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Filed on behalf of: Zimmer Biomet Holdings, Inc.

By: Naveen Modi (Zimmer-FMB-IPR@paulhastings.com)
Srikala P. Atluri (Zimmer-FMB-IPR@paulhastings.com)
Paromita Chatterjee (Zimmer-FMB-IPR@paulhastings.com)
Paul Hastings LLP

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

U.S. Patent No. 8,821,582

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,821,582

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1007	J.D. Bobyn, "Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial," The Journal of Bone and Joint Surgery (Sept. 5, 1999).
1008	Excerpt from Webster's Third New International Dictionary (2002)
1009	M. Martens et al. "The Mechanical Characteristics of Cancellous Bone at the Upper Femoral Region," J. Biomechanics, Vol. 16, No. 12, pp. 971-983 (1983).
1010	Prosecution History of U.S. Application No. 13/592,349
1011	U.S. Patent No. 4,570,271 to Sump ("*Sump*")
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I. INTRODUCTION

Zimmer Biomet Holdings, Inc. ("Petitioner") requests *inter partes* review of claims 1-5, 7-11, 13-15, and 17-20 of U.S. Patent No. 8,821,582 ("the '582 patent") (Ex. 1001), which is assigned to Four Mile Bay, LLC ("Patent Owner"). The '582 patent broadly claims known methods of manufacturing hip implants with a "neck body" and a "bone fixation body" having a "porous metal structure." Ex. 1001 at 15:51-18:20. The '582 patent discloses that the porous metal structure can be fabricated using well-known materials and techniques. *Id.* at 4:29-31. While the claims recite that the porous metal structure of the bone fixation body "ha[s] a size and a shape that emulate a size and a shape of a porous structure of natural human bone" (claims 1 and 14) and has "interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone" (claim 8), these features were also well-known at the time of the alleged invention. Indeed, during prosecution of a parent application, the Examiner rejected the Applicant's contentions that these features were patentable over the prior art. *See* Section V.B.1. Applicant ultimately obtained the '582 patent by amending the claims to recite, among other things, that "the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view." *See* Section V.B.2. However, as discussed in more detail below, a bone fixation body having a porous metal structure and a trapezoidal cross-sectional shape were well-

known long before the earliest filing date of the ’582 patent.

This petition shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims, and thus a trial should be instituted. This petition also establishes by a preponderance of the evidence that claims 1-5, 7-11, 13-15, and 17-20 of the ’582 patent are unpatentable under 35 U.S.C. § 103(a). Accordingly, a trial should be instituted and these claims should be canceled.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

Real Party-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Zimmer Biomet Holdings, Inc., as the real party-in-interest.

Related Matters: Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matter. The ’582 patent and a related patent, U.S. Patent No. 8,506,642 (“the ’642 patent”), are involved in *Four Mile Bay LLC v. Zimmer Holdings, Inc.*, No. 3:15-cv-00063 (N.D. Ind.) (PPS)-(CAN). Petitioner is concurrently filing a petition for *inter partes* review of the ’642 patent challenging claims 1-4.

Counsel and Service Information: Lead counsel is Naveen Modi (Reg. No. 46,224). Srikala P. Atluri (*pro hac vice* admission to be requested) and Paromita Chatterjee (Reg. No. 63,721) are back-up counsel. The mailing address for all correspondence is Paul Hastings LLP, 875 15th St. N.W., Washington, D.C.,

20005 (Telephone: 202.551.1700/Fax: 202.551.1705). Petitioner consents to electronic service of documents at Zimmer-FMB-IPR@paulhastings.com.

III. PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15 AND 42.103

Petitioner submits the required fees with this petition. Please charge any additional fees required for this proceeding to Deposit Account No. 50-2613.

IV. GROUNDS FOR STANDING AND IDENTIFICATION OF CHALLENGE

Claims 1-5, 7-11, 13-15, and 17-20 of the '582 patent are unpatentable in view of the following prior art references and grounds: U.S. Patent No. 5,018,285 to Zolman et al. ("*Zolman*") (Ex. 1005); U.S. Patent No. 3,906,550 to Rostoker et al. ("*Rostoker*") (Ex. 1006); J.D. Bobyn et al., "Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial," J. of Bone and Joint Surgery, Vol. 81-B, No. 5 (Sept. 1999) ("*Bobyn*") (Ex. 1007); U.S. Patent No. 4,570,271 to Sump ("*Sump*"); and U.S. Patent No. 5,863,295 to Averill et al. ("*Averill*"). *Zolman* issued on May 28, 1991, *Rostoker* issued on September 23, 1975, *Bobyn* was published in September 1999, *Sump* issued on February 18, 1986, and *Averill* issued on January 26, 1999. These references are all prior art under 35 U.S.C. § 102(b).

Claims 1-5, 7-11, 13-15, and 17-20 of the '582 patent should be cancelled in view of the following grounds: Claims 1-5, 8-11, 14, 15, and 17-20 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman* and *Rostoker*

(Ground 1); Claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Rostoker*, and *Sump* (Ground 2); Claim 20 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Rostoker*, and *Averill* (Ground 3); Claims 1-5, 8-11, 13-15, and 17-20 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman* and *Bobyn* (Ground 4); Claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Bobyn*, and *Sump* (Ground 5); Claim 20 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Bobyn*, and *Averill* (Ground 6). Petitioner certifies that the '582 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '582 patent on the grounds identified.

V. BACKGROUND

The '582 patent issued from U.S. Patent Application No. 13/592,349 ("the '582 patent application"), filed August 23, 2012, which purports to be continuation-in-part of U.S. Patent Application No. 11/409,611 ("the '642 patent application"), filed April 24, 2006, now the '642 patent, which purports to be a continuation of U.S. Patent Application No. 10/446,069, filed May 27, 2003, now abandoned. Ex. 1001 at title page.

A. The '582 Patent

The '582 patent relates to hip implants, as shown in the embodiments of Figures 1 and 2. *See e.g.*, Ex. 1001 at Title, Abstract, 3:41-42. The disclosed hip

implant 10 includes two components or bodies: a neck body 14 and a bone fixation body 16. *See e.g.*, *id.* at Abstract, 3:29-32, 3:45-47, Figs. 1-2. Figure 2 shows hip implant 10 embedded in an intramedullary canal 52 of a femur 50 of a patient:

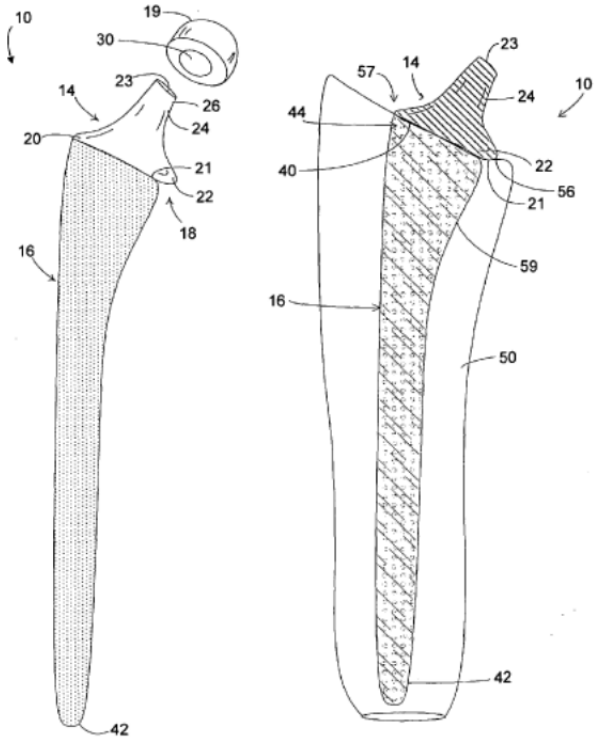

Fig. 1 **Fig. 2**

See also id. at 4:12-14; Ex. 1002, ¶ 12.

Neck body 14 can be formed from a solid metal piece of titanium, titanium alloy, or other metals or alloys. Ex. 1001 at 3:62-64. As shown above, a collar 22 of neck body 14 is configured to seat against a resected end 56 of the femur about an entrance 57 to intramedullary canal 52. *Id.* at 4:16-18. Neck body 14 extends outwardly from the resected end of the intramedullary canal 52 and includes a base portion 20 with a neck portion 24 that is configured to connect hip implant 10 to a

femoral ball 19, which is received by an acetabular component (not shown). *Id.* at 3:48-51, 3:56-57, 4:16-23. A distal end surface 21 of neck body 14 connects or fuses to a proximal end surface 40 of bone fixation body 16 at a junction 44. *Id.* at 4:3-5; *see also* Ex. 1002, ¶ 13.

The specification includes an embodiment (shown in Figure 5 below) in which a protrusion 74 extends from the distal end surface of the neck body into the bone fixation body. Ex. 1001 at 5:57-59. Protrusion 74 can have any shape such as, for example, "cylindrical or polygonal, such as rectangular or square." *See id.* at 6:6-9. Protrusion 74 can partially extend into the bone fixation body or protrusion 74 can extend farther toward the distal end surface 82 of the bone fixation body. *Id.* at 5:66–6:3. In the latter embodiment, "[t]he protrusion gradually tapers as it extends toward the distal end surface." *Id.* at 6:3-5. According to the '582 patent, "the protrusion can be sized and shaped to provide a strong connection between the neck body and bone fixation body" and "provide an anti-rotational interface between the neck body and bone fixation body." *Id.* at 6:13-17; *see also* Ex. 1002, ¶ 14.

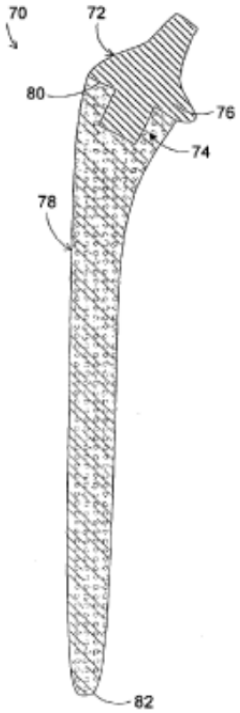

Fig. 5

As shown in the figures above, bone fixation body 16 has an elongated tapering shape that extends from proximal end surface 40 to a rounded distal end

surface 42 or 82. Ex. 1001 at 4:1-3, 6:1-3, Figs. 1, 5. The elongated tapering shape of bone fixation body 16 also has "a slight bow." *Id.* at 5:24-25, Figs. 1-5. The specification also states that "[t]he bone fixation body . . . may have other configurations and still be within the scope of the invention." *Id.* at 5:25-27. In certain embodiments, the specification describes the bone fixation body as having "a trapezoidal cross-sectional shape." *See id.* at 6:45-46, Fig. 7; Ex. 1002, ¶ 15.

Bone fixation body 16 is formed of a porous metal such as, for example, titanium, and "has a completely porous structure that extends throughout the entire body from the proximal surface 40 to distal end surface 42." Ex. 1001 at 4:6-10. "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." *Id.* at 4:26-28. Further, the specification explains that "body 16 does not include a solid metal substrate." *Id.* at 4:11; Ex. 1002, ¶ 16.

The specification broadly describes the porous structure as being "adapted for the ingrowth of cancellous and critical bone spicules" and having a size and shape that "emulates the size and shape of the porous structure of natural bone." Ex. 1001 at 4:32-36. In certain disclosed embodiments, "the average pore diameter of body 16 is about 40 μm to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than

50-60 microns."[1] *Id.* at 4:37-40. The specification 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." *Id.* at 4:43-46; Ex. 1002, ¶ 17.

