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Paper 16
Entered: September 3, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RTI SURGICAL, INC.,
Petitioner,

v.

LIFENET HEALTH,
Patent Owner.

Case IPR2019-00570
Patent 8,182,532 B2

Before GEORGE R. HOSKINS, TIMOTHY J. GOODSON, and CHRISTOPHER C. KENNEDY, *Administrative Patent Judges*.

GOODSON, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner RTI Surgical, Inc., filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 4 and 6–21 of U.S. Patent No. 8,182,532 B2 (Ex. 1001, "the '532 patent"). Patent Owner LifeNet Health filed a Preliminary Response. Paper 11 ("Prelim. Resp.").

Pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a), the Board has authority to determine whether to institute *inter partes* review. *Inter partes* review may not be instituted unless "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). A decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

For the reasons set forth below, we institute *inter partes* review as to all challenged claims of the '532 patent on all grounds presented in the Petition.

II. BACKGROUND

A. Related Matters

Patent Owner is asserting the '532 patent against Petitioner in *LifeNet Health v. RTI Surgical, Inc.*, No. 1:18-cv-00146-MW-GRJ (N.D. Fla.). *See* Pet. 2; Paper 5, 1. The parties also list another proceeding at the Board as a related matter: Case IPR2019-00569, which challenges U.S. Patent No. 6,458,158. *See* Pet. 2; Paper 5, 1.

B. The '532 Patent

The '532 patent relates to a composite bone graft for spinal fusion. 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 implantation procedure, the natural healing process of bones causes the vertebrae to fuse together over time. *Id.*; Ex. 1016 ¶¶ 21–23. Implants for spinal fusion can be made from various materials, including bone obtained from the patient, which is referred to as autologous bone, or bone obtained from a human donor, which is allogenic bone. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26. A bone graft made from autologous bone is an autograft, and a graft made from allogenic bone is called an allograft. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26.

The composite bone graft of the ’532 patent includes a plurality of bone portions layered to form a graft unit and one or more biocompatible connectors that hold the graft unit together. Ex. 1001 at [57] (Abstract), 1:18–24, 2:30–33. In the “Background of the Invention,” the ’532 patent explains that the limited size of cortical bone grafts sometimes prevented their use for spinal fusions:

> Strong cortical bone (the outer layer) is required as a strut in the interbody position to prevent collapse of the disc space while healing occurs. For example, cortical bone obtained from a cadaver source fashioned into struts, is not wide enough for optimum load bearing. This natural limitation often excludes the use of a bone graft product.

Id. at 1:52–58. The ’532 patent also states that “[b]one grafts for spinal application often fail because they are extruded from the implantation site due to shifting, rotation, and slippage of the graft, are not cellularized, or fail mechanically.” *Id.* at 1:66–2:2.

The ’532 patent purports to solve these problems with a composite bone graft that 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 1:33–37, 2:5–11. Figure 6 of the '532 patent is reproduced below:

FIG. 6

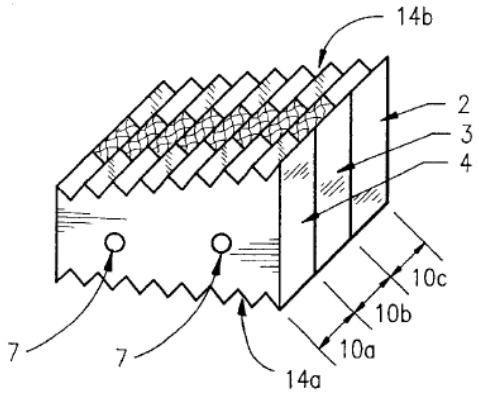


Figure 6 is a perspective view of a composite bone graft. Ex. 1001, 8:55–56.

As depicted in Figure 6, the composite bone graft is made up of a first cortical bone portion 2, a second cortical bone portion 4, and a cancellous bone portion 3 disposed between them. *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.*

C. Illustrative Claim

Petitioner challenges claims 4 and 6–21. Of the challenged claims, claims 4 and 12 are independent claims. Claim 12, reproduced below, is illustrative of the challenged claims.

12. A load-bearing composite spinal bone graft for implantation into a host, the load-bearing composite graft comprising:

a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone;

a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone;

one or more osteoconductive substances disposed between said first cortical bone portion and said second cortical bone portion

> and configured to contact a portion of the host bone to form a graft unit;
>
> one or more non-adhesive mechanical connectors for holding together said load-bearing spinal bone graft unit, said spinal bone graft being configured for implantation into the anterior spinal column of the host.

Ex. 1001, 47:51–67.

D. Asserted Grounds of Unpatentability

Petitioner asserts nine grounds of unpatentability:

Gr.	References	Basis[1]	Claims Challenged
1.	Grooms[2]	§ 103(a)	12–21
2.	Grooms in view of McIntyre[3]	§ 103(a)	4, 6–11
3.	Paul[4]	§ 102(e) or § 103(a)	12, 20
4.	Paul in view of Coates[5]	§ 103(a)	13–19
5.	Paul in view of McIntyre and Coates	§ 103(a)	4, 6–9, 11
6.	Wolter[6]	§ 102(b)	12, 20

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. Because the application that issued as the '532 patent was filed before March 16, 2013, we apply the pre-AIA versions of these statutes.

[2] U.S. Patent App. Pub. No. 2002/0138143 A1, published Sept. 26, 2002 (Ex. 1003).

[3] U.S. Patent No. 4,950,296, issued Aug. 21, 1990 (Ex. 1005).

[4] U.S. Patent No. 6,258,125 B1, issued July 10, 2001 (Ex. 1006).

[5] U.S. Patent No. 5,989,289, issued Nov. 23, 1999 (Ex. 1008).

[6] Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," *Scientific and Clinical Aspects of Bone Transplantation*, 185:166–75 (Ex.

Gr.	References	Basis[1]	Claims Challenged
7.	Wolter in view of Grooms, Paul, or Coates	§ 103(a)	12, 20
8.	Wolter in view of Grooms	§ 103(a)	4, 6–11
9.	Wolter in view of Paul and Coates	§ 103(a)	4, 6–9, 11

See Pet. 4–5.

III. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner proposes that a person of ordinary skill in the art

> would typically 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. 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 3–5 years of experience; or would be a practicing orthopedic surgeon with at least five years of experience.

Pet. 13–14 (citing Ex. 1015 ¶ 22). Patent Owner proposes that an ordinarily skilled artisan

> would have at least a B.S. in biology, chemistry, biochemistry, biomedical engineering, or related fields, and two years of research or work experience related to bone regeneration, bone grafts, or tissue processing. Such experience may include harvesting, processing, developing, and clinically using bone grafts.

1009). Citations to Wolter in this decision refer to the English translation in Exhibit 1010. We note that Patent Owner objected to the Wolter translation Petitioner originally filed as lacking a proper affidavit under 37 C.F.R. § 42.63(b) (*see* Prelim. Resp. 52–53), but that objection is moot in view of the corrected version of Exhibit 1010 that Petitioner filed with our permission. *See* Paper 12, 4.

Prelim. Resp. 26 (citing Ex. 1001, 16:17–20, 17:29–34, 27:12–16, 38:31–33, 38:60–64).

