### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE PATENT TRIAL AND APPEAL BOARD

SURGALIGN SPINE TECHNOLOGIES, INC. Petitioner,

v.

LIFENET HEALTH Patent Owner.

Case IPR2019-00570

U.S. Patent No. 8,182,532

#### PATENT OWNER'S NOTICE OF APPEAL

Notice is hereby given, pursuant to 35 U.S.C. §§ 141(c), 142, 319; 37 C.F.R. §§ 90.2(a), 90.3(a), and 104.2 that Patent Owner LifeNet Health ("Patent Owner") appeals from the Patent Trial and Appeal Board's ("PTAB") Final Written Decision on Remand entered on November 15, 2022 (Paper No. 82) in the above-captioned *inter partes* review of U.S. Patent No. 8,182,532 ("532 patent") to the United States Court of Appeals for the Federal Circuit. A copy of the Final Written Decision on Remand is attached to this notice as Exhibit A. This notice is timely filed within 63 days of the PTAB's Final Written Decision on Remand. 37 C.F.R. § 90.3(a)(l).

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner further indicates that the issues on appeal include, without limitation: (i) the PTAB's determination that claims 4 and 6-11 of the '532 patent are unpatentable over the art of record; (ii) the PTAB's claim construction of "through-holes"; (iii) the PTAB's secondary considerations analysis; (iv) the PTAB's obviousness analysis; and (v) any finding or determination supporting or related to the above-mentioned issues, including in any orders, decisions, rulings, and/or opinions.

Simultaneous with this submission, Patent Owner is filing a true and correct copy of this Notice of Appeal with the Director of the U.S. Patent and Trademark Office and electronically filing the same, along with the required docketing fees, with the Clerk of the Federal Circuit as set forth in the accompanying Certificate of Filing.

Dated: January 12, 2023

Respectfully submitted,

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Counsel for Patent Owner

# **CERTIFICATE OF FILING**

The undersigned hereby certifies that, in addition to being filed with the PTAB through the P-TACTS electronic filing system, a true and correct copy of the above-captioned PATENT OWNER'S NOTICE OF APPEAL is being filed with the Director of the U.S. Patent and Trademark Office on January 12, 2023 by hand at the following address:

> Director of the U.S. Patent & Trademark Office c/o Office of the General Counsel, 10B20 Madison Building East 600 Dulany Street Alexandria, Virginia 22314

The undersigned also hereby certifies that a true and correct copy of the abovecaptioned PATENT OWNER'S NOTICE OF APPEAL and the filing fee is being filed via the electronic filing system, CM/ECF, with the Clerk's Office of the U.S. Court of Appeals for the Federal Circuit on January 12, 2023. Pursuant to Fed. Cir. R. 15(a)(1), one copy of this Notice of Appeal is also being sent to the Clerk's Office of the Federal Circuit by first class mail on January 12, 2023.

Respectfully submitted,

Dated: January 12, 2023

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#### **Certificate of Service**

The undersigned hereby certifies that on January 12, 2023, a true and correct copy of the foregoing was served by email on the following counsel of record for Petitioner:

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Counsel for Patent Owner

# **EXHIBIT A**

Trials@uspto.gov 571-272-7822 Paper 84 Entered: December 1, 2022

# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SURGALIGN SPINE TECHNOLOGIES, INC., Petitioner,

v.

LIFENET HEALTH, Patent Owner.

IPR2019-00570 Patent 8,182,532 B2

Before GEORGE R. HOSKINS, CHRISTOPHER C. KENNEDY, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

HOSKINS, Administrative Patent Judge.

JUDGMENT Final Written Decision on Remand Determining All Challenged Claims Unpatentable 35 U.S.C. §§ 144, 318(a)

# I. INTRODUCTION

On August 26, 2020, the Board entered a Final Written Decision (Papers 71 and 74, "the First FWD")<sup>1</sup> regarding nine Grounds of unpatentability asserted by Surgalign Spine Technologies, Inc. ("Petitioner") against claims 4 and  $6-21^2$  of U.S. Patent No. 8,182,532 B2 ("the '532 patent"), owned by LifeNet Health ("Patent Owner"). *See* First FWD 9–10 (listing the Grounds). The First FWD determined a preponderance of the evidence supported Petitioner's contentions as to claims 12–21 but not as to claims 4 and 6/4-11/4. *See id.* at 72–73 (listing the result for each Ground and each claim).

Petitioner appealed the First FWD as to claims 4 and 6/4–11/4 to the U.S. Court of Appeals for the Federal Circuit. *See* Paper 75. Patent Owner cross-appealed the First FWD as to claims 12–21. *See* Paper 76.

On April 11, 2022, the Federal Circuit entered an opinion and judgment, which affirmed in part and reversed in part, and remanded the case back to the Board. *See Surgalign Spine Techs., Inc., f/k/a RTI Surgical, Inc. v. LifeNet Health*, Nos. 2021-1117, 2021-1118, 2021-1236, 2022 WL 1073606 (Fed. Cir. Apr. 11, 2022) ("Federal Circuit Decision" or "FCD"). The Federal Circuit issued its mandate on May 18, 2022.

<sup>&</sup>lt;sup>1</sup> Paper 71 is a sealed version of the First FWD, and Paper 74 is a redacted public version of the First FWD.

<sup>&</sup>lt;sup>2</sup> Claims 6–11 are multiple dependent claims, depending from either independent claim 4 or independent claim 5. See Ex. 1001, 47:28–50; see also 35 U.S.C. § 112 ¶¶ 3 & 5 (providing claims may be "written in . . . multiple dependent form"). These dependent claims are at issue here only to the extent they depend from claim 4 (see infra Sections IV.D and V.E), so at times we refer to them as claims 6/4, 7/4, 8/4, 9/4, 10/4, and 11/4.

The parties agree that the Federal Circuit Decision affirmed the First FWD as to claims 12–21. *See* Paper 78, 3 (discussing Ground 1); Paper 79, 2 ("[T]he parties agreed with our preliminary views concerning the substantive scope of what we must do on remand, as set forth in our previous Order (Paper 78)."); Ex. 1049, 4:20–5:18, 7:7–16, 10:9–15. Thus, we do not consider these claims further here on remand.

The parties also agree that the Federal Circuit Decision reversed the First FWD as to Petitioner's Grounds 2 and 5 challenging claims 4 and 6/4–11/4, and remanded the case back to the Board for further proceedings concerning these challenges. *See* Paper 78, 3–5 (discussing Grounds 2 and 5); Paper 79, 2; Ex. 1049, 4:20–5:18, 7:7–16, 10:9–15. Thus, we reconsider Grounds 2 and 5 in this Decision.

We have jurisdiction under 35 U.S.C. §§ 6 and 144. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 4 and 6/4–11/4 of the '532 patent. Based on the record before us, Petitioner has demonstrated, by a preponderance of the evidence, that independent claim 4, and claims 6–11 to the extent they depend from claim 4, are unpatentable.

#### II. BACKGROUND

# A. The Parties' Briefs and Oral Arguments

Petitioner's Grounds of unpatentability are set forth in the Petition (Paper 2, "Pet."). Patent Owner's opposition is set forth in the Patent Owner IPR2019-00570 Patent 8,182,532 B2

Response (Papers 28 and 29, "PO Resp.").<sup>3</sup> Petitioner filed a Reply (Paper 39, "Pet. Reply"). Patent Owner filed a Sur-reply (Paper 54, "Sur-reply"). The Board held a hearing on June 2, 2020, a transcript of which is included in the record (Paper 68, "Tr.").

#### B. Related Matters

Patent Owner has asserted the '532 patent, and four other patents, against Petitioner in *LifeNet Health v. RTI Surgical, Inc.*, No. 1:18-cv-00146 (N.D. Fla.). *See* Pet. 2–3; Paper 5, 1. The Court has stayed the litigation in view of the present *inter partes* review and other *inter partes* reviews concerning other patents at issue in the litigation. *See* District Court Docket Nos. 93 and 110.

# C. The '532 Patent Specification and Claims At Issue 1. The '532 Patent Specification

The '532 patent relates to a composite bone graft for spinal fusion. See Ex. 1001, 1:15–16. Spinal fusion is a surgical procedure in which a patient's intervertebral disc is removed and replaced with an implant to fill the void between adjacent vertebrae. See Ex. 2001 ¶ 21. After the procedure, the natural healing process of bones causes the vertebrae to fuse together over time. See id. ¶¶ 21–23; Ex. 1016 ¶¶ 21–23. Implants for spinal fusion can be made from various materials, including bone obtained from the patient, or bone obtained from a human donor. See Ex. 1016 ¶ 25; Ex. 2001 ¶ 26.

<sup>&</sup>lt;sup>3</sup> Paper 28 is a sealed version of the Patent Owner Response, and Paper 29 is a redacted public version of the Patent Owner Response.

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The composite bone graft of the '532 patent includes a plurality of bone portions layered to form a graft unit, and one or more bone pins that hold the graft unit together. *See* Ex. 1001, code (57), 1:18–24, 2:30–33. Figure 6 of the '532 patent is reproduced below:



The '532 Patent, Figure 6.

Figure 6 is a perspective view of a composite bone graft. *Id.* at 8:55–56, 19:40. The graft includes first cortical bone portion 2, second cortical bone portion 4, and cancellous bone portion 3. *Id.* at 19:40–42. Cortical bone pins 7 hold the bone portions together. *Id.* at 19:42–43. The graft also includes textured surfaces 14a and 14b. *Id.*; *see also id.* at 15:29–40 (defining the term "textured").

According to the '532 patent, the disclosed composite bone graft can be sized for any application, promotes the growth of patient bone at the implantation site, provides added stability and mechanical strength, and does not shift, extrude, or rotate after implantation. *Id.* at code (57), 1:30–37, 2:5–11.

# 2. The '532 Patent Claims 4 and 6/4–11/4

As discussed above, claims 4 and 6/4-11/4 of the '532 patent are at issue here. Claim 4 is reproduced here:

4. A composite spinal bone graft comprising:

a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:

a first plate-like cortical bone portion configured to contact a portion of the host bone;

a second plate-like cortical bone portion configured to contact a portion of the host bone;

a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion and configured to contact a portion of the host bone to form said graft unit; and

one or more cortical bone pins connecting bone portions of said bone graft unit, said composite spinal bone graft having a shape selected from the group consisting of a parallelepiped, a parallel block, a square block, a trapezoid wedge, a cylinder, a flattened curved block, a tapered cylinder, and a polyhedron,

wherein said composite spinal bone graft comprises one or more textured surfaces comprising a plurality of closely spaced continuous protrusions in a linear arrangement and said spinal bone graft is configured for implantation into the anterior spinal column of the host.

