Paper No. ____
Filed: October 11, 2017

Filed on behalf of: Zimmer Biomet Holdings, Inc.

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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. 9,283,080

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,283,080

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1023	Campbell's Operative Orthopedics, Vol. 1 (S. Terry Canale, MD. ed., Mosby, 10th ed. 2003).
1024	U.S. Patent No. 8,821,582

I. INTRODUCTION

Zimmer Biomet Holdings, Inc. ("Zimmer" or "Petitioner") requests *inter partes* review of claims 1-3, 5, 7, and 9-11 of U.S. Patent No. 9,283,080 ("the '080 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 the challenged claims by a preponderance of evidence. Trial should be instituted and claims 1-3, 5, 7, and 9-11 of the '080 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 '080 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 '080 patent, U.S. Patent No. 9,308,093 ("the '093 patent"), and U.S. Patent No.

9,265,612 ("the '612 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 '093 patent and the '612 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 '080 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 '080 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '080 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 '080 patent against Petitioner. (*See* Ex. 1013.)

V. PRECISE RELIEF REQUESTED AND GROUNDS RAISED

Petitioner respectfully requests review of claims 1-3, 5, 7, and 9-11 of the '080 patent and cancellation of these claims as unpatentable in view of the following grounds[1]:

- **Ground 1**: Claims 1-3, 5, 7, and 9-11 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**: Claims 1-3, 5, 7, and 9-11 are 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); and
- **Ground 3**: Claims 1-3, 5, 7, and 9-11 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, J.D. Bobyn et al., "Characteristics of Bone Ingrowth and Interface Mechanics of a New

[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 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).

Porous Tantalum Biomaterial," J. of Bone and Joint Surgery, Vol. 81-B, No. 5 (Sept. 1999) ("*Bobyn*") (Ex. 1011), and *Averill*.

On its face, the '080 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 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

A. Overview of the '080 Patent

The '080 patent discloses a "hip implant with [a] porous body." (Ex. 1001, Title; Ex. 1002, ¶12.) The disclosed implant includes two distinct components, a neck body 14 and a bone fixation body 16. (*See, e.g.*, Ex. 1001, Abstract, 2:18-20, 3:34-36, 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:

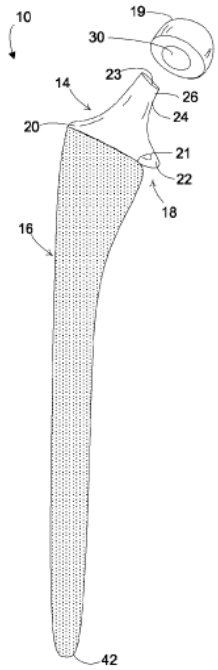

Fig. 1

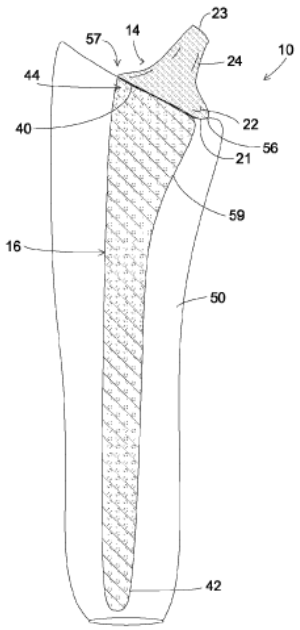

Fig. 2

(*See id.*, 1:38-41, 3:30-31, 4:1-3, Figs. 1-2.)

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.,* 3:37-40.) 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.*, 3:40-46, 3:59-61; Ex. 1002, ¶13.) Bone fixation body 16 is formed from a porous metal structure that is "completely porous" and "does not include a metal substrate." (Ex. 1001, 2:31-33; 3:62-67.) The '080 patent also discloses an embodiment in

which a protrusion 74 extends from the base portion into the bone fixation body. (*Id.*, 5:45-51; Ex. 1002, ¶14.)

In a preferred embodiment, the porous structure of the bone fixation body is made by sintering titanium alloy powder. (Ex. 1001, 4:39, 4:53-5:6.) The specification also teaches that "[t]he 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." (*Id.*, 4:19-21; Ex. 1002, ¶15.) The specification teaches that the neck body is made of solid metal and machined "using conventional and known machining techniques" to have the size and shape shown in the figures. (Ex. 1001, 3:32-34, 3:51-56, 4:42-44.) In one embodiment, the bone fixation body "simultaneously forms and attaches to the neck body." (*Id.*, 5:7-8.) In an alternative embodiment, these bodies are "fabricated independently and subsequently connected together" using known techniques. (*Id.*, 5:9-13; Ex. 1002, ¶15.)

The porous structure allows bone to grow into the bone fixation body.[2] (Ex. 1001, 2:36-48, 4:22-23, 4:30-33; Ex. 1002, ¶16.) To promote this bone ingrowth,

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[2] The femur includes cortical bone and trabecular bone, which is also known as cancellous bone. (Ex. 1002, ¶16.)

the porous metal structure "emulates the size and shape of the porous structure of natural bone," and provides preferred ranges for the pore diameter, porosity, and interconnection diameter. (Ex. 1001, 4:23-30.[3]) The specification also states that "these ranges are exemplary" and "could be modified, and the resulting hip implant still within the scope of the invention." (*Id.*, 4:33-38.)

The '080 patent includes 13 claims, but this petition only requests review of claims 1-3, 5, 7, and 9-11. Claims 1 and 5 relate to a method of manufacturing a two-piece hip implant composed of a neck body and a bone fixation body. (*Id.*, 15:39-16:2, 16:11-37.) Claim 10 is directed to a two-piece hip implant. (*Id.*, 16:50-17:10.) Claims 1 and 10 recite that the bone fixation body is formed of "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 claim 5 recites "a porous metal structure . . . with interconnected pores having a geometric structure that replicates a porous structure of natural human bone" (collectively, "the porous-metal-structure claim terms"). (*Id.*, 15:50-54, 16:21-25; 16:61-64; Ex. 1002, ¶17.)

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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, 84:15-86:22; Ex. 1019, 100:8-102:3.)

B. Overview of the Prosecution History

Relevant portions of the prosecution history of the '080 patent and certain related patents are discussed below.

1. The '642 Patent Prosecution

The '080 patent claims priority to the '611 application, which issued as the '642 patent. (Ex. 1001, title page.) During prosecution of the '611 application, Applicant attempted to 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.*)[4] Patent Owner ultimately amended the claims to require the bone fixation body to have "a trapezoidal shape in a

[4] All emphasis added unless otherwise indicated.

horizontal cross-sectional view," which led to allowance of the claims. (*Id.*, 16-20, 34-46, 53-64.)

2. The '080 Patent Prosecution

The '482 patent application matured into the '080 patent after one rejection. (*See* Ex. 1007, 27-38.) The examiner did not provide reasons for allowance.

C. The '582 IPR

The '080 patent is related to the '582 patent, which is a parent of the '080 patent. (Ex. 1001, title page.) Like the '080 patent claims, certain claims of the '582 patent recite the phrase "a porous metal structure . . . having a size and a shape that emulate a size and shape of a porous structure of natural human bone" and "a porous metal structure . . . with interconnected pores having a geometric structure . . . that emulate . . . natural human bone." (Ex. 1024, 15:55-60, 16:32-36, , 17:1-4.) During the '582 IPR, Patent Owner argued that these 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, 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 ("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.[5] [6]

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 '080 patent should be given their broadest reasonable interpretation ("BRI"). Under this standard, Petitioner provides constructions for the terms identified below. The

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

[6] Petitioner submits the declaration of Dr. Timothy Harrigan (Ex. 1002), an expert in the field of the '080 patent.

remaining terms should be interpreted in accordance with their plain and ordinary meaning under the BRI standard.[7]

A. "Porous-Metal-Structure" Claim Terms

The porous-metal-structure claim terms appear in claims 1, 5 and 10. (Ex. 1001, 15:50-54, 16:21-25; 16:61-64). The term in claims 1 and 10 should be construed to require "emulating the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but they do not require emulating the size and shape of the interconnected plates and rods that form trabecular bone." The Board previously adopted this construction for the same term in the '582 IPR (Ex. 1008, 12-13).[8] In addition, the Board adopted this construction for the phrase "a porous metal structure . . . with interconnected pores having a geometric structure . . . that

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

[8] In the '582 IPR, the Board separately construed the terms "porous." and "emulate." (Ex. 1008, 9, fn.6; *see also* Ex. 1014, 744.)

emulate[s] . . . natural human bone" in claim 8 of the '582 patent. (*Id.*, 9.) Claim 5 of the '080 patent contains similar language as claim 8 of the '582 patent with the term "replicate" in place of "emulate," thus, this porous-metal-structure term should be construed to require "replicating a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but does not require replicating the interconnected plates and rods that form trabecular bone."

