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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RTI SURGICAL, INC.,
Petitioner,

v.

LIFENET HEALTH,
Patent Owner.

Case IPR2019-00569
Patent 6,458,158 B1

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 1–15 of U.S. Patent No. 6,458,158 B1 (Ex. 1002, "the '158 patent"). Patent Owner LifeNet Health filed a Preliminary Response. Paper 10 ("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 '158 patent on all grounds presented in the Petition.

II. BACKGROUND

A. Related Matters

Patent Owner is asserting the '158 patent against Petitioner in *LifeNet Health v. RTI Surgical, Inc.*, No. 1:18-cv-00146-MW-GRJ (N.D. Fla.). *See* Pet. 3; Paper 4, 1. The parties also list another proceeding at the Board as a related matter: Case IPR2019-00570, which challenges U.S. Patent No. 8,182,532. *See* Pet. 3; Paper 4, 1.

B. The '158 Patent

The '158 patent relates to a composite bone graft for spinal fusion. Ex. 1002, 1:10–16. 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 ’158 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. 1002, [57] (Abstract), 1:10–16, 2:26–28. In the “Background of the Invention,” the ’158 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 1:48–54. The ’158 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 1:62–65.

The ’158 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 1:26–33, 2:1–7. Figure 6 of the '158 patent is reproduced below:

FIG. 6

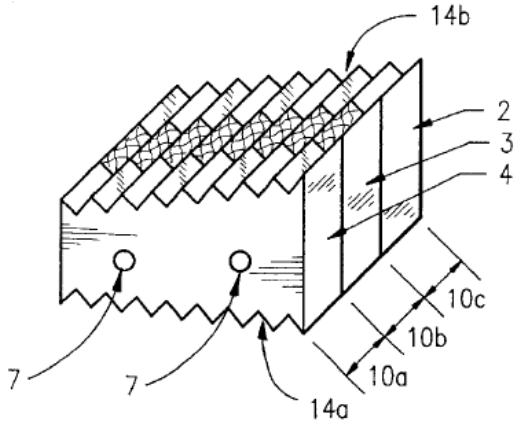


Figure 6 is a perspective view of a composite bone graft. Ex. 1002, 8:63–65.

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 19:61–63. Cortical bone pins 7 hold the bone portions together. *Id.* at 19:63–64. The graft also includes textured surfaces 14a and 14b. *Id.*

C. Illustrative Claim

Petitioner challenges claims 1–15, which are all of the claims in the '158 patent. Claims 1, 2, and 13–15 are independent claims. Claim 1 is illustrative of the challenged claims and is reproduced below, with additional line breaks to facilitate review:

1. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion;

a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit; and

one or more bone pins for holding together said graft unit,

wherein said first cortical bone portion and said second cortical bone portion are not in physical contact, and

wherein said composite bone graft does not comprise an adhesive and

said bone graft is not demineralized.

Ex. 1002, 45:1–12 (additional line breaks added).

D. Asserted Grounds of Unpatentability

Petitioner asserts seven grounds of unpatentability:

Gr.	References	Basis[1]	Claim(s) Challenged
1.	Wolter[2] in view of Grooms[3]	§ 103(a)	1–12
2.	Wolter in view of Paul[4]	§ 103(a)	1, 2, 11, 12
3.	Wolter in view of Paul and Coates[5]	§ 103(a)	3–10

[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 '158 patent was filed before March 16, 2013, we apply the pre-AIA version of § 103.

[2] Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," *Accident Medicine: Scientific and Clinical Aspects of Bone Transplantation*, vol. 185, pp. 166–75 (1987) (Ex. 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. 37–39), but that objection is moot in view of the corrected version of Exhibit 1010 that Petitioner filed with our permission. *See* Paper 11, 4.

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

[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).

Gr.	References	Basis[1]	Claim(s) Challenged
4.	Wolter in view of either (1) Grooms or (2) the combination of Paul and Kozak[6]	§ 103(a)	13
5.	Wolter in view of either (1) Grooms in combination with Boyce[7] or (2) Paul in combination with Boyce	§ 103(a)	14
6.	Wolter in view of either (1) Grooms or (2) Paul	§ 103(a)	15
7.	Boyce in view of either (1) Grooms or (2) Paul	§ 103(a)	1, 2, 11, 12, 14

See Pet. 5–7.

III. PRELIMINARY ISSUES

A. Discretionary Denial Under § 325(d)

A threshold issue raised by the Preliminary Response is whether we should deny institution under 35 U.S.C. § 325(d). *See* Prelim. Resp. 30–33. Patent Owner asserts that Boyce, which serves as the primary reference in Petitioner's Ground 7 and plays a supporting role in Ground 5, was already considered by the Examiner during prosecution of the '158 patent. *Id.* at 31. Specifically, Patent Owner contends that it overcame anticipation and obviousness rejections based on Boyce by arguing that the claimed graft is not demineralized, whereas Boyce teaches to demineralize the bone-derived elements that make up the implant. *Id.* at 32 (citing Ex. 1014, 3–5, 13).