Petitioner's proposal requires more education or experience than Patent Owner's proposal. Based on our review of the record at this stage, we find that Petitioner's proposal is more consistent with the level of skill reflected in the prior art references of record. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (listing the type of problems encountered in the art, prior art solutions to those problems, and the sophistication of the technology as factors that may be considered in determining the level of ordinary skill in the art). Petitioner's proposal is also more consistent with the capabilities that the '532 patent ascribes to a person of ordinary skill in the art, including the ability to select and employ methods for demineralizing bone (Ex. 1001, 13:1–5, 18:18–20), the ability to select appropriate dimensions for depressions or protrusions to provide an interlocking fit of bone portions (*id.* at 13:55–60), the ability to employ suitable methods for processing bone tissue for use in the graft (*id.* at 16:17–20), the ability to select appropriate dimensions for the graft based on the particular application and site of implantation in a patient (*id.* at 17:6–9), and the ability to produce pins from cortical bone and to select the appropriate number, orientation, and dimensions of pins (*id.* at 17:46–49, 27:19–25).

Thus, for purposes of this decision, we adopt Petitioner's proposed definition of the level of ordinary skill in the art.

IV. CLAIM CONSTRUCTION

"In an *inter partes* review proceeding, a claim of a patent . . . shall be construed 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)." *See* Changes to

the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b) (2019)) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018).[7] That standard "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." *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); Prelim. Resp. 12 (noting that the *Phillips* claim construction standard governs).

We discuss one term below. No other claim term requires express construction to reach a decision on institution. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (claim terms need only be construed "to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

A. "Composite Spinal Bone Graft"

The phrase "composite spinal bone graft" appears in each of the challenged claims. Petitioner proposes that "composite" means "a bone graft which is made up of two or more distinct bone portions." Pet. 14 (citing Ex. 1001, 12:26–28). Patent Owner does not point to any defect in Petitioner's proposal, but offers its own construction for "composite spinal

[7] The Petition in this case was filed February 19, 2019. *See* Paper 4, 1. Moreover, Patent Owner points out that regardless of the rule change, the *Phillips* standard would apply in this proceeding because the '532 patent is expired. *See* Prelim. Resp. 22 n.5.

bone graft" as meaning "a bone graft which is made up of and assembled from two or more distinct bone portions, and configured for implantation in a patient's spine." Prelim. Resp. 26.

These proposed constructions overlap substantially. The parties agree that the '532 patent includes a definition for "composite," and that definition is the same as Petitioner's construction. *See* Pet. 14; Prelim. Resp. 27; Ex. 1001, 12:26–28. Patent Owner's claim construction adds that the graft is "configured for implantation in a patient's spine," but each of the independent claims separately recite that the spinal bone graft is "configured for implantation into the anterior spinal column of the host." Ex. 1001, 47:2–3, 47:66–67. Accordingly, we see no need to construe the phrase "composite spinal bone graft" to require that the graft is configured for implantation in a patient's spine — indeed, doing so would seem to introduce redundancy into the claims.

Patent Owner's claim construction also adds the phrase "and assembled from" to the Specification's definition. The point of emphasis in Patent Owner's claim construction argument is that "the individual bone portions of the fully assembled bone grafts remain distinct" and "are held together solely by mechanical means." *See* Prelim. Resp. 27–29. Patent Owner argues that "[e]xamples from the specification" and testimony from the experts support its view. *Id.* at 27, 30. On the current record, Patent Owner does not persuade us that the examples in the Specification or the cited extrinsic evidence supports a narrower understanding of "composite" than the express definition of that word provided in the Specification. Moreover, the plain language of Patent Owner's own proposed construction

does not require that in the fully assembled graft, the bone portions remain distinct and are held together solely by mechanical means.

For purposes of this Decision, we construe "composite spinal bone graft" to mean "a spinal bone graft which is made up of two or more distinct bone portions."

V. ANALYSIS OF PROPOSED GROUNDS

A. Legal Standards

1. Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. Inc., v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Moreover, "[b]ecause the hallmark of anticipation is prior invention, the prior art reference — in order to anticipate under 35 U.S.C. § 102 — must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Whether a reference anticipates is assessed from the perspective of an ordinarily skilled artisan. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) ("[T]he dispositive question regarding anticipation [i]s whether *one skilled in the art* would reasonably understand or infer from the [prior art reference's] teaching that every claim element was disclosed in that single reference.").

2. Obviousness

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103 that requires consideration of four factors: (1) the "level of ordinary skill in

the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of non-obviousness such as "commercial success, long-felt but unsolved needs, failure of others, etc." *Id.* at 17–18.

At this stage of the proceeding, neither party has presented evidence or argument directed to secondary considerations. The first *Graham* factor was discussed above in Section III. Our discussion below addresses the remaining *Graham* factors.

B. Ground 1: Obviousness over Grooms

Petitioner contends that claims 12–21 would have been obvious over Grooms. Pet. 23–30. Patent Owner disputes these contentions. Prelim. Resp. 33–36. After considering the arguments and evidence currently of record, we determine that Petitioner has established a reasonable likelihood of prevailing in this ground.

1. Summary of Grooms

Grooms relates to a bone implant for use in spinal fusion procedures. Ex. 1003 ¶ 3. Specifically, Grooms describes "a cortical bone intervertebral implant having a substantially 'D'- or breadloaf-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. Figure 8A of Grooms is reproduced below:

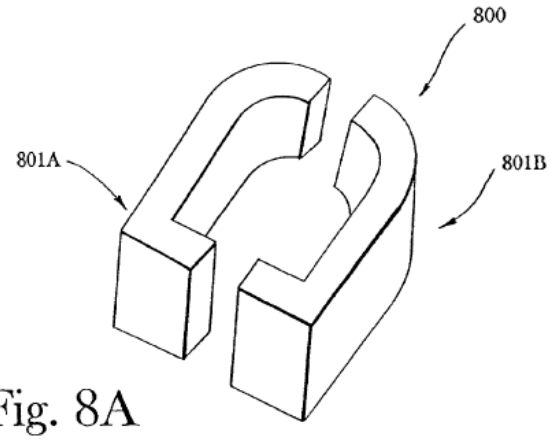


Fig. 8A

Figure 8A shows implant 800 made of two side-by-side halves 801A and 801B of cortical bone. *Id.* ¶ 49.

Grooms discloses that the implant halves can be held together by drilling holes through the implants and forcing pins, made of cortical bone, through the holes. *Id.* ¶¶ 48–49.

2. Analysis

a. Claim 12

(1) "A load-bearing composite spinal bone graft for implantation into a host, the load-bearing composite graft comprising:"

Under the construction we adopted in Section IV.A., "composite spinal bone graft" means "a spinal bone graft which is made up of two or more distinct bone portions." Petitioner asserts that Grooms describes an implant for use in anterior spinal fusion procedures. Pet. 16 (citing Ex. 1003, at Abstract, ¶ 5). Noting that Grooms teaches bone implants to support and induce fusion of adjacent vertebrae, Petitioner contends that ordinarily skilled artisans would have understood that Grooms' implant is load-bearing. *Id.* at 16, 24 (citing Ex. 1015 ¶ 109). Petitioner further asserts that Grooms describes that the implant can be assembled from two cortical bone halves with osteogenic materials, such as allograft or autograft bone,

filling a central canal between the cortical bone halves. *Id.* at 17–18 (citing Ex. 1003, ¶¶ 49, 57, Figs. 8A-8B).

