UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

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

Inter Partes Review No. IPR2023-00477

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

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I. INTRODUCTION

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

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

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

1. United States Patent and Trademark Office

The '511 Patent is a continuation of U.S. Patent No. 10,993,757 ("Parent") (Exhibit 1009), which is a continuation-in-part of U.S. Patent No. 9,119,732 ("Grandparent") (Exhibit 1010).

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

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

U.S. Patent No. 10,426,539 ("'539 Patent") is a sibling of the '511 Patent and is a continuation of and claims priority to the Parent patent. Petitioner challenged validity of claims 26-28 and 31 of the '539 Patent in IPR2022-00335, which the Board instituted on June 2, 2022.

On January 9, 2023, Petitioner filed a parallel IPR petition challenging the validity of claims 1-23 of the '511 Patent in IPR2023-00451. The Explanation of Parallel Petitions filed herewith explains the reasons for filing two parallel petitions against the '511 Patent and explains why the Board should consider both petitions and institute both IPR trials.

2. District Court Litigation

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

C. Counsel And Service Information

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

III. PAYMENT OF FEES

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

IV. CERTIFICATION OF STANDING

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

V. NO BASIS FOR DISCRETIONARY DENIAL

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

In addition, the Litigation involving the '511 Patent is in its infancy. As of the filing date of this petition, a trial date has not been set, nor will one be set until after a *Markman* hearing (which has not been scheduled as of the filing of this petition). There is a high likelihood that the final written decision in this IPR (which would be due in or about July of 2024) would be issued prior to a district court trial. The district court has not yet issued orders related to the '511 Patent, which "weighs against exercising discretion to deny intuition decision under NHK." *Apple Inc. v. Fintiv, Inc., IPR2020-00019*, Paper 11 at 10 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). Furthermore, the Litigation has seen minimal discovery, no depositions have been set, claim construction is still pending, and there are no dispositive motion deadlines, expert deadlines, or discovery deadlines set as of the filing of this petition. Finally, the primary prior art reference asserted in this petition—Stoffman—has not been presented in the district court. *See* USPTO Guidance dated June 21, 2022 at 7 ("[I]f the petition includes materially different grounds, arguments, and/or evidence than those presented in the district court, this fact has tended to weigh against exercising discretion to deny institution.") (citing *Fintiv* at 12-13).

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

VI. STATEMENT OF PRECISE RELIEF REQUESTED

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

Ground	Claims	Statute	Prior Art
1A	1-8	§ 103	Stoffman and McCormack
1B	9-23	§ 103	Stoffman, McCormack, and Stark

VII. OVERVIEW OF THE '511 PATENT

The '511 Patent discloses and claims a method for repairing a sacroiliac joint ("SI joint"). Ex-1001 at 2:15-40. The '511 Patent has three independent claims: claims 1, 10, and 18. All three independent claims recite the following steps: (1) creating an incision proximal to the patient's SI joint, (2) inserting a "working channel" / "surgical channel tool" into the incision,[1] and (3) inserting a fusion implant into the SI joint (or a void created therein), wherein the implant has at least one protrusion that engages with the bone tissue thereby preventing pullout of the implant. *Id*. at 41:64-13; 43:4-39; 44:24-64. During prosecution of the '511 Patent,

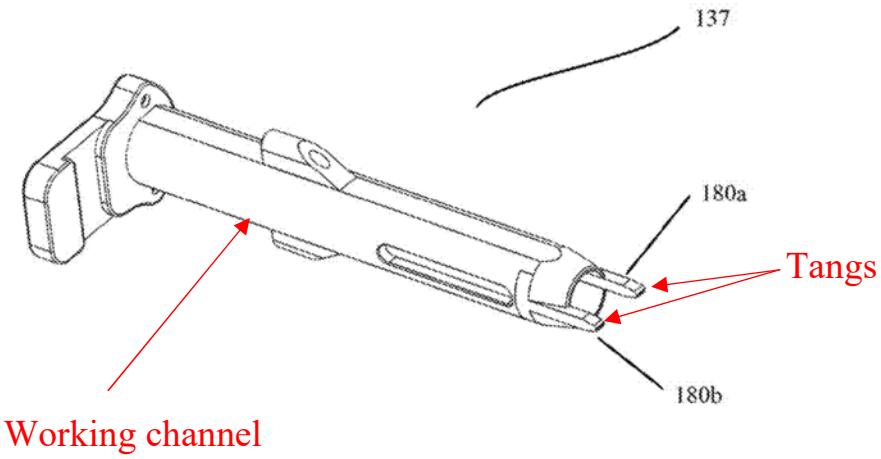
[1] The '511 Patent uses the terms "working channel" and "surgical channel" interchangeably to refer to the same medical cannula. Unless referring specifically to claim 10, which recites "surgical channel," this petition will use the term "working channel" to facilitate clarity.

the examiner found that these limitations have been known in the prior art. (Ex-1008 at 337-354).

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

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

FIG. 30



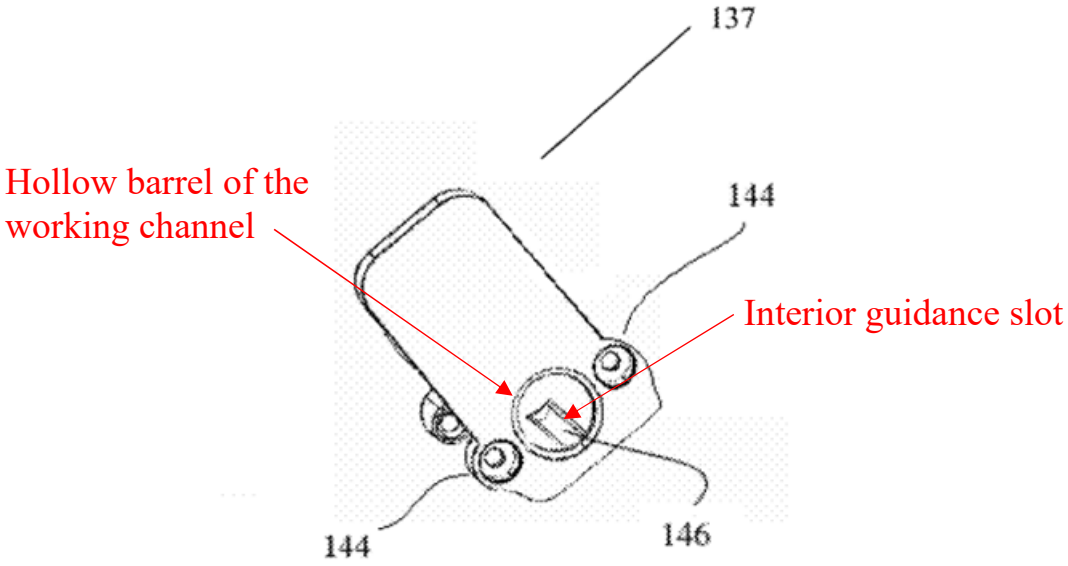


FIG. 29

VIII. THE LEVEL OF ORDINARY SKILL IN THE ART

A Person of Ordinary Skill in the Art ("POSA") would have had a medical or an engineering degree and would have had experience with surgical instruments and implants used for spinal joint fusion, including SI joint fusion. Ex-1002, ¶15.

IX. CLAIM INTERPRETATION

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

Joint claim construction filed in the Litigation is submitted as Exhibit 1004. The grounds set forth in this petition render the challenged claims obvious under either party's construction. Ex-1002, ¶34. Notably, in the Litigation the parties disagree with respect to the meaning of the phrase "controlling the advancement" recited in claim 1. Patent Owner asserts that this claim term means "guiding forward motion," while Petitioner proposes that this term should be construed as "arresting the extent of axial progress" or, alternatively, as "controlling the depth of advancement." Ex-1004 at 2. The analysis provided in this petition establishes that the cited prior art renders this limitation obvious under either construction.

X. PRIORITY DATE OF THE '511 PATENT

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

"[A] patent's claims are not entitled to an earlier priority date merely because the patentee claims priority." *In re NTP, Inc*., 654 F.3d 1268, 1276 (Fed. Cir. 2011) (citing *Bausch & Lomb, Inc. v. Barnes–Hind/Hydrocurve*, *Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986)). "It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *PowerOasis, Inc. v. T-Mobile USA, Inc*., 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quoting *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)). In an IPR proceeding, the Board has authority to invalidate the priority claim of a challenged patent. *See Anthrex, Inc. v. Smith & Nephew, Inc*., 35 F.4th 1328, 1345 (Fed. Cir. 2022).

1. The earliest effective priority date for any claim of the '511 Patent is March 25, 2015

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

XI. SUMMARY OF THE CHALLENGED CLAIMS

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

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

Ground 1A of this petition establishes that (1) U.S. Pub. No. 2014/0207240

("**Stoffman**") (Ex-1005) teaches a fusion implant having bone-engaging protrusions and also teaches a method of SI joint fusion that involves the steps of creating an incision, inserting a working channel into the incision, creating a void in the SI joint, and inserting a fusion implant into the void; while (2) U.S. Pub. No. 2010/0191241 ("**McCormack**") (Ex-1006) teaches a working channel with a hollow barrel, tangs, and a guidance slot for controlling advancement of surgical tools. This petition demonstrates that POSA had motivation to combine Stoffman and McCormack and that this combination would yield a predictable result that renders claim 1 obvious.

Ground 1A establishes that claims 2-8 recite only conventional limitations taught or suggested by the Stoffman-McCormack combination. Ground 1B introduces U.S. Pub. No. 2009/0216238 (Stark) (Ex-1007) in combination with Stoffman and McCormack for a narrow purpose of establishing obviousness of the limitation requiring that the tangs of the working channel be inserted between the articular surfaces of sacrum and ilium (recited in claims 9, 10, and 18). The petition establishes that the remaining claims are rendered obvious by this prior art combination.

XII. GROUNDS FOR UNPATENTABILITY

A. Grounds 1A and 1B

1. Ground 1A: Claims 1-8 are obvious over the combination of Stoffman and McCormack

a. Overview of Stoffman

Stoffman is a published patent application that was filed on January 24, 2013 and published on July 24, 2014 and therefore qualifies as prior art against the '511 Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Furthermore, even if Patent Owner were to establish that one or more Challenged Claims is entitled to claim the benefit of the filing date of the Grandparent, Stoffman still qualifies as prior art under 35 U.S.C. § 102(a)(2).

(1) Fusion implant with bone-engaging protrusions

With respect to a fusion implant with bone-engaging protrusions, Stoffman discloses the following:

> SI joint fusion device 10 … comprises body 20 and first and second ancillary members 90 and 100, respectively, protruding outwardly from body 20. … Body 20 further comprises threading 50 to help secure SI joint fusion device 10 between sacrum 13 and right ilium bone 15. In the preferred embodiment, threading 50 is helical. … [T]hreading 50 could comprise a plurality of protrusions. Additionally, body 20 comprises a plurality of openings 60 through which fusion-facilitating substances can pass.

Ex-1005 at [0033]. Further, Stoffman teaches an embodiment in which the proximal end (open end 40) of the implant is "segmented"—meaning that the proximal end of the implant has slots. Ex-1005 at [0036], Ex-1002, ¶48. Stoffman's SI joint fusion implant is depicted in Figure 4, which is reproduced and annotated below (to facilitate clarity, sacrum is emphasized in light orange and ilium is emphasized in dark orange). Ex-1002, ¶48.

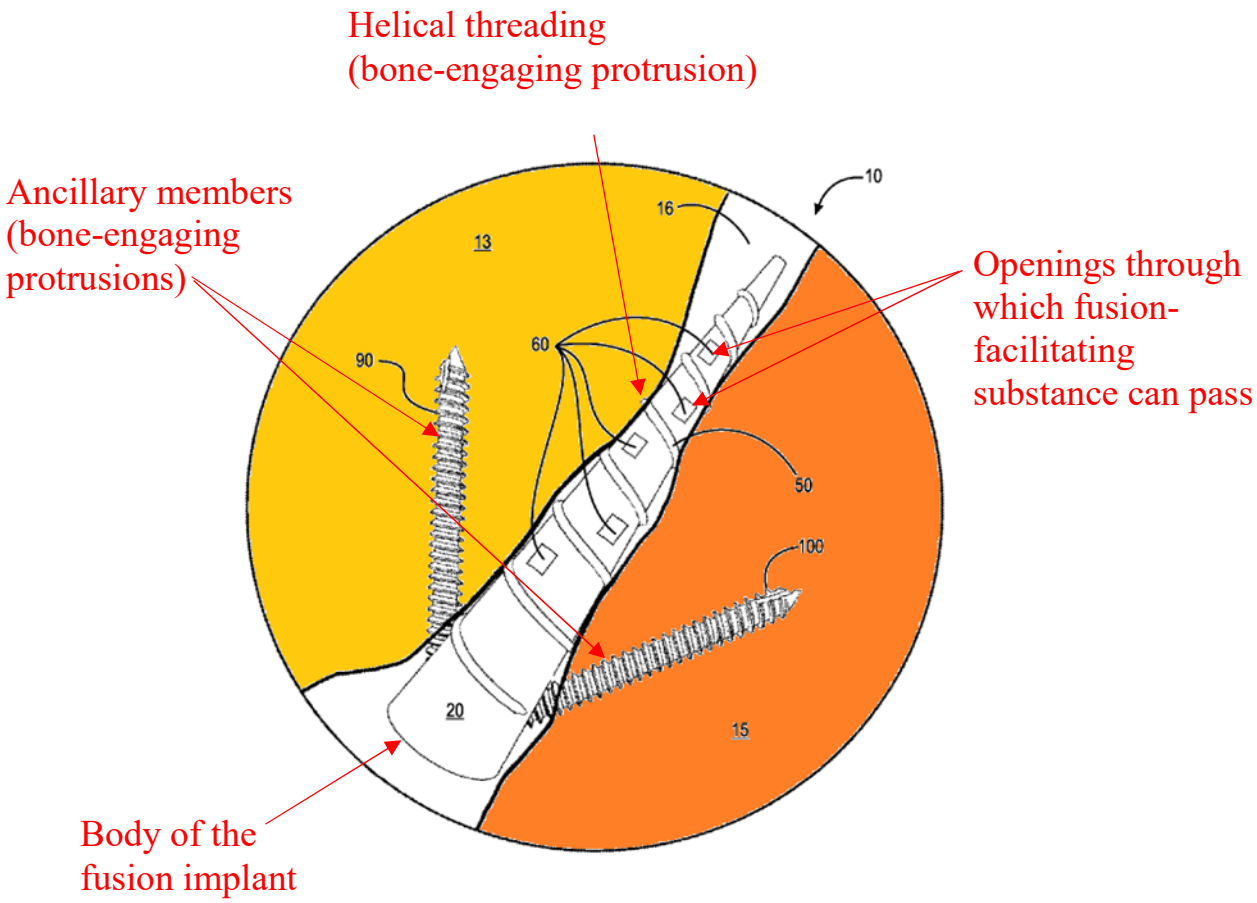


Fig. 4

(2) SI joint fusion method

Stoffman also discloses a method of fusing (repairing) an SI joint by implanting a fusion implant described above. Ex-1002, ¶49. Stoffman discloses a posterior approach in which "an incision is made to access SI joint 16 … Preferably, the incision is made along the dimple of Venus." Ex-1005 at [0043]; Ex-1002, ¶49. Stoffman further describes a step of creating a void within the SI joint for receiving the fusion implant, wherein "cartilaginous end plates of SI joint 16 are removed and a hole is drilled across SI joint 16." Ex-1005 at [0043]; Ex-1002, ¶49.

