UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOCISION, INC.
Petitioner

v.

PAINTEQ, LLC
Patent Owner.

Case No. IPR2022-00625

U.S. Patent No. 11,020,129
Issue Date: June 1, 2021
Title: Drill-Less Method of Fusing a Sacroiliac Joint

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,020,129

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,020,129 ("'129 Patent")
1002	File history of the '129 Patent
1003	U.S. Patent No. US11,083,511 (Schifano et al.)
1004	U.S. Patent No. 10,219,841 (Compton et al.)
1005	U.S. Patent Publication No. 2016/0310197 (Black et al.)
1006	U.S. Patent Publication No. 2018/0036017 (Donner et al.)
1007	U.S. Patent Publication No. 2005/0080422 (Otte et al.)
1008	U.S. Patent Publication No. 2005/0090829 (Martz et al.)
1009	WIPO Patent Publication No. WO2014091454 (Sharma et al.)
1010	Sembrano J.N., Polly D.W. *How often is low back pain not coming from the back?* Spine (Philadelphia, PA 1976). 2009; 34(1): E27–E32.
1011	Cohen, Steven P. *Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis, and Treatment.* Anesth Analg 2005;101:1440–53.
1012	Falowski, Steven, Sayed, Dawood, Pope, Jason, Patterson, Denis, Fishman, Michael, Gupta, Mayank, Mehta, Pankaj. *A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain*. Journal of Pain Research 2020:13 3337–3348.
1013	Hamidi-Ravari, Behdad, Tafazoli, Sharwin, Chen, Hamilton, Perret, Danielle. *Diagnosis and Current Treatments for Sacroiliac Joint Dysfunction: A Review.* Curr Phys Med Rehabil Rep (2014) 2:48–54
1014	Ebraheim N.A., Lu J., Biyani A., Yeasting R.A. Anatomic considerations for posterior approach to the sacroiliac joint. Spine (Philadelphia, Pa 1976). 1996 Dec 1; 21(23): 2709-12.
1015	Haid Jr., R.W., McLaughlin, M.R., and Fessler, R.G. (2003). Lumbar Interbody Fusion Techniques – Cages, Dowels, and Grafts. (Quality Medical Publishing, Inc.).

1016	U.S. Patent No. 6,174,311 (Branch et al.)
1017	Declaration of Troy D. Drewry in Support of Petition for Inter Partes Review of U.S. Patent No. 11,020,129
1018	Curriculum Vitae of Troy D. Drewry
1019	File history of U.S. Provisional Application No. 62910913

LISTING OF CLAIMS

U.S. Patent No. 11,020,129 (Claims 1, 2 and 9-10)

Claim Designation	Claim Language
Independent Claim 1 "Preamble"	A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument, the method comprising the steps of:
Limitation 1(a) "locating insertion point"	locating an insertion point in the sacroiliac joint, the insertion point defining an intended location for the implant void;
Limitation 1(b) "introducing working channel"	introducing a working channel into the insertion point, the working channel having an insertion end and a working end, the insertion end of the working channel further comprising a first iliac contour, a first sacral contour, and insertion arms;
Limitation 1(c) "inserting arms"	inserting the insertion arms into the sacroiliac joint at the insertion point such that the first sacral contour is seated against a sacrum bone and the first iliac contour is seated against an ilium;
Limitation 1(d) "introducing abrading device comprising"	introducing an abrading device into the working channel, the abrading device comprising:
Limitation 1(d)(i) "an abrading head"	an abrading head at a distal end of the abrading device, the abrading head having:
Limitation 1(d)(i)(a) "abrading surfaces"	abrading surfaces on each of a first pair of opposing sides, the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint; and
Limitation 1(d)(i)(b) "an open tip / cutting edge"	an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint; and

Limitation 1(d)(i)(c) "a slide hammer / released position / locked position / releasing means"	II. a slide hammer assembly at a proximal end of the abrading device, the slide hammer assembly having a released position that enables operation of the slide hammer assembly, a locked position that prohibits operation of the slide hammer assembly, and a releasing means for transitioning the slide hammer assembly between the locked position and the released position; and
Limitation 1(e) "advancing the abrading device"	advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium and the abrading surfaces decorticate the cortical bone inside the sacroiliac joint, thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument.
Claim 2 Preamble 2(a)	The method of claim 1, wherein, upon the abrading head becoming lodged inside the sacroiliac joint,
Limitation 2(b) "unlocking slide hammer"	unlocking the slide hammer assembly via the releasing means,
Limitation 2(c) "dislodge abrading head"	and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint.
Claim 9 Preamble 9(a)	The method of claim 1, wherein forming the decorticated implant void at the insertion point further comprises
Limitation 9(b) "forming rectangular shape"	forming a generally rectangular cross sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape.

Claim 10 Preamble 10(a)	The method of claim 9, wherein, upon the abrading head becoming lodged inside the sacroiliac joint,
Limitation 10(b) "unlocking slide hammer"	unlocking the slide hammer assembly via the releasing means,
Limitation 10(c) "dislodge abrading head"	and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint.

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 et seq., Petitioner Orthocision Inc. ("Orthocision" or "Petitioner") seeks *Inter Partes* review and cancellation of claims 1, 2 and 9-10 of U.S. Patent No. 11,020,129 ("the '129 patent" "Ex.1001") titled "Drill-Less Method of Fusing a Sacroiliac Joint" assigned to PainTEQ, LLC ("Patent Owner" or "PainTEQ"). This Petition and supporting exhibits demonstrate that there is a reasonable likelihood that claims 1, 2 and 9-10 of the '129 patent are unpatentable because each claim would have been obvious to a person of ordinary skill in the art ("POSITA").

II. MANDATORY NOTICES

A. Real Parties-in-Interest (37 C.F.R. 42.8(b)(1))

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

B. Related Matters (37 C.F.R. 42.8(b)(2))

There are no pending matters affecting the '129 Patent.

C. Lead and Backup Counsel (37 C.F.R. 42.8(b)(3))

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D. Service Information (37 C.F.R. 42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email at the following email address: ipmail@sierraiplaw.com.

E. Power of Attorney

Filed concurrently herewith in accordance with 37 C.F.R. 42.10(b).

III. PAYMENT OF FEES

The fee set forth in 37 C.F.R. §42.15(a) for this petition has been paid. Any additional fees due in connection with this petition may be charged to Deposit Account 600741.

IV. GROUNDS FOR STANDING

Petitioner hereby certifies that the '129 Patent is available for *Inter Partes* review and that Petitioner is not barred or estopped from requesting *Inter Partes* review challenging the patent claims on the grounds identified herein.

V. STATEMENT OF RELIEF REQUESTED UNDER 37 C.F.R. § 42.104(B)(1)-(2)

Petitioner requests institution of IPR based on the following grounds:

Ground	Claims	Statute	References and Type of Challenge
1	1, 2, 9-10	§103	US10,219,841 (Compton) [Ex.1004] in view of US2018/0036017 (Donner) [Ex.1006] US2005/0080422 (Otte) [Ex.1007] WO2014091454 (Sharma) [Ex.1009]
2	1, 2, 9-10	§103	US11,083,511 (Schifano) [Ex.1003] in view of US10,219,841 (Compton) [Ex.1004] US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]
3	1, 2, 9-10	§103	US10,219,841 (Compton) [Ex.1004] in view of US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]
4	1, 2, 9-10	§103	US2016/0310197 (Black) [Ex.1005] in view of US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]
5	1, 2, 9-10	§103	US2016/0310197 (Black) [Ex.1005] in view of US2018/0036017 (Donner) [Ex.1006] US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]

This Petition is supported by the expert declaration of Troy D. Drewry. (Ex._1017) (hereinafter "Drewry"), a qualified technical expert. Mr. Drewry's experience is reflected in his Curriculum Vitae (Ex.1018) and within his Declaration. (Ex.1017, ¶¶6-11).

VI. CONSIDERATIONS UNDER 35 U.S.C. § 325(d)

This Petition does not present "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). This Petition relies both on prior art references that are and are not of record in the '129 Patent. US 11,083,511 ("Schifano"), US Pat. Publ. No. 2005/0090829 ("Martz"), and WO2014091454 ("Sharma") are not of record in the prosecution of the '129 Patent. The remaining prior art references relied on are of record in the '129 Patent, but the examination of the '129 Patent includes no discussion of any prior art reference.

The only discussion regarding the patentability of the challenged claims is found in the Notice of Allowance dated February 3, 2021 ("NOA"), which states simply that the claims were allowed because the prior art of record did not disclose or suggest "a method of forming an implant void in a sacroiliac joint comprising at least the steps of *inserting working channel including arms and iliac/sacral contours* and *introducing*

abrading device including open tip and slap hammer" (emphasis added). (Ex.1002, 46). Thus, there is no prior art analysis provided by the examiner, there are no amendments, remarks, or arguments by PainTEQ related to any prior art, and there is essentially no prosecution history for the '129 patent.

However, US 10,219,841 ("Compton", of record in the '129 Patent) discloses a cannula having arms and contours that are similar to those of the cannula disclosed and illustrated in the '129 Patent. FIG. 3 of Compton and the cannula as shown in FIGS. 5-7 of the '129 Patent are juxtaposed below to demonstrate the high degree of similarity between them. (Ex.1017, ¶106). FIGS. 6-7 of the '129 Patent provide close-up views of the distal end of the cannula 10 with contours and arms that closely resemble the features of Compton. (*Ibid*.).

For at least this reason, there is good cause to believe that the examination of the '129 Patent did not include a thorough review and consideration of the prior art of record in the '129 Patent. The statement in the NOA that the prior art does not disclose *"inserting working channel including arms and iliac/sacral contours"* demonstrates that the Office overlooked specific teachings of Compton, constituting material error supporting institution of *inter partes* review of the '129 Patent. *Advanced*

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US 10,219,841 (Compton et al.)

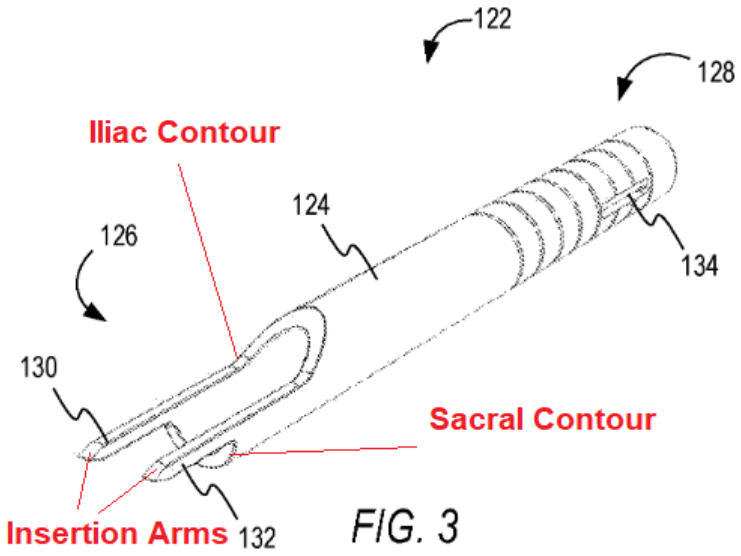
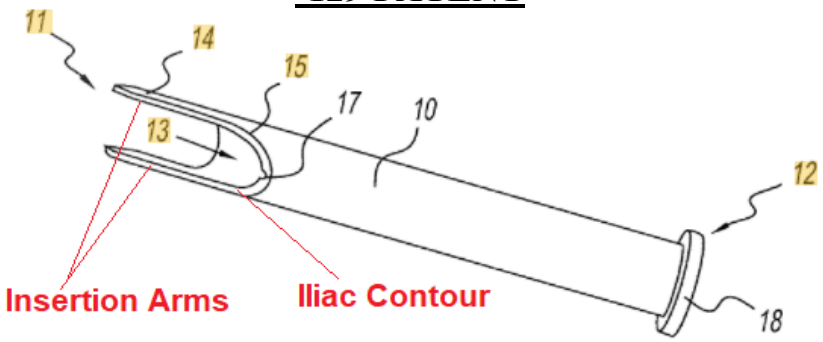


FIG. 3

'129 PATENT



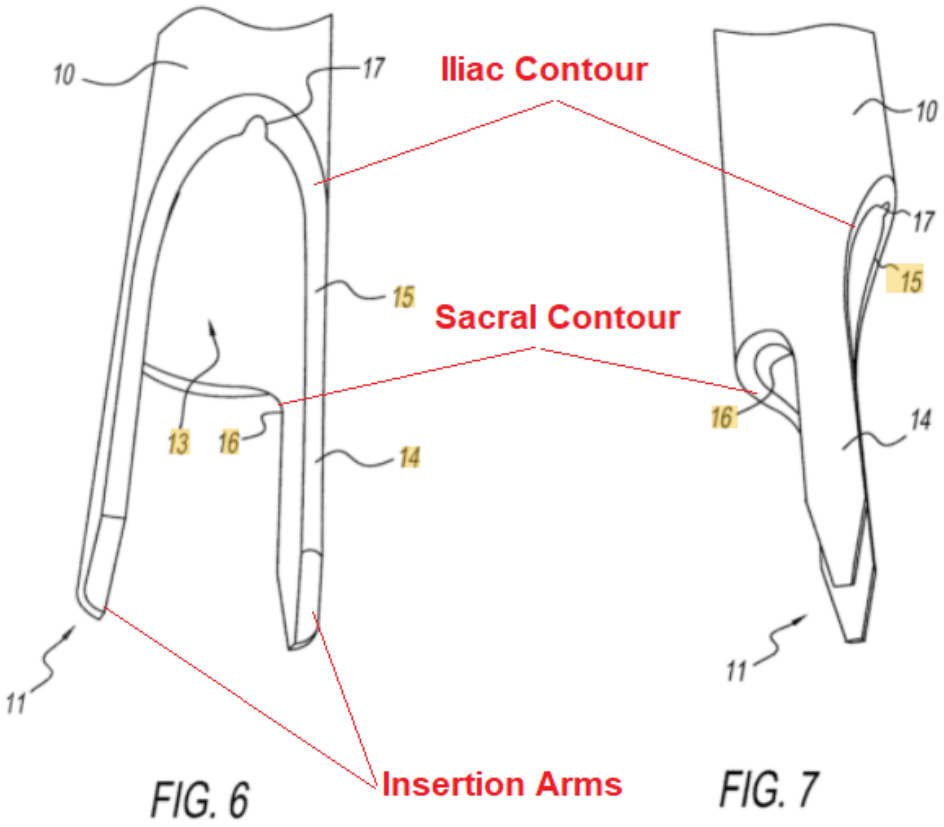
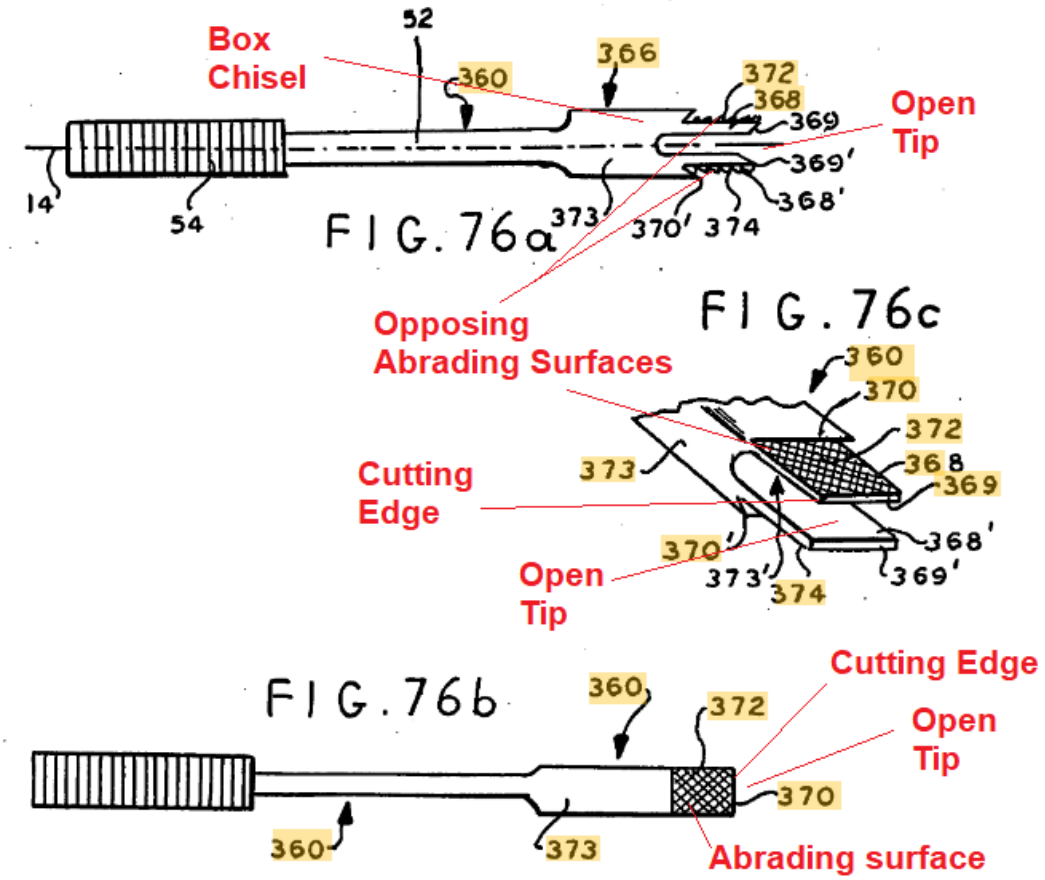


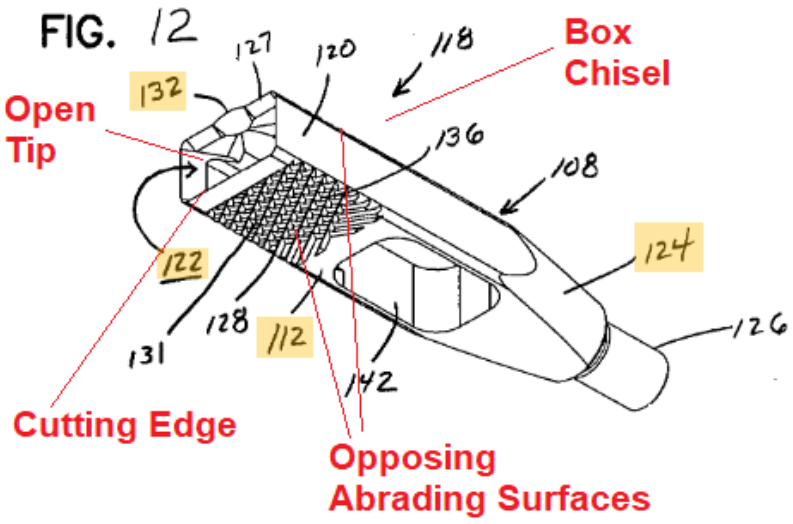
FIG. 6 FIG. 7

Additionally, multiple prior art references disclose an "abrading device having an open tip", including the following references relied on in this petition: US Pat. Publ. No. 2005/0090829 ("Martz") (Ex.1008, US Pat. Publ. No. 2005/0080422 ("Otte") (Ex.1007), and US Pat. Publ. No. 2018/0036017 ("Donner"). (Ex.1006). Figures from the foregoing references are provided below to illustrate the disclosed abrading devices.