Neither party squarely addresses whether the preamble should be considered a limitation. If it is limiting, we determine that Petitioner has adequately shown, for purposes of institution, that Grooms discloses the subject matter recited in the preamble.

> *(2) "a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone;"*

Petitioner asserts that Grooms teaches that the implant can be assembled from two cortical bone halves. Pet. 18 (citing Ex. 1003 ¶ 49, Figs. 8A–8B), *see also id.* at 24. Regarding the requirement that the first and second cortical bone portions have textured surfaces and contact the host bone, Petitioner asserts that in Grooms, the top and bottom surfaces of the implant contact the bone of adjacent vertebrae and have angled teeth to retain the graft in the spine. *Id.* at 18–19 (citing Ex. 1003 ¶¶ 33–34, Figs. 1C–1D); *see also id.* at 26–27.

For purposes of institution, Petitioner has adequately shown that Grooms discloses first and second cortical bone portions as claimed.

> *(3) "one or more osteoconductive substances disposed between said first cortical bone portion and said second cortical bone portion and configured to contact a portion of the host bone to form a graft unit;"*

Petitioner asserts that Grooms teaches to pack the central canal of the implant with osteogenic materials such as allograft bone, autograft bone

hydroxyapatite, or bioactive ceramics. Pet. 17 (citing Ex. 1003, at [57] (Abstract), ¶ 57). Petitioner notes that hydroxyapatite and bioactive ceramics are among the materials that the '532 patent describes as being osteoconductive. *Id.* at 24–25 (citing Ex. 1001, 14:29–41). Petitioner also asserts that allograft and autograft bone were well-known osteoconductive materials. *Id.* at 25 (citing Ex. 1015 ¶ 83). Petitioner contends that it would have been obvious to select one of the conductive substances Grooms discloses and place it between the cortical bone portions because those substances were known to promote bone growth. *Id.* at 23 (citing Ex. 1015 ¶¶ 81, 114).

Patent Owner argues that the testimony of Petitioner's expert that the osteoconductive substances disclosed in Grooms were known to promote bone growth for successful spinal fusions lacks underlying evidentiary support and should be disregarded. *See* Prelim. Resp. 36 (citing Ex. 1015 ¶¶ 81, 114). Yet even leaving aside Dr. Sherman's testimony on this point, Grooms itself describes packing the canal of the implant "with osteogenic, osteoinductive, or osteoconductive materials," and that the purpose of the implant is to "induce fusion of the adjacent vertebrae." Ex. 1003 ¶¶ 10, 57. Grooms' description of these materials as osteogenic, osteoinductive, or osteoconductive demonstrates an appreciation that they promote bone growth. As stated in the '532 patent, the definition of an osteoconductive substance is one that conducts osteoinductive activity, and the definition of osteoinductivity is the ability to promote bone growth. Ex. 1001, 14:29–32, 14:42–44.

Patent Owner also argues that Grooms is distinguishable because its two pieces of cortical bone are joined in a single, continuous shell, whereas

claim 12 requires "a configuration where the two cortical bone portions are separate from each other in the assembled graft." Prelim. Resp. 34. Patent Owner does not tie this purported distinction to any specific language in claim 12. Claim 12 recites that osteoconductive substances are "disposed between said first cortical bone portion and said second cortical bone portion." We see no requirement in the language of claim 12 that the first and second cortical bone portions must be physically separated at all points in the graft. We note that U.S. Patent No. 6,458,158 ("the '158 patent"), which shares a common specification and priority claim with the '532 patent, includes claims reciting a cancellous bone portion "disposed between said first cortical bone portion and said second cortical bone portion" and further reciting that the first and second cortical bone portions "are not in physical contact." *See* Ex. 1002, 45:5–10. The separate recitation of those features in the claims of the '158 patent supports the view that in claim 12 of the '532 patent, a graft having a substance "disposed between" first and second cortical bone portions does not necessarily mean that the first and second cortical bone portions are physically separated throughout the graft. *See Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (explaining that a claim interpretation that renders a claim term or phrase superfluous is disfavored).

Patent Owner relies on the statement it made during prosecution of the '532 patent that the claim that ultimately issued as claim 12 has "the precise configuration of a first and second layer of cortical bone with a layer of cancellous bone in between." Prelim. Resp. 34 (quoting Ex. 2021, 9). That statement simply summarizes the claim language and does not demonstrate that the claim requires that the first and second cortical bone portions are

physically separated throughout the graft. Indeed, first and second cortical bone portions that were physically separated throughout the graft would not even have been a point of distinction from the prior art the applicant was attempting to distinguish. In the cited Office Action Response, the applicant was responding to a rejection the Examiner made based on U.S. Patent No. 6,123,731 (Ex. 1011, "Boyce"). *See* Ex. 2021, 9. The applicant amended what became claim 12 to add that the graft was "load-bearing" and requested withdrawal of the anticipation rejection because:

> [t]he claims now recite a load-bearing graft and Boyce does not teach a load-bearing graft with the precise configuration of a first and second layer of cortical bone with a layer of cancellous bone in between. Indeed, the only embodiment in Boyce to which the Examiner points, Figure 6, is not a load-bearing implant, but is instead an implant that [is] placed on and around the transverse process of the vertebra (Figure 7 of Boyce).

Id. at 5, 9. Thus, the distinction Patent Owner was emphasizing was the absence of a "load-bearing" implant in Boyce, not whether Boyce's implant had physically separated cortical bone layers. In fact, Figure 6 of Boyce shows cortical bone layers that ***are*** physically separated throughout the graft, so that structural feature would present no distinction to Boyce's Figure 6. Ex. 1011, Fig. 6, 8:16–21.

Patent Owner also asserts that its contention that claim 12 requires "the two cortical bone portions [to be] separate from each other in the assembled graft" is "consistent with corresponding embodiments in the specification." Prelim. Resp. 34 (citing Ex. 1001, Figs. 1–6, 8, 13A, 19:16–43, 19:58–63, 20:8–24). But mere consistency with some embodiments in the Specification is insufficient to establish that the claimed invention requires a particular configuration. Patent Owner does not identify any

statement in the Specification disavowing grafts in which the cortical bone portions are in physical contact. *See Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1378 (Fed. Cir. 2018) ("Since '[i]t is the claims that define the metes and bounds of the patentee's invention,' '[t]he patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly . . . disavows its full scope.") (quoting *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012)); *see also Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015) ("Disavowal requires that 'the specification make[] clear that the invention does not include a particular feature.'"). In short, Patent Owner does not persuade us that claim 12 requires the first and second cortical bone portions to be physically separated throughout the graft.

After reviewing the evidence and arguments currently of record, we determine that Petitioner has adequately shown that Grooms discloses this limitation for institution purposes.

