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Paper 8
Entered: April 1, 2016

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 IPR2016-00012
Patent 8,821,582 B1

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

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Zimmer Biomet Holdings, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–5, 7–11, 13–15, and 17–20 ("the challenged claims") of U.S. Patent No. 8,821,582 B1 (Ex. 1001, "the '582 Patent"). 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). Petitioner has shown a reasonable likelihood that it would prevail with respect to all of the challenged claims, and, accordingly, we institute an *inter partes* review with respect to those claims.

A. Related Proceedings

We are informed that Petitioner is named as a defendant in a federal district court case involving the '582 Patent (*Four Mile Bay LLC v. Zimmer Holdings, Inc. et al.*, No. 3:15-cv-00063 (N.D. Ind.) (PPS)-(CAN)). Pet. 2; Paper 5, 2. We also are informed that Petitioner has filed a Petition seeking *inter partes* review with respect to U.S. Patent No. 8,506,642 B1, which is related to the '582 Patent. Pet. 2; Paper 5, 2; *see* Case IPR2016-00011, Paper 2.

B. The '582 Patent

The '582 Patent, titled "Hip Implant with Porous Body," issued on September 2, 2014, from U.S. Application No. 13/592,349, filed August 23, 2012. Ex. 1001, at [54], [21], [22]. The '582 Patent application states that it is a continuation-in-part of U.S. Application No. 11/409,611, filed April 24, 2006, now U.S. Patent No. 8,506,642 B1, which is a continuation of

U.S. Application No. 10/446,069, filed May 27, 2003, now abandoned. *Id.* at (63). Figures 1 and 2 of the '582 Patent are reproduced below.

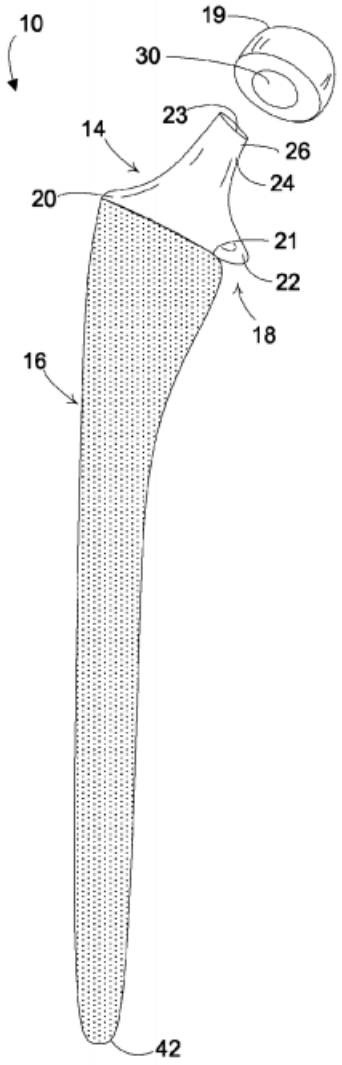


Fig. 1

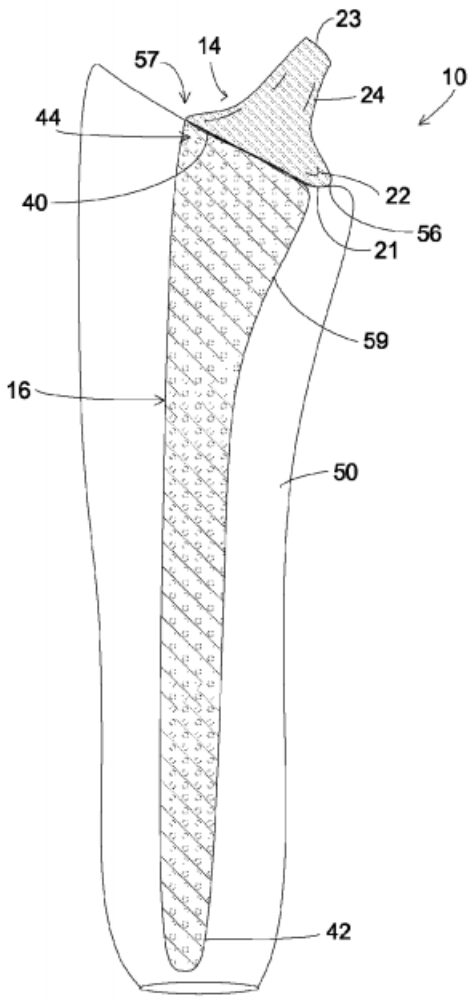


Fig. 2

Figure 1 is a side view of exemplary hip implant embodiment 10, showing neck body 14 and bone fixation body 16; and Figure 2 is a cross-sectional view of the implant embedded in intramedullary canal 52 of femur 50. *Id.* at 1:49–52, 3:41–47, 4:12–14. Bone fixation body 16 has a porous structure, i.e., "the material at and under the surface is permeated

