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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. 9,308,093

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,308,093

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1024	U.S. Patent No. 8,821,582

I. INTRODUCTION

Zimmer Biomet Holdings, Inc. ("Zimmer" or "Petitioner") requests *inter partes* review of claims 1-12 of U.S. Patent No. 9,308,093 ("the '093 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 prevail and establish the unpatentability of the challenged claims by a preponderance of evidence. Trial should be instituted and claims 1-12 of the '093 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 '093 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 '093 patent, U.S. Patent No. 9,283,080 ("the '080 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 '080 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 '093 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: 212.318.6689/Fax: 212.230.7829). 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 '093 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '093 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 '093 patent against Petitioner. (*See* Ex. 1013.)

V. PRECISE RELIEF REQUESTED AND GROUNDS RAISED

Petitioner respectfully requests review of claims 1-12 of the '093 patent and cancellation of these claims as unpatentable in view of the following grounds[1]:

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

- **Ground 1**: Claims 1-12 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 6 and 12 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);
- **Ground 3**: Claims 1-12 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman* and J.D. Bobyn et al., "Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial," J. of Bone and Joint Surgery, Vol. 81-B, No. 5 (Sept. 1999) ("*Bobyn*") (Ex. 1011); and
- **Ground 4**: Claims 6 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Zolman*, *Bobyn*, and *Averill*.

On its face, the '093 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

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

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

The '093 patent issued from U.S. Patent Application No. 14/878,092 ("the '092 application"), filed October 8, 2015, which purports to be a continuation of U.S. Patent Application No. 13/947,069 ("the '7069 application"), filed on July 21, 2013, now the '612 patent, which purports to be a continuation of U.S. Patent Application No. 11/409,611 ("the '611 application"), filed on April 24, 2006, now the '642 patent, which purports to be a continuation of U.S. Patent Application No. 10/446,069 ("the '6069 application"), filed on May 27, 2003, now abandoned. (Ex. 1001, title page.)

A. Overview of the '093 Patent

The '093 patent discloses a "hip implant with [a] porous body." (Ex. 1001, Title; Ex. 1002, ¶ 12.) The disclosed hip implant includes two distinct bodies, a neck body 14 and a bone fixation body 16. (*See, e.g.,* Ex. 1001, Abstract, 1:46-48, 3:1-3, Figs. 1-2.) Figure 1 illustrates an exemplary embodiment of hip implant 10, and Figure 2 illustrates the implant embedded inside a patient's femur 50:

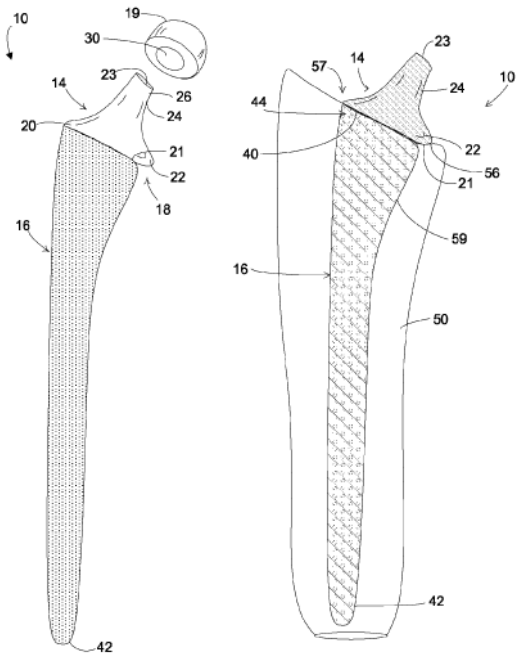

Fig. 1 **Fig. 2**

(*See id.*, 2:43-46, 2:64-65, 3:35-37, Figs. 1-2.)

Neck body 14 "is located at a proximal end 18 of hip implant 10 and functions to connect the hip implant 10 to a spherically shaped femoral ball 19 and acetabular component (not shown)." (*Id.*, 3:4-7.) It includes a neck portion 24 that extends outwardly from a base portion 20, which has a distal end surface 21 that connects or fuses to a proximal end surface 40 of bone fixation body 16 at a junction 44. (*Id.*, 3:7-13, 3:26-28; Ex. 1002, ¶13.) The bone fixation body is formed from a porous metal structure that is "completely porous" and "does not include a metal substrate." (Ex. 1001, 2:6-7; 3:29-34.) "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." (*Id.*, 3:49-51.) The '093

patent also discloses an embodiment in which a protrusion 74 extends from the base portion into the bone fixation body. (Ex. 1001, 5:11-18; Ex. 1002, ¶14.)

In a preferred embodiment, the porous structure of the bone fixation body is made by sintering titanium alloy powder. (Ex. 1001, 4:5, 4:19-39.) 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.*, 3:52-54; Ex. 1002, ¶15.) The specification teaches that the neck body can be made of solid metal and machined "using conventional and known machining techniques" to have the size and shape shown in the figures. (Ex. 1001, 3:18-23, 4:8-10.) In one embodiment, the bone fixation body "simultaneously forms and attaches to the neck body." (Ex. 1001, 4:40-41.) In an alternative embodiment, these bodies are "fabricated independently and subsequently connected together" using known techniques. (*Id.*, 4:42-46; Ex. 1002, ¶15.)

The porous structure allows bone to grow into the bone fixation body.[2] (Ex. 1001, 1:39-41, 2:10-16, 3:55-56, 3:62-65; Ex. 1001, ¶16.) To promote this bone ingrowth, the porous metal structure "emulates the size and shape of the porous

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

structure of natural bone." (*Id.*, 3:56-59.) A preferred embodiment of the porous metal structure has the following characteristics: "[T]he average pore diameter of body 16 is about 40 μm to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50-60 microns." (Ex. 1001, 3:59-62.)[3] The specification also states that these disclosed ranges "are exemplary" and "could be modified, and the resulting hip implant still within the scope of the invention." (*Id.*, 3:66-4:4.)

The '093 patent includes 15 claims, but this petition only requests review of claims 1-12. Claims 1 and 7 relate to a method of manufacturing a two-piece hip implant comprising "a neck body" and "a bone fixation body." (Ex. 1001, 6:21-47, 6:62-7:21.) Claims 1 and 7 recite that the "bone fixation body" is formed of a "porous metal structure" that has "a size and a shape that emulate a size and a shape of a porous structure of natural human bone." (*Id.*, 6:30-35, 7:4-8; Ex. 1002, ¶17.)

B. Overview of the Prosecution History

Relevant portions of the prosecution history of the '093 patent and certain related patents and applications are discussed below.

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[3] The disclosed ranges overlap with known pore diameters and porosities of cancellous (trabecular) bone. (Ex. 1002, ¶16, fn.1 (citing Ex. 1016 at 954).)

1. Prosecution of the ’6069 Application

The ’093 patent claims priority to the ’6069 application. (Ex. 1001, title page.) Applicant filed the ’6069 application with three independent claims that recited a “bone fixation body” formed of a “completely porous structure.” (Ex. 1004, 177-79.) Applicant appealed the Examiner’s rejection of these claims as being anticipated by multiple references. (*Id.*, 111-118, 140-147.) In its decision on appeal, the Board identified the issue on appeal as being “the proper interpretation of ‘completely porous.’” (*Id.*, 58.) The Board found that while the term “porous” is explicitly defined, the term “completely porous” is not. (*Id.*, 59.) The Board construed the term “completely porous” to mean “entirely porous,” and found that this interpretation was consistent with the specification “which describes the porous structure as extending ‘entirely’ through the implant body.” (*Id.* (internal citations omitted).)

