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Paper 34
Entered: March 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER BIOMET HOLDINGS, INC.,
Petitioner,

v.

FOUR MILE BAY, LLC,
Patent Owner.

Case IPR2016-00012
Patent 8,821,582 B1

Before JOSIAH C. COCKS, RICHARD E. RICE, and MICHAEL L. WOODS, *Administrative Patent Judges.*

RICE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Zimmer Biomet Holdings, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–5, 7–11, 13–15, and 17–20 of U.S. Patent No. 8,821,582 B1 (Ex. 1001, "the '582 Patent"). Petitioner supported the Petition with a declaration from Timothy P. Harrigan (Ex. 1002).

We instituted a trial as to all of the challenged claims, on the following grounds.

Reference(s)	Basis	Claims Challenged
Zolman[1] and Rostoker[2]	§ 103(a)	1–5, 8–11, 14, 15, and 17–20
Zolman, Rostoker, and Sump[3]	§ 103(a)	7
Zolman, Rostoker, and Averill[4]	§ 103(a)	20
Zolman and Bobyn[5]	§ 103(a)	1–5, 8–11, 13–15, and 17–20
Zolman, Bobyn, and Sump	§ 103(a)	7
Zolman, Bobyn, and Averill	§ 103(a)	20

Paper 8 ("Inst. Dec."), 21.

[1] U.S. Patent No. 5,018,285, issued May 28, 1991 (Ex. 1005, "Zolman").
[2] U.S. Patent No. 3,906,550, issued Sept. 23, 1975 (Ex. 1006, "Rostoker").
[3] U.S. Patent No. 4,570,271, issued Feb. 18, 1986 (Ex. 1011, "Sump").
[4] U.S. Patent No. 5,863,295, issued Jan. 26, 1999 (Ex. 1012, "Averill").
[5] J.D. Bobyn, et al., *Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial*, 81-B:5 JOURNAL OF BONE AND JOINT SURGERY 907 (Sept. 1999) (Ex. 1007, "Bobyn").

After institution of the trial, Four Mile Bay, LLC ("Patent Owner") filed a Patent Owner Response (Paper 17, "PO Resp."), to which Petitioner filed a Reply (Paper 24, "Pet. Reply"). Patent Owner supported the Patent Owner Response with declarations from Michael N. Hemus (Ex. 2041) and Jay M. Vincelli (Ex. 2042).

We heard oral argument on January 9, 2017. A transcript of the argument has been entered in the record. Paper 33 ("T.").

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons explained below, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–5, 7–11, 13–15, and 17–20 are unpatentable.

B. Related Proceedings

The parties identify a related federal district court case involving the '582 Patent: *Four Mile Bay LLC v. Zimmer Holdings, Inc. et al.*, No. 3:15-cv-00063 (N.D. Ind.) (PPS)-(CAN). Pet. 2; Paper 5, 2.

C. The '582 Patent

The '582 Patent, titled "Hip Implant with Porous Body," issued on September 2, 2014, from an application filed August 23, 2012. Ex. 1001, 1. The '582 Patent application is a continuation-in-part of an application filed April 24, 2006, now U.S. Patent No. 8,506,642 B1 ("the '642 Patent"), which is a continuation of an application filed May 27, 2003, now abandoned. *Id.*

Figures 1 and 2 of the ’582 Patent are reproduced below.

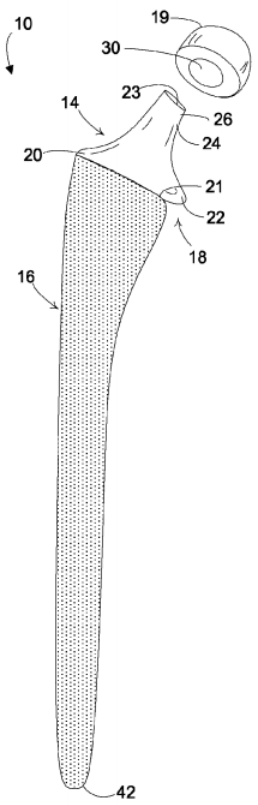


Fig. 1

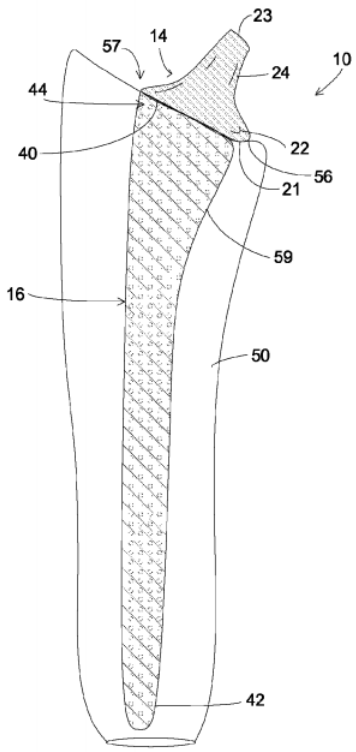


Fig. 2

Figure 1 is a side view of hip implant embodiment 10, showing neck body 14 and bone fixation body 16; and Figure 2 is a cross-sectional view of the implant embedded in intramedullary canal 52 of femur 50. *Id.* at 1:49–52, 3:41–47, 4:12–14. Bone fixation body 16 has a porous structure, i.e., “the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface.” *Id.* at 4:26–28. The Specification states that “[t]he porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules,” and that “the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone.” *Id.* at 4:32–36. The Specification also states that, preferably, the average pore diameter of body 16 is about 40 µm to about

800 µm, the porosity is from about 45% to 65%, and the interconnections between pores can have a diameter larger than 50–60 µm. *Id.* at 4:37–40. The Specification states that neck body 14 can be machined from a solid piece of metal to have a size and shape shown in the figures (*id.* at 3:62–67), and that bone fixation body 16 is created with a sintering process (*id.* at 4:49).

The Specification describes two methods of manufacturing the bone fixation body. In a first exemplary embodiment, body 16 is fabricated using a mold having two cavities—a first cavity that is sized and shaped for fabrication of the bone fixation body, and a second cavity that is adjacent and connected to the first cavity and sized and shaped to receive the already-fabricated neck body. *Id.* at 4:55–60. "The neck body is positioned in the second cavity such that the distal end surface is adjacent and continuous with the first cavity." *Id.* at 4:60–62. Next, the sintering material is placed in the first cavity, and the mold then is heated to perform the sintering process. *Id.* at 4:63–67. "During this process, as the material in the first cavity heats and sinters, the bone fixation body forms and simultaneously bonds or fuses to the distal end surface of the neck body." *Id.* at 4:67–5:3.

In a second exemplary embodiment, the bone fixation body and the neck body are each fabricated independently from the other and subsequently attached together:

> One skilled in the art though will appreciate that each of these bodies can be *fabricated independently and subsequently connected together*. If the bodies are made separately, then they may be attached or fused together using known welding or brazing techniques, for example.

Id. at 5:17–23 (emphasis added).

Claims 1, 8, and 14 are independent. Claims 2–5 and 7 depend directly from claim 1, claims 9–11 and 13 depend directly from claim 8, and claims 15 and 17–20 depend directly from claim 14. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method, comprising:
>
> machining a neck body formed of solid metal to include a neck that receives a femoral ball and having a male protrusion that extends outwardly from the neck body;
>
> fabricating, separately from the neck body, a bone fixation body with a porous metal structure that extends completely throughout the bone fixation body with the porous metal structure having a size and a shape that emulate a size and a shape of a porous structure of natural human bone; and
>
> attaching, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body to create a hip implant such that the male protrusion extends into and permanently attaches with the porous metal structure of the bone fixation body to create the hip implant before the hip implant is implanted, wherein the porous metal structure of the bone fixation body includes a trapezoidal shape in a horizontal cross-sectional view of the hip implant, and the male protrusion extends to a distal end of the hip implant.

Id. at 15:51–16:4.

D. Prosecution History

Petitioner summarizes the prosecution history relating to the claim requirement for a bone fixation body with 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. Pet. 9–12. Petitioner notes that the applicant introduced this requirement by an amendment during prosecution of the related '642 Patent application in an effort to distinguish over U.S. Patent No. 5,522,894, referred to as "Draenert II." *See id.* at 10 (citing Ex. 1004, 196–207). The Examiner, however, rejected the applicant's argument that the porous structure comprising spherical particles taught in Draenert II does not have a size and a shape that emulate a size and a shape of a porous structure of natural human bone. Ex. 1004, 182–183. In the subsequent appeal, the Examiner maintained his position, arguing 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." *See id.* at 10–11 (citing Ex. 1004, 105). The applicant subsequently dismissed its appeal and, on continuation of prosecution, relied on other grounds to distinguish Draenert II. *See id.* at 11 (citing Ex. 1004, 34–36, 53–64).

