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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 IPR2018-00053
Patent 9,283,080 B1

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

HOSKINS, *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") has filed a Petition (Paper 2, "Pet.") pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1–3, 5, 7, and 9–11 of U.S. Patent No. 9,283,080 B1 ("the '080 patent"). Four Mile Bay, LLC ("Patent Owner") has filed a Preliminary Response (Paper 5, "Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute, on behalf of the Director (37 C.F.R. § 42.4(a)), an *inter partes* review to determine whether claims 1–3, 5, 7, and 9–11 of the '080 patent are unpatentable, as described further below.

II. BACKGROUND

A. Real Parties in Interest and Related Proceedings

Petitioner identifies Zimmer Biomet Holdings, Inc. as the real party in interest for this proceeding. Pet. 1. Patent Owner identifies Four Mile Bay, LLC as the real party in interest for this proceeding. Paper 4, 1. The parties identify one U.S. District Court litigation as related to this proceeding. Pet. 1–2; Paper 4, 1. The parties additionally identify four *inter partes* review proceedings as related to the present proceeding. Pet. 2; Paper 4, 1.

The first related *inter partes* review is IPR2016-00011 ("the '011 IPR"), filed by Petitioner to challenge U.S. Patent No. 8,506,642 B1 ("the '642 patent"). The '011 IPR is related to the present proceeding because the presently challenged '080 patent asserts continuation priority to the filing date of the application that issued as U.S. Patent No. 8,821,582 B1 ("the '582 patent"), which in turn asserts continuation-in-

part priority to the filing date of the application that issued as the '642 patent. *See* Ex. 1001, (63). The '011 IPR ended when the Board issued a decision denying institution of trial. That decision is included in the record of the present proceeding as Exhibit 2010.

The second related *inter partes* review is IPR2016-00012 ("the '012 IPR"), filed by Petitioner to challenge the '582 patent. The '012 IPR resulted in a final written decision of the Board, included in the record of the present proceeding as Exhibit 1008. That decision is currently on appeal to the Federal Circuit. *See* Pet. 2; Paper 4, 1.

The third related *inter partes* review is IPR2018-00051 ("the '051 IPR"), filed by Petitioner on the same day as the present proceeding, to challenge U.S. Patent No. 9,265,612 B1 ("the '612 patent"). The '051 IPR is related to the present proceeding because the '612 patent asserts continuation priority to the filing date of the '642 patent. *See* '051 IPR, Ex. 1001, (63).

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

B. The '080 Patent

The '080 patent discloses several embodiments of a hip implant. *See* Ex. 1001, 1:36–55. Figures 1 and 2 of the '080 patent show a first embodiment, and are reproduced below.

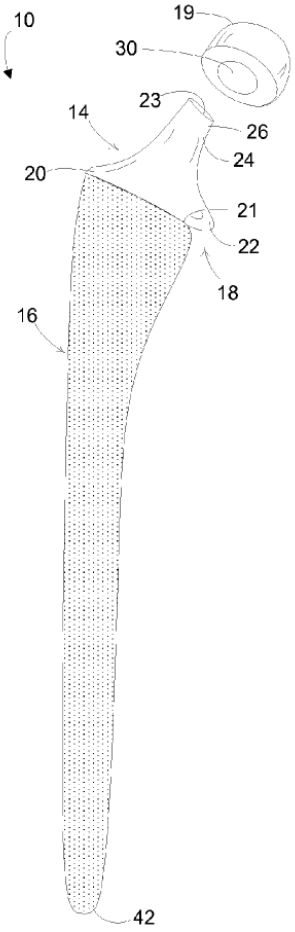


Fig. 1

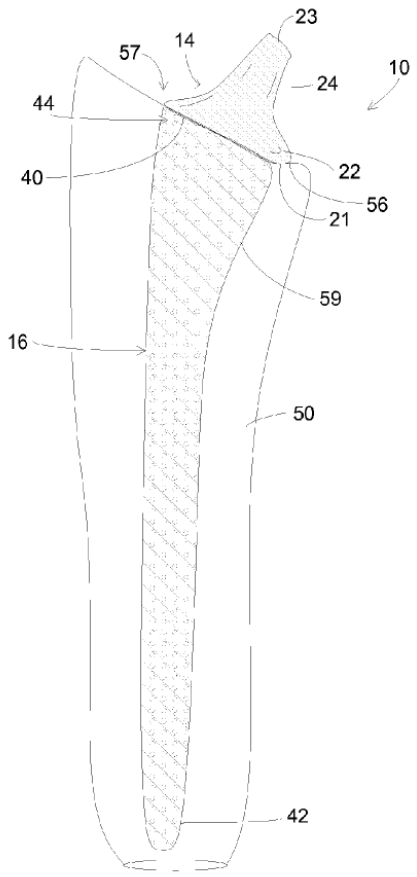


Fig. 2

These Figures illustrate hip implant 10 including two separate and distinct bodies, neck body 14 and bone fixation body 16. *Id.* at 2:18–21, 3:30–36. Figure 2 shows hip implant 10 embedded within femur 50. *Id.* at 1:40–41, 4:1–3.

Neck body 14 functions to connect implant 10 to ball 19 and an acetabular component (not shown), and may be machined from a solid metal such as titanium. *Id.* at 3:37–40, 3:51–53, 4:42–44. As such, neck body 14 has base portion 20 adapted to be connected to bone fixation body 16, and neck portion 24 extending outwardly from base portion 20 to end 26 which is received in ball 19. *Id.* at 3:40–50, 3:57–61.

