

IPR2023-00451
Patent No. 11,083,511
Petition For *Inter Partes* Review
Attorney Docket No. 013438.021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

Patent No. 11,083,511
Title: METHOD AND IMPLANT SYSTEM FOR SACROILIAC
JOINT FIXATION AND FUSION

Inter Partes Review No. IPR2023-00451

**PETITION FOR *INTER PARTES*
REVIEW OF U.S. PATENT NO. 11,083,511**

TABLE OF CONTENTS

I.	Introduction	1
II.	Mandatory Notices	1
A.	Real Parties-In-Interest	1
B.	Related Matters	1
1.	United States Patent and Trademark Office	1
2.	District Court Litigation.....	2
C.	Counsel And Service Information	2
III.	Payment of Fees	3
IV.	Certification of Standing.....	3
V.	Statement of precise relief requested.....	4
VI.	OVERVIEW of the ‘511 patent.....	5
VII.	The Level of Ordinary Skill in the Art	7
VIII.	Claim Interpretation	7
IX.	Priority Dates of the Challenged Claims	8
A.	Summary of the Challenged Claims	9
X.	Grounds for unpatentability.....	11

A. Grounds 1A and 1B: Vestgaarden-based combinations	11
1. Ground 1A: Claims 1-5, 8, and 9 are obvious over the combination of Vestgaarden-981, Vestgaarden-818, and Lins	11
a. Vestgaarden-981	11
b. Vestgaarden-818	17
c. Lins.....	20
d. Combination of Vestgaarden-981 with Vestgaarden-818	23
e. Combination of Vestgaarden-981 and Lins	27
f. Vestgaarden-Vestgaarden-Lins combination.....	34
g. Claim 1	35
h. Claim 2	42
i. Claim 3	43
j. Claim 4	45
k. Claim 5	45
l. Claim 8	46
m. Claim 9	47

2. Ground 1B: Claims 6, 7, and 10-23 are obvious over the combination of Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer	49
a. Paltzer.....	49
b. Vestgaarden-Vestgaarden-Lins-Paltzer Combination	52
c. Claim 6	59
d. Claim 7	63
e. Claim 10	65
f. Claim 11	69
g. Claim 12	69
h. Claim 13	71
i. Claim 14	72
j. Claim 15	73
k. Claim 16	74
l. Claim 17	74
m. Claim 18.....	75
n. Claim 19	79
o. Claim 20	79

p.	Claim 21	81
q.	Claim 22	81
r.	Claim 23	82
XI.	Conclusion	82

TABLE OF AUTHORITIES

Cases

<i>Anthrex, Inc. v. Smith & Nephew, Inc.</i> , 35 F.4th 1328 (Fed. Cir. 2022)	9
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 at 10 (PTAB Mar. 20, 2020) ..	4
<i>Bausch & Lomb, Inc. v. Barnes–Hind/Hydrocurve, Inc.</i> , 796 F.2d 443 (Fed. Cir. 1986).....	8
<i>DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.</i> , 464 F.3d 1356 (Fed. Cir. 2006)	32
<i>In re Chu</i> , 66 F.3d 292 (Fed. Cir. 1995)	8
<i>In re NTP, Inc.</i> , 654 F.3d 1268 (Fed. Cir. 2011)	8
<i>Nidec Motor v. Zhongshan Broad Ocean</i> , 868 F.3d 1013 (Fed. Cir. 2017).....	7
<i>PainTEQ, LLC v. Orthocision, Inc.</i> , IPR2022-00335.....	8, 43
<i>PowerOasis, Inc. v. T-Mobile USA, Inc.</i> , 522 F.3d 1299 (Fed. Cir. 2008)	8

Statutes

35 U.S.C. § 102(a)(1).....	11, 17, 49
35 U.S.C. § 102(a)(2).....	12, 17, 20, 49
35 U.S.C. § 103	5
35 U.S.C. § 112	9
37 C.F.R. § 42.100(b)	8

37 C.F.R. § 42.103(a).....	3
37 C.F.R. § 42.104(1)	5
37 C.F.R. § 42.104(a).....	3
37 C.F.R. § 42.104(2)	5
37 C.F.R. § 42.15(a).....	3
37 C.F.R. § 42.22(a)(1).....	5
37 C.F.R. § 42.24(a)(1)	83
37 C.F.R. § 42.24(a)(1)(i)	83
37 C.F.R. § 42.24(d)	83
37 C.F.R. § 42.8	83

PETITIONER’S EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 11,083,511 (“511 Patent”)
1002	Declaration of Christopher J. Bovinet, DO in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,083,511
1003	Christopher J. Bovinet, DO, C.V.
1004	Declaration of Dwayne Polzer in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,083,511
1005	Dwayne Polzer, C.V.
1006	U.S. Patent No. 10,993,757 (“Parent”)
1007	U.S. Patent No. 9,119,732 (“Grandparent”)
1008	‘511 Patent Prosecution History
1009	U.S. Patent No. 8,162,981 (“Vestgaarden-981”)
1010	U.S. Patent No. 8,882,818 (Vestgaarden-818”)
1011	U.S. Patent Application Publication No. 2015/0088200 (“Lins”)
1012	U.S. Patent No. 8,029,512 (“Paltzer”)
1013	U.S. Patent Application No. 16/689,073 Prosecution History
1014	Deposition Transcript of Victor Zaporozhan, MD
1015	“Screw” Definition
1016	U.S. Patent No. 9,668,781
1017	Joint Claim Construction and Prehearing Statement

I. INTRODUCTION

PainTEQ, LLC (“Petitioner”) hereby petitions for *Inter Partes* Review (“IPR”) of claims 1-23 of U.S. Patent No. 11,083,511 (“‘511 Patent”) (Exhibit 1001), assigned to Orthocision, Inc. (“Orthocision” or “Patent Owner”).

This petition shows a reasonable likelihood that claims 1-23 of the ‘511 Patent are unpatentable.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

The real parties-in-interest in this petition is PainTEQ, LLC, Orthocision, Inc., and Omnia Medical, LLC.

B. Related Matters

1. United States Patent and Trademark Office

The ‘511 Patent is a continuation of U.S. Patent No. 10,993,757 (“Parent”) (Exhibit 1006), which is a continuation-in-part of U.S. Patent No. 9,119,732 (“Grandparent”) (Exhibit 1007).

U.S. Patent Application No. 17/364,906 claimed priority to the ‘511 Patent, but has been abandoned.

U.S. Patent No. 10,426,539 (“‘539 Patent”) is a sibling of the ‘511 Patent and is a continuation of and claims priority to the Parent patent. Petitioner challenged

validity of claims 26-28 and 31 of the ‘539 Patent in IPR2022-00335, which the Board instituted on June 2, 2022.

Pending U.S. Patent Applications Nos. 16/689,073, 17/864,367, and 17/745,896 also claim priority to the Parent Patent.

2. District Court Litigation

The ‘511 Patent is at issue in the following pending case: *Omnia Medical, LLC v. PainTEQ, LLC*, Case No. 8:22-cv-00145-VMC-TGW in the U.S. District Court for the Middle District of Florida (the “Litigation”).

C. Counsel And Service Information

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A power of attorney is submitted with this petition. Counsel for Petitioner consent to electronic service of all documents at the email addresses provided above.

III. PAYMENT OF FEES

Pursuant to 37 C.F.R. § 42.103(a), the Office is authorized to charge the fee set forth in 37 C.F.R. § 42.15(a) and any additional fees to Deposit Account No. 60-0193.

IV. CERTIFICATION OF STANDING

Petitioner certifies that the ‘511 Patent is available for IPR and Petitioner is not barred or estopped under 37 C.F.R. § 42.104(a).

V. NO BASIS FOR DISCRETIONARY DENIAL

First and foremost, Petitioner believes that institution is warranted because the grounds presented in this petition are meritorious and compelling. *See USPTO Interim Procedure For Discretionary Denial In AIA Post-Grant Proceedings With Parallel District Court Litigation* (June 21, 2022) (“USPTO Guidance”) at 4 (“[C]ompelling, meritorious challenges will be allowed to proceed at the PTAB even where district court litigation is proceeding in parallel.”).

In addition, the Litigation involving the ‘511 Patent is in its infancy. As of the filing date of this petition, a trial date has not been set, nor will one be set until after a *Markman* hearing (which has not been scheduled as of the filing of this petition). There is a high likelihood that the final written decision in this IPR (which would be

due in or about July of 2024) would be issued prior to a district court trial. The district court has not yet issued orders related to the ‘511 Patent, which “weighs against exercising discretion to deny institution decision under NHK.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 10 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). Furthermore, the Litigation has seen minimal discovery, no depositions have been set, claim construction is still pending, and there are no dispositive motion deadlines, expert deadlines, or discovery deadlines set as of the filing of this petition. Finally, there is no overlap between issues raised in this petition and in the litigation, because none of the prior art references in this petition have been presented in the district court. *See* USPTO Guidance dated June 21, 2022 at 7 (“[I]f the petition includes materially different grounds, arguments, and/or evidence than those presented in the district court, this fact has tended to weigh against exercising discretion to deny institution.”) (citing *Fintiv* at 12-13).

Stipulation: Petitioner hereby stipulates that if the Board institutes trial based on the grounds stated in this Petition, Petitioner will not pursue the same grounds in the Litigation.

VI. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.22 and § 42.104(a)-(b), Petitioner challenges claims 1-23 of the ‘511 Patent based on the following grounds:

Ground	Claims	Statute	Prior Art
1A	1-5, 8 and 9	§ 103	Vestgaarden-981, Vestgaarden-818, and Lins
1B	6, 7, and 10-23	§ 103	Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer

VII. OVERVIEW OF THE ‘511 PATENT

The ‘511 Patent discloses and claims a method for repairing a sacroiliac joint (“SI joint”). Ex-1001 at 2:15-40. The ‘511 Patent has three independent claims: claims 1, 10, and 18. All three independent claims recite the following steps: (1) creating an incision proximal to the patient’s SI joint, (2) inserting a “working channel” / “surgical channel tool” into the incision,¹ and (3) inserting a fusion implant into the SI joint (or a void created therein), wherein the implant has at least one protrusion that engages with the bone tissue thereby preventing pullout of the implant. *Id.* at 41:64-13; 43:4-39; 44:24-64. During prosecution of the ‘511 Patent, the examiner found that these limitations have been known in the prior art. (Ex-1008 at 337-354).

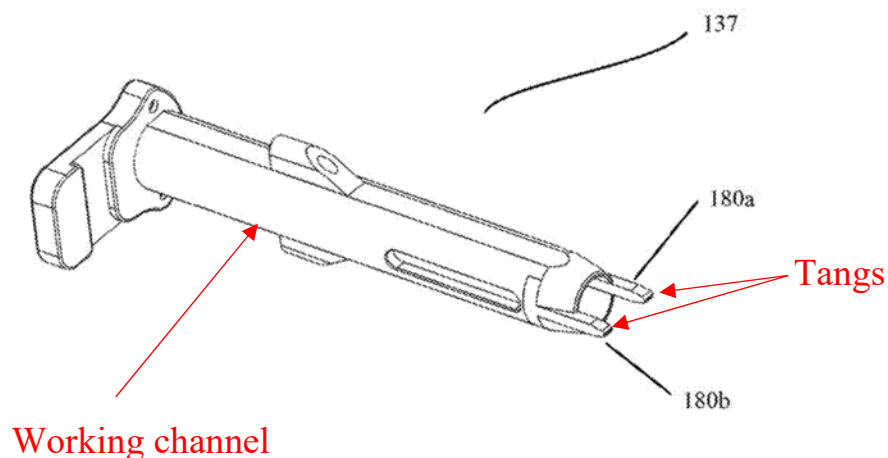
In subsequent amendments, Patent Owner amended all independent claims to require that the distal end of the working channel must have one or more tangs. Ex-

¹ The ‘511 Patent uses the terms “working channel” and “surgical channel” interchangeably to refer to the same medical cannula. Unless referring specifically to claim 10, which recites “surgical channel,” this petition will use the term “working channel” to facilitate clarity.

1001 at 42:7 (“at least one tang”); 43:9-11 (“two bilateral blunt tangs”); 44:31-32 (“a plurality of blunt tangs”). Another limitation Patent Owner introduced into all independent claims is “an interior guidance slot in an interior diameter of said hollow barrel ... [that] does not traverse an outer diameter of said hollow barrel.” *Id.* at 42:2-5; 43:17-24; 44:37-43. The ‘511 Patent claims that the guidance slot is configured “for controlling the advancement of surgical tools” (claim 1) or “for controlling a depth of advancement of surgical tools ... and maintaining said surgical tools in proper orientation for insertion into said incision” (claims 10 and 18). *Id.* at 42:5-6; 43:19-22; 44:38-41.

The tangs and the guidance slot are depicted in Figures 29 and 30 of the ‘511 Patent, respectively, which are reproduced and annotated below. *See* Ex-1002, ¶40.

FIG. 30



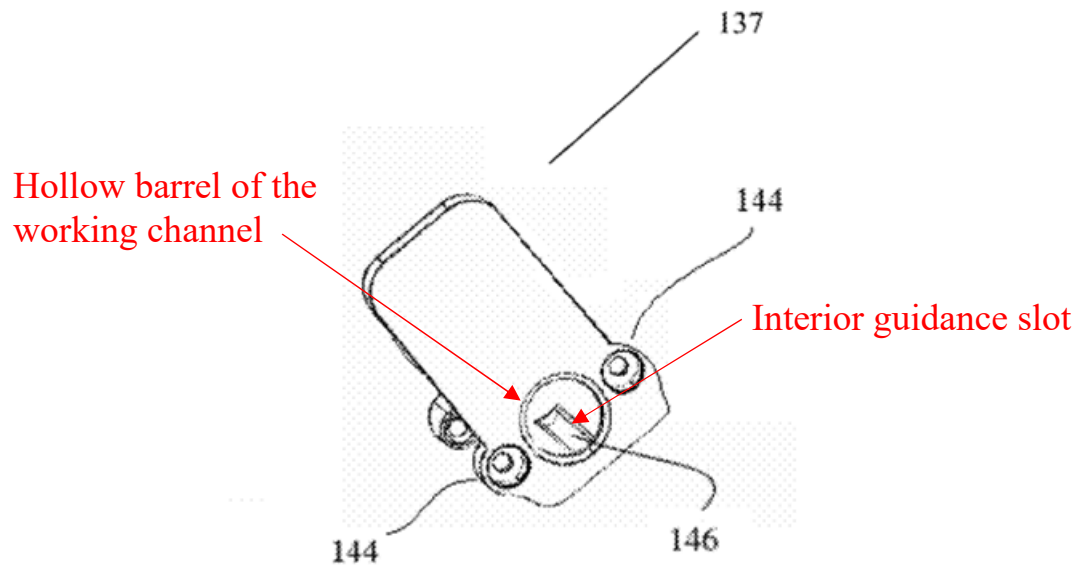


FIG. 29

VIII. THE LEVEL OF ORDINARY SKILL IN THE ART

A Person of Ordinary Skill in the Art (“POSA”) 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 SI joint fusion. Ex-1002, ¶15.

IX. CLAIM INTERPRETATION

Claim terms are construed according to their ordinary meaning to POSA and in light of the prosecution history of the patent. 37 C.F.R. § 42.100(b). When the prior art plainly discloses claim elements, as it does in this case, express construction is not necessary. *See Nidec Motor v. Zhongshan Broad Ocean*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).²

² In IPR2022-00335 instituted against the ‘539 Patent—which is a sibling of the ‘511 Patent and both share the same specification and drawings—the Board found that

Joint claim construction filed in the Litigation is submitted as Exhibit 1017. The grounds set forth in this petition render the challenged claims obvious under either party's construction. Ex-1002, ¶34.

X. PRIORITY DATE OF THE '511 PATENT

The application for the '511 Patent was filed on December 18, 2019 and claims priority to the Parent patent filed on March 25, 2015, which is a continuation-in-part ("CIP") of and claims priority to the Grandparent patent filed on March 15, 2013.

"[A] patent's claims are not entitled to an earlier priority date merely because the patentee claims priority." *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) (citing *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986)). "It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quoting *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)). In an IPR proceeding, the Board has authority to invalidate the priority claim of a

Vestgaarden-818 (and the incorporated subject matter of Vestgaarden-981) plainly recited all limitations of the challenged claims which use similar terminology as the claims of the '511 Patent, without necessitating express construction of any claim terms. *PainTEQ, LLC v. Orthocision, Inc.*, IPR2022-00335, Paper 7.

challenged patent. *See Anthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1345 (Fed. Cir. 2022).

All independent claims of the ‘511 Patent recite a working channel with tangs. Ex-1001 at 42:7 (“at least one tang”); 43:9-11 (“two bilateral blunt tangs”); 44:31-32 (“a plurality of blunt tangs”). The Grandparent does not disclose this subject matter. Ex-1002, ¶¶42-43. Thus, none of the claims of the ‘511 Patent are entitled to the priority date of the Grandparent. Accordingly, the earliest possible priority date for the ‘511 Patent is the filing date of the Parent, which is March 25, 2015.

XI. SUMMARY OF THE CHALLENGED CLAIMS

Independent claim 1 is reproduced and annotated in color below. The limitations of this claim fall within the following four categories: (1) well-known steps for implanting a fusion implant into an SI joint (**emphasized in green**); (2) a conventional working channel with tangs (**emphasized in blue**); (3) a guidance slot for controlling advancement of the surgical tools (**emphasized in purple**); and (4) a fusion implant with bone-engaging protrusions for preventing pullout from the joint (**emphasized in orange**). *Id.*, ¶45.

- [1 pre] A method for repairing a sacroiliac joint of a patient, comprising:
- [1 a] a. creating a first incision proximal to the patient's sacroiliac joint;
- [1 b.1] b. 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] c. creating a void in said sacroiliac joint; and
- [1 d.1] d. 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.

Ground 1A of this petition establishes that (1) U.S. Patent No. 8,162,981 (“**Vestgaarden-981**”) (Ex-1009) teaches a working channel having a hollow barrel and blunt tangs and a fusion implant having bone-engaging protrusions; (2) U.S. Patent No. 8,882,818 (“**Vestgaarden-818**”) (Ex-1010) teaches a method of SI joint fusion that involves the steps of creating an incision, inserting a working channel into the incision, creation a void in the SI joint, and inserting a fusion implant into the void; and (3) U.S. Patent Application Publication No. 2015/0088200 (“**Lins**”) (Ex-1011) teaches a guidance slot disposed within the interior of the working channel for controlling advancement of surgical tools. This petition demonstrates that POSA had a reason to combine Vestgaarden-981, Vestgaarden-818, and Lins to achieve the subject matter recited in claim 1 and further establishes that POSA had a reasonable expectation of success in this combination. In fact, the specifications of both Vestgaarden-818 and Lins expressly reference Vestgaarden-981, indicating

their compatibility. Ex-1010 at 4:10-16; Ex-1011 at [0005].