Stoffman teaches the step of inserting the fusion implant via a working channel, wherein "SI joint fusion device 10 is guided within a guide tube to protect the surrounding soft tissue." Ex-1005 at [0043]; Ex-1002, ¶50. After the body of the implant is positioned within the SI joint, "a surgeon taps and places ancillary screw members 90 and 100, respectively, into right ilium bone 15 and sacrum 13" at angles that "effectively immobiliz[e] SI joint 16." Ex-1005 at [0043]; Ex-1002, ¶50. After implantation into the SI joint, "SI joint fusion device 10 promotes the arthrodesis or fusion process." Ex-1005 at [0043]; Ex-1002, ¶50.

A schematic top view of Stoffman's fusion implant positioned within an SI joint is depicted in Figure 2, which is reproduced and annotated in color below, with the sacrum emphasized in light orange and the ilium emphasized in dark orange. Ex-1002, ¶51.

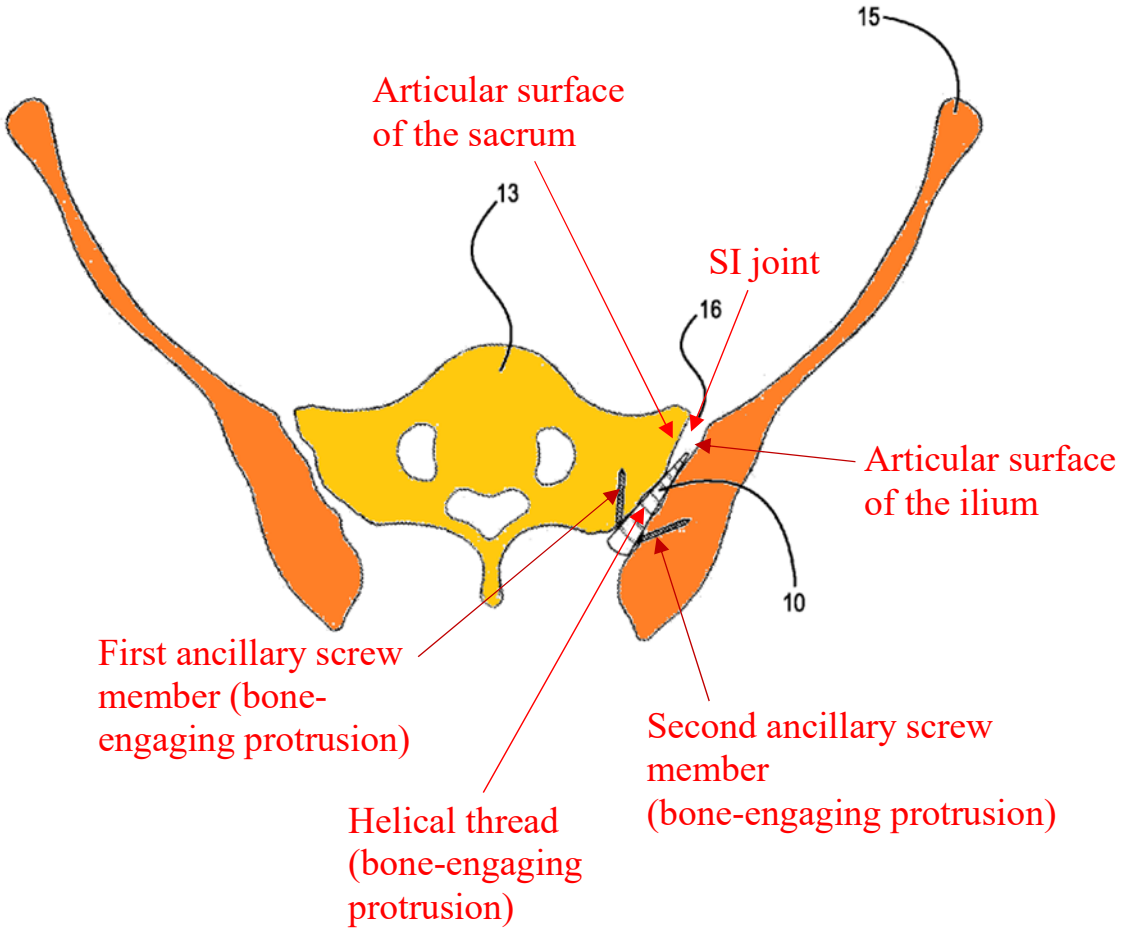


Fig. 2

b. Overview of McCormack

McCormack is a published patent application that was filed on December 10, 2009 and published on July 29, 2010 and therefore qualifies as prior art against the '511 Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Furthermore, even if Patent Owner establishes that one or more Challenged Claims is entitled to claim the benefit

of the filing date of the Grandparent, McCormack still qualifies as prior art under 35 U.S.C. § 102(a)(1) and § 102(a)(2).

(1) Working channel

McCormack discloses a surgical tool set for implanting an implant into a joint. This surgical tool set includes a working channel ("delivery device 104") having a hollow barrel ("tubular shaft 114") and bilateral tangs ("anchoring forks 112"). Ex-1006 at [0238]; Ex-1002, ¶53. McCormack discloses that the tangs may have "bull nose" (blunt) tips, as depicted in Figure 95A. Ex-1006 at [0333]; Ex-1002, ¶53.

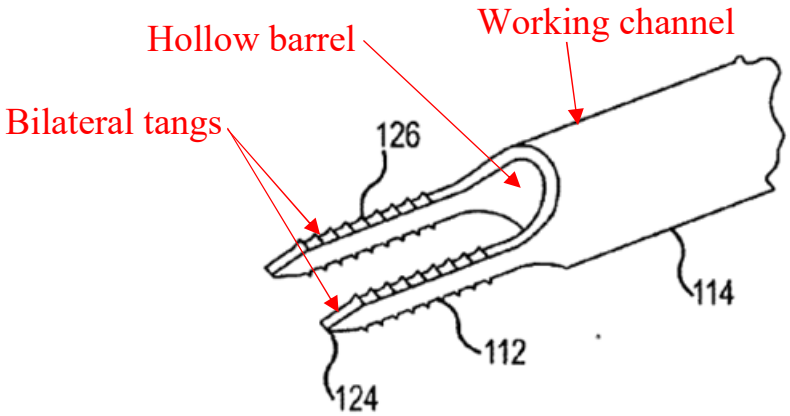


FIG.2

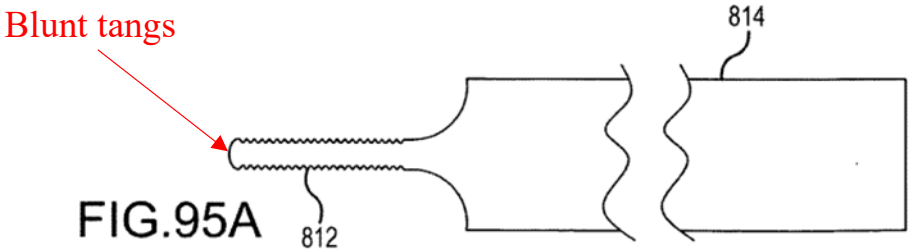


FIG.95A

(2) Implant inserter

Another surgical tool in McCormack's tool set is an implant inserter ("driver assembly 142") configured to insert an implant into a joint via the working channel. Ex-1006 at [0250]; Ex-1002, ¶54. The implant inserter has "implant holding arms 148" configured to hold an implant during the insertion procedure. Ex-1006 at [0250]; Ex-1002, ¶54.

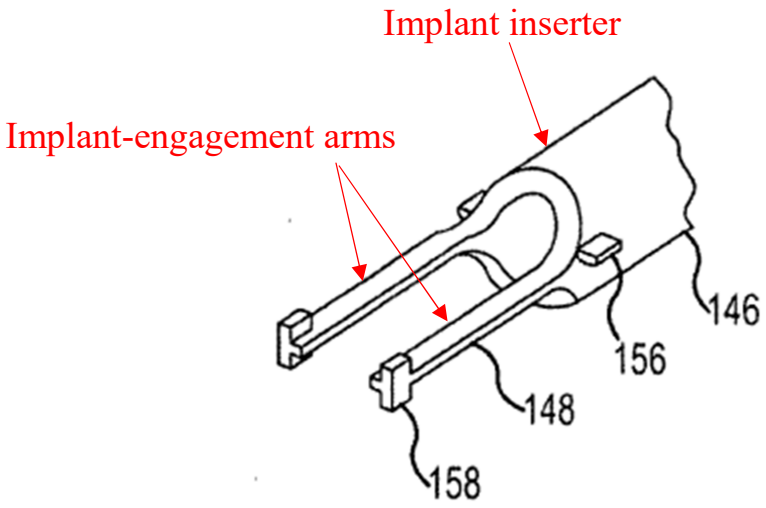


FIG.10

(3) Guidance slot

(i) "Seating recesses"

McCormack discloses an embodiment in which the proximal end of the working channel has "***seating*** recesses 119" positioned on "the inner surface of the bore," while the surgical tools have "positionally matched ***protrusions***." Ex-1006 at [0240] (emphasis added); Ex-1002, ¶55. McCormack teaches that the engagement

between the seating recesses and corresponding protrusions "may allow for ***orienting the devices*** properly relative to the forks 112 positioned in the … joint," wherein "one or several ***orientations may be controlled***." Ex-1006 at [0240] (emphasis added); Ex-1002, ¶55. Figure 6A, which is reproduced and annotated in color below, depicts that the seating recesses are positioned on the interior diameter of the hollow barrel and do not traverse the hollow barrel's outer diameter. Ex-1002, ¶55.

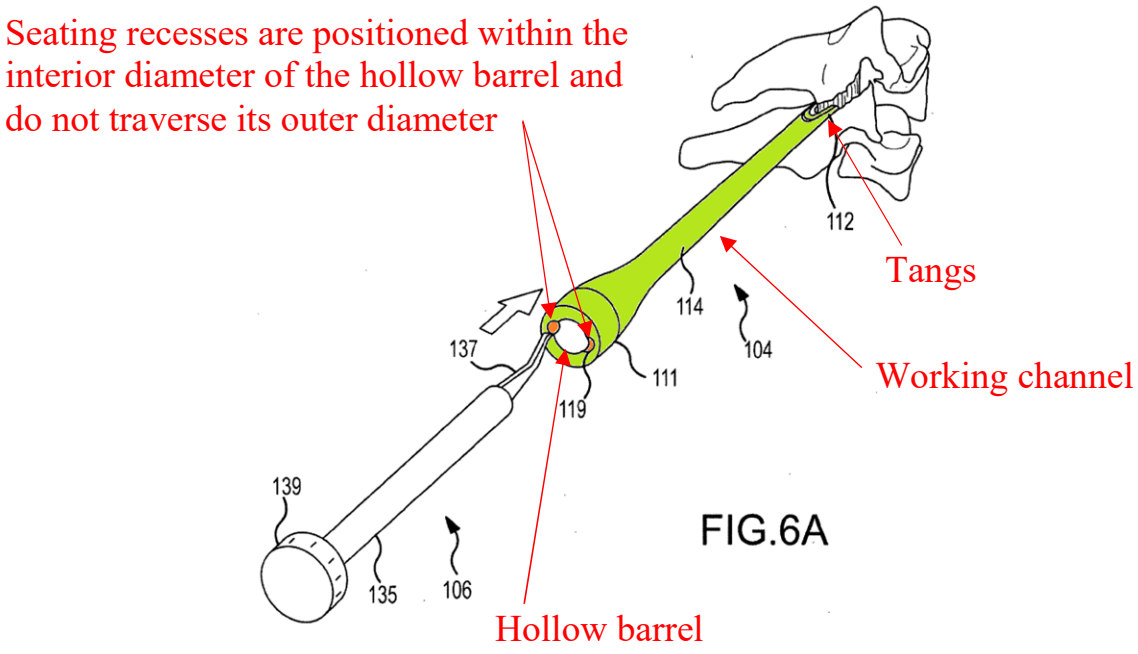


FIG.6A

Although McCormack's description of the "seating recesses" focuses on their ability to control *orientations* of surgical tools, POSA understands that the term "***seating***" conveys that the seating recesses and the corresponding protrusions establish a "seating relationship" with one another. Ex-1002, ¶56. McCormack

generally teaches that a "*seating relationship* may prevent the driver assembly [] ***from being inserted too far*** and may also allow the driver assembly [] to be aligned with the delivery device [] rotationally to ***ensure proper rotational orientation*** of the implant." Ex-1006 at [0376] (emphasis added); Ex-1002, ¶56. In light of this disclosure, POSA understands that McCormack teaches that the "seating recesses 119" depicted in Figure 6A control both the *orientation* of the surgical tools and the *depth* of their advancement relative to the working channel. Ex-1002, ¶56.

(ii) "Keyway feature"

Further, McCormack discloses a "keyway feature 156 for ***preventing relative rotation*** between the tubular shaft 114 of the delivery device 104 and the implant shaft 146 of the driver assembly 142." Ex-1006 at [0251] (emphasis added); Ex-1002, ¶57. The "keyway feature 156" comprises two components: (1) "a pair of tabs on opposing sides of the implant shaft 146" and (2) "a corresponding ***longitudinal slot*** in the inner surface of the tubular shaft 114 of the delivery device 104." Ex-1006 at [0251] (emphasis added); Ex-1002, ¶57. Figure 9 of McCormack, which is reproduced and annotated below, depicts that the longitudinal slot is not present on the exterior surface of the working channel, thereby teaching that the longitudinal slot does not traverse the outer diameter of the hollow barrel. Ex-1002, ¶57.

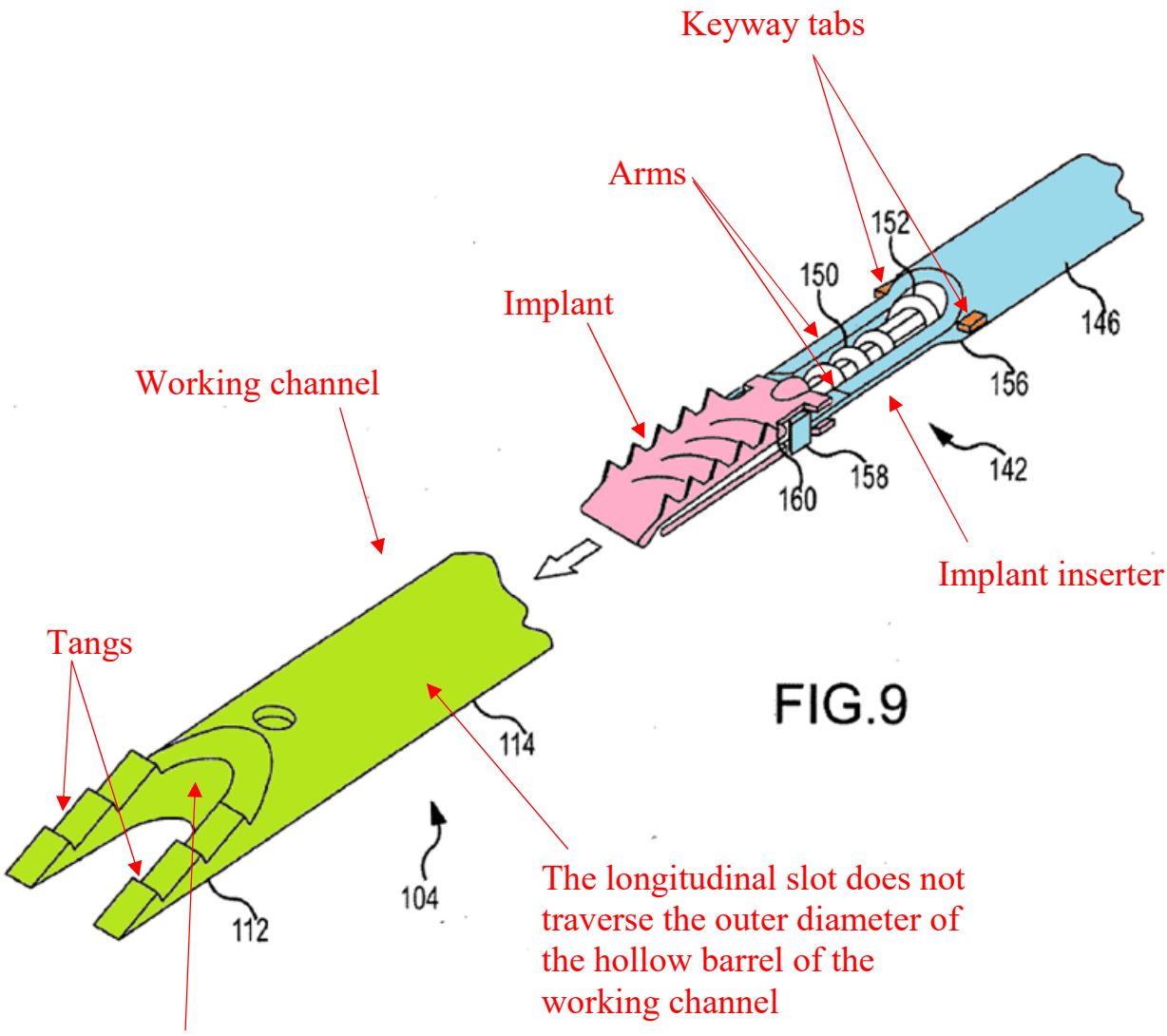

Keyway tabs
Arms
Implant
Working channel
Tangs
Implant inserter
The longitudinal slot does not traverse the outer diameter of the hollow barrel of the working channel
The longitudinal slot is not present on the interior surface of the distal end of the working channel, which conveys that the longitudinal slot has a terminal point within the hollow barrel and does extend the entire length of the working channel
152
150
146
156
142
158
160
114
104
112

