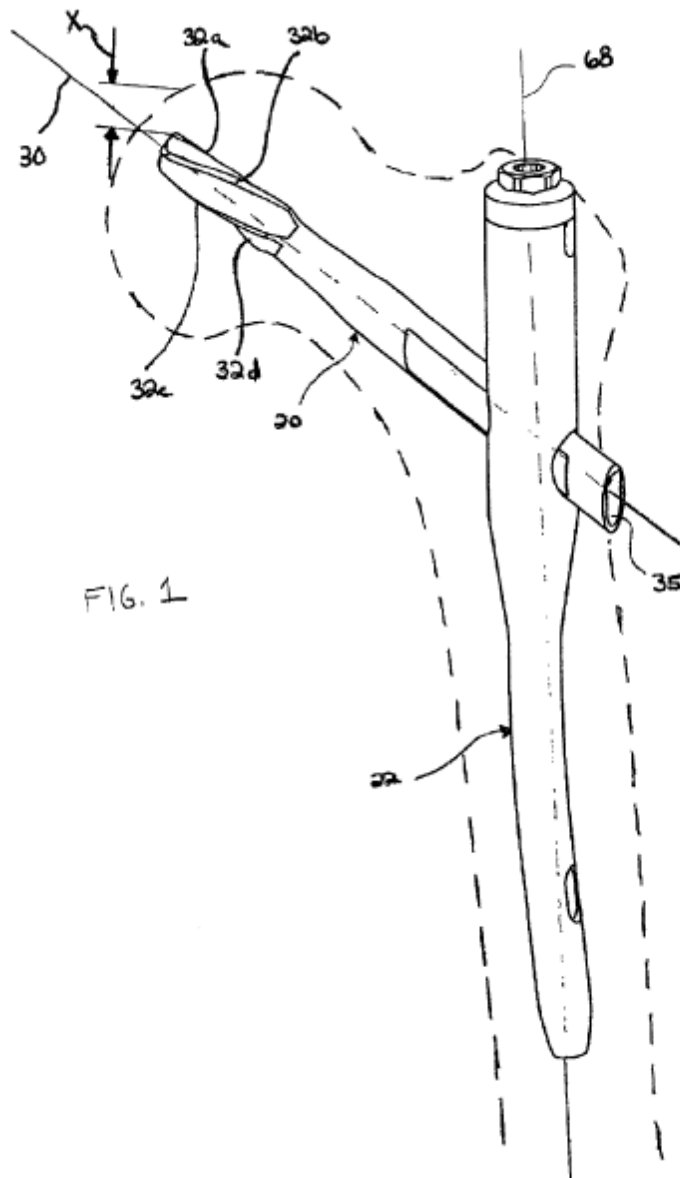


Figure 1 of Roth is a perspective view of a fracture fixation system. *Id.* at 2:63–65.

As shown in Figure 1, fracture fixation implant 20 is shown implanted in a femur, and coupled to second fixation implant 22, shown as an intramedullary nail. *Id.* at 3:45–49.

Figure 2 of Roth is reproduced below:

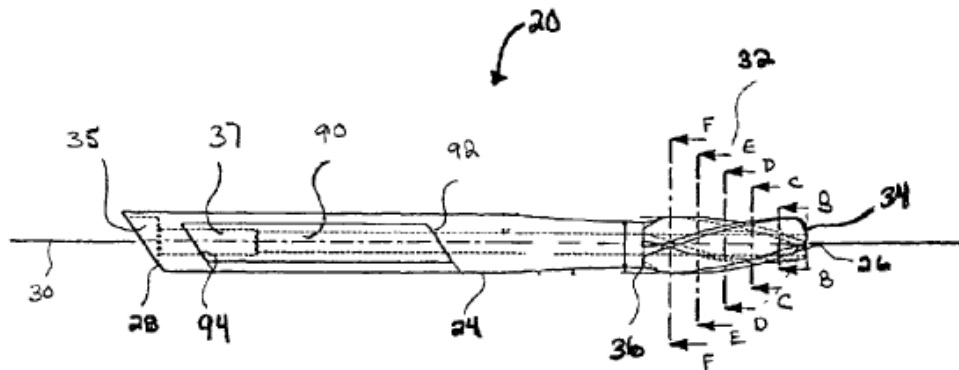


Figure 2 of Roth “is a left side view of . . . a fracture fixation implant of FIG. 1.” *Id.* at 2:66–67.

