UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SURGALIGN SPINE TECHNOLOGIES, INC. (f/k/a RTI SURGICAL, INC.),

Petitioner

v.

LIFENET HEALTH,

Patent Owner

Case IPR2019-00569
Patent No. 6,458,158

SURGALIGN SPINE TECHNOLOGIES, INC.'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Via PTAB E2E
Patent Trial and Appeal Board

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

Via CM/ECF
United States Court of Appeals for the Federal Circuit

Pursuant to 35 U.S.C. §§ 141, 142, and 319, 37 C.F.R. §§ 90.2, 90.3, and 104.2, and Rule 15 of the Federal Circuit Rules, Petitioner Surgalign Spine Technologies, Inc. hereby appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision (Paper 73) entered by the Patent Trial and Appeal Board on August 26, 2020. The Decision is attached to this Notice.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner identifies at least the following issues for appeal:

- The Board's judgment that Claims 1-15 of Patent No. 6,458,158 are not unpatentable and any finding or determination supporting or related to that judgment;
- Any Board finding, determination, judgment, or order supporting or related to the Final Written Decision and decided adversely to Petitioner.

Petitioner is concurrently filing true and correct copies of this Notice of Appeal, along with the required fees, with the United States Court of Appeals for the Federal Circuit, and with the USPTO Patent Trial and Appeal Board.

Respectfully submitted,

Dated: October 27, 2020

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CERTIFICATE OF FILING

The undersigned hereby certifies that, in addition to being electronically filed through PTAB E2E, a true and correct copy of the above-captioned **SURGALIGN SPINE TECHNOLOGIES, INC.'S NOTICE OF APPEAL** is being served by hand delivery to the Director of the United States Patent and Trademark Office, on October 27, 2020, at the following address:

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

The undersigned also herby certifies that a true and correct copy of the above-captioned **SURGALIGN SPINE TECHNOLOGIES, INC.'S NOTICE OF APPEAL** and the filing fee is being filed via CM/ECF with the Clerk's Office of the United States Court of Appeals for the Federal Circuit on October 27, 2020.

Dated: October 27, 2020

/David D. Headrick/
David D. Headrick
(Registration No. 40,642)
Counsel for Petitioner
Surgalign Spine Technologies, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certify that the foregoing **SURGALIGN SPINE TECHNOLOGIES INC.'S NOTICE OF APPEAL** was filed through the PTAB's E2E Processing System as well as served electronically via e-mail on October 27, 2020 in its entirety on the following:

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Paper 73
Date: August 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SURGALIGN SPINE TECHNOLOGIES, INC.,
Petitioner,[1]

v.

LIFENET HEALTH,
Patent Owner.

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*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Dismissing Petitioner's Motion to Exclude
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

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[1] Petitioner recently filed Updated Mandatory Notices indicating that its name has changed from RTI Surgical, Inc. to Surgalign Spine Technologies, Inc. *See* Paper 72.

I. INTRODUCTION

A. Background and Summary

Petitioner 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 filed a Preliminary Response. Paper 10. We instituted an *inter partes* review on all claims and all grounds asserted in the Petition. *See* Paper 15 ("Dec. on Inst.").

After institution of trial, Patent Owner filed a Patent Owner Response. Paper 31 ("PO Resp.").[2] Petitioner filed a Reply. Paper 42 ("Pet. Reply"). Patent Owner filed a Sur-Reply. Paper 57 ("Sur-Reply"). We held a hearing on June 2, 2020, a transcript of which is included in the record. *See* Paper 70 ("Tr.").

We have authority under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons discussed below, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–15 of the '158 patent are unpatentable.

[2] A public, redacted version of the Patent Owner Response was filed as Paper 30.

B. Real Parties in Interest

The parties list only themselves as real parties in interest. *See* Pet. 3; Paper 4, 1.

C. Related Matters

Patent Owner asserted the '158 patent against Petitioner in *LifeNet Health v. RTI Surgical, Inc.*, No. 1:18-cv-00146-MW-GRJ (N.D. Fla.), filed June 27, 2018. *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.

D. 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, code (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

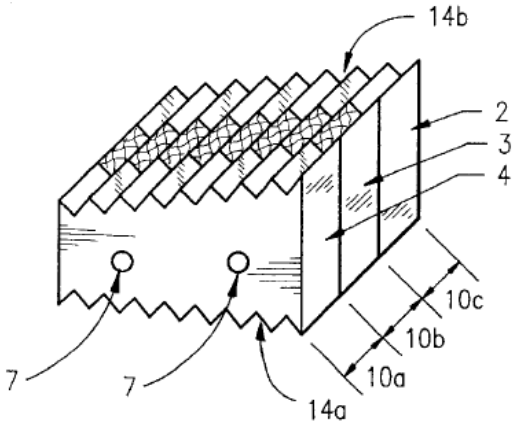

Figure 6 is a perspective view of a composite bone graft. *Id.* at 8:63–65.

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.*

E. 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).

F. Prior Art References and Testimonial Evidence

Petitioner relies on the following references for its challenges:

Name	Description	Date	Exhibit
Wolter	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).	1987	1010[3]

[3] Exhibit 1009 is the original, foreign language version of Wolter. Citations to Wolter in this decision refer to the English translation in Exhibit 1010.

Name	Description	Date	Exhibit
Grooms	U.S. Patent App. Pub. No. 2002/0138143 A1	Sept. 26, 2002	1003[4]
Paul	U.S. Patent No. 6,258,125 B1	July 10, 2001	1006[5]
Coates	U.S. Patent No. 5,989,289	Nov. 23, 1999	1008[6]
Kozak	U.S. Patent No. 5,397,364	Mar. 14, 1995	1012
Boyce	U.S. Patent No. 6,123,731	Sept. 26, 2000	1011[7]

[4] Petitioner asserts that Grooms claims priority, as a continuation-in-part, to U.S. Patent Application No. 08/920,630 ("the '630 application"), filed August 30, 1997. Pet. 20. Petitioner further asserts that Grooms qualifies as prior art under 35 U.S.C. § 102(e) for its disclosure supported by the written description of the '630 application. *Id.* Patent Owner does not contest that Grooms qualifies as prior art as to the disclosures cited by the Petitioner cited in the Petition. PO Resp. 28, 28 n.5.

[5] Petitioner contends that Paul claims priority to U.S. Provisional Patent Application No. 60/095,209 ("the '209 application"), filed August 3, 1998. Pet. 23. Petitioner asserts that Paul is prior art under 35 U.S.C. § 102(e) as to the disclosure supported by the written description of the '209 application. Patent Owner does not contest that Paul qualifies as prior art. *See generally* PO Resp. 29–30.

[6] Petitioner asserts that Coates is prior art under 35 U.S.C. § 102(e) because the patent issued from an application filed October 9, 1997. Pet. 6. Patent Owner does not contest that Coates qualifies as prior art. *See generally* PO Resp.

[7] Petitioner argues that Boyce qualifies as prior art under 35 U.S.C. § 102(e) because the patent issued from an application filed February 6, 1998. Pet. 6–7. Patent Owner does not contest that Boyce qualifies as prior art. *See generally* PO Resp.

The parties have also provided witness testimony. The table below lists the witnesses, their roles in this proceeding, and the exhibits in which their testimony is presented:

Witness	Role	Exhibits
Michael C. Sherman	Petitioner's technical expert[8]	Ex. 1015 (declaration of Feb. 18, 2019) Ex. 2032 (transcript of deposition of Nov. 7, 2019) Ex. 1026 (declaration of Feb. 25, 2020) Ex. 2092 (transcript of deposition of Mar. 19, 2020)
Jeffrey S. Fischgrund, M.D.	Petitioner's technical expert[9]	Ex. 1016 (declaration of Feb. 18, 2019) Ex. 2031 (transcript of deposition of Oct. 31, 2019) Ex. 1028 (declaration of Feb. 23, 2020) Ex. 2091 (transcript of deposition of Mar. 16, 2020)
John R. Bianchi	Petitioner's fact witness[10]	Ex. 1025 (declaration of Jan. 24, 2020) Ex. 2093 (transcript of deposition of Mar. 26, 2020)

[8] *See* Ex. 1015 ¶ 1 ("I have been retained as an expert witness to offer technical opinions on behalf of RTI Surgical, Inc. . . .").
[9] *See* Ex. 1016 ¶ 1 ("I have been retained as an expert witness to offer technical opinions on behalf of RTI Surgical, Inc. . . .").
[10] *See, e.g.*, Ex. 1025 ¶ 1 ("I continued working for RTI until 2006."); *id.* ¶ 4 ("I can confirm that the [Confidential Memorandum of Understanding in Ex. 1024] is a record kept by RTI personnel in the ordinary course of business.").

