Trials@uspto.gov
571-272-7822

Paper No. 6
Entered: March 30, 2018

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 IPR2018-00052
Patent 9,308,093 B2

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

IPPOLITO, *Administrative Patent Judge*.

DECISION
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") filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claims 1–12 of U.S. Patent No. 9,308,093 B2 (Ex. 1001, "the '093 patent"). Patent Owner, Four Mile Bay LLC, filed a Preliminary Response to the Petition (Paper 5, "Prelim. Resp."). This is a preliminary proceeding to decide whether *inter partes* review of the '093 patent should be instituted under 35 U.S.C. § 314(a), which provides that *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See* 37 C.F.R. § 42.108 (regarding institution of *inter partes* review); 37 C.F.R § 42.4(a) (delegating authority to institute trial to the Board).

Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows that there is a reasonable likelihood that Petitioner will prevail in establishing the unpatentability of at least one of the challenged claims of the '093 patent.

A. Related Matters

According to Patent Owner, the '093 patent is involved in pending district court litigation between the parties in, *Four Mile Bay LLC v. Zimmer Biomet Holdings, Inc.*, No. 3:15-cv-00063-PPSMGG (N.D. Ind.). Paper 4, 1. Patent Owner further indicates that related patents U.S. Patent No. 8,506,642 ("the '642 patent"); U.S. Patent No. 8,821,582 ("the '582 patent"); U.S. Patent No. 9,283,080 ("the '080 patent"); and U.S. Patent No. 9,265,612 ("the '612 patent") have also been asserted in the above referenced district court litigation. *Id.*

Additionally, Petitioner has filed petitions seeking *inter partes* review of claims in the ’642 patent (IPR2016-00011), the ’582 patent (IPR2016-00012), the ’612 patent (IPR2018-00051), and the ’080 patent (IPR2018-00053). On April 1, 2016, the Board declined to institute an *inter partes* review in IPR2016-00011. IPR2016-00011, Paper 8.

With regard to IPR2016-00012, trial was instituted on the challenged claims. IPR2016-00012, Paper 8. A Final Written Decision issued on March 10, 2017, determining that all of the challenged claims were unpatentable. *Id.*, Paper 34 (Exhibit 1008). Patent Owner appealed the Board’s decision to the Federal Circuit in *Four Mile Bay, LLC v. Zimmer Biomet Holdings, Inc.*, Appeal No. 17-2017. That appeal is currently pending.

B. The ’093 Patent

The ’093 patent is directed to a hip implant that integrates with surrounding bone. *Id.* at 1:45–46. In one embodiment, the implant includes two distinct bodies, a neck body and a bone fixation body. *Id.* at 1:47–48. Figure 5, reproduced below, illustrates the relevant embodiment.

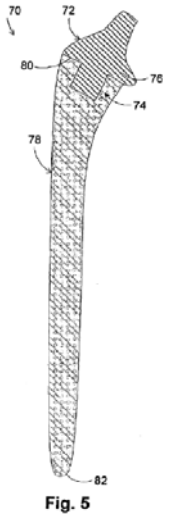


Fig. 5

Figure 5 is a side cross-sectional view of femoral hip implant 70

comprising neck body 72 and bone fixation body 78. *Id.* at 5:11–17. The neck body connects to a spherically shaped femoral ball and acetabular component (not shown). *Id.* at 3:5–8; *see id.* at Fig. 1. The neck body is preferably made from a solid piece of biocompatible metal such as titanium. *Id.* at 3:18–20. The bone fixation body may also be made from titanium, and may have a porous structure that extends throughout the body. *Id.* at 3:46–55. In use, the implant is embedded into the intramedullary canal of the femur so that the bone fixation body contacts surrounding bone. *Id.* at 3:36–37, 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 2:14–15.

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 5:11–18. The protrusion provides a strong connection and anti-rotational interface between the neck body and the bone fixation body. *Id.* at 5:39–41.

C. Illustrative Claim

Of the challenged claims, claims 1 and 7 are independent. Independent claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method, comprising:
>
> machining a neck body from solid metal to have a base portion, a neck portion that extends outwardly from the base portion and includes a cylindrical configuration with a taper that receives a femoral ball, and a male protrusion that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a polygonal shape

in a cross-sectional view;

fabricating, separately from the neck body, a bone fixation body that is formed of a porous metal structure without a solid metal substrate but with the porous metal structure that extends throughout 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, has a trapezoidal shape in a cross-sectional view, and has a tapering body with an external bow; and

permanently connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body at an interface where the male protrusion extends into and engages the bone fixation body and forms a core for the bone fixation body, the bone fixation body abuts the base portion of the neck body, and the bone fixation body abuts the polygonal shape of the male protrusion in order to provide anti-rotation at the interface between the neck body and the bone fixation body.

Id. at 6:21–47.

D. The Asserted Grounds

Petitioner contends that claims 1–12 of the challenged patent are unpatentable under 35 U.S.C. § 103 based on the following grounds. (Pet. 4):

References	Claims Challenged
Zolman[1] and Rostoker[2]	1–12
Zolman, Rostoker, and Averill[3]	6, 12
Zolman and Bobyn[4]	1–12

[1] U.S. Patent No. 5,018,285, issued May 28, 1991 (Ex. 1009, "Zolman").
[2] U.S. Patent No. 3,906,550, issued Sept. 23, 1975 (Ex. 1010, "Rostoker").
[3] U.S. Patent No. 5,863,295, issued Jan. 26, 1999 (Ex. 1012, "Averill").
[4] J.D. Bobyn, et al., *Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial*, 81-B:5 JOURNAL OF

Zolman, Bobyn, and Averill	6, 12

Petitioner also relies on the Declaration of Dr. Timothy P. Harrigan, Sc.D. (Ex. 1002, "Harrigan Declaration").

II. ANALYSIS

A. Principles of Law

A 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 of the invention to a person having ordinary skill in the art. *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.[5] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Consideration of the *Graham* factors "helps inform the ultimate obviousness determination." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc), *cert. denied* (Nov. 6, 2017).

At this preliminary stage, we determine whether the information presented in the Petition shows there is a reasonable likelihood that Petitioner will prevail in establishing that one of the challenged claims would have been obvious over the proposed combinations of prior art.

BONE AND JOINT SURGERY 907 (Sept. 1999) (Ex. 1011, "Bobyn").

[5] Neither party presents any objective evidence of nonobviousness for our consideration. *See generally* Pet. and Prelim. Resp.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. "The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991).

Petitioner asserts a person having 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. Patent Owner does not contest Petitioner's proffered level of ordinary skill or propose an alternative for the level of ordinary skill in the art. *See generally* Prelim. Resp.

We determine on the current record that the level of ordinary skill proposed by Petitioner is consistent with the challenged patent and the asserted prior art. We, therefore, adopt that level for the purposes of determining whether to institute an *inter partes* review.

C. Claim Construction

In an *inter partes* review, we interpret claim terms in the challenged patent according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see*

Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of broadest reasonable construction standard in *inter partes* review). Consistent with the broadest reasonable construction standard, the challenged claims are presumed to be given 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 shall construe only terms that are in controversy and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'r, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

1. "porous metal structure" (claims 1 and 7)

Petitioner contends that the term "porous metal structure" should be construed to require "emulating the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but they do not require emulating the size and shape of the interconnected plates and rods that form trabecular bone." Pet. 14 (citing Ex. 1008, 12–13) (emphasis omitted).