US Pat. Publ. No. 2005/0090829 (Martz et al.)



US Pat. Publ. No. 2005/0080422 (Otte et al.)



US Pat. Publ. No. 2018/0036017 (Donner et al.)

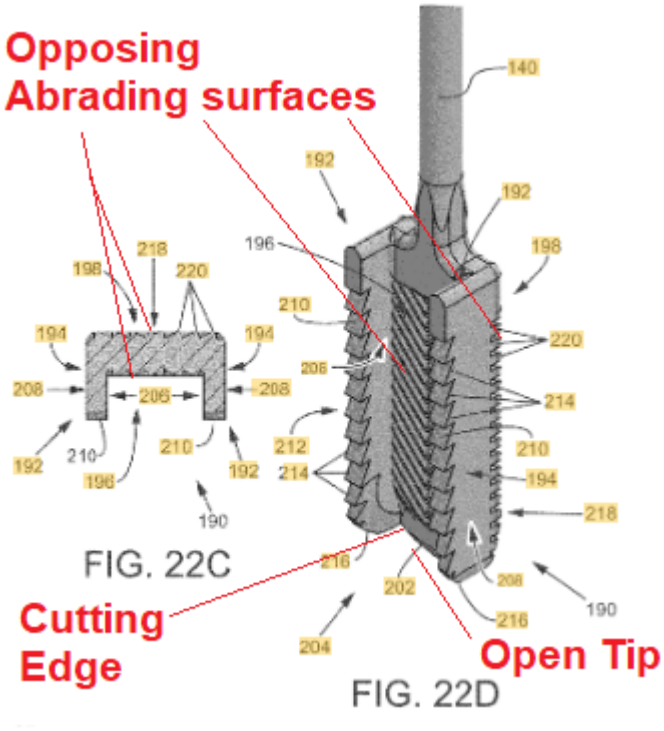


FIG. 22C

FIG. 22D

Furthermore, Donner discloses a joint preparation tool 50 that includes a slap hammer assembly 54 and a cutting tool assembly 56, as shown in FIGS. 6 and 8 provided below. (Ex.1006, ¶[0164]). The tooling head 52 can be backed out of the SI Joint by sliding the proximal handle 58 until it contacts a proximal stop feature 82 to transmit proximal force to back the tooling head 52 out of the SI Joint. (Ex.1006, ¶¶[0166]-[0167]).

FIG. 6

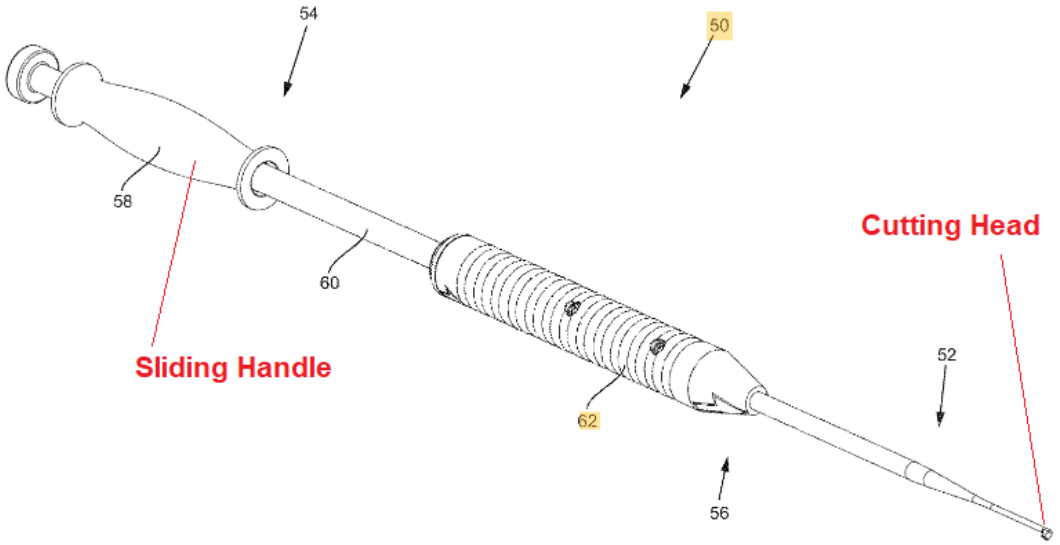
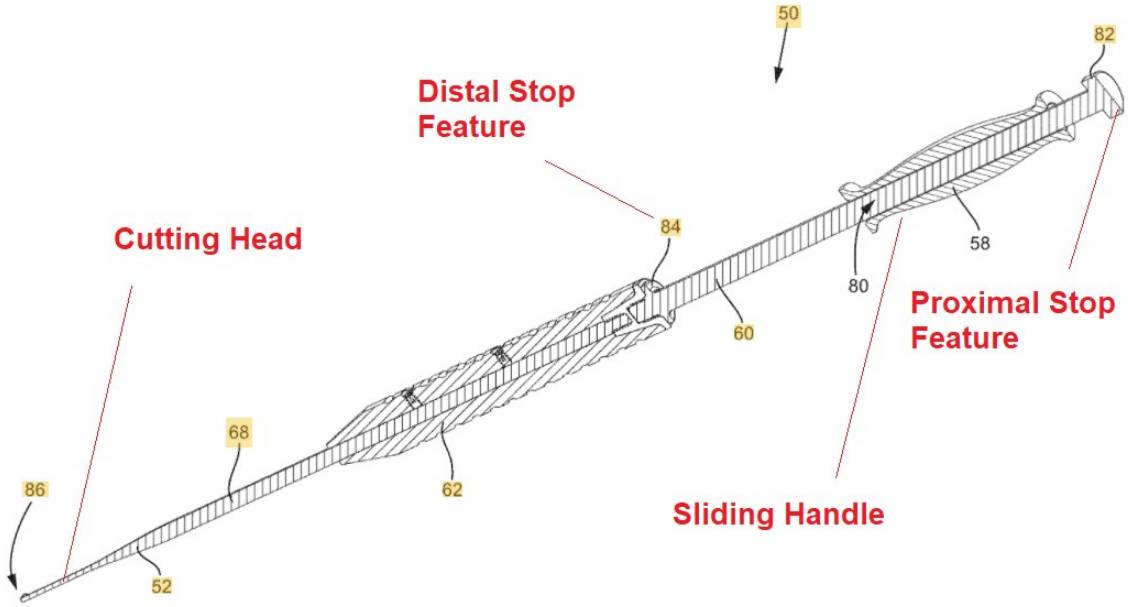

54
50
58
Cutting Head
60
Sliding Handle
52
62
56

FIG. 8


50
82
Distal Stop
Feature
84
Cutting Head
58
80
Proximal Stop
Feature
60
68
86
62
Sliding Handle
52

The joint preparation tool 50 of Donner is configured to be used with a variety of interchangeable tooling heads 52, including the rasping, joint cutting tool shown above in FIGS. 22C-22D. (Ex.1006, ¶¶[0168],[0189]). The tooling head 52 shown above includes abrading surfaces (rasping surfaces 218) on opposing sides of the tooling head and an open tip having a cutting edge 216 for cutting through the ilium and sacrum. (Ex.1006, ¶¶[0188]-[0190]). The tooling head 52 is used to prepare the SI Joint and form a decorticated implant void in the absence of a drill or other rotary cutting instrument. (Ex.1006, ¶[0188]). Drills are discussed in Donner as an alternative tissue cutting element to a box chisel. (Ex.1006, ¶[0270]). Thus, the *abrading device including open tip and slap hammer* discussed as a basis for patentability in the NOA is also found in the prior art of record.

The prosecution history of the '129 Patent is silent with regard to any particular prior art reference, yet the features identified as critical to patentability in the NOA are present in the prior art of record. (Ex.1002, p.46). As a result, the Petition raises new issues of patentability that were not considered by the examiner of the '129 Patent and that demonstrate a reasonable likelihood that the challenged claims are unpatentable.

VII. OVERVIEW OF THE '129 PATENT

A. Overview of the '129 Patent

The '129 Patent is titled "Drill-Less Method of Fusing a Sacroiliac Joint." (Ex.1001, Title.) The '129 Patent issued from U.S. Application No. 17/063,613 which was filed on October 5, 2020, which was a continuation-in-part of U.S. Application No. 16/851,840 filed on April 17, 2020, and claims priority to U.S. Provisional Application No. 62/910,913 filed on October 4, 2019. (*Id*., face page.).

The '129 Patent relates to a "method for installing a fusion implant into a sacroiliac joint ("SI Joint"). (*Id*., Abstract). The general objective of the '129 Patent is to improve the efficiency of the instrumentation and procedure of a sacroiliac fusion surgery. (*Id.*, 2:7-12). The particular improvements identified in the '129 Patent is the integration of a slide hammer and an abrading device in a single tool, and eliminating the need for a rotary cutting instrument. (*Ibid*.).

According to the '129 patent, the method includes locating an insertion point in a sacroiliac joint, the insertion point defining an intended location for the implant void. (*Id.*, 8:13-20). A working channel is introduced into the insertion point, the working channel having an insertion end and a working end. (*Id.*, 5:56-61). The insertion end of the working

channel includes a first iliac contour, a first sacral contour, and insertion arms. (*Id.*, 5:8-17). The method further includes inserting the insertion arms into the sacroiliac joint at the insertion point such that the first sacral contour is seated against a sacrum bone and the first iliac contour is seated against an ilium. (*Id.*, 9:1-7).

An abrading device is introduced into the working channel, the abrading device comprising an abrading head at a distal end of the abrading device, the abrading head having abrading surfaces on each of a first pair of opposing sides, the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint; and an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint. (*Id.*, 6:14-38). The specification describes the introduction of the abrading head being forced into the SI Joint, e.g., using a mallet. (*Id.*, 9:60-65).

The abrading device also includes a slide hammer assembly at a proximal end of the abrading device, the slide hammer assembly having a released position that enables operation of the slide hammer assembly, a locked position that prohibits operation of the slide hammer assembly, and a releasing means for transitioning the slide hammer assembly between the

locked position and the released position. (*Id.*, 6:66-7:12). The method further includes advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium and the abrading surfaces decorticate the cortical bone inside the sacroiliac joint, thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument. (*Id.*, 9:60-10:8).

The method may include unlocking the slide hammer assembly via the releasing means, and using the slide hammer assembly to dislodge the abrading head from the sacroiliac upon the abrading head becoming lodged inside the sacroiliac joint. (*Id.*, 10:32-40).

The method may include forming a generally rectangular cross-sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross-sectional shape. (*Id.*, 10:8-12).

B. Prosecution History

The ‘129 Patent issued from US Patent Application Number 17/063,613, filed on October 5, 2020 (“the ‘613 Application”). The ‘613 Application claimed priority to US Provisional Patent Application Number

62/910,913, filed on October 4, 2019 ("the '913 Provisional"). (Ex.1001, Face Page).

A Notice of Allowance was mailed by the USPTO on February 3, 2021. (Ex.1002, pp.41-47). The Notice of Allowance included an Examiner's Amendment making the following amendments to Claim 1:

"In claim 1, line 6: deleted "connected by a working channel"

In claim 1, line 10: replaced "sacral contour seated" with ---sacral contour is seated—

In claim 1, line 10: replaced "iliac contour seated" with ---iliac contour is seated---

In claim 1, line 11: replaced "the ilium" with ---an ilium---". (Ex.1002, 46).

The Notice of Allowance also included an Examiner's reasons for allowance, which states: "The claims distinguish over closest prior art cited in the 892. The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof could be found which disclose, or suggest, a method of forming an implant void in a sacroiliac joint comprising at least the steps of inserting working channel including arms and iliac/sacral contours and introducing abrading device including open tip and slap hammer." (Ex.1002, 46). The "892" referenced

in the quote is the patent examiner's reference sheet that provides a list of the prior art references purportedly reviewed by the patent examiner.

C. The Challenged Claims

Petitioner challenges Claims 1, 2 and 9-10. The single independent claim (Claim 1) is directed to a method of forming an implant void in a sacroiliac joint. In the Grounds below, claim elements are listed as: 1[a], 1[b], 1[c], etc. for ease of reference.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA is a person possessing at least (1) a Bachelor of Science in Mechanical, Biomechanical or Biomedical engineering, or a related field of science, as well as at least three years of experience in the field of orthopedic implants or would be a practicing spinal orthopedic surgeon with at least 3 years of experience and at least some experience in the design and/or use of spinal orthopedic implants. (Ex.1017, ¶19.)

IX. CLAIM CONSTRUCTION

In an *inter partes* review a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a

civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted).

To give meaning to the inventor's language, the Court “looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Phillips*, 415 F.3d at 1314. Among those sources are: (i) the words of the claims themselves; (ii) the remainder of the patent's specification; (iii) the prosecution history of the patent; (iv) extrinsic evidence concerning relevant scientific principles; (v) the common meanings of technical terms used; and (vi) the state of the art at the time of the invention. *Ibid*. Terms are be construed in light of the entirety of the patent, not just in the context of the particular claim(s) they appear in. *Id*. at 1313. There are certain terms in the challenged claims that require reference to the specification of ‘129 Patent because their meaning is not self-evident. (Ex.1017, ¶¶47-61). Terms requiring construction are addressed in the table provided below.

Extrinsic evidence of disputed terms — that is, “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises” — can also shed light on the

proper construction to be given to those terms, but extrinsic evidence "in general [is] less reliable than the patent and prosecution history in determining how to read claim terms." *Id*. at 1318.

	Asserted Claim Term	**Proposed Construction**	**Affected Claim(s)**	**Support for terms in '129 Patent**
1.	"working channel"	*A passage for guiding surgical instruments*	1	"The working channel has an insertion end and a working end and a channel extending therebetween". (Ex 1001, col. 2, ll. 19-21; FIG. 5).
2.	"working end"	*An end opposite from the insertion end through which instruments are introduced into the working channel*	1	"The working channel 10 has an insertion end 11 and a working end 12, and a channel 13 …" (Ex.1001, col. 4, ll. 59-61; FIG. 5)
3.	"a first iliac contour"	*A contoured surface on the working channel to accommodate the anatomy of the ilium.*	1	"…first iliac contour 15, which is configured for abutment against the ilium 2 when the arms 14 are inserted into, and seated within the SI Joint 3…" (Ex 1001, col. 5, ll. 14-16; FIG. 5).
4.	"a first sacral contour"	*A contoured surface on the working channel to accommodate the anatomy of the sacrum*	1	"…sacral contour 16, which is configured for abutment against the sacrum 1 when the arms 14 are inserted into, and seated within the SI Joint 3…" (Ex 1001, col. 5, ll. 19-21; FIG. 5).
5.	"insertion arms"	*Extensions from an end of the working channel*	1	"The insertion end 11 has a pair of arms 14 for providing engagement of the SI Joint 3… [t]he arms are probes, prongs, or other member

	Asserted Claim Term	Proposed Construction	Affected Claim(s)	Support for terms in '129 Patent
				protruding from the insertion end" (Ex 1001, col. 4, ll. 64-67; FIGS. 4-9).
6.	"abrading head"	*A structure at an end of an abrading device having an abrasive surface*	1	"The abrading head 32 is a rasp, broach, or other abrading tool that is used to grate, abrade, or otherwise decorticate the cortical bone inside the SI Joint 3." (Ex 1001, col. 6, ll. 16-18; FIG. 13).
7.	"open tip"	*A structure on the abrading head having an exposed tapered edge*	1	"The open tip 34 comprises a cutting edge 36 around all or part of the leading edge of the open tip 34, the cutting edge 36 configured for cutting bone tissue inside the SI Joint 3" (Ex 1001, col. 6, ll. 28-30; FIG. 14).
8.	"decorticated implant void"	*A space in the sacroiliac joint from which bone tissue has been removed*	1,9	"…cutting edge 36 cuts through the relevant bone portions of the sacrum 1 and ilium 2, and the abrading surfaces 33 work simultaneously in connection with the cutting edge 36 to decorticate the cortical bone inside the SI Joint 3, thereby forming a decorticated implant void…" (Ex 1001, col. 10, ll. 3-7).
9.	"releasing means"	*A mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, a clamp or other equivalent connection structure*	1,2,10	"The releasing means could be a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, a clamp, or other equivalent connection structure." (Ex 1001, col. 7, ll. 9-12). This limitation is to be interpreted under 35 U.S.C. § 112(f) as it recites a releasing "means". Petitioner's proposed

	Asserted Claim Term	Proposed Construction	Affected Claim(s)	Support for terms in '129 Patent
				construction tracks the definition of the "releasing means" provided in the specification.
10.	"without using a rotary instrument"	*Without the use of a rotary drill*	1	'129 Patent identifies only drills and drill bits as rotary cutting instruments: "procedure for installing an allograft implant in the SI Join, without using a drill, drill bits, or other rotary cutting instruments". (Ex 1001, col. 2, ll. 52-54)
11.	"lodged inside the sacroiliac joint"	*Frictionally engaged with the sacroiliac joint*	2,10	'…the abrading head 32 may become lodged in the SI Joint 3, becoming difficult to remove." (Ex 1001, col. 10, ll. 27-29)

X. THE CHALLENGED CLAIMS ARE UNPATENTABLE UNDER 35 U.S.C. § 103

A. Overview of Grounds

Ground	Claims	Statute	References and Type of Challenge
1	1,2, 9-10	§103	US10,219,841 (Compton) [Ex.1004] in view of US2018/0036017 (Donner) [Ex.1006] US2005/0080422 (Otte) [Ex.1007] WO2014091454 (Sharma) [Ex.1009]
2	1,2, 9-10	§103	US11,083,511 (Schifano) [Ex.1003] in view of US10,219,841 (Compton) [Ex.1004] US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]
3	1,2, 9-10	§103	US10,219,841 (Compton) [Ex.1004] in view of US2005/0090829 (Martz) [Ex.1008]

			WO2014091454 (Sharma) [Ex.1009]
4	1,2, 9-10	§103	US2016/0310197 (Black) [Ex.1005] in view of US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]
5	1,2, 9-10	§103	US2016/0310197 (Black) [Ex.1005] in view of US2018/0036017 (Donner) [Ex.1006] US2005/0090829 (Martz) [Ex.1008] WO2014091454 (Sharma) [Ex.1009]

The '129 Patent discloses a posterior approach for fusing the SI Joint. There are numerous prior art references that disclose closely related methods using the same or similar tools. (Ex.1017, ¶¶62-64). While the prior art references included herein do not anticipate challenged Claims 1, 2, and 9-10, all of the limitations of the challenged claims are disclosed in multiple prior art references. (Ex.1017, ¶27). The particular improvement identified in the '129 Patent is the integration of a slide hammer and an abrading device in a single tool, and eliminating the need for a rotary cutting instrument. (Ex.1001, 2:7-12; Ex.1017, ¶21). However, such an instrument is disclosed in multiple prior art references, including US 2018/0036017 (Donner et al.) (Ex.1006). (Ex.1017, ¶27).