Witness	Role	Exhibits
Mark E. Shaffrey, M.D.	Patent Owner's technical expert[11]	Ex. 2001 (declaration of June 6, 2019) Ex. 2028 (declaration of Nov. 26, 2019) Ex. 1037 (transcript of deposition of Feb. 5, 2020)
David L. Kaplan, Ph.D.	Patent Owner's technical expert[12]	Ex. 2002 (declaration of June 6, 2019) Ex. 2029 (declaration of Nov. 25, 2019) Ex. 1038 (transcript of deposition of Jan. 31, 2020)
Barton D. Gaskins	Patent Owner's fact witness[13]	Ex. 2030 (declaration of Nov. 26, 2019) Ex. 1039[14] (transcript of deposition of Jan. 29, 2020)

G. Asserted Grounds

Petitioner asserts that claims 1–15 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–12	103(a)[15]	Wolter in view of Grooms
1, 2, 11, 12	103(a)	Wolter in view of Paul
3–10	103(a)	Wolter in view of Paul and Coates

[11] *See, e.g.*, Ex. 2001 ¶ 1 ("I have been retained by Patent Owner LifeNet Health ("LifeNet") as an expert. . . .").
[12] *See* Ex. 2002 ¶ 1 ("I have been retained as an expert witness on behalf of LifeNet Health. . . .").
[13] *See* Ex. 2030 ¶ 1 ("I am currently a Senior R&D Manager for LifeNet Health. . . ."); *see also* Tr. 61:8–21 (Patent Owner confirming that Mr. Gaskins is a fact witness); Ex. 1022, 14:19–23 (same).
[14] A public, redacted version of the Mr. Gaskins' deposition was filed as Ex. 1044.
[15] 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.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
13	103(a)	Wolter in view of either (1) Grooms or (2) the combination of Paul and Kozak
14	103(a)	Wolter in view of either (1) Grooms in combination with Boyce or (2) Paul in combination with Boyce
15	103(a)	Wolter in view of either (1) Grooms or (2) Paul
1, 2, 11, 12, 14	103(a)	Boyce in view of either (1) Grooms or (2) Paul

See Pet. 5–7.

II. 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. "While the sequence of these questions might be reordered in any particular case," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007), the Federal Circuit has explained that an obviousness determination can be made only after consideration of all of the *Graham* factors. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012).

III. LEVEL OF ORDINARY SKILL IN THE ART

In our Decision on Institution, we adopted Petitioner's proposal that an ordinarily skilled artisan at the time of the invention of the '158 patent would have had the following education and experience:

> 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.

Dec. on Inst. 9–10 (quoting Pet. 16–17).

> 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.

PO Resp. 16 (citing Ex. 2028 ¶¶ 19–24). Patent Owner argues that Petitioner's proposed level of skill in the art is not sufficiently related to the relevant field, as the use of "and/or" in Petitioner's proposal does not require any experience with bone grafts. *Id.* at 17. At the oral hearing, however, Petitioner confirmed that it agrees that an ordinarily skilled artisan must have experience with bone grafts. Tr. 12:25–14:2. Consistent with the parties' agreement on this point, we determine that the level of ordinary skill in the art requires experience with bone grafts, given the focus on composite bone grafts in the '158 patent's claims and disclosure.

Petitioner's proposal requires more education or experience than Patent Owner's proposal. Based on the full record developed during trial, we find that Petitioner's level of education and experience is more consistent with the level of skill reflected in the prior art references of record and the disclosure of the '158 patent. *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). In particular, we are unpersuaded that persons with an undergraduate degree and two years of experience with tissue processing would have 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).

Accordingly, we generally adopt Petitioner's proposed level of ordinary skill in the art but modified to reflect that experience with bone grafts is required. Thus, we determine that the person of ordinary skill in the art would have had at least a bachelor's degree in mechanical, biomechanical, or biomedical engineering or a closely-related discipline, as well as 5–10 years of experience designing and developing orthopedic implants and/or spinal interbody devices and/or bone graft substitutes, at least some of which experience includes working with bone grafts. Alternatively, such a person would typically have had an advanced degree (master's or doctorate) in one of the above-identified fields, as well as 3 to 5 years of experience, at least some of which includes working with bone

grafts. As still another alternative, the person of ordinary skill would be a practicing orthopedic surgeon with at least five years of experience, at least some of which experience includes working with bone grafts.

We also note that the differences between the parties' proposed definition of the level of ordinary skill in the art are not determinative. In that regard, we agree with Patent Owner that the analysis would be materially the same under either party's proposed definition. *See* PO Resp. 18 ("Nevertheless, the analysis of the issues in this proceeding is the same regardless of the level of skill ultimately adopted by the Board").

IV. MOTIONS TO EXCLUDE

A. Petitioner's Motion to Exclude

Petitioner moves to exclude Exhibits 2085 and 2086, which are two claim charts Patent Owner relies on to support its assertions of nexus and copying. *See* Paper 60. As explained below, we determine that Petitioner's obviousness challenges are unpersuasive even without evidence of secondary considerations. Therefore, we dismiss Petitioner's motion as moot.

B. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Exhibits 1015, 1016, 1026, and 1028. For the reasons below, we deny Patent Owner's motion.

1. Exhibits 1015 and 1026

Patent Owner moves to exclude Exhibits 1015 and 1026, which are declarations of Michael C. Sherman. *See* Paper 61. Patent Owner urges the exclusion of Mr. Sherman's testimony pursuant to Federal Rule of Evidence 702. *Id.* at 1; Paper 68, 1. Specifically, Patent Owner argues that Mr. Sherman has insufficient experience regarding composite bone grafts for spinal fusion and that certain opinions he expresses are based on insufficient

facts. Paper 61, 4–12; Paper 68, 2–5. Relatedly, Patent Owner argues that Mr. Sherman's testimony regarding issues to be considered from the perspective of an ordinarily skilled artisan is speculative and therefore inadmissible under Federal Rule of Evidence 402. Paper 61, 4–5, 12.

Petitioner opposes the motion, arguing that Mr. Sherman has extensive experience under any definition of the field of invention and provides testimony with a sufficient factual basis. Paper 65, 7–14.

We are not persuaded that Mr. Sherman's testimony should be excluded. Mr. Sherman holds both a B.S. and M.S. in Biomedical Engineering. Ex. 1015, 181. He has "over thirty years of experience in the medical device industry," including "over twenty years working in orthopedic product development with a particular emphasis on spine implants and instrumentation." *Id.* ¶ 5; *see also id.* ¶¶ 3–8 (describing education and experience related to spinal implants and bone grafts); Ex. 1026 ¶¶ 14–27 (same). His experience includes developing allogenic bone spinal implants and cortical bone screws. Ex. 1026 ¶¶ 19–25. Mr. Sherman testifies that his experience most directly relevant to the design of spinal bone grafts occurred between 1991 and 2006. Ex. 1026 ¶ 14. Thus, Mr. Sherman qualifies as a person of ordinary skill in the art under the definition we have adopted. *See supra* § III.