The '582 patent discloses that the porous structure can be fabricated using well-known materials and techniques such as "sintering titanium, titanium alloy powder, metal beads, metal wire mesh, or other suitable materials, metals, or alloys known in the art." Ex. 1001 at 4:29-31. The '582 patent does not disclose any processes, materials, or material characteristics for achieving a porous structure that "emulates a size and shape of the porous structure of natural bone." *See id.* at 4:33-36. The '582 patent discloses that the neck body can also be formed using well-known machining techniques. *See id.* at 4:52-54. In certain disclosed embodiments, these bodies are fabricated independently and subsequently connected or fused together. *See id.* at 5:14-16, 5:19-23. Figures 15A-15B, added as part of the '582 patent application, show exemplary cross-sections of the interface or junction where the porous structure of the bone fixation body connects to the neck body. *Id.* at 12:3-12, Figs. 15A-15B. In Figure 15A "[t]he neck body

[1] The disclosed ranges overlap with known pore diameters and porosities of cancellous bone. Ex. 1002 at ¶ 18 (citing Ex. 1013).

610 has a trapezoidal shape" and in Figure 15B "[t]he bone fixation body 620 has a trapezoidal shape." *Id.* at 12:7, 12:11-12; Ex. 1002, ¶ 18.

The '582 patent includes 20 claims, of which claims 1, 8, and 14 are independent. *See* Ex. 1001 at 15:51–18:20. Independent claims 1, 8, and 14 are all directed to a method and recite, among other things, a "bone fixation body" having "a porous metal structure" with "a size and a shape that emulate a size and a shape of a porous structure of natural human bone" (claims 1 and 14) or "interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone" (claim 8). *Id.*

B. Prosecution History of the '642 Patent and the '582 Patent

1. The '642 Patent Prosecution

Applicant filed the '642 patent application, which matured into the '642 patent (a parent to the '582 patent) with three broad independent claims such as claim 21, reciting "a bone fixation body having a porous structure that continuously extends, in a cross-sectional view of the bone fixation body, through the bone fixation body." Ex. 1004 at 274-79 (including similarly broad independent claims 28 and 34).

The Examiner rejected the independent claims and their dependent claims over numerous anticipatory references including U.S. Patent No. 5,552,894 (referred to as *Draenert II*). *Id.* at 219-26. In order to distinguish *Draenert II*,

Applicant amended independent claim 21 to recite, among other things, that the porous structure of the bone fixation body "has a size and a shape that emulate a size and a shape of a porous structure of natural human bone." *See id.* at 196-207 (including similar changes to claims 28 and 34). Applicant argued that "[t]he spherical structure taught in Draenert II does not have a size and a shape that emulate a size and a shape of a porous structure of natural human bone" (*id.* at 204) and submitted a declaration under 37 C.F.R. 1.132 (*id*. at 194-5) in support of this statement. In response, the Examiner found the declaration insufficient and sustained the rejection stating that "[t]he porous structure disclosed in [the prior art] is intended to behave like or imitate the behavior of bone by providing pores of a certain size and shape to provide bone ingrowth." *Id.* at 182-83. On appeal, the Examiner maintained his positions and stated the following:

> It is [] noted that the porous structure is being claimed in a functional language recitation rather than a positive recitation setting forth the specific structural features of the porous structure. The porous structure disclosed in Draenert II is intended to behave like or imitate the behavior of bone by providing pores of a certain size and shape to provide bone ingrowth. While the structure of the instant Applicant [sic] may more closely 'emulate' or 'replicate' the size and shape of the porous structure of natural human bone, Draenert II attempts to emulate and replicate a size and a shape of a porous structure of

natural human bone.

Id. at 105.

Applicant conceded to this understanding of a porous structure and subsequently dismissed the appeal by filing a Request for Continued Examination (RCE). *Id.* at 53-54. Rather than further addressing the porous structure, the applicant included amendments detailing that the bone fixation body has "a trapezoidal shape in a horizontal cross-sectional view." *Id*. 55-64; *see also id.* at 34-46 (Supplemental Amendment and Response). Following an Applicant-initiated Examiner interview, the Examiner issued a notice of allowability cancelling all but four claims, and amending each remaining independent claim (now claims 1-3) to recite, among other things, "a trapezoidal cross-sectional shape." *Id.* at 16-20.

2. The '582 Patent Prosecution

During prosecution of the '642 patent application, applicant also filed the '582 patent application, which matured into the '582 patent, with three independent claims directed to a method broadly reciting, among other things, forming a bone fixation body with a porous metal structure that "emulate[s]" the features of "natural human bone." Ex. 1010 at 54-58. The Examiner issued prior art rejections on all of the claims. *Id*. at 34-44. But, in a summary of an Applicant-initiated interview, the Examiner agreed that "adding that the bone fixation body is permanently attached to the neck body, the male protrusion extends to the distal

end of the body and the horizontal cross section shape is trapezoidal would overcome the art of record." *Id.* 20-23.

Applicant subsequently amended independent claim 21 (now claim 1) to recite that "[a] male protrusion [of the neck body] extends into and permanently attaches with the porous metal structure of the bone fixation body to create the hip implant before the hip implant is implanted, wherein the porous metal structure of the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and the male protrusion extends to a distal end of the hip implant," and made similar amendments to the other independent claims (now claims 8 and 14). *Id*. at 24-30.

VI. CLAIM CONSTRUCTION

In an *inter partes* review, claim terms are given their broadest reasonable interpretation (BRI).[2] *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275-79 (Fed. Cir. 2015). Under this standard, claim terms are given their "broadest

[2] Petitioner notes that district courts apply a different claim construction standard and reserves its rights to make arguments based on that standard in the district court. Should the Board's claim construction standard change during the course of the proceeding, Petitioner reserves its rights to make arguments based on the new standard.

reasonable interpretation, consistent with the specification." *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012). Claim terms are also "generally given their ordinary and customary meaning," which is the meaning that the term would have to a person of ordinary skill in the art[3] at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1313 (Fed. Cir. 2005) (*en banc*)). Petitioner proposes a construction for claim features related to "emulating" natural human bone below, but all of the claim terms in the '582 patent should be given their plain and ordinary meaning under the BRI standard.

Each independent claim of the '582 patent recites a "bone fixation body" having "a porous metal structure." *See* Ex. 1001 at 15:51–16:4, 16:28-46, 16:63–17:14. Claims 1 and 14 recite that the porous metal structure has "a size and a shape that emulate a size and a shape of a porous structure of natural human bone."

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[3] A person of ordinary skill in the art 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.

Id. at 15:56-60, 17:2-4. Claim 8 similarly recites that "the porous metal structure . . . with interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone." *Id.* at 16:33-36. To the extent that these phrases (referred to hereinafter as "the emulating claim features") are amenable to construction,[4] the broadest reasonable interpretation includes "a structure that is sufficiently porous so as to permit bone ingrowth." This interpretation is consistent with the plain language of the claims, the specification, and the prosecution history of the '642 patent application.

The plain and ordinary meaning of the term "emulate" is "imitate." Ex. 1008 at 3. Thus, the plain language of the claims simply requires the porous structure of the bone fixation body to "imitate" the porous structure of natural human bone. This understanding is not inconsistent with the specification, which equates "[t]he porous structure of body 16 [] adapted for the ingrowth of cancellous and cortical bone spicules" with "emulat[ing] the size and shape of the porous structure of natural bone." Ex. 1001 at 4:32-36. To adapt a porous structure for ingrowth and emulate natural bone, the specification discloses

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[4] These phrases raise issues under 35 U.S.C. § 112 (e.g., enablement and indefiniteness). Petitioner understands that such grounds cannot be raised in this proceeding, but reserves the right to argue them where appropriate.

exemplary or preferred ranges for the pore diameter, porosity, and interconnections. For example, the specification provides that "the average pore diameter of body 16 is about 40μm to about 800μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50-60 microns." *Id.* at 4:37-40. The specification provides that "[i]n short, the geometric configuration of the porous structure should encourage natural bone to migrate and grow into and throughout the entire body 16." *Id.* at 4:40-43.

The proposed construction is also consistent with the Office's interpretation of the claim language during prosecution of the '582 patent's parent application. During prosecution, Applicant attempted to overcome the applied prior art by amending the claims to include similar "emulating" claim features. In response, the Examiner rejected an interpretation of the claims that would require the porous structure to "replicate" the porous structure of natural bone. Ex. 1004 at 182-3. Instead, the Examiner maintained the prior art rejections explaining that "[t]he porous structure disclosed in [the prior art] is intended to behave like or imitate the behavior of bone by providing pores of a certain size and shape to provide bone ingrowth." *Id*. at 183; *see also id*. at 105. Applicant acquiesced to this interpretation, ultimately abandoning this argument as the patentable distinction between the claims and the prior art, and instead focusing on a "trapezoidal shape" of an interface between the bone fixation body and the neck body.

Thus, the broadest reasonable interpretation of the "emulating" claim features includes "a metal structure that is sufficiently porous so as to permit bone ingrowth." To the extent Patent Owner argues that the phrases should be more narrowly construed, such a construction is not supported by the '582 patent.

VII. CLAIMS 1-5, 7-11, 13-15, AND 17-20 OF THE '582 PATENT ARE UNPATENTABLE

A. The Board Should Adopt Both Sets of Proposed Grounds

Zolman and *Rostoker*, alone and in combination with *Sump* or *Averill* render claims 1-5, 7-11, 14, 15, and 17-20 of the '582 patent obvious under Petitioner's claim construction of the "emulating" claim features. *See* Sections VII.B-D (Grounds 1-3). *Zolman* and *Bobyn*, alone and in combination with *Sump* or *Averill* render claims 1-5, 7-11, 13-15, and 17-20 of the '582 patent obvious under a narrower claim interpretation where the "emulating" claim features require the porous structure of the claimed "bone fixation body" to resemble a porous structure of natural human bone. *See* Sections VII.E-G (Ground 3-6). The Board should adopt both sets of grounds in the event Patent Owner argues for a narrower construction either in its Preliminary Response or after institution. Moreover, Petitioner has attempted to streamline the petition to achieve the goal of "just, speedy, and inexpensive resolution" consistent with 37 C.F.R. § 42.1(b).

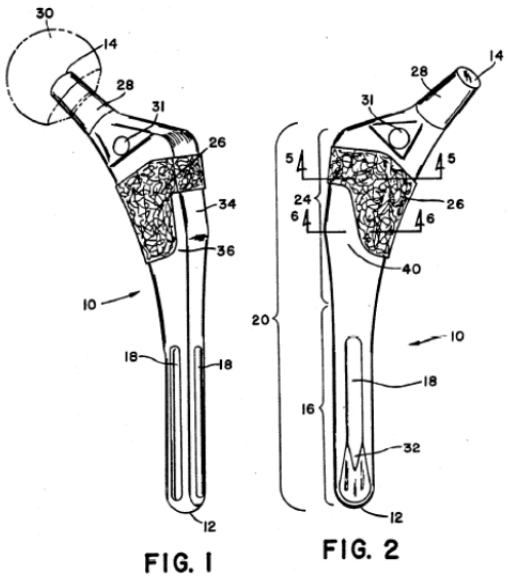
Petitioner notes that *Zolman*, relied on under all grounds, and *Averill* and *Sump*, relied on under certain grounds, are not cited on the face of the '582 patent.