> *(4) "one or more non-adhesive mechanical connectors for holding together said load-bearing spinal bone graft unit,"*

Petitioner asserts that Grooms discloses non-adhesive mechanical connectors because it teaches that the two halves of the graft shown in Figure 8A can be held in contact by forming holes in each and forcing pins through the holes. Pet. 18 (citing Ex. 1003 ¶¶ 48–49); *see also id.* at 27. Patent Owner does not contest that assertion in its Preliminary Response. We determine that Petitioner has made a sufficient showing that Grooms discloses this limitation for institution purposes.

(5) "said spinal bone graft being configured for implantation into the anterior spinal column of the host."

Petitioner asserts that Grooms' implant is for use in anterior spinal fusion procedures. Pet. 16 (citing Ex. 1003, at Abstract, ¶ 5); *see also id.* at 24; Ex. 1009 ¶ 9. Patent Owner does not contest that assertion in its Preliminary Response. We determine that Petitioner has made a sufficient showing that Grooms discloses this limitation for institution purposes.

(6) Conclusion

We determine that Petitioner's arguments and evidence establish a reasonable likelihood that Petitioner will prevail with respect to claim 12.

b. Claims 13–21

Petitioner provides a detailed explanation of its challenge to claims 13–21. Pet. 27–30. At this stage of the proceeding, Patent Owner has not presented separate arguments regarding these claims, but simply notes their dependency from claim 12. *See* Prelim. Resp. 36. After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to those claims.

C. Ground 2: Obviousness over Grooms in view of McIntyre

Petitioner asserts that claims 4 and 6–11 would have been obvious over Grooms in view of McIntyre. Pet. 30–41. Patent Owner disputes these contentions. Prelim. Resp. 36–40.

1. Summary of McIntyre

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

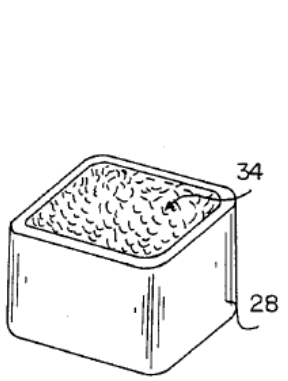


FIG. 4

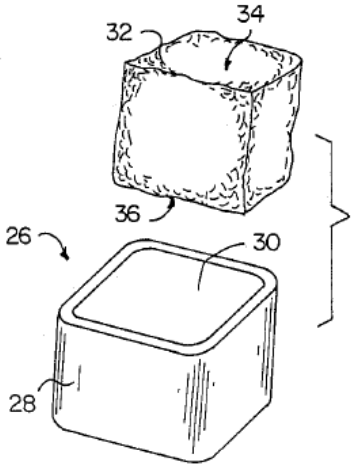


FIG. 3

Figures 3 and 4 are perspective views of cortical cancellous block 26. *Id.* at 2:14–18, 3:5–7.

Outer shell 28, formed of cortical bone, is hollowed out to provide cavity 30 for receiving cancellous block 32. *Id.* at 3:8–12. "The cancellous block 32 is selected and sized to snugly fit the cavity 30 in the block 28, with top and bottom surfaces 34 and 36 exposed. This combination cortical and cancellous block provides a bridging segment, with the best features of both cortical and cancellous structures." *Id.* at 3:17–22.

2. Analysis

a. Claim 4

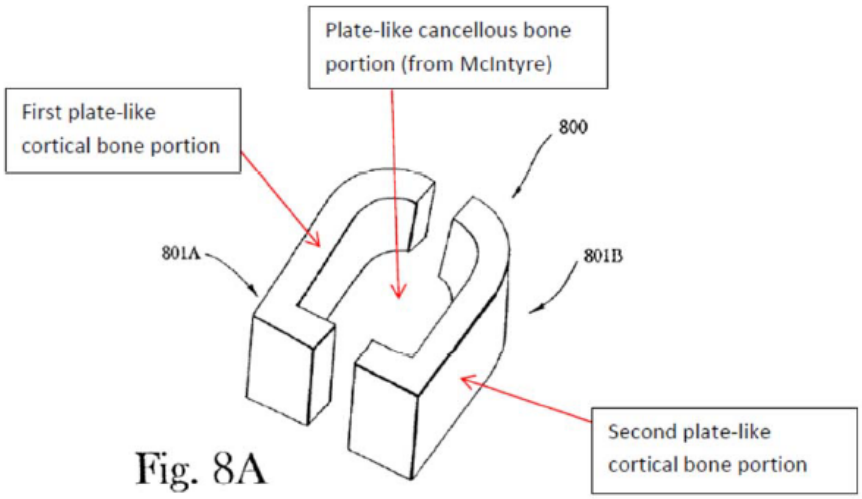
Claim 4 recites "a graft unit having one or more through-holes configured to accommodate one or more pins." Claim 4 also recites "one or

more cortical bone pins connecting bone portions of said bone graft unit." Petitioner asserts that Grooms teaches these limitations because it describes forming holes in the two halves of the graft and forcing cortical bone pins through those holes. *See* Pet. 35 (citing Ex. 1003 ¶ 48, Figs. 7A–7B, 8A). At this stage, Petitioner's contentions regarding these limitations are undisputed. We determine that Petitioner has made a sufficient showing on these limitations for institution purposes.

Claim 4 further recites "a first plate-like cortical bone portion configured to contact a portion of the host bone" and "a second plate-like cortical bone portion configured to contact a portion of the host bone." Petitioner asserts that Grooms discloses these limitations because it describes that the graft can be assembled from first and second pieces of cortical bone. *See* Pet. 31 (citing Ex. 1003 ¶ 49). Petitioner further asserts that ordinarily skilled artisans would have considered Grooms' first and second cortical portions to be plate-like because they are generally flat. *Id.* (citing Ex. 1015 ¶¶ 155, 33–39). Patent Owner does not contest Petitioner's contentions regarding these limitations, other than to argue that Grooms' cortical bone portions are not separate from each other and that "McIntyre does not cure this deficiency" because McIntyre's cortical shell is continuous. Prelim. Resp. 37. But, for essentially the same reasons as already discussed in connection with claim 12, we are not persuaded that claim 4 requires the cortical bone portions to be physically separated throughout the graft. *See supra* § V.B.2.a.(3). Because we are not persuaded that Grooms is deficient in the way Patent Owner contends, it is unnecessary for McIntyre to cure the purported deficiency. Based on the

arguments and evidence currently of record, we determine that Petitioner has made a sufficient showing on these limitations for institution purposes.

Next, claim 4 recites "a plate-like cancellous bone portion disposed between said 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." Petitioner asserts that Grooms teaches packing the central canal with osteogenic materials, such as allograft bone, but it does not disclose packing the central canal with a "plate-like cancellous bone." Pet. 32 (citing Ex. 1003 ¶ 57). Petitioner asserts that McIntyre discloses a cancellous bone plug. *Id.* (citing Ex. 1005 at Abstract, 1:43–64, 3:32–36, Figs. 3–4). According to Petitioner, if McIntyre's bone plug were sized to fit into Grooms' central canal, it would be generally flat and plate-like. Petitioner illustrates its contentions with the following annotated version of Grooms' Figure 8A:



Petitioner's annotated version of Grooms' Figure 8A illustrates Petitioner's proposed combination of Grooms and McIntyre. Pet. 34.