with interconnected interstitial pores that communicate with the surface." *Id.* at 4:26–28. The Specification states that "[t]he porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules," and that "the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone." *Id.* at 4:32–36. The Specification also states that, preferably, the average pore diameter of body 16 is about 40 μm to about 800 μm, the porosity is from about 45% to 65%, and the interconnections between pores can have a diameter larger than 50–60 μm. *Id.* at 4:37–40.

C. Illustrative Claim

Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method, comprising:
>
> machining a neck body formed of solid metal to include a neck that receives a femoral ball and having a male protrusion that extends outwardly from the neck body;
>
> fabricating, separately from the neck body, a bone fixation body with a porous metal structure that extends completely throughout the bone fixation body with the porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone; and
>
> attaching, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to create a hip implant such that the male protrusion extends into and permanently attaches with the porous metal structure of the bone fixation body to create the hip implant before the hip implant is implanted, wherein the porous metal structure of the bone

> fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and the male protrusion extends to a distal end of the hip implant.

Id. at 15:51–16:4.

D. The Asserted References

Petitioner relies upon the following references (Pet. 3–4):

Reference	**Patent No./Title**	**Date**	**Exhibit No.**
Zolman	US 5,018,285	May 28, 1991	Ex. 1005
Rostoker	US 3,906,550	Sept. 23, 1975	Ex. 1006
Bobyn	J.D. Bobyn, et al., *Characteristics of bone ingrowth and Interface Mechanics of a new porous tantalum biomaterial*, 81-B:5 JOURNAL OF BONE AND JOINT SURGERY 907 (Sept. 1999)	Sept. 1999	Ex. 1007
Sump	US 4,570,271	Feb. 18, 1986	Ex. 1011
Averill	US 5,863,295	Jan. 26, 1999	Ex. 1012

E. The Asserted Grounds

Petitioner challenges claims 1–5, 7–11, 13–15, and 17–20 of the '582 Patent on the following grounds (Pet. 3–4):

Reference(s)	Basis	Claims Challenged
Zolman and Rostoker	§ 103(a)	1–5, 8–11, 14, 15, and 17–20
Zolman, Rostoker, and Sump	§ 103(a)	7
Zolman, Rostoker, and Averill	§ 103(a)	20
Zolman and Bobyn	§ 103(a)	1–5, 8–11, 13–15, and 17–20
Zolman, Bobyn, and Sump	§ 103(a)	7
Zolman, Bobyn, and Averill	§ 103(a)	20

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278, 1279 (Fed. Cir. 2015) ("We conclude that 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 (mem.) (2016). Under that standard, a claim term generally is given its 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). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner contends that a person of ordinary skill in the art ("POSITA")

> would have had an undergraduate degree in a relevant engineering field (e.g., Mechanical Engineering, Materials Science 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. 13 n.3; *see* Ex. 1002 ¶ 10. Patent Owner asserts the same definition. *See* Prelim. Resp. 9. For purposes of this Decision, we adopt the parties' common definition of a POSITA.

1. "porous"

The Specification provides the following lexicographical definition of "porous": "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." Ex. 1001, 4:26–28. For purposes of this Decision, we regard this definition as the broadest reasonable interpretation of the term "porous."

2. *"a porous metal structure . . . having a size and a shape that emulate a size and a shape of a porous structure of natural human bone"*

and

"a porous metal structure . . . with interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone."

Claim 1 recites "a porous . . . structure . . . having a size and a shape that *emulate* a size and a shape of a porous structure of natural human bone" (emphasis added). Claim 14 contains essentially the same recitation. Claim 8 recites "a porous . . . structure . . . with interconnected pores having a geometric structure with a shape and a size that *emulate* a shape and a size of natural human bone" (emphasis added).

