

EXHIBIT 1017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Orthocision, Inc.,
Petitioner

v.

Painteq, Inc.
Patent Owner

Case IPR2022-00625
U.S. Patent 11,020,129
Issue Date: June 1, 2021
Title: DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

**DECLARATION BY TROY D. DREWRY REGARDING CLAIMS 1,
2, AND 9-10 OF U.S. PATENT NO. 11,020,129**

Petitioner Exhibit 1017

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION AND SCOPE OF WORK	1
II. QUALIFICATIONS.....	3
III. LEGAL PRINCIPLES.....	5
IV. STUDY	8
V. LEVEL OF ORDINARY SKILL IN THE ART	9
VI. TECHNICAL FIELD OF THE ‘129 PATENT	9
A. OVERVIEW OF THE ‘129 PATENT.....	9
B. BACKGROUND OF RELEVANT ANATOMY AND RELATED TECHNOLOGIES	14
VII. INTERPRETATION OF THE ‘129 PATENT CLAIMS	21
A. CLAIM TERMS AT ISSUE IN THE ‘129 PATENT	21
B. PROSECUTION HISTORY OF THE ‘129 PATENT	22
C. CONSTRUCTION OF TERMS OF CLAIMS 1, 2, AND 9-10..	23
a. Claim 1: Preamble	26
b. Claim 1: Limitation 1(b) “working channel”	27
c. Claim 1: Limitation 1(d) - 1(d)(i)(b) “introducing an abrading device”	30
d. Claim 1: Limitation 1(d)(ii) “slide hammer assembly”.	31
e. Claim 1: Limitation 1(e) “advancing abrading device”	32

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

f.	Claims 2 and 10: Limitations 2(a)-(c) and 10(a)-(c) “dislodge abrading head”	33
g.	Claim 9: Limitations 9(a)-(b) “rectangular cross- section”	34
VIII. THE CHALLENGED CLAIMS ARE OBVIOUS IN VIEW OF THE PRIOR ART		35
A. OVERVIEW OF GROUNDS.....		35
B. THE SCOPE AND CONTENT OF THE PRIOR ART		36
a.	US 10,219,841 (Compton et al.).....	37
b.	US 11,083,511 (Schifano et al.).....	40
c.	US 2016/0310197 (Black et al.)	45
d.	US 2018/0036017 (Donner et al.).....	50
e.	US 2005/0080422 (Otte et al.).....	53
f.	US 2005/0090829 (Martz et al.)	56
g.	WO 2014/091454 (Sharma et al.).....	58
C. OBVIOUSNESS ANALYSIS OF CLAIMS 1-2 and 9		61
a.	GROUND 1: Compton in view of Donner, Otte, and Sharma	68
1.	Motivation to Combine	68
2.	Independent Claim 1	71
3.	Dependent Claim 2.....	76
4.	Dependent Claim 9.....	76

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

5.	Dependent Claim 10.....	77
b.	GROUND 2: Schifano in view of Compton, Martz, and Sharma	77
1.	Motivation to Combine	77
2.	Independent Claim 1	80
3.	Dependent Claim 2.....	85
4.	Dependent Claim 9.....	85
5.	Dependent Claim 10.....	86
c.	GROUND 3: Compton in view of Martz and Sharma ..	86
1.	Motivation to Combine	86
2.	Independent Claim 1	87
3.	Dependent Claim 2.....	90
4.	Dependent Claim 9.....	90
5.	Dependent Claim 10.....	90
d.	GROUND 4: Black in view of Martz and Sharma.....	90
1.	Motivation to Combine	90
2.	Independent Claim 1	92
3.	Dependent Claim 2.....	97
4.	Dependent Claim 9.....	97

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

5.	Dependent Claim 10.....	97
e.	GROUND 5: Black in view of Donner and Sharma	98
1.	Motivation to Combine	98
2.	Independent Claim 1	99
3.	Dependent Claim 2.....	102
4.	Dependent Claim 9.....	102
5.	Dependent Claim 10.....	102
IX. RIGHT TO SUPPLEMENT.....		103
X. CONCLUSION		103

I, Troy D. Drewry, hereby declare and state as follows:

I. INTRODUCTION AND SCOPE OF WORK

1. My name is Troy D. Drewry. I have been retained by petitioner Orthocision, Inc. as an independent expert in the relevant art. I herein provide my analysis of U.S. Patent No. 11,020,129 (the “‘129 patent”) and its claims, certain prior art relevant to the ‘129 patent, and the question of whether the claims of the ‘129 patent are obvious in view of the relevant prior art. This declaration is submitted in connection with Orthocision’s corresponding petition for *Inter Partes* Review of the “‘129 patent” (the “Petition”).

2. I have been asked to provide my opinions and views on the ‘129 patent based on the materials I have reviewed in preparing this declaration and my scientific and technical knowledge regarding the same subject matter. I have been asked to consider what one of ordinary skill in the art would have understood from the ‘129 patent. I have also considered whether certain prior art references disclose or suggest the features, and the combinations of features, recited in the claims of the ‘129 patent. My opinions are set forth below.

3. My opinions are guided by my appreciation of how a person of

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

ordinary skill in the art would have understood the claims of the '129 patent at the time of the alleged invention. The earliest filing date potentially attributable to the '129 patent is October 4, 2019, and I have analyzed the claims of the '129 Patent based on prior art and information that was published and/or publicly known prior to that date.

4. I have based my opinion below on my experiences and expertise in the design of surgical devices and implants generally and my experience in developing sacroiliac fusion instruments and methods specifically. It is my opinion based on these experiences and expertise that certain references, as discussed in detail below disclose or suggest all the features recited in the claims of the '129 patent, that they were not new or novel as of the priority date of the '129 patent claims, that any differences from these prior references are trivial, and that these claims combine well known features in a manner that would have been obvious to one of ordinary skill in the art at the time of the alleged invention to provide predictable results.

5. For the reasons set forth below, it is my opinion that at least claims 1, 2, and 9-10 of the '129 patent would have been obvious to one of ordinary skill in the art in view of prior art spinal fusion, sacroiliac fusion, and spinal orthopedic procedures, instruments, and devices, well known

attributes and uses of such procedures, instruments, and devices and design features as disclosed in the prior art, and known design motivations in the related art that existed at the time of the alleged invention.

II. QUALIFICATIONS

6. I have extensive experience in the design, development, and manufacture of orthopedic implants and instruments, predominately for spinal applications, spanning a career of over twenty-five years in the field. My relevant expertise includes the design of bone fixation systems including plates and screws and the relevant biomechanical principles and constraints associated with implantation into a living patient. My expertise further includes spinal instrument design, including spinal implants and systems, spinal screw systems, plates, vertebral body spacers, spreader systems, among others. My most recent Curriculum Vitae included as Exhibit 1018.

7. I also have extensive consulting experience in the design and development of medical devices. My consulting experience has involved project management, engineering design and development, design control and design history file (DHF) management, intellectual property landscape and analysis, and forensic engineering and expert witness services, all directed to medical devices.

8. I have served on many professional committees and organizations. For example, I have served as a member of the Engineering Advisory Board for the University of Mississippi, the Engineering Biotech Advisory Board for Christian Brothers University, the Industrial Advisory Board for the University of Memphis' Department of Mechanical Engineering, the American Society of Mechanical Engineers, the American Society of Testing and Materials, and the Industrial Advisory Board for the University of Southwestern Louisiana's Department of Mechanical Engineering, and a former member of the Society of Biomedical Engineers, the Orthopedic Research Society, and the Society of Biomaterials. I have also received the Engineer in Training (EIT) designation from the National Council of Examiners for Engineering and Surveying (NCEES).

9. I earned my Bachelor of Science in Mechanical Engineering (CAD/CAM Option) from the University of Southwestern Louisiana in 1992, my Masters of Biomedical Engineering from the University of Memphis in 1994, and my Masters of Engineering Management from Christian Brothers University in 2000.

10. I am a named inventor on over sixty patents on technology including bone screw assemblies, spinal deformity reduction, fusionless scoliosis treatment, connector assemblies, implant devices, shape memory

alloy staples, vertebral body spacers, tensioning instruments, adjustable spine tethers, vertebral rod assemblies, vertebral stabilization assemblies, and expandable anterior lumbar interbody fusion devices. In addition to designing and inventing new technologies, I have, throughout my career, mentored, trained, and supervised young engineers and appreciate how a less experienced engineer would perceive the prior art and approach the technical problems disclosed in the prior art.

11. I am being compensated for my time spent on the present matter at my standard consulting rate of \$450 per hour for most work and \$650 per hour while I am giving testimony, for example, in a deposition. My compensation is not in any way contingent on my performance, the result of this proceeding, or any of the issues involved therein. I am also being compensated for actual expenses incurred as a result of activities performed as an expert.

III. LEGAL PRINCIPLES

12. I understand that, in *inter partes* review, patent claims are given their ordinary and customary meaning to a person of ordinary skill in the art at the time of the invention, by considering the claims, specification, and prosecution history, as well as evidence extrinsic to the patent, when

construing patent claims. I further understand that under this legal standard, the claim language is read in light of the specification, as it would be interpreted by the person of ordinary skill in the art (defined below). I also understand that the words in a claim are generally given their ordinary and accustomed meaning, unless the inventor has provided a specific definition in the specification or the file history of the patent.

13. I have been informed that anticipation of a claim requires that every element of a claim is disclosed expressly or inherently in a single prior art reference, arranged as in the claim.