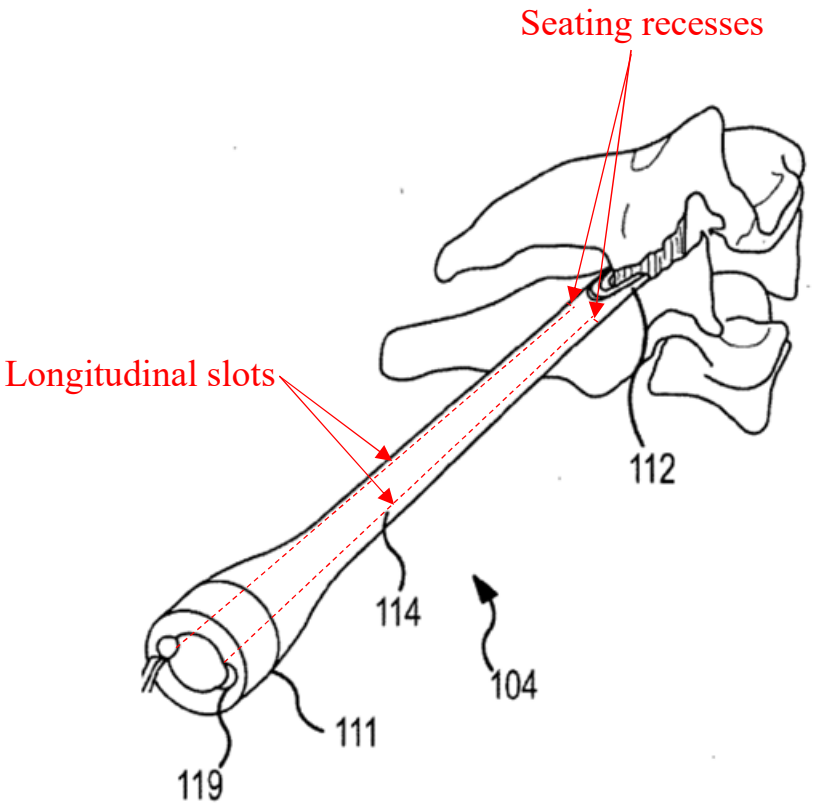
FIG.9

Notably, Figure 9, which is "a close-up view of a distal end of a driver assembly and a delivery device," shows that the keyway tab is positioned near the distal end of the inserter. Ex-1002, ¶58. Figure 9 also shows that the longitudinal slot is not present on the interior wall of the distal end of the working channel, thereby conveying that the longitudinal slot terminates within the hollow barrel and does not extend the entire length of the working channel. Ex-1002, ¶58. Thus, Figure 9 suggests to POSA that when the inserter is advanced into the hollow barrel of the working channel, the tab on the distal end of the inserter will arrive at the terminal end of the longitudinal slot within the hollow barrel, at which point the longitudinal slot will arrest the tab against further advancement. Ex-1002, ¶58. Accordingly, POSA understands that McCormack suggests that the longitudinal slot controls not only the orientation of the inserter but also its depth of advancement relative to the working channel. Ex-1002, ¶58.

(iii) Combination of the "seating recesses" and the "longitudinal slots"

Figure 6A of McCormack depicts an embodiment of the working channel in which the "seating recesses" are positioned at the proximal end of the hollow barrel. Ex-1006 at FIG.6; Ex-1002, ¶59. However, Figures 9 and 10 show a pair of the keyway tabs positioned near the distal end of the inserter. Ex-1006 at FIGS. 9, 10; Ex-1002, ¶59. To make the working channel of Figure 6A compatible with this

inserter, POSA had motivation to relocate the seating recesses farther into the hollow barrel, toward the distal end of the working channel, thereby effectively combining McCormack's "seating recesses" and "longitudinal slots." Ex-1002, ¶60. The predictable result of this combination is schematically illustrated in an annotated drawing provided below. Ex-1002, ¶60.



McCormack expressly teaches the step of "***seating*** the driver assembly in the delivery device ***thereby positioning*** the implant between the forks of the delivery device and in the … joint." Ex-1006 at [0046] (emphasis added); Ex-1002, ¶61. This disclosure provides motivation for placing the seating recesses at a location inside

the hollow barrel that corresponds to the location of the leading edges of the inserter's tabs when the inserter is properly aligned with the working channel. Ex-1002, ¶61. By positioning the seating recesses at a proper location in the hollow barrel near the distal end of the working channel, the *seating* recesses would be configured to perform their intended function of establishing a *seating* relationship with the tabs of the inserter when the inserter is longitudinally aligned with the working channel, as shown in Figure 13, which depicts "[t]he ***advanced*** position of the driver assembly 142 and implant 154 within the delivery device 104." Ex-1006 at [0264]; Ex-1002, ¶61.

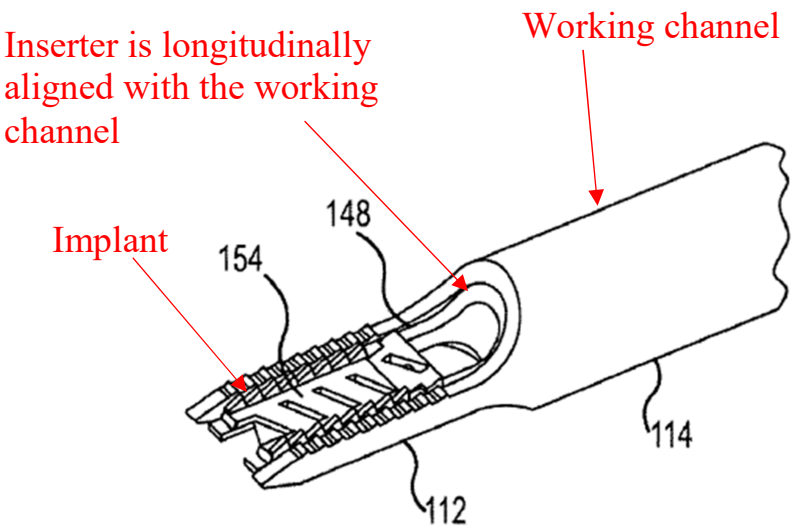


FIG.13

McCormack generally explains that a "***seating relationship*** may prevent the driver assembly [] ***from being inserted too far*** and may also allow the driver

assembly [] to be aligned with the delivery device [] rotationally to ***ensure proper rotational orientation*** of the implant." Ex-1006 at [0376] (emphasis added) Ex-1002, ¶61. Accordingly, the combination of McCormack's "seating recesses" and "longitudinal slots" would yield a predictable result, in which McCormack's longitudinal slots would continue performing their intended function of "preventing relative rotation" between the inserter and the working channel, while the "seating recesses" positioned at the terminal points of the longitudinal slots would perform their intended function of establishing a seating relationship with the inserter's tabs, thereby preventing the inserter "from being inserted too far." *See* Ex-1006 at [0251], [0376]; Ex-1002, ¶61.

(iv) Obvious to try

The analysis provided in Part XII.A.1.b.(3)(ii), *supra*, established that McCormack teaches or suggests that in addition to preventing the inserter from rotating within the hollow barrel of the working channel, "longitudinal slots" also control the depth of insertion. Ex-1002, ¶62. However, even in the absence of such teaching or suggestion, it would have been obvious to configure McCormack's longitudinal slots to achieve this functionality under the "obvious to try" rationale. *See* MPEP § 2143(I)(E) (citing *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 521 (2007)); Ex-1002, ¶62. The "obvious to try" rationale has three prongs that are pertinent here—(1) a known need, (2) a finite number of identified, predictable

solutions, and (3) a reasonable expectation of success—each of which is addressed below. Ex-1002, ¶¶62-65.

A known need: McCormack explains a known need for a surgical tool set in which a "mechanical engagement"—rather than a surgeon's judgement and skill—controls the proper positioning of the implant. Ex-1006 at [0421]; Ex-1002, ¶63. McCormack explains,

> once the delivery device [] is properly positioned, the *mechanical engagement* of the several pieces of the tool [] can control the proper position of the implant *thereby simplifying and expediting* the delivery and implantation process. The user can rely on the position of the delivery device [] for placement of the implant *thereby minimizing time and/or adjustments* to ensure that the implant is properly positioned.

Ex-1006 at [0421] (emphasis added); Ex-1002, ¶63. Furthermore, prevention of over-penetration of a joint by surgical tools was a well-known consideration prior to the '511 Patent. *See, e.g.,* Ex-1011 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 numbers that pass close to the sacroiliac joint."); Ex-1002, ¶63.

A finite number of identified, predictable solutions: McCormack discloses several potential solutions for controlling the depth of insertion of surgical tools into the working channel via a mechanical engagement therebetween. Ex-1002, ¶64.

McCormack describes that one known solution involves establishing a "seating relationship" between the working channel and the surgical tools to prevent the surgical tools from "being inserted too far" and to "ensure [their] proper rotational orientation." Ex-1006 at [0376]; Ex-1002, ¶64.

Third prong (reasonable expectation of success): POSA would have had a reasonable expectation of success in configuring McCormack's longitudinal slots such that the longitudinal slots would establish a "seating relationship" with the corresponding tabs on the distal end of the inserter. Ex-1002, ¶65. In this manner, the longitudinal slots would effectively address the known need for controlling the depth of insertion and ensuring proper orientation via a "mechanical engagement." Ex-1002, ¶65. To establish such "seating relationship," POSA would simply select an appropriate predetermined length for the longitudinal slots such that the terminal points of the longitudinal slots would establish a "seating relationship" with the inserter's tabs when the inserter is longitudinally aligned with the working channel (as shown in Figure 13). Ex-1002, ¶65. This "seating relationship" would predictably ensure that the implant is inserted into a joint at a proper depth and would prevent over-penetration of the joint. *See* Ex-1006 at [0376] ("***[S]eating relationship*** may prevent the driver assembly [] ***from being inserted too far*** and may also allow the

driver assembly [] to be aligned with the delivery device [] rotationally to ***ensure proper rotational orientation*** of the implant.") (emphasis added); Ex-1002, ¶65.

(4) Rasp

McCormack discloses a chisel having a "series of ridges ... [that] can be relatively sharp and can aid the user in roughening or decorticating the facet surfaces as the chisel [] is inserted and removed from a facet joint." Ex-1006 at [0400]; Ex-1002, ¶66. McCormack further discloses that "the ridges 2033 can include a chevron pattern as shown. Patterns such as straight rows, diagonal rows, wavy rows, or other alternative patterns can be included." Ex-1006 at [0400]; Ex-1002, ¶66. POSA understands that this disclosure teaches a "rasp." Ex-1002, ¶66.

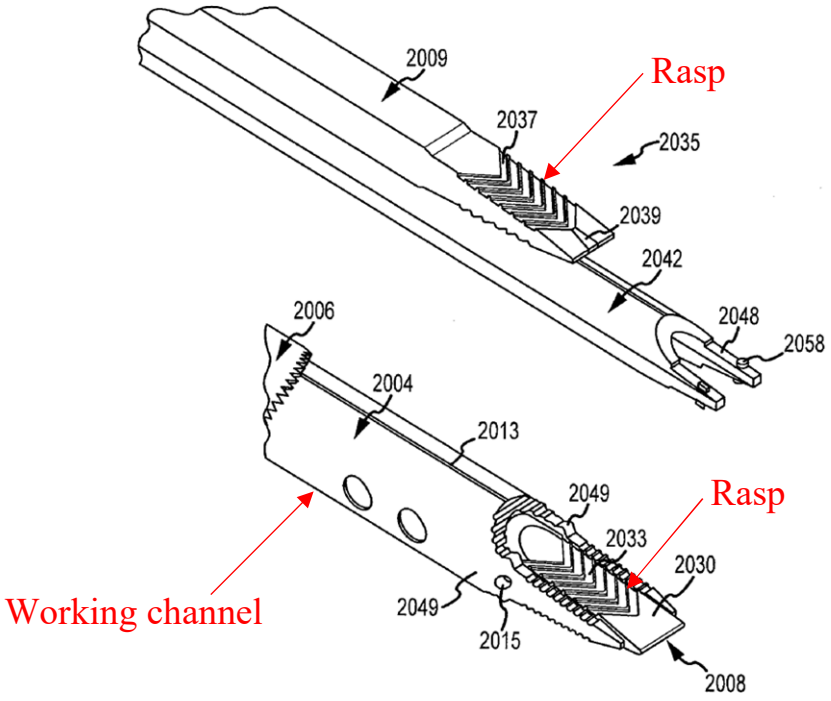


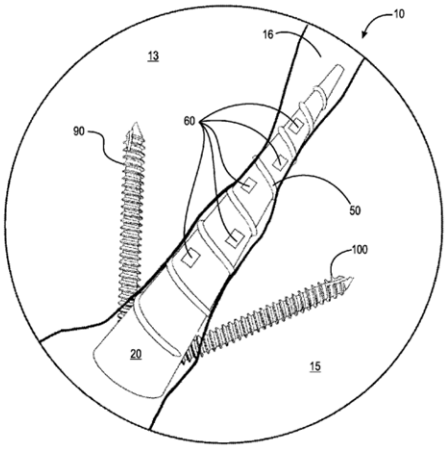
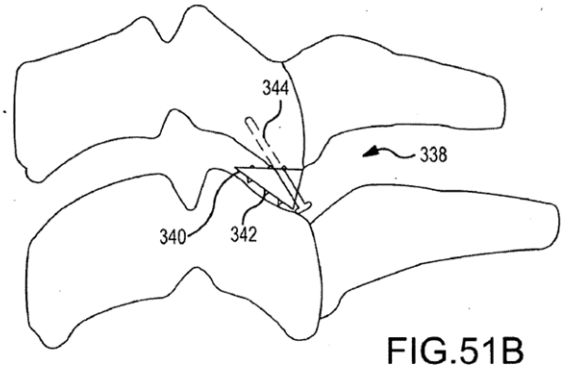
FIG.149

c. Combination of Stoffman and McCormack

(1) Motivation to combine

POSA had motivation to combine Stoffman's implant and method of SI joint fusion with McCormack's surgical tools. Ex-1002, ¶71. Stoffman discloses an SI joint implant and a method according to which that implant can be implanted into an SI joint, but does not disclose the surgical tools for performing this procedure. Ex-1002, ¶71. Stoffman does, however, explain that during insertion into the SI joint, "SI joint fusion device 10 [can be] guided within a guide tube to protect the surrounding soft tissue." Ex-1005 at [0043]; Ex-1002, ¶71. POSA understands that protecting the surrounding soft tissue is an advantageous objective and therefore would be motivated to apply a surgical tool set that enables insertion of an implant via a working channel (guide tube). Ex-1002, ¶71. This motivation would have led POSA to McCormack which discloses a surgical tool set for inserting an implant into a joint via a working channel. Ex-1002, ¶71.

