

Exhibit 1002

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

Patent No. 11,083,511
Issue Date: August 10, 2021
Title: METHOD AND IMPLANT SYSTEM FOR SACROILIAC
JOINT FIXATION AND FUSION

Inter Partes Review No. IPR2023-00477

DECLARATION OF DR. CHRISTOPHER J. BOVINET

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

I. INTRODUCTION

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

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

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

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

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

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

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

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

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

II. QUALIFICATIONS

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

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

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

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

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

III. LEVEL OF ORDINARY SKILL IN THE ART

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

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

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

IV. RELEVANT LEGAL STANDARDS

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

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

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

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

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

A. Person of Ordinary Skill In the Art

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

B. Prior Art

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

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

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

C. Obviousness

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

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

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

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

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

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

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

D. Claim Construction

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

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

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

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

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

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

E. Priority

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

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

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

V. THE '511 PATENT

A. Overview

39. The ‘511 Patent is directed to a method for repairing a sacroiliac joint (“SI joint”) of a patient. Ex. 1001 at 2:15-40. The ‘511 Patent has three independent claims: claims 1, 10, and 18, all of which recite generic steps of an SI joint fusion procedure via a posterior approach, including (1) creating an incision proximal to the patient’s SI joint, (2) inserting a working channel into the incision, (3) creating a void within the SI joint, and (4) inserting a fusion implant into the created void. *Id.* at 41:64-13; 43:4-39; 44:24-64. Independent claims 1, 10, and 18 specify that the working channel (commonly referred to in the art as a “surgical cannula” or simply “cannula”) must have at least one tang on its distal end. ‘511 Patent at 42:7 (“at least one tang”); 43:9-11 (“two bilateral blunt tangs”); 44:31-32 (“a plurality of blunt tangs”). All three independent claims further specify that the working channel must have “an interior guidance slot in an interior diameter of said hollow barrel ... [that] does not traverse an outer diameter of said hollow barrel.” *Id.* at 42:3-5; 43:17-24; 44:37-43. The functionality of this interior guidance slot is claimed as follows: “for controlling the advancement of surgical tools” (claim 1) or “for controlling a depth of advancement of surgical tools ... and maintaining said surgical tools in proper orientation for insertion into said incision” (claims 10 and 18). *Id.* at 42:5-6; 43:19-22; 44:38-41.

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

FIG. 30

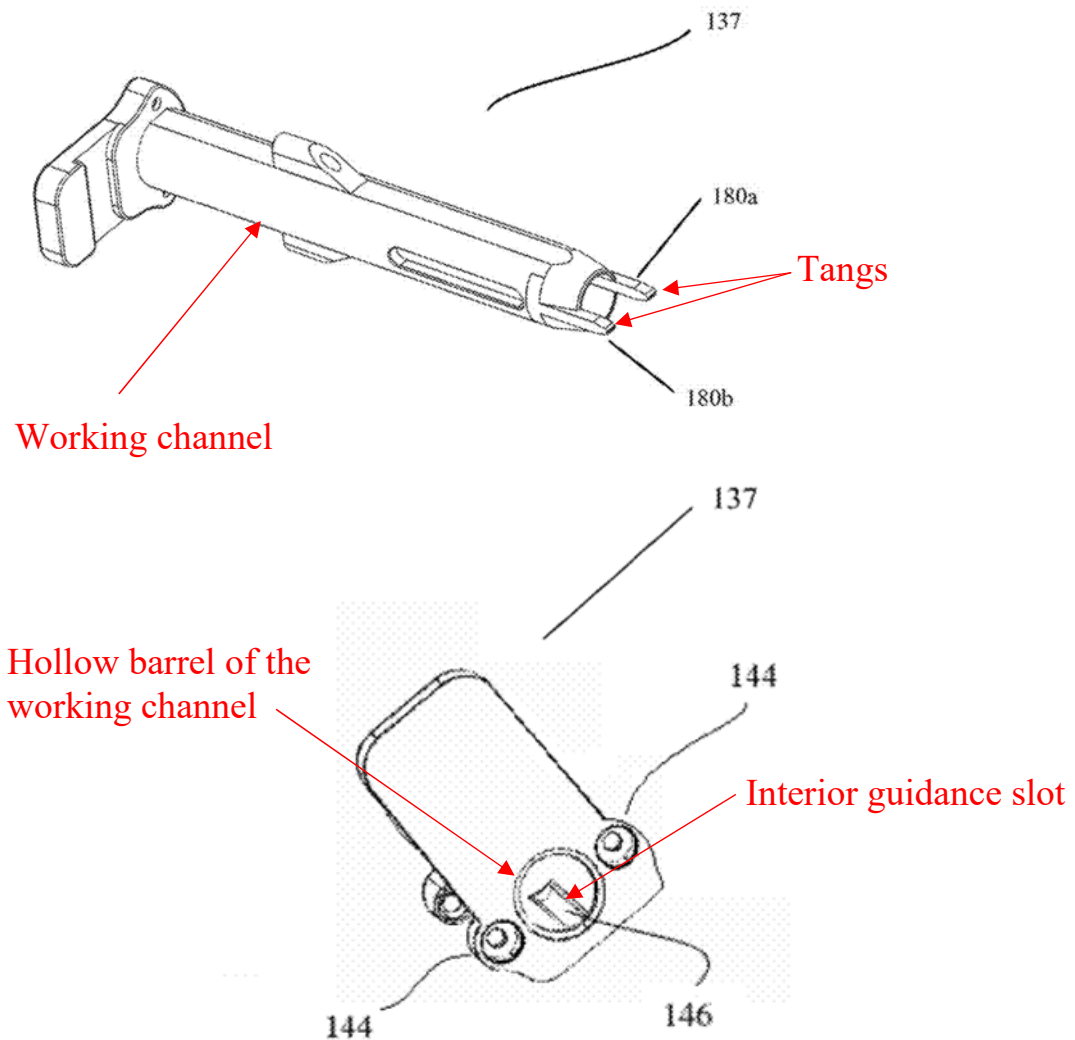


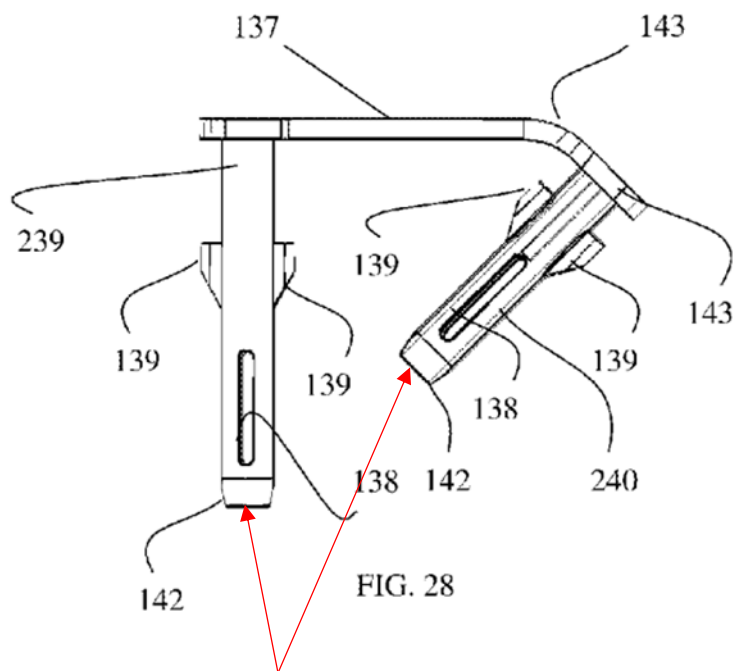
FIG. 29

B. Priority Date of the '511 Patent

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

2015, which is a continuation-in-part of the U.S. Patent No. 9,119,732 ('732 Patent) filed on March 15, 2013.

42. All independent claims of the '511 Patent recite a working channel with tangs. Ex. 1001 at 42:7 ("at least one tang"); 43:9-11 ("two bilateral blunt tangs"); 44:31-32 ("a plurality of blunt tangs"). Upon my review of the '732 Patent, I have concluded that the '732 Patent does not mention anything pertaining to this structural feature of the working channel. To the contrary, all figures of the '732 Patent show the working channel with a flat distal end, most clearly visible in the elevation drawing provided in Fig. 28:



Flat distal ends with no tangs

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

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

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

C. Summary of the challenged claims

45. Independent claim 1 is a representative claim of the ‘511 Patent. This claim is reproduced and annotated in color below. The subject matter recited in this claim can be categorized as follows: (1) well-known steps for implanting a fusion implant into an SI joint (**emphasized in green**); (2) a conventional working channel with tangs (**emphasized in blue**); (3) a guidance slot for controlling advancement of the surgical tools (**emphasized in purple**); and (4) a fusion implant with bone-engaging protrusions for preventing pullout from the joint (**emphasized in orange**).

[1 pre] A method for repairing a sacroiliac joint of a patient,
comprising:

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

joint;

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

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

VI. OVERVIEW OF THE PRIOR ART

A. U.S. Patent Publication No. 2014/0207240 (“Stoffman”) (Ex. 1005)

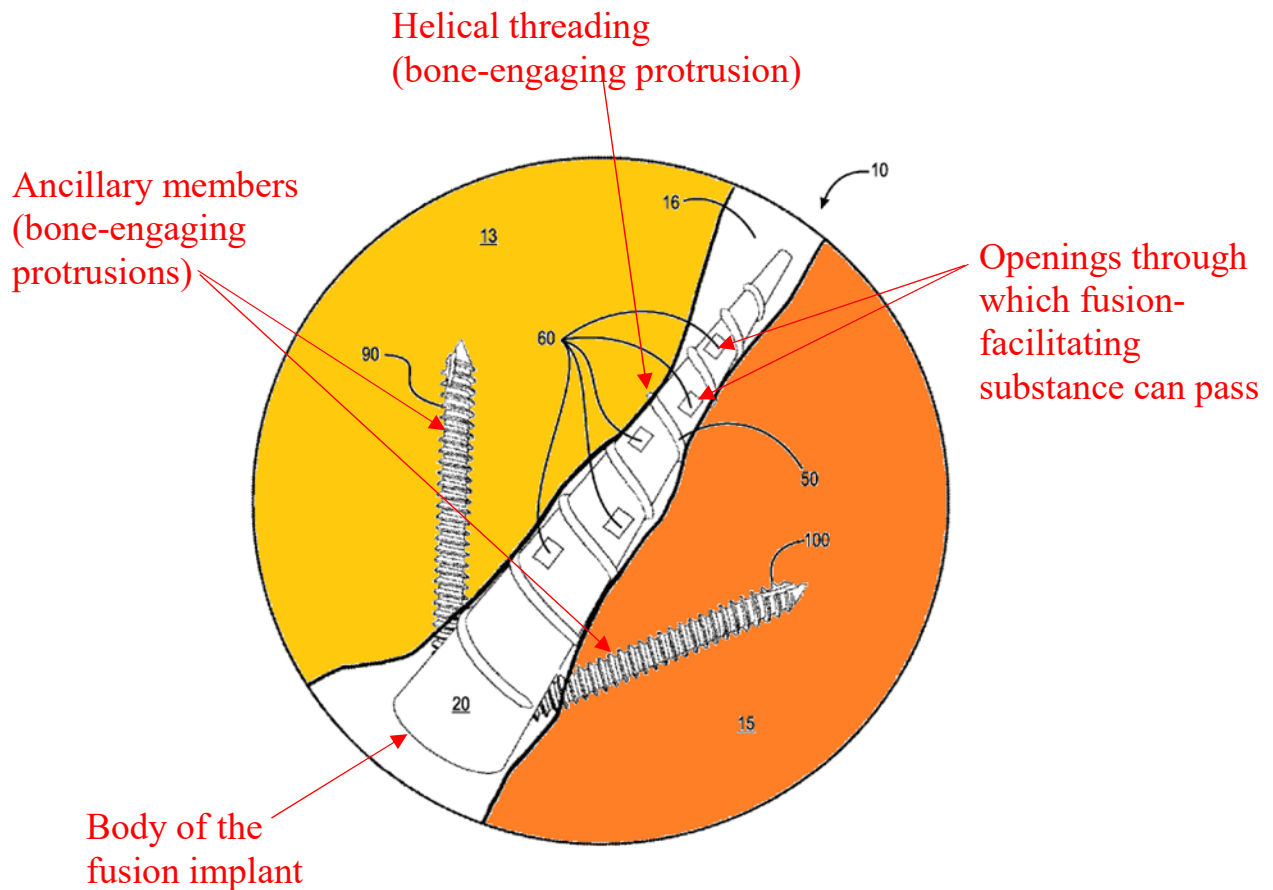
47. Stoffman is a prior art published patent application filed on January 24, 2013 and published on July 24, 2014.

1. Fusion implant with bone-engaging protrusions

48. Stoffman discloses:

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 through which fusion-facilitating substances can pass.