The prosecution history of the '582 Patent application is brief. In a first office action rejecting the claims (Ex. 1010, 34–44), the Examiner found that U.S. Patent No. 6,296,667 ("Johnson et. al.") discloses a 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 (abstract) to allow for a three dimensional labyrinth for bone ingrowth and vascularization (col. 7, ll. 14–16)." Ex. 1010, 37. The applicant subsequently amended the claims to overcome the Examiner's rejections, without challenging the Examiner's findings. *Id.* at 24–30.

II. ANALYSIS

A. Level of Skill in the Art

Petitioner and Patent Owner agree that "[a] person of ordinary skill in the art would have had an undergraduate degree in a relevant engineering field (e.g., Mechanical Engineering, Materials Science Engineering, Biomedical Engineering) with 3–5 years of experience with hip implants or similar implants or a graduate degree in a relevant field with 1–3 years of experience with hip implants or similar implants." Pet. 13 n.3; PO Resp. 1; *see* Ex. 1002 ¶ 10; Ex. 1041 ¶ 26; Ex. 1042 ¶ 22. We agree with, and adopt, the parties' common definition of a person having ordinary skill in the art ("PHOSITA").

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the

specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "porous"

In our Institution Decision, we preliminarily determined that the claim term "porous" has the following lexicographical meaning: "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." Inst. Dec. 7 (quoting Ex. 1001, 4:26–28). As neither party proposes any change to our interpretation, and our review of the evidence does not indicate that any change is necessary, we maintain that interpretation.

2. "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" (claim 1)

and

"a porous metal structure . . . with interconnected pores having a geometric structure with a shape and a size that emulate a shape and a size of natural human bone" (claim 8)

Claim 1 recites "*a porous metal structure* . . . having a size and a shape that *emulate*[6] a size and a shape of a porous structure of natural human bone" (emphasis added). Claim 14 contains essentially the same term. Claim 8 recites "*a porous metal structure* . . . with interconnected pores

[6] In our Institution Decision, we preliminarily determined that the broadest reasonable interpretation consistent with the Specification of "emulate" is "imitate." Inst. Dec. 8–9. The parties have adopted our interpretation of "emulate." PO Resp. 1; Pet. Reply 5–8.

having a geometric structure with a shape and a size that *emulate* a shape and a size of natural human bone" (emphasis added).

Patent Owner does not propose an explicit claim construction of these porous-metal-structure claim terms, but nevertheless argues to distinguish over prior art (Zolman and Rostoker) that the terms *require emulating the size and shape of the interconnected plates and rods that form trabecular bone*. PO Resp. 25–33. Patent Owner asserts that a PHOSITA "would understand that the term 'porous metal structure' recited in the claims is directed to cancellous bone, which is also known as trabecular bone." PO Resp. 26 (citing Ex. 2041 ¶ 68). Patent Owner presents evidence that "[t]he shape of the cellular structure of trabecular bone is formed of a series of straight rod-like struts that connect together to form a foam-like cellular structure" (*id.* at 28 (citing Ex. 2041 ¶ 72; Ex. 2042 ¶ 59)), and argues that "[o]ne of ordinary skill in the art would know that the porous structure taught in Rostoker being formed of sinusoidal kinked wires 'has no relationship to the straight rod-like porous structure of natural human bone'" (*id.* at 31 (citing Ex. 2041 ¶ 73)).

Petitioner responds that Patent Owner's implicit construction is inconsistent with the Specification and overly narrow. Pet. Reply 6. Petitioner emphasizes that the purpose of emulating the size and shape of the porous structure of natural bone, as described in the Specification, is to promote bone ingrowth. *Id*. (citing Ex. 1001, 4:33–36). Petitioner asserts that the Specification describes exemplary ranges for average pore diameter, porosity, and interconnection diameter to achieve that purpose, but does not "limit the invention to a porous metal structure with those parameters, much less a porous structure that is the same as human bone." *Id* at 7 (citing

Ex. 1001, 4:37–40; Ex. 1019[7], 100:8–102:6). Petitioner argues that, "[i]nstead, the specification emphasizes that the purpose of the porous structure [is] to 'encourage natural bone to migrate and grow into and throughout the entire [bone fixation body].'" *Id.* (citing Ex. 1001, 4:40–43).

Patent Owner has not persuaded us that the porous-metal-structure claim terms *require* emulating the size and shape of the interconnected plates and rods that form trabecular bone. First, Patent Owner's argument that a PHOSITA "would understand that the term 'porous metal structure' recited in the claims is directed to . . . trabecular bone" (PO Resp. 26) is conclusory, and the cited testimony of Dr. Hemus is also conclusory. *See* PO Resp. 26 (citing Ex. 2041 ¶ 68). Patent Owner's focus on trabecular bone, which is only one type of natural human bone, is inconsistent with the broader recital of "natural human bone" in the claim terms themselves. Moreover, Patent Owner's focus on trabecular bone also is inconsistent with the Specification, which describes the bone fixation body as adapted for the ingrowth of *both* cancellous (trabecular) *and* cortical bone. Ex. 1001, 4:32–33 ("The porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules."); *see id.* at 15:31–34 ("The porosity of the porous structure where the hip implant contacts cortical bone can be lower than the porosity of the porous structure where the hip implant contacts cancellous bone.").

Second, the Specification does not mention the interconnected plates and rods that form trabecular bone. Rather, the Specification more generally describes an exemplary embodiment in which the size and shape of the

[7] Vincelli deposition transcript.

porous structure of body 16 emulates the size and shape of the porous structure of natural bone:

> The porous structure of body 16 is adapted for the ingrowth of cancellous and cortical bone spicules. In the exemplary embodiment, the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone.

Id. at 4:32–36. The Specification indicates that the size and shape of the porous structure of natural bone can be measured by pore diameter, porosity, and intersection diameter, for which the Specification discloses preferred ranges. *Id.* at 4: 4:37–40. The Specification makes clear that "these ranges could be modified, and the resulting hip implant still within the scope of the invention" (*id.* at 4:37–48); and nothing in the Specification indicates that emulating the size and shape of the porous structure of natural bone requires emulating the size and shape of the interconnected plates and rods that form trabecular bone. As such, there is no support in the Specification for Patent Owner's argument that the porous-metal-structure claim terms require emulating that particular structure.

Third, nothing in the prosecution history supports interpreting the porous-metal-structure claim terms to require emulating the size and shape of the interconnected plates and rods that form trabecular bone. During prosecution, the applicant acquiesced in the Examiner's interpretation that those claim terms use functional language to define the porous structure "rather than a positive recitation setting forth the specific structural features of the porous structure." Ex. 1004, 105; *see supra* Section I.D.

For the reasons given, we determine 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.

3. Attaching the Bone Fixation Body "After" Separately Fabricating it

Claim 1 recites the step of "attaching, after the bone fixation body is separately fabricated from the neck body, the bone fixation body to the neck body." Claims 8 and 14 contain similar recitations.[8] Patent Owner argues that the "attaching" step requires attachment of the bone fixation body to the neck body "after" fabrication of the bone fixation body. Specifically, Patent Owner argues:

> Because claim[s] 1, 8, and 14 are method claims, one of ordinary skill in the art would understand the importance of the ordering in which these steps occur. Specifically, claim 1 states that the bone fixation body is attached to the neck body "after" the bone fixation body is separately fabricated from the neck body. This clearly means that the neck body is formed (step 1); the bone fixation body is separately fabricated from the neck body (step 2); and then these two bodies are attached together to create the hip implant after the bone fixation body is separately fabricated from the neck body (step 3). Claims 8 and 14 follow a similar three step method format.

[8] Claim 8 recites "connecting, after the bone fixation body is separately made from the neck body, the bone fixation body to the neck body." Claim 14 recites "engaging, after the neck body and the bone fixation body are separately formed, the bone fixation body to the neck body such that the porous metal structure permanently engages to the protrusion [of the neck body]."

PO Resp. 36. Patent Owner asserts that the "attaching" step is not directed to the first exemplary embodiment. *Id.* at 37; *see supra* Section I.C. In that embodiment, as explained by Patent Owner, "the neck body and bone fixation body are placed in adjacent cavities in a mold, and the bone fixation body forms and *simultaneously* bonds to the neck body during a sintering process." *Id.* (citing Ex. 1001, 4:49–5:3) (emphasis added); *see also* Ex. 1001, 5:17–18 ("In the aforementioned sintering process, the bone fixation body simultaneously forms and attaches to the neck body."). Patent Owner asserts that the "attaching" step is directed to the second exemplary embodiment, in which the bone fixation body and the neck body are fabricated independently from each other, and *subsequently* connected together. *Id.* (citing Ex. 1001, 5:17–23); *see supra* Section I.C; *see also* Ex. 1001, 5:19–21 ("One skilled in the art [] will appreciate that each of these bodies can be fabricated independently and subsequently connected together.").