Ground 1A establishes that claims 1-5, 8, and 9 recite only conventional limitations that are obvious over the Vestgaarden-Vestgaarden-Lins combination. Ground 1B establishes that claims 6, 7, and 10-23 are obvious over the Vestgaarden-Vestgaarden-Lins combination in view of U.S. Patent No. 8,029,512 (“Paltzer”) (Ex-1012), which is cited for the narrow purpose of establishing that (1) a pair of slots on a proximal end of an implant configured to engage with arms of an implant inserter (claims 6, 10, and 18), and (2) a rasp for preparing a void within a joint prior to insertion of a fusion implant (claims 7 and 16) were known in the prior art.

XII. GROUNDS FOR UNPATENTABILITY

A. Grounds 1A and 1B

1. Ground 1A: Claims 1-5, 8, and 9 are obvious over the combination of Vestgaarden-981, Vestgaarden-818, and Lins

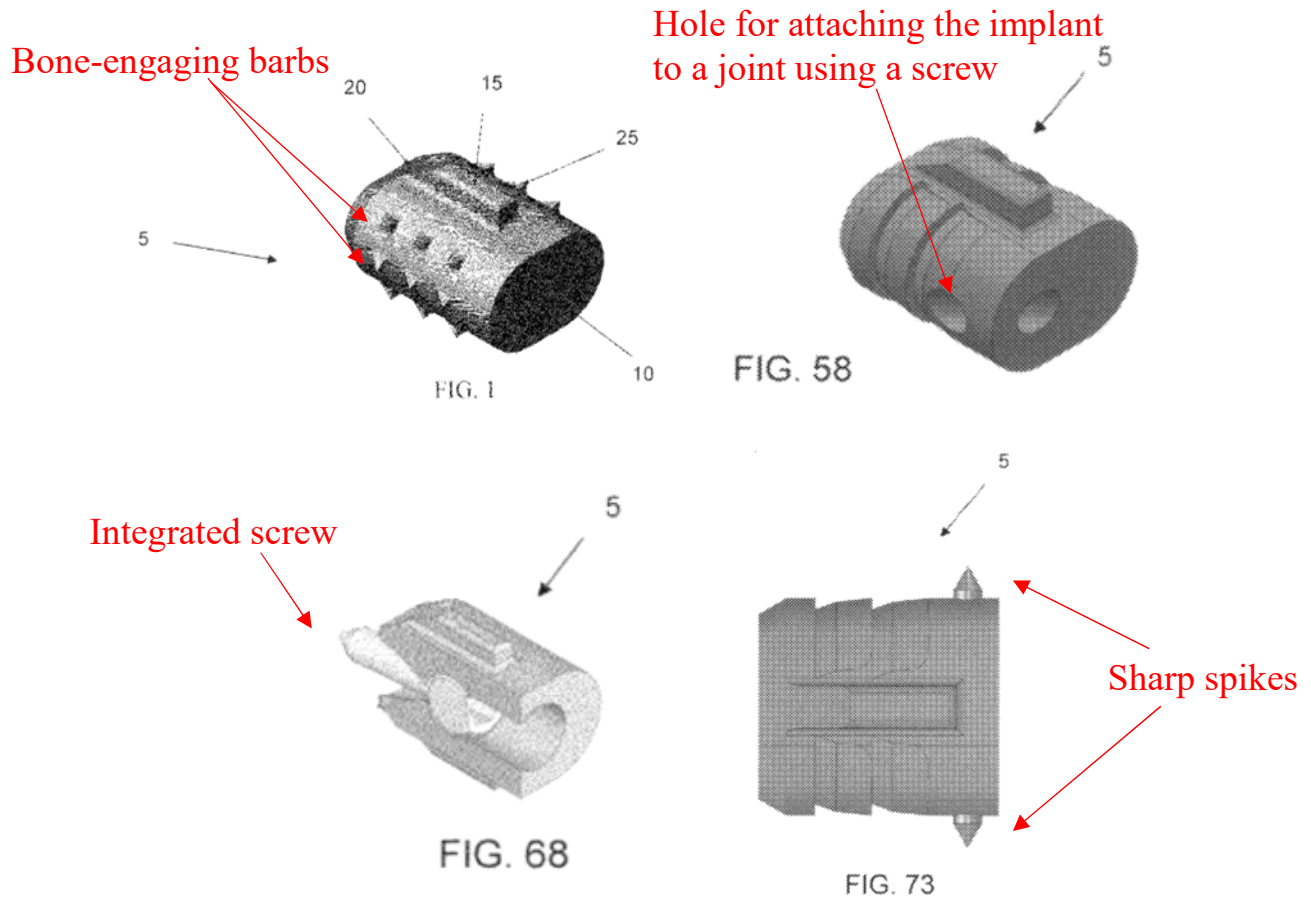
a. Overview of Vestgaarden-981

Vestgaarden-981 was filed on May 22, 2008 and issued on April 24, 2012 and therefore qualifies as prior art against the ‘511 Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Vestgaarden-981 discloses several embodiments of a fusion implant and a set of surgical instruments for inserting the fusion implant into a facet joint to achieve fusion. Ex-1009 at Abstract; Ex-1002, ¶47. Vestgaarden-981 explains that applicability of its disclosure is not limited to facet joints and contains a dedicated

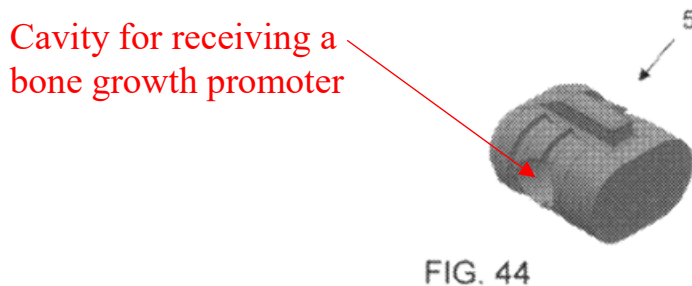
section entitled “Application to Joints Other than Facet Joints” explaining that “it should also be appreciated that fusion implant 5 may be used to stabilize and fuse *any* joint having anatomy similar to the facet joint, i.e., a pair of opposing bony surfaces defining a gap therebetween.” Ex-1009 at 8:50-58 (emphasis added); Ex-1002, ¶47.

(1) Fusion implant with bone-engaging protrusions

Vestgaarden-981 discloses an embodiment of a fusion implant having a plurality of barbs (protrusions) extending around the surface of its body, wherein the barbs are designed to “impede retraction” (prevent pullout) of the implant from the joint. Ex-1009 at 4:33-37; Ex-1002, ¶48. Vestgaarden-981 further discloses that the implant may include other types of bone-engaging protrusions including a screw and sharp spikes. Ex-1009 at 8:19-41; FIGS. 58-74; Ex-1002, ¶48. Representative figures 1, 58, 68, and 73 depicting these embodiments of fusion implants are reproduced and annotated below. *See* Ex-1002, ¶48.



In addition, Vestgaarden-981 discloses that the body of the implant may have a through-hole (cavity) that allows “a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant.” Ex-1009 at 7:66-8:4, FIGS. 44 and 47; Ex-1002, ¶49.



(2) Surgical instruments for creating a void within a joint and inserting and driving a fusion implant into the created void

Vestgaarden-981 discloses a set of nesting surgical instruments for creating a void within a joint and inserting the fusion implant thereinto. Ex-1009 at 6:10-15; Ex-1002, ¶50; Ex-1004, ¶19. This instrument set includes a directional cannula (working channel) with blunt tangs disposed on its distal end. Ex-1009 at 6:12, 30-39; FIG. 8; Ex-1002, ¶50; Ex-1004, ¶19.

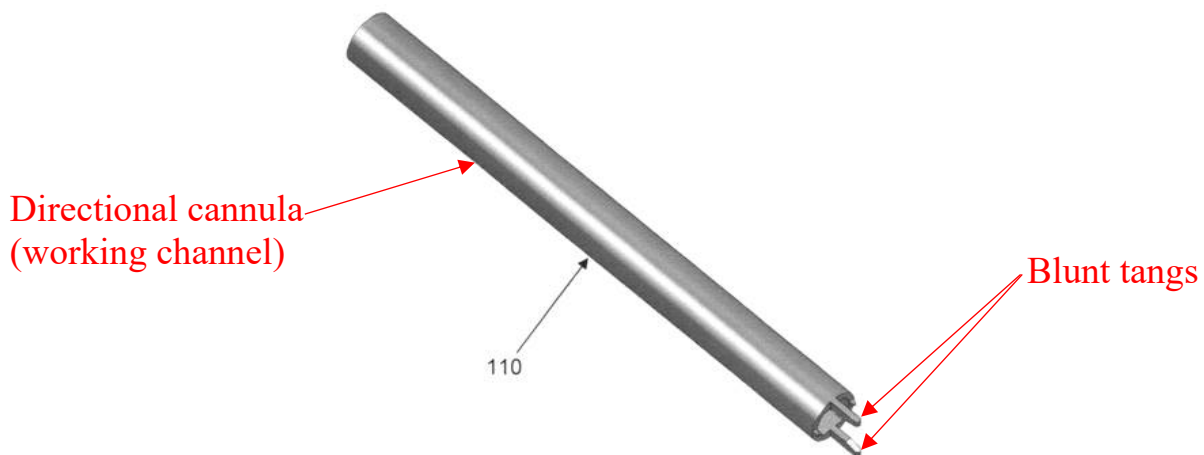


FIG. 8

The instrument set further includes a cavity cutter configured to “make an opening [within a joint] having the perfect shape for fusion implant.” Ex-1009 at 6:57-58; FIG. 9A. In addition, the instrument set includes an implant holder (inserter) for inserting the fusion implant into the void created within the joint. *Id.* at

6:59-64; FIG. 11; Ex-1002, ¶51; Ex-1004, ¶20. Figure 11, which is reproduced and annotated below, depicts the implant holder having two implant-engaging arms at its distal end for holding the implant. Ex-1009 at FIG. 11; Ex-1002, ¶51; Ex-1004, ¶20. The implant holder is configured to advance the implant through the working channel and insert the implant into the void within the joint. Ex-1009 at 6:59-64; Ex-1002, ¶51; Ex-1004, ¶20.

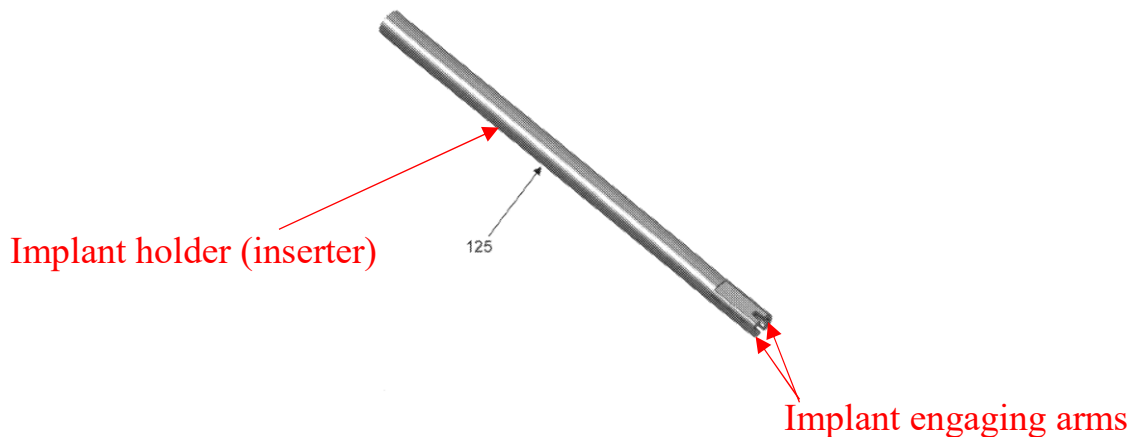


FIG. 11

Another instrument in Vestgaarden-981's surgical set is an implant tamp. Ex-1009 at 6:15. After the implant holder inserts the implant into the void, the implant tamp is advanced through the lumen of the implant holder and then "lightly tapped" to drive the implant into the void, so that the implant is countersunk 1-2 millimeters. *Id.* at 6:64-7:2; Ex-1002, ¶52.

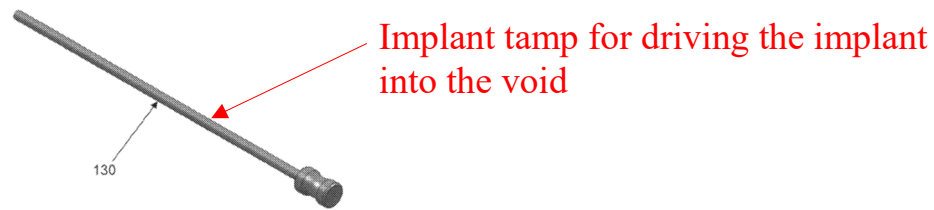
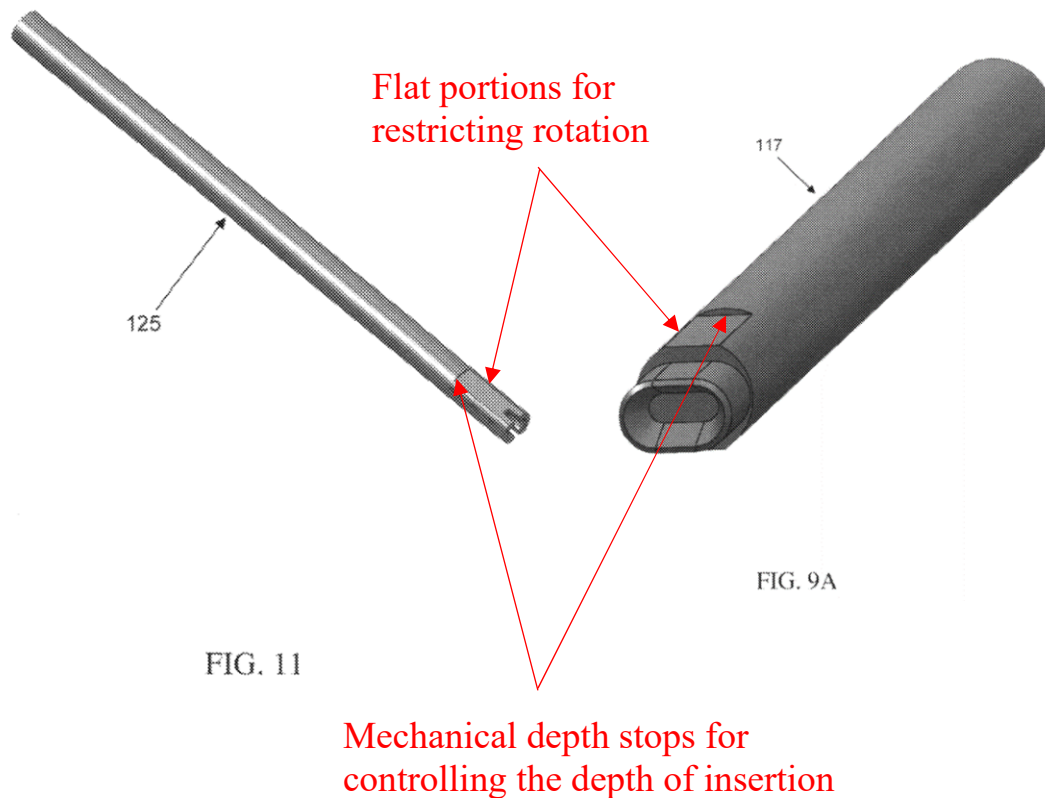


FIG. 12

(3) “Directional features” for maintaining alignment between the surgical instruments and the working channel

Vestgaarden-981 discloses that the working channel (directional cannula) and the surgical instruments may have “directional feature[s] which [are] used to maintain the alignment of the instrumentation with ... the joint.” Ex-1009 at 5:1-4. Vestgaarden-981 provides an example of such directional features, which include a flat surface disposed within the interior lumen of the working channel and complementary flat surfaces disposed on external distal ends of the surgical tools. *Id.* at 5:4-9 (“By way of example but not limitation, a directional cannula may comprise a flat portion and the remaining instruments may comprise a flat portion on an opposite portion of the instrument so that the instruments may only be inserted through the cannula at 0 degrees and/or 180 degrees.”); Ex-1002, ¶54; Ex-1004, ¶21. Figures 9A and 11, which are reproduced and annotated below, depict the cavity cutter and the implant holder with the exemplary “flat portions” serving the role of the “directional features” for maintaining radial alignment between the surgical tools

and the working channel. Ex-1002, ¶54; Ex-1004, ¶21. Figures 9A and 11 also depict that the flat portions have mechanical depth stops that control the depth of advancement of the surgical tools into the working channel, as shown below. Ex-1002, ¶54; Ex-1004, ¶21.

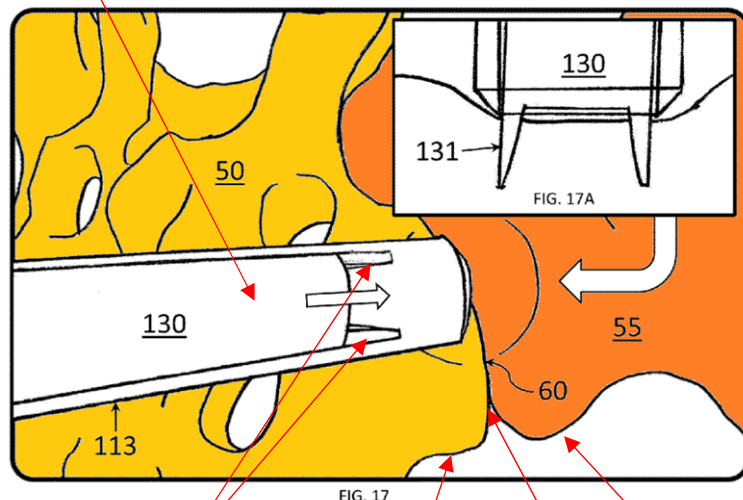


b. Overview of Vestgaarden-818

Vestgaarden-818 was filed on September 24, 2012 and issued on November 11, 2014 and therefore is prior art against the '511 Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Vestgaarden-818 discloses “[a] method for fusing a spinal sacroiliac joint.” Ex-1010 at Abstract. The method involves the step of making an incision

proximal to the patient's SI joint. *Id.* at 5:22-26; Ex-1002, ¶56. Next, the soft tissue is retracted using dilation tubes, and a working channel (directional cannula) is inserted into the incision via the largest dilation tube. Ex-1010 at 5:27-30; 5:49-51; Ex-1002, ¶56. The working channel is then aligned with the plane of the SI joint and is lightly tapped to insert the tangs (teeth) of the working channel into the SI joint. Ex-1010 at 5:51-56; Ex-1002, ¶56. The process of inserting the tangs of the working channel between the articular surfaces of sacrum and ilium is depicted in Figures 17 and 17A of Vestgaarden-818, which are reproduced and annotated below (to facilitate clarity, the sacrum is emphasized in light orange, while the ilium is emphasized in dark orange).