Ex. 1001, 46:48–47:3.

# D. Asserted Prior Art and Grounds

As discussed above, only Grounds 2 and 5 of the Petition are at issue here. These Grounds rely on the following four references. *See* Pet. 4–5.

Name	Reference	<b>Publication Date</b>	Exhibit No.
McIntyre	US 4,950,296	Aug. 21, 1990	1005
Coates	US 5,989,289	Nov. 23, 1999	1008
Paul	US 6,258,125 B1	July 10, 2001	1006
Grooms	US 2002/0138143 A1	Sept. 26, 2002	1003

Petitioner asserts all four references are prior art to the '532 patent as to their respective disclosures cited in Grounds 2 and 5. *See* First FWD 6–7 & nn.3–5. Patent Owner does not dispute this assertion. *See id*.

Petitioner's Grounds 2 and 5 are as follows. See Pet. 4–5.

Ground	<b>Claims Challenged</b>	35 U.S.C. §	References
2	4,6/4–11/4	$103(a)^4$	Grooms, McIntyre
5	4, 6/4–9/4, 11/4	103(a)	Paul, McIntyre, Coates

# E. Testimonial Evidence and Patent Owner's Motions to Exclude

Petitioner relies on the testimony of Michael C. Sherman as a technical expert. *See* Exs. 1015, 1026, 2032, and 2092. Petitioner also relies on the testimony of Jeffrey S. Fischgrund, M.D. as a technical expert. *See* Exs. 1016, 1028, 2031, and 2091.

The First FWD denied Patent Owner's motion to exclude Exhibits 1015 and 1026 (Mr. Sherman's declaration testimony) and Exhibits 1016 and 1028 (Dr. Fischgrund's declaration testimony). *See* First FWD 14–17, 73. The Federal Circuit Decision did not disturb that denial, so we do not revisit it here.

<sup>&</sup>lt;sup>4</sup> The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), revised 35 U.S.C. § 103 effective March 16, 2013. The '532 patent was filed before March 16, 2013, so we refer to the pre-AIA version.

Patent Owner relies on the testimony of Mark E. Shaffrey, M.D. as a technical expert. *See* Exs. 1037, 2001, and 2028. Patent Owner also relies on the testimony of David L. Kaplan, Ph.D. as a technical expert, but this testimony mostly concerns a prior art reference (Wolter) that is not at issue in Grounds 2 and 5. *See* Exs. 1038, 2002, and 2029.

# F. Legal Standards

Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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 said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). 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 ordinary skill in the art; and (4) objective evidence of nonobviousness, if in the record, as it is here. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). "While the sequence of these questions might be reordered in any particular case," *KSR*, 550 U.S. at 407, the Federal Circuit has explained that an obviousness determination can be made only after consideration of all of the Graham factors. See, e.g., Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1360 (Fed. Cir. 2012).

# G. Person of Ordinary Skill in the Art

In the First FWD, the formulation of a person of ordinary skill in the art was a disputed issue. *See* First FWD 10–12. The First FWD concluded:

[T]he person of ordinary skill in the art would have had at least a bachelor's degree in mechanical, biomechanical, or biomedical engineering or a closely-related discipline, as well as 5–10 years of experience designing and developing orthopedic implants and/or spinal interbody devices and/or bone graft substitutes, at least some of which experience includes working with bone grafts. Alternatively, such a person would typically have had an advanced degree (master's or doctorate) in one of the above-identified fields, as well as 3 to 5 years of experience, at least some of which includes working with bone grafts. As still another alternative, the person of ordinary skill would be a practicing orthopedic surgeon with at least five years of experience, at least some of which experience includes working with bone grafts.

*Id.* at 12. That conclusion was not disturbed by the Federal Circuit Decision, so we do not revisit it here.

#### III. CLAIM CONSTRUCTION

We interpret the '532 patent claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b); *see also* First FWD 18 & n.16 (noting the Petition was filed after § 42.100(b) was amended to include this provision). This "includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b).

We accordingly construe several limitations of claim 4.

# A. Claim 4—"composite spinal bone graft"

The First FWD construed the term "composite spinal bone graft," found in the preamble of claim 4 (Ex. 1001, 46:48), to mean "a spinal bone graft which is made up of two or more distinct bone portions." First FWD 19. The Federal Circuit Decision did not disturb that construction, so we do not revisit it here.

# B. Claim 4—"plate-like"

Claim 4 recites first and second "plate-like" cortical bone portions, and a "plate-like" cancellous bone portion. Ex. 1001, 46:52–58.

The First FWD construed the term "plate-like" to mean "generally flat." First FWD 26–28. The Federal Circuit Decision concluded: "[W]e agree with [Petitioner] that it was error for the Board to effectively construe 'generally flat' to exclude consideration of the horizontal plane." FCD 15–16; *see also id.* at 13–15 (discussion leading to conclusion).

The Federal Circuit Decision further concluded: "The evidence and arguments presented to the Board support *only one possible evidence-supported finding*: that substantial evidence does not support the Board's determination that Grooms and Paul do not teach 'plate-like' bone portions when the correct construction is employed." *Id.* at 16 (emphasis added). Therefore, we must take as given that Grooms and Paul both disclose "plate-like" first and second cortical bone portions. The parties agree. *See* 

Paper 78, 4 (preliminarily concluding "we must take as given that Grooms and Paul both disclose plate-like first and second cortical bone portions"); Paper 79, 2 ("[T]he parties agreed with our preliminary views concerning the substantive scope of what we must do on remand" as set forth in Paper 78); Ex. 1049, 4:20–5:18, 7:7–16, 10:9–15.

However, the Federal Circuit Decision addressed only whether Grooms and Paul disclose the plate-like *cortical* portions of claim 4. *See* FCD 13–16. The Court did not address whether the prior art discloses or suggests a plate-like *cancellous* bone portion, as claimed. *See id*. We therefore address that issue below when considering the prior art, applying the Federal Circuit Decision's focus on the horizontal plane of the graft.

# C. Claim 4—"disposed between"

Claim 4 recites a cancellous bone portion "disposed between" first and second cortical bone portions. Ex. 1001, 46:56–58.

The First FWD construed an identical limitation in claim 12, reciting one or more osteoconductive substances "disposed between" first and second cortical bone portions. Ex. 1001, 47:60–62; First FWD 20. The First FWD "determine[d] that the term 'disposed between' does not require the first and second cortical bone portions to be completely separated throughout the graft." First FWD 20–26. The Federal Circuit Decision expressly sustained this construction of claim 12, over Patent Owner's objection. *See* FCD 20–23.

The only pertinent difference between claim 4 at issue here, and claim 12 at issue before the Federal Circuit, is the material that is disposed between the two cortical bone portions—it is a cancellous bone portion in claim 4, and it is an osteoconductive substance in claim 12. *See, e.g.*,

Ex. 1001, 4:19–37 (disclosing that cancellous bone is one suitable example of an osteoconductive substance). This difference does not affect the analysis in the First FWD, or the discussion in the Federal Circuit Decision, as to whether the term "disposed between" requires the first and second cortical bone portions to be completely separated by the intervening material throughout the graft. *See, e.g.*, PO Resp. 15–16, 34, 41 (arguing claims 4 and 12 together as a group in this regard). Therefore, we apply the First FWD's construction of "disposed between" in claim 12 to the same term that appears in claim 4.

#### D. Claim 4—"through-holes"

Claim 4 recites "a graft unit having one or more through-holes configured to accommodate one or more pins." Ex. 1001, 46:49–50.

The First FWD did not construe this limitation, despite it being disputed between the parties, because the First FWD determined Grounds 2 and 5 were deficient for reasons unrelated to this limitation. *See* First FWD 18. Therefore, there was no construction of this limitation for the Federal Circuit Decision to review on appeal. Now, we conclude that we need to construe this claim limitation to resolve the parties' disputes as to whether Grooms and Paul each disclose a graft unit having one or more through-holes to accommodate one or more pins.

Patent Owner argues the claim term "through-hole" should be construed to mean a hole that: (1) "travers[es] each bone portion of the composite bone graft"; and (2) has "an entry and exit point." PO Resp. 21–22. Petitioner argues the claim term "through-hole" should be construed simply as "a hole that has an entry point and an exit point." Pet. Reply 8 (citing Ex. 1026 ¶¶ 53–55).

We separately consider the two aspects of Patent Owner's claim construction.

# 1. Whether a "Through-Hole" Must Traverse Each Bone Portion of the Composite Bone Graft

Claim 4 recites:

4. A composite spinal bone graft comprising: *a graft unit having one or more through-holes* configured to accommodate one or more pins, *said graft unit comprising*:

a first-plate like cortical bone portion . . . ;

a second plate-like cortical bone portion . . . ;

a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion . . . *to form said graft unit*; and

one or more cortical bone *pins connecting bone portions of said bone graft unit*....

Ex. 1001, 46:48–61 (emphases added).

Patent Owner argues the plain meaning of this claimed subject matter is that each through-hole must "travers[e] each bone portion of the composite bone graft"—that is, both of the two cortical bone portions, and the cancellous bone portion. PO Resp. 21–23 (emphasis added); Ex. 2028 ¶¶ 69–71. Patent Owner focuses on the claim limitations requiring "the 'through-holes' to be 'configured to accommodate one or more pins' that are recited as 'connecting bone portions of said bone graft unit." PO Resp. 22. Patent Owner additionally relies on the claim's requirement of "three plate-like bone portions, with a cancellous bone portion disposed between two cortical bone portions," which Patent Owner asserts a person of ordinary skill in the art would have understood requires "that the through-holes and pins must pass through each of the three plate-like bone layers *in order to hold them together*." *Id.* at 22–23 (emphasis added); Ex. 2028 ¶¶ 70–71.