The commonplace nature of elements of the challenged claims is illustrated by the following table, which identifies the prior art references

relied upon in this petition that disclose the steps and limitations of the challenged claims. (Ex.1017, ¶28).

Claim Limitations	**Prior Art Disclosing Limitations**
Independent Claim 1 *Preamble*	Schifano [Ex.1003], Compton [Ex.1004], Black [Ex.1005], or Donner [Ex.1006] in view of Otte [Ex.1007], or Martz [Ex.1008]
Limitation 1(a) *Locating insertion point*	Schifano [Ex.1003], Compton [Ex.1004], Black [Ex.1005], or Donner [Ex.1006]
Limitation 1(b) *Introducing working channel*	Schifano [Ex.1003], Compton [Ex.1004], or Black [Ex.1005]
Limitation 1(c) *Inserting arms*	Schifano [Ex.1003], Compton [Ex.1004], or Black [Ex.1005]
Limitation 1(d) *Introducing abrading device*	Schifano [Ex.1003], Compton [Ex.1004], or Black [Ex.1005]

Limitation 1(d)(i) *An abrading head*	Schifano [Ex.1003], Compton [Ex.1004], Black [Ex.1005], Donner [Ex.1006], Otte [Ex.1007], or Martz [Ex.1008]
Limitation 1(d)(i)(a) *Abrading surfaces*	Schifano [Ex.1003], Compton [Ex.1004], Black [Ex.1005], Donner [Ex.1006], Otte [Ex.1007], or Martz [Ex.1008]
Limitation 1(d)(i)(b) *An opent tip/cutting edge*	Donner [Ex.1006], Otte [Ex.1007], or Martz [Ex.1008]
Limitation 1(d)(i)(c) *A slide hammer/released position/locked position/releasing means*	Sharma [Ex.1009]
Limitation 1(e) *Advancing the abrading device*	Donner [Ex.1006], or Schifano [Ex.1003], Compton [Ex.1004], or Black [Ex.1005], in view of Donner [Ex.1006], Otte [Ex.1007], or Martz [Ex.1008]
Claim 2 *Preamble* 2(a)	
Limitation 2(b) *Unlocking slide hammer*	Sharma [Ex.1009]
Limitation 2(c) *Dislodge abrading head*	Sharma [Ex.1009]

Claim 9 *Preamble* 9(a)	
Limitation 9(b) *Forming rectangular shape*	Schifano [Ex.1003], Compton [Ex.1004], Black [Ex.1005], Donner [Ex.1006], Otte [Ex.1007], or Martz [Ex.1008]
Claim 10 *Preamble* 10(a)	
Limitation 10(b) *Unlocking slide hammer*	Sharma [Ex.1009]
Limitation 10(c) *Dislodge abrading head*	Sharma [Ex.1009]

B. Summary and Date Qualification of the Prior Art

All of the asserted references in these grounds are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000-1001 (Fed. Cir. 2016). Each reference relates to orthopedic surgeries, and all but Sharma (Ex.1009) relate to fusion surgeries involving the spine. Thus, the prior art is highly related to the methods and instruments of the '129 patent. (Ex.1017, ¶¶35,62,64). The references are also pertinent to the problem the inventor was focused on, e.g., to improve the efficiency and simplify spinal orthopedic procedures. (Ex.1017, ¶64).

As analogous art, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

1. US 10,219,841 (Compton et al.)

Compton, U.S. Patent No. 10,219,841, titled "Bone structure coupling systems and methods of use," was filed on October 25, 2017 and issued on March 5, 2019. Compton qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its issue date of March 5, 2019 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

Compton discloses devices and methods for treating an SI Joint by fitting one or more grafts inside the SI Joint to fuse the sacrum and ilium. (Ex.1004, 3:8-12). The method involves using a finder device 100 is placed in a space 238 between the sacrum and ilium. (Ex.1004, 3:35-45, 7:8-11). A retraction guide 122 (cannula) is passed over the finder device 100 and has distal arms 130 and 132 inserted into the space 238 between the articular surfaces of the sacrum and ilium. (Ex.1004, 3:52-65, 7:8-11). The retraction guide 122 includes a hollow tubular guide body 124, arms 130 and 132, and a notch 131 for receiving a detent of various instruments to be inserted through the retraction guide 122 to thereby guide the instruments and maintain their proper orientation. (Ex.1004, 3:59-4:10). Although

Compton does not expressly discuss a sacral or an iliac contour in the specification, FIG. 3 clearly shows offset contoured cutaways on either side of the insertion arms 130 and 132 that very closely resemble the sacral and iliac contours disclosed in the '129 Patent. (Ex.1017, ¶66).

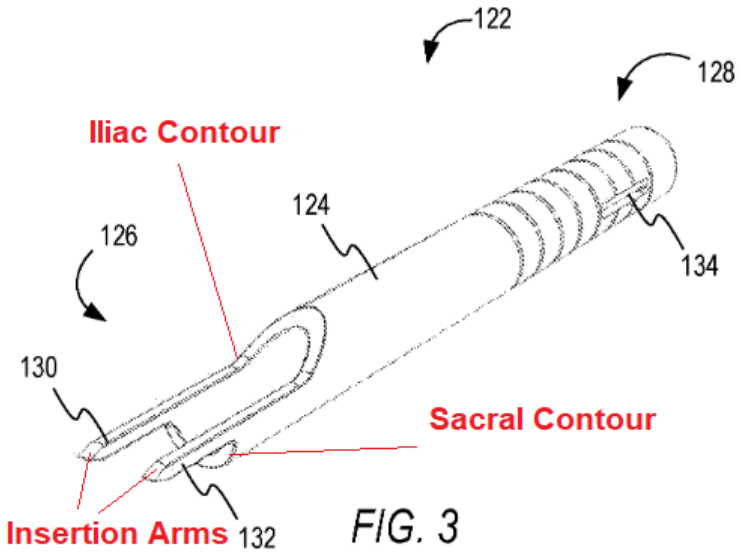


FIG. 3

A drill 136 may be used to create a pilot hole in the SI Joint tissue. (Ex.1004, 4:14-22). A broach device 148 (rasp) having cutting teeth 166 on a rectangular incising member 164 thereof is used to further excavate bone tissue of the sacrum and ilium in the pilot hole and give the pilot hole a rectangular shape, see below in FIGS. 6-7. (Ex.1004, 4:35-53, 5:1-44).

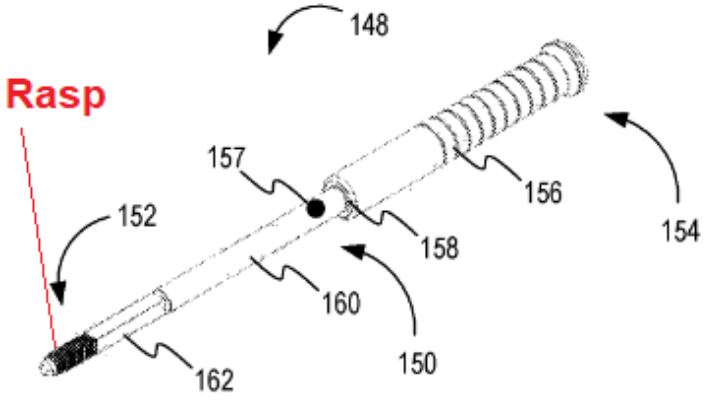


FIG. 6

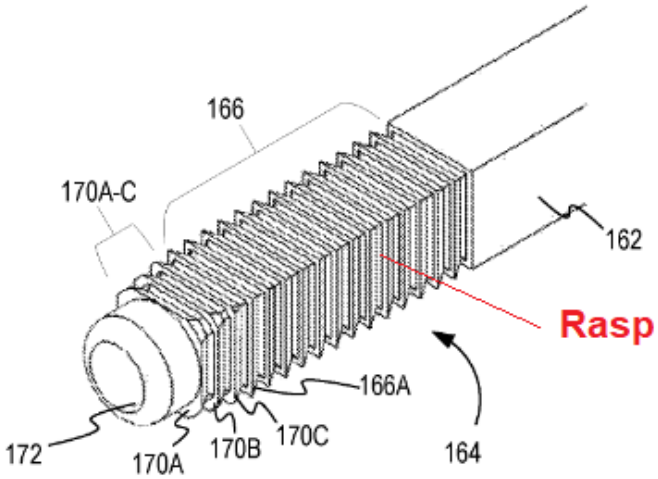


FIG. 7

A rectangular graft implant 180 is inserted into the rectangular pilot hole in the SI Joint, as shown below in FIG. 10. (Ex.1004, 5:40-51). The rectangular graft 180 has teeth 192 (ridges) to prevent migration of the graft body in the pilot hole. (Ex.1004, 5:63-6:3).

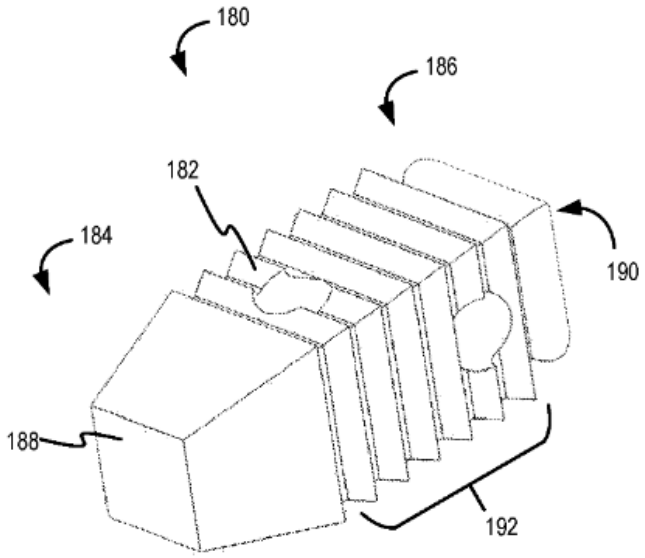


FIG. 10

2. US 11,083,511 (Schifano et al.)

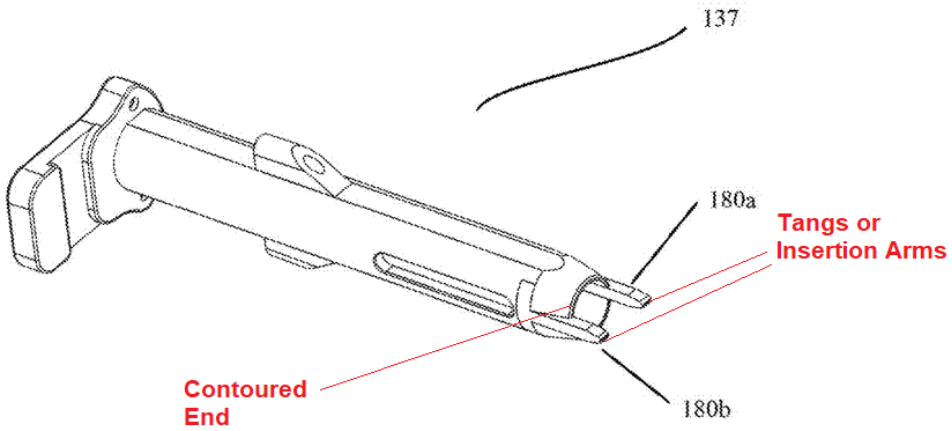
Schifano, U.S. Patent No. 11,083,511, titled "Method and Implant System for Sacroiliac Joint Fixation and Fusion" was filed on December 18, 2019 and issued on August 10, 2021 (the "Schifano"). Schifano is a continuation of Patent No. 10,993,757 filed on March 25, 2015 and issued on October 1, 2019, which is a continuation-in-part of application No. 13/842,277 filed on March 15, 2013, now Pat. No. 9,119,732. Schifano qualifies as prior art under AIA 35 U.S.C. § 102(a)(2) because its priority date of March 25, 2015 predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

Schifano discloses methods for fusing a sacroiliac joint ("SI Joint") to repair the SI Joint of the pelvis and spine. (Ex.1003, Abstract). Schifano discloses a method that utilizes several instruments in forming an incision, cutting the SI Joint tissues to form a void in the SI Joint, and inserting a joint fusion implant to immobilize and fuse the SI Joint. (Ex.1003, Abstract).

The method includes locating the SI Joint and an incision point, inserting a pin or wire to create an incision and inserting a dilator over the pin or wire to create an incision. (Ex.1003, 4:56-65, 18:52-19:16). A working channel having a tubular structure may be passed over the dilator and engaged with the posterior of the SI Joint for guiding surgical instruments into the SI Joint. (Ex.1003, 4:65-67, 18:52-19:16).

The insertable end of the working channel has two tangs (or insertion arms) 180a and 180b extending therefrom that stabilize the working channel in the SI Joint, being inserted along the plane between the articular surfaces of the SI Joint, as shown in FIG. 30 provided below. (Ex.1003, 15:21-34).

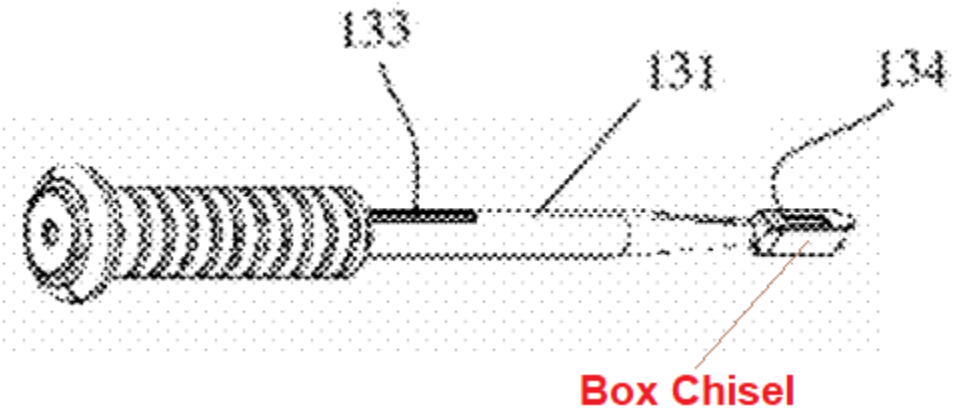
FIG. 30

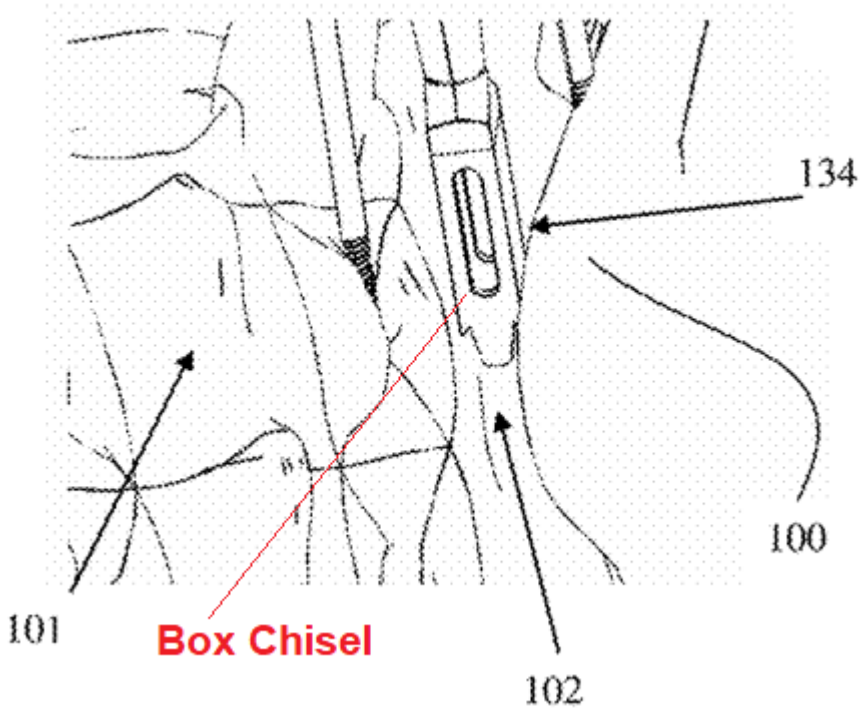


A void is created in the SI Joint that is configured to receive a joint fusion implant. (Ex.1003, 35:28-30). The method may include passing multiple surgical implements through the working channel into the void to prepare the void for receiving the fusion implant. (Ex.1003, 35:36-44).

A box chisel 131 is passed through the working channel and into the SI Joint and used to penetrate cortical tissue of the sacrum and ilium to prepare the SI joint. (Ex.1003, 19:40-65). The box chisel has a cutting edge at its distal tip to allow the chisel to dig into cortical tissue of the sacrum and ilium and shape the opening in the SI Joint to desired dimensions to better facilitate insertion of a joint fusion implant, as shown below in FIGS. 24 and 87. (Ex.1003, 19:40-50). The box chisel has a rectangular cross-section and may be maintained in alignment with the SI Joint by an alignment

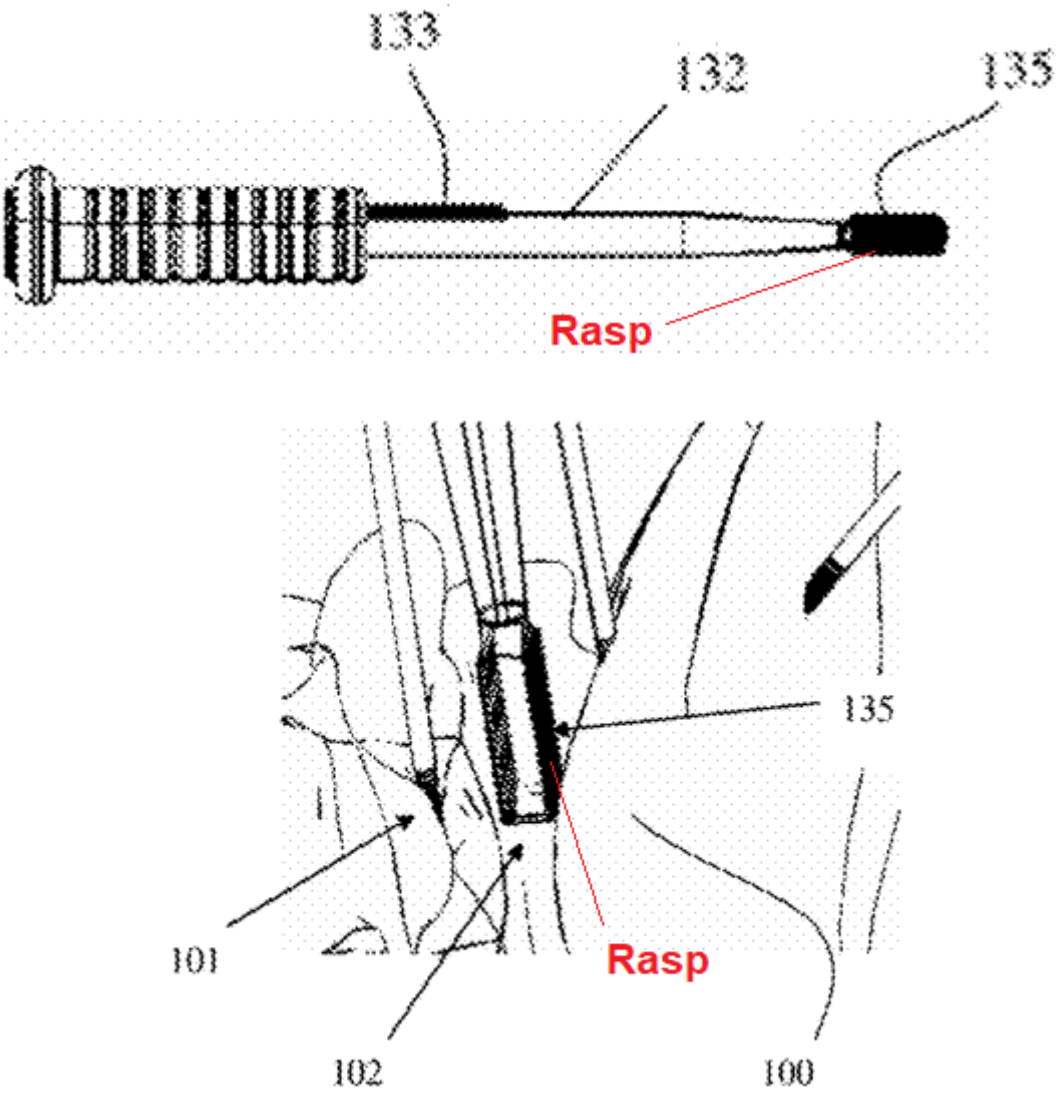
mechanism as it used to penetrate the cortical tissue of the SI Joint. (Ex.1003, 19:61-65).





