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Filed on behalf of: Zimmer Biomet Holdings, Inc.

By: Naveen Modi (Zimmer-FMB-IPR@paulhastings.com)
Young J. Park (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. 9,265,612

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,265,612

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1023	Campbell's Operative Orthopedics, Vol. 1 (S. Terry Canale, MD. ed., Mosby 10th ed. 2003).
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I. INTRODUCTION

Zimmer Biomet Holdings, Inc. ("Zimmer" or "Petitioner") requests *inter partes* review of claims 12, 13, and 15-19 of U.S. Patent No. 9,265,612 ("the '612 patent") (Ex. 1001), which is assigned to Four Mile Bay, LLC ("FMB" or "Patent Owner"). This petition shows that there is a reasonable likelihood that Petitioner will establish the unpatentability of claims 12, 13, and 15-19 of the '612 patent by a preponderance of evidence. Trial should be instituted and claims 12, 13, and 15-19 of the '612 patent should be cancelled.

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 matters: The '612 patent is asserted in the co-pending litigation *Four Mile Bay LLC v. Zimmer Biomet Holdings, Inc.*, No. 3:15-cv-00063-PPS-MGG (N.D. Ind.). FMB filed a complaint against Zimmer on February 6, 2015, asserting U.S. Patent Nos. 8,506,642 ("the '642 patent") and 8,821,582 ("the '582 patent"). (No. 3:15-cv-00063, Dkt. No. 1.) An amended complaint was filed on October 13, 2016, adding the following patents, which are in the same family: the '612 patent, U.S. Patent No. 9,283,080 ("the '080 patent"), and U.S. Patent No. 9,308,093 ("the '093 patent"). (*Id.*, Dkt. No. 76 (Exhibit 1013).)

On October 2, 2015, Zimmer filed IPR petitions for the '642 patent (IPR2016-00011, "the '642 IPR") and the '582 patent (IPR2016-00012, "the '582 IPR"). On April 1, 2016, the Board declined to institute the '642 IPR. (IPR2016-00011, Paper No. 8.) On the same day, the Board instituted the '582 IPR on all of the challenged claims and adopted all of the proposed grounds. (IPR2016-00012, Paper No. 8.) The Board issued its Final Written Decision ("FWD") in the '582 IPR on March 10, 2017, finding all of the challenged claims unpatentable. (*Id.*, Paper No. 34 (Exhibit 1008).) FMB has appealed the Board's decision to the Federal Circuit in *Four Mile Bay, LLC v. Zimmer Biomet Holdings, Inc.*, Appeal No. 17-2017.

Petitioner is concurrently filing petitions for *inter partes* review of the '080 patent and the '093 patent. To the best of Petitioner's knowledge, U.S. Patent Application Nos. 15/050,490 and 15/065,917 are pending before the Office and claim priority to one or more of the same application(s) to which the '612 patent claims priority.

Counsel and Service Information: Lead counsel is Naveen Modi (Reg. No. 46,224). Young J. Park (Reg. No. 51,114) and Paromita Chatterjee (Reg. No. 63,721) are back-up counsel. Mr. Modi and Ms. Chatterjee can be reached at Paul Hastings LLP, 875 15th St. NW, Washington, DC, 20005 (Telephone: 202.551.1700/Fax: 202.551.1705). Mr. Park can be reached at Paul Hastings LLP,

75 E. 55th St., New York, NY 10022 (Telephone: 212.318.6000/Fax: 212.319.4090). 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 UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '612 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '612 patent on the grounds identified. This petition is timely filed under 35 U.S.C. § 315(b) because it is filed within one year of service of Patent Owner's amended complaint, which is the first complaint by Patent Owner alleging infringement of the '612 patent against Petitioner. (*See* Ex. 1013.)

V. PRECISE RELIEF REQUESTED AND GROUNDS RAISED

Petitioner respectfully requests review of claims 12, 13, and 15-19 of the '612 patent and cancellation of these claims as unpatentable in view of the following grounds[1]:

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[1] For each proposed ground, Petitioner does not rely on any prior art reference other than those listed here. Other references discussed herein are provided to

- **Ground 1**: Claims 12, 13, and 15-19 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,018,285 to Zolman et al. ("*Zolman*") (Ex. 1009) and U.S. Patent No. 3,906,550 to Rostoker et al. ("*Rostoker*") (Ex. 1010);
- **Ground 2**: Claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Rostoker*, and U.S. Patent No. 5,863,295 to Averill et al. ("*Averill*") (Ex. 1012);
- **Ground 3**: Claims 12, 13, and 15-19 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman* and 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. 1011); and
- **Ground 4**: Claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Bobyn*, and *Averill*.

On its face, the '612 patent claims a priority date of May 27, 2003. (Ex. 1001, title page.) *Zolman* issued on May 28, 1991 (Ex. 1009, title page), *Rostoker* issued on September 23, 1975 (Ex. 1010, title page), *Bobyn* was published in September

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show the state of the art at the time of the alleged invention. *See, e.g.*, *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015).

1999 (Ex. 1011, 907), and *Averill* issued on January 26, 1999 (Ex. 1012, title page). Thus, these references are all prior art under pre-AIA 35 U.S.C. § 102(b).

VI. BACKGROUND

The ’612 patent issued from U.S. Application No. 13/947,069 (“the ’7069 application”), filed on July 21, 2013, which purports to be a continuation of U.S. Patent Application No. 11/409,611 (“the ’611 application”), filed on April 24, 2006, now the ’642 patent, which purports to be a continuation of U.S. Patent Application No. 10/446,069, filed on May 27, 2003, now abandoned. (Ex. 1001, title page.)

A. Overview of the ’612 Patent

The ’612 patent discloses a “hip implant with [a] porous body.” (Ex. 1001, title page; Ex. 1002, ¶ 12.) The disclosed implant includes two distinct bodies, a neck body 14 and a bone fixation body 16. (*See, e.g.*, Ex. 1009, Abstract, 1:55-58, 3:10-12, Figs. 1-2.) Figure 1 illustrates an exemplary embodiment of hip implant 10, and Figure 2 illustrates the implant embedded inside a patient’s femur 50:

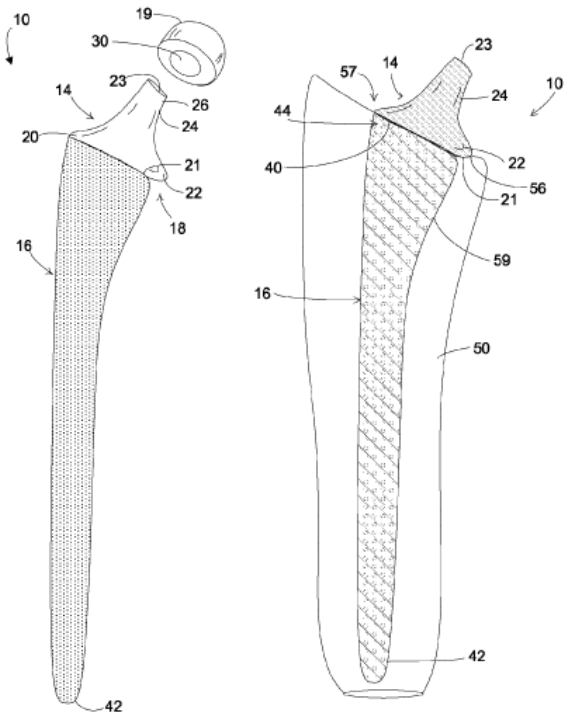

Fig. 1 Fig. 2

(*See id.*, 2:52-55, 3:6-7, 3:44-46.)

Neck body 14 "is located at the proximal end 18 of the hip implant 10 and functions to connect the hip implant 10 to a spherically shaped femoral ball 19 and acetabular component (not shown)." (*Id.*, 3:13-16.) It includes a neck portion 24 that extends outwardly from a base portion 20, which has a distal end surface 21 that connects to a proximal end surface 40 of bone fixation body 16. (*Id.*, 3:13-26, 3:35-37.) Bone fixation body 16 is formed from porous metal structure that extends throughout the entire body. (*Id.*, 3:38-43, 2:6-9; Ex. 1002, ¶13.) The '612 patent also discloses an embodiment in which a protrusion 74 extends from the base portion into the bone fixation body. (Ex. 1001, 5:21-37; Ex. 1002, ¶14.)

In a preferred embodiment, the porous structure of the bone fixation body is made by sintering titanium alloy powder. (Ex. 1001, 4:14, 4:28-48.) The specification also teaches that "[t]he porous structure can be formed by sintering titanium . . . metal beads, metal wire mesh, or other suitable materials, metals, or alloys known in the art." (*Id.*, 3:61-63; Ex. 1002, ¶15.) The specification teaches that the neck body can be made of solid metal and machined "using conventional and known machining techniques" to have the size and shape shown in the figures. (Ex. 1001, 3:27-32, 4:17-19.) In one embodiment, the bone fixation body "simultaneously forms and attaches to the neck body." (*Id.*, 4:49-50.) In an alternative embodiment, these bodies are "fabricated independently and subsequently connected together." (*Id.*, 4:51-55; Ex. 1002, ¶15.)

The porous structure allows bone to grow into the bone fixation body.[2] (Ex. 1001, 1:48-50, 2:19-23, 3:64-65, 4:4-7; Ex. 1002, ¶16.) To promote this bone ingrowth, the porous structure "emulates the size and shape of the porous structure of natural bone." (Ex. 1001, 3:65-4:1.) A preferred embodiment of the porous structure has the following characteristics: "[T]he 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

[2] The femur includes cortical bone and cancellous bone. (Ex. 1002, ¶16.)

microns." (*Id.*, 4:1-4:4.[3]) The specification states that "these ranges are exemplary" and "could be modified, and the resulting hip implant still within the scope of the invention." (*Id.*, 4:8-13.)

The '612 patent includes 19 claims, but this petition only requests review of claims 12, 13, and 15-19. The challenged claims are directed to a two-piece hip implant. (*Id.*, 7:28-50, 7:58-8:63.) Independent claims 12 and 19 recite that the bone fixation body has a "porous metal structure" and further recites that "the porous structure . . . "has a size and a shape that emulate a size and a shape of a porous structure of natural human bone." (*Id.*, at 7:33-34, 7:43-45, 8:24-26, 8:36-38; Ex. 1002 ¶17.)

B. Overview of the Prosecution History

Relevant portions of the prosecution history of the '612 patent and certain related patents are discussed below.