Petitioner asserts the '093 patent's Specification is consistent with this proposed construction because the Specification teaches "the geometric configuration of the porous structure should encourage natural bone to migrate and grow into and throughout the entire body 16," and a porous structure that "is adapted for the ingrowth of cancellous and cortical bone spicules" by "emulat[ing] the size and shape of the porous structure of natural bone." Pet. 16 (citing Ex. 1001, 3:55–59, 3:62–65). Petitioner adds that the Specification also characterizes the porous structure based on pore diameter, porosity, and intersection diameter. Pet. 16 (citing Ex. 1001,

3:59–62).

Patent Owner construes the term "porous metal structure" to mean "emulate a size and a shape of a porous structure of natural human bone with size being measured, for example, by pore diameter, porosity, and intersection diameter, and shape being straight rods that connect together to form a porous structure." Prelim. Resp. 16–17.

To start, we note that Petitioner's and Patent Owner's proposed constructions are largely the same, but differ primarily in that Patent Owner's construction requires the "porous metal structure" to have a shape of "straight rods that connect together to form a porous structure." In this regard, Patent Owner first asserts that Dr. Harrigan and Patent Owner's declarant, Dr. Helmus, agree a POSITA would read the porous metal structure described in the '093 patent as being directed to cancellous bone. Prelim. Resp. 11–12 (citing Ex. 1002, 13; Ex. 2003, 65). However, looking to the cited testimony of Dr. Harrington, while Dr. Harrigan testifies that the disclosed range of pore diameters and porosities *overlap* with known pore diameters and porosities of cancellous bone, Dr. Harrigan did not state that the '093 patent is directed to only or limited to cancellous bone. Rather, Dr. Harrigan testifies that

> The '093 patent explains, however, that "[a]though specific ranges are given for pore diameters, porosity, and interconnection diameters, these ranges are exemplary and are applicable to one exemplary embodiment" and "could be modified, and the resulting hip implant still within the scope of the invention." *Id.* at 3:66-4:4.

Ex. 1002 ¶ 16.

Dr. Harrigan's reading of the '093 patent is consistent with the disclosure, which is generally broad and not expressly limiting. For

example, as acknowledged by the Patent Owner, in column 2, lines 17 through 21, the '093 patent explains that

> [i]n one example embodiment, the geometric structure of the porous body may be shaped and sized to emulate the shape and size of natural bone surrounding the implant. Specifically, the porous structure of the bone fixation body thus replicates the porous structure of natural bone itself.

Ex. 1001, 2:17–21. Patent Owner concedes that

> [n]othing at this location of the specification justifies changing the plain meaning of the porous-metal-structure claim terms. In fact, this portion of the specification solidifies a finding that the claim terms are being used in accordance with their plain meaning and should not be interpreted to add extra words, add functional language, or remove words from the claim.

Prelim. Resp. 5. Yet, essentially, Patent Owner's proposed construction seeks to do exactly that which it opposes, that is to add the extra words "shape being straight rods that connect together to form a porous structure" to the claim language while acknowledging the Specification does not support this construction. *Id.* at 5–6 (citing Ex. 1001, 2:17–21, 3:56–4:4).

Further, turning to page 65 of Exhibit 2003 (which was a declaration submitted in IPR2016-00012), Dr. Helmus's testimony is not helpful in this instance. Dr. Helmus states:

> 160. Response: In paragraph 17 of his written opinion, Harrigan states that the specification of the '582 patent and the claims are directed to cancellous bone: "In my opinion, a person of ordinary skill in the art would have understood that the disclosed range of pore diameters and porosities overlap with known pore diameters and porosities of cancellous bone." Ex. 1002 at para 17. Harrigan's arguments ignore the fact that the claims require the porous structure to have "a shape" emulating natural bone, and Rostoker's porous sinusoidal kinked wires do not have such a shape.

Ex. 2003 ¶ 160.[6] Again, in this proceeding, as noted above, Dr. Harrigan does not state that the '093 patent is directed solely to cancellous bone, and further, indicates that the disclosure is broader and not limited to the specific examples described in the patent. Ex. 1002 ¶ 16.

Additionally, while Patent Owner acknowledges that the Specification of the '093 patent, file history of the '093 patent, and the claim language do not expressly define the shape of natural bone, Patent Owner, nonetheless, asserts that a POSITA would understand the shape of natural bone to require a particular shape. *See* Prelim. Resp. 4–13 ("The specification and the file history of the '093 patent are not required to expressly define the shape of natural human bone because the shape of natural human bone was clearly known to a POSITA."). Here, Patent Owner relies on four references, Exhibits 2004–2007, as showing natural human bone having the same shape of straight rods that connect together to form a porous structure. Prelim. Resp. 13. Patent Owner further contends that Dr. Helmus and Dr. Vincelli provide testimony and supporting publications that the shape of natural bone is straight rods that connect together to form a porous structure. *Id.* at 14 (citing Ex. 2003, 30; Ex. 2008, 24).

Based on the current record in the instant proceeding, we are not persuaded that the broadest reasonable construction of the term "porous metal structure" requires the "shape being straight rods that connect together to form a porous structure." As acknowledged by Patent Owner, and noted by Petitioner, the claim language at issue, Specification of the '093 patent, and file history of the '093 patent do not limit the shape of natural bone to

[6] Page 65 of 74 according to the pagination on the lower left portion of Exhibit 2003.

any particular shape or natural bone. *See* Ex. 1001, 2:17–21, 3:56–4:4; Pet. 15–18; Prelim. Resp. 4, 6–11. Rather, the Specification describes the bone fixation body as adapted for the ingrowth of *both* cancellous (trabecular) *and* cortical bone. Ex. 1001, 3:55–56 ("The porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules."). Further, the Specification does not mention straight rods that form a porous structure. The Specification more generally describes an exemplary embodiment in which the size and shape of the porous structure of body 16 emulates the size and shape of the porous structure of natural bone:

> The porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules. In the exemplary embodiment, the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone.

Ex. 1001, 3:55–59.

The Specification indicates that the size and shape of the porous structure of natural bone can be measured by pore diameter, porosity, and intersection diameter, for which the Specification discloses preferred ranges. *Id.* at 3:59–65. The Specification makes clear that "these ranges could be modified, and the resulting hip implant still within the scope of the invention" (*id.* at 3:66–4:4); and nothing in the Specification indicates that emulating the size and shape of the porous structure of natural bone requires emulating the shape of straight rods to form a porous structure.

