

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ZIMMER BIOMET HOLDINGS, INC.,  
Petitioner,

v.

FOUR MILE BAY, LLC,  
Patent Owner.

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Case IPR2016-00011  
Patent 8,506,642 B1

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Before BENJAMIN D. M. WOOD, RICHARD E. RICE, and  
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

WOOD, *Administrative Patent Judge*.

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

## I. INTRODUCTION

### A. *Background*

Zimmer Biomet Holdings, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–4 of U.S. Patent No. 8,506,642 B1 (Ex. 1001, “the ’642 patent”). Paper 2 (“Pet.”). Four Mile Bay, LLC (“Patent Owner”) filed a Preliminary Response. Paper 7 (“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.” 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we deny the Petition.

### B. *Related Proceedings*

As required by 37 C.F.R. § 42.8(b)(2), the parties identify the following matter in which the ’642 patent has been asserted: *Four Mile Bay LLC v. Zimmer Holdings, Inc.*, No. 3:15-cv-00063 (N.D. Ind.) PPS-CAN. Pet. 2; Paper 5. In addition, a related patent, US 8,821,582, is the subject of IPR2016-00012. *Id.*

### C. *The ’642 Patent*

The ’642 patent issued August 13, 2013 from an application filed April 24, 2006, and claims priority to May 27, 2003. Ex. 1001, cover page. The ’642 patent is directed to a hip implant that integrates with surrounding bone. *Id.* at 1:47–48. In one embodiment, the implant includes two distinct

bodies, a neck body and a bone fixation body. *Id.* at 1:49–50. Figure 5, reproduced below, illustrates the relevant embodiment.

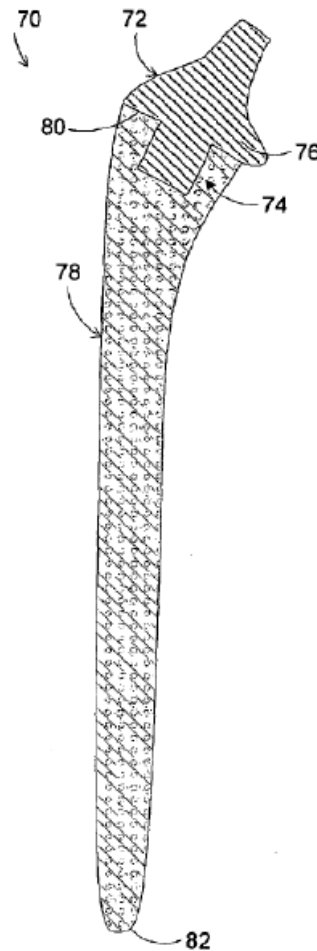


**Fig. 5**

Figure 5 is a side cross-sectional view of femoral hip implant 70 comprising neck body 72 and bone fixation body 78. *Id.* at 5:15–19. Neck body 72 connects to a spherically shaped femoral ball and acetabular component (not shown). *Id.* at 3:5–8, 5:14–15; *see id.* at Fig. 1. The neck body is preferably made from a solid piece of biocompatible metal such as titanium. *Id.* at 3:20–21. Bone fixation body 78 may also be made from titanium, but has a completely porous structure that extends throughout the body. *Id.* at 3:31–35, 5:14–15. In use, the implant is embedded into the

intramedullary canal of the femur so that the bone fixation body contacts surrounding bone. *Id.* at 37–41, Fig. 2. The porous structure permits bone ingrowth deeply into the body of the implant such that the implant can “become fully integrated into surrounding bone with the structure of bone dispersed throughout the body of the implant.” *Id.* at 2:9–17.

In the embodiment depicted in Figure 5, neck body 74 includes a male protrusion 74 that is adapted to extend partially into bone fixation body 78 to form a core for the bone fixation body. *Id.* at 5:17–21. The protrusion provides a strong connection and anti-rotational interface between the neck body and the bone fixation body. *Id.* at 5:38–44.

*D. The Challenged Claims*

Claims 1–3 are independent. Claim 4 depends from claim 3. Claim 1 is representative and is reproduced below:

1. 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 completely porous metal structure that extends throughout an exterior and an interior of the bone fixation body and that includes a proximal end that engages the distal end surface of the neck body at an interface,
    - wherein the interface has a trapezoidal cross-sectional shape in which the trapezoidal cross-section shape continues and tapers in a distal direction toward a distal end of the bone fixation body,
    - wherein the bone fixation body is made separately from the neck body, and the bone fixation body is bonded to the neck body after the bone fixation body is made separately from the neck body,

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 completely 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 shape of a porous structure of natural human bone.

