

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER BIOMET HOLDINGS, INC.,
Petitioner,

v.

FOUR MILE BAY, LLC,
Patent Owner.

Case IPR2018-00051
Patent 9,265,612 B1

Before JOSIAH C. COCKS, GEORGE R. HOSKINS, and
FRANCES L. IPPOLITO, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a) and 37 C.F.R. § 42.108

I. INTRODUCTION

Zimmer Biomet Holdings, Inc. (“Petitioner”) has filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 12, 13, and 15–19 of U.S. Patent No. 9,265,612 B1 (“the ’612 patent”). Four Mile Bay, LLC (“Patent Owner”) has filed a Preliminary Response (Paper 7, “Prelim. Resp.”). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we do not institute review in this case.

II. BACKGROUND

A. *Real Parties in Interest and Related Proceedings*

Petitioner identifies Zimmer Biomet Holdings, Inc. as the real party in interest for this proceeding. Pet. 1. Patent Owner identifies Four Mile Bay, LLC as the real party in interest for this proceeding. Paper 5, 1. The parties identify one U.S. District Court litigation as related to this proceeding. Pet. 1; Paper 5, 1. The parties additionally identify four *inter partes* review proceedings as related to the present proceeding. Pet. 2; Paper 5, 1.

The first related *inter partes* review is IPR2016-00011 (“the ’011 IPR”), filed by Petitioner to challenge U.S. Patent No. 8,506,642 B1 (“the ’642 patent”). The ’011 IPR is related to the present proceeding because the presently challenged ’612 patent asserts continuation priority to the filing date of the application that issued as the ’642 patent. *See* Ex. 1001, (63). The ’011 IPR ended when the Board issued a decision denying institution of trial. That decision is included in the record of the present proceeding as Exhibit 2010.

The second related *inter partes* review is IPR2016-00012 (“the ’012 IPR”), filed by Petitioner to challenge U.S. Patent No. 8,821,582 B1 (“the ’582 patent”). The ’012 IPR is related to the present proceeding because the ’582 patent asserts continuation-in-part priority to the filing date of the application that issued as the ’642 patent. *See* Ex. 1024, (63). The ’012 IPR resulted in a final written decision of the Board, included in the record of the present proceeding as Exhibit 1008. That decision is currently on appeal to the Federal Circuit. *See* Pet. 2; Paper 5, 1.

The third related *inter partes* review is IPR2018-00052 (“the ’052 IPR”), filed by Petitioner on the same day as the present proceeding, to challenge U.S. Patent No. 9,308,093 B1 (“the ’093 patent”). The ’052 IPR is related to the present proceeding because the ’093 patent asserts continuation priority to the filing date of the presently challenged ’612 patent. *See* ’052 IPR, Ex. 1001, (63).

The fourth related *inter partes* review is IPR2018-00053 (“the ’053 IPR”), filed by Petitioner on the same day as the present proceeding, to challenge U.S. Patent No. 9,283,080 B1 (“the ’080 patent”). The ’053 IPR is related to the present proceeding because the ’080 patent asserts continuation priority to the filing date of the ’582 patent. *See* ’053 IPR, Ex. 1001, (63).

B. The ’612 Patent

The ’612 patent discloses several embodiments of a hip implant. *See* Ex. 1001, 1:12–17, 2:50–3:2. Figures 1 and 2 of the ’612 patent show a first embodiment, and are reproduced below.