The implant 20 has proximal end 26 and distal end 28, which define longitudinal axis 30 between them. *Id.* at 3:61–64. Roth teaches further that implant 20 has an engagement surface 90 that extends along longitudinal axis 30. *Id.* at 7:63–67. Roth teaches that first and second stops 92, 94 may be located at the ends of the engagement surface 90. *Id.* at 7:67–8:2. Specifically, Roth teaches “engagement surface 90 is recessed into shaft 24 of implant 20, and stops 92, 94 are formed at the boundaries of the recessed surface.” *Id.* at 8:2–5. Roth notes that that implant 20 may be provided with two or more engagement surfaces 90. *Id.* at 8:10–12.

ii. Analysis

a. 35 U.S.C. § 325(d)

As an initial matter, Patent Owner argues that Roth was considered by the Examiner during prosecution, and we should, therefore, exercise our

discretion under 35 U.S.C. § 325(d) to deny institution on this ground.
Prelim. Resp. 12–13.

Title 35 U.S.C. § 325(d) states, in relevant part (emphasis added), that “[i]n determining whether to institute or order a proceeding under this chapter . . . the Director *may* take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” We have considered the facts and circumstances of the instant proceeding, and we decline to exercise our discretion to deny the Petition under 35 U.S.C. § 325(d).

b. Claims 1 and 6

Petitioner contends that Roth teaches all of the limitations of challenged claims 1 and 6, and provides a detailed explanation of how each limitation of claims 1 and 6 are taught by Roth. Pet. 13–20, 26–29. Patent Owner argues in its Preliminary Response that Roth fails to teach “a bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves.” Prelim. Resp. 10. We, thus, focus our analysis on that limitation.

Petitioner contends that Roth discloses a bone screw, implant 20 of Roth, with a plurality of longitudinally extending grooves, that is, the engagement surfaces 90 of Roth. Pet. 19 (citing Ex. 1006, 7:41–8:51, Fig. 2; Ex. 1001 ¶¶ 66–68). Specifically, Petitioner asserts:

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.)

Pet. 19.

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We must analyze prior art references as a skilled artisan would. *See Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (stating that to anticipate, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention”), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). After careful consideration of all of Petitioner’s evidence and contentions as to each limitation of independent challenged claims 1 and 6, we determine that Petitioner has shown a reasonable likelihood that challenged independent claims 1 and 6 are anticipated by Roth.

Patent Owner responds that Roth does not teach “longitudinally extending grooves” as required by challenged claims 1 and 6. Prelim. Resp. 10. Specifically, Patent Owner argues that the engagement surface 90 of Roth is not a “‘longitudinally extending groove’ according to the plain and ordinary meaning of the term.” *Id.* at 11.

As discussed above in the section of claim construction, we have construed “longitudinally extending grooves” as “a plurality of longitudinally extending cuts or depressions.” We determine, based on the

record currently before us, that Petitioner has sufficiently demonstrated that the engagement surfaces 90 of Roth meet that limitation.

Patent Owner contends further that even if one were to consider the engagement surface 90 of Roth a groove, “its longitudinal axis extends perpendicular to the longitudinal axis of the bone screw.” Prelim. Resp. 11. According to Patent Owner the first and second stops 92, 94 of define the ends of the engagement surface 90, and, thus, its orientation. *Id.* As those stops extend perpendicularly to the longitudinal axis 30 of implant 20, the engagement surfaces are not longitudinally extending grooves. *Id.* at 11–12.

That argument is not convincing as Roth specifically teaches that the engagement surface 90 extends along longitudinal axis 30. Ex. 1006, 7:65–67.

c. Claims 2 and 10

Claim 2 is drawn to the fixation instrument of claim 1, wherein:

said aperture extending at an angle through the proximal end of the nail member; and

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.

