

Exhibit 1002

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
Issue Date: August 10, 2021
Title: METHOD AND IMPLANT SYSTEM FOR SACROILIAC
JOINT FIXATION AND FUSION

Inter Partes Review No. IPR2023-00451

DECLARATION OF DR. CHRISTOPHER J. BOVINET

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I, Christopher J. Bovinet, hereby declare and state as follows:

I. INTRODUCTION

1. I have been engaged by Hill Ward Henderson, P.A. on behalf of PainTEQ, LLC (“Petitioner”) for the above captioned *inter partes* review (“IPR”) by the U.S. Patent & Trademark Office Patent Trial and Appeal Board.

2. I have been asked to provide my analysis and expert opinions with respect to the validity of claims 1-23 (“the Challenged Claims”) of U.S. Patent No. 11,083,511 (“the ‘511 Patent”).

3. It is my opinion that the Challenged Claims are invalid in view of the prior art as discussed in my declaration. Specifically, my opinion is that the Challenged Claims are rendered obvious by the prior art. The specific combinations of prior art references that invalidate the Challenged Claims, as well as the rationale for my opinions, are set forth below.

4. I am being compensated for my time at a rate of \$500 per hour, plus reimbursement for my expenses. My compensation in this matter is not dependent on or related to the outcome of this matter.

5. Any citations I make in this declaration may refer to specific pages or patents and other technical documents, but these citations are exemplary and are not intended to convey the citations as the only source of evidence to support the propositions for which they are cited.

6. I understand that the ‘511 Patent was filed on December 18, 2019 and issued on August 10, 2021. I understand that the ‘511 Patent is currently assigned to Orthocision, Inc. (“Orthocision”).

7. I understand the ‘511 Patent is a continuation of and claims priority to U.S. Patent No. 10,993,757 (“the Parent”) filed on March 25, 2015, which is a continuation-in-part of and claims priority to U.S. Patent No. 9,119,732 (“the Grandparent”), which was filed on March 15, 2013.

8. I have reviewed and am familiar with the specification of the ‘511 Patent and understand that it has been provided as Exhibit 1001. I have also reviewed and am familiar with the prior art stated herein.

9. The ‘511 Patent is for a “method and implant system for sacroiliac joint fixation and fusion.” (Ex. 1001, at 1:1-3). I am familiar with the methods and associated medical tools described in the ‘511 Patent as of its filing date (December 18, 2019), as well as the filing dates of its Parent (March 25, 2015) and Grandparent (March 15, 2013).

II. QUALIFICATIONS

10. My *curriculum vitae* is attached to this Declaration as Exhibit 1003 and describes my qualifications in detail.

11. I am a Board Certified physician in Physical Medicine & Rehabilitation by American Board of Physical Medicine and Rehabilitation, with a sub-specialty in Pain Medicine.

12. I am an interventional pain management physician and the medical director at The Spine Center of Southeast Georgia and The Brunswick Pain Treatment Center, both located in Brunswick, Georgia. I have held these positions since 2014. In my medical practice, I specialize in spinal injections and minimally-invasive spinal and sacroiliac joint surgery techniques. I have performed over three hundred minimally-invasive posterior sacroiliac joint (SI joint) fusion procedures.

13. I am the director-at-large of the Georgia Society of Interventional Pain Physicians. In addition, I serve as a consultant for several spine and neuromodulation medical advisory boards. In the past, I have served on the medical advisory board for St. Jude's Medical.

14. I graduated *cum laude* with a Bachelor of Science degree in Biochemistry from Lee University in Cleveland, Tennessee in 2001. I graduated with a Doctor of Osteopathy degree from Michigan State University College of Osteopathic Medicine in East Lansing, Michigan in 2008. I have completed my residency in 2013 and fellowship at Virginia Commonwealth University Physical Medicine & Rehabilitation in Richmond, Virginia in 2014.

III. LEVEL OF ORDINARY SKILL IN THE ART

15. I believe that a person of ordinary skill in the art (“POSA”) with respect to the subject matter claimed in the ‘511 Patent would have had a medical or an engineering degree and would have had experience with surgical instruments and implants used for spinal or joint fusion, including SI joint fusion.

16. I am a person of ordinary skill in the art and was such as of the earliest effective filing date of the ‘511 Patent, which is March 25, 2015.

17. In forming my opinions, in addition to my own knowledge and experience, I have considered the ‘511 Patent, the cited prior art references , and any other references referred to or cited in this declaration.

IV. RELEVANT LEGAL STANDARDS

18. In developing my opinions, I have discussed with Petitioner’s attorneys various legal principles. I understood those legal principles and have relied upon them in forming my opinions set forth in this declaration. I am not an attorney and have not researched legal issues of patent validity. I am relying solely on explanations from Petitioner’s attorneys for these legal standards.

19. I understand that an *inter partes* review (IPR) is a proceeding before the Patent Trial and Appeal Board (PTAB) for evaluating patentability of a challenged patent claim based on prior art patents and publications.

20. I understand that Petitioner is challenging the validity of claims 1-23 of the '511 Patent and that Petitioner has the burden of establishing that these claims are unpatentable.

21. I understand that to determine whether a particular patent or a publication constitutes prior art with respect to a challenged claim, the priority date of the challenged claim must be established. I understand that a patent claim is entitled to a priority date of an earlier filed patent application only if the earlier patent application describes the subject matter of that claim in sufficient detail to convey to a person of ordinary skill in the art that the inventors had possession of the claimed subject matter as of the filing date of the earlier application.

22. I understand that a claim that would have been obvious to a person of ordinary skill in the art prior to its effective filing date (sometimes also referred to in this declaration as the "priority date") is unpatentable. My understanding of the legal standard for obviousness is set forth below.

A. Person of Ordinary Skill In the Art

23. I understand that a person of ordinary skill in the art is a hypothetical person who is presumed to have average knowledge and skill in the technical field of the invention at the time it was invented. I understand that a person of ordinary skill in the art understands related references in the technical field and reasonably understands the problem the claimed invention attempts to address.

B. Prior Art

24. I understand that a threshold issue for evaluating obviousness of a patent claim is that the patents and printed publications used in an invalidity challenge must qualify as prior art.

25. I understand that an issued patent or a published patent application qualifies as prior art if (1) it was published prior to the earliest effective filing date of a challenged claim or (2) it names another inventor and was filed before the earliest priority date of the challenged patent claim.

26. I understand that a non-patent printed publication qualifies as prior art if the publication was publicly available prior to the earliest priority date of the patent claim at issue.

C. Obviousness

27. I understand that a patent claim is unpatentable for being obvious if the difference between the claimed subject matter and the prior art as a whole, would have been obvious to a person of ordinary skill in the art at the time of invention.

28. I understand that an obviousness analysis is based on the understanding of a person of ordinary skill in the art at the time of the claimed invention and involves a consideration of the scope and content of the prior art, the differences between the prior art and the challenged claims, the knowledge of a person of

ordinary skill in the art in the pertinent art, and objective factors indicative of non-obviousness, when such are present.

29. I understand that in determining whether a patent claim would have been obvious over a combination of prior art references, a person of ordinary skill in the art must have had a reason for combining teachings from these references in the fashion proposed and would have reasonably expected success in such combination.

30. I have been informed of the following examples of rationales for combining teachings from multiple prior art references: (A) combining prior art elements according to known methods to yield predictable results; (B) simple substitution of one known element for another to obtain predictable results; (C) use of known technique to improve similar devices (methods, or products) in the same way; (D) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and (G) some teaching, suggestion, or motivation in the prior art that would have led one

of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

31. I understand that an obviousness analysis requires comparing the properly construed claim language to the prior art on a limitation-by-limitation basis.

D. Claim Construction

32. I understand that claim construction is a matter of law. Further, I understand that during an IPR, claim terms are generally given their plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of the invention of the patent at issue, in light of the specification and the prosecution history.

33. I understand that there is currently pending litigation in federal court between the Petitioner and Orthocision's licensee, Omnia Medical, LLC ("Omnia"). I understand that the parties to that litigation have proposed the claim construction shown below, but that the court has not yet issued a ruling on this issue:

U.S. Patent No. 11,083,511 Claim Numbers	U.S. Patent No. 11,083,511 Claim Term	Omnia's Preliminary Proposed Construction	PainTEQ's Preliminary Proposed Construction
10.e, 15, & 18.e	driving said fusion implant	Advancing the fusion implant	Applying a force via an impactor or torquing tool onto the fusion implant to

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			advance the position thereof
1.d, 2, 10.d, 10.e, 15, 18.c, & 18.e	protrusion (in reference to the fusion implant)	Something that extends from a main body	A structure extending from the fusion implant configured to pierce or penetrate bone tissue
1.d, 2, 10.d, 10.e, 18.e, & 19	“engages with bone tissue,” “engagement of said at least one protrusion with said ilium and sacrum,” “engagement with said bone tissue,” and “engage with said articular surfaces	Creates a mechanical engagement between a protrusion and the bone	Interlocking with bone tissue in a piercing or penetrating manner in order to resist retractive forces
1.d, 10.e, & 18.e	preventing pullout	Securing into position	Immobilizing (the fusion implant) against non-destructive removal via the application of a linear retraction force
1.b & 14.b	controlling the advancement	Guiding forward motion	Arresting the extent of axial progress (alternate construction) Controlling the depth of advancement
2, 10.e, & 19	fixes relative positions	Secures positions of the bones	Mechanically holds the relative positions

34. I have considered both of these constructions in my analysis. I believe that the prior art combinations analyzed in this declaration teach all limitations of the Challenged Claims irrespective of the differences in the claim constructions proposed in litigation.

35. I have understood all terms of the claims and interpreted them in accordance with their plain and ordinary meaning, as would be understood by a person of ordinary skill in the art.

E. Priority

36. I understand that a continuation-in-part application is an application that shares some common subject matter with an earlier filed application, but also contains new subject matter not previously described.

37. I also understand that a continuation-in-part application is entitled to claim priority to an earlier filed application as to the shared subject matter only and that any new subject matter will have a priority date as of the filing date of the continuation-in-part application and not the earlier filed application.

38. I understand that the priority date of a continuation-in-part application is determined on a claim-by-claim basis.

V. THE '511 PATENT

A. Overview

39. The ‘511 Patent is directed to a method for repairing a sacroiliac joint (“SI joint”) of a patient. Ex. 1001 at 2:15-40. The ‘511 Patent has three independent claims: claims 1, 10, and 18, all of which recite generic steps of an SI joint fusion procedure via a posterior approach, including (1) creating an incision proximal to the patient’s SI joint, (2) inserting a working channel into the incision, (3) creating a void within the SI joint, and (4) inserting a fusion implant into the created void. *Id.* at 41:64-13; 43:4-39; 44:24-64. Independent claims 1, 10, and 18 specify that the working channel (commonly referred to in the art as a “surgical cannula” or simply “cannula”) must have at least one tang on its distal end. ‘511 Patent at 42:7 (“at least one tang”); 43:9-11 (“two bilateral blunt tangs”); 44:31-32 (“a plurality of blunt tangs”). All three independent claims further specify that the working channel must have “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 42:3-5; 43:17-24; 44:37-43. The functionality of this interior guidance slot is claimed as follows: “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.

40. The tangs and the guidance slot are shown in Figures 29 and 30 of the ‘511 Patent as noted (in red ink) below:

FIG. 30

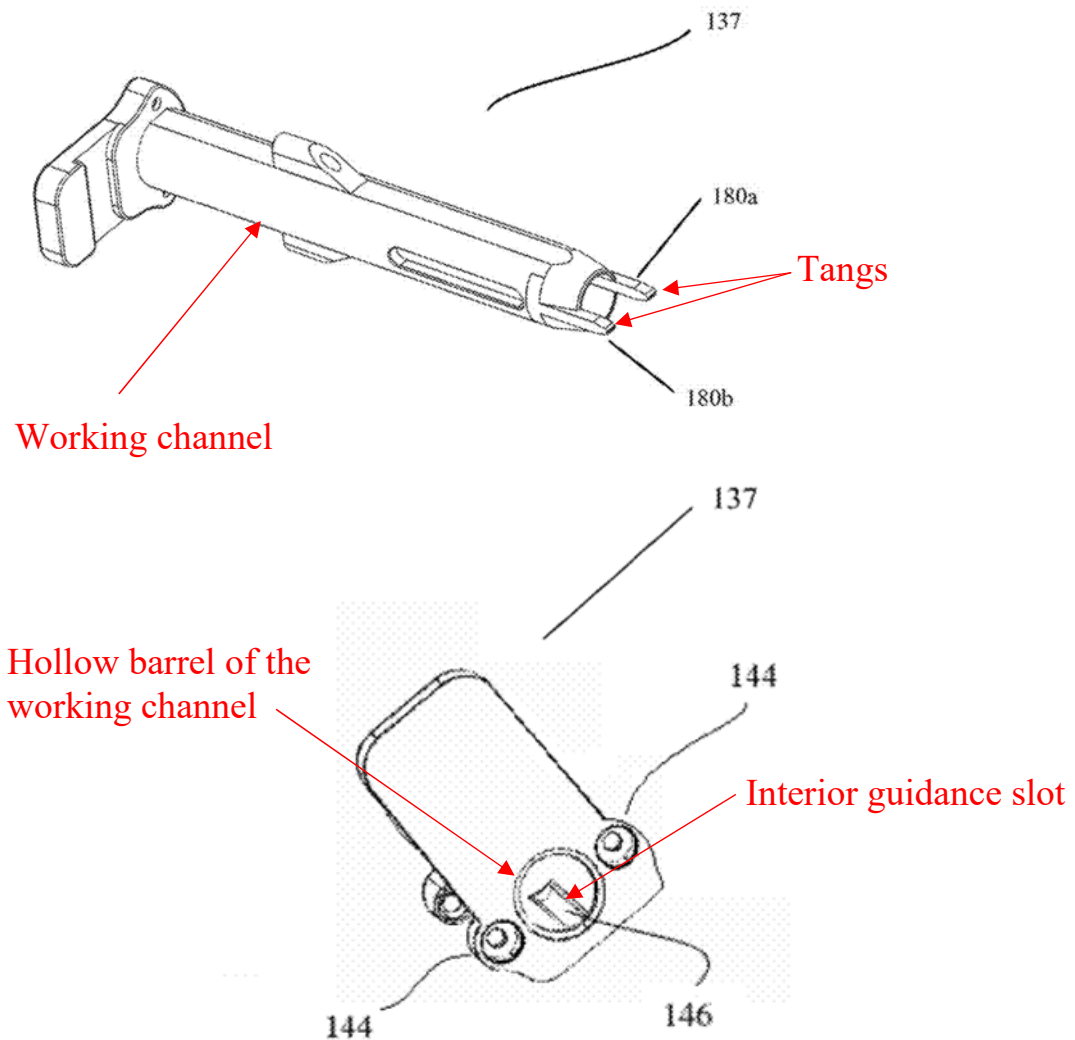


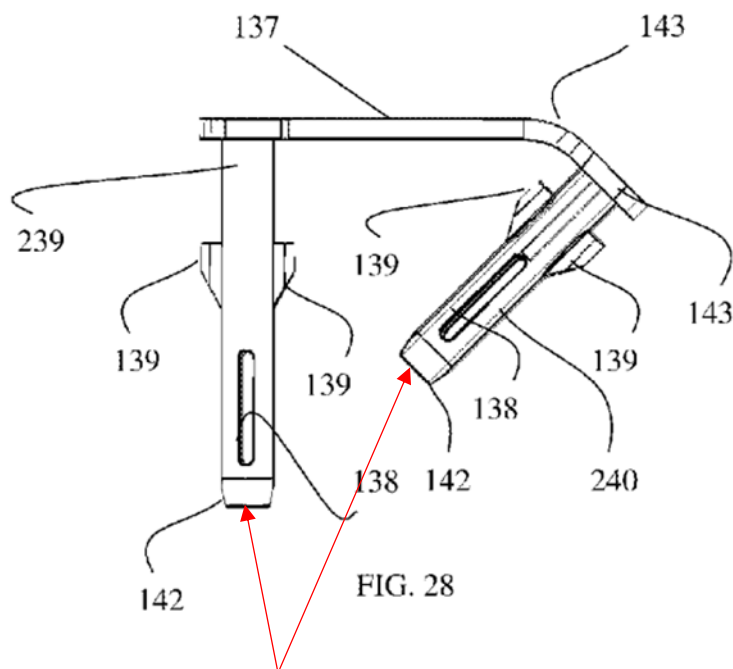
FIG. 29

B. Priority Date of the '511 Patent

41. The front page of the '511 Patent states that it was filed on December 18, 2019. Under the "Related U.S. Application Data" section, the '511 states that is a continuation of U.S. Patent No. 10,993,757 ('757 Patent) filed on March 25, 2015,

which is a continuation-in-part of the U.S. Patent No. 9,119,732 ('732 Patent) filed on March 15, 2013.

42. As explained in the preceding section, 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"). Upon my review of the '732 Patent, I have concluded that the '732 Patent does not mention anything pertaining to this structural feature of the working channel. To the contrary, all figures of the '732 Patent show the working channel with a flat distal end, most clearly visible in the elevation drawing provided in FIG. 28:



Flat distal ends with no tangs

43. In the '511 Patent, the tangs are shown in FIGS. 30 and 32A-B, which are not present in the '732 Patent. Likewise, the passages describing prongs/tangs in

the ‘511 Patent—for example, “[t]he insertable end of the working channel may also include one or more prongs or tangs that extend beyond the end of the hollow barrel”—do not appear in the ‘732 Patent. *See* Ex. 1001 at 15:25-27. Thus, the ‘732 Patent does not convey to a person of ordinary skill in the art that the inventors had possession of the tangs/prongs as of the filing date of the ‘732 Patent.

44. For the reasons set forth above, none of the claims of the ‘511 Patent are entitled to claim benefit of the priority date of the ‘732 Patent. Accordingly, the earliest possible priority date of any claim of the ‘511 Patent is the filing date of the ‘757 Patent, which is March 25, 2015.

