

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

IPR2023-00451
Patent 11,083,511 B2

Before JAMES A. WORTH, *Acting Vice Chief Administrative Patent Judge*,
ZHENYU YANG and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

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

I. INTRODUCTION

PainTEQ, LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”), seeking *inter partes* review of claims 1–23 of U.S. Patent No. 11,083,511 B2 (Ex. 1001, “the ’511 patent”). *See* Pet. 1. We instituted trial on all grounds in the Petition.

Following institution, Orthocision, Inc. (“Patent Owner”) waived its rights to file a response and/or motion to amend and indicated that it would not file any of the other papers contemplated in the Scheduling Order. Paper 15, 2. Petitioner similarly indicated it would not file additional briefing or request oral argument. *Id.* Accordingly, the final record consists of the argument in and evidence submitted with the Petition.

Based on this record, we find that Petitioner has shown by a preponderance of the evidence that the challenged claims of the ’511 patent are unpatentable. *See* 35 U.S.C. § 316(e). Our reasoning is explained below.

II. BACKGROUND

A. Real Parties in Interest

The parties identify themselves and Patent Owner’s exclusive licensee, Omnia Medical, LLC, as the only real parties-in-interest. Pet. 1; Paper 6, 1.

B. Related Matters

The parties identify *Omnia Medical, LLC v. PainTEQ, LLC*, Case No. 8:22-cv-00145-VMC-TGW (M.D. Fla.), referred to herein as “the parallel litigation,” as a related matter involving the ’511 patent. Pet. 2; Paper 6, 1.

The parties identify IPR2022-00335 as a proceeding involving the same parties and challenging related U.S. Patent No. 10,426,539. Pet. 1–2;

Paper 6, 1. Patent Owner additionally identifies IPR2023-00477, which involves the same parties and challenges the same claims of the '511 patent. Paper 6, 1.

Petitioner identifies U.S. Patent Nos. 10,993,757 and 9,119,732 as patents related to the '511 patent. Pet. 1.

The parties identify U.S. Patent Application No. 17/364,906 as a related application that has been abandoned. Pet. 1; Paper 6, 2. Petitioner additionally identifies related and pending U.S. Patent Application Nos. 16/689,073, 17/864,367, and 17/745,896. Pet. 2.

C. The '511 Patent

The '511 patent issued on August 10, 2021, and is a continuation of an application filed on March 25, 2015 that issued as U.S. Patent No. 10,993,757 B2 (“the '757 patent” or “Parent”), which in turn is a continuation-in-part of an application filed on March 15, 2013 that issued as U.S. Patent No. 9,119,732 B2 (“the '732 patent” or “Grandparent”).¹ Ex. 1001, codes (45), (63).

The '511 patent is directed to “[a]n improved method of fusing the sacroiliac joint and tools for accomplishing the same.” Ex. 1001, Abstr. Figure 55 illustrates the sacroiliac joint (“SI joint”) and an implant used to fuse the joint and is reproduced below. *Id.* at 7:45–48.

¹ The Petition refers to these related patents as the “Parent” and “Grandparent” to the '511 patent. For ease of reference, we do the same.

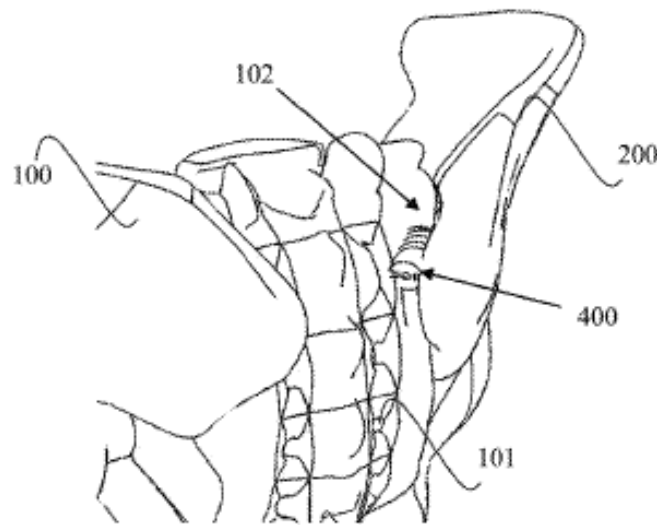


FIG. 55

Figure 55 shows “an oblique, posterior view of the sacroiliac joint with a fusion implant having helical fixation elements placed in the sacroiliac joint through a posterior approach.” *Id.* In particular, Figure 55 depicts ilium or iliac wing (100), sacrum (101), iliac crest (200), sacroiliac joint (102) defined between the ilium and the sacrum, and fusion implant (400) in its desired operative position in the sacroiliac joint. *Id.* at 12:56–63, 24:4–6.

The Specification describes that the method is performed using a “working channel . . . for guiding other surgical tools for use in repairing an SI joint.” Ex. 1001, 13:49–50. Figure 30, reproduced below, show an embodiment of this working channel.

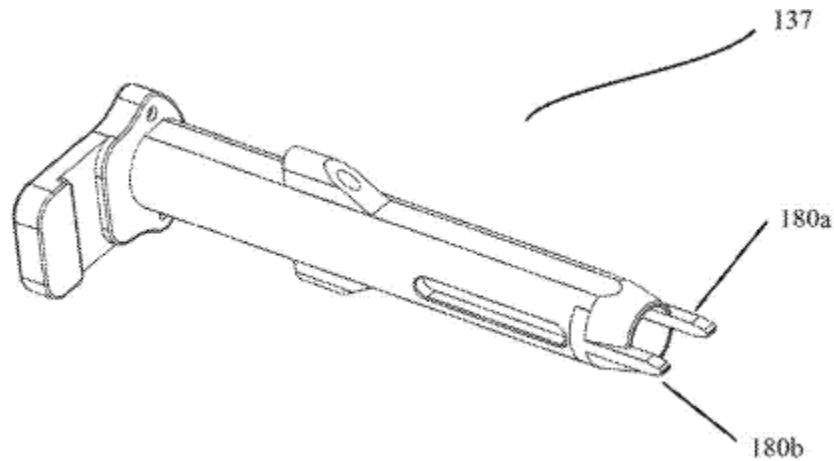


Figure 30 depicts a working channel with tangs 180a and 180b extending from its distal, insertable end to “allow the working channel to be more easily centered on the SI joint (e.g., with the tangs aligned along the plane between the articular surfaces of the SI joint)” and “to help stabilize the position of the working channel in the SI joint.” *Id.* at 15:25–35. The working channel has a hollow barrel as shown in Figure 29, which is reproduced below.

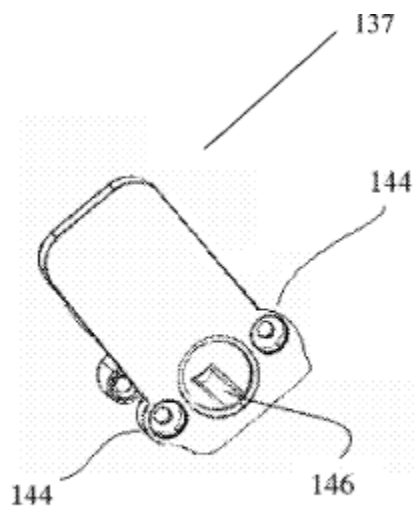


FIG. 29

Figure 29 shows a view of working channel 137 from the top with a hollow barrel that allows surgical tools to be inserted down the channel. The working channel depicted in Figure 29 has a slot 146 on the interior of the

barrel. *Id.* at 14:44–50. According to the Specification, tools used with the working channel “may have a protrusion that is complementary to the slot 146, such that the slot is effective in controlling a depth to which the surgical implement can be inserted” and to “ensure that such surgical implements . . . are and remain properly oriented in the hollow barrel of the working channel.” *Id.* at 14:50–57.

D. Challenged Claims

The Petition challenges claims 1–23. Independent claim 1 and dependent claims 6 and 7 are illustrative. These claims are reproduced below with the same bracketed annotations Petitioner uses to identify particular limitations.

1. [1 pre] A method for repairing a sacroiliac joint of a patient, comprising:
 - [1 a] creating a first incision proximal to the patient’s sacroiliac joint;
 - [1 b.1] inserting a working channel into said first incision,
 - [1 b.2] said working channel having a hollow barrel
 - [1 b.3] with an interior guidance slot in an interior diameter of the hollow barrel that does not traverse an outer diameter of said hollow barrel for controlling the advancement of surgical tools passed through said working channel, and
 - [1 b.4] having at least one tang on a distal end thereof;
 - [1 c] creating a void in said sacroiliac joint; and
 - [1 d.1] inserting a fusion implant into said void,
 - [1 d.2] wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.

Ex. 1001, 41:64–42:13.

6. [6.a.1] The method of claim 1, wherein the inserting said fusion implant comprises: a. attaching said fusion implant to an inserter having a plurality of implant engagement arms at a

distal end of said inserter by engaging said implant engagement arms with slots on a proximal end of said fusion implant,

[6.a.2] said inserter further having a slot-engagement protrusion for engaging with said interior guidance slot; and

[6.b.1] inserting said inserter into the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel

[6.b.2] advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.

Ex. 1001, 42:31–47.

7. [7.a.1] The method of claim 1, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said working channel with said slot-engagement protrusion nested in the interior guidance slot in the interior diameter of said hollow barrel,

[7.a.2] wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into the void.

Ex. 1001, 42:48–56. The other challenged claims recite similar subject matter and are addressed in our analysis below.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability, which it refers to as Grounds 1A and 1B.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5, 8, 9	103	Vestgaarden-981, ² Vestgaarden-818, ³ Lins ⁴
6, 7, 10–23	103	Vestgaarden-981, Vestgaarden-818, Lins, Paltzer ⁵

Petitioner also offers declarations from Dr. Christopher J. Bovinet (Ex. 1002) and Dwayne Polzer (Ex. 1004) in support of these grounds.

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art (“POSA”)

² US 8,162,981 B2, issued Apr. 24, 2012 (Ex. 1009) (“Vestgaarden-981”).

³ US 8,882,818 B1, issued Nov. 11, 2014 (Ex. 1010) (“Vestgaarden-818”).

⁴ US 2015/0088200 A1, published Mar. 26, 2015 (Ex. 1011) (“Lins”).

⁵ US 8,029,512 B2, issued Oct. 4, 2011 (Ex. 1012) (“Paltzer”).

“would have had a medical or an engineering degree and would have had experience with surgical instruments and implants used for spinal joint fusion, including [sacroiliac (“SI”)] joint fusion.” Pet. 7 (citing Ex. 1002 ¶ 15).

Petitioner’s description of the level of ordinary skill in the art is sufficiently supported by the record. Therefore, we apply that understanding in our analysis herein.

C. Claim Construction

In an *inter partes* review, claim terms “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), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b).

Petitioner submits that the parties have submitted joint claim construction in the Florida litigation, and asserts that “[t]he grounds set forth in this [P]etition render the challenged claims obvious under either party’s construction.” Pet. 8 (citing Ex. 1002 ¶ 34; Ex. 1017). Nevertheless, Petitioner urges that “express construction is not necessary.” *Id.* at 7.