Bone fixation body 16 resides within femur 50 and is composed of a porous metal structure having a size and shape emulating a size and shape of natural human bone, which is "adapted for the ingrowth of cancellous and cortical bone spicules" of natural human bone from femur 50. *Id.* at 3:62–67, 4:22–33.

Figure 5 of the '080 patent shows another hip implant embodiment, and is reproduced below:

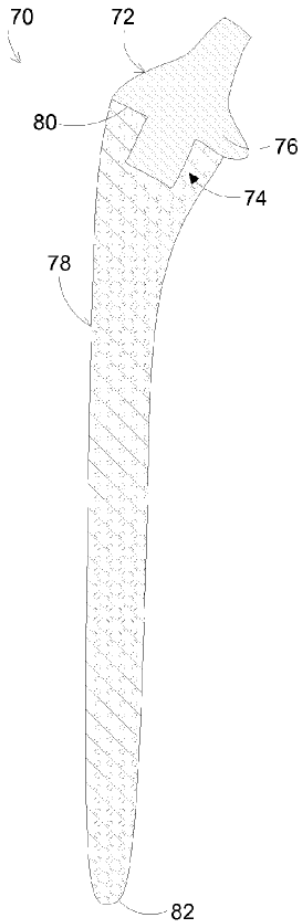


Fig. 5

Figure 5 illustrates hip implant 70 which "is similarly configured to the implant 10" of Figures 1–2. *Id.* at 5:45–47. "As one difference, neck body 72 includes a male protrusion 74 that extends outward from base

portion 76." *Id.* at 5:47–49. Protrusion 74 extends into bone fixation body 78 of implant 70. *Id.* at 5:49–62. The protrusion provides a strong connection and anti-rotational interface between neck body 72 and bone fixation body 78. *Id.* at 6:3–7.

C. The Challenged Claims

The '080 patent contains thirteen claims, but Petitioner challenges only claims 1–3, 5, 7, and 9–11. Claim 1 illustratively recites:

> 1. A method, comprising:
>
> machining a neck body formed of solid metal to include a base portion, to include a neck portion that extends outwardly from the base portion and that has an end with a cylindrical shape that engages a femoral component, and to include an elongated male protrusion that extends outwardly from the base portion and that has a cylindrical shape that tapers;
>
> fabricating, separately from the neck body, a bone fixation body with an elongated tapering body with a bow, with a trapezoidal shape in a horizontal cross-sectional view, with a proximal end including an opening, and with a porous metal structure that extends 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
>
> connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to permanently attach the bone fixation body to the neck body and create a hip implant,
>
> wherein the elongated male protrusion extends into the opening of the bone fixation body, forms a core for the bone fixation body, extends toward a distal end of the hip implant, and includes a section with a non-circle shape in a cross-sectional view of the hip implant in order to provide an anti-rotational interface between the neck body and the bone fixation body,
>
> wherein the porous metal structure of the bone fixation body permanently attaches to an exterior surface of the elongated male

> protrusion to create the hip implant before the hip implant is implanted.

Ex. 1001, 15:39–16:2. Claims 2 and 3 depend from claim 1. *Id.* at 16:3–7.

Claim 5 is an independent claim reciting a method similar to the method of claim 1, with claims 7 and 9 depending therefrom. *Id.* at 16:11–49. Claim 10 is an independent claim reciting a hip implant similar to the hip implant which results from the method of claim 1, with claim 11 depending therefrom. *Id.* at 16:50–17:14.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–3, 5, 7, and 9–11 of the '080 patent under 35 U.S.C. § 103(a) on the following three grounds. *See* Pet. 4–5.

References	Claims Challenged
Zolman[1] and Rostoker[2]	1–3, 5, 7, and 9–11
Zolman, Rostoker, and Averill[3]	1–3, 5, 7, and 9–11
Zolman, Bobyn,[4] and Averill	1–3, 5, 7, and 9–11

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

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

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

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

III. ANALYSIS

A. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if made available in the record.[5] *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Petitioner contends a person having ordinary skill in the art pertaining to the '080 patent ("POSITA") would have "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. 12. The Preliminary Response does not take a position as to the level of ordinary skill in the art.

[5] Neither party has offered objective evidence of nonobviousness at this stage of the proceeding.

We determine on the current record that the level of ordinary skill proposed by Petitioner is consistent with the '080 patent and the asserted prior art. We, therefore, adopt that level in deciding whether to institute trial.

C. Claim Interpretation

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable construction standard); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

1. "porous metal structure" (claims 1, 5, and 10)

Petitioner contends the limitations reciting a "porous metal structure having a size and shape that emulate a size and a shape of a porous structure of natural human bone" in independent claims 1 and 10 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. 13–18. Petitioner similarly contends the limitation of "a porous metal structure . . . with interconnected pores having a geometric structure that replicates a porous structure of natural human bone" in independent claim 5 should be construed to require "replicating a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection

diameter, but does not require replicating the interconnected plates and rods that form trabecular bone." *Id.*

Petitioner asserts '080 patent's Specification is consistent with these proposed constructions 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. 15 (citing Ex. 1001, 4:22–26, 4:30–33). Petitioner adds that the Specification also characterizes the porous structure based on pore diameter, porosity, and intersection diameter. *Id.* at 16 (citing Ex. 1001, 4:26–30).

