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Paper No. 6
Entered: June 7, 2016

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 IPR2016-00311
Patent 8,092,454 B2

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

GREEN, *Administrative Patent Judge*.

DECISION
Denying 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 6–11, 13–15, 19, and 20 of U.S. Patent No. 8,092,454 B2 (Ex. 1004, "the '454 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 failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of any of the challenged claims. Accordingly, we decline to institute an *inter partes* review.

A. Related Proceedings

Petitioner notes that "[t]he '454 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, IPR2016-00236, which challenges related U.S. Pat. No. 8,702,707 B2. Trial was instituted in IPR2016-00236 on May 31, 2016. IPR2016-00236, Paper 6.

B. The '454 Patent (Ex. 1004)

The '454 patent issued on January 10, 2012, with Gary W. Sohngen as the listed inventor. Ex. 1004.

The ’454 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 1:12–14. “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 1:49–52. “[A] locking insert disposed within the nail engages the bone screw and prevents rotation thereof.” *Id*. at 1:53–55.

Figure 1 of the ’454 patent is reproduced below:

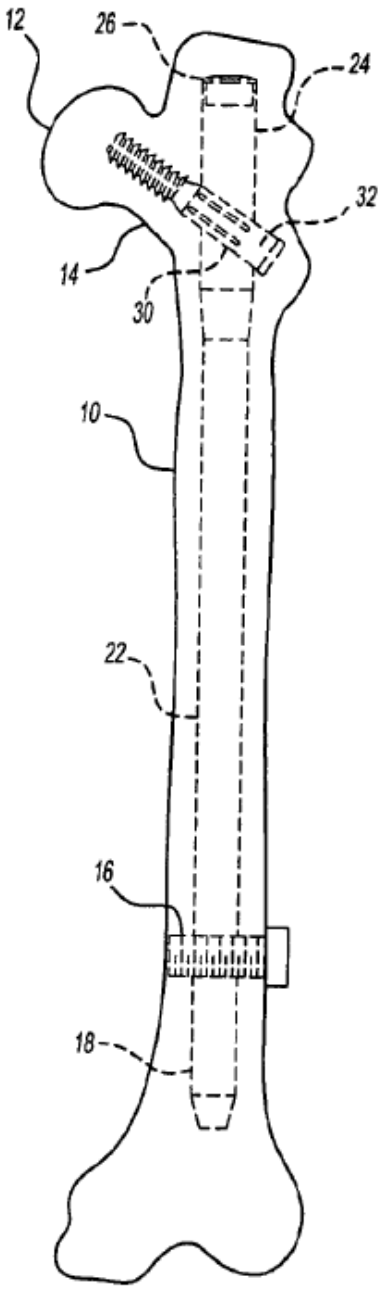


Fig-1

Figure 1 “is a diagrammatic front view of a fixation instrument . . . shown implanted within a femur.” *Id.* at 1:65–67. 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 2:45–47.

Figure 2 of the ’454 patent is reproduced below:

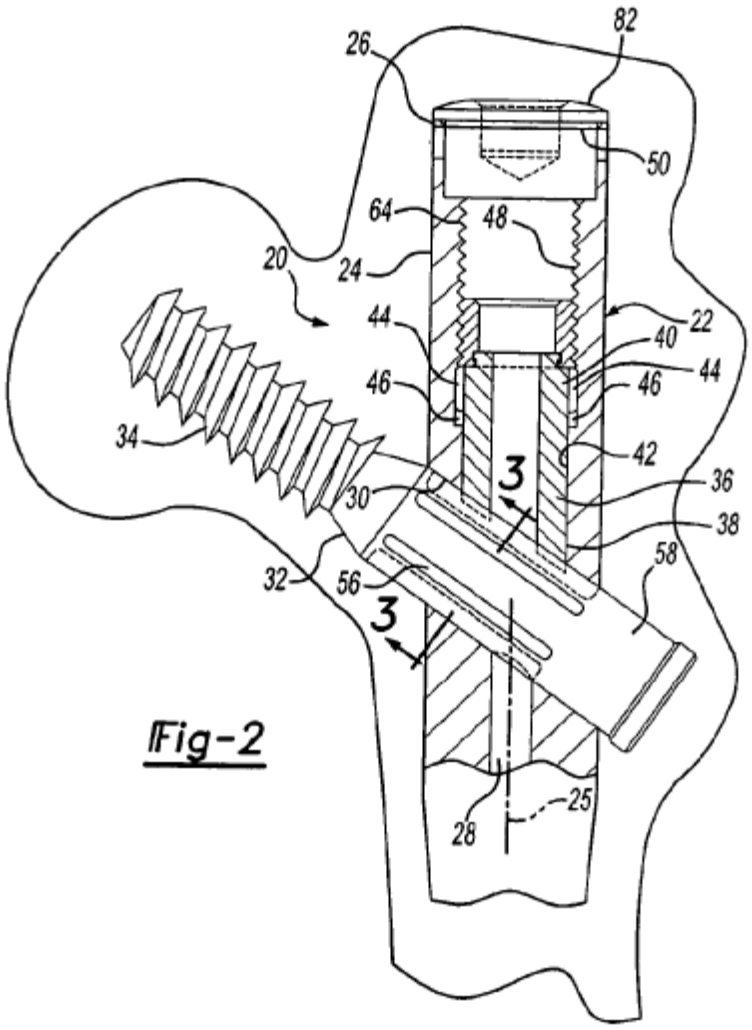


Fig-2

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 2:1–3.

As shown in Figure 2, passageway 28 extends through the nail longitudinally between the proximal and distal ends. *Id.* at 2:52–54. The

passageway may receive a guide wire that may be used to position the nail member 22 into the bone 10. *Id.* at 2:54–57.

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 3:25–29 (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 3:37–42 (emphasis omitted).

The '454 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 1:57–61.

C. Illustrative Claim

Petitioner challenges claims 6–11, 13–15, 19, and 20 of the '454 patent. Claims 6, 13, and 19 are independent. Claim 6 is illustrative of the challenged claims, and is reproduced below (emphasis added):

> 6. A fixation instrument for treating a bone fracture comprising:
>
> a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough and said nail member having a chamber located in said proximal end;
>
> an insert adapted to be positioned within said chamber and having a lower surface, *said lower surface operative to contact a bone screw extending through said aperture*;

> a locking ring received in said chamber and engaging said insert, said locking ring operative to secure said insert within said chamber;
>
> a locking projection located on said lower surface of said insert; and
>
> said bone screw having a longitudinally axis and having a plurality of longitudinal extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein said locking projection is located in one of said grooves when said lower surface contacts said bone screw.

Relative to the claim language shown in italics above, claim 13 requires that the "lower surface [of an insert]. . . engaging said bone screw when said bone screw extends through said aperture." Finally, claim 19 recites "said lower surface [of an insert] operative to engage a bone screw extending through said aperture."

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 6–11, 13–15, 19, and 20 of the '454 patent on the following grounds (Pet. 4–5):

References	**Basis**	**Claims Challenged**
Shavit[1]	§ 102	6, 7, 9, 10, and 13
Shavit and Kilpela[2]	§ 103(a)	8
Shavit and Kilpela	§ 103(a)	14, 15, 19, and 20

[1] Shavit et al., WO 03/061495 A2, published Jul. 31, 2003 (Ex. 1005) ("Shavit").

[2] Kilpela et al., US Patent No. 6,123,708, issued Sep. 26, 2000 (Ex. 1006) ("Kilpela").

References	Basis	Claims Challenged
Shavit, Kilpela, and Bramlet[3]	§ 103(a)	14, 15, 19, and 20
Shavit and Bramlet	§ 103(a)	11

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. 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).

We determine that, for purposes of this Decision, none of the 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.