Petitioner proposes to construe each of the phrases as "a structure that is sufficiently porous so as to permit bone ingrowth." Pet. 14. Relying on a dictionary definition, Petitioner also states that the plain and ordinary meaning of the term "emulate" is "imitate" and, "[t]hus, the plain language of the claims simply requires the porous structure . . . to 'imitate' the porous structure of natural human bone." *Id.* (citing Ex. 1008, 3).

Patent Owner disagrees. Prelim. Resp. 4–7. Patent Owner argues that Petitioner's construction (i.e., "a structure that is sufficiently porous so as to permit bone ingrowth") "completely disregards or ignores words expressly used in the claim stating that the bone fixation body emulates a porous structure of *natural human bone." Id.* at 6. Patent Owner also "disagrees that the word 'emulate' merely means 'imitate.'" *Id.* at 5. Based on a dictionary definition of its own, Patent Owner proposes to construe

"emulate" to mean "to try to equal or excel; imitate with effort to equal." *Id.* at 5 (citing Ex. 2002).

We are not persuaded by Patent Owner's proposed construction of "emulate." Specifically, the words "to try" and "with effort" in Patent Owner's construction do not help to clarify the meaning of "emulate" in the context of the claims, particularly because they impute an element of subjective intent that is inappropriate for an inanimate object.

Although we agree with Petitioner at this stage of the proceeding that an appropriate synonym for "emulate" is "imitate," we are not persuaded by Petitioner's proposed construction (i.e., "a structure that is sufficiently porous so as to permit bone ingrowth"). Petitioner's proposed construction does not give sufficient meaning to the words of the claims, as Patent Owner argues.

After considering the competing arguments of the parties, we determine that the broadest reasonable interpretation of "emulate" is "imitate." Accordingly, "a porous . . . structure . . . having a size and a shape that emulate a size and a shape of a porous structure of natural human bone" means "a porous structure having a size and a shape that imitate a size and a shape of a porous structure of natural human bone." Similarly, "a porous . . . structure . . . with interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone" means "a porous structure with interconnected pores having a geometric structure with a shape and a size that imitate a shape and a size of natural human bone."

3. "fabricating, separately from the neck body, a bone fixation body"

Patent Owner argues that the broadest reasonable interpretation of the term "separately" is "to set or keep apart." Prelim. Resp. 7 (citing Ex. 2004, 2). Based on this construction, Patent Owner argues that the claims require a method in which, during fabrication of the bone fixation body, it is set or kept apart from the neck body. *See, e.g.*, *id.* at 18. Petitioner does not propose an express construction for either "separately" or "fabricating, separately from the neck body, a bone fixation body." Implicitly, however, Petitioner argues that "fabricating, separately from the neck body, a bone fixation body" merely requires fabrication of the bone fixation body independent of fabrication of the neck body. *See, e.g.*, Pet. 22–24.

At this stage of the proceeding, we agree with Petitioner's implicit claim construction because it is consistent with the Specification, as discussed below. Conversely, Patent Owner's proposed construction is not consistent with the Specification.

The Specification states that neck body 14 can be machined from a solid piece of metal to have a size and shape shown in the figures, Ex. 1001, 3:62–67, and that bone fixation body 16 is created with a sintering process. *Id.* at 4:49. In an exemplary embodiment, body 16 is fabricated using a mold having two cavities—a first cavity that is sized and shaped for fabrication of the bone fixation body, and a second cavity that is adjacent and connected to the first cavity and sized and shaped to receive the already-fabricated neck body. *Id.* at 4:55–60. "The neck body is positioned in the second cavity such that the distal end surface is adjacent and continuous

with the first cavity." *Id.* at 4:60–62. The sintering material is then placed in the first cavity, and the mold is then heated to perform the sintering process. *Id.* at 4:63–67. "During this process, as the material in the first cavity heats and sinters, the bone fixation body forms and simultaneously bonds or fuses to the distal end surface of the neck body." *Id.* at 4:67–5:3. The Specification further discloses:

> In the aforementioned sintering process, the bone fixation body simultaneously forms and attaches to the neck body. One skilled in the art though will appreciate that *each of these bodies can be fabricated independently* and subsequently connected together. *If the bodies are made separately*, then they may be attached or fused together using known welding or brazing techniques, for example.

Id. at 5:17–23 (emphasis added).