The proposed construction is consistent with the plain meaning of the claim language. The porous-metal-structure claim terms in claims 1 and 10 simply require "***a*** porous metal structure" that "ha[s] ***a*** size and ***a*** shape that emulate ***a*** size and ***a*** shape of ***a*** porous structure of natural human bone." (Ex. 1001, 15:50-51, 15:52-54, 16:61-64.) By using the indefinite article "a" in this context, the claim language 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.) Similarly the porous-

metal-structure claim term in claim 5 requires "***a*** porous metal structure . . . with interconnected pores having ***a*** geometric structure that replicates ***a*** porous structure of natural human bone." (Ex. 1001, 16:21-25) Thus, claim 5 also uses the indefinite article "a," which specifies that any aspect of the "interconnected pores" can replicate natural human bone, such as structure measured by pore diameter, porosity, and intersection diameter. The Examiner had a similar understanding of the plain meaning of this claim language during prosecution of the '611 application, finding that the prior art structure formed pores of a certain size and shape that emulated and replicated 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 bone fixation body of the hip implant." (Ex. 1001, 2:53-56.) 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.*, 4:30-33.) To that end, the specification generally describes a porous structure that "is adapted for the ingrowth of cancellous and cortical bone spicules" by "emulat[ing] the size and shape of the porous structure of natural bone." (*Id.*, 4:22-26.)

The specification also specifically characterizes the porous structure based on pore diameter, porosity, and intersection diameter. (*Id.*, 4:26-30.) In a preferred embodiment, the specification discloses a porous structure with the following shape and size: "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.*[9]) These ranges correspond to the shape and size of pores in natural human bone. (Ex. 1002, ¶16, fn.1 (citing Ex. 1016, 954); Ex. 1018, 84:15-86:22; Ex. 1019 at 100:8-102:3.) According to the specification, however, "these ranges are exemplary" and "could be modified, and the resulting hip implant still within the scope of the invention." (*Id.*, 4:33-38.) Thus, the specification supports construing the porous-metal-structure claim terms of claims 1 and 10 to encompass structures that emulate the size and shape of a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection

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

diameter. The porous-metal-structure claim term of claim 5 similarly encompasses interconnected pores that replicate a 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 the porous-metal-structure claim terms require emulating the size and shape of the interconnected plates and rods that form trabecular bone. (Ex. 1008, 10.) Patent Owner's focus on trabecular bone is inconsistent with the broader recital of "natural human bone" in the claims, and the '080 specification, which does not even mention "interconnected plates and rods that form trabecular bone."[10] (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, and other suitable materials, metals, or alloys known in the art" (Ex. 1001, 4:19-21), 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

[10] Moreover, the '080 patent specification discloses that the bone fixation body contacts both cortical and cancellous bone. (Ex. 1001, 12:20-23; 15:16-22.)

from the '582 IPR for claims 1 and 10 (Ex. 1008, 12-13) and adopt a similar construction for claim 5.

B. Separate Fabrication

Claim 1 recites "fabricating, separately from the neck body, a bone fixation body." (Ex. 1001, 15:47-48.) Claims 5 and 10 contain similar recitations. (*Id.*, 16:18-19, 16:65-66.) In the '582 IPR, Patent Owner proposed, and the Board accepted, that the BRI of the same "fabricating" step requires "that fabrication of the bone fixation body and the neck body must be performed independently from each other." (Ex. 1008, 17-18; *see also* Ex. 1024, 15:55-56) As it did in the '582 IPR, the Board should adopt this construction for the "fabrication" step of claim 1, and the similar recitations of claims 5 and 10. 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, 5:9-11.)

C. Connection "After" Separate Fabrication

Claim 1 recites "connecting, *after* the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body." (Ex. 1001, 15:55-58.) Claim 5 and 10 contain similar recitations. (*Id.*, 16:26-32, 16:65-17:4.) In the '582 IPR, Patent Owner proposed, and the Board accepted, that the BRI of a similar "connecting" step requires that "attachment of the bone fixation

body to the neck body must take place subsequent to fabrication of the bone fixation body." (Ex. 1024, 16:37-39; Ex. 1008, 13, fn. 8, 15.) As it did in the '582 IPR, the Board should adopt this construction for the "connecting" step of claim 1, and the similar recitations in claims 5 and 10. 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, 5:9-11.)

IX. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY UNDER THE BRI

A. Overview of Prior Art

1. *Zolman*

Zolman discloses a method of constructing an implant "suitable for use as a femoral component for a hip prosthesis." (Ex. 1009, Title, 1:11-15; Ex. 1002, ¶24.) In an exemplary embodiment, a porous pad 26 is wrapped around a stem portion 20 of 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" including "the fiber metal structure disclosed in U.S. Patent No. 3,906,550 to Rostoker." (*Id.*, 4:12-24; Ex. 1002, ¶25.) An embodiment of *Zolman*'s implant and its porous pad 26 are shown below:

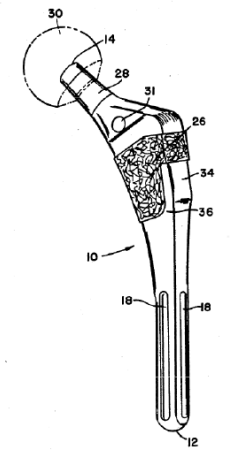


FIG. I

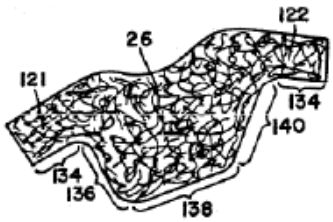


FIG. II

(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; 5:16-21, Figs. 5-6; Ex. 1002, ¶28.) Porous pad 26 is positioned securely in a recess 74 in a proximal portion 24 of stem portion 20 which corresponds to the wrapped shape of pad 26. (Ex. 1009, 5:13-16, 6:44-46, Fig. 6; Ex. 1002, ¶26.) Porous pad 26 is then bonded to stem portion 20. (Ex. 1009, 6:39-54.) *Zolman* also discloses that porous pad 26 can be formed into its final shape on a mandrel, which has the same shape as the implant, removed from the mandrel, and then attached to stem portion 20. (*Id.*, 7:1-14; Ex. 1002, ¶27.)

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, ¶29.) 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, ¶30.) An embodiment of the fiber metal mesh is show below:

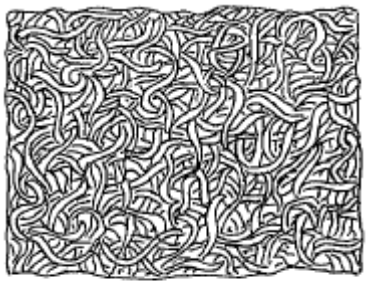


FIG. 4

(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, ¶31.) "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, ¶32.) 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, ¶¶33-34.) The porous tantalum material is 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." (*Id.*, 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, ¶¶ 35-37.)

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.) *Bobyn* states that 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, ¶38.)

4. *Averill*

Averill discloses a hip prosthesis 10 having a stem 12 that includes a tapered portion 22 which defines a proximal locking zone 24 and a cylindrical portion 26. (Ex. 1012, 5:5-10; 5:21-29, Fig. 1; Ex. 1002, ¶¶39-41.)

B. Ground 1: Claims 1-3, 5, 7, and 9-11 are Obvious Based on *Zolman* and *Rostoker*

Zolman and *Rostoker* disclose each and every element of claims 1-3, 5, 7 and 9-11. (Ex. 1002, ¶42.) *Zolman* discloses all of the claimed limitations except for the porous-metal-structure claim terms. *Zolman*, however, expressly discloses

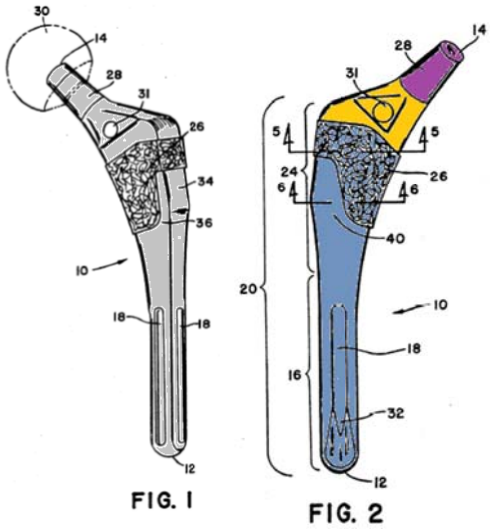
fabricating porous pad 26 from *Rostoker*'s fiber metal mesh, which discloses the porous-metal-structure claim terms. (Ex. 1009, 4:12-15; *see infra* Sections IX.B.1.vi, IX.B.4.vi, IX.B.7.vi.)