Further, we are not persuaded that the file history supports Patent Owner's narrower construction of "porous metal structure," which is inconsistent with the express claim language and Specification that does not limit the emulated shape to straight rods. Patent Owner refers to the file history of the '642 patent (parent to the '093 patent) as showing that the Applicant added the "porous metal structure" to distinguish the spherical

porous structure in the prior art from the claimed shape of the porous structure of natural human bone. Prelim. Resp. at 10. Patent Owner further contends "[n]othing in the file history supports reading out the shape of the porous metal structure recited in the claims or replacing this language with the functional language proposed by the Zimmer." *Id.* at 10. However, Patent Owner does not argue, nor is it apparent otherwise, that a disclaimer or disavowal of claim scope occurred during prosecution of the '642 patent. Moreover, in the First Office Allowance of the '093 patent, the Examiner considered a single reference, U.S. Patent No. 6,361,566 B1 (Al-Hafez). Ex. 1007, 7–8. In doing so, the Examiner determined that

> Al-Hafez fails to teach the neck body having an elongated shape that tapers and the bone fixation body being formed of a porous metal structure without a solid metal substrate but with the porous metal structure that extends throughout 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, has a trapezoidal shape in a cross-sectional view. ***The main point of novelty being the solid metal neck body interfacing with and becoming a core for the completely porous bone fixation body***.

Id. (emphasis added). Here, there is no mention of a disavowal, disclaimer, or narrowing of claim scope with regard to "porous-metal-structure." *Id.*

We also observe that the prior art reference "Draenert II" discussed by Patent Owner in its Preliminary Response is a different reference from Al-Hafez considered by the Examiner in the '093 patent. Prelim. Resp. 6–11. As such, it is unclear whether the Examiner in the '093 patent considered the prior art in the file history of the '642 patent as these references, including "Draenert II," do not appear on the face of the '093 patent under "References Cited," and were not discussed by the Examiner. Ex. 1001, [56]; Ex. 1007, 7–8. Thus, under these particular circumstances, we are not

persuaded that the claim scope of the term "porous-metal-structure" was clearly narrowed to a particular bone shape during prosecution of the '093 patent or its parent, the '642 patent.

Moreover, at this junction, we are not persuaded by the testimony of Patent Owner's experts that a narrower construction is appropriate. *See* Ex. 2003, 30; Ex. 2008, 24. Based on the current record, this testimony is inconsistent with the Specification, which does not limit the shape of natural human bone to straight rods (or cancellous bone). *See* Ex. 1001, 3:55–56. Rather, we construe the term "porous metal structure" as "a structure that emulates the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter." For clarity of the record, we note that this construction does not require the "porous metal structure" to have a shape of straight rods as suggested by Patent Owner.

2. "base portion" claims 1 and 7

Patent Owner asserts that the broadest reasonable construction of the term "base portion" is "the larger bottom part of an extension considered as its support." Patent Owner contends that claims 1 and 7 recite three distinct and different features: (1) neck portion, (2) base portion, and (3) male protrusion. Prelim. Resp. 26. Further, Patent Owner argues that Figures 1 and 5 of the '093 patent show the base portions being a feature at the bottom of the neck portions and that the male protrusion and neck portion are both shown as skinnier than the base portion in side views. Prelim. Resp. 27. Additionally, Patent Owner relies on a dictionary definition of "base" as showing the customary and ordinary meaning to be "b. the bottom of something considered its support: Foundation • the base of the mountain •

the lamp's heavy base." *Id.* at 28 (citing Ex. 2015, 1).

Based on the current record, we determine that Patent Owner's proposed construction is too narrow. Neither the express claim language nor the Specification indicates that the base portion must be the "larger bottom part of an extension" or different and distinct from another structure. Yet, Patent Owner imports these limitations into its construction based on particular embodiments it alleges are shown in Figures 1 and 5 of the '093 patent. However, the '093 patent does not describe the base portions in Figure 1 or 5 as being a *larger bottom* of an extension, or that the base portion must be a different and distinct element from a neck portion or male protrusion. *See* Ex. 1001, 3:12–13, 5:14–15. Instead, even assuming that Figure 5 shows the male protrusion extending from the base portion, the '093 patent does not teach that the male protrusion cannot be part of another feature such as the base portion.

Indeed, even the dictionary definition relied upon by the Patent Owner does not state that a base is a larger bottom. Ex. 2015. Rather, consistent with the customary and ordinary meaning of the term as evidenced by Exhibit 2015, the claim language, and the Specification, we determine, for the purposes of this Decision that the term "base portion" means a "bottom support" portion.

3. Remaining Claim Terms

No further explicit interpretations of any other claim terms are 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*

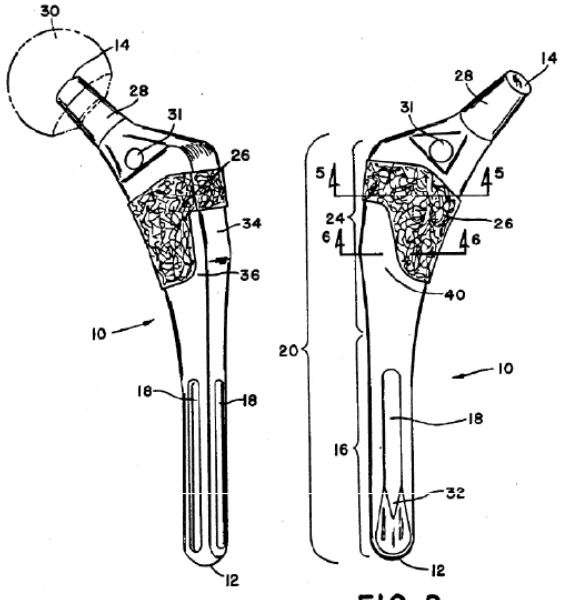
Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Obviousness Challenge Based on Zolman and Rostoker – claims 1–12

Petitioner asserts claims 1–12 of the '093 patent would have been obvious based on a combination of the teachings and suggestions of Zolman and Rostoker. Pet. 24–45.

1. Zolman

Zolman discloses a method of constructing a prosthetic implant that involves wrapping a porous pad about a prosthesis stem. Ex. 1009, 2:23–43. 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. Porous pad 26 encircles proximal portion 24 of stem portion 20. *Id.* at 4:5–8. 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.

Zolman also discloses that, instead of forming porous pad 26 about stem portion 20, porous pad 26 alternatively can be formed about a mandrel having a shape that corresponds to the portion of the implant to which the pad is to be attached. *Id.* at 7:1–6. The formed pad is then removed from the mandrel, placed about femoral component 10, and securely bonded to stem portion 20. *Id.* at 7:10–14.

2. Rostoker

Rostoker explains that "[a]n open-pore material into which bone could grow should provide ideal skeletal fixation." Ex. 1010, 1:50–51. Rostoker further explains that conventional porous materials were less than ideal, however, because they needed to be formed from fine powders to achieve the desired "high level of porosity and acceptable green strength." *Id.* at 1:54–59. These materials, Rostoker states, suffered from limited pore size and insufficient connectivity between pores. *Id.* at 1:59–63. According to Rostoker, "[t]his isolation limits bone ingrowth and results in a situation similar to the roughened surface of a solid." *Id.* at 1:63–65. Rostoker states: "Consolidated metal powders with porosities in the range of 40–60% void, are stronger than the consolidated ceramics but still are very brittle and have poor toughness." *Id.* at 2:3–7.

To solve these problems, Rostoker discloses a prosthetic device having "an open-pore attachment for bone ingrowth which attachment is highly compliant, not brittle, resistant to crack propagation and has a broad range of readily controllable pore sizes." *Id.* at 2:15–19. A porous aggregate is 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. *Id.* at 2:21–41. "[I]n view of the use of fiber metals, the pores are interconnecting and remain so after sintering." *Id.* at 2:40–41. "Thus bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." *Id.* at 2:42–44. 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.