Thus, in the exemplary embodiment described in the Specification, body 16 is fabricated adjacent and continuous with neck body 14. As such, during fabrication of body 16, it is not set or kept apart from neck body 14, contrary to Patent Owner's proposed claim construction. Consistent with Petitioner's implicit claim construction, however, fabrication of body 16 is independent of fabrication of neck body 14, which is machined to its final form prior to being placed in the mold used to fabricate body 16.

At this stage of the proceeding, we determine that the broadest reasonable interpretation consistent with the Specification of "fabricated, separately from the neck body, a bone fixation body" requires fabrication of the bone fixation body independent of fabrication of the neck body.

4. Other claim terms

At this stage of the proceeding, none of our determinations regarding Petitioner's proposed grounds of unpatentability requires us to interpret expressly any other claim term.

B. Asserted Obviousness

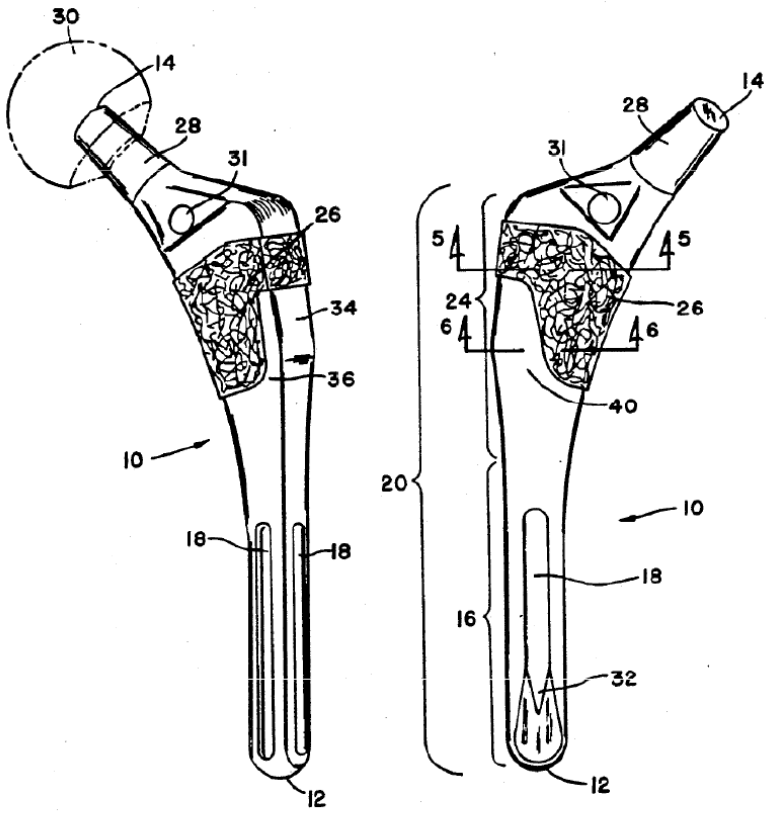
A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. 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 skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

1. Asserted Obviousness of Claims 1–5, 8–11, 14, 15, and 17–20 over Zolman and Rostoker

Petitioner challenges claims 1–5, 8–11, 14, 15, and 17–20 as obvious over Zolman and Rostoker. For the reasons discussed below, and on the current record, we are persuaded that the combination of Zolman and Rostoker renders obvious the challenged claims.

a. Overview of Zolman

Zolman discloses a method of constructing a prosthetic implant that involves wrapping a porous pad about a prosthesis stem. Ex. 1005, 23–43. Figures 1 and 2 of Zolman are reproduced below.



Figures 1 and 2 provide perspective and elevation views, respectively, of femoral component 10. *Id.* at 2:58–60, 31–35. Porous pad 26 encircles

proximal portion 24 of stem portion 20. *Id.* at 3:53–54. As described in Zolman, porous pad 26 preferably is formed first as a substantially flat sheet and then is wrapped or formed about stem portion 20 (for example, using a forming fixture with forming jaws) into a final shape corresponding to the shape of the stem portion. *Id.* at 4:29–41, 5:22–35. Zolman states that Rostoker, discussed below, discloses a suitable fiber metal material for forming porous pad 26. *Id.* at 4:12–14.