In its Petition, Petitioner addressed the potential § 325(d) argument and argued that the Examiner did not consider the specific combinations

[6] U.S. Patent No. 5,397,364, issued Mar. 14, 1995 (Ex. 1012).

[7] U.S. Patent No. 6,123,731, issued Sept. 26, 2000 (Ex. 1011).

Petitioner asserts, because neither Grooms nor Paul was before the Examiner. Pet. 65. What Grooms and Paul add to the analysis, according to Petitioner, is a teaching that bone pins can be used to secure bone portions together without requiring demineralization. *Id.* at 66. Responding to that argument, Patent Owner argues that modifying Boyce as Petitioner proposes would destroy Boyce's core purpose. Prelim. Resp. 33.

We are not persuaded that applying § 325(d) to deny institution of the entire petition is appropriate in these circumstances. As to Petitioner's Boyce-based challenge, Patent Owner does not persuade us that the Examiner considered the substance of Petitioner's obviousness challenge. Patent Owner does not refute Petitioner's assertion that neither Grooms nor Paul was considered by the Examiner, nor does Patent Owner assert that Grooms and Paul are cumulative of other art the Examiner considered. Patent Owner's argument that Boyce teaches away from the proposed combination goes to the merits of Petitioner's challenge, not whether the arguments and evidence in the Petition have already been evaluated by the Office. Further, five of the seven grounds asserted by Petitioner do not rely on Boyce at all.

Accordingly, we do not exercise our discretion under § 325(d) to deny institution.

B. Redundancy

Patent Owner argues that the Petition should be denied because it presents grounds that "are horizontally redundant, i.e., they present alternative references for the same purpose without explaining their relative strengths and weaknesses." Prelim. Resp. 34. Patent Owner's argument relies primarily on *Liberty Mutual Insurance Co. v. Progressive Casualty*

Insurance Co., Case CBM2012-00003, slip op. at 2 (PTAB Oct. 25, 2012) (Paper 7). We note that the *Liberty Mutual* order cited by Patent Owner required the petitioner to select which combinations it wished to maintain; it did not deny institution of the entire petition, which is the relief Patent Owner seeks here. *See id.* at 17.[8]

Patent Owner also cites *Adaptics Ltd. v. Perfect Co.*, Case IPR2018-01596 (PTAB Mar. 6, 2019) (Paper 20) (informative). In *Adaptics*, the Board found that the petition "suffer[ed] from a lack of particularity that results in voluminous and excessive grounds," in part because the petitioner's statement of its grounds "yield[ed] hundreds of possible combinations" and none of those combinations were presented with sufficient particularity. *Id.* at 18–19. Here, Patent Owner does not point to any catch-all language in Petitioner's grounds of the type that was found most problematic in *Adaptics*. And while it does appear that Petitioner may have been able to present a more streamlined challenge or an explanation of why so many grounds are necessary, we are not persuaded that the seven grounds asserted here are so overwhelming or unwieldy as to warrant denial of institution.

[8] We are aware that, for a period of time, the Board issued partial institution decisions that denied institution as to subsets of grounds that were deemed to substantially overlap with the instituted grounds. But that approach, which was already largely moribund by the time of the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), is now foreclosed by *SAS* and the Office's guidance implementing *SAS*. *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018), *available at* www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (explaining that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

IV. 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 to 5 years of experience; or would be a practicing orthopedic surgeon with at least five years of experience.

Pet. 16–17 (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.

Prelim. Resp. 26 (citing Ex. 1002, 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 '158 patent ascribes to a person of ordinary skill in the art, including the ability to select and employ

methods for demineralizing bone (Ex. 1002, 13:25–28, 18:41–43), the ability to select appropriate dimensions for depressions or protrusions to provide an interlocking fit of bone portions (*id.* at 14:12–17), the ability to employ suitable methods for processing bone tissue for use in the graft (*id.* at 16:40–43), the ability to select appropriate dimensions for the graft based on the particular application and site of implantation in a patient (*id.* at 17:27–31), and the ability to produce pins from cortical bone and to select the appropriate number, orientation, and dimensions of pins (*id.* at 18:1–3, 27:42–56).

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

V. 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) (amending 37 C.F.R. § 42.100(b) (effective Nov. 13, 2018)).[9] 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

[9] The Petition in this case was filed February 19, 2019. *See* Paper 3, 1. Moreover, Patent Owner points out that regardless of the rule change, the *Phillips* standard would apply in this proceeding because the '158 patent is expired. *See* Prelim. Resp. 23 n.5.

banc); Prelim. Resp. 23 (noting that the *Phillips* claim construction standard governs).

The parties propose constructions for several terms (*see* Pet. 17; Prelim. Resp. 27–30), but we determine that only two terms require 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 Bone Graft"

The phrase "composite 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. 17 (citing Ex. 1002, 12:49–51). Patent Owner does not point to any defect in Petitioner's proposal, but offers its own construction for "composite bone graft" as meaning "a bone graft which is made up of and assembled from two or more distinct bone portions." Prelim. Resp. 27.