Patent Owner construes the porous metal structure limitations of claims 1 and 10 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. 3–18. Patent Owner similarly construes the porous metal structure limitation of claim 5 to mean "replicates a porous structure of natural human bone with a shape being straight rods that connect together to form a porous structure." *Id.*

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 shape to have "straight rods that connect together to form a porous structure." In this regard, Patent Owner asserts that Dr. Harrigan (testifying on behalf of

Petitioner) and Dr. Helmus (testifying on behalf of Patent Owner) agree a POSITA would read the porous metal structure described in the '080 patent as being directed to cancellous bone. Prelim. Resp. 12–13 (citing Ex. 1002, 13; Ex. 2003, 65). However, looking to the cited testimony of Dr. Harrigan, 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 '080 patent is directed only to or limited to cancellous bone. Rather, Dr. Harrigan testifies that:

> The '080 patent explains, however, that "[a]though [sic] 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." [Ex. 1001,] 4:32–38.

Ex. 1002 ¶ 16.

Dr. Harrigan's reading of the '080 patent is consistent with the disclosure, which is generally broad and not expressly limiting. For example, as acknowledged by Patent Owner, in column 2, lines 49 through 53, the '080 patent explains that:

> In one example embodiment, the geometric structure of the porous structure of the bone fixation body is shaped and sized to emulate the shape and size of natural bone surrounding the hip implant. The porous structure of the bone fixation body thus replicates the porous structure of natural bone itself.

Ex. 1001, 2:49–53. 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. 6. 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 6–7 (citing Ex. 1001, 2:49–53, 4:23–38).

Further, turning to page 65 of Exhibit 2003 (which is a declaration submitted in the '012 IPR), 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 '080 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 '080 patent, file history of the '080 patent, and the claim language do not expressly define the shape of natural bone, Patent Owner, nonetheless,

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

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 '080 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. *Id.* at 14–15. Patent Owner further contends that Dr. Helmus and Dr. Vincelli provided testimony and supporting publications that the shape of natural bone is straight rods that connect together to form a porous structure. *Id.* at 16 (citing Ex. 2003, 30; Ex. 2008, 24–25).

Based on the current record in the instant proceeding, we are not persuaded that the broadest reasonable construction of the "porous metal structure" limitations in claims 1, 5, and 10 require 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 '080 patent, and file history of the '080 patent do not limit the shape of natural bone to any particular shape or natural bone. *See* Ex. 1001, 2:49–53, 4:22–38; Pet. 13–18; Prelim. Resp. 3–12. Rather, the Specification describes the bone fixation body as adapted for the ingrowth of *both* cancellous (trabecular) *and* cortical bone. Ex. 1001, 4:22–23 ("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.

Id. at 4:22–26.

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 4:27–33. The Specification makes clear that "these ranges could be modified, and the resulting hip implant still within the scope of the invention" (*id.* at 4:33–38); 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 '080 patent) as showing that the Applicant added "porous metal structure" limitations to distinguish the spherical porous structure in the prior art from the claimed shape of the porous structure of natural human bone. Prelim. Resp. 7–12. 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 11. 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. Further, there appears to be no mention of a disavowal, disclaimer, or narrowing of claim scope with regard to “porous metal structure” in the file history of the ’080 patent. *See* Ex. 1007. Thus, based on the present record, we are not persuaded that the claim scope of the “porous metal structure” limitations was clearly narrowed to a particular bone shape during prosecution of the ’080 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, 24–25. 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, 4:22–23. Rather, we construe the “porous metal structure” limitations in claims 1, 5, and 10 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, 5, and 10)

Patent Owner asserts that the broadest reasonable construction of the term “base portion” in claims 1, 5, and 10 is “the larger bottom part of an extension considered as its support.” Prelim. Resp. 28–31. Patent Owner contends that these claims recite three distinct and different features: (1) neck portion; (2) base portion; and (3) male protrusion. *Id.* at 28–29. Further, Patent Owner argues that Figures 1 and 5 of the ’080 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. *Id.* at 29–30. 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 30 (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 '080 patent. However, the '080 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, 3:45–46, 5:47–49. Instead, even assuming that Figure 5 shows the male protrusion extending from the base portion, the '080 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)). This includes fabricating, making, or forming the bone fixation body "separately" from the neck body (*see* Pet. 18; Prelim. Resp. 18–25), and connecting the two bodies "after" such separate fabrication, making, or formation (*see* Pet. 18–19; Prelim. Resp. 25).