1. Claim 1

i. [1.a] "A method, comprising:"

To the extent the preamble is limiting, *Zolman* discloses a method of constructing a hip implant by wrapping a separate porous pad 26 about a stem portion 20. (*See, e.g.*, Ex. 1009, Title, Abstract, 1:11-15, 2:23-26; *see also infra* Sections IX.B.1.ii-x; Ex. 1002, ¶¶43-44; Ex. 1008, 19.)

ii. [1.b] "machining a neck body formed of solid metal to include a base portion, to include a neck portion that extends outwardly from the base portion and that has an end with a cylindrical shape that engages a femoral component, and to include an elongated male protrusion that extends outwardly from the base portion and that has a cylindrical shape that tapers;"



Zolman discloses a component 10 (shaded in grey) including a neck 28, a base portion with aperture 31, and a stem portion 20 (collectively referred to hereinafter as "neck body"). *Zolman* teaches that its neck body is formed of solid titanium metal (Ex. 1009, 4:26-27), but does not expressly disclose that it is made by a machining process. However, it was common practice in 2003 to machine a solid metal neck body.[11] (Ex. 1002, ¶45 (citing Ex. 1012, 6:54-58).)

As the Board found, a PHOSITA would have inferred that *Zolman*'s neck body was formed by machining solid metal. (Ex. 1008, 31.) A PHOSITA would have recognized that the Morse taper, recess 74, and grooves 18 on *Zolman*'s neck body would have been formed by removing material from the solid-metal neck body through a machining process.[12] (Ex. 1009, 3:51-53, 5:13-16, Ex. 1002, ¶45.)

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[11] The '080 patent concedes that it was well-known to machine a neck body. (Ex. 1001, 4:42-44); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art.").

[12] Patent Owner's declarant, Vincelli, testified that machining is "forming an object from a larger piece of metal," such as by milling. (Ex. 1019, 86:12-24.) Patent Owner's declarant, Helmus, testified that a PHOSITA would have understood

Even if *Zolman*'s neck body was created through another process, it would have been obvious to a PHOSITA that the neck body would have undergone a final machining process to finish, polish, or roughen the solid metal after molding, casting, or machining the neck body to a near final shape to obtain the required dimensions and surface characteristics of the neck body.[13] (Ex. 1002, ¶45.) For example, the Morse taper on *Zolman*'s neck body, if made by another process, would have undergone some machining and polishing steps to achieve the final dimensions and surface roughness to allow for the attachment of ball 30. (Ex. 1002, ¶45.)

Zolman's neck body includes a neck 28 having a base portion (shaded in orange) and a neck portion (shaded in purple) that extend outwardly from the base portion. (*See* Ex. 1009, 3:44-51, 3:56-59, Figs. 1-2; Ex. 1002, ¶45.) The neck portion has an end 14 with a cylindrical shape that engages a ball 30, *i.e.*, the

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Zolman's neck body to have been made by milling solid metal. (Ex. 1018, 243:6-244:2; 253:9-254:21.)

[13] Patent Owner's declarant, Vincelli, conceded that finishing processes could be used as machining processes to obtain the final dimensions of a neck body. (*See* Ex. 1019, 56:12-20.)

claimed "femoral component." (Ex. 1009, 3:45-51, 3:56-59, Figs. 1-4.) A PHOSITA would have understood ball 30 to be the claimed "femoral component" based on *Zolman*'s disclosure that neck 28 is "adapted to carry" ball 30. (*Id*., 3:45-51, 3:56-59; Ex. 1002, ¶45.) The base portion is shaped to position ball 30 relative to stem portion 20 to restore the patient's leg length and the offset between the center of rotation of the prosthetic femoral head and the femur. (Ex. 1002, ¶45 (citing Ex. 1023, 320, 321, 330).) *Zolman* teaches that stem portion 20 has a non-circular shape that tapers to distal end 12. (*See, e.g.*, Ex. 1009, 3:54-56, 5:19-21, Figs. 1-6 (annotated to the right); Ex. 1002, ¶45.)

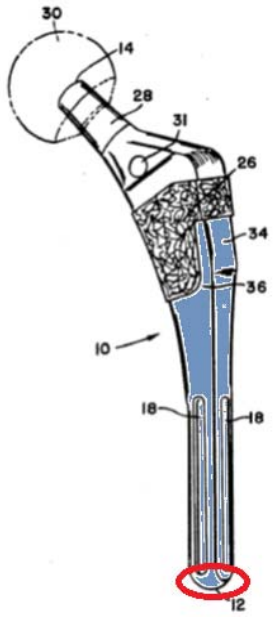

FIG. 1

It would have been obvious to form *Zolman*'s stem portion 20 to have a cylindrical shape that tapers. (Ex. 1002, ¶45.) *Rostoker*, for example, discloses a femur prosthesis 12 that includes a rod 24 that has a cylindrical shape and a cylindrical bottom end member 26 that tapers. (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 that tapers, as taught by *Rostoker*. (*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398,

416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results."); Ex. 1002, ¶45.) A PHOSITA would have shaped the stem portion 20 to have this configuration to facilitate insertion into the intramedullary canal and to reduce the stiffness of the implant. (Ex. 1002, ¶45 (citing 1023, 335).)

iii. [1.c] "fabricating, separately from the neck body, a bone fixation body with an elongated tapering body with a bow,"

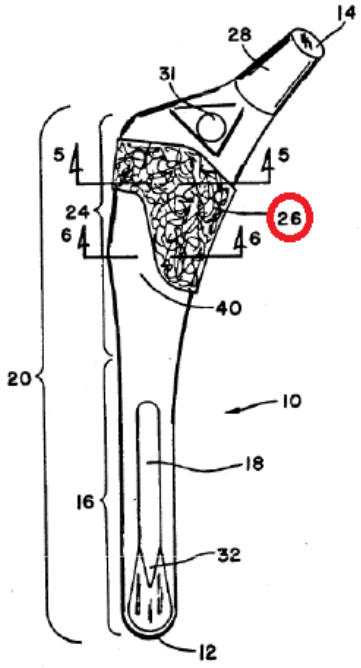

FIG. 2

As the Board found, *Zolman* discloses fabricating a porous pad 26, identified in annotated Figure 2, separately from *Zolman*'s neck body. (Ex. 1008, 27.) In particular, *Zolman* discloses fabricating porous pad 26 by cutting the pad from a porous material having "any desired thickness or dimensions" and shaping it about

a mandrel into a final shape that is then attached to stem portion 20. (Ex. 1009, 4:46-49, 7:1-14; Ex. 1008, 27.) *Zolman* teaches that the final shape of the pad is an elongated tapering body (*see* Ex. 1009, 5:5-11, Figs. 1-4) with a bow, *i.e.*, with at least one side having a curvature. (*Compare* Ex. 1009, Fig. 2 *with* Ex. 1001 at 5:14-15, Fig. 1; Ex. 1002, ¶46 (citing Ex. 1023, 330).)

Zolman teaches that the porous nature of *Zolman*'s pad allows "bony ingrowth" to "biologically affix or further secure the implant in the bone." (*Id.*, 1:20-24; Ex. 1002, ¶46.)[14] *Zolman* also teaches that the pad can be made from *Rostoker*'s fiber metal structure. (Ex. 1009, 4:12-15.) *Rostoker* teaches that "bone growth can penetrate for a substantial distance into [its] fiber metal structure and thereby provide a very secure connection." (Ex. 1010, 2:42-44.) For at least these reasons, *Zolman*'s porous pad 26 is a bone fixation body. (Ex. 1002, ¶46.)