Petitioner contends that “Roth teaches an insert with a locking projection at its distal end.” Pet. 21 (citing Ex. 1006, 2:31–34; Ex. 1001 ¶¶ 74–75). Relying on Figures 8 and 9 of Roth, Petitioner asserts that a “portion of this locking projection extends at an angle substantially the same as the angle of the aperture.” *Id.*

Specifically, Petitioner provides the following annotated versions of Figures 8 and 9 of Roth (Pet. 22):

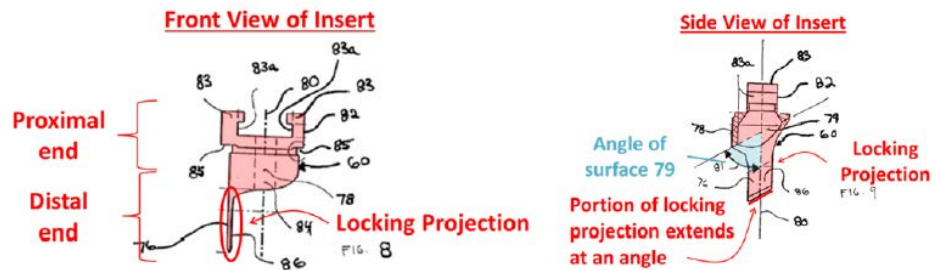


Figure 8 of Roth is a front view of the body member of the coupling mechanism, and Figure 9 is a left side view of the body member of the coupling mechanism. Ex. 1006, 3:15–18.

According to Petitioner, as shown in the annotated figures above, “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.)” Pet. 22.

Patent Owner contends that Petitioner relies on Dr. Kyle’s Declaration to support its contention that Roth meets the limitation of claim 2 that the “distal end of the locking projection 76 is angled and . . . appears to be at the same angle of the aperture.” Prelim. Resp. 13 (citing Ex. 1001 ¶¶ 76, 140). According to Patent Owner, Dr. Kyle opines that “[b]ecause the engagement surface 86 of the prong 76 engages the engagement surface 90 of the implant 20, . . . the portion of the locking projecting extending at an angle extends into and is adjacent the second engagement surface.” *Id.* at 13–14. Patent Owner asserts, however, that Dr. Kyle cites no support in Roth, and his opinion is, thus, without sufficient evidentiary basis. *Id.* at 14.

We determine that Petitioner has sufficiently demonstrated that claim 2 is anticipated by Roth. As noted by Petitioner, Roth teaches that the surface 79 of the body member 60 is “preferably oriented at an angle 81 with respect to longitudinal axis 80 that is substantially equal to angle 70.” Ex. 1006, 7:23–27 (emphasis omitted). Angle 70 is the angle at which the bore in which the implant 20 is received in the nail 22. *Id.* at 6:54–59. Roth teaches, therefore, “[a]ccording to the configuration where angle 81 is substantially equal to angle 70, angled surface 79 remains at a constant distance from implant 20 when the coupling mechanism is assembled and locked.” *Id.* at 7:27–30 (emphasis omitted). Thus, Petitioner has sufficiently established that Roth teaches that the “locking projection having a portion thereof that extends at an angle substantially the same as the angle of said aperture” as required by challenged claim 2.

Similarly, claim 10 is drawn to the fixation instrument of claim 8 (which depends from claim 6 through claim 7), “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.”

Petitioner contends that once a portion of the lower surface, that is, the locking projection, “is received in the groove, the ‘portion of said lower surface’ . . . engages the grooves on the bone screw to prevent the bone screw from further rotation.” Pet. 35 (citing Ex. 1001 at ¶ 137; Ex. 1006, Fig. 9). As explained above, Petitioner argues that Roth teaches that a portion of the lower surface “extends at an angle substantially the same as the angle of the aperture.” *Id.* at 36.

Patent Owner contends that Petitioner again improperly relies on the Declaration of Dr. Kyle to meet the limitation added by claim 10. Prelim.

Resp. 14. In particular, Patent Owner notes:

Dr. Kyle opines that the angle of the prong 76 is that portion of the lower surface engaging the grooves in the locking screw. (Kyle Declaration, Ex. 1001, ¶138). Dr. Kyle then opines that if the bone screw is misaligned, the lower surface will engage the groove to rotate the bone screw until it is properly align[ed]. (Kyle Declaration, Ex. 1001, ¶139). According to Dr. Kyle once aligned, the portion of the lower surface at the distal end of the locking projection also engages the grooves on the bone screw. (Kyle Declaration, Ex. 1001, ¶139).

Id.

Patent Owner asserts that Dr. Kyle does not point to any support in Roth, and his opinion is, thus, without sufficient evidentiary basis. *Id.* This argument is not persuasive because Dr. Kyle is testifying as to his understanding of Roth's specific disclosure, particularly Ex. 1006, 8:62–9:5. See Ex. 1001 ¶¶ 138–140.