We agree that no express construction is required for this decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

D. Priority of the ’511 patent

Petitioner contends that the ’732 patent, i.e., the Grandparent of the ’511 patent, does not provide sufficient written description support for the independent claims of the ’511 patent and therefore the challenged claims

are not entitled to the benefit of the Grandparent’s March 15, 2013 filing date. Pet. 9. More specifically, Petitioner notes that “[a]ll independent claims of the [’]511 Patent recite a working channel with tangs.” *Id.* (citing Ex. 1001, 42:7, 43:9–11, 44:31–32; Ex. 1002 ¶¶ 42–43). According to Petitioner, the Grandparent does not include written description for these limitations. *Id.* Thus, Petitioner urges that the challenged claims are not entitled to the benefit of Grandparent’s earlier filing date, but rather “the earliest possible priority date . . . is the filing date of the Parent, which is March 25, 2015.” *Id.*

We agree with Petitioner. Figures 30, 32A and 32B in the Specification depict a working channel with tangs 180a and 180b. *See* Ex. 1001, Figs. 30, 32A–B. These figures and all of the related description in the Specification describing a working channel with tangs appear in the Parent (Ex. 1006, Figs. 30, 32A–B, 3:17–21, 6:47–54, 15:25–51), but not in the Grandparent. *See also* Ex. 1002 ¶¶ 42–43 (explaining the same). Accordingly, the Grandparent application does not provide sufficient written description for the limitations requiring that the working channel have tangs in the independent claims. *See* Ex. 1001, 42:7 (limitation 1.b.4 “at least one tang on a distal end”), 43:9–11 (limitation 10.b.2 “two bilateral blunt tangs on a distal end”), 44:31–32 (limitation 18.b.2 “plurality of blunt tangs on a distal end”). For this reason, the challenged claims are not entitled to the benefit of the Grandparent’s filing date.

E. References Relied Upon

i. Vestgaarden-981

Vestgaarden-981 is a U.S. patent issued April 24, 2012. Ex. 1009, code (45). Vestgaarden-981 qualifies as prior art under 35 U.S.C. §§ 102(a)(1) and 102(a)(2).

Vestgaarden-981 discloses a method and apparatus for spinal facet fusion. Ex. 1009, code (54). Vestgaarden-981 teaches a spinal facet fusion implant having a body that may include barbs permitting the body to be inserted into a facet joint and impeding retraction therefrom. *Id.* at Abstr., 4:33–37. Figure 1 of Vestgaarden-981 illustrates an exemplary fusion implant and is reproduced below. *Id.* at 4:4–5.

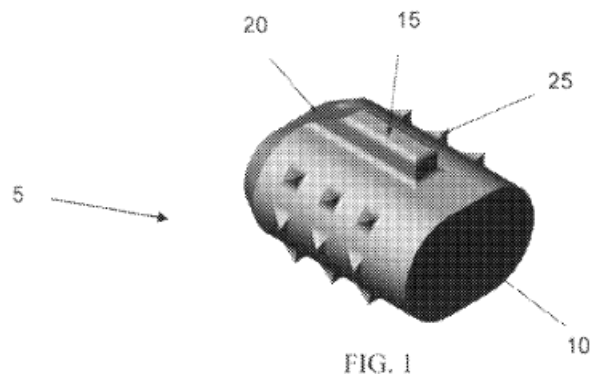


Figure 1 of Vestgaarden-981, above, shows spinal facet fusion implant (5) having body (10), at least one stabilizer (15), chamfered distal end (20), and barbs (25) extending outwardly from the body. *Id.* at 4:21–37.

Vestgaarden-981 describes the insertion of its fusion implant through the use of various surgical instruments, including a directional cannula, cavity cutter, and implant holder. Ex. 1009, 6:10–15, 6:30–39, 6:57–7:2. Figure 8 of Vestgaarden-981 shows directional cannula (110) and is reproduced below. *Id.* at 6:12.

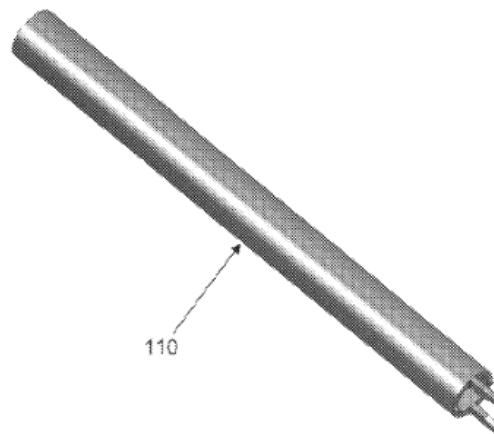


FIG. 8

Figure 8 of Vestgaarden-981, above, shows directional cannula (110). *Id.* Vestgaarden-981 explains that “the tip of directional cannula 110 is pushed into the facet joint.” *Id.* at 6:31–32. After entering the joint, “the directional cannula is lightly tapped so as to seat the cannula in the facet joint. This aligns directional cannula 110 with the vertical plane of the facet joint.” *Id.* at 6:32–36. Vestgaarden-981 subsequently uses cavity cutter (117) “to make an opening having the perfect shape for fusion implant 5.” *Id.* at 6:57–58.

An implant holder is then used to insert the implant into the opening. *See Ex. 1009, 6:59–7:2.* Figure 11 of Vestgaarden-981 is reproduced below.

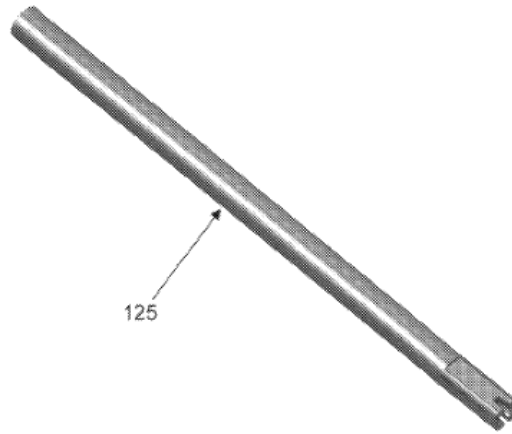


FIG. 11

Figure 11 depicts implant holder 125. Vestgaarden-981 explains that “implant 5 is . . . inserted into implant holder 125 . . . [t]hen implant holder 125, with fusion implant 5 in place, is placed into directional cannula 110.” *Id.* at 6:59–62. “Next, implant holder 125 is lightly tapped so as to insert fusion implant 5 into the cavity created in the facet joint.” *Id.* at 6:62–64. Once being positioned in the facet joint cavity, the fusion implant is driven into the cavity a preferred distance. *Id.* at 6:64–7:2.

While primarily describing spinal facet fusion, Vestgaarden-981 additionally states that “fusion implant 5 may be used to stabilize and fuse any joint having anatomy similar to the facet joint, i.e., a pair of opposing bony surfaces defining a gap therebetween, with the stabilizer of the fusion implant being sized to be positioned within the gap.” Ex. 1009, 8:54–58.

ii. Vestgaarden-818

Vestgaarden-818 is a U.S. patent issued November 11, 2014, which was filed September 24, 2012. Ex. 1010, codes (22), (45). Vestgaarden-818 qualifies as prior art under 35 U.S.C. §§ 102(a)(1) and 102(a)(2).

Vestgaarden-818 discloses “a method for fusing a spinal sacroiliac joint and a surgical kit.” Ex. 1010, Abstr. Vestgaarden-818 incorporates Vestgaarden-981 by reference, explaining that the “novel sacroiliac stabilization implant” disclosed in Vestgaarden-981 “is denoted as a whole by the reference number numeral 5,” i.e., stabilization implant 5 in Vestgaarden-818’s disclosure. *Id.* at 4:10–14.

Vestgaarden-818 teaches that stabilization implant 5 “is inserted into a sacroiliac joint using a posterior approach.” Ex. 1010, 4:34–35. Figure 3A of Vestgaarden-818, reproduced below, depicts a “sacroiliac joint and a drilled, bored, punched or cut cavity.” *Id.* at 3:22–23.

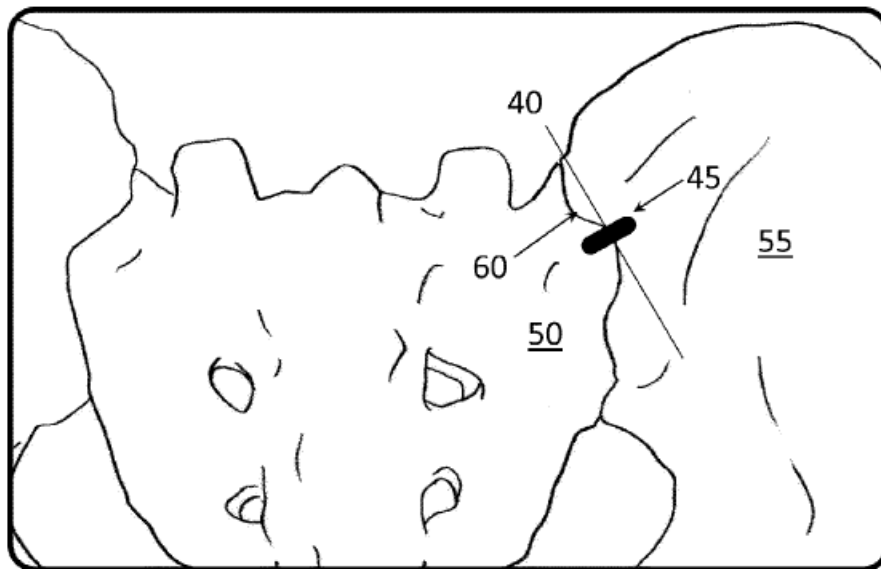


FIG. 3A

Figure 3A shows sacroiliac joint (60) having “[c]avity 45 . . . formed across plane 40 so that substantially one-half of cavity 45 is formed in sacrum 50, and substantially one-half is formed in ilium 55.” *Id.* at 4:62–65. Figure 3B of Vestgaarden-818, reproduced below, shows stabilization implant 5 in the sacroiliac joint. *Id.* at 3:24–26.



FIG. 3B

Figure 3B shows stabilization implant (5) inserted into cavity (45) from Figure 3A. *Id.* at 5:1. The stabilization implant is preferably “slightly oversized relative to cavity (45) so as to create a press fit.” *Id.* at 5–7.

Vestgaarden-818’s technique for inserting the stabilization implant involves engaging a directional cannula having teeth with the sacroiliac joint and lightly tapping the cannula to insert the teeth into the joint. Ex. 1010, 5:49–56. Figures 17 and 17A of Vestgaarden-818, reproduced below, illustrate cannula (130) with its teeth (131) inserted into sacroiliac joint (60). *Id.*

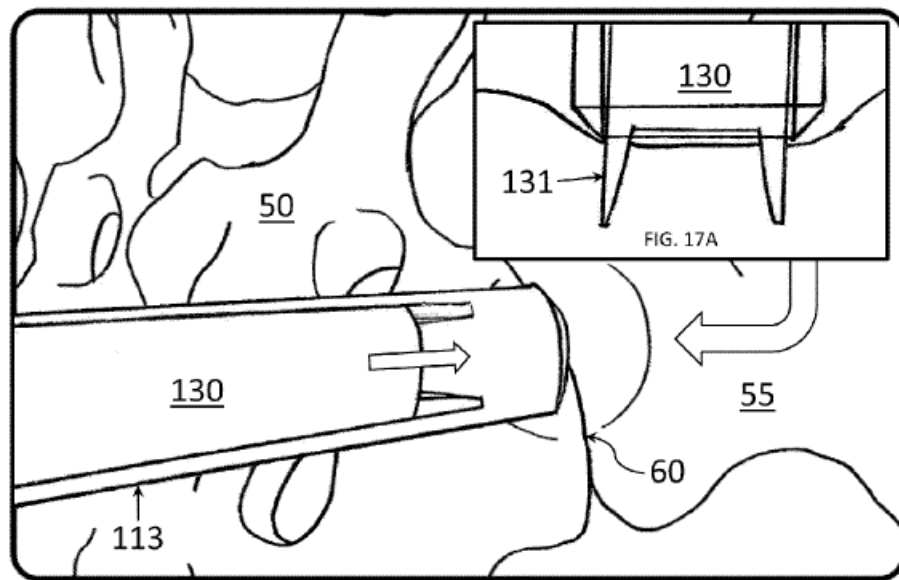


FIG. 17

Figures 17 and 17A depict cannula (130) engaged with sacroiliac joint (60) and are reproduced above. *Id.* Vestgaarden-818 explains that after the cavity is created, a stabilization implant is inserted into the lumen of the cannula followed by an “implant positioner” that is advanced down the cannula “until resistance is felt, indicating that the distal end of the implant” has engaged the cavity. *Id.* at 6:25–32. The implant positioner is then “lightly tapped to drive” the implant into the cavity “created laterally across sacroiliac joint 60.” *Id.*

iii. Lins

Lins is a published U.S. patent application that was filed on December 1, 2014. Ex. 1011, codes (22), (43). Petitioner asserts, and we agree, that Lins qualifies as prior art under 35 U.S.C. § 102(a)(2). Pet. 20; *see also* Paper 9, 1 (Patent Owner stipulating that it does not dispute Lins’s status as prior art).