Ex. 1005 at [0033]. Stoffman also teaches an implant embodiment that has a “segmented” proximal end (“open end 40”), which means the implant has slots on the proximal end. Ex. 1005 at [0036]. An annotated version of the implant in Figure 4 is Stoffman is provided below (for ease of reference, the sacrum is emphasized in light orange and the ilium is emphasized in dark orange).



2. Sacroiliac joint fusion method

49. Stoffman discloses a method of fusing/repairing a sacroiliac joint via a fusion implant as described above. Stoffman discloses a posterior approach where “an incision is made to access SI joint 16 ... Preferably, the incision is made along the dimple of Venus.” Ex. 1005 at [0043]. Stoffman also discloses creating a void within the sacroiliac joint for 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].

50. Stoffman further discloses inserting a fusion implant through a working channel/cannula, wherein “SI joint fusion device 10 is guided within a guide tube to protect the surrounding soft tissue.” Once the implant is inserted into the sacroiliac joint, “a surgeon taps and places ancillary screw members 90 and 100, respectively, into right ilium bone 15 and sacrum 13.” Ex. 1005 at [0043]. The ancillary screw members (protrusions that engage bone tissue) help “effectively immobiliz[e] SI joint 16.” Once inserted into the sacroiliac joint, the “SI joint fusion device 10 promotes the arthrodesis or fusion process.” Ex. 1005 at [0043].

51. Figure 2 of Stoffman shows a schematic top view of a sacroiliac joint with the Stoffman implant inserted therein, a copy of which is annotated and produced below.

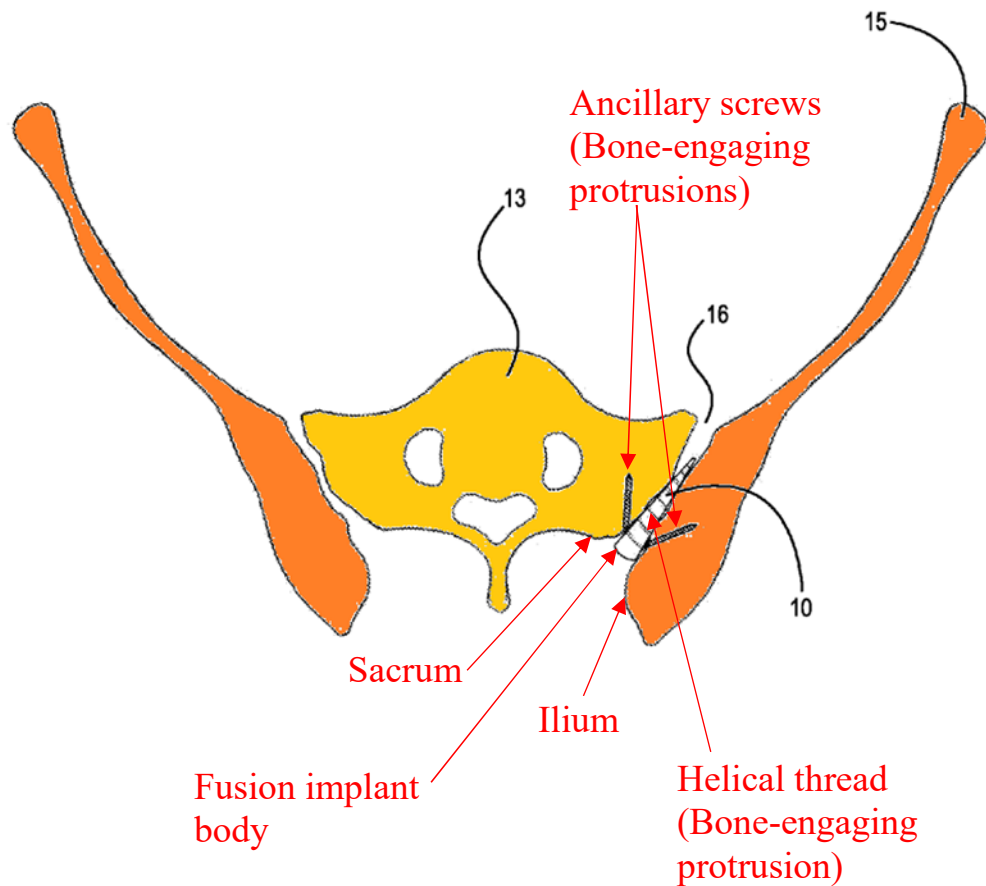


Fig. 2

B. U.S. Patent Publication No. 2010/0191241 (“McCormack”) (Ex. 1006)

52. McCormack is a published patent application that is prior art to the ‘511 Patent because McCormack was filed on December 10, 2009 and published on July 29, 2010.

1. Working channel/cannula

53. McCormack discloses a set of surgical tools used for inserting an implant into a joint. The McCormack surgical tool set includes a working channel/cannula (“delivery device 104” that has a hollow barrel (“tubular shaft 114”) and bilateral tangs (“anchoring forks 112”) on the distal end. Ex. 1006 at [0238]. Figure 95A of McCormack discloses that the bilateral tangs (“Anchoring forks 112”) may have blunt (“bull-nose”) tips as depicted below.

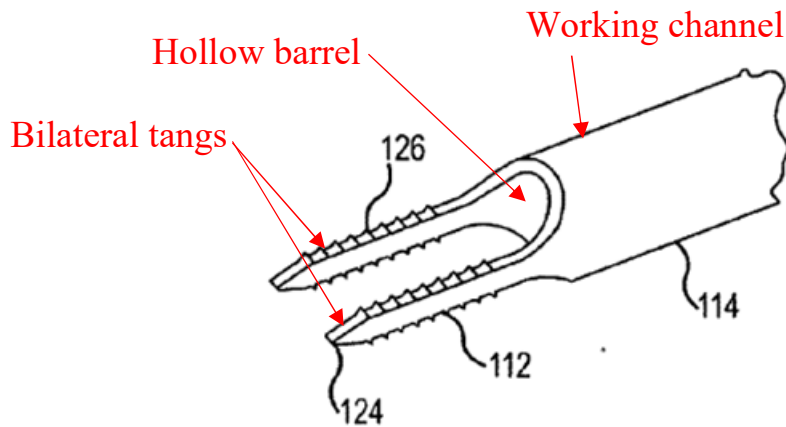
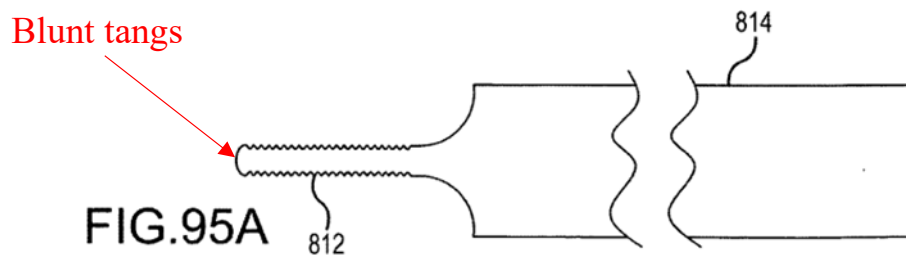


FIG. 2



2. Implant inserter

54. McCormack’s surgical tool set also includes an implant inserter (“driver assembly 142”) that is used to insert the implant into the joint through the

working channel/cannula. Ex. 1006 at [0250]. The implant inserter uses “implant holding arms 148” that engage with “U-shaped receiving feature slots 160 on the lateral edges of the implant” to hold the implant during insertion into the joint. Ex. 1006 at [0250]. McCormack also teaches

[a]dditionally, the implant holding arms [] can be adapted to hold the implant from behind rather than from the sides. That is, the arms [] can pass within the implant and remain within the width defined by the implant. This allows the driver assembly [] to have a smaller size ... and also allows the [working channel] to have a smaller size.

Ex. 1006 at [0423].

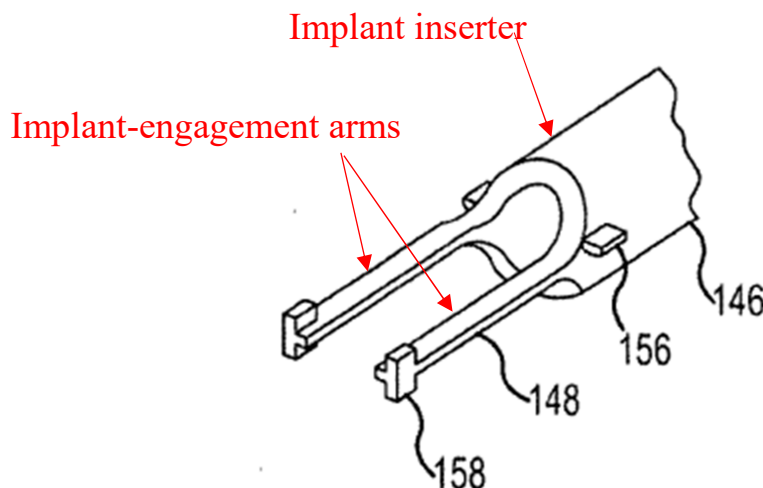


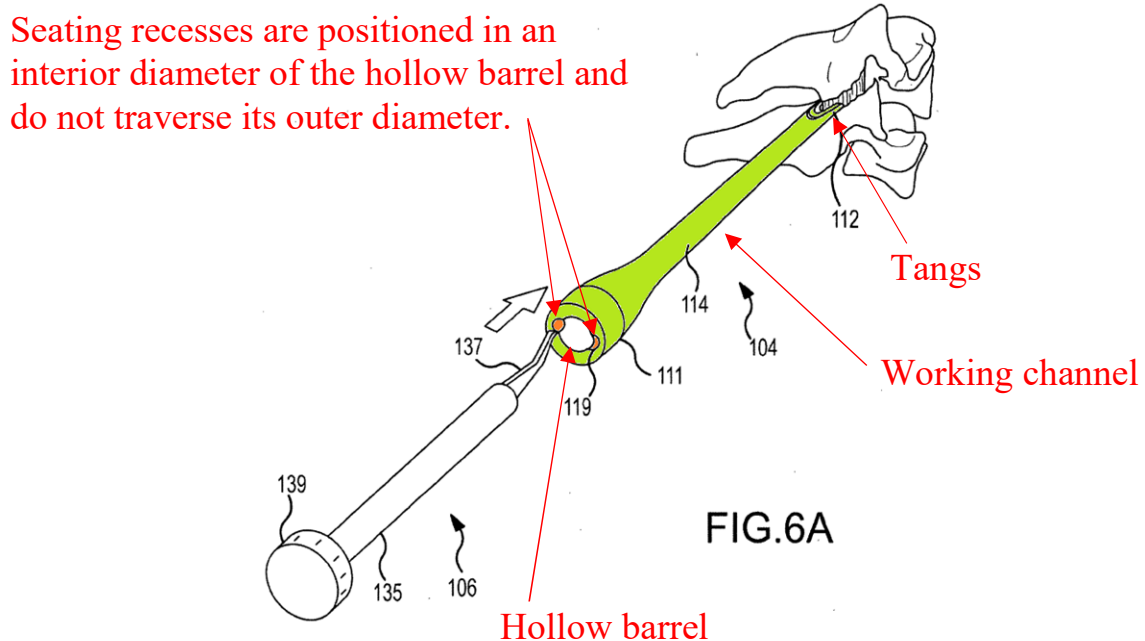
FIG.10

3. Guidance slot

a) “Seating recess”

55. McCormack discloses an embodiment of a working channel/cannula where the proximal end of the working channel/cannula has “*seating* recesses 119”

positioned on “the inner surface of the bore,” and the surgical tools have “positionally matched *protrusions*.” Ex. 1006 at [0240]. McCormack teaches that these seating recesses and corresponding protrusions “may allow for *orienting the devices* properly relative to the forks 112 positioned in the ... joint.” Ex. 1006 at [0240] (emphasis added). Figure 6A of McCormack shows the seating recesses within an interior diameter of the hollow barrel and not traversing the outer diameter of the hollow barrel.