1. The '642 Patent Prosecution

The'612 patent claims priority to the '611 application. (Ex. 1001, title page.) During prosecution of the '611 application, Applicant attempted to

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[3] The disclosed ranges overlap with known pore diameters and porosities of cancellous bone. (Ex. 1002, ¶16, fn.1 (citing Ex. 1016, 954); Ex. 1018, 84:23-86:22; Ex. 1019, 100:8-102:3.)

distinguish U.S. Patent No. 5,522,894 ("Draenert"), which discloses an implant with a porous metal structure formed of spheres, by amending the claims to recite a porous structure having "a size and a shape that emulate a size and a shape of a porous structure of natural human bone." (Ex. 1005, 194-207.) On appeal, the Examiner explained 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." (*Id.*, 105.) According to the Examiner, Draenert disclosed a porous structure that was "intended to behave like or imitate the behavior of bone *by providing pores of a certain size and shape* to provide bone ingrowth." (*Id*. (emphasis added).) Patent Owner ultimately accepted the Examiner's determination that Draenert disclosed the claimed porous structure, and amended the claims to require the bone fixation body to have "a trapezoidal shape in a horizontal cross-sectional view," which led to allowance of the claims. (*Id.*, 16-20, 34-46, 53-64.)

2. The '612 Patent Prosecution

During prosecution of the '7069 application, the Examiner rejected claims based on a combination of references, including Draenert. (Ex. 1006, 37-44.) Rather than addressing the Examiner's assertion that Draenert discloses a bone fixation body having a porous structure with "a size and a shape that emulate a size and a shape of a porous structure of natural human bone to increase the surface

area for attachment to the surrounding bone" (*id.*, 40), Applicant amended the rejected claims to recite "a male protrusion" or "elongated protrusion" that "extends into the bone fixation body" (*id.*, 24-31). The Examiner ultimately found the '612 patent claims allowable

> due to at least the limitation of the bone fixation body being porous throughout, wherein a male protrusion on the neck extends into a porous structure of the bone fixation body such that the porous bone fixation body surrounds an exterior surface of the male protrusion.

(*Id.*, 13.)

C. The '582 IPR

The '612 patent is related to the '582 patent, which claims priority to the same parent applications as the '612 patent. (Ex. 1001, title page; Ex. 1024, title page.) Like the '612 patent claims, certain claims of the '582 patent recite a porous metal structure having "a size and a shape that emulate a size and shape of a porous structure of natural human bone." (Ex. 1024, 15:55-60, 17:1-4.) During the '582 IPR, Patent Owner argued that the porous-metal-structure claim terms additionally "*require emulating the size and shape of the interconnected plates and rods that form trabecular bone*." (Ex. 1008, 10) (emphasis in original).) The Board rejected FMB's implicit construction in its FWD, and instead found that "the broadest reasonable interpretation consistent with the Specification of the porous-metal-structure claim terms is that they require emulating the size and

shape of the porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but they do *not require* emulating the size and shape of the interconnected plates and rods that form trabecular bone." (*Id.*, 12-13 (emphasis in original).)

This petition includes similar grounds to those raised in the '582 IPR. In its FWD, the Board held that Zimmer demonstrated by "a preponderance of the evidence that claims 1-5, 8-11, 14, 15, and 17-20 [of the '582 patent] are unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman and Rostoker." (Ex. 1008, 36.) The Board found that "the combination of Zolman and Rostoker teaches a porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone" and that "Rostoker discloses values for pore size and porosity within the preferred ranges taught by the '582 Patent for ingrowth of cancellous and cortical bone spicules." (*Id.*, 24.) The Board also held that Zimmer demonstrated by "a preponderance of the evidence that 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." (Ex. 1008, 46.) The Board found that "a PHOSITA would have been motivated to use Bobyn's porous tantalum biomaterial in Zolman's porous pad in order to obtain the advantages of porous tantalum as taught by Bobyn, such as increased porosity and improved bone ingrowth in comparison with conventional porous bone-fixation materials." (*Id.*, 42.)

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the art ("a PHOSITA") 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.[4, 5]

VIII. CLAIM CONSTRUCTION

A claim in an unexpired patent in an IPR receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). For purposes of this proceeding, the claims of the '612 patent should be given their broadest reasonable interpretation ("BRI"). Under this standard, Petitioner provides constructions for the terms identified below. The remaining terms should be interpreted in accordance with their plain and ordinary meaning under the BRI standard.[6]

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[4] The parties agreed to this level of ordinary skill in the '582 IPR. (Ex. 1008, 8.)

[5] Petitioner submits the declaration of Dr. Timothy Harrigan (Ex. 1002), an expert in the field of the '612 patent.

[6] Petitioner notes that district courts apply a different claim construction standard and reserves its rights to make arguments based on that standard in district court.

A. "Porous-Metal-Structure" Claim Term

Independent claims 12 and 19 recite a "porous metal structure" that "has a size and a shape that emulate a size and a shape of a porous structure of natural human bone" ("the porous-metal-structure claim term"). (Ex. 1001, 7:43-45, 8:36-38.) This term should be construed to require "emulating the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but they do not require emulating the size and shape of the interconnected plates and rods that form trabecular bone."[7] The Board previously adopted this construction for this same claim term in the '582 IPR. (Ex. 1008, 12-13).

The proposed construction is consistent with the plain meaning of the claim language. The porous-metal-structure claim terms in claims 12 and 19 simply require "***a*** porous metal structure" that "has ***a*** size and ***a*** shape that emulate ***a*** size and ***a*** shape of ***a*** porous structure of natural human bone." (Ex. 1001, 7:34, 7:44-45, 8:37-38) By using the indefinite article "a" in this context, the claim language

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Moreover, Petitioner does not concede that the challenged claims are not invalid under other sections of the Patent Act.

[7] In the '582 IPR, the Board seperately construed the terms "porous" and emulate." (Ex. 1008, 9, fn.6; *see also* Ex. 1014, 744 (defining "emulate" to mean "imitate").)

specifies that any aspect of the porous metal structure can "emulate" natural human bone, and not just the size and shape of the struts forming the pores in a porous structure, as FMB argued unsuccessfully in the '582 IPR. For example, the claim terms would be satisfied by any structure in the porous metal structure that emulates the size and shape of natural human bone, such as structure that forms the pores in such a structure, which can be measured by pore diameter, porosity, and intersection diameter. (Ex. 1008, 11-13.) The Examiner had a similar understanding of the plain meaning of this claim language during prosecution of the '611 application, finding that the claim limitation was met by a prior art structure that formed pores of a certain size and shape that emulated the size and shape of bone. (Ex. 1005, 105.)

This interpretation is also consistent with the specification, which discloses a hip implant seeking to improve the design of prior hip implants by providing a porous structure that "readily accepts and encourages surrounding bone to grow into and even through the body of the implant." (Ex. 1001, 2:31-33.) The specification states that "the geometric configuration of the porous structure should encourage natural bone to migrate and grow into and throughout the entire body 16." (*Id.*, 4:4-7.) To that end, the specification generally describes a porous structure of bone fixation body 16 that "is adapted for the ingrowth of cancellous

and cortical bone spicules" by "emulat[ing] the size and shape of the porous structure of natural bone." (*Id.*, 3:64-4:1.)

The specification also specifically characterizes the porous structure based on pore diameter, porosity, and intersection diameter. (*Id.*, 4:1-4.) In a preferred embodiment, the specification discloses a porous structure with the following size and shape: "Preferably, 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." (*Id.*)[8] These ranges correspond to the shape and size of pores in natural human bone. (Ex. 1002, ¶16, fn.1 (citing Ex. 1018, 84:23-86:22; Ex. 1019, 100:8-102:3.) According to the specification, "these ranges are exemplary" and "could be modified, and the resulting hip implant still within the scope of the invention." (*Id.*, 4:8-13.) Thus, the specification supports construing the porous-metal-structure claim terms to encompass structures that emulate the size and shape of a

[8] Patent Owner's declarant, Dr. Helmus, testified that the specification's reference to pore diameter implies the shape of the structure forming the pores, *i.e.*, shapes measurable by diameter such as circles and ovals. (Ex. 1018, 87:6-21.)

porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter.

Patent Owner, in the '582 IPR, alleged that porous-metal-structure claim terms require emulating the size and shape of the interconnected plates and rods that form cancellous (also known as trabecular) bone. (Ex. 1008, 10.) Patent Owner's focus on cancellous bone is inconsistent with the broader recital of "natural human bone" in the claims and the '612 specification, which does not even mention "interconnected plates and rods that form trabecular bone."[9] (Ex. 1008, 12.) FMB's requirement of "interconnected plates and rods" is also contrary to the specification's broad disclosure that the porous structure "can be formed by sintering titanium, titanium alloy powder, metal beads, metal wire mesh, or other suitable materials, metals, or alloys known in the art" (Ex. 1001, 3:61-63), which FMB has previously argued would not form "interconnected plates and rods" (Ex. 1008, 23-24). For the reasons discussed above, the Board should continue to apply its claim construction from the '582 IPR. (Ex. 1008, 12-13 (emphasis in original).)

B. Separate Fabrication

Claim 13 recites that "the bone fixation body . . . is bonded to the neck body after being *formed separately* from the neck body." (Ex. 1001, 7:46-50 (emphasis

[9] Indeed, the '612 patent does not mention plates, rods, or cancellous bone.

added).) Claim 19 recites that these bodies are "fabricated separately." (*Id.*, 8:48-52.) In the '582 IPR, Patent Owner proposed, and the Board accepted, that the BRI of a similar "fabrication" step requires that fabrication of the bone fixation body and the neck body must be performed independently from each other. (Ex. 1024, 15:55-56; Ex. 1008, 17-18.) The Board should adopt this construction for the separate fabrication terms of claims 13 and 19. This construction is consistent with the specification's disclosure that the neck and bone fixation bodies can be fabricated independently and subsequently connected together. (Ex. 1001, 4:51-55.)

IX. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY UNDER THE BRI

A. Overview of Prior Art

1. *Zolman*

Zolman discloses a method of constructing a prosthetic implant "suitable for use as a femoral component for a hip prosthesis." (Ex. 1009, Title, 1:11-15; Ex. 1002, ¶21.) In an exemplary embodiment, a porous pad 26 is wrapped around a stem portion 20 of femoral component 10 to form a hip implant. (*See, e.g.*, Ex. 1009, Abstract, 2:23-26, 3:53-54, 4:33-36, Figs. 1-6.) *Zolman* teaches that porous pad 26 may be formed of "any suitable porous material," and that "[o]ne such suitable material is the fiber metal structure disclosed in U.S. Patent No. 3,906,550

to Rostoker." *(Id.,* 4:12-24; Ex. 1002, ¶22.) An embodiment of *Zolman*'s implant and its porous pad 26 are shown below:

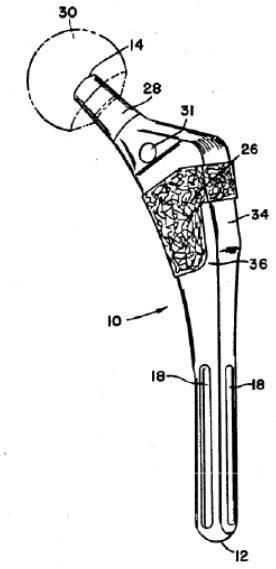

FIG. 1

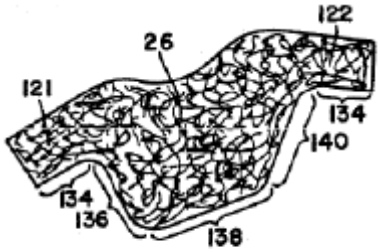

FIG. 11

(Ex. 1009, Figs. 1, 11, 2:58-59, 3:13-14.)