For the reasons set forth with respect to claim 2, we determine that Petitioner has sufficiently established that Roth teaches a “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.” as required by challenged claim 10.

d. Remaining Claims

Patent Owner does not present additional arguments as to dependent claims 3–5 and 7–9. We have reviewed Petitioner's evidence and contentions as to the challenge of those claims as anticipated by Roth, and conclude that Petitioner has established a reasonable likelihood that it would prevail in showing that those claims also are anticipated by Roth.

iii. Conclusion

For the reasons set forth above, we determine that Petitioner has established a reasonable likelihood that claims 1–10 are anticipated by Roth.

*C. Obviousness over Shavit (Ex. 1007)
and Kilpela (Ex. 1008)*

Petitioner contends that claims 1–10 are rendered obvious by the combination of the Shavit and Kilpela. Pet. 36–59. Patent Owner disagrees. Prelim. Resp. 15–23.

i. Overview of Shavit (Ex. 1007)

Shavit “relates to the field of surgical nails used to repair bone fractures, in particular intramedullary nails used for fractures of the proximal femur.” Ex. 1007, 1:3–4. In particular, Shavit discloses “a nail with two screws going through it, one screw closer to the proximal end of the nail than the other screw, and a locking mechanism, accessible from the proximal end, which locks the screw that is further from the proximal end.” *Id.* at 2:6–9. The locking mechanism may be an integral part of the nail, such that it cannot be removed by mistake. *Id.* at 2:14–16.

Shavit teaches further that the distal end of the screw is optionally hollow, and a “channel is used to inject liquid under pressure into the distal portion of the nail, causing it to expand radially and lock the nail against the medullar channel. Alternatively or additionally, the channel is used to inject some kind of cement to hold one or more of the one or more screws in place or to hold the nail in place.” *Id.* at 2:19–23.

Figures 1A and 1B of Shavit are reproduced below:

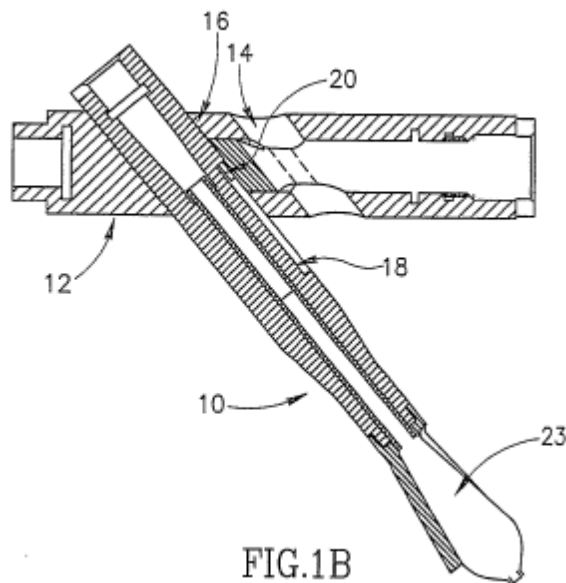
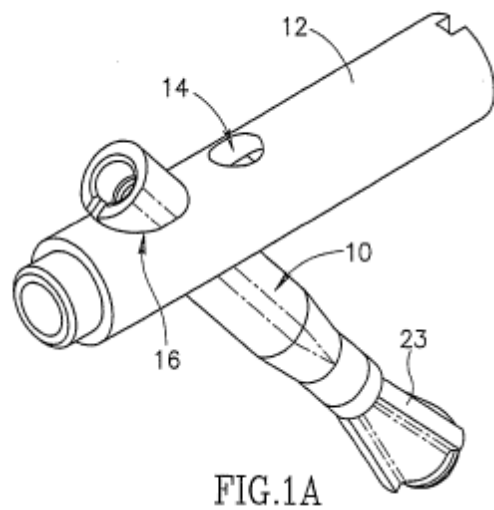


Figure 1A shows a perspective view, and Figure 1B shows a cross-sectional view, of the proximal portion of a nail with holes for inserting two screws, with one screw being shown inserted into the nail. *Id.* at 7:13–15.