These constructions are very similar. The parties agree that the '158 patent includes a definition for "composite," and that definition is the same as Petitioner's construction. *See* Pet. 17; Prelim. Resp. 27; Ex. 1002, 12:49–51. Patent Owner's claim construction 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. 27–28. Patent Owner

argues that "[e]xamples from the specification" and testimony from the experts support its view. *Id.* at 27, 29. 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 bone graft" to mean "a bone graft which is made up of two or more distinct bone portions."

B. "Discontinuous Bone Portion"

Claim 14 recites that "one or more of said bone portions comprise a discontinuous bone portion." Ex. 1002, 46:64–65. Petitioner proposes that "discontinuous bone portion" means "a bone portion that contains artificially created void areas including for example, a perforated bone portion." Pet. 17. Patent Owner proposes "a bone portion that contains artificially created void areas that transverse the bone portion." Prelim. Resp. 30.

The parties agree that the Specification includes a definition of discontinuous bone portion. *See* Pet. 17; Prelim. Resp. 30. Petitioner's proposal reproduces the definition in the Specification. Ex. 1002, 13:29–32. Patent Owner's proposal requires that the void areas must "transverse the bone portion," but the portion of the Specification Patent Owner relies on only states that the perforations or channels "***may*** partially or completely transverse the bone portion." *Id.* at 13:33–34 (emphasis added).

For purposes of this Decision, we construe "discontinuous bone portion" to mean "a bone portion that contains artificially created void areas including for example, a perforated bone portion."

VI. ANALYSIS OF PROPOSED GROUNDS

A. Legal Standards for 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 IV. Our discussion below addresses the remaining *Graham* factors.

B. Ground 1: Obviousness over Wolter in view of Grooms

Petitioner contends that claims 1–12 would have been obvious over Wolter in view of Grooms. *See* Pet. 27–41. Patent Owner disputes these contentions. Prelim. Resp. 40–54. 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 Wolter

Wolter describes methods of bone transplantation in the vertebral column. Ex. 1010, 4. The portion of Wolter's disclosure of greatest relevance to Petitioner's challenge is its description of 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. 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:

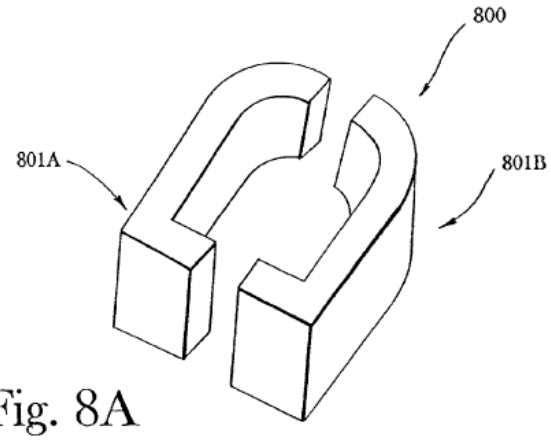


Fig. 8A

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.

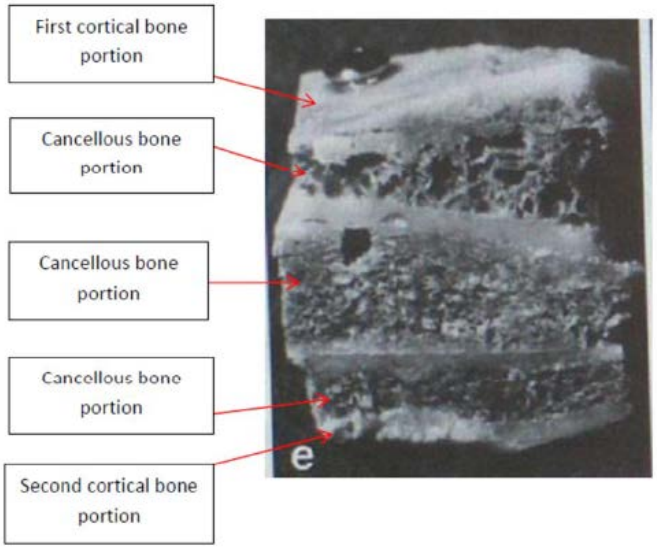
3. Analysis

a. Claim 1

Petitioner asserts that Wolter teaches each of the limitations of claim 1 except that Wolter's graft is held together by a metal screw and so does not disclose "one or more bone pins for holding together said graft unit." *See* Pet. 27, 29. We discuss each limitation of claim 1 below, but in a slightly different order than the claim itself: we first address all of the limitations for which Petitioner relies on Wolter, and save the bone pin limitation for the end.

> *(1) "A composite bone graft, comprising: a first cortical bone portion; a second cortical bone portion; a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit"*

Petitioner's annotated version of Wolter's Figure 1e is reproduced below:



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 1.

See Pet. 29. 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 "cancellous bone portion." *Id.*

Patent Owner counters that Wolter does not disclose two distinct cortical bone portions and a distinct cancellous bone portion disposed between. Prelim. Resp. 41–46. 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 46. These arguments do not identify any structural feature of the composite bone graft as recited claim 1 that is absent from Wolter's sandwich block. Under the construction of "composite 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. Even if we were to agree with Patent Owner that an area of cancellous bone that is already connected to cortical bone in its naturally occurring state is not "distinct" from the connected cortical bone, that still leaves the middle cancellous bone portion identified in Petitioner's annotated Figure 1e, which was cut from a different section of bone than the top and bottom layers of cortical bone.