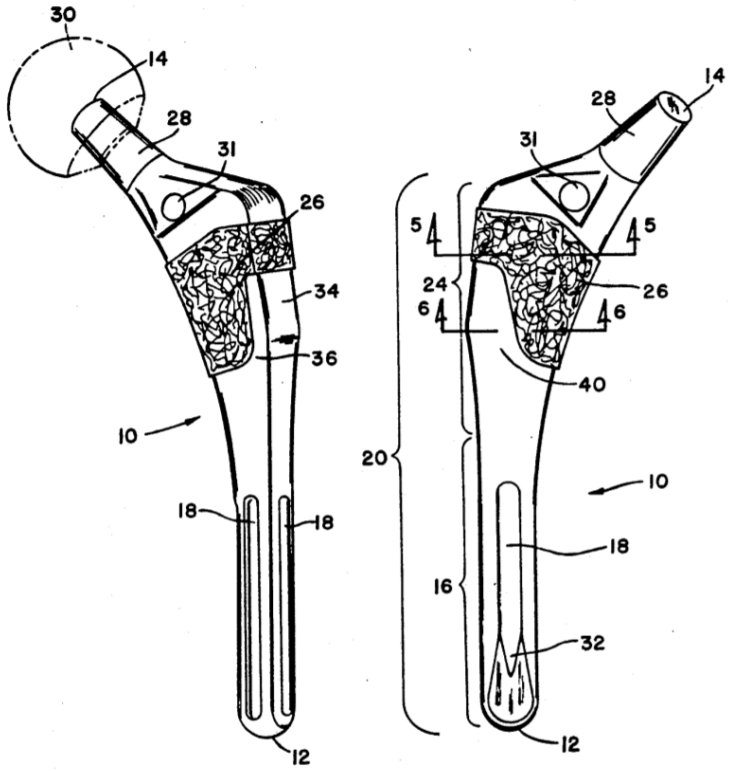
D. Obviousness over Zolman and Rostoker

Petitioner asserts claims 1–3, 5, 7, and 9–11 of the '080 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman and Rostoker. Pet. 4, 23–49. Patent Owner opposes Petitioner's assertions.

We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 1–3, 5, 7, and 9–11. We begin our analysis with brief summaries of the Zolman and Rostoker disclosures, and we then address Petitioner's and Patent Owner's contentions.

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, 3:31–35. 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 4:12–15.

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 2:15–18. 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, 5, and 10

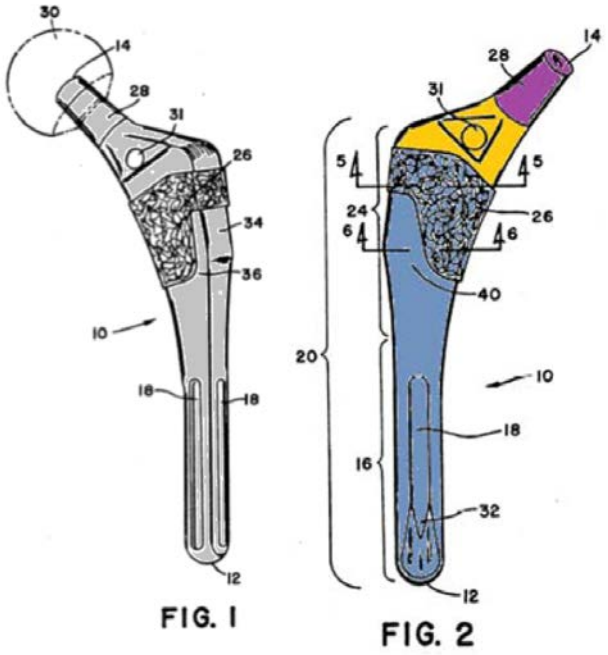
Petitioner provides detailed claim charts, arguments, and evidence, including the Declaration of Dr. Harrigan (Ex. 1002), showing that the combination of Zolman and Rostoker teaches or suggests all the limitations recited in independent claims 1, 5, and 10. Pet. 24–36 (claim 1), 38–43 (claim 5), 45–49 (claim 10). Below we principally discuss claim 1, which is largely representative of the similar subject matter recited in claims 5 and 10.

Claim 1 is directed generally to a method that includes:

> machining a neck body formed of solid metal to include a base portion, to include a neck portion that extends outwardly from the base portion and that has an end with a cylindrical shape that engages a femoral component, and to include an elongated male protrusion that extends outwardly from the base portion and that has a cylindrical shape that tapers.

Ex. 1001, 15:40–46. For this limitation, Petitioner provides annotated versions of Figures 1 and 2 from Zolman (below) that Petitioner asserts

teach a "base portion" in orange, a "neck portion" in purple, and a "male protrusion" in blue. Pet. 24–25, 26.



According to Petitioner, annotated Figures 1 and 2 from Zolman show a neck body that includes neck 28, base portion with aperture 31, and stem portion 20. Pet. 24–26. 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. 25–26 (citing Ex. 1002 ¶ 45).

Petitioner further argues that stem portion 20 has a "non-circular shape that tapers to distal end 12," which does not correspond to the "cylindrical shape that tapers" required by claim 1. *Id.* at 27. Petitioner nonetheless contends it would have been obvious to form Zolman's stem

portion 20 to have a cylindrical shape that tapers, based on Rostoker's disclosure of prosthesis 12 including cylindrically-shaped rod 24 with cylindrical bottom end member 26 that tapers. *Id.* (citing Ex. 1010, Fig. 1, 3:11–20). Petitioner's proposed rationale for such a modification is that it would "facilitate insertion into the intramedullary canal and . . . reduce the stiffness of the implant." *Id.* at 28 (citing Ex. 1002 ¶ 45).

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. 33–34 (citing Ex. 1009, 3:54–57). Relying on Patent Owner's annotated version of Zolman's Figure 2, reproduced below, Patent Owner contends that stem portion 20 in Zolman ends at the bottom of neck 28.

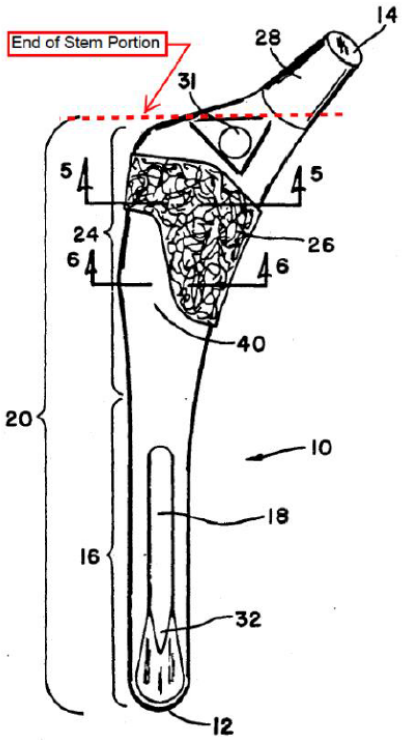


FIG. 2

Id. 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 34–36. Patent Owner adds that Petitioner's annotated figures contradict the disclosure in Zolman because they use "nomenclature" contrary to Zolman. *Id.* at 36–38.