As shown in Figures 1A and 1B, a nail 12 has holes 14 and 16 for inserting two screws. *Id.* at 7:29–30. Shavit refers to the larger screw as a hip peg, and the smaller screw as a hip pin. *Id.* at 7:33–8:1. The nail has a

locking mechanism 22 (not labeled), which is accessible from the proximal end of the nail and locks in place the larger screw 10 without interfering with the smaller screw, which is closer to the proximal end. *Id.* at 7:30–33.

As shown in Figure 1B, the hip peg 10 “has a slot 18, and there is a tab 20, at the end of locking mechanism 22, which fits into slot 18, preventing hip peg 10 from coming out of hole 16.” *Id.* at 8:7–9.

Specifically, according to Shavit:

If slot 18 is 20 mm longer, for example, than tab 20, in a direction along the axis of the hip peg, then the hip peg is able to move back and forth along its axis a distance of 20 mm, even when it is locked. Optionally, slot 18 is also wider azimuthally than tab 20, so that the hip peg is free to rotate by a limited angle when tab 20 is inserted into slot 18, in addition to being free to move a limited distance along its axis. . . . Optionally, there is a second slot in hip peg 10, shorter than slot 18, so that hip peg 10 would not be free to move at all when tab 20 is inserted into the second slot. Then hip peg 10 can either be locked completely, or partially locked with freedom to move a limited amount. Optionally, the second slot is inside slot 18. Alternatively, the second slot is separate from slot 18.

Id. at 8:10–20.

Figure 4 of Shavit is reproduced below:

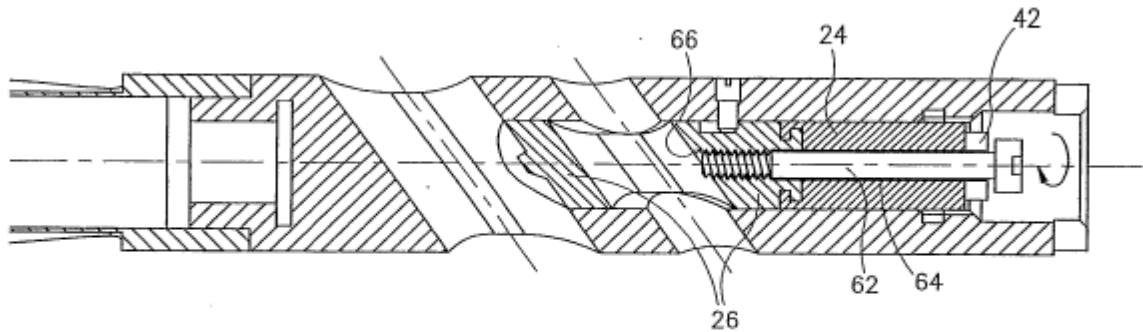


FIG. 4

Figure 4 is drawn to a different embodiment than Figure 1, and showing locking mechanisms for two screws. *Id.* at 7:21–22.

As shown in the figure, the “locking mechanism for the hip pin comprises a lag screw 62 which is inserted into a hole 64 going along the axis of locking mechanism 22.” *Id.* at 13:30–32. Hole 64 extends all the way through adapter 24, up to hole 32 in stem 26. *Id.* at 13:32–33. There are threads 66 in part of hole 64 that match the threads of lag screw 62. *Id.* at 13:33–14:1. “When the lag screw is screwed down all the way, it extends a short distance into hole 32, and hits the hip pin.” *Id.* at 14:1–2.

Shavit teaches:

In the embodiment shown in Fig. 4 there is no valve and there are no channels for injecting liquid into the distal portion of the nail, but optionally such parts exist, in addition to a locking mechanism for the hip pin. For example, the channel for fluid and the valve could be located inside lag screw 62. Alternatively, they are located in adapter 24 to the side of lag screw 62, or the channel goes through both lag screw 62 and adapter 24.

Id. at 14:10–14.

ii. Overview of Kilpela (Ex. 1008)

Kilpela teaches a rod or nail for insertion into a large or long bone, for support of the bone. Ex. 1008, 1:65–67. A central bore extends through the body of the rod, allowing the rod to be placed using a guidewire. *Id.* at 2:1–4, 2:30–36.