*E. Asserted Grounds of Unpatentability*

Petitioners contend that the challenged claims are unpatentable based on the following specific grounds (Pet. 18–60):

| Reference[s]                                  | Basis | Claim[s] Challenged |
|-----------------------------------------------|-------|---------------------|
| Zolman <sup>1</sup> and Rostoker <sup>2</sup> | § 103 | 1–4                 |
| Zolman and Bobyn <sup>3</sup>                 | § 103 | 1–4                 |

## II. ANALYSIS

*A. Claim Construction*

On this record and for purposes of this decision, we determine that no claim terms require express construction.

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<sup>1</sup> US 5,018,285 to Zolman et al. (May 28, 1991) (Ex. 1005).

<sup>2</sup> US 3,906,550 to Rostoker et al. (Sept. 23, 1975) (Ex. 1006).

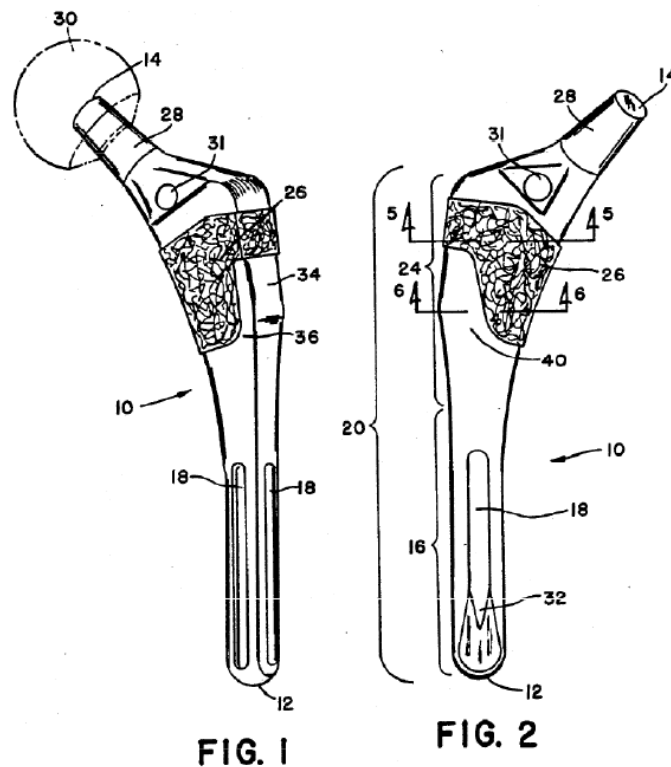
<sup>3</sup> J.D. Bobyn et al., *Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial*, 81-B:5 J. BONE AND JOINT SURGERY 907–914 (Sept. 1999) (Ex. 1007).

*B. Claims 1–4, Obviousness over Zolman and Rostoker*

Petitioners allege that claims 1–4 would have been obvious over Zolman and Rostoker. Pet. 24–54. A patent claim is unpatentable under 35 U.S.C. § 103(a) 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. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). The level of ordinary skill in the art is reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

*1. Zolman and Rostoker*

Zolman issued May 28, 1991, and is prior art under 35 U.S.C. § 102(b). Zolman relates to a prosthetic implant device for use as a femoral component for a hip prosthesis. Ex. 1005, 1:11–15. Figures 1 and 2 are illustrative of Zolman’s invention, and are reproduced below:



Figures 1 and 2 depict a perspective view and an anterior side elevational view, respectively, of femoral component 10 of a prosthetic hip implant. Femoral component 10 is intended to fit within the intramedullary canal of a femur, with proximal end 14 extending outwardly from the intramedullary canal and neck 28 adapted to carry ball 30 and an acetabular prosthetic member. *Id.* at 3:46–51. Porous surface or pad 26 encircles proximal portion 24 of stem portion 20, and extends slightly outwardly from it. *Id.* at 3:53–54, 62–65. Proximal portion 24 includes recess 74 having a shape corresponding to pad 26 and adapted to receive the pad. *Id.* at 5:13–16.