Petitioner argues that an ordinarily skilled artisan would have been motivated to incorporate McIntyre's cancellous plug and would have had a reasonable expectation of success in doing so based on McIntyre's teaching of the advantages of using a cancellous plug as an osteogenic material for spinal fusion bone grafts. *Id.* at 33 (citing Ex. 1015 ¶¶ 157–158, 272). At this stage, Patent Owner does not dispute Petitioner's contentions that the proposed combination teaches this limitation, and that an ordinarily skilled artisan would have been motivated to combine the references in the proposed manner and would have had a reasonable expectation of success in doing so. We determine that Petitioner has made a sufficient showing for institution purposes on this limitation, as well as on motivation and reasonable expectation of success.

Claim 4 then recites that the graft has "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." Petitioner asserts that the shape of Grooms' implant is a flattened curved block. Pet. 36. At this stage, Petitioner's contentions regarding this limitation are undisputed. We determine that Petitioner has made a sufficient showing on this limitation for institution purposes.

Claim 4 next recites that the graft includes "one or more textured surfaces comprising a plurality of closely spaced continuous protrusions in a linear arrangement." Petitioner argues that Grooms teaches this feature because it describes that the top and bottom surfaces of the implant are inscribed with teeth to retain the graft in the spine. *See* Pet. 36 (citing Ex. 1003, Figs. 1C–1D, 6A–6I; Ex. 1015 ¶ 163). Patent Owner contests Petitioner's showing on the basis that Petitioner cites to the testimony of Dr.

Sherman, which testimony in turn relies on Grooms' Fig. 8E, whereas Patent Owner contends that disclosure in Grooms is not prior art because it was added after the effective filing date of the '532 patent. Prelim. Resp. 39. Patent Owner's argument does not persuasively rebut Petitioner's arguments based on Grooms' disclosures relating to Figures 1C–1D. Petitioner showed that the disclosure relating to those figures is present in both Grooms and the application to which Grooms claims priority. *See* Pet. 18–19 (citing Ex. 1003 ¶¶ 33–34, Figs. 1C-1D; Ex. 1004, 8:21–9:4, 9:21–10:6, 15:7–9). Those teachings in Grooms show and describe teeth that protrude continuously across the top and bottom surfaces of the implant. *See* Ex. 1003 ¶ 33. The purpose of the teeth in Grooms is "to prevent backing out of the implant," which appears to be the same purpose the '532 patent has for adding the protrusions. *See id.*; Prelim. Resp. 38 (noting Specification's disclosure that spinal grafts often fail due to extrusion from the implantation site, so texture prevents extrusion). On the current record, we determine that Petitioner has made a sufficient showing that the cited disclosures in Grooms describe textured surfaces as recited in claim 4.

Finally, claim 4 recites that the graft "is configured for implantation into the anterior spinal column of the host." Petitioner argues that Grooms discloses this limitation. Pet. 31 (citing Ex. 1003 ¶¶ 5, 10). Petitioner's contentions are similar to those it provides for the corresponding limitation in claim 12. *See supra* § V.B.2.a.(5). We determine that Petitioner has made a sufficient showing on this limitation for institution purposes.

For the foregoing reasons, we determine that Petitioner's arguments and evidence establish a reasonable likelihood that Petitioner will prevail with respect to claim 4.

b. Claims 6–11

Petitioner provides a detailed explanation of its challenge to claims 6–11. Pet. 37–41. At this stage of the proceeding, Patent Owner has not presented separate arguments regarding these claims, but simply notes their dependency from claim 4. *See* Prelim. Resp. 40. After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to those claims.

D. Ground 3: Anticipation or Obviousness over Paul

Petitioner contends that Paul anticipates or renders obvious claims 12 and 20. Pet. 41–44. Patent Owner disputes those contentions. Prelim. Resp. 40–43. For the reasons set forth below, we determine that Petitioner's arguments and evidence establish a reasonable likelihood that Petitioner will prevail with respect to this proposed ground of unpatentability.

1. Summary of Paul

Paul discloses an allogenic intervertebral implant for spinal fusion. Ex. 1006, 1:9–11, 2:12–14. Figure 7 of Paul is reproduced below:

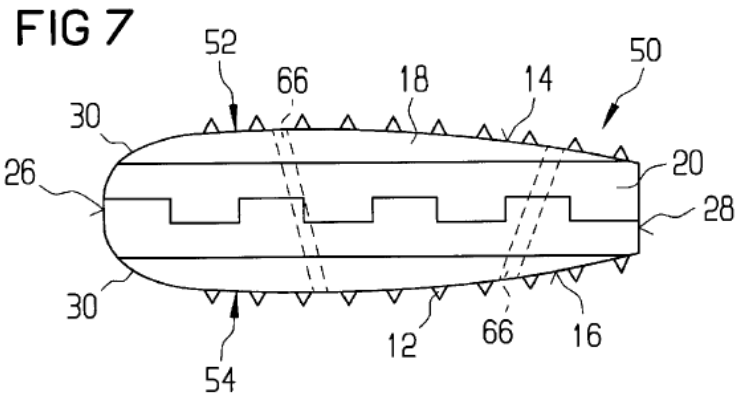
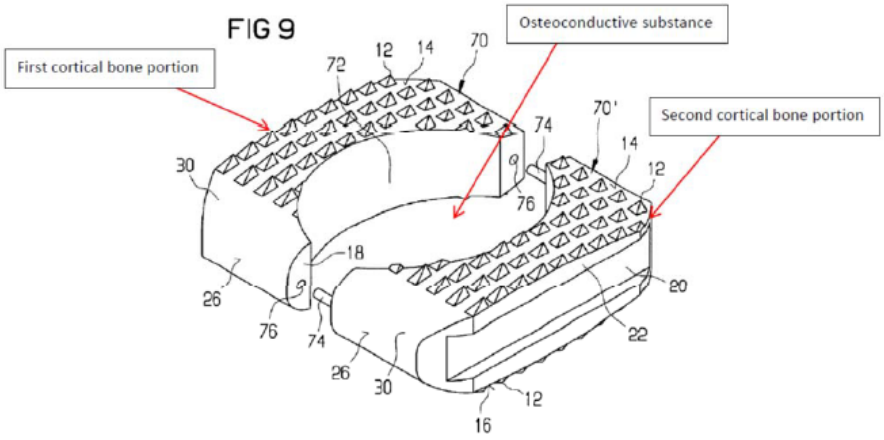


Figure 7 shows a side view of implant 50. *Id.* at 3:1.

Implant 50 includes top and bottom portions 52, 54, which are retained together with pins 64 passing through aligned holes 66. *Id.* at 4:58–60. "Although pin 64 can be made of any biocompatible material, pin 64 is preferably made of allogenic bone." *Id.* at 4:60–62.

2. Analysis

Petitioner presents a detailed explanation of how Paul discloses the limitations of claims 12 and 20. Pet. 41–44. The Petition includes an annotated version of Paul's Figure 9:



Petitioner's annotated version of Paul's Figure 9 illustrates the portions of Paul's implant that Petitioner relies on to disclose the first and second cortical bone portions and osteoconductive substance recited in claim 12. Pet. 43.