Furthermore, McCormack teaches that its surgical tools can be used with an implant that is very similar to Stoffman's implant—a side-by-side comparison is provided below. Ex-1002, ¶72.

Stoffman	McCormack
	 FIG.51B

McCormack describes the implant depicted in Figure 51B as having the following three main structural features: (1) "the wedge shaped or triangular implant 338;" (2) "[t]he surfaces of this implant 338 may include teeth, spikes, cleats, surface roughening, and/or keels 342 to help prevent migration or backout;" and (3) "implant 338 may be anchored in position by one or two (one shown in FIG.) lateral mass screws/nails 344." Ex-1006 at [0291]; Ex-1002, ¶73. Stoffman's implant has the same structural elements: (1) "body 20 is tapered and frusto-conical" and "could be a non-tapered cone, a cylinder, a tapered cylinder, or a square-based or triangular-based pyramid;" (2) "threading 50 to help secure SI joint fusion device 10 between sacrum 13 and right ilium bone 15 … threading 50 could comprise a plurality of protrusions;" and (3) "ancillary members 90 and 100 are typical screws," wherein "a surgeon can anchor first and second ancillary members 90 and 100 … to bone."

Ex-1005 at [0033]; [0039]; Ex-1002, ¶73. Because of these similarities, POSA had motivation to combine McCormack's surgical instrument set with Stoffman's SI joint fusion method and SI joint fusion implant. Ex-1002, ¶73.

(2) Predictable result

Combining Stoffman and McCormack would yield a predictable result in which known components would be used for their intended functions. Ex-1002, ¶74. Specifically, McCormack's working channel (delivery device) would be used as a "guide tube" mentioned in Stoffman. Ex-1002, ¶74. Further, McCormack's implant inserter (driver assembly) would be used to insert Stoffman's implant into an SI joint via the working channel. McCormack teaches that the inserter has arms configured to "hold the implant from behind," and therefore Stoffman's implant having a slotted ("segmented") proximal end is perfectly compatible with McCormack's inserter arms. Ex-1002, ¶74.

Next, Stoffman's method involves a step of "drilling" the tapered body of the implant into the SI joint, and McCormack teaches that the implant inserter (drive assembly) includes an "internal actuator" adapted for "slidable longitudinal and rotational movement relative to the driver assembly." Ex-1005 at [0010]; Ex-1006 at [0255]; Ex-1002, ¶75. McCormack further teaches that the "internal actuator" can be equipped with "various driving engagements [] known in the art including flat screwdriver types, phillips head types, square drive, etc." Ex-1006 at [0255]; Ex-

1002, ¶75. Thus, after McCormack's implant inserter (driver assembly) inserts the implant into a patient's SI joint, the "internal actuator" can be used to drill/drive Stoffman's implant into its final position within the SI joint. Ex-1002, ¶75. In addition, McCormack discloses a standalone "turning tool" that could be used to drive Stoffman's ancillary screws into the sacrum and ilium. Ex-1006 at [0323]; FIG. 81C; Ex-1002, ¶75.

Finally, Stoffman teaches a step of removing "cartilaginous end plates of SI joint" to form a void within the SI joint, but does not disclose a tool for performing this step. Ex-1002, ¶76. McCormack teaches a chisel that includes a series of ridges, wherein "[t]he ridges [] can be relatively sharp and can aid the user in roughening or decorticating the [bone] surfaces as the chisel [] is inserted and removed from a … joint." Ex-1006 at [0400]; Ex-1002, ¶76. POSA would predictably use McCormack's chisel with sharp ridges ("a rasp") to remove the cartilage within the SI joint. Ex-1002, ¶76.

For the reasons set forth above, POSA had motivation to combine Stoffman's SI joint fusion method and implant with McCormack's surgical tools. Ex-1002, ¶77. Because McCormack teaches an implant structurally similar to the implant disclosed in Stoffman, POSA had a reasonable expectation of success in this combination, which would have yielded a predictable result in which McCormack's surgical tools

and Stoffman's implant and surgical method would be used in accordance with their known and intended functions. Ex-1002, ¶77.

The following claim-by-claim analysis establishes that the Stoffman-McCormack combination renders obvious claims 1-8. Ex-1002, ¶78.

d. Claim 1

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

Stoffman discloses that "[a] primary object of the present invention is to provide a safe, accurate, reliable, and minimally invasive method and apparatus for a percutaneous sacroiliac joint fusion." Ex-1005 at [0011]; Ex-1002, ¶81.

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

Stoffman teaches that "an incision is made to access SI joint." Ex-1005 at [0043]; Ex-1002, ¶82.

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

Stoffman teaches that "SI joint fusion device 10 is guided within a guide tube to protect the surrounding soft tissue." Ex-1005 at [0043]; Ex-1002, ¶83. POSA understands that to guide the fusion implant (SI joint fusion device) to the SI joint, the working channel (guide tube) must be inserted into the incision proximal to the SI joint. Ex-1002, ¶83.

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

The analysis set forth in Part XII.A.1.c., *supra*, established that it would have been obvious to use McCormack's working channel (delivery device 104) as the "guide tube" mentioned in Stoffman. Ex-1002, ¶84.

McCormack discloses the working channel has a "generally tubular shaft 114" (hollow barrel). Ex-1006 at [0238]; Ex-1002, ¶84. The hollow barrel of the working channel is depicted in Figure 2, which is reproduced and annotated below. Ex-1002, ¶84.

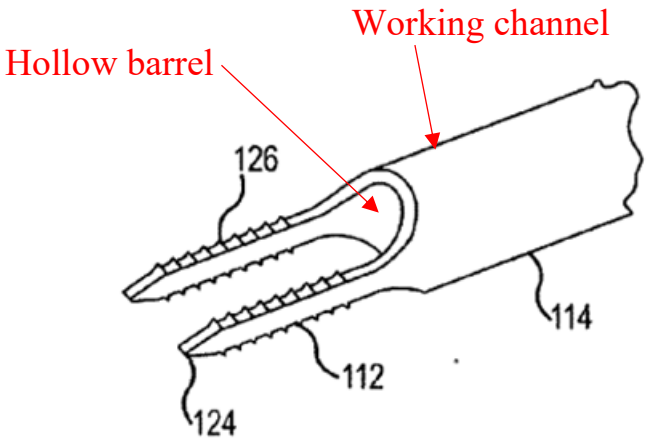


FIG.2

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

The analysis set forth in Parts XII.A.1.b.(3)(i)-(iv), *supra*, establishes four rationales according to which McCormack teaches or suggests an interior guidance slot for controlling advancement of surgical tools. Ex-1002, ¶85.

To summarize, McCormack teaches two types of interior guidance slots for controlling the advancement of the surgical tools passed through the working channel: (1) "seating recesses 119" positioned on the "the inner surface of the bore" and (2) "a keyway feature 156" that includes a "longitudinal slot in the inner surface of the tubular shaft 114 of the delivery device 104." Ex-1006 at [0240]; [0251]; FIGS. 6A and 9; Ex-1002, ¶86. McCormack teaches that both the "seating recesses" and the "longitudinal slot" control orientation of surgical tools relative to the working channel (delivery device). Ex-1006 at [0240] ("[T]he recesses 119, may allow for orienting the [surgical] devices properly … one or several orientations may be controlled.)"]; [0251] ("[K]eyway feature 156 for preventing relative rotation between the tubular shaft 114 of the delivery device 104 and the implant shaft 146 of the driver assembly 142 when inserted."). Ex-1002, ¶86.

Turning now to Parts XII.A.1.b.(3)(i)-(iv), *supra*, the analysis set forth therein establishes four rationales as to why McCormack teaches the limitation "interior guidance slot … for controlling advancement of surgical tools," even when this limitation is construed in a manner that requires controlling the depth of advancement. Ex-1002, ¶¶87-88. ***First***, McCormack's description of the "seating recesses" in Paragraph [0240] and Figure 6A render obvious a guidance slot that controls both orientation and depth of insertion of the surgical tools. Ex-1002, ¶¶87-88. ***Second***, McCormack's disclosure in Paragraph [0251] pertaining to the "keyway feature" teaches a "longitudinal slot" on the interior of the working channel for controlling the orientation of a surgical tool ("delivery assembly 142"), while Figure 9 suggests that the "longitudinal slot" also controls the surgical tool's depth of advancement. Ex-1002, ¶¶87-88. ***Third***, the combination of McCormack's "seating recesses" and the "longitudinal slot" teaches a combined guidance slot that controls both the depth of advancement and orientation of the surgical tools relative to the working channel. Ex-1002, ¶¶87-88. ***Fourth***, adapting McCormack's "longitudinal slot" to control the depth of advancement in addition to the orientation of the surgical tool would have been obvious under the "obvious to try" rationale. Ex-1002, ¶¶87-88.

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

McCormack discloses that the working channel has "anchoring forks 112 at a distal end." Ex-1006 at [0238]; FIG. 2. Ex-1002, ¶89.

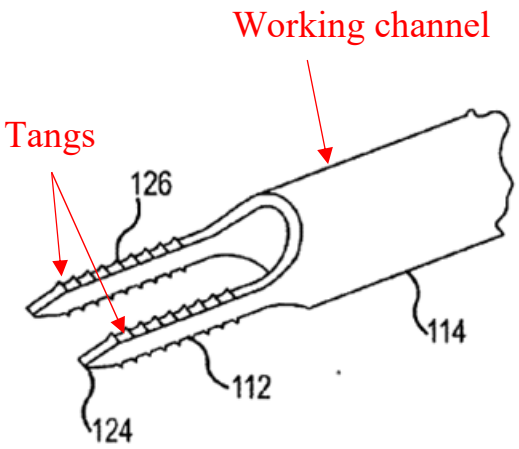


FIG.2

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

Stoffman discloses that after making the incision, "[t]he cartilaginous end plates of SI joint 16 are removed and a *hole* is drilled across SI joint." Ex-1005 at [0043] (emphasis added); Ex-1002, ¶90. Additionally, Stoffman teaches that "a surgeon … drills *holes* under fluoroscopic guidance for placement of ancillary screw members 90 and 100 into right ilium bone 15 and sacrum 13." Ex-1005 at [0043] (emphasis added); Ex-1002, ¶90.

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

Stoffman teaches that after a cavity is created within the SI joint, a fusion implant is guided through a working channel (guide tube). Ex-1005 at [0043]; Ex-1002, ¶91. POSA understands that the guiding step involves inserting the fusion implant into the "hole [] drilled across SI joint" in the preceding step. Ex-1002, ¶91.

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

Stoffman discloses that the body of the fusion implant has "threading 50 [that] could comprise a plurality of ***protrusions***" and that an intended function of the threading is to "***help secure*** SI joint fusion device 10 between sacrum 13 and right ilium bone 15." Ex-1005 at [0033] (emphasis added); Ex-1002, ¶92. Furthermore, Stoffman discloses that the fusion implant has "first and second ancillary members 90 and 100, respectively, ***protruding*** outwardly from body 20" and teaches that "first ancillary member 90 is ***secured*** within sacrum 13 and second ancillary member 100 is ***secured*** within right ilium bone 15." Ex-1005 at [0033], [0034] (emphasis added); Ex-1002, ¶92. Thus, Stoffman teaches that the implant has multiple bone-engaging protrusions—the threading and the ancillary members—that prevent pullout of the fusion implant from the SI joint. Ex-1002, ¶92.

Stoffman's implant with its bone-engaging protrusions is most clearly depicted in Figure 4, which is reproduced and annotated in color below, wherein the sacrum is emphasized in light orange and the ilium is emphasized in dark orange. Ex-1002, ¶92.

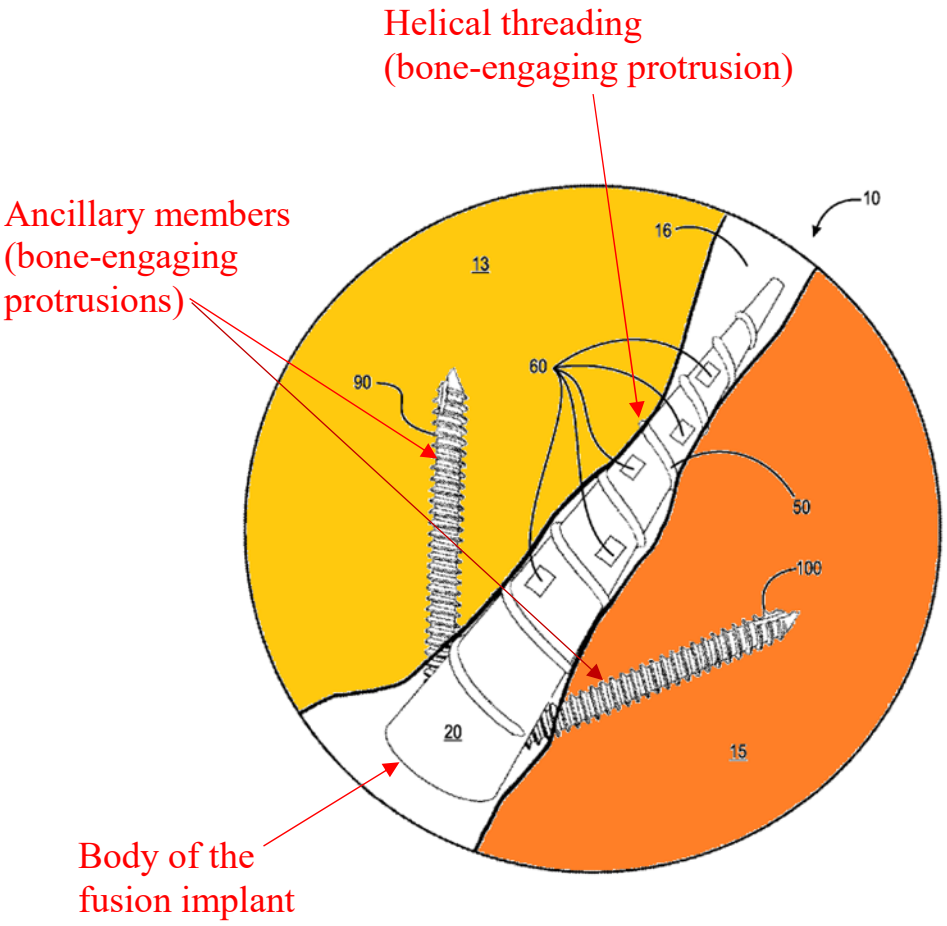


Fig. 4

e. Claim 2

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

Stoffman discloses that the fusion implant "comprises body 20 and first and second ancillary members 90 and 100, respectively, protruding outwardly from body 20." Ex-1005 at [0033]; Ex-1002, ¶93. In addition, "threading 50" also extends from the central body. Ex-1005 at [0033] ("Body 20 further comprises threading 50 … [wherein] threading 50 could comprise a plurality of protrusions."); Ex-1002, ¶93. Figure 5 of Stoffman depicts that the fusion implant has a central body with the threading and the two ancillary screw members extending therefrom. Ex-1002, ¶93.