C. Summary of the challenged claims

45. Independent claim 1 is a representative claim of the ‘511 Patent. This claim is reproduced and annotated in color below. The subject matter recited in this claim can be categorized as follows: (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**).

[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.

46. As will be explained in more detail below, the remaining independent and dependent claims of the '511 Patent do not introduce any patentable subject matter because they only recite what has been well-known in the prior art and would have been obvious to a person of ordinary skill in the art as of March 25, 2015.

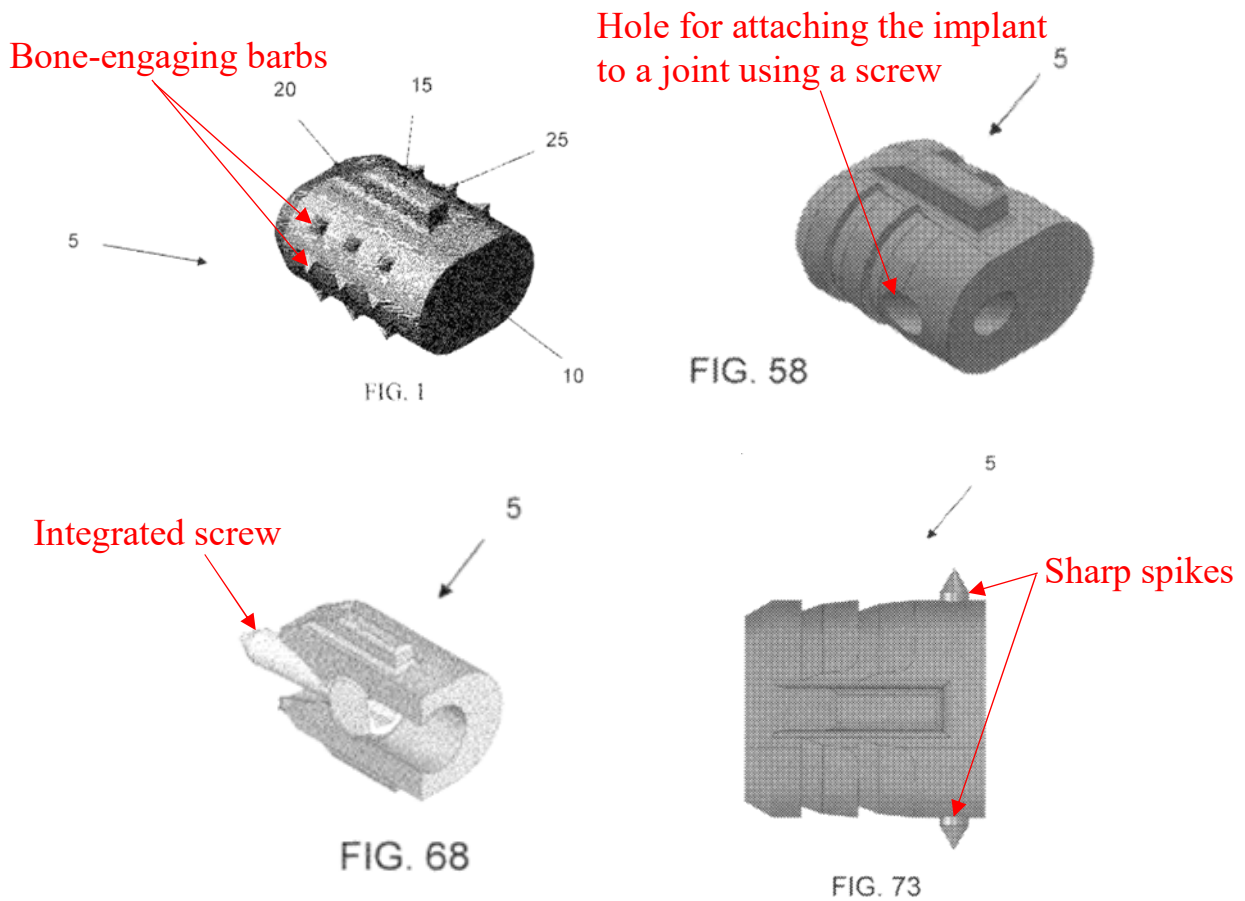
VI. OVERVIEW OF THE PRIOR ART

A. U.S. Patent No. 8,162,981 (“Vestgaarden-981”) (Ex. 1009)

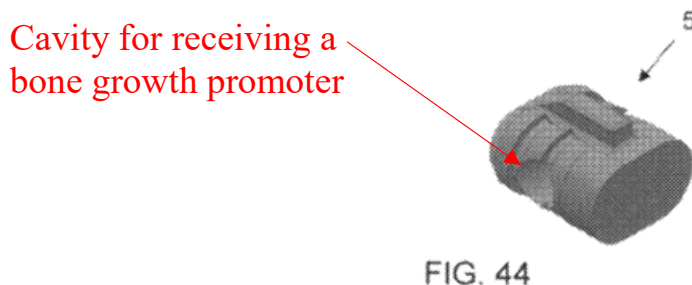
47. Vestgaarden-981 issued on April 24, 2012 and therefore qualifies as prior art against the ‘511 Patent. Vestgaarden-981 describes various fusion implants for fusing a facet joint. Ex. 1009 at Abstract; FIGS. 29-74. Vestgaarden-981 further describes a set of surgical instruments for implanting the implant into a facet joint. *Id.* at Abstract. Vestgaarden-981 explains that its teachings are not limited to facet joints. *Id.* at 8:50-58. In fact, Vestgaarden-981 provides an entire section entitled “Application to Joints Other than Facet Joints,” which explains 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.” *Id.* (emphasis added).

1. Fusion implant with bone-engaging protrusions

48. Vestgaarden-981 describes a fusion implant having a plurality of barbs that protrude from the lateral surface of the implant and are designed to “impede retraction” of the implant from the joint. *Id.* at 4:35-37. In addition, Vestgaarden-981 describes that a fusion implant may include other types of bone-engaging protrusions, such as a screw (FIGS. 58-68) and sharp spikes (FIGS. 69-74). *Id.* at 8:19-41; FIGS. 58-74. Figures 1, 58, 68, and 73 showing these embodiments of fusion implants are reproduced and annotated below.



49. Vestgaarden-981 also describes that the implant may include a through-hole (cavity) so that “a bone growth promoter to be packed through and across the width of the fusion implant, thereby enabling rapid fusion through the implant.” *Id.* at 7:66-8:4, FIGS. 44 and 47.



2. Surgical instruments

50. With respect to surgical devices for implantation of the fusion implant, Vestgaarden-981 describes a set of nesting surgical instruments. *Id.* 6:10-15. This instrument set includes a directional cannula (working channel) having rounded (blunt) tangs on its distal end. *Id.* at 8:36-39; FIG. 8.

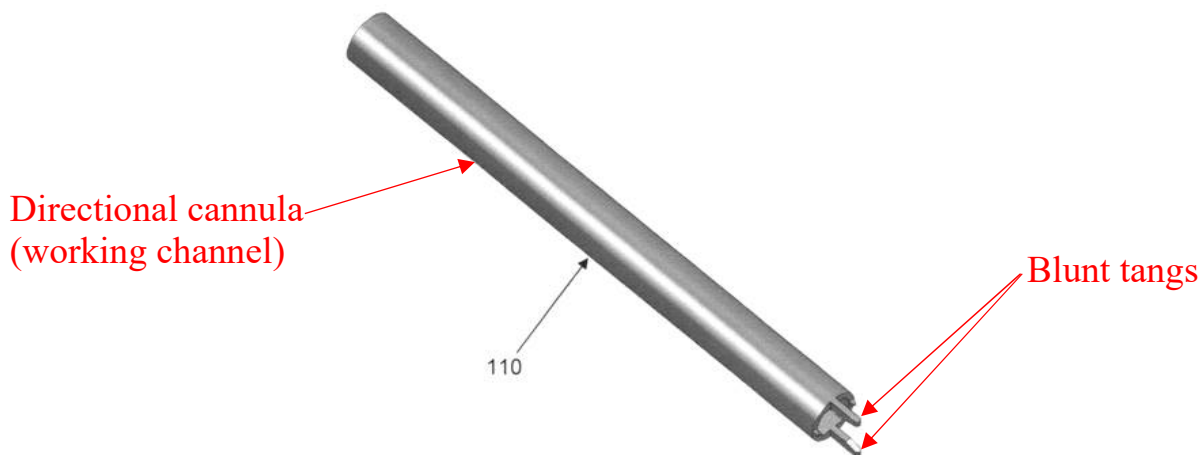


FIG. 8

51. The described surgical tools include a cavity cutter that is used to “make an opening having the perfect shape for fusion implant.” *Id.* at 6:57-58; FIG. 9A. Another surgical tool in Vestgaarden-981’s set is an implant holder (inserter), which is used to insert the fusion implant into the void within the joint. *Id.* at 59-64; FIG. 11. FIG. 11 shows that the implant holder has a pair of implant-engaging arms for

holding the implant as the implant holder advances the implant through the working channel and inserts the implant into the void within the joint. *Id.* at 6:59-64.

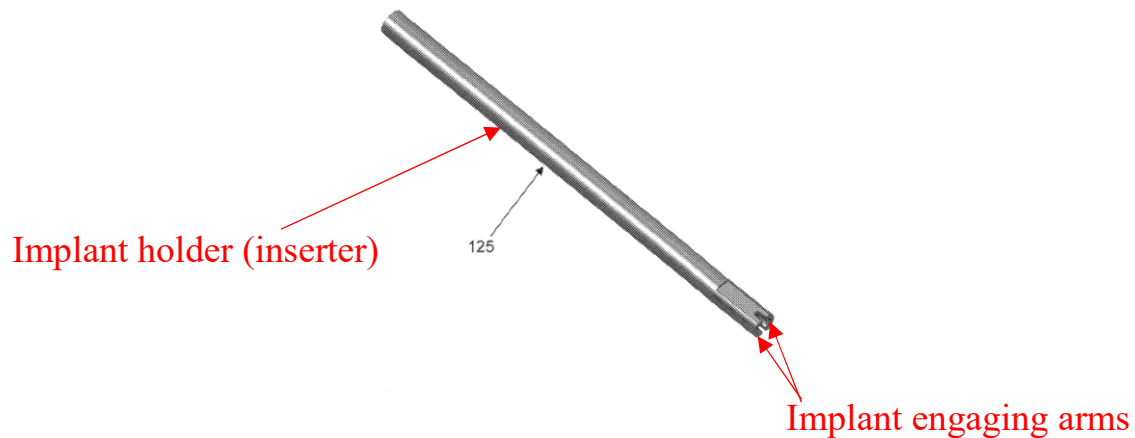


FIG. 11

52. Another surgical tool described in Vestgaarden-981 is an implant tamp. *Id.* at 6:15. After the implant holder is used to insert the implant into the void within the joint, the implant tamp is inserted into the internal lumen of the implant holder and then “lightly tapped” to drive the implant into the void, countersinking the implant 1-2 millimeters. *Id.* at 6:64-7:1.

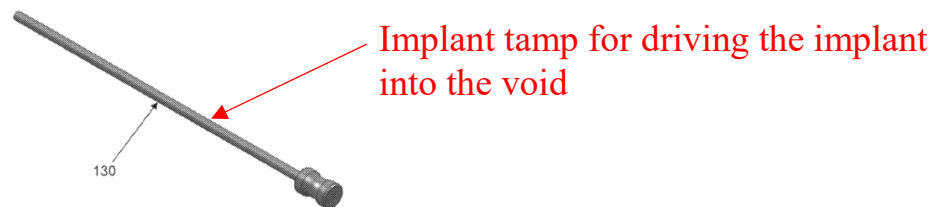
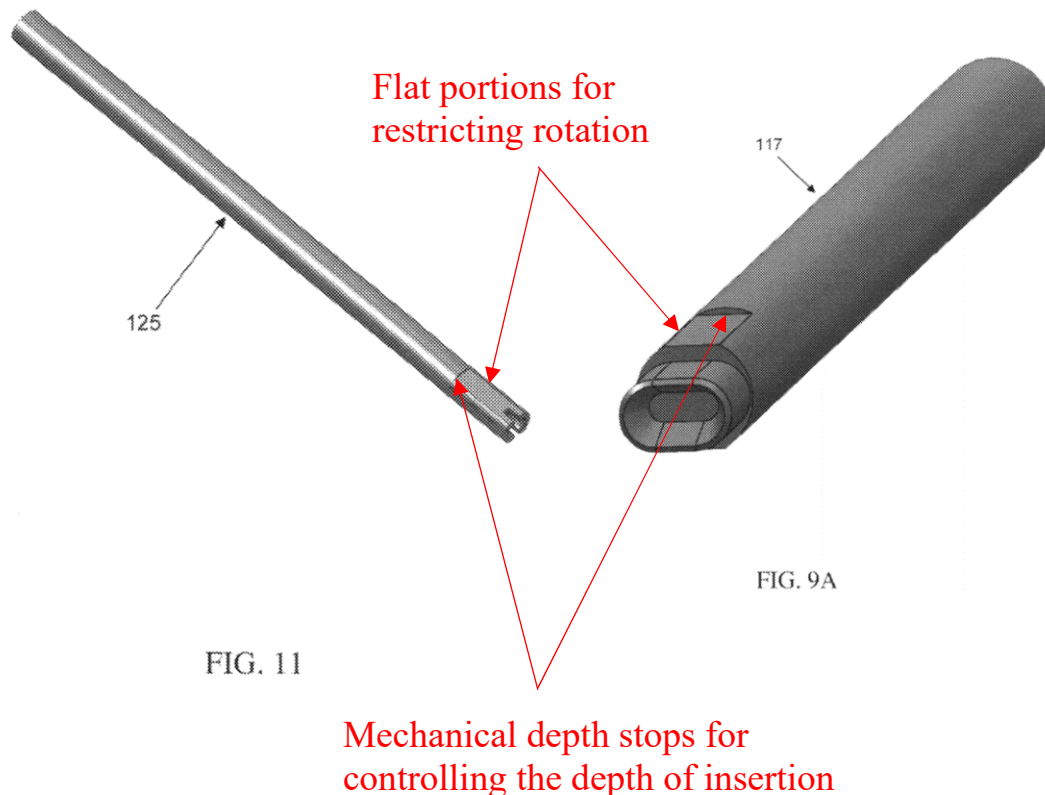


FIG. 12

53. After the implant has been properly implanted into the joint, “implant tamp 130, implant holder 125 and directional cannula 110 are removed from the surgical site and the incision is closed.” *Id.* at 7:5-7.

3. “Directional features”

54. Vestgaarden-981 describes that the working channel and the surgical tools have “directional feature[s] which [are] used to maintain the alignment of the instrumentation with ... the joint.” *Id.* at 5:1-4. Vestgaarden-981 describes an example of directional features, in which the directional features are implemented as complementary flat surfaces placed within the interior surface of the working channel and also positioned on the external surfaces of the distal ends of the surgical tools, respectively. *Id.* at 5:4-9. Figures 9A and 11 show the cavity cutter and the implant holder with the exemplary “flat portions,” which serve the role of the “directional features” for maintaining radial alignment between the surgical tools and the working channel. Figures 9A and 11 also show that the flat portions have mechanical depth stops that control the depth to which the surgical tools can be inserted into the working channel and the joint.



B. U.S. Patent No. 8,882,818 (“Vestgaarden-818”) (Ex. 1010)

55. Vestgaarden-818 was filed on September 24, 2012 and issued on November 11, 2014, which means that Vestgaarden-818 is prior art with respect to the ‘511 Patent. Vestgaarden-818 describes an instrument set and a method for fusing an SI Joint. Ex. 1010 at Abstract. Vestgaarden-818 explains that “[f]usion is a surgical treatment to relieve pain generated from joint dysfunction.” *Id.* at 1:46-47.

56. Vestgaarden-818 teaches a posterior approach to an SI joint, which “is familiar to spine surgeons, thereby providing an increased level of comfort for the surgeon.” *Id.* at 4:34-37. A directional surgical cannula (working channel) with

tangs is inserted into the posterior incision, such that the tangs are positioned between the sacrum and ilium, thus aligning the working channel with the plane of the SI joint and securing the working channel in the proper position. *Id.* at 2:7-11; 4:38-43; 5:51-56.

57. Next, Vestgaarden-818 teaches that a cavity is formed in the SI Joint for receiving the implant, wherein the implant is inserted via the working channel and then driven into the cavity so that the implant is countersunk 1-2 mm. *Id.* at 2:12-24, 4:60-65, 6:28-36. After the implantation procedure, all instruments are removed from the surgical site, and the incision is closed. *Id.*, at 6:37-40. The implant implanted into an SI Joint is shown in FIG. 1:



58. In addition, Vestgaarden-818 incorporates by reference the fusion implants described in Vestgaarden-981. *Id.* at 4:10-14.