[3] Bramlet et al., US Patent No. 6,443,954 B1, issued Sep. 3, 2002 (Ex. 1007) ("Bramlet").

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 Shavit (Ex. 1005)

Petitioner contends that claims 6, 7, 9, 10, and 13 are anticipated by Shavit. Pet. 14–27. Patent Owner disagrees. Prelim. Resp. 12–20.

i. Overview of Shavit (Ex. 1005)

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. 1005, 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.

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

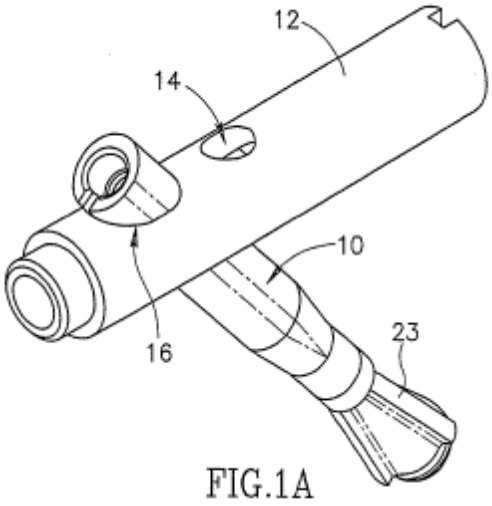


FIG.1A

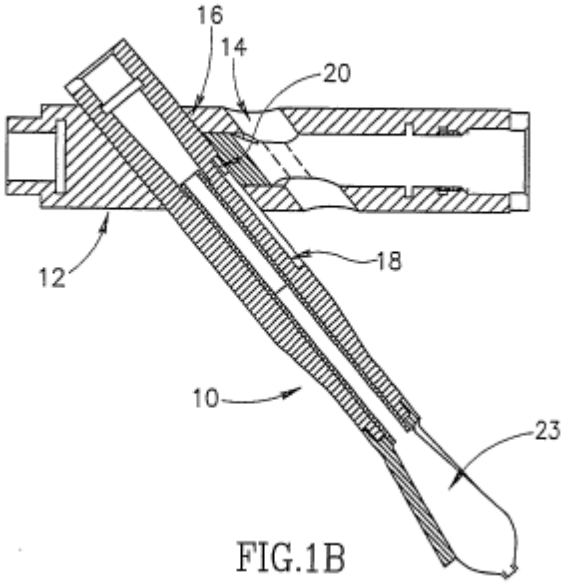


FIG.1B

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, 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 larger screw 10 without interfering with the smaller screw, which is closer to the proximal end. *Id.* at 7:30–33. Shavit teaches that the "[l]ocking mechanism 22 comprises a linear adapter 24 and a stem 26." *Id.* at 9:1–2.

As shown in Figure 1B, 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:

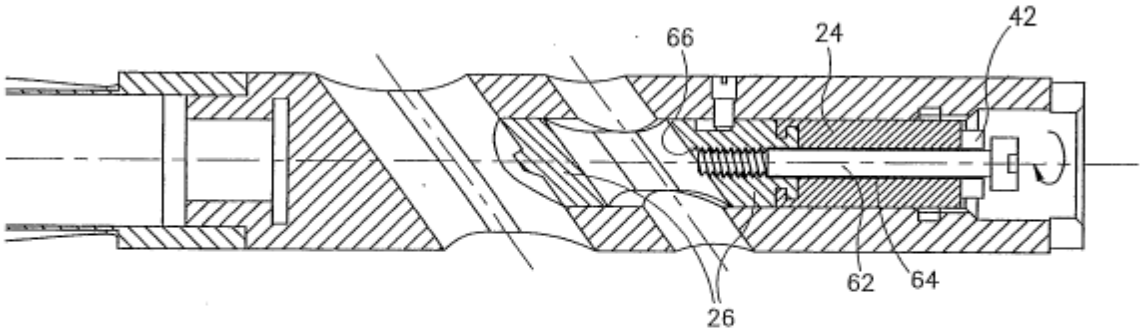


FIG.4

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

As shown in Figure 4, 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.