Moreover, complete overlap between a witness's technical qualifications and the field of the invention is not necessary for the witness's testimony to be admissible under Federal Rule of Evidence 702. For example, the Federal Circuit has upheld a district court's admission under Rule 702 of the testimony of a witness who lacked experience in the design of the patented invention, but had experience with materials selected for use in the invention. *See SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d

1360, 1372–73 (Fed. Cir. 2010); *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019[16] at 34 ("There is . . . no requirement of a perfect match between the expert's experience and the relevant field."). Mr. Sherman has extensive experience and expertise related to spinal implants, including experience related to spinal bone grafts. Ex. 1015 ¶¶ 3, 5–7; Ex. 1026 ¶¶ 14–27. Mr. Sherman's lack of experience specific to composite spinal bone grafts may detract from the weight to be given his testimony on certain matters, but it does not render his testimony inadmissible under Rule 702 or 402.

To support its motion, Patent Owner relies heavily on *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008). *See* Paper 61, 4–11. There, the Federal Circuit reviewed the district court's denial of a motion to exclude a patent lawyer having no relevant technical expertise from testifying in a jury trial. *Sundance*, 550 F.3d at 1361–62. The Federal Circuit held that because the patent attorney "was never offered as a technical expert, and in fact was not qualified as a technical expert, it was an abuse of discretion for the district court to permit him to testify as an expert on the issues of noninfringement or invalidity." *Id.* at 1362. The Federal Circuit further explained:

> The court, in its role as gatekeeper, must exclude expert testimony that is not reliable and specialized, and which invades the province of the jury to find facts and that of the court to make ultimate legal conclusions. Allowing a patent law expert without any technical expertise to testify on the issues of infringement and validity amounts to nothing more than advocacy from the witness stand.

[16] *Available at* www.uspto.gov/sites/default/files/documents/tpgnov.pdf.

Id. at 1364–65. Here, Mr. Sherman is offered as a technical expert, and he has substantial technical expertise related to the field of the '158 patent. Moreover, in this proceeding, fact-finding and legal determinations are carried out by the same panel of administrative patent judges, which eliminates the concern of invading the jury's province. These distinctions make *Sundance* inapposite as a basis for excluding Mr. Sherman's testimony.

For the foregoing reasons, we deny Patent Owner's motion to exclude Exhibits 1015 and 1026.

2. Exhibits 1016 and 1028

Patent Owner moves to exclude Exhibits 1016 and 1028, which are declarations of Jeffrey S. Fischgrund, M.D. *See* Paper 61. Patent Owner asserts that Dr. Fischgrund's testimony regarding the state of the art prior to January 1999 should be excluded pursuant to Federal Rules of Evidence 702 and 402 because they are not based on sufficient facts. *Id.* at 5, 13–14; Paper 68, 5. In opposition, Petitioner counters that Dr. Fischgrund's testimony is based on his personal knowledge and experience. Paper 65, 13–14 (citing Ex. 1016 ¶ 11, 32–46; Ex. 1028 ¶ 3–4, 8–11; Ex. 2091, 110:9–13).

We are not persuaded that Dr. Fischgrund's testimony should be excluded. Dr. Fischgrund testifies that he has performed spinal fusion surgery since 1993, and has performed over 5,000 spinal and cervical fusions in his career. Ex. 1016 ¶ 11. Dr. Fischgrund states that his knowledge regarding the state of the art is based on the "compendium of my knowledge of the state-of-the-art, my practice, my partners' practice, my knowledge in the field, and expertise in the field." Ex. 2091, 110:9–13. Moreover, Dr. Fischgrund cites to contemporaneous publications to support

his testimony regarding the state of the art throughout the 1980s and 1990s. Ex. 1028 ¶¶ 9–10. Patent Owner's arguments go to the weight to be given Dr. Fischgrund's testimony, not its admissibility. Accordingly, we deny Patent Owner's motion to exclude Exhibits 1016 and 1028.

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, 51,358 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)).[17] 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).

The only term that requires express construction is "composite bone graft." That phrase appears in each of the challenged claims. In the Decision on Institution, we preliminarily construed "composite bone graft" to mean "a bone graft which is made up of two or more distinct bone portions," which is the definition in the '158 patent and the construction proposed by Petitioner. Dec. on Inst. 11–12 (citing Ex. 1002, 12:49–51; Pet. 17). Following institution, Patent Owner agreed with that construction. PO Resp. 19. Therefore, we maintain the construction of "composite bone

[17] The Petition in this case was filed February 19, 2019. *See* Paper 3, 1.

graft" in our Decision on Institution, which construction is agreed on by both parties and supported by the intrinsic record.

The parties also propose different meanings for the term "[cortical/cancellous] bone portion." *See* PO Resp. 19 (proposing "distinct piece(s) of bone made solely of [cortical or cancellous] bone"); Pet. Reply 2 (proposing "part or piece of [cortical/cancellous] bone"). We determine that we need not construe "[cortical/cancellous] bone portion" because even assuming that this limitation is taught by the references Petitioner relies upon, we still are not persuaded that Petitioner has demonstrated obviousness for the reasons discussed below. Thus, construing "[cortical/cancellous] bone portion" is not necessary to resolve the parties' dispute. *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).

VI. OBVIOUSNESS GROUNDS LED BY WOLTER

Wolter is the primary reference in each of Petitioner's first six grounds. Each of Petitioner's obviousness challenges led by Wolter relies on a base combination of Wolter with a reference that teaches a bone pin, either Grooms or Paul. As discussed in greater detail below, Petitioner's proposed combination involves converting Wolter from an autograft to an allograft and substituting a bone pin (from Grooms or Paul) for Wolter's metal screw. Petitioner's arguments regarding the motivation to modify Wolter in those ways are common to all of the Wolter-led grounds. *See* Pet. 27–28, 42–43, 46–47, 53, 57, 62–63; Tr. 35:13–17. Likewise, Patent Owner presents the same arguments concerning motivation for the Wolter and

Grooms combination as for the Wolter and Paul combination. *See* PO Resp. 35–48. Our discussion below focuses on these disputed issues regarding the motivation to combine Wolter with Grooms or Paul, which issues are dispositive of all of the Wolter-led grounds.

A. 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 challenges 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. *Id.* at 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.

Id. at 5 (citations omitted).

In preparing the sandwich block transplant, Wolter discloses that "[o]nly 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." *Id.* at 9.

B. 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 bread-loaf-shaped structure having a canal into which osteogenic, osteoinductive, or osteoconductive materials may be packed, which sustains spinal loads, and which is remodeled into the spine in the course of fusion." *Id.* ¶ 9. Figure 8A of Grooms is reproduced below:

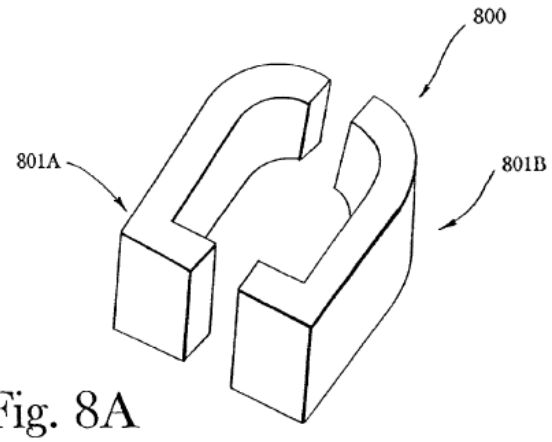

Fig. 8A

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. Grooms discloses that the implant may be made of autograft or allograft bone. *Id.* ¶ 24.