Lins discloses a surgical implant device and insertion assembly for translation and fusion of a facet joint. Ex. 1011, code (54). Lins teaches a

surgical implant insertion assembly including translation portion (34) and “cannulated retention portion 36 configured to be disposed about the translation portion 34.” Ex. 1011 ¶ 34. Figure 11 of Lins illustrates an exemplary embodiment of the translated and retention portions in a partially assembled state and is reproduced below. *Id.* ¶ 25.

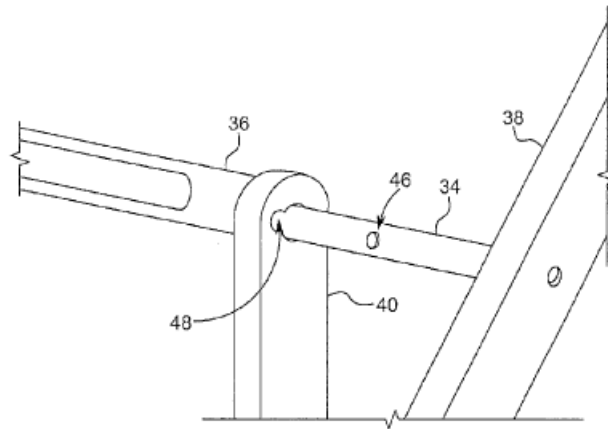


FIG. 11

Figure 11 depicts translation portion (34) of a surgical instrument partially inserted into cannulated retention portion (36) via hole (48). *Id.* ¶ 38. The translation portion has handle portion (38), and the retention portion has handle portion (40). *Id.* Figure 11 further shows one or more guide protrusions (46) along the shaft of the translation portion that “are configured to engage one or more recesses (not illustrated) manufactured into the interior bore of the substantially cylindrical cannulated retention portion 36 . . . that control and guide the depth of penetration and degree of rotation of the translation portion 34 with respect to” the cannula and facet joint. *Id.*

iv. *Paltzer*

Paltzer is a U.S. patent issued October 4, 2011. Ex. 1012, code (45). Petitioner asserts that Paltzer qualifies as prior art under 35 U.S.C. §§ 102(a)(1) and 102(a)(2). Pet. 49.

Paltzer “relates to spinal stabilization devices” implanted between vertebrae “for immobilization and fusion of the vertebrae” and methods for implanting these devices. Ex. 1012, 1:14–20. Paltzer teaches that the implants “hav[e] protrusions thereon for substantially fixedly securing with the vertebrae.” *Id.* at Abstr.

Figure 3 of Paltzer, reproduced below, illustrates an exemplary vertebral body replacement (“VBR”) device, or implant. Paltzer 2:50–53, 4:41–43.

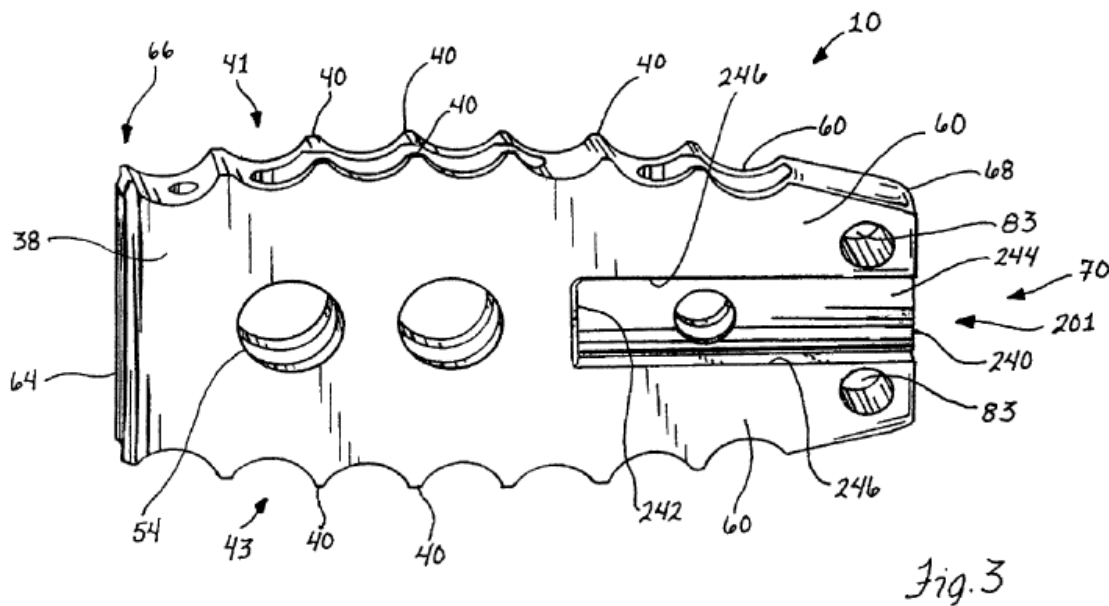


Figure 3 shows implant (10) having sidewalls (60) “includ[ing] elongate recesses or receiver channels 240 for receiving arm or prong portions 202 of the inserter 200.” *Id.* at 9:48–50.

In addition, Paltzer describes using rasp scraping member (590), “for preparing the facing endplates of adjacent vertebrae for receiving a VBR

device,” which is shown in Figure 33 reproduced below. Paltzer 4:10–12, 15:32–40.

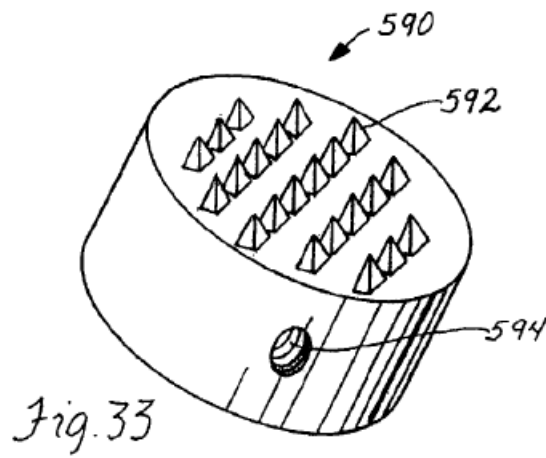


Figure 33, above, depicts rasp (590) having “disc-shaped body 591 with one or more roughened faces or rasping surfaces 592 for scraping and wounding the endplates . . . and inducing fluid and blood flow into the intervertebral space.” *Id.* at 15:36–40. Paltzer’s rasp may be manipulated and handled by, for example, “a tool (not shown) having a threaded member for being received in the connection opening 556 [similar to connection opening 594] and having pegs or bosses cooperating with recesses in the rasp 590, or vice versa.” *Id.* at 15:40–47.

F. Ground 1A: obviousness over Vestgaarden-981, Vestgaarden-818, and Lins

Petitioner contends claims 1–5, 8, and 9 would have been obvious over Vestgaarden-981, Vestgaarden-818, and Lins. More specifically, Petitioner asserts that it would have been obvious to equip “Vestgaarden-981’s working channel and surgical instruments . . . with Lins’s guidance slots and guide protrusion” in order to “control the depth of advancement and orientation of the surgical tools relative to the working channel and the joint, ensuring a proper countersink of the implant, and ensuring that the

tools do not over-penetrate.” Pet. 34–35 (citing Ex. 1002 ¶¶ 86–87). According to Petitioner, “[t]hese improved surgical tools would be used to insert Vestgaarden-981’s fusion implant with bone-engaging protrusions into an SI joint in accordance with the method taught in Vestgaarden-818 to achieve SI joint fusion.” *Id.* at 35 (citing Ex. 1002 ¶¶ 87–88).

We begin our analysis by assessing Petitioner’s reasoning for combining the references.

1. Rationale to combine Vestgaarden-981, Vestgaarden-818, and Lins

Petitioner asserts that a POSA would have been motivated to apply the surgical tools and implants in Vestgaarden-981 to the method of SI joint fusion in Vestgaarden-818 because Vestgaarden-818 “explicitly incorporates Vestgaarden-981 by reference” and a POSA would recognize that Vestgaarden-981’s tools and implants offer certain advantages. *See* Pet. 23–27 (articulating reasoning).

In addition, Petitioner asserts that a POSA would have been motivated to modify Vestgaarden-981’s tools to incorporate certain features taught in Lins. *See* Pet. 27–33. Petitioner explains that Vestgaarden-981 depicts the use of “flat portions . . . disposed on the distal ends of the surgical tools” that “function as mechanical depths-stops when they engage the corresponding shelves of the flat portions in the working channel.” *Id.* at 28 (Ex. 1002 ¶¶ 78–97; Ex. 1004 ¶ 26; Ex. 1009, Figs. 9A, 11). According to Petitioner, “Lins teaches a different and more advantageous mechanism for controlling the depth and orientation of the surgical tools relative to the joint” involving the use of “guide protrusions” on the tools and “complementary recesses (guidance slots) disposed on the interior bore of the working channel.” *Id.* at 28–29 (citing Ex. 1002 ¶ 79; Ex. 1004 ¶ 30; Ex. 1011 ¶ 38). Petitioner contends that a POSA would have been motivated to modify Vestgaarden-

981’s tools to include Lins’s mechanism because it offers certain advantages over the flat portions already taught in Vestgaarden-981. *See id.* at 29–33 (explaining that, *inter alia*, “Lins enables a surgeon to visually align the guide protrusions” which “eliminat[es] the need for blind adjustment” in the unmodified tool thereby providing the “surgeon a greater feeling of control and better user experience”). Petitioner supports these contentions with declarant testimony and other record evidence.

We find that Petitioner has articulated sufficient reasoning with rational underpinning for combining the asserted references. Vestgaarden-818 expressly incorporates the teachings of Vestgaarden-981, providing a motivation to use the implant and related tools taught in Vestgaarden-981 in its method for fusing a SI joint. Ex. 1010, 4:10–16. Moreover, we credit Dr. Bovinet’s testimony describing additional reasons for combining Vestgaarden-981’s implant and surgical implants with Vestgaarden-818’s method. Ex. 1002 ¶¶ 67–74.

Petitioner’s reasoning for combining Lins’s guidance slots and protrusions is also supported by the evidence of record. Ex. 1002 ¶¶ 77–84. In particular, Dr. Bovinet persuasively testifies that a POSA would have motivated to make this combination because it “enables a surgeon to *visually* align the guide protrusions on a shaft with the guidance slots of the working channel,” which is “a major improvement” over the flat portion depth stop taught in Vestgaarden-981. *Id.* ¶ 83; *see also id.* ¶ 84 (“As someone who has personally performed hundreds of SI joint fusion surgeries, I can attest that the guide protrusions and guidance slots taught in Lins would offer a surgeon a significantly better user experience” as compared to Vestgaarden-981’s flat portions). Finally, Petitioner has demonstrated that the combination would have produced a “predictable result” and therefore that a

POSA would have had a reasonable expectation of success. *See* Pet. 27, 33 (citing Ex. 1002 ¶¶ 76, 85).