Rostoker further discloses molding sintered metal aggregates "having void or a porosity of 40 to 50 percent per unit area." *Id.* at 5:6–8. "The largest principal dimension of the pores is approximately equal to the wire diameter when the void content is about 50 percent." *Id.* at 5:21–24. Rostoker discloses using wire sizes as fine as 0.013 cm in diameter and as coarse as 0.030 cm in diameter. *Id.* at 5:14–16.

3. Claims 1 and 7

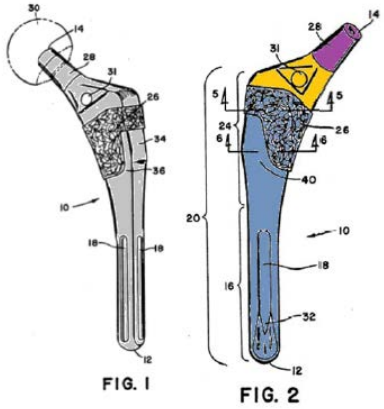
Petitioner provides detailed claim charts, arguments, and evidence, including the Harrigan Declaration, showing that the combination of Zolman and Rostoker teaches or suggests all the limitations recited in claims 1 and 7. Pet. 24–37, 40–43. Petitioner also provides reasons why one of ordinary skill in the art would have been motivated to combine the relevant teachings and suggestions of Zolman and Rostoker. *See id.* at 32–33. Below we discuss independent claim 1, which is representative of the similar subject matter recited in independent claim 7.

Claim 1 is directed generally to a method that includes

> machining a neck body from solid metal to have a base portion, a neck portion that extends outwardly from the base portion and

> includes a cylindrical configuration with a taper that receives a femoral ball, and a male protrusion that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a polygonal shape in a cross-sectional view.

Ex. 1001, 6:22–28. For this limitation, Petitioner provides an annotated version of Figure 2 from Zolman (below) that Petitioner asserts teaches a "base portion" in orange, "neck portion" in purple, and a "male protrusion" in blue. Pet. 25, 27.



According to Petitioner, annotated Figure 2 from Zolman shows a neck body that includes neck 28, base portion with aperture 31, and stem portion 20. Pet. 25. Petitioner adds that a POSITA would have inferred that Zolman's neck body was formed by machining solid metal, or, alternatively that it would have been obvious "that the neck body would have undergone a final machining process to finish, polish, or roughen the solid metal after molding, casting, or machining the neck body to a near final shape to obtain the required dimensions and surface characteristics of the neck body." Pet. 26–27 (citing Ex. 1002 ¶ 42). Petitioner further argues that a proximal portion 24 of stem portion 20 has a noncircular, polygonal shape, in a cross-sectional view that is shown in Figures 5 and 6 of Zolman. Pet. 33 (citing Ex. 1009, 5:19–21, Figs. 5–6; Ex. 1002 ¶ 42).

In its Preliminary Response, Patent Owner asserts that Zolman expressly teaches a hip implant with only a stem portion and a neck portion. Prelim. Resp. 30–31 (citing Ex. 1009, 3:54–57). Relying on Patent Owner's annotated version of Zolman's Figure 2, Patent Owner contends that stem portion 20 in Zolman ends at the bottom of neck 28.

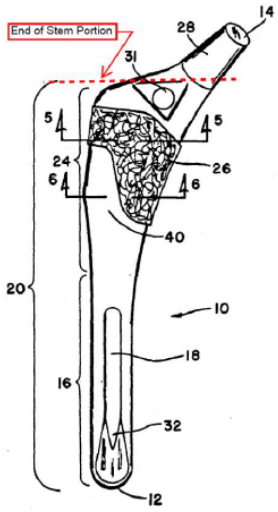


FIG. 2

Zolman's annotated Figure 2 above depicts femoral component 10 with an added portion identifying an "End of Stem Portion'." Patent Owner argues that neck 28 in Zolman does not have a separate and distinct base portion, or a male protrusion that extends outwardly from a base portion. *Id.* at 32. Patent Owner adds that Petitioner's annotated figure contradicts the disclosure in Zolman because it uses "nomenclature" contrary to Zolman. *Id.* at 35.

We note that we have not adopted Patent Owner's proposed construction that requires the base portion to be, among other things, a different/distinct/separate structure. *See supra* Claim Construction. However, even assuming that Patent Owner's construction is correct, we are

not persuaded that Zolman's "nomenclature" contradicts Petitioner's position that it would have been obvious to a POSITA that Zolman discloses the step of "machining a neck body from solid metal to have a base portion, a neck portion that extends outwardly from the base portion." Petitioner alleges that Zolman's Figure 2, as annotated by Petitioner, shows three distinct structures identified as a "base portion" in orange, "neck portion" in purple, and a "male protrusion" in blue. While the nomenclature may be different, based on the current record, we are persuaded that Petitioner has explained sufficiently how Zolman discloses these three structures.

Further, based on the current record, we are persuaded by Petitioner's arguments that a POSITA would have recognized "the Morse taper, recess 74, and grooves 18 on Zolman's neck body would have been formed by removing material from the solid-metal neck body through a machining process," and that "proximal portion 24 of stem portion 20 has a noncircular shape, and in particular a polygonal shape, in a cross-sectional view." Pet. 26, 28. Based on the current record, Petitioner's position is consistent with Zolman's teaching of a non-circular cross-section shown in Figures 5 and 6. Further, Dr. Harrigan's testimony, relied upon by Petitioner, provides that

> it was common practice in 2003 to machine a solid metal neck body. *See, e.g.*, Ex. 1012 at 6:54-58 ("The prosthesis of the present invention can be manufactured from titanium alloy, cobalt-chromium alloy or any other suitable material well known in the art. The prosthesis can be made by forging, casting and/or machining operations or any other well-known technique.").
>
> In my opinion, a person having ordinary skill in the art at the time of the purported invention would have known that *Zolman's* neck body was made through a machining process to have the shape, dimensions, and finish shown in *Zolman's* figures. Such a person would have, in my opinion, recognized that grooves 18 and recess 74 (*see* Figure 6 and Figures 14 and 15 for an alternative

> example of recess 74) of *Zolman's* neck body were formed by a machining process using a tool (*e.g.*, a lathe or mill) to remove material from the solid metal stem portion 20.
>
> Such a skilled artisan would have also recognized that neck 28 has a Morse taper which, at the time of the purported invention, would have been created by machining processes.

Ex. 1002 ¶ 42.

Claim 1 further recites the step of:

> fabricating, separately from the neck body, a bone fixation body that is formed of a porous metal structure without a solid metal substrate but with the porous metal structure that extends throughout 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, has a trapezoidal shape in a cross-sectional view, and has a tapering body with an external bow.

Ex. 1001, 6:30–37.