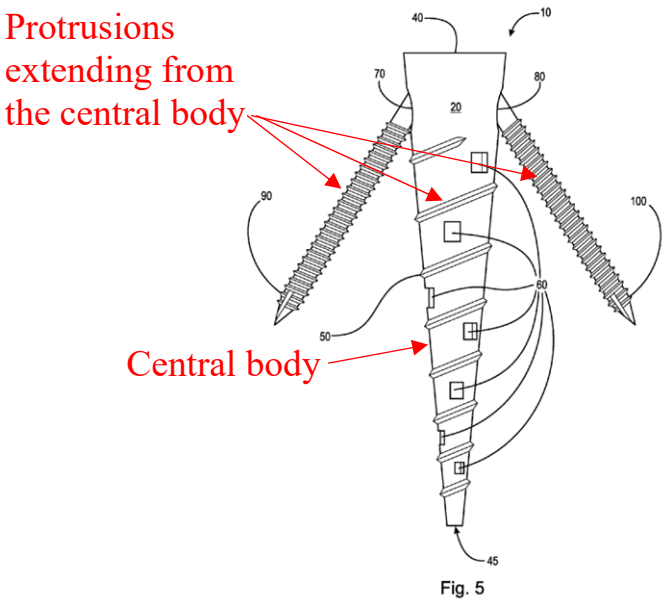


Fig. 5

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

Stoffman teaches that the ancillary members (protrusions) are configured to "ensure[] an effective securement between SI joint 16 and sacrum 13 and right ilium bone 15." Ex-1005 at [0038]; Ex-1002, ¶94. Moreover, Stoffman teaches that the ancillary screw members can be used to "effectively immobilize[e] SI joint." Ex-1005 at [0043]; Ex-1002, ¶94.

Additionally, Stoffman discloses that "the depth of threading 50 tapers along with the taper of body 20. Ex-1002, ¶94. These tapers are effective in ***fusing*** the SI joint." Ex-1005 at [0034] (emphasis added); Ex-1002, ¶94. Accordingly, "threading 50" engages the sacrum and ilium and fixes their relative positions through bone fusion. Ex-1002, ¶94.

f. Claim 3

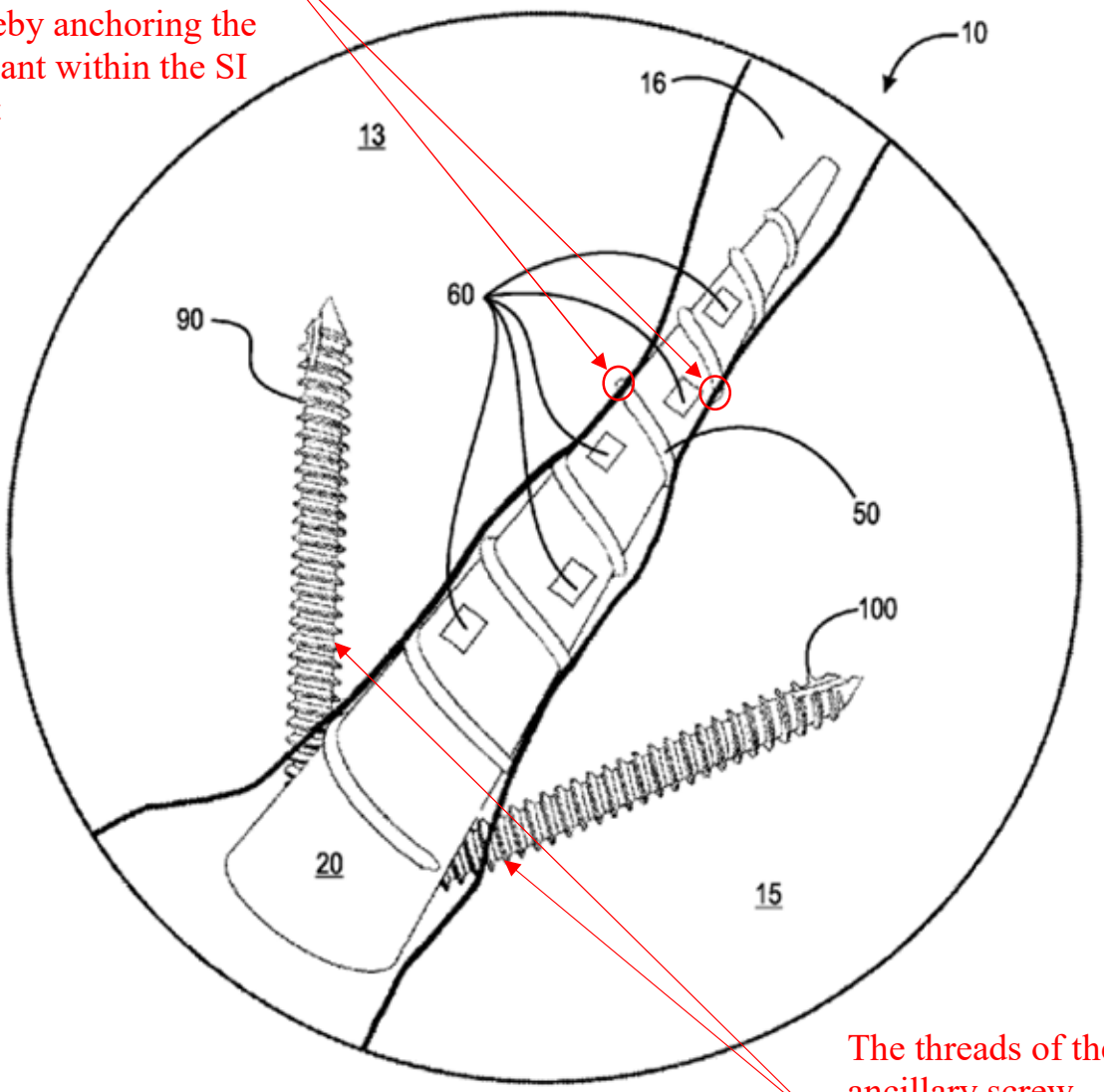
(1) "The method of claim 2, wherein said at least one protrusion includes an anchor that penetrates at least one of the patient's ilium and the patient's sacrum and thereby fixes relative positions of said ilium and sacrum."

Stoffman teaches that "a surgeon can ***anchor*** first and second ancillary members 90 and 100 … to bone." Ex-1005 at [0039] (emphasis added); Ex-1002, ¶95. Stoffman further discloses that the "first and second ancillary members 90 and 100 are self-tapping screws … [and] feature threading 95 and 105," thereby teaching

that the thread of the ancillary members is configured to penetrate the bone tissue. Ex-1005 at [0037]; Ex-1002, ¶95. Thus, Stoffman teaches that the ancillary screw members (bone-engaging protrusions) have threads ("anchors") that penetrate the ilium and sacrum, thereby fixing their relative positions. Ex-1002, ¶95.

Additionally, Figure 4 of Stoffman depicts that the "threading 50" penetrates the sacrum and the ilium and anchors the implant into the SI joint. Ex-1005 at FIG. 4; Ex-1002, ¶95. Accordingly, "threading 50" also satisfies the limitations of claim 3. Ex-1002, ¶95.

Threading penetrates the sacrum and ilium, thereby anchoring the implant within the SI joint



The threads of the ancillary screw members penetrate the sacrum and ilium, thereby anchoring the implant within the SI joint

Fig. 4

g. Claim 4

(1) "The method of claim 3, wherein said anchor is a helical anchor operable to substantially fix the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint."

As established above, the threads of Stoffman's screws are anchors operable to fix the ilium to the sacrum, thereby substantially immobilizing the SI joint. Ex-1005 at [0043] ("ancillary screw members 90 and 100 and body 20 … effectively immobilizing SI joint"); Ex-1002, ¶96. Furthermore, by definition, a screw thread is helical. Ex-1012 (a dictionary defining the word "screw" as "a metal fastener having a tapered shank with a *helical* thread") (emphasis added); Ex-1002, ¶96. Thus, Stoffman's ancillary screw members have helical threads/anchors operable to substantially fix the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac join. Ex-1002, ¶96.

In addition, the analysis provided above with respect to claim 3 established that Stoffman's "threading 50" is an anchor. *See supra* Part XII.A.1.f.(1). Stoffman further teaches that the "threading 50 is *helical*." Ex-1005 at [0033] (emphasis added); Ex-1002, ¶96. Thus, the "threading 50" is a helical anchor. Ex-1002, ¶96. As has been established with respect to claim 2, the taper of the threading is "effective in *fusing* joint," thereby immobilizing it. Ex-1005 at [0034] (emphasis added); Ex-1002, ¶96.

h. Claim 5

(1) "The method of claim 2, wherein said fusion implant comprises a cavity for holding a fusion-promoting material and having at least one hole therein for allowing the growth of bone tissue into said cavity."

Stoffman teaches that the body of the fusion implant has a "hollow cavity" and that the "hollow cavity 30 of body 20 is optionally, filled with bone graft." Ex-1005 at [0043]; Ex-1002, ¶97. Stoffman further teaches that "body 20 comprises plurality of openings 60 through which fusion-facilitating substances can pass." Ex-1005 at [0033]; Ex-1002, ¶97. The cavity and the openings are depicted in Figure 3, which is reproduced and annotated below. Ex-1002, ¶97.

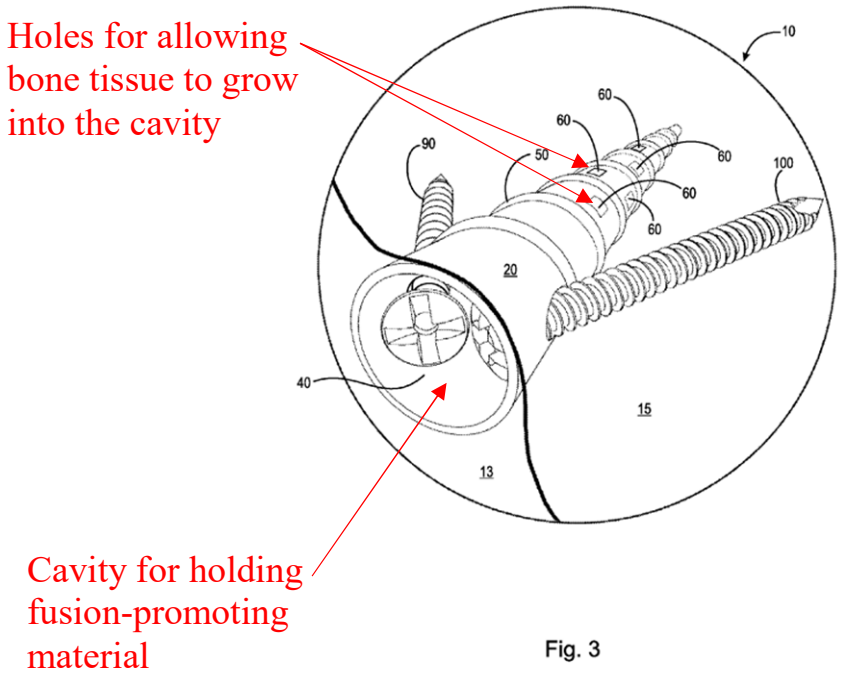


Fig. 3

i. Claim 6

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

McCormack teaches an implant inserter (driver assembly 142) having a plurality of "implant holding arms 148." Ex-1006 at [0250]; FIG. 10; Ex-1002, ¶98. McCormack further teaches that an "implant [] may be positioned to be held by the arms 148 of the driver assembly 142." Ex-1006 at [0264]; Ex-1002, ¶98. The implant inserter is depicted in Figure 10, which is reproduced and annotated below. Ex-1002, ¶98.

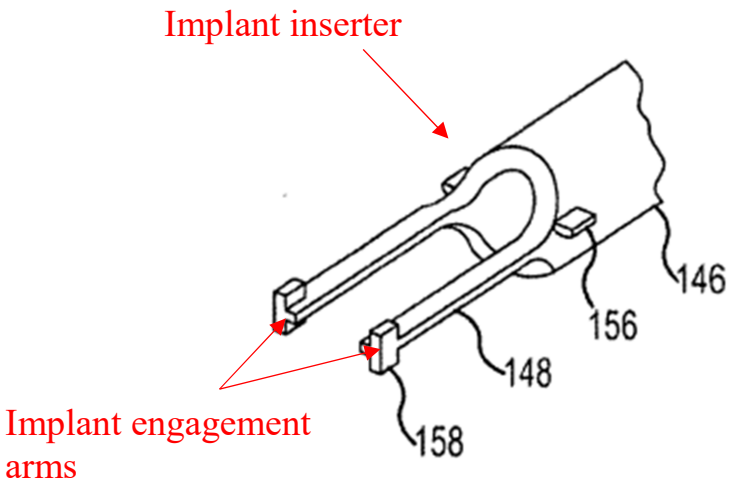


FIG.10

McCormack generally teaches that it is advantageous for the implant holding arms to "be adapted to hold the implant from behind rather than from the sides" because "[t]his allows the driver assembly [] to have a smaller size than the driver assembly [] and also allows the delivery device [] to have a smaller size than the delivery device []." Ex-1006 at [0423]; Ex-1002, ¶99.

Stoffman provides a complementary teaching to McCormack by describing that the implant's "[o]pen end 40 … could be … segmented." Ex-1005 at [0036]; Ex-1002, ¶100. POSA understand that this description teaches that the proximal end ("open end 40") of the fusion implant has slots. Ex-1002, ¶100. Thus, POSA had motivation to adapt the implant-engaging arms of McCormack's inserter to engage with the slots on the segmented proximal end of Stoffman's implant Ex-1002, ¶100.

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

McCormack discloses that the implant inserter has a "pair of ***tabs*** on opposing sides of the implant shaft 146 for engaging with a corresponding longitudinal slot in the inner surface of the tubular shaft 114 of the delivery device 104." Ex-1006 at [0251] (emphasis added); Ex-1002 at ¶101.

Alternatively, McCormack also discloses "positionally matched ***protrusions*** … [on] any one or all of the devices being inserted into the deliver[y] device"

adapted to be received into the "seating recesses" of the working channel. Ex-1006 at [0240] (emphasis added); Ex-1002, ¶102.

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

McCormack teaches that "[t]he driver assembly 142 and implant 154 may then be inserted into the delivery device 104." Ex-1006 at [0264]; Ex-1002, ¶103. McCormack further teaches the "pair of *tabs* on opposing sides of the implant shaft 146 … *engaging with a corresponding longitudinal slot in the inner surface of the tubular shaft* 114 of the delivery device 104." Ex-1006 at [0251] (emphasis added); Ex-1002, ¶103. Figure 9 of McCormack depicts this step. Ex-1002, ¶103.

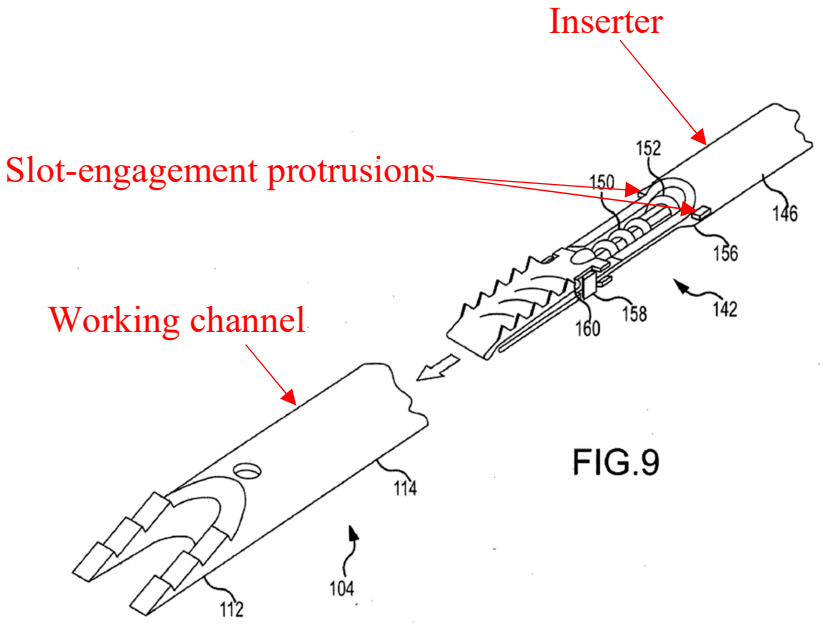


FIG.9

Alternatively, McCormack also teaches that during insertion of a surgical device (including the implant inserter), "seating recesses 119" are configured "to ***receive*** positionally matched ***protrusions*** from any one or all of the devices ***being inserted*** into the deliver[y] device." Ex-1006 at [0240] (emphasis added); Ex-1002, ¶104.