Petitioner's back-up obviousness position is offered to the extent Paul does not expressly disclose certain features. *See, e.g.*, *id.* at 41 (arguing that Paul discloses to an ordinarily skilled artisan that the bone used for its implant is not demineralized, and arguing in the alternative that using non-demineralized bone would have been obvious based on Paul's intended use for the implant) (citing Ex. 1015 ¶¶ 96–99, 190).

Patent Owner counters that "Paul's graft . . . suffers from the same deficiencies as Grooms' disclosed graft." Prelim. Resp. 43. Specifically, Patent Owner asserts that "[j]ust as [in] Grooms, this configuration [in Paul's Figure 9] is predicated on joining two cortical bone portions to form a single, continuous cortical shell; it does not disclose two cortical bone portions that are separate from each other with a layer disposed between." *Id.* at 41. This argument is unpersuasive for the same reasons discussed in connection with Ground 1. *See supra* § V.B.2.a.(3). In short, based on the current record, we are not persuaded that claim 12 requires the first and second cortical bone portions to be separated at all points in the graft. Rather, as discussed above, claim 12 simply requires osteoconductive substances "disposed between said first cortical bone portion and said second cortical bone portion." Ex. 1001, 47:60–62. Petitioner's annotated version of Paul's Figure 9 shows a configuration that satisfies that requirement. *See* Pet. 43.

At this stage of the proceeding, Patent Owner has not presented any separate arguments regarding claim 20, but simply notes its dependency from claim 12. *See* Prelim. Resp. 43. After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to those claims.

E. Ground 4: Obviousness over Paul in view of Coates

Petitioner presents a detailed explanation of its contention that dependent claims 13–19 would have been obvious over Paul in view of Coates. *See* Pet. 45–48. Patent Owner's argument concerning this ground refers back to its arguments regarding Paul and asserts that Coates does not make up for Paul's deficiencies. Prelim. Resp. 43. According to Patent

Owner, "Coates simply discloses . . . yet another plug-based graft with a single, continuous shell" and therefore does not disclose "two cortical bone portions that are separated by a layer of osteoconductive substances disposed between." Prelim. Resp. 43–44. As discussed above, on the current record, we are not persuaded that Paul is deficient in the way Patent Owner contends. *See supra* § V.D.2. After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in this ground.

F. Ground 5: Obviousness over Paul in view of McIntyre and Coates

Petitioner asserts that claims 4, 6–9, and 11 would have been obvious over Paul in view of McIntyre and Coates. Pet. 48–59. Patent Owner disputes these contentions. Prelim. Resp. 44–51.

1. Summary of Coates

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

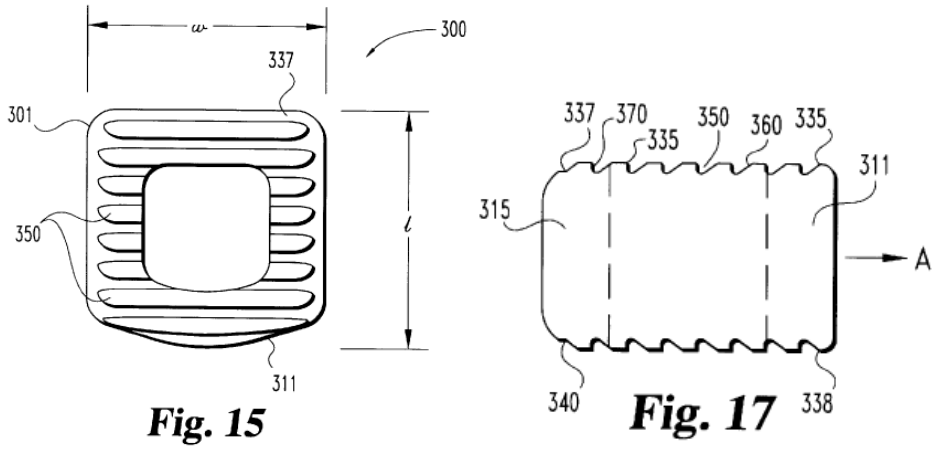


Figure 15 is a top view, and Figure 17 is a side view, of spacer 300 having migration resistance grooves 350. Ex. 1008, 4:48–52.

Coates describes that "the superior and inferior vertebral engaging surfaces 337 and 340 define a set of migration resistance grooves 350." *Id.* at 10:43–47. The faces of grooves 350 "define a pocket 370 therebetween for trapping vertebral bone." *Id.* at 10:56–58.

2. Claim 4

Petitioner asserts that Paul discloses most of the limitations of claim 4, but "does not specifically disclose that the space [between first and second cortical bone portions] is filled with a plate-like cancellous bone portion." Pet. 48. Petitioner asserts that McIntyre discloses a cancellous bone plug, and contends that fitting McIntyre's bone plug into Paul would have been obvious because cancellous bone was known to be a highly suitable material for promoting bone growth. Pet. 48–49; *see also id.* at 51 (citing Ex. 1005, 1:43–64, 3:32–36). Petitioner argues that when McIntyre's cancellous plug is sized to fit into the space of Paul's graft, an ordinarily skilled artisan would consider it to be plate-like. *Id.* at 52 (citing Ex. 1015 ¶¶ 232–233). With regard to the limitation in claim 4 that the textured surfaces comprise "a plurality of closely spaced continuous protrusions in a linear arrangement," Petitioner acknowledges that Paul's teeth may not be considered continuous. *Id.* at 49. However, Petitioner asserts that Coates teaches linear protrusions and contends that it would have been obvious to replace Paul's discrete teeth with Coates' continuous linear protrusions "to achieve the advantage of better preventing migration and/or expulsion of the graft." *Id.* at 49; *see also id.* at 55–56 (arguing that ordinarily skilled artisans would have been motivated to replace Paul's teeth with Coates' linear protrusions because they would have been expected to be easier to form and less likely to break than Paul's teeth).

Patent Owner argues that McIntyre and Coates do not cure Paul's deficiencies in teaching cortical bone portions that are separate from each other. Prelim. Resp. 45. As discussed above, we are not persuaded on the current record that Paul is deficient in this regard.

Patent Owner further argues that Coates does not teach continuous protrusions in a linear arrangement because Coates' protrusions do not traverse all surface areas across the width of the bone graft, including the two cortical bone portions and the osteoconductive substance disposed between them. Prelim. Resp. 48–49. Patent Owner's argument that the continuous linear protrusions must traverse all surface areas across the width of the graft is premised on Patent Owner's assertion that the two cortical bone portions may not be joined to each other. *See id.* at 46. As already discussed, we are not persuaded that claim 4 prohibits the cortical bone portions from being in contact with each other at any portion of the graft. We also are not persuaded that claim 4 requires that the "plurality of closely spaced continuous protrusions in a linear arrangement" must extend over each of the two cortical bone portions and the interposed osteoconductive substance. For purposes of institution, Petitioner has shown that the proposed combination discloses a textured surface having a plurality of closely spaced continuous linear protrusions. *See* Pet. 55. In particular, Petitioner relies on the raised surfaces between Coates' migration resistance grooves 350, which Figures 15, 17, and 18 depict extending across the implant in a linear arrangement. *See id.* (citing Ex. 1008, Fig. 15).