A rasp 132 is passed through the working channel and into the SI Joint to further prepare the bone for the fusion implant. (Ex.1003, 15:21-34, 19:66-20:2). The rasp 132 has teeth 135 operable to scrape the bone tissue

to prepare the bone surface for receiving the joint fusion implant, as shown below in FIGS. 25 and 89. (Ex.1003, 15:21-34, 20:11-16).



Schifano teaches a substantially rectangular implant 151 having a ribbing 153 on opposing sides to grip the surfaces in the void (Ex.1003, 31:47-56).

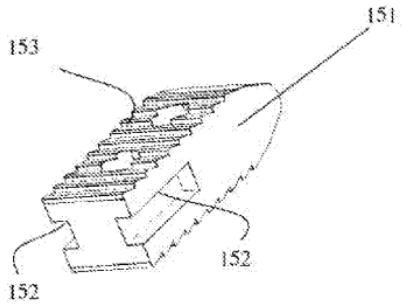


FIG.126

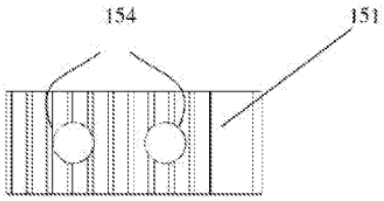


FIG. 127

3. US Pat. Publ. No. 2016/0310197 (Black et al.)

Black, U.S. Patent Publication No. 2016/0310197, titled "System for Sacroiliac Joint Fusion," was filed on April 22, 2016 and was published on October 26, 2016. Black qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of April 22, 2016 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

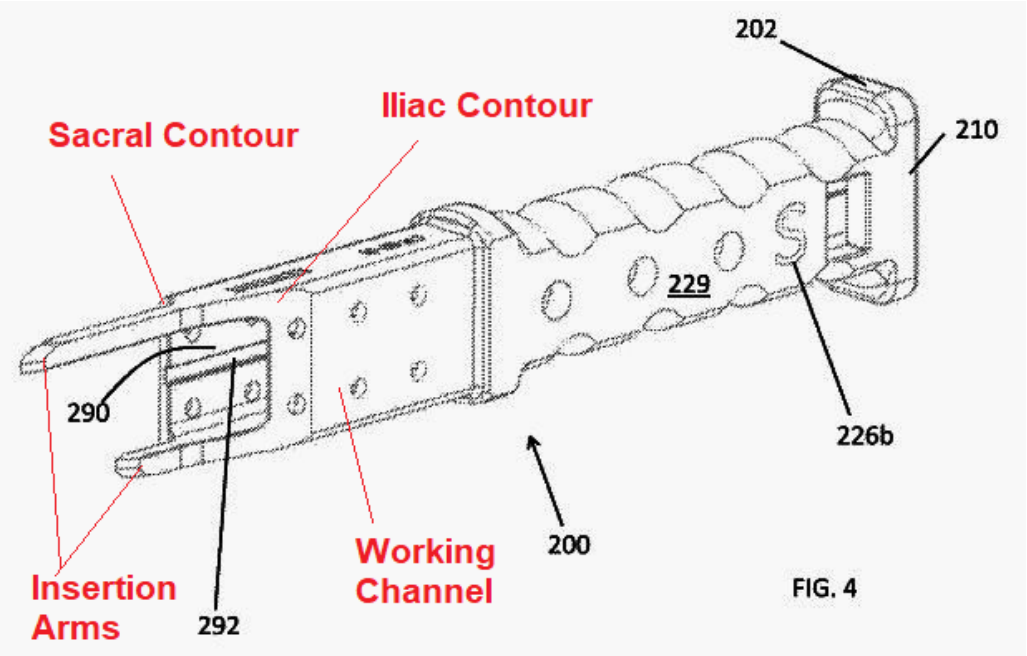
Black discloses a method for delivering an SI Joint implant or other fixation device to the SI Joint. (Ex.1005, ¶[0087]). Fluoroscopy is used to visualize the SI joint and isolate the affected SI joint. (Ex.1005, ¶[0088]). An incision is made in a region below the back of a patient and may be in alignment with the longitudinal axis of the SI joint. (Ex.1005, ¶[0090]). A guide wire or guide pin is inserted through the incision and advanced until it

reaches the SI joint. (*Ibid*.) The guide wire is used to guide a joint finder 100 to the desired site. (*Ibid*.)

A working cannula 200 is inserted over the sliding joint finder 100 and engaged with the SI Joint. (Ex.1005, ¶[0093]). Various excavation tools and implant insertion tools are configured for insertion through the working cannula into the SI Joint. (Ex.1005, ¶[0012]).

The working cannula may have a rectangular shaped cavity, but is not limited to a rectangular shape. (Ex.1005, ¶[0045]). The cavity of the working cannula can have any suitable shape and size that allows the tools to fit inside of it, and optionally, an implant, such as a spacer, to be inserted through it. (*Ibid.*). The tools that are used with the working cannula have a suitable shape and size to fit in the working cannula. (*Ibid.*).

The proximal end of the working cannula contains two protrusions that hold the joint open and retain the working cannula in position. (Ex.1005, ¶[0046]). An exemplary rectangular working cannula 200 is illustrated in FIGS. 3A and 4 of Black. (Ex.1005, ¶[0047]). The proximal end 240 of the working cannula includes two protrusions 242a and 242b, which are for insertion directly into the SI Joint. (Ex.1005, ¶[0048]).



The working cannula has a shelf 260 on side 228 that is to be positioned adjacent to the ilium and that controls the depth of insertion into the SI joint. (Ex.1005, ¶[0049]). The opposing side 229 is to be positioned adjacent to the sacrum when the cannula 200 is engaged with the SI Joint. (Ex.1005, ¶¶[0049]-[0050]).

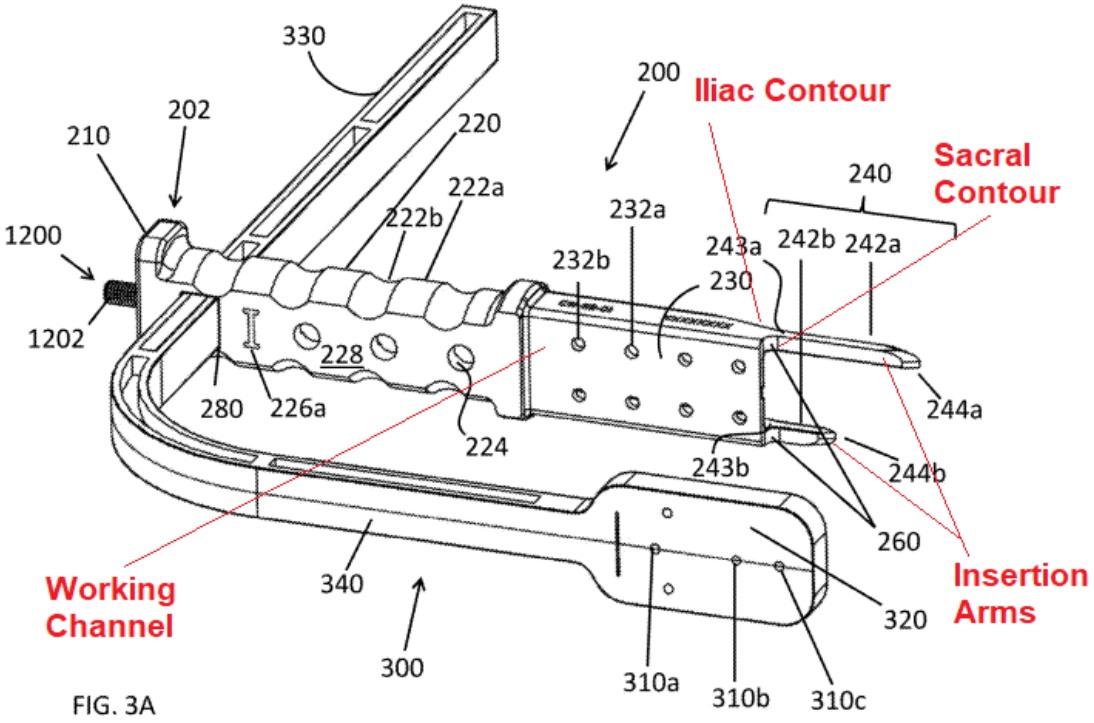


FIG. 3A

A box chisel 900 is passed through the working cannula 200 and is used to create an implant void as it is inserted into the SI Joint. (Ex.1005, ¶[0096]). Black also discloses using a drill guide 1100 and drill, but Black indicates that the box chisel 900 can be used alternatively to a drill. (Ex.1005, ¶[0096]).

The box chisel 900 has a box-shaped cavity 920 with one or more slots or windows to collect and remove bone fragments from the chisel and a sharp rectangular cutting edge 912 at its proximal end 910. (*Ibid.*). The distal end 940 of the box chisel 900 may be configured to attach to a slap handle for insertion or removal of the box chisel 900. (Ex.1005, ¶[0073]).

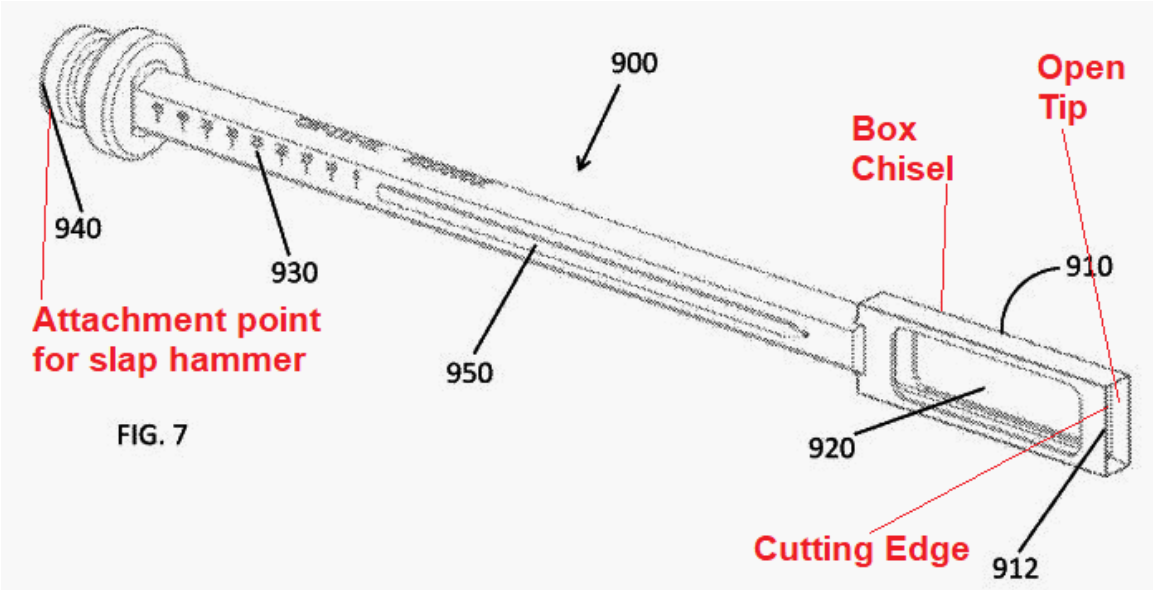


FIG. 7

Black further discloses passing a rasp 1000 through the working cannula 200 to prepare the SI Joint, as shown in FIG. 8 provided below. (Ex.1005, ¶[0075]). The rasp 1000 has a size and shape that corresponds to an implant to be inserted into the SI Joint contains. (Ex.1005, ¶[0076]). The rasp 1000 has a pattern of sharp protrusions to create an abrasive surface for cut away uneven areas in bone surfaces of the SI Joint. (Ex.1005, ¶[0077]). The distal end 1040 of the rasp 1000 may be configured to attach to a slap handle for insertion or removal of the rasp 1000. (Ex.1005, ¶[0080]).

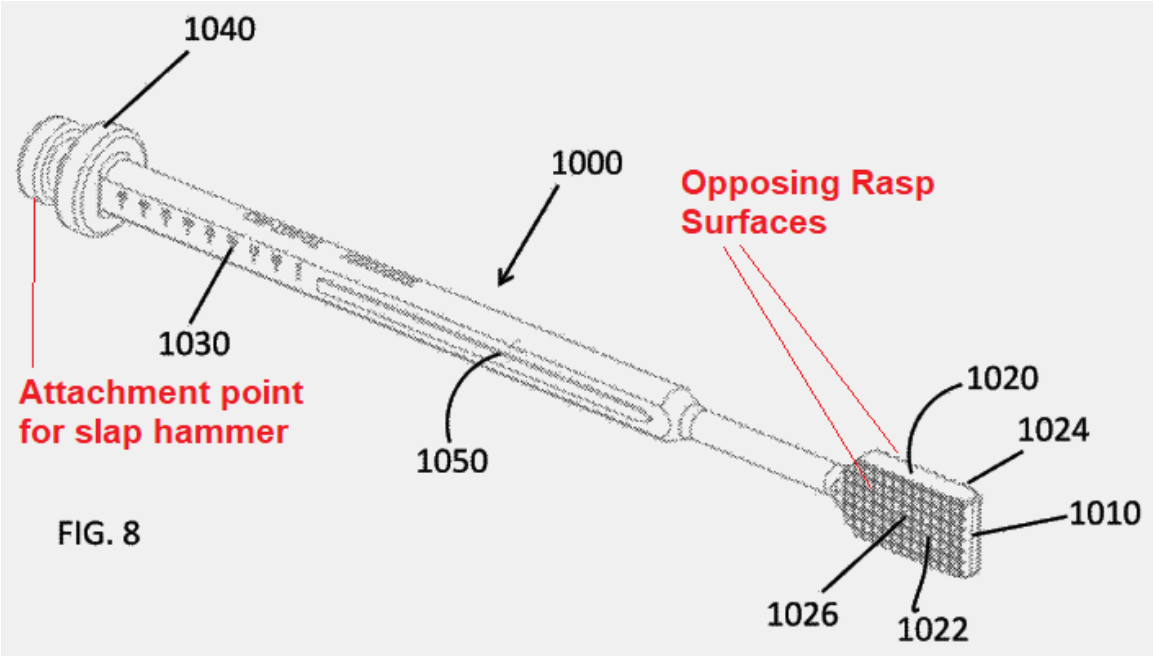


FIG. 8

Once the SI Joint is prepared, an implant having a rectangular shape (as shown in FIGS. 5C and 6A-6D provided below) may be inserted into the prepared SI Joint. (Ex.1005, ¶¶[0101],[0109]). The implant 600 may be inserted through the working cannula 200 into the SI Joint, which has been prepared with a complementary rectangular void using the rectangularly shaped box chisel 900. (Ex.1005, ¶[0071]).

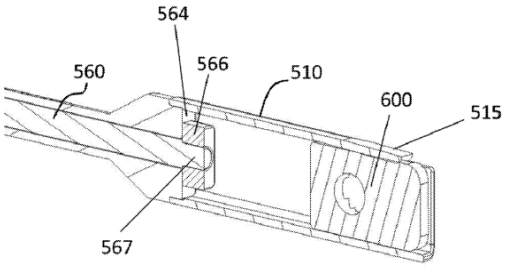


FIG. 5C

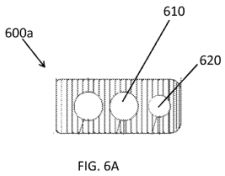


FIG. 6A

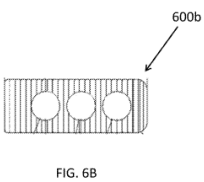


FIG. 6B

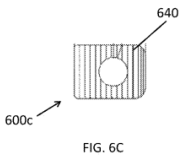


FIG. 6C

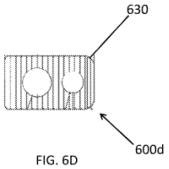


FIG. 6D

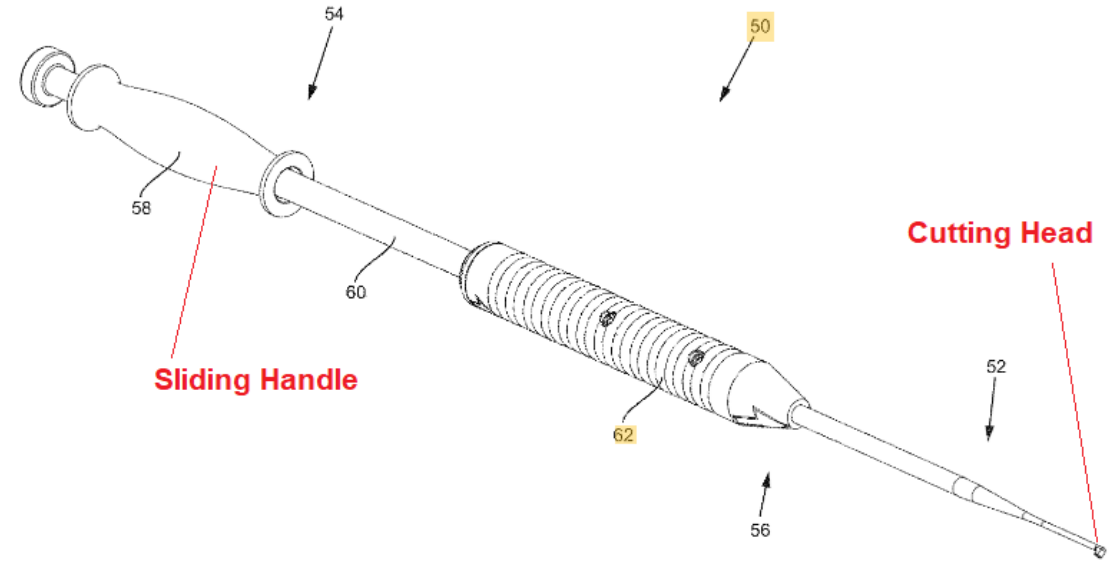
4. US Pat. Publ. No. 2018/0036017 (Donner et al.)