Working channel
(directional cannula)



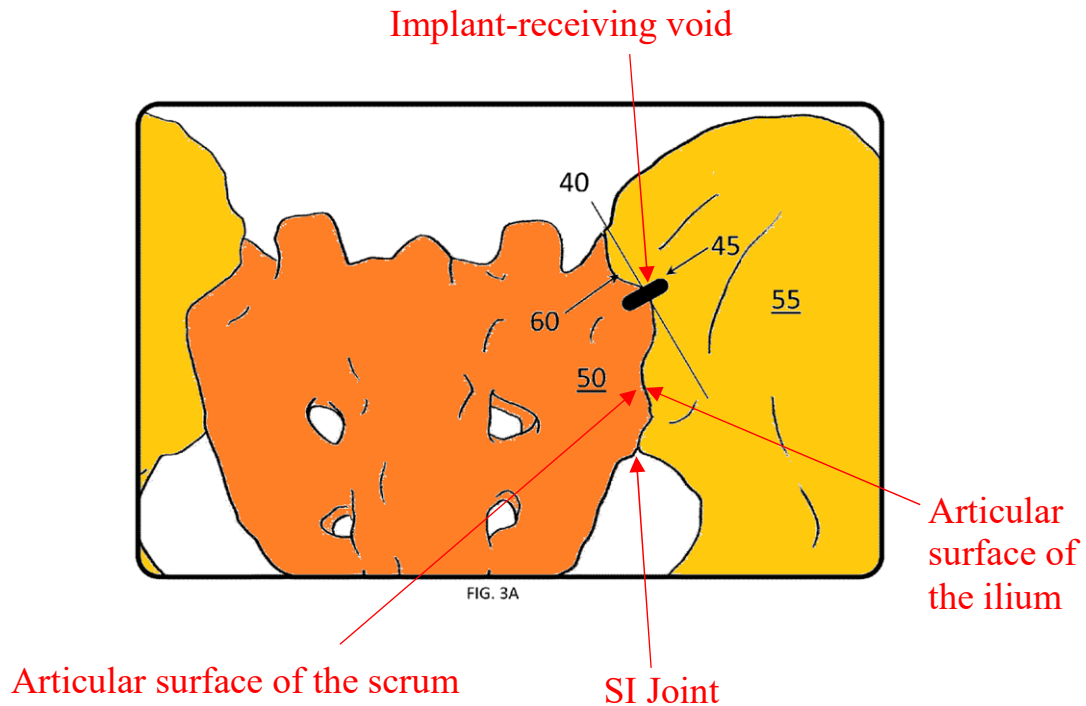
Teeth (tangs)

Sacrum (50)

Ilium (55)

SI joint (60)

Next, a cavity (void) for receiving an implant is created across the SI joint as depicted in Figure 3A, which is reproduced and annotated in color below. Ex-1010 at 6:25-27; Ex-1002, ¶57.



Then, a fusion implant is inserted into the void via “the lumen of [the] directional cannula.” Ex-1010 at 6:28-32; Ex-1002, ¶57. “Next, implant positioner 160 is lightly tapped to drive implant 5 into cavity 45 created laterally across sacroiliac joint 60,” such that the implant is “countersunk 1-2 mm into the sacroiliac joint.” Ex-1010 at 6:33-36. All instruments are then removed from the surgical site, and the incision is closed. *Id.* at 6:37-40; Ex-1002, ¶57. Figure 23, which is

reproduced and annotated in color below, depicts the final position of the implant within the SI joint.

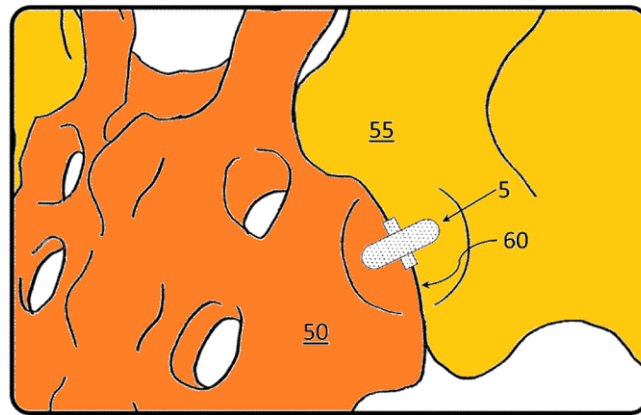


FIG. 23.

c. Overview of Lins

Lins is a published patent application that was filed on December 1, 2014 and therefore is prior art against the '511 Patent under 35 U.S.C. § 102(a)(2). Analogously to Vestgaarden-981 and Vestgaarden-818, Lins discloses a method of inserting an implant into a joint using a nesting surgical tool set, which includes a working channel ("cannulated retention portion 36") with a hollow barrel and tangs and a surgical tool ("translation portion 34") configured to access the joint via the working channel. Ex-1011 at [0034]-[0035]; [0038]; FIGS. 4-6; FIG. 16; Ex-1002, ¶60; Ex-1004, ¶22. Lins's nesting surgical tool set is depicted in Figure 6, which is reproduced and annotated below. *See* Ex-1002, ¶61; *see also* Ex-1004, ¶23.

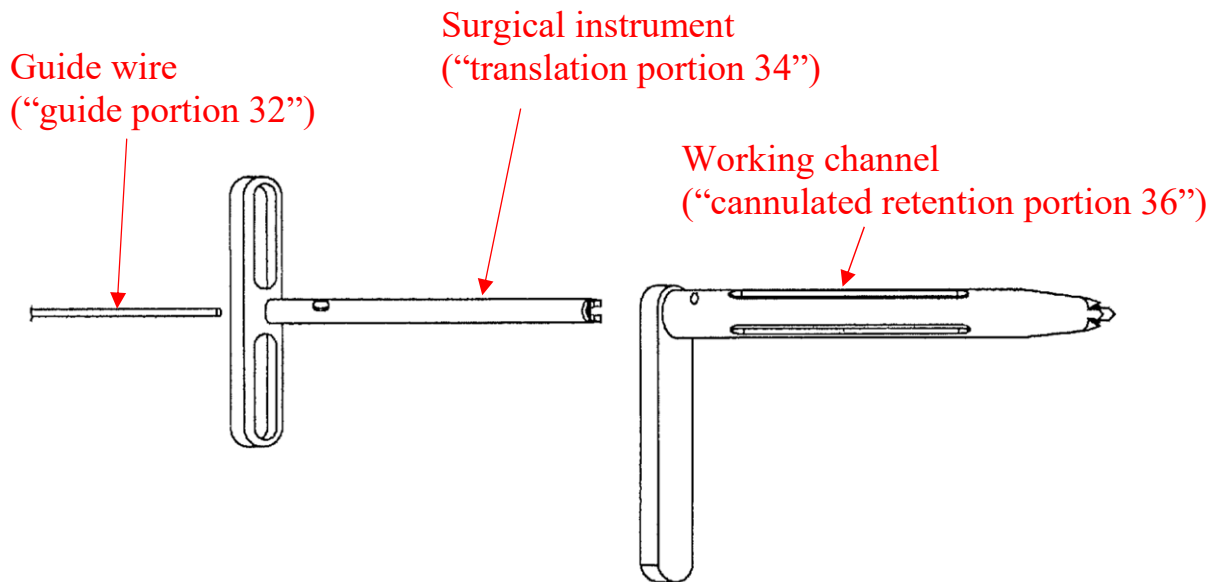


FIG. 6

Lins's working channel is depicted in more detail in Figure 16, which is reproduced and annotated below. *See* Ex-1002, ¶60; *see also* Ex-1004, ¶22.

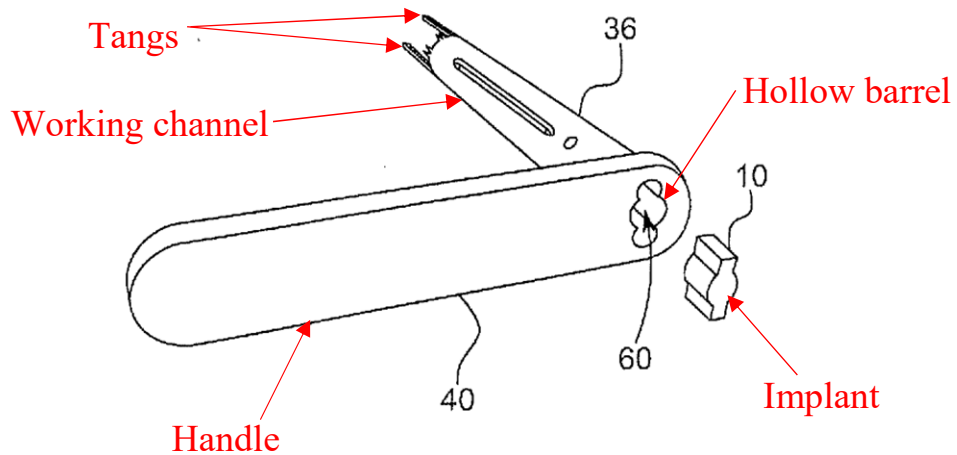


FIG. 16

Lins discloses that the surgical instrument "includes one or more guide protrusions 46 along its shaft," wherein

[t]hese ***guide protrusions 46 are configured to engage one or more recesses*** (not illustrated) manufactured into the ***interior bore*** of the substantially cylindrical [working channel] (FIGS. 4-6) ***that control and guide the depth of penetration and degree of rotation*** of the [surgical instrument] with respect to the [working channel], and with respect to the facet joint.

Ex-1011 at [0038] (emphasis added); Ex-1002, ¶62 Ex-1004, ¶24. Figure 11 of Lins depicts the opening of the recess (interior guidance slot) within the working channel and the guide protrusion on a shaft of the surgical instrument. Ex-1011 at FIG. 11; Ex-1002, ¶62; Ex-1004, ¶24. This figure is reproduced and annotated below. *See* Ex-1002, ¶62; *see also* Ex-1004, ¶24.

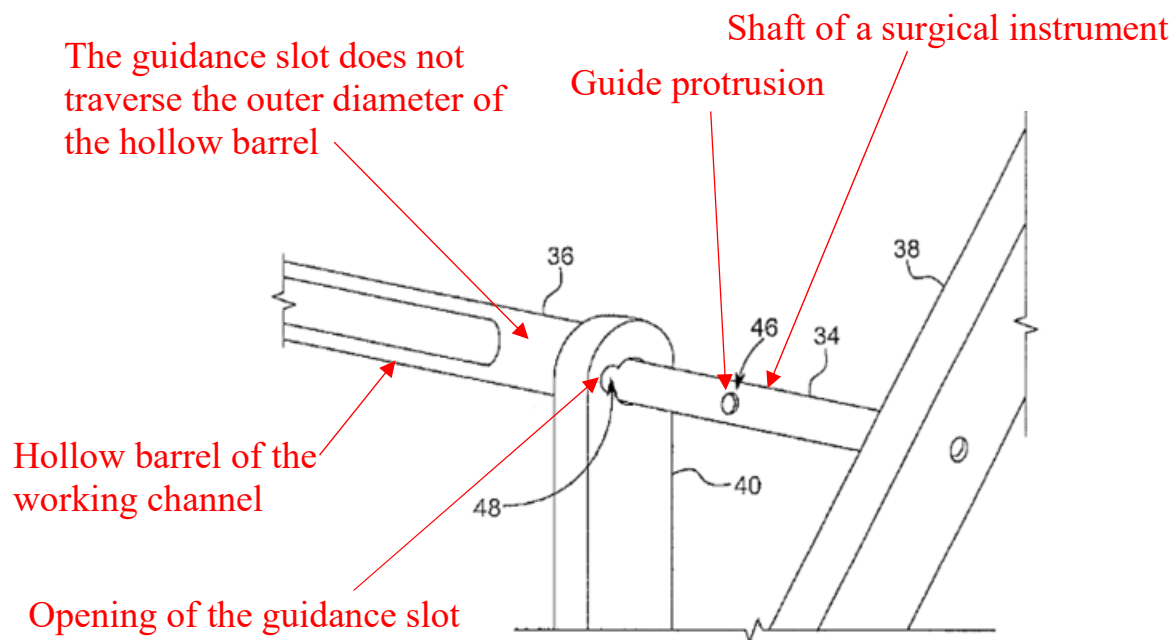


FIG. 11

d. Combination of Vestgaarden-981 with Vestgaarden-818

(1) Motivation to combine

POSA had motivation to apply the surgical tools and fusion implants disclosed in Vestgaarden-981 to the method of SI joint fusion disclosed in Vestgaarden-818 at least for the following two reasons: (1) Vestgaarden-981 itself provides motivation to apply its invention to “any joint” having a gap between two bones, while Vestgaarden-818 explicitly incorporates Vestgaarden-981 by reference and states that Vestgaarden-981’s fusion implants can be applied to SI joint fusion; and (2) Vestgaarden-981’s implants and surgical tools have several advantages over their counterparts disclosed in Vestgaarden-818. *See* Ex-1009 at 8:50-50; *see also* Ex-1010 at 4:10-14; Ex-1002, ¶66. Each of these reasons to combine Vestgaarden-981 and Vestgaarden-818 is explained in more detail below.

i. The specification passages from Vestgaarden-981 and Vestgaarden-818 provide motivation for their combination

The specification of Vestgaarden-981 contains a section entitled “Applications to Joints *Other* than Facet Joints,” which teaches 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 at 8:50-60 (emphasis added). Thus, Vestgaarden-981 itself provides motivation for

applying its surgical tools and implants with stabilizers and bone-engaging protrusions to a wide range of various joints. Ex-1002, ¶67. In turn, Vestgaarden-818 discloses a method of fusing an SI joint that involves positioning an implant with stabilizers in a gap between bony surfaces of a sacrum and an ilium. Ex-1010 at 2:56-62. Based on the parallel descriptions of the implants and the joints in Vestgaarden-981 and Vestgaarden-818, a POSA had motivation to combine these references. Ex-1002, ¶68. Further, the specification of Vestgaarden-818 explicitly incorporates Vestgaarden-981 by reference, thereby establishing explicit motivation for this combination. Ex-1010 at 4:10-14 (“[T]he novel sacroiliac stabilization implant, disclosed further in U.S. Pat. No. 8,162,981 to Vestgaarden, entitled ‘Method and Apparatus for Spinal Facet Fusion,’ [is] incorporated herein by reference ...”); *see also* Ex-1002, ¶76.

ii. Advantages of Vestgaarden-981’s implants and surgical instruments over their counterparts in Vestgaarden-818

POSA had motivation to apply Vestgaarden-981’s implant and surgical tools to Vestgaarden-818’s SI joint fusion method because Vestgaarden-981’s implants and surgical tools provide multiple advantages over their counterparts taught in Vestgaarden-818. Ex-1002, ¶69. For example, POSA had motivation to use Vestgaarden-981’s fusion implant with bone-engaging protrusions—such as barbs, a screw, sharp spikes, or a combination thereof—because the bone-engaging

protrusions help secure an implant within a joint. *Id.* In addition, POSA had motivation to implement Vestgaarden-981's implant with a cavity ("through-hole") because the cavity "allows a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant." Ex-1009 at 8:1-4; Ex-1002, ¶70.

POSA also had motivation to use Vestgaarden-981's implant holder and implant tamp for inserting and driving the implant into the SI joint because these tools would enable a surgeon to precisely place the implant into the SI joint. Ex-1002, ¶71. On the other hand, Vestgaarden-818 does not disclose an inserter tool for holding an implant, and only discloses an "implant positioner" for driving the implant into the SI joint. Ex-1010 at 6:29-36; FIG. 22; Ex-1002, ¶71.

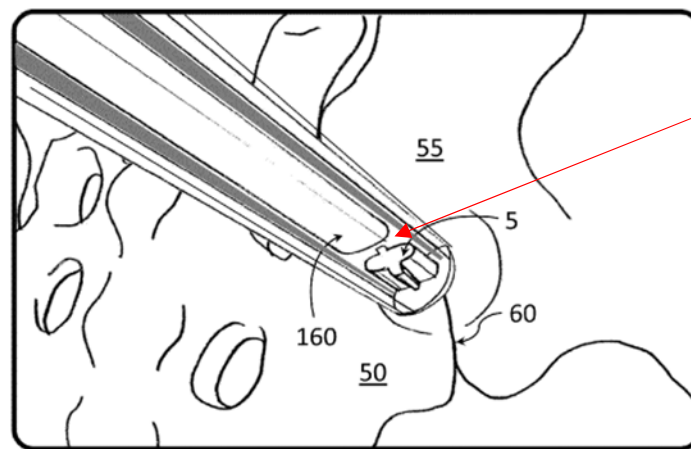


FIG. 22.

A major disadvantage of Vestgaarden-818 is that because the implant positioner does not hold the implant, a surgeon cannot control the orientation and the position of the implant as the implant advances through the working channel.

Ex-1002, ¶72. As depicted in Figure 21 of Vestgaarden-818, after a surgeon inserts the implant into the working channel, the implant is essentially in freefall. *Id.*

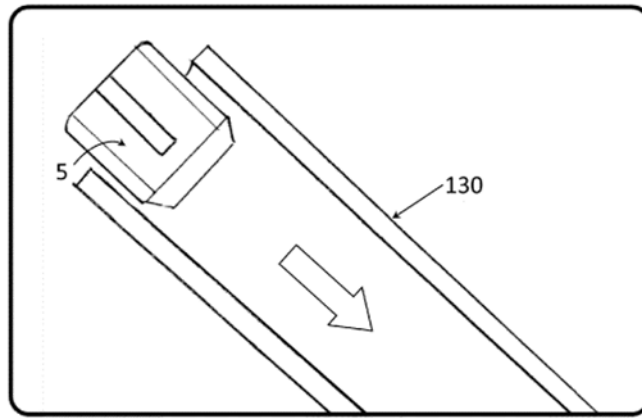


FIG. 21.

“The absence of a tool for holding the implant places a great amount of stress on a surgeon and makes the surgery more difficult, less efficient, and increases the risk of improper implantation.” Ex-1002, ¶73. Accordingly, because Vestgaarden-818 does not disclose a surgical tool for holding the implant, POSA had motivation to improve Vestgaarden-818’s implant-insertion method by combining it with Vestgaarden-981’s implant holder, thereby enabling a surgeon to precisely position the implant into the void within the SI joint, prior to using Vestgaarden-981’s implant tamp to drive the implant into the void. Ex-1002, ¶74.

Finally, Figure 8 of Vestgaarden-981 depicts that distal ends of the tangs of the working channel are rounded (blunt). *Id.*, ¶75. POSA would have understood that such blunt tangs are advantageous because they reduce the likelihood of injuring ligaments or soft tissue during the surgery. *Id.* Thus, POSA had motivation to apply

Vestgaarden-981's working channel with blunt tangs to Vestgaarden-818's method.
Id.

(2) Predictable result

Combination of Vestgaarden-981 and Vestgaarden-818 would have yielded a predictable result, in which Vestgaarden-981's surgical instruments and implants would be used for their intended functions to perform an SI joint fusion procedure taught in Vestgaarden-818. *Id.*, ¶76. The predictability of this result is evidenced by the fact that Vestgaarden-818 incorporates by reference Vestgaarden-981, thereby indicating that these references are readily combinable with one another. *See* Ex-1010 at 10-14; *see also* Ex-1002, ¶76. Furthermore, both Vestgaarden-981 and Vestgaarden-818 include parallel disclosures stating that their inventions can be "used to stabilize and fuse *any* joint having ... a pair of opposing bony surfaces defining a gap therebetween," thereby further reinforcing their compatibility and the predictable results achieved by their combination. *See* Ex-1009 at 8:52-60; Ex-1010 at 7:13-21; *see also* Ex-1002, ¶76.

e. Combination of Vestgaarden-981 and Lins

(1) Motivation to combine

Prior to the priority date of the '511 Patent, POSA understood that controlling the depth of insertion and orientation of the surgical tools were critical considerations for SI joint fusion procedures. Ex-1002, ¶77; Ex-1004, ¶25. Both

Vestgaarden-981 and Lins disclose mechanisms for controlling the depth and alignment of surgical tools relative to the working channel and the joint. *Compare* Ex-1009 at 5:4-9; 7:1-2, *with* Ex-1011 at [0038]; *see also* Ex-1002, ¶¶78-79; Ex-1004, ¶¶26, 30. Vestgaarden-981 discloses “by way of example but not limitation” that the surgical tools and the working channel may have complementary “flat portions” for maintaining alignment with the joint. Ex-1009 at 5:1-9. Figures 9A and 11 of Vestgaarden-981 depict that the flat portions are disposed on the distal ends of the surgical tools and have shoulders that would function as mechanical depth-stops when they engage the corresponding shelves of the flat portions within the working channel. Ex-1002, ¶78; Ex-1004, ¶26.