Patent Owner asserts the '532 patent "specification likewise makes clear that the pins and through-holes are intended to hold [all three of] the graft's components together." PO Resp. 22 (citing Ex. 1001, 6:4–12, 6:13–18, 17:9–14); *id.* at 23 (citing Ex. 1001, 19:16–24 (Fig. 1), 19:44–57 (Fig. 7), 16:59–21 (Fig. 11B), 17:29–53 (Fig. 12), 19:64–67 (Fig. 9), 20:8–24 (Fig. 13A), 20:64–21:10 (Fig. 27), 21:11–18 (Fig. 28), 21:25–34 (Fig. 31B), 21:35–22:11 (Figs. 32A–32C), 22:13–59 (Figs. 33A–33C), 22:59–23:24 (Fig. 34), 23:52–24:25 (Figs. 36A–36C)); Ex. 2028¶71.

Patent Owner also contends Petitioner's witness Mr. Sherman agreed with Patent Owner's construction during cross-examination, by "admitt[ing] that, because the through-holes in the '532 patent must 'hold[] components together' they 'need[] to go *through all the components* [they are] holding together." PO Resp. 22, 23 (quoting Ex. 2032, 53:22–54:14).

Petitioner argues that adopting Patent Owner's claim construction "would contradict the claim language and the use of 'through-hole' throughout the specification" of the '532 patent. Pet. Reply 8–9; Ex. 1026 ¶¶ 53–67. Petitioner contends that, by reciting "that 'the graft unit' has 'one or more through-holes," claim 4 specifies "that each of the one or more through-holes goes *through the graft unit*." Pet. Reply 9; Ex. 1026 ¶¶ 56–58. Petitioner concludes claim 4 requires only "that each of the pins connect[s] at least two bone portions." Pet. Reply 9–10; Ex. 1026 ¶¶ 60–62.

Petitioner asserts the '532 patent specification "consistently refers to *the graft* or *graft unit*... as having the one or more through-holes," as opposed

to "each bone portion" as Patent Owner would construe the claim. Pet. Reply 9 & n.2 (citing Ex. 1001, 23:25–52 (Fig. 35A)); Ex. 1026 ¶¶ 59, 62. Petitioner acknowledges claim 4 recites pins that are "connecting bone portions of said bone graft unit," but contends "nothing in that language limits the claim to a graft in which *each* pin goes through *each* bone portion," because "[t]he claim does not say 'connecting *each [or all] of the* bone portions." Pet. Reply 9. Petitioner finally contends its witness Mr. Sherman did not admit "that a hole must go through every bone portion of a composite graft for it to be considered a 'through-hole." Pet. Reply 10; Ex. 1026 ¶¶ 63–66.

Patent Owner replies that Petitioner's reliance on Figure 35A of the '532 patent to support its claim construction is inapposite, because that figure "is not an embodiment of the challenged claims." Sur-reply 7. Patent Owner also contends the '532 patent's description of Figure 35A as illustrating through-hole 83 to receive *cancellous bone* "has no relevance to" the claimed through-hole to receive *a bone pin. Id.* 

Patent Owner further insists Petitioner overlooks the specification's teaching that the bone pins "hold together" the graft unit. *Id.* at 8–9 (quoting Ex. 1001, 28:7–9, and citing *id.* at 6:4–18, 17:9–14, 27:47–49; Ex. 2092, 196:11–14). Patent Owner asserts: "To do so, the pins must go through each component." *Id.* at 8 (citing Ex. 1001, 5:17–23). According to Patent Owner, Petitioner's witness Mr. Sherman admitted during cross-examination that the figures of the '532 patent depict "that the 'through-holes' (and pins) 'need[] to go through all the components [they are] holding together." *Id.* (alterations in original) (quoting Ex. 2032, 53:22–54:14, and citing Ex. 1026¶65). Patent

Owner also alleges "Mr. Sherman further admitted that for a single pin to hold together the claimed graft in Figure 6, 'that pin and the through-hole has to go through all three' bone portions." *Id.* (quoting Ex. 2092, 197:22–201:9).

Upon review of the foregoing, we disagree with Patent Owner's claim construction, because it would improperly incorporate a limitation into claim 4 from the '532 patent specification. We must be careful not to import limitations from the specification that are not part of the claim language. See SuperGuide Corp. v. DirecTVEnters., Inc., 358 F.3d 870, 875 (Fed. Cir. 2004) ("The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language," and "a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." (citations omitted)). The Federal Circuit "has emphasized that the disclosure in the written description of a single embodiment does not limit the claimed invention to the features described in the disclosed embodiment," absent a clear intention to limit claim scope by using words of manifest exclusion or restriction. Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004) (citations omitted). 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).

The language of claim 4 first specifies "*a graft unit having* one or more through-holes configured to accommodate one or more pins." Ex. 1001, 46:49–51. Thus, the through-holes must be found in the graft unit, to accommodate pins. Claim 4 then defines the graft unit as comprising two cortical bone portions and a cancellous bone portion. *See id.* at 46:52–59.

However, the claim does not specify whether the through-holes must be found in any particular bone portion of the graft unit. *See id.* at 46:49–59.

Claim 4 additionally requires "pins *connecting bone portions* of said graft unit." *Id.* at 46:60–61 (emphasis added). This limitation supports our claim construction, because it does not specify which bone portions of the graft unit must be connected by the pin(s), which are accommodated in the through-hole(s) of the graft unit. *See id.* at 46:49–51, 46:60–61. Patent Owner's proffered claim construction, requiring the through-hole(s) to "travers[e] *each* bone portion of the composite bone graft" (PO Resp. 21–22 (emphasis added)), is not supported by the claim language. Patent Owner effectively reads the claim as requiring "pins connecting <u>the</u> bone portions of said graft unit" or "<u>all</u> bone portions," which the claim does not do. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 ("[T]he context in which a term is used in the asserted claim can be highly instructive.").

Patent Owner appears to be correct in asserting that every bone graft illustrated in the '532 patent figures as having bone pins accommodated in through-holes has through-holes extending through each bone portion of the illustrated graft unit. For example, we disagree with Petitioner's argument that Figure 35A of the '532 patent discloses a through-hole that does not traverse each bone portion of the illustrated graft. *See* Pet. Reply 9 & n.2 (citing Ex. 1001, 23:25–52). We find that each bone portion 82 of the graft unit illustrated in Figure 35A has a through-hole 83 to contain cancellous bone 109, and additional through-holes to contain bone pins 7. *See* Ex. 1001, Fig. 35A, 23:25–33, 23:39–42; *see also id.* at Figs. 14A–14C, 20:25–38 (illustrating and describing a substantially identical graft unit comprising two

bone portions 82, each having through-hole 83 and additional through-holes to contain bone pins 7). Nonetheless, as discussed above, the language of claim 4 does not incorporate this feature of the '532 patent figures into the claim.

Further, as Petitioner points out, the written description of the '532 patent belies Patent Owner's narrow claim construction. Specifically, the '532 patent states "[t]he through-holes can traverse *any dimension of the graft*, provided that they are placed such that when [the] graft unit is connected the graft is held together." Ex. 1001, 27:47–49 (emphasis added); Tr. 25:3–7; Pet. Reply 9 (citing Ex. 1026 ¶ 59).

For similar reasons, we are not persuaded by Patent Owner's discussions focusing on whether the pins accommodated in the through-holes of claim 4 must "hold together" all three portions of the graft unit. *See* PO Resp. 22–23; Sur-reply 8–9. In this regard, claim 4 specifies only that the pins are accommodated in through-holes of the graft unit for "*connecting bone portions* of said graft unit." Ex. 1001, 46:60–61 (emphasis added). By contrast, claim 12 recites "mechanical connectors [such as cortical bone pins] *for holding together* said load-bearing spinal bone graft unit." *Id.* at 47:64–65 (emphasis added), 48:28–32. Even if we were to construe the term "connect" in claim 4 to mean "hold together" as in claim 12, as Patent Owner posits, still the claim does not specify that all three bone portions of the graft unit must be held together by the pins in the through-holes.

For the foregoing reasons, we do not adopt Patent Owner's construction of claim 4 as requiring through-holes to be present in both of the two cortical bone portions and the cancellous bone portion of the graft unit. This

conclusion is sufficient for us to apply the claim to the prior art presently before us in this respect.

# 2. Whether a "Through-Hole" Must Have an Entry Point and an Exit Point in the Graft Unit

Patent Owner argues the plain meaning of the claim term "through-hole" requires a hole having an entry and an exit point—that is, the hole passes entirely through the graft unit structure that forms the hole. *See* PO Resp. 21–22; Ex. 2028 ¶¶ 69–70. Patent Owner asserts Petitioner's witness Mr. Sherman agreed with this construction during cross-examination. *See* PO Resp. 22 (citing Ex. 2032, 50:7–10, 53:22–54:14).

Petitioner agrees "[t]he term 'through-hole' should be construed as meaning 'a hole that has an entry point and an exit point." Pet. Reply 8; Ex. 1026 ¶¶ 55, 58, 62, 67.

We concur with the parties' mutual understanding that the through-holes recited in claim 4 must have an entry point and an exit point in the graft unit structure(s) that form the through-holes. This construction gives weight to the claim term "through," which a broader construction would read out of the claim.

# 3. Conclusion

We construe the "through-hole" term in claim 4 to require that the through-holes must have an entry point and an exit point in the graft unit structure(s) that form the through-holes.

### *E. Claim* 4—"cortical bone portion" and "cancellous bone portion"

Claim 4 recites first and second "cortical bone portions," and a "cancellous bone portion." Ex. 1001, 46:52–58.

The First FWD did not construe these terms, despite it being disputed between the parties. *See* First FWD 18–19. Therefore, there was no construction of these terms for the Federal Circuit Decision to review on appeal.

Now, we determine that we again do not need to reach this claim construction dispute, to resolve the parties' disputes concerning Grounds 2 and 5 of the Petition. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

There are at least two reasons for this. First, Patent Owner does not rely on its claim construction to oppose Ground 2 or Ground 5. *See* PO Resp. 34–39 (opposition to Ground 2), 41–43 (opposition to Ground 5); *id*. at 30–31, 43–44 (relying on the claim construction to oppose Ground 6, on the basis that it distinguishes Wolter, a prior art reference that is not at issue in Grounds 2 and 5). Second, as discussed further below, even if we were to adopt Patent Owner's proffered construction that claim 4 requires "distinct" cortical and cancellous bone portions (*see* PO Resp. 23–26; Sur-reply 9–12; Ex. 2028 ¶¶ 54–58), we find in Ground 2 that Grooms discloses distinct graft portions, and in Ground 5 that Paul discloses distinct graft portions.