We agree with Patent Owner that the "attaching" step in claim 1 requires attachment of the bone fixation body to the neck body after fabrication of the bone fixation body and thus excludes the first exemplary embodiment. Petitioner's opposing arguments do not address the "attaching" step, but instead focus on the "fabricating" step,[9] i.e., "fabricating, separately from the neck body, a bone fixation body." Pet. Reply 8–10 (citing PO Resp. 18–19); *see* PO Resp. 16.

To the extent Petitioner argues that Patent Owner's interpretation *improperly* excludes the first exemplary embodiment (*see* Pet. 9–10), we

[9] We discuss the "fabricating" step below in Section II.B.4.

disagree because Petitioner has not persuaded us that the "attaching" step can be interpreted reasonably to include that embodiment. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (holding that the mere fact the patent disclosed an alternative embodiment not encompassed by the district court's claim construction did not outweigh the language of the claim, especially given the intrinsic evidence supporting the court's construction). Petitioner does not dispute that under Patent Owner's interpretation the "attaching" step reads on the second exemplary embodiment. As such, there is intrinsic evidence supporting Patent Owner's interpretation.

We determine that the broadest reasonable interpretation consistent with the Specification of the "attaching" step is that attachment of the bone fixation body to the neck body must take place subsequent to fabrication of the bone fixation body. We reach a similar conclusion with respect to the similar recitations in claims 8 and 14.

4. "fabricating, separately from the neck body, a bone fixation body"

In our Institution Decision, we adopted Petitioner's implicit construction that the "fabricating" step in claim 1 requires fabrication of the bone fixation body *independent of fabrication of the neck body*. Inst. Dec. 10–11. We rejected, as overly narrow, Patent Owner's construction that the "fabricating" step requires the bone fixation body to be physically separated, i.e., set or kept apart, from the neck body during fabrication of the bone fixation body. Inst. Dec. 10–11. We reasoned at that stage of the proceeding that Patent Owner's construction did not encompass the first exemplary embodiment, in which neck body 14 is adjacent to the cavity in

the mold in which bone fixation body 16 is fabricated, and thus interpreting "separately" in claim 1 to mean "set or kept apart" would not be the broadest reasonable construction consistent with the Specification. We determined that Petitioner's construction is broader, and encompasses both the first and second exemplary embodiments, i.e., in both embodiments, neck body 14 is fabricated independently from fabrication of fixation body 16. *Id.* at 11; *see supra* Section I.C.

In the Patent Owner Response, Patent Owner argues in support of its narrower construction that the "fabricating" step, like the "attaching" step discussed above, is directed specifically to the second exemplary embodiment "in which the two bodies (bone fixation and neck body) are fabricated independently from each other and subsequently attached":

> If this "fabricated/made separately" claim language in the step for fabricating/making the bone fixation body separately from the neck body is not by itself enough to make clear that the claims are directed to the second and not the first embodiment at column 4, line 49 to column 5, line 23, a further review of the subsequent attaching/connecting/engaging step confirms it. In the subsequent attaching/connecting/engaging step, the claims recite that the bone fixation body is attached/connected/engaged to the neck body after the bone fixation body is separately fabricated/made/formed, which makes it absolutely clear that the claims are directed to the second embodiment *in which the two bodies (bone fixation and neck body) are fabricated independently and subsequently attached*, and excludes the first embodiment in which the bone fixation body forms and simultaneously bonds/fuses to the neck body that is adjacent to the mold cavity in which the bone fixation body is formed.
>
> Accordingly, Patent Owner respectfully requests that the Board give meaning to the claim terms "after" and "separately fabricated/made/formed" in the step 3 attaching/connecting/engaging step, and regardless of the interpretation of the term "separately" in the step 2 for fabricating/making/forming the

> bone fixation body, interpret the terms "after" and "separately fabricated/made/formed" in step 3 to exclude the first embodiment at column 4, line 49 to column 5, line 23, require that the bone fixation body is not adjacent to the neck body when the bone fixation body is formed, and require that the two bodies are attached/connected/engaged only after each of the two bodies are separately (not adjacently) made.

Id. at 18–19 (italics added).

We agree with, and adopt, Patent Owner's argument. As discussed above, the "attaching" step requires attachment of the bone fixation body to the neck body *subsequent to* fabrication of the bone fixation body. Accordingly, the bone fixation body and the neck body must be fabricated independently from each other, and then attached together as in the second exemplary embodiment. This means that the neck body cannot be adjacent to the cavity of the mold in which the bone fixation body is formed as in the first exemplary embodiment.

We do not agree with Petitioner that Patent Owner's narrow construction improperly imports a limitation from a disclosed embodiment. *See* Pet. 9. Rather, Patent Owner's construction gives a reasonable meaning to the phrase "separately from the neck body," is consistent with the second exemplary embodiment, and considers the context of the surrounding words of the claim (i.e., the "attaching" step). *See ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered.").

We also note that Patent Owner's construction is consistent with the "engaging" step of claim 14, which recites "engaging, after *the neck body and the bone fixation body are separately formed*, the bone fixation body to

the neck body" (emphasis added). The most natural reading of the emphasized language in light of the Specification is that the neck body and the bone fixation body are formed independently of each other.

We determine that the broadest reasonable construction consistent with the Specification of the "fabricating" step in claim 1 is that fabrication of the bone fixation body and the neck body must be performed independently from each other (and thus this step does not encompass fabricating the bone fixation body in contact with the neck body as in the first exemplary embodiment). We reach the same conclusion with respect to the phrase "separately from the neck body" in claim 8. The "connecting" step of claim 14 contains the same requirement, i.e., that the neck body and the bone fixation body must be formed independently from each other.

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective

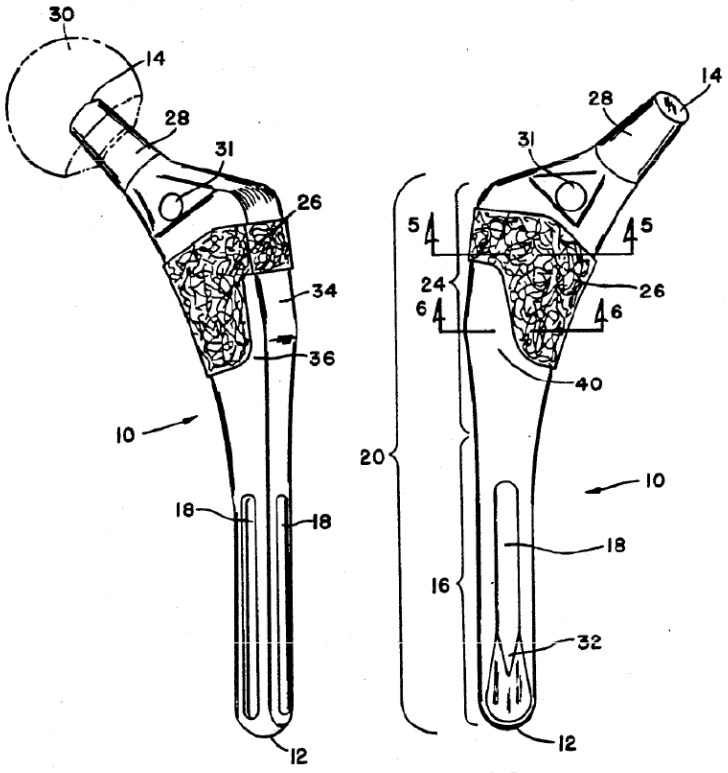
evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

1. Asserted Obviousness of Claims 1, 8, and 14 over Zolman and Rostoker

Petitioner challenges claims 1–5, 8–11, 14, 15, and 17–20 as obvious over Zolman and Rostoker. We first consider independent claims 1, 8, and 14.

a. Overview of Zolman

Zolman discloses a method of constructing a prosthetic implant that involves wrapping a porous pad about a prosthesis stem. Ex. 1005, 23–43. Figures 1 and 2 of Zolman are reproduced below.