Donner et al., U.S. Patent Publication No. 2016/0310197, titled "Systems for and Methods of Preparing a Sacroiliac Joint for Fusion," was filed on October 17, 2017 and was published on February 8, 2018 (hereinafter, "Donner"). Donner et al. qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of February 8, 2018 is earlier than the earliest claimed priority date of the '129 patent, which is October 4, 2019.

Donner discloses a system and method for preparing the SI joint and delivering an implant to the SI joint through a posterior approach. (Ex.1006, Abstract, ¶¶[0145],[0156]). In particular, Donner discloses a method for preparation of the SI joint with a preparation tool for removing articular cartilage from the SI Joint space, abrading the articular surfaces to enhance bony fusion, and removal of cortical bone for implantation of a fusion device. (Ex.1006, ¶[0145]). The joint preparation tool 50 includes a slap hammer assembly 54 and a cutting tool assembly 56, as shown in FIGS. 6-7 provided below. (Ex.1006, ¶[0164]). The slap hammer assembly 54 includes a proximal handle 58 that translates on a shaft 60 between a proximal stop feature 82 and a distal stop feature 84. (Ex.1006, ¶[0165]). The proximal handle 58 translates force along shaft 60 and transmits the

force through stop feature 84 to drive the tooling head 52 into the SI Joint. (*Ibid*.).

FIG. 6



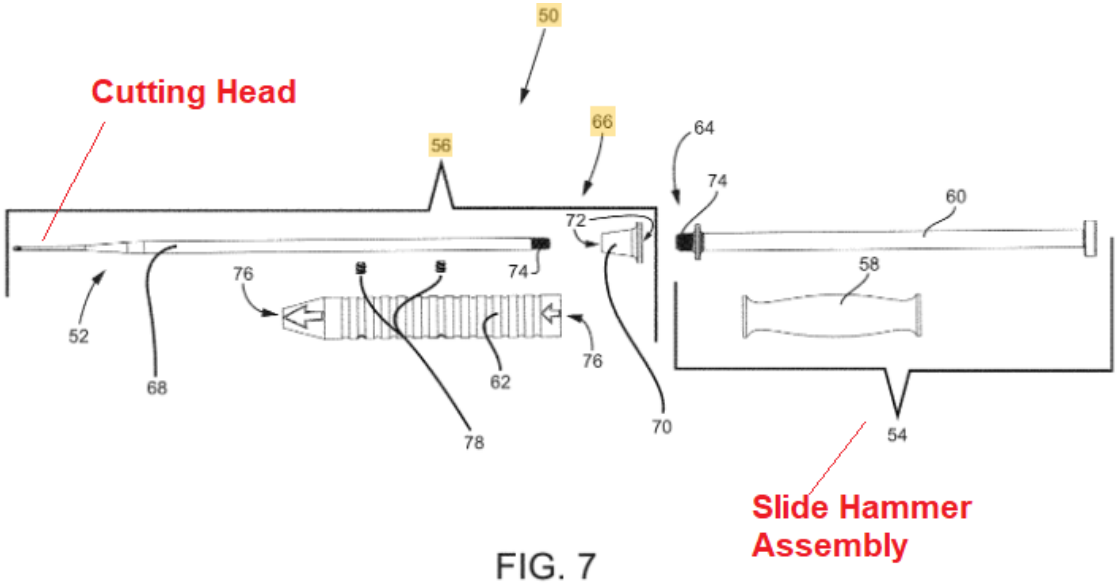
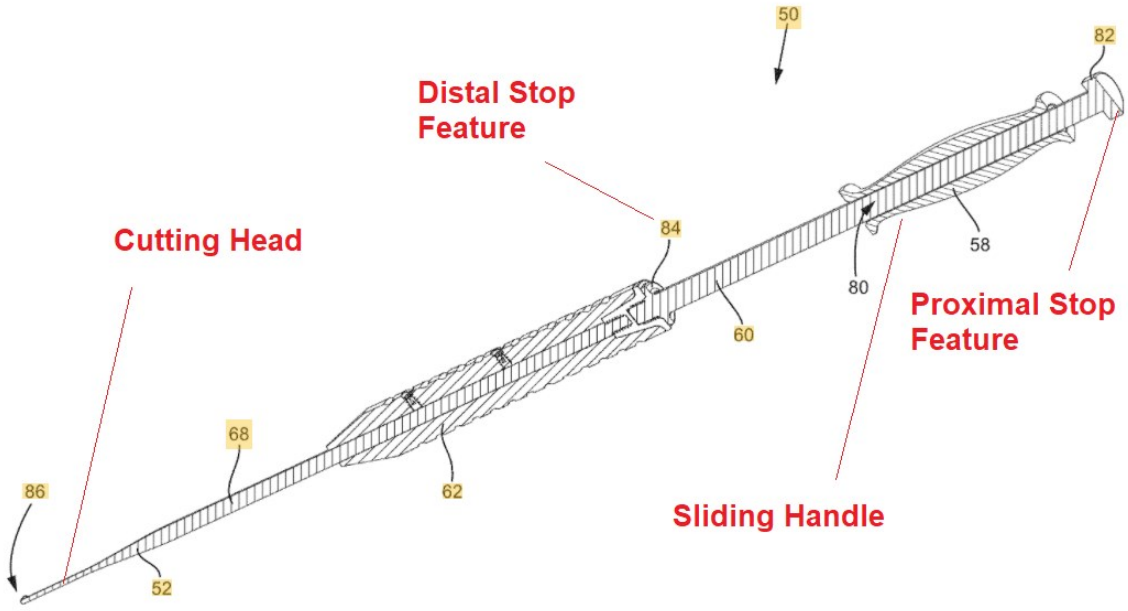


FIG. 7

FIG. 8



Additionally, the tooling head 52 can be backed out of the SI Joint by proximally sliding the proximal handle 58 until it contacts a proximal stop feature 82 to the transmission of proximal force to back the tooling head 52 out of the SI Joint. (Ex.1006, ¶¶[0166]-[0167]).

The joint preparation tool 50 is configured to be used with a variety of interchangeable tooling heads 52. (Ex.1006, ¶[0168]). Donner discloses an embodiment of a tooling head 52 for forming a space in the SI Joint that matches the shape of an implant for placement in the SI Joint. (Ex.1006, ¶[0189]). The tooling head 52 includes abrading surfaces (rasping surfaces 218) including ridges 220 on each of a pair of opposing sides (top surface 196 and bottom surface 198) and an open tip having a cutting edge 216 for

cutting through the ilium and sacrum, as shown below in FIGS. 22C-22D. (Ex.1006, ¶¶[0188]-[0190]). The tooling head 52 is used to prepare the SI Joint and form a decorticated implant void in the absence of a drill or other rotary cutting instrument. Drills are discussed in Donner as an alternative tissue cutting element to a box chisel. (Ex.1006, ¶[0270]).

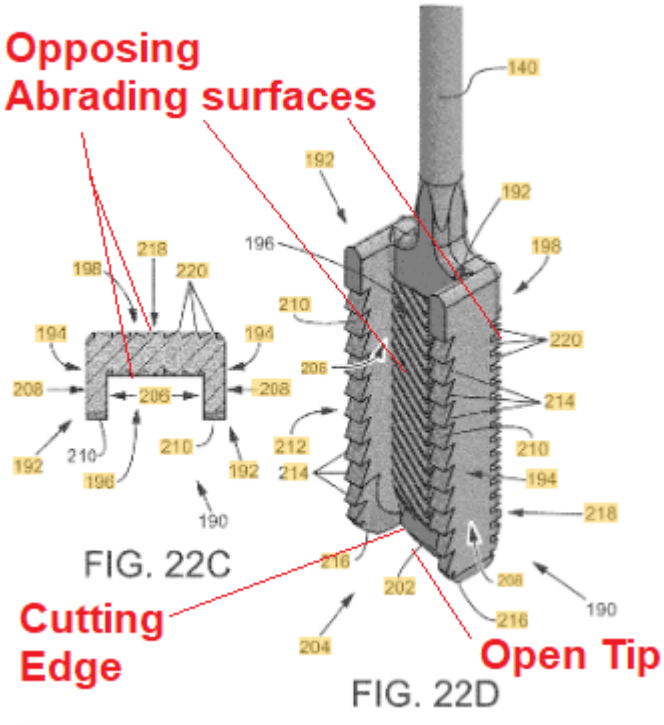


FIG. 22C

FIG. 22D

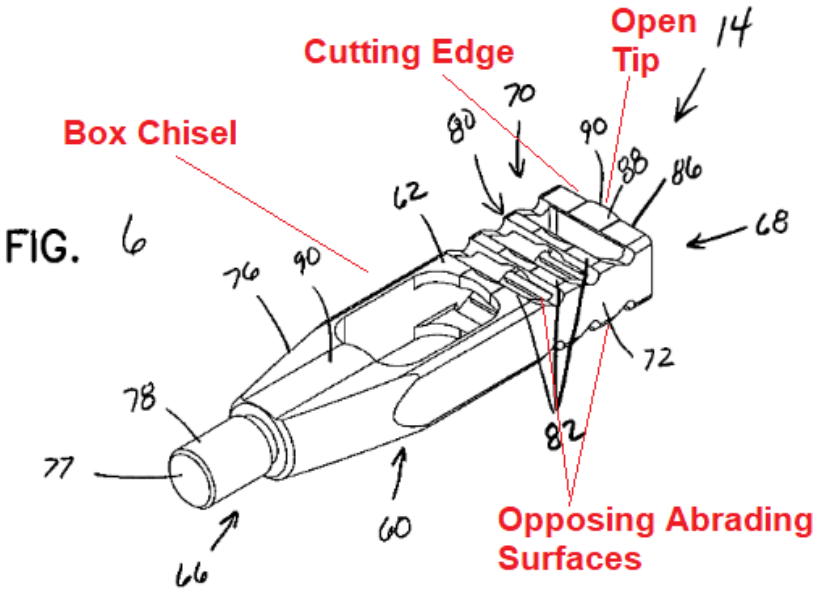
5. US Pat. Publ. No. 2005/0080422 (Otte et al.)

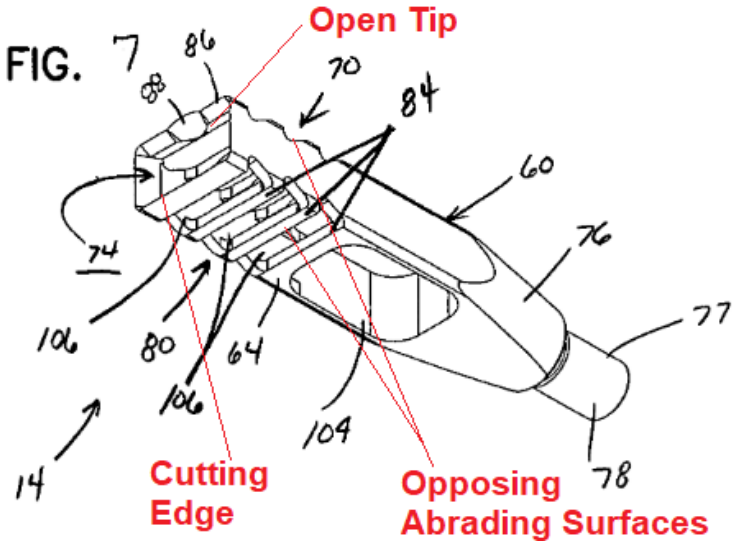
Otte et al., U.S. Patent Publication No. 2005/0080422, titled "Instruments for use with Implants, and Methods," was filed on October 14, 2003 and published on April 14, 2005 (hereinafter, "Otte"). Otte qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of

April 14, 2005 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

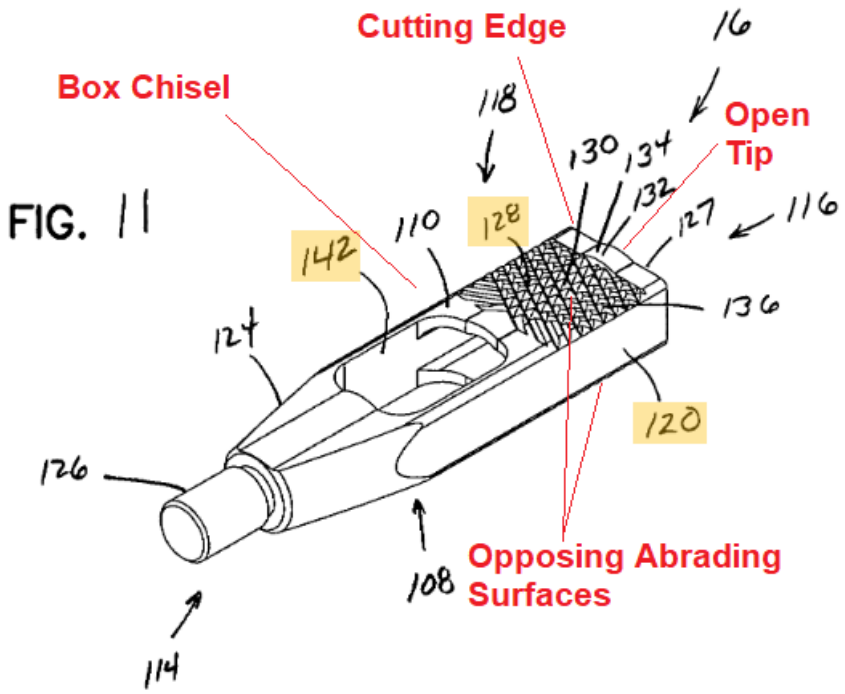
Otte discloses a variety of instruments that can be used in a spinal implant surgery, including a box chisel for preparing and shaping an implant site to corresponding to the shape of a vertebral implant. (Ex.1007, ¶¶[0056]-[0057],[0064]). Otte makes no disclosure of the use of a drill in preparing an implant site for the implant.

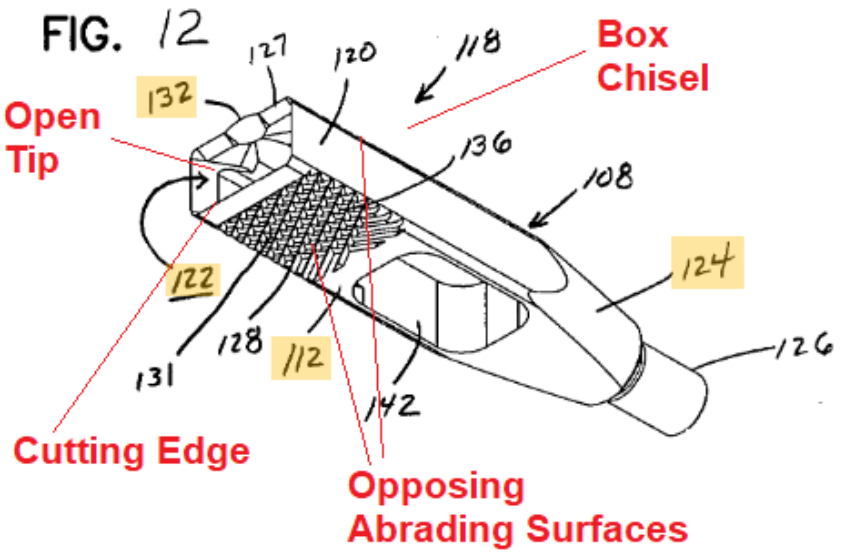
Box chisel 14 includes the box chisel 14 includes a perimeter cutting edge 86 having a rectangular shape and a surface texture 80. (Ex.1007, ¶¶[0066],[0068]). The perimeter cutting edge 86 is used as a leading cutting edge that is forcibly inserted into and between the vertebral bones by hammering to cut out a plug of material to form the implant site. (Ex.1007, ¶[0068]). The surface texture 80 includes rasping structures or elements, such as teeth 82 and 84 formed in each of the first and second planar surfaces 62 and 64. (Ex.1007, ¶[0072]). The teeth 82 and 84 of the box chisel 14 are designed to scrape the vertebral bones to remove bone tissue for further site preparation of the implant site. (Ex.1007, ¶¶[0072]-[0073]). The cutting edge 86 and the surface texture 80 together prepare a channel or implant bore between adjacent vertebral bones corresponding to the particular profile of the implant. (Ex.1007, ¶[0069]).





Otte discloses a second embodiment of a box chisel, box chisel 16, which is similar to box chisel 14 and includes a distal a perimeter cutting edge 127 and a scraping surface texture 128, as shown below in FIGS. 11-12. (Ex.1007, ¶¶[0078], [0080], [0082]).





6. US Pat. Publ. No. 2005/0090829 (Martz et al.)

Martz et al., U.S. Patent Publication No. 2005/0090829, titled "Spinal Bone Chisels," was filed on March 23, 2004 and published on April 28,

2005 (hereinafter, "Martz"). Martz et al. qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of April 28, 2005 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

Martz discloses a spinal implant chisel tool having various cutting edges for preparing the intervertebral disc space for implants and method of preparing the spinal disc space. (Ex.1008, ¶[0002]). The chisel prepares adjacent vertebrae for insertion of a spinal implant into the disc space between adjacent vertebrae. (Ex.1008, ¶[0025]). The chisel tool includes a cutting head (a chisel) that is operable to be positioned between adjacent vertebrae. (Ex.1008, ¶[0093]). The chisel removes a first portion of endplate material from at least one of two adjacent vertebrae using cutting edges and removes disc material between the adjacent vertebrae using a second cutting edge on a distal end of the chisel. (*Ibid*.).

In one embodiment, the chisel instrument 360 may include a shank 52, a handle 54, and a cutting head 366. (Ex.1008, ¶[0305]). The cutting head 366 includes a spaced pair of guide members 368 and 368′ extending distally and terminating with distal cutting edges 369 and 369′. (*Ibid*.). The outer surfaces of the guide members 368 and 368′ include rasping surfaces 372 and 374, respectively. (Ex.1008, ¶[0306]). The rasp surfaces include a

plurality of sharp protuberances or raised projections, such as pyramidal, conical or other rasp projections. (*Ibid.*). The rasping surfaces 372 and 374 are used to scrape disc material and bone from adjacent vertebrae to prepare the disc space for insertion of a spinal implant. (*Ibid.*). Martz makes no disclosure of the use of a drill in preparing an implant site for the spinal implant.