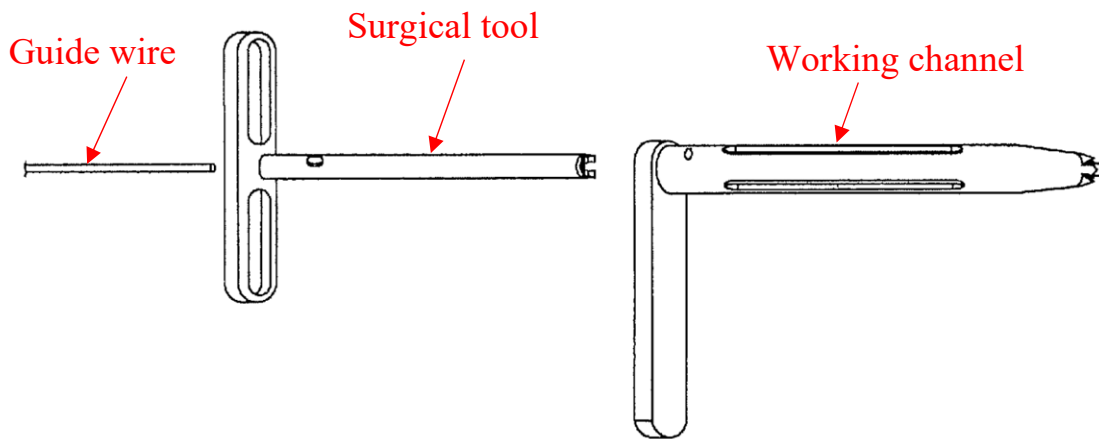
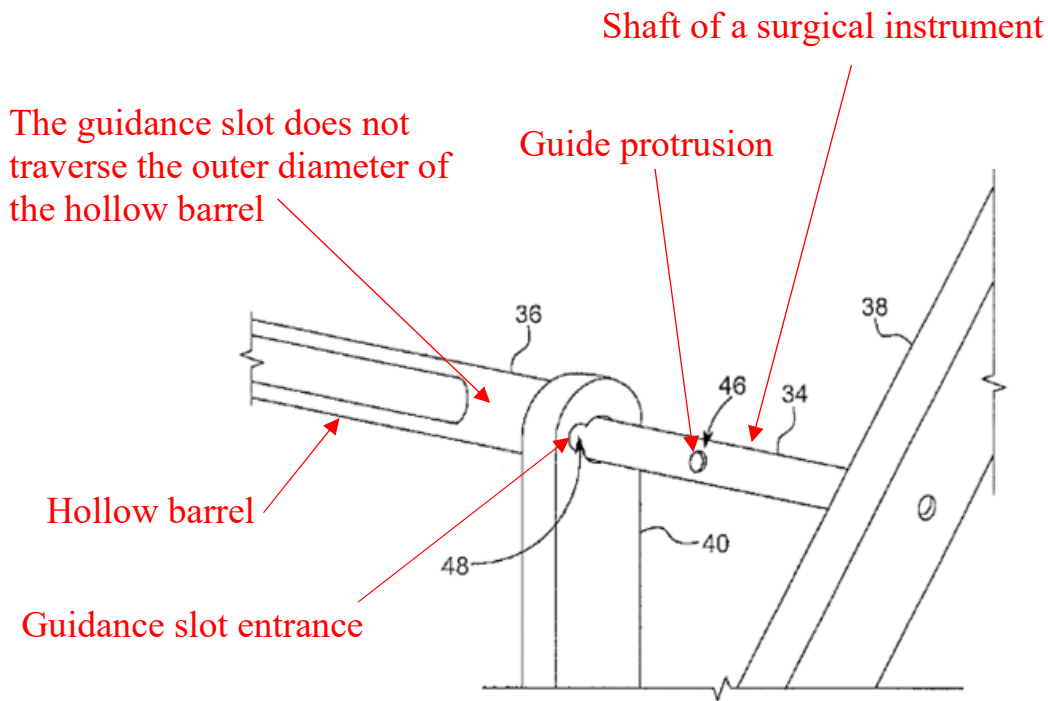


FIG. 6

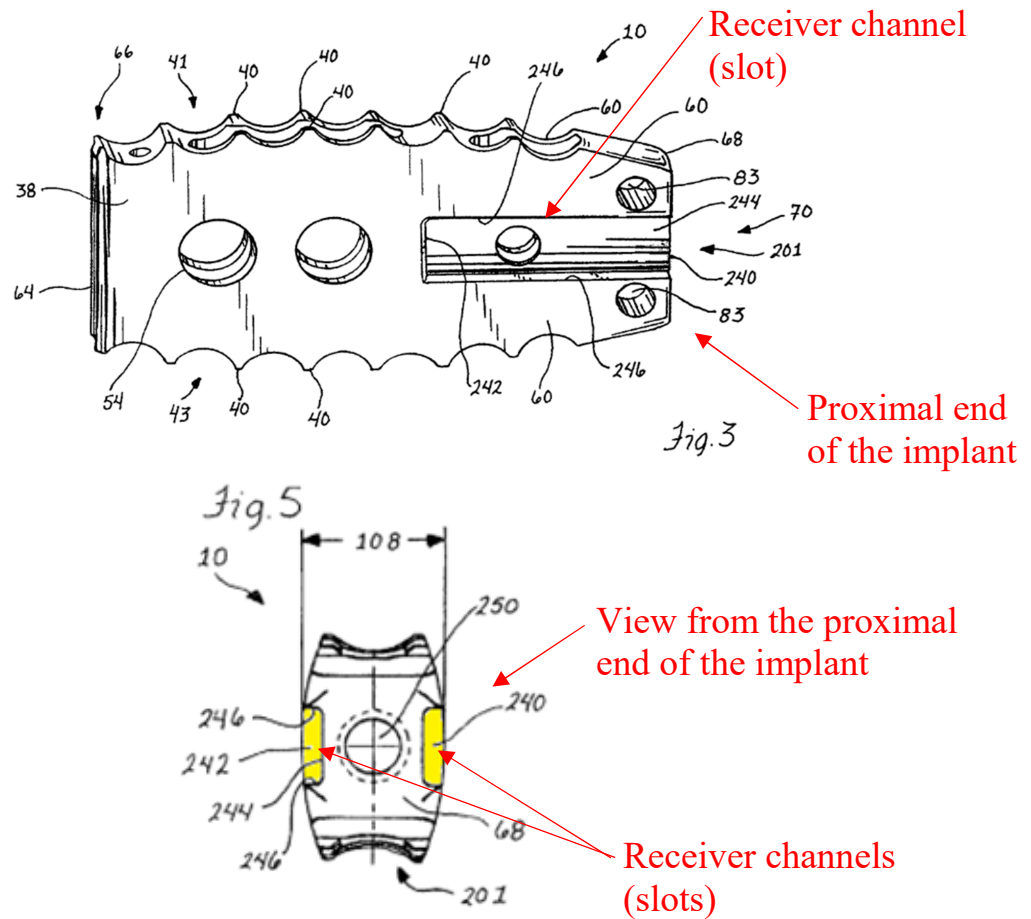
62. Lins teaches that the hollow barrel of the working channel has interior guidance slots, to which Lins refers to as “recesses.” *Id.* [0034]. Lins explains that the surgical tools have “guide protrusions” that are configured to engage the interior guidance slots of the working channel to “control and guide the depth of penetration and degree of rotation” of the surgical instruments relative to the working channel and relative to the joint. *Id.* FIG. 11 of Lins shows the entrance of the guidance slot and the complementary guide protrusion positioned on the shaft of the surgical tool. *Id.* at FIG. 11. This figure also shows that the guidance slot does not traverse an outer circumference of the hollow barrel because the guidance slot is fully concealed within the hollow barrel and is not visible in an exterior view shown in FIG. 11. *Id.* Annotated FIG. 11 is provided below.



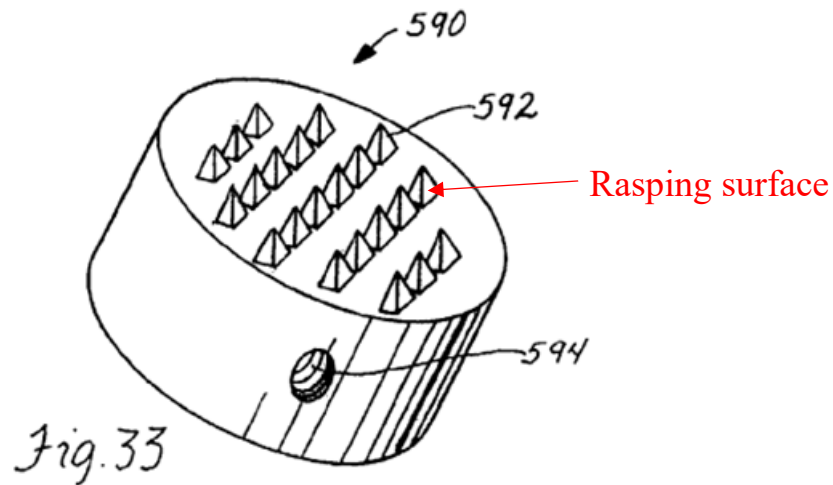
D. U.S. Patent No. 8,029,512 (“Paltzer”) (Ex. 1012)

63. Paltzer issued on October 4, 2011 and therefore is prior art against the ‘511 Patent. Analogous to Vestgaarden-981, Paltzer describes a method of fusing a joint using an implant, in which the implant is inserted into a joint using an implant holder (inserter). Paltzer describes several advantageous features.

64. First, Paltzer describes 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. Figures 3 and 5 are reproduced and annotated below.



65. Second, Paltzer describes “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.” *Id.* at 15:34-40. Paltzer also describes an embodiment of a dedicated tool (not shown in the figures) that is configured to couple to the rasp to insert the rasp into the joint. *Id.* at 15:44-47.



E. Combination of Vestgaarden-981, Vestgaarden-818, and Lins

1. Vestgaarden-981 and Vestgaarden-818

a) Motivation to combine

66. A person of ordinary skill in the art would have been motivated to apply the surgical tools and the implants described in Vestgaarden-981 to a method of fusing an SI joint described in Vestgaarden-818. Vestgaarden-981 expressly encourages a person of ordinary skill in the art to use the surgical tools and fusion implants in “any joint” having “a pair of opposing bony surfaces defining a gap therebetween”—and the SI joint fits this description perfectly. Ex. 1009 at 8:50-50. In fact, Vestgaarden-818 itself references the fusion implants described in Vestgaarden-981 and specifies that those implants can be applied to the SI joint fusion method described in Vestgaarden-818. Ex. 1010 at 4:10-14. In addition, a person of ordinary skill in the art would have been motivated to use the surgical tools

and fusion implants described in Vestgaarden-981 when performing the SI joint fusion procedure described in Vestgaarden-818 because Vestgaarden-981's tools and implants are superior to those described in Vestgaarden-818.

i. Vestgaarden-981 and Vestgaarden-818 themselves include language that provides motivation for their combination

67. Vestgaarden-981 contains a section entitled "Applications to Joints *Other than Facet Joints*," which explains 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 8:50-50 (emphasis added). This description provides motivation for applying Vestgaarden-981's surgical tools and implants to a wide array of joints.

68. Vestgaarden-818 describes an SI joint fusion method that involves inserting an implant into "the gap between the sacrum and ilium making up a sacroiliac joint." Ex. 1010 at 2:60-62. Because this description in Vestgaarden-818 mirrors Vestgaarden-981's the description of applicability of its surgical instruments and fusion implants to other joints, Vestgaarden-981 and Vestgaarden-818 themselves provide a clear motivation for their combination.

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

69. Vestgaarden-981's implants and tools provide multiple advantages over their counterparts taught in Vestgaarden-818, and therefore a person of ordinary skill in the art would have been motivated to apply Vestgaarden-981's implant and surgical tools to Vestgaarden-818's SI joint fusion method. For example, a person of ordinary skill in the art would have been motivated 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 to better secure an implant within a joint, thereby reducing likelihood that the implant may shift its position or become dislodged.

70. In addition, Vestgaarden-981 describes that an implant may have a “through-hole” 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. Because achieving fusion is an objective described in Vestgaarden-818, a person of ordinary skill in the art would have been motivated to implement the through-hole described in Vestgaarden-981 to further facilitate bone fusion. *See* Ex. 1010 at 1:56-58.

71. Furthermore, a person of ordinary skill in the art would have been motivated to use Vestgaarden-981's implant holder and implant tamp for inserting

and driving the implant into the SI joint because they offer a higher degree of control and precision with respect to placement of the implant into the SI joint. *See* Ex. 1009 at 6:59-7:2. In contrast, Vestgaarden-818 does not describe a tool for holding an implant, and only describes an implant positioner that is capable of only reaming the implant into the joint. Ex. 1010 at 6:29-36; FIG. 22. Furthermore, because Vestgaarden-818 does not teach an implant holder, Vestgaarden-818 requires the surgeon to “feel” resistance of the implant relative to the SI joint to determine that the implant is positioned at the void. *See id.* at 6:29-32 (“[I]mplant positioner 160 is inserted into the lumen of directional cannula 130 and advanced until resistance is *felt*, indicating that the distal end of implant 5 has engaged cavity 45.”) (emphasis added).

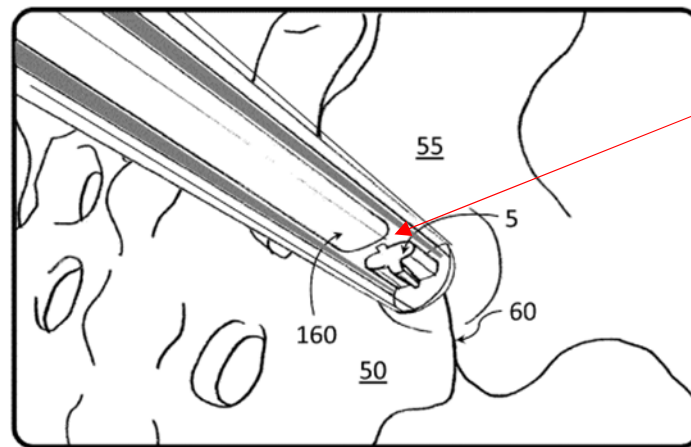
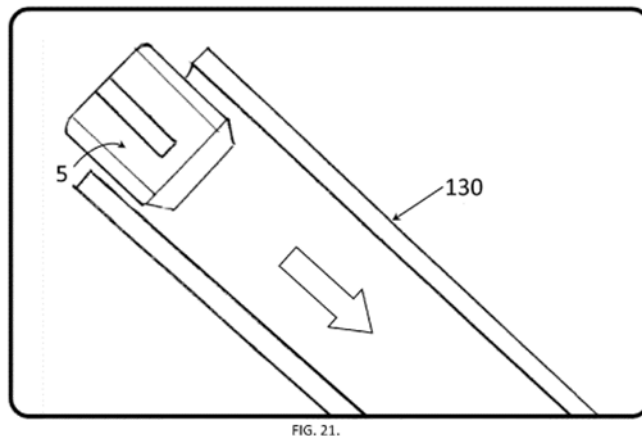


FIG. 22.

72. The lack of precise control over the implant is a major concern from a surgeon’s perspective. Because Vestgaarden-818’s implant positioner does not hold the implant, a surgeon would be unable to control the orientation of the implant as

they advance the implant through the working channel. As depicted in FIG. 21 of Vestgaarden-818, after a surgeon inserts the implant into the working channel, the implant is essentially in freefall.



73. Furthermore, because the surgeon must “feel” the resistance of the implant relative to the void, the implantation procedure is susceptible to user error, which is especially problematic considering that Vestgaarden-818 teaches a very precise depth of implantation: “[s]tabilization implant 5 is preferably countersunk 1-2 mm into sacroiliac joint 60.” 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.

74. Because Vestgaarden-818 does not describe a surgical tool for holding the implant, a person of ordinary skill in the art would have been motivated to improve Vestgaarden-818’s implant-insertion method by using Vestgaarden-981’s implant holder, which would allow a surgeon to precisely position the implant into

the void within the SI joint. After the implant is properly inserted into the SI joint, the surgeon would use Vestgaarden-981's implant tamp to drive the implant to a precise depth within the void.

75. Another advantageous feature described in Vestgaarden-981 is the rounded (blunt) tangs of the working channel. Ex. 1009 at FIG. 8. A person of ordinary skill in the art would have recognized the advantages of rounded tangs because this shape reduces the likelihood of damaging ligaments or soft tissue during the surgery. Thus, a person of ordinary skill in the art would have been motivated to apply Vestgaarden-981's working channel with rounded tangs to Vestgaarden-818 implant-insertion method.

b) Predictable Result

76. A person of ordinary skill in the art would have expected success in the combination of Vestgaarden-981 and Vestgaarden-818, and this combination would have yielded a predictable result with known components performing their intended functions. The fact that Vestgaarden-981 is incorporated by reference into Vestgaarden-818 indicates that they are readily combinable with one another. The fact that both Vestgaarden-981 and Vestgaarden-818 include identical language stating that their inventions can be "used to stabilize and fuse *any* joint having ... a pair of opposing bony surfaces defining a gap therebetween" further underscores their compatibility. Furthermore, Vestgaarden-981 and Vestgaarden-818 share many

similarities including (1) implants having an oblong, elongated body with stabilizers, (2) working channels with tangs, (3) tools for forming a cavity within the joint, and (4) an implant tamp / positioner for driving the implant into the cavity. These similarities are extensive, and a person of ordinary skill in the art would have reasonably expected success when applying Vestgaarden-981's surgical tools and implants to Vestgaarden-818's method of SI joint fusion. This combination would have been straightforward and would have only required ordinary skill in the art.

2. Vestgaarden-981 and Lins

a) Motivation to combine

77. Controlling depth and orientation of the surgical tools are important and well-known considerations when performing SI joint fusion. *See, e.g.*, 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.”). Furthermore, Vestgaarden-818 requires that “implant 5 is preferably countersunk 1-2 mm into sacroiliac joint.” Ex. 1010 at 6:35-36. To consistently achieve this precise implantation depth, it is important that the surgical tools be equipped with a mechanism for precisely controlling the depth at which the implant holder positions the implant into the void within the joint. In addition, because Vestgaarden-981's cavity cutter and implant have oblong cross-sections, it is important to restrict their ability to rotate within the working channel to ensure

that they are properly oriented with respect to the joint, thereby enabling a surgeon to consistently create a correctly oriented void and to precisely orient the implant relative to that void, as depicted in Figures 3 and 3A of Vestgaarden-818.

78. Vestgaarden-981 recognizes these important considerations and explains that the surgical tools and the working channel have “directional features” that control the advancement of the surgical tools within the working channel. Ex. 1009 at 5:1-9. Vestgaarden-981 provides a non-limiting example of directional features that involves complementary “flat portions.” *Id.* at 5:1-9. Figures 9, 9A, and 11 of Vestgaarden-981 depict that the flat portions are positioned on the distal ends of the surgical tools and have shoulders that would function as depth-stops when they engage the corresponding shelves of the flat portions within the working channel. These features are indicated in red ink in the figures reproduced below.