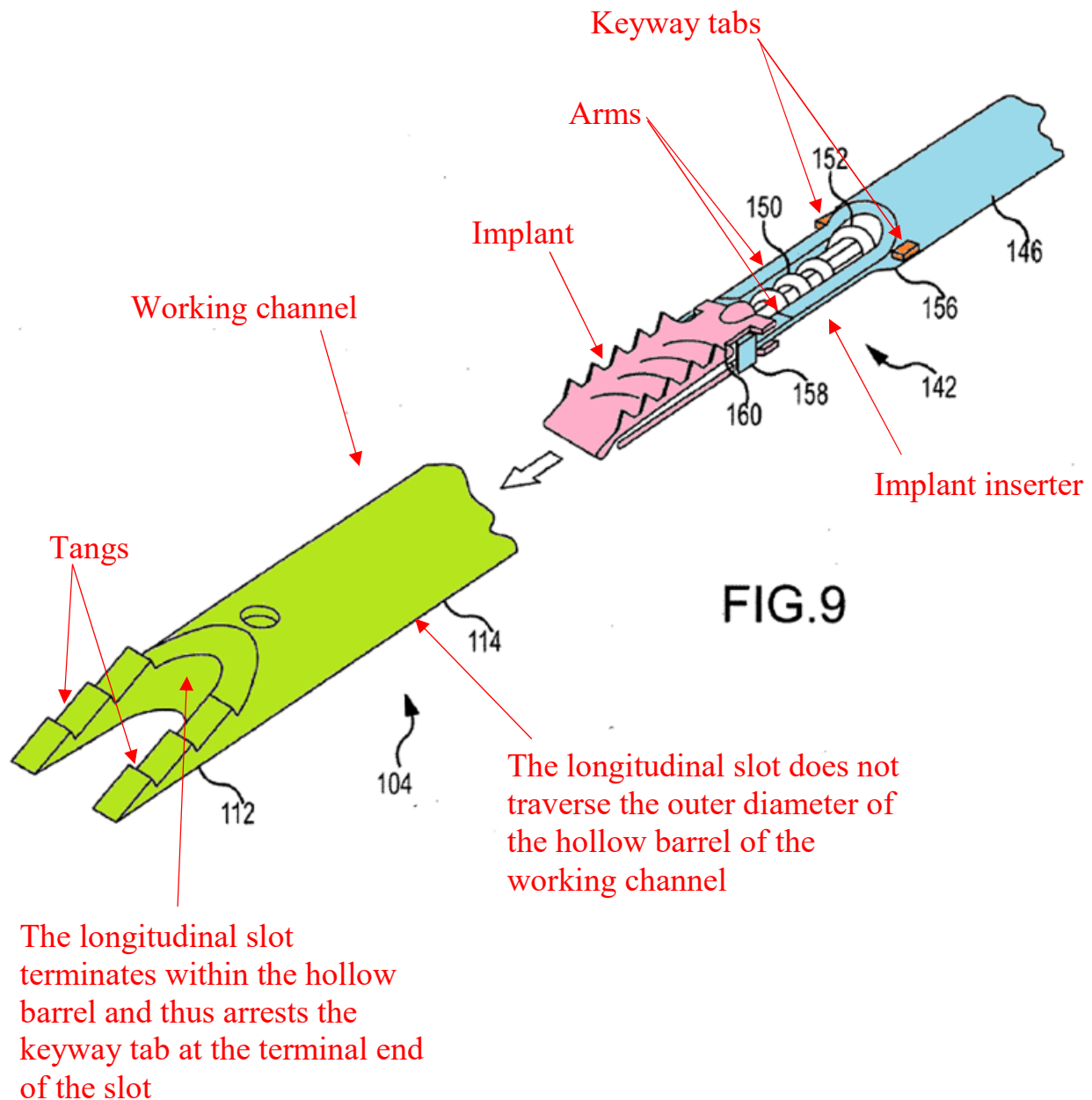
56. A person of ordinary skill in the art would have understood that even though McCormack’s description of “seating recesses” discusses controlling the orientation of tools, the term “**seating**” clearly conveys that once the protrusions *seat* themselves into the seating recesses, the seating recesses prevent the tools from

advancing any further into the working channel/cannula (and thus, the joint). McCormack teaches that “the 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). Thus, a person of ordinary skill in the art would have understood that the “seating recesses 119” in Figure 6A control both the depth of advancement of surgical tools within the working channel/cannula and the orientation of the tools within the working channel/cannula.

b) “Keyway feature”

57. McCormack also discloses “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). The “keyway feature 156” comprises: (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). Figure 9 of McCormack, which is a close-up view of the distal ends of the working channel and the implant inserter, shows that the longitudinal slot is positioned entirely within an interior diameter of the working channel’s/cannula’s hollow barrel and does not traverse the outer diameter of the hollow barrel of the working

channel/cannula (as evidenced by the fact that the longitudinal slot is concealed from the exterior view depicted in Figure 9).



58. Figure 9 of McCormack shows the keyway tab positioned near the distal end of the inserter. Figure 9 also shows the longitudinal slot not extending to

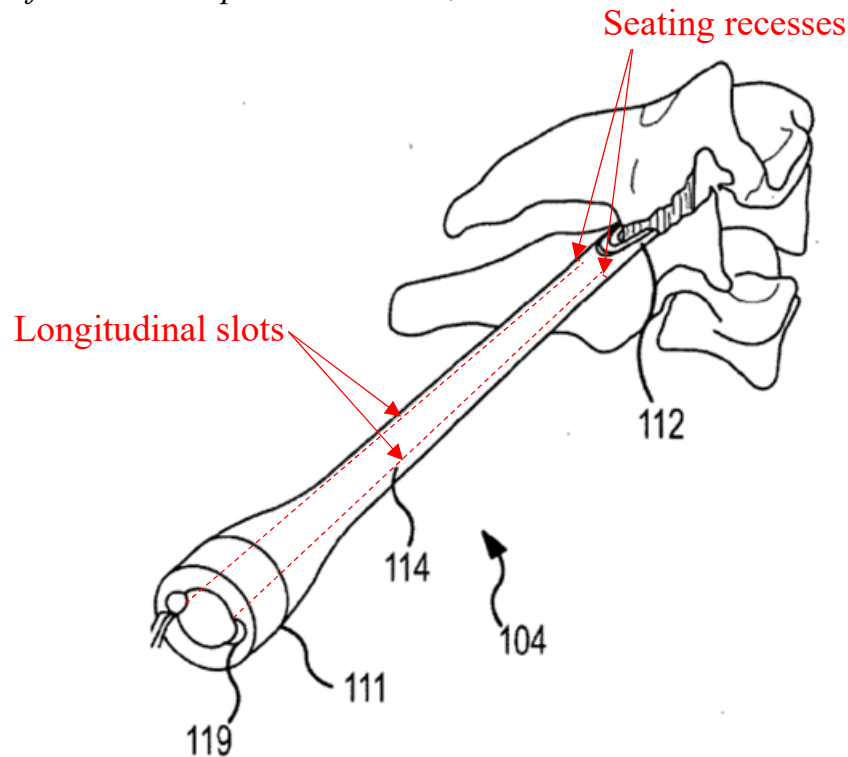
the distal end of the working channel's interior hollow barrel, meaning the longitudinal slot terminates within the hollow barrel of the working channel/cannula prior to approaching the distal end of the working channel/cannula. Thus, Figure 9 of McCormack conveys to a person of ordinary skill in the art that the tabs of the inserter will slide with the longitudinal slots within the working channel/cannula's hollow barrel until the tabs on the inserter are stopped by the terminal end of the longitudinal slots, at which point the tabs of the inserter are prevented from moving any further down the working channel and thus the inserter is arrested from moving farther into the joint. Therefore, McCormack conveys that longitudinal slots of the keyway features are configured to control both the depth of advancement or surgical tools and the orientation of surgical tools relative to the working channel/cannula as they are inserted into a joint.

c) Combination of the “seating recesses” and the “longitudinal slot”

59. Figure 6A of McCormack shows an embodiment of the working channel/cannula where the “Seating recesses” are located on the proximal end of the hollow barrel of the working channel/cannula. Ex. 1006 at Fig. 6. However, the embodiments shown in figures 9 and 10 show keyway tabs positioned on a distal end of an inserter. Ex. 1006 at Figs. 9, 10. To configure the working channel in figure 6A to work with the inserter embodied in figures 9 and 10, a person of ordinary skill

in the art would have been motivated to combine the “seating recesses” with the “longitudinal slots” (which are configured for engaging and guiding the keyway tabs of the inserter). *See* Ex. 1006 at [0251]. McCormack expressly teaches “**seating** the driver assembly in the delivery device thereby positioning the implant between the forks of the delivery device and in the ... joint,” and therefore provides motivation for adapting the “seating recesses” of the delivery device (working channel/cannula) to establish a “seating relationship” with the keyway tabs of the driver assembly (implant inserter). Ex. 1006 at [0046] (emphasis added).

60. Combining the “seating recesses” with the “longitudinal slots” simply results in extending the length of the “seating recesses” within the hollow barrel of the working channel/cannula. The predictable result of this combination is illustrated in an annotated version of figure 6A of McCormack below.



61. When the inserter (driver assembly) is fully inserted into the working channel/cannula (Delivery device) in this combination, the tabs of the inserter would seat within the “seating recesses” at the end of the longitudinal slots. As explained earlier, McCormack teaches that “the *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). Therefore, combining the “seating recesses” and the “longitudinal slots” would have predictably resulted in a “guidance slot” that controls the depth of advancement of

surgical tools while also controlling orientation of the surgical tools and maintaining them in proper orientation with respect to the working channel/cannula and the joint.

d) Obvious to try

62. To a person of ordinary skill in the art, it would have been obvious to try adapting the longitudinal slots of McCormack to control the depth of advancement of surgical tools relative to the working channel/cannula and sacroiliac joint.

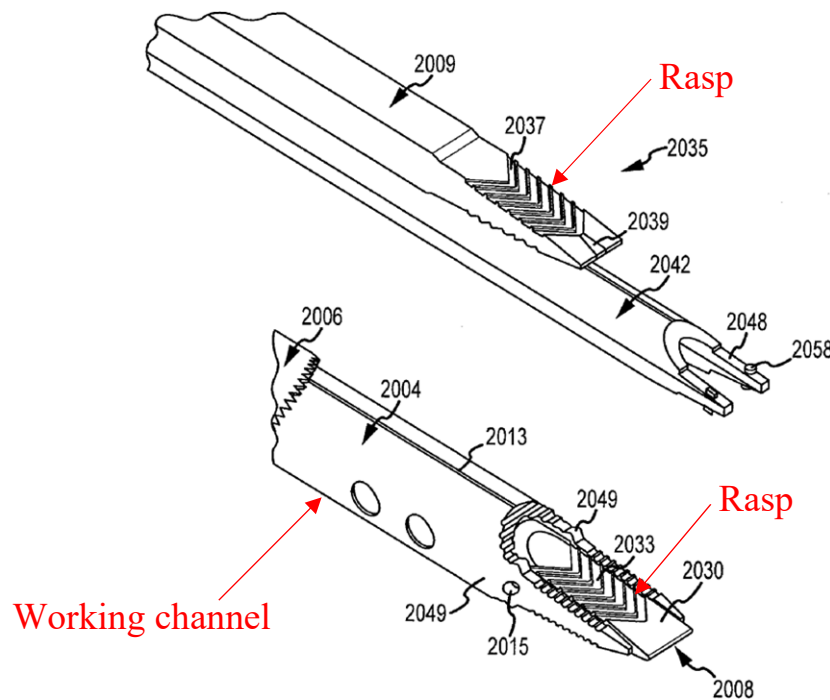
63. McCormack explains there is a well-known need for surgical tool sets to have a “mechanical engagement” to control the positioning of implants within a joint rather than relying on a particular surgeon’s judgement or skill. Ex. 1006 at [0421] (“[O]nce the delivery device [] is properly positioned, 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.”). Importantly, preventing surgical tools and implants from over-penetrating a joint was a well-known concern 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 members that pass close to the sacroiliac joint.”).

64. McCormack discloses multiple ways of potentially controlling the depth of insertion of surgical tools and implants in a working channel/cannula via a mechanical engagement between the cannula and the tools. McCormack discloses one such way by creating a “seating relationship” between a structural feature of the working channel/cannula and the surgical tools that get inserted into the working channel/cannula that prevent the surgical tools from “being inserted too far.” Ex. 1006 at [0376].

65. A person of ordinary skill in the art would have had a reasonable expectation of success in adapting the longitudinal slot to create a “seating relationship” with the keyway tabs of the inserter to effectively control the depth of advancement of the inserter into the joint via a “mechanical engagement.” To create the “seating relationship,” a person of ordinary skill in the art would have only needed to create a pre-determined length for the longitudinal slot within the working channel/cannula. The “seating relationship” between the keyway tab of the inserter and the longitudinal slot of the working channel/cannula would have then predictably ensured proper depth of insertion and orientation of the implant and surgical tools within the joint and would have prevented over-penetration of the joint.

4. Rasp

66. McCormack discloses a chisel device with 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]. McCormack also states 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]. This description of the chisel head provided in McCormack teaches a “rasp.”



C. U.S. Patent Pub. No. 2009/0216238 (“Stark”) (Ex. 1007)

67. Stark is a published patent application that was filed on February 27, 2008 and published on August 27, 2009 and therefore is prior art against the ‘511 Patent.

68. Stark conveys that it was well-known to one of ordinary skill in the art that when a working channel/cannula with tangs is used in a sacroiliac joint fusion procedure, the tangs of the working channel/cannula are inserted between the articular surfaces of the sacrum and the ilium to stabilize the working channel/cannula relative to the sacroiliac joint. Stark specifically teaches “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]. Stark also states “the tangs can have different shapes,” and Figure 10 shows an embodiment of Stark’s working channel/cannula with rounded tangs (projections). Ex. 1007 at [0072].

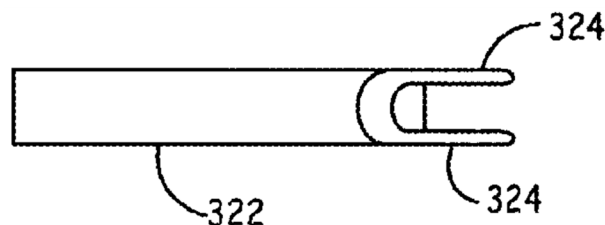


FIG. 10

69. Figure 9A of Stark shows “a top view into the sacroiliac joint showing a set of inserted tangs into the joint.” Ex. 1007 at [0022].