[14] 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 '080 patent. (Ex. 1008, 31-32.)

iv. [1.d] "[fabricating the bone fixation body] with a trapezoidal shape in a horizontal cross-sectional view,"

Zolman discloses that "pad[] 26 can be shaped to conform to any desirable and suitable . . . surface configuration." (Ex. 1009, 5:16-18.) *Zolman* also discloses 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, Fig. 5; Ex. 1002, ¶47.) Figure 5 is a cross-sectional view of stem portion 20 along line 5—5 in Figure 2. (Ex. 1009, 2:63-64, Figs. 2, 5.) As shown in Figure 5, porous pad 26 conforms to stem portion 20, which has a trapezoidal cross-sectional shape.[15] (*Compare id.*, Fig. 5 *with* Ex. 1001, 6:34-35, Fig. 7 (describing Fig. 7 as

[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, 195:9-11; 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, 262:11-23; Ex. 1019, 108:4-9.) Patent Owner's declarant, Vincelli, 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

showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶47.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to fabricate *Zolman*'s pad with a trapezoidal shape given that *Zolman*'s discloure that "pad 26 can be shaped to 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 the pad 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, ¶47 (citing Ex. 1023, 333).)

v. [1.e] "[fabricating the bone fixation body] with a proximal end including an opening, and"

Zolman discloses that porous pad 26 can be formed about a mandrel which has a shape that corresponds to the shape of proximal portion 24 of stem portion 20. (Ex. 1009, 7:1-6.) The formed pad that is removed from the mandrel includes

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manufacture, and also to help prevent against rotation of the bone fixation body." (Ex. 1019, 116:11-15.)

a proximal end with an opening that corresponds to the shape of proximal portion 24. (*See* Ex. 1009, 7:10-12, Figs. 1-5, Ex. 1002, ¶48.)

vi. [1.f] "[fabricating the bone fixation body] with a porous metal structure that extends throughout the bone fixation body with the porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone; and"

Zolman and *Rostoker* disclose these limitations. (Ex. 1002, ¶49.) *Zolman* discloses fabricating porous pad 26 from "any suitable porous material" and "particularly fibrous (wire-type) porous structures." (Ex. 1009, 4:21-26.) *Zolman* states that *Rostoker* discloses a suitable porous material formed of kinked fiber metal. (Ex. 1009, 4:12-15; Ex. 1010, 2:21-31, Fig. 4.) In one embodiment, the "kinked titanium fiber metal[] is press formed into a sheet" and "prebonded" in a vacuum to form the porous material shown in Figure 9 of *Zolman* comprised of a three-dimensional network of fibers. (*Id.*, 4:46-49, 4:52-56, Fig. 9.) *Zolman* teaches that porous pad 26 is "cut from the sheet" and thus has a porous metal structure that extends throughout the pad. (*Id.*, 4:56-58, Figs. 9-11; Ex. 1002, ¶49.)

Rostoker also discloses fabricating a completely porous fiber metal structure. (Ex. 1002, ¶49.) *Rostoker* discloses making a porous fiber metal structure 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.* at 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 that 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 '080 patent, which fall within the known ranges of pore diameters and porosities for cancellous bone and "encourage natural bone to migrate and grow into and throughout the entire body 16." (Ex. 1001, 4:27-33; Ex. 1002, ¶49 (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, 4:27-30.) *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, 4:27-30.) Therefore, *Rostoker* discloses the porous-metal-structure

claim terms under its BRI. (*See supra* Section VIII.A; Ex. 1002, ¶49.) 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 shares the same specification as the '080 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. (*Id.*)

Given *Zolman*'s explicit teachings to use *Rostoker*, fabricating *Zolman*'s porous pad 26 from the porous structure of *Rostoker* would have been obvious to a PHOSITA.[16] (Ex. 1009, 4:12-15; Ex. 1002, ¶49.) A PHOSITA would have been motivated to fabricate *Zolman*'s pad 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, ¶49; *see also* Ex. 1008, 22.) A porous structure that is conducive to bone formation and enables tissue infiltration facilitates a strong attachment and long-

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

term stability of the implant. (Ex. 1002, ¶49; 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, ¶49; *See KSR*, 550 U.S. at 416.)

vii. [1.g] "connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to permanently attach the bone fixation body to the neck body and create a hip implant,"

As discussed *supra* at Section IX.B.1.iii, *Zolman* discloses that porous pad 26 is fabricated into a final shape separately from *Zolman*'s neck body. As the Board found, *Zolman* teaches that, after the pad has been shaped into its final shape about a mandrel, it is removed from the mandrel, and then bonded to *Zolman*'s neck body to permanently attach the two bodies to create a hip implant. (Ex. 1009, 6:46-54, 7:10-14; Ex. 1008, 27; Ex. 1002, ¶50.)

viii. [1.h] "wherein the elongated male protrusion extends into the opening of the bone fixation body, forms a core for the bone fixation body, extends toward a distal end of the hip implant, and"

As discussed *supra* at Section IX.B.1.v, porous pad 26 ("the bone fixation body") has an opening at the proximal end of the pad. Porous pad 26 completely encircles proximal portion 24 of stem portion 20, thus, stem portion 20 extends into the opening in pad 26, forms a core for pad 26, and extends through the pad

toward a distal end 12 of the implant. (Ex. 1009, 3:53-56, 4:41-45, Figs. 1-5; Ex. 1002, ¶51.)

ix. [1.i] "includes a section with a non-circle shape in a cross-sectional view of the hip implant in order to provide an anti-rotational interface between the neck body and the bone fixation body,"

Zolman discloses that porous pad 26 is positioned in recess 74 on proximal portion 24 of stem portion 20, which has an "asymmetric noncircular cross-section." (Ex. 1009, 5:13-16, 5:19-21, 6:44-46, Figs. 1-6.) A PHOSITA would have recognized the non-circular shape of recess 74 to provide an anti-rotational interface between the pad and stem portion 20 because the angles of proximal portion 24 and the lips/edges of recess 74 would prevent the pad from rotating relative to stem portion 20. (Ex. 1002, ¶52.)

x. [1.j] "wherein the porous metal structure of the bone fixation body permanently attaches to an exterior surface of the elongated male protrusion to create the hip implant before the hip implant is implanted."

Zolman discloses placing porous pad 26 in a recess 74 in an exterior surface of stem portion 20, and permanently bonding the porous metal structure of porous pad 26 to the exterior surface of stem portion 20 to create the hip implant before the hip implant is implanted. (Ex. 1009, 6:44-54; Ex. 1002, ¶53.)

2. Claim 2

i. "The method of claim 1, wherein the bone fixation body induces bone to grow partially into the bone fixation body."

As discussed *supra* at Section IX.B.1.vi, *Zolman* discloses that porous pad 26 ("the bone fixation body") is made from a porous metal structure and states that *Rostoker*'s porous material is suitable for forming porous pad 26. *Rostoker*'s porous structure is fabricated by molding and sintering short metal fibers. (Ex. 1010, 2:21-23.) "In the molded and sintered fiber metal aggregate, the metal fibers are completely interconnected." (*Id.*, 5:16-18.) *Rostoker* found that this configuration induces bone to "penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." (*Id.*, 2:40-44; *see also id.*, 3:28-34.) Based on *Rostoker*'s teachings, a PHOSITA would have understood that a porous pad 26 formed of *Rostoker*'s porous structure would induce bone to grow at least partially into the pad. (Ex. 1002, ¶¶54-55.)

3. Claim 3

i. "The method of claim 1, wherein the bone fixation body induces bone to grow entirely throughout the bone fixation body."

As discussed *supra* at Section IX.B.1.vi, *Zolman* discloses that porous pad 26 ("the bone fixation body") is made from a porous metal structure and states that *Rostoker*'s porous material is suitable for forming porous pad 26. *Rostoker*'s porous fiber metal structure is fabricated by molding and sintering short metal

fibers. (Ex. 1010, 2:21-23.) "In the molded and sintered fiber metal aggregate, the metal fibers are completely interconnected." (*Id.*, 5:16-18.) *Rostoker* found that this configuration induces bone to "penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." (*Id.*, 2:40-44; *see also id.*, 3:28-34.) Given *Rostoker*'s teachings that its material is open-pored and *Zolman*'s teachings that the porous structure extends throughout the pad, a PHOSITA would have known that the porous structure of the combination of *Zolman* and *Rostoker* would not only induce bone to grow "a substantial distance" into the structure, as expressly disclosed in *Rostoker*, but also entirely through the structure. (Ex. 1002, ¶¶56-57.)