2. The ’642 Patent Prosecution

The ’093 patent claims priority to the ’611 application. (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.) Nevertheless, the Examiner found that 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] Applicant ultimately accepted the Examiner's determination that Draenert disclosed the claimed porous structure, and amended the claims to require the bone fixation body to have "a trapezoidal shape in a horizontal cross-sectional view," which led to allowance of the claims. (*Id.*, 16-20, 34-46, 53-64.)

3. The '612 Patent Prosecution

During prosecution of the '7069 application (the '093 patent's parent application), the Examiner rejected claims based on a combination of references, including Draenert. (Ex. 1006, 37-44.) Rather than addressing the Examiner's assertion that Draenert discloses a bone fixation body having a porous structure with "a size and a shape that emulate a size and a shape of a porous structure of natural human bone to increase the surface area for attachment to the surrounding bone" (*id.*, 40), Applicant amended the rejected claims to recite "a male

[4] All emphasis added unless otherwise indicated.

protrusion" or "elongated protrusion" that "extends into the bone fixation body" (*id.*, 24-31). The Examiner ultimately found the '612 patent claims allowable "due to at least the limitation of the bone fixation body being porous throughout, wherein a male protrusion on the neck extends into a porous structure of the bone fixation body such that the porous bone fixation body surrounds an exterior surface of the male protrusion." (*Id.*, 13.)

4. The '093 Patent Prosecution

The '092 application received a first action allowance. (Ex. 1007, 2-8.) In its statement of reasons for allowance, the Examiner characterized "[t]he main point of novelty" of the allowed claims as "the solid metal neck body interfacing with and becoming a core for the completely porous bone fixation body." (Ex. 1007, 8.)

C. The '582 IPR

The '093 patent is related to the '582 patent, which claims priority to the same applications as the '093 patent. (Ex. 1001, title page; Ex. 1024, title page.) Like the '093 patent claims, certain claims of the '582 patent recite a "porous metal structure" that has "a size and a shape that emulate a size and shape of a porous structure of natural human bone." (Ex. 1024, 15:55-60, 17:1-4.) During the '582 IPR, Patent Owner argued that 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 in its FWD, and instead found that "the broadest reasonable interpretation consistent with the Specification of the porous-metal-structure claim terms is that they require emulating the size and shape of the porous structure of natural human bone as measured, for example, by pore diameter, porosity, and intersection diameter, but they do *not require* emulating the size and shape of the interconnected plates and rods that form trabecular bone." (*Id.*, 12-13 (emphasis in original).)

This petition includes similar grounds to those raised in the '582 IPR. In its FWD, the Board held that Zimmer demonstrated by "a preponderance of the evidence that claims 1-5, 8-11, 14, 15, and 17-20 [of the '582 patent] are unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman and Rostoker." (Ex. 1008, 36.) The Board found that "the combination of Zolman and Rostoker teaches a porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone" and that "Rostoker discloses values for pore size and porosity within the preferred ranges taught by the '582 Patent for ingrowth of cancellous and cortical bone spicules." (*Id.*, 24.) The Board also held that Zimmer demonstrated by "a preponderance of the evidence that claims 1-5, 8-11, 13-15, and 17-20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman and Bobyn." (*Id.*, 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 '093 patent should be given their broadest reasonable interpretation ("BRI"). Under this standard, Petitioner provides constructions for the terms identified below. The

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[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 '093 patent.

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

A. "Porous-Metal-Structure" Claim Term

Claims 1 and 7 recite a "porous metal structure" that has "a size and a shape that emulate a size and a shape of a porous structure of natural human bone." (Referred to herein as "the porous-metal-structure claim term") (Ex. 1001, 6:30-35, 7:4-8.) These terms 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." (Ex. 1008, 12-13 (emphasis in original).)[8] The Board previously

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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, 9 fn.6; *see also* Ex. 1014, 744 (defining "emulate" to mean "imitate").)

adopted this construction for this same claim term in the '582 IPR. (Ex. 1008, 12-13).

The proposed construction is consistent with the plain meaning of the claim language. The porous-metal-structure claim terms in claims 1 and 7 simply require "***a*** porous metal structure" (claim 1) or "***a*** completely porous metal structure"[9] (claim 7) that "has ***a*** size and ***a*** shape that emulate ***a*** size and ***a*** shape of ***a*** porous structure of natural human bone." (Ex. 1001, 6:31-37, 7:5-8) 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, 12-13.) The Examiner had a similar understanding of the plain meaning of this claim language during prosecution of the '611 application, finding that the

[9] The Board construed the term "completely porous" during prosecution of the '6069 application. (Ex. 1004, 59.)

claim limitation was met by a prior art structure that formed pores of a certain size and shape that emulated the size and shape of bone. (Ex. 1005, 105.)

This interpretation is also consistent with the specification, which discloses a hip implant seeking to improve the design of prior hip implants by providing a porous structure that "readily accepts and encourages surrounding bone to grow into and even through the body of the implant." (Ex. 1001, 2:21-24.) 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.*, 3:62-65.) 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.*, 3:55-59.)

The specification also specifically characterizes the porous structure based on pore diameter, porosity, and intersection diameter. (*Id.*, 3:59-62.) In a preferred embodiment, the specification discloses a porous structure with the following size and shape: "Preferably, the average pore diameter of body 16 is about 40 μm to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50-60

microns." (*Id.*)[10] 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, 84:23-86:22; Ex. 1019, 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.*, 3:66-4:4.) Thus, the specification supports construing the porous-metal-structure claim terms 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 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 cancellous (trabecular) bone. (Ex. 1008, 10.) Patent Owner's focus on cancellous (trabecular) bone is inconsistent with the broader recital of "natural human bone" in the claims and the specification, which does not even mention

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

"interconnected plates and rods that form trabecular bone."[11] (Ex. 1008, 12.) FMB's requirement of "interconnected plates and rods" is also contrary to the specification's broad disclosure that the porous structure "can be formed by sintering titanium, titanium alloy powder, metal beads, metal wire mesh, or other suitable materials, metals, or alloys known in the art" (Ex. 1001, 3:52-54), which FMB has previously argued would not form "interconnected plates and rods" (Ex. 1008, 23-24) For the reasons discussed above, the Board should continue to apply its claim construction from the '582 IPR. (Ex. 1008, 12-13.)

B. Separate Fabrication

Claim 1 recites "*fabricating, separately* from the neck body, a bone fixation body." (Ex. 1001, 6:30-31.) Claim 7 contains a similar recitation. (*Id.*, 7:4-5.) In the '582 IPR, Patent Owner proposed, and the Board accepted, that the BRI of the "fabricating" step requires the bone fixation body and the neck body to be formed independently from each other. (Ex. 1008, 18; 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 claim 7. This construction is consistent with the specification which discloses that the neck and bone fixation bodies can be

[11] Indeed, the '093 patent specification does not mention plates, rods, or cancellous (trabecular) bone.

fabricated independently and subsequently connected together. (Ex. 1001, 4:42-44.)

C. Connection "After" Separate Fabrication

Claim 1 recites "permanently connecting, *after* the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body." (Ex. 1001, 6:38-40). Claim 7 contains a similar recitation. (*Id.*, 7:11-13.) In the '582 IPR, Patent Owner proposed, and the Board accepted, that the BRI of the "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. 1008 at 13, fn. 8, 15; Ex. 1024, 16:37-39.) This is consistent with the specification's disclosure that the neck and bone fixation bodies can be fabricated independently and subsequently connected together. (Ex. 1001, 4:42-44.)