Having determined that Petitioner has shown by a preponderance of the evidence that it would have been obvious to combine the references as articulated in the Petition, we next turn to Petitioner’s contention that this combination of references teaches or suggests all of the limitations of claims 1–5, 8 and 9.

2. Claim 1

a. [1.Pre] “A method for repairing a sacroiliac joint of a patient, comprising:”

Petitioner asserts that “Vestgaarden-818 discloses ‘[a] method for fusing a spinal sacroiliac joint.’” Pet. 35 (citing Ex. 1010, Abstr.; Ex. 1002 ¶ 102) (alteration in original).

We need not decide whether the preamble is limiting because, even if it is, Petitioner has shown that the articulated combination of references teaches such a method. In particular, Vestgaarden-818 teaches a method for repairing a SI joint and, as noted above, incorporates the use of Vestgaarden-981’s implants and tools for use in that method. *See* Ex. 1010, 4:10–16.

b. [1.a] “creating a first incision proximal to the patient’s sacroiliac joint”

Petitioner cites to Vestgaarden-818’s disclosure that after the SI joint is localized by fluoroscopy or direct visualization, “[a] path through soft tissue to the sacroiliac joint is then created via surgeon’s preference, such as open, minimally-invasive, percutaneous, or arthroscopic.” Pet. 35 (citing Ex. 1010, 5:23–26; Ex. 1002 ¶ 103) (alteration in original). Petitioner further relies on Dr. Bovinet’s testimony to support that a “POSA understands that creating a path through soft tissue to the SI joint involves making an incision proximal to the SI joint.” *Id.* (citing Ex. 1002 ¶ 103).

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Vestgaarden-818 teaches that its method is performed using a "posterior approach" and that an instrument is used to determine the plane of the SI joint and in turn the proper position for the cavity that will be made to receive the fusion implant. Ex. 1010, 4:34–43. After the joint is localized, Vestgaarden-818 teaches the creation of an incision near the SI joint to create a path to that joint. *See Id.* at 5:23–26.

c. [1.b.1] "inserting a working channel into said first incision,"

Petitioner maps the claimed "working channel" to Vestgaarden-818's directional cannula, and argues that Vestgaarden-818 teaches inserting the directional cannula into the incision. Pet. 36 (citing Ex. 1010, 5:49–50; Ex. 1002 ¶ 104).

We find Petitioner's showing sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Petitioner has shown that Vestgaarden-818's directional cannula is a working channel as recited in the challenged claims and that Vestgaarden-818 teaches inserting this cannula into the incision until the teeth on its distal end are aligned with the plane of the SI joint. Ex. 1010, 5:49–56. The cannula is then lightly tapped to insert those teeth into the SI joint. *See id.*, Fig. 17A (illustrating insertion of working channel).

d. [1.b.2] "said working channel having a hollow barrel"

According to Petitioner, a POSA would have understood Vestgaarden-981's disclosure that "instruments may . . . be inserted through the cannula," to mean that the cannula has a hollow barrel. Pet. 36 (citing Ex. 1009, 5:5–9, 6:40–43, 6:60–63; Ex. 1002 ¶ 105). Petitioner additionally

relies on Figure 8 of Vestgaarden-981 as illustrating the claimed limitation.
Id.

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Figure 8 of Vestgaarden-981 shows that the cannula has a hollow barrel. Ex. 1009, Fig. 8. Moreover, both Vestgaarden-981 and Vestgaarden-818 disclose that surgical tools are inserted into the lumen of the directional cannula, thereby teaching that the cannula has a hollow barrel through which those tools can pass to access the SI joint. *See, e.g.*, Ex. 1009, 5:5–9, 6:40–43, 6:60–63; Ex. 1010, 5:57–6:27 (teaching the insertion of a drill guide and other tools into the cannula to create a cavity in the SI joint to receive the implant).

e. [1.b.3] “with an interior guidance slot in an interior diameter of the hollow barrel that does not traverse an outer diameter of said hollow barrel for controlling the advancement of surgical tools passed through said working channel,”

Petitioner cites Lins's teaching that “one or more **recesses** (not illustrated) manufactured into the **interior bore** of the substantially cylindrical [working channel] . . . that **control and guide the depth of penetration and degree of rotation** of [a surgical tool] with respect to the [working channel].” Pet. 37 (citing Ex. 1011 ¶ 38) (emphases and alterations in original). Petitioner provides an annotated version of Figure 11 of Lins, reproduced below, to illustrate its contentions for this limitation. *Id.*
limitation [1.b.3]. Pet. 22.

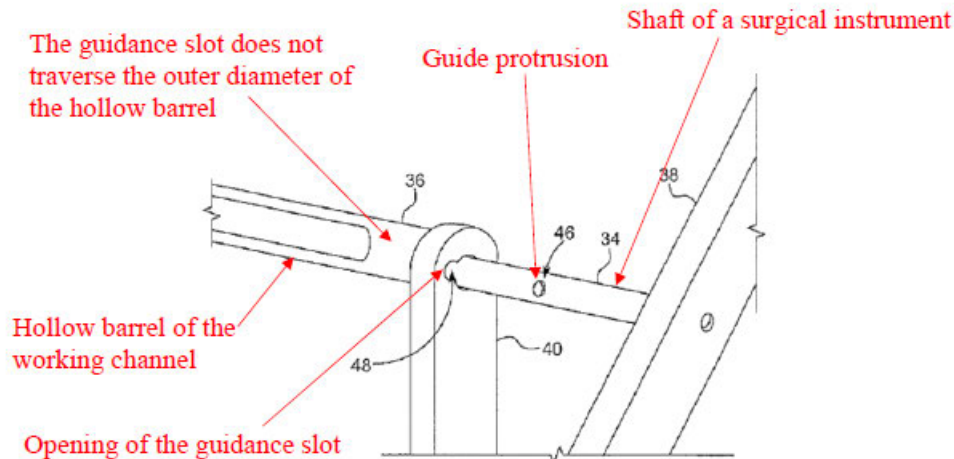


FIG. 11

Figure 11 depicts the shaft of a surgical instrument inserted into the barrel of a working channel. Petitioner adds red annotations to Figure 11 identifying guide protrusion 46 on the shaft of a surgical instrument and recess 48, which Petitioner calls the “guidance slot,” on the interior bore of the hollow barrel of the working channel. *Id.*

We find Petitioner’s showing sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Lins teaches a working channel with a guidance slot on its interior bore that does not traverse the outer diameter of the hollow barrel. *See* Ex. 1011, Fig. 11, ¶ 38 (explaining that the “guide protrusions 46 are configured to engage one or more recesses . . . manufactured into the interior bore of the [working channel]” in order to “control and guide the depth of penetration and degree of rotation of the translation portion 34” of the surgical instrument). As shown in Figure 11 of Lins, the guidance slot 48 on the interior barrel of the working channel (i.e., cannulated retention portion 36) aligns with guide protrusion 46 on the shaft of the surgical instrument (i.e., translation portion 34) to control the angle of advancement of that instrument through the channel. *Id.*; *see also* Ex. 1002 ¶ 62 (describing Figure 11). Moreover, as

explained above, Petitioner has articulated sufficient reasoning to demonstrate that it would have been obvious to combine this feature with the working channels and instruments taught in Vestgaarden-818 and Vestgaarden-981. *See supra* § III.F.1.

f. [1.b.4] “and having at least one tang on a distal end thereof;”

Petitioner asserts that Vestgaarden-981 teaches a working channel having two tangs positioned on its distal end. Pet. 38 (citing Ex. 1009, Fig. 8; Ex. 1002 ¶ 109).

Petitioner’s showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Figure 8 of Vestgaarden-981 shows a cannula having tangs on its distal end similar to those described in the Specification of the ’511 patent. Ex. 1009, Fig. 8. Vestgaarden-818 similarly teaches tangs (or “teeth”) at the distal end of its working channel. *See* Ex. 1010, Fig. 17 (depicting tangs **131**), 5:49–56.

g. [1.c] “creating a void in said sacroiliac joint; and”

Petitioner cites Vestgaarden-818’s teaching of ““creating a cavity in the ilium and sacrum to a predetermined depth that spans the sacroiliac joint.”” Pet. 39 (citing Ex. 1010, Abstr., 4:60–65; Ex. 1002 ¶ 110).

Petitioner’s showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Figure 3A of Vestgaarden-818 shows “a close-up perspective view of said sacroiliac joint” having “a drilled, bored, punched, or cut cavity.” Ex. 1010, 3:22–23; *see also id.* at 4:60–65. Thus, Vestgaarden-818 teaches creating a “void” in the SI joint as recited in claim 1.

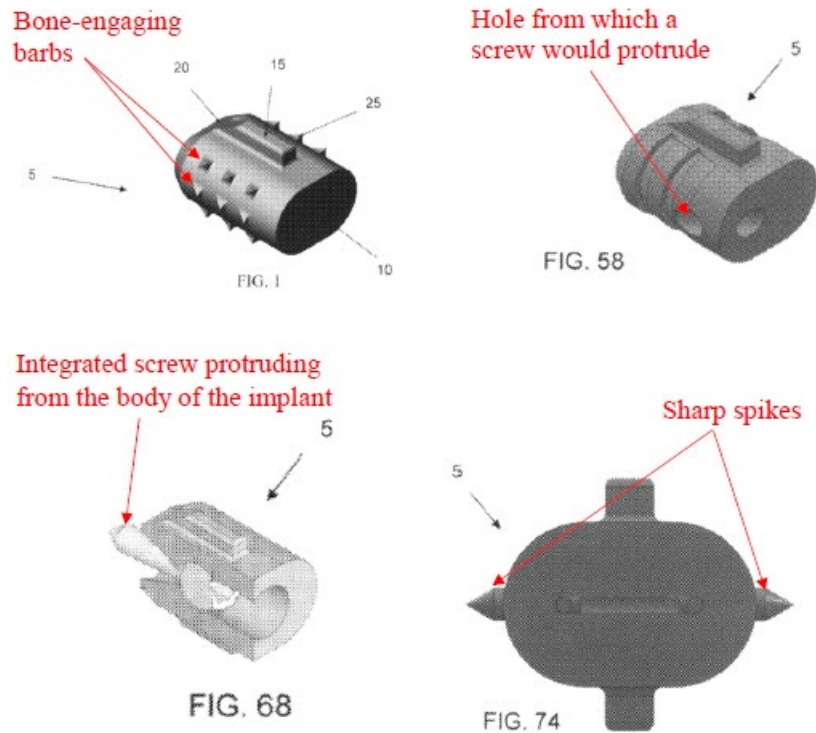
h. [1.d.1] “inserting a fusion implant into said void,”

Petitioner cites Vestgaarden-818’s teaching of “inserting [the] implant into the cavity.” Pet. 39 (citing Ex. 1010, Abstr., 5:2–7; Ex. 1002 ¶ 111).

Petitioner’s showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. As explained above, Figure 3A of Vestgaarden-818 illustrates the step of creating a void in the SI joint. The implant is then inserted using a surgical tool, i.e., an implant positioner or inserter, which is inserted into the working channel and advanced so as to drive the implant into the cavity. *See* Ex. 1010, Fig. 3B, 3:24–26 (explaining that Figure 3B of Vestgaarden-818 shows “a close-up perspective view of said sacroiliac joint” with the “stabilization implant in the final position in the sacroiliac joint”); 6:28–36 (describing insertion of the implant into the cavity).