On the current record, Petitioner has made a sufficient showing that Wolter discloses first and second cortical bone portions and a cancellous bone portion arranged as recited in claim 1.

(2) "said first cortical bone portion and said second cortical bone portion are not in physical contact"

Pointing to its annotated version of Wolter's Figure 1e, Petitioner asserts that there are multiple portions of cortical and cancellous bone physically separating the layers of cortical bone that Petitioner relies on as the claimed first and second cortical bone portions. *See* Pet. 30 (citing Ex. 1015 ¶ 341). Patent Owner argues that in Wolter, the cortical bone of each iliac section combining to form the sandwich block illustrated in Figure 1e is in physical contact with cortical bone of another iliac section in the

sandwich block, and that this arrangement is distinguished by claim 1's requirement that "said first cortical bone portion and said second cortical bone portion are not in physical contact." Prelim. Resp. 46. This argument does not respond to the challenge as Petitioner has framed it. The layers of cortical bone Petitioner relies on are the top and bottom of Wolter's sandwich block. It is irrelevant to Petitioner's challenge that other layers of cortical bone within Wolter's sandwich block are adjacent to each other.

Petitioner has shown sufficiently for institution purposes that the identified first and second cortical bone portions in Wolter's sandwich block are not in physical contact.

(3) "said composite bone graft does not comprise an adhesive"

Petitioner contends that an ordinarily skilled artisan would have understood from Wolter's disclosure that adhesive is not used because it describes using screws to hold the graft together. Pet. 30–31 (citing Ex. 1010, 5–6; Ex. 1015 ¶ 342). Patent Owner does not dispute this assertion in its Preliminary Response. For purposes of institution, Petitioner has made a sufficient showing that Wolter discloses this limitation to a person of ordinary skill in the art.

(4) "said bone graft is not demineralized"

Petitioner contends that an ordinarily skilled artisan would have understood from Wolter's disclosure that the graft is not demineralized because the reference says nothing about demineralization. Pet. 30–31 (citing Ex. 1010, 5–6; Ex. 1015 ¶ 345). Patent Owner does not dispute this assertion in its Preliminary Response. For purposes of institution, Petitioner has made a sufficient showing that Wolter discloses this limitation to a person of ordinary skill in the art.

(5) "one or more bone pins for holding together said graft unit"

Petitioner relies on Grooms as disclosing the claimed one or more bone pins. *See* Pet. 29 (citing Ex. 1003 ¶¶ 48–49). In particular, Petitioner asserts that "Grooms teaches that distinct portions of an intervertebral composite bone graft may be held together by forming holes in portions of the graft and forcing a pin through the holes to create a unitary graft." *Id.* Petitioner contends that an ordinarily skilled artisan would have been motivated to replace Wolter's metal screws with Grooms' cortical bone pins to eliminate a foreign object from being permanently present in the patient's spine and to avoid potential complications from loosening of the screw. *See id.* at 27–28 (citing Ex. 1015 ¶¶ 300, 348). An ordinarily skilled artisan would have had a reasonable expectation of success in making the proposed substitution, Petitioner further argues, based on Grooms' disclosure that bone pins are suitable to hold together distinct portions of a composite bone graft. *Id.* at 30 (citing Ex. 1015 ¶¶ 77–79).

Patent Owner argues that Wolter does not disclose cortical bone pins holding together distinct bone portions. Prelim. Resp. 47. This argument is not responsive to the obviousness challenge Petitioner has presented, which relies on Grooms, not Wolter, for the bone pin limitation. *See* Pet. 29–30.

Patent Owner also contests Petitioner's obviousness theory on the basis that an ordinarily skilled artisan "would not look to Wolter" and that "if a larger piece of bone is needed, one of ordinary skill would simply cut a larger piece of bone rather than stacking smaller pieces of bone." Prelim. Resp. 48 (citing Ex. 2001 ¶ 48). On the current record, we are not persuaded that an ordinarily skilled artisan would simply reject Wolter's teachings out of hand. Wolter is a published article from what appears to be a scientific

journal reporting on procedures the authors performed, the results they obtained, and their recommendations based on those procedures. *See, e.g.*, Ex. 1010, 5 ("***According to experience***, a large ventral defect can be filled out by a so-called sandwich block." (emphasis added)). Patent Owner cites the testimony of its expert, Dr. Mark Shaffrey, that he is not aware of anyone performing Wolter's procedure (Prelim. Resp. 48–49 (citing Ex. 2001 ¶ 48)), but on the current record, we are not persuaded that this is a sufficient basis to conclude that an ordinarily skilled artisan would have disregarded the entirety of Wolter's teachings as not worth considering. *See Polaris Industries, Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018) (explaining that in the obviousness analysis, "a reference 'must [be] considered for all it taught'") (quoting *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985)). Patent Owner also cites Dr. Shaffrey's testimony that Wolter's graft presents a risk that the sharp end of the screw would contact the spinal cord. *Id.* Yet that risk would not seem to be present in Petitioner's proposed combination, which replaces Wolter's screw with Grooms' bone pin—indeed, Dr. Shaffrey's testimony may suggest another reason why Petitioner's proposed modification would be viewed as beneficial.