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* Section III.C.2. 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 formed of solid metal to include a base portion, [and] to include 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, a "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." Pet. 25. 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 ¶ 45.

Moreover, Petitioner's contentions concerning the obviousness of modifying Zolman's stem portion 20 to have a cylindrical tapering shape stand unrebutted in the preliminary record presently before us. Therefore, we credit the supporting testimony of Dr. Harrigan in that regard. *See* Ex. 1002 ¶ 45 (pgs. 33–34).

Claim 1 further recites the step of:

> fabricating, separately from the neck body, a bone fixation body with an elongated tapering body with a bow, with a trapezoidal shape in a horizontal cross-sectional view, with a proximal end including an opening, and with a porous metal structure that extends 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.

Ex. 1001, 15:47–54. Petitioner argues that Zolman's disclosure of porous pad 26 teaches these limitations. Pet. 28–35. 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. 28–29 (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. *Id.* at 29, 32 (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." *Id.* at 32–34 (citing Ex. 1010, 2:40–44, 5:6–8, 5:14–18, 5:21–24; Ex. 1001, 4:27–33; Ex. 1002 ¶ 49 (citing Ex. 1016, 954)). With regard to the "bow" limitation, Petitioner asserts that "*Zolman* teaches that the final shape of the pad [26] is an elongated tapering body . . . with a bow, *i.e.*, with at least one side having a curvature." *Id.* at 29 (citing Ex. 1009, 5:5–11, Figs. 1–4; Ex. 1001, 5:14–15, Fig. 1; Ex. 1002 ¶ 46). With regard to the "trapezoidal shape" limitation, 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. *Id.* at 30–31 (citing Ex. 1009, Figs. 2, 5).

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. 38–45. 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 human bone, because natural human bone has a structure of trabeculae formed of rods and plates that are quite different from the structure of bonded S-shaped wires of Rostoker." *Id.* at 39–42 (citing Ex. 2008, 22–27, and quoting Ex. 2008, 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[.]" *Id.* at 42–45 (citing Ex. 2003, 30–33, and quoting Ex. 2003, 32).

Based on the current record, Petitioner's position is persuasive. As discussed above, our construction of the "porous metal structure" limitations as requiring "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 ¶ 49. Further, Rostoker discloses values for pore size and porosity within the preferred ranges taught by the '080 patent for ingrowth of cancellous and cortical bone spicules. *See* Pet. 33–34 (Rostoker discloses "'[t]he largest principal dimensions of pores' . . . can be 0.013 cm (130 μm) or 0.03 cm (300 μm)"); Ex. 1002 ¶ 49; 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, 4:27–33 (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:

> connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to permanently attach the bone fixation body to the neck body and create a hip implant,
>
> wherein the elongated male protrusion extends into the opening of the bone fixation body, forms a core for the bone fixation body, extends toward a distal end of the hip implant, and includes a section with a non-circle shape in a cross-sectional view of the hip implant in order to provide an anti-rotational interface between the neck body and the bone fixation body.

Ex. 1001, 15:55–65. For these limitations, Petitioner asserts that Zolman's porous pad 26 and neck body are permanently connected to each other when porous pad 26 is bonded within recess 74 of stem portion 20. Pet. 35 (citing Ex. 1009, 6:46–54, 7:10–14). Petitioner argues that porous pad 26 "completely encircles proximal portion 24 of stem portion 20," and that "stem portion 20 extends into the opening in pad 26, forms a core for pad 26, and extends through the pad toward a distal end 12 of the implant." *Id.* at 35–36 (citing Ex. 1009, Figs. 1–5, 3:53–56, 4:41–45). Further, Petitioner contends that the cross-sectional shape of porous pad 26 matches the "asymmetric noncircular cross-section" of proximal portion 24 (Ex. 1009,

5:19–21), such that the angles of proximal portion 24 would prevent porous pad 26 from rotating relative to stem portion 20. *Id.* at 36 (citing Ex. 1009, 5:13–16, 5:19–21, 6:44–46; Ex. 1002 § 52).

Patent Owner does not, in the Preliminary Response, address Petitioner's contentions concerning how Zolman discloses a permanent connection between porous pad 26 and stem portion 20 with an elongated protrusion and a non-circle shaped, anti-rotational interface.

Based on the preliminary record, Petitioner's position is persuasive. 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 and form a core for the porous pad (i.e., bone fixation body). *See* Ex. 1009, 4:8–14, 5:12–21. We also note that Dr. Harrigan's testimony at paragraph 52 further supports Petitioner's position that the angles of the shape of stem portion 20 would prevent porous pad 26 from rotating. Ex. 1002 ¶ 52.

Claims 5 and 10 recite a "polygonal shape" anti-rotational interface between the neck body and the bone fixation body, where claim 1 recites a "non-circular" interface. *See* Ex. 1001, 15:62–65, 16:35–37, 17:8–10. On the present preliminary record, we are persuaded by Dr. Harrigan's unrebutted testimony that a person of ordinary skill in the art would understand the Zolman interface to be polygonal as well as non-circular, based on the angles of the shape of stem portion 20 where it receives porous pad 26. *See* Pet. 42 (citing Ex. 1002 ¶ 67), 49 (citing Ex. 1002 ¶ 81).