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

McCormack teaches that "the driver assembly 142 may be tapped on to ***fully advance*** the driver assembly 142 and ***properly position*** the implant 154." Ex-1006 at [0264] (emphasis added); Ex-1002, ¶105. In addition, McCormack teaches the step of "***seating*** the driver assembly in the delivery device thereby positioning the implant between the forks of the delivery device and in the … joint." Ex-1006 at [0046] (emphasis added); Ex-1002, ¶105. Finally, with respect to the limitation requiring that "said interior guidance slot arrests the penetration of said inserter," obviousness of this limitation has been established in the detailed analysis set forth in Parts XII.A.1.b.(3)(i)-(iv), *supra*, and further discussed with respect to the limitation [1.b.3] in Part XII.A.1.d.(5), *supra*. Ex-1002, ¶105.

j. Claim 7

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

McCormack discloses a chisel having a series of ridges, which "can be relatively sharp and can aid the user in roughening or decorticating the facet surfaces as the chisel [] is inserted and removed from a facet joint." Ex-1006 at [0400]; Ex-1002, ¶106. This description reads on the "rasp" recited in [7.a.1]. Ex-1002, ¶106. Furthermore, Figure 149 depicts that the rasp is inserted through the hollow barrel of the working channel. Figure 149 also depicts that the rasp is both rotationally and longitudinally aligned with the working channel. Ex-1002, ¶106.

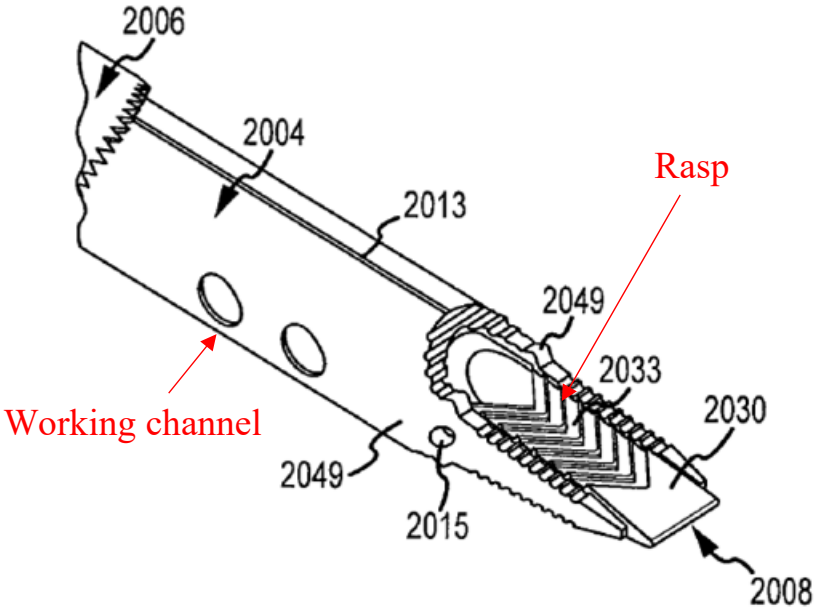


FIG.149

In addition, because over-penetration of an SI joint is well-known concern, POSA had motivation to control the depth of insertion of the rasp relative to the SI joint. Ex-1002, ¶107; Ex-1011 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."). This motivation would have led to McCormack's disclosure pertaining to the "seating recesses"/"longitudinal slots" positioned within the interior of the working channel (delivery device) and the complementary "positionally matched protrusions from *any one or all* of the devices being inserted into the deliver[y] device"/"a pair of tabs on opposing sides of the … shaft." Ex-1006 at [0240]; Ex-1002, ¶107. Positioning such slot-engagement

protrusions on the shaft of the chisel (rasp) would have been a routine exercise of ordinary skill in the art and would have yielded a predictable result with known components performing their known and intended functions. Ex-1002, ¶107.

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

The analysis in the preceding section with respect to the limitation [7.a.1] established that it would have been obvious to position McCormack's protrusion or a keyway tab on the shaft of the rasp for engagement with McCormack's "seating recesses" / "longitudinal slots." Ex-1002, ¶108. Further, obviousness of the "interior guidance slot" capable of controlling the depth and orientation of the surgical tools relative to the working channel has been established in the detailed analysis set forth in Parts XII.A.1.b.(3)(i)-(iv), *supra*, and has been further discuss in relation to the limitations [1.b.3] in Part XII.A.1.d.(5), *supra*. Ex-1002, ¶108. Thus, claim 7 is obvious. Ex-1002, ¶108.

k. Claim 8

(1) "The method of claim 1, wherein said interior guidance slot is operable to engage and align a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision."

McCormack teaches "positionally matched protrusions" on the surgical instruments operable to align with and engage the "seating recesses" within the interior wall of the working channel. *See* Ex-1006 at [0240]; Ex-1002, ¶109.

Alternatively, McCormack teaches a surgical tool (driver assembly) having "a pair of tabs" disposed on its shaft configured to align with and engage the "longitudinal slot" within the working channel. Ex-1006 at [0251]; Ex-1002, ¶109.

Finally, obviousness of the "guidance slot" for controlling the depth of advancement and orientation of the surgical tools relative to the working channel is established in Parts XII.A.1.b.(3)(i)-(iv), *supra*, and further discussed in relation to the limitation [1.b.3] in Part XII.A.1.d.(5), *supra*. Ex-1002, ¶109.

2. Ground 1B: Claims 9-23 are obvious over the combination of Stoffman, McCormack, and Stark

a. Overview of Stark

Stark is a published patent application that was filed on February 27, 2008 and published on August 27, 2009 and therefore qualifies as prior art against the '511

Patent under 35 U.S.C. § 102(a)(1) and § 102(a)(2). Furthermore, even if Patent Owner establishes that one or more Challenged Claims is entitled to claim the benefit of the filing date of the Grandparent, Stark still qualifies as prior art under 35 U.S.C. § 102(a)(1) and § 102(a)(2).

This petition cites Stark for a narrow purpose of showing that prior to the '511 Patent, it was well-known that when a working channel (cannula) with tangs is used in an SI joint fusion surgery, the tangs of the working channel are inserted between the articular surfaces of the ilium and the sacrum to stabilize the working channel relative to the SI joint. Ex-1002, ¶68. Specifically, Stark teaches that "a cannula can have two or more projections distributed to fix a cannula relative to the joint while providing an open channel to the joint … With two projections sticking into the joint, the orientation of the cannula relative to the joint is more secure." Ex-1007 at [0045]; Ex-1002, ¶68. Stark further teaches that "the tangs can have different shapes," and an exemplary embodiment of Stark's working channel (cannula) with rounded tangs (projections) is depicted in Figure 10. Ex-1007 at [0072]; Ex-1002, ¶68.

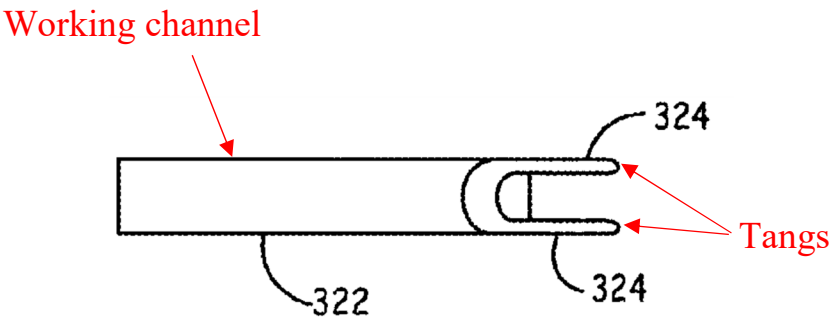


FIG. 10

With respect to positioning of the tangs within an SI joint, Stark provides Figure 9A, which is "a top view into the sacroiliac joint showing a set of inserted tangs into the joint," showing the tangs inserted between the articular surfaces of the ilium and sacrum. Ex-1007 at [0022]; Ex-1002, ¶69.

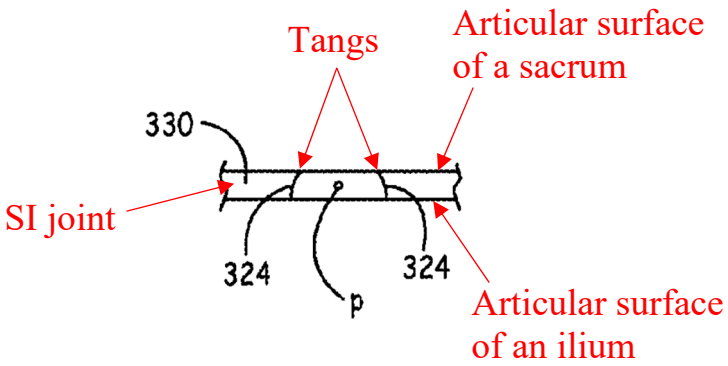
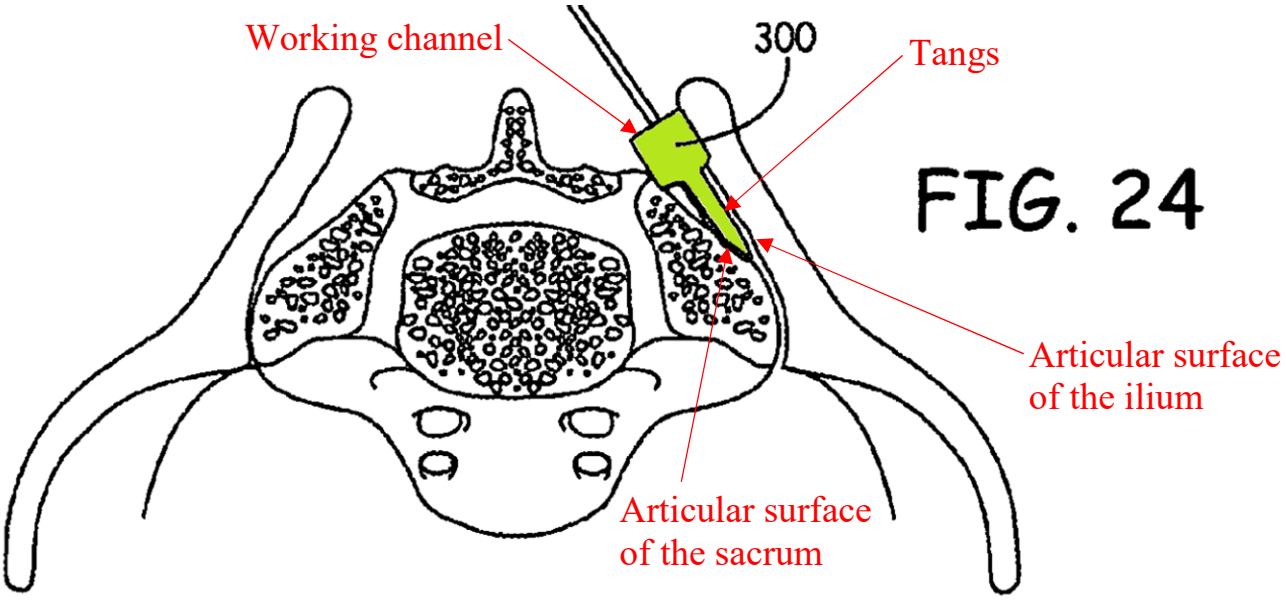


FIG. 9A

Additionally, Stark provides Figure 24 which depicts a schematic cross-sectional view of an SI joint showing the tangs of the working channel inserted between the articular surfaces of the ilium and sacrum of the SI joint. Ex-1002, ¶70.



b. Stoffman-McCormack-Stark Combination

(1) Motivation to Combine

The analysis set forth in Part XII.A.1.c., *supra*, established that it would have been obvious to use McCormack's working channel as a "guide tube" taught in Stoffman. In this Stoffman-McCormack combination, McCormack's working channel with tangs would be used to insert Stoffman's implant into a patient's SI joint. Ex-1002, ¶79. When positioning McCormack's working channel within an SI joint, POSA had reason to refer to Stark because Stark teaches a method of using a working channel with tangs to guide a fusion implant into an SI joint. Ex-1002, ¶79.

(2) Predictable result

The Stoffman-McCormack-Stark combination would have produced a predictable result in which known components would perform their known and

intended functions. Ex-1002, ¶80. Specifically, the tangs of McCormack's working channel would be inserted between the articular surfaces of the sacrum and ilium, as taught in Stark, to secure the working channel relative to the SI joint and provide a passage for Stoffman's implant into the SI joint via the working channel. Ex-1002, ¶80.

c. Claim 9

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

McCormack teaches that the working channel has a plurality of tangs (forks) and further teaches that the tangs may be blunt with "bull nose tips." Ex-1006 at [0333]; Ex-1002, ¶110. Figure 95A depicting a working channel with blunt tangs is reproduced below. Ex-1002, ¶110.

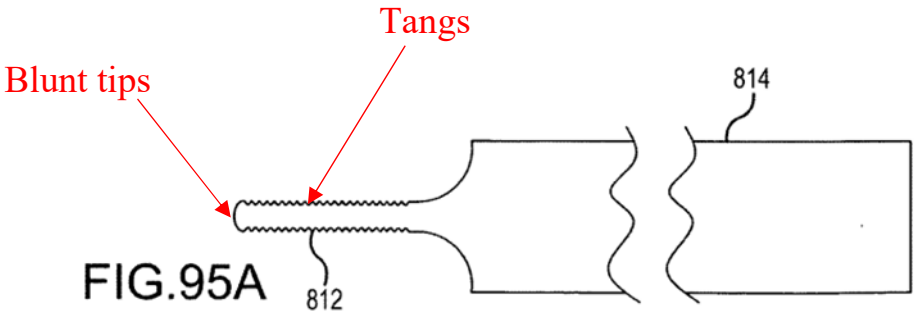


FIG.95A

In Stoffman-McCormack combination, POSA had motivation to use the working channel with blunt tangs depicted in Figure 95A of McCormack because

such blunt tangs are advantageous as they reduce the likelihood of injuring ligaments or soft tissue during an SI joint surgery. Ex-1002, ¶111.

(2) [9.a.2] "that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint."

Stark teaches that when performing an SI joint fusion procedure, tangs of a working channel (cannula) are inserted into the SI joint "to fix a cannula relative to the joint while providing an open channel to the joint … With two projections sticking into the joint, the orientation of the cannula relative to the joint is more secure." Ex-1007 at [0045]; Ex-1002, ¶112. Stark provides Figure 9A, which is "a top view into the sacroiliac joint showing a set of inserted tangs into the joint." Ex-1007 at [0022]; Ex-1002, ¶112.