While *Rostoker* and *Bobyn* were cited during prosecution of the ’642 patent application, they were simply two of several references included in a long listing of references and not relied on by the Examiner. Moreover, the Examiner did not have the benefit of the declaration of Dr. Timothy P. Harrigan (Ex. 1002), an expert in the field of the prior art and the ’582 and ’642 patents. Thus, the arguments here are new, and the prosecution of the ’642 patent application should not preclude institution of this petition on both sets of the grounds.

B. Ground 1: Claims 1-5, 8-11, 14, 15, and 17-20 Are Obvious Over *Zolman* and *Rostoker*

1. Overview of the Combination of *Zolman* and *Rostoker*

Zolman discloses a method of constructing a prosthetic implant “suitable for use as a femoral component for a hip prosthesis.” *See* Ex. 1005 at 1:11-15. In one embodiment, *Zolman* discloses a femoral component 10 that is “intended to fit within the intramedullary canal of a femur (not shown) such that the proximal end extends outwardly from the intramedullary canal of the femur to cooperate with an acetabulum or acetabular prosthetic member via a ball or the like carried at the proximal end 14.” *Id.* at 3:46-51. Femoral component 10 is formed



of, for example, titanium, and includes a stem portion 20 and a neck 28 extending proximally from stem portion 20. *See id.* at 3:54-59, 4:26-27. As shown in Figures 1, 2, 5 and 6, proximal portion 24 of stem portion 20 of *Zolman* "has an asymmetric non-circular cross-section." *Id.* at 5:19-21; Ex. 1002, ¶ 23.

A porous pad 26, as shown in the embodiments of Figures 1-6, is circumferentially wrapped around proximal portion 24 of stem portion 20. *Id.* at 3:53-54, 4:5-8, 5:12-16, 6:44-48. Porous pad 26 is positioned in a recess 74 having a shape corresponding to porous pad 26 and adapted to receive porous pad 26. *Id.* at 5:13-16. In certain disclosed embodiments, porous pad 26 conforms to the shape of stem portion 20, and has an asymmetric or symmetric configuration. *See id.* 5:5-11, 5:16-18, Figs. 1-6. *Zolman* teaches that "[t]he shape of the porous pad 26 may have any desirable configuration" and that "[t]he outer boundary of the pad 26 may have any suitable contour." *Id.* at 4:29-33; Ex. 1002, ¶ 24.

Zolman discloses forming porous pad 26 "separate[ly] from the stem portion 20." *See* Ex. 1005 at 4:29-34. In particular, *Zolman* discloses that a "porous material, such as a kinked titanium fiber metal, is [first] press formed into a sheet 126 of porous material" and that "[a] porous pad 26 having the desired outer contour is then cut from the sheet . . . ." *Id.* at 4:46-58. "The porous pad 26 has a first preliminary precontoured shape as shown in FIG. 11 and is then subsequently wrapped and/or formed about the stem portion 20 for attachment thereto in a

second and final shape corresponding to the shape of the stem portion 20 as shown in FIGS. 1-4." *Id.* at 4:36-41. Further, *Zolman* discloses that "[t]he femoral component 10 with the conformed pad 26 surrounding it is . . . placed in an appropriate bonding fixture 80" and that "[t]he porous pad 26 is [] bonded to the stem portion 20 to securely attach it thereto." *Id.* at 6:39-48. *Zolman* teaches that the bond may be achieved by diffusion bonding, sintering, or any "other suitable bonding methods." *Id.* at 6:39-54; Ex. 1002, ¶ 25.

As *Zolman* explains, porous pad 26 facilitates "bony ingrowth [] in and around the porous surface to biologically affix or further secure the implant in the bone." Ex. 1005 at 1:20-23. *Zolman* discloses that porous pad 26 can be made from "any suitable porous material" and "particularly fibrous (wire-type) porous structures which are adaptable to be practiced in accordance with the present invention." *Id.* at 4:21-24. *Zolman* expressly discloses that one such suitable material is the fiber metal structure disclosed in *Rostoker*. *Id.* at 4:12-15. Based on at least this disclosure, a person of ordinary skill in the art would have been motivated to look to *Rostoker* for the porous material from which to fabricate the porous pad of *Zolman*. Ex. 1002 at ¶ 26.

Rostoker discloses a femur prosthesis 12 having a sintered fiber metal attachment structure 18 composed of a plurality of tubular fiber metal segments 28a, 28b, 28c, 28d, and 28e. Ex. 1006 at 3:14-17, 3:21-23. *Rostoker* discloses that

the fiber metal segments 28 are "all porous aggregates produced by molding and sintering short metal fibers." *Id.* at 4:22-27. "The sintering process creates metallurgical bonds at the points of contact of the fibers." *Id.* at 2:23-25. Like *Zolman*, *Rostoker* discloses embodiments in which the fiber metal structure is formed from kinked metal fibers such as, for example, kinked titanium fiber metal. *See* Ex. 1005 at 4:46-48; Ex. 1006 at 4:42-62; Ex. 1002, ¶ 27.

Rostoker further describes its disclosed fiber metal structure as having "considerable mechanical strength due to the sintered bonds and the mechanical interlocks." Ex. 1006 at 4:28-31; *see also id.* at 2:25-27. Additionally, *Rostoker* discloses that "in view of the use of fiber metals, the pores are interconnecting and remain so after sintering. Thus bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." *Id.* at 2:40-44. Given *Rostoker*'s teachings of the benefits of its disclosed porous fiber metal structure and *Zolman*'s teachings that porous surfaces may be used to allow bony ingrowth, a person of ordinary skill in the art would have been motivated to use the porous fiber metal structure of *Rostoker* in *Zolman*'s porous pad 26 to facilitate "bony ingrowth to biologically affix or secure the implant to the bone." Ex. 1005 at 1:20-23; Ex. 1002 at ¶ 28.

Rostoker additionally discloses that "[b]y using fiber metals[,] the range of pore sizes can be readily controlled . . . ." Ex. 1006 at 2:35-36. *Rostoker* states

that "[s]ince the pore size can be readily controlled by the pressing and forming parameters [of the sintering process], 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 (emphasis added). *Rostoker* discloses pore diameters and porosities of its fiber metal structure that fall within the range of pore diameters and porosities that are disclosed in the '582 patent as "emulat[ing] the size and shape of the porous structure of natural bone." *Compare* Ex. 1006 at 5:6-24 *with* Ex. 1001 at 4:33-43; *see also* Ex. 1002, ¶ 29.

Given *Rostoker*'s teachings, it would have been obvious to one of ordinary skill in the art to fabricate *Zolman*'s porous pad 26 from the porous fiber metal structure of *Rostoker*. Ex. 1002, ¶¶ 31-34. Indeed, as noted above, *Zolman* expressly discloses fabricating the porous pad 26 from *Rostoker*'s fiber metal structure. Ex. 1005 at 4:12-15. A person of ordinary skill in the art would have recognized that fabricating porous pad 26 with the porous material of *Rostoker* to have a porous fiber metal structure "emulating" a porous structure of natural human bone would have amounted to nothing more than a simple substitution of known porous structures, and that the modification would yield nothing more than predictable results, i.e., bone ingrowth. Ex. 1002, ¶ 33; *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007). For these reasons and those discussed below, *Zolman* in combination with *Rostoker* render claims 1-5, 8-11, 14, 15, and

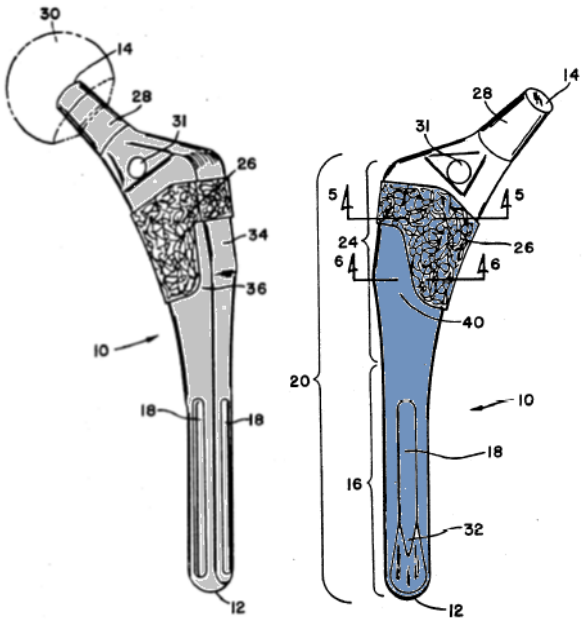
17-20 of the '582 patent obvious. *See* Ex. 1002, ¶ 35.

2. Claim 1

i. **[1.1] A method, comprising:**

Zolman discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral component 10. *See e.g.*, Ex. 1005 at Abstract; Ex. 1002, ¶ 36 ([1.a]); Sections VII.B.2.ii-v.

ii. **[1.2] machining a neck body formed of solid metal to include a neck that receives a femoral ball and having a male protrusion that extends outwardly from the neck body;**



Zolman discloses forming a neck body (shaded in grey). *See e.g.*, Ex. 1005 at 3:56-59, Figs. 1-4; Ex. 1002, ¶ 36 ([1.b]). The neck body includes a neck 28, an adjacent portion with aperture 31, and stem portion 20 (collectively referred to hereinafter as "neck body"). *Zolman* teaches that neck 28 of the neck body

receives a femoral ball, i.e., ball 30. Ex. 1005 at 3:56-59. A person of ordinary skill in the art would understand ball 30 to be a femoral ball based on *Zolman*'s disclosure that ball 30 cooperates with an acetabulum or acetabular prosthetic member. *Id.* at 3:45-51; Ex. 1002, ¶ 36 ([1.b]). *Zolman* also discloses that the neck body has a male protrusion, i.e., stem portion 20 (shaded below in blue), that extends outwardly from the neck body. *See* Ex. 1005 at 3:54-56, Figs. 1-4; Ex. 1002, 36 ([1.b]).

Zolman discloses forming the neck body from a solid metal such as, for example, titanium. Ex. 1005 at 4:26-27. Given this, one of skill in the art would have understood the neck body of *Zolman* would have been likely to have been formed by a machining process. Ex. 1002, ¶ 36 ([1.b]). More specifically, one of skill would have understood that it was common practice to machine the neck body of a femoral component made of metal in 2003. Ex. 1002, ¶ 36 ([1.b]).

Zolman also teaches that neck 28 of the neck body has a morse taper, which, at the time of the alleged invention, was commonly formed using machining techniques. Ex. 1002, ¶ 36 ([1.b]). Even if the neck body of *Zolman* was created through another process, a person of ordinary skill in the art would have known that the neck body would have been likely to undergo a final machining (e.g., grinding). Ex. 1002, ¶ 36 ([1.b]). Thus, it would have been obvious to one of skill in the art, given the neck body disclosed in *Zolman*, to form the neck body through

a machining process. Ex. 1002, ¶ 36 ([1.b]).

iii. **[1.3] fabricating, separately from the neck body, a bone fixation body with a porous metal structure that extends completely throughout the bone fixation body with the porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone; and**

Zolman discloses fabricating, separately from the neck body, a porous pad 26. Ex. 1005 at 4:8-12 (disclosing forming a porous pad 26); *id.* at 4:33-34 (disclosing that porous pad 26 is formed separately from femoral component 10). *Zolman* discloses that porous pad 26 is formed of a "kinked titanium fiber metal[] [that] is press formed into a sheet 126 of porous material. The sheet 126 may have any desired thickness or dimensions." *See id.* at 4:46-49. Figure 9 of *Zolman* depicts sheet 126 as an entirely porous material. *Id.* at Fig. 9. Porous pad 26 is "cut from the sheet" and thus has a porous metal structure that extends completely throughout the pad. *Id.* at 4:56-58; Ex. 1002, ¶ 36 ([1.c]).