IX. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY UNDER THE BRI

A. Overview of Prior Art

1. *Zolman*

Zolman discloses a method of constructing a prosthetic implant "suitable for use as a femoral component for a hip prosthesis." (Ex. 1009, Title, 1:11-15; Ex. 1002, ¶21.) In an exemplary embodiment, a porous pad 26 is wrapped around a stem portion 20 of femoral component 10 to form a hip implant. (*See, e.g.*, *id.*, 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, ¶22.) An embodiment of *Zolman*'s implant and its porous pad 26 are shown below:

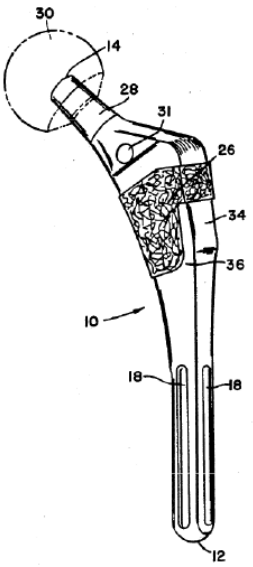


FIG. 1

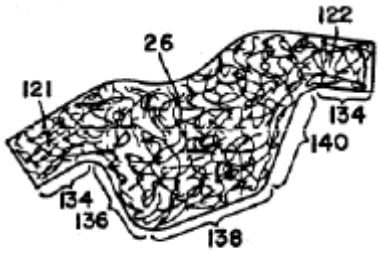


FIG. 11

(*Id.*, Figs.1, 11, 2:58-59, 3:13-14.)

As described in *Zolman*, porous pad 26 is preferably formed first as a substantially flat sheet and is then wrapped around stem portion 20 into a final shape conforming to the shape of stem portion 20. (*See, e.g., id.*, Abstract, 2:44-49, 4:29-41, 4:46-58.) Porous pad 26 is positioned securely in a recess 74 in a proximal portion 24 of stem portion 20 which corresponds to the wrapped shape of pad 26. (*Id.*, 5:13-16, 6:44-46, Fig. 6; Ex. 1002, ¶23.) Porous pad 26 is then bonded to stem portion 20 by diffusion bonding, sintering, or "other suitable

bonding methods." (*Id*., 6:39-54.) *Zolman* also discloses that porous pad 26 can be formed into its final shape separately on a mandrel, which has the same shape as the implant, removed from the mandrel, and then attached to stem portion 20. (*Id.*, 7:1-14; Ex. 1002, ¶24.) *Zolman* states that porous pad 26 "can be shaped to conform to any desirable and suitable implant stem or fixation surface configuration" and discloses that, in one embodiment, a proximal portion of stem portion 20 has a non-circular cross-section. (Ex. 1009, 5:16-21, Figs. 5-6; Ex. 1002, ¶25.)

2. *Rostoker*

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

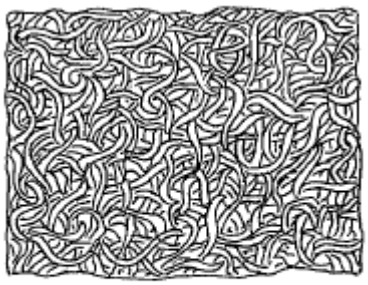


FIG. 4

(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, ¶28.) "Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." (*Id.*, 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." (Ex. 1010, 2:48-52.)

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

3. *Bobyn*

Bobyn studies bone ingrowth in a porous metal structure formed of a tantalum biomaterial for use in reconstructive orthopedics and other surgical disciplines. (Ex. 1011, 907; Ex. 1002, ¶¶30-31.) The porous tantalum material 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* also teaches that the structural and mechanical properties of the tantalum material are similar to those of subchondral bone, which is composed of cancellous (trabecular) bone. (*Id.*, 913; Ex. 1002, ¶¶32-34.)

According to *Bobyn*, tantalum "is a strong, ductile metal with excellent corrosion resistance" that was "used for a wide variety of implants." (Ex. 1011, 913.) *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, ¶35.)

4. *Averill*

Averill discloses a hip prosthesis 10 having a stem 12 that includes a tapered portion 22 and a cylindrical portion 26. (Ex. 1012, 5:5-10; 5:21-29, Fig. 1; Ex. 1002, ¶¶ 36-38.) *Averill* discloses that Figures 2 and 3 illustrate cross-sections of stem portion 12 at lines 2—2 and 3—3 of Figure 1, respectively. (*Id.*, 5:30-32, Figs. 1-3.) *Averill* discloses that "[t]he cross-sectional shape of the tapered portion 22 [of stem 12] at line 2—2, (FIG. 2) . . . presents a greater medial-lateral dimension 28 as compared with the overall anterior-posterior dimension 30" and changes to "an almost circular cross-section at line 3—3, (FIG. 3)." (*Id.*, 5:30-39.)

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

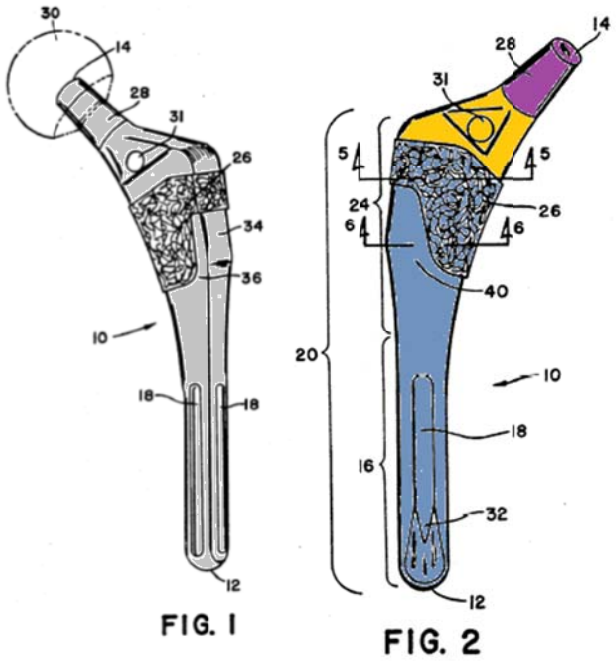
Zolman and *Rostoker* disclose each and every element of claims 1-12. (Ex. 1002, ¶39.) *Zolman* discloses all of the claimed limitations except for the porous-metal-structure claim terms. *Zolman*, however, expressly discloses fabricating porous pad 26 from *Rostoker*'s fiber metal mesh, which discloses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

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 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-vii; Ex. 1002, ¶40-41; Ex. 1008, 19.)

ii. [1.b] "machining a neck body from solid metal to have a base portion, a neck portion that extends outwardly from the base portion and includes a cylindrical configuration with a taper that receives a femoral ball, and a male protrusion that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a polygonal shape in a cross-sectional view;"



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.[12] (Ex. 1002, ¶42 (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.[13] (Ex. 1002, ¶42.) Even if *Zolman*'s neck

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[12] The '093 patent concedes that it was well-known to machine a neck body. (Ex. 1001, 4:8-10) (stating that the neck body could be "prepared using conventional and known machining techniques"); *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.").

[13] 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, in turn, testified that a PHOSITA would have understood *Zolman*'s femoral component 10 to have been made by milling solid metal. (Ex. 1018, 243:6-244:2; 253:9-254:21.)

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.[14] (Ex. 1002, ¶42.) 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, ¶42.)