# F. Remaining Claim Terms

We determine no further explicit constructions of any claim terms are needed to resolve the issues presented by the arguments and evidence here. *See Realtime Data*, 912 F.3d at 1375.

# IV. GROUND 2—OBVIOUSNESS OF CLAIMS 4 AND 6/4–11/4 OVER GROOMS AND MCINTYRE

Petitioner asserts in Ground 2 that claims 4 and 6/4-11/4 of the '532 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Grooms and McIntyre. *See* Pet. 4, 16–19, 30–41; Ex. 1015 ¶¶ 53–59, 67–85, 151–188. Patent Owner opposes Petitioner's assertions. *See* PO Resp. 26–27, 29, 34–39, 66–76; Ex. 2028 ¶¶ 46–51, 80–82, 123–132.

We have reviewed the arguments and evidence of record, as well as the Federal Circuit Decision. Based on our review, and for the following reasons, we determine a preponderance of the evidence demonstrates claims 4 and 6/4–11/4 are unpatentable in Ground 2. We begin our analysis with brief summaries of Grooms and McIntyre, then we address Petitioner's and Patent Owner's contentions as to obviousness.

# A. Grooms

Grooms relates to a bone implant for use in spinal fusion procedures. See Ex. 1003  $\P$  3. Figure 8A of Grooms is reproduced below:



Grooms, Figure 8A.

Figure 8A is a perspective view of implant 800 composed of two side-by-side halves 801A and 801B, made of cortical bone, and juxtaposed to form a unitary unit. *Id.* ¶¶ 18, 49. Implant 800 has "a substantially 'D'- or bread-loaf-shaped structure having a canal into which osteogenic, osteoinductive, or osteoconductive materials may be packed, which sustains spinal loads, and which is remodeled into the spine in the course of fusion." *Id.* ¶¶ 9, 57; *see also id.* at Fig. 1A, ¶ 34 (describing D-shaped cortical bone implant 100 with internal canal 104). "[H]oles may be formed in each half [801A and 801B], and the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described [in connection with Figures 7A and 7B] for maintaining stacked implants in contact with each other." *Id.* ¶49.



Figures 7A and 7B of Grooms are reproduced below:

#### Grooms, Figure 7A.

# Grooms, Figure 7B.

Figure 7A is a top view of implant 700, and Figure 7B shows how the implant is formed by stacking together two implants 700A and 700B at adjacent flat surfaces 710A and 710B. *Id.* ¶¶ 17, 48. "Each implant blank is placed in a drill jig, and by means of a drill press or like means, holes [701, 702, 703, and 704] are drilled through the implants." *Id.* ¶ 48. "Pins, composed of cortical bone . . . of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins." *Id.* 

The top and bottom surfaces of implant 800 shown in Figure 8A may have teeth formed therein, to optimize retention of implant 800 within the spine after proper placement. *See id.* ¶33 (stating Grooms' implants may have "an external feature . . . machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space"); *id.* ¶34 (explaining that Figures 1A–1E illustrate implant 100 having teeth 121 in top and bottom surfaces 110, 111, to optimize retention of implant 100 within the spine after proper placement).

# B. McIntyre

McIntyre describes "improved combined cortical cancellous bone graft units." Ex. 1005, 1:12–13. Figures 3 and 4 of McIntyre are reproduced below:



McIntyre, Figure 3.

McIntyre, Figure 4.

Figure 3 is an exploded perspective view of cortical cancellous block 26, and Figure 4 is a perspective view of assembled block 26. *See id.* at 2:14–18, 3:5–7. Block 26 is composed of outer shell 28 made of cortical bone and forming cavity 30, and cancellous block 32 received within cavity 30. *See id.* at 3:7–12.

McIntyre explains that a beneficial feature of using cancellous bone as a grafting material is that its loose structure "permits rapid and usually complete revascularization," which enhances bone regeneration. *Id.* at 1:43–50.

Cortical bone has high strength and can be used for support structures, but the revascularization it provides "is rather slow and incomplete." *Id.* at 1:51–56. McIntyre purports to offer "a combination structure that provides both of these desirable qualities." *Id.* at 1:57–60, 3:19–22.

# C. Independent Claim 4

Petitioner provides arguments and evidence in support of contending claim 4 is unpatentable as having been obvious over Grooms and McIntyre. *See* Pet. 16–19, 30–37; Ex. 1015 ¶¶ 53–59, 67–85, 151–164. Patent Owner opposes Petitioner's assertions. *See* PO Resp. 26–27, 29, 34–39, 66–76; Ex. 2028 ¶¶ 80, 82, 123–132. We address Petitioner's contentions and Patent Owner's opposition comparing the claimed subject matter with Grooms and McIntyre, and then we turn to Petitioner's case for a motivation to combine Grooms and McIntyre to reach the claimed invention. Finally we consider Patent Owner's reliance on objective indicia of nonobviousness. We ultimately conclude a preponderance of the evidence establishes claim 4 is unpatentable.

Comparing Claim 4 with Grooms
 a. Petitioner's Undisputed Contentions

Petitioner contends Grooms' implant embodies the subject matter recited in claim 4, except that the material disposed between Grooms' first and second cortical bone portions 801A and 801B is an osteogenic material

such as allograft bone,<sup>5</sup> whereas claim 4 requires this material to be "a plate-like cancellous bone portion."<sup>6</sup> See Pet. 30–31, 32, 34 (citing Ex. 1003, Fig. 8A, ¶ 57); Ex. 1015 ¶¶ 80–83, 156, 158. Patent Owner raises three arguments in opposition, which we discuss in the next section of this Decision. Here we first provide the reasons why we find a preponderance of the evidence supports Petitioner's unopposed contentions as to Grooms disclosing subject matter recited in claim 4.

We find Grooms discloses a spinal bone graft configured for implantation into the anterior spinal column of the host. *See* Pet. 10 (claim element 1); *id.* at 16–17, 24, 31 (citing Ex. 1003, code (57), ¶¶ 5, 24); Ex. 1015 ¶¶ 68–70, 109, 152. In particular, Grooms provides "[a]n implant composed substantially of cortical bone . . . for use in cervical Smith-Robinson vertebral fusion procedures." Ex. 1003, code (57), ¶ 3. Mr. Sherman testifies that, in a Smith-Robinson procedure: "The anatomical structures of the spine, between which the implant resides and to which the plate is attached, are vertebral bodies" and "[t]he portion of the spine

<sup>&</sup>lt;sup>5</sup> Bone obtained from the patient receiving the spinal implant is autologous bone, whereas bone obtained from a human donor is allogenic bone. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26. A graft made from autologous bone is an autograft, and a graft made from allogenic bone is an allograft. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26.

<sup>&</sup>lt;sup>6</sup> Grooms states that "osteogenic, osteoinductive, or osteoconductive materials" include "bone marrow cancellous bone." Ex. 1003 ¶ 57. However, this disclosure is not found in the Grooms priority document. *See* Ex. 1004, 19:21–27. Therefore, this disclosure in Grooms does not appear to be prior art to the '532 patent. *See* First FWD 6 n.3. That appears to be why Petitioner relies on McIntyre for disclosures concerning cancellous bone.

comprising the vertebral bodies is also referred to as the anterior spine or as the anterior column of the spine." Ex. 1015 ¶¶ 69–70.

We find Grooms' bone graft is a composite graft comprising first cortical bone portion 801A, second cortical bone portion 801B, and an osteogenic material such as allograft bone disposed in a canal surrounded by the two cortical bone portions. See Pet. 10 (claim element 2); id. at 17, 24-26, 31–32 (citing Ex. 1003, code (57), Figs. 1A and 8A, ¶ 48–49, 57); Ex. 1015 ¶¶ 75–84, 110–114, 154–156. In particular, Grooms' Figure 8A illustrates implant 800 composed of two side-by-side halves 801A and 801B, made of cortical bone, and juxtaposed to form a unitary unit. See Ex. 1003 ¶ 49. Also, implant 800 has "a substantially 'D'- or bread-loaf-shaped structure having a canal into which osteogenic, osteoinductive, or osteoconductive materials may be packed." Id. ¶¶9, 57. Those materials may include allograft bone. See id. ¶ 57. Moreover, these three portions of Grooms' bone graft are each "distinct" from one another, per Patent Owner's proffered construction of "cortical bone portion" and "cancellous bone portion" as recited in claim 4. See supra Section III.E; Ex. 1003, Fig. 8A, ¶¶ 9, 49 (illustrating and disclosing that the two cortical bone portions 801A and 801B are formed separately and joined together to form a canal, which is packed with an osteogenic material).

We find each of the three bone portions in Grooms' bone graft is configured to contact a portion of the host bone. *See* Pet. 10 (claim element 3); *id.* at 18–19, 26–27, 34–35 (citing Ex. 1003, Figs. 1C and 1D,  $\P\P$  33–34); Ex. 1015  $\P\P$  68–72, 75, 80–85, 111–113, 155–156. In particular, Grooms discloses that the top and bottom surfaces of implant 800 may have

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teeth formed therein, to optimize retention of implant 800 within the spine after proper placement, which a person of ordinary skill in the art would understand involves contact between the implant and its adjacent vertebrae. *See* Ex. 1003 ¶¶ 33–34; Ex. 1015 ¶¶ 69–72, 75, 85, 111, 155. Further, Grooms discloses that its osteogenic material (i.e., allograft bone) functions "to expedite vertebral fusion and to allow autologous bony ingrowth," which a person of ordinary skill in the art would understand involves contact between the allograft bone and the adjacent vertebrae. *See* Ex. 1003, code (57); Ex. 1015 ¶¶ 80–81, 84, 112–113, 156.

We find Grooms discloses cortical bone pins accommodated in holes of bone portions 801A and 801B to connect bone portions 801A and 801B of the graft unit. *See* Pet. 10 (claim element 4); *id.* at 18, 27, 35 (citing Ex. 1003, Figs. 7A, 7B, and 8A, ¶¶ 48–49); Ex. 1015 ¶¶ 75–79, 110, 154, 160. In particular, Grooms discloses that "holes may be formed in each half" 801A and 801B of implant 800, and "the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described [in connection with Figures 7A and 7B] for maintaining stacked implants in contact with each other." Ex. 1003 ¶ 49; *see also id.* ¶ 48 (explaining that Figures 7A and 7B illustrate holes 701, 702, 703, and 704 in adjacent implants 700A and 700B to receive cortical bone pins "such that the implants are formed into a unitary body by" the bone pins).