14. I have been informed that in order to assess whether a claim is obvious in light of the prior art, I must analyze the claims from the perspective of a hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. I have also been informed that when considering the obviousness of a patent claim, one may consider whether there existed at the relevant time a teaching, suggestion, or motivation provided in the prior art that would have led one of ordinary skill in the art to modify the prior art or to combine prior art teachings to arrive at the claimed invention. I understand that other rationales that may support a conclusion of obviousness include, but are not limited to: combining prior art elements according to known methods to yield predictable results; the

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

simple substitution of one known element for another to obtain predictable results; the use of a known technique to improve similar devices or products in the same way; the application of a known technique to improve a known device or product ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and variations of known work or designs based on design incentives or other market forces where the variations are predictable to one skilled in the art. I have been informed that hindsight is impermissible and that the obviousness or non-obviousness of a claim must be determined on the basis of the facts gleaned from the prior art and the knowledge of a person of ordinary skill at the relevant time. I have been informed that I must, in view of all of the factual information, determine whether the claimed invention “as a whole” would have been obvious at the relevant time to the hypothetical person of ordinary skill in the art. I have been informed that in an *inter partes* review, a prior art reference must be construed in its entirety, including portions that would teach away from the claimed invention.

IV. STUDY

15. My opinions set forth in this declaration are based on my education, training, and experience as described above as well as the information pertaining to the '129 patent and Exhibits 1001-1016 and 1019 submitted with the Petition.

16. In preparing this declaration, I have read and understood Ex. 1001, the '129 patent", including its specification, figures, claims, and file history.

17. I have also reviewed several prior art patents, patent applications, and other printed publications. These include all of the references and documents referred to in the Exhibit List attached to the Petition: Exhibits 1001-1019. I have read, understood, and rely upon the documents in the Exhibit List in forming my opinions, which is attached as Appendix B.

18. Further, I am familiar with certain sacroiliac fusion methods and devices that I have helped to design or have encountered as part of my professional career.

V. LEVEL OF ORDINARY SKILL IN THE ART

19. I understand that a person of ordinary skill in the art is presumed to be aware of all pertinent art and is a person of ordinary creativity. As such, the level of ordinary skill in the art is evidenced by the prior art. Thus, it is my opinion that, as of October 4, 2019, a person of ordinary skill with respect to the subject matter of the ‘129 patent would typically have had at least a Bachelor’s 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. Such a POSITA would have at least had knowledge of spinal joint fusion implants, surgical instruments for spinal fusion surgeries, and the application of fusion implants in spinal fusion procedures and/or sacroiliac fusion procedures.

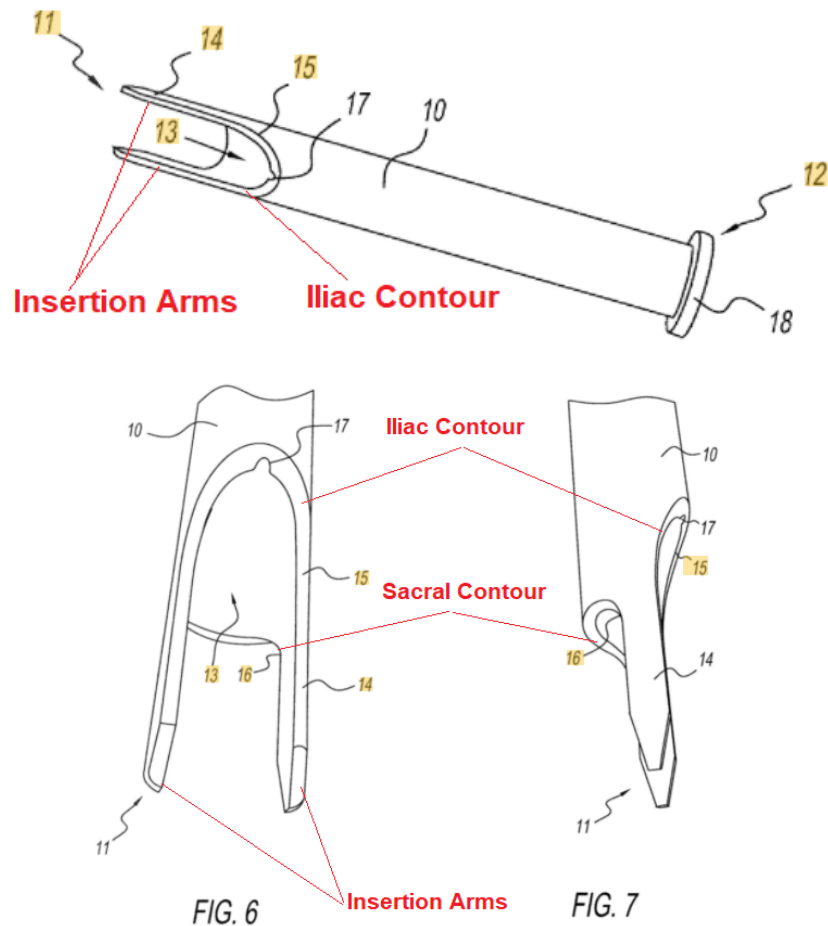
VI. TECHNICAL FIELD OF THE ‘129 PATENT CLAIMS AT ISSUE

A. OVERVIEW OF THE ‘129 PATENT

20. I have reviewed the overview of the ‘129 patent set forth in Section VII of the Petition. In my opinion, the overview accurately describes the claims of the ‘129 patent.

21. The ‘129 patent, entitled “DRILL-LESS METHOD OF FUSING A SACROILLIAC JOINT”, is generally directed to the method and instruments for installing a fusion implant into a sacroiliac joint (“SI Joint”) without the use of a rotary cutting instrument (i.e., a drill). (Ex. 1001, Abstract). The general objective of the ‘129 Patent is to improve the efficiency of the instrumentation and procedure of a sacroiliac fusion surgery. (Ex. 1001, 2:7-12). 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 using multiple tools and the need for a rotary cutting instrument. (*Ibid*).

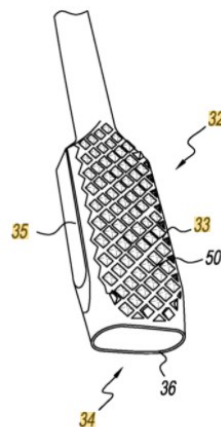
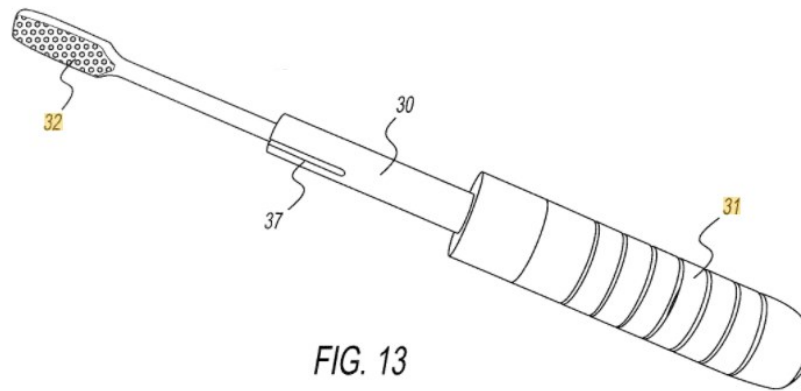
22. According to the ‘129 patent, the method includes locating an insertion point in a sacroiliac joint from the posterior side of the patient, where the insertion point defining an intended location for the implant void. (Ex. 1001, 8:13-20). A working channel is introduced into the insertion point, the working channel having an insertion end and a working end. (Ex. 1001, 5:56-61). The insertion end of the working channel includes a first iliac contour 15, a first sacral contour 16, and insertion arms 14. (Ex. 1001, 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. (Ex. 1001, 9:1-7).

23. 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 33 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 34 comprising a cutting edge 36 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. (Ex. 1001, 9:60-65).

24. 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. (Ex. 1001, 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. (Ex. 1001, 9:60-10:8).

25. In some implementations, the method 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. (Ex. 1001, 10:32-40).

26. In some implementations, the method includes 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).

27. In summary, the '129 Patent discloses a posterior approach for fusing the SI Joint, in which the incision and joint access is created from the posterior aspect of the patient (*Id.*, 3:13, 8:22-25). There are numerous prior

art references that disclose closely related methods using the same or similar tools. 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. The particular improvement identified as the critical innovation of 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). However, such an instrument is disclosed in multiple prior art references, including US 2018/0036017 (Donner et al.). (Ex. 1006).

28. The commonplace nature of elements of the steps and limitations of the challenged claims is demonstrated by the prior art and literature identified in the Exhibit List of the Petition.