As described in *Zolman*, porous pad 26 is preferably formed first as a substantially flat sheet and is then wrapped around stem portion 20 into a final shape conforming to the shape of stem portion 20. (*See, e.g., id.*, Abstract, 2:44-49, 4:29-41, 4:46-58.) Porous pad 26 is positioned securely in a recess 74 in stem portion 20 which corresponds to the wrapped shape of pad 26. (*Id.*, 5:13-16, 6:44-46, Fig. 6; Ex. 1002, ¶23.) Porous pad 26 is then bonded to stem portion 20 by diffusion bonding, sintering, or "other suitable bonding methods." (Ex. 1009, 6:39-54.) *Zolman* also discloses that porous pad 26 can be formed into its final shape separately on a mandrel, which has the same shape as the implant, removed

from the mandrel, and then placed onto stem portion 20 and bonded. (*Id.*, 7:1-14; Ex. 1002, ¶24.) *Zolman* states that porous pad 26 "can be shaped to conform to any desirable and suitable implant stem or fixation surface configuration" and discloses that, in one embodiment, a proximal portion of stem portion 20 has a non-circular cross-section. (Ex. 1009, 5:16-21, Figs. 5-6; Ex. 1002, ¶25.)

2. *Rostoker*

Rostoker discloses an implant with "[a]n open-pore material" that allows bone ingrowth and "should provide ideal skeletal fixation." (Ex. 1010, title, Abstract, 1:51-52; Ex. 1002, ¶26.) The porous material is formed by first kinking wire into a sinusoidal pattern, cutting that wire into short fibers, and molding and sintering those fibers into a porous structure having interconnecting pores. (Ex. 1010, 2:21-41, 4:22-27, 5:16-18; Ex. 1002, ¶27.) An embodiment of the fiber metal structure is show below:

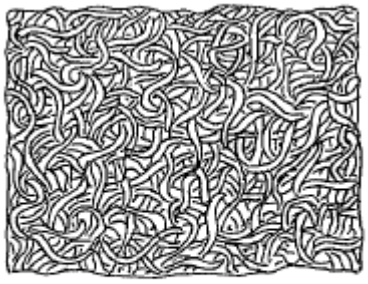

FIG. 4

(Ex. 1010, Fig. 4, 2:67-68.)

Rostoker teaches that by forming its porous structure with interconnected metal fibers, "the range of pore sizes can be readily controlled" and "the pores are interconnecting and remain so after sintering." (*Id.*, 2:35-41; *see also id.*, 2:12-18; Ex. 1002, ¶28.) "Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." (Ex. 1010, 2:42-44.) Further, "[s]ince the pore size can be readily controlled . . . the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted." (*Id.*, 2:48-52.)

Rostoker teaches that "[t]he largest principal dimension of the pores is approximately equal to the wire diameter when the void content is about 50 percent." *(Id.,* 5:21-24.) *Rostoker* discloses using wire with a range of diameters from 0.013 centimeters (130 μm) to 0.030 centimeters (300 μm). (*Id.*, 5:14-16; Ex. 1002, ¶29.) Moreover, the porous structure "may be molded having void or a porosity of 40 to 50 percent per unit area." (Ex. 1010, 5:6-8.)

3. *Bobyn*

Bobyn studies bone ingrowth in a porous metal structure formed of a tantalum biomaterial for use in reconstructive orthopedics and other surgical disciplines. (Ex. 1011, 907; Ex. 1002, ¶¶30-31.) The porous tantalum material was fabricated by coating a pre-formed carbon skeleton with tantalum. (*Id.*, 907-8.) While fiber-metal coatings have a porosity of 40% to 50%, *Bobyn*'s tantalum

material was "75% to 80% porous by volume" and had "a repeating arrangement of slender interconnecting struts which form[] a regular array of dodecahedron-shaped pores." (Ex. 1011, 907, 912.) Based on animal studies, *Bobyn* determined that "[t]his porous tantalum biomaterial has desirable characteristics for bone ingrowth." (*Id.*, 907.) *Bobyn*'s tantalum material has a structure similar to cancellous bone. (Ex. 1002, ¶¶ 31-34.)

According to *Bobyn*, tantalum "is a strong, ductile metal with excellent corrosion resistance" that was "used for a wide variety of implants." (Ex. 1011, 913.) Moreover, the tantalum biomaterial has properties allowing it to "be made into complex shapes and used either as a bulk implant or as a surface coating." (*Id.*, 907; *see also id.*, 913.) For example, *Bobyn* states that "[t]he material could be used as a backing for direct compression moulding of polyethylene-bearing components or as a fixation surface on an implant substrate." (*Id.*, 913.) *Bobyn* concludes that the material "offers interesting potential for orthopedic reconstructive procedures." (*Id.*; Ex. 1002, ¶35.)

4. *Averill*

Averill discloses a hip prosthesis 10 having a stem 12 that includes a tapered portion 22 and a cylindrical portion 26. (Ex. 1012, 5:5-10; 5:21-29, Fig. 1; Ex. 1002, ¶¶36-37.) *Averill* discloses that Figures 2 and 3 illustrate cross-sections of stem portion 12 at lines 2—2 and 3—3 of Figure 1, respectively. (*Id.*, 5:30-32,

Figs. 1-3.) *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.*, 5:34-39.)

B. Ground 1: Claims 12, 13, and 15-19 are Obvious Based on *Zolman* and *Rostoker*

The combination of *Zolman* and *Rostoker* disclose each and every element of claims 12, 13, and 15-19. (Ex. 1002, ¶39.) *Zolman* discloses or suggests all of the claimed features except for the porous-metal-structure claim terms. *Zolman*, however, expressly discloses fabricating porous pad 26 from *Rostoker*'s fiber metal mesh, which discloses the porous-metal-structure claim terms. (Ex. 1009, 4:12-15; *See infra* Sections IX.B.1.vii, IX.B.7.vii.)

1. Claim 12

i. [12.a] "A hip implant, comprising:"

To the extent the preamble is limiting, *Zolman* discloses a hip implant "suitable for use as a femoral component for a hip prosthesis." (Ex. 1009, 1:11-15, 2:58-62, 3:33-35, Figs. 1-6; *see also infra* Sections IX.B.1.ii-vii; Ex. 1002, ¶¶40-41.)

ii. [12.b] "a neck body having a proximal end that connects with an acetabular component, having a distal end surface with an elongated protrusion that extends outwardly therefrom, and being formed of solid metal; and"

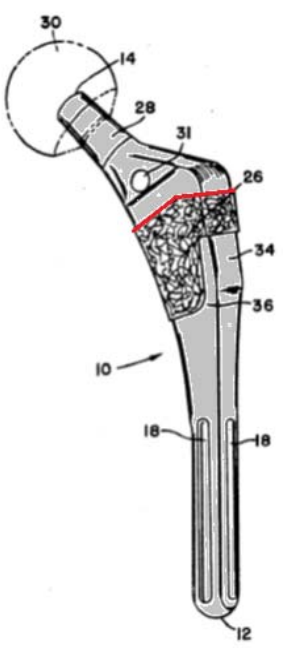

FIG. 1

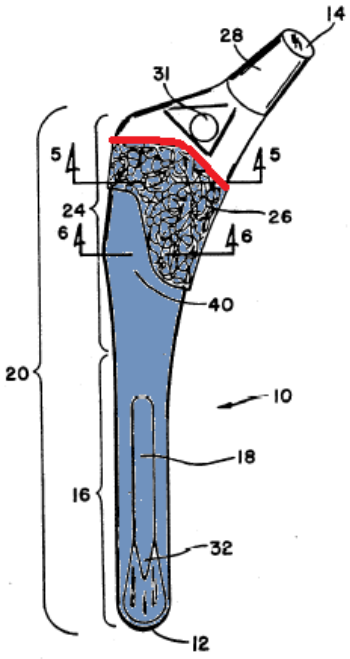

FIG. 2

Zolman discloses a structure 10 (shaded in grey) formed of solid titanium metal having a neck 28, a base portion with aperture 31, and a stem portion 20 (collectively referred to hereinafter as "neck body"). (Ex. 1009, 3:54-62, 4:24-27, Figs. 1-4; Ex. 1002, ¶41.) Neck 28 is located at a proximal end 14 of the neck body and "is adapted to carry a ball 30 shown in phantom lines in FIG. 1." (*Id.*, 3:44-51, 3:56-59, Fig. 1.) A PHOSITA would have understood ball 30 to be the claimed "acetabular component" because is adapted to connect to neck 28 and it cooperates with an acetabulum or acetabular prosthetic member. (*Id.*, 3:45-51; Ex. 1002, ¶42.)

Zolman's neck body has a distal end surface (annotated in red) with stem portion 20, *i.e.*, the claimed "elongated protrusion" (shaded in blue), extending

outwardly therefrom.[10] [11] (*See* Ex. 1009, 3:54-59, Figs. 1-4; Ex. 1002, ¶42.) The distal end surface is formed by a recess 74 in proximal portion 24 of stem portion 20, corresponds to the distally-facing surface of the upper lip of recess 74, and encompasses the surface area between the outer edge of the lip and where the stem

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[10] In the '642 IPR decision denying institution, the Board stated that Petitioner did not sufficiently explain why the location marked in red in the annotated Figures corresponds to the claimed surface of the neck body. Petitioner explains herein why the identified structure is the "distal end surface of the neck body," as required by the challenged claims. IPR2016-00011, Paper No. 8, at 10-11. To be sure, Petitioner is not changing the structure relied upon in the '642 IPR, and thus we are not using the Board's previous decision as a post-hoc roadmap. Petitioner understands that the Board determined in the '642 IPR that Petitioner's explanation relating to the identified "distal end surface" was insufficient, rather than finding that the identified structure was not "a distal end surface of the neck body," as required by the '642 challenged claims.