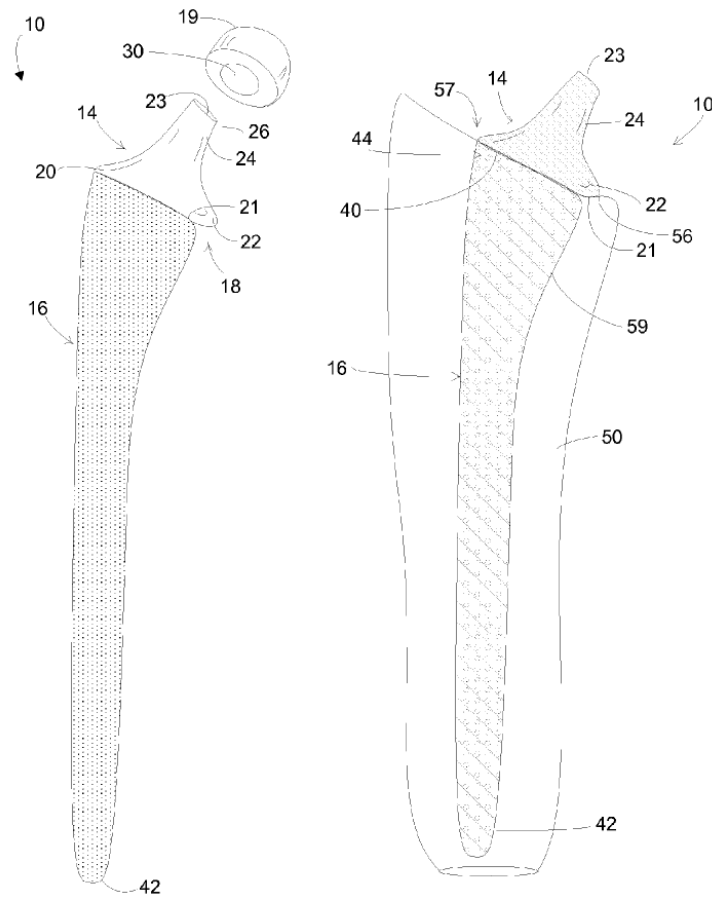


Fig. 1

Fig. 2

These Figures illustrate hip implant 10 including two separate and distinct bodies, neck body 14 and bone fixation body 16. *Id.* at 1:54–58, 3:6–12. Figure 2 shows hip implant 10 embedded within femur 50. *Id.* at 2:54–55, 3:44–46. Thus, in the orientation of Figures 1–2, the “proximal” direction is up and the “distal” direction is down. *Id.* at 3:13–19, 3:33–37.

Neck body 14 “extends from a flat or planar distal end surface 21 to a proximal end surface 23.” *Id.* at 3:16–17. Distal end surface 21 of neck body 14 connects or fuses to proximal end surface 40 of bone fixation body 16 at junction 44, which is disposed at resected end 56 of femur 50 when hip implant 10 is implanted. *Id.* at Fig. 2, 3:35–37, 3:44–55.

Figure 5 of the '612 patent shows another hip implant embodiment, and is reproduced below:

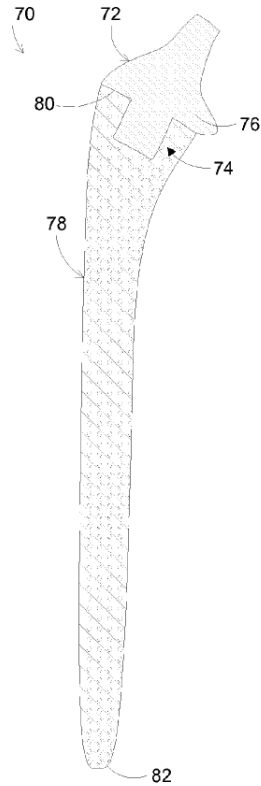


Fig. 5

Figure 5 illustrates hip implant 70 which “is similarly configured to the implant 10” of Figures 1–2. *Id.* at 5:21–23. “As one difference, neck body 72 includes a male protrusion 74 that extends outward from base portion 76.” *Id.* at 5:23–25. Protrusion 74 extends into bone fixation body 78 of implant 70. *Id.* at 5:25–38.

C. The Challenged Claims

The '612 patent contains nineteen claims, but Petitioner challenges only claims 12, 13, and 15–19. Claim 12 illustratively recites:

12. A hip implant, comprising:

a neck body having a proximal end that connects with an acetabular component, having a distal end surface with an elongated protrusion that extends outwardly therefrom, and being formed of solid metal; and

a bone fixation body having an elongated tapering shape and being formed as a porous metal structure that includes a proximal end that engages the distal end surface of the neck body at an interface,

wherein the elongated protrusion of the neck body forms a core for the bone fixation body and tapers and extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the elongated protrusion that extends into the bone fixation body, and

wherein the porous structure of the bone fixation body has a size and a shape that emulate a size and a shape of a porous structure of natural human bone.