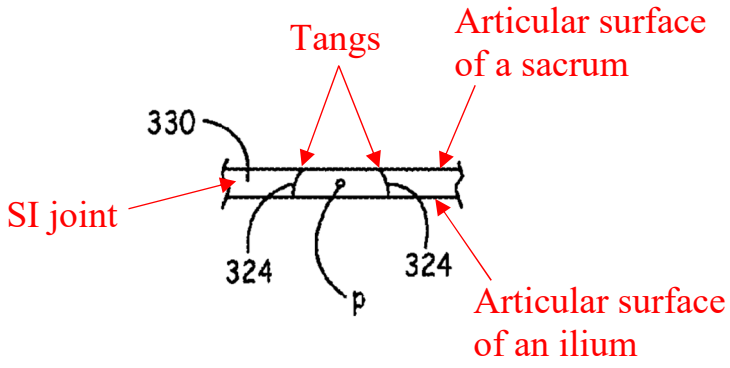
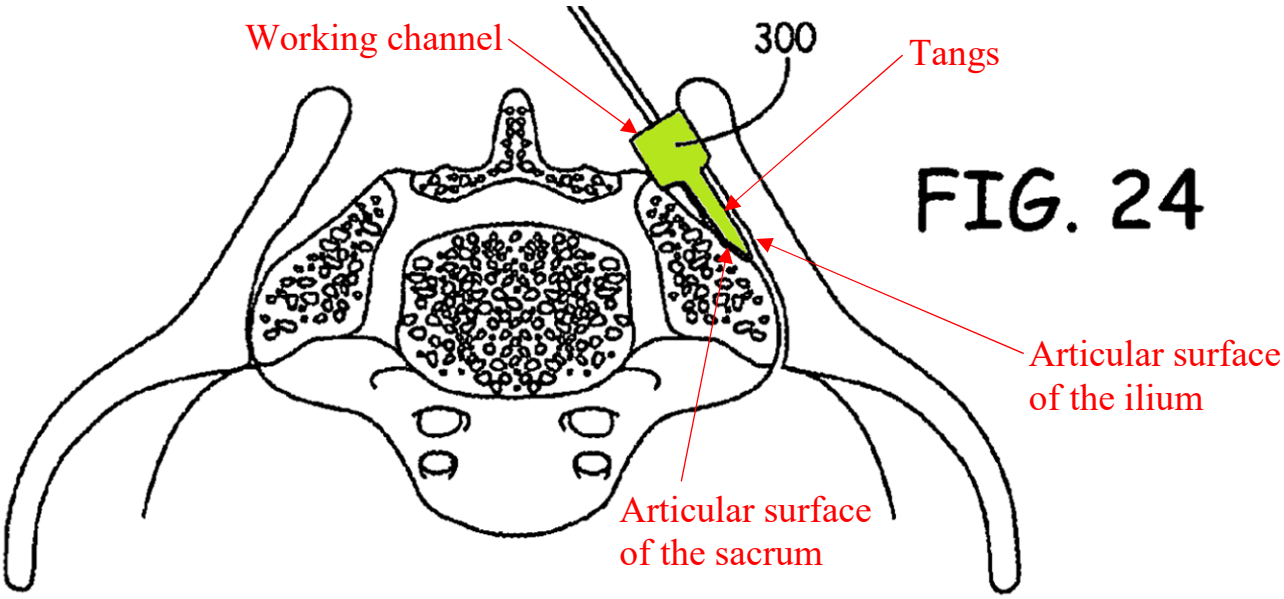


FIG. 9A

Additionally, Stark provides Figure 24 which depicts a schematic cross-sectional side view of an SI joint showing the tangs of the working channel inserted between articular surfaces of an ilium and a sacrum of an SI joint. Ex-1002, ¶113.



Thus, Stark teaches that the tangs of the working channel are inserted between the articular surfaces of the sacrum and ilium thereby stabilizing the working channel relative to the SI joint. Ex-1002, ¶¶112-113.

d. Claim 10

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

The preamble of claim 10 is the same as the preamble of claim 1, obviousness of which has been established in Part XII.A.1.d.(1), *supra*. Ex-1002, ¶114.

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

The step recited in [10.a] is the same as the step recited in [1.a], obviousness of which has been established in Part XII.A.1.d.(2), *supra*. Ex-1002, ¶115.

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

The step of inserting a surgical channel tool into the incision is substantively the same as the step recited in [1.b.1], obviousness of which has been established in Part XII.A.1.d.(3), *supra*. Ex-1002, ¶116. In addition, Stoffman discloses that "[p]referably, the incision is made along the dimple of Venus," thereby teaching that the surgical channel is inserted into the incision from the posterior of the patient. Ex-1005 at [0043]; Ex-1002, ¶116.

(4) [10.b.2] "said surgical channel tool having two bilateral blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through a surgical channel of said surgical channel tool and into the sacroiliac joint,"

Figure 2 of McCormack depicts that the tangs are bilateral. Ex-1006 at FIG. 2; *See* Ex-1002, ¶117. The remaining limitations recited in [10.b.2] are substantively the same as the limitations of claim 9, obviousness of which has been established in Part XII.A.2.c., *supra*. Ex-1002, ¶117.

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

The limitations recited in [10.b.3] are substantively the same as the limitations of [1.b.3] and claim 8, obviousness of which has been established in Parts XII.A.1.d.(5) and XII.A.1.k.(1), *supra*. Ex-1002, ¶118.

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

The step recited in [10.c] is the same as the step recited in [1.c], obviousness of which has been established in Part XII.A.1.d.(7), *supra*. Ex-1002, ¶119.

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

The step of inserting a fusion implant into the void is recited in [1.d.1], and its obviousness has been established in Part XII.A.1.d.(8), *supra*. Ex-1002, ¶120. The remaining limitations recited in [10.d.1] are substantively the same as the limitations recited in [6.a.1], and their obviousness has been established in Part XII.A.1.i.(1), *supra*. Ex-1002, ¶120.

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

The limitations recited in [10.d.2] are substantively the same as the limitations recited in [1.d.2], obviousness of which has been established in Part XII.A.1.d.(9), *supra*. Ex-1002, ¶121.

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

Stoffman discloses the step of "***drilling*** a tapered body [of the implant] into the sacroiliac joint." Ex-1005 at [0010] (emphasis added); Ex-1002, ¶122. POSA understands that this "drilling" step teaches that the body of the implant is *driven* into the "hole [previously] drilled across SI joint." *See* Ex-1005 at [0043]; Ex-1002, ¶122. Additionally, with respect to the implant protrusions ("ancillary screw members"), Stoffman teaches that "[o]nce the holes are drilled, a surgeon ***taps*** and ***places*** ancillary screw members 90 and 100, respectively, into right ilium bone 15 and sacrum 13." Ex-1005 at [0043] (emphasis added); Ex-1002, ¶122. Thus, Stoffman teaches that all three components of the implant—the body and the two ancillary members—are driven into their respective voids (holes) within the SI joint. Ex-1002, ¶122.

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

Stoffman teaches that the body of the implant has "threading 50 to help secure SI joint fusion device 10 between sacrum 13 and right ilium bone 15" and further teaches that "threading 50 could comprise a plurality of protrusions." Ex-1005 at [0033]; Ex-1002, ¶123. When the body of Stoffman's implant is driven (drilled) into the void within the SI joint, the threading (plurality of protrusions) engages with the bone tissue, thereby preventing pullout of the implant. Ex-1005 at [0010], [0033], [0034]; Ex-1002, ¶123. Further, Figure 4 of Stoffman depicts that the threading (protrusion) of the implant is embedded within the ilium and sacrum, thereby teaching that the threading engages the bone tissue and prevents pullout of the implant. *See* Ex-1005 at [0033], [0034]; Ex-1002, ¶123.

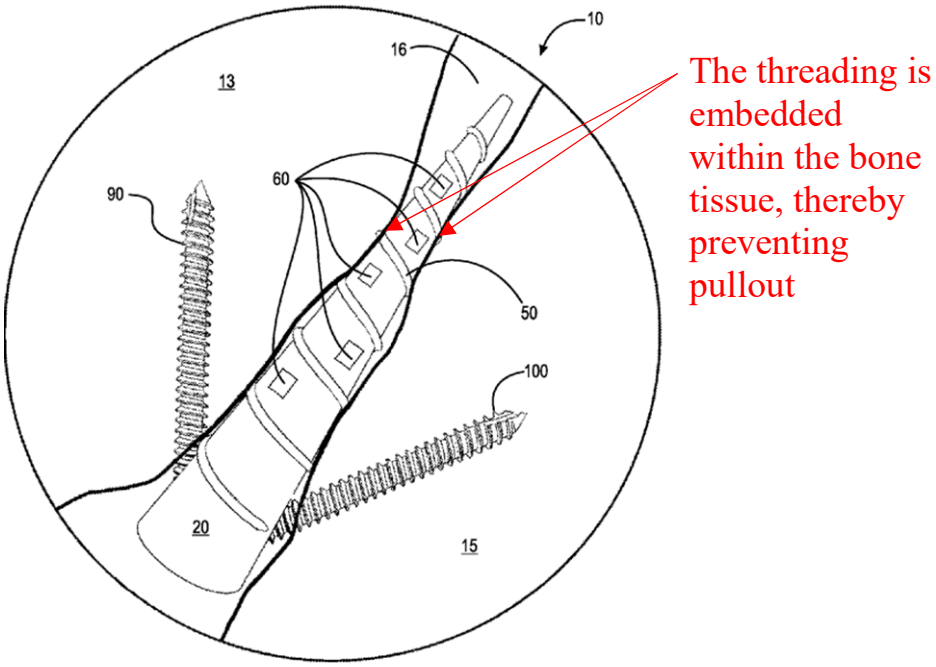


Fig. 4

In addition, Stoffman discloses that "a surgeon can anchor first and second ancillary members 90 and 100 … to bone" and therefore teaches that driving of the ancillary members (protrusions) into their respective holes (voids) engages the ancillary members with the bone tissue within the SI joint, thereby preventing pullout of the implant as clearly depicted in Figure 4. Ex-1005 at [0039]; Ex-1002, ¶124.

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

Stoffman teaches that the fusion implant "ensure[s] an effective securement between SI joint 16 and sacrum 13 and right ilium bone 15," and further teaches that

the implant is designed to "effectively immobilize[e] SI joint." Ex-1005 at [0038], [0043]; Ex-1002, ¶125.

e. Claim 11

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

The analysis set forth above with respect to obviousness of limitation [1.d.2] established that "Stoffman teaches that the implant has multiple bone-engaging protrusions—the threading and the ancillary members." *See* Part XII.A.1.d.(9), *supra*; Ex-1002, ¶126. With respect to the threading, Stoffman teaches that "threading 50 is helical" and that "threading 50 could be sharp." Ex-1005 at [0033], [0034]; Ex-1002, ¶126. Figure 4 of Stoffman depicts that the threading pierces the bone tissue in the articular surfaces of the sacrum and ilium. Ex-1002, ¶126. Thus, the threading of Stoffman's implant satisfies all limitations of claim 11 and therefore renders this claim obvious. Ex-1002, ¶126.

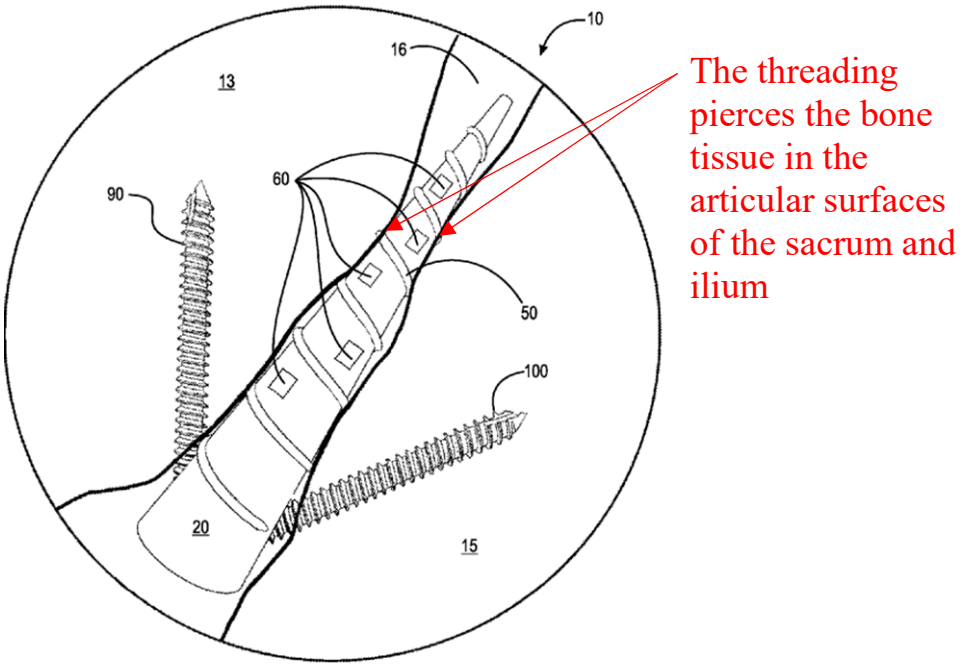


Fig. 4

In addition, the analysis set forth with respect to claim 4 in Part XII.A.1.g.(1), *supra*, established that the threads of Stoffman's ancillary screw members are "helical anchors." Ex-1002, ¶127. Stoffman further teaches that "first and second ancillary members 90 and 100 are self-tapping screws," which means that their threads have sharp ends for piercing bone tissue. Ex-1005 at [0037]; Ex-1002, ¶127. Therefore, Stoffman's ancillary screws also teach all limitations of claim 11, thus rendering this claim obvious. Ex-1002, ¶127.

f. Claim 12

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

Stoffman teaches that a "hollow cavity 30 of body 20 is optionally, filled with bone graft" and further teaches that "body 20 comprises plurality of openings 60 through which fusion-facilitating substances can pass". Ex-1005 at [0033], [0043] Ex-1002, ¶128. In addition, Stoffman teaches that "[b]ody 20 is open at both ends and includes open end 40." Ex-1005 at [0036]; Ex-1002, ¶128. Accordingly, Stoffman renders claim 12 obvious. Ex-1002, ¶128.

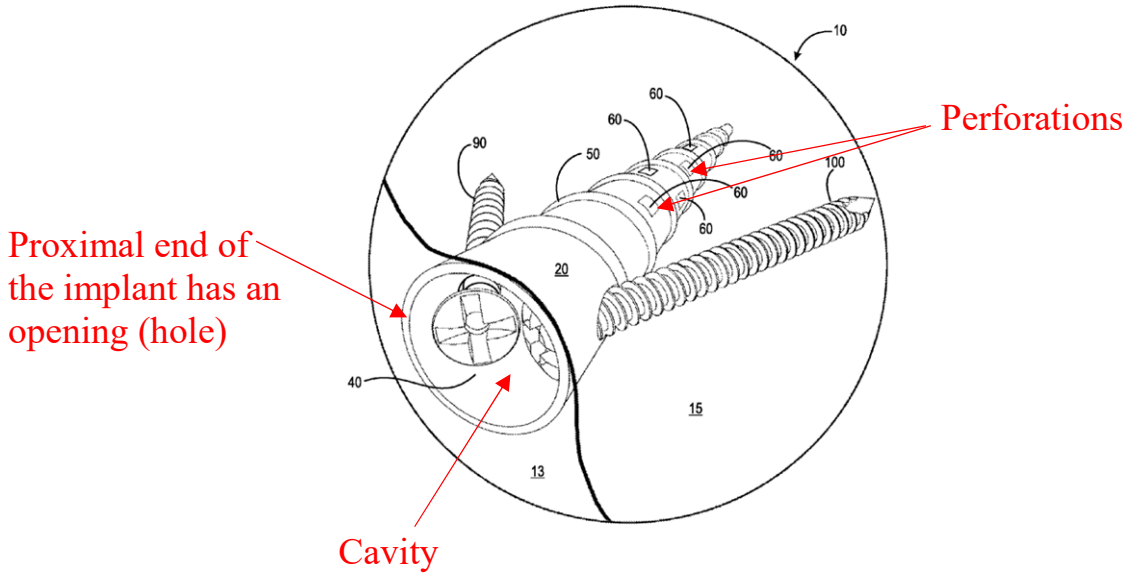


Fig. 3

g. Claim 13

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

The analysis provided with respect to the limitations [2.a.2] and [10.e.3] in Parts XII.A.1.e.(2) and XII.A.2.d.(11), *supra*, established that Stoffman teaches that the fusion implant fixes relative positions of the sacrum and ilium. Ex-1002, ¶129. Further, Figure 2 of Stoffman depicts that the fusion implant connects the sacrum to the ilium. Ex-1002, ¶129.