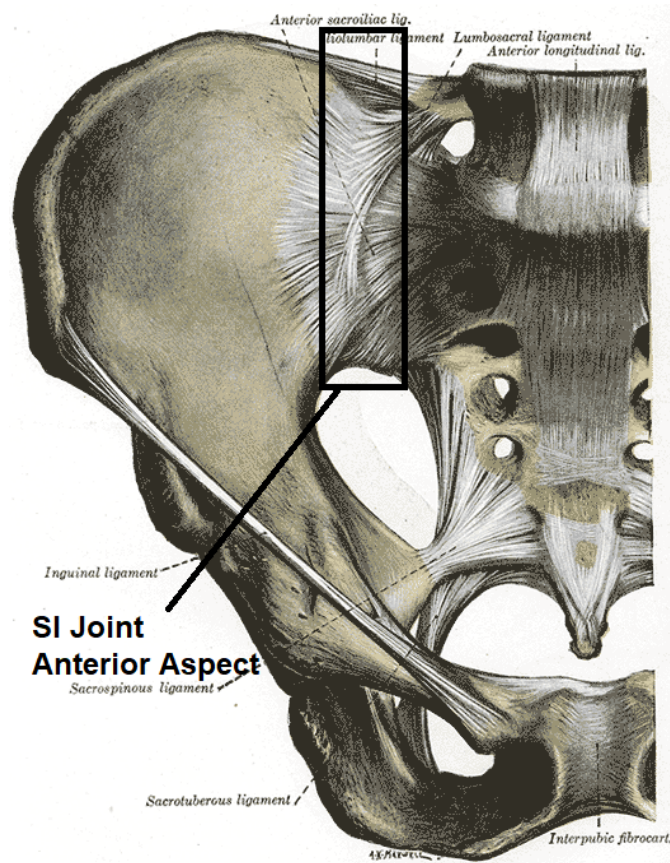
B. BACKGROUND OF RELEVANT ANATOMY AND RELATED TECHNOLOGIES

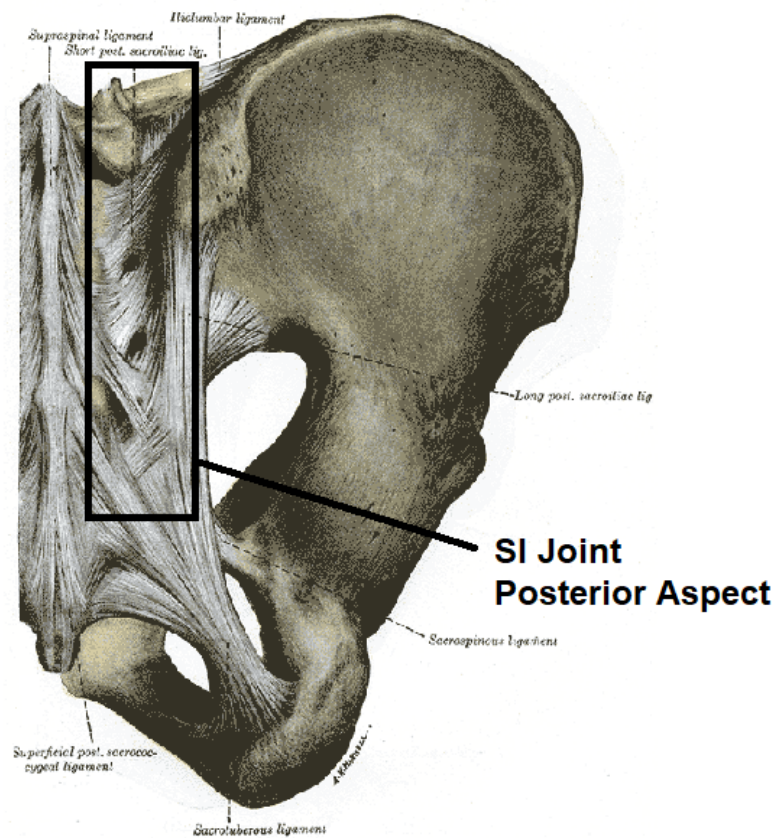
29. The SI Joints are articulating joints located on both sides of the sacrum where the ilium bones and the sacrum meet in the pelvis. The SI Joints are characterized as ligamentous joints that transfer load from the spine to the legs. The SI Joints are located laterally to the L5-S1

Declaration of Troy D. Drewry

Petition for Inter Partes Review of U.S. Patent No. 11,020,129

intervertebral joints in the lumbar spine and sacrum. The following anatomical images show the bony anatomy of the SI Joint. (Ex. 1013, p. 49).





30. Clinical literature, along with the inventors of the '129 patent, that significant proportion of chronic lower back pain is attributed to SI Joints (about 15% or more). (Ex. 1001, 1:36-50; Ex. 1010, Abstract; Ex. 1011, Abstract; Ex. 1012, Abstract; Ex. 1013, p. 48; Ex. 1014, p. 2709). Given the SI Joint proximity to the spine and similarities in surgical approach and fusion techniques, orthopedic and neurological spine surgeons have recognized these joints as pain generators for decades and have adapted traditional spinal and intervertebral disc preparation instruments as their obvious choices for SI Joint fusion surgery. (*Ibid.*).

31. Posterior Lumbar Interbody Fusion (PLIF) surgical techniques evolved from threaded cylindrical interbody cages to impacted rectangular interbody cages. Rotary drills were used in PLIF procedures that utilized cylindrical cage designs. A drill was used in such procedures to create a space in the intervertebral joint for the insertion of the cylindrical cage. The drill causes significant distraction of the spinal cord and soft tissues that creates risks of surgical complications. These complications included the risk of “wrapping” soft tissue, nerve roots, and other sensitive anatomical structures around the drill bit as it spun. In addition, the cylindrical geometry of the drill and implant reduced the amount of endplate bone and implant surface contact. This reduced surface contact led to implant subsidence into the vertebral bodies and resulted into loss of disc height restoration and often led to non-fusion of the adjacent bones and a clinical surgical failure.

32. During my employment with Medtronic Sofamor Danek from 2000 to 2005, I personally worked on impacted rectangular lumbar cages (“RLCs”) to address the shortcomings of using drills in vertebral fusion procedures. I was engaged in research and development of procedures that eliminated the need for (1) the conventional cylindrical spinal cages in use at the time and (2) rotary drills. A surgical method and tool set was developed

that utilizes box chisel, broach, and rasp tools to prepare the intervertebral joint space to receive an RLC implant. A rectangular space was formed using box chisel, broach, and rasp to cut a rectangular impression into the adjacent intervertebral bodies to provide a complementary space for the RLC implant in the intervertebral joint.

33. The RLC implant design allowed for (1) the bone to be prepared with a box chisel, broach, and rasp thus eliminating the need for a large diameter rotary drill bit, and (2) a reduction in the amount of spinal cord and soft tissue retraction thereby reducing surgical complications. (Ex. 1015, p.216-226, p.235-246.) The use of the box chisel to debride the intervertebral bodies is demonstrated in the following image of a drill-less PLIF method. (*Ibid.*)

34. US Patent 6,174,311 (filed on October 28, 1998) and entitled, “INTERBODY FUSION GRAFTS AND INSTRUMENTATION” (the “311 patent”) describes an interbody fusion method that utilizes a box chisel and scrapers to prepare the intervertebral space for receiving an implant, rather than a drill. (Ex.1016, 3:32-43, 4:28-30). The inventors disclose general surgical instruments used to prepare a joint space for introduction of an implant used to fuse the joint without a drill. The instruments used to prepare the joint space include working channels (guide

sleeves), open-ended box chisels, scrapers, toothed scrapers, and slap hammer. (Ex. 1016, 15:49-56, 19:8-14). The use of a drill is mentioned, but only optionally in the context of harvesting autograft material from other areas, such as the iliac crest. (Ex.1016, 3:44-48, 14:12-19). As of the '129 priority date, drill-less surgical methods and instruments used to decorticate and prepare a joint space for fusion in the spine, as noted by the '311 patent, were well known to a POSITA. Based on the clinical benefits and complications reductions provided by a drill-less spinal surgical technique, it is my opinion that it would have been obvious for a POSITA to apply this drill-less technique to sacroiliac joint procedures.

35. All of the references discussed herein are from the related field of endeavor, as they all relate to orthopedic surgeries, and all but Sharma (Ex. 1009) relate to fusion surgeries involving the spine. Combinations made from these references are merely simple combinations of known methods and instruments, guided by known anatomical attributes or constraints that achieve the same or complimentary functions and because of their well-known uses, structure and function, provide safe and predictable results.

36. I specifically note that prior art teachings directed to instruments designed for use in interbody fusion surgeries between adjacent

vertebrae are intuitively applicable to fusion surgeries between the sacrum and ilium as both procedures include weight-bearing spinal bones with large, substantially planar interfacing articular surfaces. While there are some anatomical distinctions, the core mechanical principals of fusing bodies of adjacent vertebrae and fusing the sacrum and ilium are highly similar.

37. Thus, it is my opinion that a POSITA would have found methods and instruments utilized in orthopedic fusion procedures involving the spine, including interbody fusion and sacroiliac fusion methods, and general instruments used in orthopedic procedures (e.g., cannulas, slide hammers, chisels, and rasps) to be highly related, and that a POSITA would look to such related procedures in devising a posterior sacroiliac fusion approach like that disclosed in the '129 patent with reasonable expectations of success.

38. As discussed in the subsequent sections, each of the components of the challenged claims were well-known in the prior art, and the claims of the '129 patent are, at most, simple combinations of these prior art elements.

39. The prior art references discussed herein demonstrate that each of the elements of the challenged claims of the '129 patent was well-known

in the art and would have been obvious to a POSITA well before the October 4, 2019, the earliest claimed priority date of the ‘129 patent.

VII. INTERPRETATIONS OF THE ‘129 PATENT CLAIMS

A. CLAIM TERMS AT ISSUE IN THE ‘129 PATENT

40. It is my understanding that Claims 1-2 and 9-10 of the ‘129 patent are challenged in the petition, which are provided below in Table 1.

41. My opinions herein concern what I believe a POSITA would have understood the meaning of certain claim terms to be based on the patent documents. My methodology for determining the meaning of claim phrases was first to carefully study the patent. In particular, I studied the claims themselves, followed by the background, detailed specification, figures, and other patent content. Next, I reviewed the prosecution history looking for any clarifications or limitations that might be attached to claim terms. I also reviewed references that were considered by the patent office.

42. I understand that, for the purposes of my analysis, PTAB rules require that the claim terms of the ‘129 patent be construed in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and informed by the prosecution history. I also understand that this “ordinary and customary meaning” is with respect to how one of ordinary skill in the art would interpret the claim language. I

also understand that the claim terms are to be construed in light of the specification, including the written description and the associated drawings.

I have followed these principles in my analysis.

B. PROSECUTION HISTORY OF THE ‘129 PATENT

43. It is my understanding that the ‘129 Patent issued from US Patent Application Number 17/063,613, filed on October 5, 2020 (“the ‘613 Application”), which was a continuation-in-part of U.S. Application No. 16/851,840 filed on April 17, 2020. (Ex. 1001, face page). It is also my understanding that 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).

44. A Notice of Allowance was mailed by the USPTO on February 3, 2021 (the “NOA”). (Ex. 1002, pp.41-47). The NOA 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).

45. The NOA 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.*"¹ (Ex. 1002, 46; emphasis added). This is the only discussion regarding the patentability of the challenged claims that is found in the prosecution history of the '129 patent.