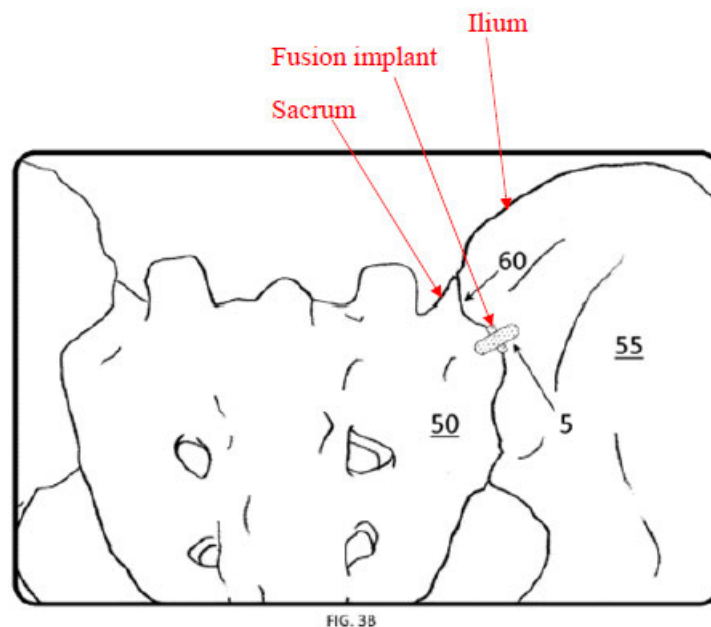
i. [1.d.2] “wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.”

Petitioner cites Vestgaarden-981’s teaching that the implant “may include a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom” as well as other disclosures of “bone-engaging devices” on the body of the implant. Pet. 39 (citing Ex. 1009, Figs. 1, 65–68, 72–74, 4:33–35, 8:30–34, 8:39–41; Ex. 1002 ¶ 112). Petitioner provides annotated versions of Figures 1, 58, 68, and 74 of Vestgaarden-981, reproduced below, to illustrate its contentions for this limitation. *Id.* at 40.



Petitioner's annotated figures include red arrow and text identifying different types of protrusions on the surface of the fusion implant. *Id.*

Petitioner also provides an annotated version of Figure 3B of Vestgaarden-818, which is reproduced below. Pet. 41.



Petitioner's annotated figure shows an implant placed in the SI joint as taught in Vestgaarden-818 with red annotations used to identify the location of the implant between the sacrum and ilium. *Id.* According to Petitioner,

[w]hen Figures 1, 58, 68, and 74 of Vestgaarden-981 are viewed in the context of Figure 3B of Vestgaarden-818, it is clear that when Vestgaarden-981's implant is positioned within an SI joint as taught in Vestgaarden-818, implant protrusions (barbs, screw, sharp spikes) would engage the articular surfaces of the sacrum, the ilium, or both and would prevent pullout of the implant.

Pet. 41–42 (citing Ex. 1009, 4:35–37, 8:19–42; Ex. 1002 ¶ 114; Ex. 1014, 91:4–12).

Petitioner's showing above is sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, the annotated figures above show that Vestgaarden-981's fusion implants include the recited protrusions. When the implant is placed as shown in Figure 3B of Vestgaarden-181 those protrusions would engage with an articular surface of the sacrum and/or ilium. Ex. 1002 ¶ 114.

In sum, Petitioner has demonstrated by a preponderance of the evidence that the combination of references teaches or suggests all of the limitations of claim 1 and that it would have been obvious to combine those references as explained above.

3. Claim 2

Claim 2 depends from claim 1 and additionally recites “wherein said fusion implant has a central body and said at least one protrusion that extends from said central body and fixes relative positions of said ilium and sacrum with engagement of said at least one protrusion with said ilium and sacrum.” Ex. 1001, 42:14–18.

Petitioner relies on the same combination of Vestgaarden-981, Vestgaarden-818, and Lins for claim 2. Petitioner's contentions regarding the limitations incorporated from claim 1 are addressed above. According to Petitioner, Vestgaarden-981 additionally discloses fusion implants having a central body with various protrusions. Pet. at 42 (citing Ex. 1009, 4:33–35, Figs. 58–60, 65–68, 72–74). Petitioner asserts that when such implants are placed as taught in Vestgaarden-818, a POSA would have understood that “the protrusions (barbs, screw, spikes) of Vestgaarden-981's implant engage the articular surfaces of the sacrum and/or the ilium” to “fix the relative position of the sacrum and ilium.” *Id.* at 43 (citing Ex. 1002 ¶ 116; Ex. 1009, 5:23–29).

Petitioner's showing is sufficient to establish that claim 2 would have been obvious over the articulated combination of references. In particular, Vestgaarden-981 teaches implants having a central body with protrusions extending therefrom. *See* Ex. 1009, 4:33–35, Figs. 58–60, 65–68, 72–74. For example, Petitioner offers annotated versions of Figures 68 and 74 of Vestgaarden-981, reproduced below, that identify these features. Pet. 40.

Integrated screw protruding
from the body of the implant

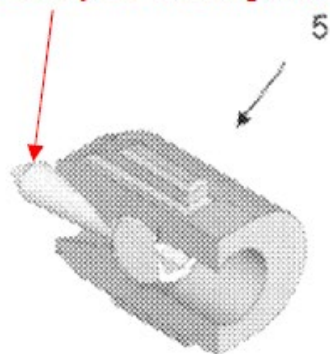


FIG. 68

Sharp spikes

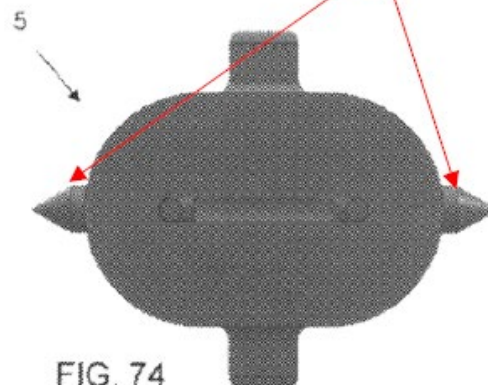


FIG. 74

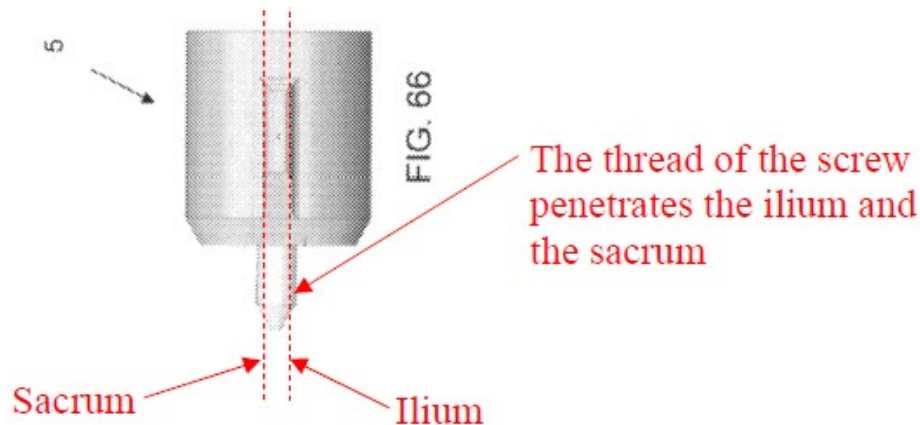
Figures 68 and 74 above show fusion implants having a central body and protrusions (i.e., an integrated screw and spikes) that are identified by Petitioner's annotations in red. When placed in the SI joint as taught in Vestgaarden-818, such protrusions would engage the sacrum and/or ilium. Ex. 1002 ¶¶ 115–116. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 2.

4. Claims 3 and 4

Claim 3 depends from claim 2 and additionally recites that the “protrusion includes an anchor that penetrates at least one of the patient's ilium and the patient's sacrum and thereby fixes relative positions of the ilium and sacrum.” Ex. 1001, 42:19–22. Claim 4 depends from claim 3 and additionally recites that the “anchor is a helical anchor operable to substantially fix the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.” *Id.* at 42:23–26.

Petitioner's contentions regarding the limitations incorporated from claims 1 and 2 are addressed above. For the additional limitations recited in claims 3 and 4, Petitioner relies on the implant in Figures 65–68 of Vestgaarden-981, which has a screw, i.e., a protrusion, that extends from the implant's central body. Pet. 43–44. According to Petitioner, “[w]hen this implant is inserted into an SI joint according to Vestgaarden-818's method, the screw would extend into the natural gap of the SI joint, whereby the thread of the screw would penetrate the ilium and the sacrum, thereby fixing their relative positions.” *Id.* (citing Ex. 1002 ¶ 117). Thus, Petitioner contends that the thread of the screw is an “anchor” as recited in claim 3 and a “helical anchor” as recited in claim 4. *Id.* at 44–45 (citing Ex. 1002 ¶¶ 118–120).

Petitioner's showing is sufficient to establish that claims 3 and 4 would have been obvious over the articulated combination of references. In particular, Petitioner offers an annotated version of Figure 66 of Vestgaarden-981, reproduced below, that illustrates the location of that implant's screw when placed according to Vestgaarden-818's method. Pet. 44.



As shown by Petitioner's annotations in red above, the thread of the screw abuts both the ilium and sacrum. We credit Dr. Bovinet's testimony that a POSA would "use a screw having dimension that would enable the thread of the screw to embed in the bone tissue of both the ilium and sacrum thereby 'attaching the implant to the [] joint' as discussed in Vestgaarden-981." Ex. 1002 ¶ 118 (quoting Ex. 1009, 8:32–33). We also agree that a POSA would have understood the thread of this screw to be a helical anchor. Ex. 1002 ¶ 120. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claims 3 and 4.

5. Claim 5

Claim 5 depends from claim 2 and additionally recites that the implant has "a cavity for holding a fusion-promoting material and having at least one

hole therein for allowing the growth of bone tissue into said cavity.” Ex. 1001, 42:27–30.

Petitioner’s contentions regarding the limitations incorporated from claims 1 and 2 are addressed above. For the additional limitations recited in claim 5, Petitioner relies on Vestgaarden-981’s teaching that the implant “may include ‘a through-hole extending through the elongated body . . . allow[ing] a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant.’” Pet. 45 (quoting Ex. 1009, 7:66–8:4); *see also id.* at 46 (annotating Figure 44 of Vestgaarden-981, which depicts such a through-hole).

Petitioner’s showing is sufficient to establish that claim 5 would have been obvious over the articulated combination of references. In particular, Vestgaarden-981 teaches the inclusion of a “through-hole” in the body of the implant, which comprises a cavity for holding a fusion-promoting material with holes on either end to allow bone growth into that hole. *See* Ex. 1009, Figs. 44, 47 (depicting implant with a through-hole), 7:66–8:4. We also credit Dr. Bovinet’s testimony that a POSA would have been motivated to include this feature “to aid in rapidly fusing the implant within the sacroiliac joint.” Ex. 1002 ¶ 122. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 5.

6. Claim 8

Claim 8 depends from claim 1 and additionally recites that the “interior guidance slot is operable to engage and align a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel.” Ex. 1001, 42:57–61. Claim 8 further recites that this engagement

“controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.” *Id.* at 42:61–64.

Petitioner’s contentions regarding the limitations incorporated from claim 1 are addressed above. For the additional limitations of claim 8, Petitioner reiterates its contention that “it would have been obvious to implement guidance slots and guide protrusions disclosed in Lins as the directional features taught in Vestgaarden-981.” Pet. 46. According to Petitioner, “Lins discloses that ‘*guide protrusions 46 are configured to engage one or more recesses [] manufactured into the interior bore of the substantially cylindrical [working channel] that **control and guide the depth of penetration and degree of rotation** of the [surgical tool].*” *Id.* at 47 (quoting Ex. 1011 ¶ 38) (emphasis added by Petitioner).