Petitioner argues that Zolman's disclosure of porous pad 26 teaches these limitations. According to Petitioner, Zolman discloses separately fabricating porous pad 26 from porous material shaped about a mandrel and then attaching the shaped porous pad to stem portion 20. Pet. 29 (citing Ex. 1009, 4:46–49, 7:1–14; Ex. 1008, 27). Petitioner further asserts that Zolman explicitly teaches that the porous pad can be formed from Rostoker's porous fiber metal. Pet. 30 (citing Ex. 1009, 4:12–15; Ex. 1010, 2:21–31, Fig. 4). Petitioner adds that Rostoker teaches that its porous fiber metal structure can be fabricated with pore diameters and porosities that fall within the known range of pore diameters and porosities of cancellous (trabecular) bone and that "encourage natural bone to migrate and grow into and throughout the entire body 16." Pet. 31–32 (citing Ex. 1010, 5:6–8, 5:14–16, 5:21–24; Ex. 1001, 3:59–65; Ex. 1002 ¶ 43 (citing Ex. 1016, 954)). With regard to the "trapezoidal shape" and "external bow" limitations, Petitioner asserts that

Zolman's porous pad 26 conforms to proximal portion 24 of stem portion 20 in Figure 5 of Zolman, which Petitioner argues is a trapezoidal cross-sectional shape. Pet. 33–34 (citing Ex. 1009, Figs. 2, 5). Further, Petitioner contends that "Zolman discloses that porous pad 26 has a tapering body with an external bow, i.e., with at least one side having a curvature." Pet. 35 (citing Ex. 1002 ¶ 45).

In response, Patent Owner argues "that it is impossible to make a hip implant having a porous metal structure emulating the shape of human bone with the method taught in Zolman and Rostoker." Prelim. Resp. 40–46. Patent Owner relies on Dr. Vincelli's testimony that "it is not possible to make Rostoker's sinusoidal kinked wires into a shape of natural bone, because natural human bone has a structure of trabeculae formed of rods and plates that are quite different from the structure of S-shaped wires of Rostoker." *See* Prelim. Resp. 39–43 (citing Ex. 2008, 25–26). Further, Patent Owner relies on similar testimony by Dr. Helmus that "the shape of the bonded kinked S-shaped wires would not emulate or imitate the shape of the interstitial porous structure of natural human bone. By contrast, the shape of the porous structure of natural human bone is formed of rods that interconnect in a foam-like structure." Prelim. Resp. 45 (quoting Ex. 2003, 32–33).

Based on the current record, Petitioner's position is persuasive. As discussed above, our construction of "porous metal structure" as "a structure that emulates the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter" does not limit the emulated shape to straight rods as Patent Owner contends. With this construction in mind, we note that consistent with

Petitioner's position, Rostoker teaches fabricating a fiber metal structure that contains interconnecting pores and a controlled pore size such that the porosity of the metal structure approximates the porosity of surrounding bone, permitting bone ingrowth. Ex. 1010, 2:40–52; Ex. 1002 ¶ 28. Further, Rostoker discloses values for pore size and porosity within the preferred ranges taught by the '093 patent for ingrowth of cancellous and cortical bone spicules. *See* Pet. 31–32 ("Rostoker discloses can be 0.013 cm (130 μm) or 0.03 cm (300 μm)"); Ex. 1002 ¶ 29; Ex. 1010, 5:6–8 ("[t]he sintered fiber metal aggregates . . . may be molded having void or a porosity of 40 to 50 percent per unit area," 5:14–16, 5:21–24; Ex. 1001, 3:59–65 (e.g., pore size from 40 μm to 800 μm and porosity from 45% to 65%).

As argued by Petitioner, we discern that Zolman explicitly refers to Rostoker's porous fiber metal as a material suitable for porous pad 26, and also teaches that porous pad 26 is "subsequently wrapped about the stem portion 20 into a second shape conforming to the shape of the stem portion 20." *See* Ex. 1009, 4:8–21, Fig. 5. Thus, for the purposes of this Decision, we are persuaded that the record supports Petitioner's position.

Additionally, claim 1 recites the step of:

> permanently connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body at an interface where the male protrusion extends into and engages the bone fixation body and forms a core for the bone fixation body, the bone fixation body abuts the base portion of the neck body, and the bone fixation body abuts the polygonal shape of the male protrusion in order to provide anti-rotation at the interface between the neck body and the bone fixation body.

Ex. 1001, 6:38–47. For these limitations, Petitioner asserts that Zolman's recess 74 in proximal portion 24 of stem portion 20 corresponds to

an "interface." Pet. 35–36 (citing Ex. 1009, 5:13–16, 6:44–48). Referring to Figures 2 and 5, Petitioner argues that porous pad 26 "completely encircles stem portion 20, and that stem portion 20 extends into and engages porous pad 26 and forms a core for porous pad 26 when porous pad 26 is positioned in recess 74." *Id.* at 36 (citing Ex. 1009, Figs. 1–5, 3:53–54, 4:41–45). Further, Petitioner contends that the distal end of Zolman's base portion forms the upper lip of recess 74 so that when porous pad 26 is positioned within recess 74 and bonded to stem portion 20, porous pad 26 abuts the base portion of Zolman's neck body. Pet. 36 (citing Ex. 1009, Figs. 1–4, 3:62–65, 5:12–16, 6:44–48; Ex. 1002 ¶ 46). Additionally, Petitioner argues that porous pad 26 abuts the polygonal shape of stem portion 20 when positioned in recess 74, and a POSITA would have recognized that the angles of the polygonal shape of stem portion 20 shown in Figures 1–5 would prevent porous pad 26 from rotating relative to proximal portion. Pet. 36–37 (citing Ex. 1009, 5:13–21, 6:44–48, Figs. 1–6; Ex. 1002 ¶ 47).

Patent Owner responds that Zolman teaches that the porous surface or pad wraps around the exterior surface of the hip implant, which Patent Owner contends does not show a separate, distinguishable element of a base portion, and an interface, where the bone fixation body abuts the base portion. Prelim. Resp. 36–39.

Based on the preliminary record, Petitioner's position is persuasive. As discussed above, we do not agree with Patent Owner's argument that Zolman does not teach a "base portion." Further, consistent with Petitioner's arguments, Zolman discloses that porous pad 26 can be wrapped around an interface (i.e., recess 74), which is on the neck body (i.e., implant 10), allowing the alleged male protrusion to extend into and engage the

porous pad (i.e., bone fixation body). *See* Ex. 1009, 4:8–14, 5:12–16. Additionally, we note that porous pad 26 is positioned in recess 74, which is adjacent to what Petitioner has alleged to be the base portion (i.e., orange portion in annotated Figure 2). In this respect, we are persuaded, on this record, that Petitioner has explained sufficiently how this disclosure teaches porous pad 26 abuts the "base portion" via the upper lip of recess 74. *See* Pet. 36. We also note that Dr. Harrigan's testimony at paragraph 47 further support Petitioner's position that the angles of the shape of stem portion 20 would prevent porous pad 26 from rotating. Ex. 1002 ¶ 47.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge that claim 1 of the '093 patent would have been obvious over the combination of Zolman and Rostoker. Petitioner presents similar arguments for independent claim 7. Pet. 40–43. For essentially the same reasons discussed above, with regard to claim 1, we are also persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge that claim 7 of the '093 patent would have been obvious over the combination of Zolman and Rostoker.

4. Claims 2–6 and 8–12

Based on the current record, Petitioner's showing that the combination of Zolman and Rostoker teaches or suggests all the elements of claims 2–6 and 8–12 of the '093 patent is detailed and well-supported by citations to the prior art and the Harrigan Declaration. Pet. 37–40, 43–45.