b. Overview of Rostoker

Rostoker discloses a prosthetic device produced by kinking wire into a sinusoidal pattern, cutting the wire into short metal fibers, and then molding and sintering the fibers into a porous structure having interconnecting pores. Ex. 1006, 2:21–41. Rostoker states: "Since the pore size can be readily controlled by the pressing and forming parameters, the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted." *Id.* at 2:48–52.

c. Analysis

Petitioner contends that the combination of Zolman and Rostoker teaches the subject matter of claims 1–5, 8–11, 14, 15, and 17–20. Pet. 17–42. As applied by Petitioner to the embodiment depicted in Figure 1 of Zolman, the "neck body" recited in the claims corresponds to the aggregate structure comprising neck 28, the adjacent portion with aperture 31, and stem 20, *see, e.g.*, *id.* at 22, and the "bone fixation body" recited in the claims corresponds to porous pad 26, *see, e.g.*, *id.* at 24. Petitioner argues that Zolman discloses "fabricating, separately from the neck body, a bone fixation body," as required by claim 1. *Id.* Petitioner further argues that a POSITA would have been motivated to use Rostoker's porous material in

Zolman's porous pad 26 so as to have a porous metal fiber structure that "emulates" natural human bone:

> A person of ordinary skill in the art would have been motivated to fabricate *Zolman's* porous pad 26 so as to have a porous fiber metal structure that "emulates" natural human bone, as taught in *Rostoker*, to increase the strength of the attachment of the implant to the surrounding bone, allowing the implant to better withstand the load applied to the hip joint.

Id. at 26 (citing Ex. 1002 ¶¶ 31, 36 ([1.c]). In support of Petitioner's argument, Dr. Harrigan testifies that "*Rostoker* discloses a 'porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone' as recited in claim 1 as it discloses 'a structure that is sufficiently porous so as to permit bone ingrowth." Ex. 1002 ¶ 36 ([1.c]).

In opposition, Patent Owner advances several arguments. First, Patent Owner argues that the Zolman/Rostoker combination does not teach fabricating a bone fixation body with a porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone. Prelim. Resp. 12–16. Specifically, Patent Owner argues that the porous structure of Zolman/Rostoker is formed from sinusoidal kinked wires that are bonded together, and "this structure does not look anything like the porous structure of natural human bone." *Id.* at 14. We determine, however, that Petitioner has shown sufficiently at this stage of the proceeding that Rostoker's porous metal structure has a size and a shape that imitate a size and a shape of a porous structure of natural human bone. *See supra* Section II.A.2; Ex. 1002 ¶ 36 ([1.c]).

Next, Patent Owner argues that "Rostoker actually *teaches away* from forming a porous structure with a size and shape that emulate a size and

shape of a porous structure of natural human bone because the porosity of natural human bone includes values of at least sixty percent (60%)." Prelim. Resp. 16. In this regard, Patent Owner directs our attention to Rostoker's teaching that the maximum porosity of sintered fiber metal structures is between 40–50 percent. *Id.* (citing Ex. 1006, 5:6–13). This argument is also unpersuasive. We are not persuaded at this stage of the proceeding, for example, that a porous structure with a porosity between 40–50% necessarily lacks a size and shape that imitate a size and a shape of a porous structure of natural human bone. *See supra* Section II.A.2.

Patent Owner also argues that the Zolman/Rostoker combination does not teach a method of making, separately from the neck body, the bone fixation body. Prelim. Resp. 17–20. For example, Patent Owner argues:

> The porous pad in Zolman is not made separately from the stem portion; rather, the stem portion must be placed into the jaws together with the sheet of porous material so that the sheet of porous material can be pressed against and bent around the stem portion and formed into the shape of the porous pad. *Id.* In other words, the stem in Zolman is used to make the porous pad.

Id. at 18. Patent Owner's argument is based on a proposed construction that we have not adopted for purposes of this Decision. *See supra* Section II.A.3. Zolman teaches the pertinent claim requirement because fabrication of the bone fixation body (porous pad) is independent of fabrication of the neck body (structure including stem portion).

Finally, Patent Owner argues that Rostoker does not teach a method of attaching the bone fixation body to the neck body after the bone fixation body is made separately from the neck body. Prelim. Resp. 20–22. At this stage of the proceeding, however, we are persuaded that Zolman discloses bonding (attaching) the porous pad to the neck body after the bone fixation

body is made. *See* Pet. 27–28 (citing Ex. 1005, 6:46–54); *see also* Ex. 1005, 7:1–14 (describing bonding pad 26 to stem portion 20 after forming pad 26 about a mandrel, removing it from the mandrel, and placing it about the femoral component).