Zolman's neck body includes a neck 28 having a base portion (shaded in orange) and a neck portion (shaded in purple) that extends outwardly from the base portion. (*See* Ex. 1009, 3:44-51, 3:56-59, Figs. 1-2; Ex. 1002, ¶42.) The neck portion has a Morse taper, which is a cylindrical configuration with a taper, to receive a ball 30, *i.e.*, the claimed "femoral ball," at proximal end 14. (Ex. 1009, 3:45-51, 3:56-59, Figs. 1-4; Ex. 1002, ¶42.) A PHOSITA would have understood ball 30 to be the claimed "femoral ball" based on *Zolman*'s disclosure that

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[14] 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.)

component 10 is "adapted to carry" ball 30 and that ball 30 cooperates with an acetabulum or acetabular prosthetic member. (*Id.*, 3:45-51, 3:56-59; Ex. 1002, ¶42.) A PHOSITA would have recognized the base portion of neck 28, which 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 (*e.g.*, ball 30) and the femur. (Ex. 1002, ¶42.) Stem portion 20, which corresponds to the claimed "elongated male protrusion," extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers. (Ex. 1009, 3:54-56, Figs. 1-4; Ex. 1002, ¶42.) A proximal portion 24 of stem portion 20 has a noncircular shape, and in particular a polygonal shape, in a cross-sectional view. (Ex. 1009, 5:19-21 ("The proximal portion 24 of stem portion 20 of the femoral component shown has an asymmetric noncircular cross-section as shown in FIGS. 5 and 6."); *see also id.*, 4:3-5, Figs. 1-6; Ex. 1002, ¶42.)

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, ¶42.) A PHOSITA would have made stem portion 20 with a polygonal shape in a horizontal cross-sectional view to prevent rotation of porous pad 26 relative to the neck body and to prevent the

implant from rotating within the femur bone. (Ex. 1002, ¶42 (citing Ex. 1023, 334 (Fig. 7-27).)

iii. [1.c] "fabricating, separately from the neck body, a bone fixation body that is formed of a porous metal structure without a solid metal substrate but with the porous metal structure that extends throughout the bone fixation body, has a size and a shape that emulate a size and a shape of a porous structure of natural human bone,"

Zolman and *Rostoker* disclose these limitations. (Ex. 1002, ¶43.) As the Board found, *Zolman* discloses separately fabricating a porous pad 26, identified in annotated Figure 2 to the right, by forming porous pad 26 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 porous nature of *Zolman*'s porous pad 26 allows "bony ingrowth" to "biologically affix or further secure the

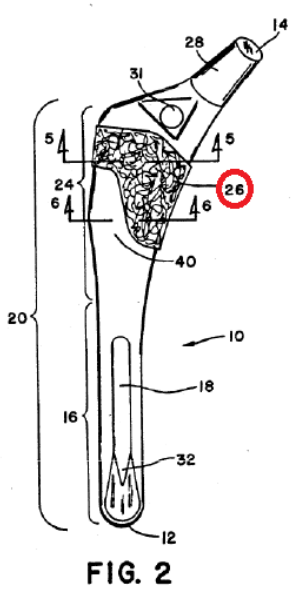

FIG. 2

implant in the bone." (*Id.*, 1:20-24; Ex. 1002, ¶43.)[15] For at least this reason, *Zolman*'s pad is a bone fixation body. (Ex. 1002, ¶43.)

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 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 without a solid metal substrate but with the porous metal structure that extends throughout the pad. (*Id.*, 4:56-58, Figs. 9-11; Ex. 1002, ¶43.)

Rostoker also discloses fabricating a completely porous fiber metal structure without a solid metal substrate. (Ex. 1010, 3:21-23; Ex. 1002, ¶43.) *Rostoker* discloses making a porous fiber metal structure by molding and sintering short

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[15] 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 '093 patent. (Ex. 1008, 31-32.)

metal fibers. (Ex. 1010, 2:21-23.) The fiber metal structure "is . . . open-pored so that the bone and tissue into which the prosthetic device is implanted will grow into such fiber metal structure." (*Id.*, Abstract; *see also id.*, 3:28-34.) *Rostoker* states that its fiber metal porous structure has "pores [that] are interconnecting and remain so after sintering. Thus, bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." (*Id.*, 2:40-44; *see also id.*, 5:16-18.) *Rostoker* also states that "the pore size can be readily controlled" and thus "the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted." (*Id.*, 2:48-52.)

Rostoker teaches that its porous fiber metal structure can be fabricated with pore diameters and porosities that fall within the known range of pore diameters and porosities of cancellous (trabecular) bone and that "encourage natural bone to migrate and grow into and throughout the entire body 16." (Ex. 1001, 3:59-65; Ex. 1002, ¶43 (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, 3:59-62.) *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, 3:59-62.) Therefore, *Rostoker* discloses the porous-metal-structure claim terms under its BRI. (*See supra* Section VIII.A; Ex. 1002, ¶43.) Indeed, the Board found that *Rostoker* "discloses values for pore size and porosity within the preferred ranges . . . for ingrowth of cancellous and cortical bone" disclosed in the specification of the '582 patent, which is related to the '093 patent. (Ex. 1008, 24.) The Board also concluded that the combination of *Zolman* and *Rostoker* discloses the same porous-metal-structure claim terms in the '582 IPR. (Ex. 1008, 24.)

Given *Zolman*'s explicit teachings to use *Rostoker*, fabricating *Zolman*'s porous pad 26 from the fiber metal structure of *Rostoker* would have been obvious to a PHOSITA.[16] (Ex. 1009, 4:12-15; Ex. 1002, ¶43.). As the Board recognized, a PHOSITA would have been motivated to fabricate *Zolman*'s porous pad 26 to have a porous structure that "emulates" natural human bone, as taught in *Rostoker*, to increase the strength of the attachment of the implant to the surrounding bone. (Ex. 1010, 2:40-44; 5:16-18; Ex. 1002, ¶43; Ex. 1008, 22.) A porous structure that is conducive to bone formation and enables tissue infiltration facilitates a strong attachment and long-term stability of the implant. (Ex. 1002, ¶43 (citing Ex. 1009,

[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.)

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, ¶43; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).)

iv. [1.d] "[fabricating a bone fixation body that] has a trapezoidal shape in a cross-sectional view, and"

Zolman discloses that "pad[] 26 can be shaped to conform to any desirable and suitable . . . surface configuration." (Ex. 1009, 5:16-18.) *Zolman* also states 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, ¶44.) Figure 5 is a cross-sectional view of a proximal portion 24 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 proximal portion 24 of stem

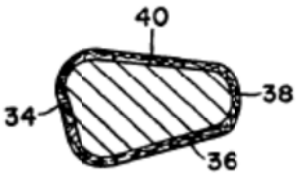

FIG. 5

portion 20 and has a trapezoidal cross-sectional shape as it is shaped like or similar to a trapezoid.[17] (*Compare id.*, Fig. 5 *with* Ex. 1001, 6:1-2, Fig. 7 (describing Fig. 7 as showing a "trapezoidal . . . cross-sectional shape"); Ex. 1002, ¶44.)