C. CONSTRUCTION OF TERMS IN CLAIMS 1-2 AND 9-10.

46. There are certain terms in the challenged claims that require reference to the specification of '129 Patent because their meaning is not self-evident. My interpretation of the certain claim terms are provided in the

¹ 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.

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

paragraphs below. The literal claim recitations of Claims 1, 2 and 9-10 of the '129 Patent are provided in Table 1 below.

TABLE 1: Challenged Claims 1, 2, and 9-10 of the '129 Patent	
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	an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

edge”	configured to cut bone tissue in the sacroiliac joint; and
Limitation 1(d)(ii) “a slide hammer / released position / locked position / releasing means”	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

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

	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.

a. Claim 1: Preamble - “forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument”

47. It is my understanding that, based on the prosecution history of the ‘129 patent, Patent Owner never argued that the preamble is a limitation of claims 1, 2, and 910 during prosecution of the ‘129 patent.

48. It is my opinion that a person of ordinary skill would not find that the preamble of Claim 1 is redundant of limitations in the body of Claim 1. Even so, a POSITA would view the preamble as merely a statement of the intended use of the claimed method. It is also my opinion that a POSITA would read the body of the claim to set out the complete invention because no element of the body requires reference to any feature of the preamble for antecedent basis. In my opinion, a person of ordinary skill would understand that the preamble of claim 1 is not limiting.

b. Claim 1: Limitation 1(b) – “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”

49. Claim 1 recites a “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”. It is my opinion that a POSITA would find the term “working channel” means a passage for guiding surgical instruments, as indicated by the description in the specification. See, e.g., col. 2, ll. 19-24 and FIG. 5 of the ‘129 patent (Ex. 1001), which states: “The working channel has an insertion end and a working end and a channel extending therebetween. The working channel provides a working passage for insertion of the other instruments of the system, and for delivery of the implant to the SI Joint”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “working channel”. (Ex. 1002).

50. It is my opinion that a POSITA would find the term “insertion end” means an end of the working channel that is engaged with the insertion point in a sacroiliac joint that includes insertion arms for engagement with the sacroiliac joint. See, e.g., col. 2, ll. 24-26; col. 3, ll. 22-23; and FIG. 6 of

the ‘129 patent (Ex. 1001), which states: “The insertion end has a pair of arms for providing engagement of the SI Joint and distraction of tissue surrounding the insertion end... FIG. 6 shows a close up of the insertion end of one embodiment of a working channel”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “insertion end”. (Ex. 1002).

51. It is my opinion that a POSITA would find the term “working end” means an end opposite from the insertion end through which instruments are introduced into the working channel. See, e.g., col. 3, ll. 31-32; col. 4, ll. 59-61; and FIGS. 5 and 10 of the ‘129 patent (Ex. 1001), which states: “FIG. 10 shows a close up of the working end of one embodiment of a working channel... The working channel 10 has an insertion end 11 and a working end 12, and a channel 13”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “working end”. (Ex. 1002).

52. It is my opinion that a POSITA would find the term “a first iliac contour” means a contoured surface on the insertion end of the working channel to accommodate the anatomy of the ilium. See, e.g., col. 5, ll. 14-16 and FIG. 5 of the ‘129 patent (Ex. 1001), which states: “...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...”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “a first iliac contour”. (Ex. 1002).

53. It is my opinion that a POSITA would find the term “a first sacral contour” means a contoured surface on the insertion end of the working channel to accommodate the anatomy of the sacrum. See, e.g., col. 5, ll. 19-21 and FIG. 5 of the ‘129 patent (Ex. 1001), which states: “...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...”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “a first sacral contour”. (Ex. 1002).

54. It is my opinion that a POSITA would find the term “insertion arms” means extensions from the insertion end of the working channel. See, e.g., col. 4, ll. 64-67 and FIGS. 4-9 of the ‘129 patent (Ex. 1001), which states: “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 protruding from the insertion end”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “insertion arms”. (Ex. 1002).

c. Claim 1: Limitation 1(d) - 1(d)(i)(b) – “introducing an abrading device into the working channel”

55. Claim 1 recites a “introducing an abrading device into the working channel, the abrading device comprising an 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”. It is my opinion that a POSITA would find the term “abrading head” means a structure at an end of an abrading device having an abrasive surface. See, e.g., col. 6, ll. 16-18 and FIG. 13 of the ‘129 patent (Ex. 1001), which states: “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”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “abrading head”. (Ex. 1002).

56. It is my opinion that a POSITA would find the term “open tip” means a structure on the abrading head having an exposed tapered edge. See, e.g., col. 6, ll. 28-30 and FIG. 14 of the ‘129 patent (Ex. 1001), which states: “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”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “open tip”. (Ex. 1002).

d. Claim 1: Limitation 1(d)(ii) – “a slide hammer assembly at a proximal end of the abrading device, the slide hammer assembly having ... a releasing means for transitioning the slide hammer assembly between the locked position and the released position”

57. Claim 1 recites a “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”. It is my opinion that a POSITA would find the term “releasing means” 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. See, e.g., col. 7, ll. 9-12 of the ‘129 patent (Ex. 1001), which states: “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”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “releasing means”. (Ex. 1002).

e. Claim 1: Limitation 1(e) – “advancing the abrading device into the sacroiliac joint ... thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument”

58. Claim 1 recites a “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”. It is my opinion that a POSITA would find the term “decorticated implant void” means a space in the sacroiliac joint from which bone tissue has been removed. See, e.g., col. 10, ll. 3-7 of the ‘129 patent (Ex. 1001), which states: “...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...”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “decorticated implant void”. (Ex. 1002).

59. It is my opinion that a POSITA would find the term “without using a rotary instrument” means without the use of a rotary drill. The ‘129 Patent identifies only drills and drill bits as rotary cutting instruments. See, e.g., col. 2, ll. 52-54 of the ‘129 patent (Ex. 1001), which states: “procedure for installing an allograft implant in the SI Joint, without using a drill, drill bits, or other rotary cutting instruments”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “without using a rotary instrument”. (Ex. 1002).

**f. Claims 2 and 10: Limitations 2(a)-(c) and 10(a)-(c) –
“upon the abrading head becoming lodged inside the sacroiliac joint, unlocking the slide hammer assembly via the releasing means, and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint.”**

60. Claims 2 and 10 recite a “upon the abrading head becoming lodged inside the sacroiliac joint, unlocking the slide hammer assembly via the releasing means, and using the slide hammer assembly to dislodge the

abrading head from the sacroiliac joint”. It is my opinion that a POSITA would find the term “lodged inside the sacroiliac joint” means frictionally engaged with the sacroiliac joint. See, e.g., col. 10, ll. 27-29 of the ‘129 patent (Ex. 1001), which states: “...the abrading head 32 may become lodged in the SI Joint 3, becoming difficult to remove”. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “lodged inside the sacroiliac joint”. (Ex. 1002).

g. Claim 9: Limitations 9(a)-(b) – “... forming a generally rectangular cross sectional shape for the decorticated implant void ... for receiving a fusion implant having a generally rectangular cross sectional shape.”

61. Claim 9 recite a “forming the decorticated implant void at the insertion point further comprises 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”. It is my opinion that a POSITA would find the meaning of the terms “forming a generally rectangular cross-sectional shape” and “a fusion implant having a generally rectangular cross sectional shape” to be plain and self-evident and do not require further

construction. There is no prosecution history in the ‘129 patent that provides any further understanding of the term “lodged inside the sacroiliac joint”. (Ex. 1002).

VIII. THE CHALLENGED CLAIMS ARE OBVIOUS IN VIEW OF THE PRIOR ART

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]

B. THE SCOPE AND CONTENT OF THE PRIOR ART

62. All of the references discussed herein are closely related to the methods disclosed in the '129 patent, as they all relate to orthopedic surgeries, and all but Sharma (Ex. 1009) relate to fusion procedures involving the spine. Further, many of the references specifically teach the implantation of a fusion implant into the sacroiliac joint, therefore one of ordinary skill in the art would look to the combined teachings of these references to develop sacroiliac fusion procedures. Thus, combinations made from these references are merely simple combinations of known methods and instruments, guided by known anatomical attributes or constraints that achieve the same or complimentary functions and because of their well-known uses, structure and function, provide safe and predictable results.

63. I specifically note that prior art teachings directed to instruments designed for use in interbody fusion surgeries between adjacent vertebrae are intuitively applicable to fusion surgeries between the sacrum and ilium as both procedures include weight-bearing spinal bones with large, substantially planar interfacing articular surfaces. While there are some anatomical distinctions, the core mechanical principals of fusing bodies of adjacent vertebrae and fusing the sacrum and ilium are highly similar.

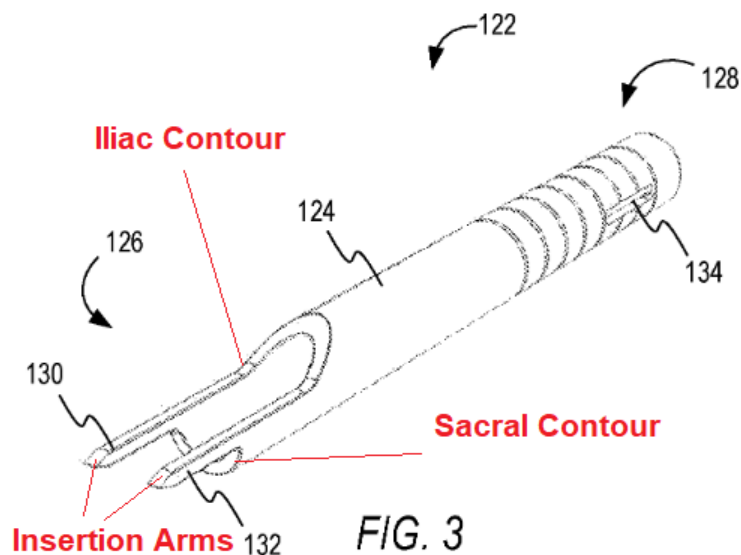
64. Each reference relates to orthopedic surgeries, and all but Sharma (Ex. 1009) relate to fusion surgeries involving the spine. Thus, the prior art references are highly related to the ‘129 patent, and are pertinent to the objectives the inventor was focused on, e.g., to improve the efficiency and to simplify sacroiliac fusion procedures.