C. 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:

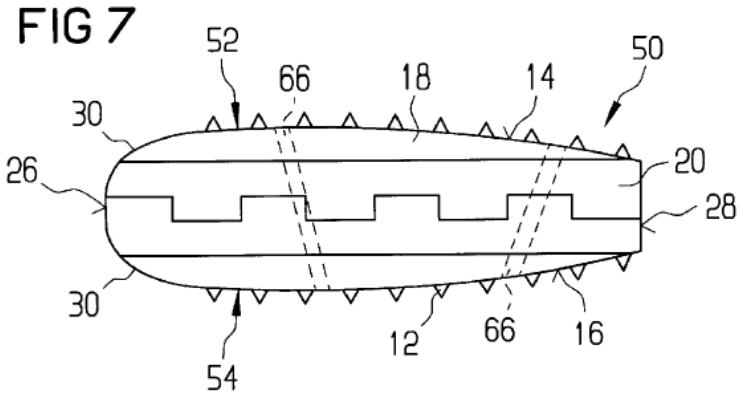

Figure 7 shows a side view of implant 50. *Id.* at 3:1. Implant 50 includes top and bottom portions 52, 54, which are retained together with pins 64 passing through aligned holes 66. *Id.* at 4:58–60. "Although pin 64 can be made of any biocompatible material, pin 64 is preferably made of allogenic bone." *Id.* at 4:60–62.

D. Analysis of Petitioner's Proposed Combinations Based on Wolter

1. Claim 1

a) Petitioner's Proposed Combination

Petitioner contends in Ground 1 that Wolter teaches each limitation of claim 1, except for the limitation of one or more bone pins to hold together portions of the graft. *See* Pet. 27–31, 42–45. Petitioner asserts that Grooms teaches the bone pin limitation, and that an ordinarily skilled artisan would have been motivated to incorporate that feature from Grooms into Wolter. *Id.* at 29–30. Petitioner also contends in Ground 2 that Paul teaches the bone pin limitation, and that an ordinarily skilled artisan would have been motivated to incorporate that feature from Paul into Wolter. *Id.* at 42–45.

In the Decision on Institution, we noted that the specific manner in which Petitioner proposes to combine Wolter with Grooms in Ground 1 was unclear. Dec. on Inst. 21. In particular, we explained that "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." *Id.* As to the former possibility, our assessment based on the preliminary record was that Petitioner had not shown a sufficient motivation or reasonable expectation of success for that manner of combining Wolter and Grooms. *Id.* at 21–23. But we understood Petitioner's challenge to encompass combinations in which Wolter's implant, including a bone pin, was made from allogenic bone, and as to that second possibility, we determined that Petitioner had made a sufficient showing regarding motivation and reasonable expectation of success to justify institution. *Id.* at 23–25. We also determined that, for Ground 2, "Petitioner's arguments . . . make it clear that the proposed combination modifies Wolter to be an allograft" in light of Paul. *Id.* at 27.

Following institution, Patent Owner disputed that one of ordinary skill in the art would have been motivated to combine the bone pins of Grooms or Paul with Wolter. *See* PO Resp. 35–48. Patent Owner's motivation arguments addressed three potential ways of combining Wolter with Grooms or Paul: first, an autograft implant from Wolter with an autologous bone pin from Grooms (*id.* at 37–38); second, an autograft implant from Wolter with an allogenic bone pin from Grooms (*id.* at 38–42); and third, an allograft implant based on Wolter with an allogenic bone pin from Grooms or Paul (*id.* at 42–48).

In its Reply, Petitioner asserted that its position "has always been that it would have been obvious to make the Wolter graft from allogenic bone." Pet. Reply 9.[18] With that clarification, we need not address potential combinations in which Wolter remains an autograft because Petitioner has made clear that its challenge is based on modifying Wolter to an allograft.

b) Summary of Parties' Arguments Regarding Motivation

Petitioner argues that an ordinarily skilled artisan "would have known that the Wolter graft could be advantageously prepared from allograft bone . . . 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); *see also id.* at 42 ("By the late 1990s, . . . it was well-accepted that the preparation of spinal implants from allograft bone . . . was preferred to the use of autograft bone.") (citing Ex. 1016 ¶¶ 36–39). Petitioner argues that at the time of the '158 patent's invention in 1999, allografts were a known alternative that avoided morbidity associated with harvesting autograft bone. Pet. Reply 10 (citing Ex. 1015 ¶¶ 317–318; Ex. 1037, 20:15–19, 37:12–18; Ex. 1039, 131:11–12). According to Petitioner, Wolter would not have led ordinarily skilled artisans away from allograft bone because by 1999, allograft implants were widely used and Wolter's reasons for using exclusively autograft bone "were outdated." *Id.* at 11 (citing Ex. 1028 ¶¶ 12–17). Petitioner points to testimony from Dr. Shaffrey that "in the time of 1999, there was a significant move away from using autologous bone." *Id.* (quoting Ex. 1037, 89:12–91:9); *see also*

[18] Furthermore, Petitioner did not present any argument in its Reply or at oral argument directed to a combination in which Wolter remains an autograft. *See generally* Pet. Reply; Tr. 33:22–35:17.

id. at 12 (disputing Patent Owner's assertion that autograft was preferred to allograft at the time of the invention) (citing Ex. 1039, 128:2–129:5).

As to replacing Wolter's metal screw with a bone pin, Petitioner argues that an ordinarily skilled artisan would have been motivated to make that substitution in order to eliminate a permanent foreign body in the patient's spine and to avoid potential complications from loosening of the screw. Pet. 27–28 (citing Ex. 1015 ¶¶ 300, 348); *see also id.* at 42 (same arguments as to combination of Wolter and Paul). Petitioner further argues that an ordinarily skilled artisan "would have had a reasonable expectation of successfully making such a substitution because Grooms discloses that bone pins are suitable to secure distinct portions of a composite bone graft together." *Id.* at 30 (citing 1015 ¶¶ 77–79); *see also id.* at 42–43 (same argument as to combination of Wolter with Paul's bone pin). Petitioner contends that a bone pin of sufficient strength could be made and inserted into Wolter's graft. *See* Pet. Reply 13–15.

Patent Owner disputes that ordinarily skilled artisans would have been motivated to make either of the changes to Wolter that Petitioner proposes. Regarding converting Wolter from an autograft to an allograft, Patent Owner argues that "Wolter explicitly teaches away from making its graft configuration from allogenic donor bone." PO Resp. 44 (citing Ex. 1010, 4, 9). And Patent Owner argues that autografts remained the gold standard even in 2009, so ordinarily skilled artisans at the time of the invention would not have "overlook[ed] Wolter's disavowal of allogenic bone." PO Resp. 44–45; *see* Sur-Reply 11–12.

With respect to substituting a bone pin for Wolter's metal screw, Patent Owner argues that Wolter's stacking of three pieces of iliac crest would prevent a precise fit, which negatively affects stability and detracts

from Petitioner's arguments regarding motivation and reasonable expectation of success. PO Resp. 43; Sur-Reply 13. Patent Owner further argues that a bone pin impelled through three stacks of iliac crest allografts, as Petitioner proposes, would break and could not withstand the compressive forces imposed by Wolter's configuration. PO Resp. 44; Sur-Reply 14–15.

c) Analysis of Motivation to Combine

We agree with Patent Owner that Petitioner has not shown persuasively that a skilled artisan would have been motivated to make the proposed modifications to Wolter, or would have reasonably expected success in doing so. Our discussion below separately addresses the two modifications Petitioner proposes to make to Wolter's graft.

(1) Modifying Wolter to Allograft

Looking first at Petitioner's modification of Wolter from an autograft to an allograft, we find that Wolter teaches away from using allogenic bone because it repeatedly emphasizes that only autologous bone should be used. *See KSR*, 550 U.S. at 416 (explaining that when the prior art teaches away from a combination, that combination is more likely to be nonobvious); *see also* PO Resp. 44 (arguing that Wolter teaches away); Sur-Reply 10 (same). In the first sentence of the article, Wolter discloses that "[a]utologous bone transplantation represents . . . the most important measure for achieving the surgical objective." Ex. 1010, 4. "The use of exclusively autologous bone material therefore appears to be necessary" for several reasons, including that "[a]utologous bone material represents, in accordance with the general view, the best transplant material." *Id.* Wolter returns to this point in its Summary section at the end of the article, explaining again that "[o]nly 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." *Id.* at 9. And each of the three forms of transplants that Wolter describes use autologous bone. *Id.* at 5. Petitioner's proposed combination, which requires modifying Wolter's autologous bone graft to an allograft, runs counter to Wolter's explicit teachings that only autologous bone should be used.