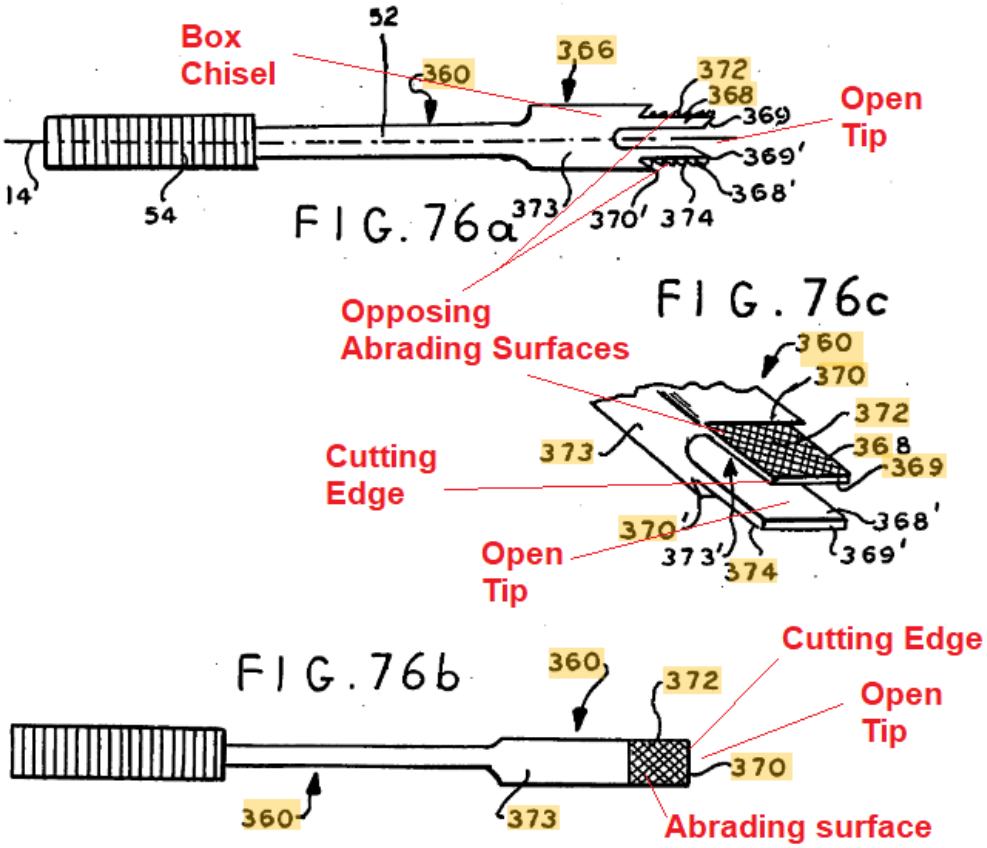


FIG. 76a

FIG. 76c

FIG. 76b

7. WO2014091454 (Sharma et al.)

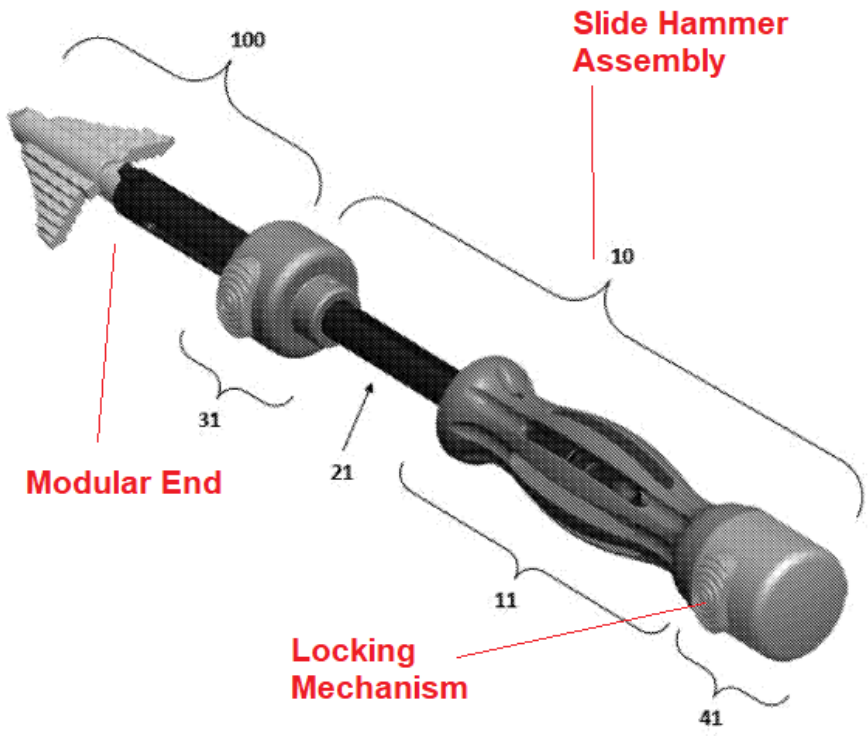
Sharma et al., International Patent Publication No. WO2014091454, titled "Universal Impactor with Slap Hammer" was filed on December 13, 2013 and published on June 19, 2014 (hereinafter, "Sharma"). Sharma et al. qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of April 28, 2005 significantly earlier than the earliest claimed priority date of the '129 patent, which is October 4, 2019.

Sharma et al. discloses a universal impactor with slap hammer device for use to assist in the impaction and/or extraction of a surgical instrument attached thereto, such as a chisel or rasp. (Ex.1009, Abstract; p.19, ll.15-18). The universal impactor and slap hammer device can be used as an impactor and an extractor to perform the function of extracting a surgical instrument. (Ex.1009, p.2, ll.29-32). The universal impactor and slap hammer includes a locking mechanism that, when locked, allows the universal tool to function as an impact hammer and, when unlocked, allows the universal tool to act as a slap hammer. (Ex.1009, p.3, ll.1-3). The universal tool has a modular end that can connect to different types of instruments during a surgical procedure. (Ex.1009, p.3, ll.7-9). The locking mechanism may be a quick connect device operated by a spring-biased button, a threaded screw connection, or a taper lock. (Ex.1009, p.4, ll.24-

32).

An exemplary universal impactor and slap hammer tool 10 includes a distal quick connect mechanism 31, a proximal impaction end 41, and an attached medical instrument 100 on the modular end. (Ex.1009, p.9, ll.1-5). The universal impactor may be converted between extractor and impactor by the operation of the locking mechanism 42 in the proximal end of the handle. (Ex.1009, p.20, ll.6-10).

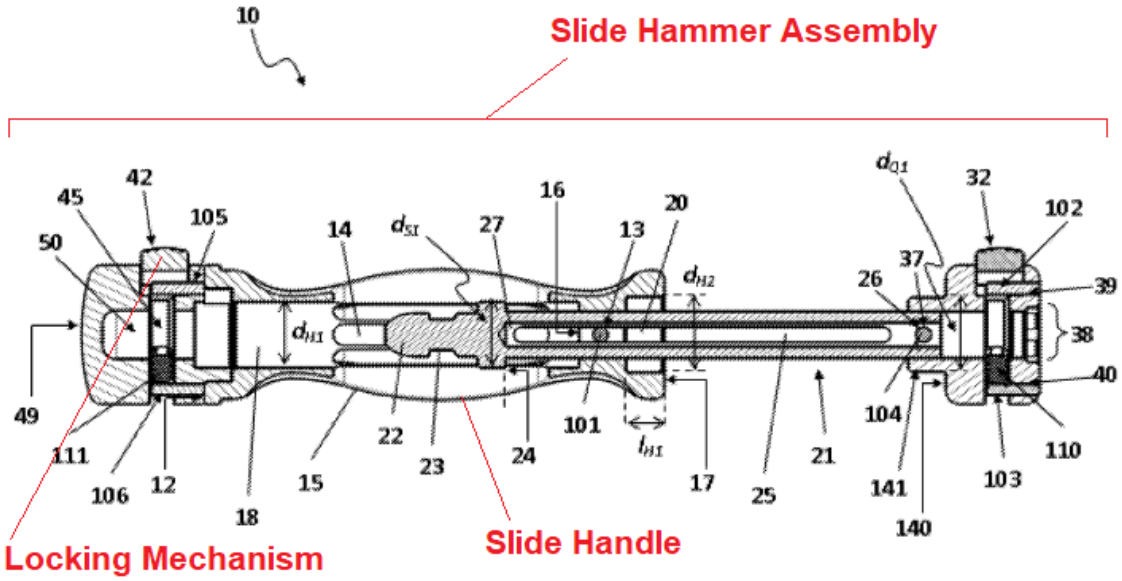
FIGURE 1



The device can be used as an impactor when the central shaft is pushed into the integrated hollow handle and is locked into the handle by

passing through proximal button hole 45. (Ex.1009, p.10, ll.20-24). In this mode, the impaction head 43 of the impaction end 41 can be struck with a mallet to hammer the surgical instrument 100 into bone during surgery. (Ex.1009, p.20, ll.9-10).

FIGURE 4



The device can be used to extract a surgical device by pressing button 42 to release the tip 22 of the central shaft, enabling the shaft to move within the hollow handle up to the predetermined length, allowing operation as an extractor or as a slap hammer. (Ex.1009, p.20, ll.11-16).

C. Legal Standard for Obviousness

A claim is obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. The obviousness analysis includes an assessment of the Graham factors: (1) the scope and content of the prior art; (2) any differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

D. Ground 1: Claims 1, 2 and 9-10 are Unpatentable as Obvious over Compton in view of Donner, Otte, and Sharma.

1. Motivation to combine

A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the of the '129 Patent to modify the posterior SI Joint approach disclosed by Compton in view of the instruments and methods disclosed by Donner, Otte, and Sharma. (Ex.1017; ¶111). Compton and Donner disclose posterior approaches for SI Joint fusion with an implant inserted into the articular space between the sacrum and ilium with similar instrumentation. (*Ibid*.). Thus, the methods and instruments of Compton and Donner are related and have significant overlap in both instrumentation and methodology. (*Ibid*.). Both Compton and Donner

discuss using rasps and chisels for preparing the SI Joint for a fusion implant. (Ex.1004, 4:35-53; Ex.1006, ¶[0188]). It would be obvious to a POSITA to combine the use of joint preparation tool of Donner with the SI Joint method of Compton because the joint preparation tool of Donner prepares the SI Joint and articular surfaces of the SI Joint with a single tool, instead of multiple separate tools such as a chisel, a rasp, and other tools. (Ex.1017; ¶111). Additionally, the joint preparation tool of Donner includes a slap hammer portion, and thus provides a single tool that in includes a cutting tool and slap hammer functionalities operable to efficiently prepare the SI Joint for the insertion of a fusion implant. (Ex.1006, ¶[0164]). It would be obvious to a POSITA that the joint preparation tool of Donner would be beneficially used in the method of Compton with predictable improvements in efficiency. (Ex.1017; ¶111).

Otte discloses methods and instruments for preparing the intervertebral disc space for implants in a spinal fusion surgery and methods of preparing the spinal disc space. (Ex.1007, ¶¶[0056]-[0059]). Spinal fusion surgeries are closely related to SI Joint fusion surgeries as they both deal with fusion of vertebral bones, both are performed by orthopedic spinal surgeons, and they use similar tool sets in similar manners. (Ex.1017; ¶112). Thus, it would be obvious to a POSITA to combine the teachings of Otte,

including the disclosed instruments and techniques, with the SI Joint fusion methods of Compton and Donner. (Ex.1017; ¶112).

Sharma discloses a universal impactor with slap hammer device for applying force for use to assist in the impaction and/or extraction of an attached surgical instrument from an orthopedics structure. The slap hammer device of Sharma is designed for general use in orthopedic procedures. (Ex.1009, p.3, ll.1-3). It would be obvious to use the universal impactor with slap hammer device of Sharma to assist in the impaction and/or extraction of attached surgical instruments in an SI Joint fusion procedure, such as chisels and rasps. (Ex.1017, ¶113). Compton discloses an orthopedic spinal procedure that includes the use of an impactor and tools that are conventionally used with hammers and slap hammers, such as a box chisel or rasp. (Ex.1004, 4:35-53, 5:1-44; Ex.1017, ¶113). It would be obvious to a POSITA that the universal impactor with a slap hammer device would be beneficially used with the tools (e.g., the box chisel and rasp) used in the method of Compton with predictable improvements in efficiency, particularly in view of the disclosure of the joint preparation tool of Donner. (Ex.1017, ¶113).

2. INDEPENDENT CLAIM 1

i) (*Preamble*) "*A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument*"

Compton teaches a method that includes forming an implant void in an SI Joint. (Ex.1004, 2:51-3:16).

Donner discloses a method for preparing the SI joint fusion through a posterior approach using a preparation tool for excavating and preparing an SI Joint for implantation of a fusion device without the use of a rotary cutting instrument. (Ex.1006, ¶¶[0145],[0156],[0188]-[0190]; Ex.1017, ¶115).

ii) (1(a)) *Locating insertion point*

Compton discloses locating the SI Joint and positioning a guide rod in the SI Joint and inserting a finder device 100 over the guide rod and into the SI Joint. (Ex.1004, 3:28-45).

iii) (1(b)) *Introducing working channel*

Compton discloses retraction guide 122 (cannula) that has distal arms 130 and 132 that are inserted into a space 238 between the articular surfaces of the sacrum and ilium. (Ex.1004, 3:52-65, 7:8-11, Fig. 3 below). The

retraction guide 122 has contours at the insertion end of the retraction guide 122 on each side of the arms 130 and 132 that have the same shape and arrangement as the sacral and iliac contours as shown in FIGS. 4-9 and recited in Claim 1 of the '129 Patent.

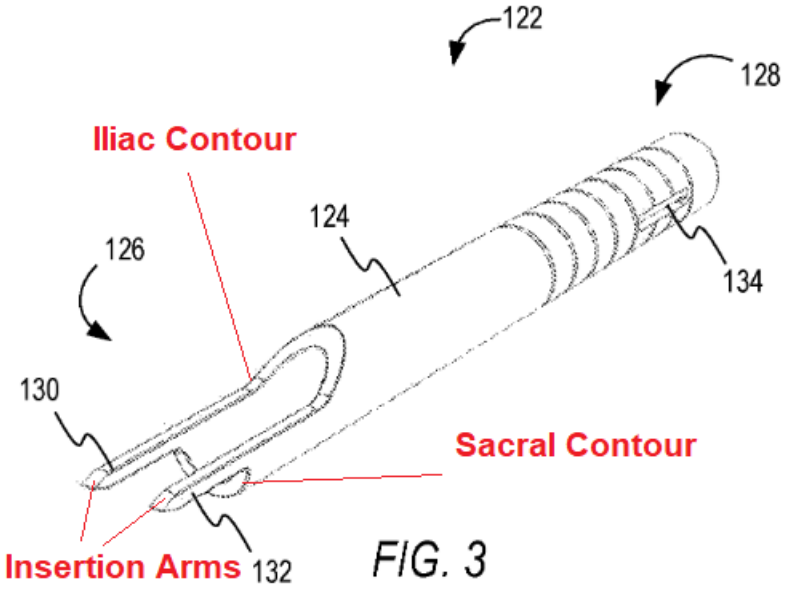


FIG. 3

iv) (1(c)) *Inserting arms*

Compton discloses retraction guide 122 (cannula) that has distal arms 130 and 132 that are inserted into a space 238 between the articular surfaces of the sacrum and ilium. (Ex.1003, 3:52-65, 7:8-11).

v-vii) (1(d), 1(d)(i), 1(d)(i)(a)) *Introducing Abrading Device*

Compton discloses a broach 148 (abrading device) having an incising member 164 having cutting teeth 166 on opposing sides of the incising

member 164 for preparing the bone tissue in the SI Joint for fusion. (Ex.1003, 5:1-25). The broach 148 is inserted into the SI Joint through the retraction guide 122 (working channel). (Ex.1003, 20:3-20).

viii) (1(d)(i)(b)) *An open tip / cutting edge*

Compton discloses an abrading device as discussed in section X.D.2.v-vii, but not an open tip with a leading, cutting edge for cutting bone tissue in the SI Joint.

Donner discloses a joint preparation tool 50 having a tooling head 52 for forming a space in the SI Joint that matches the shape of an implant for placement in the SI Joint. (Ex.1006, ¶[0189]). The tooling head 52 used to prepare to form a decorticated implant void that includes abrading surfaces (rasping surfaces 218) including ridges 220 on each of a pair of opposing sides (top surface 196 and bottom surface 198) and an open tip having a cutting edge 216 for cutting through the ilium and sacrum. (Ex.1006, ¶¶[0188]-[0190]).

Otte discloses a box chisel for preparing and shaping an implant site including a perimeter open cutting edge 86 used as a leading cutting edge having a rectangular shape and a surface texture 80 including rasping

structures or elements. (Ex.1007, ¶¶[0056]-[0057],[0064],[0066],[0068], [0072]).

ix) (1(d)(i)(c)) ***A slide hammer / released position / locked position / releasing means***

Compton discloses the use of an impactor for use in connection with the disclosed working channel, and slap hammers and slide hammers are commonly used in the relevant art with the instruments disclosed by Compton, including the broach 148. (Ex.1017, ¶123; Ex.1004, 6:51-59). A POSITA would understand that slap hammer or a related device would be routinely used with a broach (such as broach 148) disclosed in Compton. (Ex.1017, ¶123).

Donner discloses a slide hammer assembly for use in a SI Joint fusion procedure. The joint preparation tool 50 of Donner includes a slap hammer assembly 54 and a cutting tool assembly 56. (Ex.1006, ¶[0164]). The tooling head 52 can be backed out of the SI Joint using the slap hammer assembly 54 by proximally sliding the proximal handle 58 until it contacts a proximal stop feature 82 to the transmission of proximal force to back the tooling head 52 out of the SI Joint. (Ex.1006, ¶¶[0165]-[0167]).

Sharma discloses a universal impactor with slap hammer device for applying force for use to assist in the impaction and/or extraction of a surgical instrument attached thereto, such as chisels and rasps. (Ex.1009, Abstract; p. 2, ll. 29-32; p. 19, ll. 15-18). The universal tool has a modular end that can connect to different types of instruments, including chisels and rasps during a surgical procedure. (Ex.1009, p. 3, ll. 7-9). The universal impactor and slap hammer includes a locking mechanism that, when locked, allows the universal tool to function as an impact hammer and, when unlocked, allows the universal tool to act as a slap hammer. (Ex.1009, p. 3, ll. 1-3). As further explained above in section X.D.1. herein, it would be obvious to combine the slide hammer of Sharma with the methods of Compton and Donner. (Ex.1017, ¶125).

x) (1(e)) ***Advancing the abrading device***

Compton discloses inserting the broach 148 into the SI Joint through the working channel to decorticate the cortical tissue of the sacrum and ilium and prepare the bone tissue in an implant void in the SI Joint. (Ex.1006, 5:12-25, 7:42-53).