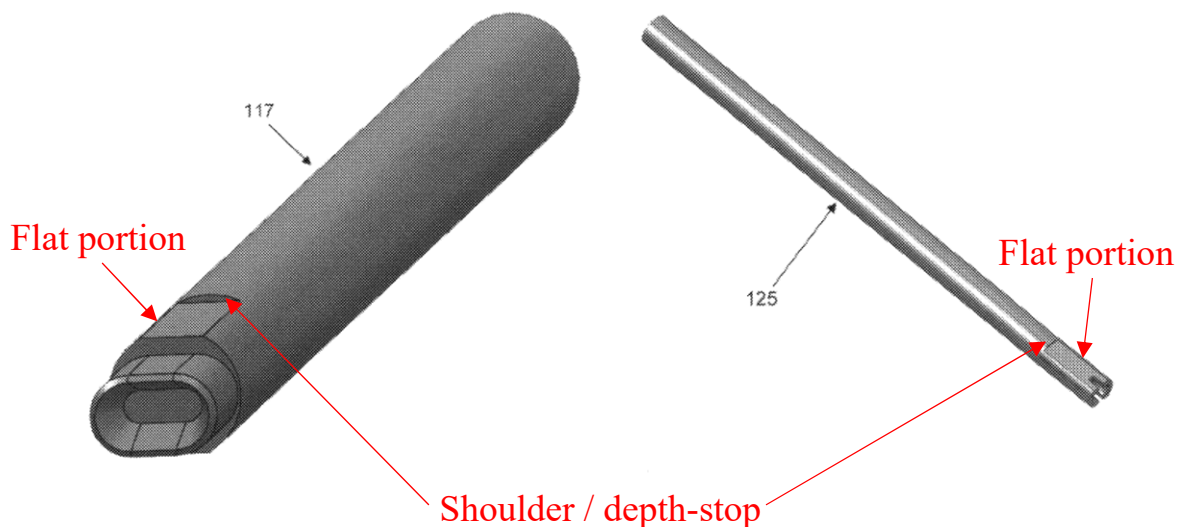


FIG. 9A

FIG. 11

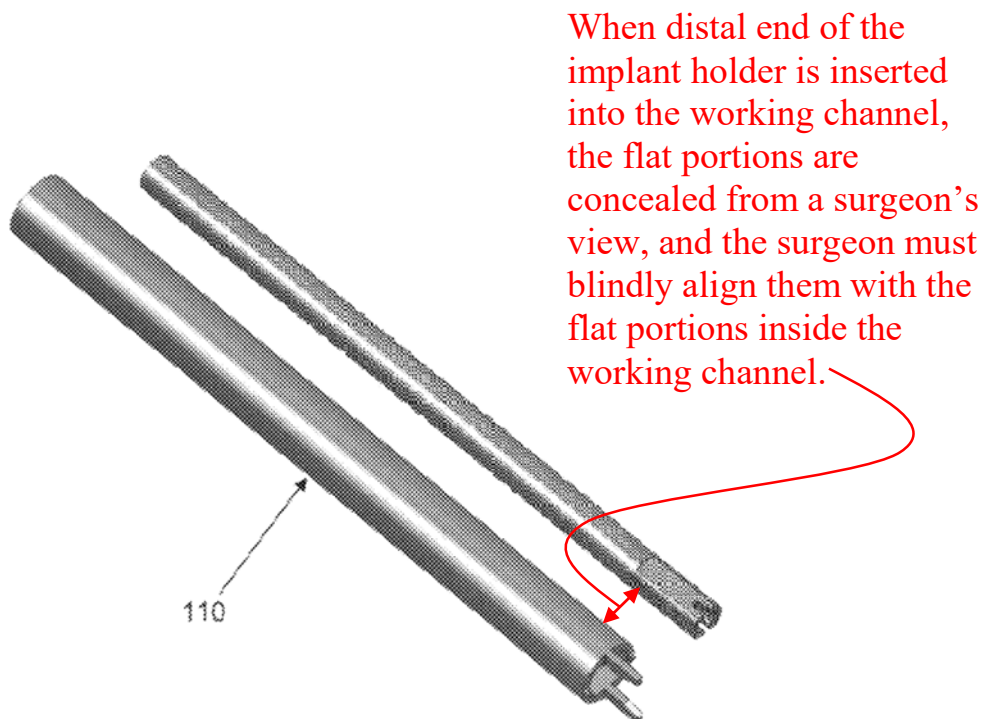
Lins teaches a different and more advantageous mechanism for controlling the depth and orientation of the surgical tools relative to the joint. *See* Ex-1011 at [0038];

see also Ex-1002, ¶79; Ex-1004, ¶30. In Lins, the depth of insertion and orientation of the surgical tools are controlled via engagement between guide protrusions disposed on surgical instruments and complementary recesses (guidance slots) disposed on the interior bore of the working channel. Ex-1011 at [0038]; Ex-1002, ¶79; Ex-1004, ¶30.

As explained in detail below, because Lins's guide protrusions and guidance slots offer several advantages over Vestgaarden-981's "flat portions," POSA had motivation to substitute Lins's guidance slot and guide protrusion for Vestgaarden-981's "flat portions" to achieve these advantages. Ex-1002, ¶80; Ex-1004, ¶37.

First, Vestgaarden-981's flat portions do not provide a surgeon with a visual reference for aligning the implant holder with the working channel. Ex-1002, ¶81; Ex-1004, ¶27. After the distal end of the implant holder is inserted into the working channel, the barrel of the working channel conceals the flat portions of the implant holder, and the surgeon cannot see them. Ex-1002, ¶81; Ex-1004, ¶27. Furthermore, during advancement of the implant holder into the working channel, until the distal end of the implant holder reaches a flat surface at the distal end of the working channel, the implant holder can freely rotate. Ex-1002, ¶81; Ex-1004, ¶27. If a surgeon inadvertently rotates the implant holder while advancing it into the working channel, the flat portions of the implant holder and the working channel will become misaligned. Ex-1002, ¶81; Ex-1004, ¶27.

When this happens, the surgeon must blindly realign the flat portions of the implant holder with the flat portions within the working channel to continue advancing the implant holder. Ex-1002, ¶82; Ex-1004, ¶28. To do so, the surgeon will gradually rotate the implant holder while applying a linear force thereto to “feel” for the flat portions of the implant holder and the working channel to come into alignment, so that the distal end of the implant holder can continue its advancement into the working channel. Ex-1002, ¶82; Ex-1004, ¶28. Only during these final few centimeters of advancement, Vestgaarden-981’s flat portions control the alignment between the surgical tool and the working channel. Ex-1002, ¶82; Ex-1004, ¶28.



In contrast, Lins enables a surgeon to visually align the guide protrusions on a shaft of a surgical tool with recesses (guidance slots) of the working channel, as depicted in Figure 11. Ex-1002, ¶83; Ex-1004, ¶31. After the guide protrusion enters the guidance slot, the guidance slot controls the orientation of the surgical tool during the entire advancement process, thereby giving the surgeon a feeling of control and eliminating the need for blind adjustment. Ex-1002, ¶83; Ex-1004, ¶31.

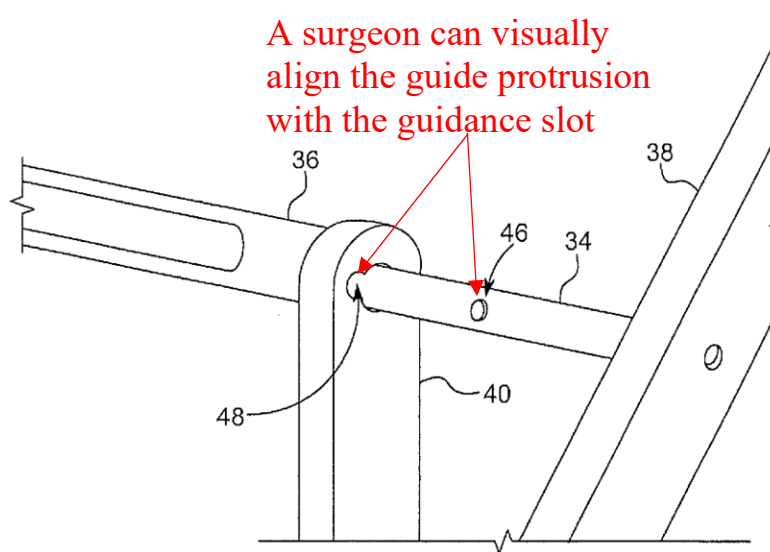


FIG. 11

For the reasons explained above, the guide protrusions and guidance slots taught in Lins offer a surgeon a greater feeling of control and a better user experience over the exemplary directional features (flat portions) mentioned in Vestgaarden-981. Ex-1002, ¶84; *see also* Ex-1004, ¶31. Therefore, to achieve these advantages, POSA had motivation to improve Vestgaarden-981's surgical tools and working

channel by substituting Lins’s guidance slot and guide protrusions for Vestgaarden-981’s “flat portions.” Ex-1002, ¶84; Ex-1004, ¶37.

Second, Lins’s guidance slot and guide protrusions offer manufacturing advantages over Vestgaarden-981’s flat portions. Ex-1004, ¶¶29, 32, 40. Machining a slot into an interior of a uniform tubular barrel entails a simpler manufacturing process than creating a working channel with a non-uniform lumen, whose proximal portion has a circular cross-section while the distal end has flat interior surfaces. *Id.* Likewise, affixing guide protrusions to a tubular shaft of a surgical instrument entails a simpler manufacturing process than creating a tubular shaft with flat faces of precise dimensions. *Id.*

Thus, POSA had motivation to implement Lins’s guidance slots and guide protrusions as Vestgaarden-981’s “directional features” to achieve a surgical tool set that offers an improved user-experience and manufacturing efficiency.³ *Id.*, ¶33-37; *see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) (“[M]otivation to combine exists ... when the ‘improvement’ is technology-independent and the combination of references results

³ In fact, in the large-scale commercial implementation, due to manufacturing and ease-of-use considerations, VG Innovations—the owner of Vestgaarden-981 patent—replaced “flat portions” of the working channel and surgical tools with a “pin and groove mechanism.” Ex. 1004 at ¶¶33-36.

in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient.”).

(2) Predictable result

Implementing Lins’s guidance slot and guide protrusions as the “directional features” of Vestgaarden-981’s working channel and surgical tools is a simple substitution of one known element (guidance slot and guide protrusion) for another known element (“flat portions”) that yields a predictable result—a working channel with a guidance slot for controlling the depth of advancement and orientation of surgical instruments. Ex-1002, ¶85; Ex-1004, ¶¶38-39. The fact that Lins expressly references Vestgaarden-981 in its Background section indicates that combination of these two references would have been readily apparent to POSA. Ex-1011 at [0005]; Ex-1002, ¶85. Furthermore, Vestgaarden-981 expressly states that “flat portions” are disclosed “[b]y way of example but not limitation,” thereby clearly conveying to POSA that other directional features can be readily substituted for the exemplary “flat portions.” Ex-1009 at 5:4-9; Ex-1002, ¶85.

(3) The USPTO found that the combination of Lins’s guidance slot and guide protrusions with a prior art working channel and surgical tools would have been obvious

Patent Owner is currently prosecuting a sibling application of the ‘511 Patent—App. Serial No.: 16/689,073 (“the ‘073 Application”). Claim 98 of the ‘073

Application recites “a guidance slot within said hollow barrel [of said working channel]” and “an inserter having a slot-engagement protrusion.” Ex-1013 at 858-59. On November 8, 2022, a patent examiner—who by definition is a POSA—rejected this claim on the ground that it would have been obvious to improve a working channel and surgical tools to include Lins’s guidance slots and guide protrusions:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify [a] working channel and related surgical tools [disclosed in the prior art] to include the guidance slot and to modify the surgical tools associated with the working channel to include the slot-engagement protrusions, as taught by Lins, for the purpose of controlling and guiding a depth of penetration of the surgical tools relative to the working channel.

Ex-1013 at 888. The USPTO’s finding quoted above corroborates that the combination of Lins’s guidance slots and guide protrusions and Vestgaarden-981’s working channel and surgical tools would have been obvious.

f. Explanation of Vestgaarden-Vestgaarden-Lins combination

The resultant combination of Vestgaarden-981, Vestgaarden-818, and Lins is straightforward: Vestgaarden-981’s working channel and surgical instruments would be equipped with Lins’s guidance slots and guide protrusions as the “directional features.” Ex-1002, ¶86. In this combination, Lins’s guidance slots and

guide protrusions would 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 the SI joint and maintain proper orientation therewith. *Id.*, ¶87. These 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.*, ¶¶87-88.

The combination of Vestgaarden-981, Vestgaarden-818, and Lins teaches all limitations of claims 1-5, 8, and 9 as set forth in the analysis provided below.

g. Claim 1

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

Vestgaarden-818 discloses “[a] method for fusing a spinal sacroiliac joint.” Ex-1010 at Abstract; Ex-1002, ¶102.

(2) [1.a] “creating a first incision proximal to the patient's sacroiliac joint”

Vestgaarden-818 discloses that “[a] path through soft tissue to the sacroiliac joint is then created via surgeon's preference, such as open, minimally-invasive, percutaneous, or arthroscopic.” Ex-1010 at 5:23-26; Ex-1002, ¶103. POSA understands that creating a path through soft tissue to the SI joint involves making an incision proximal to the SI joint. Ex-1002, ¶103.

(3) [1.b.1] “inserting a working channel into said first incision,”

Vestgaarden-818 teaches the step of inserting a directional cannula (working channel) into the incision. Ex-1010 at 5:49-50; Ex-1002, ¶104.

(4) [1.b.2] “said working channel having a hollow barrel”

Vestgaarden-981 discloses that “instruments may ... be inserted through the cannula.” Ex-1009 at 5:5-9; 6:40-43, 60-63. POSA understands this disclosure to mean that the working channel (directional cannula) has a hollow barrel. Ex-1002, ¶105. Furthermore, Figure 8 of Vestgaarden-981 depicts a working channel having a hollow barrel. *Id.*

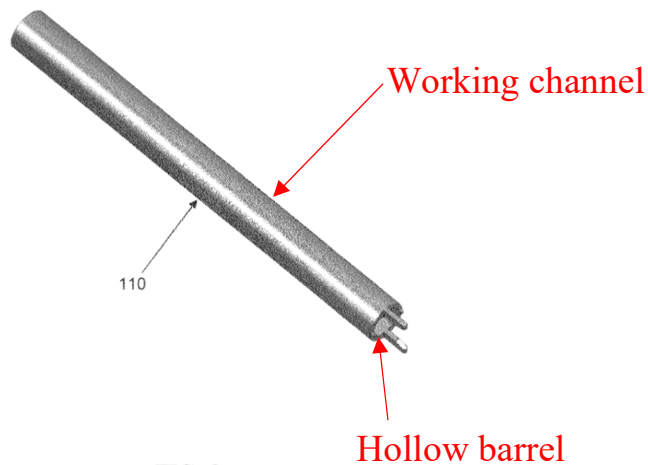


FIG. 8

(5) [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,”

Lins discloses “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].” Ex-1011 at [0038] (emphasis added); Ex-1002, ¶106. Figure 11 of Lins, which is reproduced and annotated below, depicts an opening of the guidance slot disposed on the interior diameter of the hollow barrel and not traversing the outer diameter thereof. Ex-1002, ¶107.

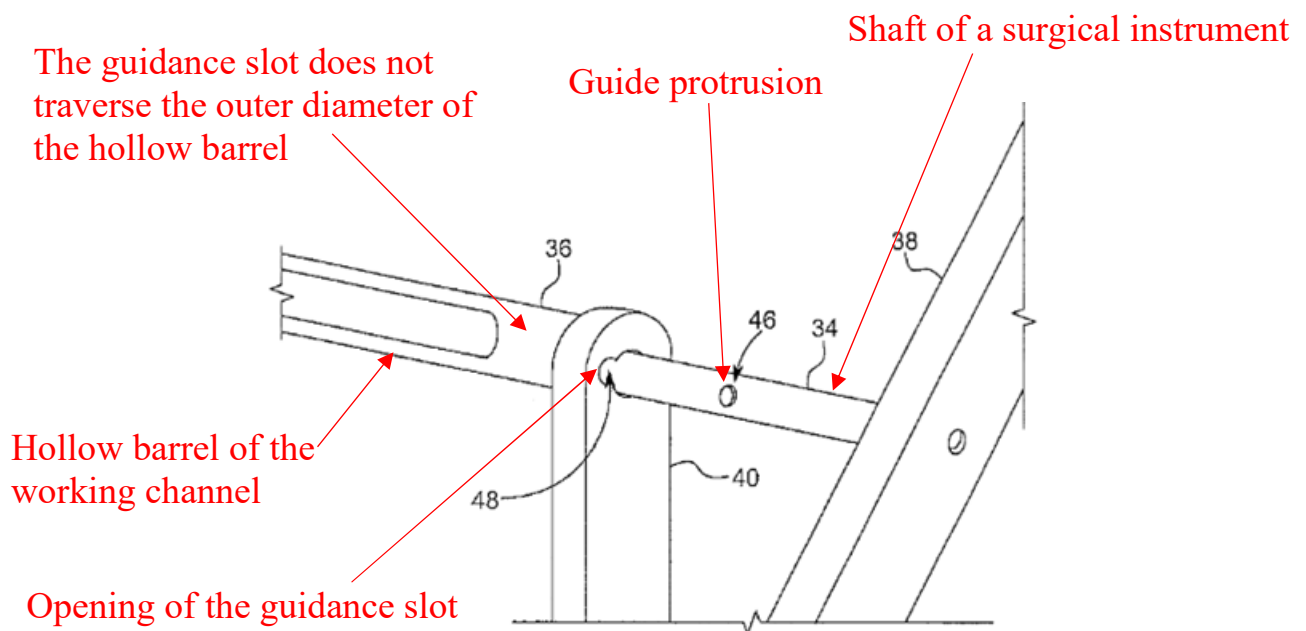


FIG. 11

Accordingly, Lins teaches the limitation [1.b.3] of the ‘511 Patent.⁴ Ex-1002, ¶108. As established in Part XII.A.1.e.(1), *supra*, it would have been obvious to combine Lins’s guidance slot with Vestgaarden-981’s working channel.