Patent Owner also challenges Petitioner's contention that an ordinarily skilled artisan would have been motivated to replace Paul's teeth with Coates' linear protrusions. Prelim. Resp. 49. Patent Owner argues that

Petitioner's asserted motivation — i.e., that the proposed substitution would be easier to form and less likely to break — lacks underlying evidentiary support. *Id.* But Petitioner's reliance on the testimony of Dr. Sherman provides some evidentiary support for those contentions. *See* Pet. 56 (citing Ex. 1015 ¶¶ 65–66, 243). Although Dr. Sherman does not cite underlying evidence for his testimony, he does provide the explanation that Coates' continuous linear protrusions would be less likely to break because they "provide a better distributed contact area of resistance between the bone graft and the adjacent vertebra." Ex. 1015 ¶ 243. Petitioner's asserted motivations are adequately supported for purposes of institution.

Relatedly, Patent Owner argues that Petitioner's proposed modification changes Paul's principle of operation. Prelim. Resp. 49–51. Patent Owner argues that while Paul's teeth "provide the mechanical interlock by *penetrating the* [vertebral] *end plates*," the grooves and protrusions in Coates "are intended to provide friction to reduce migration of the graft." *Id.* at 50 (citing Ex. 1006, 3:39–40; Ex. 1008, 3:26–32). On the current record, we are not persuaded that the proposed substitution changes Paul's principle of operation. As Petitioner points out, Paul's teeth and Coates' protrusions are both intended to prevent post-operative migration or expulsion of the graft by penetrating or digging into adjacent vertebrae. *See* Pet. 55; Ex. 1006, 3:39–42; Ex. 1008, 11:18–22.

After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to claim 4.

3. Claims 6–9 and 11

Petitioner provides a detailed explanation of its challenge to dependent claims 6–9 and 11. Pet. 57–59. At this stage of the proceeding, Patent Owner has not presented separate arguments regarding these claims. *See* Prelim. Resp. 44–51 (arguing only claim 4). After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to those claims.

G. Ground 6: Anticipation by Wolter

Petitioner contends that Wolter anticipates claims 12 and 20. Pet. 60–63. Patent Owner disputes those contentions. Prelim. Resp. 54–60.

1. Summary of Wolter

Wolter describes methods of bone transplantation in the vertebral column. Ex. 1010, 4. As relevant here, Wolter discloses using a "composite corticospongial block," also referred to as a "sandwich block." Figure 1e of Wolter is reproduced below:

Figure 1e depicts the sandwich block. Ex. 1010, 10.

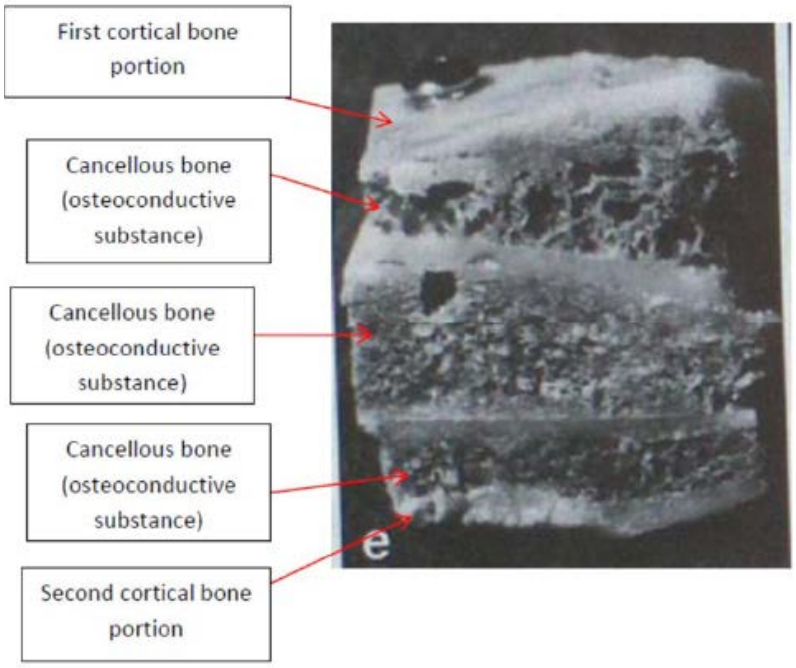
Wolter describes the sandwich block as follows:

> This transplant is characterized in that several large corticospongial bone pieces are united by 1 or 2 small-fragment spongiosa screws into a fixed block. The removal is carried out from the iliac wing. The large bone piece is sawed into 2 or 3 parts, which can be placed against one another in a precisely-fitting manner. This composite corticospongial block has a high load resistance and is able to bridge over even large defects.

Ex. 1010, 5 (citations omitted).

2. Analysis

Petitioner presents a detailed explanation of its contention that Wolter discloses the limitations of claims 12 and 20. Pet. 60–63. The Petition includes the following annotated version of Wolter's Figure 1e:



Petitioner's annotated version of Wolter's Figure 1e illustrates how Petitioner correlates the layers of Wolter's sandwich block to the features of claim 12. Pet. 61.

Petitioner identifies the uppermost cortical layer as the claimed "first cortical bone portion," the lowermost cortical layer as the claimed "second cortical

bone portion," and the layers of cancellous bone in between as the claimed "one or more osteoconductive substances." *See* Pet. 61.

Patent Owner counters that Wolter does not disclose two distinct cortical bone portions and a distinct osteoconductive substance disposed between. Prelim. Resp. 54–58. Patent Owner argues that Wolter's sandwich blocks "are not made up of distinct bone portions. . . . They are simply naturally occurring bone with a cortical surface around a cancellous center." *Id.* at 58. These arguments do not identify any structural feature of the composite bone graft as recited claim 12 that is absent from Wolter's sandwich block. Under the construction of "composite spinal bone graft" we have adopted in Section V.A. above, the bone graft must be made up of two or more distinct bone portions. Petitioner has made a sufficient showing that the bone portions it relies upon, as shown in annotated Figure 1e, are distinct. They are physically separated and have different characteristics.

Claim 12 also recites that the first and second cortical bone portions comprise "one or more textured surfaces." *See* Ex. 1001, 47:54–59. Petitioner asserts that the surfaces are textured by virtue of the surgical saw used to form the graft. Pet. 62 (citing Ex. 1015 ¶¶ 49, 274). In response, Patent Owner argues that the evidence of record does not support Petitioner's assertion that Wolter's graft has textured surfaces. Prelim. Resp. 58–59. According to Patent Owner, Wolter does not disclose textured surfaces and only describes that the bone is sawed into parts which are placed together "in a precisely-fitting manner." *Id.* (quoting Ex. 1010, 5). With supporting testimony from Dr. Shaffrey, Patent Owner argues that Wolter's need for precision indicates that "the resulting surfaces would be rather flat or planar, not textured." *See* Prelim. Resp. 59; Ex. 2001 ¶ 53.