We find Grooms' bone graft includes textured surfaces comprising a plurality of closely spaced continuous protrusions in a linear arrangement. *See* Pet. 10 (claim element 5); *id.* at 18–19, 36 (citing Ex. 1003, Figs. 1C–1D, ¶¶ 33–34); Ex. 1015 ¶¶ 85, 163. In particular, Grooms discloses that the top

and bottom surfaces of implant 800 may have teeth formed therein, which are closely spaced from each other in a linear arrangement. *See* Ex. 1003, Figs. 1C–1D, ¶ 34 (illustrating and describing implant 100 having external feature 120 in the form of teeth 121); *id.* ¶ 33 (disclosing that any of Grooms' implants may be provided with a "tooth profile" on the upper and lower surfaces).

We find Grooms' bone graft has "a flattened curved block" shape, as recited in claim 4. *See* Pet. 10 (claim element 6); *id.* at 36–37 (citing Ex. 1003, Fig. 6A; Ex. 1001, Fig. 15, 17:65–67); Ex. 1015 ¶¶ 161–162.

#### b. Patent Owner's Opposition to Petitioner's Contentions

Patent Owner raises three arguments in opposition to Petitioner's contentions comparing Grooms with claim 4. *See* PO Resp. 26–27, 34–39. For the following reasons, we conclude Petitioner's contentions are supported by a preponderance of the evidence, despite Patent Owner's opposition.

# (i) Whether Grooms' Osteogenic Material is "Disposed Between" Two Cortical Bone Portions

First, Patent Owner argues Grooms' osteogenic material is not "disposed between" first and second cortical bone portions 801A and 801B, as claim 4 requires. *See* PO Resp. 32–34 (discussing claim 12), 34 (discussing claim 4); Sur-reply 12–16; Ex. 2028 ¶¶ 80–82, 117–124. The First FWD considered this opposition in the context of an identical limitation in claim 12, and concluded Patent Owner's opposition rests upon an incorrect claim construction. *See* First FWD 20–26, 31–33. The Federal Circuit Decision sustained the First FWD's claim construction. *See* FCD 20–23. Thus, Patent Owner now is foreclosed from relying on its claim construction as a basis for distinguishing Grooms from claim 4.

The First FWD also found Grooms' osteogenic material is in fact "disposed between" first and second cortical bone portions 801A and 801B, as claim 4 requires. *See* First FWD 32–35 (comparing claim 12 with Grooms). The Federal Circuit Decision was limited to the claim construction issue, and did not review the First FWD's application of the "disposed between" claim term to Grooms. *See* FCD 20–23. Therefore, we now maintain the earlier finding as set forth in the First FWD, for the reasons expressed therein. *See* First FWD 32–35. Accordingly, we conclude Petitioner has shown Grooms discloses an osteogenic material "disposed between" first and second cortical bone portions 801A and 801B.

#### (ii) Whether Grooms' Cortical Bone Portions are "Plate-Like"

Second, Patent Owner argues Grooms' first and second cortical bone portions 801A and 801B are not "plate-like," as claim 4 requires. *See* PO Resp. 34–37; Sur-reply 16–17. As already noted above in connection with the claim construction of the "plate-like" term, this argument was resolved against Patent Owner by the Federal Circuit Decision. *See supra* Section III.B. Therefore, we will not re-consider this argument here.

#### (iii) Whether Grooms Discloses "Through-Holes" of a Graft Unit

Third, Patent Owner argues Grooms lacks the "through-holes" required by claim 4. *See* PO Resp. 37–39; Sur-reply 17–18; Ex. 2028 ¶¶ 80, 82, 123, 130–131. This argument is premised on Patent Owner's claim construction, which would require the through-holes to pass through all three bone portions of claim 4 (i.e., the first and second cortical bone portions, and the cancellous bone portion). *See* PO Resp. 37–38; Sur-reply 17; Ex. 2028 ¶ 130. Grooms, in contrast, provides through-holes only through first and second cortical bone portions 801A and 801B, not through the osteogenic material disposed between the cortical bone portions. *See, e.g.*, PO Resp. 26–27, 38–39 (citing Ex. 1003, Fig. 8A, ¶¶ 48–49); Ex. 2028 ¶¶ 80, 82, 130–131.

Petitioner replies that "there is no reasonable basis for" Patent Owner's construction of claim 4, so Patent Owner's attempt to distinguish Grooms on this basis is not persuasive. Pet. Reply 16.

We have concluded claim 4 does not require all three bone portions of the graft unit to have a through-hole. *See supra* Section III.D.1. Instead, claim 4 requires that the graft unit has one or more through-holes, to accommodate bone pins to connect bone portions of the graft unit. *See id.* Grooms' implant correspondingly discloses bone portions 801A and 801B both having holes to accommodate bone pins to connect bone portions 801A and 801B. *See* Ex. 1003, Figs. 7A, 7B, and 8A, ¶¶ 48–49. Moreover, these holes form "through-holes" of the graft unit because they each have an entry point and an exit point in the graft unit structure. *See id.* at Fig. 7B.

Accordingly, we conclude Petitioner has shown Grooms discloses the "through-holes" required by claim 4.

#### c. Conclusion

We find a preponderance of the evidence supports Petitioner's contention that Grooms discloses each and every limitation of claim 4, except that the material disposed between Grooms' first and second cortical bone portions 801A and 801B is an osteogenic material such as allograft bone,

whereas claim 4 requires this material to be "a plate-like cancellous bone portion."

#### 2. Comparing Claim 4 with McIntyre

Petitioner contends McIntyre "discloses spinal fusion bone grafts in which a cancellous bone plug is fitted into a central cavity of a cortical shell." Pet. 31, 32 (citing Ex. 1005, code [57], Figs. 3–4, 2:14–16, 2:22–29); Ex. 1015 ¶¶ 54–59, 157–158. Patent Owner does not dispute this contention. *See* PO Resp. 29, 34–39; Ex. 2028 ¶¶ 123–124. We find a preponderance of the evidence supports Petitioner's reliance on McIntyre in this regard. *See, e.g.*, Ex. 1005, Figs. 3–4, 3:5–12 (illustrating and describing block 26 composed of outer shell 28 made of cortical bone and forming cavity 30, and cancellous block 32 received within cavity 30).

#### 3. Motivation to Combine Grooms and McIntyre

As discussed above, Grooms' bone graft exhibits each and every limitation of claim 4, except that the material disposed between Grooms' first and second cortical bone portions 801A and 801B is an osteogenic material such as allograft bone, whereas claim 4 requires this material to be "a plate-like cancellous bone portion." *See supra* Section IV.C.1. Petitioner contends it would have been obvious to modify Grooms' bone graft to practice the invention of claim 4 in light of McIntyre, and provides reasons for doing so. *See* Pet. 30–31, 32–34.

Patent Owner does not oppose Petitioner's motivation contentions. See PO Resp. 34–39.

For the following reasons, we find Petitioner's undisputed contentions in this regard are supported by a preponderance of the evidence.

An osteogenic material such as disclosed by Grooms is a material that "encourage[s] bone formation, bone remodeling and/or bone healing." Ex. 1015 ¶¶ 80–81, 114, 156, 158; Ex. 2028 ¶¶ 30, 32 (explaining "osteogenesis" is "the synthesis of new bone at the implant site").

McIntyre discloses that "[t]he spongy cancellous bone provides the most suitable matrix for rapid bone regeneration and repair" because it "permits rapid and usually complete revascularization." Ex. 1005, 1:43–50; see Pet. 31, 32–33; Ex. 1015 ¶¶ 56–58, 156–157. McIntyre therefore proposes a bone graft in its Figures 3 and 4 comprising cortical bone shell 28 for structural stability, with central cavity 30 filled with cancellous bone 32 to allow rapid bone regeneration and repair, thereby providing "a combination structure that provides both of these desirable properties." Ex. 1005, 1:43-60, 3:5–22; see Pet. 32–33; Ex. 1015 ¶¶ 54, 56–58, 157–158. We conclude these disclosures in McIntyre would have motivated a person of ordinary skill in the art to use cancellous bone as the osteogenic material between Grooms' cortical bone portions 801A and 801B. See Pet. 32–33; Ex. 1015 ¶¶ 156–158. This usage of cancellous bone as Grooms' osteogenic material is a predictable substitution of art-recognized equivalent materials. See KSR, 550 U.S. at 416–17 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, it must do more than yield a predictable result.").

Further, Grooms discloses that its osteogenic material is "packed" into the canal formed between cortical bone portions 801A and 801B. Ex. 1003 IPR2019-00570 Patent 8,182,532 B2

¶ 57. McIntyre similarly discloses that its cancellous bone portion 32 is packed in cavity 30 of cortical bone shell 28, to provide top and bottom exposed surfaces 34 and 36 to encourage bone regeneration through the graft. *See* Ex. 1005, Figs. 3–4, 1:43–50, 3:5–22. Therefore, the cancellous bone portion in the combined Grooms-McIntyre graft would be "plate-like," that is, "generally flat" "in the horizontal plane, i.e., the plane in which [the graft is] inserted." *See supra* Section III.B; FCD 13–16; Pet. 33–34 ("A person of ordinary skill would have considered the cancellous plug of McIntyre, as sized to fit into the central canal of a graft such as disclosed by Grooms, to be 'plate-like' . . . . "); Ex. 1015 ¶ 159.

#### 4. Objective Indicia / Secondary Considerations of Nonobviousness

Now we turn to objective indicia of nonobviousness, also called secondary considerations of nonobviousness. We begin by discussing Petitioner's motion to exclude some of Patent Owner's evidence in this regard, and then we consider the issue of nexus. Finally we weigh the admitted evidence as it relates to Petitioner's alleged unpatentability of claim 4.

#### a. Petitioner's Motion to Exclude Exhibits 2085 and 2086

The First FWD granted Petitioner's motion to exclude Exhibits 2085 and 2086, which relate to Patent Owner's reliance on objective indicia of nonobviousness. *See* First FWD 12–14, 73. The Federal Circuit Decision did not disturb that holding, so we do not revisit it here.