Figures 1 and 2 provide perspective and elevation views, respectively, of femoral component 10. *Id.* at 2:58–60, 31–35. Porous pad 26 encircles

proximal portion 24 of stem portion 20. *Id.* at 3:53–54. As described in Zolman, porous pad 26 preferably is formed first as a substantially flat sheet and then is wrapped or formed about stem portion 20 (for example, using a forming fixture with forming jaws) into a final shape corresponding to the shape of the stem portion. *Id.* at 4:29–41, 5:22–35. Zolman states that Rostoker, discussed below, discloses a suitable fiber metal material for forming porous pad 26. *Id.* at 4:12–14.

Zolman also discloses that, instead of forming porous pad 26 about stem portion 20, porous pad 26 alternatively can be formed about a mandrel having a shape that corresponds to the portion of the implant to which the pad is to be attached. *Id.* at 7:1–6. The formed pad is then removed from the mandrel, placed about femoral component 10, and securely bonded to stem portion 20. *Id.* at 7:10–14.

b. Overview of Rostoker

Rostoker explains that "[a]n open-pore material into which bone could grow should provide ideal skeletal fixation." Ex. 1006, 1:50–51. Rostoker further explains that conventional porous materials were less than ideal, however, because they needed to be formed from fine powders to achieve the desired "high level of porosity and acceptable green strength." *Id.* at 1:54–59. These materials, Rostoker states, suffered from limited pore size and insufficient connectivity between pores. *Id.* at 1:59–63. According to Rostoker, "[t]his isolation limits bone ingrowth and results in a situation similar to the roughened surface of a solid." *Id.* at 1:63–65. Rostoker states: "Consolidated metal powders with porosities in the range of 40–60% void, are stronger than the consolidated ceramics but still are very brittle and have poor toughness." *Id.* at 2:3–7.

To solve these problems, Rostoker discloses a prosthetic device having "an open-pore attachment for bone ingrowth which attachment is highly compliant, not brittle, resistant to crack propagation and has a broad range of readily controllable pore sizes." *Id.* at 2:15–19. A porous aggregate is produced by kinking wire into a sinusoidal pattern, cutting the wire into short metal fibers, and then molding and sintering the fibers into a porous structure having interconnecting pores. *Id.* at 2:21–41. "[I]n view of the use of fiber metals, the pores are interconnecting and remain so after sintering." *Id.* at 2:40–41. "Thus bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection." *Id.* at 2:42–44. Rostoker states: "Since the pore size can be readily controlled by the pressing and forming parameters, the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted." *Id.* at 2:48–52.

Rostoker further discloses molding sintered metal aggregates "having void or a porosity of 40 to 50 percent per unit area." *Id.* at 5:6–8. "The largest principal dimension of the pores is approximately equal to the wire diameter when the void content is about 50 percent." *Id.* at 5:21–24. Rostoker discloses using wire sizes as fine as 0.013 cm in diameter and as coarse as 0.030 cm in diameter. *Id.* at 5:14–16.

c. Analysis

Petitioner contends that the combination of Zolman and Rostoker teaches the subject matter of claims 1, 8, and 14, and Petitioner provides a claim chart identifying elements of the combination that correspond to the limitations of the claims. Pet. 17–42. As applied by Petitioner to the embodiment depicted in Figure 1 of Zolman, the "neck body" recited in the

claims corresponds to the aggregate structure comprising neck 28, the adjacent portion with aperture 31 and stem 20 (*see, e.g.*, *id.* at 22), and the "bone fixation body" recited in the claims corresponds to porous pad 26 (*see, e.g.*, *id.* at 24). Petitioner argues that Zolman discloses "fabricating, separately from the neck body, a bone fixation body," as required by claim 1. *Id.* Petitioner further argues that a PHOSITA would have been motivated to use Rostoker's porous material in Zolman's porous pad 26 so as to have a porous metal fiber structure that emulates natural human bone:

> A person of ordinary skill in the art would have been motivated to fabricate *Zolman's* porous pad 26 so as to have a porous fiber metal structure that "emulates" natural human bone, as taught in *Rostoker*, to increase the strength of the attachment of the implant to the surrounding bone, allowing the implant to better withstand the load applied to the hip joint.

Id. at 26 (citing Ex. 1002 ¶¶ 31, 36 (claim chart element [1.c])).

Dr. Harrigan testifies that "*Rostoker* discloses 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' as recited in claim 1 as it discloses 'a structure that is sufficiently porous so as to permit bone ingrowth.'" Ex. 1002 ¶ 36 (claim chart element [1.c]).

Patent Owner argues in opposition that the '582 Patent represents a patentable improvement over the prior art. PO Resp. 9. Patent Owner asserts that "the state of the art before the priority date of the '582 patent was to use porous metal material that emulated human bone as either a porous coating applied to the hip stem or as an entire bulk implant." PO Resp. 3 (citing Ex. 2041 ¶ 103). Patent Owner further asserts that "[t]his type of porous material had never been used as a separate structure that attached to create a hip implant." *Id.* at 4. Patent Owner argues that "[m]aking a hip

implant from two separate bodies that include a bone fixation body with a porous structure that emulates bone and then connecting this body to a neck body to form a hip implant was an important advancement for the orthopedic hip implant industry." *Id.* at 9 (citing Ex. 2042 ¶ 42). According to Patent Owner, the '582 Patent solves problems that plagued conventional hip implants, such as loosening attributable to inadequate bone ingrowth into thin coatings and roughened metal substrates. *Id.* at 10–11.

(i) Emulating a Size and a Shape of a Porous Structure of Natural Human Bone

Patent Owner argues that the combination of Zolman and Rostoker does not teach or suggest a method to fabricate/make/form a porous metal structure with a size and a shape that emulate a size and a shape of a porous structure of natural human bone. *Id.* at 25. Patent Owner asserts that "[n]atural human bone has a structural shape that is quite different than the structural shape taught in Zolman and Rostoker." *Id.* at 29. Patent Owner relies on differences explained by Mr. Vincelli as follows:

> Natural human bone is formed of *interconnecting straight rods and plates* that connect together to form a three-dimensional porous foam structure. By contrast, the porous structure in Zolman and Rostoker is formed of interconnecting curved, S-shaped wires that bond together in a random order . . . . *The shape of natural human bone is significantly different than the shape of the porous metal structure taught in Zolman and Rostoker.*

Id. at 30 (citing Ex. 2042 ¶¶ 61–63) (underlining added). Based on these differences, Patent Owner argues that "[o]ne of ordinary skill in the art would know that the porous structure taught in Rostoker being formed of sinusoidal kinked wires 'has no relationship to the *straight rod-like* porous structure of natural human bone.'" *Id.* at 31 (citing Ex. 2041 ¶ 73)

(emphasis added). Patent Owner further argues that "the shape of the bonded kinked S-shaped wires would not emulate or imitate the shape of the interstitial porous structure of natural human bone." *Id.* at 32.

Based upon our review of the competing arguments of the parties and the evidence of record, we find 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. *See* Pet. Reply 16–18; Pet. 17–22, 24–27; *supra* Section II.C.1.b; Ex. 1002 ¶¶ 26–32, 36 (claim chart element [1.c]). We credit specifically Dr. Harrigan's testimony that the porous metal structure disclosed in Rostoker is sufficiently porous so as to permit bone ingrowth, and satisfies the requirement for 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. *See* Ex. 1002 ¶ 36 (claim chart element [1.c]). Moreover, we find that Rostoker teaches fabricating a fiber metal structure that contains interconnecting pores and a controlled pore size such that the porosity of the metal structure approximates the porosity of surrounding bone, permitting bone ingrowth. *See supra* Section II.C.1.b; Ex. 1006, 2:40–52; Ex. 1002 ¶ 29. As Petitioner argues, 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. *See* Pet. 25–26; Ex. 1002 ¶ 29; Ex. 1006, 5:6–24 (pore size of 0.03 cm (300 μm) and porosity of 50%); Ex. 1001, 4:33–43 (pore size from 40 μm to 800 μm and porosity from 45% to 65%).

Patent Owner's opposing argument is predicated on an erroneous claim construction, and is not persuasive. *See supra* Section II.B.2 (rejecting Patent Owner's argument that the porous-metal-structure claim terms require

emulating the size and shape of the interconnected plates and rods that form trabecular bone).

(ii) "Separately" Fabricating the Bone Fixation Body and Attaching the Bone Fixation Body "After" Separately Fabricating it

Patent Owner argues that Zolman and Rostoker do not teach "separately" fabricating the bone fixation body and then attaching the bone fixation body to the neck body "after" separately fabricating it. PO Resp. 38–41. Focusing on Zolman's disclosure, Patent Owner asserts that Zolman does not teach separately forming the porous pad and subsequently connecting it to the femoral component:

> Zolman does not form the porous pad separately from the femoral component and then, after forming the porous pad, connect it to the femoral component. Instead, *Zolman uses the femoral component as part of the process to form the porous pad*.