Petitioner argues that ordinarily skilled artisans would have understood Wolter's teachings in 1987 to use only autologous bone as "outdated" by 1999 because by then, allografts had been developed and were a well-known and widely used alternative to autografts. Pet. Reply 10–11. Yet the record evidence supports Patent Owner's responsive point that allograft implants were already available, known, and used at the time of Wolter's publication in 1987. *See* Sur-Reply 10. Petitioner's expert, Dr. Fischgrund, testifies that surgeons were aware of allograft becoming more available in the 1980s. Ex. 2091, 116:6–22; *see also* Ex. 1028 ¶ 6 ("[I]n the 1980s, a notable shift in thinking occurred among surgeons, and they began substituting allografts . . . for traditional autograft surgeries.") (quoting Ex. 2035, 1). Dr. Fischgrund took note of a publication showing that in 1985, 5,000–10,000 allograft procedures were performed. Ex. 1028 ¶ 6 (citing Ex. 2035, 1). Dr. Fischgrund agreed that a surgeon who published or wrote journal articles would have known of the availability of allograft implants in the late 1980s. Ex. 2091, 121:9–16. Dr. Wolter was the head physician in the Department for Accident, Restoration and Manual Surgery at the St. Georg General Hospital and a journal editor. Ex. 1010, 1–2, 4. Despite Dr. Wolter fitting Dr. Fischgrund's profile for a person who would have known of the availability of allograft implants, Wolter taught exclusively using autologous bone materials in 1987. Ex. 1010, 4. While Dr. Fischgrund testifies that allografts became more popular between the

mid-1980s and the mid-1990s (Ex. 1028 ¶ 6), the salient point is that allografts were already known, available, and used by the time Wolter was published. Against this backdrop, we are not persuaded by Petitioner's argument that the availability of allografts as an alternative to autografts would have led an ordinarily skilled artisan in 1999 to dismiss Wolter's teachings away from allogenic bone as outdated.

The parties dispute whether ordinarily skilled artisans would have preferred autografts or allografts in 1999. PO Resp. 44–45; Pet. Reply 12; Sur-Reply 11–13. Patent Owner presents testimony and contemporaneous articles showing that autografts were the "gold standard" at that time and for some years afterward. *See* Ex. 2012, 4; Ex. 2039, 1; Ex. 2011, 1; Ex. 2035, 1; Ex. 2005, 2; Ex. 2014, 1–2; Ex. 2028 ¶¶ 107–109. Petitioner presents countervailing evidence, including cross-examination testimony from Patent Owner's witnesses, suggesting that a shift toward allogenic sources had taken root by 1999. *See* Ex. 1037, 89:12–91:9; Ex. 1039, 128:2–129:5; Ex. 1028 ¶ 8. While the record includes evidence supporting both parties' contentions, Patent Owner's collection of numerous publications from the late 1990's through the next decade describing autografts as the gold standard represents a strong showing that in 1999, autografts were the more widely studied and accepted option. *See* Ex. 2091, 132:24–133:5. However, we need not decide whether ordinarily skilled artisans in 1999 preferred autografts or allografts in the abstract. The pertinent question is narrower and more focused: whether an ordinarily skilled artisan in 1999 would have been motivated to modify Wolter's autograft to an allograft.

On that question, we are not persuaded that if ordinarily skilled artisans in 1999 were interested in creating an allograft, they would have begun with Wolter, an obscure reference from 12 years earlier, and adapted

it to an allograft against the reference's teachings. *See* PO Resp. 27 ("Wolter's graft was not accepted or even well-known in the industry in 1999"). Dr. Shaffrey testifies that in the more than 30 years since its publication, only four German papers have cited Wolter. Ex. 2028 ¶ 74 n.5. Despite their substantial experience, none of Mr. Sherman, Dr. Fischgrund, or Dr. Shaffrey were familiar with Wolter before this case began. *See* Ex. 2032, 107:8–18 (Mr. Sherman testifying that he had no memory of having read Wolter before this case); Ex. 2091 (Dr. Fischgrund testifying that he first saw Wolter in late 2018); Ex. 2001 ¶ 48 (Dr. Shaffrey testifying that "I am not aware of anyone performing the procedure in Wolter where multiple blocks are stacked and connected with a metal screw and inserted into the patient's spine.").

Wolter uses autologous bone that is harvested and then implanted in a single procedure. Ex. 1010, 5 ("Both operating areas are covered simultaneously, so that the removal of the bone material can be carried out either in a staggered manner or simultaneously with the vertebral column operation."); Ex. 1015 ¶ 43 ("As disclosed by Wolter, autologous bone is taken from the patient at the time of surgery for use as a transplant."); PO Resp. 24 ("Wolter's procedure follows the traditional Smith-Robinson methods and principles of harvesting and transplanting autografts."); Ex 2028 ¶ 75 (same). In such procedures, surgeons seek to limit the harvest-to-implant time to the extent possible. Ex. 2028 ¶ 39; Ex. 2031, 47:4–19. Dr. Shaffrey testifies that once a bone block has been removed from the patient's iliac crest, "[a]ny time spent on modifying the block means extended operative times, which translates to potentially higher risks and complications for the patient." Ex. 2028 ¶ 39. Dr. Fischgrund testifies that typically in a Smith-Robinson procedure, "it should take less than five

minutes to revise a graft after you cut it." Ex. 2031, 48:5–10. Aside from time constraints, Dr. Shaffrey explains that "the type of instruments we have available in the operating room for shaping bone are very, very rudimentary and difficult." Ex. 1037, 90:25–91:2.

Wolter's teaching to stack together pieces of iliac crest in a sandwich block is a way of filling out a large defect with an autograft that can be created during surgery. Ex. 1010, 5; Ex. 1015 ¶¶ 44, 49; Ex. 2028 ¶¶ 76–77, 79. Allografts need not be fashioned in an operating room during a time-limited procedure because "[t]hey are harvested from donated bone of a cadaver." Ex. 2028 ¶ 41; *see also* Ex. 2032, 131:17–132:11 (Mr. Sherman testifying that in the proposed modification of Wolter to an allograft, it could be manufactured "in a more refined setting," and it is "unlikely to be done" in an operating room because it "wouldn't be an efficient use of an operating room"). Thus, as Dr. Fischgrund testifies, "[a]llograft bone can be cut, machined and assembled to specific configurations and sizes. . . ." Ex. 1016 ¶ 38. Considering these differences, we are not persuaded that an ordinarily skilled artisan seeking to make an allograft in 1999 would have turned to Wolter, which was tailored to the demands of filling a large defect using an autograft that can be made during surgery. *See* Sur-Reply 14 (arguing that "[t]here is no record evidence that a POSA would have made an allograft having the structure of Wolter's allograft").

While Wolter's sandwich block may have been expedient and suitable for the application in which it was intended, we find persuasive Dr. Shaffrey's blunt assessment that "it makes no sense to make an allograft by stacking two or three iliac crest bones." Ex. 2028 ¶ 104. As Dr. Shaffrey explains, the irregular surfaces of the iliac crest would impede a precise fit at the interfaces of the sandwich block. *Id.* ¶ 105; *see also* Ex. 1037, 90:20–24

(Dr. Shaffrey explaining in cross-examination testimony that "iliac crest is very difficult to work with" and getting pieces of iliac bone "to fit together is extremely challenging and time-consuming"); Ex. 2032, 112:23–113:14 (Mr. Sherman explaining that Wolter's graft would not easily rotate, one section to the other, because of the "slanted . . . and irregular surfaces" of the bone portions that are in contact with each other in the middle of the graft). And an imprecise fit, Patent Owner convincingly notes, would negatively impact the stability of the graft. PO Resp. 43 (citing Ex. 2030 ¶ 27).