#### b. Nexus

"For objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *Lectrosonics, Inc. v. Zaxcom, Inc.,* IPR2018-01129, Paper 33, 32 (PTAB Jan. 24, 2020) (precedential); *see also In re Affinity Labs of Tex., LLC,* 856 F.3d 883, 901 (Fed. Cir. 2017) ("Evidence of [objective indicia] is only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia]."). "[T]he patentee bears the burden of showing that a nexus exists." *Henny Penny Corp. v. Frymaster LLC,* 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *WMS Gaming, Inc. v. Int'l Game Tech.,* 184 F.3d 1339, 1359 (Fed. Cir. 1999)). A presumption of nexus applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them."" *Lectrosonics,* Paper 33, 32 (quoting *Fox Factory, Inc. v. SRAM, LLC,* 944 F.3d 1366, 1373 (Fed. Cir. 2019)).

The First FWD considered the issue of nexus within the context of challenged claim 12 which is not at issue here, but not claim 4 which is at issue here. *See* First FWD 35–39 (discussing nexus and claim 12); *id.* at 46–48, 51–53 (discussing claim 4). The First FWD concluded Patent Owner had shown a nexus between the objective indicia of nonobviousness related to Patent Owner's VG2 grafts and claim 12, but had failed to show a nexus between Petitioner's grafts and claim 12. *See id.* at 35–39. The Federal Circuit Decision did not disturb that holding, despite that it underpinned the Board's overall conclusion that claim 12 had been shown to be unpatentable,

which the Federal Circuit Decision affirmed. *See* First FWD 29–44; FCD 20–23.

Now, for substantially the same reasons articulated in the First FWD, we conclude Patent Owner has shown a nexus between the objective indicia of nonobviousness related to Patent Owner's VG2 grafts and claim 4, but has failed to show a nexus between Petitioner's grafts and claim 4. *See* First FWD 35–39. For example, Patent Owner's arguments in support of a nexus address claims 4 and 12 together as a group. *See* PO Resp. 67–69, 75–76; Sur-reply 29–31. If anything, Patent Owner's case for a nexus in the context of claim 4 is weaker than in the context of claim 12, because Patent Owner's arguments in relation to Patent Owner's VG2 grafts do not address directly the "through-hole" and "shape" limitations of claim 4. *See* PO Resp. 67–68; Ex. 2028 ¶ 46, 51 (citing Ex. 2052, 2).

# c. Evidence of Long-Felt Need, Copying, Industry Praise, and Commercial Success

The First FWD considered evidence relating to long-felt need, copying, industry praise, and commercial success. *See* First FWD 39–44. The First FWD concluded: Patent Owner's inconsistent identification of an alleged long-felt need points to a weakness in this evidence which detracted from its persuasiveness (*see id.* at 39–40); the evidence did not establish any copying of Patent Owner's VG2 grafts by Petitioner's graft products (*id.* at 40–41); Petitioner's copying of Patent Owner's pending patent application claims into Petitioner's own patent application, in an attempt to provoke an interference proceeding, was not an objective indicator of nonobviousness (*see id.* at 40–42); Patent Owner's industry praise evidence weighs only modestly in

favor of nonobviousness (*id.* at 42–43); and Patent Owner's evidence of the VG2 product's substantial revenues weighs in favor of nonobviousness, but the lack of context-providing market data diminishes the probative value of Patent Owner's sales data (*see id.* at 43–44).

The Federal Circuit Decision did not disturb those conclusions, despite that they underpinned the Board's overall conclusion that claim 12 had been shown to be unpatentable, which the Federal Circuit Decision affirmed. *See* FCD 20–23. We therefore do not revisit them here.

#### 5. Conclusion Regarding Claim 4

Petitioner has shown that the individual limitations of claim 4 are disclosed by Grooms and McIntyre, and Petitioner provides persuasive and undisputed arguments regarding why a person of ordinary skill in the art would have combined those teachings. Patent Owner's objective indicia is comparatively weak. When considering all of the evidence of obviousness and nonobviousness together (*see In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012)), we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 4 would have been obvious over Grooms and McIntyre.

#### D. Dependent Claims 6–11

As to the claim 4 dependency of claims 6–11, Petitioner provides arguments and evidence in support of contending claims 6–11 are unpatentable as having been obvious over Grooms and McIntyre. *See* Pet. 37–41; Ex. 1015 ¶ 165–188. Patent Owner does not present any

argument for the dependent claims other than what we have already considered with respect to the parent claim 4.

After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that claims 6–11 would have been obvious based on Grooms and McIntyre, to the extent these claims depend from claim 4. The reasons for this determination are provided above in connection with parent claim 4 (*see supra* Section IV.C), and the additional reasons provided in the Petition in connection with claims 6–11 which we adopt here as our own (*see* Pet. 37–41).<sup>7</sup>

As to the claim 5 dependency of claims 6–11, the Petition does not present any challenge to the patentability of claim 5. *See, e.g.*, Pet. 4–5 (identifying the challenges raised in the Petition). Therefore, we determine Petitioner has not demonstrated by a preponderance of the evidence that claims 6–11 would have been obvious based on Grooms and McIntyre, to the extent these claims depend from claim 5.

<sup>&</sup>lt;sup>7</sup> We note further that "[t]he Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." *LG Elecs., Inc. v. Conversant Wireless Licensing S.A.R.L.*, 759 F. App'x 917, 925 (Fed. Cir. 2019) (quoting *In re Nuvasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016)); *see also Papst Licensing GmbH & Co. v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250 (Fed. Cir. 2019) (holding that patentee forfeited argument for patentability because it did not present it to the Board); *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1047–48 (Fed. Cir. 2019) (explaining that arguments not presented to the Board are waived).

# V. GROUND 5—OBVIOUSNESS OF CLAIMS 4, 6/4–9/4, AND 11/4 OVER PAUL, MCINTYRE AND COATES

Petitioner asserts in Ground 5 that claims 4, 6/4-9/4, and 11/4 of the '532 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Paul, McIntyre, and Coates. *See* Pet. 5, 19–21, 48–59; Ex. 1015 ¶¶ 53–66, 93–107, 225–268. Patent Owner opposes Petitioner's assertions. *See* PO Resp. 27–29, 41–43, 66–76; Ex. 2028 ¶¶ 46–51, 81–82, 123–132.

We have reviewed the arguments and evidence of record, as well as the Federal Circuit Decision. Based on our review, and for the following reasons, we determine a preponderance of the evidence demonstrates claims 4, 6/4–9/4, and 11/4 are unpatentable in Ground 5. We begin our analysis with brief summaries of Paul, McIntyre, and Coates, and then we address Petitioner's and Patent Owner's contentions as to obviousness.

# A. Paul

Paul discloses an allogenic intervertebral implant for spinal fusion. *See* Ex. 1006, 1:9–11, 2:12–14. Figure 9 of Paul is reproduced below:

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Paul, Figure 9.

Figure 9 is a perspective view of an implant, including first implant 70 and second implant 70'. *See id.* at 5:7–10. Implants 70 and 70' are made of allogenic bone. *See id.* at code (57), 1:35–54, 2:12–14. Placing implants 70 and 70' side by side forms cylindrical space 72. *See id.* at 5:15–17.

Cylindrical space 72 can be filled with osteoconductive material to help promote the formation of new bone. *See id.* at 5:17–20. Locking pins 74 can engage apertures 76 to maintain the spatial relationship between implants 70 and 70'. *See id.* at 5:20–23. Teeth 12 are provided on superior surface 14 and inferior surface 16 to provide a mechanical interlock that minimizes the risk of post-operative expulsion of the implant. *See id.* at 3:36–42, 5:10–13.

# B. McIntyre

We have summarized the McIntyre disclosure above in Section IV.B.

#### C. Coates

Coates describes a spinal spacer formed of a bone composition for engagement between vertebrae. *See* Ex. 1008, code [57]. The vertebral engaging surfaces include migration resistant grooves. *See id*. Figures 15 and 17 are reproduced below:





Coates, Figure 17.

Figure 15 is a top view, and Figure 17 is a side view, of spacer 300. *See id.* at 4:48–52, 10:43–45. "[T]he superior and inferior vertebral engaging surfaces 337 and 340 define a set of migration resistance grooves 350." *Id.* at 10:46–48. The faces of grooves 350 "define a pocket 370 therebetween for trapping vertebral bone." *Id.* at 10:48–58.

# D. Independent Claim 4

Petitioner provides arguments and evidence in support of contending claim 4 is unpatentable as having been obvious over Paul, McIntyre, and Coates. See Pet. 19–21, 48–57; Ex. 1015 ¶¶ 53–66, 93–107, 225–244. Patent Owner opposes Petitioner's assertions. See PO Resp. 27–29, 41–43, 66–76; Ex. 2028 ¶¶ 46–51, 81–82, 123–132. We address Petitioner's contentions and Patent Owner's opposition comparing the claimed subject matter with Paul, McIntyre, and Coates, and then we turn to Petitioner's case for a motivation to combine these references to reach the claimed invention. Finally we consider Patent Owner's reliance on objective indicia of nonobviousness. We ultimately conclude a preponderance of the evidence establishes claim 4 is unpatentable.

# Comparing Claim 4 with Paul Petitioner's Undisputed Contentions

Petitioner contends the implant illustrated in Paul's Figure 9 embodies much of the subject matter recited in claim 4. *See* Pet. 19–21, 48–57; Ex. 1015 ¶¶ 93–107, 225–244. Many of these contentions are undisputed by Patent Owner. *See* PO Resp. 41–43; Ex. 2028 ¶¶ 81–82, 123–132. For the following reasons, we find Petitioner's undisputed contentions in this regard are supported by a preponderance of the evidence.