To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape given that *Zolman* discloses that "pad 26 can be shaped to conform to any desirable and suitable implant stem or fixation surface configuration." (Ex. 1009, 5:16-18; Ex. 1002, ¶ 44.) A PHOSITA would have been motivated to make the stem portion 20, and therefore porous pad 26, with a trapezoidal shape in order to fill the intramedullary canal and place porous pad 26

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

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, ¶44 (citing Ex. 1023, 333).)

v. [1.e] "[fabricating a bone fixation body that] has a tapering body with an external bow; and"

Zolman discloses that porous pad 26 has a tapering body with an external bow, *i.e.*, with at least one side having a curvature. (*Compare* Ex. 1009, Fig. 2 *with* Ex. 1001, 4:47-48, Fig. 1; Ex. 1002, ¶45 (citing Ex. 1023, 330 (disclosing a hip stem with a bow was known).)

vi. [1.f] "permanently connecting, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body at an interface where the male protrusion extends into and engages the bone fixation body and forms a core for the bone fixation body, the bone fixation body abuts the base portion of the neck body, and"

As discussed *supra* at IX.B.1.iii, *Zolman* discloses that porous pad 26 is fabricated separately from *Zolman*'s neck body by shaping the porous pad 26 into a final shape about a mandrel. As the Board found, *Zolman* teaches that, after pad 26 has been shaped into its final shape, it is removed from the mandrel and then bonded to a proximal portion 24 of *Zolman*'s stem portion 20 to permanently connect it thereto. (Ex. 1009, 6:46-54, 7:10-14; Ex. 1008, 27; Ex. 1002, ¶46.)

A proximal portion 24 of stem portion 20 has a recess 74, which corresponds to the claimed "interface" as "[t]he pad 26 is positioned securely in the recess 74 which corresponds to the wrapped shape of the pad 26" and "[t]he porous pad 26 is

then bonded to the stem portion 20 to securely attach it thereto." (Ex. 1009, 5:13-16, 6:44-48.) Figure 5 is a cross-section of proximal portion 24 of stem portion 20 in Figure 2 and shows that porous pad 26 completely encircles stem portion 20, and that stem portion 20 extends into and engages porous pad 26 and forms a core for porous pad 26 when porous pad 26 is positioned in recess 74. (*See id.*, Fig. 5; *see also id.*, Figs. 1-4, 3:53-54, 4:41-45.) As shown in the annotated Figures 1 and 2 *supra* at Section IX.B.1.ii, the distal end of the base portion forms the upper lip of recess 74 so that when porous pad 26 is positioned within recess 74 and bonded to stem portion 20, porous pad 26 abuts the base portion of *Zolman*'s neck body. (Ex. 1009, Figs. 1-4, 3:62-65, 5:12-16, 6:44-48; Ex. 1002, ¶46.)

vii. [1.g] "the bone fixation body abuts the polygonal shape of the male protrusion in order to provide anti-rotation at the interface between the neck body and the bone fixation body."

As discussed *supra* at Section IX.B.1.ii, *Zolman* discloses that a proximal portion 24 of stem portion 20 has a polygonal shape. As discussed *supra* at Section IX.B.1.vi, *Zolman* teaches that porous pad 26 is adapted to be received in and attached to a recess 74 in proximal portion 24 of stem portion 20. Porous pad 26 abuts the polygonal shape of stem portion 20 when positioned in recess 74. (Ex. 1009, 5:13-21, 6:44-48, Figs. 1-6; Ex. 1002, ¶47.) A PHOSITA would have recognized that the angles of the polygonal shape of stem portion 20 shown in Figures 1-5 would prevent porous pad 26 from rotating relative to proximal portion

24 of stem portion 20, and also that the shape of recess 74 would also prevent rotation of porous pad 26 relative to stem portion 20 at the interface between *Zolman*'s neck body and porous pad 26. (Ex. 1002, ¶47.)

2. Claim 2

i. "The method of claim 1, wherein the bone fixation body has a size and a shape to distribute loads from the neck body to the bone fixation body."

Zolman and *Rostoker* disclose this limitation. (Ex. 1002, ¶¶48-49.) It was well-known that compressive load on a hip implant is transferred to the bone at the bone-implant interface. (Ex. 1002, ¶49.) *Zolman* teaches that stem portion 20 is designed to fit within the intramedullary canal. (*See* Ex 1009, 3:45-51.) Like the '093 patent, which discloses a protrusion for "equally or efficiently distribut[ing] loads from the neck body to the bone fixation body," (Ex 1001, 5:41-45), *Zolman*'s stem portion 20 distributes loads from the neck portion and base portion of *Zolman*'s neck body to the attached porous pad 26. (*See* Ex. 1009, Figs. 1-4, 6:44-48; Ex. 1002, ¶49.) As discussed *supra* at Section IX.B.1.iv, porous pad 26 conforms to proximal portion 24 of stem portion 20 and has a trapezoidal cross-sectional shape. The size and shape of porous pad 26, which is attached to stem portion 20, emulates the size and shape of the intramedullary canal, which positions porous pad 26 in contact with walls of the intramedullary canal to support the vertical load on the hip implant and distributes the load on the neck body to porous pad 26 and ultimately to the surrounding bone. (Ex. 1002, ¶49.)

3. Claim 3

i. "The method of claim 1, wherein the bone fixation body has a size and a shape that emulate a size and a shape of a human intramedullary canal."

Zolman discloses that its neck body is "intended to fit within the intramedullary canal of a femur," and teaches that the neck body is contoured to fit a size and a shape of an intramedullary canal of a femur. (Ex. 1009, 3:38-43, 3:45-51, 3:66-4:2.) *Zolman* teaches that porous pad 26 conforms to the shape of stem portion 20 and forms "a continuous porous surface circumferentially about the stem portion." (*Id.*, 3:53-54, 4:41-45, 5:12-18, Figs. 1-5.) Thus, porous pad 26, like *Zolman*'s neck body, emulates the size and the shape of a human intramedullary canal to allow for the hip implant to "fit within the intramedullary canal of a femur." (*Id.*, 3:45-51; Ex. 1002, ¶¶50-51.)

4. Claim 4

i. "The method of claim 1, wherein the bone fixation body is fused to the male protrusion of the neck body after the bone fixation body is formed."

As discussed *supra* at Section IX.B.1.vi, *Zolman* teaches that porous pad 26 is permanently connected to stem portion 20 after the pad is formed. *Zolman* discloses that a permanent connection "may be achieved by diffusion bonding the pad to the stem portion by holding the pad securely thereagainst at a sufficient temperature for a sufficient length of time to achieve secure bonding." (Ex. 1009, 6:46-54.) Diffusion bonding occurs by applying high pressure in conjunction with

high temperatures to fuse the components together. (Ex. 1002, ¶¶52-53 (citing Ex. 1024 at 3:48-59, 4:28-40).)

5. Claim 5

i. "The method of claim 1, wherein the bone fixation body is bonded to the male protrusion of the neck body after the bone fixation body is formed."

As discussed *supra* at Section IX.B.1.vi, *Zolman* teaches that porous pad 26 is permanently connected to stem portion 20 after the pad is formed. *Zolman* discloses that, in one embodiment, porous pad 26 is permanently connected to stem portion 20 by diffusion bonding. (Ex. 1009, 6:46-54, 7:12-14; Ex. 1002, ¶¶54-55.)

6. Claim 6

i. "The method of claim 1, wherein the male protrusion also includes a circular shape in a cross-sectional view."