4. Claim 5

i. [5.a] "A method, comprising:"

As discussed for claim 1, *Zolman* discloses a method of constructing a hip implant. (*See supra* Section IX.B.1.i; *see also infra* Sections IX.B.4.ii-ix; Ex. 1002, ¶¶58-59.)

ii. [5.b] "machining solid metal to form a neck body that includes a base portion, a neck portion that extends outwardly from the base portion and that has an end with a cylindrical shape to engage a femoral ball, and an elongated male protrusion that extends outwardly from the base portion and that includes a cylindrical shape that tapers;"

As discussed for claim 1, *Zolman* discloses fabricating a component 10 ("neck body") formed of solid metal that includes a base portion (*i.e.*, the portion

of neck 28 including aperture 31), a neck portion (*i.e.*, the portion of neck 28 at end 14) that extends outwardly from the base portion and that has an end 14 with a cylindrical shape to engage a ball 30 ("a femoral ball") and a stem portion 20 ("an elongated male protrusion") that extends outwardly from the base portion that tapers to a cylindrical shape at distal end 12. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶60.) As also discussed above, it would have been obvious to a PHOSITA that *Zolman*'s neck body was formed through a machining process or machined-finished. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶60.) As further discussed, it would have been obvious to machine *Zolman*'s stem portion 20 to have any one of a number of cross-sectional shapes, including a cylindrical shape that tapers, as taught by *Rostoker*. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶60.)

iii. [5.c] "making, separately from the neck body, a bone fixation body with an elongated tapering body having a bow shape,"

As discussed for claim 1, *Zolman* discloses making, separately from the neck body, a porous pad 26 ("a bone fixation body") with an elongated tapering body having a bow shape. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶61.)

iv. [5.d] "[making the bone fixation body] with a trapezoidal shape in a cross-sectional view,"

As discussed for claim 1, *Zolman* teaches making porous pad 26 ("the bone fixation body") with a trapezoidal shape in a cross-sectional view. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶62.)

v. [5.e] "[making the bone fixation body] with an opening at a proximal end, and"

As discussed for claim 1, *Zolman* discloses making porous pad 26 ("the bone fixation body") with an opening at a proximal end. (*See supra* Section IX.B.1.v; Ex. 1002, ¶63.)

vi. [5.f] "[making the bone fixation body] with a porous metal structure that extends throughout the bone fixation body with interconnected pores having a geometric structure that replicates a porous structure of natural human bone; and"

The combination of *Zolman* and *Rostoker* discloses these limitations. (Ex. 1002, ¶64.) As discussed *supra* at Section IX.B.1.vi, *Zolman* discloses making porous pad 26 from *Rostoker*'s fiber metal structure to have a porous metal structure that extends throughout the pad.

Rostoker teaches that its porous fiber metal structure can be fabricated with pore diameters and porosities that fall within the known ranges for cancellous bone and that "encourage natural bone to migrate and grow into and throughout the entire body 16." (*Compare* Ex. 1010, 5:6-8, 5:14-16, 5:21-24 *with* Ex. 1001, 4:27-

33; Ex. 1002, ¶64 (citing Ex. 1016, 954).) Thus, the interconnected pores in *Rostoker*'s porous structure have a geometric structure that replicates a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter. (*See supra* Section VIII.A.) As explained above, it would have been obvious to a PHOSITA to fabricate *Zolman*'s porous pad 26 to have *Rostoker*'s porous structure in view of *Zolman*'s explicit teachings to use *Rostoker*'s porous fiber metal structure. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶64.) The use of *Rostoker*'s fiber metal structure in *Zolman*'s porous pad 26 would have been nothing more than a simple substitution of known porous materials and would facilitate bone ingrowth to increase the strength of attachment of the implant to the surrounding bone. (*See supra* Section IX.B.1.vi; *KSR*, 550 U.S. at 416; Ex. 1002, ¶64.)

vii. [5.g] "permanently 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 elongated male protrusion extends through the opening and 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 for claim 1, *Zolman* discloses connecting, after porous pad 26 ("the bone fixation body") is separately made from *Zolman*'s neck body, porous pad 26 to *Zolman*'s neck body and bonding the two components to permanently connect the two components and create a hip implant. (*See supra* Section

IX.B.1.vii; Ex. 1002, ¶65.) Porous pad 26 encircles and is bonded to a proximal portion 24 of stem portion 20, therefore, stem portion 20 extends through the opening in the pad to permanently connect the pad to *Zolman*'s neck. (Ex. 1009, 3:53-54, 4:41-45, 6:41-54, Figs. 1-5; Ex. 1002, ¶65.).

viii. [5.h] "wherein the elongated male protrusion forms a core for the bone fixation body, extends to a distal end of the hip implant, and"

As discussed for claim 1, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") forms a core for porous pad 26 ("the bone fixation body") and extends to a distal end 12 of the hip implant. (*See supra* Section IX.B.1.viii; Ex. 1002, ¶66.)

ix. [5.i] "includes a location having a polygonal shape that provides an anti-rotational interface between the neck body and the bone fixation body."

As discussed for claim 1, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") includes a section having a noncircular shape that provides an anti-rotational interface between *Zolman*'s neck body and porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.1.ix; Ex. 1002, ¶67.) In particular, *Zolman* discloses that proximal portion 24 of stem portion 20 has a polygonal shape that provides the anti-rotational interface discussed *supra* at Section IX.B.1.ix. (*See* Ex. 1009, 5:19-21, Figs. 1-6; Ex. 1002, ¶67.)

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 the pad 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 7

i. "The method of claim 5, wherein the bone fixation body bonds to the neck body after the bone fixation body is made separately from the neck body."

As discussed above for claim 5, *Zolman* discloses that porous pad 26 ("the bone fixation body") is permanently connected to *Zolman*'s neck body after porous pad 26 is made separately from the neck body. (*See supra* Section IX.B.4.vii; Ex. 1002, ¶¶ 68-69.) *Zolman* teaches securing porous pad 26 to stem portion 20 by a diffusion bonding process. (Ex. 1009, 6:48-54.)

6. Claim 9

i. "The method of claim 5, wherein the base portion includes a proximal end surface, and the bone fixation body attaches to the proximal end surface."[17]

FMB has asserted in the related litigation that the claimed "proximal end surface" is the surface of the base portion from which a protrusion extends. For purposes of this IPR, Petitioner is applying the definition asserted by FMB.

Zolman teaches that the outer surface of its neck body has a recess 74 formed therein. (*Id.*, 5:13-16, Fig. 6.) Recess 74 includes an upper lip and teaches that stem portion 20 extends outwardly from this surface. (*See id.*, Figs. 1-6, 14, and 15; Ex. 1002, ¶71.) The distally-facing surface of the upper lip of recess 74, which encompasses the surface area between the outer edge of the lip and where the stem portion extends outwardly from the lip, corresponds to the claimed "proximal end surface" because it is the end surface of the base portion and because stem portion 20 extends from this surface. (*See* Ex. 1009, 3:51-56, Figs. 1-4; Ex. 1002, ¶71.) Porous pad 26 attaches to this surface when the pad 26 is received within and secured to recess 74. (Ex. 1009, 5:13-16, 6:44-48, Figs. 1-4; Ex. 1002, ¶¶70-71.)

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[17] Petitioner does not concede that that claim 9 is valid under 35 U.S.C. § 112.

7. Claim 10

i. [10.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; *see also id.*2:58-62, 3:33-35, Figs. 1-6; *see also infra* Sections IX.B.7.ii-ix; Ex. 1002, ¶¶72-73.)

ii. [10.b] "a neck body formed of solid metal to include a base portion, to include a neck portion that extends outwardly from the base portion and that has an end with a cylindrical shape that engages a femoral component, and to include an elongated male protrusion that extends outwardly from the base portion; and"

As discussed for claim 1, *Zolman*'s hip implant has a solid-metal component 10 ("neck body") formed of solid metal that includes a base portion (*i.e.*, the portion of neck 28 including aperture 31), a neck portion (*i.e.,* the portion of neck 28 at end 14) that extends outwardly from the base portion and that has an end 14 with a cylindrical shape that engages a ball 30 ("a femoral component"), and a stem portion 20 ("an elongated male protrusion") that extends outwardly from the base portion. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶74.)

iii. [10.c] "a bone fixation body that has an elongated tapering body with a bow shape,"

As discussed for claim 1, *Zolman* discloses a porous pad 26 ("a bone fixation body") that has an elongated tapering body with a bow shape. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶75.)

iv. [10.d] "[a bone fixation body] that has an opening extending into the bone fixation body,"

As discussed above for claim 1, *Zolman* discloses a porous pad 26 ("the bone fixation body") that has an opening. (*See supra* Section IX.B.1.v; Ex. 1002, ¶76.) The opening formed in a pad formed on a mandrel extends into and throughout porous pad 26. (*See* Ex. 1009, 7:1-14; Ex. 1002, ¶76.) This is confirmed by Figures 1-4, which show that porous pad 26 completely encircles stem portion 20 and that stem portion 20 extends through an opening in the pad. (Ex. 1009, 3:53-54, 4:41-45, Figs. 1-4.)