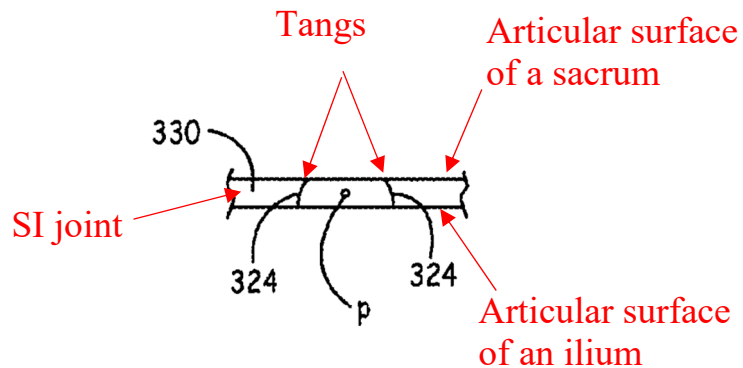
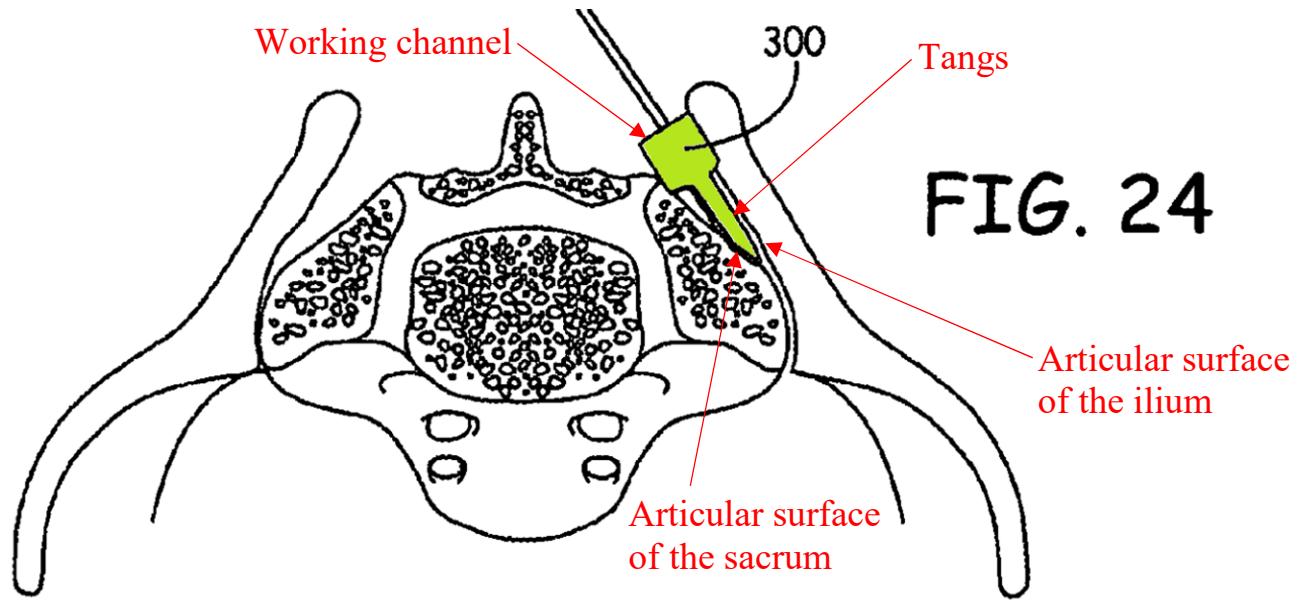


FIG. 9A

70. Figure 24 of Stark shows a schematic view of the tangs of the working channel/cannula inserted into the sacroiliac joint between the articular surfaces of an ilium and a sacrum.



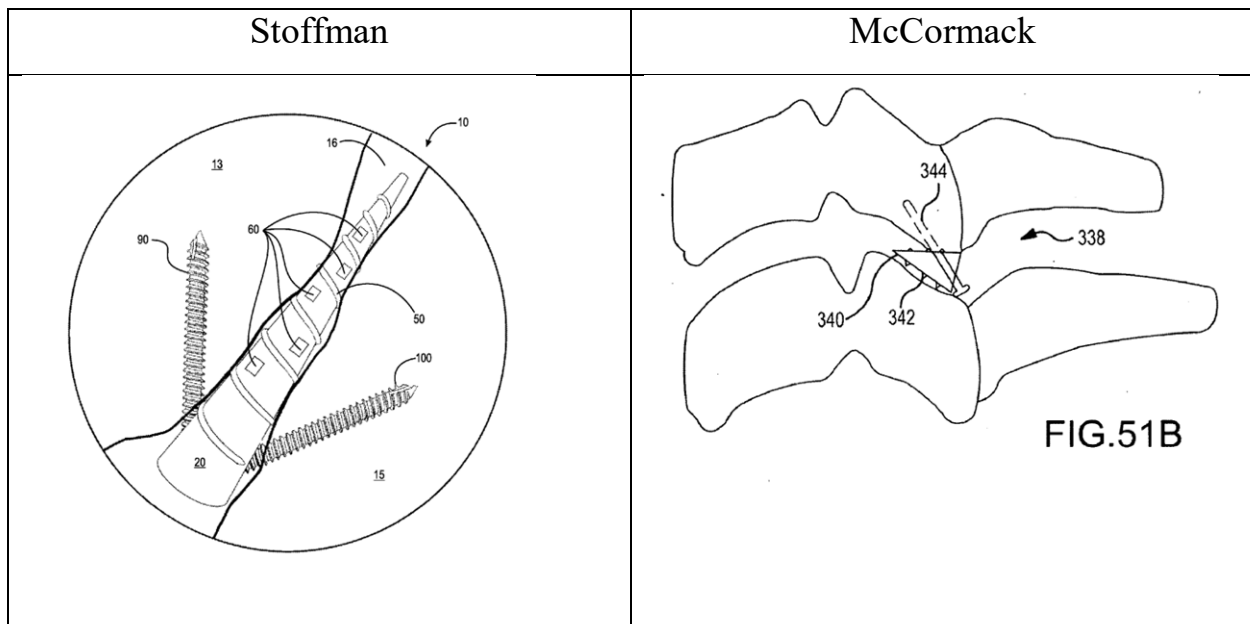
D. Combination of Stoffman and McCormack

1. Motivation to combine

71. A person of ordinary skill in the art would have been motivated to combine Stoffman's implant and method of sacroiliac joint fusion with McCormack's surgical tools. Stoffman clearly discloses a method of performing sacroiliac joint fusion including an implant for the sacroiliac joint but does not disclose the tools for performing the method. However, Stoffman does disclose that during insertion "SI joint fusion device 10 [can be] guided within a guide tube to protect the surrounding soft tissue." Ex. 1005 at [0043]. A person of ordinary skill in the art would have understood that it is important to protect the surrounding tissue during an SI joint fusion surgery and, thus, would have been motivated to use surgical tools that involve a working channel/cannula (guide tube) and the remaining

tools (e.g., implant inserter, rasp, driving tool) that are configured to operate within the working channel/cannula (guide tube). This motivation would have lead to McCormack, which discloses a surgical tool set that is configured to insert an implant into a joint through a working channel/cannula (guide tube).

72. McCormack also teaches that its surgical tool set can be used with similar implants such as Stoffman's. A comparison is provided below.



73. The implant depicted in figure 51B of McCormack is described as having 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]. Stoffman’s implant shares similar 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]. Therefore, a person of ordinary skill in the art would have been motivated to use Stoffman’s sacroiliac joint implant and method in combination with McCormack’s surgical tool set.

2. Predictable result

74. The combination of Stoffman and McCormack would have yielded a predictable result where known components would have performed their intended functions. For example, McCormack’s working channel/cannula (Delivery device) would have been used as the “guide tube” described in Stoffman. Additionally, McCormack’s implant inserter (driver assembly) would have been used to insert the implant described in Stoffman into the sacroiliac joint through the working channel/cannula. McCormack’s inserter has implant engagement arms that are configured to “hold the implant from behind” and, thus, the slotted (“segmented”)

proximal end of Stoffman's implant would be perfectly compatible with McCormack's inserter arms.

75. Stoffman's method includes "drilling" the tapered implant body into the sacroiliac joint, and McCormack teaches an "internal actuator" of the implant inserter (driver assembly) that is "adapted for slidable longitudinal and rotational movement relative to the driver assembly." Ex. 1005 at [0010]; Ex. 1006 at [0255]. McCormack further teaches that the "internal actuator" can have "various driving engagements [] known in the art including flat screwdriver types, phillips head types, square drive, etc." Ex. 1006 at [0255]. Thus, once the implant inserter of McCormack is used to insert the implant into the sacroiliac joint, the "internal actuator" can then be used to drill/drive Stoffman's implant into its final intended location within the sacroiliac joint. McCormack also discloses a "turning tool" that could also drive Stoffman's implant and/or ancillary screws into the sacrum and ilium after the implant is inserted into an SI joint using the implant inserter (driver assembly). Ex. 1005 at [0323]; Fig. 81C.

76. Stoffman also teaches creating a void within the sacroiliac joint by removing "cartilaginous end plates of SI joint" but does not disclose the tool used to create the void. McCormack teaches a chisel tool with ridges (rasp), 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]. A person of ordinary skill in the art would have predictably used McCormack's chisel with ridges (rasp) to remove cartilage and tissue from within the sacroiliac joint.

77. As stated above, a person of ordinary skill in the art would have been motivated to use Stoffman's sacroiliac joint fusion method and implant with the surgical tools of McCormack. Because the implants of Stoffman and McCormack are structurally similar, a person of ordinary skill in the art would have had a reasonable expectation of success in combining Stoffman and McCormack. This combination would have predictably resulted in an SI joint fusion method in which Stoffman's implant and McCormack's tools would have been used in accordance with their known and intended functions as described above.

78. A claim-by-claim analysis rendering obvious claims 1-8 in view of the combination of Stoffman and McCormack is provided below.

E. Combination of Stoffman, McCormack, and Stark

1. Motivation to combine

79. Section VI(D), *supra*, established that it would have been obvious to one of skill in the art to use McCormack's working channel/cannula as the "guide tube" mentioned in Stoffman. In the Stoffman-McCormack combination, McCormack's working channel/cannula with tangs would be used to insert the implant of Stoffman into the sacroiliac joint of a patient. A person of ordinary skill

in the art would have been motivated to combine the Stoffman-McCormack combination with Stark because Stark teaches a method of sacroiliac joint fusion using a working channel/cannula with tangs to insert an implant into the sacroiliac joint.

2. Predictable result

80. The combination of Stoffman, McCormack, and Stark would have led to a predictable result where well known components would have performed their known and intended functions. The tangs of McCormack's working channel/cannula would have been inserted into the sacroiliac joint between the articular surfaces of an ilium and a sacrum, as taught by Stark, to secure the working channel/cannula in place relative to the sacroiliac joint and provide a path for Stoffman's implant to be inserted into the sacroiliac joint through the working channel/cannula.

VII. CLAIM ANALYSIS

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

1. Claim 1

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

81. Stoffman states 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].

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

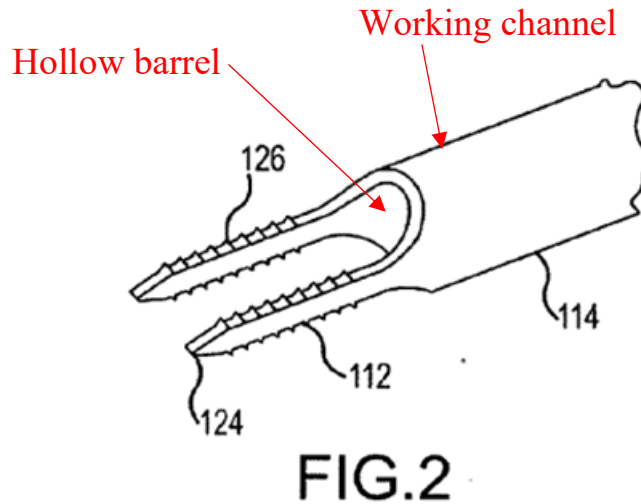
82. Stoffman teaches that “an incision is made to access SI joint.” Ex. 1005 at [0043].

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

83. Stoffman teaches that an “SI joint fusion device 10 is guided within a guide tube to protect the surrounding soft tissue.” Ex. 1005 at [0043]. A person of ordinary skill in the art would have understood that in order for the fusion implant (SI joint fusion device) to be guided into the sacroiliac joint, the working channel/cannula (guide tube) must have been inserted into the incision proximal to the patient’s sacroiliac joint.