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

65. Compton et al., 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 (hereinafter, “Compton”). Compton et al. 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.

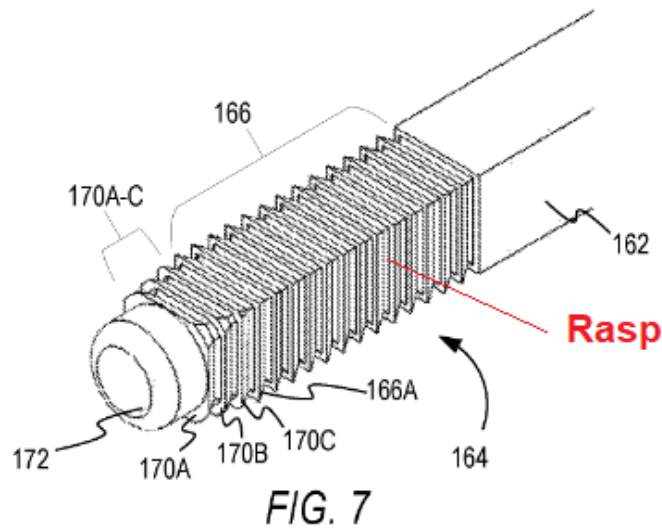
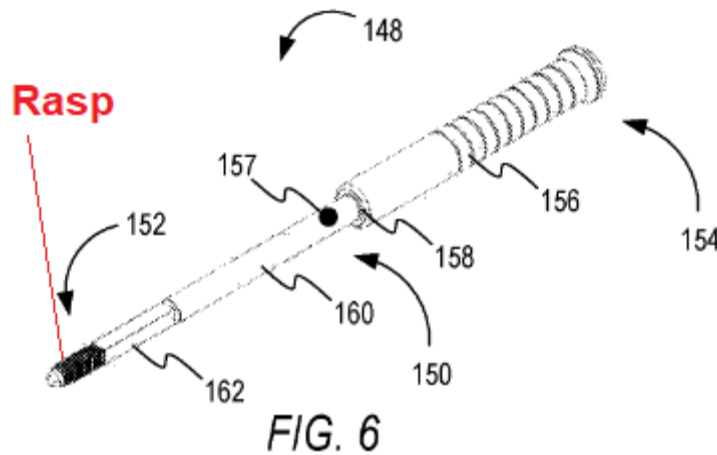
66. Compton discloses devices and methods for treating an SI Joint by fitting one or more grafts inside the SI Joint to fuse the sacrum and ilium. (Ex.1004, 3:8-12). The method involves using a finder device 100 that is placed in a space 238 between the sacrum and ilium. (Ex.1004, 3:35-45, 7:8-11). A 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.



67. 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, as shown below in FIGS. 6-7. (Ex.1004, 4:35-53, 5:1-44).



68. 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).

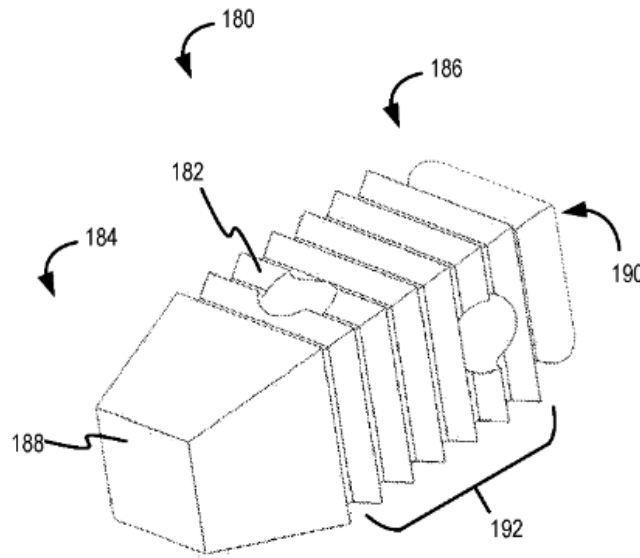


FIG. 10

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

69. Schifano, et al., 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.

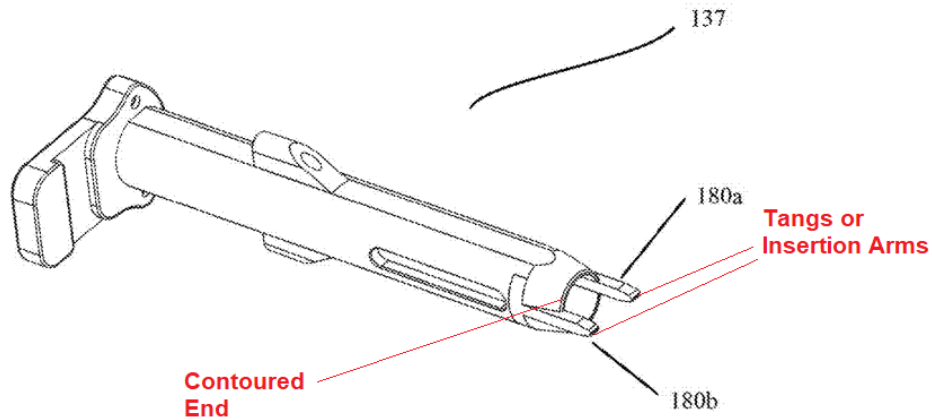
70. Schifano discloses methods for fusing a sacroiliac joint (“SI Joint”) to repair the SI Joint of the pelvis and spine. (Ex.1003, Abstract).

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).

71. 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).

72. 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



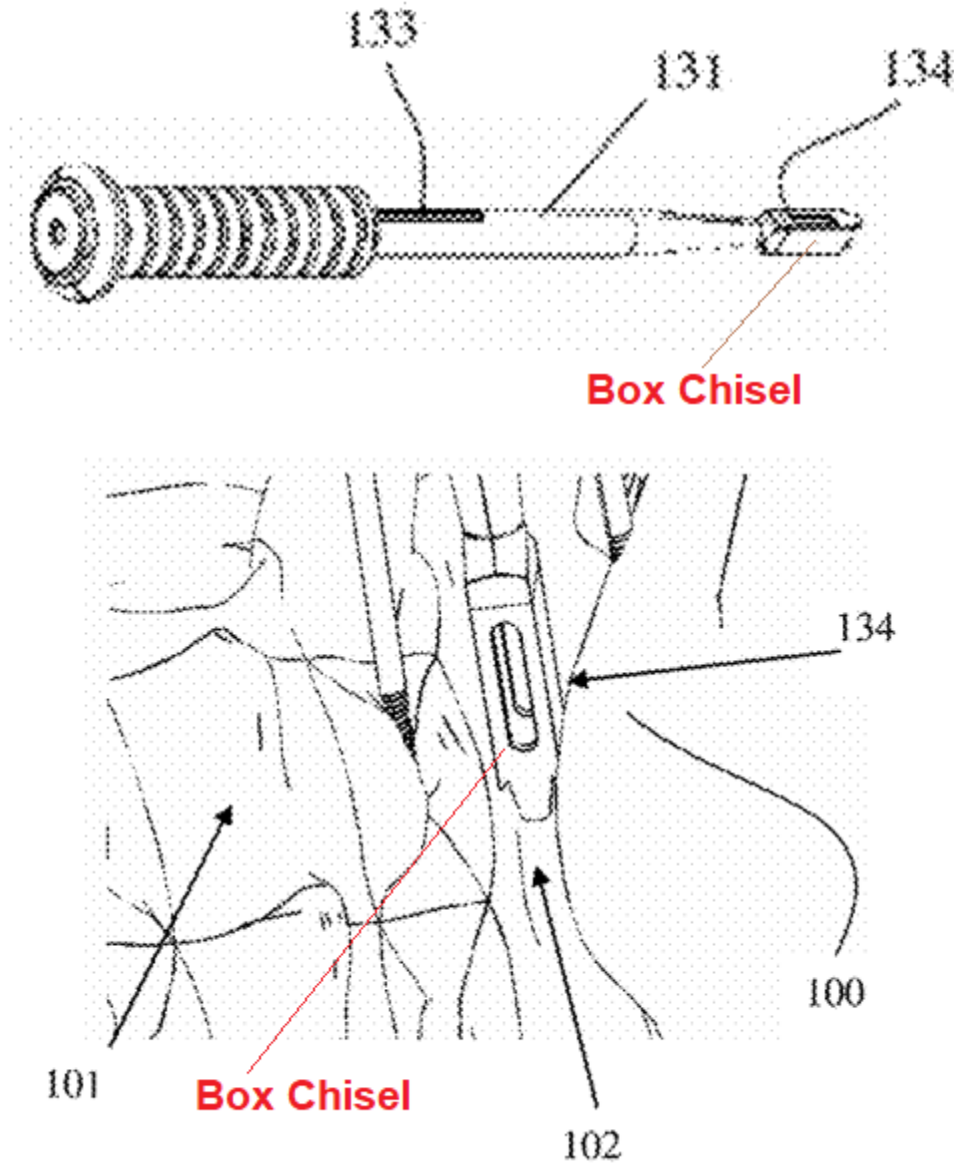
73. A void is created in the SI Joint that is configured to receive a joint fusion implant. (Ex.1003, 35:28-30). The method may include passing multiple surgical implements through the working channel into the void to prepare the void for receiving the fusion implant. (Ex.1003, 35:36-44).