v. [10.e] "[a bone fixation body] that has a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and"

As discussed above for claim 1, *Zolman* discloses a porous pad 26 ("the bone fixation body") that has a trapezoidal shape in a horizontal cross-sectional view of the hip implant. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶77.) 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.1.iv.

vi. [10.f] "[a bone fixation body] that has a porous metal structure throughout the bone fixation body with the porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone,"

As discussed above for claim 1, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a porous metal structure that extends throughout porous pad 26. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶78.) As also discussed above for claim 1, the combination of *Zolman* and *Rostoker* discloses the porous-metal-structure claim term. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶78.) As explained above, it would have been obvious to a PHOSITA to fabricate *Zolman*'s porous pad 26 to have *Rostoker*'s porous structure in view of *Zolman*'s explicit teachings to use *Rostoker*'s porous fiber metal structure. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶78.) The use of *Rostoker*'s fiber metal structure in *Zolman*'s porous pad 26 would have been nothing more than a simple substitution of known porous materials and would facilitate bone ingrowth to increase the strength of attachment of the implant to the surrounding bone. (*See supra* Section IX.B.1.vi; *KSR*, 550 U.S. at 416; Ex. 1002, ¶78.)

vii. [10.g] "wherein the bone fixation body and the neck body are separately formed from each other, and the elongated male protrusion extends into the opening of the bone fixation [*sic*] such that the bone fixation body permanently connects to an outer surface of the elongated male protrusion to form the hip implant after being separately formed from the neck body,"

As discussed for claim 1, *Zolman* discloses an embodiment in which *Zolman*'s neck body and porous pad 26 are separately formed from each other and are subsequently bonded together to permanently connect the two components. (*See* Section IX.B.1.vii; Ex. 1002, ¶79.) Porous pad 26 completely encircles a proximal section 24 of stem portion 20 ("the elongated male protrusion") and is bonded to the outer surface of proximal portion 24 to form the hip implant after the pad is separately formed from *Zolman*'s neck body. (Ex. 1009, 3:53-54, 4:41-45, 6:41-54, 7:1-14, Figs. 1-5; Ex. 1002, ¶79.) In this arrangement, stem portion 20 extends into the opening of porous pad 26. (*See* Ex. 1009, Figs. 1-5.)

viii. [10.h] "wherein the elongated male protrusion includes a cylindrical shape that tapers, forms a core for the bone fixation body, extends to a distal end of the hip implant, and"

As discussed for claim 1, *Zolman* discloses stem portion 20 ("the elongated male protrusion") that forms a core for porous pad 26, extends to a distal end 12 of the hip implant, and tapers to distal end 12. (*See supra* Sections IX.B.1.ii, IX.B.1.viii; Ex. 1002, ¶80.) As also discussed, it would have been obvious to machine *Zolman*'s stem portion 20 to have any one of a number of cross-sectional

shapes, including a cylindrical shape that tapers, as taught by *Rostoker*. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶80.)

ix. [10.i] "[the elongated male protrusion] includes a polygonal shape that provides an anti-rotational interface between the neck body and the bone fixation body."

As discussed for claim 5, *Zolman* discloses that a proximal portion 24 of stem portion 20 ("the elongated male protrusion") includes a polygonal shape that provides an anti-rotational interface between *Zolman*'s neck body and porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.4.ix; Ex. 1002, ¶81.)

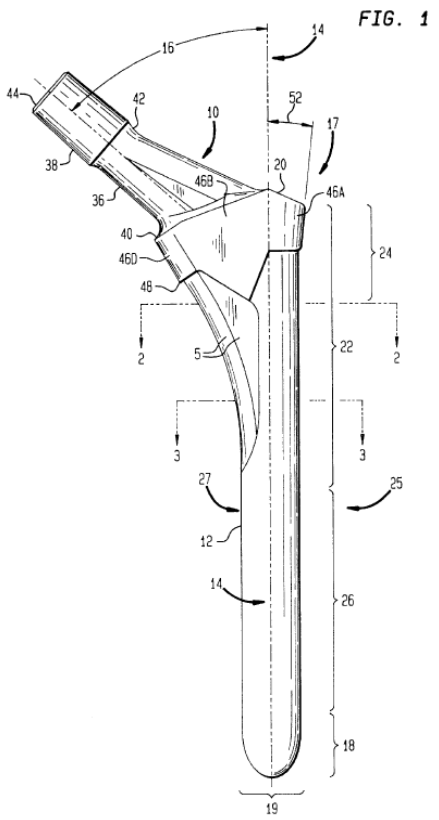
8. Claim 11

i. "The hip implant of claim 10, wherein the bone fixation body is heated to permanently bond the bone fixation body to the neck body after the bone fixation body is separately made from the neck body."

As discussed above for claim 10, *Zolman* discloses that the neck body and porous pad 26 can be separately formed from each other and subsequently bonded together to permanently connect the two components. (*See supra* Section IX.B.7.vii; Ex. 1002, ¶¶82-83.) *Zolman* states that "[t]he bonding may be achieved by diffusion bonding the pad to the stem portion . . . to achieve secure bonding." (Ex. 1009, 6:48-54.) Diffusion bonding applies high pressure in conjunction with high temperatures to weld the components together. (Ex. 1002, ¶83; Ex. 1017, 3:48-59, 4:28-40.)

C. Ground 2: Claims 1-3, 5, 7, and 9-11 are Obvious Based on *Zolman, Rostoker,* and *Averill*

As discussed in Ground 1 for claims 1, 5, and 10, the combination of *Zolman* and *Rostoker* teach a hip implant having, *inter alia*, an "elongated male protrusion" that has "a cylindrical shape that tapers." (*See supra* Sections IX.B.1.ii, IX.B.4.ii, IX.B.7.viii.) If the Board finds that the combination of *Zolman* and *Rostoker* do not disclose this limitation, it would have been obvious to form the distal stem portion of the hip implant of *Zolman* and *Rostoker* to have a cylindrical shape that tapers in light of *Averill*'s disclosure. (Ex. 1002, ¶¶84-85.) *Averill* discloses



a prosthesis 10 including stem 12 having two different shapes, a tapered portion 22 having a proximal locking zone with a geometry shown in Figure 2 that "circumferentially press-fits within the canal" and a cylindrical portion 26 shown in Figure 1 above. (Ex. 1012, 3:4-6, 5:5-10, 5:21-29, Figs. 1-2.) The free end of stem 12 "tapers down from the cylindrical portion 26 to a generally spherical tip portion 19." (*Id.* at 5:26-29.) In light of *Averill*'s disclosure, a PHOSITA would have appreciated that fabricating a distal stem portion to have a cylindrical shape

that tapers would have been an obvious design choice at the time of the alleged invention. (Ex. 1002, ¶87.) 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 that tapers, 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, ¶87; *KSR,* 550 U.S. at 416.) A PHOSITA would have been motivated to fabricate the stem of the hip implant of *Zolman* and *Rostoker* to have this geometry to facilitate insertion into the intramedullary canal while reducing the overall stiffness of the implant. (Ex. 1002, ¶86 (citing Ex. 1023 at 335).)

D. Ground 3: Claims 1-3, 5, 7, and 9-11 are Obvious Based on *Zolman*, *Bobyn*, and *Averill*

The combination of *Zolman*, *Bobyn*, and *Averill* teach or suggest every element of the challenged claims, including the porous-metal-structure claim terms under Petitioner's construction, *supra* Section VIII.A, and Patent Owner's more narrow interpretation. (Ex. 1002, ¶42.)