ii. Analysis

a. Independent Claims 6 and 13

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 independent challenged claim 6, we determine that Petitioner has not sufficiently demonstrated that Shavit teaches "an insert adapted to be positioned within said chamber and having a lower surface, *said lower surface operative to contact a bone screw extending through said aperture*" (emphasis added). Moreover, similar to claim 6, we determine that Petitioner has not sufficiently demonstrated that Shavit teaches a "lower surface [of an insert]. . . engaging said bone screw when said bone screw extends through said aperture," as required by independent claim 13. We, thus, focus our analysis on those limitations.

Petitioner contends that "Shavit discloses 'an insert adapted to be positioned within said chamber and having a lower surface, said lower surface operative to contact a bone screw extending through said aperture.'" Pet. 16. Specifically, Petitioner notes that Shavit teaches a locking mechanism 22 that comprises a linear adaptor 24, which Petitioner equates to the locking ring required by claim 13, and a stem 26, which Petitioner equates to the insert required by claim 13. *Id.* (citing Ex. 1005, 9:1–2).

Petitioner provides the following annotated versions of Figures 1B and 4 of Shavit (*id.* at 17):

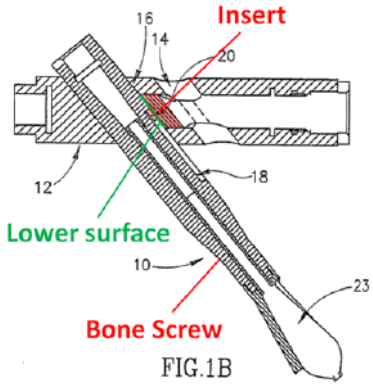


FIG.1B

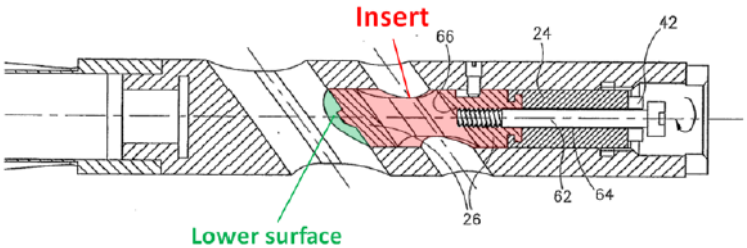


FIG.4

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, (Ex. 1005, 7:13–15) and Figure 4 shows a locking mechanisms for two screws (*id.* at 7:21–22).

According to Petitioner, as shown in the figures, the "insert is positioned within the chamber and includes a lower surface." Pet. 16. Petitioner contends that "Figure 1B also shows that the lower surface of the insert is operative to contact the bone screw extending through the aperture." *Id.* (citing Ex. 1001 ¶¶ 54–55).

Patent Owner responds that Shavit does not disclose that the lower surface of the insert is operative to contact a bone screw. Prelim Resp. 15. According to Patent Owner:

> Shavit expressly discloses the purpose of the tab 20 fitting in slot 18 allows the hip peg 10 to move in the aperture 16. Nothing in Shavit cites or refers to a lower surface of stem 26 contacting the hip peg 10.

Id. at 16.

Patent Owner provides the following annotated versions of Figures 3A and 3B of Shavit (*id.* at 17):