Ex. 1001, 7:28–45 (emphases added).

D. Claim Interpretation

The Board interprets claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012). We determine no explicit interpretation of any claim term is needed to resolve the issues presented by the arguments and evidence of record. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed “only to the extent necessary to

resolve the controversy”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 12, 13, and 15–19 of the ’612 patent under 35 U.S.C. § 103(a) on the following four grounds. *See* Pet. 3–4.

References	Claim(s) Challenged
Zolman ¹ and Rostoker ²	12, 13, and 15–19
Zolman, Rostoker, and Averill ³	18
Zolman and Bobyn ⁴	12, 13, and 15–19
Zolman, Bobyn, and Averill	18

III. ANALYSIS

A. Obviousness over Zolman and Rostoker

Petitioner asserts claims 12, 13, and 15–19 of the ’612 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman and Rostoker. Pet. 4, 22–47. Petitioner cites the testimony of Dr. Timothy P. Harrigan in support. Ex. 1002. Patent Owner opposes Petitioner’s assertions.

¹ Ex. 1009, U.S. Patent No. 5,018,285, iss. May 28, 1991.

² Ex. 1010, U.S. Patent No. 3,906,550, iss. Sept. 23, 1975.

³ Ex. 1012, U.S. Patent No. 5,863,295, iss. Jan. 26, 1999.

⁴ Ex. 1011, J.D. Bobyn et al., *Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial*, *J. Bone & Joint Surgery*, Vol. 81–B, No. 5, 907–914 (Sept. 1999).

Based on the arguments and evidence of record, we conclude Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertions as to any one of the challenged claims. We begin our analysis with a brief statement of the law of obviousness, then we consider the level of ordinary skill in the art, then we briefly summarize the disclosure of Zolman, and we finally address the contentions of Petitioner and Patent Owner which are pertinent to our decision.

1. *Law of Obviousness*

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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, if made available in the record.⁵ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

2. *Level of Ordinary Skill in the Art*

Petitioner contends a person having ordinary skill in the art pertaining to the '612 patent would have “an undergraduate degree in a relevant engineering field (*e.g.*, Mechanical Engineering, Materials Science

⁵ Neither party has offered objective indicia of nonobviousness.

Engineering, Biomedical Engineering) with 3–5 years of experience with hip implants or similar implants or a graduate degree in a relevant field with 1–3 years of experience with hip implants or similar implants.” Pet. 12. The Preliminary Response does not take a position as to the level of ordinary skill in the art.

We determine on the current record that the level of ordinary skill proposed by Petitioner is consistent with the ’612 patent and the asserted prior art. We, therefore, adopt that level in deciding whether to institute trial.

3. *Zolman Disclosure*

Zolman discloses hip prosthesis femoral component 10, which is partially illustrated in Figures 1–2, reproduced below. *See* Ex. 1009, 3:31–35, 3:44–51.