Upon consideration of the Petition and the Preliminary Response, we are persuaded Petitioner has established a reasonable likelihood of prevailing on its challenges to claims 1–5, 8–11, 14, 15, and 17–20 as obvious over Zolman and Rostoker.

2. Asserted Obviousness of Claim 7 over Zolman, Rostoker, and Sump and Claim 20 over Zolman, Rostoker, and Averill

Petitioner challenges claim 7 as obvious over Zolman, Rostoker, and Sump, and claim 20 as obvious over Zolman, Rostoker, and Averill. *See* Pet. 43–45. With respect to claim 7, Petitioner argues that "it would have been obvious to modify stem portion 20 of the hip implant of *Zolman* and *Rostoker* to have one of a square or rectangular shape [as required by claim 7] in light of *Sump's* disclosure." *Id.* at 43 (citing Ex. 1002 ¶ 51). With respect to claim 20, Petitioner argues that "it would have been obvious to form the stem portion of the hip implant of *Zolman* and *Rostoker* to have a cylindrical shape in a horizontal cross-sectional view [as required by claim 20] in light of *Averill's* disclosure." *Id.* at 44 (citing Ex. 1002 ¶ 54). Patent Owner argues the patentability of independent claims 1 and 14, as discussed above, and relies solely on those arguments with respect to dependent claims 7 and 20.

Upon consideration of the Petition and the Preliminary Response, we are persuaded Petitioner has established a reasonable likelihood of prevailing

on its challenges to claim 7 as obvious over Zolman, Rostoker, and Sump, and claim 20 as obvious over Zolman, Rostoker, and Averill.

3. Asserted Obviousness of Claims 1–5, 8–11, 13–15, and 17–20 over Zolman and Bobyn

Petitioner challenges claims 1–5, 8–11, 13–15, and 17–20 as obvious over Zolman and Bobyn. For the reasons discussed below, and on the current record, we are persuaded that the combination of Zolman and Bobyn renders obvious the challenged claims.

a. Overview of Bobyn

Bobyn discloses a study of implants made from a porous tantalum biomaterial with desirable characteristics for bone ingrowth, having a porosity of 75% to 80%. Ex. 1007, 907, 912. *Id.* at 912. Bobyn states that the structural stiffness of porous tantalum is "similar to subchondaral bone, which could be advantageous in bone remodeling." *Id.* at 913. Bobyn also discloses that "[t]he material could be used as a backing for direct compression moulding of polyethylene-bearing components or as a fixation surface on an implant substrate." *Id.*

b. Analysis

Petitioner contends that the combination of Zolman and Bobyn teaches the subject matter of claims 1–5, 8–11, 13–15, and 17–20. Pet. 45–59. Petitioner argues that:

> Given *Bobyn's* teachings of the advantages of the porous tantalum biomaterial over other conventional porous surfaces, a person of ordinary skill in the art would have been motivated to use [] *Bobyn's* porous biomaterial for *Zolman's* porous pad 26 to form a high strength femoral component 10 with a structure similar to natural cancellous bone.

Id. at 48 (citing Ex. 1002 ¶ 61). In support of Petitioner's argument, Dr. Harrigan testifies that "[a]t the time of the alleged invention, tantalum was understood to be a 'strong, ductile metal with excellent corrosion resistance' that was a standard material used in surgical implants." Ex. 1002 ¶ 60 (citing Ex. 1007, 913). Dr. Harrigan also testifies that "[l]ike the fiber metal structure of *Zolman* (Ex. 1005 at 4:46-48), *Bobyn* discloses that the porous tantalum biomaterial can be compression molded." *Id.* ¶ 63 (citing Ex. 1007, 913).

In opposition, Patent Owner argues that combining Bobyn with Zolman is improper because: "[o]ne skilled in the art would . . . not consider using the experimental substance of tantalum from a dog study with the human implant taught in Zolman"; Bobyn "teaches tiny cylindrical implants formed of completely porous tantalum during a vapour deposition process"; and Bobyn "provides no teaching whatsoever as how to modify these tiny implants or its manufacturing process for use as a porous pad on a femoral stem." Prelim. Resp. 25. We have considered Patent Owner's arguments, but at this preliminary stage of the proceeding, we are persuaded that Petitioner has provided a sufficient rationale for combining Zolman and Bobyn based on the arguments in the Petition, the combined teachings of the references, and the testimony of Dr. Harrigan. *See, e.g.*, Ex. 1002 ¶¶ 57–64.