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

84. Section VI(D), *supra*, establishes that it would have been obvious to a person of ordinary skill in the art to use McCormack’s working channel/cannula (delivery device 104) as the “guide tube” disclosed in Stoffman. McCormack discloses a working channel/cannula having a “generally tubular shaft 114” and further discloses that “tubular shaft 114 may have an annular shaped cross-section with an inner radius and an outer radius.” Ex. 1006 at [0238]. Figure 2 of McCormack showing the hollow barrel of the working channel/cannula is annotated and reproduced below.



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

85. Section VI(B), *supra*, establishes that McCormack teaches or suggests an interior guidance slot within a working channel/cannula for controlling the advancement of surgical tools.

86. McCormack teaches two types of interior guidance slots that control the depth and orientation of surgical tools as they are passed through a working channel/cannula and into a joint: (1) “seating recesses” positioned on the “the inner surface of the bore” and (2) “a keyway feature” 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. McCormack teaches that both the “longitudinal

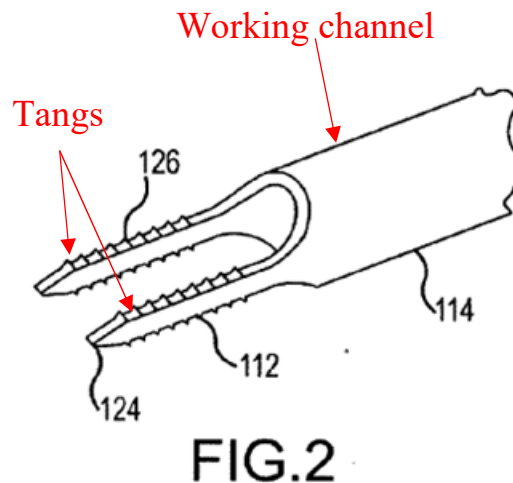
slots” and “seating recesses” control the orientation of surgical tools relative to the working channel/cannula (delivery device). Ex. 1006 at [0240] (“[T]he recesses 119, may allow for orienting the [surgical] devices properly ... one or several orientations may be controlled.”); [0251] (“[K]eyway feature 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.”)

87. As explained above, the term “**seating** recesses” conveys to one of ordinary skill in the art that when the surgical tool advances within the working channel/cannula, the protrusions on the shaft of the surgical tool would become **seated** within the “seating recesses” of the working channel/cannula, thereby preventing further advance of the surgical tools. McCormack expressly teaches “**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). Thus, the seating relationship between the protrusions and the seating recesses stops the advancement of surgical tools within the working channel/cannula. McCormack corroborates this by generally explaining 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).

88. There are four rationales in Section VI(B)(3), *supra*, that explain why McCormack teaches an “interior guidance slot ... for controlling advancement of surgical tools.” **First**, the “seating recesses” disclosed in Paragraph [0240] and Figure 6A of McCormack render obvious an interior guidance slot for controlling both the depth of advancement and orientation of surgical tools as they are passed through a working channel/cannula. **Second**, the “keyway feature” and corresponding “longitudinal slot” on the interior of the working channel/cannula discussed in Paragraph [0251] of McCormack are expressly used for controlling the orientation for surgical tools (“delivery assembly 142”), while Figure 9 of McCormack conveys to one of ordinary skill in the art that the “longitudinal slot” controls the depth of advancement of surgical tools. **Third**, a combination of McCormack’s “seating recesses” and “longitudinal slot” teaches a guidance slot that controls the depth of advancement and orientation of surgical tools within the working channel/cannula. **Fourth**, modifying the “longitudinal slot” of McCormack to control the depth of advancement as well as the orientation of surgical tools would have been obvious to one of ordinary skill in the art under the “obvious to try” rationale.

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

89. McCormack's working channel has "anchoring forks 112 at a distal end." Ex. 1006 at [0238]; Fig. 2.



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

90. Stoffman discloses that once the incision is made, "[t]he cartilaginous end plates of SI joint 16 are removed and a hole is drilled across SI joint." Ex. 1005 at [0043]. Stoffman further 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." *Id.*

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

91. Stoffman teaches that after creating a void/cavity within the sacroiliac joint, a fusion implant is guided into place through the working channel/cannula Ex.

1005 at [0043]. A person of ordinary skill in the art would have understood that this step requires inserting the fusion implant into the “hole [] drilled across SI joint.”

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

92. Stoffman discloses a fusion implant body having “threading 50 [that] could comprise a plurality of *protrusions*” and that the threading is intended to “*help secure* SI joint fusion device 10 between sacrum 13 and right ilium bone 15.” Ex. 1005 at [0033] (emphasis added). Stoffman further discloses 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). Thus, Stoffman teaches a fusion implant with bone-engaging protrusions (the threading and the ancillary members) that penetrate the bone tissue and prevent pullout of the implant from the sacroiliac joint. Figure 4 of Stoffman, which clearly depicts the implant, is annotated and reproduced below (the sacrum is emphasized in light orange and ilium is emphasized in dark orange).

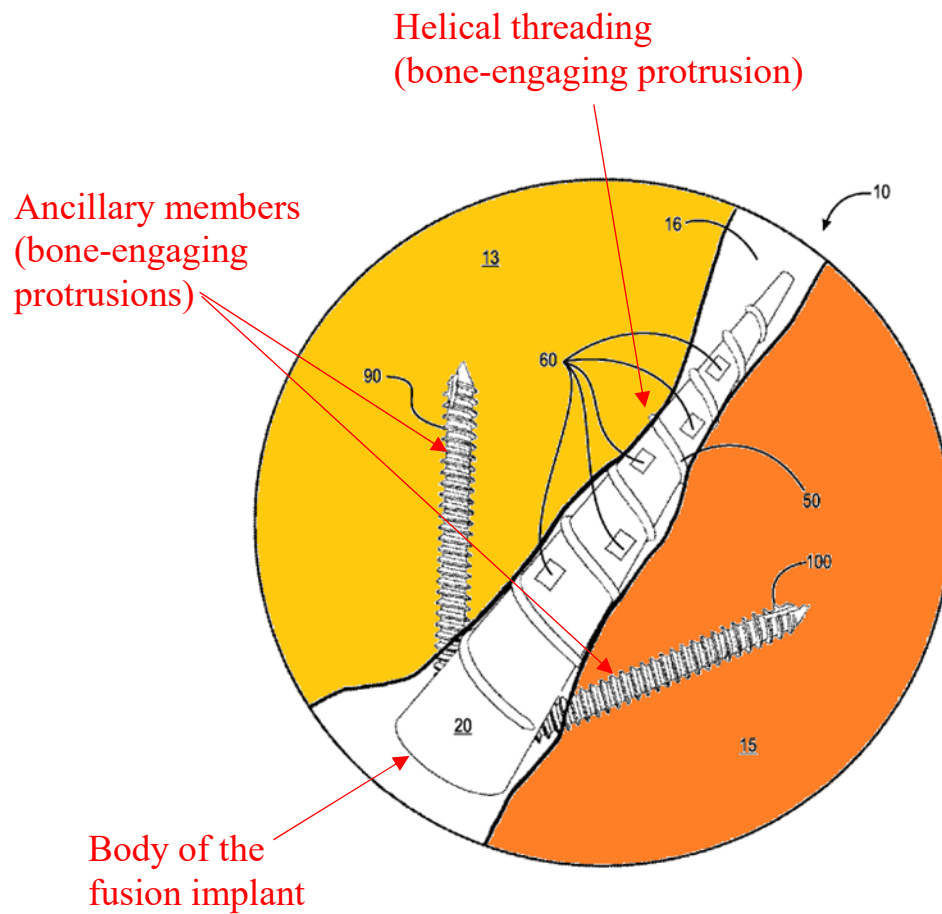
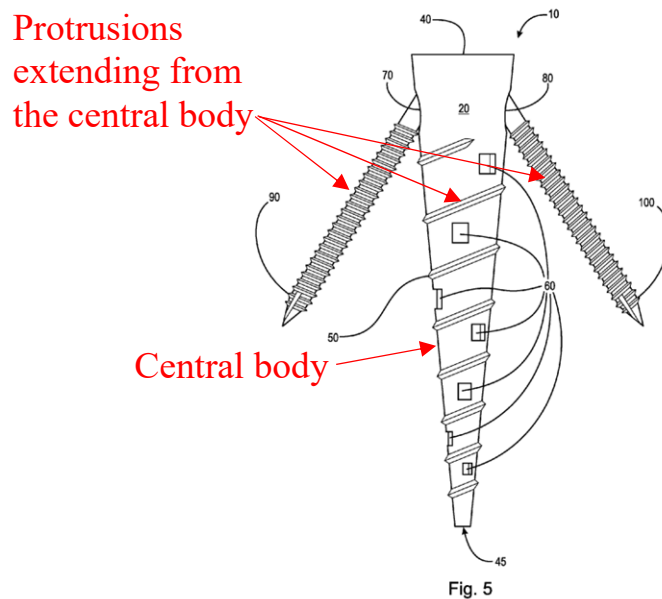


Fig. 4

2. Claim 2

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

93. Stoffman discloses a fusion implant that “comprises body 20 and first and second ancillary members 90 and 100, respectively, protruding outwardly from body 20.” Ex. 1005 at [0033]. In addition, Stoffman teaches that [b]ody 20 further comprises threading 50 ... [wherein] threading 50 could comprise a plurality of protrusions.” *Id.* Figure 5 of Stoffman shows the treading and the ancillary members extending from the central body of the fusion implant.



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

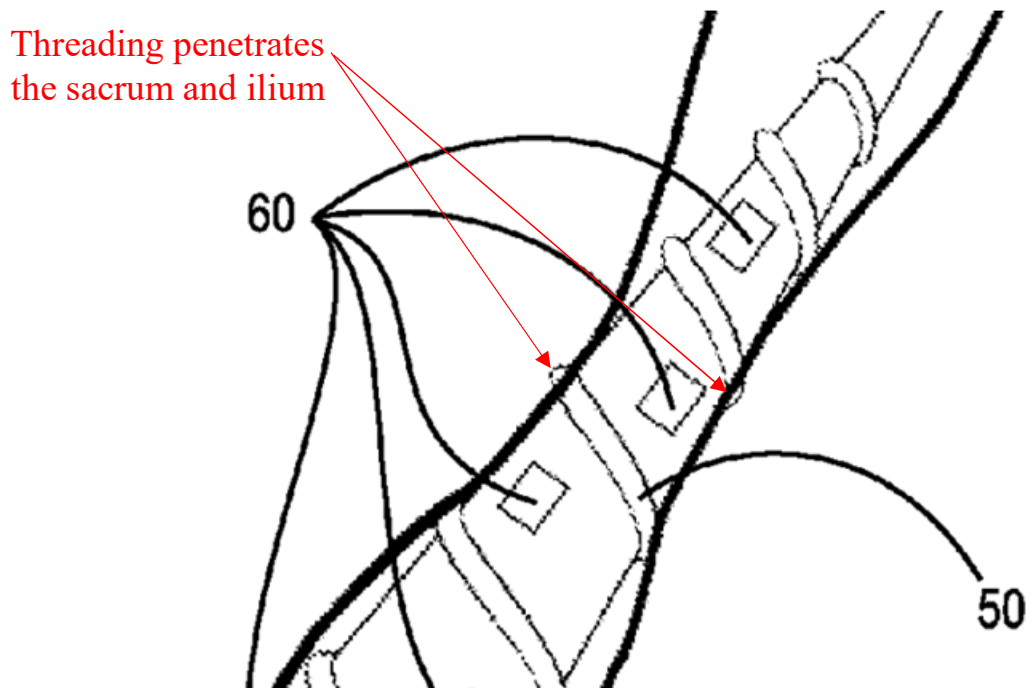
94. Stoffman teaches that the ancillary members (protrusions) “ensure[] an effective securement between SI joint 16 and sacrum 13 and right ilium bone 15.” Ex. 1005 at [0038]. Stoffman also teaches that the ancillary members (protrusions) can “effectively immobilize[e] SI joint.” Ex. 1005 at [0043]. In addition, Stoffman teaches that “the depth of threading 50 tapers along with the taper of body 20. These tapers are effective in fusing the SI joint.” Ex. 1005 at [0034]. Accordingly, the ancillary members and the “threading 50” of the fusion implants are bone-engaging protrusions that fix relative positions of the ilium and sacrum.

3. Claim 3

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

95. Stoffman teaches “a surgeon can anchor first and second ancillary members 90 and 100 ... to bone.” Ex. 1005 at [0039]. Stoffman further states that the “first and second ancillary members 90 and 100 are self-tapping screws ... [and] feature threading 95 and 105.” “Ex. 1005 at [0037]. Figure 4 of Stoffman clearly depicts the threading of the screws (protrusions) penetrating the ilium and the sacrum, thus fixing their relative positions. Stoffman, therefore, teaches a screw

(protrusion) with threads (“anchors”) penetrating the ilium and sacrum, and thereby fixing the relative positions of the ilium and sacrum. In addition, Figure 4 of Stoffman depicts that the “threading 50” penetrates the sacrum and the ilium, and Stoffman teaches that “the depth of threading 50 tapers along with the taper of body 20. These tapers are effective in fusing the SI joint.” *Id.* at [0034].