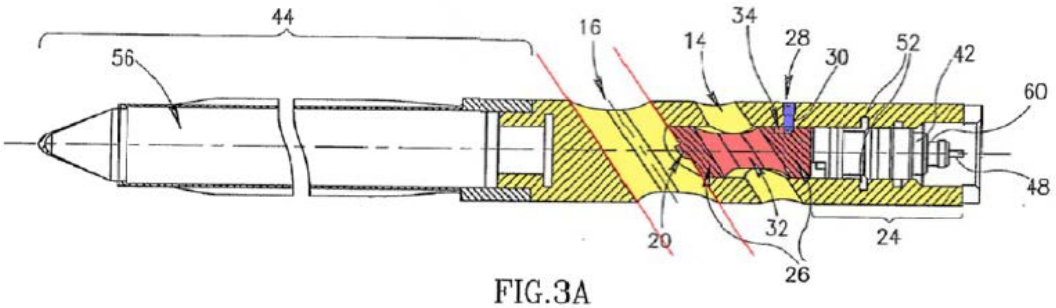


FIG.3A

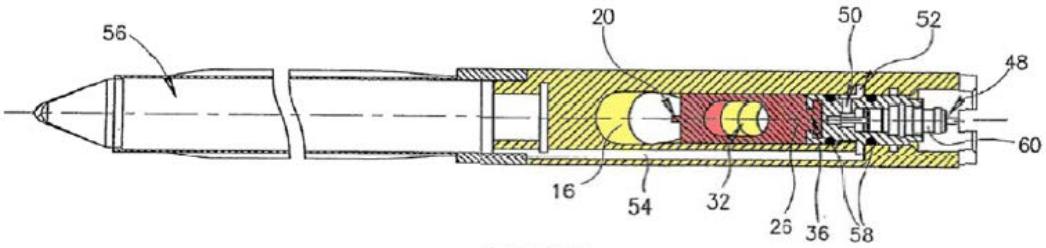


FIG.3B

Figures 3A and 3B of Shavit "show side cross-sectional views of the nail seen from two different directions, according to the same embodiment as Figs. 1A and 1B, showing the details of the locking mechanism, valve and channels." Ex. 1005, 7:18–20.

Patent Owner contends that as seen in the above annotated figures, "no portion of the stem 26, other than the tab 20, extends past the inner circumferential or peripheral surface, illustrated by the red line, defining the outer boundary of the hole 16." Prelim. Resp. 17. Patent Owner notes in particular that "Shavit discloses the locking mechanism 22 and tab 20 cooperating with the slot 18 in the hip peg 10 to whereby the hip peg 10 moves back and forth in the direction of its longitudinal axis." *Id.* at 18. If the lower surface of stem 26 were to contact hip peg 10, Patent Owner contends, it would prevent movement of hip peg 10. *Id.*

As to Petitioner's reliance on the testimony of Dr. Kyle, Patent Owner argues that "Dr. Kyle provides no specific explanation or identifies evidence supporting his opinion." *Id.* at 16 (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")).

We agree with Patent Owner that Petitioner has not sufficiently established that Shavit discloses an insert having a lower surface that is operative to contact a bone screw. Petitioner relies primarily on Figures 1B and 4 of Shavit to establish that the insert contacts the bone screw. As noted by Patent Owner (Prelim. Resp. 16), "[i]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000). "Ordinarily drawings which accompany an application for a patent are merely illustrative of the principles embodied in the alleged invention claimed therein and do not define the precise proportions of elements relied upon to endow the claims with patentability." *In re Olson*, 212 F.2d 590, 592 (CCPA 1954).

We have considered the testimony of Dr. Kyle relied upon by Petitioner, but it does not convince us otherwise. Dr. Kyle opines, relying on annotated Figures 1b and 4 of Shavit:

> Figure 1B shows a cross section of the bone screw, nail member, and insert. The bone screw, labeled 10, extends through the aperture, labeled 16. In this position, the lower surface contacts the bone screw extending through the aperture.

Ex. 1001 ¶ 55. Dr. Kyle, however, does not point to any disclosure of Shavit, or any other evidence, to support his interpretation of the Figures of Shavit.