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

Figure 8 of Vestgaarden-981 teaches that the working channel has two tangs on a distal end thereof. *See* Ex-1009 at FIG. 8; Ex-1002, ¶109.

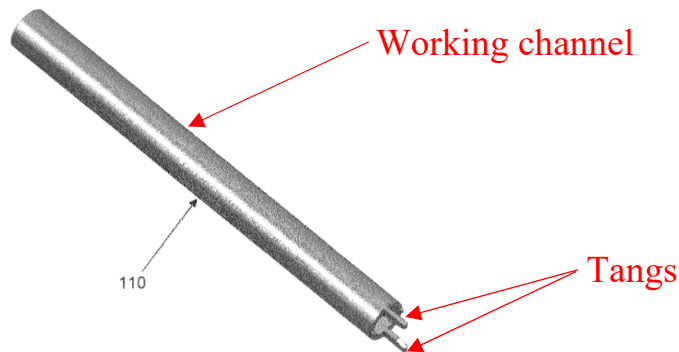


FIG. 8

⁴ The same USPTO patent examiner who examined and allowed the ‘511 Patent corroborated this statement in the Office Action issued on November 8, 2022 against a sibling of the ‘511 Patent (the ‘073 Application), finding that “Lins teach[es] ... a working channel including a guidance slot for controlling the advancement of surgical tools into said working channel.” Ex. 1013 at 888.

**(7) [1.c] “creating a void in said sacroiliac joint;
and”**

Vestgaarden-818 discloses the step of “creating a cavity in the ilium and sacrum to a predetermined depth that spans the sacroiliac joint.” Ex-1010 at Abstract; 4:60-65; Ex-1002, ¶110.

**(8) [1.d.1] “inserting a fusion implant into said
void,”**

Vestgaarden-818 discloses the step of “inserting a novel stabilization implant into the cavity.” Ex-1010 at Abstract; 5:2-7; Ex-1002, ¶111.

**(9) [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.”**

Vestgaarden-981 discloses that the body of the fusion implant “may include a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom.” Ex-1009 at 4:33-35, FIG. 1; Ex-1002, ¶112. Vestgaarden-981 explains that the barbs are advantageous because they “impede retraction” of the fusion implant from the joint. Ex-1009 at 4:35-37; Ex-1002, ¶112. In addition, Vestgaarden-981 teaches a wide array of bone-engaging devices—including “sharp spikes,” “K-Wire, suture, staple, screw, or other fixation device,”—that protrude from the body of the implant and are configured for “attaching the implant to the ... joint.” Ex-1009 at 8:30-34, 8:39-41; FIGS. 65-68, 72-74; Ex-1002, ¶112. Figures 1, 58, 68, and 74 of Vestgaarden-

981 illustrate several fusion implant embodiments with protrusions—these figures are reproduced and annotated below. Ex-1002, ¶112.

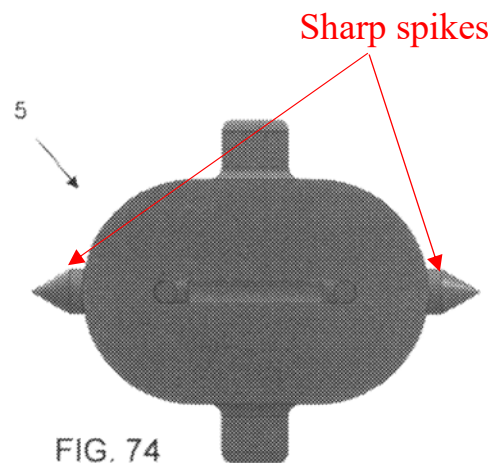
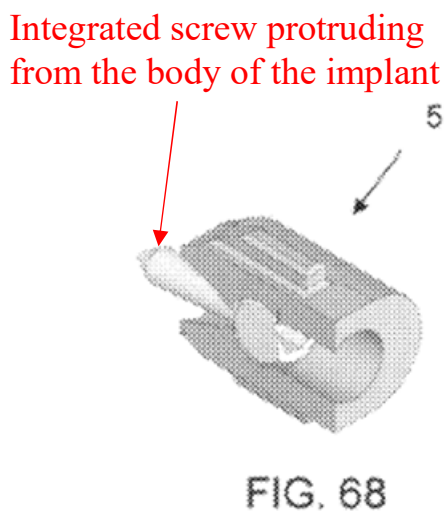
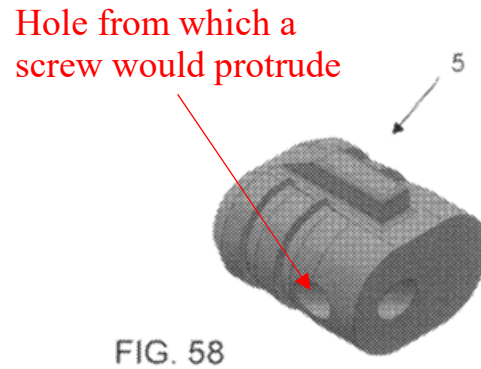
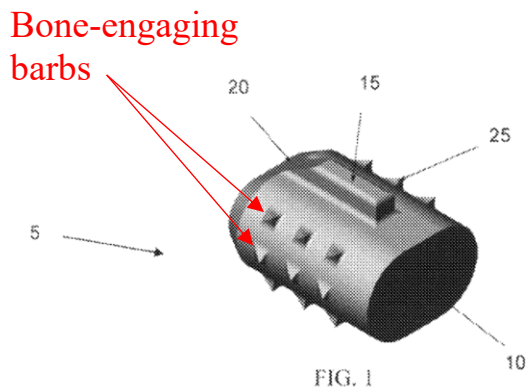
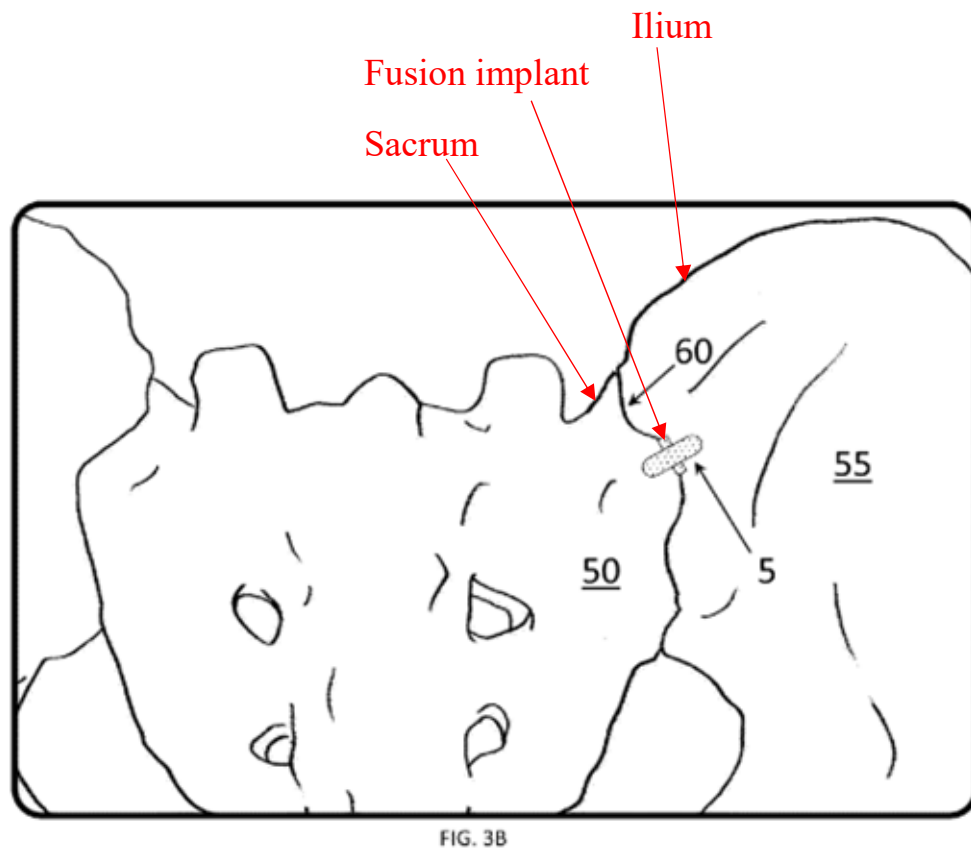


Figure 3B of Vestgaarden-818 depicts the fusion implant positioned within a void in the SI joint, between the articular surfaces of the sacrum and ilium. Ex-1010 at 4:25-33, FIG. 3B; Ex-1002, ¶113.



When 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. Ex-1009 at 4:35-37 ("Barbs 25 are designed ... to impede retraction of body 10 out of the [] joint."); 8:19-42 (describing screws, sharp spikes and other devices for "attaching the implant to the [] joint"); Ex-1002, ¶114; Ex-1014 at 91:4:12 (Patent Owner's expert witness testifying with respect to the implant depicted in Figure 58 of Vestgaarden-981: "So

once the implant is in its final position, then they are -- the screw which would have been -- would have been a component of the implant -- would have been inserted from proximal to distal, and it would pass through the implant, and the screw would end up in the bone tissue to stabilize the implant and secure its position in the final location.”).

h. Claim 2

(1) [2.a.1] “The method of claim 1, wherein said fusion implant has a central body and said at least one protrusion that extends from said central body”

Vestgaarden-981 discloses that the fusion implant depicted in Figure 1 has a central body and “a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom.” Ex-1009 at 4:33-35, FIG. 1; Ex-1002, ¶115. Likewise, each of the fusion implants depicted in Figures 58-60, 65-68, and 72-74 has a central body and at least one protrusion—i.e., a transverse screw (Figures 58-60), a longitudinal integrated screw (Figures 65-68), sharp lateral spikes (Figures 72-74)—extending from the central body. Ex-1002, ¶115.

(2) [2.a.2] “and fixes relative positions of said ilium and sacrum with engagement of said at least one protrusion with said ilium and sacrum.”

Vestgaarden-818 teaches that the “[s]tabilization implant 5 provides the stability and strength needed to immobilize the sacroiliac joint 60 while fusion occurs” and “holds sacrum 50 and ilium 55 stable relative to one another.” Ex-1010

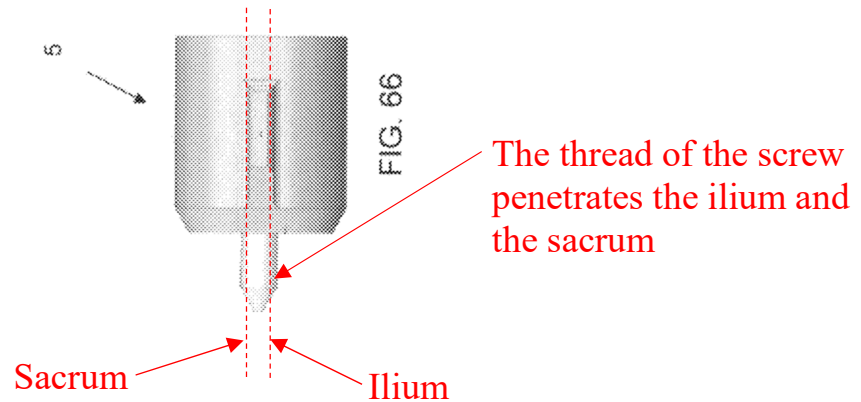
at 5:7-14; Ex-1002, ¶116. Furthermore, POSA understands that when the protrusions (barbs, screw, spikes) of Vestgaarden-981's implant engage the articular surfaces of the sacrum and/or the ilium, the protrusions fix the relative positions of the sacrum and ilium. See Ex-1009 at 5:23-29; Ex-1002, ¶116; see also *PainTEQ, LLC v. Orthocision, Inc.*, IPR2022-00335, Paper 16 at 11-12 (finding that the combination of Vestgaarden-981 and Vestgaarden-818 teaches the limitation “the fusion implant having at least one fixation element [(protrusion)]... fixing the ilium and sacrum in relative lateral positions”).

i. Claim 3

(1) “The method of claim 2, wherein said at least one 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 said ilium and sacrum.”

Vestgaarden-981 discloses a fusion implant, depicted in Figures 65-68, having an integrated screw that extends longitudinally from the body of the implant. Ex-1009 at 8:30-34; FIGS. 65-68; Ex-1002, ¶117. When 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 as depicted in the diagram below.⁵ Ex-1002, ¶117.



Accordingly, the implant disclosed in Figures 65-68 of Vestgaarden-981 has an integrated screw (“protrusion”) that includes a thread (“anchor”) that penetrates at least one of the patient’s ilium and sacrum, thereby fixing their relative positions. Ex-1002, ¶119.

⁵ It would have been obvious to select a screw having such dimensions that would enable the thread of the screw to embed into the bone tissue, thus accomplishing the objective of “attaching the implant to the [] joint” taught in Vestgaarden-981. *See* Ex. 1009 at 8:32-33. Ex. 1002 at ¶118.

j. Claim 4

(1) “The method of claim 3, wherein said 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.”

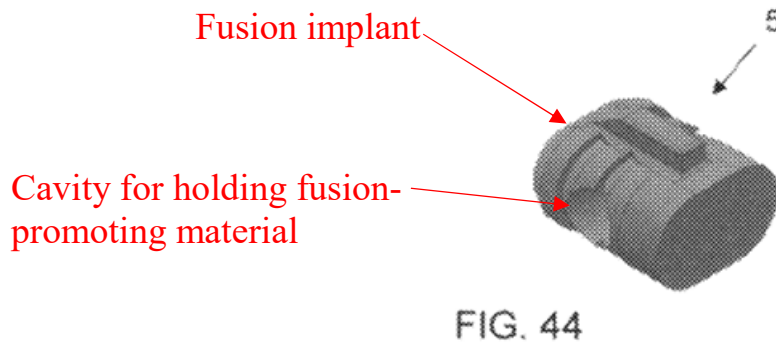
As established above, the thread of the screw is an anchor operable to fix the ilium to the sacrum, thereby substantially immobilizing the SI joint. *See supra* Part XII.A.1.i.(1); Ex-1002, ¶120. Furthermore, by definition, a screw thread is helical. Ex-1015 (a dictionary defining the word “screw” as “a metal fastener having a tapered shank with a *helical* thread”) (emphasis added). Thus, the embodiment of the implant depicted in Figures 65-68 of Vestgaarden-981 teaches all limitations of claim 4. Ex-1002, ¶120.

k. Claim 5

(1) “The method of claim 2, wherein said fusion implant comprises 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.”

Vestgaarden-981 teaches that the fusion 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.” Ex-1009 at 7:66-8:4. Figure 44 depicting the implant

with the cavity for holding fusion-promoting material is reproduced below. Ex-1002, ¶121.



Because rapid fusion through the implant is an advantageous feature, POSA had motivation to combine the through-hole (cavity) for holding fusion-promoting material with an embodiment of the fusion implant having protrusions (i.e., barbs, a screw, sharp spikes, or other fixation devices). *Id.*, ¶122.

I. Claim 8

(1) “The method of claim 1, wherein said 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, wherein engagement of said slot-engagement protrusion with said guidance slot 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.”

As established in Parts XII.A.1.f. and XII.A.1.g.(5), *supra*, it would have been obvious to implement guidance slots and guide protrusions disclosed in Lins as the directional features taught in Vestgaarden-981. In this implementation,

Vestgaarden-981's working channel would have been equipped with one or more guidance slots, while the surgical tools would have been equipped with Lins's "guide protrusions." Ex-1002, ¶123. 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].*" Ex-1011 at [0038] (emphasis added). Thus, the combination of Vestgaarden-981 and Lins teaches the limitations of claim 8. Ex-1002, ¶123.

m. Claim 9

(1) [9.a.1] "The method of claim 1, wherein the at least one tang comprises a plurality of blunt tangs on the distal end thereof"

Figure 8 of Vestgaarden-981, which is reproduced and annotated below, depicts the directional cannula having two bilateral blunt tangs on the distal end thereof. Ex-1002, ¶124.

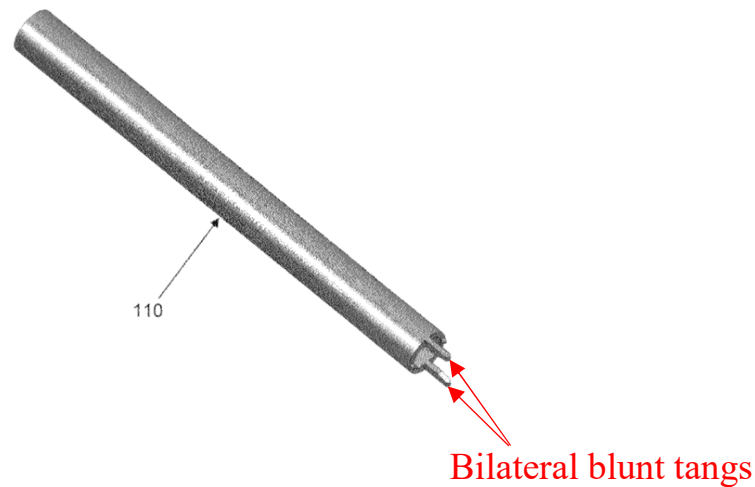
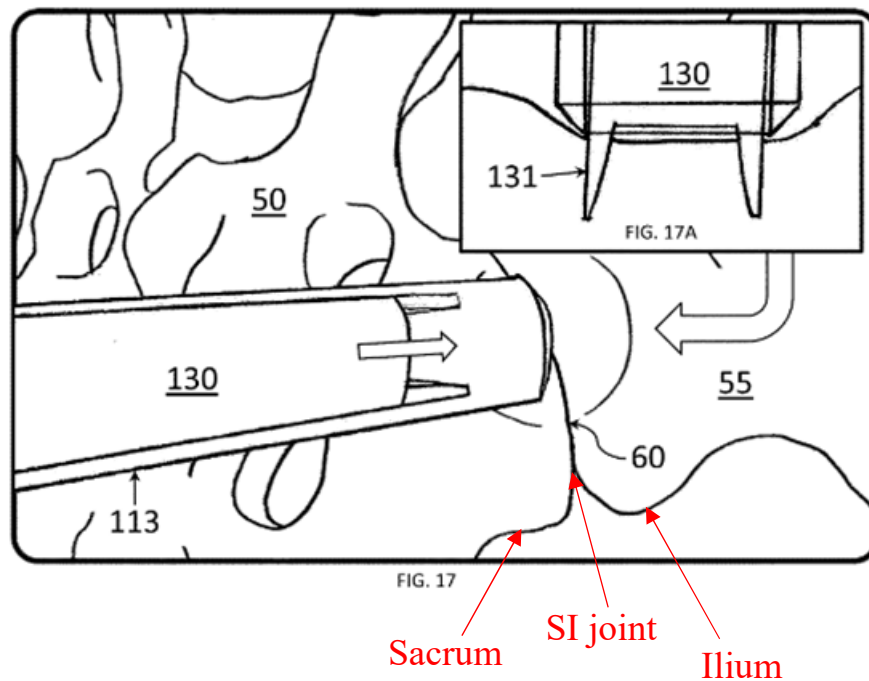


FIG. 8

(2) [9.a.2] “that 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”

Vestgaarden-818 teaches the steps of “aligning the teeth located on the distal end of the cannula with the plane of the joint, [and] tapping a proximal end of the directional cannula to reversibly secure the alignment teeth into the sacroiliac joint.” Ex-1010 at 2:7-12; 5:51-56; Ex-1002, ¶125. Figures 17 and 17A of Vestgaarden-818 depict teeth (tangs) of the working channel being inserted into the SI joint between the articular surfaces of the ilium and sacrum, thereby securing (stabilizing) the working channel relative to the SI joint. Ex-1002, ¶125.