Dependent claim 2 depends from claim 1 and claim 8 depends from claim 7. Both further recite "wherein the bone fixation body has a size and a shape to distribute loads from the neck body to the bone fixation body."

For these limitations, Petitioner asserts that Zolman's stem portion 20 and porous pad 26 are designed to fit within the intramedullary canal and porous pad 26 is positioned to contact "walls of the intramedullary canal to support the vertical load on the hip implant and distributes the load on the neck body to porous pad 26 and ultimately to the surrounding bone." Pet. 37 (citing Ex. 1009, Figs. 1–4, 3:45–51, 6:44–48; Ex. 1002 ¶ 49). Based on the current record, Petitioner's arguments are persuasive and consistent with the disclosure in Zolman, which provides, for example, that "femoral component 10 is intended to fit within the intramedullary canal of a femur" and that porous pad 26 encircles the femoral component "to form a continuous porous surface circumferentially about the stem portion 20." Ex. 1009, 3:46–47, 4:41–45.

Similarly, claims 3 and 9, which depend from claims 1 and 7 respectively, both require that "the bone fixation body has a size and a shape that emulate a size and a shape of a human intramedullary canal." For these claims, Petitioner argues that Zolman's implant is intended to fit in the intramedullary canal of a femur and that porous pad 26 conforms to the shape of stem portion 20, which means that porous pad 26 also fits into the intramedullary canal. *See* Pet. 38. Based on the current record, Petitioner's explanation is persuasive.

Dependent claims 4 and 10 recite that "the bone fixation body is fused to the male protrusion of the neck body after the bone fixation body is formed." In a similar fashion, claims 5 and 11 both require that "the bone fixation body is bonded to the male protrusion of the neck body after the bone fixation body is formed." For these limitations, Petitioner asserts that

> Zolman discloses that a permanent connection "may be achieved by diffusion bonding the pad to the stem portion by holding the

> pad securely thereagainst at a sufficient temperature for a sufficient length of time to achieve secure bonding." (Ex. 1009, 6:46-54.) Diffusion bonding occurs by applying high pressure in conjunction with high temperatures to fuse the components together. (Ex. 1002, ¶¶52-53 (citing Ex. 1024 at 3:48-59, 4:28-40).)

Pet. 38–39. Based on the current record, Petitioner's explanation is persuasive.

Claims 6 and 12 recite that "the male protrusion also includes a circular shape in a cross-sectional view." For these limitations, Petitioner points to the annotated Figure 2 of Zolman. Pet. 39.

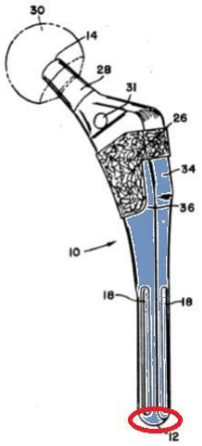


FIG. 1

The annotated version of Zolman's Figure 2 above shows a circular shape in a cross-section view circled in red. Petitioner further asserts that, alternatively, it would have been obvious to form distal portion 16 of stem portion 20 to have a circular shape in a cross-sectional view such as the circular shape disclosed in Rostoker's rod 27. *Id.* (citing Ex. 1002 ¶ 57; Ex. 1010, 3:11–20, Fig. 1). Based on the current record, Petitioner's arguments are persuasive.

Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 2–6 and 7–12 of the '093 patent would have been obvious over the

combination of Zolman and Rostoker.

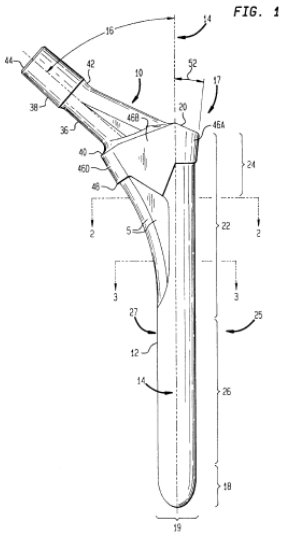
E. Obviousness Challenge Based on Zolman, Rostoker, and Averill – claims 6 and 12

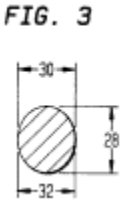
Petitioner asserts claims 6 and 12 of the '093 patent would have been obvious based on a combination of the teachings and suggestions of Zolman, Rostoker, and Averill. Pet. 45–46.

Averill discloses a hip prosthesis 10 having a stem 12 that includes a tapered portion 22 and a cylindrical portion 26. Ex. 1012, 5:5–10; 5:21–29, Fig. 1. Averill discloses that Figures 2 and 3 illustrate cross-sections of stem portion 12 at lines 2—2 and 3—3 of Figure 1, respectively. *Id.* at 5:30–32, Figs. 1–3. Averill further discloses that "[t]he cross-sectional shape of the tapered portion 22 of stem 12 at line 2—2 (FIG. 2) . . . presents a greater medial-lateral dimension 28 as compared with the overall anterior-posterior dimension 30" and changes to "an almost circular cross-section at line 3—3, (FIG. 3)." *Id.* at 5:30–39.

As discussed above, claims 6 and 12 recite that "the male protrusion also includes a circular shape in a cross-sectional view." Here, Petitioner argues that Averill discloses a prosthesis 10 including stem 12 with a tapered portion 22 and "an almost circular cross-section at line 3–3, (FIG. 3)." Pet. 46 (citing Ex. 1012, 5:34–39, Figs. 1–3; Ex. 1002 ¶ 77). Petitioner further reasons a POSITA would have appreciated that forming a distal portion of Zolman's stem portion to have a circular shape in a cross-sectional view would have been an obvious design choice, and, alternatively that POSITA would have been motivated to form the stem of Zolman and Rostoker to have this shape to facilitate insertion into the intramedullary canal. Pet. 46 (citing Ex. 1002 ¶ 78).

Based on the current record, Petitioner's position is persuasive. In particular, we note that Averill discloses in Figure 3 a circular cross-section along line 3–3 of the implant shown in Figure 1 (both shown below).





As shown above, Figure 1 is an anterior elevational view of a hip implant prosthesis that shows distal end 18 of cylindrical portion 26 tapers down to form spherical tip portion 19. Ex. 1012, 5:26–29. As mentioned, Figure 3 is a cross-sectional view taken along line 3–3 of Figure 1. *Id.* at 3:52–53; 3:56–57. Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 6 and 12 of the '093 patent would have been obvious over the combination of Zolman, Rostoker, and Averill.

F. Obviousness Challenge Based on Zolman and Bobyn – claims 1–12

Petitioner asserts that claims 1–12 would have been obvious based on a combination of the teachings and suggestions of Zolman and Bobyn. Pet. 46–59.

1. Bobyn

Bobyn is a study of the characteristics of bone ingrowth of a new porous tantalum biomaterial in a transcortical canine model using cylindrical

implants. Ex. 1011, 907. Bobyn states:

> A new porous biomaterial made of tantalum has recently been developed for potential application in reconstructive orthopaedics and other surgical disciplines. The material has an unusually high and interconnecting porosity with a very regular pore shape and size. It can be made into complex shapes and used either as a bulk implant or as a surface coating. Our aim in this study was to characterize this porous tantalum material in terms of the extent and rate of bone ingrowth as well as the strength of fixation at the interface.

Id. (footnotes omitted).