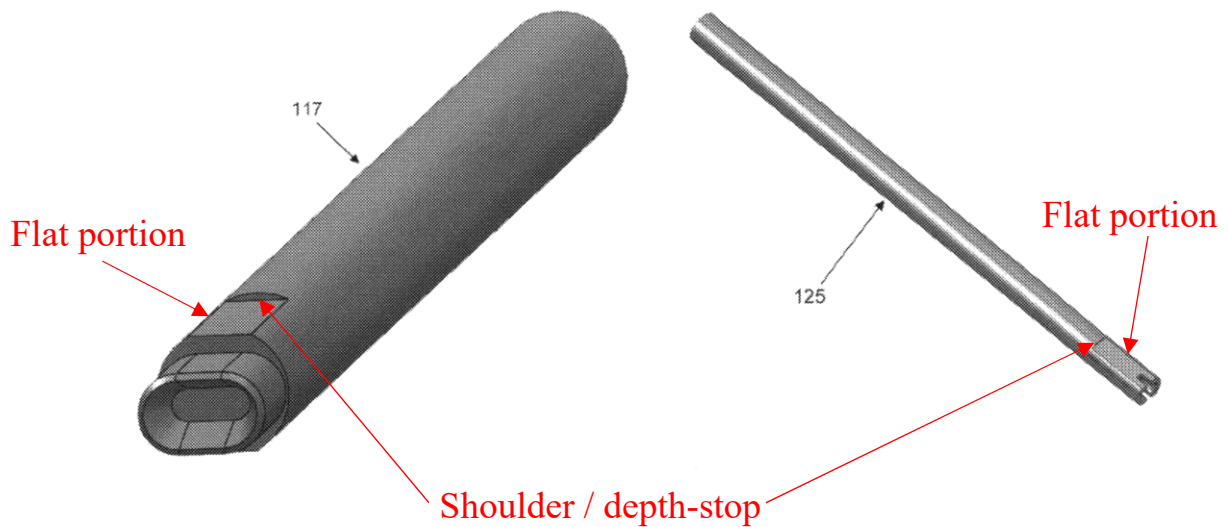


FIG. 9A

FIG. 11

79. Lins describes a different (better) mechanism for controlling the depth and orientation of the surgical tools relative to the joint. Ex. 1011 at [0038]. In Lins, guide protrusions are affixed to shaft of a surgical tool while complementary guidance slots are positioned on the interior surface of the hollow bore of the working channel. *Id.* The engagement between the guide protrusions and the guidance slots controls the depth of insertion and orientation of the surgical tools relative to the working channel and the joint. *Id.*

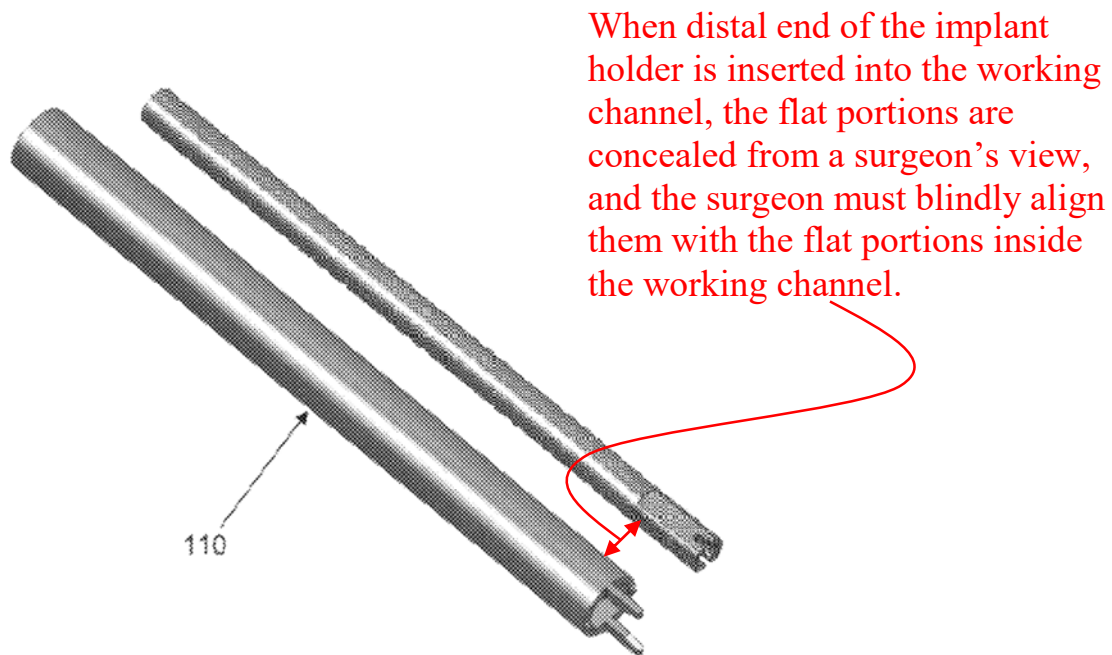
80. Lins's guide protrusions and guidance slots offer several advantages (explained below) over Vestgaarden's "flat portions." To achieve these advantages, a person of ordinary skill in the art would have been motivated to combine Vestgaarden-981 and Lins, and in this combination, a person of ordinary skill in the

art would have implemented Lins's guide protrusions and guidance slots as the "directional features" of Vestgaarden-981's surgical tools and working channel.

81. Vestgaarden-981's exemplary directional features—i.e., flat portions—do not provide a surgeon with a visual reference for aligning the implant holder with the working channel. After the distal end of the implant holder is inserted into the working channel, the hollow barrel conceals the flat portions on the distal end of the implant holder, such that the surgeon cannot see these "directional features." After the implant holder is inserted into the working channel and until the distal end of the implant holder reaches the flat surfaces at the distal end of the working channel, the orientation of the implant holder (and the implant coupled thereto) is only controlled by the surgeon's hand. Even slight rotation of the surgeon's hand as they advance the implant holder into the working channel can misalign the flat portions of the implant holder and the flat portions within the working channel.

82. When this happens, the rounded edge of the distal end of the implant holder will hit the straight edge of the flat portion within the working channel, which will stop the advancement of the implant holder. At that point, 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. To do so, the surgeon will gradually rotate the implant holder while pushing it forward to "feel" for the flat portions of the implant holder and the working channel to come into alignment. After

the alignment is achieved, the distal end of the implant holder can continue its advancement into the working channel. Only during these final few centimeters of advancement, Vestgaarden-981's flat portions control the alignment between the surgical tool and the working channel.



83. In contrast—and in a major improvement—to Vestgaarden-981, Lins enables a surgeon to **visually** align the guide protrusions on a shaft of a surgical tool with the guidance slots of the working channel, as depicted in Figure 11. 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 entirely eliminating a need for blind adjustment.

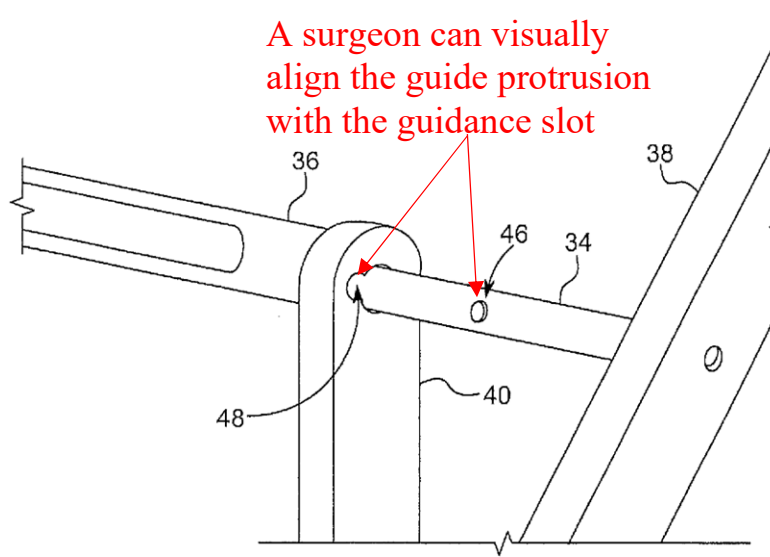


FIG. 11

84. As someone who has personally performed hundreds of SI joint fusion surgeries, I can attest that the guide protrusions and guidance slots taught in Lins would offer a surgeon a significantly better user experience over the exemplary directional features (flat portions) mentioned in Vestgaarden-981. To improve the working channel of Vestgaarden-981, a person of ordinary skill in the art would have been motivated to implement Lins’s guidance slot and guide protrusions as the “directional features” of Vestgaarden-981’s surgical tools and working channel, instead of the exemplary “flat portions” described in Vestgaarden-981.

b) Predictable Result

85. Implementing Lins’s guidance slot and guide protrusions as the directional features of Vestgaarden-981’s working channel and surgical tools would

have been straightforward and a person of ordinary skill in the art would have had a reasonable expectation of success in making this improvement. This combination would be a simple substitution of one known type of a (superior) directional feature—i.e., Lins’s guidance slot and guide protrusions—for another known (inferior) directional feature—i.e., Vestgaarden-981’s exemplary “flat portions.” Indeed, Vestgaarden-981 explains that the “flat portions” are described “[b]y way of example but not limitation.” Ex. 1009 at 5:4-9. This statement clearly conveys that other types of directional features can be readily implemented with Vestgaarden-981’s working channel and surgical instruments. Furthermore, Lins references Vestgaarden-981 in its Background section, which further indicates that the invention described in Lins is intended to improve upon Vestgaarden-981. In conclusion, I believe that a person of ordinary skill in the art would have had a reasonable expectation of success when implementing Lins’s guidance slots and guide protrusions as the directional features of Vestgaarden-981’s working channel and surgical tools, and that this combination would be simple substitution of one known feature for another known feature and would produce a predictable result.

3. Vestgaarden-Vestgaarden-Lins combination and its method of operation

86. The surgical method, tools, and fusion implants achieved by combining Vestgaarden-981, Vestgaarden-818, and Lins would be straightforward:

Vestgaarden-981's surgical instruments and working channel would be improved with Lins's guide protrusions and guidance slot and then used to implant Vestgaarden-981's fusion implant into an SI joint to achieve bone fusion, as taught in Vestgaarden-818.

87. In this combination, Vestgaarden-981's working channel would be equipped with Lins's guidance slot, while Vestgaarden-981's cavity cutter and implant holder would be equipped with Lins's guide protrusions. The engagement between Lins's guidance slot and guide protrusions would control the depth of advancement and orientation of the surgical tools relative to the working channel and the joint, ensuring that the tools do not over-penetrate the SI joint and maintain proper orientation in relation to the SI joint. These improved surgical tools would be used to create a void within an SI joint and then insert and drive Vestgaarden-981's fusion implant into the void to achieve SI joint fusion, as taught in Vestgaarden-818.

88. The resultant SI joint fusion method would include the following steps: first, a surgeon would make an incision proximal to a patient's SI joint, as taught in Vestgaarden-818. Ex. 1010 at 5:22-26. Next, the surgeon would insert Vestgaarden-981's working channel into the incision, positioning the rounded (blunt) tangs of the working channel between the articular surfaces of the sacrum and ilium, as taught in Vestgaarden-818. *Id.* at 5:49-56. The surgeon would then create a void within the SI joint according to the method taught in Vestgaarden-818. *Id.* at 5:57-6:27. Then, the

surgeon would use Vestgaarden-981's cavity cutter to perfectly shape the void, preparing it for a fusion implant. Ex. 1009 at 6:57-58. Then, the surgeon would use Vestgaarden-981's implant holder to insert Vestgaarden-981's fusion implant into the void. *Id.* at 6:59-64; *see also* Ex. 1010 at 6:28-32. Finally, the surgeon would use Vestgaarden-981's implant tamp to drive the implant into the void, countersinking the implant 1-2 millimeters into the SI joint, as taught in Vestgaarden-818. Ex. 1009 at 6:64-7:2; *see also* Ex. 1010 at 6:33-36. When the implant is positioned within the SI joint, the implant's bone-engaging protrusion(s) would engage the articular surfaces of the sacrum and/or the ilium. *See* Ex. 1010 at FIG. 23; *see also* Ex. 1009 at FIG. 1. In this manner, the protrusion(s) will prevent pullout of the implant from the SI joint and will immobilize the SI joint while bone fusion takes place.

F. Combination of Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer

1. Combination of Vestgaarden-981's implant with Paltzer's receiving channels (slots)

a) Motivation to combine

89. A person of ordinary skill in the art would have been motivated to improve Vestgaarden-981 by including Paltzer's receiving channels (slots) on the proximal ends of fusion implants. Although Vestgaarden-981 describes an implant holder having a pair of implant-engaging arms, Vestgaarden-981 does not describe how these arms are configured to couple to an implant. Ex. 1009 at FIG. 11. Like

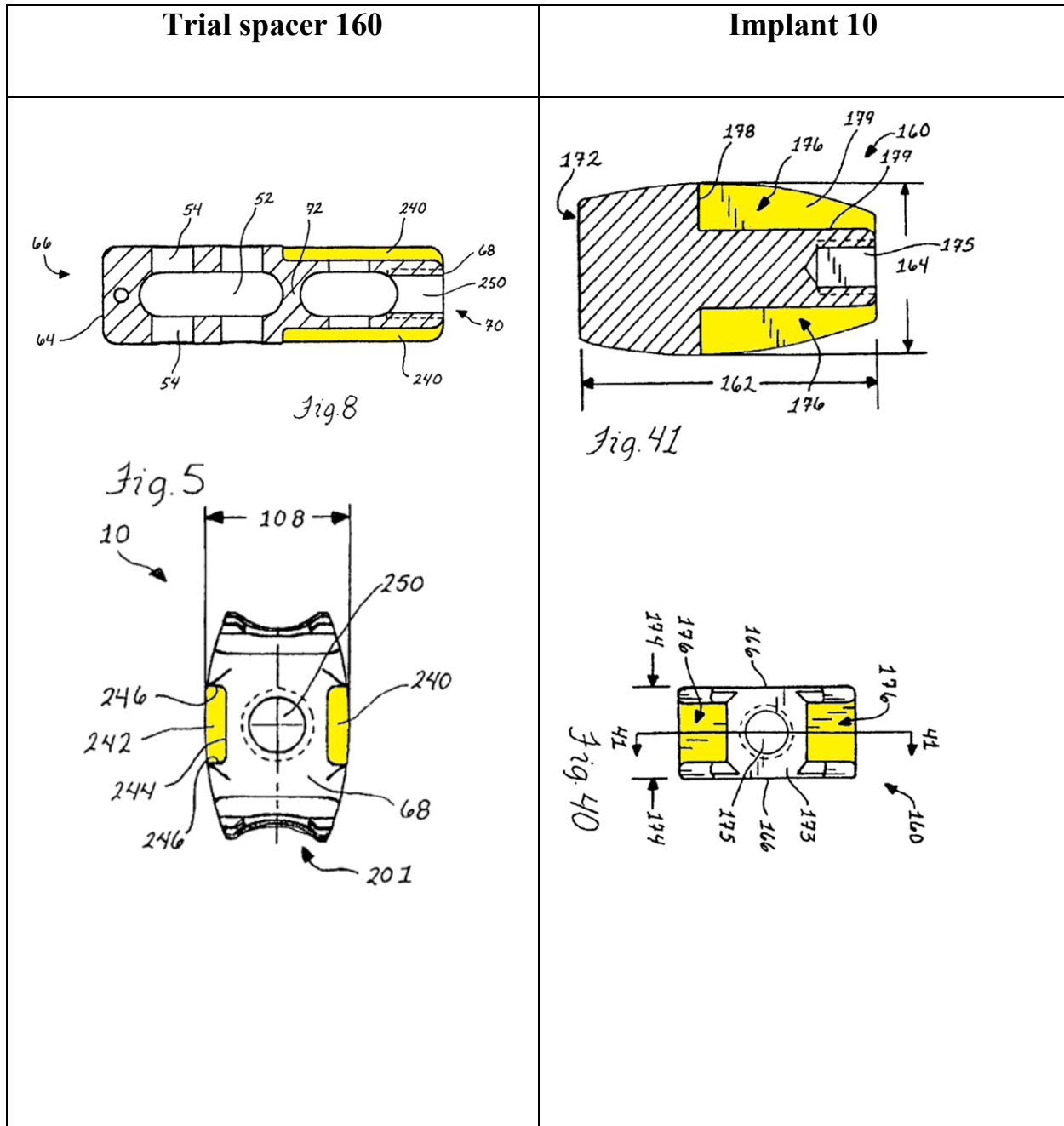
Vestgaarden-981, Paltzer also describes an implant holder (inserter) having a pair of arms and, in addition, describes an implant having slots configured to receive the arms of the inserter. Paltzer provides at least three reasons for including such slots on the proximal end of Vestgaarden-981's fusion implants.