Kilpela teaches the use of a set screw to retain a bone screw that extends through a hole in the rod. *Id.* at 3:14–17. According to Kilpela:

such a set screw may carry an axial aperture, to permit a guidewire to extend completely through the central bore despite the presence of the set screw. Thus, the humeral rod may be installed by a guidewire technique, as is frequently a surgical desire, while at the same time the set screw may be pre-emplaced and ready to secure a transverse screw for retaining the rod in the desired position in the humerus or other long bone.

Id. at 3:20–27.

iii. Analysis

a. Claims 1 and 6

Petitioner contends that Shavit teaches all of the limitations of challenged claims 1 and 6, and provides a detailed analysis of how each limitation of claims 1 and 6 are taught by Shavit. Pet. 37–45, 50–53. Petitioner notes that Shavit alone does not teach “an insert having . . . a passageway extending longitudinally through said insert from said proximal end to said distal end,” are required by independent claims 1 and 6. Pet. 40, 51–52. Petitioner relies on Kilpela to address that limitation. *Id.* at 41–42, 51–52. Patent Owner argues in its Preliminary Response that one would not have combined Shavit with Kilpela to provide such a passageway in the insert. Prelim. Resp. 19–23. We, thus, focus our analysis on that limitation.

Specifically, Petitioner argues “Shavit teaches that the locking mechanism, which includes the locking ring and insert, is preferably preloaded into the bone nail.” Pet. 40 (citing Ex. 1007, 12:28–13:2; Ex. 1001 ¶ 154). Petitioner argues further that “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.’” *Id.* (citing Ex. 1008, 3:14–22; Ex. 1001 ¶ 155). According to Petitioner, the ordinary artisan would have included a passageway in the insert of Shavit so that the bone nail, with the insert preloaded, could be implanted over a guidewire. *Id.* at 40–41.

In particular, Petitioner contends “[b]ecause 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 41 (citing Ex. 1001 ¶¶ 28–29, 151). Adding a passageway through the insert of Shavit, Petitioner asserts, “would allow a bone nail with preloaded insert to be implanted over a guide wire.” *Id.* at 41–42 (citing Ex. 1001 ¶¶ 153–154).

Petitioner argues further that Shavit does not teach away from the combination with Kilpela. *Id.* at 42. Specifically, Petitioner notes that Shavit specifically teaches a fixation device that does not have valves or channels for fluid. *Id.* (citing Ex. 1007 14:10–11; Ex. 1001 ¶ 154).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406

(2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

After careful consideration of Petitioner's evidence and contentions as to each limitation of independent challenged claims 1 and 6, we determine that Petitioner has shown a reasonable likelihood that challenged independent claims 1 and 6 are rendered obvious by Shavit and Kipela. In particular, we conclude it would have been obvious at the time of invention add a passageway as taught by Kipela through the insert of Shavit as Kipela teaches that such a passageway allows a guidewire to be used to guide the nail to the appropriate site. *See, e.g., KSR*, 550 U.S. at 417 (“[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 unless its actual application is beyond his or her skill.”). We have carefully considered Patent Owner's arguments to the contrary, but they do not convince us otherwise.

Patent Owner responds “Shavit and Kilpela cannot be properly combined because they expressly teach away from one another.” Prelim. Resp. 15. In particular, Patent Owner argues that the bone nail of Shavit would be rendered inoperable if used with a guide wire. *Id.* at 16.

Specifically, Patent Owner notes:

Shavit discloses a device that keeps the locking mechanism 22 attached to the nail 12. As shown a nail-stopping screw 28, which goes through a hole 30 in the nail 12, engages a slot 34 in the stem 26 to keep the adapter 24 from being unscrewed whereby the locking mechanism 22 becomes separated from the

nail. (Ex. 1007, 12:17-20). Shavit explains “making the locking mechanism an integral part of the nail in this way means that there is less chance of the locking mechanism getting lost during surgery. Also, it is not necessary for the surgeon to repeatedly probe the injured area trying to insert the locking mechanism into the nail after the nail is in place in the bone, saving time and possibly avoiding additional trauma. (Ex. 1007, 12:31–32 – 13:1–2).

Id. at 20 .

Patent Owner acknowledges that Petitioner’s expert, Dr. Kyle, notes that Shavit recognizes these issues, but contends that Dr. Kyle only provides a conclusory statement that providing a passageway would allow the bone nail with the preloaded insert and locking ring to be implanted over a guide wire. *Id.* at 21 (citing Ex. 1001 ¶ 154). That statement, Patent Owner asserts, “does not articulate sufficient reasoning with rational underpinnings to support the legal conclusion of obviousness.” *Id.* at 21.