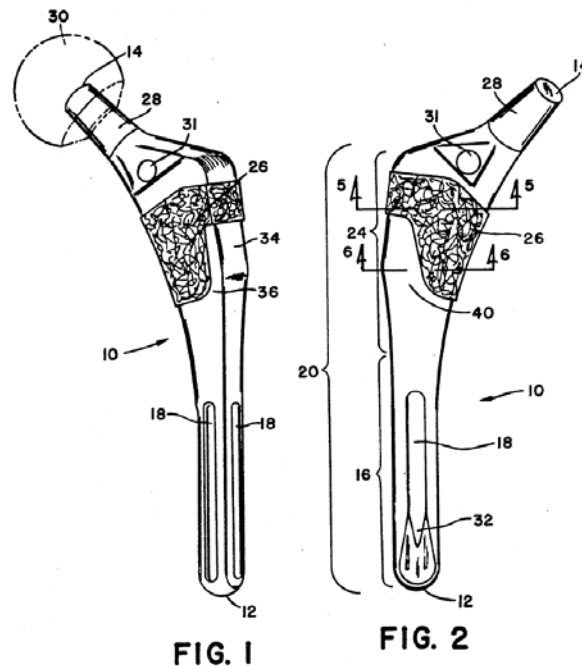
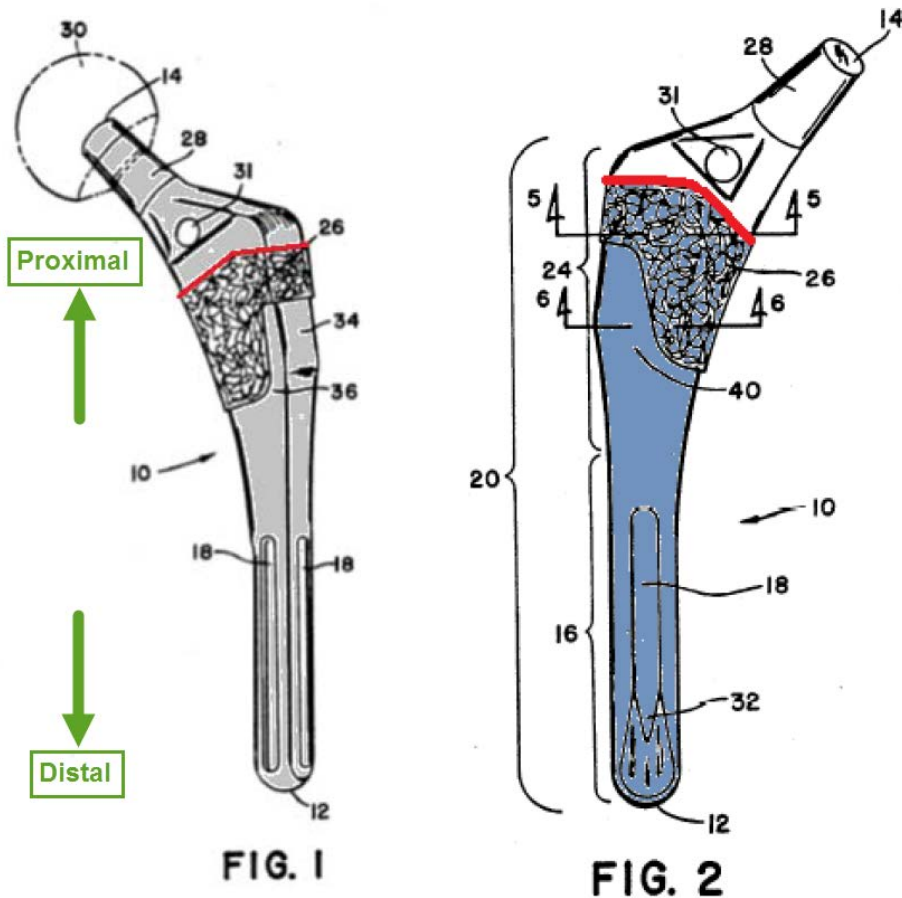


Figure 1 is a perspective view, and Figure 2 is a side view, of femoral component 10. *Id.* at 2:58–60, 3:44–45. Component 10 includes distal

end 12 for fitting within a femur, and proximal end 14 extending outwardly from the femur to cooperate with an acetabular component (not shown) via ball 30. *Id.* at 3:44–59. Porous pad 26 is received within recess 74 that encircles proximal portion 24 of stem portion 20 of femoral component 10. *Id.* at 3:53–56, 5:12–16, Fig. 6.

4. *Claim 12*

Petitioner contends Zolman discloses a hip implant having a neck body exhibiting the structural configuration recited in claim 12. Pet. 22–25; Ex. 1002 ¶¶ 41–42. Petitioner provides the following colored annotations to Zolman’s Figures 1 and 2 to illustrate these contentions, to which we have added some of our own annotations:



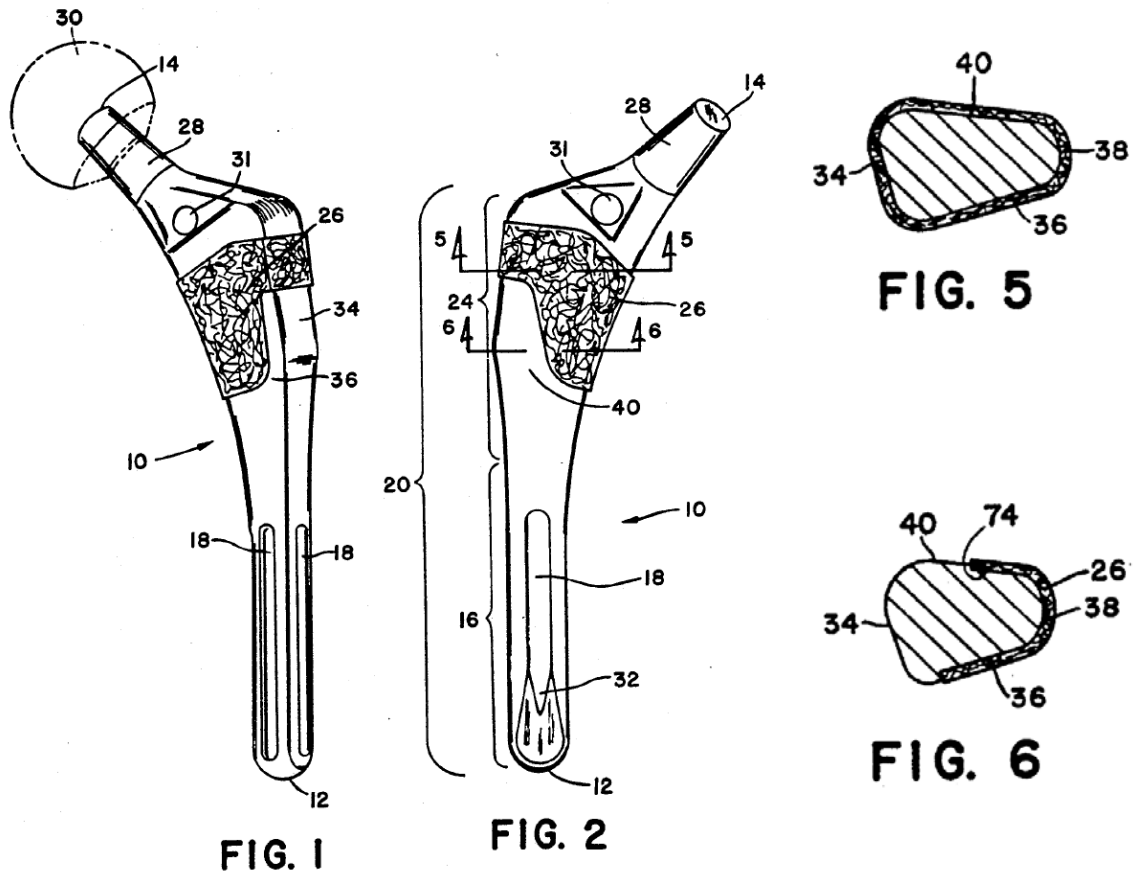
Pet. 23. In these annotated Figures, Petitioner has identified the alleged neck body with grey color shading (hereafter “the Neck Body”), the alleged location of the distal end surface with a red line, and the alleged elongated protrusion with blue color shading.⁶ *Id.* at 22–24; Ex. 1002 ¶ 42. We have added green arrows to reflect the “proximal” and “distal” directions in Zolman’s Figures 1 and 2. *See* Ex. 1009, 3:44–45.

Petitioner explains the alleged distal end surface of the Neck Body “is formed by” recess 74 in the Neck Body, and “corresponds to the distally-facing surface of the upper lip of recess 74, and encompasses the surface area between the outer edge of the lip and where the stem portion 12 [of the Neck Body] extends outwardly” (hereafter “the Upper Lip”).

Pet. 24–25. The Upper Lip is not shown *per se* in Zolman’s Figures 1–6, because it is covered by porous pad 26 in the views of Figures 1–4.

However, the nature of recess 74 in the Neck Body, and therefore the Upper Lip helping to form recess 74, is revealed by comparing Figures 1, 2, 5, and 6, which are reproduced below.

⁶ Zolman’s porous pad 26 is shaded grey in Figure 1, and is shaded blue in Figure 2. This appears to be a mistake, because Petitioner’s overall case is premised upon porous pad 26 corresponding to the bone fixation body of claim 12, not the neck body of claim 12. *See, e.g.*, Pet. 25–26. Therefore, Zolman’s porous pad 26 seemingly should not be shaded at all in Petitioner’s annotations. As discussed in more detail below, Petitioner contends the portion of the Neck Body *underneath* porous pad 26, which portion therefore is not seen in Figures 1 and 2, is part of the alleged elongated protrusion of the Neck Body.