Finally, claim 1 concludes by reciting:

> wherein the porous metal structure of the bone fixation body permanently attaches to an exterior surface of the elongated male protrusion to create the hip implant before the hip implant is implanted.

Ex. 1001, 15:66–16:2. For this limitation, Petitioner asserts Zolman discloses placing porous pad 26 in recess 74 in an exterior surface of stem portion 20, and permanently bonding those structures. Pet. 36 (citing Ex. 1009, 6:44–54). Patent Owner does not, in the Preliminary Response, address that contention. Based on the current record, Petitioner's position is persuasive.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 1, 5, and 10 of the '080 patent would have been obvious over the combination of Zolman and Rostoker.

4. Claims 2, 3, 7, 9, and 11

Claim 2 depends from claim 1 to add that "the bone fixation body induces bone to grow partially into the bone fixation body," and claim 3 depends from claim 1 to add that "the bone fixation body induces bone to grow entirely throughout the bone fixation body." Ex. 1001, 16:3–7. Petitioner asserts Rostoker's porous material satisfies both limitations, given Rostoker's disclosure that its structure has "completely interconnected" fibers, such that bone growth can "penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." Pet. 37 (citing Ex. 1010, 2:40–44, 3:28–34, 5:16–18; Ex. 1002 ¶¶ 54–55).

Based on the current record, Petitioner's arguments in this regard are unrebutted and persuasive, based on the cited disclosures in Rostoker.

Claim 7 depends from claim 5 to add that "the bone fixation body bonds to the neck body after the bone fixation body is made separately from the neck body." Ex. 1001, 16:41–43. Petitioner asserts Zolman correspondingly discloses that porous pad 26 is permanently bonded to Zolman's neck body after those components are made separately, substantially as already described above in connection with the independent claims. Pet. 43. For the reasons provided above, based on the current record, Petitioner's arguments in this regard are persuasive.

Claim 9 depends from claim 5 to add that "the base portion includes a proximal end surface, and the bone fixation body attaches to the proximal end surface." Ex. 1001, 16:47–49. Petitioner, without conceding that claim 9 is valid under 35 U.S.C. § 112, alleges Patent Owner "has asserted in the related litigation that the claimed 'proximal end surface' is the surface of the base portion from which a protrusion extends." Pet. 44. Applying that construction, Petitioner asserts Zolman's implant includes such a proximal end surface via a distally facing "upper lip" forming recess 74 in stem portion 20 which receives porous pad 26. *Id.* (citing Ex. 1009, 3:51–56, 5:13–16, Figs. 1–6, 14, and 15; Ex. 1002 ¶ 71). Petitioner additionally contends "[p]orous pad 26 attaches to this surface when the pad 26 is received within and secured to recess 74." *Id.* (citing Ex. 1009, 5:13–16, 6:44–48, Figs. 1–4; Ex. 1002 ¶¶ 70–71). Based on the current record, Petitioner's arguments in this regard are unrebutted and persuasive, based on the cited disclosures in Zolman.

Claim 11 depends from claim 10 to add that "the bone fixation body is heated to permanently bond the bone fixation body to the neck body after the bone fixation body is separately made from the neck body." Ex. 1001, 17:11–14. Petitioner asserts that Zolman correspondingly discloses a "diffusion bonding" between porous pad 26 and stem portion 20 of the neck body, and cites Dr. Harrigan's testimony that "[d]iffusion bonding applies high pressure in conjunction with high temperatures to weld the components together." Pet. 49 (citing Ex. 1009, 6:48–54; Ex. 1002 ¶ 83; Ex. 1017, 3:48–59, 4:28–40). Based on the current record, Petitioner's arguments in this regard are unrebutted and persuasive, based on the cited disclosure in Zolman and Dr. Harrigan's testimony.

Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 2, 3, 7, 9, and 11 of the '080 patent would have been obvious over the combination of Zolman and Rostoker.

E. Obviousness over Zolman, Rostoker, and Averill

Petitioner asserts claims 1–3, 5, 7, and 9–11 of the '080 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman, Rostoker, and Averill. Pet. 4, 50–51. Patent Owner opposes Petitioner's assertions.

We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 1–3, 5, 7, and 9–11. We begin our analysis with a brief summary of the Averill disclosure, and we then address Petitioner's and Patent Owner's contentions.

1. Averill

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.

2. Claims 1, 5, and 10

Independent claims 1, 5, and 10 each recite an "elongated male protrusion" having "a cylindrical shape that tapers." Ex. 1001, 15:44–46, 16:15–17, 17:5–6. Petitioner asserts that, if the Board finds Zolman and Rostoker fail to disclose that limitation as set forth in Petitioner's first proposed unpatentability ground, then alternatively "it would have been obvious to form the distal stem portion of the hip implant of Zolman and Rostoker to have a cylindrical shape that tapers in light of Averill's disclosure." Pet. 50 (citing Ex. 1002 ¶¶ 84–85).