The cylindrical implants were manufactured by depositing commercially pure tantalum on a carbon skeleton using chemical vapor deposition/ infiltration ("CVD/CVI"). *Id.* at 908. Four transcortical implants were inserted into perpendicular drill holes in each femur of each animal in the study. *Id.* at 909. Bobyn states that "[a]lthough not as realistic as a fully-functional load-bearing model, the transcortical model is very useful for the initial characterization of new porous biomaterials." *Id.* at 913.

Bobyn reports that "[c]ompared with previous studies using porous-coated transcortical implants, high fixation strength occurred much earlier with porous tantalum." *Id.* at 912. "The increased rate of development of the interfacial shear strength with porous tantalum can best be attributed to the higher volume fraction available for ingrowth." *Id.* While fiber metal coatings have a porosity of 40% to 50%, the porous tantalum biomaterial used in the study had a substantially higher porosity of 75% to 80%. *Id.* "The histological studies clearly showed that the porous tantalum served as an effective scaffold for relatively complete incorporation with new bone by 16 weeks, with little change after 52 weeks of implantation." *Id.*

Bobyn states that "[f]rom a manufacturing standpoint, tantalum is particularly well suited to the complex CVD/CVI process used for deposition on to the vitreous carbon substrate." *Id.* at 913. Bobyn also discloses that tantalum "is a strong, ductile metal," and "[i]ts superb biocompatibility and suitable mechanical properties have led to its standardization as a surgical implant material." *Id.*

Bobyn discloses that "[t]he tantalum construct which we have evaluated represents a departure from conventional porous materials in many respects." Bobyn explains that because of the tantalum biomaterial's high porosity, the structural stiffness of porous tantalum is "similar to subchondaral bone, which could be advantageous in bone remodeling." *Id.* Bobyn states 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.* Bobyn also states that the material's "structural integrity allows it to be readily formed in bulk parts for the filling of bone defects or other reconstructive applications requiring standard or customized shapes and sizes of the implant." *Id.* Bobyn concludes: "Based on the results of our study we conclude that [the tantalum biomaterial] offers interesting potential for orthopaedic reconstructive procedures and that further studies are warranted." *Id.*

2. Analysis

Petitioner has challenged claims 1–12 as unpatentable over the combination of Zolman and Bobyn. Pet. 46–59. Petitioner asserts that Zolman primarily teaches all of the recited limitations of the challenged claims except for those directed to the porous metal structure in claims 1 and 7, and load distribution limitations in dependent claims 2 and 8. *Id.*

With respect to Petitioner's arguments relying on Zolman, Patent Owner also relies on the same arguments that Petitioner's annotation of Figure 2 of Zolman is inconsistent with the nomenclature used in Zolman, and that Zolman does not disclose an "interface" or a bone fixation body that abuts the base portion. Prelim. Resp. 26–39. For the same reasons discussed above, we are persuaded that Petitioner has explained sufficiently, for the purposes of this Decision, how Zolman teaches the recited limitations. Pet. 46–59.

Below we discuss Petitioner's arguments based on the combination of Zolman and Bobyn for specific limitations recited in claims 1, 2, 7, and 8.

Claim 1 recites the step of:

> fabricating, separately from the neck body, a bone fixation body that is formed of a porous metal structure without a solid metal substrate but with the porous metal structure that extends throughout 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, has a trapezoidal shape in a cross-sectional view, and has a tapering body with an external bow,

and claim 7 recites:

> making, separately from the neck body, a bone fixation body that is formed of a completely porous metal structure without a solid metal substrate, has a size and a shape that emulate a size and a shape of a porous structure of natural human bone, has a trapezoidal shape in a cross-sectional view, and has a tapering body with an external bow.

Ex. 1001, 6:30–37, 7:4–10.

For these limitations, Petitioner argues that Bobyn discloses a porous tantalum biomaterial with "desirable characteristics for bone ingrowth" having structural and mechanical properties that closely resemble the properties of cancellous (trabecular) bone. Pet. 48 (citing Ex. 1011, 907,

913). According to Petitioner, Bobyn's biomaterial is fabricated by coating a vitreous carbon skeleton with elemental tantalum through a chemical vapor deposition process to form a porous metal structure. *Id.* at 48 (citing Ex. 1011, 907–908; Ex. 1002 ¶ 82). Petitioner adds that Bobyn's biomaterial structure is "75% to 80% porous by volume," has "a repeating arrangement of slender interconnecting struts which form[] a regular array of dodecahedron-shaped pores," and has pore sizes from 430μm to 650 μm. *Id.* at 48–49 (citing Ex. 1011, 907–909). Petitioner reasons that Bobyn's porosity and pore size fall within the preferred ranges taught by the '093 patent for ingrowth of cancellous (trabecular) and cortical bone spicules, and also fall within the known range of pore diameters and porosities of natural cancellous (trabecular) bone. *Id.* at 49 (citing Ex. 1001, 3:55–62; Ex. 1002 ¶ 82 (citing Ex. 1016, 954)).

Petitioner adds that "[i]n light of Bobyn's teachings of the advantages of the porous tantalum material over other conventional porous surfaces and its use in other orthopedic applications," a POSITA would have been motivated to fabricate porous pad 26 of Zolman's implant from Bobyn's porous tantalum biomaterial. Pet. 50 (citing (Ex. 1002 ¶ 82). Petitioner further asserts a POSITA would have had a reasonable expectation of success manufacturing Zolman's implant with Bobyn's porous tantalum biomaterial because: (1) Bobyn states that its material is readily shapeable into any configuration, including the shape of Zolman's pad; (2) Bobyn teaches that tantalum is "a strong, ductile metal" which enables it to bend without breaking; and (3) a POSITA would have known how to manipulate the porous tantalum biomaterial so that it could be bent without breaking the tantalum struts, such as, for example, heating the tantalum material. Pet. 51–

52 (citing Ex. 1011, 907, 913; Ex. 1020, 8:7–11; Ex. 1002 ¶ 82 (citing Ex. 1022, 2)). Petitioner also argues that a POSITA would have shaped Bobyn's porous tantalum biomaterial into a final configuration prior to attachment to an implant substrate, like in Zolman's "mandrel" manufacturing process. Pet. 52 (citing Ex. 1002 ¶82; Ex. 1020, 8:7–11, 9:17; Ex. 1021, 1:11–24, 3:51–55, Fig. 1).

While Patent Owner does not dispute that Bobyn's porous structure emulates the size and the shape of natural bone, Patent Owner asserts that Zolman's method steps of pressing, cutting, and bending the porous metal structure in Bobyn would "destroy the structure of this material when it has a size and shape emulating the size and the shape of natural human bone." Prelim. Resp. 46–47. Patent Owner asserts that the Mane Publication[7], Frank Publication[8], and U.S. Patent No. 9,795,708 ("the '708 patent") show that traditional machining methods destroy the porous structure in Bobyn's material. Prelim. Resp. 46–55. For example, Patent Owner relies on its experts' testimony that cutting Bobyn's material would destroy it and that the Mane Publication teaches Bobyn's material suffers from deformation when cut. Prelim. Resp. 49 (citing Ex. 2012, 22, 28; Ex. 2003, 52–53, Ex. 2008, 44–42). Similarly, Patent Owner asserts that the Frank Publication states a problem with Bobyn's material is that the "surface porosity is often compromised by traditional methods." Prelim. Resp. 51 (citing Ex. 2017, 6).