These Figures illustrate Zolman's femoral component 10, with Figure 1 showing a perspective view, Figure 2 showing a side view, Figure 5 showing a cross-sectional view taken along lines 5-5 in Figure 2, and Figure 6 showing a cross-sectional view taken along lines 6-6 in Figure 2. Ex. 1009, 2:58-66, 3:44. These Figures pertinently illustrate how porous pad 26 is received within recess 74 of the Neck Body. They indicate recess 74 is a shallow depression formed in the Neck Body, with the outer periphery of the depression, including the Upper Lip, matching the outer periphery of porous pad 26. *See id.* at 5:13-16, 6:44-46. The depth of the depression is approximately half of the thickness of porous pad 26 (*see id.* at Fig. 6), such that a portion of porous pad 26 rests within recess 74 and the remainder

extends above the outer surface of the Neck Body (*see id.* at Figs. 2 and 6, 3:62–65).

Zolman’s illustration of an alternate femoral component 400 in Figures 14 and 15 helps to elucidate the structure of recess 74 in the Neck Body of femoral component 10 shown in Figures 1–6. *See id.* at 3:21–27, 7:15–16; Pet. 25 (citing alternate embodiment). Figures 14 and 15 are reproduced below, with red oval annotations we have added.

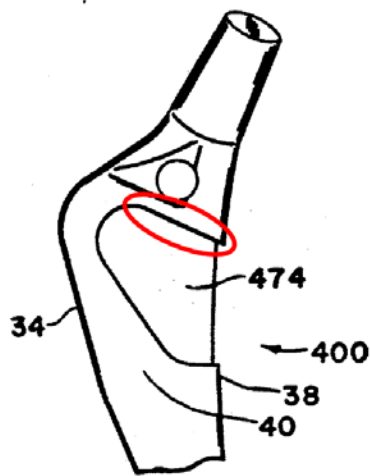


FIG. 14

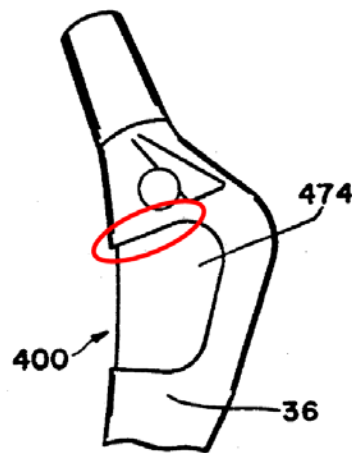


FIG. 15

Figures 14 and 15 illustrate opposing side views of alternate femoral component 400, including recess 474 for receiving porous pad 426, although porous pad 426 is shown only in Figure 16. Ex. 1009, 3:21–27, 7:15–19. The alternate embodiment differs from the first embodiment in that porous pad 426, and therefore the corresponding recess 474 for receiving porous pad 426, wraps only part way around the implant. *Id.* at 7:19–25. Thus, these illustrations of recess 474 without a porous pad are instructive as to the configuration of recess 74. We have identified with red ovals the location of the upper lip of recess 474, which corresponds to the Upper Lip of the first

embodiment upon which Petitioner’s case for obviousness relies as being a distal end surface of the Neck Body.

Petitioner contends a person of ordinary skill in the art would have recognized the Upper Lip “defines the distal end of the portion of the [N]eck [B]ody that extends outwardly from the intramedullary canal of the femur.” Pet. 25 (citing Ex. 1009, 3:45–51, Figs. 1–6); Ex. 1002 ¶ 42. Petitioner further contends a person of ordinary skill in the art would have recognized the Upper Lip “is the distal end surface of a base portion of the [N]eck [B]ody which functions to position ball 30 connected to proximal end 14 relative to stem portion 20.” Pet. 25 (citing Ex. 1009, 3:45–59); Ex. 1002 ¶ 42.