Id. at 39 (citing Ex. 2041 ¶ 95). In reference to Zolman's alternative embodiment (*see supra* Section II.C.1.a; Ex. 1005, 7:1–14), in which the porous pad is formed about a mandrel and subsequently attached to the femoral component, Patent Owner further asserts:

> Zolman's method requires that the porous material is wrapped around the femoral component (*or a mandrel*) while the porous material and the femoral component are placed in a forming fixture that bends the material into its final shape. [Ex. 1005,] 5:22-64. Jaws of this fixture press against the sheet of porous material and shape it into the porous pad. *Id.* at 5:52-57.
>
> The porous pad in Zolman is not made separately from the stem portion. Instead, the stem portion must be placed into the jaws together with the sheet of porous material so that the sheet of porous material can be pressed against and bent around the stem portion and formed into the shape of the porous pad. The stem in Zolman is used to make the porous pad. Ex. 2041 ¶ 97.

PO Resp. 40 (emphasis added).

At the oral hearing, Patent Owner elaborated on its argument that Zolman's alternative mandrel embodiment does not satisfy the claim requirements. T. 24:10–30:19, 31:5–33:21. Patent Owner argued that using a mandrel to form the porous pad does not satisfy the claim requirements because: (i) the attachment process begins with wrapping the pad around the mandrel and thus does not take place subsequent to formation of the porous pad; and (ii) the mandrel has the size and shape of the femoral component and thus forming the porous pad about the mandrel involves the same wrapping process as forming the porous pad adjacent to the femoral component itself. T. 31:5–25.

We are not persuaded by Patent Owner's argument. In Zolman's alternative embodiment, the mandrel "has a shape which corresponds to the portion of the implant to which the pad is to be attached." Ex. 1005, 7:5–6. Zolman teaches that, after pad 26 has been shaped about the mandrel, it is removed from the mandrel and placed about femoral component 10. *Id.* at 7:10–12. "The pad 26 can *then* be securely bonded to the stem portion 20." *Id.* at 7:12–14 (emphasis added). Thus, as taught by Zolman, attachment of pad 26 to stem portion 20 of femoral component 10 does not begin until after pad 26 has been fabricated and removed from the mandrel, contrary to Patent Owner's argument. Patent Owner's additional argument that wrapping pad 26 about a mandrel involves the same wrapping process as forming the porous pad about the femoral component itself is not commensurate with the scope of the claims. That is, fabricating the bone fixation body independently from the neck body as required by the claims does not preclude fabricating the bone fixation body in or about a mold,

mandrel, or similar tool having a shape that corresponds to the portion of the neck body to which the bone fixation body is to be attached.

For the reasons given, we find that Zolman teaches "separately" fabricating the bone fixation body (porous pad) about a mandrel and then attaching the bone fixation body to the neck body (femoral component) "after" the bone fixation body is separately fabricated. *See* Pet. Reply 15 (citing Ex. 1005, 7:1–14).

(iii) "Machining" a Neck Body

Claim 1 recites "machining a neck body formed of solid metal to include a neck that receives a femoral ball and having a male protrusion that extends outwardly from the neck body." Claim 8 recites "machining solid metal to form a neck body that includes a neck to receive a femoral ball and that includes a male protrusion that extends outwardly from the neck body."

Patent Owner argues that Petitioner has failed to show that Zolman and Rostoker teach or suggest "machining" a neck body. PO Resp. 19–25. In particular, Patent Owner challenges the testimony of Dr. Harrigan that a PHOSITA would have known that Zolman's femoral component likely was formed by machining. *Id.* at 21–25. In his declaration, Dr. Harrigan testifies as follows:

> *Zolman* discloses that the neck body is formed of a solid metal, i.e., titanium. *See* [Ex. 1005,] 4:26-27 ("the material for the femoral component may [] be titanium"). Given this, in my opinion, one of skill in the art would have understood the neck body of Zolman would have been likely to have been formed by a machining process such as, for example, grinding or grit blasting, at the time of the alleged invention. More specifically, one of skill, in my opinion, would have understood that it was common practice to machine the neck body of a femoral

component made of metal in 2003.

> *Zolman* also teaches that neck 28 of the neck body has a Morse taper, which, at the time of the invention, was commonly formed using machining techniques. Even if the neck body of *Zolman* was created through another process, in my opinion, a person of ordinary skill in the art would have known that the neck body would have been likely to undergo a final machining (e.g., grinding).

Ex. 1002 ¶ 36 (claim element [1.b]).

Patent Owner argues that, contrary to Dr. Harrigan's assertion, grit blasting and grinding could not have been used to machine or form Zolman's femoral component from solid metal because grit blasting and grinding are surface or finishing treatments. PO Resp. 22–23. Patent Owner relies on the testimony of Dr. Hemus that machining processes such as grit blasting and grinding cannot be used to form a solid metal hip stem:

> Grit blasting is a process that accelerates an abrasive material thru air to texturize a surface. *You cannot "grit blast" titanium and other metals to form a solid metal hip stem.* Grinders use a high-spinning abrasive wheel. These machines were used for finishing or performing a type of surface function (e.g., deburring, polishing, or surface roughening). By way of example, hip stems are machined with multi-axis turning machines or thread-whirling machines. By contrast, grit-blasting and grinders were used for surface treatments.

Ex. 2041 ¶ 158 (emphasis added); PO Resp. 22 (quoting Ex. 2041 ¶ 158).

The testimony of Dr. Hemus that machining processes such as grit blasting and grinding cannot be used to form a solid metal hip stem is conclusory and unpersuasive. In particular, Dr. Hemus does not explain sufficiently why using machines to finish, deburr, polish, or roughen solid metal to obtain the required dimensions and surface characteristics of a hip stem does not constitute machining to form the hip stem.

Rather, we credit the testimony of Mr. Vincelli and Dr. Harrigan that machining could be used to obtain the final dimensions and surface characteristics of a neck body. *See* Pet. Reply 23–24 (citing Ex. 1019, 56:12-20; Ex. 1002 ¶ 36 (claim element [1.b]). Mr. Vincelli testified that "some machining processes and polishing steps" are used after casting or machining a device to a near final shape, in order "to get to the final dimension and the final surface roughness":

> Q. How are you familiar with the techniques for manufacturing hip implants?
>
> A. Typically, they are either cast or machined. And then there [are] different finishing processes where, for instance with cast devices, they're cast to a near final shape and then they go through some machining processes and polishing steps to get to the final dimension and the final surface roughness that they're looking to achieve.

Ex. 1019, 56:12–20. Dr. Harrigan testified that Zolman's neck 28 has a Morse taper, which is commonly formed using machining techniques, and that, even if the neck body were created through a process other than machining, "a person of ordinary skill in the art would have known that the neck body would have been likely to undergo a final machining (e.g., grinding)." *See* Ex. 1002 ¶ 36 (claim chart element [1.b]).

To the extent Patent Owner argues that the claim terms "machining a neck body formed of solid metal" (claim 1) and "machining solid metal to form a neck body" (claim 8) ("the machining requirements") do not encompass surface or finishing treatments such as grit blasting and grinding, we disagree. That argument not only is contrary to the ordinary meaning of "machining," as evidenced by the testimony of Mr. Vincelli and Dr. Harrigan, discussed above, but also is inconsistent with the

Specification, which describes using conventional machining processes to form the neck body. *See* Ex. 1001, 4:53–54 ("In the exemplary embodiment, the neck body is formed from a solid piece of metal and prepared using conventional and known machining techniques."); 5:42–49 (describing an embodiment having a neck body with a bone-engaging region on its outer surface that can be formed using grit-blasting, etching, and other "non-porous surface treatments").

We do not agree, therefore, with Patent Owner's argument that Petitioner has failed to show that Zolman teaches or suggests the machining requirements. *See* PO Resp. 19–25. Petitioner has demonstrated that Zolman discloses "forming the neck body from a solid metal such as, for example, titanium." Pet. 23 (citing Ex. 1005, 4:26–27). Petitioner also has demonstrated through Dr. Harrigan's testimony, quoted above, that a PHOSITA would have known that Zolman's solid metal neck body "would have been likely to undergo a final machining (e.g., grinding)." *Id.* (citing Ex. 1002 ¶ 36 (claim chart element [1.b])). This evidence supports Petitioner's argument that "it would have been obvious to one of skill in the art, given the neck body disclosed in *Zolman*, to form the neck body through a machining process." *Id.* at 23–24 (citing Ex. 1002 ¶ 36 (claim chart element [1.b])).