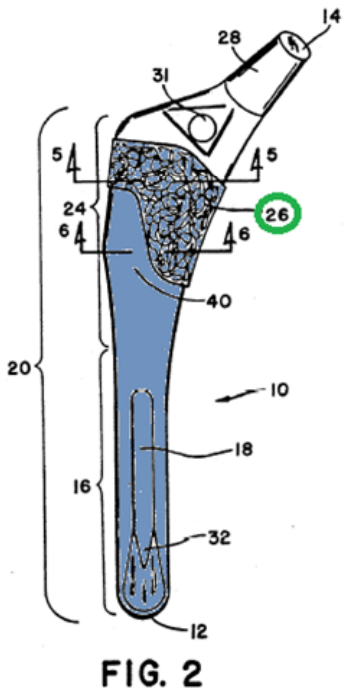


FIG. 2

Zolman teaches that porous pad 26 can be made from "any suitable porous material" and "particularly fibrous (wire-type) porous structures which are adaptable to be practiced in accordance with the present invention." Ex. 1005 at 4:21-24; *see also* Ex. 1001 at 4:30-31 (disclosing that "the porous structure can be

formed by . . . metal wire mesh"). In particular, *Zolman* discloses that porous pad 26 "may be formed of any suitable porous material that is adapted to be preliminarily pressed into a first shape and then subsequently wrapped around the stem portion 20 into a second shape conforming to the shape of the stem portion." Ex. 1005 at 4:8-12. *Zolman* expressly discloses that one such suitable material is the fiber metal structure disclosed in *Rostoker*. *Id.* at 4:12-15.

Rostoker discloses fabricating a porous fiber metal structure by molding and sintering short metal fibers. Ex. 1006 at 2:21-23. *Rostoker* discloses that "[b]y using fiber metals the range of pore sizes can be readily controlled" and as such "the density of the sintered composite can *approximate* the density of the bone to which the prosthetic device is implanted." *Id*. at 2:35-52 (emphasis added). *Rostoker* also discloses that the porous fiber metal structure can be fabricated with pore diameters and porosities that are similar to the range of pore diameters and porosities disclosed in the '582 patent that "encourage natural bone to migrate and grow into and throughout the entire body 16." Ex. 1001 at 4:37-43. For example, *Rostoker* discloses that "[t]he largest principal dimension of the pores is approximately equal to the wire diameter," which *Rostoker* discloses can be 0.013 cm (130μm) or 0.03 cm (300 μm). *Compare* Ex. 1006 at 5:14-16, 5:21-24 *with* Ex. 1001 at 4:37-38. *Rostoker* also discloses that "[t]he sintered fiber metal aggregates . . . may be molded having void or a porosity of 40 to 50 percent per unit area."

Compare Ex. 1006 at 5:6-8 *with* Ex. 1001 at 4:38-39. *Rostoker* also discloses that "in view of the use of fiber metals, the pores are interconnecting and remain so after sintering. Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." Ex. 1006 at 2:40-44. Thus, *Rostoker* discloses the "emulating" claim feature of claim 1 as it discloses "a structure that is sufficiently porous so as to permit bone ingrowth." *See* Section VI; Ex. 1002, ¶ 36 ([1.c]).

A person of ordinary skill in the art would have been motivated to fabricate *Zolman*'s porous pad 26 so as to have a porous fiber metal structure that "emulates" natural human bone, as taught in *Rostoker*, to increase the strength of the attachment of the implant to the surrounding bone, allowing the implant to better withstand the load applied to the hip joint. *See* Section VII.B.1; Ex. 1002, ¶¶ 31, 36 ([1.c]). A person of ordinary skill in the art would have understood that a structure that is conducive to bone formation and enables tissue infiltration facilitates a strong attachment and long-term implant stability of the implant. *Id*. As discussed above, fabricating *Zolman*'s porous pad 26 from the porous fiber metal structure of *Rostoker* would have been a simple and common sense combination in light of *Rostoker*'s disclosure that its fiber metal structure can "approximate" the structure of bone and encourage bone growth to firmly secure the implant to the surrounding tissue—the importance of which is recognized in

Zolman. *See* Section VII.B.1; Ex. 1002, ¶¶ 32, 36 ([1.c]).

Given *Rostoker*'s teachings and *Zolman*'s explicit teachings to use *Rostoker*, modifying *Zolman*'s method to fabricate porous pad 26 form the fiber metal structure of *Rostoker* would constitute no more than an obvious design choice—one of a "finite number of identified, predictable solutions"—to one skilled in the art. Ex. 1002, ¶¶ 34, 36 ([1.c]); *see also KSR*, 550 U.S. at 402-3 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.").

iv. **[1.4] attaching, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to create a hip implant such that the male protrusion extends into and permanently attaches with the porous metal structure of the bone fixation body to create the hip implant before the hip implant is implanted,**

Zolman discloses attaching, after porous pad 26 is separately fabricated from the neck body, porous pad 26 to stem portion 20 of the neck body to create femoral component 10. *See* Ex. 1005 at 4:36-41, 6:44-48. *Zolman* further discloses that stem portion 20 extends into porous pad 26 and that porous pad 26 encircles stem portion 20. *See id.* at 3:53-54, Fig. 1-5; Ex. 1002, ¶ 36 ([1.d]). *Zolman* discloses bonding porous pad 26 to stem portion 20 to permanently attach porous pad 26 to

stem portion 20 to create femoral component 10 before femoral implant 10 is implanted. *See id.* at 6:46-54 (disclosing that "[t]he bonding may be achieved by diffusion bonding the pad to the stem portion" and that "other suitable bonding methods may be utilized").

v. **[1.5] wherein the porous metal structure of the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and the male protrusion extends to a distal end of the hip implant.**

Porous pad 26, and thus the porous structure of porous pad 26, includes a non-circular, trapezoidal shape in a horizontal cross-sectional view of femoral component 10. *See* Ex. 1005 at Fig. 5; *see also id.* at 5:16-21 (disclosing that "pad[] 26 can be shaped to conform to any desirable and suitable . . . surface configuration"). Figure 5 is a cross-sectional view of femoral component 10 along line 5—5 in Figure 2. Ex. 1005 at 2:63-64. As shown in Figure 5, stem portion 20 of the neck body and porous pad 26 both have a trapezoidal cross-sectional shape as they are shaped like or similar to a trapezoid. *Compare id.* at Fig. 5 to Ex. 1001 at 6:45-46 (describing Fig. 7 as showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶ 36 ([1.e]). *Zolman* further discloses that stem portion 20 extends to a distal end 12 of femoral component 10. *See* Ex. 1005 at 3:53-54 ("[t]he distal portion 16 and the proximal portion 24 comprise the stem portion 20 of the femoral component 10"), *id.* at Figs. 1-4; Ex. 1002, ¶ 36 ([1.e]).

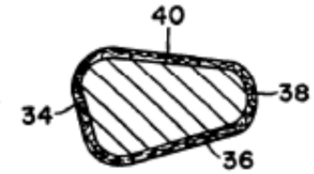


FIG. 5

3. Claim 2

i. **"The method of claim 1, wherein the bone fixation body and the neck body have an area with a polygonal shape in a horizontal cross-sectional view of the hip implant."**

As shown in Figure 5, *Zolman* discloses that porous pad 26 and stem portion 20 of the neck body have an area with a polygonal shape in a horizontal cross-sectional view of femoral component 10. *See* Ex. 1005 at Fig. 5, *id.* at 5:16-21 (disclosing that "pad[] 26 can be shaped to conform to any desirable and suitable . . . surface configuration" and that "[t]he proximal portion 24 of stem portion 20 of the femoral component [] has an asymmetric noncircular cross-section as shown in FIG[]. 5"). Porous pad 26 and stem portion 20 of the neck body have an area with a polygonal shape in a horizontal cross-sectional view, as shown in Figure 5, as the area is shaped like or similar to a polygon. Ex. 1002, ¶ 37.

4. Claim 3

i. **"The method of claim 1, wherein the male protrusion of the neck body has a noncircular tapering shape and extends into the porous metal structure of the bone fixation body such that the porous metal structure surrounds an exterior surface of the male protrusion."**

Zolman discloses that "stem portion 20 of the femoral component [] has an asymmetric noncircular cross-section . . . in FIGS. 5 and 6." Ex. 1005 at 5:19-21. Further, stem portion 20 has a non-circular tapering shape. *See id.* at 5:19-21, Figs. 1-4; Ex. 1002, ¶ 38. *Zolman* discloses that porous pad 26 encircles proximal portion 24 of stem portion 20, thus completely surrounding and engaging an

exterior surface of stem portion 20. *See e.g., id.* at 3:53-54, Figs. 1-5.

5. Claim 4

i. **"The method of claim 1, wherein the neck body engages the bone fixation body at an interface that has a trapezoidal shape in a horizontal cross-sectional view.**

Zolman discloses that porous pad 26 engages the neck body at an interface

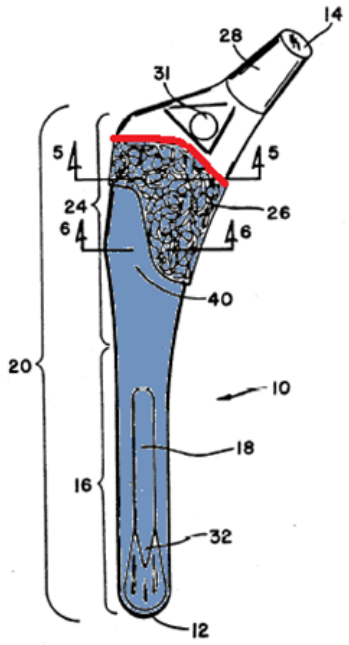


FIG. 2

that has a trapezoidal shape in a horizontal cross-sectional view. Ex. 1002, ¶ 39. A proximal end of porous pad 26 engages a surface of the neck body (annotated in red) formed by a recess 74 at the interface between the neck body and porous pad 26 when porous pad 26 is received in recess 74. Ex. 1005 at 5:13-16; Figs. 5-6; Ex. 1002, ¶ 39. Recess 74 is formed in proximal portion 24 of stem portion 20. Ex. 1005 at 5:13-16. *Zolman* discloses that "[t]he proximal portion 24 of stem portion 20 of the femoral component [] has an asymmetric noncircular cross-section as shown in FIGS. 5 and 6." Ex. 1005 at 5:19-21. Figure 5 is a cross-sectional view of proximal portion 24 along line 5—5, just below the distal end surface of the neck body and the interface. *See id.* at 2:63-64. As shown in Figure 5, porous pad 26 and proximal portion 24 both have a trapezoidal cross-sectional shape as they are shaped like or similar to a trapezoid. *Compare id.* at Fig. 5 to Ex. 1001 at 6:45-

46 (describing Fig. 7 as showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶ 39. Figures 1-4 further disclose that the shape of the neck body at the interface is consistent with the shape of the neck body at line 5—5, revealing that the interface has a trapezoidal shape in a cross-sectional view. *See* Ex. 1005 at Figs. 1-4; Ex. 1002, ¶ 39.