Patent Owner also challenges Petitioner's use of Grooms in the proposed combination. *See* Prelim. Resp. 48–52. Specifically, Patent Owner argues that it is uncertain how Grooms' bone pin could be used in Wolter's procedure because it "is unclear how one would harvest it from the patient, machine it during a time-sensitive procedure, and then use it to somehow connect the stacked blocks in Wolter." *Id.* at 49. Patent Owner further argues that a skilled artisan would not use allograft bone pins in

combination with Wolter's autograft because Wolter teaches the use of "exclusively autologous bone material." *Id.* (quoting Ex. 1010, 4).

These arguments from Patent Owner highlight that the specific manner in which Petitioner proposes combining Wolter with Grooms in this ground is somewhat unclear. In particular, Petitioner does not specify whether the proposed combination contemplates making and inserting an autologous bone pin during Wolter's autograft procedure, or whether Wolter's autograft is modified to be an allograft in the proposed combination.

To the extent Petitioner's proposed combination incorporates the fabrication and insertion of an autologous bone pin into Wolter's autograft procedure, Patent Owner makes a persuasive case that Petitioner has not shown a sufficient motivation or reasonable expectation of success for that manner of combining the references. As both parties' experts agree, Wolter's procedure uses autologous bone. *See* Ex. 1015 ¶ 43; Ex. 2001 ¶ 40. Wolter teaches 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." Ex. 1010, 4; *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 parties' experts further agree that Wolter's procedure involves harvesting the bone and implanting the graft in a single procedure. Dr. Sherman testifies that "[a]s disclosed by Wolter, autologous bone is taken from the patient at the time of surgery for use as a transplant."

Ex. 1015 ¶ 43. Likewise, Dr. Shaffrey testifies that in Wolter's procedure, "the iliac block is surgically removed from the patient's own iliac wing and inserted into the patient's spinal column during the same procedure." Ex. 2001 ¶ 41. In such a procedure, Dr. Shaffrey testifies that "surgeons must work very quickly. There would be no time to machine, for instance pins from the patient's own bone." *Id.* ¶ 49; *see also id.* ¶ 51. Dr. Shaffrey cites documentary evidence to support his testimony that in a spinal fusion procedure using autologous iliac grafts, any time spent modifying the bone block would translate to extended operative times and the potential for complications. *See id.* ¶ 32 (citing Ex. 2008, 476; Ex. 2006, 374; Ex. 2004, 79).

Petitioner does not point to, and we do not find, any description in Grooms that teaches how to create a bone pin during the course of a single procedure in which bone material is harvested, fashioned into a bone pin, inserted into an implant, and then implanted in the patient's spine. Rather, Grooms describes extensive machining, under aseptic conditions, to produce an implant that may include a bone pin, after which the implant is stored and shipped to physicians for use in implantation procedures. Ex. 1003 ¶¶ 23, 28–33, 48–49. Consistent with that understanding, Dr. Sherman testifies that Grooms' "bone graft would be provided to the surgeon as a unitary component." Ex. 1015 ¶ 76.

Petitioner does not explain or cite evidence to show how or why an ordinarily skilled artisan would have had a reasonable expectation of success in creating a bone pin during Wolter's autograft procedure without unduly extending the surgical time. In the absence of any such explanation, and in view of Grooms' description of how bone pins are fabricated, we are

persuaded by Dr. Shaffrey's testimony that an ordinarily skilled artisan would not have expected there to be sufficient time to process or machine bone pins during Wolter's autograft procedure. Ex. 2001 ¶¶ 49, 51.

However, we understand Petitioner's challenge to encompass combinations in which Wolter's implant, including a bone pin, is made from allogenic bone. That understanding is based on Petitioner's arguments in this ground concerning dependent claim 12, which recites that the composite bone graft "compris[es] allogenic or xenogenic bone." Ex. 1002, 46:42–43. Regarding that claim, Petitioner contends that an ordinarily skilled artisan "would have known that the Wolter graft could advantageously be prepared from allograft bone, as taught by Grooms . . . because the advantages of allograft bone over autograft bone were well-understood before the relevant date of the 158 patent." Pet. 41 (citing Ex. 1003 ¶ 24; Ex. 1015 ¶¶ 392–397). We also note that Patent Owner's rebuttal arguments regarding Ground 1 in its Preliminary Response address whether Wolter could be made of allogenic bone (*see* Prelim. Resp. 50 n.10), which indicates that Patent Owner also understood Petitioner's challenge to encompass a combination in which Wolter's implant is an allograft rather than an autograft.