Zolman teaches that stem portion 20 (which corresponds the claimed "male protrusion") has a circular shape in a cross-sectional view at distal end 12. (*See* Ex. 1009, Fig. 1 (annotated to the right); Ex. 1002, ¶¶56-57.) Additionally, it would have been obvious to form distal portion 16 of stem portion 20 to have a circular shape in a cross-sectional view. (Ex. 1002, ¶57.) *Rostoker*, for example, discloses a femur prosthesis 12 that includes a rod 24 that has a circular shape in a cross-sectional view. (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

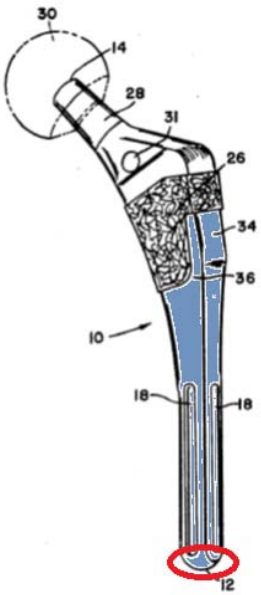


FIG. 1

of a number of cross-sectional shapes, including a circular shape in a cross-sectional view, as taught by *Rostoker*. (*KSR*, 550 U.S. at 416 ("The combination of familiar elements according to known method is likely to be obvious when it does not more than yield predictable results"); Ex. 1002, ¶57.) A PHOSITA would have shaped a distal portion 16 of *Zolman*'s stem portion 20 to have this shape to facilitate insertion into the intramedullary canal and achieve distal fixation in the femur bone. (Ex. 1002, ¶57.)

7. Claim 7

i. [7.a] "A method, comprising:"

As discussed above 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.7.ii-vii; Ex. 1002, ¶¶58-59.)

ii. [7.b] "machining, from solid metal, a neck body that includes a base portion, a neck portion that extends outwardly from the base portion and has a cylindrical configuration with a taper that receives a femoral ball, and a male protrusion that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a non-circle shape in a cross-sectional view;"

As discussed above for claim 1, *Zolman* teaches fabricating a femoral component 10 ("neck body") from solid metal to include a base portion (*e.g.*, portion of neck 28 with aperture 31), a neck portion (*e.g.*, portion of neck 28 at end 14) that extends outwardly from the base portion and has a cylindrical configuration with a taper that receives a femoral ball 30, and a stem portion 20 ("a

male protrusion") that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a non-circle shape, particularly a polygonal shape, in a cross-sectional view. (*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 would have been produced or finished through a machining process. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶60.)

iii. [7.c] "making, separately from the neck body, a bone fixation body that is formed of a completely porous metal structure without a solid metal substrate, has a size and a shape that emulate a size and a shape of a porous structure of natural human bone,"

As discussed above for claim 1, *Zolman* discloses making a porous pad 26 ("a bone fixation body") separate from *Zolman*'s neck body, and also teaches that porous pad 26 can be formed of a completely or entirely porous metal structure without a solid metal substrate. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶61.) 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.iii; Ex. 1002, ¶61.) As explained above, it would have been obvious to a PHOSITA to fabricate *Zolman*'s porous pad 26 from *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.iii; Ex. 1002, ¶61.) 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.iii; *KSR*, 550 U.S. at 416; Ex. 1002, ¶61.)

iv. [7.d] "[making a bone fixation body that] has a trapezoidal shape in a cross-sectional view, and"

As discussed above for claim 1, *Zolman* discloses making porous pad 26 ("a bone fixation body") with a trapezoidal shape in a cross-sectional view. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶62.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.1.iv.

v. [7.e] "[making a bone fixation body that] has a tapering body with an external bow; and"

As discussed above for claim 1, *Zolman* discloses making porous pad 26 ("a bone fixation body") with a tapering body having an external bow. (*See supra* Section IX.B.1.v; Ex. 1002, ¶63.)

vi. [7.f] "permanently attaching, after the bone fixation body is separately made from the neck body, the bone fixation body to the neck body at an interface that occurs where the male protrusion extends into and engages the bone fixation body to form a core for the bone fixation body, where the bone fixation body engages the base portion of the neck body, and"

As discussed above for claim 1, *Zolman* discloses permanently attaching or connecting, after porous pad 26 ("the bone fixation body") is separately made from *Zolman*'s neck body, porous pad 26 to the neck body at a recess 74 formed in stem portion 20 ("at an interface") so that stem portion 20 ("the male protrusion")

extends into and engages porous pad 26 and forms a core for porous pad 26. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶64.) As also discussed above, when porous pad 26 is seated in recess 74, it abuts the base portion of *Zolman*'s neck body and thus engages the base portion of *Zolman*'s neck body. (*See supra* Section IX.B.1.vi; Ex. 1002, ¶64.)

vii. [7.g] "where the bone fixation body engages the non-circle shape of the male protrusion and provides anti-rotation at the interface where the neck body and the bone fixation body attach."

As discussed above for claim 1, *Zolman* discloses that porous pad 26 ("the bone fixation body") engages the non-circle, polygonal shape of stem portion 20 ("the male protrusion") when porous pad 26 is seated in recess 74 which provides anti-rotation at the interface where *Zolman*'s neck body and porous pad 26 attach. (*See supra* Section IX.B.1.vii; Ex. 1002, ¶65.)

8. Claim 8

i. "The method of claim 7, wherein the bone fixation body has a size and a shape to distribute loads from the neck body to the bone fixation body."

As discussed above for claim 2, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape to distribute loads from *Zolman*'s neck body to porous pad 26. (*See supra* Section IX.B.2.i; Ex. 1002, ¶¶66-67.)

9. Claim 9

i. "The method of claim 7, wherein the bone fixation body has a size and a shape that emulate a size and a shape of a human intramedullary canal."

As discussed above for claim 3, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape that emulate a size and a shape of a human intramedullary canal. (*See supra* Section IX.B.3.i; Ex. 1002, ¶¶68-69.)

10. Claim 10

i. "The method of claim 7, wherein the bone fixation body is fused to the male protrusion of the neck body after the bone fixation body is formed."

As discussed above for claim 4, *Zolman* discloses that porous pad 26 ("the bone fixation body") is fused by diffusion bonding to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.4.i; Ex. 1002, ¶¶70-71.)

11. Claim 11

i. "The method of claim 7, wherein the bone fixation body is bonded to the male protrusion of the neck body after the bone fixation body is formed."

As discussed above for claim 5, *Zolman* discloses that porous pad 26 ("the bone fixation body") is bonded by diffusion bonding to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.5.i; Ex. 1002, ¶¶72-73.)

12. Claim 12

i. "The method of claim 7, wherein the male protrusion also includes a circular shape in a cross-sectional view."

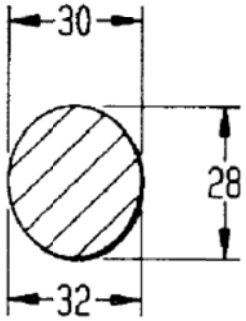
As discussed above for claim 6, stem portion 20 ("the male protrusion") includes a circular shape in a cross-sectional view at distal end 12. (*See supra* Section IX.B.6.i; Ex. 1002, ¶¶74-75.) As also discussed above, it would have been obvious to machine *Zolman*'s stem portion 20 to have any one of a number of cross-sectional shapes, including a circular shape in a cross-sectional view, as taught by *Rostoker*. (*See supra* Section IX.B.6.i; Ex. 1002, ¶75.)