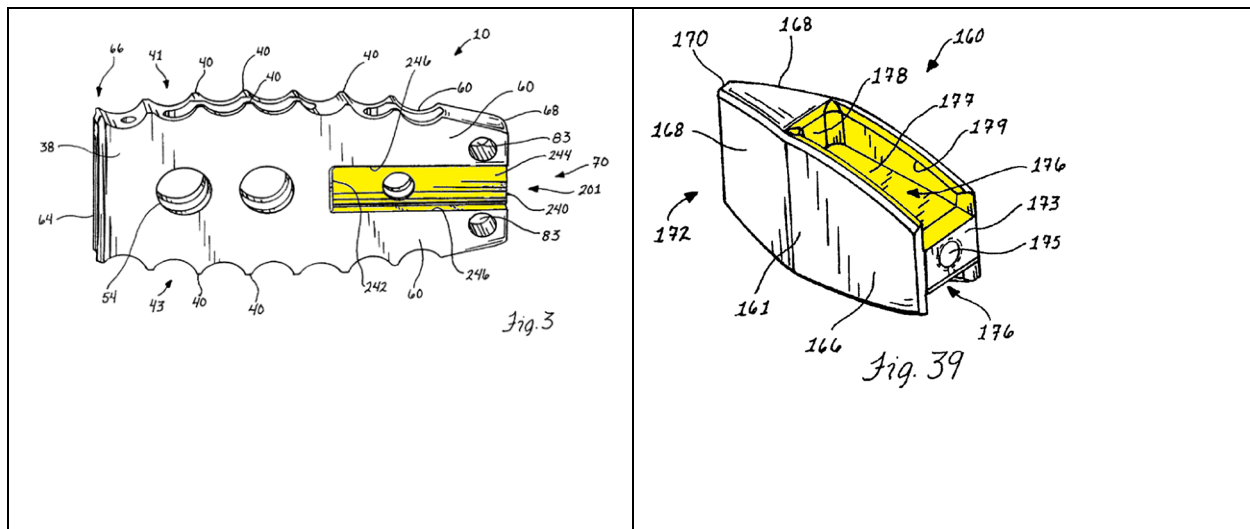
90. First, Paltzer describes that the engagement between the arms and the slots "maximizes surface area contact between the tool 200 and implant 10 to assist in distributing the forces endured by the tool engaging portions of the implant 10." Ex. 1012 at 9:54-10:2.

91. Second, Paltzer explains that the slots 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. *Id.* at 10:4-13.

92. Third, Paltzer explains that because the slots have uniform dimensions regardless of the shape of the implant, the slots make it possible for implants of various sizes to be universally compatible with a single inserter. *See id.* at 11:31-43. Paltzer provides an example in which a trial spacer which has a different shape and width than a standard implant can be inserted into the joint using the same inserter because the slots on the trial spacer have the same dimensions as the slots on the implant. *Id.* The differences between the overall dimensions of the implant and the

trial spacer in Paltzer's example are illustrated below with a side-by-side comparison, where their universally dimensioned slots are emphasized in yellow.





93. This feature of Paltzer would be a very beneficial improvement for Vestgaarden-981. Vestgaarden-981 explains 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. A person of ordinary skill in the art would understand that if Vestgaarden-981’s implants had Paltzer’s uniformly dimensioned slots, then a single implant holder could be used universally across the “wide range” of differently sized implants. This improvement would reduce the cost and complexity of Vestgaarden-981’s surgical instrument set because instead of providing a uniquely dimensioned implant holder for each implant based on the implant size, a single implant holder would have been universally compatible with *any* implant as long as that implant had the standardized slots, irrespective of the implant’s external dimensions.

b) Predictable Result

94. Including slots on a proximal end of an implant would have been well within the ordinary skill in the art and this combination would have produced a predictable result. A person of ordinary skill in the art would have had a reasonable expectation of success in this improvement to Vestgaarden-981 because Vestgaarden-981 already describes an implant holder having a pair of implant engaging arms—all that is needed to achieve this improvement is a pair of corresponding slots on the proximal end of the implant. This improvement would require nothing more than a routine application of ordinary skill to achieve a predictable and advantageous result described in Paltzer. In the resultant combination, known features would perform their intended functions—i.e., Paltzer’s slots on the proximal end of Vestgaarden-981’s implant would receive the arms of Vestgaarden-981’s implant holder.

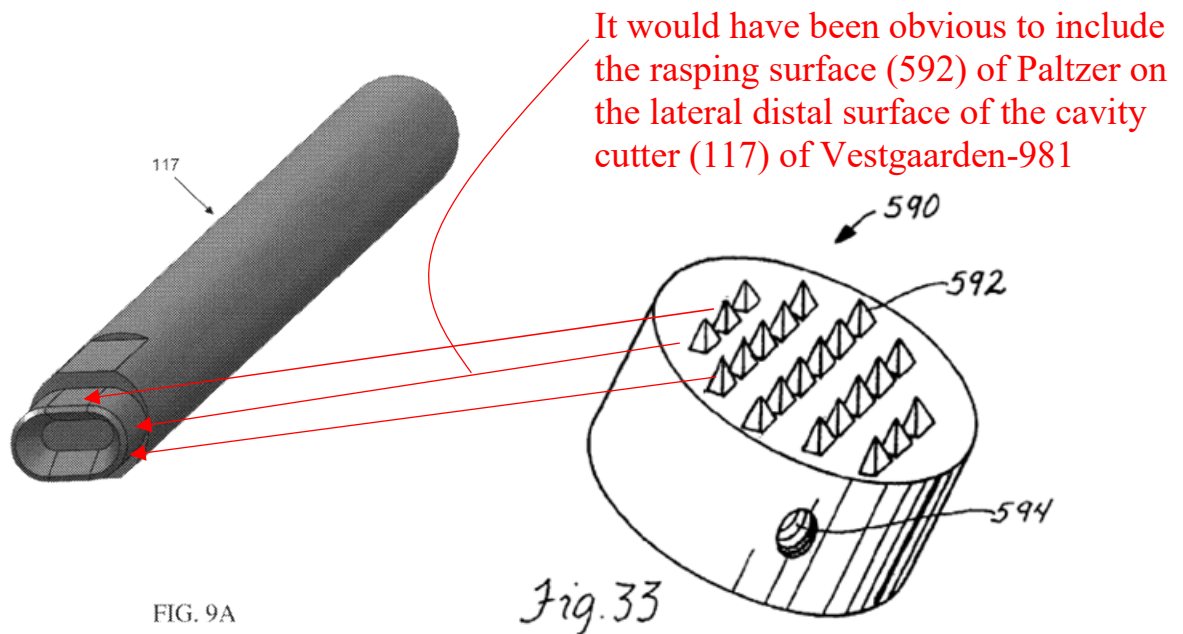
2. Combination of Vestgaarden-981’s cavity cutter and Paltzer’s rasping surface

a) Motivation to combine

95. A person of ordinary skill in the art would have been motivated to improve Vestgaarden-981’s cavity cutter by adding Palzer’s 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

description of advantages achieved by rasping the bone tissue is synergistic with Vestgaarden-981's description pertaining to an implant having "[a] through-hole 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. Because Vestgaarden-981 and Paltzer teach complementary ways of promoting bone growth across an implant, a person of ordinary skill in the art would have been motivated to combine these teachings, such that Paltzer's rasping surface would be used to prepare the void prior to insertion of Vestgaarden-981's implant, thereby facilitating bone growth through the implant subsequent to implantation.

96. Figure 9A of Vestgaarden-981 shows a cavity cutter for creating "an opening [within the joint] having the perfect shape for [the] fusion implant." *Id.* at 6:57-58; *see also id.* at FIG 9A. Placing Paltzer's rasping surface on a lateral wall of Vestgaarden-981's cavity cutter would have been an obvious improvement to Vestgaarden-981. In this combination, in addition to creating an "opening having a perfect shape" within a joint, Vestgaarden-981's cavity cutter would also serve an additional function of scraping the bone tissue to promote bone ingrowth, as described in Paltzer. Figure 9A of Vestgaarden-981 and Figure 33 of Paltzer are reproduced and annotated below.



b) Predictable Result

97. A person of ordinary skill in the art would have had a reasonable expectation of success in combining Paltzer's rasping surface with Vestgaarden-981's cavity cutter because this combination would produce an improved cavity cutter with rasping capabilities, wherein both the cavity cutter and the rasping surface would perform their respective functions. Implementation of this combination would have required only routine exercise of ordinary skill and would yield a well-known and predictable benefit of promoting bone growth across the implant as a result of induced fluid and blood flow within the joint. In this combination, known features would continue to perform their intended functions—i.e., Vestgaarden-981's cavity cutter would shape the void for the implant while

Paltzer's rasping surface positioned on the lateral wall of the cavity cutter would scrape and wound bone tissue within the void.

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

a) Motivation to combine Paltzer's rasp with Vestgaarden-981

98. Paltzer teaches a rasp connected to a standalone tool. Ex. 1012 at 15:44-47. As an alternative to combining Paltzer's rasping surface with Vestgaarden-981's cavity cutter, a person of ordinary skill in the art would have been motivated to use Paltzer's rasp as a standalone additional tool in Vestgaarden-981's tool set for the reasons set forth in Paltzer—mainly, to enable a surgeon to abrade the joint prior to inserting an implant to “induc[e] fluid and blood flow ... promot[ing] bone ingrowth.” Ex. 1012 at 15:36-40. In this combination, after forming the void within a joint using Vestgaarden-981's cavity cutter, the surgeon would use Paltzer's standalone rasp to abrade/scrape the bone tissue within the cavity as taught in Paltzer. *See* Ex. 1009 at 6:57-58; Ex. 1012 at 15:36-40.

b) Predictable Result

99. The combination of Paltzer's standalone rasp and Vestgaarden-981's surgical tool set would yield a predictable result in which known components would perform their intended functions—i.e., Paltzer's rasp would abrade the bone tissue within the void formed within a joint.

c) Motivation to combine Lins's guide protrusion with Paltzer's rasp

100. A person of ordinary skill in the art would have understood that the shape of a rasp must be complementary to the shape of the void. Since the shape of the void is oblong, a person of ordinary skill in the art would have been motivated to use a mechanism for controlling the orientation of the rasp with respect to the cavity to ensure prior alignment. Also, because over-penetration of the SI joint was a well-known concern, a person of ordinary skill in the art would have been motivated to control the depth of insertion of the rasp in the SI joint. *See, e.g.,* 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.”). Lins teaches that engagement between a guide protrusion and guidance slot accomplishes these objectives. Thus, a person of ordinary skill in the art would have been motivated to use Lins's guide protrusion on Paltzer's rasp tool, in which combination, the guide protrusion on the rasp would engage with the guidance slot of Vestgaarden-981's working channel to control the depth of insertion and orientation of the rasp relative to the SI joint.

d) Predictable Result

101. This combination of Lins's guide protrusion and Paltzer's standalone rasp tool would yield a predictable result in which known components would

perform their intended functions—i.e., Paltzer’s rasp tool would be used to abrade bone tissue while Lins’s guide protrusion would engage the guide slot of the working channel thereby controlling the depth of insertion and orientation of Paltzer’s rasp relative to the joint.

VII. CLAIM ANALYSIS

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

1. Claim 1

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

102. Vestgaarden-818 discloses on its face that it is directed to “[a] method for fusing a spinal sacroiliac joint.” Ex. 1010 at Abstract.

b) [1.a] creating a first incision proximal to the patient's sacroiliac joint

103. Vestgaarden-818 states 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. A person of ordinary skill in the art understands that creating a path to the sacroiliac joint through soft tissue requires first making an incision proximal to the patient’s sacroiliac joint.

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

104. Vestgaarden-818 describes the step of inserting a directional cannula (working channel) into the first incision (via a dilation tube). Ex. 1010 at 5:49-50.

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

105. Vestgaarden-981 describes a directional cannula (working channel) and “instruments [that] may ... be inserted through the cannula.” Ex. 1009 at 5:5-9. A person of ordinary skill in the art would understand that the working channel/cannula described in Vestgaarden-981 would be hollow in order for instruments to be inserted through it. Figure 8 shows the working channel/cannula having a hollow barrel.

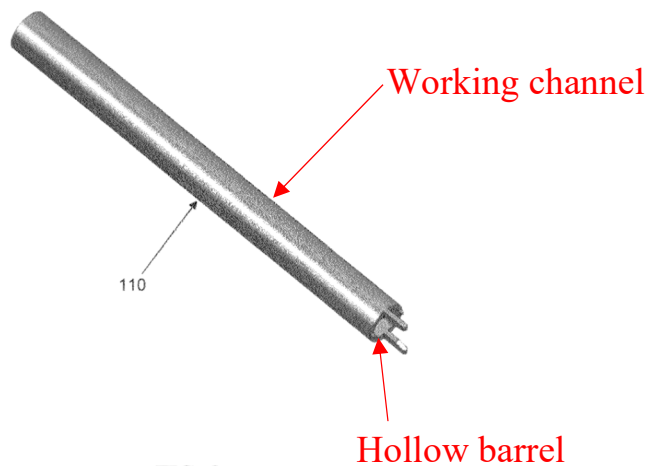


FIG. 8

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

106. Lins teaches a working channel (cannulated retention portion 36) with a hollow barrel that is configured for passing surgical instruments through it (translation portion 34). Ex. 1011 at [0034]. Lins describes “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).

107. Figure 11 of Lins clearly shows an opening of a guidance slot that is located in an interior diameter of the hollow barrel of the working channel/cannula and not traversing the outer diameter thereof.

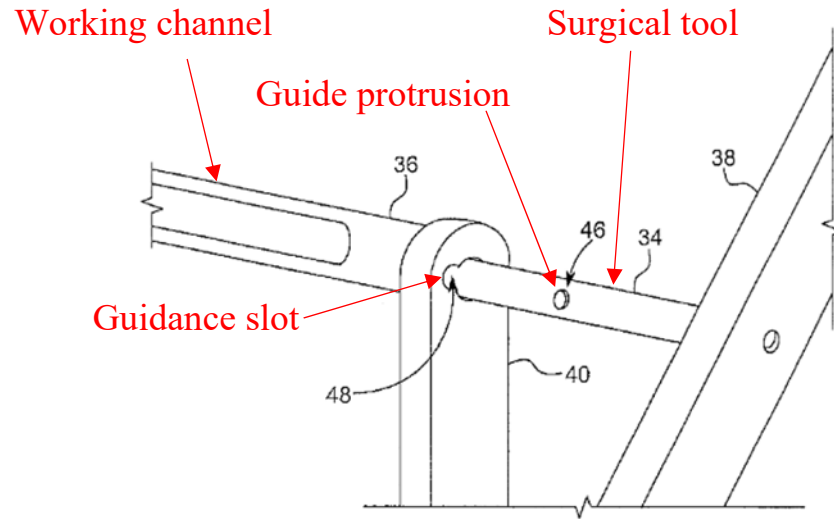


FIG. 11

108. Paragraph [0038] and Figure 11 of Lins clearly teach the limitation of [1.b.3] of the '511 Patent.

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

109. Figure 8 of Vestgaarden-981 shows the working channel has two tangs on its a distal end. Ex. 1009 at FIG. 8.

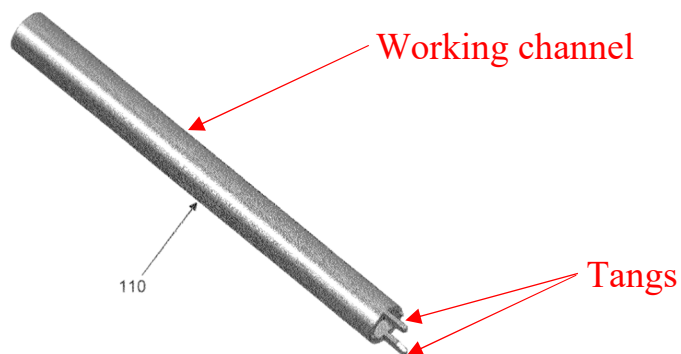


FIG. 8

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

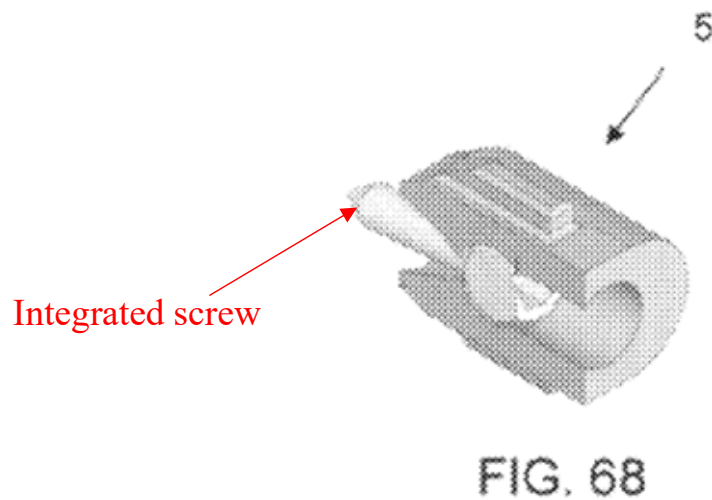
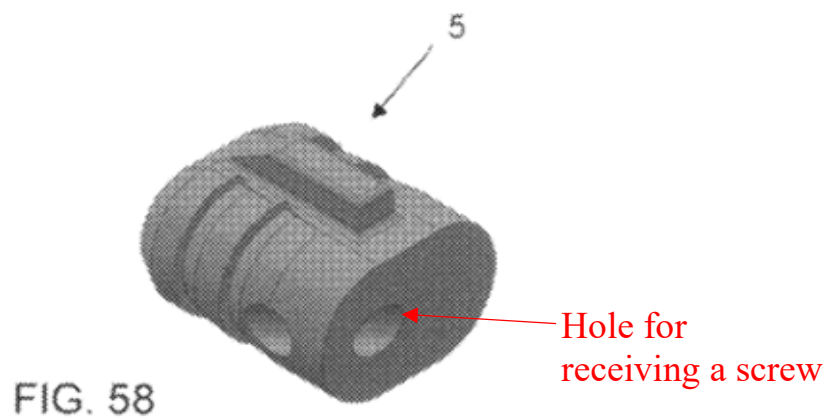
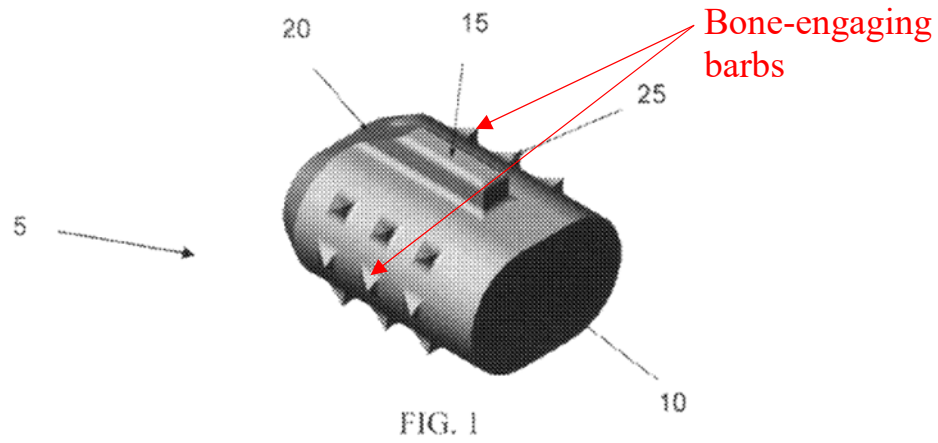
110. Vestgaarden-818 teaches “creating a cavity in the ilium and sacrum to a predetermined depth that spans the sacroiliac joint.” Ex. 1010 at Abstract.