Petitioner’s showing is sufficient to establish that claim 8 would have been obvious over the articulated combination of references. As explained above, Lins teaches a configuration in which a guide protrusion on the surgical tool engages with a slot on the interior surface of the working channel. *See supra* § III.F.2.e. Lins also teaches that the engagement of the protrusion with this slot controls both the depth of advancement and the “degree of rotation,” i.e., the orientation of the tool, through the working channel. Ex. 1011 ¶ 38; *see also* Ex. 1002 ¶ 123. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 8.

7. Claim 9

Claim 9 depends from claim 1 and additionally recites that the “at least one tang” on the distal end of the working channel is “a plurality of blunt tangs.” Ex. 1001, 42:65–66. Claim 9 further recites that these tangs

“are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint.” *Id.* at 42:67–43:3.

Petitioner’s contentions regarding the limitations incorporated from claim 1 are addressed above. For the additional limitations of claim 9, Petitioner again relies on the two tangs depicted in Figure 8 of Vestgaarden-981. Pet. 47–48. Petitioner urges that Vestgaarden-818 teaches the insertion of these tangs or “teeth” (as they are referred to in that reference) into the SI joint such that they are between the articular surfaces of the ilium and sacrum as shown in Figures 17 and 17A of Vestgaarden-818. *Id.* 48–49. According to Petitioner, this serves to stabilize “the working channel relative to the SI joint.” *Id.* at 48 (citing Ex. 1002 ¶ 125).

Petitioner’s showing is sufficient to establish that claim 9 would have been obvious over the articulated combination of references. Figure 8 of Vestgaarden-981 is reproduced below with annotations added by Petitioner. Pet. 48.

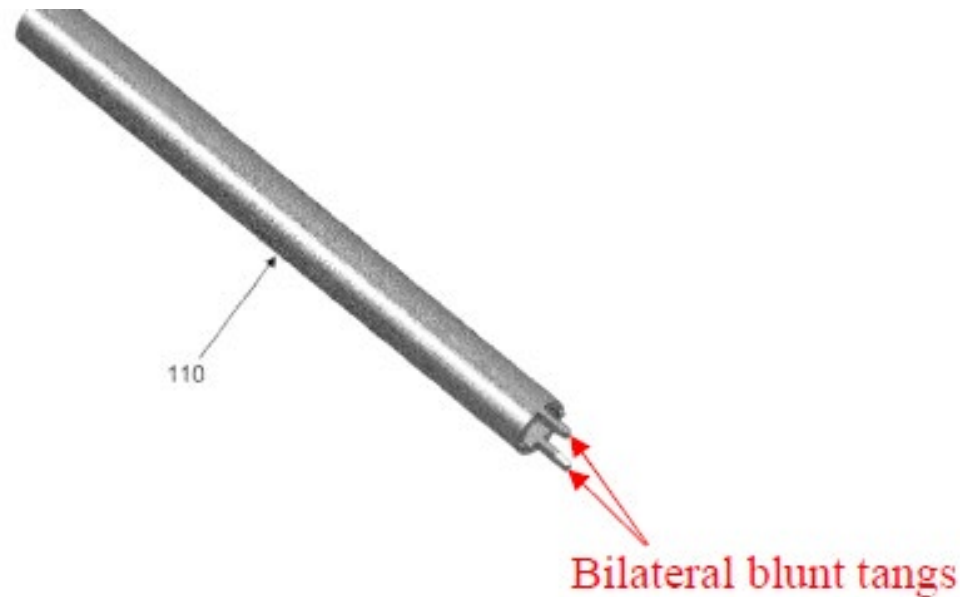


FIG. 8

Petitioner adds red annotations to the Figure 8 above, identifying two, bilateral tangs with blunt, rounded tips on the distal end of that working channel. Pet. 48; Ex. 1002 ¶ 50. Moreover, we credit Dr. Bovinet’s testimony that a POSA would have understood the use of rounded tangs like those depicted in Figure 8 above to be advantageous because it reduces the likelihood of damaging ligaments or soft tissue during surgery. Ex. 1002 ¶ 75. When inserted into the SI joint, as taught in Vestgaarden-818, these tangs would be positioned similarly to the “teeth” on the working channel shown in Figures 17 and 17A of Vestgaarden-818, which show the teeth/tangs inserted between the articular surfaces of ilium and sacrum to reversibly secure the working channel in place. *See* Ex. 1002 ¶ 125; Ex. 1010, Fig. 17, 2:7–12, 5:49–56. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 9.

G. Ground 1B: obviousness over Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer

Petitioner contends claims 6, 7, and 10–23 would have been obvious over Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer. More specifically, Petitioner relies on the same combination of references as in Ground 1A and additionally cites Paltzer for two limitations found in these additional claims: “(1) slots disposed on a proximal end of an implant configured to be engaged by the arms of an implant inserter; and (2) a rasp for preparing a void within the joint.” Pet. 49. Petitioner contends it would have been obvious to combine these features taught in Paltzer with the same combination of Vestgaarden-981, Vestgaarden-818, and Lins analyzed above for Ground 1A. *See id.* at 52–59.

As before, we begin by assessing Petitioner’s reasoning for combining these features from Paltzer with the other references.

1. Rationale to combine Paltzer with Vestgaarden-981, Vestgaarden-818, and Lins

Petitioner asserts that a POSA would have been motivated to add receiving slots for engaging the arms of an implant insert, as taught in Paltzer, to Vestgaarden-981’s implant. Pet. 52. According to Petitioner, Vestgaarden-981 “discloses an implant holder having a pair of implant-engaging arms,” but “does not explain how these implant-engaging arms hold the implant.” *Id.* Petitioner contends that a POSA would have been motivated to add Paltzer’s receiving slots to engage with the arms of the implant holder “for at least three reasons.” *Id.* First, Petitioner contends that Paltzer teaches that doing so maximizes the surface area contact between the tool and the implant “*distributing the forces endured by the tool engaging portions of the implant.*” *Id.* (quoting Ex. 1012, 9:54–10:2). Second,

Petitioner asserts that “Paltzer teaches that the slots of the implant function as sheaths for the arms of the inserter,” which minimizes the risk of damaging the surfaces of the joint during implantation. *Id.* at 52–53 (citing Ex. 1012, 10:4–13). Third, Petitioner argues that “Paltzer teaches that uniformly dimensioned slots enable implants of various widths to be universally compatible with a single inserter,” which would be advantageous because Vestgaarden-981 teaches that “the ‘fusion implant may be manufactured in a **wide range of different sizes** in order to accommodate any size of facet joint.’” *Id.* at 53–54 (quoting Ex. 1009, 5:57–59 (emphasis added by Petitioner)). Petitioner further supports these contentions with testimony from Dr. Bovinet. *See* Ex. 1002 ¶¶ 89–93.

Petitioner also asserts that a POSA would have been motivated to combine Paltzer’s rasping surface with Vestgaarden-981’s cavity cutter. Pet. 55. More specifically, Petitioner asserts that “Paltzer teaches a rasping surface for ‘scraping and wounding’ bone tissue to ‘induc[e] fluid and blood flow into the intervertebral space 30, which promotes bone ingrowth.’” *Id.* (quoting Ex. 1012, 15:34–40). According to Petitioner, this teaching “perfectly complements Vestgaarden-981’s disclosure pertaining to ‘enabling rapid fusion through the implant.’” *Id.* at 55–56 (quoting Ex. 1009, 7:66–8:4). Thus, Petitioner contends that a POSA would have been motivated to include “a rasping surface on the lateral wall of Vestgaarden-981’s cavity cutter” so as to “enable the cavity cutter to ‘scrap[] and

wound[]’ bone tissue within the cavity.” *Id.* at 56 (citing Ex. 1002 ¶ 96) (internal quotations omitted).⁶

We find that Petitioner has articulated sufficient reasoning with rational underpinning for the asserted combination of references. As with Ground 1 A, Petitioner provides plausible reasoning supported by record evidence for combining the indicated elements from Paltzer, i.e., receiving slots on the implant that engage with arms on the inserter and a rasping surface on the cavity cutter, with the other references and supports that reasoning with declarant testimony and other evidence. *See* Ex. 1002 ¶¶ 89–93, 95–96. Petitioner’s showing is unrebutted and persuasive to meet its burden. Petitioner has also demonstrated that the combination of these elements would have produced a “predictable result” and therefore that a POSA would have had a reasonable expectation of success. *See* Pet. 55, 57 (citing Ex. 1002 ¶¶ 94, 97).

Having determined that Petitioner has shown by a preponderance of the evidence that it would have been obvious to combine the references as articulated in the Petition, we next turn to Petitioner’s contention that this combination of references teaches or suggests all of the limitations of claims 6, 7 and 10–23.

⁶ Petitioner alternatively asserts that a POSA could employ Paltzer’s rasp as “a standalone tool” to abrade the joint prior to inserting Vestgaarden-981’s implant. Pet. 64; *see also* Ex. 1002 ¶¶ 98, 135. Because we find that Petitioner has met its burden on its primary theory, i.e., that it would have been obvious to combine Paltzer’s rasping surface with Vestgaarden-981’s cavity cutter, we do not reach Petitioner’s showing for this alternative theory.

2. Claim 6

a. [6.a.1] “The method of claim, wherein the inserting said fusion implant comprises: a. attaching said fusion implant to an inserter having a plurality of implant engagement arms at a distal end of said inserter by engaging said implant engagement arms with slots on a proximal end of said fusion implant,”

Petitioner cites Vestgaarden-981’s disclosure of “an implant holder (inserter) having two implant engagement arms at the distal end.” Pet. 59 (citing Ex. 1002 ¶ 127). Petitioner provides an annotated version of Figure 11 of Vestgaarden-981, reproduced below, to illustrate its contention. *Id.*

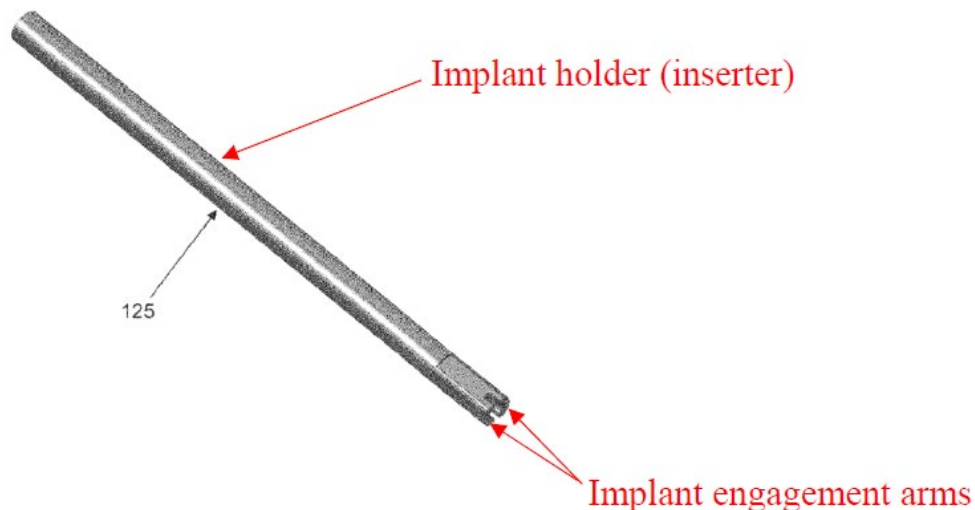


FIG. 11

In the annotated figure above, Petitioner adds red arrows to identify the “Implant engagement arms” on the distal end of implant holder 125.