The version of the combination in which Wolter's graft is made from allogenic bone presents a somewhat close case, in that both parties have presented arguments that may ultimately prevail. Patent Owner argues that Wolter teaches that only autologous bone should be used for the graft, which teaches away from Petitioner's proposed use of allegenic bone. *See* Prelim. Resp. 49–50 (citing Ex. 1010, 4). But Petitioner argues that Wolter was published in 1987, and by the time of the invention of the '158 patent in the

late 1990s, ordinarily skilled artisans recognized the benefits of allografts over autografts. *See* Pet. 41, 42.

The parties' experts appear to be in general agreement that practitioners in the spinal fusion field moved from a preference for autografts to a preference for allografts, but disagree as to when that shift occurred relative to the date of the invention of the '158 patent. *Compare* Ex. 1016 ¶¶ 33–39, *and* Ex. 1015 ¶¶ 317–318, 394–396, *with* Ex. 2001 ¶¶ 27–37. Aside from the testimony of its experts, there is other record evidence to support Petitioner's argument that it was known in the prior art that allografts provided were advantageous in certain respects and that autografts had known drawbacks. For example, Grooms describes its "implant is derived from allograft or autograft cortical bone sources," but expresses a preference for allograft bone sources "due to possible complications at the donor site." Ex. 1003 ¶¶ 10, 24; Ex. 1004, 3:22, 4:29–5:7; *see also* Ex. 1006, 1:35–47 (Paul discussing benefits of allografts and referencing known techniques to preserve the allograft to reduce the risk of an adverse immunological response when implanted); Ex. 1008, 3:11–16 (Coates describing disadvantages of autografts).

The disputed issue of whether, by the time of the invention of the '158 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, in our view, better left for resolution after a complete trial record is developed. *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."). For present purposes, we determine that Petitioner has made a sufficient showing regarding motivation and reasonable expectation of success to justify institution.

(6) Conclusion

Based on the current record, we determine that Petitioner's arguments and evidence establish a reasonable likelihood that Petitioner will prevail with respect to claim 1.

b. Claim 2

Claim 2 contains many of the same limitations as claim 1 but uses the linking word "consisting essentially of" rather than "comprising" as in claim 1. Petitioner argues that "[c]laim 2 is unpatentable over Wolter in view of Grooms for the same reasons that claim 1 is unpatentable as obvious over that combination. . . ." Pet. 32–33. Patent Owner also refers back to its arguments regarding claim 1, and further argues that the "consisting essentially of" language in claim 2 "limit[s] the claim[] to the specified steps, elements or materials and those that do not materially affect the basic and novel characteristics of the invention." Prelim. Resp. 52 (quoting *Sonoco Prod. Co. v. Mobil Oil Corp.*, 895 F.2d 1420 (Fed. Cir. 1990)). Patent Owner argues that Wolter's sandwich block includes more layers of bone than what is recited in claim 2. *Id.* at 53. According to Patent Owner, "[t]he graft of Wolter is therefore not limited to the claimed configuration and is in fact materially different." *Id.* at 54. On the current record, Patent Owner's argument is not persuasive because it does not explain how the

additional bone layers in Wolter "materially affect the basic and novel characteristics of the invention." *Sonoco*, 895 F.2d 1420. For example, Patent Owner does not show that the additional layers prevent the regions of Wolter's block Petitioner correlates to the claimed bone portions from carrying out the functions those portions are intended to have in the '158 patent. On the current record, Petitioner has shown a reasonable likelihood of prevailing as to claim 2.

c. Claims 3–12

Petitioner provides a detailed explanation of its challenge to claims 3–12. Pet. 34–41. At this stage of the proceeding, Patent Owner's only argument concerning these claims is that they "are not obvious at least by virtue of their dependency" from claims 1 or 2. Prelim. Resp. 54. 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 Wolter in view of Paul

Petitioner contends that claims 1, 2, 11, and 12 would have been obvious over Wolter in view of Paul. *See* Pet. 42–46. Patent Owner disputes these contentions. Prelim. Resp. 54–56. 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 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:

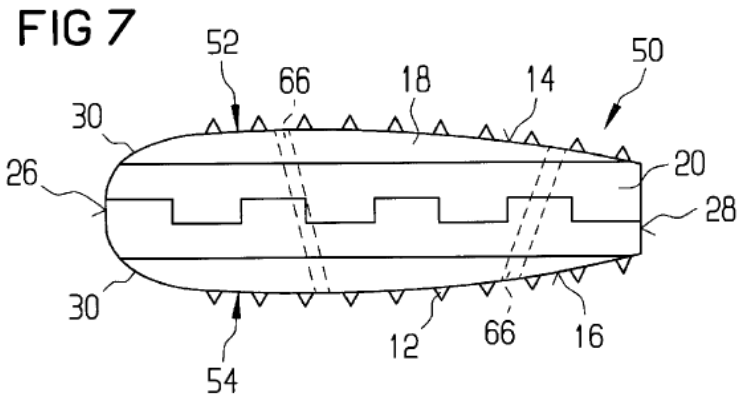


Figure 7 shows a side view of implant 50. *Id.* at 3:1.