[11] Claim 14 of the '582 patent discloses "forming a neck body having . . . a distal end surface with a protrusion that extends outwardly therefrom." Petitioner's arguments that *Zolman* teaches this feature were unrebutted in the '582 IPR.

portion 12 extends outwardly. (*See* Ex. 1009, 5:13-16, 6:44-48, Figs. 1-6; *see also id.*, Figs. 14, 15 (illustrating the lip of a recess in an alternative embodiment); Ex. 1002, ¶42.) A PHOSITA would have recognized that this surface defines the distal end of the portion of the neck body that extends outwardly from the intramedullary canal of the femur because it engages porous pad 26, which is designed to fit within the proximal portion of the femur adjoining the resected surface of the bone. (*See* Ex. 1009, 3:45-51, Figs. 1-6; Ex. 1002, ¶42.) Moreover, a PHOSITA would have recognized that the distally-facing surface of the upper lip of recess 74 is the distal end surface of a base portion of the neck body which functions to position ball 30 connected to proximal end 14 relative to stem portion 20. (Ex. 1009, 3:45-59; Ex. 1002, ¶42 (citing Ex. 1023, 320, 321, 330).) This is confirmed by the fact that stem portion 20, *i.e.*, the claimed "elongated protrusion," extends outwardly from the distal end surface and has a tapering shape for insertion into the intramedullary canal of a patient's femur. (Ex. 1009, 3:44-51, 3:54-56, Figs. 1-4; Ex. 1002, ¶42.)

iii. [12.c] "a bone fixation body having an elongated tapering shape and"

Zolman discloses a porous pad 26, identified in annotated Figure 2, having an elongated tapering shape. (*See, e.g.*, Ex. 1009, 3:53-54, 5:5-11, Figs. 1-4). *Zolman* teaches that the porous nature of *Zolman*'s porous pad 26 allows "bony ingrowth" to "biologically affix or further secure the implant in the bone." (*Id.*,

1:20-24; Ex. 1002, ¶43.) *Zolman* teaches that porous pad 26 is a separate structure or body from stem portion 20. (Ex. 1009, 4:33-34.) Porous pad 26 is cut from a porous material having "any desired thickness or dimensions" and formed, in one embodiment, about a mandrel into a final shape that is attached to stem portion 20. (Ex. 1009, 4:33-34, 4:46-49, 7:1-14.) *Zolman* states that *Rostoker* discloses a suitable porous material for pad 26, and *Rostoker* teaches a porous structure that allows bone to "penetrate for a substantial distance" to "provide a secure connection." (Ex. 1009, 4:12-14; Ex. 1010, 2:42-44; Ex. 1002, ¶43.)[12] For at least these reasons, *Zolman*'s pad is a bone fixation body. (Ex. 1002, ¶43.)

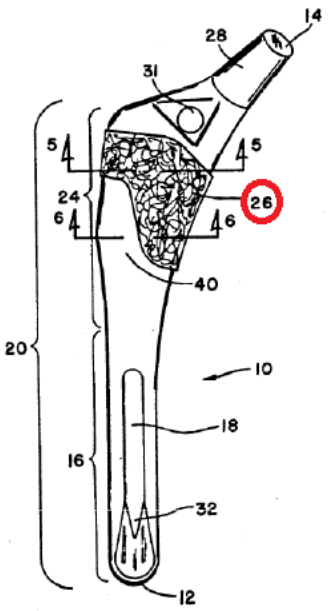

FIG. 2

iv. [12.d] "[a bone fixation body] being formed as a porous metal structure"

Zolman discloses that porous pad 26 can be made from "any suitable porous material" and "particularly fibrous (wire-type) porous structures." (Ex. 1009, 4:21-

[12] As the Board recognized in the '582 IPR, porous pad 26 is structurally and functionally different than the thin porous coatings discussed in the background of the '582 and '612 patents. (Ex. 1008, 31-32.)

26.) *Zolman* expressly discloses that one such suitable material is the structure disclosed in *Rostoker* which is formed of kinked fiber metal. (Ex. 1009, 4:12-14; Ex. 1010, 2:21-41, Fig. 4.) In one embodiment, *Zolman* teaches that "kinked titanium fiber metal[] is press formed into a sheet" and "prebonded" in a vacuum to form a porous metal structure. (Ex. 1009, 4:46-56, Fig. 9; Ex, ¶44.) Porous pad 26 is cut from the sheet and has a porous metal structure. (Ex. 1009, 4:56-58, Figs. 9-11; Ex. 1002, ¶44.)

v. [12.e] "[a bone fixation body] that includes a proximal end that engages the distal end surface of the neck body at an interface,"

Zolman discloses that porous pad 26 is positioned in recess 74 "which corresponds to the wrapped shape of the pad 26." (Ex. 1009, 5:13-16, 6:44-46.) As discussed *supra* at Section IX.B.1.ii, the distally-facing surface of the upper lip of recess 74 corresponds to the claimed "distal end surface." A proximal end of porous pad 26 (the end closest the hip joint) engages the distal end surface when porous pad 26 is fitted into the correspondingly-shaped recess to hold pad 26. (Ex. 1009, 5:13-16, 6:44-46, Figs. 1-4). The claimed "interface" is the area of *Zolman*'s hip implant where the distal end surface engages the proximal end of porous pad 26. (Ex. 1002, ¶45.)

vi. [12.f] "wherein the elongated protrusion of the neck body forms a core for the bone fixation body and tapers and extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the elongated protrusion that extends into the bone fixation body, and"

In one embodiment, *Zolman* discloses that porous pad 26 is shaped about a mandrel that is shaped like the implant into a final contoured shape before removing porous pad 26 from the mandrel and attaching it to stem portion 20 ("elongated protrusion"). (Ex. 1009, 7:1-14.) A PHOSITA would have known that the pad formed on the mandrel would have an opening. (*See* Ex. 1009, 7:10-12, Ex. 1002, ¶46.) *Zolman* discloses that porous pad 26 completely encircles proximal portion 24 of stem portion 20, and that stem portion 20 forms a core for porous pad 26. (Ex. 1009, 3:53-54, 4:5-12, 4:41-45, Figs. 1-6; Ex. 1002, ¶46.) Stem portion 20 extends into an opening of porous pad 26 and tapers to distal end 12 of the implant. (*See* Ex. 1009, 3:53-56, Figs. 1-4.) Figure 5, which is a cross section at line 5─5 in Figure 2, shows how stem portion 20 (shaded in blue) extends into porous pad 26, how stem portion 20 forms a core for porous pad 26, and how the porous metal structure of porous pad 26 surrounds and engages an exterior surface of a proximal portion 24 of stem portion 20. (*Id.*, 2:63-64, Figs. 2, 5; Ex. 1002, ¶46.)

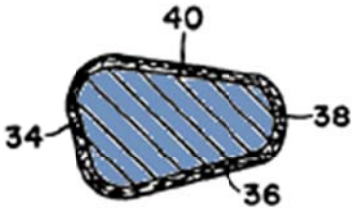

FIG. 5

vii. [12.g] "wherein 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."

As discussed above, *Zolman* discloses that porous pad 26 is formed of a porous metal structure. *See supra* Section IX.B.1.iv. *Zolman* discloses fabricating porous pad 26 from "any suitable porous material" and "particularly fibrous (wire-type) porous structures." (Ex. 1009, 4:21-26.) *Zolman* expressly discloses that one such suitable material is the fiber metal structure disclosed in *Rostoker*. (*Id.*, 4:12-15.)

Rostoker discloses a porous fiber metal structure formed by molding and sintering short metal fibers. (Ex. 1010, 2:21-23.) The fiber metal structure "is . . . open-pored so that the bone and tissue into which the prosthetic device is implanted will grow into such fiber metal structure." (*Id.*, Abstract; *see also id.*, 3:28-34.) *Rostoker* states that its fiber metal porous structure has "pores [that] 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.*, 2:40-44; *see also id.*, 5:16-18.) *Rostoker* also states that "the pore size can be readily controlled" and thus "the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted." (*Id.*, 2:48-52.)

Rostoker teaches the porous-metal-structure claim terms as its porous fiber metal structure can be fabricated with pore diameters and porosities that fall within

the ranges of pore diameters and porosities disclosed in the ’612 patent, which fall within the known ranges of diameters and porosities for cancellous bone and “encourage natural bone to migrate and grow into and throughout the entire body 16.” (Ex. 1001, 4:1-4; Ex. 1002, ¶47 (citing Ex. 1016, 954).) 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 (130 μm) or 0.03 cm (300 μm). (*Compare* Ex. 1010, 5:14-16, 5:21-24 *with* Ex. 1001, 4:1-3.) *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. 1010, 5:6-8 *with* Ex. 1001, 4:1-3.) Therefore, *Rostoker* discloses the porous-metal-structure claim terms under its BRI. (*See supra* Section VIII.A; Ex. 1002, ¶47.) Indeed, the Board found that *Rostoker* “discloses values for pore size and porosity within the preferred ranges . . . for ingrowth of cancellous and cortical bone” disclosed in the specification of the ’582 patent, which is related to the ’612 patent. (Ex. 1008, 24.) The Board also concluded that the combination of *Zolman* and *Rostoker* disclosed the same porous-metal-structure claim terms in the ’582 IPR. (*See* Ex. 1008, 24.)

Given *Zolman*’s explicit teachings to use *Rostoker*, fabricating *Zolman*’s porous pad 26 from the fiber metal structure of *Rostoker* would have been obvious

to a PHOSITA.[13] (Ex. 1009, 4:12-15; Ex. 1002, ¶47). A PHOSITA would have been motivated to fabricate *Zolman*'s porous pad 26 to have a porous structure that "emulates" natural human bone, as taught in *Rostoker*, to increase the strength of the attachment of the implant to the surrounding bone. (Ex. 1010, 2:40-44; 5:16-18; Ex. 1002, ¶47; *see also* Ex. 1008, 22.) A porous structure that is conducive to bone formation and enables tissue infiltration facilitates a strong attachment and long-term stability of the implant. (Ex. 1002, ¶47; Ex. 1009, 1:16-23; Ex. 1010, 1:50-52).) Fabricating porous pad 26 from *Rostoker*'s fiber metal structure would have amounted to nothing more than a simple substitution of known porous materials that would yield nothing more than predictable results, *i.e.*, bone ingrowth. (Ex. 1002, ¶47; *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).)

2. Claim 13

i. [13.a] "The hip implant of claim 12, wherein the bone fixation body has one of the group consisting of a polygonal and noncircular closed shape in a horizontal cross-sectional view of the bone fixation body and"

[13] In the '582 IPR, there was no dispute that a PHOSITA would have combined the teachings of *Zolman* and *Rostoker*. (*See* Ex. 1008, 34.)

Zolman discloses that porous pad 26 is "shaped to conform to any desirable and suitable implant stem or fixation surface configuration" and can have "any desirable configuration." (Ex. 1009, 4:29-30, 5:9-11, 5:16-18.) *Zolman* discloses an embodiment in which proximal portion 24 has a noncircular cross-section, and in particular, a polygonal shape. (*Id.*, 5:19-21, Fig. 5; Ex. 1002, ¶¶48, 49.) When porous pad 26 is shaped to conform to proximal portion 24, as shown in Figure 5, porous pad 26 has a polygonal shape in a horizontal cross-sectional view of the pad. (Ex. 1009, 3:53-54, 4:36-41, Fig. 5; Ex. 1002, ¶49.)

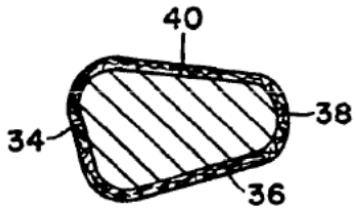

FIG. 5

ii. [13.b] "[the bone fixation body] is bonded to the neck body after being formed separately from the neck body."