4. Claim 4

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

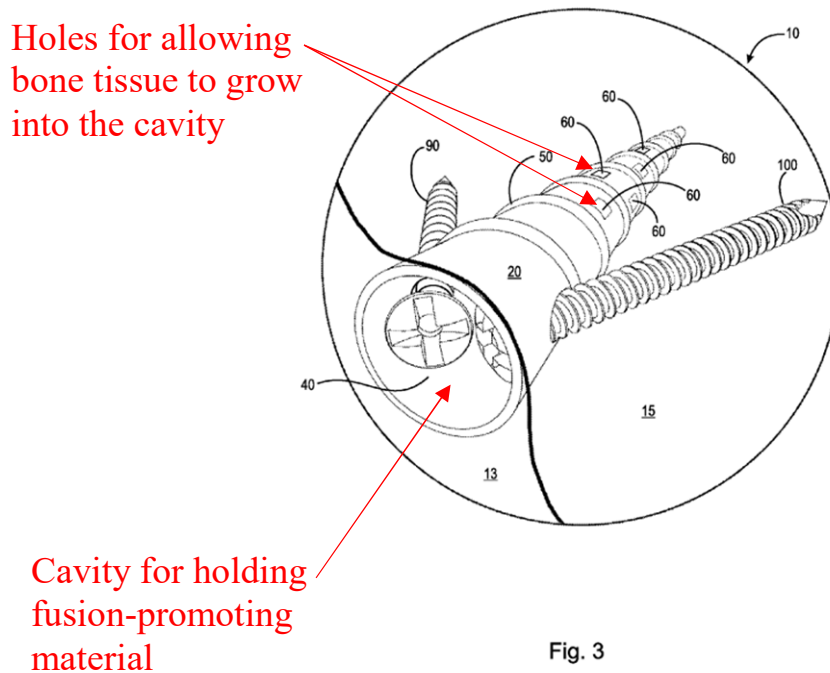
96. As established above, Stoffman's screws are anchors that are operable to fix the ilium and sacrum, thereby substantially immobilizing the sacroiliac joint. Ex. 1005 at [0043] ("ancillary screw members 90 and 100 and body 20 ... effectively immobilizing SI joint"). The thread of a screw is, by definition, helical. Ex. 1012 (a dictionary defining the word "screw" as "a metal fastener having a tapered shank with a *helical* thread") (emphasis added). In addition, Stoffman teaches that the "threading 50 is helical." *Id.* at [0033]. Thus, Stoffman teaches a helical anchor operable to substantially fix a patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.

5. Claim 5

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

97. Stoffman teaches an implant with a "hollow cavity" and wherein the "hollow cavity 30 of body 20 is optionally, filled with bone graft." Ex. 1005 at [0043]. Stoffman further teaches "body 20 comprises plurality of openings 60

through which fusion-facilitating substances can pass.” Ex. 1005 at [0033]. Figure 3 of Stoffman showing the cavity and opening is annotated below.



6. Claim 6

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

98. McCormack teaches an inserter (driver assembly 142) with a plurality of implant engagement arms (“implant holding arms 148”). Ex. 1006 at [0250]; Fig. 10. McCormack also teaches that an “implant [] may be positioned to be held by the

arms 148 of the driver assembly 142.” Ex. 1006 at [0264]. Figure 10 of McCormack depicting the implant inserter is annotated below.

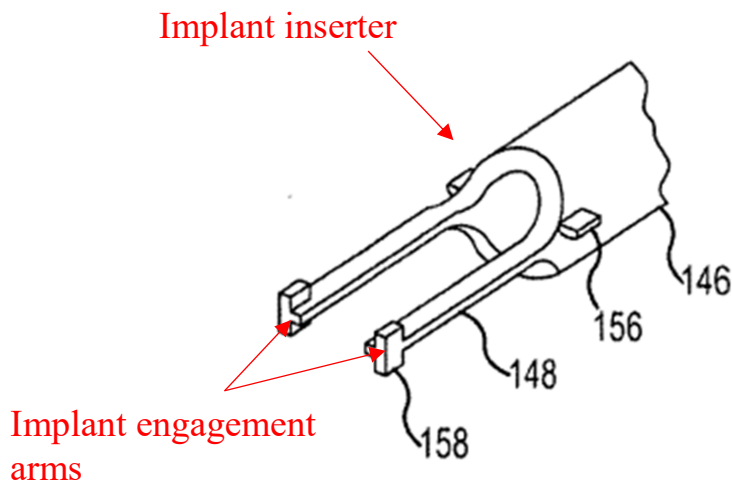


FIG.10

99. McCormack generally teaches that it may be advantageous for the implant engagement arms “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].

100. Stoffman complements McCormack by disclosing that the implant’s “[o]pen end 40 ... could be ... segmented.” Ex. 1005 at [0036]. A person of ordinary skill in the art would have understood that this description teaches that the proximal end (“open end 40”) of the implant has slots. Thus, a person of ordinary skill in the

art would have been motivated to use the implant engagement arms of the inserter taught by McCormack to engage the slots on the segmented proximal end of Stoffman's implant.

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

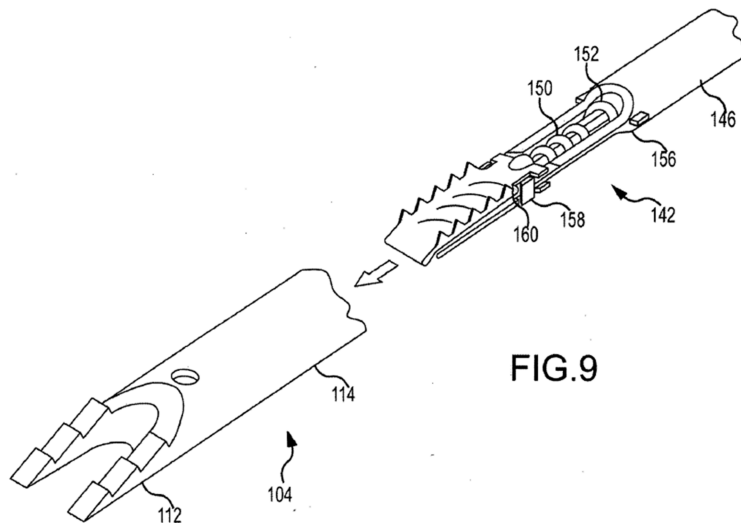
101. McCormack discloses an inserter with a “pair of *tabs* on opposing sides of the implant shaft 146 for engaging with a corresponding longitudinal slot in the inner surface of the tubular shaft 114 of the delivery device 104.” Ex. 1006 at [0251] (emphasis added).

102. McCormack also discloses “positionally matched *protrusions* ... [on] any one or all of the devices being inserted into the deliver[y] device” that are adapted to be seated into the “seating recesses” of the working channel/cannula. Ex. 1006 at [0240] (emphasis added).

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

103. McCormack teaches that “[t]he driver assembly 142 and implant 154 may then be inserted into the delivery device 104.” Ex. 1006 at [0264]. McCormack further teaches a “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). Figure 9 of McCormack depicts this.



104. McCormack also teaches “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” (including the implant inserter). Ex. 1006 at [0240].

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

105. 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). McCormack also 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). The limitation in [6.b.2] requiring that “said interior guidance slot arrests the penetration of said inserter,” would have been obvious to a person of ordinary skill in the art as established in Section VI(B)(3), *supra*, and further discussed with respect to the limitation [1.b.3] in Section VII(A)(1)(e), *supra*.

7. Claim 7

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

106. McCormack discloses a chisel with 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]. This disclosure reads on the “Rasp” limitation in [7.a.1]. Figure 149 shows the rasp inserted into the hollow barrel of the working channel/cannula and being radially and longitudinally aligned with the working channel/cannula.

107. Since over-penetration of the sacroiliac joint was a well-known concern, a person of ordinary skill in the art would have been motivated to control the depth of advancement of the rasp relative to the sacroiliac joint. *Id.* (citing 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 a person of ordinary skill in the art to McCormack’s disclosure of “seating recesses” in the interior diameter of the working channel/cannula (delivery device) and the complimentary “positionally matched protrusions from *any one or all* of the devices being inserted into the deliver[y] device.” Ex. 1006 at [0240]. McCormack also discloses a “keyway feature 156 may include 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.” Placing these protrusions or keyway tab features on the shaft of the chisel/rasp would have been a routine exercise of ordinary skill in the art and would have yielded predictable results with well-known components performing their known and intended functions.

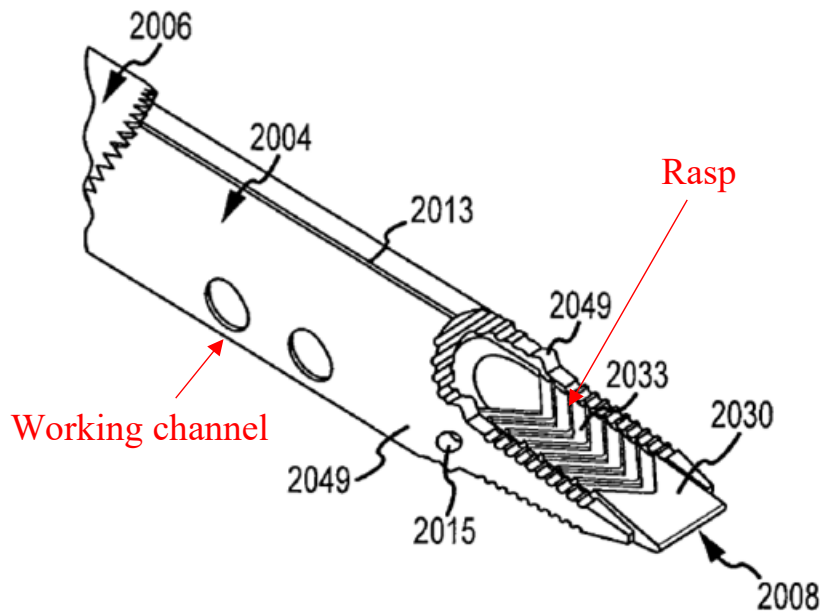


FIG. 149

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

108. The above analysis established that it would have been obvious to use McCormack’s protrusion or keyway tab on the shaft of the rasp for engagement with McCormack’s “seating recesses” / “longitudinal slot.” Sections VI(B)(3) and VII(A)(1)(e), *supra*, established the obviousness of an “interior guidance slot” capable of controlling the depth of advancement and orientation of surgical tools relative to the working channel/cannula and joint.

8. Claim 8

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

109. McCormack teaches surgical instruments with “positionally matched protrusions” that are operable to align with and engage “seating recesses” within the interior of the working channel/cannula barrel. *See* Ex. 1006 at [0240]. McCormack also teaches a surgical tool (driver assembly) with “a pair of tabs” on the shaft that align and engage with the “longitudinal slot” inside of the working channel/cannula. Ex. 1006 at [0251]. Sections VI(B)(3) and VII(A)(1)(e), *supra*, established the obviousness of a “guidance slot” capable of controlling the depth of advancement and orientation of surgical tools relative to the working channel/cannula and joint.

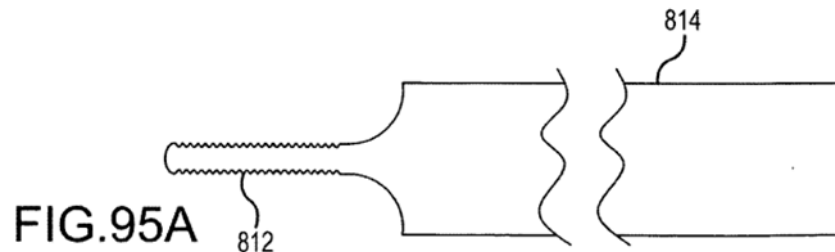
B. Ground 1B: Claims 9-23 are obvious over the combination of Stoffman, McCormack, and Stark

1. Claim 9

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

110. McCormack teaches a working channel/cannula with a plurality of blunt (“bull nose tips”) tangs (forks). Ex. 1006 at [0333]. Figure 95A of

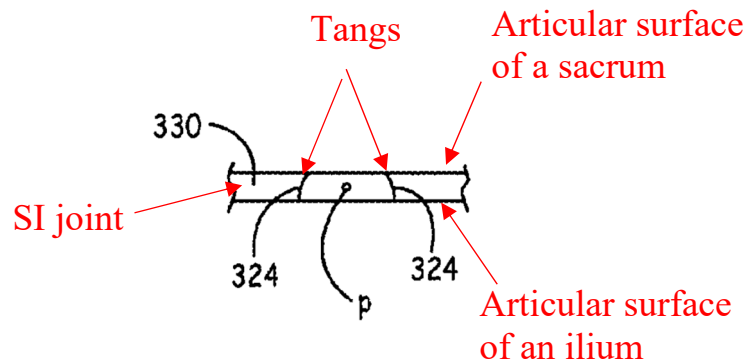
McCormack's working channel/cannula with a plurality of blunt tangs is shown below.