[7] "An effective method to reduce smearing in machining of metallic foams using ice as an infiltrant," by Vishal Mane, published 2006 (Exhibit 2012, "Mane Publication").

[8] "Rapid Manufacturing in Biomedical Materials: Using Subtractive Rapid Prototyping for Bone Replacement," by Mathew Frank, published Sept. 10, 2008 (Ex. 2017, "Frank Publication").

Additionally, Patent Owner refers to the '708 patent as teaching that if "the Bobyn material is cut using traditional methods of machining, the cut surface smears." Prelim. Resp. 53.

Moreover, Patent Owner asserts that these references contradict Dr. Harrigan's testimony that Bobyn's material could have been "potted" with an infiltrated wax or other substance to reinforce the structure before cutting. Prelim. Resp. 61. Patent Owner contends Dr. Harrigan's testimony is unsupported in this regard and the Mane and Frank Publications state potting Bobyn's material was developed in 2008, five years after the priority date of the '093 patent. *Id.* Separately, Patent Owner also argues that Zolman's method of pressing and bending would crush/smash the rod-like struts and pores of Bobyn's biomaterial. Prelim. Resp. 57–59. Patent Owner further adds that the ductility of Bobyn's material causes deformation. *Id.*

Based on the current record, for the limited purposes of this Decision, Petitioner's position is persuasive. We discern that Petitioner relies on Dr. Harrigan's testimony that

> Bobyn states that its material is readily shapeable into any configuration. Ex. 1011 at 907, 913. As I explained previously, Bobyn teaches that tantalum is "a strong, ductile metal" (Ex. 1011 at 913) which enables it to be bent without breaking. See also Ex. 1022 at 2. In my opinion, a pad constructed from the porous tantalum biomaterial would have sufficient ductility to be fitted onto Zolman's neck body and positioned within recess 74 for attachment to stem portion 20. Moreover, persons having ordinary skill in the art at the time of the purported invention would have known how to manipulate the porous tantalum biomaterial so that it could be sufficiently ductile to bend without breaking the tantalum struts. It was well-known, for example, that heating a metal like tantalum would increase its ductility so that it could be bent about a mandrel or the like to shape the material into a desired shape as disclosed in Zolman. This would

> also be true for the porous tantalum biomaterial of Bobyn.
>
> ***I have been informed that Patent Owner argued that the steps of cutting in Zolman would damage Bobyn's biomaterial by deforming the pores. It is my opinion, however, that a person having ordinary skill in the art at the time of the purported invention would have known how to avoid this issue. It was well-known, for example, to pot porous materials in a polymer (or other materials), cut the porous material, and then dissolve the polymer (or other material) to limit smeared edges. In addition, a person skilled in the art would have known to use non-contact machining tools to avoid smearing the pores.***

Ex. 1002 ¶ 82 (emphasis added). Dr. Harrigan further testifies that

> Bobyn also teaches that its porous tantalum structure "can be made into complex shapes and used either as a bulk implant or as a surface coating." Ex. 1011 at 907; see also id. at 913 ("its structural integrity allows it to be readily formed [into] . . . customised [sic] shapes and sizes of the implant."). Like Zolman, Bobyn teaches the use of its biomaterial as a "fixation surface on an implant substrate" (id. at 913) and "surface coating" (id. at 907). In my opinion, in view of Bobyn's teachings, a person having ordinary skill in the art would have readily appreciated that Bobyn's porous tantalum biomaterial could be shaped into a final configuration prior to attachment to an implant substrate, suitable for use in Zolman's hip implant, using a process similar to Zolman's "mandrel" manufacturing process.

Id.

For the limited purpose of this Decision, we determine that Dr. Harrigan's testimony supports Petitioner's position that a POSITA would have combined Bobyn's biomaterial with Zolman's methods and implant, and, further, would have had a reasonable expectation of success doing so. *See* Pet. 46–59. Thus, at this preliminary stage, we determine Petitioner has provided sufficient evidence to meet the threshold showing required for institution of *inter partes* review. However, we note that the parties will have opportunities to further develop the record, including the opportunity to

cross-examine the declarants (*see, e.g.*, Ex. 1002 ¶ 82) and submit additional briefing regarding disputed issues, particularly as to whether a POSITA would have been able to perform Zolman's methods on Bobyn's material without destroying Bobyn's material. In doing so, we encourage the parties to specifically address Dr. Harrigan's testimony that "[i]t was well-known . . . to pot porous materials in a polymer (or other materials), cut the porous material, and then dissolve the polymer (or other material) to limit smeared edges. In addition, a person skilled in the art would have known to use non-contact machining tools to avoid smearing the pores." *See* Ex. 1002 ¶ 82.

With regard to claims 2 and 8, Petitioner contends that the combination of Zolman and Bobyn teaches that pad 26 can be made to have a size and shape to distribute loads from Zolman's neck body. Pet. 54 (citing Ex. 1002 ¶¶ 89–90); *id.* at 58–59. Petitioner explains that while Bobyn acknowledges its study is not as realistic as a fully functional load-bearing model, Bobyn, nonetheless teaches that its tantalum material has properties that allow elastic deformation and load distribution like cancellous bone. Pet. 54 (citing Ex. 1011, 913; Ex. 1020, 6:61–7:4). Based on the current record, Petitioner's arguments are persuasive.

Accordingly, based on this record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with regard to claims 1–12. For the purposes of this Decision, we determine that Petitioner has also demonstrated a reasonable likelihood that it would prevail on this challenge.

F. Obviousness Challenge Based on Zolman, Bobyn, and Averill

Petitioner also argues that it would have been obvious to form Zolman's distal portion 16 of stem portion 20 to have a circular shape in a cross-sectional view in light of Averill's teachings of stem 12 with a circular

cross-section. Pet. 60. For the same reasons discussed above with respect to Petitioner's challenge based on Zolman, Rostoker, and Averill, Petitioner's position is persuasive for the purposes of this Decision.

III. CONCLUSION

For the above reasons, we determine that the information presented establishes there is a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute an *inter partes* review. 35 U.S.C. § 314(a).

At this preliminary stage, the Board has not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues. The Board's final determination will be based on the record as developed during the *inter partes* review.

IV. ORDER

For the reasons given, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted for claims 1–12 of U.S. Patent No. 9,308,093 B2 on the following asserted grounds:

(1) Claims 1–12 under 35 U.S.C. § 103 as unpatentable over Zolman and Rostoker;

(2) Claims 6 and 12 under 35 U.S.C. § 103 as unpatentable over Zolman, Rostoker, and Averill;

(3) Claims 1–12 under 35 U.S.C. § 103 as unpatentable over Zolman and Bobyn; and

(4) Claims 6 and 12 under 35 U.S.C. § 103 as unpatentable over Zolman, Bobyn, and Averill; and

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

PETITIONER:

Naveen Modi
Young Park
Paromita Chatterjee
PAUL HASTINGS, LLP
naveenmodi@paulhastings.com
youngpark@paulhastings.com
mitachatterjee@paulhastings.com

PATENT OWNER:

Philip S. Lyren
EAGLE IP LIMITED
philip_lyren@yahoo.com