6. Claim 5

i. **"The method of claim 1, wherein the bone fixation body has an elongated tapering body with a bow."**

Porous pad 26 has an elongated tapering body with a bow i.e., with at least one side having a curvature. *Compare e.g.*, Ex. 1005 at Fig. 2 *with* Ex. 1001 at 5:24-25, Fig. 1 (depicting the bone fixation body as having a "slight bow"); *see also* Ex. 1002, ¶ 40.

7. Claim 8

i. **[8.1] "A method, comprising:"**

As discussed above for claim 1, *Zolman* discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral component 10. *See* Section VII.B.2.i; Ex. 1002, ¶ 41 ([8.a]); Sections VII.B.7.ii-v.

ii. **[8.2] "machining solid metal to form a neck body that includes a neck to receive a femoral ball and that includes a male protrusion that extends outwardly from the neck body;"**

As discussed above for claim 1, *Zolman* discloses machining solid metal, i.e., titanium, to form a neck body that includes a neck 28 to receive a femoral ball

30 and that includes a stem portion 20 that extends outwardly from the neck body. *See* Section VII.B.2.ii; Ex. 1002, ¶ 41 ([8.b]).

iii. **[8.3] "making, separately from the neck body, a bone fixation body with a porous metal structure that extends throughout the bone fixation body with interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone; and"**

As discussed above for claim 1, *Zolman* discloses making porous pad 26 separately from the neck body. *See* Section VII.B.2.iii. As also discussed above for claim 1, *Zolman* teaches that porous pad 26 can be formed with a porous metal structure that extends throughout porous pad 26. *Id.*; Ex. 1002, ¶ 41 ([8.c]).

Further, *Zolman* discloses that porous pad 26 can be made from "any suitable porous material," and expressly discloses that one such suitable material is the fiber metal structure disclosed in *Rostoker*. Ex. 1005 at 4:8-14; Sections VII.B.1, VII.B.2.iii. *Rostoker* teaches the "emulating" claim feature of claim 8 by disclosing that its fiber metal structure is "a structure that is sufficiently porous so as to permit bone ingrowth." *See* Sections VI, VII.B.1, VII.B.2.iii; Ex. 1002, ¶ 41 ([8.c]). In fact, *Rostoker* states that "in view of the use of fiber metals, the pores are interconnecting and remain so after sintering. Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." Ex. 1006 at 2:40-44. As discussed above for claim 1, it would have been obvious to a person of ordinary skill in the art to make *Zolman*'s porous pad 26 from *Rostoker*'s fiber metal structure having a porous structure with

"interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone" to increase the strength of attachment of the implant to the surrounding bone. *See* Sections VII.B.1, VII.B.2.iii; Ex. 1002, ¶¶ 31, 41 ([8.c]). Modifying *Zolman*'s method to make porous pad 26 from *Rostoker*'s fiber metal structure would have been an obvious design choice at the time of the alleged invention given *Rostoker*'s teachings and *Zolman*'s explicit teachings to use *Rostoker*. *See* Section VII.B.2.iii; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 34, 41 ([8.c]).

iv. **[8.4] "connecting, after the bone fixation body is separately made from the neck body, the bone fixation body to the neck body to create a hip implant such that the male protrusion extends into the bone fixation body in order to permanently connect the neck body to the bone fixation body and create the hip implant,"**

As discussed above for claim 1, *Zolman* discloses connecting, after porous pad 26 is separately made from the neck body, the porous pad 26 to the neck body to create femoral component 10. *See* Section VII.B.2.iv; Ex. 1002, ¶ 41 ([8.d]). As further discussed above for claim 1, *Zolman* discloses that stem portion 20 extends into porous pad 26 in order to permanently connect the neck body to porous pad 26 and create the femoral component 10 before it is implanted. *See* Section VII.B.2.iv; Ex. 1002, ¶ 41 ([8.d]).

v. **[8.5] "wherein the porous metal structure of the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and the male protrusion extends toward a distal end of the hip implant."**

As discussed above for claim 1, *Zolman* discloses that the porous metal structure of porous pad 26 includes a trapezoidal shape in a horizontal cross-sectional view of femoral component 10. *See* Section VII.B.2.v; Ex. 1002, ¶ 41 ([8.e]). Stem portion 20 of *Zolman* extends toward a distal end 12 of femoral component 10. *See* Ex. 1005 at 3:54-56, Figs. 1-4; Ex. 1002, ¶ 41 ([8.e]).

8. Claim 9

i. **"The method of claim 8, wherein the bone fixation body is fused to the neck body after the bone fixation body is made separately from the neck body."**

As discussed above for claim 8, *Zolman* teaches making porous pad 26 separately from the neck body. *See* Section VII.B.7.iii. As further discussed above for claim 8, *Zolman* discloses connecting, after porous pad 26 is separately made from porous pad 26, porous pad 26 to stem portion 20. *See* Section VII.B.7.iv. In particular, *Zolman* discloses fusing porous pad 26 to the neck body by "diffusion bonding the pad to the stem portion." *See* Ex. 1005 at 6:48-51. *Zolman* also discloses that other bonding methods may be utilized. *See id.* at 6:52-54; Ex. 1002, ¶ 42.

9. Claim 10

i. **"The method of claim 8, wherein the male protrusion of the neck body is a core for the bone fixation body and has a polygonal and tapering shape that extends into the porous metal structure of the bone fixation body."**

Zolman discloses that stem portion 20 is a core for porous pad 26. *See* Ex.

1005 at Figs. 1-5 (depicting porous pad 26 as encircling stem portion 20); Ex. 1002, ¶ 43. *Zolman* discloses that stem portion 20 has a polygonal shape as stem portion 20 is shaped like or similar to a polygon as shown in the cross-sectional views of Figures 5 and 6. *See* Ex. 1005 at 5:19-21, Figs. 5-6; Ex. 1002, ¶ 43. *Zolman* discloses that stem portion 20 also has a tapering shape that extends into the porous metal structure of porous pad 26. *See* Ex. 1005 at 3:53-54, Figs. 1-4.

10. Claim 11

i. **"The method of claim 8, wherein the bone fixation body tapers and includes a bow shape."**

As discussed above for claim 5, porous pad 26 tapers and includes a bow shape. *See* Section VII.B.6; Ex. 1002, ¶ 44.

11. Claim 14

i. **[14.1] "A method, comprising:"**

As discussed above for claim 1, *Zolman* discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral component 10. *See* Section VII.B.2.i; Ex. 1002, ¶ 45 ([14.a]); Sections VII.B.11.ii-v.

ii. **[14.2] "forming a neck body having a proximal end that connects with an acetabular component, having a distal end surface with a protrusion that extends outwardly therefrom, and being formed of solid metal;"**

As discussed above for claim 1, *Zolman* discloses forming a neck body from solid metal i.e., titanium, having a proximal end (e.g., neck 28) that connects with a femoral ball 30. *See* Section VII.B.1.ii; Ex. 1002, ¶ 45 ([14.b]). Ball 30

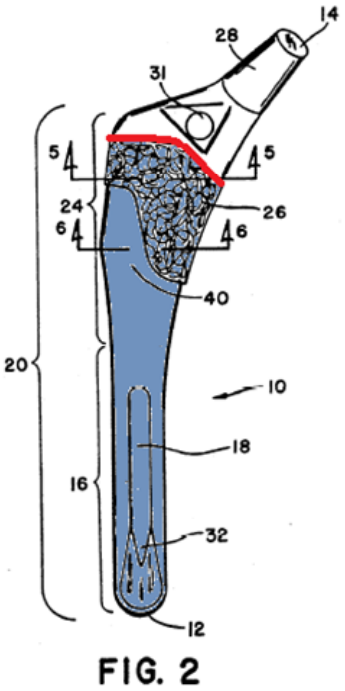


FIG. 2

cooperates with an acetabulum or acetabular prosthetic member. Ex. 1005 at 3:45-51. *Zolman* also teaches that the neck body has a distal end surface (annotated in red) with an elongated protrusion, stem portion 20 (shaded below in blue), which extends outwardly therefrom. *See id.* at Figs. 1-4; Ex. 1002, ¶ 45 ([14.b]). The distal end surface of the neck body is formed by a recess 74 and is where the neck body interfaces porous pad 26. *Id.* at 5:13-16, Figs. 1-6.

iii. **[14.3] "forming a bone fixation body having an elongated tapering shape and having a porous metal structure with a size and a shape that emulate a size and a shape of a porous structure of natural human bone; and"**

As discussed above for claims 1 and 8, *Zolman* discloses forming a bone fixation body, i.e., porous pad 26. *See* Sections VII.B.2.iii, VII.B.7.iii. As shown in Figure 2, porous pad 26 has an elongated tapering shape. *See* Ex. 1005 at Figs. 1-4; Ex. 1002, ¶ 45 ([14.c]). *Zolman* further teaches that porous pad 26 can conform to the shape of stem portion 20, *id.* at 4:10-12, which continues and tapers in a distal direction, *see e.g.*, *id.* at Fig. 2. *See also* Ex. 1002, ¶ 45 ([14.c]). Thus, porous pad 26 continues and tapers in a distal direction towards a distal end of porous pad 26. *See e.g.*, Ex. 1005 at Fig. 2; Ex. 1002, ¶ 45 ([14.c]).

Further, as discussed above for claims 1 and 8, *Zolman* discloses that porous

pad 26 can be made from "any suitable porous material," and expressly discloses that one such suitable material is the fiber metal structure disclosed in *Rostoker*. Ex. 1005 at 4:8-15; Sections VII.B.1, VII.B.2.iii, VII.B.7.iii. As discussed for claim 1, *Rostoker* teaches the "emulating" claim feature recited in claims 1 and 14 by disclosing that its fiber metal structure is "a structure that is sufficiently porous so as to permit bone ingrowth." *See* Sections VI, VII.B.1, VII.B.2.iii; Ex. 1002, ¶ 45 ([14.c]). In fact, *Rostoker* states that "in view of the use of fiber metals, the pores are interconnecting and remain so after sintering. Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." Ex. 1006 at 2:40-44. As discussed above for claims 1 and 8, it would have been obvious to a person of ordinary skill in the art to make *Zolman*'s porous pad 26 from *Rostoker*'s fiber metal structure having a porous structure "that emulate a shape and a size of a porous structure of natural human bone" to increase the strength of attachment of the implant to the surrounding bone. *See* Sections VII.B.1, VII.B.2.iii, VII.B.7.iii; Ex. 1002, ¶¶ 31, 45 ([14.c]). Modifying *Zolman*'s method to make porous pad 26 from *Rostoker*'s fiber metal structure would have been an obvious design choice at the relevant time given *Rostoker*'s teachings and *Zolman*'s explicit teachings to use *Rostoker*. *See* Section VII.B.2.iii; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 34, 45 ([14.c]).

iv. **[14.4] "engaging, after the neck body and the bone fixation body are separately formed, the bone fixation body to the neck body such that the**

porous metal structure permanently engages to the protrusion and the protrusion extends to a distal end of a hip implant and tapers and extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the protrusion that extends into the bone fixation body,"

As discussed above for claim 1, *Zolman* discloses engaging, after the neck body and porous pad 26 are separately formed, the porous pad 26 to the neck body. *See* Section VII.B.2.iv; Ex. 1002, ¶ 45 ([14.d]). As also discussed above, the porous metal structure of porous pad 26 permanently engages stem portion 20 as it is bonded to stem portion 20 by, for example, diffusion bonding. *See* Section VII.B.2.iv; Ex. 1002, ¶ 45 ([14.d]). Further, as discussed above for claim 14, stem portion 20 extends to a distal end 12 of femoral component 20. *See* Section VII.B.7.iv; Ex. 1002, ¶ 45 ([14.d]). Because porous pad 26 is wrapped around stem portion 20, *Zolman* further discloses that stem portion 20 extends into an opening of porous pad 26 such that the porous metal structure of porous pad 26 surrounds and engages an exterior surface of stem portion 20 that extends into porous pad 26. *See id.* at 3:53-54, 4:8-12, 4:36-45, 4:62-5:5, 6:32-36, 6:44-48, Figs. 1, 3-5; Ex. 1002, ¶ 45 ([14.d]).

v. **[14.5] "wherein the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the bone fixation body."**

As discussed above for claim 1, *Zolman* discloses that porous pad 26 includes a trapezoidal shape in a horizontal cross-sectional view of porous pad 26. *See* Section VII.B.2.v; Ex. 1002, ¶ 45 ([14.e]).