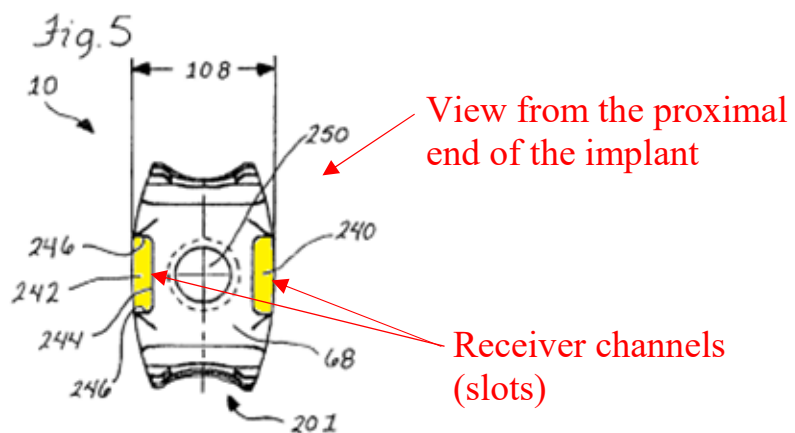
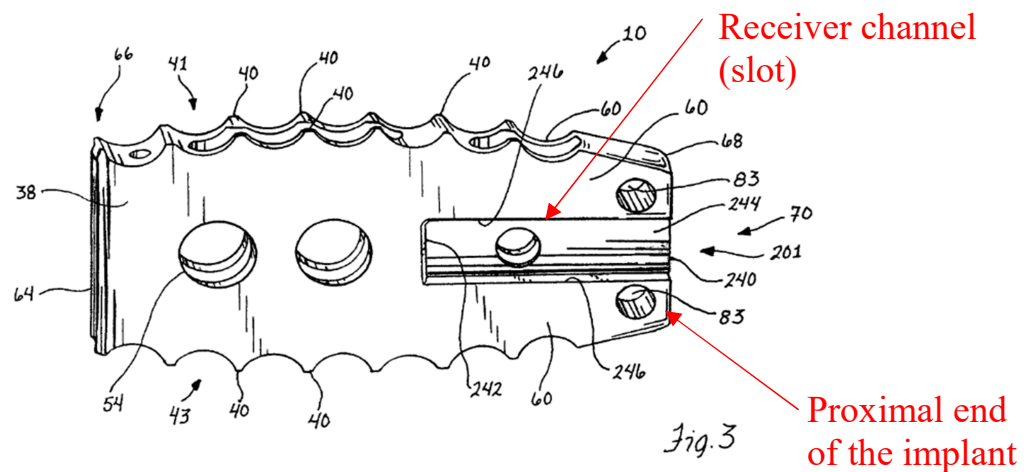


2. Ground 1B: Claims 6, 7, and 10-23 are obvious over the combination of Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer

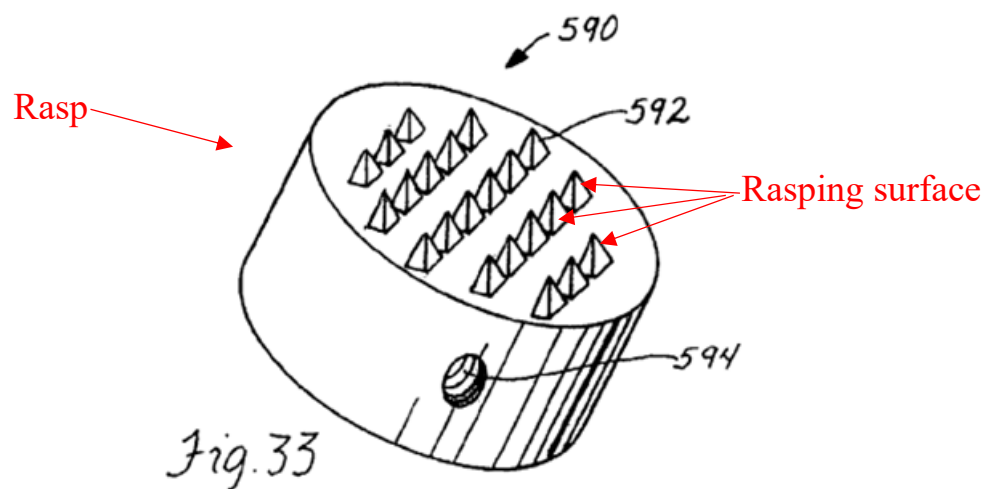
a. Overview of Paltzer

Paltzer issued on October 4, 2011 and therefore is prior art against all claims of the '511 Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Analogously to Vestgaarden-981, Vestgaarden-818, and Lins, Paltzer discloses a method of fusing a joint using an implant. Ex-1012 at 1:14-19; Ex-1002, ¶63. This petition cites Paltzer for a narrow purpose of showing that the following two limitations claimed in the '511 Patent have been known in the art before the '511 Patent's priority date: (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.

First, with respect to the implant slots, Paltzer discloses that “the implant 10 includes a plurality of **recesses** for receiving portions of the inserter 200 therein. Specifically, the implant sidewalls 60 include **elongate recesses** or **receiver channels** 240 for receiving arm or prong portions 202 of the inserter 200.” Ex-1012 at 9:46-50 (emphasis added); Ex-1002, ¶64. Figures 3 and 5, which are reproduced and annotated below, depict a fusion implant having receiver channels (slots) disposed on the proximal end thereof. Ex-1002, ¶64.



Second, with respect to a rasp, Paltzer discloses “a rasp scraping member 590” having “rasping surfaces 592 for scraping and wounding the endplates 42, 46, as described above, and inducing fluid and blood flow into the intervertebral space 30, which promotes bone ingrowth.” Ex-1012 at 15:34-40; Ex-1002, ¶65. Paltzer teaches an embodiment in which a dedicated tool (not shown in the figures) is configured to couple to the rasp to insert the rasp into a joint. Ex-1012 at 15:44-47; Ex-1002, ¶65. Paltzer’s rasp with a rasping surface is depicted in Figure 33, which is reproduced and annotated below. Ex-1002, ¶65.



b. Vestgaarden-Vestgaarden-Lins-Paltzer Combination

(1) Combination of Paltzer's implant slots with Vestgaarden-981's fusion implant

(i) Motivation to Combine

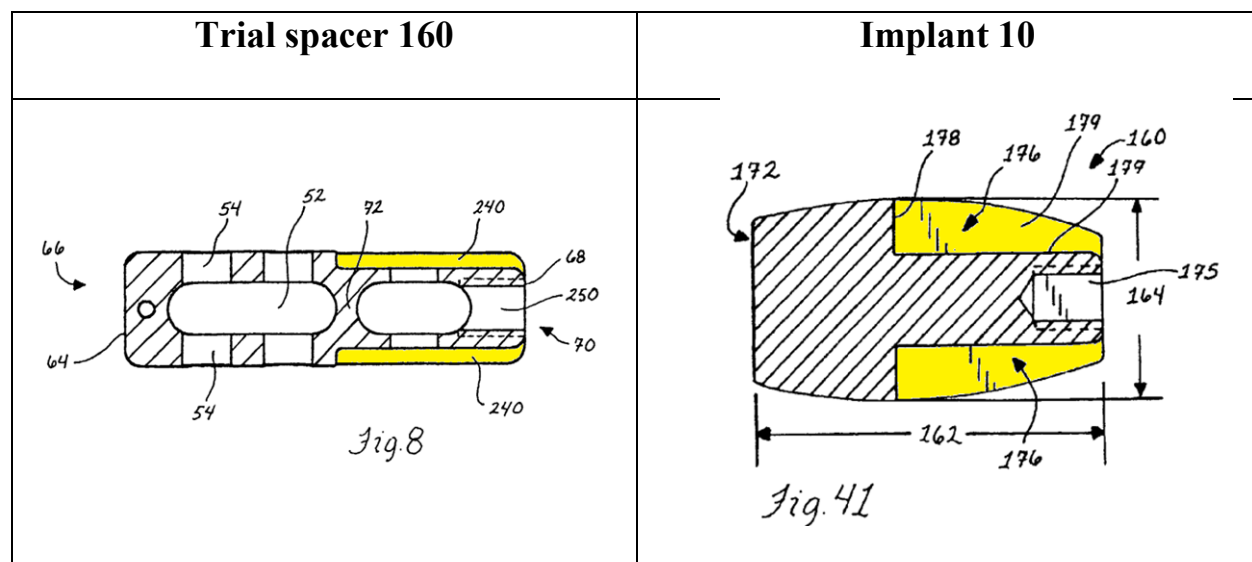
POSA had reason to combine Paltzer's receiving channels (slots) with Vestgaarden-981's fusion implants. Ex-1002, ¶89. Although Vestgaarden-981 discloses an implant holder having a pair of implant-engaging arms, Vestgaarden-981 does not explain how these implant-engaging arms hold the implant. Ex-1009 at FIG. 11; Ex-1002, ¶89. Paltzer also discloses an implant holder having implant-engaging arms and further discloses that implants have slots on their proximal ends for receiving the arms of the implant holder. Ex-1012 at 9:46-50; Ex-1002, ¶89. Paltzer provides at least three reasons that would have motivated POSA to combine Paltzer's slots with Vestgaarden-981's fusion implants. Ex-1002, ¶89.

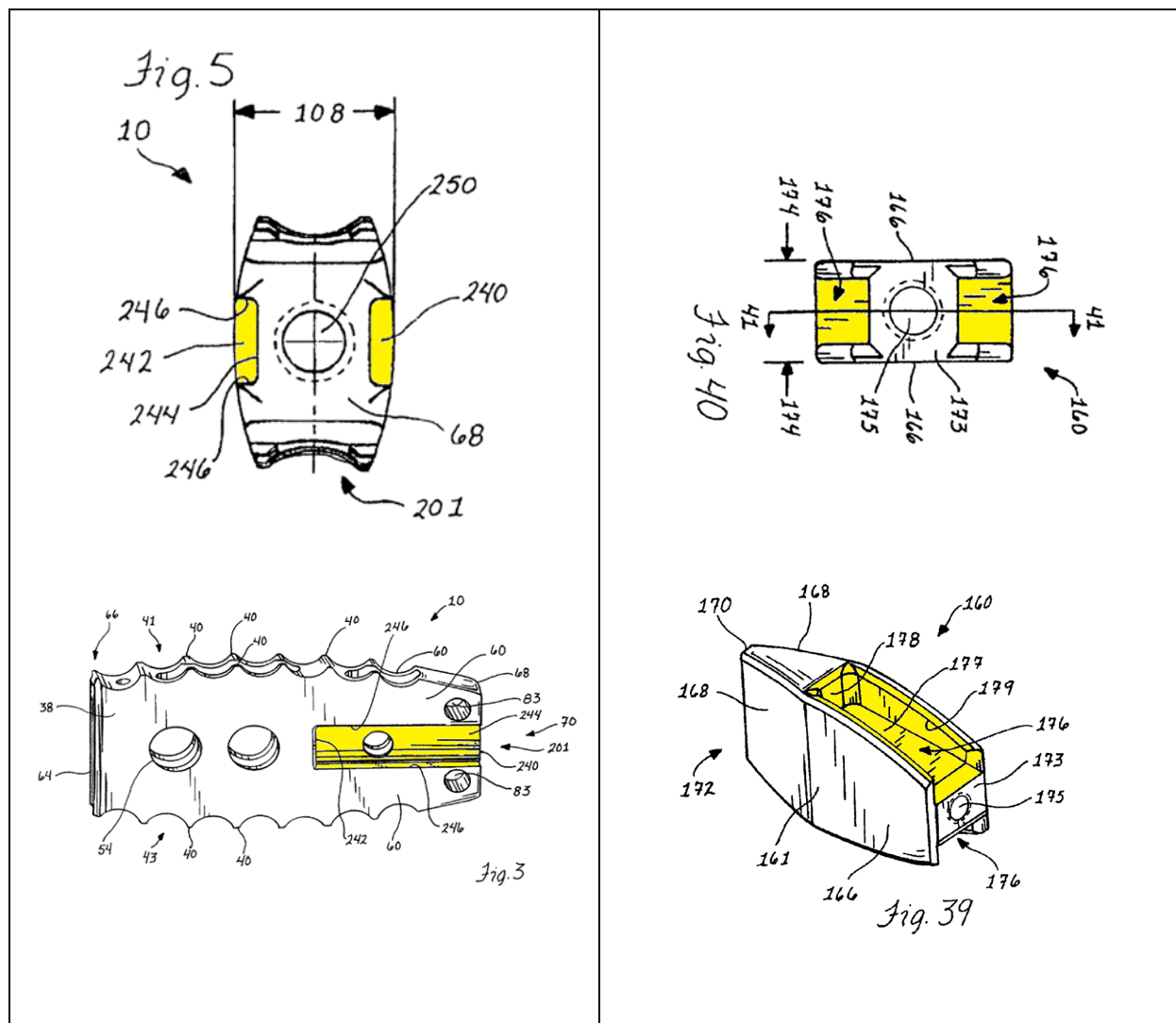
First, Paltzer teaches that when the arms of the inserter are received within the slots, engagement between the arms and the slots is distributed over multiple contact surfaces, thereby “maximiz[ing] surface area contact between the tool 200 and implant 10 *to assist in distributing the forces endured by the tool engaging portions of the implant 10.*” Ex-1012 at 9:54-10:2 (emphasis added); Ex-1002, ¶90.

Second, Paltzer teaches that the slots of the implant function as sheaths for the arms of the inserter, thereby “minimiz[ing] or reduc[ing] the possibility of

unnecessarily or undesirably damaging” the surfaces of the joint during insertion of the implant. Ex-1012 at 10:4-13; Ex-1002, ¶91.

Third, Paltzer teaches that uniformly dimensioned slots enable implants of various widths to be universally compatible with a single inserter. *See* Ex-1012 at 11:31-43 (disclosing that “the trial spacer member 160 is provided with a width 174 smaller than width 108 of the implant 10 (see FIG. 5). For this purpose, the trial spacer 160 has upper and lower receiver channels 176 corresponding to the sidewall receiver channels 240 of the implant 10. The prongs 202 of the inserter 200 are received within the upper and lower receiver channels 176 ...”) (emphasis added); Ex-1002, ¶92. The differences between the overall dimensions of the implant 10 and the trial spacer 160 are illustrated below with a side-by-side comparison, and their universally dimensioned slots are emphasized in yellow. Ex-1002, ¶92.





Vestgaarden-981 discloses that the “fusion implant may be manufactured in a *wide range of different sizes* in order to accommodate any size of facet joint.” Ex-1009 at 5:57-59 (emphasis added); Ex-1002, ¶93. Thus, POSA had motivation to implement Paltzer’s uniformly dimensioned slots across Vestgaarden-981’s “wide range” of differently sized implants to enable a surgeon to use a single universal implant holder across all implants, irrespective of their sizes. Ex-1002, ¶93. This

improvement would reduce the cost and complexity of Vestgaarden-981's surgical instrument set because a single implant holder would be universally compatible with all implants, irrespective of their external dimensions. *Id.*

(ii) *Predictable result*

Combination of Paltzer's slots and Vestgaarden-981's implants would yield a predictable result, in which Vestgaarden-981's implant holder would serve its intended function of inserting an implant into a joint, while Paltzer's slots positioned on Vestgaarden-981's implant would perform their intended function of receiving the arms of an implant holder. *Id.*, ¶94. Indeed, Vestgaarden-981 already discloses an implant holder having a pair of implant-engaging arms and therefore placing complementary slots on a proximal end of a fusion implant would have been a simple and obvious improvement in light of the advantages of such slots described in Paltzer. *See* Ex-1009, FIG. 11; Ex-1002, ¶94.

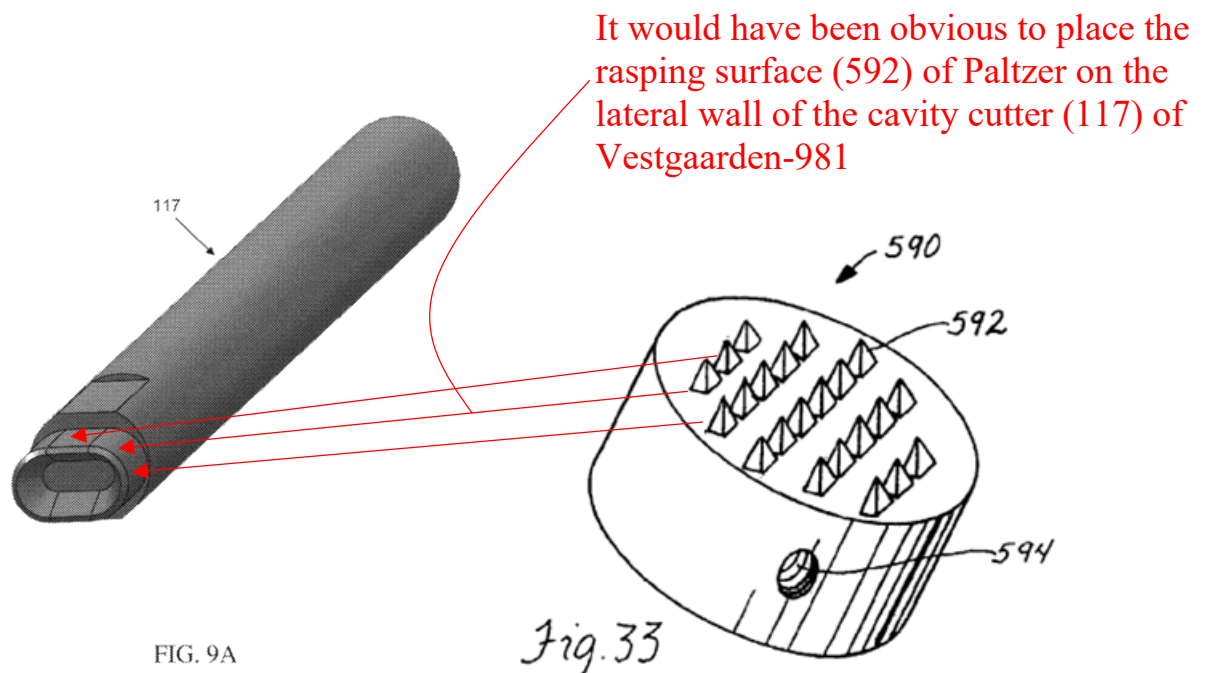
(2) Combination of Vestgaarden-981's cavity cutter with Paltzer's rasping surface

(i) *Motivation to combine*

POSA had motivation to combine Paltzer's "rasping surface" with Vestgaarden-981's cavity cutter. Ex-1002, ¶95. 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." Ex-1012 at 15:34-40. This result achieved by rasping the bone tissue prior to insertion of an implant perfectly

complements Vestgaarden-981's disclosure pertaining to "enabling rapid fusion through the implant." Ex-1009 at 7:66-8:4; Ex-1002, ¶95.