Patent Owner argues further that the intramedullary nail of Shavit has “a hollow distal portion 44 wherein water or other fluid is injected under pressure” causing “the distal portion 44 to expand radially, locking the nail in place in the medullar channel.” *Id.* at 21–22 (citing Ex. 1007 13:3–7). Thus, Patent Owner asserts, adding a passageway between the proximal and distal end of the nail member 12 of Shavit for use with a guide wire renders the nail inoperable, as it prevents pressure build-up in the distal end. *Id.* at 22. According to Patent Owner, “[b]ecause Shavit teaches away from cannulating the bone nail 12, it also teaches away from cannulating the insert; i.e., providing a passageway through the insert, because there is no reason to provide a passageway in the insert for a guide wire if there is no passageway in the nail for a guide wire.” *Id.*

Like our reviewing court, “[w]e will not read into a reference a teaching away from a process where no such language exists.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006). Under the proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the invention. “A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination.” *Syntex (USA) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). “The fact that the motivating benefit comes at the expense of another benefit . . . should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.” *Medichem, S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citations omitted).

We have considered Patent Owner’s allegations that Dr. Kyle’s testimony is conclusory and is entitled to little weight. The Declarant has not been subjected to cross-examination at this point of the proceeding, and we decline to discount it for purposes of this Decision. Moreover, we determine that the opinions expressed in the Declaration are sufficiently supported by Shavit and Kilpela. That is, as already discussed, Petitioner does provide a reason to combine Shavit with Kilpela. Specifically, Kilpela teaches that such a passageway allows a guidewire to be used to guide the nail to the appropriate site. That reason is supported not only by the testimony of Dr. Kyle but by Kilpela, which teaches the use of a guidewire to help guide such an implant to the desired region for implantation.

Moreover, Shavit teaches that the distal end of the screw is only *optionally* hollow (Ex. 1007, 2:19–20), and specifically teaches an embodiment in which there are no channels for injecting a fluid into the distal end of the nail (*id.* at 14:10–11, Fig. 4). Thus, Shavit contemplates a nail which does not have a hollow distal portion, and, thus, introducing a passageway through that nail for use with a guidewire as suggested by Petitioner would not render that nail inoperable.

Patent Owner contends further that the “locking mechanism 22 of Shavit is a solid component and an integral part of the nail.” Prelim. Resp.

16. Patent Owner asserts:

Cannulating the nail 12 expressly contradicts both Dr. Kyle’s testimony and the disclosure of Shavit explaining that the locking mechanism 22 is a solid, integral part of the bone nail 12. Nothing in FIG. 4 of Shavit or the associated disclosure supports a different conclusion.

Id. at 22–23.

Shavit, however, notes that in the embodiment shown by Figure 4 of that reference, a channel could be placed through both lag screw 62 and adapter 24. Ex. 1007, 14:14. There is no evidence currently of record demonstrating that the ordinary artisan would not have a reasonable expectation of success of extending that channel through the nail of Shavit such that it could be implanted over a guidewire. *See, e.g., In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (“[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.”); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) (“Combining the

teachings of references does not involve an ability to combine their specific structures.”).

b. Remaining Claims

Patent Owner does not present any arguments specific to dependent claims 2–5 and 7–10. We have reviewed Petitioner’s evidence and contentions as to the challenge of claims 2–5 and 7–10 over the combination of Shavit and Kilpela, and conclude that Petitioner has established a reasonable likelihood that those claims are also rendered obvious by the combination.

iv. Conclusion

For the reasons set forth above, we determine that Petitioner has established a reasonable likelihood that claims 1–10 are rendered obvious by the combination of Shavit and Kilpela.

III. CONCLUSION

For the foregoing reasons, we are persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing claims 1–10 of the ’707 patent are unpatentable under 35 U.S.C. §102 over Roth. We are persuaded also that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing claims 1–10 of the ’707 patent are unpatentable under 35 U.S.C. §103(a) over the combination of Shavit and Kilpela.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. §314(a), an *inter partes* review is hereby instituted on the following grounds:

Claims 1–10 as anticipated by Roth; and

Claims 1–10 as obvious over the combination of Shavit and Kilpela.

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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