74. 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

Declaration of Troy D. Drewry

Petition for Inter Partes Review of U.S. Patent No. 11,020,129

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

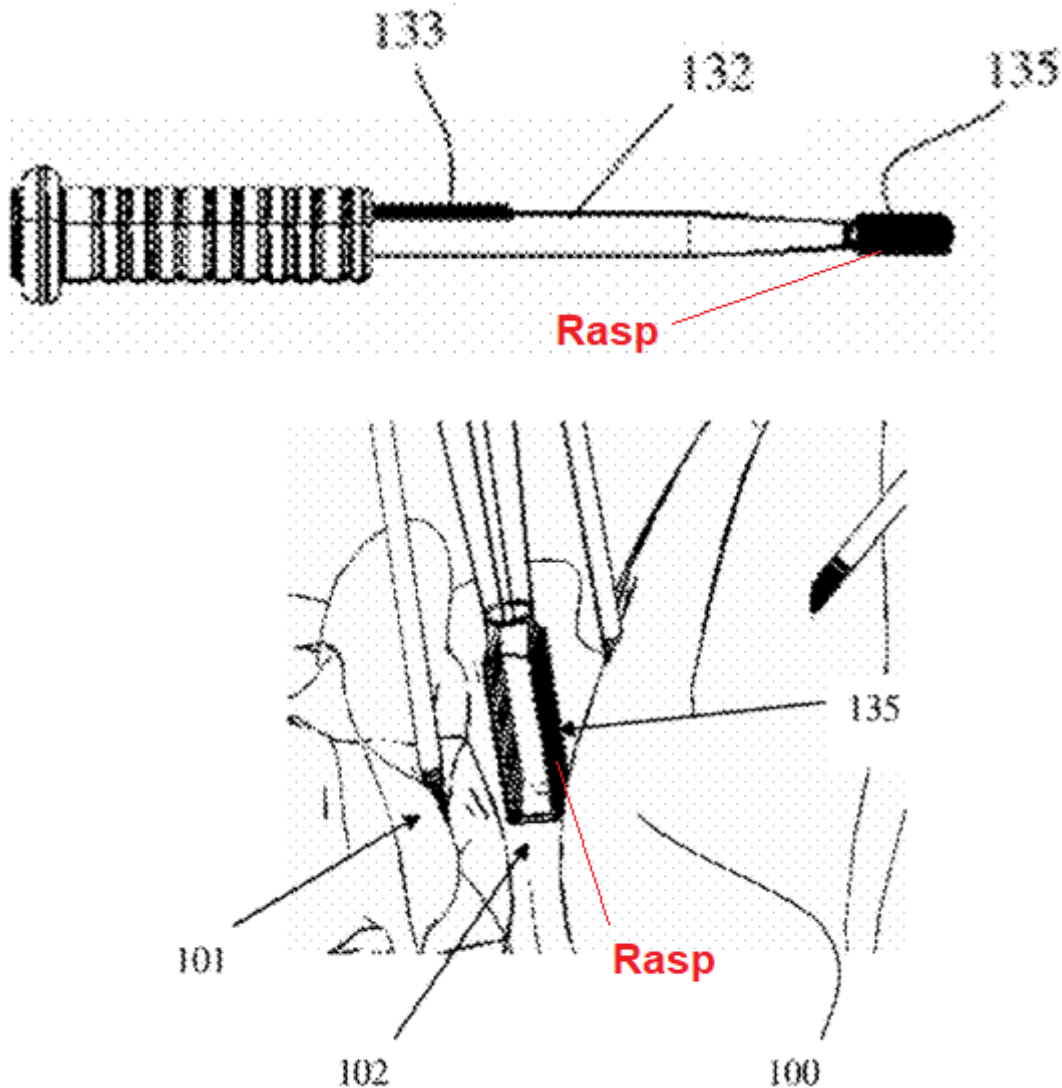


75. A rasp 132 is passed through the working channel and into the SI Joint to further prepare the bone for the fusion implant. (Ex.1003, 15:21-34, 19:66-20:2). The rasp 132 has teeth 135 operable to scrape the bone

Declaration of Troy D. Drewry

Petition for Inter Partes Review of U.S. Patent No. 11,020,129

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).



76. Schifano teaches a substantially rectangular implant 151 having a ribbing 153 on opposing sides to grip the surfaces in the void as shown in Figs. 126 and 127 below (Ex.1003, 31:47-56).

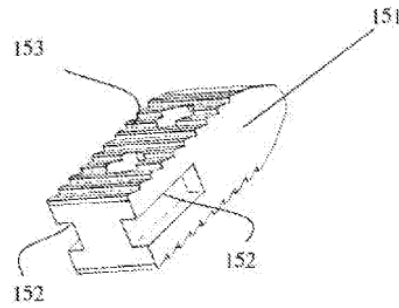


FIG. 126

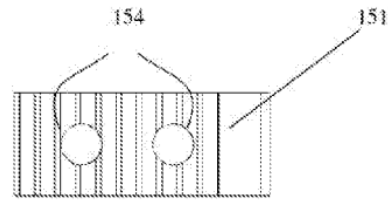


FIG. 127

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

77. Black et al., 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 (hereinafter, “Black”). Black et al. 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.

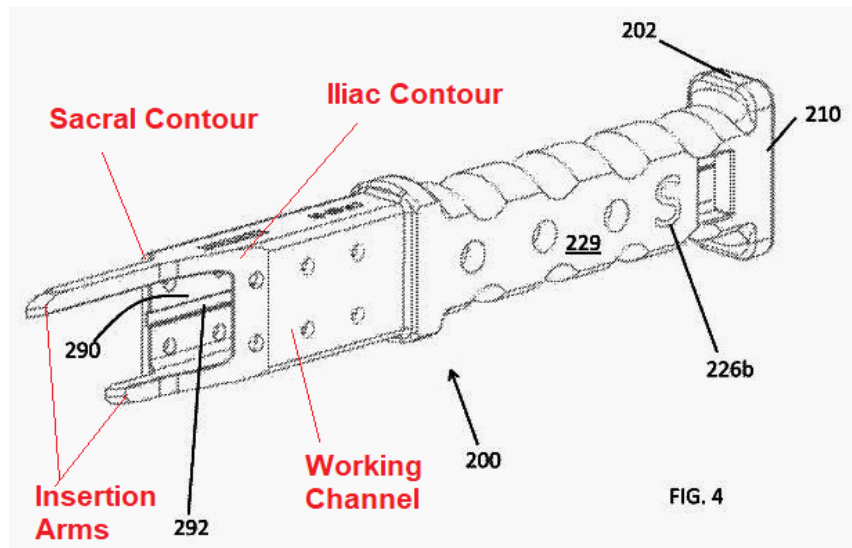
78. Black discloses a method for delivering an SI Joint implant or other fixation device to the SI Joint. (Ex.1005, ¶[0087]). Fluoroscopy is used to visualize the SI joint and isolate the affected SI joint. (Ex.1005, ¶[0088]). An incision is made in a region below the back of a patient and may be in 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.*)

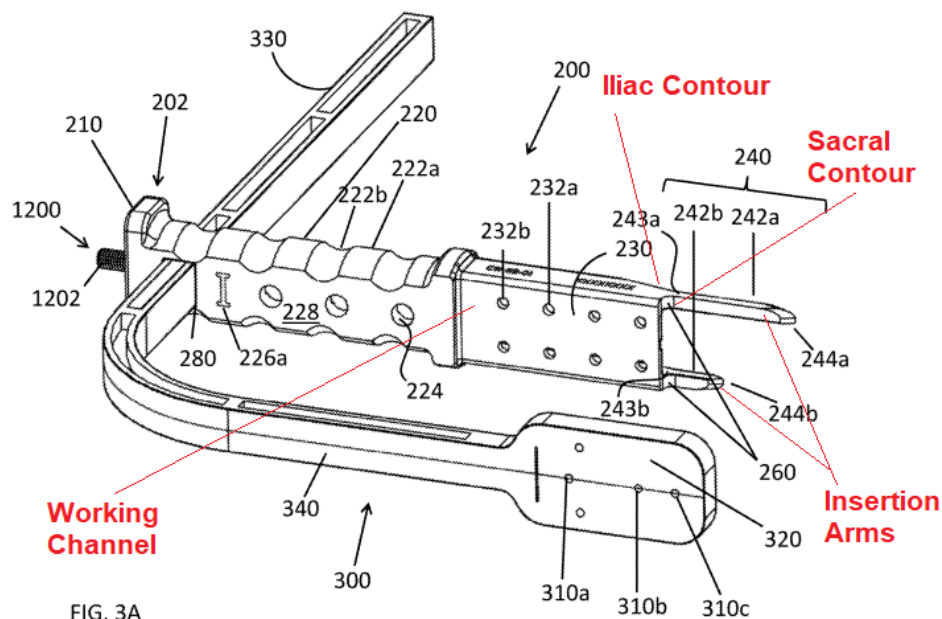
79. A working cannula 200 is inserted over the sliding joint finder 100 and engaged with the SI Joint. (Ex.1005, ¶[0093]). Various excavation tools and implant insertion tools are configured for insertion through the working cannula into the SI Joint. (Ex.1005, ¶[0012]).

80. 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.*).

81. 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 below. (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]).