Moreover, "it is proper to take into account not only specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a

person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at 1259. Here, the weight of the evidence establishes that a PHOSITA would have inferred that Zolman's neck body was formed by machining solid metal, contrary to Patent Owner's argument.

(iv) Teaching Away

Patent Owner contends that "[t]he combination of Zolman in view of Rostoker teaches away from making a porous metal structure with a shape that emulates human bone." PO Resp. 33. Specifically, Patent Owner argues that Rostoker's S-shaped wires teach away from the shape of natural bone that is comprised of a distinct rod-like columnar structure. *Id.* at 34–35 (citing Ex. 2042 ¶ 69). Patent Owner's argument is predicated on an erroneous claim construction, and is not persuasive. *See supra* Section II.B.2 (rejecting Patent Owner's argument that the porous-metal-structure claim terms require emulating the straight rod-like porous structure of trabecular bone).

(v) Porous Pad v. Prior Art Porous Coatings

To the extent Patent Owner argues that the "porous pad" of the Zolman/Rostoker combination is the type of prior art "porous coating" distinguished in the '582 Patent, we disagree. *See, e.g.*, Ex. 1001, 1:27–35, 2:50–61; PO Resp. 45 (citing Ex. 2042 ¶ 91) (arguing that the state of the art and research before the priority date of the '582 Patent was to apply surface coatings to hip stems). The '582 Patent discloses two problems with prior art porous coatings—they were thin, and they were applied to the surface of a non-porous metallic substrate of the implant. *See* Ex. 1001, 1:27–35, 2:50–61. Thus, the depth of potential bone ingrowth was restricted to the depth of the thin porous coating. *Id.*

The porous pad of the Zolman/Rostoker combination is structurally and functionally different from the thin porous coatings disclosed in the '582 Patent. In Zolman's second exemplary embodiment, discussed above, the porous pad is pressed into a sheet of porous kinked titanium fiber material of *any desired thickness* and then formed about a mandrel into its final contoured shape before being removed from the mandrel and attached to the femoral component. Ex. 1005, 4:46–48, 7:1–14. Accordingly, the porous pad is not restricted in terms of depth. Further, Rostoker teaches that bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection. Ex. 1006, 2:42–44. Thus, the Zolman/Rostoker porous pad also is not restricted in terms of its bone ingrowth functionality.

(vi) Porous Pad v. Bone Fixation Body

We also have considered the testimony of Dr. Hemus and Mr. Vincelli that Zolman's porous pad is a covering or coating that is placed on an implant, rather than a load-bearing bulk component of the implant, and thus is not a "bone fixation body" as described in the '582 Patent Specification. *See*, *e.g.*, Ex. 1018, 117:5–22, 137:2–14; 140:10–13, 141:25–142:22; 147:19–148:10; 149:5–25; 166:6–167:23; Ex. 1019, 89:16–90:7, 90:18–91:3, 93:7–12; 95:6–24. We do not credit that testimony, however, for the reasons discussed below. First, we have been directed to nothing in the claims or the Specification that limits the bone fixation body to a load bearing bulk implant.

Second, as discussed in the preceding subsection, Zolman's porous pad is not the type of prior art "porous coating" distinguished in the '582 Patent. Aside from that distinction, which is not applicable here, we

have been directed to nothing in the claims or the '582 Patent Specification that precludes the bone fixation body from being a coating or covering. While the Specification describes embodiments in which the bone fixation body does not include a metal substrate (Ex. 1001, 2:40–46; 4:10–11), the Specification does not criticize or discourage configuring the bone fixation body as a covering or coating for a male protrusion of the femoral component, such as depicted in Zolman's Figures 1 and 2 (reproduced above in Section II.C.1.a).

To the contrary, the Specification describes an embodiment having a bone fixation body that covers and surrounds a male protrusion of the neck body. Ex. 1001, 5:55–6:5, Fig. 5. In that embodiment, the male protrusion can extend for an unlimited distance into the bone fixation body: "The depth of the protrusion into the bone fixation body can be increased or decreased in various embodiments and still remain within the scope of the invention." *Id.* at 5:64–66. The testimony of Dr. Hemus and Mr. Vincelli does not account for the male protrusion embodiment.

Third, Dr. Hemus and Mr. Vincelli also do not recognize or address the claim requirements directed to the male protrusion embodiment. *See, e.g.*, *id.* at 16:9–12 (claim 3, requiring that "the male protrusion of the neck body . . . extends into the porous metal structure of the bone fixation body such that the porous metal structure surrounds an exterior surface of the male protrusion"); 17:8–13 (claim 14, requiring that "the protrusion extends to a distal end of a hip implant and tapers and extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the protrusion that extends into the bone fixation body"). These claim requirements indicate that the bone fixation

body can cover or surround the neck body, contrary to the testimony of Dr. Hemus and Mr. Vincelli.

Fourth, claim 17 depends from claim 14 and recites that "the bone fixation body is *not a porous coating* but is fabricated separately from the neck body and subsequently engaged to the neck body" (emphasis added). As a matter of claim differentiation, claim 14 should not be interpreted as requiring the limitation added by dependent claim 17. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (explaining that claim differentiation normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend) (citations omitted). Claim 17, therefore, indicates that the scope of "bone fixation body" in the independent claims includes a porous coating.

For these reasons, we are not persuaded that Zolman's porous pad is a coating or covering that is distinct from a "bone fixation body" as that term is used in the '582 Patent.

(vii) Reason to Combine

We credit the testimony of Dr. Harrigan, and find, that a PHOSITA would have been motivated to fabricate Zolman's porous pad 26 so as to have a porous fiber metal structure that emulates or imitates a size and a shape of a porous structure of natural human bone, as taught in Rostoker, to increase the strength of the attachment of the implant to the surrounding bone, allowing the implant to better withstand the load applied to the hip joint. *See* Ex. 1002 ¶¶ 31, 36 (claim chart element [1.c]). Patent Owner does not dispute that a PHOSITA would have combined the teachings of Zolman and Rostoker. T. 35:6–8.

(viii) Conclusion

For the reasons discussed above, and for the additional reasons set forth in Petitioner's claim chart (*see* Pet. 17–42), we agree with Petitioner that claims 1, 8, and 14 would have been obvious over Zolman and Rostoker.

2. Asserted Obviousness of Claims 2–5, 9–11, 15, and 17–20 over Zolman and Rostoker

Petitioner provides argument and a claim chart, supported by the testimony of Dr. Harrigan, identifying elements of the Zolman/Rostoker combination that correspond to the limitations of dependent claims 2–5, 9–11, 15, and 17–20. Pet. 17–42. We have reviewed Petitioner's arguments and the underlying evidence cited in support and are persuaded that Petitioner sufficiently establishes that dependent claims 2–5, 9–11, 15, and 17–20 would have been obvious over Zolman and Rostoker.

Patent Owner relies on its arguments as to independent claim 1, 8, and 14 with respect to the patentability of the dependent claims and does not address specifically dependent claims 2–5, 9–11, 15, and 17–20 in the Patent Owner Response. *See* PO Resp. 20, 25, 33, 36–39. Accordingly, the record now contains unrebutted arguments and evidence presented by Petitioner regarding the manner in which Zolman and Rostoker teach dependent claims 2–5, 9–11, 15, and 17–20.

We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 9, 6; *see also* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted."). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should

identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Accordingly, any challenges by Patent Owner to the unrebutted arguments and evidence presented by Petitioner with respect to dependent claims 2–5, 9–11, 15, and 17–20 are deemed waived.

For the reasons discussed above, including the unrebutted arguments and evidence set forth in Petitioner's claim chart (*see* Pet. 17–42), we determine that claims 2–5, 9–11, 15, and 17–20 would have been obvious over Zolman and Rostoker.

3. Conclusion

For the reasons given, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 8–11, 14, 15, and 17–20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman and Rostoker.

4. Asserted Obviousness of Claim 7 over Zolman, Rostoker, and Sump

Claim 7 recites "[t]he method of claim 1, wherein the male protrusion of the neck body has one of a square shape and a rectangular shape and tapers while extending toward the distal end of the hip implant." Petitioner argues that claim 7 would have been obvious over Zolman, Rostoker, and Sump. Pet. 43–44.

a. Overview of Sump

Sump discloses a known hip prosthesis configuration having an elongated shank. Ex. 1011, 3:14–19. The shank has a rectangular shape in a

horizontal cross-section and tapers from its ball end toward its distal end. *See id.* at 3:1–4, 14–22, Figs. 1, 2.

b. Analysis

We agree with Dr. Harrigan's testimony, and find, that a PHOSITA would have formed the stem portion of the hip implant of Zolman and Rostoker to have a rectangular shape as taught by Sump. *See* Ex. 1002 ¶ 53; *KSR*, 550 U.S. at 416 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). It is undisputed that Zolman discloses that stem portion 20 has a polygonal cross-section and tapers while extending toward distal end 12 of femoral component 10. Ex. 1002 ¶ 51 (citing Ex. 1005, 5:19–21, Figs. 1–6). It also is undisputed that Sump teaches that shank 11 has a rectangular shape. *See id.* ¶ 52 (citing Ex. 1011, 3:1–4, 14–22, Figs. 1, 2).