Patent Owner's remaining arguments also are unpersuasive at this stage of the proceeding (Prelim. Resp. 27–38), either because they simply repeat arguments discussed above in connection with Petitioner's challenges based on Zolman and Rostoker, or because Patent Owner does not address or rebut Petitioner's countervailing evidence relating to Zolman and Bobyn, for example, Dr. Harrigan's testimony that the Zolman/Bobyn combination

teaches a porous tantalum biomaterial that can be compression-molded like the fiber metal structure disclosed in Zolman. *See* Ex. 1003 ¶ 63 (citing Ex. 1007, 913); Prelim. Resp. 29 ("One skilled in the art would read Zolman and Bobyn as teaching the implant with the porous pad as expressly taught in Zolman (with details of the porous pad being provided in Rostoker)."); *id.* at 32 ("As discussed above, one skilled in the art would *absolutely not* read Zolman and Bobyn as teaching Zolman's stem with a porous pad made from Bobyn's experimental material used in canines."); *id.* at 34, 36 ("Bobyn fails to cure the deficiencies of Zolman.").

Upon consideration of the Petition and the Preliminary Response, we are persuaded Petitioner has established a reasonable likelihood of prevailing on its challenges to claims 1–5, 8–11, 13–15, and 17–20 as obvious over Zolman and Bobyn.

1. Asserted Obviousness of Claim 7 over Zolman, Bobyn, and Sump and Claim 20 over Zolman, Bobyn, and Averill

Petitioner challenges claim 7 as obvious over Zolman, Bobyn, and Sump, and claim 20 as obvious over Zolman, Bobyn, and Averill. *See* Pet. 59–60. With respect to claim 7, Petitioner argues that it would have been obvious "to form the stem portion of *Zolman* and *Bobyn's* implant with a rectangular shape and [] to taper [it] in a distal direction in light of *Zolman's* explicit teachings that stem portion 20 can have any desirable or suitable configuration." *Id.* at 59 (citing Ex. 1002 ¶¶ 82–84). With respect to claim 20, Petitioner argues that it would have been obvious "to have a cylindrical shape in a horizontal cross-sectional view in light of *Averill's* disclosure of a prosthesis having [] circular and elliptical cross-sections and *Zolman's* explicit teachings that stem portion 20 can have any desirable or

suitable configuration." *Id.* at 60 (citing Ex. 1002 ¶¶ 85–87). Patent Owner argues the patentability of independent claims 1 and 14, as discussed above, and relies solely on those arguments with respect to dependent claims 7 and 20.

Upon consideration of the Petition and the Preliminary Response, we are persuaded Petitioner has established a reasonable likelihood of prevailing on its challenges to claim 7 as obvious over Zolman, Bobyn, and Sump, and claim 20 as obvious over Zolman, Bobyn, and Averill.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenges to claims 1–5, 8–11, 14, 15, and 17–20 as obvious over Zolman and Rostoker; claim 7 as obvious over Zolman, Rostoker, and Sump; claim 20 as obvious over Zolman, Rostoker, and Averill; claims 1–5, 8–11, 13–15, and 17–20 as obvious over Zolman and Bobyn; claim 7 as obvious over Zolman, Bobyn, and Sump; and claim 20 as obvious over Zolman, Bobyn, and Averill.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review of claims 1–5, 7–11, 13–15, and 17–20 of the '582 Patent is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the ’582 Patent is hereby instituted commencing on the entry date of this Order, and 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; and

FURTHER ORDERED that the trial is limited to the following grounds: claims 1–5, 8–11, 14, 15, and 17–20 as obvious over Zolman and Rostoker; claim 7 as obvious over Zolman, Rostoker, and Sump; claim 20 as obvious over Zolman, Rostoker, and Averill; claims 1–5, 8–11, 13–15, and 17–20 as obvious over Zolman and Bobyn; claim 7 as obvious over Zolman, Bobyn, and Sump; and claim 20 as obvious over Zolman, Bobyn, and Averill.

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