Furthermore, Vestgaarden-981 discloses a cavity cutter (depicted in Figure 9A) for creating "an opening [within the joint] having the perfect shape for [the] fusion implant." Ex-1009 at 6:57-58; FIG. 9A. This description indicates that the lateral wall of the cavity cutter engages the bone tissue within the void. Ex-1002, ¶96. Therefore, including a rasping surface on the lateral wall of Vestgaarden-981's cavity cutter would enable the cavity cutter to "scrap[e] and wound[]" bone tissue within the cavity. *Id.* Figure 9A of Vestgaarden-981 and Figure 33 of Paltzer illustrating this combination are reproduced and annotated below. *Id.*



(ii) *Predictable result*

The combination of Vestgaarden-981's cavity cutter and Paltzer's rasping surface would yield a predictable result, wherein Vestgaarden-981's cavity cutter would continue to perform its intended function of creating a perfectly shaped cavity, while the rasping surface on its latter wall would perform the "wounding and scraping" function described in Paltzer. *Id.*, ¶97.

(3) Combination of Paltzer's standalone rasp with Vestgaarden-981's surgical tool set and Lins's guide protrusions

(i) *Obvious to combine Paltzer's rasp with Vestgaarden-981*

In addition to teaching a "rasping surface" Paltzer also teaches that rasp can be connected to a standalone tool. Ex-1012 at 15:44-47; Ex, 1002, ¶98. Alternatively to combining Paltzer's rasping surface with Vestgaarden-981's cavity cutter, POSA had motivation to include Paltzer's rasp as a standalone tool in Vestgaarden-981's surgical tool set for the reasons explained in Paltzer—i.e., to enable a surgeon to scrape and wound the joint prior to insertion of the implant to "induc[e] fluid and blood flow ... promot[ing] bone ingrowth." Ex-1012 at 15:36-40; Ex, 1002, ¶98. In this combination, subsequent to forming a cavity using Vestgaarden-981's cavity cutter, a surgeon would use Paltzer's standalone rasp to wound and scrape the bone tissue within the cavity as taught in Paltzer. *See* Ex-1009 at 6:57-58; Ex-1012 at

15:36-40; Ex, 1002, ¶98. Accordingly, the combination of Platzer’s standalone rasp and Vestgaarden-981’s surgical tool set would yield a predictable result in which known components would perform their intended functions. Ex, 1002, ¶99.

(ii) Obvious to combine Lins’s guide protrusion with Paltzer’s rasp

POSA would understand that the shape of the rasp head must complement the shape of the cavity. Ex-1002, ¶100. Because the shape of the cavity is oblong, POSA had motivation to provide a mechanism for controlling the orientation of the rasp with respect to the cavity. *Id.* Furthermore, because over-penetration of an SI joint is well-known concern, POSA had motivation to control the depth of insertion of the rasp relative to the SI joint. *Id.* (citing Ex-1016 at 5:8-11 (“Care should be taken to stay within the joint to avoid contacting any blood vessels or nerves, of which there are significant members that pass close to the sacroiliac joint.”)). Because Lins teaches that engagement between a guide protrusion and a guidance slot accomplishes both of these objectives, POSA had motivation to include Lins’s guide protrusion on Paltzer’s rasp tool, whereby the guide protrusion of the rasp would be configured to engage the guidance slot within Vestgaarden-981’s working channel. Ex-1002, ¶100. In this manner, the guidance slot within Vestgaarden-981’s working channel would control the depth of insertion and orientation of the rasp relative to

the joint. *Id.* This combination would yield a predictable result in which known components would perform their intended functions. *Id.* at 101.

For the reasons set forth below, the combination of Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer teaches all limitations of claims 6, 7, and 10-23.

c. Claim 6

(1) [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,”

Vestgaarden-981 discloses an implant holder (inserter) having two implant engagement arms at the distal end thereof, as depicted in Figure 11, which is reproduced and annotated below. Ex-1002, ¶127.

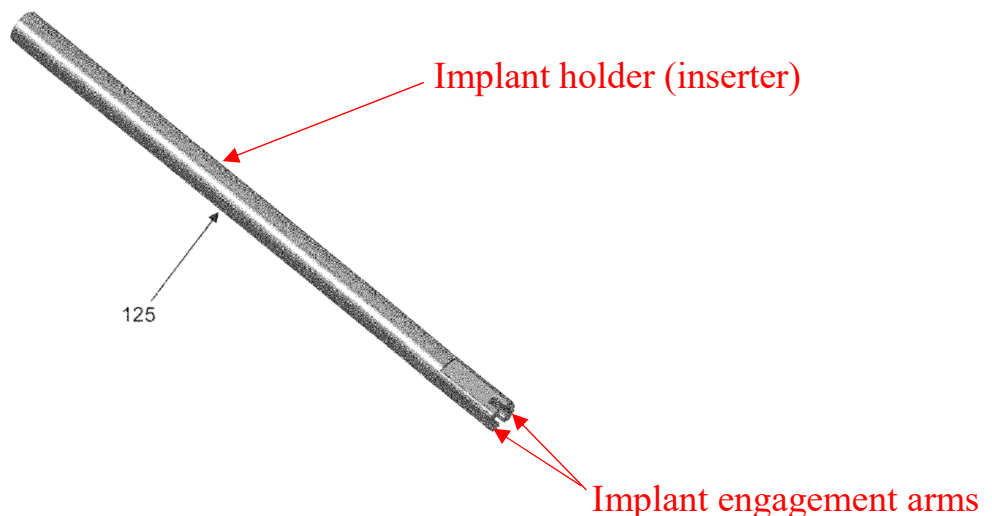
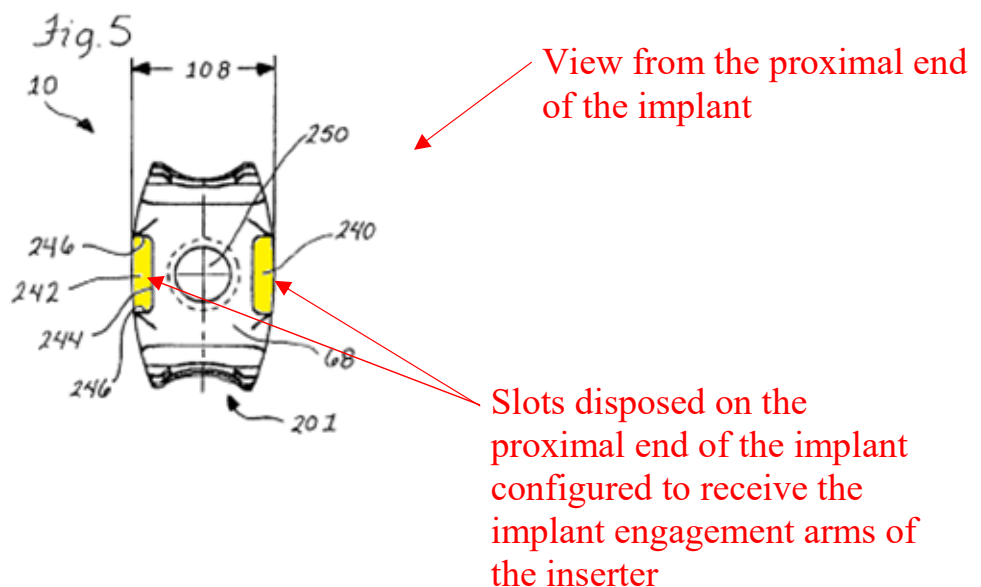
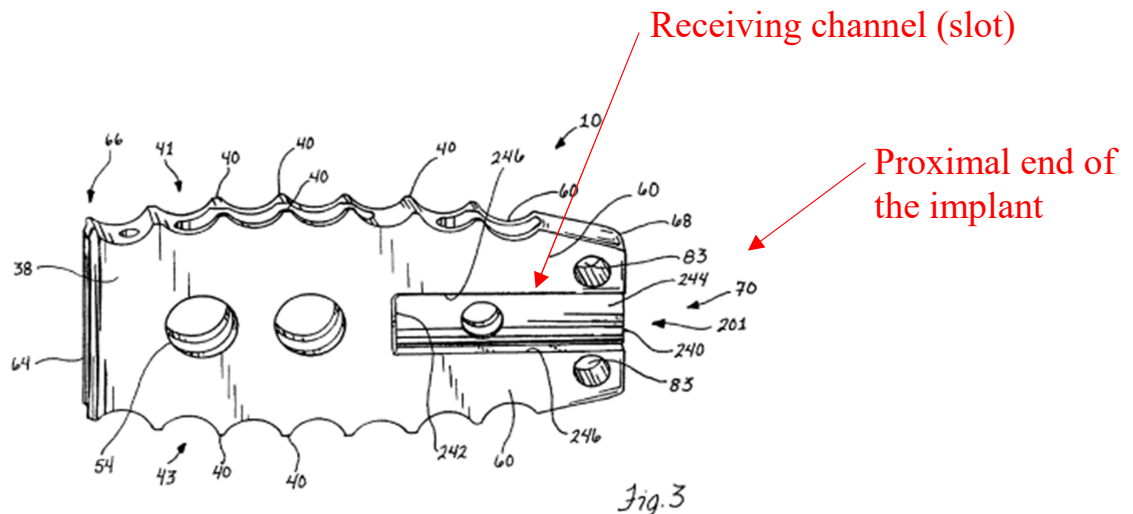
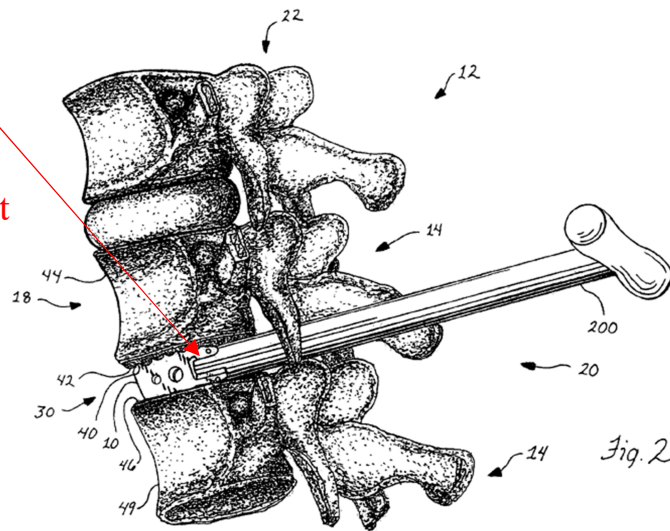


FIG. 11

Paltzer teaches slots disposed on a proximal end of the implant configured to receive implant engagement arms of the inserter, as depicted in Figures 2, 3, and 5, which are reproduced and annotated below. *Id.*, ¶128.



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



As established in Part XII.A.2.b.(1), *supra*, it would have been obvious to combine slots taught in Paltzer with the fusion implants taught in Vestgaarden-981. *See* Ex-1002, ¶129. Accordingly, Vestgaarden-981 in view of Paltzer teaches an inserter having implant engagement arms configured to engage slots on a proximal end of a fusion implant. *Id.*

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

Part XII.A.1.g.(5), *supra*, established that it would have been obvious to implement Lins’s “guide protrusions” as the “directional feature” of Vestgaarden-981, whereby Lins’s guide protrusions would be affixed to the shaft of Vestgaarden-981’s implant holder. *See* Ex-1002, ¶130. Lins teaches that “guide protrusions 46 are configured to engage one or more recesses (not illustrated) manufactured into

the interior bore of the substantially cylindrical [working channel].” Ex-1011 at [0038]; Ex-1002, ¶130. Thus, the combination of Vestgaarden-981 and Lins teaches an implant inserter having a slot-engagement protrusion for engaging with the interior guidance slot of the working channel. Ex-1002, ¶131.

(3) [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”

Figure 11 of Lins, which is reproduced and annotated below, depicts that during insertion into the working channel, the guide protrusion is aligned with the guidance slot of the working channel. Ex-1011 at [0038], FIG. 11; Ex-1002, ¶132.

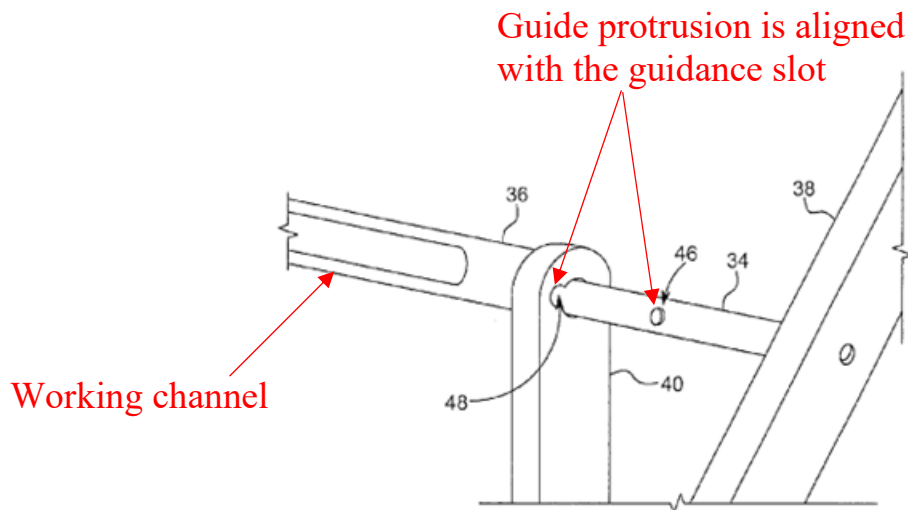


FIG. 11

(4) [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.”

Lins discloses that the engagement between the guide protrusion and the guidance slot is configured to “control and guide the depth of penetration” of a surgical tool relative to the joint. Ex-1011 at [0038]; Ex-1002, ¶133. Thus, 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 the penetration of the inserter and a fusion implant into an SI joint at a pre-determined depth. Ex-1002, ¶133.

d. Claim 7

(1) [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,”

First, Paltzer teaches a rasp having a rasping surface. Ex-1012 at 15:36-40; Ex-1002, ¶134. The analysis in Part XII.A.2.b.(2), *supra*, established that it would have been obvious to dispose a rasping surface taught in Paltzer on the lateral surface of Vestgaarden’s cavity cutter. *See* Ex-1002, ¶134. Furthermore, as established in Part XII.A.1.e., *supra*, it would have been obvious to implement Lins’s guide

protrusions as the “directional feature” of Vestgaarden-981’s surgical tools, including the cavity cutter. *See id.* Thus, Vestgaarden-981 in view of Lins teaches a rasp having a slot-engagement protrusion for creating a void within a joint. When the cavity cutter / rasp is inserted into the working channel, the guide protrusion would engage the guidance slot as taught in Lins. Ex-1011 at [0038]; Ex-1002, ¶134.

Alternatively, Paltzer teaches that a rasp could be used as a standalone tool. Ex-1012 at 15:44-47; Ex-1002, ¶135. The analysis in Part XII.A.2.b.(3), *supra*, established that it would have been obvious to include Paltzer’s standalone rasp into Vestgaarden-981’s surgical tool set and that it would have been obvious to include Lins’s guide protrusion on the shaft of Paltzer’s standalone rasp tool. *See* Ex-1002, ¶135. When this rasp tool is inserted into Vestgaarden-981’s working channel having Lins’s interior guidance slot, the guide protrusion of the rasp would engage the guidance slot, as described in Lins. Ex-1011 at [0038]; Ex-1002, ¶135.

(2) [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.”

Lins discloses that “guide protrusions 46 are configured to engage 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 the [surgical instrument].” Ex-1011 at [0038] (emphasis

added); Ex-1002, ¶136. Thus, 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. Ex-1002, ¶136.

e. Claim 10

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

The preamble of claim 10 is the same as the preamble of claim 1, obviousness of which has been established in Part XII.A.1.g.(1), *supra*. See *id.*, ¶137.

(2) [10.a] “creating a first incision proximal to the patient's sacroiliac joint;”

The step recited in [10.a] is the same as the step recited in [1.a], obviousness of which has been established in Part XII.A.1.g.(2), *supra*. See *id.*, ¶138.

(3) [10.b.1] “inserting a surgical channel tool into said first incision from the posterior of the patient,”

The step of inserting a surgical channel tool into the incision is substantively the same as the step recited in [1.b.1], obviousness of which has been established in Part XII.A.1.g.(3), *supra*. See *id.*, ¶139. In addition, Vestgaarden-818 teaches that the SI joint fusion procedure is performed via a “posterior approach.” Ex-1010 at 4:34-37; Ex-1002, ¶139.

(4) [10.b.2] “said surgical channel tool having two bilateral blunt tangs on a distal end thereof that 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 a surgical channel of said surgical channel tool and into the sacroiliac joint,”

Figure 11 of Vestgaarden-981 depicts the surgical channel having two bilateral blunt tangs. Ex-1009 at FIG. 11; *See* Ex-1002, ¶140. The remaining limitations recited in [10.b.2] are substantively the same as the limitations of claim 9, obviousness of which has been established in Part XII.A.1.m., *supra*. *See id.*, ¶141.

(5) [10.b.3] “said surgical channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said surgical channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse an outer diameter of said hollow barrel;”

The limitations recited in [10.b.3] are substantively the same as the limitations of [1.b.3] and claim 8, obviousness of which has been established in Parts XII.A.1.g.(5) and XII.A.1.l.(1), *supra*. *See id.*, ¶142.

(6) [10.c] “creating a void in said sacroiliac joint;”

The step recited in [10.c] is the same as the step recited in [1.c], obviousness of which has been established in Part XII.A.1.g.(7), *supra*. *See id.*, ¶143.

(7) [10.d.1] “inserting a fusion implant into said void through said hollow barrel of said surgical channel tool using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant,”

The step of inserting a fusion implant into the void is recited in [1.d.1], and its obviousness has been established in Part XII.A.1.g.(8), *supra*. See *id.*, ¶144. The remaining limitations recited in [10.d.1] are substantively the same as the limitations recited in [6.a.1], and their obviousness has been established in Part XII.A.2.c.(1), *supra*. See *id.*, ¶145.

(8) [10.d.2] “said fusion implant having at least one protrusion for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint;”

The limitations recited in [10.d.2] are substantively the same as the limitations recited in [1.d.2], obviousness of which has been established in Part XII.A.1.g.(9), *supra*. See *id.*, ¶146.

(9) [10.e.1] “driving said fusion implant into said void”

Vestgaarden-818 discloses the step of “*driv[ing]* implant 5 into cavity 45 created laterally across sacroiliac joint 60,” whereby the implant is “preferably countersunk 1-2 mm into sacroiliac joint.” Ex-1010 at 6:33-36 (emphasis added). Ex-1002, ¶147.

(10) [10.e.2] “such that said at least one protrusion engages with said bone tissue preventing pullout of the fusion implant,”

Vestgaarden-981 discloses that the body of the fusion implant “may include a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom. Barbs 25 are designed to permit body 10 to be inserted into the [] joint and to impede retraction of the body 10 out of the [] joint.” Ex-1009 at 4:33-37, FIG. 1. Thus, Vestgaarden-981 teaches that as the implant is driven into the joint, the barbs (protrusions) engage with bone tissue, thereby preventing pullout of the implant. Ex-1002, ¶148.