Zolman teaches that porous pad 26 may be formed from the fiber metal structure disclosed in Rostoker. *Id.* at 4:8–15. Rostoker teaches a porous fiber metal structure to be used with skeletal prosthetic devices. Ex. 1006, 1:11–18. The structure is produced by molding and sintering short

metal fibers, which creates metallurgical bonds at the points of contact of the fibers. *Id.* at 2:22–25, 4:22–28. The wire fibers are made by preinking wire into a sinusoidal pattern and cutting the wire into the desired lengths. *Id.* at 4:42–52.

## 2. Analysis

Claim 1 recites a hip implant comprising, inter alia:

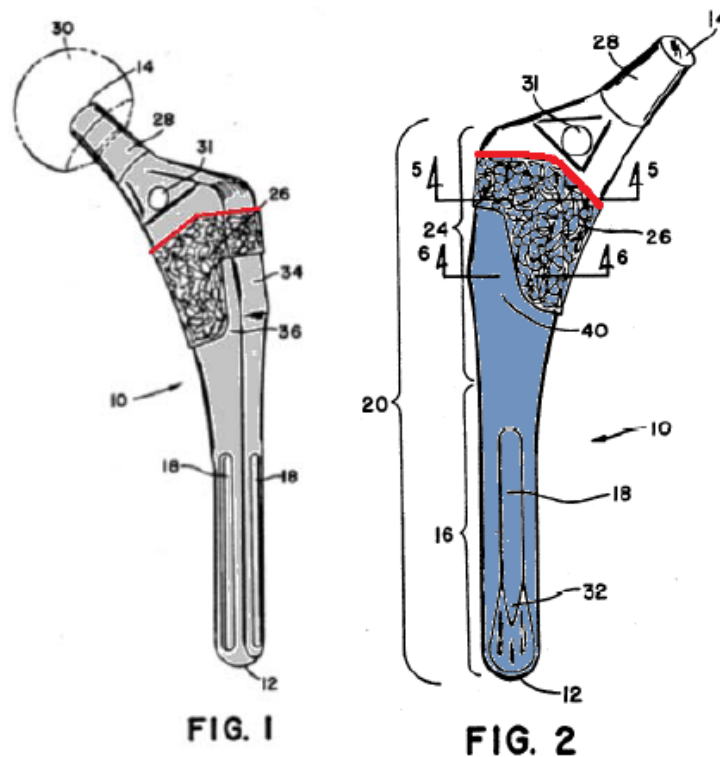
A *neck body* having a proximal end that connects with an acetabular component, having a *distal end surface* with an *elongated protrusion that extends outwardly therefrom . . .* and a *bone fixation body* having an elongated tapering shape and being formed as a completely porous metal structure . . . and *that includes a proximal end that engages the distal end surface of the neck body at an interface, wherein the interface has a trapezoidal cross-sectional shape in which the trapezoidal cross-sectional shape continues and tapers in a distal direction toward a distal end of the bone fixation body.*

Ex. 1001, 6:24–38 (emphasis added).<sup>4</sup>

Petitioner contends that claim 1 would have been obvious over Zolman and Rostoker. To illustrate its contentions, Petitioner provides annotated versions of Figures 1 and 2 of Zolman. Petitioner's annotated figures are reproduced below:

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<sup>4</sup> Independent claims 2 and 3 contain similar limitations. Therefore, this discussion applies equally to claims 2–4.



Pet. 24.

With respect to claim 1, Petitioner contends that the structure shaded in grey in Figure 1—i.e. neck 28, adjacent portion with aperture 31, and stem portion 20—corresponds to the claimed neck body, and that the area marked with a red line, which “is formed by a recess 74 and is where porous pad 28 engages the neck body,” corresponds to the claimed *distal end surface* of the neck body. *Id.* at 25 (citing Ex. 1005, 5:13–16, 6:44–48). Petitioner also contends that the portion shaded in blue, stem portion 20, corresponds to the claimed *elongated protrusion that extends outwardly* from this distal end surface. *Id.* (citing Ex. 1002 ¶ 38).

Next, Petitioner contends that porous pad 26 corresponds to the claimed bone fixation body. *Id.* Petitioner asserts that porous pad 26 “includes a proximal end that engages the distal end surface of the neck body at an interface,” in that Zolman “discloses that a proximal end of

porous pad 26 engages a distal end surface of the neck body formed by recess 74 when porous page 26 is received in recess 74.” *Id.* at 26 (citing Ex. 1005, 5:13–16, 6:44–48, Figs. 1–6; Ex. 1002, ¶ 36). Petitioner contends that this “interface” has a “trapezoidal cross-sectional shape [that] continues and tapers in a distal direction toward a distal end of the bone fixation body.” *Id.* at 27 (quoting claim 1). Specifically, according to Petitioner, “Zolman teaches that proximal portion 24 of stem portion 20, which includes recess 74, has a noncircular cross-section, and that porous pad 26 has a shape corresponding to proximal portion 24.” *Id.* (citing Ex. 1005, 5:13–21).