12. Claim 15

i. **"The method of claim 14, wherein the bone fixation body has one of a polygonal and noncircular closed shape in a horizontal cross-sectional view of the bone fixation body and is bonded to the neck body after being formed separately from the neck body."**

As discussed above for claim 1, porous pad 26 has both a polygonal and noncircular closed shape in a horizontal cross-sectional view of porous pad 26. *See* Section VII.B.2.v; Ex. 1002, ¶ 46. As further discusssed above for claims 1 and 14, porous pad 26 is bonded to the neck body after being formed separately from the neck body. *See* Sections VII.B.2.iv, VII.B.11.iv; Ex. 1002, ¶ 46.

13. Claim 17

i. **"The method of claim 14, wherein the bone fixation body is not a porous coating but is fabricated separately from the neck body and subsequently engaged to the neck body."**

Zolman discloses that porous pad 26 is not a porous coating. *See* Ex. 1005 at 3:62-65 ("[t]he porous pad 26 is designed to extend outwardly from the proximal portion 24 albeit a small extension of about 0.5 mm past the adjacent smooth surface of the proximal portion 24."); *see also id.* at 4:46-58. As discussed above, *Zolman* teaches that porous pad 26 is fabricated separately from the neck body and subsequently engaged to the neck body. *See* Section VII.B.14.iv; Ex. 1002, ¶ 47.

14. Claim 18

i. **"The method of claim 14, wherein the protrusion includes a polygonal shape in the horizontal cross-sectional view."**

Zolman's stem portion 20 includes a polygonal shape in a horizontal cross-

sectional view. Ex. 1002, ¶ 48. It discloses that "pad 26 can be shaped to conform to any desirable and suitable . . . surface configuration" and that "[t]he proximal portion 24 of stem portion 20 of the femoral component [] has an asymmetric noncircular cross-section as shown in FIGS. 5 and 6." Ex. 1005 at 5:19-21. Stem portion 20 has a polygonal shape as stem portion 20 is shaped like or similar to a polygon in the cross-sectional views of Figures 5 and 6. Ex. 1002, ¶ 48.

15. Claim 19

i. **"The method of claim 14, wherein a distal end surface of the neck body has a trapezoidal shape, a proximal end of the bone fixation body has the trapezoidal shape, and the solid metal of the trapezoidal shape of the neck body interfaces with the porous metal structure of the trapezoidal shape of the bone fixation body at an interface."**

Zolman discloses that both a distal end surface of the neck body and a proximal end of porous pad 26 have a trapezoidal shape, and the solid metal of the trapezoidal shape of the neck body interfaces with the porous metal structure of the trapezoidal shape of porous pad 26 at an interface. Ex. 1002, ¶ 49. The distal end surface of the neck body is formed by a recess 74 at the interface between the neck body and porous pad 26. *Id.* at 5:13-16, Figs. 1-6. The proximal end of porous pad 26 engages the distal end surface formed by recess 74 at the interface when pad 26 is received in recess 74. *Id.* at 5:13-16, 6:44-46, Figs. 5-6; Ex. 1002, ¶ 49.

Recess 74 is formed in a proximal portion 24 of stem portion 20. *See e.g.* Ex. 1005 at 5:13-16. *Zolman* teaches that proximal portion 24 has a noncircular

cross-section, and that porous pad 26 has a shape corresponding to proximal portion 24. *See e.g., id.* at 5:16-21. Figure 5 is a cross-sectional view of proximal portion 24 along line 5—5. *Id.* at 2:63-64. As shown in Figure 5, stem portion 20 of the neck body and porous pad 26 both have a trapezoidal cross-sectional shape as they are shaped like or similar to a trapezoid. *Compare id.* at Fig. 5 to Ex. 1001 at 6:45-46 (describing Fig. 7 as showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶ 49. Figures 1-4 further disclose that the shape of the distal end surface of the neck body at the interface is consistent with the shape of the neck body at line 5—5 and the shape of a proximal end of porous pad 26 is also consistent with the shape of porous pad 26 at line 5—5, revealing both to have a trapezoidal shape in a cross-sectional view. *See* Ex. 1005 at Figs. 1-4; Ex. 1002, ¶ 49. Accordingly, one skill in the art would understand, based on *Zolman*'s disclosure, that the solid metal of the trapezoidal shape of the neck body interfaces with the porous metal structure of the trapezoidal shape of porous pad 26 at the interface. Ex. 1002, ¶ 49.

16. Claim 20

i. **"The method of claim 14, wherein the protrusion includes a cylindrical shape in a horizontal cross-sectional view."[5]**

[5] Claim 20 fails to point out and distinctly claim the subject matter. Petitioner understands that such grounds under 35 U.S.C. § 112 cannot be raised in an IPR proceeding, but reserves the right to raise them in another forum.

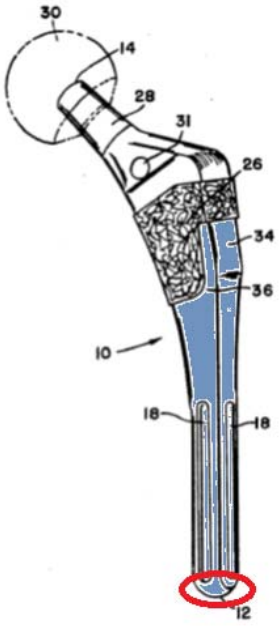


FIG. 1

Zolman teaches that stem portion 20 of *Zolman* has a polygonal shape in the horizontal cross-sectional view of Figures 5 and 6. *See* Ex. 1005 at 5:19-21, Figs. 5-6. To the extent a cross-section can be cylindrical, *Zolman* teaches that stem portion 20 at distal end 12 has a cylindrical shape in a cross-sectional view. Ex. 1002, ¶ 50.

In addition, to the extent a cross-section can be cylindrical, it would have been obvious to one of ordinary skill in the art to form stem portion 20 so that it had a cylindrical shape in a horizontal cross-sectional view based on *Rostoker*. Ex. 1002, ¶ 50. *Rostoker* discloses a femur prosthesis 12 having a rod 24 that has a circular cross-section and a cylindrical shape. Ex. 1006 at 3:11-20, Fig. 1. It would have been obvious to a person of ordinary skill in the art to form stem portion 20 to having a cylindrical shape in a horizontal cross-section based on *Rostoker*'s disclosure that a stem-like portion can have a non-polygonal shaped cross-section (i.e., a circular cross-section). Modifying *Zolman*'s stem portion 20 to have a cylindrical cross-section would have been an obvious design choice at the time of the alleged invention in view of *Zolman*'s teachings that stem portion 20 can have any desirable or suitable configuration. *See KSR*, 550 U.S. at 402-3; Ex. 1002, ¶ 50.

C. Ground 2: Claim 7 Is Obvious Over *Zolman*, *Rostoker*, and *Sump*

1. "The method of claim 1, wherein the male protrusion of the neck body has one of a square shape and a rectangular shape and tapers while extending toward the distal end of the hip implant."

As discussed above, the combination of *Zolman* and *Rostoker* teach the method of claim 1, from which claim 7 depends. *See* Section VII.B.2. *Zolman* also teaches that stem portion 20 of a femoral component 10 may have "any desirable and suitable implant stem . . . configuration." Ex. 1005 at 5:16-19, Figs. 1-6; Ex. 1002, ¶ 51. Further, *Zolman* discloses that stem portion 20 tapers while extending toward the distal end 12 of femoral component 10. *See* Ex. 1005 at Figs. 1-4. Given *Zolman's* disclosure, it would have been obvious to modify stem portion 20 of the hip implant of *Zolman* and *Rostoker* to have one of a square or rectangular shape in light of *Sump*'s disclosure. Ex. 1002, ¶ 51.

Sump discloses a hip prosthesis 10 having a shank 11. Ex. 1011 at 3:14-22. As shown in Figures 1 and 2, shank 11 has a rectangular shape in a horizontal cross-section of hip prosthesis 10. *See id.* at 3:1-4, Figs. 1-2. The rectangular shape of shank 11 tapers from an end of hip prosthesis 10 with ball 9 toward an opposite end of hip prosthesis 10. *See id.* at 3:14-22, Fig. 1; Ex. 1002, ¶ 52.

Based on *Sump*'s disclosure, it would have been obvious to a person of ordinary skill in the art would to form stem portion 20 of the hip implant of *Zolman* and *Rostoker* to have a rectangular shape. Ex. 1002, ¶ 53. One of ordinary

skill in the art would have understood that a stem portion could be fabricated to have any one of a number of shapes including a rectangular shape that tapers while extending toward a distal end of the implant, as evidenced by *Sump*. Ex. 1002, ¶ 53. In fact, forming the stem portion of *Zolman* and *Rostoker*'s implant to have a rectangular shape that tapers while extending toward a distal end of the implant would have been an obvious design choice at the time of the alleged invention in view of *Zolman*'s explict teachings that stem portion 20 can have any desirable or suitable configuration. *See KSR*, 550 U.S. at 402-3; Ex. 1002, ¶ 53.

D. Ground 3: Claim 20 Is Obvious Over *Zolman*, *Rostoker*, and *Averill*

As discussed above for claim 20, to the extent a cross-sectional shape can be cylindrical, the combination of *Zolman* and *Rostoker* suggests fabricating stem portion 20 to have a cylindrical shape in a horizontal cross-sectional view. If the Board finds that *Zolman* in view of *Rostoker* do not disclose stem portion 20 having a cylindrical shape in a horizontal cross-sectional view, it would have been obvious to form the stem portion of the hip implant of *Zolman* and *Rostoker* to have a cylindrical shape in a horizontal cross-sectional view in light of *Averill*'s disclosure. Ex. 1002, ¶ 54.

Averill discloses a prosthesis 10 including a stem 12. *See e.g.*, Ex. 1012 at 5:5-10. *Averill* discloses that Figure 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. *Averill*

discloses that "[t]he cross-sectional shape of the tapered portion 22 [of stem 12] . . . defines an almost circular cross-section at line 3—3 (FIG. 3)." *Id.* at 5:34-39. Additionally, a person of ordinary skill in the art at the relevant time would have understood the cross-sectional shape of stem portion 12 at line 2—2 to have shape that is shaped like or similar to an elliptical shape. Ex. 1002, ¶ 55.