1. Claim 1

i. Claim element 1.a

As discussed in Ground 1 for claim 1, *Zolman* discloses a method of constructing a hip implant. (*See supra* Section IX.B.1.i; *see also infra* Sections IX.D.1.ii-x; Ex. 1002, ¶¶88-89.)

ii. Claim element 1.b

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating a solid-metal component 10 ("neck body") formed of solid metal that includes a neck 28 having a base portion (*i.e.*, the portion including aperture 31) and a neck portion (*i.e.*, the portion of neck 28 at end 14) that extends outwardly from the base portion and that has an end with a cylindrical shape that engages a femoral component (*i.e.*, a ball 30). (*See supra* Section IX.B.1.ii; Ex. 1002, ¶90.) *Zolman*'s neck body also includes a stem portion 20 ("an elongated male protrusion") that extends outwardly from the base portion and tapers to distal end 12. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶90.) As also discussed above, it would have been obvious to a PHOSITA that *Zolman*'s neck body was formed through a machining process or machine-finished. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶90.) To the extent the Board finds that *Zolman* does not disclose the claimed "cylindrical shape that tapers," *Averill* discloses this shape. (Ex. 1012 at Fig. 1, 5:5-10, 5:21-29; Ex. 1002, ¶90.) 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 that tapers, as taught by *Averill*, to facilitate insertion into the intramedullary canal while reducing the stiffness of the implant. (*KSR*, 550 U.S. at 416; Ex. 1002, ¶90.)

iii. Claim element 1.c

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating, separately from *Zolman*'s neck body, a porous pad 26 ("a bone fixation body") with an elongated tapering body with a bow. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶91.)

iv. Claim element 1.d

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating porous pad 26 ("the bone fixation body") with a trapezoidal shape in a horizontal cross-sectional view. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶92.)

v. Claim element 1.e

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating porous pad 26 ("the bone fixation body") with a proximal end including an opening. (*See supra* Section IX.B.1.v; Ex. 1002, ¶93.)

vi. Claim element 1.f

The combination of *Zolman* and *Bobyn* disclose these limitations. (Ex. 1002, ¶94.) As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating

porous pad 26 ("the bone fixation body") with a porous metal structure that extends throughout the porous pad 26. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶94.) *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 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* 38-46.) *Bobyn* discloses a porous tantalum biomaterial with "desirable characteristics for bone ingrowth" having structural and mechanical properties that closely resemble the properties of cancellous (trabecular) bone. (*See* Ex. 1011, 907, 913.) The biomaterial is fabricated by coating a vitreous carbon skeleton with elemental tantalum through a chemical vapor deposition process to form a porous metal structure. (*Id*., 907-08; Ex. 1002, ¶94.) 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." (*Id*., 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 '080 patent for ingrowth of cancellous and cortical bone spicules, and also fall within the known range of pore diameters and porosities of cancellous bone. (Ex. 1001, 4:27-30; Ex. 1002, ¶94 (citing 1016, 954).) In fact, it was understood at the time of the alleged invention that the structure of *Bobyn*'s biomaterial is similar to the microstructure of cancellous bone. (Ex. 1020, Abstract, 6:1-4; Ex. 1022, 1.)

It would have been obvious to a PHOSITA to construct *Zolman*'s porous pad 26 from *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶94.) *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."[18] (Ex. 1011, 907, 913.) *Bobyn* further explains that its material overcomes deficiencies of conventional porous materials such as limited porosity by providing an open-cell structure with high and interconnecting porosity to encourage cell and tissue growth. (*Id.*, 907, 912.) By 1999, *Bobyn*'s porous

[18] 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.)

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 and its use in other orthopedic applications, a PHOSITA would have been motivated to fabricate porous pad 26 of *Zolman*'s implant from *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶94.) Indeed, the Board found in the '582 IPR 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." (Ex. 1008, 42.) The use of *Bobyn*'s material in *Zolman*'s pad 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, ¶94.)

A PHOSITA would have had a reasonable expectation of success manufacturing *Zolman*'s implant with *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶94.) A PHOSITA would have known how to construct a pad from *Bobyn*'s

material using the process taught in *Zolman*.[19] (Ex. 1002, ¶94.) *Bobyn* states that its material is readily shapeable into any configuration, including the shape of *Zolman*'s pad. (Ex. 1011, 907, 913; *see also* Ex. 1020, 8:7-11.) *Bobyn* teaches that tantalum is "a strong, ductile metal" (Ex. 1011, 913) which enables it to bend without breaking (Ex. 1022, 2). 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, ¶94.) Moreover, a PHOSITA would have known how to manipulate the porous tantalum biomaterial so that it could be bent without breaking the tantalum struts, such as, for example, heating the tantalum material. (Ex. 1002, ¶94.)

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[19] 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, ¶94.) 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.)

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).[20] As such, 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, ¶94; *see also* Ex. 1020, 8:7-11, 9:17; Ex. 1021, 1:11-24, 3:51-55, Fig. 1.) Methods for attaching the porous tantalum biomaterial to a solid metal substrate were well-known in the art at the time of the alleged invention. (Ex. 1002, ¶94 (citing Ex. 1020, 9:54-60; Ex. 1021, 1:11-24, 3:51-55, 4:7-22, Fig. 1).)

[20] 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.)

vii. Claim element 1.g

As discussed in Ground 1 for claim 1, *Zolman* discloses connecting, after porous pad 26 ("the bone fixation body") is separately fabricated from *Zolman*'s neck body, porous pad 26 to *Zolman*'s neck body to permanently attach the two components and create a hip implant. (*See supra* Section IX.B.1.vii; Ex. 1002, ¶95.)

viii. Claim element 1.h

As discussed in Ground 1 for claim 1, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") extends into the opening of porous pad 26 ("the bone fixation body"), forms a core for the pad, and extends toward a distal end 12 of the hip implant. (*See supra* Section IX.B.1.viii; Ex. 1002, ¶95.)

ix. Claim element 1.i

As discussed in Ground 1 for claim 1, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") includes a section with a non-circle shape in a cross-sectional view of the hip implant in order to provide an anti-rotational interface between *Zolman*'s neck body and porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.1.ix; Ex. 1002, ¶97.)

x. Claim element 1.j

As discussed in Ground 1 for claim 1, *Zolman* discloses bonding the porous metal structure of porous pad 26 ("the bone fixation body") to an exterior surface

of stem portion 20 ("the elongated male protrusion") to permanently attach porous pad 26 to an exterior surface of stem portion 20 to create the hip implant before implantation. (*See supra* Section IX.B.1.x; Ex. 1002, ¶98.)

2. Claim 2

As discussed *supra* at Section IX.D.1.vi, it would have been obvious to fabricate *Zolman*'s porous pad 26 ("the bone fixation body") from *Bobyn*'s biomaterial. *Bobyn* discloses that the material has "an unusually high and interconnecting porosity with a very regular pore shape and size." (Ex. 1011, 907) Due to its structure, 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.*, 912.) *Bobyn* teaches that in implants made of its tantalum porous material, "[i]ngrowth of bone across the full diameter of the implant was common." (*Id.*, 911.) Thus, a pad formed of *Bobyn*'s structure would induce bone growth at least partially through its structure. (Ex. 1002, ¶¶99-100.)[21]

[21] Patent Owner's expert, Helmus, conceded that a person of ordinary skill in the art would have no doubt as to whether the porous tantalum biomaterial facilitates bone ingrowth. (Ex. 1018, 257:23-258:4.)

3. Claim 3

As discussed *supra* at Section IX.D.1.vi, it would have been obvious to fabricate *Zolman*'s porous pad 26 ("the bone fixation body") from *Bobyn*'s biomaterial. As discussed *supra* at Section IX.D.2, a pad formed of *Bobyn*'s structure would induce bone to grow entirely throughout its structure. (Ex. 1011, 911; Ex. 1002, ¶¶101-102.)

4. Claim 5

i. Claim element 5.a

As discussed in Ground 1 for claim 5, *Zolman* discloses a method of constructing a hip implant. (*See supra* Section Section IX.B.4.i; *see also infra* Sections IX.D.4.ii-ix; Ex. 1002, ¶¶103-104.)

ii. Claim element 5.b

As discussed in Ground 1 for claim 5, *Zolman* discloses fabricating a component 10 ("neck body") formed of solid metal that includes a neck 28 having a base portion (*i.e.*, the portion including aperture 31) and a neck portion (*i.e.*, the portion of neck 28 at end 14) that has an end with a cylindrical shape to engage a femoral component (*i.e.*, a ball 30). (*See supra* Section IX.B.4.ii; Ex. 1002, ¶105.) *Zolman*'s neck body also includes a stem portion 20 ("an elongated male protrusion") that extends outwardly from the base portion and tapers to a cylindrical shape at distal end 12. (*See supra* Section IX.B.4.ii; Ex. 1002, ¶ 105.)