Patent Owner argues Zolman’s Neck Body does not include, as claimed, a distal end surface with an elongated protrusion that extends outwardly therefrom. Prelim. Resp. 27–33. Patent Owner accuses Petitioner of applying an unreasonably broad claim interpretation when asserting such disclosure to be found in Zolman. *Id.* at 27–30. Patent Owner also asserts Petitioner’s identification of an alleged distal end surface in Zolman is not based on the Zolman disclosure, and is arbitrary. *Id.* at 30–33.

Upon our review of the presented arguments and evidence, we conclude Petitioner has not established Zolman’s Upper Lip is a “distal end surface” of the Neck Body, as recited in claim 12. It is, first, important to recognize that claim 12 specifies “a *neck body . . . having* a distal end surface.” Ex. 1001, 7:28–32 (emphasis added). As claimed, the distal end surface is a distal end surface of the neck body. Petitioner’s contention (Pet. 25) and Dr. Harrigan’s testimony in support (Ex. 1002 ¶ 42, at pgs. 25–26) miss the mark in referring to a distal end surface of a *portion* of the Neck

Body which extends outwardly from the femur, or a distal end surface of a *portion* of the Neck Body which positions the acetabular component relative to the bone fixation body. Claim 12 simply refers to the neck body, and does not specify any particular portions of the neck body, much less the portions identified by Petitioner's arguments.

Zolman's Upper Lip is not an "end" surface of the Neck Body. Rather, the Upper Lip is part of a wall that forms the outer circumference of shallow recess 74 in the side of the Neck Body. The shallowness of recess 74 is demonstrated by Zolman's disclosure that porous pad 26 extends outwardly from the Neck Body by "about 0.5 mm." Ex. 1009, 3:62–65. As can be seen from Figure 6, the depth of recess 74, and correspondingly the outwardly extending length of the Upper Lip, is therefore also on the order of about 0.5 mm. The shallowness of recess 74 in Figures 1–6 is further demonstrated by Zolman's illustration of the depth of recess 474 in Figures 14–15. Given the shallowness of recess 74, in comparison to the overall width of the Neck Body at the location of the Upper Lip, a person of ordinary skill in the art would not conclude that the Upper Lip is an "end" surface of the Neck Body.

Further, even if one were to accept that Zolman's Upper Lip is somehow an end surface of the Neck Body, it is not a "distal" end surface as claimed. At best, the Upper Lip is a distally facing surface of the Neck Body, because it faces generally in the distal direction. However, claim 12 calls for a distal end surface, not a distally facing surface. The Neck Body extends distally beyond the Upper Lip to what Zolman identifies as "distal end 12" of the Neck Body. *See* Ex. 1009, Fig. 1, 3:44–45. This extension of the Neck Body distally beyond the Upper Lip represents approximately

two-thirds of the total axial extent of the Neck Body identified by Petitioner. *See id.* at Figs. 1–2. Moreover, Zolman itself describes the Upper Lip as being located within proximal portion 24 of stem portion 20 of the Neck Body, not distal portion 16. *Id.* at 3:44–56.

We recognize claim 12 requires the neck body to have an elongated protrusion that extends outwardly from the distal end surface, such as shown for example in Figure 5 of the '612 patent. We recognize, further, that the '612 patent indicates the elongated protrusion may extend past the distal end surface to varying degrees in different embodiments. *See Ex. 1001, 5:23–38.* Nonetheless, the language of claim 12 precludes the protrusion from extending outwardly from the distal end surface so far in the distal direction, or extending so far sideways in width, that the distal end surface is no longer a distal end of the Neck Body. The elongated protrusion of the Zolman Neck Body, as identified by Petitioner, extends outwardly from the Upper Lip too far in the distal direction, and extends too far sideways in width at the location of the Upper Lip, for the Upper Lip to be considered a distal end surface of the Neck Body. *See Ex. 1009, Figs. 1–6.*

The foregoing analysis is consistent with the Board's decision in the '011 IPR denying institution of trial as to the '642 patent. *See Ex. 2010.* In that decision, the Board focused on claim 1 of the '642 patent as representative. *Id.* at 4–5. That claim recites a hip implant and includes the same limitation at issue here, “a neck body . . . having a distal end surface with an elongated protrusion that extends outwardly therefrom.” *Id.* at 4. The Board decided not to institute review of claim 1 of the '642 patent as being unpatentable over Zolman and Rostoker. *Id.* at 8–13. The Board's decision was based, in part, on Petitioner's failure to explain “why the

location marked in red” in the same annotated versions of Zolman’s Figures 1 and 2 presented in this proceeding “corresponds to the claimed distal end surface of the neck body.” *Id.* at 10–11. The Board stated:

For example, this location does not appear to be “distal” to, or the “end” of, any structure specifically identified in Zolman. Nor is it evident that one of ordinary skill would have considered the “lip of recess 74,” by itself, to be a “surface.”