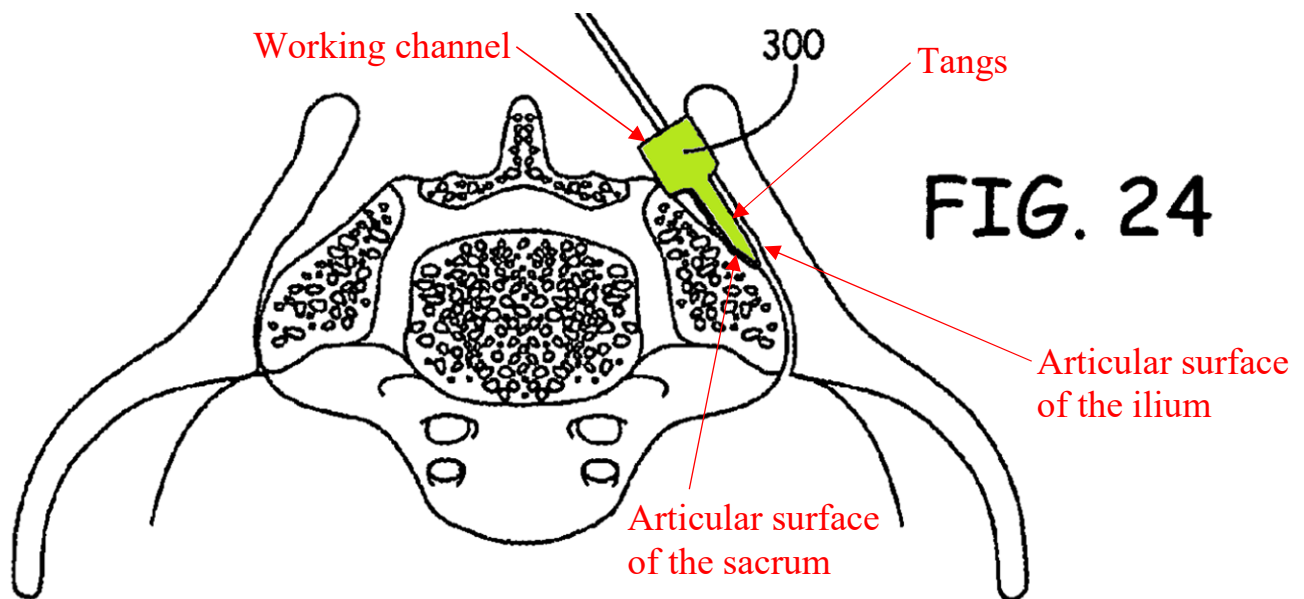
111. In the Stoffman-McCormack combination, a person of ordinary skill in the art would have been motivated to use a working channel/cannula with blunt tangs (like the one depicted in Figure 95A of McCormack) because blunt tangs would have reduced the possibility of injuring nerves, tissues, and other ligaments during the sacroiliac joint fusion procedure.

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

112. Stark teaches the step of inserting the tangs of the working channel/cannula between the articular surfaces of the sacrum and ilium “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]. Figure 9A of Stark shows “a top view into the sacroiliac joint showing a set of inserted tangs into the joint.” Ex. 1007 at [0022].



113. Figure 24 of Stark shows a schematic of a cross-sectional view of the sacroiliac joint showing the tangs of the working channel/cannula inserted between the articular surfaces of an ilium and a sacrum in the sacroiliac joint.



2. Claim 10

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

114. The preamble of claim 1 is the same as the preamble for claim 10 and, thus, Section VII(A)(1)(a), *supra*, establishes obviousness of this limitation.

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

115. Claim [10.a.] is substantively the same as claim [1.a] and, thus, Section VII(A)(1)(b), *supra*, establishes obviousness of this limitation.

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

116. Claim [1.b.1] is substantively the same as claim [10.b.1] and, thus, Section VII(A)(1)(c), *supra*, establishes obviousness of this limitation. Additionally, Stoffman discloses, “[p]referably, the incision is made along the dimple of Venus,” thus teaching that the working channel (surgical channel) is inserted into the incision from the posterior of the patient. Ex. 1005 at [0043].

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

117. Figure 2 of McCormack indicates the tangs of the working channel/cannula are bilateral. Ex. 1006 at Fig. 2. The remaining limitations of claim

[10.b.2] are substantively the same as claim 9 which Section VII(B)(1), *supra*, has established as obvious.

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

118. The limitations of claim [10.b.3] are substantively the same as those in claim [1.b.3] and claim 8 and, thus, Sections VII(A)(1)(e) and VII(A)(8), *supra*, have established obvious of this claim.

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

119. Claim [1.c] is the same as claim [10.c.] and, thus, Section VII(A)(1)(g), *supra*, establishes obviousness of this claim.

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

120. The limitation regarding inserting a fusion implant into the void is the same as that of claim [1.d.1] and, thus, Section VII(A)(1)(h), *supra*, has established obviousness of this limitation. The remaining limitations of claim [10.d.1] are

substantively the same as those in claim [6.a.1] and, thus, Section VII(A)(6)(a), *supra*, has established obviousness of these limitations.

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

121. The limitations of this claim are substantively the same as those in claim [1.d.2] and, thus, Section VII(A)(1)(i), *supra*, establishes obviousness of this claim.

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

122. Stoffman discloses the step of “*drilling* a tapered body [of the implant] into the sacroiliac joint.” Ex. 1005 at [0010] (emphasis added). A person of ordinary skill in the art would have understood that the “drilling” step involves driving the implant into the “hole [that was] drilled across SI joint.” *See* Ex. 1005 at [0043]. Stoffman also teaches the step of driving the ancillary screw members of the fusion implant into their respective voids: “[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]. Thus, Stoffman teaches driving a fusion implant into the void created in the sacroiliac joint.

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

123. Stoffman teaches that its 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]. When Stoffman’s implant is driven/drilled into the void of the sacroiliac joint, the threading/protrusions engage with bone tissue, thereby preventing pullout of the implant. Ex. 1005 at [0010]. Figure 4 of Stoffman shows the threading/protrusions of the implant embedded in the bone tissue of the ilium and sacrum and, thus, teaching that the threading of the implant engages bone tissue and prevents pullout of the implant.

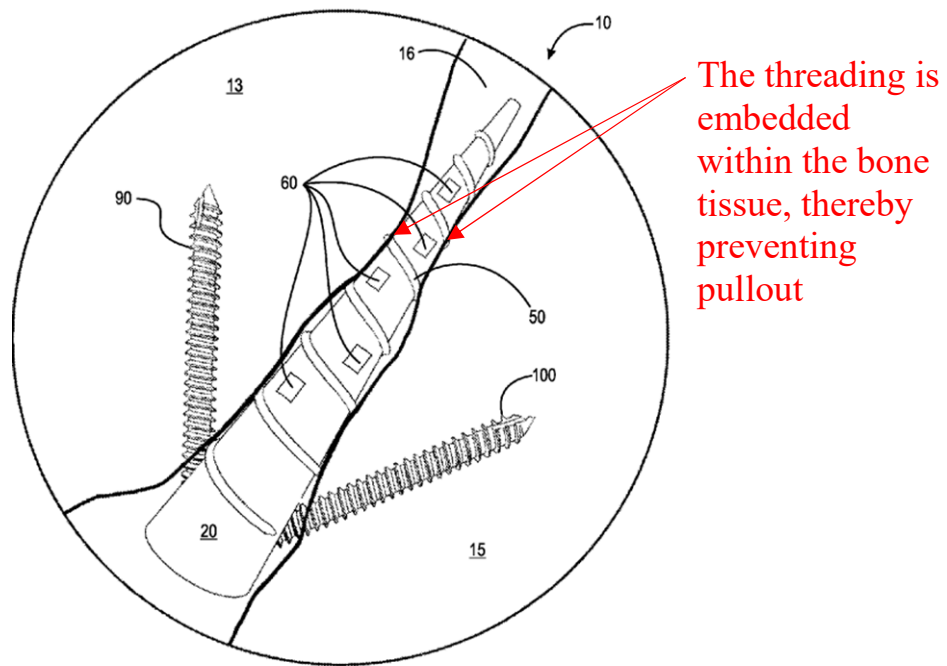


Fig. 4

124. Stoffman also discloses that “a surgeon can anchor [(drive)] first and second ancillary members 90 and 100 ... to bone” and, thus, teaches that the ancillary members (protrusions) engage bone tissue within the sacroiliac joint thereby preventing pullout of the implant as depicted in Figure 4.

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

125. Stoffman teaches that its implant is designed to “effectively immobilize[e] SI joint” and “ensure[s] an effective securement between SI joint 16 and sacrum 13 and right ilium bone 15.” Ex. 1005 at [0038], [0043].

3. Claim 11

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

126. The analysis of claim [1.d.2], *supra*, established that Stoffman teaches a fusion implant with bone-engaging protrusions (the threading and the ancillary members) that prevent pullout of the implant from the sacroiliac joint. Stoffman teaches that “threading 50 is helical” and that “threading 50 could be sharp.” Ex. 1005 at [0033], [0034]. Figure 4 of Stoffman shows the threading piercing bone tissue in an articular surface of an ilium and a sacrum in the sacroiliac joint. Thus, Stoffman’s implant satisfies all limitations of claim 11 and renders it obvious.

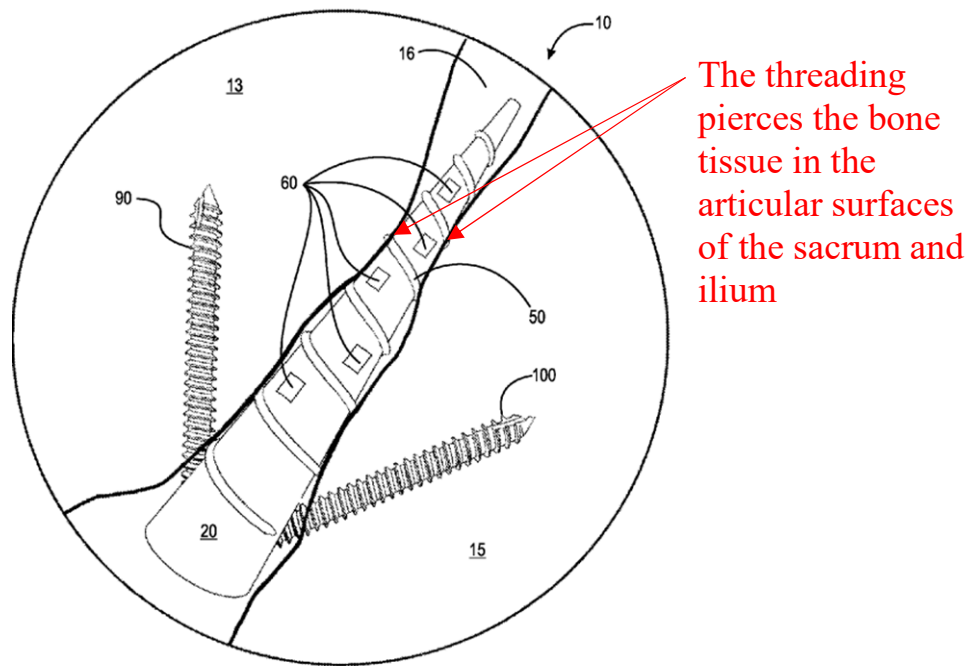


Fig. 4

127. The analysis of claim 4 in Section VII(A)(4), *supra*, established that Stoffman's ancillary screw members are "helical anchors." Stoffman further teaches that "first and second ancillary members 90 and 100 are self-tapping screws," meaning the threads are sharp and configured for piercing bone tissue. Ex. 1005 at [0037]. Thus, the ancillary screws of Stoffman also teach all limitations of claim 11, rendering claim 11 obvious.

4. Claim 12

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

128. Stoffman teaches that “hollow cavity 30 of body 20 is optionally filled with bone graft” and that “body 20 comprises plurality of openings 60 through which fusion-facilitating substances can pass”. Ex. 1005 at [0043], [0043]. Stoffman also teaches “[b]ody 20 is open at both ends and includes open end 40.” Ex. 1005 at [0036]. Thus, claim 12 is obvious in view of Stoffman.