As the Board found, *Zolman* discloses that porous pad 26 is bonded to *Zolman*'s neck body after pad 26 is formed separately on a mandrel and removed from the mandrel for attachment to *Zolman*'s neck body. (Ex. 1009, 7:1-14[14]; Ex. 1008 at 27.) *Zolman* teaches that porous pad 26 is bonded to stem portion 20 by

[14] Patent Owner's declarant, Helmus, conceded that *Zolman* discloses separately fabricating porous pad 26 and attaching porous pad 26 to *Zolman*'s neck body after porous pad 26 is separately fabricated. (Ex. 1018, 130:22-131:5, 139:23-140:3.)

diffusion bonding or other suitable bonding methods. (*See* Ex. 1009, 6:46-54, 7:12-14; *see also* Ex. 1002, ¶50.).

3. Claim 15

i. [15.a] "The hip implant of claim 12, wherein the distal end surface of the neck body has a noncircular closed shape,"

As discussed *supra* at Section IX.B.1.ii, the distally-facing surface of the upper lip of recess 74 corresponds to the claimed "distal end surface." The distal end surface extends along the entire circumference of stem portion 20, and thus has a closed shape that matches the shape of this portion of stem portion 20. (*See, e.g.*, Ex. 1009, 5:13-16, 4:41-45, Figs. 1-4; Ex. 1002, ¶52.) *Zolman* discloses that the shape of the portion of *Zolman*'s neck body having the distal end surface has "an asymmetric noncircular cross-section as shown in FIGS. 5 and 6." (Ex. 1009, 5:19-21.) Therefore, *Zolman* teaches that the distal end surface of the neck body has a noncircular closed shape. (Ex. 1002, ¶52.)

ii. [15.b] "the proximal end of the bone fixation body has a noncircular closed shape, and"

As discussed *supra* at Section IX.B.1.v, *Zolman*'s porous pad 26 has a proximal end. *Zolman* discloses that porous pad 26 has a noncircular closed shape as it completely encircles and conforms to proximal portion 24 of stem portion 20, which has "an asymmetric noncircular cross-section." (Ex. 1009, 3:53-56, 4:41-45, 5:16-21, Figs. 1-5; Ex. 1002, ¶53.) Figure 5, which is a cross section at line

5─5 in Figure 2, shows that porous pad 26 has a non-circular closed shape, and Figures 1-4 show that the proximal end of porous pad 26 has a noncircular closed shape. (Ex. 1002, ¶53.)

iii. [15.c] "the solid metal of the noncircular closed shape of the neck body interfaces with the porous metal structure of the noncircular closed shape of the bone fixation body at the interface."

As discussed *supra* at IX.B.3.i, the distal end surface of *Zolman*'s solid metal neck body has a noncircular closed shape. As discussed *supra* at IX.B.3.ii, *Zolman* discloses that the proximal end of porous pad 26 has a noncircular closed shape. Further, as discussed *supra* at IX.B.1.v, the claimed "interface" is the area where the distally-facing surface of the upper lip of recess 74, *i.e.*, the claimed "distal end surface," engages the proximal end of porous pad 26. As shown in Figures 1-6, once porous pad 26 is received in recess 74, the noncircular closed shape of the proximal end of porous pad 26 engages the solid metal of the noncircular closed shape of the neck body's distal end surface at the interface. (Ex. 1009, 3:62-65, 5:13-16, 6:44-48, Figs. 1-6; Ex. 1002, ¶¶51, 54.)

4. Claim 16

i. [16.a] "The hip implant of claim 12, wherein the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the bone fixation body, and"

Zolman teaches "pad[] 26 can be shaped to conform to any desirable and suitable . . . surface configuration." (Ex. 1009, 5:16-18). *Zolman* teaches that stem

portion 20 has an "asymmetric noncircular cross-section" having a lateral side 34, a posterior side 36, a medial side 38, and an anterior side 40 forming a shape like or similar to a trapezoid. (Ex. 1009, 4:3-5, 5:19-21; Ex. 1002, ¶¶ 55, 56.) Figure 5 is a cross-sectional view of stem portion 20 along line 5—5 in Figure 2. (Ex. 1009, 2:63-64.) As shown in Figure 5, porous pad 26 conforms to stem portion 20 and also has a trapezoidal cross-sectional shape as it is shaped like or similar to a trapezoid.[15] (*Compare id.*, Fig. 5 *with* Ex. 1001, 6:10-11 (describing Fig. 7 as showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶56.)

To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape given that *Zolman* discloses that "pad 26 can be shaped to

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[15] Patent Owner's declarants testified in the '582 IPR that they did not consider porous pad 26 to have a trapezoidal shape in Figure 5. (Ex. 1018 at 195:9-115; Ex. 1019 at 99:3-5.) Patent Owner's declarants, however, testified that a very similar shape shown in Figure 7 of the '582 patent was generally trapezoidal. (Ex. 1018 at 262:11-23; Ex. 1019 at 108:4-9.) Patent Owner's declarant also conceded during the '582 IPR that it would have been obvious to a PHOSITA to make a porous pad with a trapezoidal shape because "it's a pretty easy shape to manufacture, and also to help prevent against rotation of the bone fixation body." (Ex. 1019, 116:11-15.)

conform to any desirable and suitable implant stem or fixation surface configuration." (Ex. 1009, 5:16-18; Ex. 1002, ¶56.) A PHOSITA would have been motivated to make the stem portion 20, and therefore porous pad 26, with a trapezoidal shape in order to fill the intramedullary canal and place porous pad 26 in contact with the surrounding bone for bone ingrowth and load transfer, and to also prevent rotation of the pad relative to the bone. (Ex. 1002, ¶56 (citing Ex. 1023, 333).)

ii. [16.b] "the elongated protrusion includes a polygonal shape in the horizontal cross-sectional view."

Zolman discloses that a proximal portion 24 of stem portion 20 ("the elongated protrusion") has a polygonal shape in the horizontal cross-sectional view. (Ex. 1009, 5:19-21 ("The proximal portion 24 of the stem portion 20 . . . has an asymmetric noncircular cross-section as shown in FIGS. 5 and 6."); *see also id.*, 4:3-5 (describing that proximal portion 24 has four sides).) Figure 5 is a cross-section taken along line 5─5 of Figure 2, and shows the polygonal shape of stem portion 20 in a horizontal cross-sectional view. (*Id.*, 2:63-64, Fig. 5; Ex. 1002, ¶57.)

To the extent the Board finds that *Zolman*'s stem portion 20 does not have the claimed "polygonal shape," it would have been obvious to a PHOSITA to machine *Zolman*'s stem portion 20 to have any one of a number of cross-sectional shapes, including a polygonal shape. (Ex. 1002, ¶57.) A PHOSITA would have

made stem portion 20 with a polygonal shape in a horizontal cross-sectional view to prevent rotation of porous pad 26 relative to the neck body and to prevent the implant from rotating within the femur bone. (Ex. 1002, ¶57 (citing Ex. 1023, 334 (Fig. 7-27).)

5. Claim 17

i. [17.a] "The hip implant of claim 12, wherein the distal end surface of the neck body has a trapezoidal shape,"

As discussed *supra* at Section IX.B.1.ii, the distally-facing surface of the upper lip of recess 74 corresponds to the claimed "distal end surface." *Zolman* discloses that the shape of the portion of *Zolman*'s neck body having the distal end surface has "an asymmetric noncircular cross-section as shown in FIGS. 5 and 6" having a lateral side 34, a posterior side 36, a medial side 38, and an anterior side 40, forming a shape like or similar to a trapezoid. (Ex. 1009, 4:3-5, 5:19-21, Figs. 5, 6; Ex. 1002, ¶59.) Because the distal end surface forms a perimeter around this portion of the neck body, it has a trapezoidal shape consistent with the shape of the neck body. (*See, e.g.,* Ex. 1009, 4:41-45, 5:13-16, Figs. 1-4; Ex. 1002, ¶59.) To the extent the Board finds that the distal end surface does not have the claimed "trapezoidal shape," it would have been obvious to a PHOSITA to make the portion of neck body having the distal end surface with a polygonal shape and, in particular, a trapezoidal shape, for the reasons discussed *supra* at IX.B.4.i. (Ex. 1002, ¶59.)

ii. [17.b] "the proximal end of the bone fixation body has the trapezoidal shape, and"

As discussed *supra* at IX.B.4.i, porous pad 26 ("the bone fixation body") has a trapezoidal shape in a horizontal cross-sectional view. The proximal end of porous pad 26 has a trapezoidal shape, as it conforms to the shape of proximal portion 24 of *Zolman*'s neck body, which is shaped like or resembles a trapezoid. (Ex. 1009, 4:3-5, 5:19-21, Figs. 5, 6; Ex. 1002, ¶60.) Figures 1-4 show that the proximal end has the same trapezoidal shape as the distal end surface, discussed *supra* at IX.B.5.i. To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s porous pad 26 with a trapezoidal shape as discussed *supra* at IX.B.4.i. (Ex. 1002, ¶60.)

iii. [17.c] "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 the interface."

As discussed *supra* at IX.B.5.i, the distal end surface of *Zolman*'s solid metal neck body has a trapezoidal shape. As discussed *supra* at IX.B.5.ii, *Zolman* discloses that the proximal end of porous pad 26 also has the trapezoidal shape. Further, as discussed *supra* at IX.B.1.v, the claimed "interface" is where the distally-facing surface of the upper lip of recess 74 ("the distal end surface") engages the proximal end of porous pad 26. As shown in Figures 1-4, the distal end surface of *Zolman*'s solid metal neck body interfaces with the porous metal

structure at the proximal end of porous pad 26 at the interface. (Ex. 1009, 3:62-65, 5:13-16, 6:44-48, Figs. 1-4; Ex. 1002, ¶¶58, 61.)

6. Claim 18

i. [18.a] "The hip implant of claim 12, wherein the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the bone fixation body, and"

Zolman teaches that porous pad 26 ("bone fixation body") includes a trapezoidal shape in a horizontal cross-sectional view of the pad. (*See supra* Section IX.B.4.i; Ex. 1002, ¶63.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s porous pad 26 with a trapezoidal shape as discussed *supra* at IX.B.4.i.

ii. [18.b] "the elongated protrusion includes a cylindrical shape in the horizontal cross-sectional view."

To the extent a cross-sectional shape can be cylindrical, the combination of *Zolman* and *Rostoker* teaches a stem portion 20 having a cylindrical shape in a horizontal cross-sectional view. (Ex. 1002, ¶¶62, 64.) *Zolman* teaches that stem portion 20 has a cylindrical shape in a horizontal cross-sectional view at distal end 12. (*See* Ex. 1009, Fig. 1 (annotated to the right); Ex.