Petitioner further cites Paltzer’s disclosure of slots on “a proximal end of the implant configured to receive implant engagement arms of the inserter.” *Id.* at 60 (citing Ex. 1002 ¶ 128; Ex. 1012, Figs. 2, 3, 5). Petitioner argues that the combination of these teachings would result in an inserter

with engagement arms configured to engage with slots on the proximal end of Vestgaarden-981's implant. *Id.* at 61.

We find Petitioner's showing sufficient to demonstrate that the combination of references teaches or suggests this limitation. In particular, Petitioner offers the annotated version of Figure 3 of Paltzer reproduced below. Pet. 60.

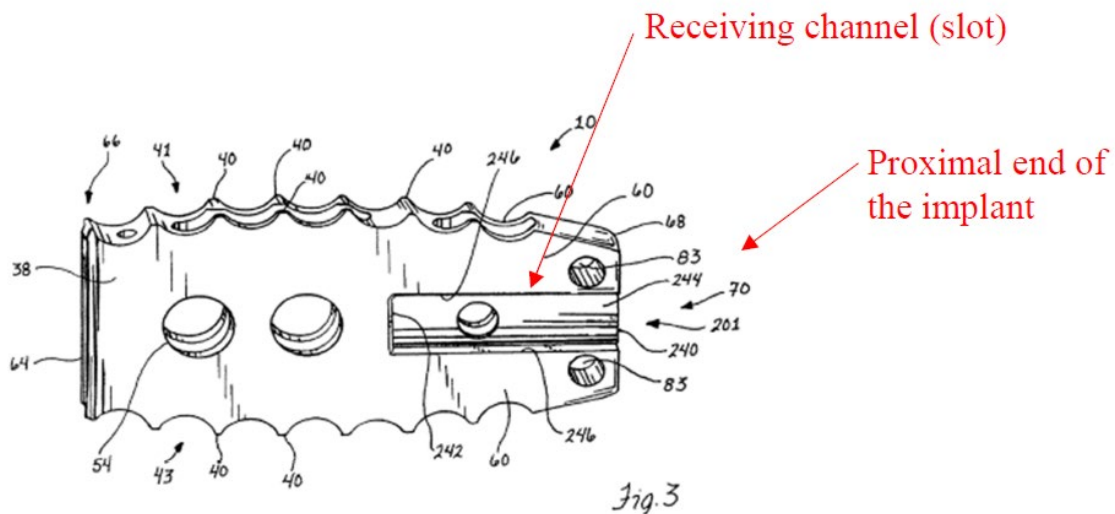


Figure 3 above shows an implant with red annotations added to identify the receiving slots located on its proximal end. *See also* Ex. 1012, Fig. 5 (showing that there is an identical slot located on the other side of the implant). Petitioner offers the annotated version of Figure 2 of Paltzer, reproduced below, to show the operation of these slots. Pet. 61.

The implant engagement arms of the inserter engaging the slots on the proximal end of the implant

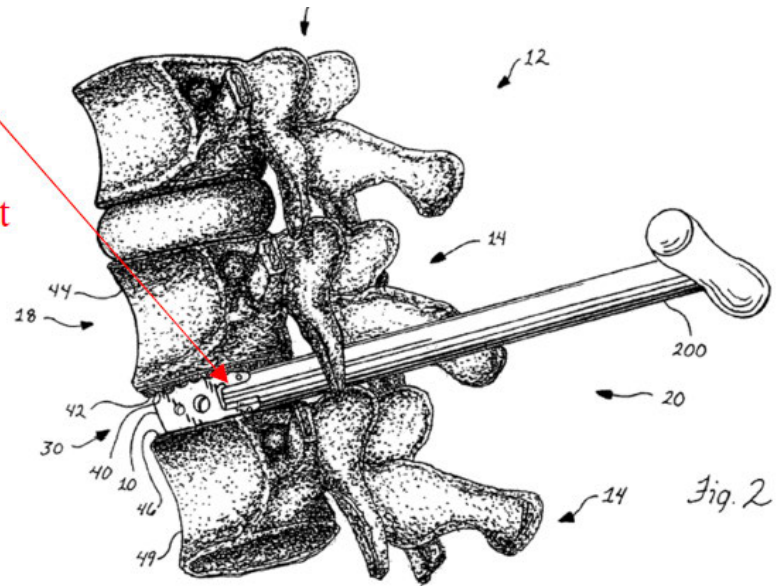


Figure 2 above shows an insertion tool 200 having two arms (marked with a red arrow added by Petitioner) that engage the two receiving slots on the implant to hold the implant as it is positioned in the joint. *See also* Ex. 1012, 9:46–50. Moreover, Petitioner has persuasively demonstrated that it would have been obvious to combine Paltzer’s receiving slots with the other references such that the implant engagement arms of Vestgaarden-981’s implant holder (*see* Ex. 1009, Fig. 11) would be sized to engage with the receiving slots of fusion implant so as to releasably attach it to the inserter. *See supra* § III.G.1.

b. [6.a.2] “said inserter further having a slot engagement protrusion for engaging with said interior guidance slot; and”

Petitioner again relies on “implement[ing] Lins’s ‘guide protrusions’ as the ‘directional feature’ of Vestgaarden-981.” Pet. 61 (citing Ex. 1002 ¶¶ 130–31). According to Petitioner, in this combination those guide protrusions “would be affixed to the shaft of Vestgaarden-981’s implant holder,” i.e., inserter, and “engage one or more recesses . . . manufactured into the interior bore” of the working channel. *Id.* at 61–62 (quoting Ex. 1011 ¶ 38).

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation for the same reasons discussed above. *See supra* § III.F.2.e.

c. [6.b.1] “inserting said inserter into the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel”

Petitioner cites Lins for this limitation, relying on an annotated version of Lins's Figure 11 similar to that discussed above to show that “during insertion into the working channel, the guide protrusion [on the inserter] is aligned with the guidance slot of the working channel.” Pet. 62.

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation for the same reasons discussed above. *See supra* § III.F.2.e.

d. [6.b.2] “advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.”

Petitioner asserts that “a surgeon would advance the inserter into the working channel until the guide protrusion of the inserter reaches the terminal end of the guidance slot, at which point the guidance slot would arrest penetration of the inserter and a fusion implant into an SI joint at a pre-determined depth.” Pet. 63 (citing Ex. 1002 ¶ 133).

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. Figure 11 of Lins does not show how far the recess Petitioner identifies as the guidance slot extends down the interior bore of the working channel. However, Lins teaches that such recess “control and guide the *depth of penetration* and degree of rotation” of the tool in cannula. Ex. 1011 ¶ 38 (emphasis added). This teaching sufficiently demonstrates that Lins's arrangement of recesses and

guide protrusions implemented on Vestgaarden-981's working channel and inserter, as articulated by Petitioner, would function to arrest penetration of the inserter at a pre-determined depth as recited in claim 6. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 6.

3. Claim 7

a. [7.a.1] "The method of claim 1, wherein the step of creating the void in the sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said working channel with said slot-engagement protrusion nested in the interior guidance slot in the interior diameter of said hollow barrel,"

Petitioner contends "it would have been obvious to dispose a rasping surface taught in Paltzer on the lateral surface of Vestgaarden's cavity cutter" and "to implement Lins's guide protrusions as the directional feature of Vestgaarden-981's surgical tools, including the cavity cutter." Pet. 63 (citing Ex. 1002 ¶ 134) (internal quotations omitted). Petitioner asserts that the guide protrusion on the tool "would engage the guidance slot, as described in Lins." *Id.* at 63–64 (citing Ex. 1011 ¶ 38).

Petitioner's showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. Paltzer teaches the use of a rasp (rasp scraping member 590) to roughen and wound the surrounding bone (i.e., endplates 42, 46) at the location where the implant is placed. Ex. 1012, 15:32–40 (referring to Fig. 33). This wounding "induc[es] fluid and blood flow" into the implant site "which promotes bone growth." *Id.* Dr. Bovinet persuasively testifies that it would have been obvious to add Paltzer's rasping surface to Vestgaarden-981's cavity cutter to achieve a similar wounding effect prior to inserting the implant given that Vestgaarden-981 teaches "complementary ways of promoting bone growth

across an implant.” Ex. 1002 ¶¶ 95–96. Thus, the combination of references teaches this limitation.

b. [7.a.2] “wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion in the void.”

Petitioner again cites Lins’s disclosure of guide protrusions on the shaft of a surgical instrument that “engage one or more recesses” in the interior bore of the working channel to “*control and guide the depth of penetration and degree of rotation.*” Pet. 64 (quoting Ex. 1011 ¶ 38). According to Petitioner, “Vestgaarden-981 in view of Paltzer and Lins, teaches a rasp having a guide protrusion that engages the guidance slot, wherein this engagement controls the depth of advancement of the rasp and maintains the rasp in a proper orientation for insertion into the void within an SI joint.” *Id.* at 65 (citing Ex. 1002 ¶ 136).

Petitioner’s showing is sufficient to demonstrate that the combination of references teaches or suggests this limitation. As explained above, the combination of Lins with the other references teaches the use of a protrusion on the surgical instrument that engages with a guidance slot on the interior of the working channel to control the orientation and depth of advancement of the instrument. *See supra* § III.F.2.e; III.F.6; III.G.2.d. In the asserted combination, the rasp is positioned on the end of the cavity cutter, i.e., one of the surgical instruments described above. Given this arrangement, the proper orientation of that rasp would similarly be maintained by the engagement of the cavity cutter’s protrusion with the working channel’s guidance slot. Ex. 1002 ¶ 136. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 7.

4. *Claims 10, 14, 16–18, and 23*

Independent claims 10 and 18 recite limitations similar to those in claims 1, 6, 8, and 9. Ex. 1001, 43:4–39, 44:5–64. Claim 14 depends from claim 10 and recites additional limitations similar to those in claims 6 and 8. *Id.* at 43:52–67. Claim 16 depends from claim 10 and recites additional limitations similar to those in claim 7. *Id.* at 44:5–14. Claim 17 depends from claim 1 and recites additional limitation similar to those in claim 8. *Id.* at 44:15–23. Claim 23 depends from claim 18 and recites additional limitations similar to those in claims 14 and 17.

Petitioner relies on largely the same showing for claims 10, 14, 16–18, and 23 that it does for claims 1 and 6–9. *See* Pet. 65–68, 72–79, 82. In addition, for the limitations in claims 10 and 18 reciting “at least one protrusion” or “a plurality of bone-engagement protrusions” that “prevent[] pullout of the fusion implant” (collectively “the pullout limitations”), Petitioner relies on Vestgarden-981’s teaching of barbs on the implant. *Id.* at 68 (citing Ex. 1009, Fig. 1, 4:33–37).

We find Petitioner’s showing sufficient to demonstrate that the combination of references teaches or suggests all of the limitations of claims 10, 14, 16–18, and 23 for the reasons discussed above for the corresponding limitations in claims 1 and 6–9. *See supra* § III.F.2.e. In addition, regarding the pullout limitations, Vestgaarden-981 teaches that the implant “may include a plurality of barbs (i.e., forward biting teeth) 25” and depicted in Figure 1 that “impede retraction of the [implant] body 10 out of the [] joint.” Ex. 1009, Fig. 1, 4:33–37, 8:5–8. Accordingly, Vestgaarden-981 discloses an implant having bone-engagement protrusions that prevent pullout as further recited in claims 10 and 18. Ex. 1002 ¶¶ 148, 175. Thus, Petitioner has

sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claims 10, 14, 16–18, and 23.

5. Claims 11, 13, 19, and 20

Claim 11 recites limitations similar to those in claims 3 and 4. Claim 13 depends from claim 10 and additionally recites that the implant “is operable to connect said sacrum to said ilium in fixed relative positions in the sacroiliac joint.” Ex. 1001, 43:49–51. Claims 19 and 20 each depends from claim 18 and recites additional limitations similar to those in claims 3, 4, 11 and 13.