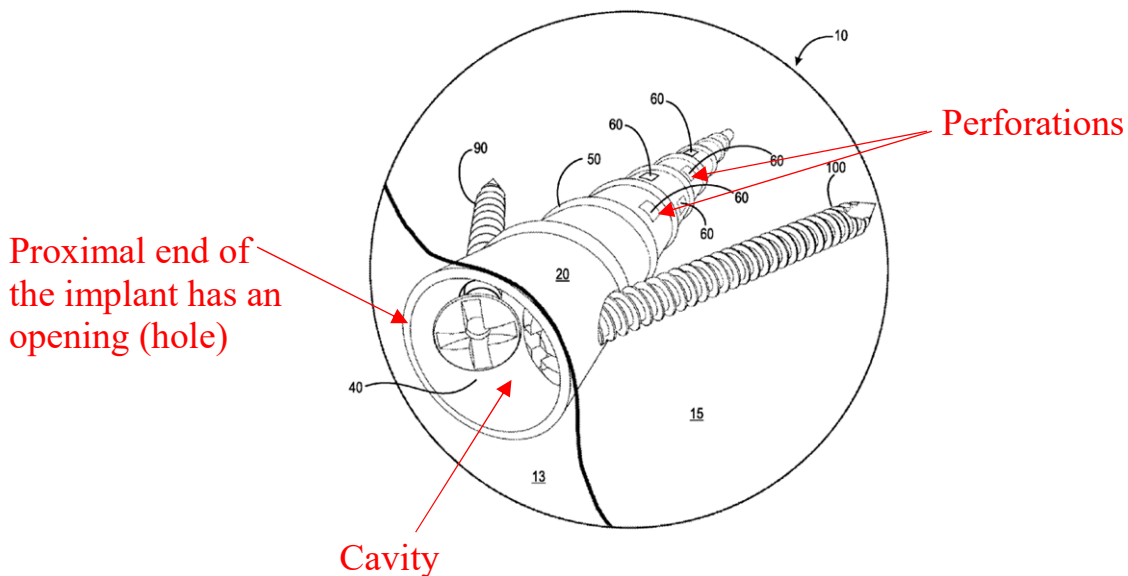


Fig. 3

5. Claim 13

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

129. Sections VII(A)(2)(b) and VII(B)(2)(k), *supra*, regarding claims [2.a.2] and [10.e.3] established that Stoffman teaches a fusion implant that fixes relative positions of a sacrum and an ilium in the sacroiliac joint. Figure 2 of Stoffman also shows the fusion implant connecting the sacrum and ilium.

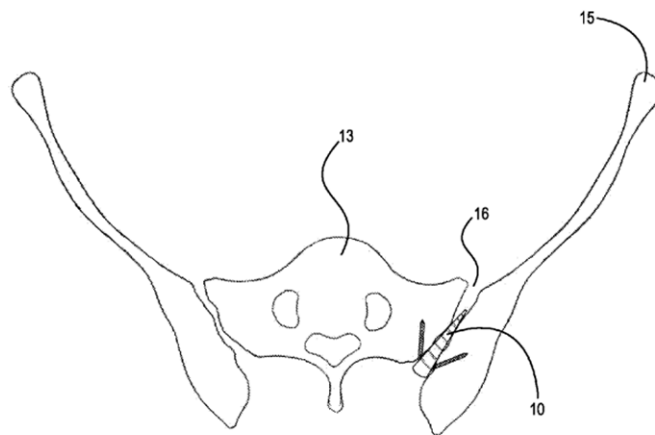


Fig. 2

6. Claim 14

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

130. The limitations of claim [14.a.1] are substantively the same as the limitations of claim [6.b.1] and, thus, Section VII(A)(6)(c), *supra*, establishes obviousness of the limitations of this claim.

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

131. The limitations of claim [14.a.2] are substantively the same as the limitations of claim [6.a.2] and, thus, Section VII(A)(6)(b), *supra*, establishes obviousness of the limitations of this claim.

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

132. The limitations of claim [14.b] are substantively the same as the limitations of claim 8 and, thus, Section VII(A)(8), *supra*, establishes obviousness of the limitations of this claim.

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

133. The limitations of claim [14.c] are substantively the same as the limitations of claim [6.b.2] and, thus, Section VII(A)(6)(c), *supra*, establishes obviousness of the limitations of this claim. Additionally, a person of ordinary skill in the art would have understood that when the guidance slot arrested the guide protrusion on the inserter, the inserter would have been prevented from moving the fusion implant further into the sacroiliac joint.

7. Claim 15

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

134. Stoffman discloses an implant embodiment in which “body 20 could be ... a square-based or triangular-based pyramid.” Ex. 1005 at [0033]. A person of ordinary skill in the art would have understood that such an implant would have been inserted with a linear (pushing) force rather than a rotational one. McCormack discloses that internal actuator of its implant inserter (driver assembly) “may be adapted for *slidable longitudinal* and rotational movement relative to the driver assembly.” Ex. 1006 at [0255]. Thus, in the combination of Stoffman and

McCormack, McCormack's internal actuator within the implant inserter would be used to drive the "square-based or triangular-based pyramid" of Stoffman by pushing the implant into the sacroiliac joint. As Stoffman's implant is pushed into the sacroiliac joint, the protrusions ("threading 50") would engage/contact bone tissue of the ilium and sacrum. Additionally, Stoffman describes 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." *Id.* at [0037]. In this embodiment, the step of driving the ancillary members (which are a part of a single implant) would involve applying a linear force (pushing) to engage them with the bone tissue. Thus, these embodiments of Stoffman render claim 15 obvious.

8. Claim 16

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

135. Claim 16 is substantively the same as claim 7. Thus, claim 16 is obvious for the reasons stated in Section VII(A)(7), *supra*.

9. Claim 17

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

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

10. Claim 18

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

137. The preamble of claim 18 is the same as the preamble of claim 10 and, thus, Section VII(B)(2)(a), *supra*, renders this claim obvious.

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

138. Claim [18.a.] is substantively the same as claim [10.a] and, thus, Section VII(B)(2)(b), *supra*, renders this claim obvious. Additionally, Stoffman teaches that the incision allows access to the posterior portion of the sacroiliac joint because “the incision is made along the dimple of Venus.” Ex. 1005 at [0043].

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

139. Claim [18.b.1] is substantively the same as [10.b.1] and, thus, Section VII(B)(2)(c), *supra*, renders this claim obvious.

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

140. Claim [18.b.2] is substantively the same as [10.b.2] and, thus, Section VII(B)(2)(d), *supra*, renders this claim obvious.

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

141. Claim [18.b.3] is substantively the same as [10.b.3] and, thus, Section VII(B)(2)(e), *supra*, renders this claim obvious.

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

142. Claim [18.c.1] is substantively the same as [10.d.1] and [10.d.2] and, thus, Sections VII(B)(2)(g) and VII(B)(2)(h), *supra*, establish obviousness of this claim.

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

143. Claim [18.c.2] is substantively the same as [10.d.1] and, thus, Section VII(B)(2)(g), *supra*, renders this claim obvious.

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

144. Section VII(B)(1), *supra*, regarding claim 9 establishes that Stark teaches inserting the tangs of a working channel/cannula between the articular surfaces of a sacrum and an ilium in the sacroiliac joint. A person of ordinary skill in the art would have understood that since the tangs are aligned with the hollow barrel of the working channel/cannula, when the working channel/cannula is inserted into the sacroiliac joint, the hollow barrel of the working channel/cannula would be substantially parallel to the articular surfaces of the sacroiliac joint and, thus, the implant would be inserted through the hollow barrel of the working channel/cannula on a path that is substantially parallel to the articular surfaces of the sacroiliac joint.

This is further illustrated in Figure 26 of Stark, which depicts an implant being inserted into the sacroiliac joint through the hollow barrel of the working channel/cannula on a path that is substantially parallel to the articular surfaces of the sacrum and ilium.

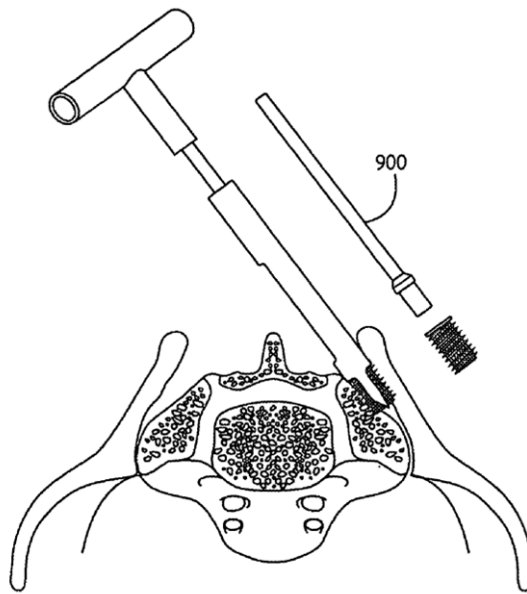


FIG. 26

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

145. Claim [18.c.4] is substantively the same as [14.a.2] and [14.b] and, thus, Sections VII(B)(6)(b) and VII(B)(6)(c), *supra*, establish obviousness of this claim.

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

146. Claim [18.d] is substantively the same as [14.c] and, thus, Section VII(B)(6)(d), *supra*, renders this claim obvious. The only additional subject matter in [18.d] is that the “inserter is prevented from moving the fusion implant beyond a pre-determined point in said sacroiliac joint.” A person of ordinary skill in the art would have understood that when the guidance slot of the working channel/cannula arrests the protrusion on the inserter, the inserter is necessarily prevented from moving the fusion implant beyond a pre-determined point relative to the sacroiliac joint. Thus, the limitations recited in [18.d] are rendered obvious.

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

147. Claim [18.e] is substantively the same as [10.d.2] – [10.e.2] and, thus, Sections VII(B)(2)(h)-VII(B)(2)(j), *supra*, establish this claim as obvious.

11. Claim 19

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

148. Claim 19 is substantively the same as [10.e.2] and [10.e.3] and, thus, Sections VII(B)(2)(j) and VII(B)(2)(k), *supra*, establish this claim as obvious.

12. Claim 20

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

149. The analysis of claim 11 in Section VII(B)(3), *supra*, establishes that Stoffman’s implant teaches all features of claim 20 and, thus, this claim is rendered obvious.

13. Claim 21

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

150. 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 that “SI joint fusion device 10 promotes the arthrodesis or fusion process.” Ex. 1005 at [0010], [0043]. A person of ordinary skill in the art would have understood that Stoffman’s method of sacroiliac joint fusion only used

one fusion implant, and Figure 1 of Stoffman confirms this understanding by showing only one implant inserted into the sacroiliac joint.

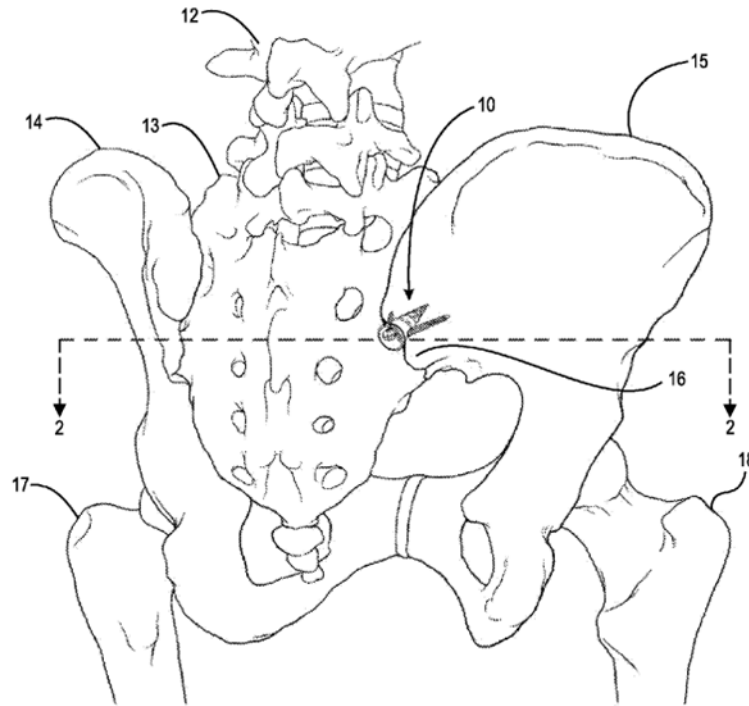


Fig. 1

14. Claim 22

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

151. Stoffman teaches “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]. A person of ordinary skill in the

art would have understood that a drilled hole has a circular shape. Stoffman teaches that its implant body and the ancillary screws both have circular cross-sections. Ex. 1005 at Fig. 3. Thus, the shape (circular) of the void/drilled holes created within the sacroiliac joint are complimentary to the implant body and the ancillary screws.

152. Claim 22 is substantively the same as [10.d.1] with respect to inserting the implant into the void and, thus, Section VII(B)(2)(g), *supra*, renders this limitation obvious. Therefore, claim 22 is obvious.

15. Claim 23

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

153. The subject matter recited in claim 23 is substantively similar to the subject matter recited in claim 17, and therefore Section VII(B)(9), *supra*, establishes that the subject matter is obvious over the cited prior art. 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). 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,” which shows the implant in proper orientation for insertion into the joint.

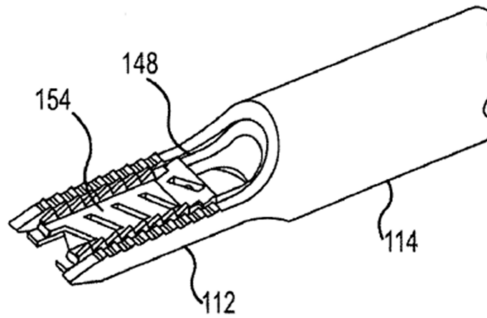


FIG.13

VIII. RIGHT TO SUPPLEMENT

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

IX. CONCLUSION

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

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

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

Dated: January 17th, 2023

Respectfully submitted,



Christopher J. Bovinet, D.O.