As also discussed above, it would have been obvious to a PHOSITA that *Zolman*'s neck body was formed through a machining process or machine-finished. (*See supra* Section IX.B.4.ii; Ex. 1002, ¶105.) As discussed in Ground 3 for claim 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 that tapers, as taught by *Averill*. (*See supra* Section IX.D.1.ii; Ex. 1002, ¶105.)

iii. Claim element 5.c

As discussed in Ground 1 for claim 5, *Zolman* discloses making, separately from the neck body, a porous pad 26 ("a bone fixation body) with an elongated tapering body having a bow shape. (*See supra* Section IX.B.4.iii; Ex. 1002, ¶106.)

iv. Claim element 5.d

As discussed in Ground 1 for claim 5, *Zolman* teaches making porous pad 26 ("the bone fixation body") with a trapezoidal shape in a cross-sectional view. (*See supra* Section IX.B.4.iv; Ex. 1002, ¶107.)

v. Claim element 5.e

As discussed in Ground 1 for claim 5, *Zolman* discloses making porous pad 26 ("the bone fixation body") with an opening at a proximal end. (*See supra* Section IX.B.4.v; Ex. 1002, ¶108.)

vi. Claim Element 5.f

The combination of *Zolman* and *Bobyn* discloses these limitations. (Ex. 1002, ¶109.) As discussed in Ground 1 for claim 5, *Zolman* discloses fabricating porous pad 26 ("the bone fixation body") from a porous metal structure that extends throughout the pad. (*See supra* Section IX.B.4.vi; Ex. 1002, ¶109.) As discussed in Ground 3 for claim 1, *Zolman* discloses that the pad can be made from "any suitable porous material" and that *Bobyn* discloses a porous tantalum material having interconnected pores with pore diameters and porosities that fall within the range recited by the '080 patent and within the known range of pore diameters and porosities for cancellous bone. (*See supra* Section IX.D.1.vi; Ex. 1002, ¶109 (citing 1016, 954).) Thus, the interconnected pores in *Bobyn*'s porous structure have a geometric structure that replicates a porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter. (*See supra* Section VIII.A.) In fact, as discussed above for claim 1, it was understood that *Bobyn*'s porous structure is similar to the microstructure of cancellous bone. (*See supra* Section IX.D.1.vi, Ex. 1002, ¶109.) As explained above for claim 1, it would have been obvious to a PHOSITA to construct *Zolman*'s porous pad from *Bobyn*'s porous tantalum biomaterial to form a high strength femoral implant with a porous structure having desirable characteristics

for bone ingrowth. (*See supra* Section Section IX.D.1.vi; Ex. 1002, ¶109; *see KSR*, 550 U.S. at 416.) As also explained above, a PHOSITA would have had a reasonable expectation of success manufacturing *Zolman*'s implant with *Bobyn*'s porous tantalum biomaterial. (Ex. 1002, ¶109.)

vii. Claim Element 5.g

As discussed in Ground 1 for claim 5, *Zolman* discloses permanently connecting, after porous pad 26 ("the bone fixation body") is separately made from *Zolman*'s neck body, porous pad 26 to *Zolman*'s neck body to create a hip implant with stem portion ("the elongated male protrusion") extending into and through the opening in porous pad 26 in order to permanently connect *Zolman*'s neck body to porous pad 26 and create the hip implant. (*See supra* Section IX.B.4.vii; Ex. 1002, ¶110.)

viii. Claim Element 5.h

As discussed in Ground 1 for claim 5, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") forms a core for porous pad 26 ("the bone fixation body") and extends to a distal end 12 of the hip implant. (*See supra* Section IX.B.4.viii; Ex. 1002, ¶111.)

ix. Claim Element 5.i

As discussed in Ground 1 for claim 5, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") includes a location having a polygonal shape that provides an anti-rotational interface between *Zolman*'s neck body and porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.4.ix; Ex. 1002, ¶112.)

5. Claim 7

As discussed in Ground 1 for claim 7, *Zolman* discloses that porous pad 26 ("the bone fixation body") is bonded to *Zolman*'s neck body after porous pad 26 is made separately from the neck body. (*See supra* Section IX.B.5.i; Ex. 1002, ¶¶113-14.)

6. Claim 9

As discussed in Ground 1 for claim 9, porous pad 26 attaches to "the proximal end" surface of the base portion (*i.e.*, the portion of neck 28 including aperture 31) when porous pad 26 is received within and secured to recess 74. (*See supra* Section IX.B.6.i; Ex. 1002, ¶¶115-16.)

7. Claim 10

i. Claim element 10.a

As discussed in Ground 1 for claim 10, *Zolman* discloses a hip implant. (*See supra* Section IX.B.7.i; *see also infra* Sections IX.D.7.ii-ix; Ex. 1002, ¶¶117-18.)

ii. Claim element 10.b

As discussed in Ground 1 for claim 10, *Zolman*'s hip implant has a component 10 ("neck body") formed of solid metal to include a base portion (*i.e.*, the portion of neck 28 including aperture 31), a neck portion (*i.e.*, the portion of neck 28 at end 14) that extends outwardly from the base portion that has an end 14 with a cylindrical shape that engages a ball 30 ("a femoral component"), and also includes a stem portion 20 ("an elongated male protrusion") that extends outwardly from the base portion. (*See supra* Section IX.B.7.ii; Ex. 1002, ¶119.)

iii. Claim element 10.c

As discussed in Ground 1 for claim 10, *Zolman* discloses a porous pad 26 ("a bone fixation body") that has an elongated tapering body with a bow shape. (*See supra* Section IX.B.7.iii; Ex. 1002, ¶120.)

iv. Claim element 10.d

As discussed in Ground 1 for claim 10, *Zolman* teaches that porous pad 26 ("the bone fixation body") has an opening extending into it. (*See supra* Section IX.B.7.iv; Ex. 1002, ¶121.)

v. Claim element 10.e

As discussed in Ground 1 for claim 10, *Zolman* teaches that porous pad 26 ("a bone fixation body") has a trapezoidal shape in a horizontal cross-sectional view of the hip implant. (*See supra* Section IX.B.7.v; Ex. 1002, ¶122.)

vi. Claim element 10.f

As discussed in Ground 1 for claim 10, *Zolman* discloses fabricating porous pad 26 ("the bone fixation body") with a porous metal structure that extends throughout the pad. (*See supra* Section IX.B.7.vi; Ex. 1002, ¶123.) As discussed in Ground 3 for claim 1, *Zolman* discloses that the pad can be made from "any suitable porous material" and *Bobyn* discloses a porous tantalum material that meets the claimed porous-metal-structure claim term under the construction adopted by the Board and under FMB's narrow interpretation. (*See supra* Section IX.D.1.vi; Ex. 1002, ¶123.) As also discussed, it would have been obvious to a PHOSITA to construct porous pad 26 from *Bobyn*'s porous material to form a high strength femoral implant with a porous structure having desirable characteristics for bone ingrowth. (*See supra* Section IX.D.1.vi; *KSR*, 550 U.S. at 416; Ex. 1002, ¶123.) As further 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.vi; Ex. 1002, ¶123.)

vii. Claim element 10.g

As discussed in Ground 1 for claim 10, *Zolman* discloses that porous pad 26 ("the bone fixation body") and *Zolman*'s neck body are separately formed and that stem portion 20 ("the elongated male protrusion") extends into the opening of

porous pad 26 such that porous pad 26 permanently connects to an outer surface of stem portion 20 to form the hip implant after being separately formed from the neck body. (*See supra* Section IX.B.7.vii; Ex. 1002, ¶124.)

viii. Claim element 10.h

As discussed in Ground 1 for claim 10, *Zolman*'s stem portion 20 ("the elongated male protrusion") extends to distal end 12 of the hip implant, tapers to a cylindrical shape at distal end 12, and forms a core for porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.7.viii; Ex. 1002, ¶125.) As discussed in Ground 3 for claim 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 that tapers, as taught by *Averill*. (*See supra* Section IX.D.1.ii; Ex. 1002, ¶125.)

ix. Claim element 10.i

As discussed in Ground 1 for claim 10, *Zolman* discloses that stem portion 20 ("the elongated male protrusion") includes a polygonal shape that provides an anti-rotational interface between *Zolman*'s neck body and porous pad 26 ("the bone fixation body"). (*See supra* Section IX.B.7.ix; Ex. 1002, ¶126.)

8. Claim 11

As discussed above for claim 11, *Zolman* teaches that porous pad 26 ("the bone fixation body") is heated to permanently bond porous pad 26 to *Zolman*'s

neck body after porous pad 26 is separately made from the neck body. (*See supra* Section IX.B.8.i; Ex. 1002, ¶¶127-28.)

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.

Moreover, 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 claims 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 trabecular 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 ground based on *Averill* in event the Board finds that the combination of *Zolman* and *Rostoker* do not disclose the claimed "elongated protrusion" that has a "cylindrical shape that tapers."

XI. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 1-3, 5, 7, and 9-11 of the '080 patent.

Respectfully submitted,

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

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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 13,911 words according to the word count of the word-processing software used to prepare the petition.

By: /Naveen Modi/

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Paul Hastings LLP

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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. 9,283,080 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:

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

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