Dr. Shaffrey testifies, with citation to several publications, that a more linear and precise fit would be provided using long bone, which has been the traditional source of allograft bone. Ex. 2028 ¶ 105. Dr. Shaffrey's testimony is supported by Dr. Fischgrund's cross-examination testimony that he has never used an allograft version of Wolter's sandwich block because he "didn't have to," and instead he "found other ways of using allograft" — namely, stacking pieces of long bone. Ex. 2091, 127:15–128:10; *see also id.* at 77:18–21 (testifying that before switching to PEEK cages in 2008, "when you had a large bony defect and you needed something bigger, the fibular allograft was the best option").

For these reasons, we are not persuaded that ordinarily skilled artisans would have been motivated to modify Wolter's sandwich block to be an allograft.

(2) Substituting Bone Pins for a Metal Screw

In addition to converting Wolter to an allograft, Petitioner also proposes to substitute a bone pin for Wolter's metal screw. For the following reasons, we agree with Patent Owner that Petitioner has not shown that an ordinarily skilled artisan would have been motivated to make that substitution, or would have reasonably expected success in doing so.

At the outset, we note that the Petition presents reasons for the substitution that are rational when considered in isolation. *See* Pet. 27–28 (citing Ex. 1015 ¶ 300) (arguing that replacement with bone pin would eliminate permanent foreign body in the patient's spine and avoid potential complications from loosening of the bone screw). However, the arguments and evidence of record lead us to conclude that these potential benefits would not have motivated the proposed combinations, considering the disclosure of the references and the technical obstacles that an ordinarily skilled artisan would have expected to encounter in making the proposed substitution.

Petitioner's and Patent Owner's witnesses are in agreement that bone pins are weaker than the metal bone screws that Wolter teaches. *See* Ex. 1010, 5; *see also* Ex. 1015 ¶ 45 (Mr. Sherman summarizing that in Wolter, the graft is assembled "by securing its several sections together with small-fragment cancellous bone screws"); Ex. 2032, 112:15–17 (Mr. Sherman agreeing that a small-fragment cancellous bone screw is a metal screw). Dr. Shaffrey testifies that "a bone pin is significantly weaker than a metal screw." Ex. 2028 ¶ 103; *see also id.* ¶ 102 (explaining that allograft bone pins are brittle due to extensive processing prior to use). Mr. Gaskins elaborates on that point, explaining that "[m]etal screws like cancellous bone screws are much stronger than bone pins and can be created in much larger sizes because they can be fabricated in virtually any size. Bone pins have to be very small because they need to be sourced from a unitary piece of donor bone." Ex. 2030 ¶ 16. Mr. Sherman agreed in his cross-examination testimony that a small-fragment cancellous bone screw is stronger than a cortical bone pin in all axes. *See* Ex. 2032, 114:2–7. Thus, we agree with Patent Owner that the proposed substitution of a bone pin for a metal screw

runs counter to Wolter's goal to fulfill a recognized need for "a transplant that is as large and stressable as possible." Ex. 1010, 5; PO Resp. 47–48; Sur-Reply 15.

Moreover, Patent Owner persuasively argues that technical difficulties would have impaired the use of a bone pin in a graft of Wolter's configuration, which undermines Petitioner's motivation arguments as well as its argument that skilled artisans would have reasonably expected success. *See* PO Resp. 39, 43. In particular, the evidence supports Patent Owner's argument that Wolter's stack of three large, irregularly shaped pieces of iliac bone would be difficult to precisely line up for a bone pin, and it is doubtful that a bone pin could withstand the force needed to impel a bone pin through the three sections and their irregular interfaces. *See id.* As discussed above, Dr. Shaffrey and Mr. Sherman both describe the surfaces of the iliac bone sections that are joined together in Wolter's sandwich block as "irregular." Ex. 2028 ¶ 105; Ex. 2032, 112:23–113:14. That description is consistent with the photographs of the sandwich block in Wolter itself. Ex. 1010, 10 Figs. 1(e)–(f).

As Mr. Gaskins explains, bone pins stabilize allografts through an "interference fit," which requires a bone pin to be inserted into a hole that is slightly smaller than the diameter of the bone pin. Ex. 2030 ¶ 20.[19]

[19] While we recognize that Mr. Gaskins is a fact witness (*see supra* note 12), we note that Petitioner did not move to exclude this aspect, or any other aspect, of Mr. Gaskins' testimony under Federal Rule of Evidence 701. Moreover, the testimony appears to be within the scope of Mr. Gaskins' experiences and observations. *See, e.g.*, Ex. 2030 ¶ 23 ("I have personally spent hundreds of hours . . . with many failures and many broken pins, working out the right dimensions of the bone pins and the holes into which they are inserted.").

Successfully creating this interference fit requires machining the bone pin and the hole in the graft "to a high level of precision." *Id.* Mr. Gaskins further explains that "[e]ach additional bone piece makes it more difficult to hold the pieces in alignment when drilling a hole through the graft pieces and when pressing the bone pins through that hole." *Id.* ¶ 26. Mr. Gaskins testifies that irregularities in the cortical surface of bone increase the probability that a bone pin will break when it is impelled through a large number of layers that each have irregular interfaces. *Id.* ¶ 28. Mr. Gaskins' testimony regarding the precision required for inserting bone pins and bone pins' sensitivity to irregular interfaces is supported by Grooms, which describes extensive machining of the components of the implant before a bone pin is inserted. *See* Ex. 1003 ¶¶ 28–33, 48–49; *see also* Ex. 1006, 4:46–63 (Paul, Petitioner's other bone pin reference, which also describes machining before inserting bone pin). We credit Dr. Shaffrey's testimony that an ordinarily skilled artisan would not expect success in pushing an allograft bone pin through Wolter's graft because passing a bone pin through "the thick bone tissue and across the irregular interfaces of the iliac crest would be considered unfeasible by a POSA." Ex. 2028 ¶ 102.

Petitioner argues that we should discard Dr. Shaffrey's testimony as irrelevant because it only relates to "a surgeon's ability to *manually* perform that procedure on *autograft bone* in an operating room. He did not address the ability of a POSA to insert a bone pin into a Wolter-style graft prepared pre-operatively from *allograft bone* using technologies known at the time." Pet. Reply 14. But in the ensuing section of Dr. Shaffrey's declaration, which addresses the possibility of turning Wolter's autograft into an allograft with an allograft bone pin, Dr. Shaffrey testifies that "using a bone pin to hold three stacked iliac crest allografts together would not work for

the same reasons I have discussed with respect to an autograft." Ex. 2028 ¶ 106. And Petitioner does not explain how "technologies known at the time" of the '158 patent's invention would have resolved the difficulties on which Dr. Shaffrey's testimony is based. Moreover, Mr. Gaskins' testimony regarding the difficulties of inserting a bone pin into a graft does discuss technologies known at the time the '158 patent was invented. Ex. 2030 ¶ 17–18, 22, 26–28.

As to Mr. Gaskins, Petitioner argues that he merely testifies that the Wolter graft's configuration "'makes it more difficult' to insert pins and 'increases the probability' that a pin will break" but does not testify that ordinarily skilled artisans "would have been incapable of inserting an appropriate bone pin into the Wolter graft." Pet. Reply 15. Yet defending against obviousness does not require proof that the proposed combination would have been impossible to make. The relevant question is not impossibility or incapability, it is whether ordinarily skilled artisans would have had a "reasonable expectation of success" in pursuing the proposed combination. *Los Angeles Biomedical Research Institute v. Eli Lilly & Co.*, 849 F.3d 1049, 1064 (Fed. Cir. 2017). Mr. Gaskins' testimony regarding the difficulty of inserting the bone pin and the increased probability of a bone pin breaking supports Patent Owner's contentions that one of ordinary skill in the art would not have been motivated to replace a stronger metal screw with a weaker bone pin, and would not have had a reasonable expectation of success in doing so.