Based on *Averill*'s disclosure, it would have been obvious to a person of ordinary skill in the art to modify stem portion 20 of the hip implant of *Zolman* and *Rostoker* to have a cylindrical shape in a horizontal cross-section. Ex. 1002, ¶ 56. One of ordinary skill in the art would have understood that a stem portion could be fabricated to have any one of a number of cross-sectional shapes including a cylindrical shape, as evidenced by *Averill*. Ex. 1002, ¶ 53. In fact, forming the stem portion of *Zolman* and *Rostoker*'s hip implant to have a cylindrical shape in a horizontal cross-section of femoral component 10 would have been an obvious design choice at the time of the alleged invention in view of *Zolman*'s explicit teachings that stem portion 20 can have any desirable or suitable configuration. *See KSR*, 550 U.S. at 402-3; Ex. 1002, ¶ 56.

E. Ground 4: Claims 1-5, 8-11, 13-15, and 17-20 Are Obvious Over *Zolman* and *Bobyn*

As discussed above, during prosecution, Applicant appeared to construe the "emulating" claim features to require the porous structure to resemble or "replicate" a porous structure of natural human bone. Ex. 1004 at 194-207. To the

extent Patent Owner attempts to advance a similarly narrow claim construction in this proceeding, Petitioner presents the following additional ground. Specifically, *Zolman* in view of *Bobyn* discloses and/or suggests each and every feature of the claims, including the "emulating" claim features under either construction.

1. Overview of the Combination of *Zolman* and *Bobyn*

Zolman discloses that porous pad 26 of femoral component 10 can be made from "any suitable porous material that is adapted to be preliminarily pressed into a first shape and then subsequently wrapped about the stem portion 20 into a second shape conforming to the shape of the stem portion 20." Ex. 1005 at 4:8-12. While *Zolman* discloses an embodiment in which porous pad 26 is formed of a fiber metal structure, *Zolman* states that "[i]t is understood that any suitable porous material . . . which [is] adaptable to be practiced in accordance with the present invention, may be utilized." *Id.* at 4:21-24, 4:8-12, 4:27-28; Ex. 1002, ¶57.

Bobyn discloses a porous tantalum biomaterial with "desirable characteristics for bone ingrowth." Ex. 1007 at 907. It discloses a porous tantalum biomaterial that is "75% to 80% porous by volume" and has "a very regular pore shape and size." *Id.* It discloses that "[b]ecause of its high porosity, its structural stiffness . . . is similar to subchondral bone," which a person of ordinary skill in the art would understand to be cancellous bone. *Id.* at 913; Ex. 1002, ¶ 58.

It would have been obvious to a person of ordinary skill in the art to

fabricate *Zolman*'s porous pad 26 from the porous tantalum biomaterial disclosed in the *Bobyn*. Ex. 1002, ¶ 60. *Zolman* contemplates that porous pad 26 can be formed from any suitable material. Ex. 1005 at 4:8-12, 4:21-24, 4:27-28. *Zolman* additionally explains that the porous structure of porous pad 26 would permit "bony ingrowth [] in and around the porous surface to biologically affix or further secure the implant in the bone." *Id.* at 1:21-23. *Bobyn* discloses a material, tantalum, with characteristics desirable for "bone ingrowth." Ex. 1007 at 907. At the time of the alleged invention, tantalum was understood to be a "strong, ductile metal with excellent corrosion resistance" that was a standard material used in surgical implants including femoral endoprostheses. *Id.* at 913. Thus, a person of ordinary skill in the art at the time of the alleged invention would have considered forming *Zolman*'s porous pad 26 from the porous tantalum biomaterial disclosed in *Bobyn*. Ex. 1002, ¶ 60.

Porous surfaces were known to support tissue ingrowth and to supplement the stability of an implant through biological fixation. Ex. 1005 at 1:20-23; Ex. 1007 at 907. *Bobyn* explains that "conventional porous materials each have certain deficiencies or weaknesses." Ex. 1007 at 907. "For instance, sintered beaded and fiber metal coatings have a porosity which is limited to 30% to 50% by volume, a factor which directly limits the maximum interfacial strength that can develop by bone growth." *Id.* By contrast, *Bobyn*'s porous tantalum material has a

substantially higher porosity of "75% to 80%." *Id.* at 907, 912. *Bobyn* explains that "[t]his mean[s] that for any given percentage filling, a greater volume of bone [is] present within the porous tantalum, thus . . . increas[ing] [the] interface strength" and the rate of fixation of the implant to the surrounding bone. *Id.* at 912. Given *Bobyn*'s teachings of the advantages of the porous tantalum biomaterial over other conventional porous surfaces, a person of ordinary skill in the art would have been motivated to use the *Bobyn*'s porous biomaterial for *Zolman*'s porous pad 26 to form a high strength femoral component 10 with a structure similar to natural cancellous bone. Ex. 1002, ¶ 61.

Bobyn discloses that unlike conventional porous materials, tantalum "is a strong, ductile metal" with a structural integrity that "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." Ex. 1007 at 913; *see also id.* at 907. Additionally, *Bobyn* contemplates that the material can be used as a fixation surface on an implant and is particularly applicable for reconstructive orthopedic procedures. *Id.* at 913; *see also id.* at 907. Like the fiber metal structure of *Zolman* (Ex. 1005 at 4:46-48), *Bobyn*'s porous tantalum biomaterial can be compression molded (Ex. 1007 at 913). Accordingly, a person of ordinary skill in the art would have understood that the porous tantalum biomaterial would have been adaptable to be used with the manufacturing

techniques disclosed in *Zolman*. Ex. 1002, ¶¶ 62-64. One of skill at the time of the alleged invention would have appreciated that fabricating *Zolman*'s porous pad 26 using the tantalum biomaterial disclosed in *Bobyn* would have been a simple substitution of known porous materials to improve the *Zolman*'s femoral component 10, and would yield nothing more than predictable results, i.e., a porous structure for bone ingrowth. *See KSR*, 550 U.S. at 417; Ex. 1002, ¶ 64. For these reasons and those discussed below, *Zolman* in combination with *Rostoker* render claims 1-5, 8-11, 14, 15, and 17-20 of the '582 patent obvious. *See* Ex. 1002, ¶ 65.

2. Claim 1

i. **Claim Element 1.1**

As discussed in Ground 1 for claim 1, *Zolman* discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral component 10. *See* Section VII.B.2.i; Ex. 1002, ¶ 66 ([1.a]); Sections VII.E.2.ii-v.

ii. **Claim Element 1.2**

As discussed in Ground 1 for claim 1, *Zolman* discloses forming a neck body of solid metal, i.e., titanium, which includes a neck 28 that receives a femoral ball 30 and a stem portion 20 that extends outwardly from the neck body. *See* Section VII.B.2.ii; *see also* Ex. 66 ([1.b]). As further discussed in Ground 1 for claim 1, it would have been obvious to a person of ordinary skill in the art given *Zolman*'s disclosure to have formed the neck body through a machining process. *See* Section VII.B.2.ii; Ex. 1002, ¶ 66 ([1.b]).

iii. **Claim Element 1.3**

As discussed in Ground 1, *Zolman* discloses fabricating a porous pad 26 separately from the neck body. *See* Section VII.B.2.iii; Ex. 1002, ¶ 66 ([1.c]). Porous pad 26 is "cut from the sheet" and thus has a porous metal structure that extends completely throughout the pad. *Id.* at 4:56-58; Ex. 1002, ¶ 66 ([1.c]). *Zolman* discloses that porous pad 26 can be made from "any suitable porous material that is adapted to be preliminarily pressed into a first shape and then subsequently wrapped about stem portion 20 into a second shape conforming to the shape of the stem portion 20." Ex. 1005 at 4:8-13. While *Zolman* discloses an embodiment in which porous pad 26 is formed of a fiber metal structure, *Zolman* states that "[i]t is understood that any suitable porous material . . . which [is] adaptable to be practiced in accordance with the present invention, may be utilized." *Id.* at 4:21-24; *see also id.* at 4:8-12, 4:27-28.

Bobyn discloses a porous tantalum biomaterial for use in orthopedic applications, including for femoral endoprostheses. Ex. 1007 at 907, 913. The material is "75% to 80% porous by volume" and has "a very regular pore shape and size." *Id.* at 907. *Bobyn* teaches that "[b]ecause of its high porosity, its structural stiffness . . . is similar to subchondral bone," which a person of ordinary skill in the art would understand as cancellous bone. *Id.* at 913; Ex. 1002, ¶ 58. Further, a person of ordinary skill in the art would have recognized that the porous

structure of the porous tantalum biomaterial resembles or replicates a porous structure of natural cancellous bone. Ex. 1002, ¶ 59 (comparing *Bobyn*'s porous tantalum biomaterial (Ex. 1007 at 908) with cancellous bone (Ex. 1009 at 976)).

Bobyn discloses that its material "has desirable characteristics for bone ingrowth." Ex. 1007 at 907. In particular, *Bobyn* discloses that the material is characterized by quicker bone in-growth rates and better interface strength development, as compared to conventional porous metals such as sintered beads and fiber metal. *Id.* at 912. Further, unlike the conventional porous metals, *Bobyn* explains that tantalum is both strong and ductile and that "its structural integrity allows it to be readily formed in bulk parts for filling of bone defects or other reconstructive applications requiring standard or customized shapes and sizes of the implant." *Id.* at 913.

Given *Bobyn*'s teachings of the advantages of the porous tantalum material over other conventional porous surfaces, a person of ordinary skill in the art would have been motivated to use the *Bobyn*'s porous material for porous pad 26 to fabricate a "porous structure having a size and shape that emulate a size and shape of a porous structure of natural human bone" as recited in claim 1. Ex. 1002, ¶¶ 61, 66 ([1.c]). Forming *Zolman*'s porous pad 26 from *Bobyn*'s porous tantalum material would have been a simple combination because *Bobyn* describes the porous tantalum material as being "ductile" and teaches that the material can be

manufactured into complex shapes. Ex. 1002, ¶¶ 62-64, 66 ([1.c]). Further, it would have been a common sense combination in light of *Bobyn*'s disclosure that the geometry of the material has "desirable characteristics for bone ingrowth." Ex. 1002 at ¶¶ 60, 65 ([1.c]). Such modification of *Zolman*'s femoral component 10 would constitute no more than an obvious design choice—one of a "finite number of identified, predictable solutions"—to one skilled in the art. Ex. 1002, ¶¶ 64, 66 ([1.c]); *see also KSR*, 550 U.S. at 402-3.

iv. **Claim Element 1.4**

As discussed in Ground 1 for claim 1, *Zolman* discloses permanently attaching, after porous pad 26 is separately fabricated from the neck body, porous pad 26 to a proximal portion 24 of stem portion 20 to create femoral component 10. *See* Section VII.B.2.iv; Ex. 1002, ¶ 66 ([1.d]). As also discussed, *Zolman* discloses that stem portion 20 extends into porous pad 26, and porous pad 26 encircles stem portion 20. *See* Section VII.B.2.iv; Ex. 1002, ¶ 66 ([1.d]).

v. **Claim Element 1.5**

As discussed in Ground 1, *Zolman* discloses that the porous metal structure of porous pad 26 includes a trapezoidal shape in a horizontal cross-sectional view of femoral component 10, and also that stem portion 20 extends to a distal end 12 of femoral component 10. *See* Section VII.B.2.v; Ex. 1002, ¶ 66 ([1.e]).

3. Claim 2

As discussed in Ground 1, *Zolman* discloses that porous pad 26 and stem

portion 20 of the neck body both have an area with a polygonal shape in a horizontal cross-sectional view of femoral component 10. *See* Section VII.B.3; Ex. 1002, ¶ 67.