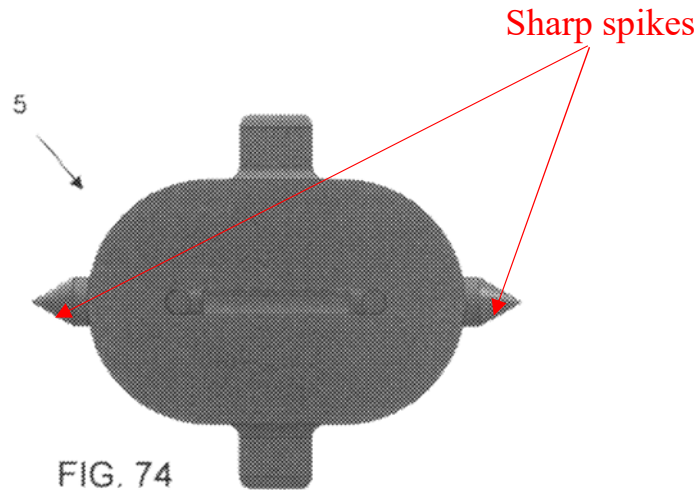
h) [1.d.1] inserting a fusion implant into said void,

111. Vestgaarden-818 teaches, “inserting a novel stabilization implant into the cavity.” Ex. 1010 at Abstract.

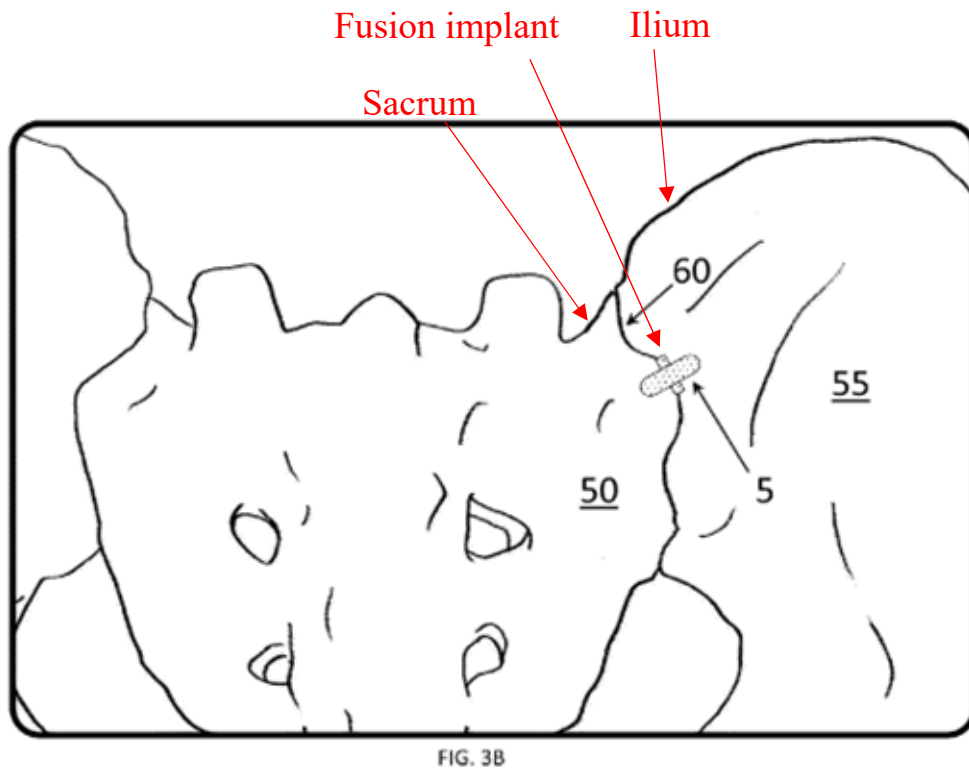
i) [1.d.2] wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.

112. Vestgaarden-981 teaches a fusion implant that “may include a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom.” Ex. 1009 at 4:33-35, FIG. 1. Vestgaarden-981 teaches that the barbs “impede retraction” of the fusion implant from the joint, therefore making the barbs advantageous. *Id.* at 4:35-37. Vestgaarden-981 also teaches multiple other bone-engaging protrusions, including “sharp spikes,” “K-Wire, suture, staple, screw or other fixation device” for “attaching the implant to the ... joint.” *Id.* at 8:19-42; FIGS. 65-68, 72-74. Figures 1, 58, 68, and 74 of Vestgaarden-981 show multiple different embodiments of fusion implants with protrusions configured to engage bone tissue as depicted and annotated below.





113. Figure 3B of Vestgaarden-818 shows the implant placed within the void created in the sacroiliac joint between the articular surfaces of the sacrum and ilium. Ex. 1010 at 4:25-33, FIG. 3B.



114. It is clear to one of ordinary skill in the art that when the implants in Vestgaarden-981 (such as Figs. 1, 58, 68, and 74 shown above) are inserted into the sacroiliac joint as taught in Vestgaarden-818 (see Fig. 3B above), the protrusions of the implant (barbs, screw, sharp spikes) would engage bone tissue in the articular surfaces of the sacrum, the ilium, or both. Vestgaarden-981 also teaches that these protrusions 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.”); *see also id.* at 8:19-42 (describing screws, sharp spikes and other devices for “attaching the implant to the [] joint”).

2. Claim 2

a) [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”

115. Figure 1 of Vestgaarden-981 shows a fusion implant having a central body with “a plurality of barbs (i.e., forward biting teeth) 25 extending outwardly therefrom.” Ex. 1009 at 4:33-35, FIG. 1. The implants depicted in Figures 58-60, 65-68, and 72-74 also have at least one protrusion extending from a central body (a transverse screw (Figures 58-60), a longitudinal integrated screw (Figures 65-68), sharp lateral spikes (Figures 72-74)).

b) [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.”

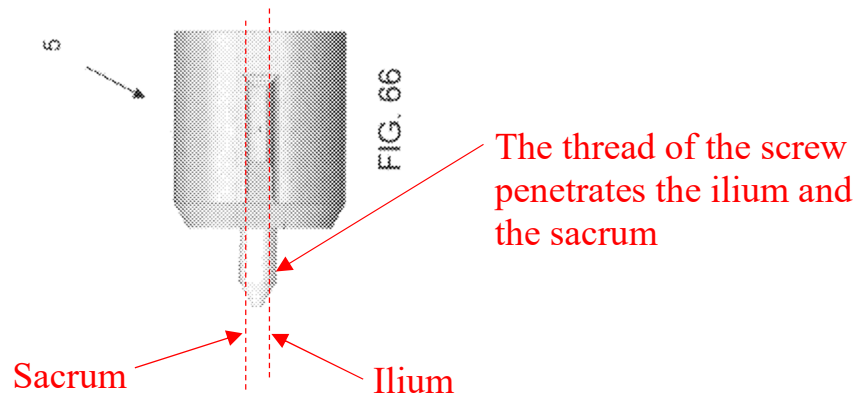
116. Vestgaarden-818 teaches that the “[s]tabilization implant 5 provides the stability and strength needed to immobilize the sacroiliac joint 60 while fusion occurs” and “holds sacrum 50 and ilium 55 stable relative to one another.” Ex. 1010 at 5:7-14; *see also* Ex. 1009 at 5:23-29. A person of ordinary skill in the art would understand that the protrusions fix the relative positions of the sacrum and/or the ilium when the protrusions engage the articular surfaces of the sacrum and/or the ilium.

3. Claim 3

a) 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.

117. Vestgaarden-981 teaches several versions of fusion implants where “a screw is used to attach the implant to the [] joint.” Ex. 1009 at 8:28-29; *see also id.* at 8:21-23; 8:32-33. When Vestgaarden-981’s implant having a screw is used in SI joint fusion procedure described in Vestgaarden-818’s, the screw thread would penetrate bone tissue of the sacrum, ilium, or both and fix their relative positions. For example, when Vestgaarden-981’s implant depicted in Figures 65-68 is used according to the method taught in Vestgaarden-818, the screw portion of the implant

would extend into the sacroiliac joint. The threads of the screw would penetrate the ilium and the sacrum, thereby fixing their relative positions as depicted and annotated below.



118. It would have been obvious to one of skill in the art to use a screw having dimensions that would enable the thread of the screw to embed in the bone tissue of both the ilium and sacrum thereby “attaching the implant to the [] joint” as discussed in Vestgaarden-981. *See* Ex. 1009 at 8:32-33.

119. Thus, Vestgaarden-981’s screw is a “protrusion,” and the thread of the screw is “an anchor” that penetrates at least one of a patient’s ilium and the patient’s sacrum thereby fixing their relative positions and immobilizing the SI joint.

4. Claim 4

a) 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.

120. As established in claim 3 above, a thread of a screw is an anchor operable to substantially fix the ilium to the sacrum, thereby substantially immobilizing the sacroiliac joint of a patient. According to the plain and ordinary definition of the word “screw,” the thread is “helical.” Ex. 1015 (defining the word “screw” as “a metal fastener having a tapered shank with a *helical* thread”) (emphasis added). Therefore, the screw thread in Figures 65-68 of Vestgaarden-981 is a “helical anchor.”

5. Claim 5

a) 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.

121. The implant of Vestgaarden-981 says it may include “a through-hole extending through the elongated body. The 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 7:66-7:4. Figure 44 of Vestgaarden-981 showing these features is reproduced and annotated in red ink below.

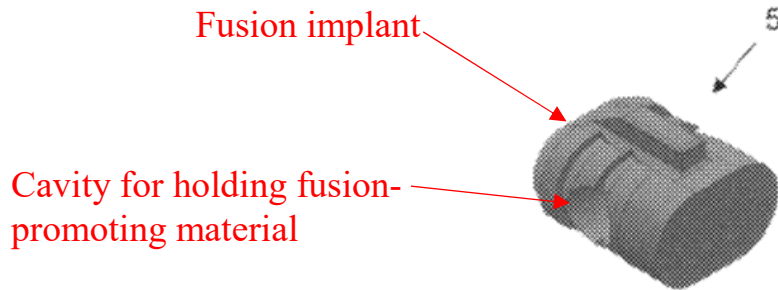


FIG. 44

122. A person of ordinary skill in the art would have been motivated to combine the through-hole/cavity feature of Vestgaarden-981 for holding bone growth material with an implant having protrusions (i.e., barbs, a screw, sharp spikes, or other fixation devices) to aid in rapidly fusing the implant within the sacroiliac joint.

6. **Claim 8**

a) **“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.”**

123. As noted *supra*, in Sections (VI)(E)(3) and VII(A)(1)(e), it would have been obvious to modify the directional features of Vestgaarden-981 with the recesses (guidance slots) and guide protrusions of Lins. The working channel/cannula of

Vestgaarden-981 would contain one or more slots/recesses and the surgical tools would have the “guide protrusions” taught in Lins. Lins specifically discloses that:

*These guide protrusions 46 are configured to engage one or more recesses (not illustrated) manufactured into the interior bore of the substantially cylindrical cannulated retention portion 36 (FIGS. 4-6) that **control and guide the depth of penetration and degree of rotation** of the translation portion 34 with respect to the retention portion 36, and with respect to the facet joint 16 (FIG. 1).*

Id. (emphasis added). Thus, the combination of Vestgaarden-818, Vestgaarden-981, and Lins teaches all of the limitations of claim 8.

7. Claim 9

a) [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”

124. Figure 8 of Vestgaarden-981 shows a directional cannula/working channel with two blunt tangs on its distal end.

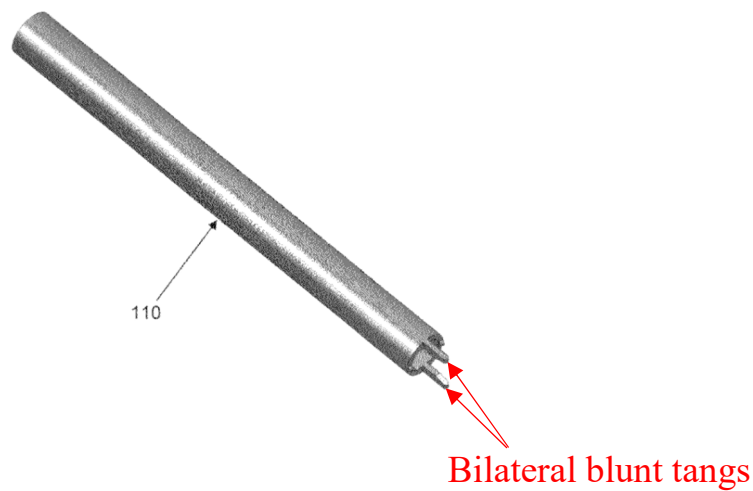
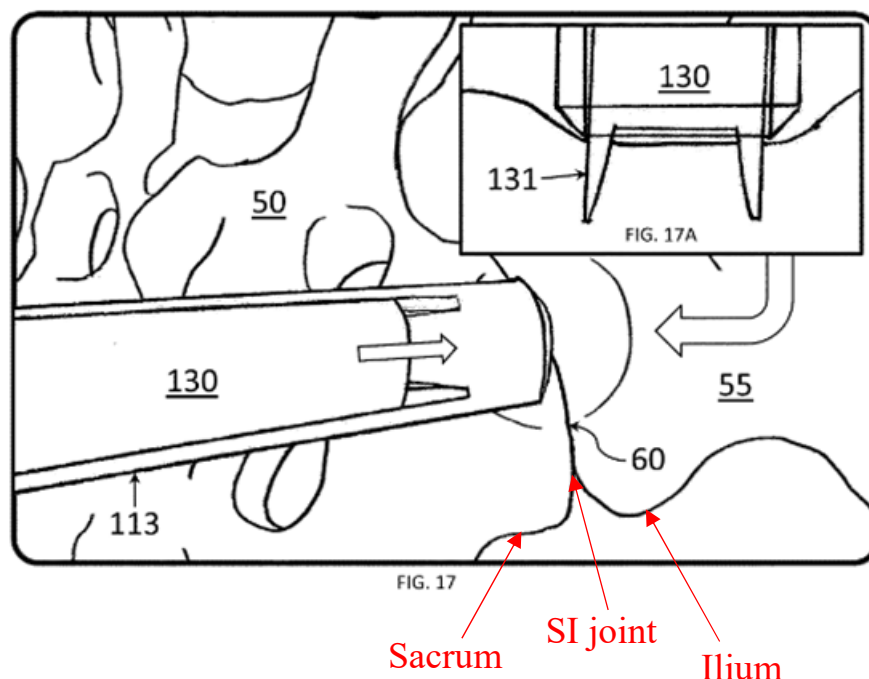


FIG. 8

b) [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”

125. Vestgaarden-818 discloses the step of “inserting a directional cannula into the sacroiliac joint aligning the teeth located on the distal end of the cannula with the plane of the joint, tapping a proximal end of the directional cannula to reversibly *secure the alignment teeth into the sacroiliac joint.*” Ex. 1010 at 2:7-12 (emphasis added). Figures 17 and 17A of Vestgaarden-818 show the teeth (tang) of the directional cannula/working channel being inserted into the sacroiliac joint between the articular surfaces of a sacrum and an ilium.



126. As established *supra* in Section VI(E)(1), a person of ordinary skill in the art would have been motivated to use the working channel/cannula with blunt

tangs in Vestgaarden 981 while performing the method of sacroiliac joint fusion taught in Vestgaarden-818. Thus, Vestgaarden-981 in view of Vestgaarden-818 teaches the limitations of claim 9.