We acknowledge that Patent Owner also relies on annotated Figures 3A and 3B of Shavit to rebut Petitioner's contention that Shavit discloses an insert having a lower surface that is operative to contact a bone screw. *See* Prelim. Resp. 17–18. The annotation of Figures 3A and 3B by Patent Owner, however, is supported by the disclosure of Shavit. Specifically, Shavit teaches that hip peg retains a limited ability to move, even when locked in place by tab 20. Ex. 1005, 8:10–12. As noted by Patent Owner (Prelim. Resp. 18), if the lower surface of the insert were to contact the hip peg, the hip peg would lose that ability to move while locked in place by tab 20. Notably, neither Petitioner nor its expert address how the hip peg retains this mobility where Shavitz's insert allegedly contacts the hip peg. Nor does Petitioner provide any evidence that the ordinary artisan would read such contact between the hip peg and the lower surface of the insert to continue to allow for such movement. Petitioner, therefore, has failed to establish a reasonable likelihood that independent claim 6 is anticipated by Shavit

As to independent claim 13, Petitioner contends that, as discussed with respect to claim 6, "Shavit discloses an insert adapted to be positioned within said chamber, with a lower surface that engages the bone screw when the bone screw extends through the aperture." Pet. 25. We determine, therefore, for the reasons discussed above with respect to independent claim 6, that Petitioner has failed to establish a reasonable likelihood that independent claim 13 is anticipated by Shavit.

b. Remaining Claims

Claims 7, 9, and 10 each depend, either directly, or indirectly from claim 6. In addressing these claims, Petitioner does not point us to any additional teaching of Shavit that addresses the deficiency discussed above.

Thus, for the reasons set forth above, Petitioner has also failed to sufficiently demonstrate that dependent claims 7, 9, and 10 are anticipated by Shavit.

iii. Conclusion

For the reasons set forth above, we determine that Petitioner has not established a reasonable likelihood that claims 6, 7, 9, 10, and 13 are anticipated by Shavit.

C. Remaining Grounds

Petitioner contends that the remaining independent claim, claim 19, is rendered obvious by the combination of Shavit and Kilpela, or by the combination of Shavit, Kilpela, and Bramlet. Pet. 34–39, 45–46.

In challenging claim 19 over the combination of Shavit and Kilpela, as to the limitation that "said lower surface [of an insert] operative to engage a bone screw extending through said aperture," Petitioner states that for the reasons discussed as to claim 8, Shavit in view of Kilpela renders that limitation obvious. Pet. 37 (emphasis added). Petitioner relies on that same analysis as to the challenge of claim 19 over the combination of Shavit, Kilpela, and Bramlet. *Id.* at 46.

In its discussion of claim 8 as being obvious over the combination of Shavit and Kilpela, Petitioner relies on Kilpela for a reason to have a longitudinal passageway through the insert. *Id.* at 28. As to the remaining limitations of claim 8, which depends from claim 6, Petitioner relies on its discussion of claim 6 as being anticipated by Shavit. *Id.* Petitioner, therefore, does not rely on either Kilpela or Bramlet to make up the deficiency of Shavit as discussed above as to the anticipation challenge of independent claim 6. Thus, for the reasons discussed above in Section II.B.ii.a, we determine that Petitioner has not sufficiently established that

claim 19 is rendered by the combination of Shavit and Kilpela, or the combination of Shavit, Kilpela, and Bramlet.

Similarly, Petitioner relies on its discussion of independent claims 6, 13, and 19 in contending that claim 8 is rendered obvious by the combination of Shavit and Kilpela (Pet. 28), that claims 14, 15, and 20 are rendered obvious by the combination of Shavit and Kilpela (Pet. 31–33, 39–40) or by the combination of Shavit, Kilpela, and Bramlet (Pet. 40–45, 47), and that claim 11 is rendered obvious by the combination of Shavit and Bramlet (Pet. 47–48). As Petitioner again does not rely on either Kilpela or Bramlet to remedy the above discussed deficiency of Shavit, we determine also that Petitioner has not sufficiently established that claims 8, 11, 14, 15, and 20 are rendered by the Shavit in combination with Kilpela and/or Bramlet.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in any of its challenges of claims 6–11, 13–15, 19, and 20.

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

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