In addition, Vestgaarden-981 further teaches that a fusion implant may include a wide array of bone-engaging protrusions including “sharp spikes,” “K-Wire, suture, staple, screw, or other fixation device,” all of which are configured to be driven into the bone tissue, thereby “attaching the implant to the ... joint.” *Id.* at 8:30-34, 8:39-41; FIGS. 65-68, 72-74; Ex-1002, ¶149.

(11) [10.e.3] “said fusion implant fixes relative positions of said sacrum and said ilium.”

Vestgaarden-818 teaches that the fusion implant “immobilize[s] the sacroiliac joint and facilitates fusion between the sacrum and ilium.” Ex-1010 at 2:28-33. Ex-1002, ¶150.

f. Claim 11

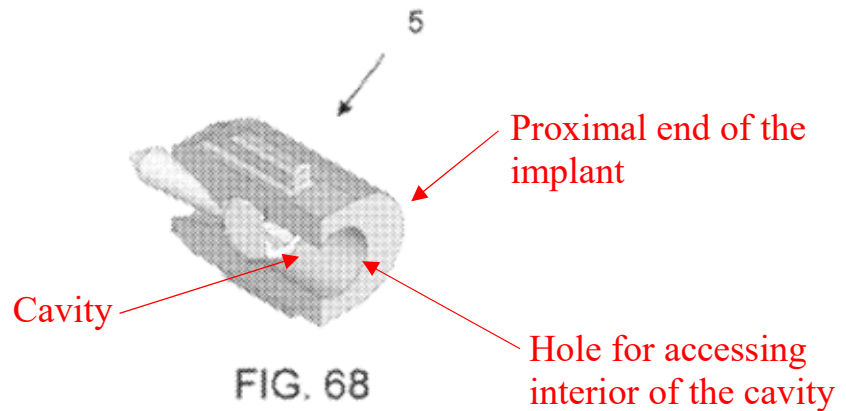
(1) “The method of claim 10, wherein said at least one protrusion comprises a helical anchor having a sharp end for piercing said bone tissue in an articular surface of at least one of said sacrum and said ilium.”

These limitations are substantively the same as the limitations recited in claims 3 and 4, obviousness of which has been established in Parts XI.A.1.i. and XI.A.1.j., *supra*. See Ex-1002, ¶151. Furthermore, POSA understands that the thread (helical anchor) of the screw would have a sharp end for piercing bone tissue, especially in the embodiment depicted in Figures 58-60 of Vestgaarden-981, in which the screw is driven directly into the bone. *Id.*

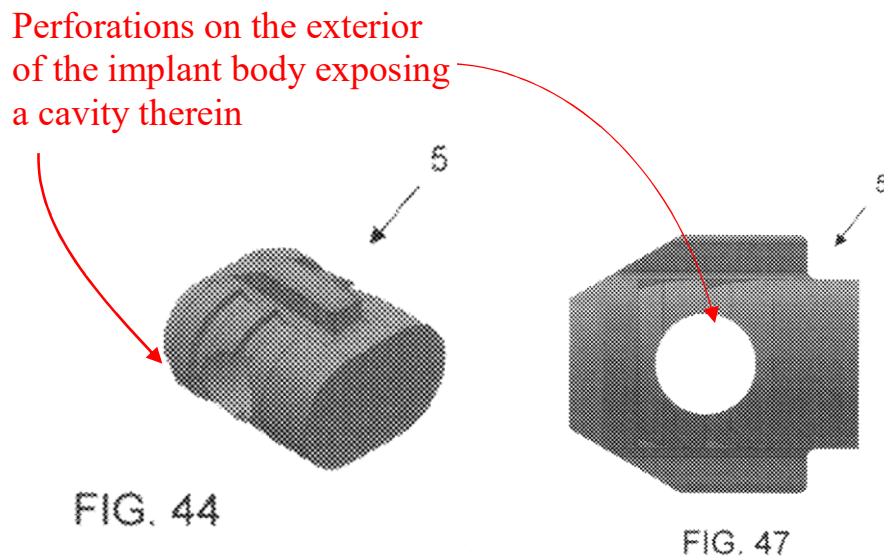
g. Claim 12

(1) “The method of claim 10, wherein said fusion implant comprises a body having a cavity therein and perforations on an exterior thereof that expose said cavity to an exterior of said body, a hole in a proximal end of said body for accessing an interior of said cavity.”

In the embodiment depicted in Figure 68 of Vestgaarden-981, the implant has a hole in a proximal end for accessing an interior of a cavity that spans the length of the implant body. *Id.*, ¶152.



Vestgaarden-981 further teaches that a “through-hole” may be disposed within an implant body for holding bone-growth promoter, wherein “[t]he through-hole allows a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant.” Ex-1009 at 7:66-8:4; Ex-1002, ¶153. This implant is depicted in Figure 11, which shows perforations on an exterior of the implant body that expose the cavity to the exterior of the implant. Ex-1002, ¶153.



Based on the advantages of the through-hole described in Vestgaarden-981 (“[t]he through-hole allows a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant”), POSA had motivation to introduce the transverse through-hole into the implant having a longitudinal screw and a cavity (depicted in Figures 65-68). *Id.*, ¶154. This 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. In this combination, the implant would have a cavity and perforations exposing the cavity to the exterior of the implant (as depicted in Figures 44 and 47) and would also have a hole on a proximal end that would provide access to the interior cavity (as depicted in Figure 68). *Id.*

h. Claim 13

(1) “The method of claim 10, wherein said fusion implant is operable to connect said sacrum to said ilium in fixed relative positions in the sacroiliac joint.”

Vestgaarden-818 discloses that the implant has “[an] elongated body [that] is simultaneously positioned within the sacrum and ilium of the sacroiliac joint,” which means that the implant connects the sacrum and ilium. Ex-1010 at 2:63-66. Vestgaarden-818 further teaches that the implant “immobilize[s] the sacroiliac joint and facilitate[s] fusion between the sacrum and ilium,” which means that the implant

fixes relative positions of the sacrum and ilium. *Id.* at 2:28-33; Ex-1002, ¶155.

Accordingly, Vestgaarden-818 teaches the limitations of claim 13. Ex-1002, ¶155.

i. Claim 14

(1) [14.a.1] The method of claim 10, wherein the inserting the fusion implant comprises: a. inserting the inserter into said hollow barrel of said surgical channel tool,”

The limitation [14.a.1] is substantively the same as [6.b.1], obviousness of which has been established in Part XII.A.2.c.(3), *supra*. *See id.*, ¶156.

(2) [14.a.2] “wherein said inserter has an insertion control protrusion;”

The limitation [14.a.2] is substantively the same as [6.a.2], obviousness of which has been established in Part XII.A.2.c.(2), *supra*. *See id.* ¶157.

(3) [14.b] “b. engaging said insertion control protrusion with the interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of said inserter into said surgical channel tool and preventing rotation of said inserter;”

The subject matter recited in the limitation [14.b] is substantively the same as the subject matter recited in claim 8, obviousness of which has been established in Part XII.A.1.1., *supra*. *See id.*, ¶158.

(4) [14.c] “c. advancing the inserter until said insertion control protrusion is arrested by the interior guidance slot at a pre-determined point in the hollow barrel, and said inserter is prevented from moving the fusion implant further into said sacroiliac joint.”

The subject matter recited in the limitation [14.c] is substantively the same as the subject matter recited in the limitation [6.b.2], obviousness of which has been established in Part XII.A.2.c.(4), *supra*. See *id.*, ¶159. In addition, POSA understands that when the guidance slot arrests the guide protrusion of the inserter, the inserter is prevented from moving the fusion implant further into the SI joint. *Id.*

j. Claim 15

(1) “The method of claim 10, 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.”

Vestgaarden-981 discloses that “implant tamp 130 is *lightly tapped* so as to *drive* the implant into the cavity.” Ex-1009 at 6:64-7:2 (emphasis added). POSA understands that when the implant tamp lightly tapped, the implant tamp pushes the fusion implant into the cavity. Ex-1002, ¶160. In the embodiment depicted in Figure 1 of Vestgaarden-981, the implant has barbs (protrusions), and when this implant is pushed into the cavity, the barbs contact the bone tissue. *Id.*, ¶161.

k. Claim 16

(1) “The method of claim 10, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into said hollow barrel of said surgical channel tool with said slot-engagement protrusion aligned with said interior guidance slot in the interior diameter of said hollow barrel, 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 said void.”

The limitations of claim 16 are substantively the same as the limitations recited in claim 7, obviousness of which has been established in Part XII.A.2.d., *supra*. See *id.*, ¶162.

l. Claim 17

(1) “The method of claim 1, wherein said interior guidance slot in the interior diameter of said working channel is for alignment and engagement with a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.”

The limitations of claim 17 are substantively the same as the limitations recited in claim 8, obviousness of which has been established in Part XII.A.1.1., *supra*. See *id.*, ¶163.

m. Claim 18

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

The preamble of claim 18 is the same as the preamble of claim 10, obviousness of which has been established in Part XII.A.2.e.(1), *supra*. See *id.*, ¶164.

(2) [18.a] “creating an incision proximal to the patient’s sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;”

The limitation [18.a] is substantively the same as [10.a], obviousness of which has been established in Part XII.A.2.e.(2), *supra*. See *id.*, ¶165. In addition, Vestgaarden-818 teaches that the SI joint fusion procedure is performed via a “posterior approach.” Ex-1010 at 4:34-37; Ex-1002, ¶165.

(3) [18.b.1] “inserting a working channel of a surgical channel tool into said incision from the posterior of the patient,”

The limitation [18.b.1] is substantively the same as [10.b.1], obviousness of which has been established in Part XII.A.2.e.(3), *supra*. See Ex-1002, ¶166.

(4) [18.b.2] “said working channel having a plurality of blunt tangs on a distal end thereof that are inserted between 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,”

The limitation [18.b.2] is substantively the same as [10.b.2], obviousness of which has been established in Part XII.A.2.e.(4), *supra*. See *id.*, ¶167.

(5) [18.b.3] “said working channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling a depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse an outer diameter of said hollow barrel;”

The limitation [18.b.3] is substantively the same as [10.b.3], obviousness of which has been established in Part XII.A.2.e.(5), *supra*. See *id.*, ¶168.

(6) [18.c.1] “inserting a fusion implant having a plurality of bone-engagement protrusions through said hollow barrel into said sacroiliac joint”

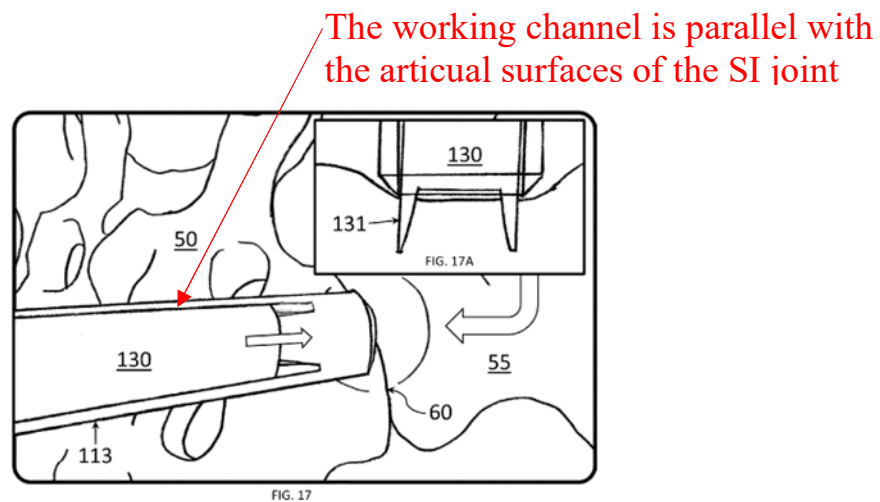
The subject matter recited in the limitation [18.c.1] is also recited in the limitations [10.d.1] and [10.d.2], obviousness of which has been established in Parts XII.A.2.e.(7) and XII.A.2.e.(8), *supra*. See *id.*, ¶169. The only additional subject matter recited in [18.c.1] is a “*plurality*” of protrusions. This limitation is disclosed in Vestgaarden-981, which teaches that the implant “may include a *plurality* of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom.” Ex-1009 at 4:33-35 (emphasis added); FIG. 1; Ex-1002, ¶169.

(7) [18.c.2] “using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant,”

The subject matter of the limitation [18.c.2] is recited in [10.d.1], obviousness of which has been established in Part XII.A.2.e.(7), *supra*. See Ex-1002, ¶170.

(8) [18.c.3] “wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac joint,”

Vestgaarden-818 discloses that the teeth (tangs) of the working channel are aligned with the plane of the SI joint, and therefore, the working channel is substantially parallel to the articular surfaces of the SI joint, as depicted in Figure 17. Ex-1010 at 5:51-56; FIG. 17; Ex-1002, ¶171.



Vestgaarden-818 teaches that the fusion implant is inserted into the SI joint via the lumen of the working channel. Ex-1010 at 6:28-32; Ex-1002, ¶172. Because the working channel is substantially parallel with the articular surfaces of the SI joint, Vestgaarden-818 teaches that the fusion implant is inserted along a path that is substantially parallel to the articular surfaces of the SI joint. Ex-1002, ¶172; see *also* Ex-1014 at 92:4:10 (“So the implant body shown in Figure 58 would have been inserted parallel to the sacroiliac joint planes.”).

(9) [18.c.4] “said inserter having an insertion control protrusion for engagement with said interior guidance slot;”

The subject matter recited in the limitation [18.c.4] is substantively the same as the subject matter recited in [14.a.2] and [14.b], obviousness of which has been established in Parts XII.A.2.i.(2) and XII.A.2.i.(3), *supra*. See Ex-1002, ¶173.

(10) [18.d] “advancing the inserter until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and placing said fusion implant into said sacroiliac joint, wherein said inserter is prevented from moving the fusion implant beyond a pre-determined point in said sacroiliac joint;”

The subject matter recited in the limitation [18.d] is substantively the same as the subject matter recited in [14.c], obviousness of which has been addressed in Part XII.A.2.i.(4), *supra*. See *id.*, ¶174. The only additional subject matter recited in the limitation [18.d] is that the inserter is prevented from moving the implant beyond a “pre-determined point in said sacroiliac joint.” *Id.* POSA understands that when the guidance slot arrests the guide protrusion of the inserter, the inserter is necessarily prevented from moving the fusion implant beyond a pre-determined point relative to the SI joint. *Id.* Therefore, this subject matter is obvious. *Id.*

(11) [18.e] “driving said fusion implant into said sacroiliac joint such that said plurality of bone-engagement protrusions engage with said articular surfaces of said ilium and said sacrum thereby preventing pullout of the fusion implant from said sacroiliac joint.”

The subject matter recited in the limitation [18.e] is substantively the same as the subject matter recited in [10.d.2] - [10.e.2], obviousness of which has been established in Parts XII.A.2.e.(8-10), *supra*. See *id.*, ¶175.

n. Claim 19

(1) “The method of claim 18, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint.”

The subject matter of claim 19 is substantively the same as the subject matter of [10.e.2] and [10.e.3], obviousness of which has been established in Parts XII.A.2.e.(10-11), *supra*. See *id.*, ¶176.

o. Claim 20

(1) “The method of claim 18, wherein said plurality of bone-engagement protrusions comprise a helical anchor having a sharp end for piercing said bone tissue, and said helical anchor first penetrates said articular surface of said at least one of said sacrum and said ilium.”

Vestgaarden-981 teaches a fusion implant having a plurality of barbs (bone-engaging protrusion). See Ex-1009 at 4:33-37; FIG. 1; Ex-1002, ¶177. Furthermore, Vestgaarden-981 teaches an embodiment depicted in Figure 58, in which the fusion

implant is configured to attach to the joint using a screw (another bone-engaging protrusion). Ex-1009 at 8:19-23; 8:26-29; 8:32-33; Ex-1002, ¶177. POSA had motivation to combine the barbs and the screw in a single implant to more securely anchor the implant within the joint. Ex-1002, ¶177; *see also* Ex-1014 at 95:16-21 (“And the other figure where [the implant] had the screw, the Figure 58, I think it was a good idea for them to add that hole for the screw or for the suture. So that one would a greater chance of being successful.”). In this combination, the plurality of bone-engaging protrusions would comprise both the barbs and the screw configured to pierce the bone tissue. Ex-1002, ¶177.

The subject matter of claim 20 pertaining to the protrusion having a helical anchor with a sharp end configured to pierce bone tissue is substantively the same as the subject matter recited in claim 11, obviousness of which has been established in Part XII.A.2.f., *supra*. *See id.* Thus, the combination of Vestgaarden-981’s implants depicted in Figures 1 and 58 (or Figures 65-68) teaches the limitations of claim 20.

p. Claim 21

(1) “The method of claim 18, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.”

Vestgaarden-818 teaches that after the fusion implant is inserted into the SI joint, the surgical tools are “removed from the soft tissue and the incision is closed.” Ex-1010 at 6:37-40. Vestgaarden-818 further teaches that “[s]tabilization implant 5 provides the stability and strength needed to immobilize the sacroiliac joint 60 while fusion occurs.” Ex-1010 at 5:7-9. Thus, Vestgaarden-818 teaches that no further fusion implants are introduced into the SI joint, and that the inserted single fusion implant is sufficient to fuse the SI joint. Ex-1002, ¶178.

q. Claim 22

(1) “The method of claim 18, further comprising creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void.”

Vestgaarden-981 teaches that “[a] cavity cutter 117 is ... used to make an opening having the perfect shape for fusion implant 5.” Ex-1009 at 6:57-58. The subject matter of claim 22 pertaining to inserting the implant into the void is recited in [10.d.1], obviousness of which has been established in Part XII.A.2.e.(7), *supra*. See Ex-1002, ¶179.

r. Claim 23

(1) “The method of claim 18, wherein engagement of said insertion control protrusion with said interior guidance slot maintains said inserter tool and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.”

The subject matter of claim 23 pertaining to maintaining the inserter tool in a proper orientation due to the engagement of the insertion control protrusion with the interior guidance slot is substantively the same as the subject matter of claim 17, obviousness of which has been established in Parts XII.A.2.1.(1), *supra*. *See id.*, ¶180. POSA understands that when the inserter is maintained in the proper orientation relative to the SI joint, the fusion implant (which is coupled to the inserter) is also necessarily maintained in the proper orientation for insertion into the SI joint. *Id.*

XIII. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of IPR trial and cancellation of claims 1-23 of the ‘511 Patent.

IPR2023-00451 (Patent No. 11,083,511)
Petition For *Inter Partes* Review

Dated: January 9, 2023

Respectfully submitted,
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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

Pursuant to Rule 37 C.F.R. § 42.24(d), the undersigned hereby certifies that, based upon the word count of the word-processing system used to prepare this petition, the number of words in this petition complies with 37 C.F.R. § 42.24(a)(1)(i) and is 13,920. Pursuant to 37 C.F.R. § 42.24(a)(1), this word count does not include “a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.”

Dated: January 9, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of January 2023, a copy of the attached **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,083,511**, together with all supporting materials (Exhibits 1001-1017) and all other papers filed therewith as indicated below on the Patent Owner and the attorneys of record in the co-pending litigation, at the following addresses:

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