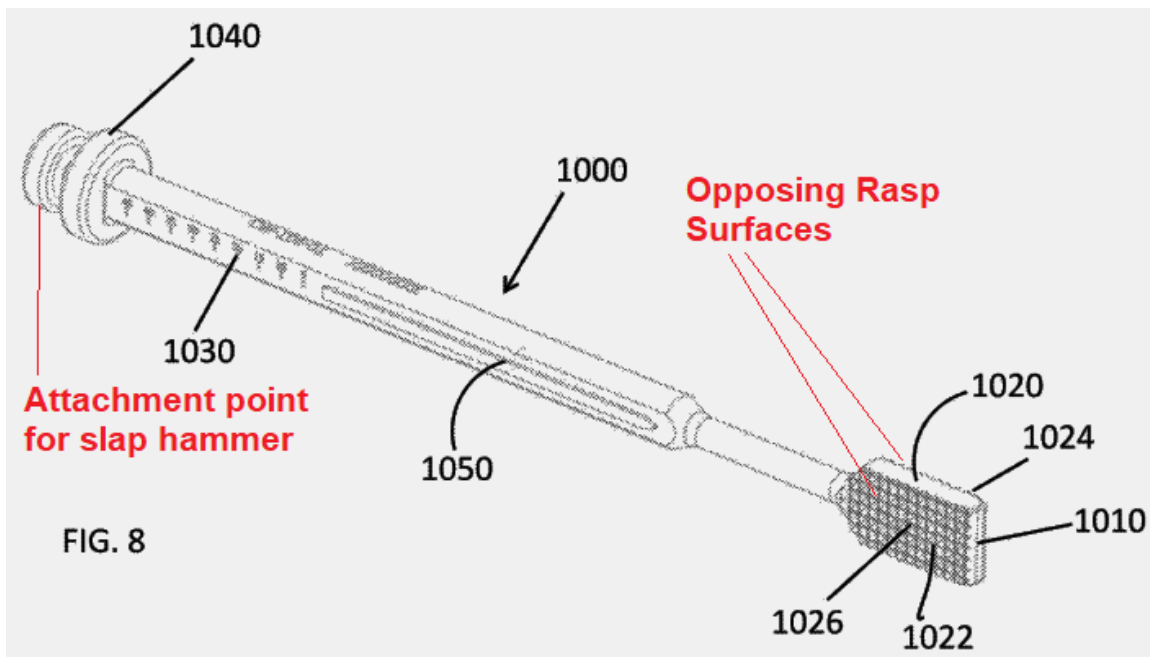
82. The working cannula has a shelf 260 on side 228 that is to be positioned adjacent to the ilium and that controls the depth of insertion into the SI joint. (Ex.1005, ¶[0049]). The opposing side 229 is to be positioned adjacent to the sacrum when the cannula 200 is engaged with the SI Joint. (Ex.1005,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



84. 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 as shown in Fig. 7 below. (Ex.1005, ¶[0073]).

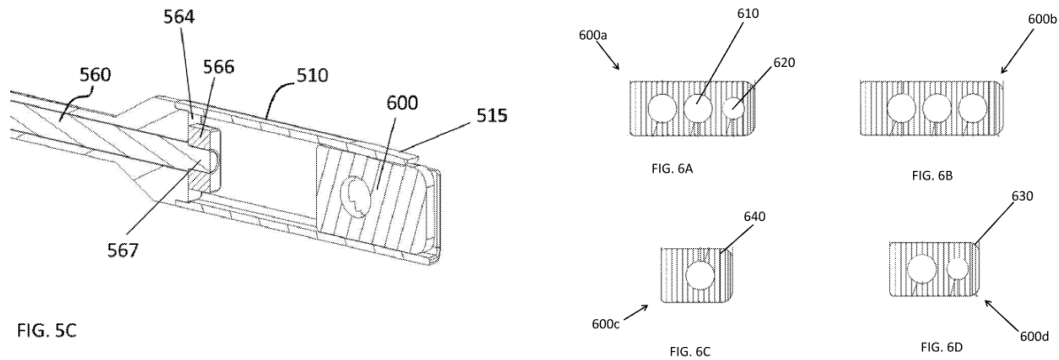


85. Black further discloses passing a rasp 1000 through the working cannula 200 to prepare the SI Joint, as shown in FIG. 8 provided below. (Ex.1005, ¶[0075]). The rasp 1000 has a size and shape that corresponds to an implant to be inserted into the SI Joint contains. (Ex.1005, ¶[0076]). The rasp 1000 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]).



86. 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]).

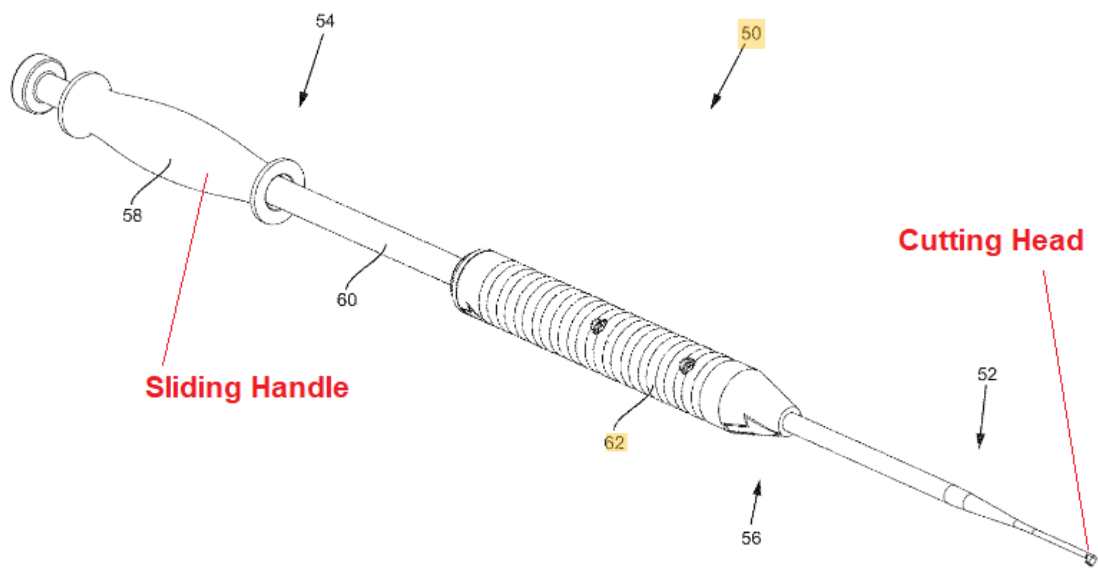


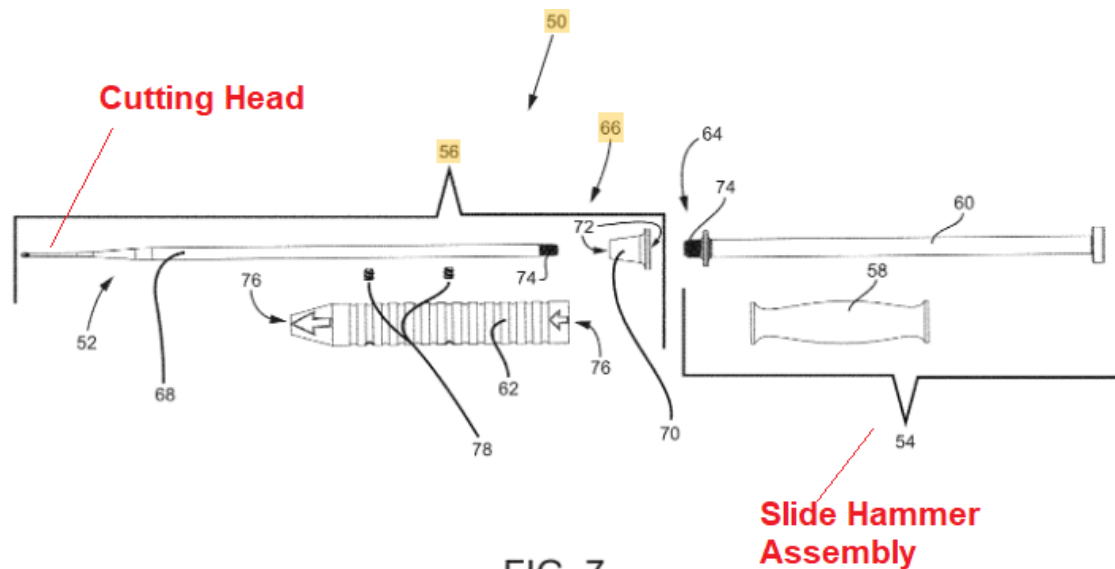
d. US Pat. Publ. No. 2018/0036017 (Donner et al.)

87. 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.

88. 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.*).





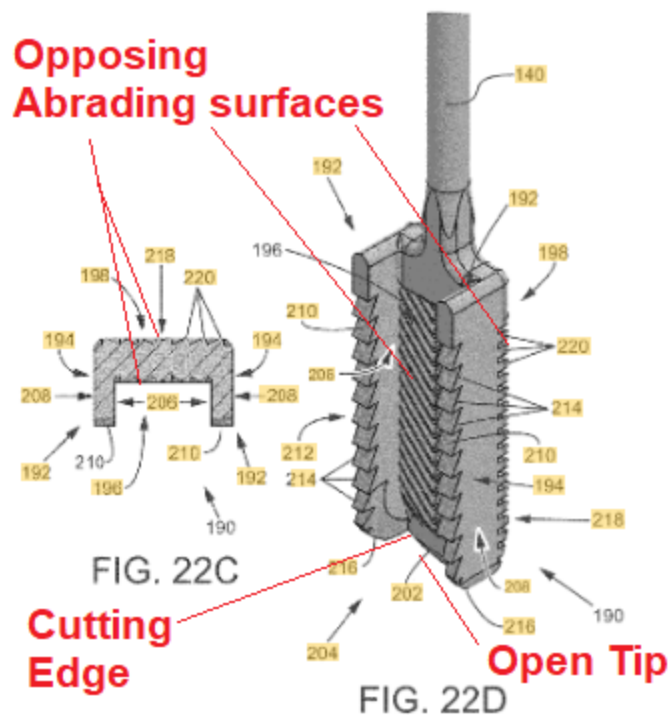
89. Additionally, the tooling head 52 can be backed out of the SI Joint by proximally sliding the proximal handle 58 until it contacts a proximal stop feature 82 to the transmission of proximal force to back the tooling head 52 out of the SI Joint. (Ex.1006, ¶¶[0166]-[0167]).

90. 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.

Declaration of Troy D. Drewry

Petition for Inter Partes Review of U.S. Patent No. 11,020,129

21A-21C, 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]).