To the extent that Compton does not teach all of the limitations of step (1(e)), Donner discloses a joint preparation tool 50 removes articular

cartilage and cortical bone from the SI Joint space and abrades the articular surfaces. (Ex.1006, ¶[0145]; Ex.1017, ¶[0127]). The tooling head 52 is used to prepare the SI Joint and form a decorticated implant void in the absence of a drill or other rotary cutting instrument. (Ex.1006, ¶[0145]; Ex.1017, ¶127). Drills are discussed in Donner as alternative embodiments to non-rotary cutting elements. (Ex.1006, ¶[0270]; Ex.1017, ¶127).

3. DEPENDENT CLAIM 2

i-iii) (2(a)-2(c)) *Unlocking slide hammer / dislodge abrading head*

The universal impactor and slap hammer disclosed by Sharma includes a locking mechanism that, when unlocked, allows the universal tool to act as a slap hammer and to extract a surgical instrument. (Ex.1009, p. 2, ll. 29-32; p. 3, ll. 1-3).

4. DEPENDENT CLAIM 9

i-ii) (9(a)-9(b)) *Forming rectangular shape*

Compton teaches inserting a rectangular implant into a pilot hole 252 (void) in the SI Joint. (Ex.1004, 7:61-8:13, 8:24-28). The pilot hole 252 may be configured to be rectangular to receive a graft 180 (fusion implant). (Ex.1004, 7:42-53).

5. DEPENDENT CLAIM 10

i-iii) (10(a)-10(c)) *Unlocking slide hammer, dislodge abrading*

Claim 10 has the same limitations as the combined limitations of Claims 2 and 9, which are fully addressed above.

E. Ground 2: Claims 1, 2 and 9-10 are Unpatentable as Obvious over Schifano in view of Compton, Martz, and Sharma

1. Motivation to combine

A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the of the '129 Patent to modify the posterior SI Joint approach disclosed by Schifano in view of the instruments and methods disclosed by Compton, Martz, and Sharma. (Ex.1017, ¶131).

Schifano discloses methods and instruments for a posterior approach for SI Joint fusion. (Ex.1003, Abstract). Compton discloses a similar posterior approach for SI Joint fusion that utilizes similar instrumentation, and is thus closely related to Schifano. (Ex.1017, ¶132). Schifano and Compton disclose that utilize a cannula having two tangs (or extensions) extending from the distal end of the cannula that are inserted into the articular space between the sacrum and ilium in the SI Joint. (Ex.1003, 15:21-34; Ex.1004, 3:52-65, 7:8-11; Ex.1017, ¶132). Though Compton does

not expressly state that the distal contours of the cannula of Compton accommodate the anatomy of the ilium and sacrum in the area of the SI Joint, it would be obvious to a POSITA that the contours shown in the cannula of Compton are intended to accommodate the anatomy of the ilium and sacrum. (Ex.1017, ¶132). It would be obvious to a POSITA to combine the contours of the cannula of Compton with the working channel of Schifano since it would predictably provide better securement of the working channel in the SI Joint in the posterior approach. (Ex.1017, ¶132).

Martz discloses spinal fusion chisel tools having various cutting edges for preparing the intervertebral disc space for implants in a spinal fusion surgery and methods of preparing the spinal disc space. (Ex.1008, ¶¶[0002],[0025]). Spinal fusion surgeries are closely related to SI Joint fusion surgeries as they both deal with fusion of vertebral bones and both intervertebral fusion and SI Joint fusion surgeries involve preparing the joint space by clearing out the connective tissue, preparing the articular surfaces in the joint with chisels and rasps, and inserting a fusion implant between the prepared bone surfaces. (Ex.1003, 19:40-20:2; Ex.1008, ¶¶[0093]-[0095]; Ex.1017, ¶133). Thus, the methods and instruments of Schifano, Compton, and Martz are highly related and have significant overlap. (Ex.1017, ¶133).

The box chisel of Martz performs the functions of two of the tools utilized in the method of Schifano: the box chisel and rasp. (Ex.1017, ¶134; Ex.1008, ¶[0305]). The box chisel tool of Martz can be easily substituted for the box chisel and rasp of Schifano and predictably improve the efficiency of the method of Schifano. (Ex.1017, ¶134). The combined box chisel and rasp accomplishes the function of the box chisel (shaping an implant void allowing for the insertion of a fusion implant in the intervertebral space) and function of the rasp (decorticating the articular bone and filing the bone surface to provide a regular surface and induce bone repair) in one operation, eliminating the time and effort needed to insert and extract a second tool and apply the tools separately in the SI Joint. (*Ibid*.). Therefore, it would be obvious to a POSITA to utilize the box chisel, rasp combination tool of Martz in the method of Schifano in substitution for the separate box chisel and rasp. (*Ibid*.).

Martz also discloses preparing articulating bone surfaces using the box chisel, rasp combination tool without the use of a drill. (Ex.1017, ¶135). The bone surfaces of intervertebral discs are analogous in their structure to the articular surfaces of the sacrum and ilium in the sacroiliac joint. (*Ibid*.). It would be obvious to a POSITA that the drill-less method of preparing the bony surfaces of adjacent vertebral bodies would be applicable to the

articular surfaces of the sacrum and ilium with a reasonable expectation of success. (*Ibid*.). Therefore, it would be obvious to a POSITA to modify the method of Schifano to utilize the box chisel, rasp combination tool of Martz to prepare an implant void in the articular surfaces of the sacrum and ilium in the SI Joint without the need for a drill. (*Ibid*.).

As explained above in Section X.D.1. herein, Sharma discloses a universal impactor with slap hammer device for applying force for use to assist in the impaction and/or extraction of an attached surgical instrument from an orthopedics structure. (Ex.1017, ¶136). The slap hammer device of Sharma is designed for general use in orthopedic procedures. (Ex.1009, 1:5-8). Schifano discloses an orthopedic spinal procedure that includes the use of an impactor and tools that are conventionally used with hammers and slap hammers, such as a box chisel or rasp. (*Ibid*.). It would be obvious to a POSITA that the universal impactor with a slap hammer device would be beneficially used with the instruments (e.g., the box chisel and rasp) used in the method of Schifano to predictably reduce the number of steps in the surgical procedure and improve the efficiency of the procedure of Schifano with predictable success. (*Ibid*.).

2. INDEPENDENT CLAIM 1

i) (*Preamble*) "*A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument*"

Schifano et al. discloses methods of a posterior surgical approach for sacroiliac fusion. (Ex.1008, Abstract). The methods include creating an incision and a void in a patient's sacroiliac joint. (*Ibid*.).

Martz discloses a method that utilizes a spinal implant chisel tool to prepare an intervertebral disc space for implant insertion without the use of a drill. (Ex.1008, ¶¶[0002],[0025],[0093], and [0305]-[0306]).

ii) (1(a)) *Locating insertion point*

Schifano discloses locating the SI Joint and an incision point for access to the SI Joint, inserting a pin or wire to create an incision, inserting a dilator over the pin or wire to create an incision, and impacting the dilator to dilate the incision to a width through which instruments may be passed. (Ex.1003, 4:56-65, 8:52-19:16).

iii) (1(b)) *Introducing working channel*

Schifano discloses a working channel that includes two tangs (or insertion arms) extending therefrom that is inserted along the plane between

the articular surfaces of the SI Joint into the incision and stabilizes the working channel in the SI Joint. (Ex.1003, 3:15-21, 15:21-34). The working channel has a distal end having tapered or rounded (contoured) profile 142. (Ex.1003, 15:15-19). The working has a proximal end that receives and passes surgical instruments to allow access to the incision in the SI Joint. (Ex.1003, 35:53-61).

As explained above in section X.D.2.iii. herein, Compton also discloses the limitations of claim designation 1(b).

iv) (1(c)) *Inserting arms*

Schifano discloses inserted the two tangs (insertion arms) of the working channel into the SI Joint along the plane between the articular surfaces of the SI Joint. (Ex.1003, 4:65-67, 18:52-19:16, 15:21-34). Compton similarly discloses that arms 130 and 132 of retraction guide 122 (cannula) are oriented in parallel with the SI Joint and are driven into the SI Joint. (Ex.1004, 1:11-16, 2:51-60, 3:59-65, 7:4-15).

v-vii) (1(d) – 1(d)(i)(a)) *Introducing Abrading Device*

Schifano discloses a rasp (abrading device) having a distal tip having teeth on opposing sides thereof for preparing the bone tissue in the SI Joint

for fusion. (Ex.1003, 20:3-20). The rasp is inserted into the SI Joint through the working channel. (Ex.1003, 20:3-20).

viii) (1(d)(i)(b)) *"an open tip / cutting edge"*

Schifano discloses a box chisel having an open distal tip (leading edge) with distal cutting edges to cut bone tissue in the SI Joint. (Ex.1003, 20:3-20). The chisel is inserted into the SI Joint through the working channel. (Ex.1003, 19:44-20:2).

The box chisel and rasp of Schifano separately have an abrading head, abrading surfaces, a leading cutting edge, and open tip of claim designations (1(d) – 1(d)(i)(b)). The '129 Patent combines the features of a box chisel and a rasp in the "abrading device" recited in Claim 1.

Martz discloses a chisel tool having a cutting head (a chisel) having (1) an open tip with two distal cutting edges and (2) rasping outer surfaces on the chisel. (Ex.1008, ¶¶[0305]-[0306]). The cutting edges and rasping surfaces are used to scrape disc material and bone from adjacent vertebrae in preparing a disc space for insertion of a spinal implant. (Ex.1008, ¶¶[0093],[0305]-[0306]). See Figs. 76a-76c of Martz below:

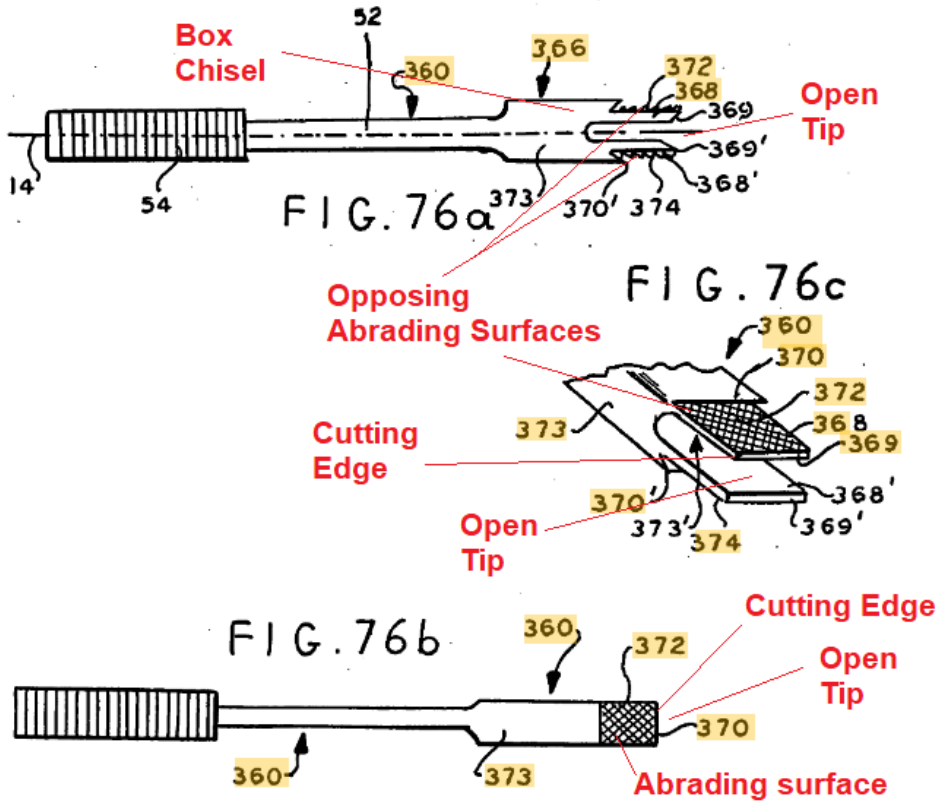


FIG. 76a

FIG. 76c

FIG. 76b

ix) (1(d)(i)(c)) *Slide hammer / released position / locked position / releasing means*

As explained above in section X.D.2.ix herein, Sharma discloses the limitations of claim designation 1(d)(i)(c).

x) (1(e)) *Advancing the abrading device*

Schifano discloses inserting the box chisel having an open distal tip (leading edge) into the SI Joint through the working channel to penetrate the cortical tissue of the sacrum and ilium. (Ex.1003, 19:44-20:2). Schifano

also discloses inserting a rasp (abrading device) having teeth on opposing sides thereof into the SI Joint through the working channel to scrape (decorticate) and prepare the bone tissue in an implant void in the SI Joint. (Ex.1003, 20:3-20).

It would be obvious to a POSITA to substitute the box chisel/rasp tool of Martz for the box chisel and rasp of Schifano to remove connective tissue and decorticate the SI Joint in preparation for insertion of a spinal implant without the use of a rotary cutting instrument. (Ex.1008, ¶¶[0093],[0305]-[0306]; Ex.1017, ¶149).

3. DEPENDENT CLAIM 2

i-iii) (2(a)-2(c)) ***Unlocking slide hammer, dislodge abrading head***

As explained above in Section X.D.3. herein, Sharma et al. discloses the limitations of Claim 2.

4. DEPENDENT CLAIM 9

i-ii) (9(a)-9(b)) ***Forming rectangular shape***

Schifano teaches inserting a rectangular implant into a void in the SI Joint. (Ex.1003, 31:47-56). The void may be configured to receive a fusion implant having a rectangular cross-sectional shape. (Ex.1003, 35:45-47).

5. DEPENDENT CLAIM 10

i-iii) (10(a)-10(c)) *Unlocking slide hammer, dislodge abrading*

Claim 10 has the same limitations as the combined limitations of Claims 2 and 9, which are fully addressed above.

F. *Ground 3: Claims 1, 2 and 9-10 are Unpatentable as Obvious over Compton in view of Martz and Sharma.*

1. Motivation to combine

As explained in Section X.D.1., a POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the of the '129 Patent to modify the posterior SI Joint approach disclosed by Compton to use the universal impactor with slap hammer device of Sharma to assist in the impaction and/or extraction of attached surgical instruments. (Ex.1017, ¶153).

As explained above in section X.E.1. herein, it would be further obvious to a POSITA to combine the use of the spinal implant chisel tools (combined rasp and box chisel) of Martz with the SI Joint fusion method like that of Compton because the chisel tool of Martz utilizes a cutting tool that are operable to prepare the SI Joint and articular surfaces of the SI Joint with a single tool, without use of multiple separate tools such as a drill, a rasp,

and other tool to prepare the SI Joint. (Ex.1017, ¶154). Also explained above in Section X.E.1. herein, it would be obvious to a POSITA to modify the method of Compton to utilize the box chisel, rasp combination tool of Martz to prepare the articular surfaces of the sacrum and ilium in the SI Joint without the need for a drill. (Ex.1017, ¶154).

2. INDEPENDENT CLAIM 1

i) (*Preamble*) "*A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument*"

As explained above in section X.D.2.i., Compton teaches the limitations of the preamble, except for the absence of rotary cutting tools.

Martz discloses a method that utilizes a spinal implant chisel tool used to prepare an intervertebral disc space for implant insertion without the use of a drill. (Ex.1008, ¶¶[0002],[0025],[0093],[0305]-[0306]; Ex.1017, ¶156).

ii) (1(a)) *Locating insertion point*

As explained above in section X.D.2.ii., Compton teaches the limitations of claim designation 1(a).

iii) (1(b)) *Introducing working channel*

As explained above in section X.D.2.ii., Compton teaches the limitations of claim designation 1(a).

iv) (1(c)) *Inserting arms*

As explained above in section X.D.2.iv., Compton discloses the limitations of claim designations 1(c).

v-vii) (1(d), 1(d)(i), 1(d)(i)(a)) *Introducing Abrading Device*

As explained above in section X.D.2.v-vii, Compton discloses the limitations of claim designations 1(d), 1(d)(i), 1(d)(i)(a).

viii) (1(d)(i)(b)) *An open tip / cutting edge*

As explained above in section X.D.2.v-vii, Compton discloses an abrading device meeting claim designations 1(d), 1(d)(i), 1(d)(i)(a).

As explained above in section X.E.2.viii, Martz teaches a chisel tool having both rasping outer surfaces and an open tip having a cutting edge, meeting the limitations of claim designation 1(d)(i)(b).

ix) (1(d)(i)(c)) *A slide hammer / released position / locked position / releasing means*

As explained above in section X.D.2.ix, (1) a POSITA would understand that a slap hammer or related device would be routinely used with a broach (e.g., broach 148) disclosed in Compton with predictable results, and (2) Sharma discloses the limitations of claim designation 1(d)(i)(c). (Ex.1017, ¶163)

x) (1(e)) *Advancing the abrading device*

Compton teaches inserting a rectangular implant into a pilot hole 252 (void) in the SI Joint. (Ex.1004, 7:61-8:13, 8:24-28). The pilot hole 252 may be configured to be rectangular to receive a graft 180 (fusion implant). (Ex.1004, 7:42-53).

To the extent that Compton does not teach all of the limitations of step (1(e)), Martz teaches a chisel tool having a cutting head (a box chisel) having an open tip with a distal cutting edge and rasping outer surfaces, as explained above in section X.E.2.x. (Ex.1017, ¶165)

3. DEPENDENT CLAIM 2

i-iii) (2(a)-2(c)) *Unlocking slide hammer / dislodge abrading head*

As explained above in Section X.D.3, Sharma discloses the limitations of Claim 2.

4. DEPENDENT CLAIM 9

i-ii) (9(a)-9(b)) *Forming rectangular shape*

As explained in section X.D.4, Compton discloses the limitations of Claim 9.

5. DEPENDENT CLAIM 10

i-iii) (10(a)-10(c)) *Unlocking slide hammer, dislodge abrading*

Claim 10 has the same limitations as the combined limitations of Claims 2 and 9, which are fully addressed above.

G. Ground 4: Claims 1, 2 and 9-10 are Unpatentable as Obvious over Black in view of Martz and Sharma

1. Motivation to combine

A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the of the '129 Patent to modify the posterior SI Joint approach disclosed by Black in view of the instruments and methods disclosed by Martz and Sharma. (Ex.1017, ¶169). Black discloses methods and instruments for a posterior approach for SI Joint fusion. (Ex.1005, Abstract, ¶¶[0048]-[0049]). Black discloses utilizing a box chisel 900 and a rasp 1000 that may be passed through the working

cannula 200 and can be used to prepare the SI Joint. (Ex.1005, ¶¶[0071],[0076]).

As explained above in section X.E.1. herein, it would be obvious to a POSITA to combine the use of the spinal implant chisel tools (combined rasp and box chisel) of Martz with the SI Joint fusion method like that of Black because the chisel tool of Martz utilizes a cutting tool that are operable to prepare the SI Joint and articular surfaces of the SI Joint with a single tool to prepare the SI Joint, without use of multiple separate tools. (Ex.1017, ¶170).