Petitioner also argues that the iliac crest bone can provide the "precise fit" to make an allograft composite bone graft because both the '158 patent and Wolter disclose using ilia bone. Pet. Reply 15 n.2. But the composite graft of the '158 patent and the sandwich block graft of Wolter are not

similar in their construction. The '158 patent describes stacking machined pieces of bone. Specifically, the '158 patent forms cortical bone planks 69 and 70 by cutting sections of cortical bone multiple times and smoothing the bone to achieve a parallel plank of predetermined dimensions. Ex. 1002, Fig. 11A, 16:55–17:13. Cancellous bone blanks are produced in a similar manner. Ex. 1002, Fig 11B, 17:21–24.[20] The machined and smoothed planks permitting the use of a bone pin in the '158 patent are not similar to Wolter's graft, in which three pieces of iliac crest bone are stacked and screwed together. Ex. 1010, 5. Given the differences between the preparation of the graft in the '158 patent and Wolter, Petitioner's reliance on the '158 patent does not persuade us that an ordinarily skilled artisan would have reasonably expected success in using a bone pin rather than a metal screw to join Wolter's graft together.

Accordingly, we determine that Petitioner has not shown that an ordinarily skilled artisan would have been motivated to substitute a bone pin for Wolter's metal screw, or would have reasonably expected success in doing so.

d) Conclusion

Aside from the issues discussed above, the parties also dispute whether the proposed combination discloses each limitation of claim 1. *See* PO Resp. 31–34; Pet. Reply 5–8; Sur-Reply 6–9. We need not decide those disputed issues because even if we were to agree with Petitioner that the combinations teach every limitation of claim 1, Petitioner's obviousness arguments would still fail because of the deficiencies discussed above

[20] Similarly, Grooms and Paul also describe machining of the components of the implant before a bone pin is inserted. *See* Ex. 1003 ¶¶ 28–33, 48–49; Ex. 1006, 4:46–63.

regarding motivation to combine and reasonable expectation of success. *See, e.g., Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (affirming Board's determination that claims were not shown to be obvious because the petitioner had not demonstrated that an ordinarily skilled artisan would have been motivated to combine the references).

We also need not consider whether Patent Owner's evidence of secondary considerations weighs further against a conclusion of obviousness. *See, e.g., See Otsuka Pharmaceutical Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("Because we agree with the district court that the Defendants failed to prove that claim 12 of the '528 patent would have been prima facie obvious over the asserted prior art compounds, we need not address the court's findings regarding objective evidence of nonobviousness."); *Palo Alto Networks, Inc. v. Finjan, Inc.*, 748 F. App'x 317, 324 (Fed. Cir. 2018) ("The Board, having found that Finjan had failed to carry its burden of showing that the instituted prior art disclosed [a particular] limitation, did not reach the issue of secondary considerations of nonobviousness. Therefore, it was not necessary for the Board to consider Dr. Bims's testimony, which was limited to the issue of secondary considerations of nonobviousness.").

We determine that Petitioner has not shown by a preponderance of the evidence that claim 1 would have been obvious to a person of ordinary skill in the art based on the combination of Wolter and Grooms or Wolter and Paul.

2. Claims 2–15

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. Claim 2, therefore, is narrower than claim 1. Claims 3–12 depend

directly or indirectly from claims 1 and 2. Petitioner does not cite to any additional evidence or present any additional arguments that address the deficiencies concerning claim 1. Instead, Petitioner only addresses the additional limitations in claims 2–12. *See* Pet. 32–41, 45–52; Pet. Reply 15–21.

For the same reasons set forth above regarding claim 1, we also determine that Petitioner has not shown by a preponderance of the evidence that: (1) claims 2–12 would have been obvious to a person of ordinary skill in the art based on the combination of Wolter and Grooms, (2) claims 2, 11, and 12 would have been obvious to a person of ordinary skill in the art based on the combination of Wolter and Paul, and (3) claims 3–10 would have been obvious to a person of ordinary skill in the art based on the combination of Wolter, Paul, and Coates. *See supra* § VI.D.1.

The Petition also challenges claims 13–15 based on combinations of either Wolter in view of Grooms or Wolter in view of Paul. Petitioner's asserted motivation for an ordinarily skilled artisan to modify Wolter to be made of allogenic bone and to substitute Wolter's metal screw with a bone pin underlies these grounds as well. *See* Pet. 53, 57, 62–63; Tr. 33:16–35:17. Petitioner does not cite to any additional evidence or present any additional arguments that address the deficiencies concerning claim 1. *See* Pet. 53–65; Pet. Reply 21–24.

For the same reasons discussed above with respect to claim 1, we determine that Petitioner has not shown by a preponderance of the evidence that it would have been obvious to modify Wolter to be made of allogenic bone and to substitute Wolter's metal screw with a bone pin. *See supra* § VI.D.1. Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that claims 13–15 would have been obvious

based on combinations of either Wolter in view of Grooms or Wolter in view of Paul.

VII. OBVIOUSNESS GROUND LED BY BOYCE

Petitioner challenges claims 1, 2, 11, 12, and 14 as obvious over Boyce in view of either (1) Grooms or (2) Paul. Pet. 65–76; Pet. Reply 24–26. Patent Owner disputes these challenges. PO Resp. 59–61; Sur-Reply 25.

A. 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, code (57) (Abstract). Figure 6 of Boyce is reproduced below:

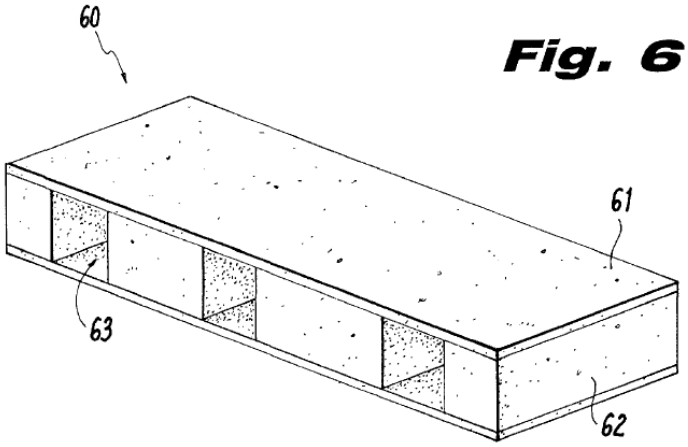

Figure 6 is a perspective view of osteoimplant 60.
Id. at 3:37–39.

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.

B. Analysis

1. Claims 1, 2, and 14

Independent claims 1, 2, and 14 each recite a bone pin to hold a composite bone graft together, and further recite that the composite bone graft is not demineralized. Ex. 1002, 45:1–23, 46:55–48:8. Petitioner contends that Boyce teaches each limitation of claims 1, 2, and 14, except for one or more bone pins and a composite bone graft that is not demineralized. *See* Pet. 67–76. Petitioner asserts that Boyce teaches adding mechanical fasteners to increase the graft's "shape-retaining and/or mechanical strength characteristics," so it would have been obvious to eliminate Boyce's chemical cross-linking and instead use only the bone pins of Grooms or Paul to hold the graft together. Pet. 68–69; Pet. Reply 26. Petitioner further asserts that in the combination of Boyce and Grooms or Paul, one of ordinary skill in the art would not demineralize the bones of the graft because demineralization is known to weaken bone. Pet. 70 (citing Ex. 1015 ¶ 28); Pet. Reply 25. Patent Owner counters that substituting a bone pin in place of Boyce's chemical crosslinking would destroy Boyce's principle of operation and intended purpose. PO Resp. 59–61; Sur-Reply 25.

We find that Petitioner has not shown that one of ordinary skill in the art would have been motivated to modify Boyce in the proposed manner.