Id. at 11. Petitioner may be correct that the present Petition provides more explanation than the ’011 IPR petition in support of contending that the Upper Lip is a distal end surface of the Neck Body. *See* Pet. 24 n.10. Nonetheless, for the reasons provided above, we have determined Petitioner still has not established the Upper Lip to be a distal end surface of the Neck Body.

In the ’012 IPR, Petitioner’s arguments regarding Zolman’s disclosure of a neck body having a distal end surface with a protrusion were un rebutted. *See* Pet. 24 n.11. However, in the present proceeding, Patent Owner has contested those arguments. *See* Prelim. Resp. 27–33. For the reasons provided, Petitioner has not shown a reasonable likelihood of prevailing on this ground, based on the record presented in this proceeding.

For the foregoing reasons, we conclude a person of ordinary skill in the art would not understand Zolman’s Upper Lip to be a distal end surface of the Neck Body. Petitioner does not rely on Rostoker in relation to the claimed structural configuration of the neck body. *See, e.g.*, Pet. 22–25. Therefore, we conclude Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claim 12 as having been obvious over Zolman and Rostoker.

5. *Claims 13 and 15–18*

Claims 13 and 15–18 each depend directly from claim 12. Ex. 1001, 7:46–50, 7:58–8:17. Petitioner’s contentions in relation to claims 13 and 15–18 being unpatentable over Zolman and Rostoker do not cure the deficiency of Zolman as to the distal end surface of the neck body, noted above. *See* Pet. 31–40; Ex. 1002 ¶¶ 48–64. Therefore, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claims 13 and 15–18 as having been obvious over Zolman and Rostoker.

6. *Claim 19*

Claim 19 is an independent claim which, like claim 12 discussed above, recites a hip implant comprising “a neck body . . . having a distal end surface with an elongated protrusion that extends outwardly therefrom.” Ex. 1001, 8:18–23. Petitioner’s contentions in relation to claim 19 rely on Zolman to disclose that limitation, based on the same arguments considered above. *See* Pet. 40–41; Ex. 1002 ¶ 67. Therefore, for the reasons provided above, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claim 19 as having been obvious over Zolman and Rostoker.

B. *Obviousness over Zolman, Rostoker, and Averill*

Petitioner asserts claim 18 of the ’612 patent, which depends directly from claim 12, is unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman, Rostoker, and Averill. Pet. 4, 47–48. Petitioner’s contentions do not cure the deficiency of Zolman as to the distal end surface of the neck body, noted above. *See* Pet. 47–48; Ex. 1002 ¶¶ 81–84.

Therefore, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claim 18 as having been obvious over Zolman, Rostoker, and Averill.

C. Obviousness over Zolman and Bobyn

Petitioner asserts claims 12, 13, and 15–19 of the '612 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman and Bobyn. Pet. 4, 48–63. Petitioner's contentions rely on Zolman and not Bobyn to disclose the distal end surface of the neck body, as recited in independent claims 12 and 19. *See* Pet. 49, 59; Ex. 1002 ¶¶ 87, 112. Therefore, for the reasons provided above, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claims 12, 13, and 15–19 as having been obvious over Zolman and Bobyn.

D. Obviousness over Zolman, Bobyn, and Averill

Petitioner asserts claim 18 of the '612 patent is unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman, Bobyn, and Averill. Pet. 4, 63. Petitioner's contentions do not cure the deficiency of Zolman as to the distal end surface of the neck body, noted above. *See* Pet. 63; Ex. 1002 ¶ 126. Therefore, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing on the challenge to claim 18 as having been obvious over Zolman, Bobyn, and Averill.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no trial is instituted.

IPR2018-00051
Patent 9,265,612 B1

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