Black discloses a SI joint fusion procedure that includes the use of an impactor and tools that are conventionally used with slap hammers, such as a box chisel or rasp. (Ex.1017, ¶171). As explained above in Section X.D.1. herein, it would be obvious to use the universal impactor with slap hammer device of Sharma to assist in the impaction and/or extraction of attached surgical instruments in an SI Joint fusion procedure, such as chisels and rasps. (Ex.1017, ¶171). Therefore, it would be obvious to a POSITA to modify the method of Black to utilize the universal impactor tool of Sharma. (Ex.1017, ¶171).

2. INDEPENDENT CLAIM 1

i) (Preamble) "*A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument*"

Black discloses methods of a posterior surgical approach for sacroiliac fusion. (Ex.1005, Abstract, ¶¶[0048]-[0049]). The methods include creating an incision and a void in a patient's sacroiliac joint. *Ibid*. See Fig. 10 of Black below.

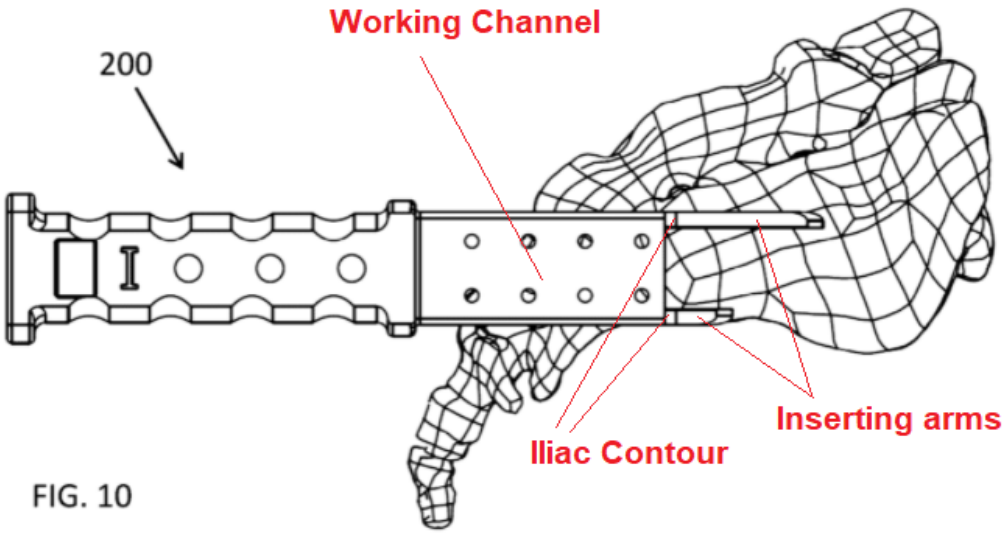


FIG. 10

Martz discloses a method that utilizes a spinal implant chisel tool used to prepare an intervertebral disc space for implant insertion without the use of a drill. (Ex.1008, ¶¶[0002],[0025],[0093], and [0305]-[0306]).

ii) (1(a)) *Locating insertion point*

Black discloses a sliding joint finder 100 for locating the SI Joint and creating a point for access to the SI Joint. (Ex.1005, ¶¶[0038]-[0039]). The sliding joint finder 100 is inserted into the SI Joint over a pin or wire. (Ex.1005, ¶[0039]).

iii) (1(b)) *Introducing working channel*

Black discloses a working cannula (working channel) that includes two protrusions 242A and 242B (or insertion arms) extending therefrom that are inserted along the plane between the articular surfaces of the SI Joint into the incision and stabilizes the working channel in the SI Joint. (Ex.1005, ¶¶[0046]-[0048]). The working cannula has a tapered (contoured) distal end with two distinct sides, a first side 228 having a shelf 260 with a contoured shape that contacts the ilium, and a second side 229 configured to face the sacrum. (Ex.1005, ¶¶[0049]-[0050]). The second side 229 also has a contoured structure along the protrusions 242a and 242b that interfaces with the sacrum, as shown in Figures 3A and 4 of Black, below. (Ex.1017, ¶175).

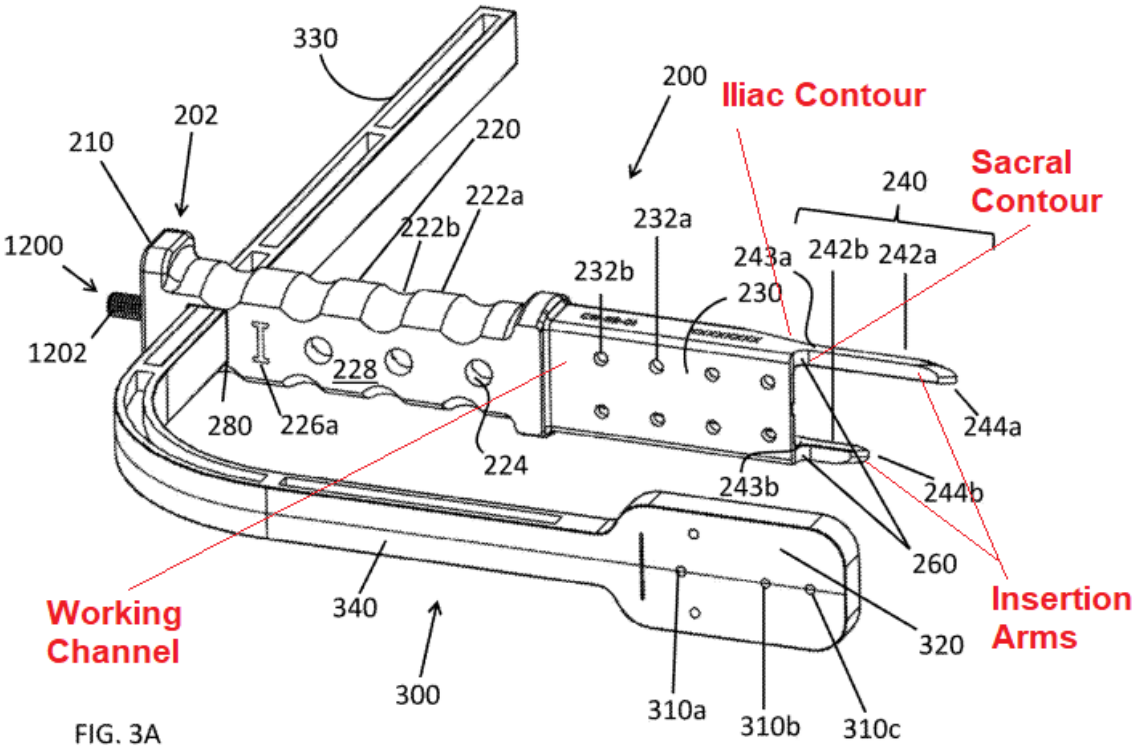

330
200
Iliac Contour
202
210
220
Sacral Contour
240
222a
222b
232a
1200
243a
242b
242a
232b
230
1202
228
280
226a
224
244a
243b
244b
260
Working Channel
340
320
Insertion Arms
300
310a
310b
310c

FIG. 3A

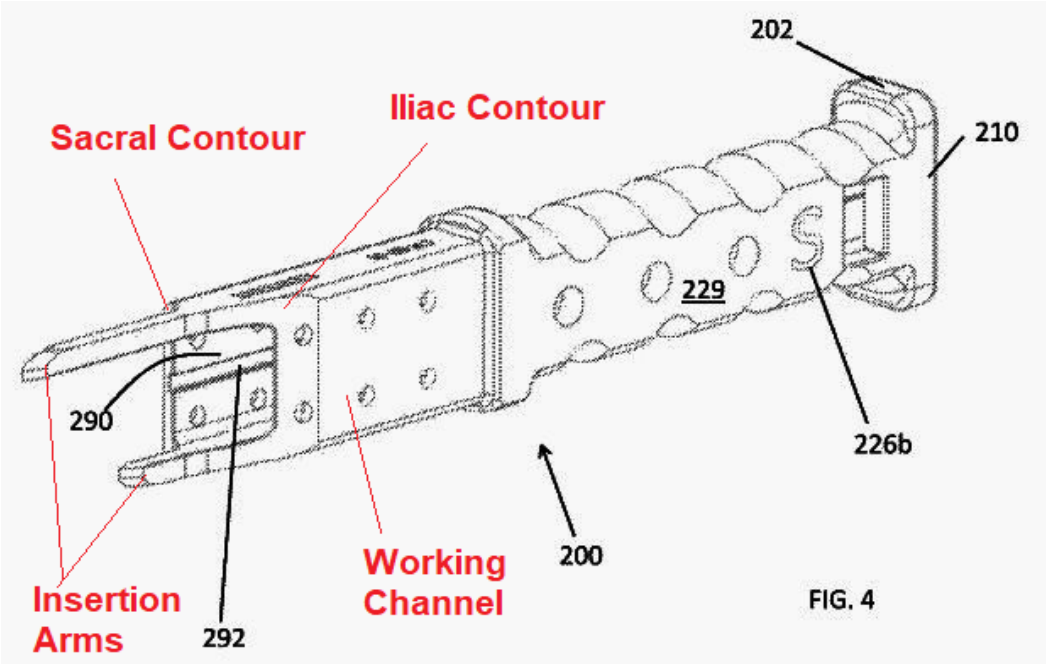

202
Iliac Contour
Sacral Contour
210
229
290
226b
200
Working Channel
Insertion Arms
292

FIG. 4

iv) (1(c)) *Inserting arms*

The working cannula 200 is inserted over the sliding joint finder 100 into the SI Joint until the unilateral shelf 260 of the working cannula contacts the edge of the posterior inferior iliac spine. (Ex.1005, ¶[0049]-[0050]). The contoured second side 229 faces and contacts the sacrum. (Ex.1005, ¶¶[0050], [0093]).

v-vii) (1(d), 1(d)(i), 1(d)(i)(a)) *Introducing Abrading Device*

Black discloses a rasp 1000 having an abrasive surface that is passed through the working cannula 200 and can be used to cut away uneven areas of the bone surfaces in the SI Joint. (Ex.1005, ¶[0075],[0077]).

viii) (1(d)(i)(b)) *An open tip / cutting edge*

Black discloses a box chisel 900 having a sharp rectangular cutting edge 912 at its proximal end 910 that is passed through the working cannula 200 and is used to prepare the SI Joint. (Ex.1005, ¶[0071]).

The box chisel and rasp of Black separately have the features abrading head, abrading surfaces, leading cutting edge, and open tip of limitations (1(d), 1(d)(i), 1(d)(i)(a)), and 1(d)(i)(b) of Claim 1 of the '129 Patent.

As explained above in section X.E.2.viii, Martz discloses a chisel tool

having a cutting head (a chisel) having an open tip with two distal cutting edges and opposing rasp surfaces.

ix) (1(d)(i)(c)) *A slide hammer / released position / locked position / releasing means*

Black discloses that box chisel 900 and rasp 1000 are passed through the working cannula 200 and may be configured to attach to a slap handle for insertion or removal from the SI Joint. (Ex.1005, paragraphs [0071],[0073],[0080]). A POSITA would understand that a slap hammer or slide hammer would be used with the box chisel and rasp surgical instruments disclosed in Black.

As explained above in section X.D.2.ix, (1) a POSITA would understand that a slap hammer or related device would be routinely used with a chisel or rasp in an orthopedic procedure with predictable results, and (2) Sharma discloses the limitations of claim designation 1(d)(i)(c). (Ex.1017, ¶182).

x) (1(e)) *Advancing the abrading device*

Black discloses inserting the box chisel having an open distal tip (leading edge) and a rasp into the SI Joint through the working cannula to

cut, decorticate, and prepare the SI Joint. (Ex.1005, ¶¶[0019],[0066],[0071]-[0072],[0075]-[0077]).

To the extent that Black does not teach all of the limitations of step (1(e)), Martz teaches using a chisel tool having a cutting head (a box chisel) having an open tip with a distal cutting edge and rasping outer surfaces for preparing an implant void without the use of a rotary cutting instrument, as explained above in section X.E.2.x. (Ex.1017, ¶184).

3. DEPENDENT CLAIM 2

i) (2(a)-2(c)) *Unlocking slide hammer / dislodge abrading head*

As explained above in Section X.D.3, Sharma discloses the limitations of Claim 2.

4. DEPENDENT CLAIM 9

i) (9(a)-9(b)) *Forming rectangular shape*

Black teaches inserting a rectangular implant into a void in the SI Joint. (Ex.1005, ¶[0109]). The void may be formed to correspond to the rectangular implant. (Ex.1005, ¶¶[0019],[0045],[0052],[0071],[0076]-[0077]).

5. DEPENDENT CLAIM 10

i-iii) (10(a)-10(c)) *Unlocking slide hammer, dislodge abrading*

Claim 10 has the same limitations as the combined limitations of Claims 2 and 9, which are fully addressed above.

H. *Ground 5*: *Claims 1, 2 and 9-10 are Unpatentable as Obvious over Black in view of Donner and Sharma*

1. Motivation to combine

A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the of the '129 Patent to modify the posterior SI Joint approach disclosed by Black in view of the instruments and method disclosed by Donner. (Ex.1017, ¶188). Black discloses methods and instruments for a posterior approach for SI Joint fusion, as explained above in section X.G.1. Donner discloses a similar posterior approach for SI Joint fusion with an implant inserted into the articular space between the sacrum and ilium using similar instrumentation, and is thus closely related to the methods and instruments of Black. (*Ibid*.). It would be obvious to a POSITA to combine the use of joint preparation tool of Donner with the SI Joint method of Black because the joint preparation tool of Donner utilizes a cutting tool that are operable to prepare the SI Joint and

articular surfaces of the SI Joint with a single tool, thereby increasing the efficiency of the method. (*Ibid*.). It would be obvious to a POSITA that the joint preparation tool of Donner would be beneficially used in the method of Black with predictable results. (*Ibid*.).

As explained above in section X.G.1. herein, it would be obvious to a POSITA to combine the use of the spinal implant chisel tools (combined rasp and box chisel) of Martz with the SI Joint fusion method of Black.

As explained above in Section X.G.1. herein, it would be obvious to use the universal impactor with slap hammer device of Sharma in the SI Joint fusion procedure of Black. (*Ibid*.).

2. <u>INDEPENDENT CLAIM 1</u>

i) (Preamble) "*A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument*"

As explained in section X.G.2.i., the combined teachings of Black and Martz meet the limitations of the Preamble of Claim 1.

ii) (1(a)) *Locating insertion point*

As explained above in Section X.G.2.ii, Black discloses the limitations of Claim 2.

iii) (1(b)) *Introducing working channel*

As explained above in Section X.G.2.iii, Black discloses the limitations of claim designation 1(b).

iv) (1(c)) *Inserting arms*

As explained above in Section X.G.2.iv, Black discloses the limitations of claim designation 1(c).

v-vii) (1(d), 1(d)(i), 1(d)(i)(a)) *Introducing Abrading Device*

As explained above in Section X.G.2.v-vii., Black discloses the limitations of claim designations 1(d), 1(d)(i), 1(d)(i)(a).

viii) (1(d)(i)(b)) *An open tip / cutting edge*

As explained above in section X.G.2.v-vii., the combined teachings of Black and Martz meet the claim designation 1(d)(i)(b).

ix) (1(d)(i)(c)) ***A slide hammer / released position / locked position / releasing means***

As explained above in section X.G.2.ix, a POSITA would understand that a slap hammer or slide hammer would be used with the box chisel and rasp surgical instruments disclosed in Black.

As explained above in section X.D.2.ix, Donner discloses a slide hammer assembly that can be used insert or remove a surgical tool for use in a SI Joint fusion procedure.

As explained above in section X.D.2.ix., Sharma discloses the limitations of claim designation 1(d)(i)(c).

x) (1(e)) ***Advancing the abrading device***

As explained above in Section X.G.2.x., the box chisel and rasp of Black separately have the features abrading head, abrading surfaces, leading cutting edge, and open tip of limitations 1(d), 1(d)(i), 1(d)(i)(a), and 1(d)(i)(b) of Claim 1 of the '129 Patent.

To the extent that Black does not teach all of the limitations of step (1(e)), Donner discloses using a joint preparation tool 50 having an abrading head to prepare (decorticate) the articular surfaces of the sacrum and ilium

without a rotary cutting instrument, and thus meets the limitations of claim designation 1(e). (Ex.1006, ¶[0145]; Ex.1017, ¶[0201]).

Martz also discloses the limitations of claim designation 1(e), as explained above in section X.E.2.x.

3. DEPENDENT CLAIM 2

i) (2(a)-2(c)) *Unlocking slide hammer / dislodge abrading head*

As explained above in Section X.D.3, Sharma discloses the limitations of Claim 2.

4. DEPENDENT CLAIM 9

i) (9(a)-9(b)) *Forming rectangular shape*

As explained above in section X.G.4., Black discloses the limitations of Claim 9.

5. DEPENDENT CLAIM 10

i-iii) (10(a)-10(c)) *Unlocking slide hammer, dislodge abrading*

Claim 10 has the same limitations as the combined limitations of Claims 2 and 9, which are fully addressed above.

I. Secondary Considerations

Although secondary considerations should be taken into account, they do not control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong *prima facie* obviousness showing exists, as here, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. See, e.g., *Leapfrog Enters. Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Furthermore, there is no evidence of a nexus between any secondary considerations and the claims of the '129 Patent.

Petitioner did not disclose or raise any relevant secondary considerations in the record of the '129 Patent, but if Petitioner puts forth any such allegations, Patent Owner respectfully requests an opportunity to respond.

XI. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that the Challenged Claims are unpatentable as obvious and, therefore, requests that the Board institute an *inter partes* review and cancel the claims.

Dated: February 22, 2023

SIERRA IP LAW, PC
A Professional Corporation

By /William K. Nelson/

WILLIAM K. NELSON
Registration No. 63501
Attorneys for Petitioner,
Orthocision Inc.

**CERTIFICATE OF TYPE VOLUME LIMITATIONS
UNDER 37 C.F.R. § 42.24**

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 11,020,129 exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 12,647 words[1] and therefore complies with the type-volume limitations of 37 C.F.R. 42.24(a)(i).

Dated: February 22, 2023

SIERRA IP LAW, PC
A Professional Corporation

By /William K. Nelson/

WILLIAM K. NELSON
Registration No. 63501
Attorneys for Petitioner,
Orthocision Inc.

[1] Must be less than 14,000 words.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I certify that on this 22nd day of February 2023, I caused to have served a copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 11,020,129** together with all of the exhibits identified in the above Table of Exhibits and Petitioner's Power of Attorney by Federal Express Next Business Day Delivery to the correspondence address of record for U.S. Patent 11,020,129 found on PAIR at the U.S. Patent and Trademark Office:

Hill Ward Henderson, P.A.
Attn: Stephen Kelly
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602.

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