We find Paul discloses a spinal bone graft configured for implantation into the anterior spinal column of the host. *See* Pet. 10 (claim element 1); *id*. at 20, 41, 49–50 (citing Ex. 1006, code (57), 1:14–2:9); Ex. 1015 ¶¶ 94–95, 190, 226. In particular, Paul indicates its implants are configured for use in "posterior lumbar interbody fusion" of "two adjacent vertebral bodies." Ex. 1006, 1:18–22. Mr. Sherman testifies that such procedures are "for implantation into the anterior spinal column." Ex. 1015 ¶¶ 94–95, 190, 226. IPR2019-00570 Patent 8,182,532 B2

We find Paul's bone graft is a composite graft comprising first cortical bone portion 70, second cortical bone portion 70', and an osteoconductive material in cylindrical space 72 formed by the two cortical bone portions. See Pet. 10 (claim element 2); id. at 20–21, 42–43, 50 (citing Ex. 1006, code (57), 1:14–2:9, 2:27–38, 4:21–25, 5:8–23); Ex. 1015 ¶¶ 96–98, 191, 228–229. In particular, Paul discloses that implants 70 and 70' are composed of allograft bone, and Mr. Sherman testifies that a person of ordinary skill in the art would have understood such allograft bone is necessarily cortical bone. See Ex. 1006, code (57), 1:35–54, 2:12–14; Ex. 1015 ¶¶ 96–98, 228. Paul also discloses that an osteoconductive material fills cylindrical space 72. See Ex. 1006, 5:17–20. Moreover, these three portions of Paul's bone graft are each "distinct" from one another, per Patent Owner's proffered construction of "cortical bone portion" and "cancellous bone portion" as recited in claim 4. See supra Section III.E; Ex. 1006, Fig. 9, 5:15–23 (illustrating and disclosing that the two cortical bone portions 70 and 70' are formed separately and joined together to form cylindrical space 72, which is filled with an osteoconductive material).

We find each of the three portions in Paul's bone graft is configured to contact a portion of the host bone. *See* Pet. 10 (claim element 3); *id.* at 21, 43–44, 53 (citing Ex. 1006, 3:27-46); Ex. 1015 ¶¶ 105–107, 191, 228–229. In particular, Paul discloses that the top and bottom surfaces of its implant may have teeth 12 formed therein, "which provide a mechanical interlock between" the implant and the adjacent vertebrae "by penetrating" the vertebrae. Ex. 1006, 3:27-40, 5:10-13. Paul also discloses that its osteoconductive material "help[s] promote the formation of new bone" (*id.* 

at 5:19–20), which Mr. Sherman testifies means "the osteoconductive material contacts the bone of adjacent vertebrae, as contact with that bone is essential to promote bone formation." Ex. 1015 ¶¶ 106, 229.

We find Paul discloses cortical bone pins 74 accommodated in holes 76 to connect cortical bone portions 70 and 70' of the graft unit. *See* Pet. 10 (claim element 4); *id.* at 20–21, 44, 54 (citing Ex. 1006, 2:30–38, 4:58–63, 5:8–23); Ex. 1015 ¶¶ 100–104, 190, 227, 235. In particular, Paul states: "First and second implants 70, 70' can be provided with locking pins 74 which engage apertures 76 to maintain the spatial relationship between first and second implants 70, 70'." Ex. 1006, 5:20–23; Ex. 1015 ¶¶ 103–104, 227, 235. Paul also discloses, in Figures 6 and 7, another implant 50 comprising two cortical bone portions 52 and 54 having aligned through-holes 66 to receive cortical bone pins 64 to retain the portions together. *See* Ex. 1006, Figs. 6–7, 4:39–49, 4:58–62; Ex. 1015 ¶¶ 100–102, 227, 235.

We find Paul's bone graft includes textured surfaces comprising a plurality of closely spaced protrusions in a linear arrangement. *See* Pet. 10 (claim element 5); *id.* at 21, 43–44, 54–55 (citing Ex. 1006, 3:27–46); Ex. 1015 ¶¶ 105–107, 191, 239. In particular, Paul provides teeth 12 which are closely spaced together, and are formed in a linear arrangement. *See* Ex. 1006, Fig. 9, 3:27–40, 5:10–13.

We find Paul discloses, in Figure 2, another implant 10 having "a trapezoid wedge" shape, as recited in claim 4. *See* Pet. 10 (claim element 6); *id.* at 56–57 (citing Ex. 1006, Fig. 2, 4:6–15); Ex. 1015 ¶¶ 236–238.

### b. Patent Owner's Opposition to Petitioner's Contentions

Patent Owner raises three arguments in opposition to Petitioner's contentions comparing Paul with claim 4. *See* PO Resp. 27–28, 41–43. For the following reasons, we conclude Petitioner's contentions are supported by a preponderance of the evidence, despite Patent Owner's opposition.

# (i) Whether Paul's Osteoconductive Material is "Disposed Between" Two Cortical Bone Portions

First, Patent Owner argues Paul's osteoconductive material is not "disposed between" first and second cortical bone portions 70 and 70′, as claim 4 requires. *See* PO Resp. 39–41 (discussing claim 12), 41 (discussing claim 4); Sur-reply 12–16; Ex. 2028 ¶¶ 81–82, 117–124. The First FWD considered this opposition in the context of an identical limitation in claim 12, and concluded Patent Owner's opposition rests upon an incorrect claim construction. *See* First FWD 20–26. The Federal Circuit Decision sustained the First FWD's claim construction. *See* FCD 20–23. Thus, Patent Owner now is foreclosed from relying on its claim construction as a basis for distinguishing Paul from claim 4.

The First FWD did not reach the further issue of whether Paul's osteoconductive material is in fact "disposed between" first and second cortical bone portions 70 and 70′. *See* First FWD 50–51 (declining to decide whether claim 12 is anticipated or rendered obvious by Paul in Ground 3), 51–53 (upholding claim 4 against Ground 5 on a different basis). We now find that Paul's osteoconductive material is "disposed between" first and second cortical bone portions 70 and 70′.

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Paul, Figure 9.

Figure 9 illustrates how first and second implants 70 and 70' are placed side by side to form cylindrical space 72 when locking pins 74 engage apertures 76. *See* Ex. 1006, 5:15–23. Paul further discloses "cylindrical space 72 can be filled with osteoconductive material." *Id.* at 5:18–19. Based on these disclosures, we find the osteoconductive material is disposed between cortical bone portions 70 and 70', as recited in claim 4.

Patent Owner argues the assembled version of Paul's Figure 9 resembles Figure 35A of the '532 patent, which neither the '532 patent nor Petitioner describes as having the "disposed between" limitation. *See* Sur-reply 13–15. We, however, agree with Petitioner that Patent Owner wrongly equates Figure 9 of Paul with Figure 35A of the '532 patent. *See* Pet. Reply 12–14. The reasons for our conclusion are the same as those set forth in the First FWD for why Grooms' osteogenic material is disposed between first and second cortical bone portions 801A and 801B, due to the substantial similarity between Grooms' Figure 8A and Paul's Figure 9 in this regard. *See* First FWD 33–35; *see also* Sur-reply 13–15 (focusing on Grooms as being representative of Patent Owner's argument concerning Paul in this regard).

Accordingly, we conclude Petitioner has shown Paul discloses an osteoconductive material "disposed between" first and second cortical bone portions 70 and 70'.

#### (ii) Whether Paul's Cortical Bone Portions are "Plate-Like"

Second, Patent Owner argues Paul's first and second cortical bone portions 70 and 70' are not "plate-like," as claim 4 requires. *See* PO Resp. 41–42; Sur-reply 16–17. As already noted above in connection with claim construction of the "plate-like" term, this argument was resolved against Patent Owner by the Federal Circuit Decision. *See supra* Section III.B. Therefore, we will not reconsider this argument here.

#### (iii) Whether Paul Discloses "Through-Holes" of a Graft Unit

Third, Patent Owner argues Paul lacks the "through-holes" required by claim 4. See PO Resp. 42–43; Sur-reply 17–18; Ex. 2028 ¶¶ 82, 130–132. This argument is premised on Patent Owner's claim construction, which would require the through-holes to pass through all three bone portions of claim 4 (i.e., the first and second cortical bone portions, and the cancellous

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bone portion). See PO Resp. 42–43; Sur-reply 17–18; Ex. 2028 ¶¶ 130–132. Paul, in contrast, provides holes 76 only within one cortical bone portion 70, not within the other cortical bone portion 70' or within the osteoconductive material between the cortical bone portions. See, e.g., PO Resp. 42–43; Sur-reply 17–18; Ex. 2028 ¶ 132.

Petitioner replies that "there is no reasonable basis for" Patent Owner's construction of claim 4, so Patent Owner's attempt to distinguish Paul on this basis is not persuasive. Pet. Reply 16.

We have concluded claim 4 does not require all three bone portions of the graft unit to have a through-hole. *See supra* Section III.D.1. Instead, claim 4 requires that the graft unit has one or more through-holes, to accommodate bone pins to connect bone portions of the graft unit. *See id.* The implant illustrated in Paul's Figure 9 similarly discloses bone portion 70 having holes 76 to accommodate bone pins 74 to connect bone portions 70 and 70', although holes 76 are not through-holes of the graft unit because they appear to have an entry point but no exit point. *See* Ex. 1006, Fig. 9, 5:20–23. Nonetheless, the implant illustrated in Paul's Figures 6 and 7 correspondingly discloses bone portions 52 and 54 forming through-holes 66 of the graft unit, because they have an entry point and an exit point in the graft unit structure, to accommodate bone pins 64 to connect bone portions 52 and 54. *See id.* at Figs. 6–7, 4:58–62.

Accordingly, we conclude Petitioner has shown Paul discloses the "through-holes" required by claim 4.

#### c. Conclusion

We find a preponderance of the evidence supports Petitioner's contention that the bone graft illustrated in Paul's Figure 9 exhibits each and every limitation of claim 4, except that: (1) the material disposed between first and second cortical bone portions 70 and 70' is an osteoconductive material, whereas claim 4 requires this material to be "a plate-like cancellous bone portion"; (2) teeth 12 are closely spaced protrusions formed in a linear arrangement, but may not be "continuous" protrusions as recited in claim 4; (3) holes 76 are not "through-holes" as recited in claim 4, but Paul discloses through-holes in Figures 6 and 7; and (4) the implant's overall shape is not one of the shapes enumerated in claim 4, but Paul discloses the claimed trapezoid wedge shape in Figure 2.

#### 2. Comparing Claim 4 with McIntyre

Petitioner contends McIntyre "discloses bone grafts . . . compris[ing] a cortical shell having a central cavity into which a cancellous plug is fitted." Pet. 50–51 (citing Ex. 1005, code [57], Figs. 3–4, 2:14–16); Ex. 1015 ¶¶ 54– 59, 230–231. Patent Owner does not dispute this contention. *See* PO Resp. 29, 41–43; Ex. 2028 ¶¶ 123–133. We find a preponderance of the evidence supports Petitioner's reliance on McIntyre in this regard. *See, e.g.*, Ex. 1005, Figs. 3–4, 3:5–12 (illustrating and describing block 26 composed of outer shell 28 made of cortical bone and forming cavity 30, and cancellous block 32 received within cavity 30).