Petitioner argues that Averill discloses a prosthesis 10 including stem 12 having a "free end" that "tapers down from the cylindrical portion 26 to a generally spherical tip portion 19." *Id.* (citing Ex. 1012, 5:21–29, Figs. 1–2). Petitioner further reasons a POSITA would have appreciated that fabricating the distal portion of Zolman's stem portion 20 to have a cylindrical that tapers would have been an obvious design choice,

and, alternatively that POSITA would have been motivated to fabricate the stem of Zolman and Rostoker to have this shape to facilitate insertion into the intramedullary canal. *Id.* at 50–51 (citing Ex. 1002 ¶¶ 86–87).

Based on the current record, Petitioner's position is persuasive. In particular, we note that Averill discloses in Figures 1 and 3, reproduced below, a stem 12 having cylindrical portion 26:

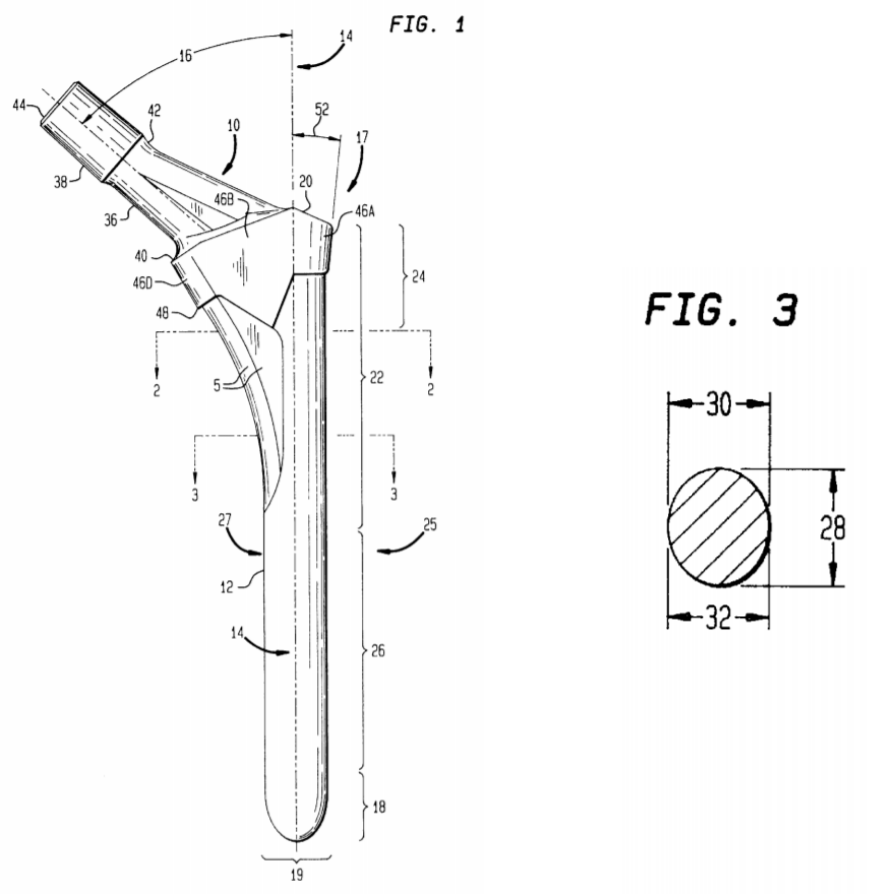


Figure 1 is an anterior elevational view of a hip implant prosthesis, and Figure 3 is a cross-sectional view taken along line 3—3 of Figure 1. Ex. 1012, 3:52–53; 3:56–57. Figure 1 further shows distal end 18 of cylindrical portion 26 tapers down to form spherical tip portion 19. *Id.* at 5:26–29. Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this

challenge that claims 1, 5, and 10 of the ’080 patent would have been obvious over the combination of Zolman, Rostoker, and Averill.

3. Claims 2, 3, 7, 9, and 11

Petitioner relies on its analysis and evidence concerning Zolman and Rostoker from its first proposed unpatentability ground in asserting dependent claims 2, 3, 7, 9, and 11 are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman, Rostoker, and Averill. Pet. 50–51 (not separately addressing dependent claims in connection with Averill). For the reasons provided above, based on the current record, Petitioner’s arguments in this regard 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, 3, 7, 9, and 11 of the ’080 patent would have been obvious over the combination of Zolman, Rostoker, and Averill.

F. Obviousness over Zolman, Bobyn, and Averill

Petitioner asserts claims 1–3, 5, 7, and 9–11 of the ’080 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Zolman, Bobyn, and Averill. Pet. 4–5, 51–69. Patent Owner opposes Petitioner’s assertions.

We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 1–3, 5, 7, and 9–11. We begin our analysis with a brief summary of the Bobyn disclosure, and we then address Petitioner’s and Patent Owner’s contentions.

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 characterise 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 characterisation 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 had 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 standardisation 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." *Id.* Bobyn explains that because of the tantalum biomaterial's high porosity, its structural stiffness 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 customised shapes and sizes of the implant." *Id.* Bobyn concludes that its tantalum biomaterial "offers interesting potential for orthopaedic reconstructive procedures and that further studies are warranted." *Id.*

2. Claims 1, 5, and 10

Petitioner provides detailed claim charts, arguments, and evidence, including the Declaration of Dr. Harrigan (Ex. 1002), showing that the

combination of Zolman, Bobyn, and Averill teaches or suggests all the limitations recited in independent claims 1, 5, and 10. Pet. 52–60 (claim 1), 61–65 (claim 5), 65–68 (claim 10). Below we discuss claim 1, which is representative of the similar subject matter recited in claims 5 and 10.