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's contentions in support of this ground are similar to Ground 1, in that Wolter is again relied on for teaching all limitations of claim 1 except for the bone pin. *See* Pet. 42. In this ground, Petitioner relies on Paul to teach the bone pin, and the asserted motivation for trading out Wolter's metal screw for a bone pin is the same as in Ground 1. *See id.* Petitioner's arguments in this ground make it clear that the proposed combination modifies Wolter to be an allograft because "[b]y the late 1990s . . . it was well-accepted that the preparation of spinal implants from allograft bone . . . was preferred to the use of autograft bone." *See id.* (citing Ex. 1015 ¶¶ 394–396; Ex, 1016 ¶¶ 36–39). Petitioner identifies where each of the features of claims 1, 2, 11, and 12 are taught by the proposed combination. Pet. 42–46.

In contesting this ground, Patent Owner asserts that "Paul and Grooms have substantially similar teachings" and refers back to its arguments against Ground 1. *See* Prelim. Resp. 55–56. Patent Owner also argues that "Paul does not disclose that the two cortical bone portions are not in physical contact." *See id.* at 55. However, Petitioner relies on Wolter, not Paul, to disclose the limitation in claim 1 that the first and second cortical bone portions are not in physical contact. *See* Pet. 44.

After reviewing Petitioner's arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to claims 1, 2, 11, and 12 as obvious over Wolter in view of Paul.

D. Grounds 3 and 4

Petitioner's challenges in Grounds 3 and 4 rely on the same base combination of Wolter with Grooms or Paul as Grounds 1 and 2, with other references added to teach certain features. *See* Pet. 42–57. In Ground 3, Petitioner argues that dependent claims 3–10 would have been obvious over Wolter in view of Paul and Coates. *See id.* at 46–52. In Ground 4, Petitioner contends that claim 13 would have been obvious over Wolter in view of either (1) Grooms or (2) Paul and Kozak. *See id.* at 53–57. At this stage of the proceeding, Patent Owner's arguments concerning these grounds simply summarize or refer back to its arguments concerning Grounds 1 and 2 and argue that the additionally cited references, Coates and Kozak, do not "cure the deficiencies of Wolter and Grooms or Wolter and Paul." *See* Prelim. Resp. 56–58. For the reasons discussed above, on the current record, we are not persuaded that the base combinations are deficient. After reviewing Petitioner's arguments and evidence, we

determine that Petitioner has demonstrated a reasonable likelihood of prevailing in these grounds.

E. Ground 5: Obviousness over Wolter in view of either (1) Grooms and Boyce or (2) Paul and Boyce

Petitioner contends that claim 14 would have been obvious over Wolter in view of either (1) Grooms and Boyce or (2) Paul and Boyce. *See* Pet. 57–62. Patent Owner disputes these contentions. Prelim. Resp. 58–61.

1. Summary of Boyce

Boyce is directed to an osteoimplant made from an "aggregate of bone derived elements possessing chemical linkages between their adjacent surface-exposed collagen." Ex. 1011, [57] (Abstract). Figure 6 of Boyce is reproduced below:

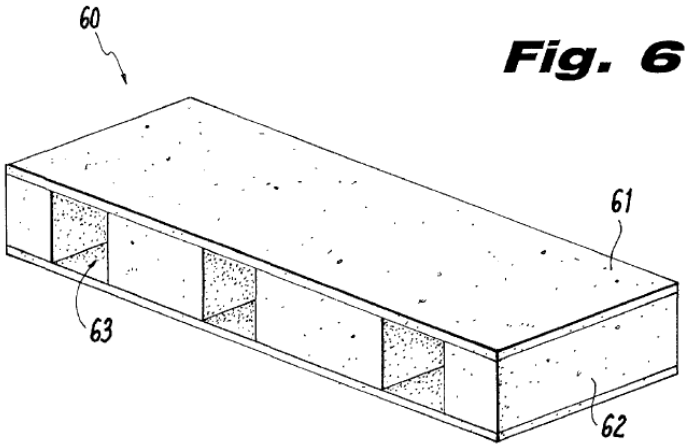


Figure 6 is a perspective view of osteoimplant 60.
Ex. 1011, 3:37–39.

Osteoimplant 60 is made up of sheet sections 61 and cube sections 62 arranged in alternating layers. *Id.* at 8:16–21. Sheet sections 61 are made from surface demineralized cortical bone, and cube sections 62 are made from surface demineralized cancellous bone. *Id.* Once assembled, the structure is treated to crosslink the surface-exposed collagen molecules to bond the adjacent bone elements to each other. *Id.* at 8:21–22, 3:53–56.

The pattern of channels 63 results in an open structure that permits vascular penetration of host bone ingrowth. *Id.* at 8:22–26.

2. Analysis

Claim 14 recites a composite bone graft having many of the same features required by claim 1, and further reciting that "one or more of said bone portions comprise a discontinuous bone portion" and that the graft includes "one or more therapeutically beneficial substances selected from" a specified list of substances. Ex. 1002, 46:64–65, 47:1–2. Under the construction we adopted in Section V.B., "discontinuous bone portion" means "a bone portion that contains artificially created void areas including for example, a perforated bone portion."