Petitioner relies on largely the same showing for claims 11, 13, 19, and 20 that it does for claims 3 and 4. *See* Pet. 69, 71–72, 79–80. Petitioner further asserts that Vestgaarden-818 teaches that the implant acts to fix the relative positions of sacrum and ilium and that when combined with Vestgaarden-981 would comprise both barb and screw protrusions configured to pierce the bone tissue and securely anchor the implant within the joint. *Id.* 71–72 (citing Ex. 1010, 2:28–33; Ex. 1002 ¶¶ 155, 177).

Petitioner’s showing is sufficient to demonstrate that the combination of references teaches or suggests all of the limitations of claims 11, 13, 19, and 20. As explained above, the cited references teach an implant comprising a helical anchor (i.e., a screw) with threads that penetrate the surrounding bone to hold the implant in place in the SI joint. *See supra* § III.F.4. The cited references also teach the use of multiple barbs on the body of the implant that engage the surrounding bone and prevent pullout. *Supra* § III.G.4. We agree with Petitioner that both the screw and these barbs constitute protrusions that penetrate or pierce the sacrum and ilium to fix the relative positions of those bones and “immobilize” the SI joint, as taught in Vestgaarden-818. *See* Pet. 71 (quoting Ex. 1010, 2:28–33). Thus, Petitioner

has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claims 11, 13, 19, and 20.

6. *Claim 12*

Claim 12 depends from claim 10 and additionally recites that the implant “comprises a body having a cavity therein and perforations on an exterior thereof that expose said cavity to an exterior of said body, and a hole in a proximal end of said body for accessing an interior of said cavity.” Ex. 1001, 43:44–48.

Petitioner’s contentions regarding the limitations incorporated from claim 10 are addressed above. For the additional limitations recited in claim 12, Petitioner relies on Figures 65–68 of Vestgaarden-981, which depict an implant with a screw and a cavity in the central body, and Figures 44 and 47, which depict a through-hole for packing bone growth promoter into the implant. Pet. 69–71. Petitioner asserts that “[b]ased on the advantages of the through-hole described in Vestgaarden-981,” a POSA would have been motivated “to introduce the transverse through-hole into the implant having the longitudinal screw and a cavity (depicted in Figures 65–68).” *Id.* at 71 (citing Ex. 1002 ¶ 154). According to Petitioner, “[t]his combination would have led to a predictable result having advantages of both the longitudinal screw for attaching the implant to the joint and a transverse through-hole for enabling rapid bone growth across the implant.” *Id.*

Petitioner’s showing is sufficient to establish that claim 12 would have been obvious over the articulated combination of references. In particular, Petitioner offers an annotated version of Figure 68 of Vestgaarden-981, reproduced below. Pet. 70.

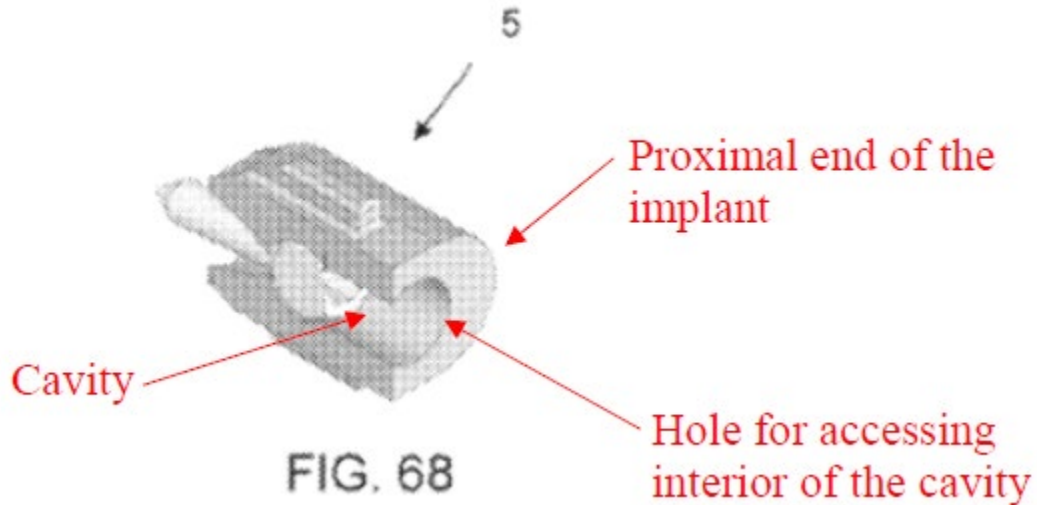
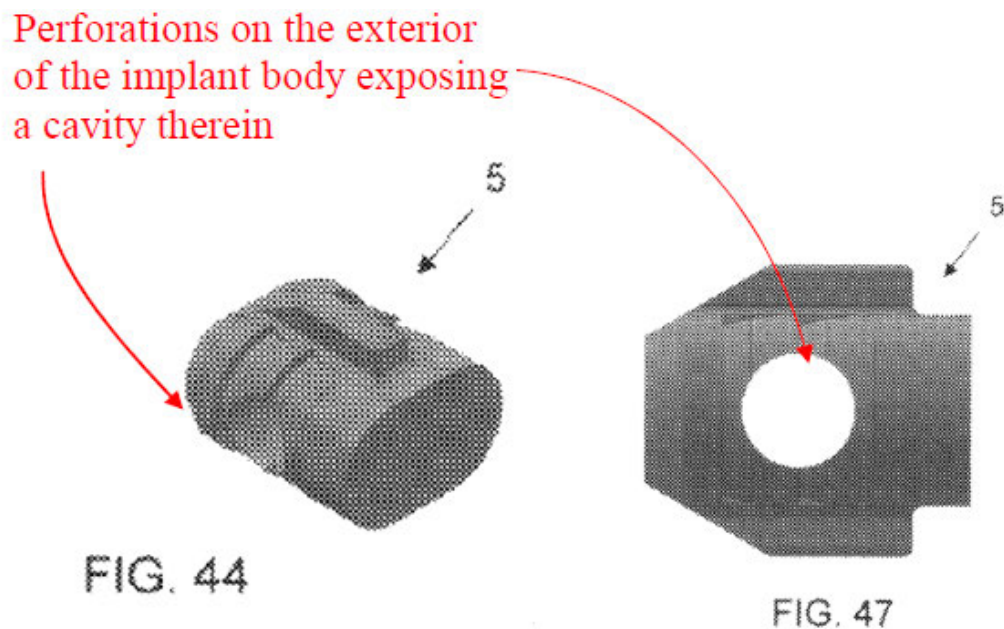


Figure 68 above depicts an implant that has a cavity within its central body (marked by Petitioner's annotation in red on the left) and a hole on its proximal end that allows access to the interior of the cavity (marked by Petitioner's annotations on the right). Vestgaarden-981 also discloses implants having a through-hole, as depicted in the annotated versions of Figures 44 and 47 reproduced below. *Id.*



Figures 44 and 47 above depict an implant with a hole (marked by Petitioner's annotations in red) that extends through its body such that there

is an opening on both sides (i.e., perforations) exposing an interior cavity. Vestgaarden-981 teaches that this “through-hole allows a bone growth promoter” to be packed into the cavity “thereby enabling rapid fusion through the implant.” Ex. 1009, 8:1–4. We credit Dr. Bovinet’s testimony that this teaching would have motivated a POSA to combine that through-hole with the implant embodiment depicted in Figure 68, thereby resulting in an implant with “perforations” exposing the interior of the cavity as well as a hole on its proximal end allowing access to that cavity as recited in claim 12. Ex. 1002 ¶ 154. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 12.

7. Claim 15

Claim 15 depends from claim 10 and additionally recites “wherein driving said fusion implant into said void comprises pushing said fusion implant into said void such that the at least one protrusion contacts said bone tissue.” Ex. 1001, 44:1–4.

Petitioner’s contentions regarding the limitations incorporated from claim 10 are addressed above. For the additional limitations recited in claim 15, Petitioner points to Vestgaarden-981’s teaching that the implant holder is lightly tapped to drive the implant into the cavity in the joint. Pet. 73 (citing Ex. 1009, 6:42–7:2). Petitioner contends this would cause the barbs on the implant to contact the bone tissue. *Id.* (citing Ex. 1002 ¶ 161).

Petitioner’s showing is sufficient to establish that claim 15 would have been obvious over the articulated combination of references. In particular, both Vestgaarden-981 and Vestgaarden-818 teach that the implant holder or positioner is “tapped” to drive the implant into the cavity created in

the joint. Ex. 1009, 6:42–7:2; Ex. 1010, 6:28–36. We credit Dr. Bovinet’s testimony that a POSA would have understood that would cause the barbs on the implant to contact the surrounding bone tissue within the SI joint. Ex. 1002 ¶ 161. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 15.

8. *Claim 21*

Claim 21 depends from claim 18 and additionally recites “wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.” Ex. 1001, 45:6–8.

Petitioner’s contentions regarding the limitations incorporated from claim 18 are addressed above. For the additional limitations recited in claim 21, Petitioner relies on Vestgaarden-818’s teaching that the implant “provides the stability and strength needed to immobilize the sacroiliac joint 60 while fusion occurs” and that the surgical tools are removed and the incision is closed after the implant is placed. Pet. 81 (quoting Ex. 1010, 5:7–9, 6:37–40).

Petitioner’s showing is sufficient to establish that claim 21 would have been obvious over the articulated combination of references. In particular, Vestgaarden-818 teaches that the insertion of a single implant to immobilize the SI joint, thereby fusing it. Ex. 1010, 5:7–9; *see also id.* at Abstr. (explaining that Vestgaarden-818 describes a “method for fusing a spinal sacroiliac joint” by insertion of an implant into a cavity in ilium and sacrum); Ex. 1002 ¶ 178. Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 21.

9. *Claim 22*

Claim 22 depends from claim 18 and additionally recites “creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void.” Ex. 1001, 45:9–12.

Petitioner’s contentions regarding the limitations incorporated from claim 18 are addressed above. For the additional limitations recited in claim 22, Petitioner points to Vestgaarden-981 teaching that the cavity cutter is “used to make an opening having the perfect shape for fusion implant 5.” Pet. 81 (quoting Ex. 1009, 6:57–58).

Petitioner’s showing is sufficient to establish that claim 22 would have been obvious over the articulated combination of references. As Petitioner points out, Vestgaarden-981 teaches that one of the surgical tools, i.e., the cavity cutter, is used to create a cavity “having the perfect shape” for the implant. Ex. 1009, 6:57–58. Similarly, Vestgaarden-818 depicts that the cavity created according to its method for repairing the SI joint has a complementary shape to the fusion implant. *See* Ex. 1010, Fig. 3A (showing cavity 45 formed across SI joint), Fig. 3B (showing implant 5 inserted into cavity); 4:60–5:7 (describing figures). Thus, Petitioner has sufficiently demonstrated that the articulated combination of references teaches or suggests all of the limitations of claim 22.

IV. CONCLUSION⁷

Petitioner has shown, by a preponderance of the evidence, that claims

⁷ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner’s attention to the April 2019 *Notice*

1–23 of the '451 patent are unpatentable.

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–5, 8, 9	103	Vestgaarden-981, Vestgaarden-818, Lins	1–5, 8, 9	
6, 7, 10–23	103	Vestgaarden-981, Vestgaarden-818, Lins, Paltzer	6, 7, 10–23	
Overall Outcome			1–23	

V. ORDER

Accordingly, it is:

ORDERED that Petitioner has shown that claims 1–23 of U.S. Patent 11,083,511 B2 are unpatentable; and

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

Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

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