Petitioner asserts that Zolman primarily teaches all of the recited limitations of the challenged independent claims, except for those directed to the porous metal structure, substantially as described above in connection with the first proposed unpatentability ground. Pet. 52–60. Petitioner relies on Averill as disclosing a stem portion having a cylindrical shape that tapers, if that structure is found not to be present in Zolman, substantially as described above in connection with the second proposed unpatentability ground. *Id.* at 52–53.

With respect to Petitioner's reliance on Zolman, Patent Owner also relies on the same arguments considered above in connection with the first proposed unpatentability ground. Prelim. Resp. 31–38. 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. 52–53, 59–60.

Claims 1 and 10 recite a bone fixation body being fabricated or formed separately from the neck body, with the bone fixation body having:

> a porous metal structure . . . 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.

Ex. 1001, 15:47–54, 16:57–64. Claim 5 recites a bone fixation body being made separately from the neck body, with the bone fixation body having:

> a porous metal structure that extends throughout the bone fixation body with interconnected pores having a geometric structure that replicates a porous structure of natural human bone.

Id. at 16:18–24.

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. 54 (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.* (citing Ex. 1011, 907–908; Ex. 1002 ¶ 94). 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 430 μm to 650 μm. *Id.* (citing Ex. 1011, 907–909). Petitioner reasons that Bobyn's porosity and pore size fall within the preferred ranges taught by the '080 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 54–55 (citing Ex. 1001, 4:27–30; Ex. 1002 ¶ 94 (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. *Id.* at 55–56 (citing Ex. 1002 ¶ 94). 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, by heating the tantalum material. *Id.* at 56–57 (citing Ex. 1011, 907, 913; Ex. 1020, 8:7–11; Ex. 1002 ¶ 94 (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. *Id.* at 58 (citing Ex. 1002 ¶ 94; 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 this claimed structure." Prelim. Resp. 45–59. Patent Owner asserts that the Mane Publication (Ex. 2012[7]), Frank Publication (Ex. 2017[8]), and U.S. Patent No. 9,795,708 ("the '708 patent," Ex. 2018) show that traditional machining methods destroy the porous structure in Bobyn's material. Prelim. Resp. 47–55. For example, Patent Owner relies on its experts' testimony that cutting Bobyn's material would destroy it and that the Mane

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

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

Publication teaches Bobyn's material suffers from deformation when cut. *Id.* at 48–50 (citing Ex. 2012, 22, 28; Ex. 2003, 52–53; Ex. 2008, 41–42). 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." *Id.* at 51–53 (citing Ex. 2017, 6–7, 9). 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." *Id.* at 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. *Id.* at 60–62. 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 '080 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. *Id.* at 55–59. Patent Owner further adds that the ductility of Bobyn's material causes deformation. *Id.* at 59–60.

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. 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 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 ¶ 94 (pgs. 75–76) (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." *See* 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. (pgs. 76–77).

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. 52–60. 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 ¶ 94) 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 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 ¶ 94 (pg. 76).

Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 1, 5, and 10 of the '080 patent would have been obvious over the combination of Zolman, Bobyn, and Averill.

3. Claims 2, 3, 7, 9, and 11

Concerning claims 2 and 3, Petitioner asserts Bobyn's tantalum biomaterial satisfies both limitations, given Bobyn's disclosure that its

material has "an unusually high and interconnecting porosity with a very regular pore shape and size" (Ex. 1011, 907) providing quicker bone in-growth rates than conventional porous metals. Pet. 60–61 (citing Ex. 1011, 907, 911, 912; Ex. 1002 ¶¶ 99–102). Based on the current record, Petitioner's arguments in this regard are unrebutted and persuasive, based on the cited disclosures in Bobyn and Dr. Harrigan's testimony.

Concerning claim 7, Petitioner asserts Zolman correspondingly discloses that porous pad 26 is permanently bonded to Zolman's neck body after those components are made separately, substantially as already described above in connection with Petitioner's first proposed unpatentability ground for the independent claims. Pet. 65. For the reasons provided above, based on the current record, Petitioner's arguments in this regard are persuasive.

Concerning claim 9, Petitioner asserts Zolman correspondingly discloses that porous pad 26 attaches to a proximal end surface of Zolman's neck body, substantially as already described above in connection with Petitioner's first proposed unpatentability ground for claim 9. Pet. 65. For the reasons provided above, based on the current record, Petitioner's arguments in this regard are persuasive.

Concerning claim 11, Petitioner asserts that Zolman correspondingly discloses a "diffusion bonding" between porous pad 26 and stem portion 20 of the neck body, which Dr. Harrigan testifies would involve applying heat, substantially as already described above in connection with Petitioner's first proposed unpatentability ground for claim 11. Pet. 68–69 (citing Ex. 1002 ¶¶ 127–128). Based on the current record, Petitioner's arguments in this

regard are persuasive, based on the cited disclosure in Zolman and Dr. Harrigan's testimony.

Accordingly, based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this challenge that claims 2, 3, 7, 9, and 11 of the '080 patent would have been obvious over the combination of Zolman, Bobyn, and Averill.

IV. 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.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted for claims 1–3, 5, 7, and 9–11 of the '080 patent on the following asserted grounds:

(1) Claims 1–3, 5, 7, and 9–11 under 35 U.S.C. § 103 as unpatentable over Zolman and Rostoker;

(2) Claims 1–3, 5, 7, and 9–11 under 35 U.S.C. § 103 as unpatentable over Zolman, Rostoker, and Averill; and

(3) Claims 1–3, 5, 7, and 9–11 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.

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