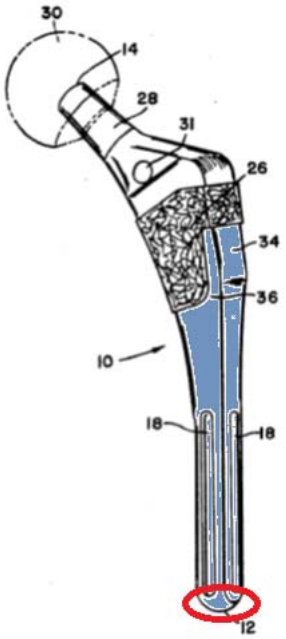


FIG. 1

1002, ¶64.) In addition, it would have been obvious to form distal portion 16 of stem portion 20 to have a cylindrical shape in a horizontal cross-sectional view. (Ex. 1002, ¶64.) *Rostoker*, for example, discloses a femur prosthesis 12 that includes a rod 24 that has a cylindrical (circular) shape in a horizontal cross-section. (Ex. 1010, 3:11-20, Fig. 1.) It would have been obvious to a PHOSITA to machine *Zolman*'s stem portion 20 to have any one of a number of cross-sectional shapes, including a cylindrical shape in a horizontal cross-section, as taught by *Rostoker*. (*KSR,* 550 U.S. at 416; Ex. 1002, ¶64.) A PHOSITA would have shaped the distal portion 16 of stem portion 20 to have this configuration to facilitate insertion into the intramedullary canal and distal fixation. (Ex. 1002, ¶64.)

7. Claim 19

i. [19.a] "A hip implant, comprising:"

As discussed above for claim 12, *Zolman* discloses a hip implant. (*See supra* Section IX.B.1.i; *see also infra* Sections IX.B.7.ii-xv; Ex. 1002, ¶¶65, 66.)

ii. [19.b] "a neck body formed of solid metal, having a proximal end with a tapering cylindrical configuration that connects with an acetabular component, and having a distal end surface with an elongated protrusion that extends outwardly therefrom; and"

As discussed above for claim 12, *Zolman* discloses a femoral component 10 ("a neck body") formed of solid metal, *e.g.*, titanium, having a neck 28 at a proximal end 14 that connects with a femoral ball 30 ("an acetabular component").

(*See supra* Section IX.B.1.ii; Ex. 1002, ¶67.) As shown in the different views of Figures 1-4, neck 28 has a tapering cylindrical configuration. (*See, e.g.*, Ex. 1009, Figs. 1-4; Ex. 1002, ¶67 (identifying the taper); 1023, 320.) As also discussed above for claim 1, *Zolman*'s neck body has a distal end surface with a stem portion 20 ("an elongated protrusion") that extends outwardly therefrom. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶67.)

iii. [19.c] "a bone fixation body having an elongated tapering shape without a solid metal substrate and"

As discussed above for claim 12, *Zolman* discloses a porous pad 26 ("a bone fixation body") having an elongated tapering shape. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶68.) *Zolman* teaches that porous pad 26 is made of a porous material that "is press formed into a sheet" and "prebonded" in a vacuum to form a porous metal structure. (Ex. 1009, 4:46-56, Fig. 9.) Porous pad 26 is cut from the sheet and has a completely porous metal structure without a solid metal substrate. (Ex. 1009, 4:56-58, Figs. 9-11; Ex. 1002, ¶68.)

iv. [19.d] "[a bone fixation body] being formed as a porous metal structure"

As discussed above for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") is formed as a porous metal structure and can be formed from the porous fiber metal structure of *Rostoker*. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶69.)

v. [19.e] "[a bone fixation body] that includes a proximal end that engages the

distal end surface of the neck body at an interface,"

As discussed above for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a proximal end that engages *Zolman*'s neck body at the claimed "interface," which is the area of *Zolman*'s hip implant where the distal end surface of the neck body engages the proximal end of porous pad 26 when porous pad 26 is held securely against stem portion 20 within recess 74. (*See supra* Section IX.B.1.v; Ex. 1002, ¶70.)

vi. [19.f] "wherein the elongated protrusion of the neck body forms a core for the bone fixation body and tapers and extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the elongated protrusion that extends into the bone fixation body,"

As discussed above for claim 12, *Zolman* discloses that stem portion 20 ("the elongated protrusion") forms a core for porous pad 26 ("the bone fixation body"), and tapers and extends into an opening of the pad such that the porous metal structure surrounds and engages an exterior surface of the portion of stem portion 20 that extends into the porous pad 26. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶71.)

vii. [19.g] "wherein the porous metal 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,"

As discussed above for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") can be made from "any suitable porous material," and states

that one suitable material is the fiber metal structure disclosed in *Rostoker*. (*See supra* Section IX.B.1.vii.) *Rostoker* discloses the porous-metal-structure claim terms through a porous metal structure that emulates the size and shape of the porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter. (*See supra* Sections VIII.A; IX.B.1.vii; Ex. 1002, ¶72.) As explained above, it would have been obvious to a PHOSITA to fabricate *Zolman*'s porous pad 26 to have *Rostoker*'s porous structure that "emulates a porous structure of natural human bone" to increase the strength of attachment of the implant to the surrounding bone. (*See supra* Section IX.B.1.vii; Ex. 1002, ¶72.) Modifying *Zolman*'s porous pad 26 to use the fiber metal structure of *Rostoker* would have been an obvious substitution of known porous structures in view of *Rostoker*'s teachings and *Zolman*'s explicit teachings to use *Rostoker*. (*See supra* Section IX.B.1.vii; *KSR*, 550 U.S. at 416; Ex. 1002, ¶72.)

viii. [19.h] "wherein the distal end surface of the neck body has a noncircular closed shape,"

As discussed above for claim 15, *Zolman* discloses that the distal end surface of *Zolman*'s neck body has a noncircular closed shape. (*See supra* Section IX.B.3.i; Ex. 1002, ¶73.)

ix. [19.i] "the proximal end of the bone fixation body has a noncircular closed shape, and"

As discussed above for claim 15, *Zolman* discloses that the proximal end of porous pad 26 ("the bone fixation body") has a noncircular closed shape. (*See supra* Section IX.B.3.ii; Ex. 1002, ¶74.)

x. [19.j] "the solid metal of the noncircular closed shape of the neck body interfaces with the porous metal structure of the noncircular closed shape of the bone fixation body at the interface,"

As discussed above for claim 15, *Zolman* discloses that the solid metal of the noncircular closed shape of *Zolman*'s neck body interfaces with the porous metal structure of the noncircular closed shape of porous pad 26 ("the bone fixation body") at the interface, which is the area of *Zolman*'s hip implant where the distal end surface of *Zolman*'s neck body engages the proximal end of porous pad 26 when porous pad 26 is held securely against stem portion 20 within recess 74. (*See supra* Section IX.B.3.iii; Ex. 1002, ¶75.)

xi. [19.k] "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 16, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a trapezoidal shape in a horizontal cross-sectional view of the pad. (*See supra* Section IX.B.4.i; Ex. 1002, ¶76.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape,"

it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.4.i.

xii. [19.l] "wherein the bone fixation body and the neck body are fabricated separately and subsequently the bone fixation body is bonded from heat to the neck body after the bone fixation body is fabricated separately from the neck body,"

As discussed above for claim 13, *Zolman*'s porous pad 26 ("the bone fixation body") is separately fabricated into a final shape and then attached to *Zolman*'s neck body. (*See supra* Section IX.B.2.ii.) *Zolman* discloses bonding porous pad 26 to *Zolman*'s neck body from heat to attach porous pad 26 to stem portion 20. (Ex. 1009, 6:46-54 (disclosing that "[t]he bonding may be achieved by diffusion bonding the pad to the stem portion by holding the pad securely thereagainst at a sufficient temperature for a sufficient length of time to achieve secure bonding" and that "other suitable bonding methods may be utilized").) Diffusion bonding occurs by applying high pressure in conjunction with high temperatures to weld the components together. (Ex. 1002, ¶77 (citing Ex. 1017, 3:48-59, 4:28-40).)

xiii. [19.m] "wherein the bone fixation body has the elongated tapering shape with a bow shape in a side-view of the bone fixation body,"

As discussed above for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") has the claimed "elongated tapering shape." (*See supra* Section IX.B.1.iii.) As shown in Figure 2, the elongated tapering shape of porous

pad 26 has a bow shape, *i.e.*, a curvature, in a side-view of the pad. (*Compare*, *e.g.*, Ex. 1009, 2:60, Fig. 2 *with* Ex. 1001, 4:56-57, Fig. 1 (depicting the bone fixation body as having a "slight bow"); Ex. 1002, ¶78.)

xiv. [19.n] "wherein the elongated protrusion of the neck body includes a polygonal shape in the horizontal cross-sectional view, and"

As discussed above for claim 16, *Zolman*'s stem portion 20 ("the elongated protrusion") has a polygonal shape in the horizontal cross-sectional view. (*See supra* Section IX.B.4.ii; Ex. 1002, ¶79.) To the extent the Board finds that the porous pad 26 does not have the claimed "polygonal shape," it would have been obvious to make *Zolman*'s porous pad 26 with a trapezoidal shape as discussed *supra* at IX.B.4.ii. (Ex. 1002, ¶79.)

xv. [19.o] "wherein the bone fixation body bonds to the neck body along the interface that includes where the polygonal shape of the elongated protrusion of the neck body engages the bone fixation body."

As discussed *supra* at IX.B.7.xii, porous pad 26 ("the bone fixation body") is bonded to *Zolman*'s neck body. As discussed *supra* at IX.B.7.ii and IX.B.7.xiv, stem portion 20 of *Zolman*'s neck body has a polygonal shape in a horizontal cross-sectional view that extends outwardly from the distal end surface. Figures 1-4 show that *Zolman*'s neck body has the polygonal, non-circular closed shape at the portion of the interface from where stem portion 20 extends outwardly. (Ex. 1009 at Figs. 1-4, Ex. 1002, ¶80.) As discussed *supra* at IX.B.7.x, *Zolman* discloses that the solid metal of the noncircular closed shape of *Zolman*'s neck

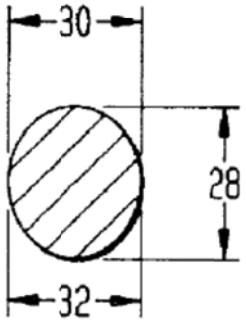
body engages with the porous metal structure of the noncircular closed shape of porous pad 26 ("the bone fixation body") along the portion of the interface where stem portion 20 extends outwardly.

C. Ground 2: Claim 18 is Obvious Based on a Combination of *Zolman*, *Rostoker*, and *Averill*

As discussed above for claim 18, to the extent a cross-sectional shape can be cylindrical, the combination of *Zolman* and *Rostoker* discloses the claimed "cylindrical shape in the horizontal cross-sectional view." (*See supra* Section IX.B.6.ii; Ex. 1002, ¶81.) If the Board finds that *Zolman* in view of *Rostoker* does 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, ¶81.)

Averill discloses a hip prosthesis 10 including a stem 12 having two different shapes: a tapered portion 22 with a proximal locking zone with the geometry shown in Figure 2 and "an almost circular cross-section at line 3—3, (FIG. 3)." (Ex. 1012, 3:4-6, 5:5-10, 5:21-29, Figs. 1-2.) A PHOSITA would have understood the portion of *Averill*'s stem having the circular cross-section to have the claimed "cylindrical shape in the horizontal cross-sectional view." (Ex. 1002, ¶82.) *Averill* also teaches

FIG. 3



that stem 12 includes a cylindrical portion 26. (Ex. 1012, Fig. 1, 5:21-29; Ex. 1002, ¶83.)