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

1. Claim 6

a) [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,”

127. Figure 11 of Vestgaarden-981 shows an implant holder (inserter) with two implant-engagement arms at its distal end.

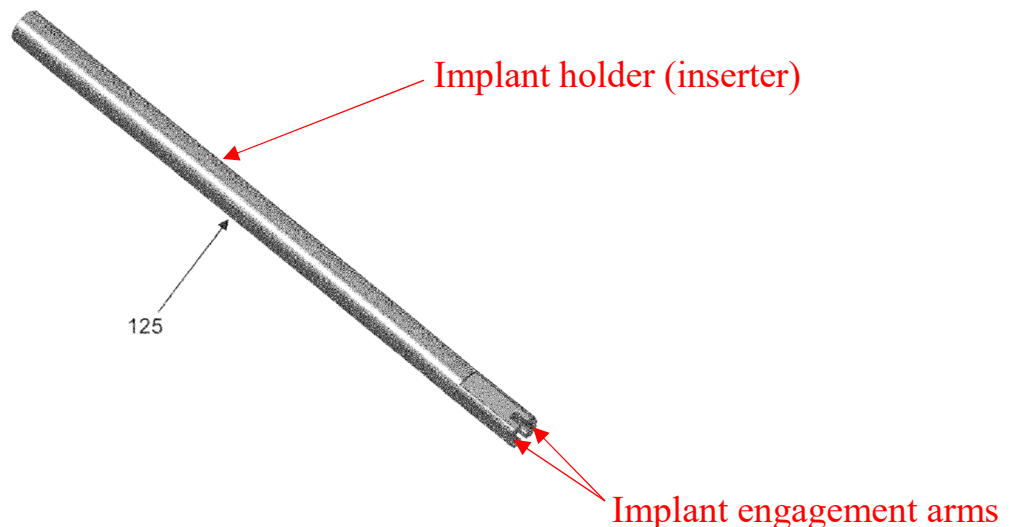
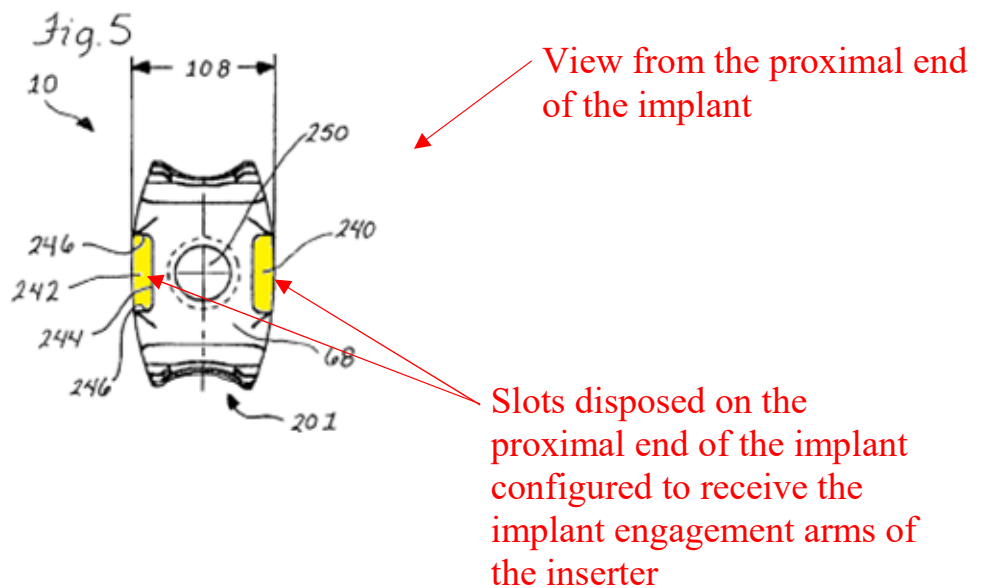
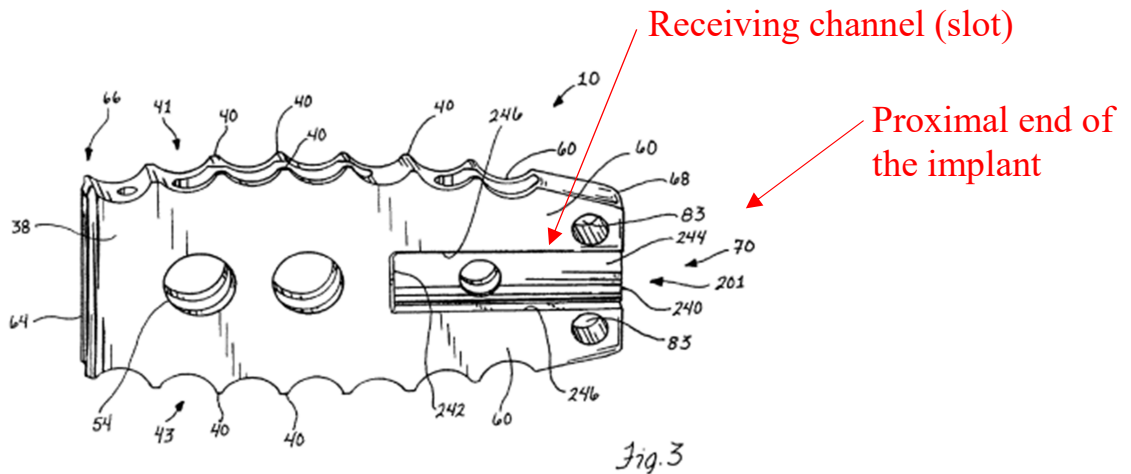
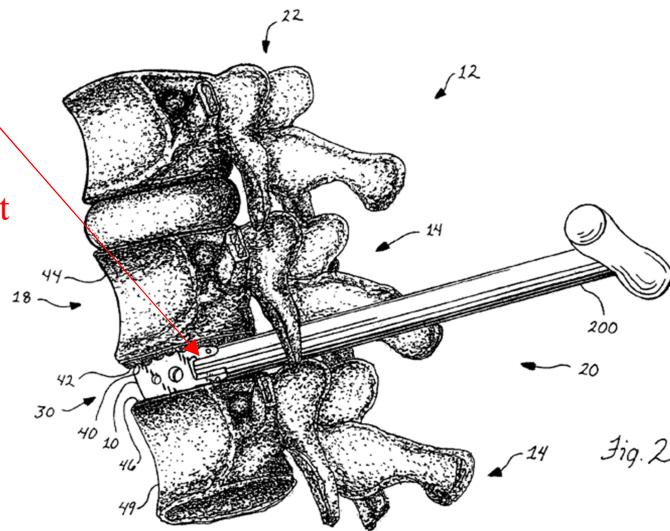


FIG. 11

128. Figures 2, 3, and 5 of Paltzer show implants with slots on a proximal end for receiving implant-engagement arms of an inserter.



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



129. As discussed *supra*, Section VI(F)(2), it would have been obvious to combine implant engagement arm slots of Paltzer with the fusion implants of Vestgaardeen-981. Thus, 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.

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

130. As discussed in Section VI(E)(2), *supra*, it would have been obvious to a person of ordinary skill in the art to use the guide protrusions of Lins as the “directional feature” taught in Vestgaarden-981. The combination of Vestgaarden-Vestgaarden-Lins-Paltzer would result in Vestgaarden-981’s implant holder having guide protrusions from Lins. Lins states (and Figure 11 shows) “guide protrusions 46 are configured to engage one or more recesses (not illustrated) manufactured into

the interior bore of the substantially cylindrical cannulated retention portion.” Ex. 1011 at [0038].

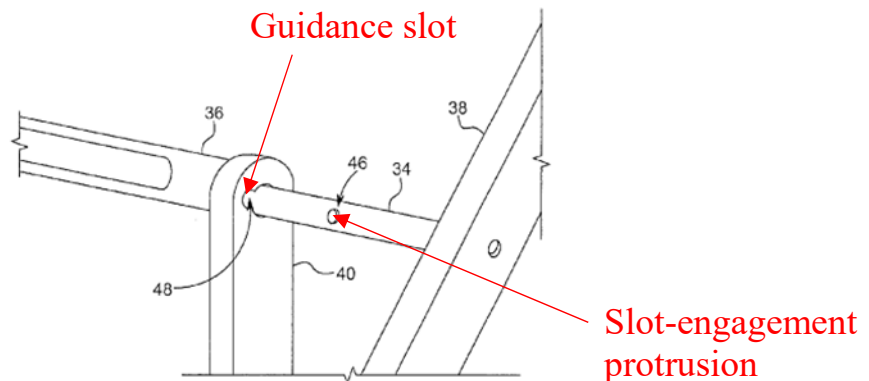
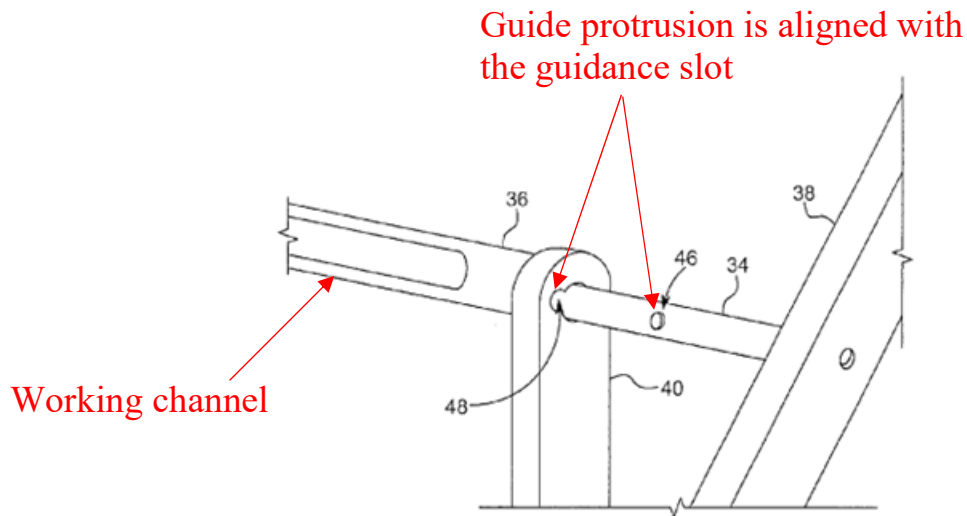


FIG. 11

131. Thus, Vestgaarden-981 in view of Lins teaches an inserter having a slot-engagement protrusion for engaging with the interior guidance slot of the working channel.

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

132. Figure 11 of Lins shows an inserter being inserted into a hollow barrel of a working channel/cannula with guide protrusions of the inserter aligned with the interior guidance slot of the hollow barrel of the working channel/cannula. Ex. 1011 at [0038], FIG. 11.



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

133. Lins’s guidance slot is configured to “control and guide the depth of penetration” of a surgical tool relative to the joint. Ex. 1011 at [0038]. The combination of Vestgaarden-981 and Lins thus teaches an implant holder (inserter) that is configured to be advanced within the working channel/cannula until the guide protrusions of the implant holder (inserter) are arrested by the guidance slot/recesses in the interior of the working channel/cannula thereby arresting the penetration of the implant holder (inserter) and implant in the sacroiliac joint at a predetermined depth.

2. Claim 7

a) [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,”

134. As noted *supra*, VI(F)(2), it would have been obvious to a person of ordinary skill in the art to position the rasping surfaces described in Paltzer on the exterior lateral surfaces of the cavity cutter described in Vestgaarden-981. Also as noted *supra*, VI(E)(2), it would have been obvious to a person of ordinary skill in the art to use the guide protrusions in Lins as the “directional feature” on Vestgaarden-981’s tools, including the cavity cutter. Therefore, it would have been obvious to one of skill in the art that Vestgaarden-981 in view of Lins teaches a rasp with slot engagement protrusions that is used for creating a void within a joint. Figure 11 of Lins shows the slot engagement protrusion on the surgical tool being nested within the guidance slot of the working channel’s inner hollow barrel. When the cavity cutter/rasp is inserted into the working channel/cannula, the guide protrusions would engage the guidance slot as described in Lins. Ex. 1011 at [0038].

135. Paltzer also describes a standalone rasp tool. Ex. 1012 at 15:44-47. Section VI(F)(3), *supra*, establishes that it would have been obvious to a person of ordinary skill in the art to include Paltzer’s standalone rasp with the tool set

described in Vestgaarden-981 and that it would have been obvious to place Lins's guide protrusion on the shaft of Paltzer's standalone rasp tool. When this rasp tool is inserted into Vestgaarden-981's working channel/cannula having Lins's interior guidance slot, the guide protrusion on the rasp would engage the guidance slot as described in Lins. Ex. 1011 at [0038].

The slot-engagement protrusion is
nested within the guidance slot

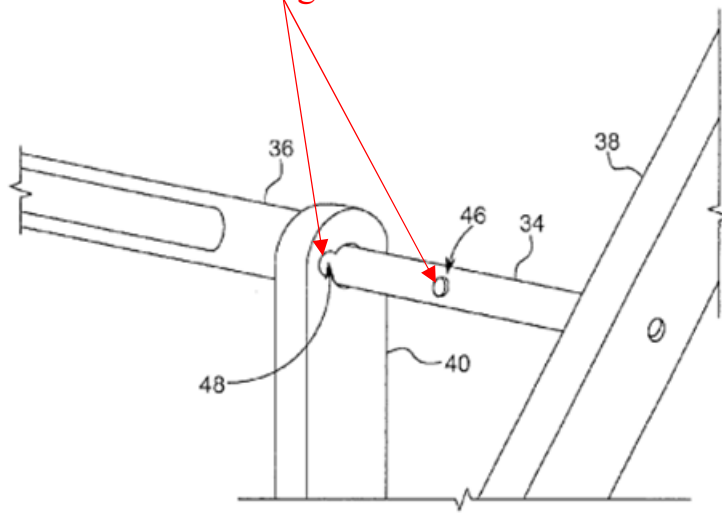


FIG. 11

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

136. Lins states 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] (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 16.” Ex. 1011 at [0038]. Therefore, Vestgaarden-981 in view of Paltzer and Lins, teaches a rasp with a slot engagement protrusion that engages with an interior guidance slot in a hollow barrel of a working channel/cannula that controls the depth of advancement of the rasp and maintains the rasp in proper orientation as it is inserted into the void within the joint.

3. Claim 10

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

137. Section VII(A)(1)(a), *supra*, established that Vestgaarden-818 teaches a method for repairing an SI joint of a patient.

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

138. Section VII(A)(1)(b), *supra*, established that Vestgaarden-818 teaches the step of “creating a first incision proximal to the patient's sacroiliac joint.”

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

139. Section VII(A)(1)(c), *supra*, established that Vestgaarden-818 teaches the step of “inserting a surgical channel tool into said first incision from the posterior of the patient.”

d) [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,”

140. Vestgaarden-981’s Figure 8 shows a surgical channel with two bilateral blunt tangs on its distal end.

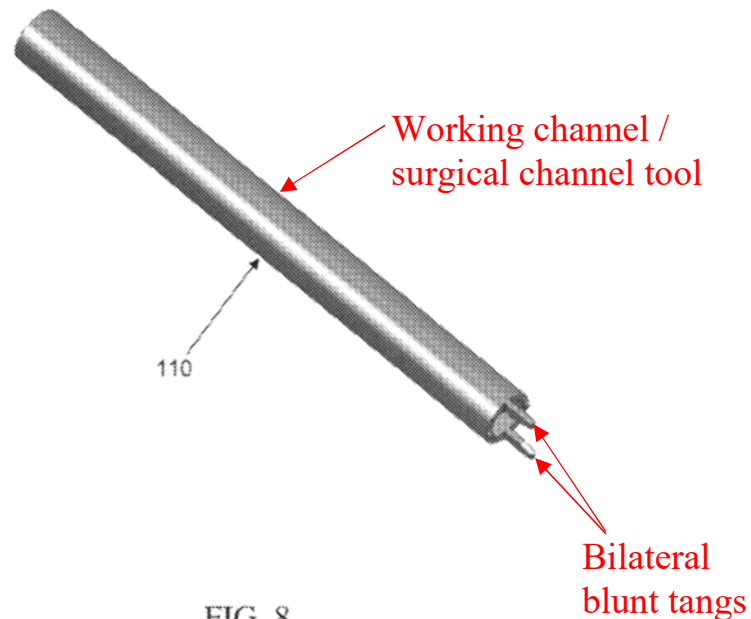


FIG. 8

141. As established in Section VII(A)(7), *supra*, Vestgaarden-818 describes the step of inserting the working channel/cannula between the articular surfaces of a sacrum and an ilium to stabilize the surgical channel/cannula relative to the sacroiliac joint. Vestgaarden-981 further teaches that surgical instruments are passed through the working channel/cannula and into the joint. *See, e.g.*, Ex. 1009 at 6:60-

64. Thus, the combination of Vestgaarden-981 and Vestgaarden-818 teach the subject matter recited in [10.b.2] of claim 10.

e) [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;”

142. Section VII(A)(1)(e), *supra*, establishes that Vestgaarden-981 in view of Lins describes a surgical channel/cannula with a hollow barrel having an interior guidance slot that controls the advancement of surgical tools passed through the surgical channel/cannula, wherein the guidance slot does not traverse an outer diameter of said hollow barrel. Section VII(A)(6), *supra*, further establishes that the interior guidance slot within the hollow barrel of the surgical channel/cannula controls the depth of advancement of surgical tools inserted into the surgical channel/cannula and maintains the surgical tools in proper orientation as they are inserted into the SI joint. Thus, Sections VII(A)(1)(e) and VII(A)(6), *supra*, show the combination of Vestgaarden-981, Vestgaarden-818, and Lins teach all limitations of [10.b.3].

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

143. Section VII(A)(1)(g), *supra*, establishes that Vestgaarden-818 teaches the step of creating a void in the SI joint.

g) [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,”

144. Section VII(A)(1)(h), *supra*, establishes that Vestgaarden-818 teaches inserting a fusion implant into a void created in the SI joint. Vestgaarden-818 further teaches inserting the implant into the void in the SI joint through a lumen (hollow barrel) of the surgical channel/cannula. Ex. 1010 at 6:28-29.

145. Section VII(B)(1), *supra*, establishes that Vestgaarden-981 teaches inserting an implant through the hollow barrel of a surgical channel/cannula using an inserter with a pair of implant engagement arms at a distal end of the inserter. Section VII(B)(1), *supra*, further establishes that Vestgaarden-981 in view of Paltzer teaches engaging the implant engagement arms of the inserter with the slots on the proximal end of the implant. Thus, Sections VII(A)(1)(h) and VII(B)(1), *supra*, clearly establish that the combination of Vestgaarden-981, Vestgaarden-818, Lins, and Paltzer teaches the subject matter recited in [10.d.1].

h) [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;”

146. Section VII(A)(1)(i), *supra*, establishes that Vestgaarden-981 in view of Vestgaarden-818 teaches a 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 the SI joint.

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

147. Vestgaarden-818 discloses the step of “driv[ing] implant 5 into cavity 45 created laterally across sacroiliac joint 60,” such that the implant is “preferably countersunk 1-2 mm into sacroiliac joint.” Ex. 1010 at 6:33-36. Vestgaarden-981 also teaches that “[o]nce the implant has been positioned in the cavity created in the facet joint, implant tamp 130 is inserted into implant holder 125. Next, implant tamp 130 is lightly tapped so as to *drive* the implant into the cavity,” such that the implant is “preferably countersunk 1-2 mm.” Ex. 1009 at 6:64-7:2. Thus, the combination of Vestgaarden-981 and Vestgaarden-818 teaches the step of driving the fusion implant into the void created within the SI joint.