# 3. Comparing Claim 4 with Coates

Petitioner contends: "Coates discloses a spinal fusion bone graft having upper and lower vertebral engaging surfaces having a series of alternating grooves and *continuous* protrusions in a linear arrangement," to prevent the graft from migrating out of the host's vertebral column. Pet. 54–55 (emphasis added) (citing Ex. 1008, code [57], Figs. 15 and 18, 3:46–67, 11:18–22); Ex. 1015 ¶¶ 65–66, 241–242. Patent Owner does not dispute this contention. *See* PO Resp. 41–43; Ex. 2028 ¶¶ 123–133. We find a preponderance of the evidence supports Petitioner's reliance on Coates in this regard. *See, e.g.*, Ex. 1008, Figs. 15 and 18, 10:59–67 (illustrating and describing that peaks 375 are formed between grooves 350, and that each peak is a continuous linear structure).

#### 4. Motivation to Combine Paul, McIntyre, and Coates

As discussed above, the bone graft illustrated in Paul's Figure 9 exhibits each and every limitation of claim 4, with four exceptions. *See supra* Section V.D.1. Petitioner contends it would have been obvious to modify the bone graft illustrated in Paul's Figure 9 to practice the invention of claim 4, and provides various reasons for doing so. *See* Pet. 48–57.

Patent Owner does not oppose Petitioner's motivation contentions. See PO Resp. 41–43.

For the following reasons, we find Petitioner's undisputed contentions in this regard are supported by a preponderance of the evidence. We discuss each of the four modifications in turn.

#### a. Motivation to Use Plate-Like Cancellous Bone Portion

In the implant of Paul's Figure 9, the material disposed between first and second cortical bone portions 70 and 70' is an osteoconductive material, whereas claim 4 requires this material to be "a plate-like cancellous bone portion." *See supra* Section V.D.1. We conclude a person of ordinary skill in the art would have been motivated to use a plate-like cancellous bone portion as Paul's osteoconductive material, in light of McIntyre, for the following reasons.

An osteoconductive material is a material that allows bone growth within the graft, between the adjacent vertebrae above and below the graft, thereby creating a fusion between the graft and the vertebrae. *See* Pet. 48 ("Paul discloses that the space of the graft is filled with a material that promotes bone growth . . . ."); Ex. 1006, 5:17–20 (Paul uses osteoconductive material to "to help promote the formation of new bone."); Ex. 1015 ¶¶ 106, 229 (discussing osteoconductive materials in the context of Paul's disclosure), ¶¶ 113–114 (discussing osteoconductive materials in the context of Grooms' disclosure); Ex. 2028 ¶ 30, 33 ("Osteoconductivity is the physical property of a graft material to allow ingrowth of new blood vessels and cells that trigger formation of new bone.").

McIntyre discloses that "[t]he spongy cancellous bone provides the most suitable matrix for rapid bone regeneration and repair" because it "permits rapid and usually complete revascularization." Ex. 1005, 1:43–50; *see* Pet. 48–49, 51; Ex. 1015 ¶¶ 56–58, 230–231. McIntyre therefore proposes a bone graft in its Figures 3 and 4 comprising cortical bone shell 28 for structural stability, with central cavity 30 filled with cancellous bone 32 to

allow rapid bone regeneration and repair, thereby providing "a combination structure that provides both of these desirable properties." Ex. 1005, 1:43–60, 3:5–22; *see* Pet. 48–49, 50–51; Ex. 1015 ¶¶ 54, 56–58, 230–231. We conclude these disclosures in McIntyre would have motivated a person of ordinary skill in the art to use cancellous bone as the osteoconductive material between Paul's cortical bone portions 70 and 70′. *See* Pet. 49, 51–53; Ex. 1015 ¶¶ 230–231. This usage of cancellous bone as Paul's osteoconductive material is a predictable substitution of art-recognized equivalent materials. *See KSR*, 550 U.S. at 416–17 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, it must do more than yield a predictable result.").

Further, Paul discloses that the osteoconductive material "fill[s]" the space between cortical bone portions 70 and 70′. Ex. 1006, 5:15–20. McIntyre similarly discloses that its cancellous bone portion 32 fills cavity 30 of cortical bone shell 28, to provide top and bottom exposed surfaces 34 and 36 to encourage bone regeneration through the graft. *See* Ex. 1005, Figs. 3–4, 1:43–50, 3:5–22. Therefore, the cancellous bone portion in the combined Paul-McIntyre graft would be "plate-like," that is, "generally flat" "in the horizontal plane, i.e., the plane in which [the graft is] inserted." *See supra* Section III.B; FCD 13–16; Pet. 52 ("A person of ordinary skill would have considered the cancellous plug of McIntyre, as sized to fit into the space of the Paul graft, for at least some configurations disclosed by Paul to be plate-like."); Ex. 1015 ¶ 233.

# b. Motivation to Use Continuous Protrusions

In the implant of Paul's Figure 9, teeth 12 are closely spaced protrusions formed in a linear arrangement, but may not be "continuous" protrusions as recited in claim 4. *See supra* Section V.D.1. We conclude a person of ordinary skill in the art would have been motivated to replace Paul's discrete teeth 12 with "continuous linear teeth (*i.e.*, protrusions)," in light of Coates. Pet. 49, 54–56. This would have been done "to achieve the advantage of better preventing migration and/or expulsion of the graft" after it is implanted into a spine. *Id.* at 49, 55–56. In particular, we are persuaded by Mr. Sherman's undisputed testimony that Coates' continuous linear protrusions are easier to form and less likely to break than Paul's discrete teeth. *See* Ex. 1015 ¶ 65–66, 241, 243.

# c. Motivation to Use Through-Holes of a Graft Unit

In the implant of Paul's Figure 9, holes 76 are not "through-holes" as recited in claim 4, but Paul discloses through-holes in Figures 6 and 7. *See supra* Section V.D.1. We conclude a person of ordinary skill in the art would have been motivated to use through-holes in the implant of Paul's Figure 9, in light of Paul's Figures 6 and 7, as the predictable substitution of art-recognized equivalent structures disclosed by Paul. *See* Pet. 56–57; Ex. 1015 ¶ 227; *KSR*, 550 U.S. at 416–17 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, it must do more than yield a predictable result.").

# d. Motivation to Use Trapezoid Wedge Shape

In the implant of Paul's Figure 9, the implant's shape is not one of the shapes enumerated in claim 4, but Paul discloses the claimed trapezoid wedge shape in Figure 2. *See supra* Section V.D.1. We conclude a person of ordinary skill in the art would have been motivated to modify the shape of Paul's Figure 9 implant to form a trapezoid wedge, in light of Paul's Figure 2, as the predictable substitution of art-recognized equivalent structures disclosed by Paul. *See* Pet. 54; Ex. 1015 ¶¶ 236–238; *KSR*, 550 U.S. at 416–17 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, it must do more than yield a predictable result."). We are further persuaded by Mr. Sherman's and Dr. Fischgrund's undisputed testimonies that this would have been done in order "to accommodate anatomic curvature of the spine." Pet. 56–57; Ex. 1015 ¶¶ 237–238 ("Paul discloses that the disclosed spacers are [trapezoid] wedge shaped, as shown by Fig. 2, to maintain the natural curvature of the spine."); Ex. 1016 ¶¶ 41, 43, 45.

#### 5. Objective Indicia / Secondary Considerations of Nonobviousness

The objective indicia of nonobviousness pertinent to claim 4 is discussed above in relation to Ground 2. *See supra* Section IV.C.4.

#### 6. Conclusion Regarding Claim 4

Petitioner has shown that the individual limitations of claim 4 are disclosed by Paul, McIntyre, and Coates, and Petitioner provides persuasive and undisputed arguments regarding why a person of ordinary skill in the art would have combined those teachings. Patent Owner's objective indicia is

comparatively weak. When considering all of the evidence of obviousness and nonobviousness together (*see Cyclobenzaprine Hydrochloride*, 676 F.3d at 1079), we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 4 would have been obvious over Paul, McIntyre, and Coates.

# *E.* Dependent Claims 6–9 and 11

As to the claim 4 dependency of claims 6–9 and 11, Petitioner provides arguments and evidence in support of contending claims 6–9 and 11 are unpatentable as having been obvious over Paul, McIntyre, and Coates. *See* Pet. 57–59; Ex. 1015 ¶¶ 245–268. Patent Owner does not present any argument for the dependent claims other than what we have already considered with respect to the parent claim 4.

After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that claims 6–9 and 11 would have been obvious based on Paul, McIntyre, and Coates, to the extent these claims depend from claim 4. The reasons for this determination are provided above in connection with parent claim 4 (*see supra* Section V.D), and the additional reasons provided in the Petition in connection with claims 6–9 and 11 which we adopt here as our own (*see* Pet. 57–59).<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Also: "[t]he Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." *LG*, 759 F. App'x at 925; *see also Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1047–48.

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As to the claim 5 dependency of claims 6–9 and 11, the Petition does not present any challenge to the patentability of claim 5. *See, e.g.*, Pet. 4–5 (identifying the challenges raised in the Petition). Therefore, we determine Petitioner has not demonstrated by a preponderance of the evidence that claims 6–9 and 11 would have been obvious based on Paul, McIntyre, and Coates, to the extent these claims depend from claim 5.

#### VI. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes that independent claim 4 of the '532 patent, and dependent claims 6–11 to the extent they depend from claim 4, are unpatentable as reflected in the table below.<sup>9</sup>

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpate ntable
4, 6/4–11/4	103(a)	Grooms, McIntyre	4, 6/4–11/4	
4, 6/4–9/4, 11/4	103(a)	Paul, McIntyre, Coates	4, 6/4–9/4, 11/4	
Ove rall Outcome			4, 6/4–11/4	

<sup>&</sup>lt;sup>9</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

# VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, based on a preponderance of evidence, that Petitioner has shown independent claim 4 of the '532 patent, and dependent claims 6–11 to the extent they depend from claim 4, are unpatentable; and

FURTHER ORDERED, because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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