On the current record, we determine that Petitioner has made a sufficient showing that the surfaces of Wolter's sandwich block are textured. Dr. Sherman points out that the '532 patent defines protrusions broadly to include surface irregularities as small as 0.1 mm. *See* Ex. 1015 ¶ 274; Ex. 1001, 15:1–5. As exemplified by the recitation in claim 4 that "textured surfaces compris[e] a plurality of closely spaced continuous protrusions," protrusions are a type of surface texture. *See also* Ex. 1001, 15:29–40. Dr. Sherman testifies that ordinarily skilled artisans would recognize that Wolter's saw would produce a texture with a depth greater than 0.1 mm. Ex. 1015 ¶ 274. Without addressing the portions of the Specification identified by Dr. Sherman, Dr. Shaffrey testifies that the surfaces produced by Wolter's saw would be "rather flat or planar." Ex. 2001 ¶ 53. Thus, the testimony currently of record presents a factual dispute as to how flat or textured an ordinarily skilled artisan would understand the surface of Wolter's graft would be based on Wolter's disclosure. At this stage, for purposes of institution, we resolve that factual dispute in Petitioner's favor. *See* 37 C.F.R. § 42.108(c) ("The Board's decision [on institution] will take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence, but a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.").

With respect to the limitation in claim 12 of "one or more non-adhesive mechanical connectors for holding together said load-bearing spinal bone graft unit," Petitioner relies on Wolter's description that the graft is secured by screws. Pet. 62 (citing Ex. 1010, 5, Fig. 1e). Patent Owner

counters that the "claimed mechanical connector holds distinct bone portions and interposed osteoconductive substances together. Wolter does disclose the use of a metal screw to stack several iliac blocks against each other, but *not* to connect bone portions to form a single graft unit." Prelim. Resp. 60. This is essentially a repetition of the argument that Wolter's bone portions are not distinct, which is unpersuasive for the reasons already discussed. On the current record, Petitioner has made a sufficient showing that Wolter's metal screw is a non-adhesive mechanical connector that holds together the graft.

At this stage of the proceeding, Patent Owner has not presented any separate arguments regarding claim 20, but simply notes its dependency from claim 12. *See* Prelim. Resp. 60. After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to claims 12 and 20.

H. Grounds 7–9: Obviousness Grounds Led by Wolter

In Ground 7, Petitioner argues that claims 12 and 20 would have been obvious over Wolter in view of any of (a) Grooms, (b) Paul, or (c) Coates. Pet. 63. Petitioner's argument in support of this ground consists of one paragraph in which it argues that if Wolter's surface is not considered textured,

> it would have been obvious to one of ordinary skill in the art to have provided the vertebral-engaging surfaces of the Wolter graft with protrusions, such as those taught by Grooms (*see* Exs. 1003, 1004, Figures 1C-E), Paul (*see* Exs. 1006, 1007, Figure 9), or Coates (*see* Ex. 1008, Figures 15-19) in order to prevent graft migration and/or expulsion, as was well known in the art.

Pet. 63. Patent Owner counters that making modifications to Wolter's graft would be impractical because it would extend surgical time and increase the

potential for complications. Prelim. Resp. 63 (citing Ex. 2001 ¶ 30). Petitioner's arguments in this ground are underdeveloped and do not explain how the proposed modification of Wolter's sandwich block would be carried out in the context of Wolter's autograft procedure, or why an ordinarily skilled artisan would reasonably expect success in extending surgical time to add the proposed protrusions. Nevertheless, under current Board practices, a decision to institute means that we institute on all challenges raised in the petition. *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) ("*SAS* Guidance");[8] *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018). Thus, we institute a review on Ground 7.

In Ground 8, Petitioner argues that claims 4 and 6–11 would have been obvious over Wolter in view of Grooms. Pet. 63–71. In this proposed combination, Wolter is modified by utilizing Grooms' bone pin in lieu of a metal screw, and also by adding linear protrusions to the upper and lower surfaces as taught by Grooms. *See* Pet. 64. Similar to Ground 7, Petitioner does not make clear how these modifications would be made in the proposed combination. One possibility is that Wolter's autograft would be modified as proposed in the course of a single procedure as taught in Wolter, during which the bone is harvested, and the graft is created and implanted. With regard to this possible manner of combining the references, Patent Owner argues that "[t]here is simply no time to machine, for instance, pins from the patient's own bone. Extensive processing or machining would only exacerbate significant problems arising from this procedure." Prelim. Resp. 63–64 (citing Ex. 2001 ¶ 30). Petitioner does not explain why an ordinarily

[8] *Available at* www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

skilled artisan would have had a reasonable expectation of success in fashioning a bone pin and adding linear protrusions to the surfaces of the graft during the course of Wolter's autograft procedure. Another possible way of combining the references would be to form Wolter's sandwich block from allograft bone, but the Petition does not explain that this is the proposed manner of combining the references for this ground. The Petition's lack of clarity regarding the proposed combination is a weakness of this ground. Nevertheless, having determined that Petitioner has demonstrated a reasonable likelihood of prevailing in other grounds, we institute a review on Ground 8.

Finally, in Ground 9, Petitioner argues that claims 4, 6–9, and 11 would have been obvious over Wolter in view of Paul and Coates. Pet. 71–77. Similar to Ground 8, this ground proposes modifying Wolter to replace the metal screw with a bone pin (as in Paul) and to add linear protrusions to the upper and lower surfaces (as in Coates). *Id.* at 72. However, in this ground, Petitioner makes clear that the proposed modification is based on modifying Wolter to be an allograft. *Id.* at 71–72 (arguing that by the late 1990s, it was accepted that allograft bone was preferred over autograft bone for spinal implants). This explanation of the proposed combination would seem to preempt Patent Owner's concern that the proposed combination would require extending "an already painful and lengthy procedure, after harvesting the iliac blocks, and before implanting them into the patient's spinal column." Prelim. Resp. 63 (citing Ex. 2001 ¶ 30). To succeed in its challenges in Ground 9, Petitioner will still have to overcome Wolter's expressed preference for autologous bone sources. *See* Ex. 1010, 4 (explaining that "[t]he use of exclusively autologous bone material . . .

appears to be necessary" for several reasons, including that "[a]utologous bone material represents, in accordance with the general view, the best transplant material"); *see also id.* at 9 ("Only autologous material should be used upon bone transplantation in the vertebral column area for the filling out of defects and for accumulations, as well as for intersegmental stiffening."). The question of whether, by the time of the invention of the '532 patent, the state of the art in the spinal fusion field was such that ordinarily skilled artisans would have considered changing Wolter's autograft to an allograft and would have reasonably expected success in doing so in spite of Wolter's teachings to use autologous bone material is better left for resolution after a complete trial record is developed. Because we have determined that Petitioner has demonstrated a reasonable likelihood of prevailing in other grounds, we institute a review on Ground 9.

I. Redundancy

Patent Owner argues that we should "exercise . . . discretion to deny institution of Grounds 6 and 7, and 8 and 9, because they are horizontally and vertically redundant." Prelim. Resp. 65. A request that we deny institution of a subset of grounds on the basis of alleged redundancy is not grantable because decisions that institute on some grounds but not others are no longer permissible. *See SAS* Guidance (explaining that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition"); *PGS Geophysical*, 891 F.3d at 1360 (interpreting 35 U.S.C. § 314(a) to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

J. Conclusion

We determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing the unpatentability of at least one claim of the '532 patent. At this preliminary stage of the proceeding, we have not made a final determination with respect to the resolution of any factual or legal issue.

VI. ORDER

It is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of claims 4 and 6–21 of the '532 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this Decision.

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