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

148. Vestgaarden-981 teaches an implant that is driven into the joint such that the protrusions (barbs, a screw, sharp spikes, or other fixation devices on the implant) engage bone tissue, thereby preventing pullout of the implant. *See, e.g.*, Ex. 1009 at 4:33-37, FIG. 1 (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.”).

149. Vestgaarden-981 describes a variety 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 8:19-42; FIGS. 65-68, 72-74.

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

150. Section VII(A)(2), *supra*, establishes the combination of Vestgaarden-981 and Vestgaarden-818 teaches a fusion implant that fixes relative positions of the sacrum and the ilium. Ex. 1010 at 2:28-33.

4. Claim 11

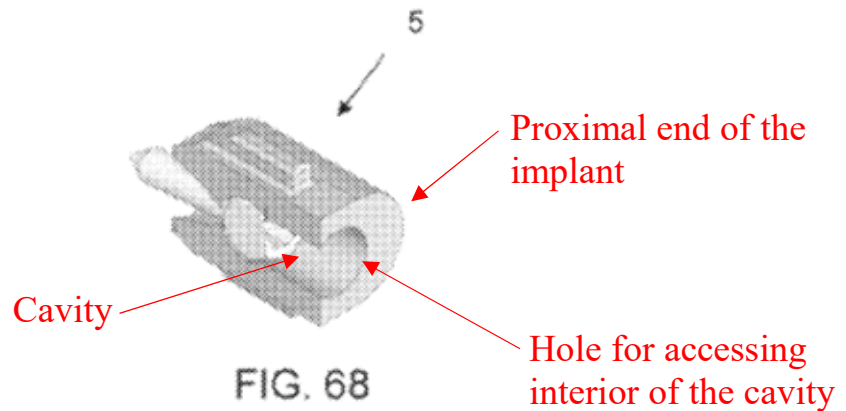
a) “The method of claim 10, wherein said at least one protrusion comprises a helical anchor having a sharp end for piercing said bone tissue in an articular surface of at least one of said sacrum and said ilium.”

151. The limitations of claim 11 are substantially the same as those limitations recited in claims 3 and 4, *supra*, and would have been obvious to a person of ordinary skill in the art as established above. Furthermore, a person of ordinary skill in the art would have understood that the thread (helical anchor) of a screw would have had a sharp end for piercing bone tissue, particularly the embodiment in Figures 58-60 of Vestgaarden-981 where the screw is driven directly into the bone.

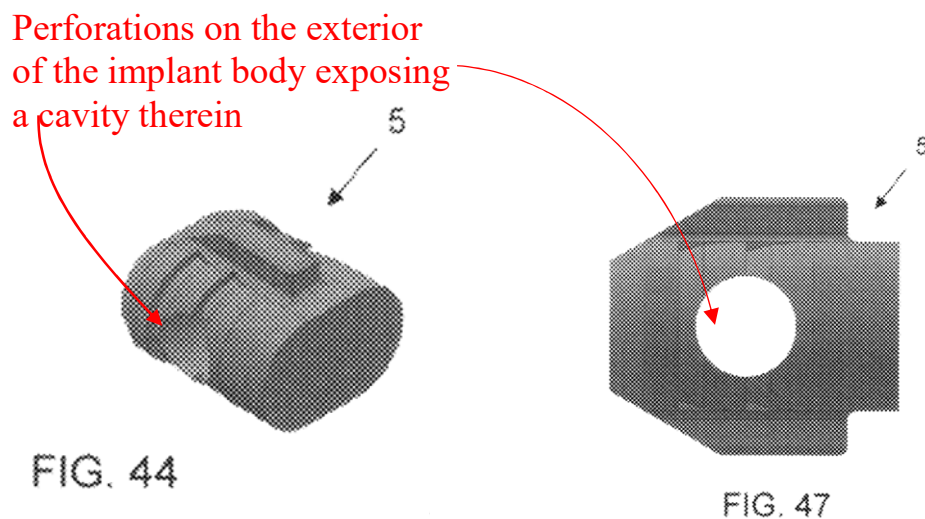
5. Claim 12

a) “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.”

152. Figure 68 of Vestgaarden-981 shows a fusion implant with a hole on a proximal end of the body of the fusion implant for accessing a cavity on the interior of the fusion implant.



153. Vestgaarden-981 teaches (and Figure 11 shows) a “through-hole” cavity within an implant body that holds bone-growth material, 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. Figure 11 of Vestgaarden-981 shows perforations on the exterior of the implant body that expose the cavity to the exterior of the implant.



154. The advantages of the through-hole described in Vestgaarden-981 (namely, “[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”), would have motivated a person of ordinary skill in the art to include the through-hole into the implant having a longitudinal screw and a cavity (depicted in Figures 65-68). This combination would have predictably resulted in an implant having both advantageous features in a single implant—a screw for engaging the implant in the bone tissue and a through-hole (cavity) for holding bone growth material in the implant to promote fusion. This combination would have been obvious to one of ordinary skill in the art, rendering the limitations of claim 12 obvious.

6. Claim 13

a) “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.”

155. Vestgaarden-818 describes an implant that has “[an] elongated body [that] is simultaneously positioned within the sacrum and ilium of the sacroiliac joint,” and that the implant “immobilize[s] the sacroiliac joint and facilitate[s] fusion between the sacrum and ilium.” Ex. 1010 at 2:63-66; 2:28-33. Thus, Vestgaarden-818 teaches the limitations of claim 13.

7. Claim 14

a) [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,”

156. The limitations of claim [14.a.1] are substantially similar to the limitations of claim [6.b.1] and thus section VII(B)(1)(c), *supra*, establishes obviousness of the limitations of this claim.

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

157. Section VII(B)(1)(b), *supra*, establishes that Vestgaarden-981 in view of Lins teaches an inserter with an insertion control protrusion (guide protrusion).

c) [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;”

158. 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 cannulated retention portion 36 (FIGS. 4-6) that control and guide the depth of penetration and degree of rotation of the translation portion 34 with respect to the retention portion 36.” Ex. 1011 at [0038]. Thus, Vestgaarden-981 in view of Lins teaches engaging the guide protrusion of the inserter with the interior guidance slot in the interior diameter of the hollow barrel of the surgical

channel/cannula to prevent rotation and control the advancement of the inserter as it is inserted through the surgical channel/cannula.

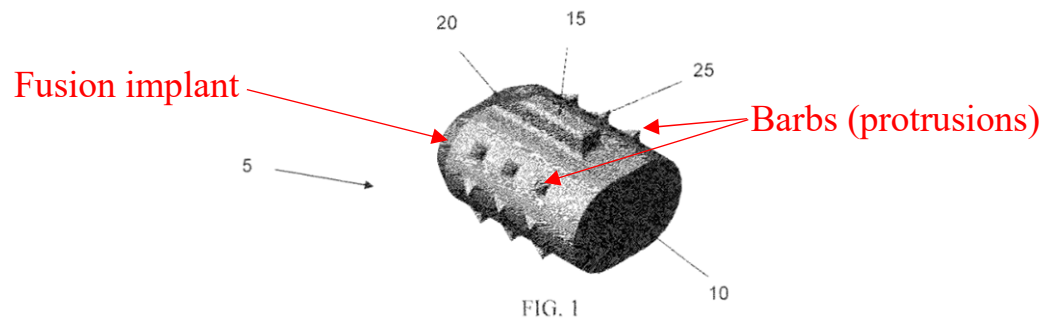
d) [14.c] “c. advancing the inserter until said insertion control protrusion is arrested by the interior guidance slot at a pre-determined point in the hollow barrel, and said inserter is prevented from moving the fusion implant further into said sacroiliac joint.”

159. Section VII(B)(1)(d), *supra*, establishes that Vestgaarden-981 in view of Lins teaches inserting an inserter until the guide protrusion (insertion control protrusion) of the inserter is arrested by the interior guidance slot of the surgical channel/cannula at a pre-determined point in the hollow barrel of the surgical channel/cannula. A person of ordinary skill in the art would have understood that once the guide protrusion was arrested by the guidance slot, the inserter would have been prevented from further advancing the implant into the sacroiliac joint.

8. Claim 15

a) “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.”

160. Vestgaarden-981 describes a fusion implant having “a plurality of barbs (i.e. forward biting teeth)” designed to “impede retraction” of the implant from a joint. Ex. 1009 at 4:33-37; FIG. 1.



161. Vestgaarden-981 further discloses that “[o]nce the implant has been positioned in the cavity ..., implant tamp 130 is inserted into implant holder 125 ... [and] lightly tapped so as to drive the implant into the cavity.” *Id.* at 6:64-7:2. Thus, the implant tamp drives the fusion implant by pushing the implant further into the cavity/void in the sacroiliac joint as the barbs (protrusions) contact the bone tissue.

9. Claim 16

a) “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.”

162. Claim 16 is substantially the same as claim 7. Thus, claim 16 is obvious for the reasons stated in Section VII(B)(2), *supra*.

10. Claim 17

a) “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.”

163. Claim 17 is substantially the same as claim 8. Thus, Claim 17 is obvious for the reasons stated in Section VII(A)(6), *supra*.

11. Claim 18

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

164. Section VII(B)(3)(a), *supra*, establishes that Vestgaarden-818 teaches a method for repairing a sacroiliac joint of a patient.

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

165. Section VII(B)(3)(b), *supra*, establishes that Vestgaarden-818 teaches the step of “creating a first incision proximal to the patient’s sacroiliac joint.” Vestgaarden-818 also discloses that a “[s]tabilization implant 5 is inserted into a sacroiliac joint using a posterior approach. The *posterior approach* is familiar to spine surgeons, thereby providing an increased level of comfort for the surgeon.”

Ex. 1010 at 4:34-37. Thus, Vestgaarden-818 teaches creating an incision proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint.

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

166. Section VII(B)(3)(c), *supra*, establishes that Vestgaarden-818 teaches the step of inserting a working channel into the incision proximal to the patient's sacroiliac joint. Vestgaarden-818 also discloses that “[s]tabilization implant 5 is inserted into a sacroiliac joint using a *posterior approach*.” *Id.* at 4:34-35. Since the implant is inserted into the sacroiliac joint through the surgical channel/cannula, Vestgaarden-818 teaches the step of inserting the surgical channel/cannula into the incision from the posterior of the patient.

d) [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,”

167. Section VII(B)(3)(d), *supra*, establishes that Vestgaarden-981 in view of Vestgaarden-818 teach a surgical channel/cannula having a plurality of blunt tangs that are inserted between the articular surfaces of an ilium and a sacrum to

stabilize the surgical channel/cannula as surgical instruments are passed through and into the SI joint.

e) [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;”

168. The subject matter of recited in [18.b.3] is substantially the same as the subject matter of [10.b.3] and therefore Section VII(B)(3)(e), *supra*, establishes that this limitation is obvious over the combination of the cited prior art.

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

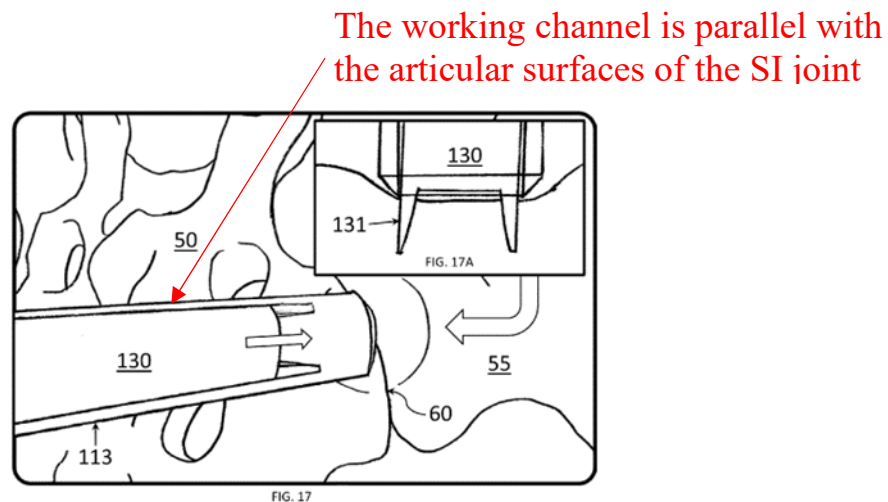
169. The subject matter recited in [18.c.1] is substantially similar to the subject matter recited in [10.d.1] and [10.d.2] and therefore Sections VII(B)(3)(g) and VII(B)(3)(h), *supra*, establish obviousness of this claim. The only limitation not present in [10.d.1] and [10.d.2] is a “plurality” of protrusions. Vestgaarden-981 clearly states 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); *see also id.* at FIG. 1. Therefore, all limitations of [18.c.1] are obvious.

g) [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,”

170. Section VII(B)(3)(g), *supra*, establishes that Vestgaarden-981 in view of Paltzer teaches using an inserter with a plurality of implant engagement arms at the distal end engaged with slots on the proximal end of a fusion implant to insert the fusion implant into the joint.

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

171. Vestgaarden-818 states (and Figure 17 shows) the teeth (tangs) of the working channel/cannula are inserted on a path that is substantially parallel to the articular surfaces of the sacroiliac joint. Ex. 1010 at 5:51-56; FIG. 17.



172. Vestgaarden-818 further discloses that the fusion implant is inserted through the hollow barrel (lumen) of the working channel/cannula. *Id.* at 6:28-32. Because the working channel/cannula is substantially parallel to the articular

surfaces of the sacroiliac joint, Vestgaarden-818 teaches the fusion implant being inserted along a path that is substantially parallel to the articular surfaces of the sacroiliac joint.

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

173. Sections VII(B)(7(b) and VII(B)(7)(c), *supra*, establish that Vestgaarden-981 in view of Lins teaches an inserter with an insertion control protrusion for engagement with an interior guidance slot of the working channel/cannula.

j) [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;”

174. Section VII(B)(7(d), *supra*, establishes that Vestgaarden-981 in view of Lins teaches advancing an inserter until the interior guidance slot of the working channel/cannula arrests the guide protrusion of the inserter at a predetermined point thereby inserting the fusion implant into the sacroiliac joint and preventing the fusion implant from being advanced beyond the predetermined point in the sacroiliac joint. A person of ordinary skill in the art would have understood that the guidance slot of the cannula arrests the protrusion on the inserter thereby necessarily preventing the

inserters from moving the fusion implant beyond a pre-determined point in the sacroiliac joint.

k) [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.”

175. Sections VII(B)(3)(h), VII(B)(3)(i), and VII(B)(3)(j), *supra*, establish that Vestgaarden-981 in view of Vestgaarden-818 teaches driving a fusion implant into the sacroiliac joint such that the bone-engagement protrusions of the implant engage with the articular surfaces of the sacrum and the ilium thereby preventing pullout of the fusion implant from the sacroiliac joint.

12. Claim 19

a) “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.”

176. Sections VII(B)(3)(j) and VII(B)(3)(k), *supra*, establish that Vestgaarden-981 in view of Vestgaarden-818 renders obvious the subject matter of claim 19.

13. Claim 20

a) “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.”

177. Vestgaarden-981 describes a fusion implant with a plurality of barbs (bone engagement protrusions). *See* Ex. 1009 at 4:33-37; 8:35-42. Vestgaarden-981 further discloses that the fusion implant may include a screw to engage bone tissue of the sacrum and the ilium. *Id.* at 8:19-23; 8:26-29; 8:32-33. A person of ordinary skill in the art would be motivated to use both the screw and the barbs with a single implant to more securely anchor the implant within the sacroiliac joint. Section VII(B)(4), *supra*, establishes that the thread of the screw is a helical anchor that penetrates bone tissue in the articular surface of the sacrum, the ilium, or both upon insertion into the sacroiliac joint.

14. Claim 21

a) “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.”

178. Vestgaarden-818 describes that after inserting the fusion implant, surgical tools are “removed from the soft tissue and the incision is closed.” Ex. 1010 at 6:37-40. Vestgaarden-818 also discloses 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 sacroiliac joint and that the single fusion implant is sufficient to fuse the sacroiliac joint.

15. Claim 22

a) “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.”

179. Vestgaarden-981 discloses that “[a] cavity cutter 117 is ... used to make an opening having the perfect shape for fusion implant 5,” and Vestgaarden-818 teaches the step of “driv[ing] implant 5 into cavity 45.” Ex. 1009 at 6:57-58; Ex. 1010 at 6:33-35. The limitation of inserting the implant into the void is substantially similar to claim [10.d.1], which has been established as obvious in Section VII(B)(3)(g), *supra*. Thus, Vestgaarden-981 in view of Vestgaarden-818 teaches the limitations of claim 22.

16. Claim 23

a) “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.”

180. The subject matter recited in claim 23 is substantially similar to the subject matter recited in [18.b.3] and [18.c.4], and therefore Sections VII(B)(11)(e)

and VII(B)(11)(i), *supra*, establish that the subject matter is obvious over the cited prior art. A person of ordinary skill in the art would have understood that maintaining the inserter in proper orientation relative to the sacroiliac joint would have also necessarily maintained the fusion implant in proper orientation for insertion into the sacroiliac joint.

VIII. RIGHT TO SUPPLEMENT

181. The opinions in this declaration are based upon my work to date. I reserve the right to supplement this declaration should additional information come to light that bears on my opinions contain herein. I reserve the right to consider and comment on additional evidence, if presented by experts for the Patent Owner. I reserve the right to add to, alter, or delete my opinions and my declaration upon discovery of any additional information and I reserve the right to make such changes as may be deemed necessary.

IX. CONCLUSION

182. For the foregoing reasons, claims 1-23 of the '511 Patent are invalid.

Inter Partes Review of U.S. Patent No. 11,083,511
Declaration of Dr. Christopher J. Bovinet, D.O.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 7th, 2023

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'CJ Bovinet', written over a horizontal line.

Christopher J. Bovinet, D.O.