In light of *Averill*'s disclosure, a PHOSITA would have appreciated that forming a distal portion of *Zolman*'s stem portion to have "a cylindrical shape in the horizontal cross-sectional view" would have been nothing more than an obvious design choice. (Ex. 1002, ¶84.) A PHOSITA would have understood that a metal stem could be fabricated using well-known techniques to have any one of a number of cross-sectional shapes, including a cylindrical shape in a horizontal cross-section, as evidenced by *Averill*. (Ex. 1012, 6:56-58 (disclosing that stem 12 can be made by "forging, casting and/or machining operations or any other well known technique"); Ex. 1002, ¶84; *KSR,* 550 U.S. at 416.) A PHOSITA would have been motivated to form the stem of the hip implant of *Zolman* and *Rostoker* to have this geometry to facilitate insertion into the intramedullary canal. (Ex. 1002, ¶84.)

D. Ground 3: Claims 12, 13, and 15-19 are Obvious Based on *Zolman* and *Bobyn*

Zolman and *Bobyn* teach or suggest every element of claims 12, 13, and 15-19, including the porous-metal-structure claim terms under Petitioner's construction, *supra* Section VIII.A, and Patent Owner's more narrow interpretation. (Ex. 1002, ¶39.)

1. Claim 12

i. Claim Element 12.a

As discussed in Ground 1 for claim 12, *Zolman* discloses a hip implant. (*See supra* Section IX.B.1.i; *see also* Sections IX.D.1.ii-vii; Ex. 1002, ¶¶ 85-86.)

ii. Claim Element 12.b

As discussed in Ground 1 for claim 12, *Zolman* discloses a femoral component 10 ("a neck body") formed of solid metal having a proximal end with a neck 28 that connects with a femoral ball 30 ("an acetabular component"), and having a distal end surface with a stem portion 20 ("an elongated protrusion") that extends outwardly therefrom. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶87.)

iii. Claim Element 12.c

As discussed in Ground 1 for claim 12, *Zolman* discloses a porous pad 26, which corresponds to the claimed "bone fixation body", and discloses that porous pad 26 has an elongated tapering shape. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶88.)

iv. Claim Element 12.d

As discussed in Ground 1 for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") is formed as a porous metal structure. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶89.)

v. Claim Element 12.e

As discussed in Ground 1 for claim 12, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a proximal end and also discloses the claimed "interface," which is the area of *Zolman*'s hip implant where the distal end surface engages the proximal end of porous pad 26 when porous pad 26 is held securely against stem portion 20 within recess 74. (*See supra* Section IX.B.1.v; Ex. 1002, ¶90.)

vi. Claim Element 12.f

As discussed in Ground 1 for claim 12, *Zolman* discloses that stem portion 20 of *Zolman*'s neck body ("the elongated protrusion") forms a core for porous pad 26 ("the bone fixation body") and tapers and extends into an opening of porous pad 26 such that its porous metal structure surrounds and engages an exterior surface of the portion of stem portion 20 that extends into porous pad 26. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶91.)

vii. Claim Element 12.g

The combination of *Zolman* and *Bobyn* discloses the porous-metal-structure claim term. (Ex. 1002, ¶92.) As discussed *supra* at Section IX.D.1.iv, *Zolman* discloses that its porous pad 26 ("the bone fixation body") is formed as a porous metal structure. *Zolman* teaches that porous pad 26 can be made from "any suitable porous material." (Ex. 1009, 4:21-24.) While *Zolman* discloses an

embodiment in which porous pad 26 is formed of a fiber metal structure, *Zolman* expressly states that "any suitable materials [*sic*] may be utilized." (*Id*., 4:27-28.)

There is no dispute between the parties that *Bobyn*'s biomaterial teaches the porous-metal-structure term, including under Patent Owner's narrow interpretation that "requires emulating the size and shape of the interconnected plates and rods that form trabecular bone." (*See generally* Ex. 1008, 38-46.) *Bobyn* discloses a porous tantalum biomaterial with "desirable characteristics for bone ingrowth" for use in orthopedic applications. (*See id*., 907, 913.) The biomaterial is fabricated by coating a vitreous carbon skeleton with elemental tantalum through a chemical vapor deposition process to have a porous metal structure. (*Id*., 907-08; Ex. 1002, ¶92.) This structure is "75% to 80% porous by volume" and has "a repeating arrangement of slender interconnecting struts which form[] a regular array of dodecahedron-shaped pores." (Ex. 1011, 907.) In addition, the biomaterial has a pore size from 430μm to 650 μm. (*Id*., 908-09.) These values for porosity and pore size fall within the preferred ranges taught by the '612 patent for ingrowth of cancellous and cortical bone spicules. (Ex. 1001 at 3:64-65, 4:1-7.) In fact, it was understood at the time of the alleged invention that *Bobyn*'s material emulates the microstructure of cancellous bone, including its interconnected rods and plates. (Ex. 1002, ¶92; Ex. 1020 at Abstract, 6:1-4; Ex. 1022, 1.)

It would have been obvious to a PHOSITA to construct *Zolman*'s porous pad from *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶92.) *Zolman* teaches a hip implant with a porous surface that allows for "bony ingrowth" to "biologically affix or further secure the implant in the bone." (Ex. 1009, 1:20-24.) *Bobyn* discloses that its porous tantalum material has "desirable characteristics for bone ingrowth."[16] (Ex. 1011, 907, 913.) *Bobyn* further explains that its material overcomes deficiencies of conventional porous materials such as limited porosity which limited the amount of interfacial strength that could develop from bone ingrowth. (*Id.*, 907, 912.) Indeed, by 1999, *Bobyn*'s porous tantalum biomaterial was used to construct components of orthopedic implants. (Ex. 1011, 913; Ex. 1022, 5.)

In light of *Bobyn*'s teachings of the advantages of the porous tantalum material over other conventional porous surfaces, a PHOSITA would have been motivated to fabricate the porous pad of *Zolman*'s implant from *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶92.) Indeed, the Board found in the '582 IPR that "a PHOSITA would have been motivated to use *Bobyn*'s porous tantalum

[16] Patent Owner's declarant, Helmus, conceded that at the time of the alleged invention, a PHOSITA would have had "no doubt" that *Bobyn*'s material would facilitate bone ingrowth. (Ex. 1018, 257:23-258:4.)

biomaterial in *Zolman*'s porous pad in order to obtain the advantages of porous tantalum as taught by *Bobyn*, such as increased porosity and improved bone ingrowth in comparison with conventional porous bone-fixation materials." (Ex. 1008 at 42.) The use of *Bobyn*'s material in *Zolman*'s porous pad 26 would have been a simple substitution of known porous materials to improve *Zolman*'s hip implant, and would have yielded predictable results, *i.e.*, a porous structure for bone ingrowth. (*See KSR*, 550 U.S. at 416; Ex. 1002, ¶92.)

A PHOSITA would have had a reasonable expectation of success manufacturing *Zolman*'s implant with *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶92.) A PHOSITA would have known how to construct a pad from *Bobyn*'s material using the process taught in *Zolman*.[17] (Ex. 1002, ¶92.) *Bobyn* teaches that

[17] In the '582 IPR, Patent Owner argued that the steps of pressing, cutting, and bending in *Zolman* would damage *Bobyn*'s biomaterial. This is incorrect for the reasons discussed herein. Moreover, a PHOSITA would have known how to adapt *Bobyn*'s porous tantalum biomaterial for use in *Zolman*'s manufacturing process using known tools and methods to address any concerns related to cutting or bending the biomaterial. (Ex. 1002, ¶92.) Indeed, the Board found in the '582 IPR that "a PHOSITA would have been able to adapt Bobyn's porous tantalum biomaterial for use in Zolman's manufacturing method." (Ex. 1008, 42.)

its material is readily shapeable into any configuration, including the shape of *Zolman*'s pad. (*See* Ex. 1011, 907, 913.) *Bobyn* teaches that tantalum is "a strong, ductile metal" (*Id.*, 913) which enables it to bend without breaking (Ex. 1022, 2). A PHOSITA would have known how to manipulate the porous tantalum biomaterial so that it could be bent without breaking the tantalum struts. (Ex. 1002, ¶92.) For example, a PHOSITA would have known that heating the porous tantalum biomaterial would increase its ductility so that it could be bent about a mandrel or the like to shape the material into a desired shape as disclosed in *Zolman*. (Ex. 1002, ¶92.) A pad constructed from the porous tantalum biomaterial would have enough ductility to be fitted onto *Zolman*'s neck body and positioned within recess 74 for attachment to stem portion 20. (Ex. 1002, ¶92.)

Bobyn's tantalum biomaterial also has properties allowing it to "be made into complex shapes and used either as a bulk implant or as a surface coating." (*Id.*, 907; *see also id.*, 913 (disclosing that the material can "be readily formed in bulk parts . . . requiring standard or customised [*sic*] shapes and sizes of the implant"). Like *Zolman*'s pad, *Bobyn* states that its material can be a "fixation

surface on an implant substrate" (*id.*, 913) and a "surface coating" (*id.*, 907).[18] A PHOSITA would have shaped *Bobyn*'s porous tantalum biomaterial into a final configuration prior to attachment to an implant substrate, like in *Zolman*'s "mandrel" manufacturing process. (Ex. 1002, ¶92.) Methods for attaching the porous tantalum biomaterial to a solid metal component were well-known in the art at the time of the invention. (Ex. 1002, ¶92 (citing Ex. 1020, 8:7-11, 9:54-60; Ex. 1021 at 1:11-24, 3:48-4:22, 5:23-40 Fig. 1).)

2. Claim 13

i. Claim Element 13.a

As discussed in Ground 1 for claim 13, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a noncircular shape, specifically a polygonal shape, in a horizontal cross-sectional view of porous pad 26. (*See supra* Section IX.B.2.i; Ex. 1002, ¶¶ 93, 94.)

ii. Claim Element 13.b

As discussed in Ground 1 for claim 13, *Zolman* discloses that *Zolman*'s neck body and porous pad 26 ("the bone fixation body") are fabricated independently

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[18] Patent Owner's declarant Vincelli acknowledged that *Bobyn* teaches customizing the shape of the material that can be used as a bulk implant or a surface coating by changing the shape of the foam carbon skeleton. (Ex. 1019, 115:24-116:10.)

and that porous pad 26 is bonded to the neck body after being formed separately from the neck body. (*See supra* Section IX.B.2.ii; Ex. 1002, ¶ 95.)