4. Claim 3

As discussed in Ground 1 for claim 3, *Zolman* discloses that stem portion 20 has a noncircular tapering shape and extends into porous pad 26 such that the porous metal structure of porous pad 26 surrounds an exterior surface of stem portion 20. *See* Section VII.B.4; *see also* Ex .1002, ¶ 68.

5. Claim 4

As discussed in Ground 1 for claim 4, *Zolman* discloses that the neck body engages porous pad 26 at an interface. *See* Section VII.B.5. Figures 1-4 disclose that the shape of the neck body at the interface is consistent with the shape of the neck body at line 5—5, revealing that the interface has a trapezoidal shape in a cross-sectional view. *See* Ex. 1005 at Figs. 1-5; Ex. 1002, ¶ 69.

6. Claim 5

As discussed in Ground 1 for claim 5, *Zolman* discloses that porous pad 26 has an elongated tapering body with a bow. *See* Section VII.B.6; Ex. 1002, ¶ 70.

7. Claim 8

i. **Claim Element 8.1**

As discussed in Ground 1 for claim 8, *Zolman* discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral

component 10. *See* Section VII.B.7.i; Ex. 1002, ¶ 71 ([8.a]); Sections VII.E.7.ii-v.

ii. **Claim Element 8.2**

As discussed in Ground 1 for claim 8, *Zolman* discloses machining solid metal, i.e., titanium, to form a neck body that includes a neck 28 to receive a femoral ball and that includes a stem portion 20 that extends outwardly from the neck body. *See* Section VII.B.7.ii; Ex. 1002, ¶ 71 ([8.b]).

iii. **Claim Element 8.3**

As discussed in Ground 1 for claim 8, *Zolman* discloses making porous pad 26 separately from the neck body. *See* Section VII.B.7.iii; Ex. 1002, ¶ 71 ([8.c]). As further discussed above for claim 1, *Zolman* teaches that porous pad 26 can be formed with a porous metal structure that extends completely throughout porous pad 26. *See* Section VII.B.7.iii; Ex. 1002, ¶ 71 ([8.c]).

As also discussed above for claim 1, *Zolman* discloses that porous pad 26 can be made from "any suitable porous material." *See* Section VII.B.7.iii. *Bobyn* discloses a porous tantalum biomaterial that resembles and thus "emulates" a porous structure of cancellous bone. *See* Sections VII.E.1, VII.E.1.iii. As further discussed above for claim 1, it would have been obvious to one of ordinary skill in the art at the time of the alleged invention to use *Bobyn*'s porous material for porous pad 26 to form a high strength femoral implant with a porous structure having desirable characteristics for bone ingrowth. *See* Sections VII.E.1,

VII.E.2.iii; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 60-64, 71 ([8.c]).

iv. **Claim Element 8.4**

As discussed in Ground 1 for claim 8, *Zolman* discloses connecting, after porous pad 26 is separately made from the neck body, porous pad 26 to the neck body to create femoral component 10. *See* Section VII.B.7.iv; Ex. 1002, ¶ 71 ([8.d]). As also discussed above, *Zolman* discloses that stem portion 20 extends into porous pad 26 in order to permanently connect the neck body to porous pad 26 and create femoral component 10. *See* Section VII.B.7.iv; Ex. 1002, ¶ 71 ([8.d]).

v. **Claim Element 8.5**

As discussed in Ground 1, *Zolman* discloses that the porous metal structure of porous pad 26 includes a trapezoidal shape in a horizontal cross-sectional view of femoral component 10, and that stem portion 20 extends toward a distal end 12 of femoral component 10. *See* Section VII.B.7.v; Ex. 1002, ¶ 71 ([8.e]).

8. Claim 9

As discussed in Ground 1 for claim 9, porous pad 26 is formed separately from the neck body and then fused to the neck body by, for example, diffusion bonding. *See* Section VII.B.8; *see* Ex. 1002, ¶ 72.

9. Claim 10

As discussed in Ground 1 for claim 10, stem portion 20 of the neck body is a core for porous pad 26 and has a polygonal and tapering shape that extends into the porous metal structure of porous pad 26. *See* Section VII.B.9; Ex. 1002, ¶ 73.

10. Claim 11

As discussed in Ground1 for claim 11, porous pad 26 tapers and includes a bow shape. *See* Section VII.B.10; *see* Ex. 1002, ¶ 74.

11. Claim 13

As discussed above for claim 8, it would have been obvious to make *Zolman*'s porous pad 26 from *Bobyn*'s porous tantalum biomaterial. *See* Section VII.E.7.iii. *Bobyn*'s porous tantalum biomaterial "has an unusually high and interconnecting porosity with a very regular pore shape and size." Ex. 1007 at 907; Ex. 1002, ¶ 75. In particular, the material has a repeating arrangement of interconnecting struts which, it discloses as "form[ing] a regular array of dodecahedron-shaped pores." *Id*.; *see also id.* at 908 (including scanning electron micrograph images of the porous tantalum biomaterial having a uniform structure).

12. Claim 14

i. **Claim Element 14.1**

As discussed in Ground 1, *Zolman* discloses a method of constructing a prosthetic implant and, in particular, constructing a femoral component 10. *See* Section VII.B.11.i; Ex. 1002, ¶ 76 ([14.a]); Sections VII.E.12.ii-v.

ii. **Claim Element 14.2**

As discussed in Ground 1, *Zolman* discloses forming a neck body from solid metal, i.e., titanium, having a proximal end (e.g., neck 28) that connects with an acetabular component and a distal end surface with a stem portion that extends

outwardly therefrom. *See* Section VII.B.11.ii; Ex. 1002, ¶ 76 ([14.b]).

iii. **Claim Element 14.3**

As in Ground 1, *Zolman* discloses forming a bone fixation body, i.e., porous pad 26. *See* Section VII.B.11.iii; Ex. 1002, ¶ 76 ([14.c]). It also discloses embodiments in which porous pad 26 has an elongated tapering shape. *Id*.

As also discussed above for claims 1 and 8, *Zolman* discloses that porous pad 26 can be made from "any suitable porous material." *See* Sections VII.E.2.iii, VII.E.7.iii. *Bobyn* discloses a porous tantalum biomaterial that resembles and thus "emulates" a porous structure of cancellous bone. *See* Sections VII.E.1, VII.E.2.iii, VII.E.7.iii; Ex. 1002, ¶ 76 ([14.c]). As further discussed above with claims 1 and 8, it would have been obvious to one of ordinary skill in the art at the time of the alleged invention to use *Bobyn*'s porous material for porous pad 26 to form a high strength femoral implant with a porous structure having desirable characteristics for bone ingrowth. *See* Sections VII.E.1, VII.E.2.iii, VII.E.7.iii; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 60-64, 76 ([14.c]).

iv. **Claim Element 14.4**

As discussed in Ground 1, *Zolman* discloses engaging, after the neck body and porous pad 26 are separately formed, the porous pad 26 to the neck body. *See* Section VII.B.11.iv; Ex. 1002, ¶ 76 ([14.d]). Also, the porous metal structure of porous pad 26 is permanently engaged to stem portion 20 by, for example,

diffusion bonding. *See* Section VII.B.11.iv; Ex. 1002, ¶ 76 ([14.d]). Stem portion 20 of femoral component 10 extends into an opening of porous pad 26 such that the porous metal structure of porous pad 26 surrounds and engages an exterior surface of stem portion 20 that extends into porous pad 26. *See* Section VII.B.11.iv; Ex. 1002, ¶ 76 ([14.d]).

v. **Claim Element 14.5**

As discussed in Ground 1, *Zolman* discloses that porous pad 26 includes a trapezoidal shape in a horizontal cross-sectional view. *See* Section VII.B.11.v; Ex. 1002, ¶ 76 ([14.e]). .

13. Claim 15

As discussed in Ground 1 for claim 15, porous pad 26 has both a polygonal and non-circular closed shape in a horizontal cross-sectional view of porous pad 26, and is bonded to the neck body after being formed separately from the neck body. *See* Section VII.B.12; Ex. 1002, ¶ 77.

14. Claim 17

As discussed in Ground 1 for claim 17, porous pad 26 of *Zolman* is not a porous coating, and is formed separately from the neck body and subsequently engaged to the neck body. *See* Section VII.B.13; Ex. 1002, ¶ 78.

15. Claim 18

As discussed in Ground 1 for claim 18, stem portion 20 includes a polygonal shape in the horizontal cross-sectional view. *See* Section VII.B.14; Ex. 1002, ¶ 79.

16. Claim 19

As discussed in Ground 1 for claim 19, *Zolman* discloses that both a distal end surface of the neck body and a proximal end of porous pad 26 have a trapezoidal shape, and the solid metal of the trapezoidal shape of the neck body interfaces with the porous metal structure of the trapezoidal shape of porous pad 26 at an interface. *See* Section VII.B.15; Ex. 1002, ¶ 80.

17. Claim 20

As discussed in Ground 1 for claim 20, *Zolman* discloses that stem portion 20 includes a cylindrical shape in a horizontal cross-sectional view. *See* Section VII.B.17; Ex. 1002, ¶ 82.

F. Ground 5: Claim 7 Is Obvious Over *Zolman*, *Bobyn*, and *Sump*

As discussed above, the combination of *Zolman* and *Bobyn* teach the method of claim 1, from which claim 7 depends. *See* Section VII.E.2. As also discussed in Ground 2, it would have been obvious to form a stem portion, like *Zolman*'s stem portion 20, with a rectangular shape that tapers while extending toward a distal end of femoral component 10, in light of *Sump*. *See* Section VII.C. Similarly, it would have been an obvious design choice to a person of ordinary skill in the art at the time of the alleged invention to form the stem portion of *Zolman* and *Bobyn*'s implant with a rectangular shape and and to taper in a distal direction in light of *Zolman*'s explicit teachings that stem portion 20 can have any desirable or suitable configuration. *See* Section VII.C; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 82-84.

G. Ground 6: Claim 20 Is Obvious Over *Zolman*, *Bobyn*, and *Averill*

If the Board finds that *Zolman* and *Bobyn* do not disclose stem portion 20 having a cylindrical shape in a horizontal cross-sectional view, it would have been an obvious design choice to form *Zolman*'s stem portion 20 to have a cylindrical shape in a horizontal cross-sectional view in light of *Averill*'s disclosure of a prosthesis having a circular and elliptical cross-sections and *Zolman*'s explicit teachings that stem portion 20 can have any desirable or suitable configuration. *See* Section VII.D; *KSR*, 550 U.S. at 402-3; Ex. 1002, ¶¶ 85-87.

VIII. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 1-5, 7-11, 13-15, and 17-20 of the '582 patent.

Respectfully submitted,

Dated: October 2, 2015 By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Counsel for Zimmer Biomet Holdings, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2015, a copy of the foregoing **Petition for *Inter Partes* Review of U.S. Patent No. 8,821,582** and supporting materials was served by express mail on the Patent Owner at the following correspondence address of record for the patent-at-issue and at the following correspondence address for Patent Owner's litigation counsel:

Philip S. Lyren, PC
289 Woodland Avenue
Wadsworth, Ohio 44281

Matthew M. Wawrzyn
Stephen C. Jarvis
Siprut PC
17 North State Street, Suite 1600
Chicago, Illinois 60602

Dated: October 2, 2015

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Paul Hastings LLP

Counsel for Zimmer Biomet Holdings, Inc.