Chemical crosslinking is a central feature of Boyce's disclosure, which Boyce describes as the basis for the advantages its graft achieves. The first sentence of the Summary of the Invention describes "an osteoimplant which, *due to chemical linkages* formed between the surface-

exposed collagen of adjacent partially demineralized bone elements from which the osteoimplant is manufactured, exhibits good mechanical strength" and has other beneficial features. Ex. 1011, 1:66–2:3 (emphasis added). The first sentence of the Description of the Preferred Embodiments similarly states that the osteoimplant "comprises a solid aggregate of bone-derived elements having chemical linkages between their surface-exposed collagen molecules[,] thus bonding adjacent bone elements to each other." *Id.* at 3:53–56. The Abstract and the Field of the Invention also highlight that the implant is made from bone derived elements bonded to each other through chemical linkages between their surface-exposed collagen. *Id.* at code (57) (Abstract), 1:10–14. Throughout its disclosure, Boyce repeatedly emphasizes that the layers of its graft are bonded to each other through chemical linkages and provides a detailed description of chemical cross-linking techniques. *Id.* at 6:28–7:49, 8:16–40. Boyce describes its figures as showing crosslinked bone sections, and describes crosslinking in each of its five examples. *Id.* at 7:62–65, 8:22–23, 8:39–40, 8:56, 9:12,[21] 9:26, 9:42–43, 9:54. Indeed, Petitioner candidly acknowledges that "[t]his chemical cross-linking process is the asserted invention of Boyce." Pet. 68; *see also* Pet. Reply 24.

Demineralization is also necessary in Boyce's process. Boyce teaches that in order to crosslink the bone elements, they "must be at least partially demineralized" to expose the collagen at their surface. *See* Ex. 1011, 3:56–58; *see also id.* at 3:4–6 (defining "surface-exposed collagen" to mean "the

[21] Unlike the other examples, Example 2 does not use the term crosslinking, but it describes placing the osteoimplant in polyethylene glycol diglycidyl ether for 12 hours, which Boyce lists as a crosslinking agent. *See* Ex. 1011, 9:12–13, 6:55.

result obtained by demineralizing the aforementioned bone-derived elements").

Against this backdrop, Petitioner's proposal eliminates the main feature that Boyce teaches. We find persuasive Patent Owner's argument that Petitioner's proposed modification to Boyce of removing the chemical linkage between the surface-exposed collagen of adjacent layers of bone elements would be inconsistent with Boyce's central purpose and its principle of operation. *See* PO Resp. 60; *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 759 (Fed. Cir. 2015) (determining that a combination that removed a system's stop valves fundamentally altered the system's principle of operation when the reference disclosed that the invention was directed to a system that added stop valves to prevent backflow); *see also In re Ratti*, 270 F.2d 810 (Fed. Cir. 1959) (concluding that a combination requiring a substantial reconstruction and redesign of elements in a reference changed the reference's basic principles of operation).

We also note that Boyce was considered during prosecution of the '158 patent, as the Petition acknowledges. *See* Pet. 65–66. The Examiner rejected the claims as anticipated by Boyce and as obvious over Boyce and another reference. Ex. 1014, 3–6. Patent Owner amended the claims to recite that the bone graft is "not demineralized" and argued that this added limitation distinguished Boyce. *Id.* at 13–14. In response to that amendment, the Examiner allowed the claims. *Id.* at 16. Petitioner argues that the Examiner did not consider Grooms and Paul, which teach "other methods (i.e. bone pins) to secure bone portions together without requiring demineralization." Pet. 66. We are not persuaded that references teaching bone pins materially alter the obviousness analysis over Boyce, because

Boyce itself discloses bone pins. Specifically, Boyce contemplates using pins or other mechanical fasteners with its graft in order to "supplement or increase the shape-retaining and/or mechanical characteristics" of the graft. Ex. 1011, 5:54–57. Petitioner argues that Boyce's teaching regarding mechanical fasteners would motivate a skilled artisan toward the proposed modification because that teaching represents "an acknowledgement of shortcomings of the cross-linking approach." Pet. Reply 26 (citing Ex. 1026 ¶¶ 90–91). We disagree. In our view, Boyce's teaching that pins can be added to supplement the graft's strength casts further doubt on Petitioner's argument that an ordinarily skilled artisan would be motivated to eliminate crosslinking, the main way Boyce teaches to provide a strong graft, and instead use only bone pins, which Boyce teaches can be added to a crosslinked graft to supplement its strength.

We appreciate, as Petitioner points out, that in an obviousness analysis, prior art references are considered for all they teach. *See* Pet. Reply 24. Yet Petitioner has not provided any persuasive reasoning as to why an ordinarily skilled artisan would adopt the structure of Boyce's graft but jettison the crosslinking that is the primary focus of Boyce's teachings. Petitioner argues that an ordinarily skilled artisan would be motivated to eliminate demineralization because it weakens bone. *See* Pet. 67, 69–70; Pet. Reply 25; Ex. 1015 ¶ 501; Ex. 1026 ¶ 91. This argument is unconvincing because it considers demineralization in isolation, whereas Boyce teaches surface demineralization as one step of the overall process—specifically, to prepare the surfaces of the bone pieces for crosslinking. The relevant comparison is not between demineralized bone and bone that has not been demineralized; it is between a graft formed of bone pieces that undergo surface demineralization *and then chemical crosslinking* and a graft

that is not demineralized and joined with a bone pin. Petitioner does not provide persuasive evidence or argument to show that an ordinarily skilled artisan would have expected the former to be weaker than the latter. And as Patent Owner points out, Boyce touts the mechanical strength of the final graft it achieves after demineralization and crosslinking. *See* Ex. 1011, 1:66–2:3, 2:44–47; PO Resp. 60. Thus, we are not persuaded that an ordinarily skilled artisan would have been motivated to eliminate demineralization and crosslinking from Boyce's graft due to a concern that demineralization would weaken the bone.

The Petition also argues, in a cursory fashion, that "improved consistency of strength of the connection between graft pieces" and avoiding the cost and difficulty of demineralization would have motivated the proposed changes to Boyce. Pet. 70; Ex. 1015 ¶ 505. The "improved consistency of strength" motivation is unpersuasive for the same reasons as just discussed. And the purported motivation to avoid cost and difficulty is undeveloped and overly simplistic. Petitioner only asserts that demineralization adds cost and difficulty, but Petitioner's proposal is not to simply eliminate demineralization and keep the rest of Boyce. Petitioner does not show that its proposed combination would be less expensive and difficult overall than Boyce, nor does Petitioner offer any explanation of the performance tradeoffs that would be expected to accompany the proposed changes.

We determine that Petitioner has not made a persuasive showing that one of ordinary skill in the art would have been motivated to substitute Boyce's chemical crosslinkage with bone pins from Grooms or Paul. Accordingly, we determine that Petitioner has not shown by a preponderance

of the evidence that claims 1, 2, and 14 would have been obvious over Boyce in view of Grooms or Paul.

2. Claims 11 and 12

Claims 11 and 12 depend from claim 2. Petitioner's challenge to these claims builds from its arguments regarding claim 2 and, therefore, also requires substitution of Boyce's chemical crosslinkage with bone pins from Grooms or Paul. *See* Pet. 73. For the same reasons just discussed, we also determine that Petitioner has not shown by a preponderance of the evidence that claims 11 and 12 would have been obvious over Boyce in view of Grooms or Paul.

3. Conclusion

We determine that Petitioner has not shown, by a preponderance of the evidence, that claims 1, 2, 11, 12, and 14 would have been obvious over Boyce in view of Grooms or Paul.

VIII. CONCLUSION

Based on the information presented, we conclude that Petitioner has not shown, by a preponderance of the evidence, that claims 1–15 of the '158 patent are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–12	103(a)	Wolter in view of Grooms		1–12
1, 2, 11, 12	103(a)	Wolter in view of Paul		1, 2, 11, 12
3–10	103(a)	Wolter in view of Paul and Coates		3–10
13	103(a)	Wolter in view of either (1) Grooms		13

		or (2) the combination of Paul and Kozak		
14	103(a)	Wolter in view of either (1) Grooms in combination with Boyce or (2) Paul in combination with Boyce		14
15	103(a)	Wolter in view of either (1) Grooms or (2) Paul		15
1, 2, 11, 12, 14	103(a)	Boyce in view of either (1) Grooms or (2) Paul		1, 2, 11, 12, 14
Overall Outcome				1–15

IX. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–15 of the ’158 patent have not been shown to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude is dismissed;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is denied; and

FURTHER ORDERED that parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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