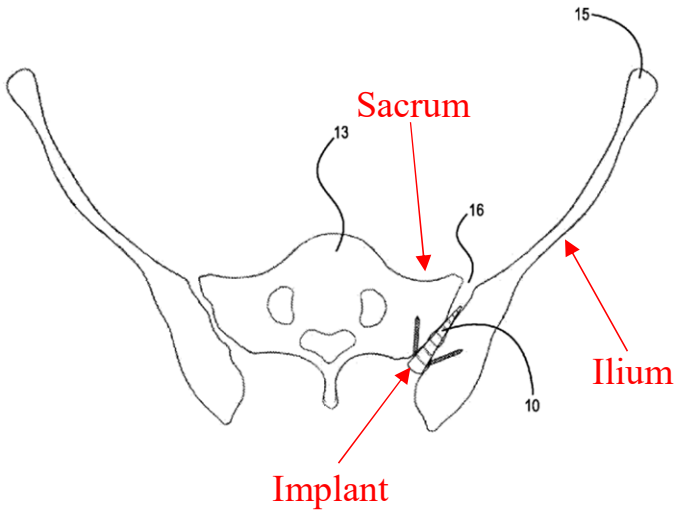


Fig. 2

h. Claim 14

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

The limitation [14.a.1] is substantively the same as [6.b.1], obviousness of which has been established in Part XII.A.1.i.(3), *supra*. Ex-1002, ¶130.

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

The limitation [14.a.2] is substantively the same as [6.a.2], obviousness of which has been established in Part XII.A.1.i.(2), *supra*. Ex-1002, ¶131.

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

The subject matter recited in the limitation [14.b] is substantively the same as the subject matter recited in claim 8, obviousness of which has been established in Part XII.A.1.k.(1), *supra*. Ex-1002, ¶132.

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

The subject matter recited in the limitation [14.c] is substantively the same as the subject matter recited in the limitation [6.b.2], obviousness of which has been

established in Part XII.A.1.i.(4), *supra*. Ex-1002, ¶133. In addition, POSA understands that when the guidance slot arrests the guide protrusion of the inserter, the inserter is prevented from moving the fusion implant further into the SI joint. *Id*.

i. Claim 15

(1) "The method of claim 10, wherein driving said fusion implant into said void comprises pushing said fusion implant into said void such that the at least one protrusion contacts said bone tissue."

Stoffman discloses an embodiment of the implant in which "body 20 could be … a square-based or triangular-based pyramid." Ex-1005 at [0033]; Ex-1002, ¶134. POSA understands that such implant is inserted via application of a linear force (pushing) rather than a rotational force. Ex-1002, ¶134. In turn, McCormack discloses that the internal actuator of the implant inserter (driver assembly) "may be adapted for *slidable longitudinal* and rotational movement relative to the driver assembly." Ex-1006 at [0255]; Ex-1002, ¶134. Accordingly, in the Stoffman-McCormack combination, the internal actuator of McCormack's implant inserter would be used to drive Stoffman's "square-based or triangular-based pyramid" by pushing the body of the implant into the SI joint. Ex-1002, ¶134. As the body of the implant is pushed into the joint, the "threading 50" (protrusion) would engage bone tissue of the sacrum and ilium. Ex-1002, ¶134.

Additionally, Stoffman discloses an embodiment, in which "first and second ancillary members 90 and 100 could have no threading at all and have some other secure means such as, a rod or a pin." Ex-1005 at [0037]; Ex-1002, ¶134. In this embodiment, the step of driving the ancillary members involves applying a linear force onto the ancillary members (i.e., pushing) to engage them with the bone tissue. Ex-1002, ¶134.

j. Claim 16

(1) "The method of claim 10, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into said hollow barrel of said surgical channel tool with said slot-engagement protrusion aligned with said interior guidance slot in the interior diameter of said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into said void."

The limitations of claim 16 are substantively the same as the limitations recited in claim 7, obviousness of which has been established in Part XII.A.1.j., *supra*. Ex-1002, ¶135.

k. Claim 17

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

The limitations of claim 17 are substantively the same as the limitations recited in claim 8, obviousness of which has been established in Part XII.A.1.k.(1), *supra*. Ex-1002, ¶136.

l. Claim 18

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

The preamble of claim 18 is the same as the preamble of claim 10, obviousness of which has been established in Part XII.A.2.d.(1), *supra*. Ex-1002, ¶137.

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

The subject matter of limitation [18.a] is substantively the same as [10.a], whose obviousness has been established in Part XII.A.2.d.(2), *supra*. *See* Ex-1002, ¶138. In addition, because Stoffman discloses that "the incision is made along the

dimple of Venus," Stoffman teaches that incision provides access to the posterior portion of the SI joint. Ex-1005 at [0043]; Ex-1002, ¶138.

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

The limitation [18.b.1] is substantively the same as [10.b.1], obviousness of which has been established in Part XII.A.2.d.(3), *supra*. *See* Ex-1002, ¶139.

(4) [18.b.2] "said working channel having a plurality of blunt tangs on a distal end thereof that are inserted between articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint,"

The limitation [18.b.2] is substantively the same as [10.b.2], obviousness of which has been established in Part XII.A.2.d.(4), *supra*. *See* Ex-1002, ¶140.

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

The limitation [18.b.3] is substantively the same as [10.b.3], obviousness of which has been established in Part XII.A.2.d.(5), *supra*. *See* Ex-1002, ¶141.

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

Obviousness of the limitation [18.c.1] has been established in the analyses set forth with respect to the limitations [10.d.1] and [10.d.2] in Parts XII.A.2.d.(7) and XII.A.2.d.(8), *supra*. *See* Ex-1002, ¶142.

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

The subject matter of the limitation [18.c.2] is recited in [10.d.1], obviousness of which has been established in Part XII.A.2.d.(7), *supra*. *See* Ex-1002, ¶143.

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

As established with respect to claim 9 in Part XII.A.2.c., *supra*, Stark teaches that the tangs of the working channel are inserted between the articular surfaces of the sacrum and ilium. Ex-1002, ¶144. POSA understands that because the tangs are parallel to the hollow barrel of the working channel, when the tangs are positioned within the SI joint, the hollow barrel is substantially parallel to the articular surfaces of the SI joint. Ex-1002, ¶144. This understanding is confirmed in Figure 26 of Stark, which depicts an implant being inserted into the SI joint via the hollow barrel of the working channel on a path that is substantially parallel to the articular surfaces of the sacrum and ilium. Ex-1002, ¶144.

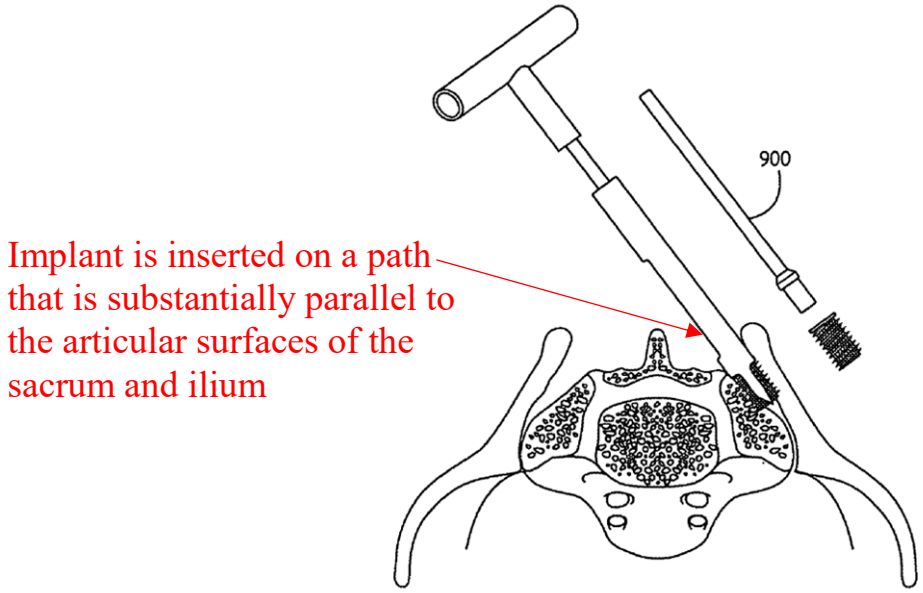


FIG. 26

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

The subject matter recited in the limitation [18.c.4] is substantively the same as the subject matter recited in [14.a.2] and [14.b], obviousness of which has been established in Parts XII.A.2.h.(2) and XII.A.2.h.(3), *supra*. *See* Ex-1002, ¶145.

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

The subject matter recited in the limitation [18.d] is substantively the same as the subject matter recited in [14.c], obviousness of which has been addressed in Part

XII.A.2.h.(4), *supra*. Ex-1002, ¶146. The only additional subject matter recited in the limitation [18.d] is that the inserter is prevented from moving the implant beyond a "pre-determined point in said sacroiliac joint." *Id*. POSA understands that when the guidance slot arrests the guide protrusion of the inserter, the inserter is necessarily prevented from moving the fusion implant beyond a pre-determined point relative to the SI joint. *Id*. Therefore, this subject matter is obvious. *Id*.

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

The subject matter recited in the limitation [18.e] is substantively the same as the subject matter recited in [10.d.2] - [10.e.2], obviousness of which has been established in Parts XII.A.2.d.(8-10), *supra*. *See* Ex-1002, ¶147.

m. Claim 19

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

The subject matter of claim 19 is substantively the same as the subject matter of [10.e.2] and [10.e.3], obviousness of which has been established in Parts XII.A.2.d.(10-11), *supra*. *See* Ex-1002, ¶148.

n. Claim 20

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

The analysis set forth with respect to claim 11 in Part XII.A.2.e.(1), *supra*, establishes that Stoffman's implant satisfies all limitations of claim 20 and therefore renders this claim obvious. Ex-1002, ¶149.

o. Claim 21

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

Stoffman teaches that "[t]he implant provides a number of significant improvements to the techniques already available, among which include a ***single*** incision approach" and further discloses that "SI joint fusion device 10 promotes the arthrodesis or fusion process." Ex-1005 at [0010], [0043] (emphasis added); Ex-1002, ¶150. POSA understands that this disclosure means that in Stoffman's SI joint fusion method only one implant is inserted into an SI joint. Ex-1002, ¶150. Figure 1 of Stoffman depicts an SI joint with a single implant positioned therein, thereby confirming this understanding. Ex-1002, ¶150.

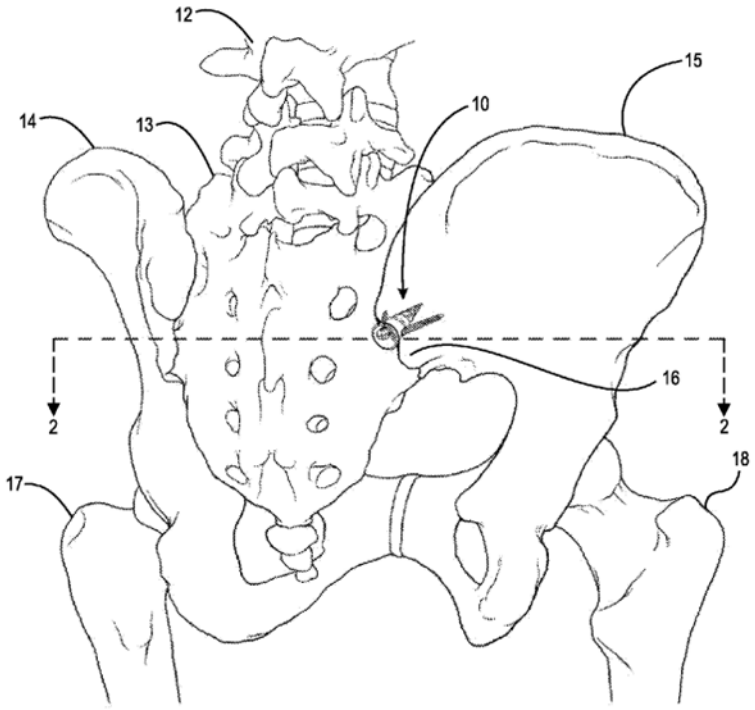


Fig. 1

p. Claim 22

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

Stoffman teaches that "a hole is drilled across SI joint," and that "a surgeon … drills holes … for placement of ancillary screw members 90 and 100 into right ilium bone 15 and sacrum 13." Ex-1005 at [0043]; Ex-1002, ¶151. POSA understands that a drilled hole has a circular shape. Ex-1002, ¶151. Stoffman teaches and POSA understands that the implant body and the ancillary screw members have

circular cross-sections. Ex-1005 at FIG. 3; Ex-1002, ¶151. Therefore, the shapes of the voids (holes) created within the SI joint are complementary to the shapes of the implant body and the ancillary screws. Ex-1002, ¶151.

With respect to the limitation of claim 22 pertaining to inserting the implant into the void, this subject matter is recited in [10.d.1] and its obviousness has been established in Part XII.A.2.d.(7), *supra*. *See* Ex-1002, ¶152. Thus, claim 22 is obvious. Ex-1002, ¶152.

q. Claim 23

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

The subject matter of claim 23 pertaining to maintaining the inserter tool in a proper orientation due to the engagement of the insertion control protrusion with the interior guidance slot is substantively the same as the subject matter of claim 17, obviousness of which has been established in Parts XII.A.2.k.(1), *supra*. Ex-1002, ¶153. Furthermore, McCormack teaches that "[t]he proximal end of the driver assembly 142 may be tapped on to fully advance the driver assembly 142 and ***properly position*** the implant 154." Ex-1006 at [0264] (emphasis added); Ex-1002, ¶153. McCormack further teaches that "[t]he advanced position of the driver assembly 142 and implant 154 within the delivery device 104 may be most clearly

seen in FIG. 13," wherein Figure 13 shows that the implant is in proper orientation for insertion into a joint. Ex-1006 at [0264] (emphasis added); Ex-1002, ¶153.

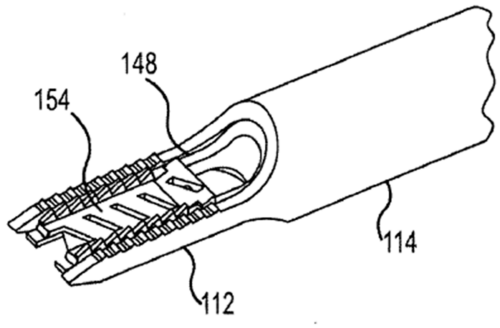


FIG.13

XIII. CONCLUSION

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

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Respectfully submitted,
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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

Pursuant to Rule 37 C.F.R. § 42.24(d), the undersigned hereby certifies that, based upon the word count of the word-processing system used to prepare this petition, the number of words in this petition complies with 37 C.F.R. § 42.24(a)(1)(i) and is 13,103. Pursuant to 37 C.F.R. § 42.24(a)(1), this word count does not include "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: January 17, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of January 2023, a copy of the attached **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,083,511**, together with all supporting materials (Exhibits 1001-1018) and all other papers filed therewith as indicated below on the Patent Owner and the attorneys of record in the co-pending litigation, at the following addresses:

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