In response, Patent Owner argues that claim 7 requires a taper that extends to the distal end of the implant. PO Resp. 55 (citing Ex. 2041 ¶ 162; Ex. 2042 ¶ 145). Patent Owner further argues that the taper of Zolman's implant "stops about midway down the stem" and thus does not teach or suggest the distal end requirement. *Id.* Patent Owner does not challenge Petitioner's reason for combining Sump with Zolman and Rostoker, and any arguments disputing Petitioner's unrebutted evidence and arguments are deemed waived, as discussed above.

Petitioner argues in its Reply that Patent Owner's claim construction is wrong because "extending *toward* the distal end of the hip implant" (emphasis added) refers to the direction of the taper, and not the length of the taper as Patent Owner contends. Pet. Reply. 24. The ordinary meaning

of "toward" is "in the direction of." *See, e.g.*, MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 1248 (10th ed. 1993) (Ex. 3001). Thus, "tapers while extending *toward* the distal end of the hip implant" (emphasis added) means tapers while extending *in the direction of* the distal end of the hip implant, as Petitioner contends.

For the reasons given, we determine that Petitioner has shown by a preponderance of the evidence that claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman, Rostoker, and Sump.

5. Asserted Obviousness of Claim 20 over Zolman, Rostoker, and Averill

We do not reach this challenge to claim 20 in view of our determination above that Zolman and Rostoker render obvious claim 20.

6. Asserted Obviousness of Claims 1–5, 8–11, 13–15, and 17–20 over Zolman and Bobyn

Petitioner challenges claims 1–5, 8–11, 13–15, and 17–20 as obvious over Zolman and Bobyn, and Petitioner provides a claim chart identifying elements of the combination that correspond to the limitations of the claims. Pet. 45–59.

a. Overview of Bobyn

Bobyn is a study of the characteristics of bone ingrowth of a new porous tantalum biomaterial in a transcortical canine model using cylindrical implants. Ex. 1007, 907. Bobyn states:

> A new porous biomaterial made of tantalum has recently been developed for potential application in reconstructive orthopaedics and other surgical disciplines. The material has an unusually high and interconnecting porosity with a very regular pore shape and size. It can be made into complex shapes and used either as a bulk implant or as a surface coating. Our aim in

> this study was to characterize this porous tantalum material in terms of the extent and rate of bone ingrowth as well as the strength of fixation at the interface.

Id. The cylindrical implants were manufactured by depositing commercially pure tantalum on a carbon skeleton using chemical vapor deposition/ infiltration ("CVD/CVI"). *Id.* at 908. Four transcortical implants were inserted into perpendicular drill holes in each femur of each animal in the study. *Id.* at 909. Bobyn states that "[a]lthough not as realistic as a fully-functional load-bearing model, the transcortical model is very useful for the initial characterization of new porous biomaterials." *Id.* at 913.

Bobyn reports that "[c]ompared with previous studies using porous-coated transcortical implants, high fixation strength occurred much earlier with porous tantalum." *Id.* at 912. "The increased rate of development of the interfacial shear strength with porous tantalum can best be attributed to the higher volume fraction available for ingrowth." *Id.* While fiber metal coatings have a porosity of 40% to 50%, the porous tantalum biomaterial used in the study had a substantially higher porosity of 75% to 80%. *Id.* "The histological studies clearly showed that the porous tantalum served as an effective scaffold for relatively complete incorporation with new bone by 16 weeks, with little change after 52 weeks of implantation." *Id.*

Bobyn states that "[f]rom a manufacturing standpoint, tantalum is particularly well suited to the complex CVD/CVI process used for deposition on to the vitreous carbon substrate." *Id.* at 913. Bobyn also discloses that tantalum "is a strong, ductile metal," and "[i]ts superb biocompatibility and suitable mechanical properties have led to its standardization as a surgical implant material." *Id.*

Bobyn discloses that "[t]he tantalum construct which we have evaluated represents a departure from conventional porous materials in many respects." Bobyn explains that because of the tantalum biomaterial's high porosity, the structural stiffness of porous tantalum is "similar to subchondaral bone, which could be advantageous in bone remodeling." *Id.* Bobyn states that "[t]he material could be used as a backing for direct compression moulding of polyethylene-bearing components or as a fixation surface on an implant substrate." *Id.* Bobyn also states that the material's "structural integrity allows it to be readily formed in bulk parts for the filling of bone defects or other reconstructive applications requiring standard or customized shapes and sizes of the implant." *Id.* Bobyn concludes: "Based on the results of our study we conclude that [the tantalum biomaterial] offers interesting potential for orthopaedic reconstructive procedures and that further studies are warranted." *Id.*

b. Analysis

Petitioner contends that the combination of Zolman and Bobyn teaches the subject matter of claims 1–5, 8–11, 13–15, and 17–20. Pet. 45–59. Petitioner argues that:

> Given *Bobyn's* teachings of the advantages of the porous tantalum biomaterial over other conventional porous surfaces, a person of ordinary skill in the art would have been motivated to use [] *Bobyn's* porous biomaterial for *Zolman's* porous pad 26 to form a high strength femoral component 10 with a structure similar to natural cancellous bone.

Id. at 48 (citing Ex. 1002 ¶ 61). In support of Petitioner's argument, Dr. Harrigan testifies that "[a]t the time of the alleged invention, tantalum was understood to be a 'strong, ductile metal with excellent corrosion resistance' that was a standard material used in surgical implants." Ex. 1002

¶ 60 (citing Ex. 1007, 913). Dr. Harrigan cites Bobyn's disclosure that tantalum can be used as a fixation surface on an implant and is particularly applicable for reconstructive orthopedic procedures:

> *Bobyn* discloses that unlike conventional porous materials, tantalum "is a strong, ductile metal" with a structural integrity that "allows it to be readily formed in bulk parts for the filling of bone defects or other reconstructive applications requiring standard or customised shapes and sizes of the implant." Ex. 1007 at 913; see also *id.* at 907. Additionally, *Bobyn* contemplates that the material can be used as a fixation surface on an implant and is particularly applicable for reconstructive orthopedic procedures. *Id.* at 913; *see also id.* at 907.

Id. ¶ 62. Dr. Harrigan also testifies that "[l]ike the fiber metal structure of *Zolman* (Ex. 1005 at 4:46-48), *Bobyn* discloses that the porous tantalum biomaterial can be compression molded." *Id.* ¶ 63 (citing Ex. 1007, 913). In Dr. Harrigan's opinion, a PHOSITA "would have understood that the porous tantalum biomaterial would have been adaptable to be used with the manufacturing techniques disclosed in Figures 1–6 of *Zolman*." *Id.*

Patent Owner disputes Petitioner's rationale for combining the teachings of Zolman and Bobyn. PO Resp. 42–55. Patent Owner argues, for example, that "one of ordinary skill in the art would not have been motivated to use Bobyn's tantalum biomaterial in the Zolman method because the steps of pressing and bending as taught in Zolman would damage Bobyn's biomaterial, and the step of cutting as taught in Zolman would deform, close, and smear the pores of Bobyn's biomaterial making it unfit for use in a hip implant. *Id.* at 48–51 (citing Ex. 2041 ¶¶ 120, 128, 130; Ex. 2042 ¶¶ 102–108). Patent Owner also repeats arguments discussed above in connection with the combination of Zolman and Rostoker, and argues that Bobyn is merely an experimental animal study limited to dogs. *Id.* at 42–48, 52–53.

Based upon our review of the competing arguments of the parties and the evidence of record, we find 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. Further, for the reasons discussed below, we credit the testimony Dr. Harrigan, and find, that a PHOSITA would have been able to adapt Bobyn's porous tantalum biomaterial for use in Zolman's manufacturing method.