3. Claim 15

i. Claim Element 15.a

As discussed in Ground 1 for claim 15, *Zolman* discloses that the distal end surface of *Zolman*'s neck body has a noncircular closed shape. (*See supra* Section IX.B.3.i, Ex. 1002, ¶97.)

ii. Claim Element 15.b

As discussed in Ground 1 for claim 15, *Zolman* discloses that the proximal end of porous pad 26 ("the bone fixation body") has a noncircular closed shape. (*See supra* Section IX.B.3.ii, Ex. 1002, ¶98.)

iii. Claim Element 15.c

As discussed in Ground 1 for claim 15, *Zolman* discloses that the solid metal of the noncircular closed shape of *Zolman*'s neck body interfaces with the porous metal structure of the noncircular closed shape of porous pad 26 ("the bone fixation body") at the interface. (*See supra* Section IX.B.3.iii; Ex. 1002, ¶¶96, 99.)

4. Claim 16

i. Claim Element 16.a

As discussed in Ground 1 for claim 16, *Zolman* teaches that porous pad 26 ("the bone fixation body") includes a trapezoidal shape in a horizontal cross-sectional view of porous pad 26. (*See supra* Section IX.B.4.i; Ex. 1002, ¶¶ 100,

101.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s porous pad 26 with a trapezoidal shape as discussed *supra* at IX.B.4.i.

ii. Claim Element 16.b

As discussed in Ground 1 for claim 16, *Zolman* discloses that stem portion 20 ("the elongated protrusion") includes a polygonal shape in a horizontal cross-sectional view. (*See supra* Section IX.B.4.ii; Ex. 1002, ¶102.)

5. Claim 17

i. Claim Element 17.a

As discussed in Ground 1 for claim 17, *Zolman* discloses the distal end surface of *Zolman*'s neck body has a trapezoidal shape. (*See supra* Section IX.B.5.i, Ex. 1002, ¶104.)

ii. Claim Element 17.b

As discussed in Ground 1 for claim 17, *Zolman* discloses that the proximal end of porous pad 26 ("the bone fixation body") has the trapezoidal shape. (*See supra* Section IX.B.5.ii, Ex. 1002, ¶105.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make the proximal end of *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.4.i.

iii. Claim Element 17.c

As discussed in Ground 1 for claim 17, *Zolman* discloses that the solid metal of the trapezoidal shape of *Zolman*'s neck body interfaces with the porous metal structure of the trapezoidal shape of porous pad 26 ("the bone fixation body") at the claimed "interface." (*See supra* Section IX.B.5.iii, Ex. 1002, ¶¶103, 106.)

6. Claim 18

i. Claim Element 18.a

As discussed in Ground 1 for claim 18, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a trapezoidal shape in a horizontal cross-sectional view of the pad. (*See supra* Section IX.B.6.i, Ex. 1002, ¶¶ 107, 108.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.4.i.

ii. Claim Element 18.b

As discussed in Ground 1 for claim 18, *Zolman* teaches that a distal end 12 of stem portion 20 ("the elongated protrusion") includes a cylindrical shape in a horizontal cross-sectional view. (*See supra* Section IX.B.6.ii, Ex. 1002, ¶109.)

7. Claim 19

i. Claim Element 19.a

As discussed in Ground 1 for claim 19, *Zolman* discloses a hip implant. (*See supra* Section IX.B.7.i, Ex. 1002, ¶¶ 110, 111.)

ii. Claim Element 19.b

As discussed in Ground 1 for claim 19, *Zolman* discloses a femoral component 10 ("a neck body") formed of solid metal, *e.g.*, titanium, having a proximal end 14 that includes a neck 28 having a tapering cylindrical configuration that connects with a femoral ball 30 ("an acetabular component"). As also discussed above for claim 1, *Zolman*'s neck body has a distal end surface with a stem portion 20 ("an elongated protrusion") that extends outwardly therefrom. (*See supra* Section IX.B.7.ii; Ex. 1002, ¶112.)

iii. Claim Element 19.c

As discussed in Ground 1for claim 19, *Zolman* discloses a porous pad 26 ("a bone fixation body") having an elongated tapering shape without a solid metal substrate. (*See supra* Section IX.B.7.iii; Ex. 1002, ¶113.)

iv. Claim Element 19.d

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") is formed as a porous metal structure. (*See supra* Section IX.B.7.iv; Ex. 1002, ¶114.)

v. Claim Element 19.e

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a proximal end and also discloses the claimed "interface", which is the area of *Zolman*'s hip implant where the distal end surface

engages the proximal end of porous pad 26 when porous pad 26 is held securely against stem portion 20 within recess 74. (*See supra* Section IX.B.7.v, Ex. 1002, ¶115.)

vi. Claim Element 19.f

As discussed in Ground 1 for claim 19, *Zolman* discloses that stem portion 20 ("the elongated protrusion") forms a core for porous pad 26 ("the bone fixation body") and tapers and extends into an opening of the pad such that the porous metal structure surrounds and engages an exterior surface of the portion of stem portion 20 that extends into the porous pad 26. (*See supra* Section IX.B.7.vi; Ex. 1002, ¶116.)

vii. Claim Element 19.g

As discussed above for claim 12, *Zolman* discloses that porous pad 26 can be made from "any suitable porous material." (*See supra* Section IX.D.1.vii.) *Bobyn* discloses a porous tantalum biomaterial that teaches the porous-metal-structure claim term under the Board's construction and FMB's narrow interpretation. (*See supra* Section IX.D.1.vii; Ex. 1002, ¶117.) As further discussed above for claim 12, it would have been obvious to a PHOSITA 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 supra* Section IX.D.1.vii; *KSR*, 550 U.S. at 416; Ex. 1002, ¶117.) As also

discussed, a PHOSITA would have had a reasonable expectation of success manufacturing *Zolman*'s implant with *Bobyn*'s porous tantalum biomaterial. (*See supra* Section IX.D.1.vii; Ex. 1002, ¶117.)

viii. Claim Element 19.h

As discussed in Ground 1 for claim 19, *Zolman* discloses that the distal end surface of *Zolman*'s neck body has a noncircular closed shape. (*See supra* Section IX.B.7.viii; Ex. 1002, ¶118.)

ix. Claim Element 19.i

As discussed in Ground 1 for claim 19, *Zolman* discloses that the proximal end of porous pad 26 ("the bone fixation body") has a noncircular closed shape. (*See supra* Section IX.B.7.ix; Ex. 1002, ¶119.)

x. Claim Element 19.j

As discussed in Ground 1 for claim 19, *Zolman* discloses that the solid metal of the noncircular closed shape of *Zolman*'s neck body interfaces with the porous metal structure of the noncircular closed shape of porous pad 26 ("the bone fixation body") at the interface, which is the area of *Zolman*'s hip implant where the distal end surface of *Zolman*'s neck body engages the proximal end of porous pad 26 when porous pad 26 is held securely against stem portion 20 within recess 74. (*See supra* Section IX.B.7.x; Ex. 1002, ¶120.)

xi. Claim Element 19.k

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") includes a trapezoidal shape in a horizontal cross-sectional view of the pad. (*See supra* Section IX.B.7.xi; Ex. 1002, ¶121.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.4.i.

xii. Claim Element 19.l

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") and *Zolman*'s neck body are fabricated separately and subsequently the porous pad 26 is bonded from heat to the neck body after the porous pad 26 is fabricated separately from the neck body. (*See supra* Section IX.B.7.xii, Ex. 1002, ¶122.)

xiii. Claim Element 19.m

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") has the claimed elongated tapering shape with a bow shape in a side-view of the pad. (*See supra* Section IX.B.7.xiii; Ex. 1002, ¶123.)

xiv. Claim Element 19.n

As discussed in Ground 1 for claim 19, *Zolman*'s stem portion 20 ("the elongated protrusion") has a polygonal shape in the horizontal cross-sectional view. (*See supra* Section IX.B.7.xiv; Ex. 1002, ¶124.)

xv. Claim Element 19.o

As discussed in Ground 1 for claim 19, *Zolman* discloses that porous pad 26 ("the bone fixation body") bonds to the neck body along the interface that includes where the polygonal shape of stem portion 20 ("the elongated protrusion") engages the porous pad 26. (*See supra* Section IX.B.7.xv; Ex. 1002, ¶125.)

E. Ground 4: Claim 18 is Obvious Based on a Combination of *Zolman, Bobyn,* and *Averill*

As discussed above for claim 18, to the extent a cross-sectional shape can be cylindrical, *Zolman* discloses the claimed "elongated protrusion includes a cylindrical shape in the horizontal cross-sectional view." (*See supra* Section IX.B.6.ii; Ex. 1002, ¶126.) If the Board finds that *Zolman* does not disclose this feature, it would have been obvious to form stem portion 20 to have a cylindrical shape in a horizontal cross-sectional view in light of *Averill*'s disclosure for the reasons discussed *supra* at IX.C. (Ex. 1002, ¶126.)

X. THE BOARD SHOULD ADOPT ALL PROPOSED GROUNDS

Petitioner has streamlined this petition by proposing similar grounds to those raised in the '582 IPR proceeding to achieve the goal of "just, speedy, and

inexpensive resolution" consistent with 37 C.F.R. § 42.1(b). Consistent with the '582 IPR proceeding, the Board should adopt all of the grounds proposed in this petition.

As noted above, FMB has appealed the Board's final claim construction of the porous-metal-structure claim terms in the '582 IPR. *Zolman*, *Rostoker*, and *Averill* render the challenged claims obvious under the Board's construction. *Zolman*, *Bobyn*, and *Averill* render the challenged obvious under the Board's construction and Patent Owner's narrower claim interpretation, which requires the porous structure to emulate the rods and plates of cancellous bone. The Board should also adopt both sets of grounds in the event the Federal Circuit adopts Patent Owner's narrow interpretation of the porous-metal-structure claim terms. In addition, Petitioner presents a set of grounds based on *Averill* in the event the Board finds that *Zolman* alone or in combination with *Rostoker* do not disclose the claimed "elongated protrusion" having "a cylindrical shape in the horizontal cross-sectional view."

XI. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 12, 13, and 15-19 of the '612 patent.

Respectfully submitted,

Dated**:** October 11, 2017 By: /Naveen Modi/

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

Counsel for Zimmer Biomet Holdings, Inc.

CERTIFICATION OF WORD COUNT UNDER 37 C.F.R. § 42.24(d)

The undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 13,523 words according to the word count of the word-processing software used to prepare the petition.

By: /Naveen Modi/

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

Counsel for Zimmer Biomet Holdings, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2017, a copy of the foregoing Petition for Inter Partes Review of U.S. Patent No. 9,265,612 for Petitioner Zimmer Biomet Holdings, Inc. was served via express mail on the Patent Owner at the following correspondence address of record as listed on PAIR:

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

A courtesy copy was also sent via electronic mail to the Patent Owner's litigation and/or prior PTAB counsel listed below:

Jeffrey Andrews
Sutton McAughan Deaver PLLC
JAndrews@SMD-IPLaw.com

Philip Lyren
Philip_lyren@yahoo.com

Dated: October 11, 2017 By: /Naveen Modi/

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

Counsel for Zimmer Biomet Holdings, Inc.