C. Ground 2: Claims 6 and 12 are Obvious Based on *Zolman*, *Rostoker*, and *Averill*

As discussed in Ground 1 for claims 6 and 12, *Zolman*'s stem portion 20 ("the male protrusion") includes a circular shape in a cross-sectional view at distal end 12. (*See supra* Sections IX.B.6.i, IX.B.12.i.) As also discussed above, it would have been obvious to form stem portion 20 to include a circular shape in a cross-sectional view based on *Rostoker*. (*See supra* Sections IX.B.6.i, IX.B.12.i.) If the Board finds that that the combination of *Zolman* and *Rostoker* does not disclose stem portion 20 having a circular shape in a cross-sectional view, it would have been obvious to form the stem of the hip implant of *Zolman* and *Rostoker* to have a circular shape in a cross-sectional view in light of *Averill*'s disclosure. (Ex. 1002, ¶76.)

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 "*an almost circular cross-section* at line 3—3, (FIG. 3)" of stem 12 shown in Figure 1. (*Id.*, 5:34-39, Figs. 1-3; Ex. 1002, ¶77.)

FIG. 3



In light of *Averill*'s disclosure, a PHOSITA would have appreciated that forming a distal portion of *Zolman*'s stem portion to have a circular shape in a cross-sectional view would have been nothing more than an obvious design choice. (Ex. 1002, ¶78.) Moreover, 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 circular shape in a horizontal cross-section, as evidenced by *Averill*. (Ex. 1012, 6:54-58 (disclosing that stem 12 can be made by "forging, casting and/or machining operations or any other well known technique"); Ex. 1002, ¶78; *KSR*, 550 U.S. at 416.) A PHOSITA would have been motivated to form the stem of the hip implant of *Zolman* and *Rostoker* to have this shape to facilitate insertion into the intramedullary canal. (Ex. 1002, ¶78.)

D. Ground 3: Claims 1-12 are Obvious Based on *Zolman* and *Bobyn*

As discussed below, the combination of *Zolman* and *Bobyn* 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, ¶39.)

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-vii; Ex. 1002, ¶¶79-80.)

ii. Claim element 1.b

As discussed above for claim 1, *Zolman* teaches fabricating a femoral component 10 ("neck body") from solid metal to have a base portion (*e.g.*, portion of neck 28 with aperture 31), a neck portion (*e.g.,* portion of neck 28 at end 14) that extends outwardly from the base portion and includes a cylindrical configuration with a taper that receives a femoral ball 30, and a stem portion 20 ("a male protrusion") that extends outwardly from the base portion oppositely from the neck portion and has an elongated shape that tapers and has a polygonal shape in a cross-sectional view. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶81.) As also discussed above, it would have been obvious to a PHOSITA that *Zolman*'s neck body would have been produced or finished through a machining process. (*See supra* Section IX.B.1.ii; Ex. 1002, ¶81.)

iii. Claim element 1.c

The combination of *Zolman* and *Bobyn* disclose these limitations. (Ex. 1002, ¶82.) 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") that is made of a porous metal structure without a metal substrate but with the porous metal structure that extends throughout the pad. (*See supra* Section IX.B.1.iii; Ex. 1002, ¶82.) *Zolman* teaches that porous pad 26 can be made from "any suitable porous material." (Ex. 1009, 4:21-24.) While *Zolman* discloses an embodiment in which porous pad 26 is formed of a fiber metal structure, *Zolman* expressly states that "any suitable materials [*sic*] may be utilized." (*Id*., 4:27-28.)

There is no dispute between the parties that *Bobyn*'s biomaterial teaches the porous-metal-structure term, including under Patent Owner's narrow interpretation that "requires emulating the size and shape of the interconnected plates and rods that form trabecular bone." (*See generally* Ex. 1008, 38-46.) *Bobyn* discloses a porous tantalum biomaterial with "desirable characteristics for bone ingrowth" 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, ¶82.) 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 '093 patent for ingrowth of cancellous (trabecular) and cortical bone spicules, and also fall within the known range of pore diameters and porosities of natural cancellous (trabecular) bone. (Ex. 1001, 3:55-62; Ex. 1002, ¶82 (citing Ex. 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 (trabecular) 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, ¶82.) *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

[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.)

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 ingrowth. (*Id.*, 907, 912.) By 1999, *Bobyn*'s porous tantalum biomaterial was used to construct components of orthopedic implants. (Ex. 1011, 913; Ex. 1022, 5.)

In light of *Bobyn*'s teachings of the advantages of the porous tantalum material over other conventional porous surfaces 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, ¶82.) 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 porous pad 26 would have been a simple substitution of known porous materials to improve *Zolman*'s hip implant, and would have yielded predictable results, *i.e.*, a porous structure for bone ingrowth. (*See KSR*, 550 U.S. at 416; Ex. 1002, ¶82.)

A PHOSITA would have had a reasonable expectation of success manufacturing *Zolman*'s implant with *Bobyn*'s porous tantalum biomaterial. (Ex.

1002, ¶82.) A PHOSITA would have known how to construct a pad from *Bobyn*'s material using the process taught in *Zolman*.[19] (Ex. 1002, ¶82.) *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. 1002, ¶82 (citing 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, ¶82.) Moreover, a PHOSITA would have known how to manipulate the porous tantalum biomaterial so that it could be bent without

[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, ¶82.) 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.)

breaking the tantalum struts, such as, for example, heating the tantalum material. (Ex. 1002, ¶82.)

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, ¶82; *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 invention. (Ex. 1002, ¶82 (citing Ex. 1020, 9:54-60; Ex. 1021, 1:11-24, 3:51-55, 4:7-22, Fig. 1).)

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[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.)

iv. Claim element 1.d

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating a porous pad 26 ("a bone fixation body") that has a trapezoidal shape in a cross-sectional view. (*See supra* Section IX.B.1.iv; Ex. 1002, ¶83.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.1.iv.

v. Claim element 1.e

As discussed in Ground 1 for claim 1, *Zolman* discloses fabricating a porous pad 26 ("a bone fixation body") that has a tapering body with an external bow. (*See supra* Section IX.B.1.v; Ex. 1002, ¶84.)

vi. Claim element 1.f

As discussed in Ground 1 for claim 1, *Zolman* discloses permanently connecting, after porous pad 26 ("the bone fixation body") is separately fabricated from *Zolman*'s neck body, porous pad 26 to the neck body at a recess 74 formed in stem portion 20 ("at an interface") where stem portion 20 ("the male protrusion") extends into and engages porous pad 26 and forms a core for porous pad 26. (*See supra* IX.B.1.vi; Ex. 1002, ¶85.) As also discussed above, when porous pad 26 is seated in recess 74, it abuts the base portion of *Zolman*'s neck body. (*See supra* IX.B.1.vi; Ex. 1002, ¶85.)

vii. Claim element 1.g

As discussed in Ground 1 for claim 1, *Zolman* discloses that porous pad 26 ("the bone fixation body") abuts the polygonal shape of stem portion 20 ("the male protrusion") in order to provide anti-rotation at the interface between *Zolman*'s neck body and the porous pad. (*See supra* IX.B.1.vii; Ex. 1002, ¶86.)

2. Claim 2

As discussed in Ground 1 for claim 2, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape to distribute loads from *Zolman*'s neck body to porous pad 26. (*See supra* Section IX.B.2.i; Ex. 1002, ¶¶87-88.)

Further, the combination of *Zolman* and *Bobyn* teaches that pad 26 can be made to have a size and a shape to distribute loads from *Zolman*'s neck body. (Ex. 1002, ¶¶89-90.) While *Bobyn* admits that its study was "not as realistic as a fully-functional load-bearing model," it teaches that its tantalum material has properties that allow elastic deformation and load distribution like cancellous (trabecular) bone. (Ex. 1011, 913; *see also* Ex. 1020 at 6:61-7:4.) Thus, one skilled in the art would have appreciated that a porous pad made from *Bobyn*'s material would have a size and a shape to distribute loads from *Zolman*'s neck body. (Ex. 1002, ¶88.)