Patent Owner disputes that Claim 1 would have been obvious over Zolman and Rostoker. Among other things, Patent Owner argues that “the neck in Zolman does not include a distal end surface as recited in claim 1.” Prelim. Resp. 12. Patent Owner also argues that “the porous surface or pad in Zolman does not have a proximal end that engages a distal end of the neck body at an interface with a trapezoidal cross-section.” *Id.* Therefore, according to Patent Owner, the combination of Zolman and Rostoker “fails to teach or suggest all of the claim elements,” and “the claims of the ‘642 patent are not a predictable variation of the art to one of ordinary skill in the art.” *Id.* at 14.

Based on the current record, we are not persuaded that there is a reasonable likelihood that Petitioner would prevail in showing that the proposed combination of Zolman and Rostoker teaches or suggests to one of ordinary skill in the art all of the limitations of claim 1. Specifically, neither Petitioner nor its declarant, Timothy P. Harrigan, explains why the location marked in red in the annotated versions of Figures 1 and 2 of Zolman

corresponds to the claimed distal end surface of the neck body. Dr. Harrigan states, without elucidation, that “[t]he distal end surface of the neck body is formed by a recess 74 at the interface between the neck body and porous pad 26 and includes the lip of recess 74 and is where porous pad 26 engages the neck body.” Ex. 1002 ¶ 38 (citing Ex. 1005, 5:13–16, 6:44–48, Figs. 6, 14, 15). Petitioner largely repeats this statement in the Petition. Pet. 25. But it is not self-evident that this is the case. 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.” Dr. Harrigan’s opinion in this respect is conclusory and, therefore, unpersuasive. See *Verlander v. Garner*, 348 F.3d 1335, 1371 (Fed. Cir. 2003) (Board has discretion to accord little weight to broad conclusory statements from expert witness).

Even assuming that the location marked in red is a distal end surface of the neck body, we are not persuaded that Zolman teaches an “interface” between this location and the proximal end of the alleged bone fixation body—porous pad 26—that “has a trapezoidal cross-sectional shape [that] continues and tapers in a distal direction toward a distal end of the bone fixation body.” In Zolman, the proximal end of porous pad 26 engages the location marked in red only at that location, indicating that this location is the claimed interface. But the location marked in red does not appear to “continue” or “taper” at all. In alleging that Zolman teaches this limitation, Petitioner asserts that “the trapezoidal cross-sectional shape of *stem portion 20* continues and tapers in a distal direction toward a distal end of porous pad 26.” Pet. 28 (emphasis added). Petitioner also asserts that “the cross-

sectional shape of *porous pad 26* can continue and taper in a distal direction.” *Id.* (emphasis added). But Petitioner does not allege that either stem portion 20 or porous pad 26 is the interface, and the claim requires that the shape of the *interface* continues and tapers in a distal direction. Nor has Petitioner proposed a claim construction to support its arguments. For these reasons, we are not persuaded that Zolman teaches the limitation “wherein the interface has a trapezoidal cross-sectional shape in which the trapezoidal cross-sectional shape continues and tapers in a distal direction toward a distal end of the bone fixation body.”

C. *Claims 1–4, Obviousness over Zolman and Bobyn*

Petitioner alleges that claims 1–4 would have been obvious over Zolman and Bobyn. Pet. 44–60. As with the previous ground, Petitioner relies on its assertions that Zolman teaches “a distal end surface with an elongated protrusion that extends outwardly therefrom,” and “wherein the interface has a trapezoidal cross-sectional shape in which the trapezoidal cross-sectional shape continues and tapers in a distal direction toward a distal end of the bone fixation body.” *Id.* at 49–50. For the reasons discussed above, we are not persuaded that Petitioner has a reasonable likelihood of making this showing. Accordingly, we decline to institute *inter partes* review of claims 1–4 on the basis of this proposed ground of unpatentability.

### III. CONCLUSION

For the foregoing reasons, we determine that Petitioner fails to show that there is a reasonable likelihood that it would prevail with regard to at least one of the claims challenged in the Petition.

IV. ORDER

For the reasons given, it is

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

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