As Petitioner asserts, "while Dr. Harrigan acknowledged that porosity may affect the ductility of the porous structure, he explained that 'there are a lot of ways to manipulate the material and the microstructure to provide enough ductility so that . . . the [Bobyn] material could be used in the [Zolman] invention' that would only require 'a small amount of experimentation.'" Pet. Reply 21 (quoting Ex. 2039, 44:8–15; 44:23–45:6). Dr. Harrigan testified persuasively that Bobyn's porous tantalum material could be cut, bent without breaking, and wrapped around a mandrel using known tools and methods. *See* Ex. 2039, 41:7–22, 43:13–20, 44:8–45:6, 45:17–24, 48:15–50:10. Dr. Harrigan explained, for example, that whether the material taught in Bobyn is sufficiently ductile to be bent and wrapped as required in the Zolman process would depend on the particulars of the design and dimensions, but "if there was an issue with ductility, you could always just warm the material up and it would be usable." *Id.* at 43:13–20. Dr. Harrigan also explained that a skilled person could have limited smearing of the edges when cutting Bobyn's material by potting the material

in polymer, making the cut, and then dissolving away the polymer. *Id.* at 49:16–50:10.

We give little weight to the conflicting testimony of Dr. Hemus and Mr. Vincelli that one of skill in the art would not consider using Bobyn's biomaterial in Zolman's method because it would be damaged by pressing, cutting, and bending the porous pad around a stem in the jaws of a vice. *See* Ex. 2041 ¶¶ 120–131; Ex. 2042 ¶¶ 102–110. Dr. Hemus testifies, for example, that "[p]ressing Bobyn's biomaterial per the method taught in Zolman would smash the struts and interstitial pores of the biomaterial *if it were made to emulate human bone (i.e., have the porosity of human bone, pore sizes of human bone, strut sizes of human bone, etc.)*." Ex. 2041 ¶ 123 (emphasis added). Mr. Vincelli similarly testifies that "[p]ressing Bobyn's biomaterial per the method taught in Zolman would crush the rod-like struts of the biomaterial *if it were made to emulate the structure of human bone*. Ex. 2042 ¶ 104 (emphasis added). The quoted testimony of Dr. Hemus and Mr. Vincelli does not appear to address the specific material taught in Bobyn, but rather a more fragile version of that material made to emulate the rod-like struts of trabecular bone. *See also* Ex. 2041 ¶ 121 (opining that Bobyn's material is much more fragile than Rostoker's material, "especially if it is fabricated to have the size and shape of porous natural bone"). Not only does the testimony of Dr. Hemus and Mr. Vincelli appear to discuss a different material than actually disclosed in Bobyn, their testimony also does not account sufficiently for Bobyn's disclosures that tantalum is a strong, ductile metal and that porous tantalum can be compression-molded. *See* Ex. 1007, 913. Those disclosures support Dr. Harrigan's testimony that Bobyn's biomaterial is sufficiently ductile to be bent and wrapped as

required in the Zolman process, while undercutting the contrary testimony of Dr. Hemus and Mr. Vincelli. Moreover, Dr. Hemus and Mr. Vincelli admit, respectively, that porous tantalum is "a soft, ductile material" (Ex. 2041 ¶ 128 (quoting Ex. 2015, 537)) and "a particularly ductile material" (Ex. 2042 ¶ 107 (quoting Ex. 2015, 529)).

In testifying that cutting Bobyn's porous tantalum biomaterial per Zolman's method would smear or deform the pores, Dr. Hemus and Mr. Vincelli each rely on an article titled "Evaluation of Machining Methods for Trabecular Metal Implants in a Rabbit Intramedullary Osseointegration Model," by Mukund Deglurkar et al., published July 12, 2006 (Exhibit 2015, "Deglurkar"). Ex. 2041 ¶ 128 (citing Ex. 2015, 537); Ex. 2042 ¶ 107 (citing Ex. 2015, 529). Deglurkar describes two methods of finish-machining a *surface* of a porous tantalum product known as Trabecular Metal™ ("TM"):

> *While [the vapor deposition manufacturing method] results in a virgin, unmachined surface of tantalum, it is not always possible to achieve the desired final shape or surface finish of the implant exactly by this approach, as the tantalum deposition alters these parameters somewhat unpredictably.*
>
> *If close dimensional tolerances are needed, the finished TM pieces must be finish-machined.* Traditional machining using a lathe or a mill results in a smearing of the surface material of porous metals, significantly occluding surface porosity. In the porous-metal filter industry, this is a recognized problem. The smearing phenomenon is exacerbated in the case of TM, as tantalum is a particularly ductile material, and the very highly porous structure of TM offers little internal support during machining. The occlusion of surface porosity has a potential negative impact on bone ingrowth.
>
> Electrical discharge machining (EDM) is a "noncontact" machining method using an electric spark to remove material. EDM is the preferred method for machining porous metal, and has attracted some attention for the preparation of high-precision

> dental implants. As the machining electrode never touches the workpiece, the problem of metal smearing is eliminated.

Ex. 2015, 529 (emphasis added).

Dr. Hemus and Mr. Vincelli each quote portions of Deglurkar to support their opinions that cutting Bobyn's porous tantalum biomaterial using a lathe or a mill would smear or deform the surface pores so as to interfere with bone ingrowth. Ex. 2041 ¶ 128 (citing Ex. 2015, 537); Ex. 2042 ¶ 107 (citing Ex. 2015, 529). We are not persuaded, however, that surface-finishing as described in the Deglurkar article is particularly relevant to Zolman's method of cutting out a pad from a sheet of porous material. *See* Ex. 1005, 4:49–52. That is, Zolman does not teach a need for close dimensional tolerances as in Deglurkar that would require finish-machining a surface of the sheet of porous material or a surface of a porous pad. Accordingly, we are not persuaded that cutting out a pad from a sheet of Bobyn's tantalum biomaterial, without substantial smearing, would have been beyond the skill in the art at the time of the invention. Further, Dr. Harrigan's testimony that a skilled person could have limited smearing of the edges (i.e., by potting the material in polymer, making the cut, and then dissolving away the polymer) is unrebutted. *See* Ex. 2039, 49:16–50:10.

Patent Owner's additional argument that Bobyn is merely an experimental animal study limited to dogs also is unpersuasive. *See* PO Resp. 45–48, 52–53. The crux of Patent Owner's argument is that "further studies would have been needed to determine whether Bobyn's biomaterial could sustain the heavy loads imparted on a human femur." *Id.* at 46–47 (citing Ex. 2041 ¶118); *see id.* at 52–53 (citing Ex. 2042 ¶ 111). Patent Owner has not shown, however, that this argument sufficiently

addresses Petitioner's rationale for the Zolman/Bobyn combination, in which Bobyn's material would be used in Zolman's porous pad to promote bone ingrowth, not in Zolman's femoral component to sustain heavy loads. On cross-examination during the trial, Dr. Hemus actually confirmed Petitioner's asserted rationale for using Bobyn's material in Zolman's porous pad, testifying that a PHOSITA would have had "no doubt" based on the results of the Bobyn study that the porous tantalum biomaterial would facilitate bone ingrowth. Ex. 1018, 257:23–258:4.

Finally, to the extent Patent Owner incorporates or repeats arguments that it made in connection with the ground based on Zolman and Rostoker, Patent Owner's arguments are unpersuasive for the reasons discussed above in connection with that ground.

For the reasons given, and based upon the arguments and underlying evidence set forth in Petitioner's claim chart, we determine that Petitioner has shown 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. The unrebutted arguments and evidence presented by Petitioner with respect to claims 1–5, 8–11, 13–15, and 17–20 are deemed waived, as discussed above.

7. Asserted Obviousness of Claim 7 over Zolman, Bobyn, and Sump

Petitioner argues that claim 7 would have been obvious over Zolman, Bobyn, and Sump for essentially the same reasons as discussed above in connection with the ground based on Zolman, Rostoker, and Sump. *See* Pet. 59. Patent Owner responds with essentially the same arguments as it made in connection with Zolman, Rostoker, and Sump. PO Resp. 55–56.

Patent Owner does not challenge Petitioner's reason for combining Sump with Zolman and Bobyn, and any arguments challenging Petitioner's unrebutted evidence and arguments are deemed waived, as discussed above.

For the reasons discussed above in connection with the ground based on Zolman, Rostoker, and Sump, we determine that Petitioner has shown by a preponderance of the evidence that claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over Zolman, Bobyn, and Sump.

8. Asserted Obviousness of Claim 20 over Zolman, Bobyn, and Averill

We do not reach this challenge to claim 20 in view of our determination above that Zolman and Bobyn render obvious claim 20.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 7–11, 13–15, and 17–20 are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 7–11, 13–15, and 17–20 of U. S. Patent No. 8,821,582 B1 are unpatentable.

This is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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