Petitioner acknowledges that Wolter does not disclose the claimed "discontinuous bone portion" but asserts that Boyce discloses that feature in the form of pores or channels such as shown in Boyce's Figure 6. Pet. 60–61. Petitioner further asserts that Boyce describes that these channels permit vascular ingrowth and diffusion of medically useful substances. *Id.* at 60 (citing Ex. 1011, 4:51–60, 8:16–26). Petitioner contends that an ordinarily skilled artisan would have included artificially created void areas within Wolter's bone portions to facilitate bone growth, including by the diffusion of bone-growth inducing substances. *Id.* at 61 (citing Ex. 1015 ¶ 478). Petitioner also asserts that Boyce discloses substances that are in the list of therapeutically beneficial substances recited in claim 14. *Id.* at 61–62 (citing Ex. 1011, 4:61–5:30).

Patent Owner responds that Petitioner's proposed combination "makes no sense" because Wolter's autologous iliac blocks already include naturally occurring osteogenic materials, so "[t]here is no motivation to cut

cavities or channels into Wolter's iliac blocks to be filled with osteogenic materials." Prelim. Resp. 60. In addition, Patent Owner argues that "machining of cavities into Wolter's iliac blocks are not only unnecessary, but potentially harmful." *Id.*

Patent Owner's argument that the asserted motivation is insufficient to support the proposed modification is potentially forceful, but currently lacks underlying evidentiary support. Patent Owner does not cite evidence to support its assertions that the cancellous bone already present in Wolter's iliac blocks have the same or comparable osteogenic properties as the therapeutic substances described in Boyce, or that machining cavities into Wolter's iliac blocks is potentially harmful.

As discussed previously, 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");[10] *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"). Thus, we institute a review of this challenge to claim 14.

F. Ground 6: Obviousness over Wolter in view of either (1) Grooms or (2) Paul

In Ground 6, Petitioner argues that claim 15 would have been obvious over Wolter in view of either (1) Grooms or (2) Paul. Claim 15 shares many of the same features as claims that have already been discussed, and

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

Petitioner's contentions in this ground are similar to those in Grounds 1 and 2. *See* Pet. 62–65.

Apart from reiterating the arguments it made against Grounds 1 and 2, Patent Owner highlights that claim 15 recites "a plurality of cancellous bone portions, where each of said cortical bone portions and each of said cancellous bone portions are alternately layered to form a graft unit." Prelim. Resp. 62. Patent Owner argues that Wolter's iliac blocks do not disclose the claimed structure but instead disclose "a naturally occurring, integral block with a single cortical surface around three sides of a cancellous center." *Id.* This argument does not address the obviousness theory Petitioner has presented. Petitioner relies on Wolter's entire sandwich block as the claimed graft, not each individual iliac block, and Petitioner identifies in that sandwich block the claimed alternating layers of cortical and cancellous bone. *See* Pet. 63.

On the current record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in this ground.

G. Ground 7: Obviousness over Boyce in view of either (1) Grooms or (2) Paul

Petitioner asserts that claims 1, 2, 11, 12, and 14 would have been obvious over Boyce in view of either (1) Grooms or (2) Paul. Pet. 65–76. Patent Owner disputes those contentions. *See* Prelim. Resp. 22, 63.

Petitioner asserts that Boyce teaches most of the limitations of claim 1, except that it describes a chemical cross-linking process to hold the graft together, and demineralization of the bone is a step in Boyce's cross-linking process. Pet. 67. Petitioner asserts that Grooms and Paul teach that a bone graft can be held together "solely" by bone pins. *Id.* at 69 (citing Ex. 1003 ¶¶ 48–49; Ex. 1006, 2:30–38, 4:43–63). Petitioner contends that an

ordinarily skilled artisan would have been motivated to use bone pins to assemble Boyce's graft "to avoid the disadvantages of demineralization," which "is known to weaken bone." *Id.* at 70 (citing Ex. 1015 ¶ 28).

Patent Owner argues that the proposed combination "would destroy Boyce's core purpose" and points out that Petitioner acknowledges that Boyce's invention is its cross-linking system, which relies on demineralization. Prelim. Resp. 33.

On the current record, we tend to agree with Patent Owner's position that Petitioner's proposed combination would eliminate Boyce's central purpose, which sets a high bar for Petitioner to show that an ordinarily skilled artisan would have been motivated to modify Boyce in the proposed manner. Petitioner's rationale for the modification that demineralization weakens bone is somewhat lacking in evidentiary support, because the cited testimony from Dr. Sherman does not provide any underlying support to show that this adverse consequence of demineralization was known by the time of the invention of the '158 patent. *See* Ex. 1015 ¶ 28. It also seems difficult to accept that an ordinarily skilled artisan would have eliminated Boyce's cross-linking process in favor of bone pins based on references teaching bone pins, when Boyce itself teaches that bone pins can "supplement" the mechanical strength of the implant. *See* Ex. 1011, 5:54–57. Nevertheless, because under current Board practice, a decision to institute means that we institute on all challenges raised in the petition (*see SAS* Guidance), we institute a review of this ground.

VII. ORDER

It is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of claims 1–15 of the ’158 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of *inter partes* review on the entry date of this Order.

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