3. Claim 3

As discussed in Ground 1 for claim 3, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape that emulate a size and a shape of a human intramedullary canal. (*See supra* Section IX.B.3.i; Ex. 1002, ¶¶89-90.)

4. Claim 4

As discussed in Ground 1 for claim 4, *Zolman* discloses porous pad 26 ("the bone fixation body") is fused to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.4.i; Ex. 1002, ¶¶91-92.)

5. Claim 5

As discussed in Ground 1 for claim 5, *Zolman* discloses porous pad 26 ("the bone fixation body") is bonded to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.5.i; Ex. 1002, ¶¶93-94.)

6. Claim 6

As discussed in Ground 1 for claim 6, *Zolman* discloses that stem portion 20 ("the male protrusion") includes a circular shape in a cross-sectional view at distal end 12. (*See supra* Section IX.B.6.i; Ex. 1002, ¶¶95-96.)

7. Claim 7

i. Claim element 7.a

As discussed in Ground 1 for claim 7, *Zolman* discloses a method of constructing a hip implant. (*See supra* Section IX.B.7.i; *see also infra* Sections IX.D.7.ii-vii; Ex. 1002, ¶¶97-98.)

ii. Claim element 7.b

As discussed in Ground 1 for claim 7, *Zolman* teaches forming a femoral component 10 ("neck body") from solid metal to include a base portion, to include a neck portion (*e.g.*, a portion of neck 28 at end 14) that extends outwardly from the base portion (*e.g.*, the portion of neck 28 having aperture 31) that has a cylindrical configuration with a taper that receives a femoral ball 30, and to have a stem portion 20 ("a male protrusion") that extends outwardly from the base portion oppositely from the neck portion and that has an elongated shape that tapers and has a non-circle shape in a cross-sectional view. (*See supra* Section IX.B.7.ii; Ex. 1002, ¶99.) As also discussed above, it would have been obvious to one skilled in the art that *Zolman*'s neck body would have been produced or finished through a machining process. (*See supra* Section IX.B.7.ii; Ex. 1002, ¶99.)

iii. Claim element 7.c

As discussed in Ground 1 for claim 7, *Zolman* discloses making a porous pad 26 ("a bone fixation body") separate from *Zolman*'s neck body, and that porous pad 26 can be formed of a completely porous metal structure without a solid metal substrate. (*See supra* Section IX.B.7.iii; Ex. 1002, ¶100.) As discussed in Ground 3 for claim 1, *Bobyn* discloses 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.iii; Ex. 1002, ¶100.) 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.iii; *KSR*, 550 U.S. at 416; Ex. 1002, ¶100.) 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.iii; Ex. 1002, ¶100.)

iv. Claim element 7.d

As discussed in Ground 1 for claim 7, *Zolman* discloses making a porous pad 26 ("a bone fixation body") that has a trapezoidal shape in a cross-sectional view. (*See supra* Section IX.B.7.iv; Ex. 1002, ¶101.) To the extent the Board finds that the porous pad 26 does not have the claimed "trapezoidal shape," it would have been obvious to make *Zolman*'s pad with a trapezoidal shape as discussed *supra* at IX.B.1.iv.

v. Claim element 7.e

As discussed in Ground 1 for claim 7, *Zolman* discloses making a porous pad 26 ("the bone fixation body") that has a tapering body with an external bow. (*See supra* Section IX.B.7.v; Ex. 1002, ¶102.)

vi. Claim element 7.f

As discussed in Ground 1 for claim 7, *Zolman* discloses permanently attaching, after porous pad 26 is separately made from *Zolman*'s neck body, the porous pad ("the bone fixation body") to the neck body within recess 74 ("at an interface") that occurs where stem portion 20 ("the male protrusion") extends into and engages the porous pad to form a core for the porous pad and where the porous pad engages the base portion of *Zolman*'s neck body. (*See supra* Section IX.B.7.vi; Ex. 1002, ¶103.)

vii. Claim element 7.g

As discussed in Ground 1 for claim 7, *Zolman* discloses that porous pad 26 ("the bone fixation body") engages the non-circle shape of stem portion 20 ("the male protrusion") and provides anti-rotation at recess 74, the interface where *Zolman*'s neck body and the porous pad attach. (*See supra* Section IX.B.7.vii; Ex. 1002, ¶104.)

8. Claim 8

As discussed in Ground 1 for claim 8, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape to distribute loads from *Zolman*'s neck body to porous pad 26. (*See supra* Section IX.B.8.i; Ex. 1002, ¶¶105-106.) As discussed in Ground 3 for claim 2, the combination of *Zolman* and *Bobyn* also

teaches that pad 26 can be made to have a size and a shape to distribute loads from *Zolman*'s neck body. (*See supra* Section IX.D.2; Ex. 1002, ¶106.)

9. Claim 9

As discussed in Ground 1 for claim 9, *Zolman* discloses that porous pad 26 ("the bone fixation body") has a size and a shape that emulate a size and a shape of a human intramedullary canal. (*See supra* Section IX.B.9.i; Ex. 1002, ¶¶107-108.)

10. Claim 10

As discussed in Ground 1 for claim 10, *Zolman* discloses that porous pad 26 ("the bone fixation body") is fused to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.10.i; Ex. 1002, ¶¶109-10.)

11. Claim 11

As discussed in Ground 1 for claim 11, *Zolman* discloses that porous pad 26 ("the bone fixation body") is bonded to stem portion 20 ("the male protrusion") after porous pad 26 is formed. (*See supra* Section IX.B.11.i; Ex. 1002, ¶¶111-12.)

12. Claim 12

As discussed in Ground 1 for claim 12, *Zolman*'s stem portion 20 ("the male protrusion") includes a circular shape in a cross-sectional view at distal end 12. (*See supra* Section IX.B.12.i; Ex. 1002, ¶113-14.)

E. Ground 4: Claims 6 and 12 are Obvious Based on *Zolman*, *Bobyn*, and *Averill*

As discussed above for claims 6 and 12, *Zolman*'s stem portion 20 includes a circular shape in a cross-sectional view at distal end 12. (*See supra* Sections IX.D.6, IX.D.12; Ex. 1002, ¶115.) If the Board finds that *Zolman* does not disclose this feature, it would have been obvious to form the distal portion 16 of stem portion 20 to have a circular shape in a cross-sectional view in light of *Averill*'s teachings of a stem 12 having a circular cross-section, for the reasons discussed *supra* at IX.C. (Ex. 1002, ¶115.)

X. THE BOARD SHOULD ADOPT ALL 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 obvious under the Board's construction and Patent Owner's narrower claim interpretation, which requires the porous structure to emulate the rods and plates of cancellous (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 set of grounds based on *Averill* in the event the Board finds that *Zolman* alone or in combination with *Rostoker* or *Bobyn* do not disclose the claimed "protrusion" having "a circular shape in a cross-sectional view."

XI. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 1-12 of the '093 patent.

Respectfully submitted,

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

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

Counsel for Zimmer Biomet Holdings, Inc.

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

The undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 12,784 words according to the word count of the word-processing software used to prepare the petition.

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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. 9,308,093 for Petitioner Zimmer Biomet Holdings, Inc. was served via express mail on the Patent Owner at the following correspondence address of record as listed on PAIR:

Philip S. Lyren, PC
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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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