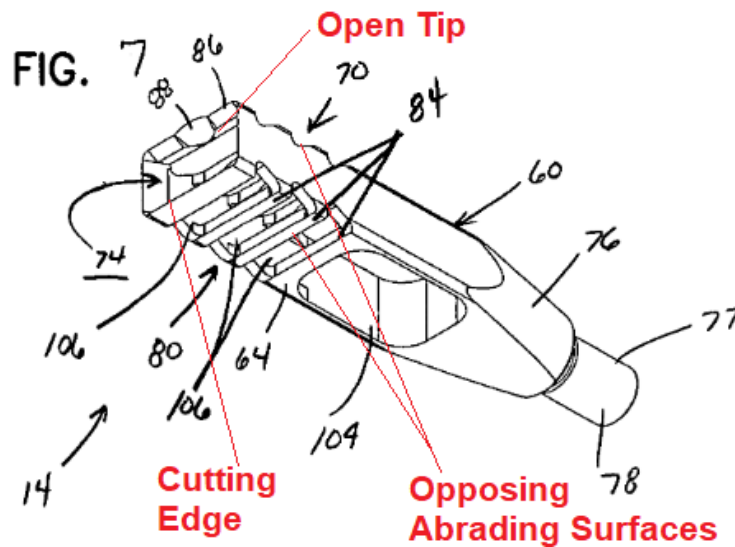
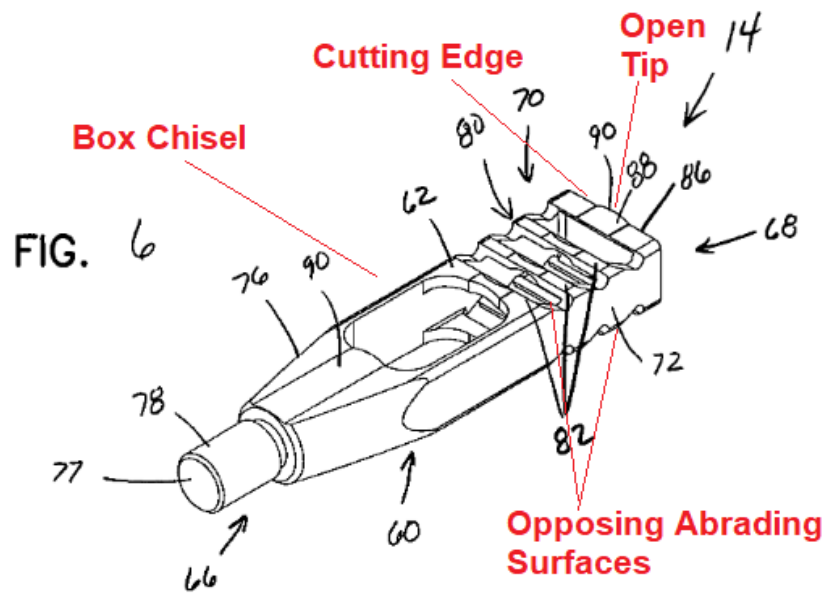
e. US Pat. Publ. No. 2005/0080422 (Otte et al.)

91. 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

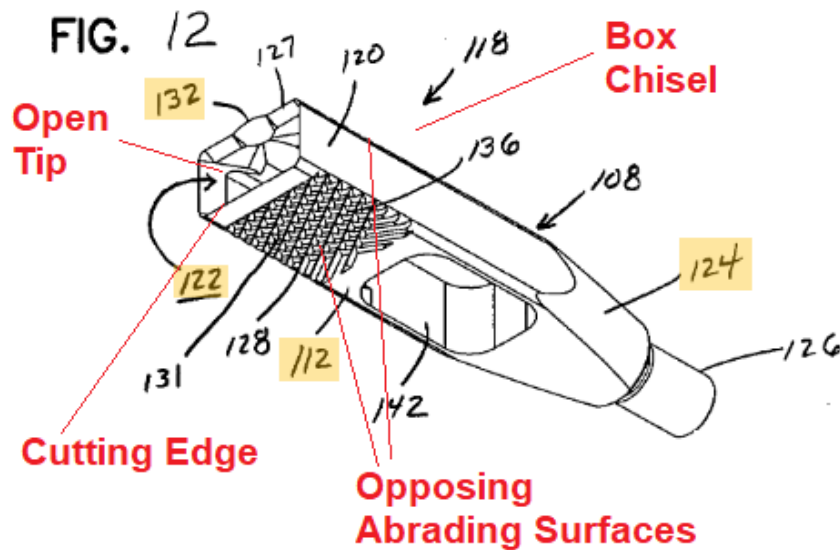
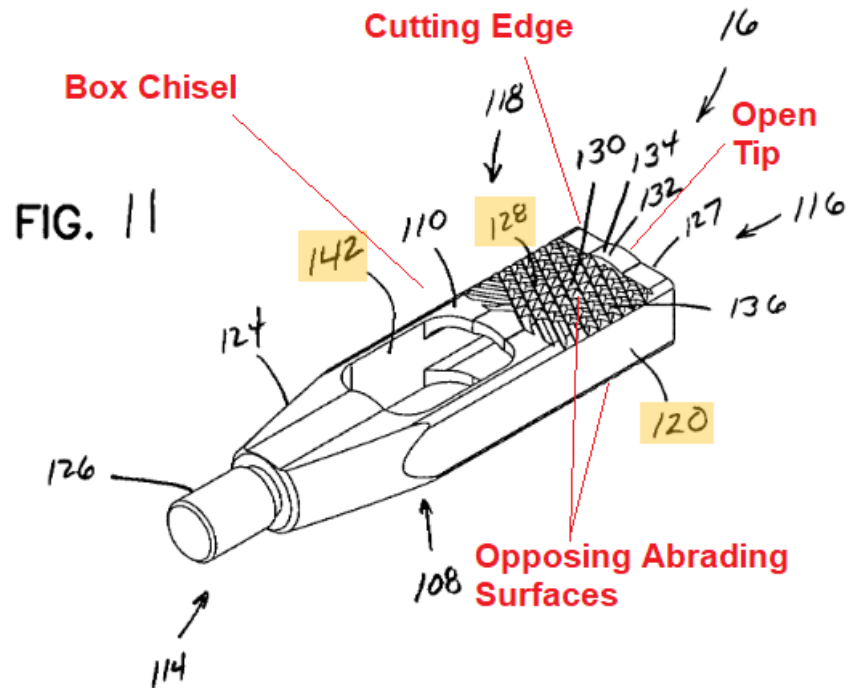
April 14, 2005 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

92. 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.

93. Box chisel 14 of Otte, one embodiment of which is illustrated in Figs. 6-7 below, 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]).



94. 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 FIG. 11. (Ex.1007, ¶¶[0078], [0080], [0082]).



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

95. 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

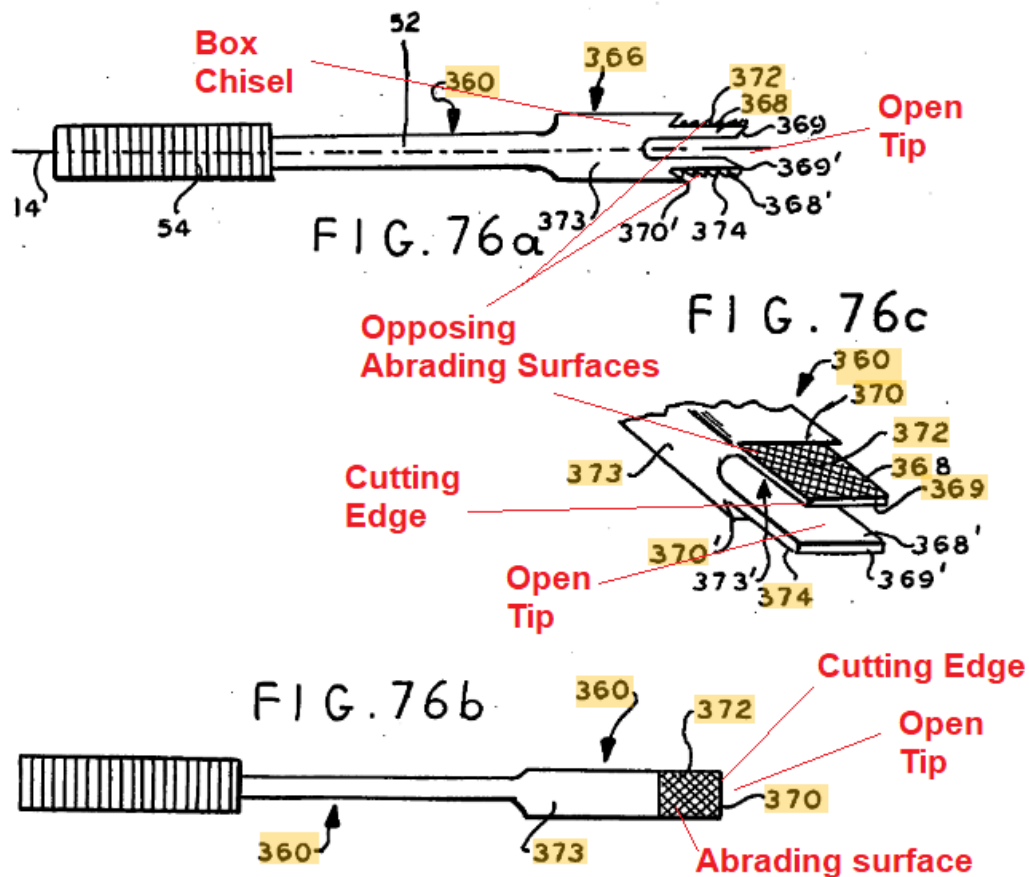
35 U.S.C. § 102(a)(1) because its publication date of April 28, 2005 significantly predates the earliest claimed priority date of the '129 patent, which is October 4, 2019.

96. 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.*).

97. In one embodiment shown in Figs. 76a-76c below, 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.



g. WO2014091454 (Sharma et al.)

98. Sharma et al., International Patent Publication No. WO2014091454, titled "Universal Impactor with Slap Hammer" was filed

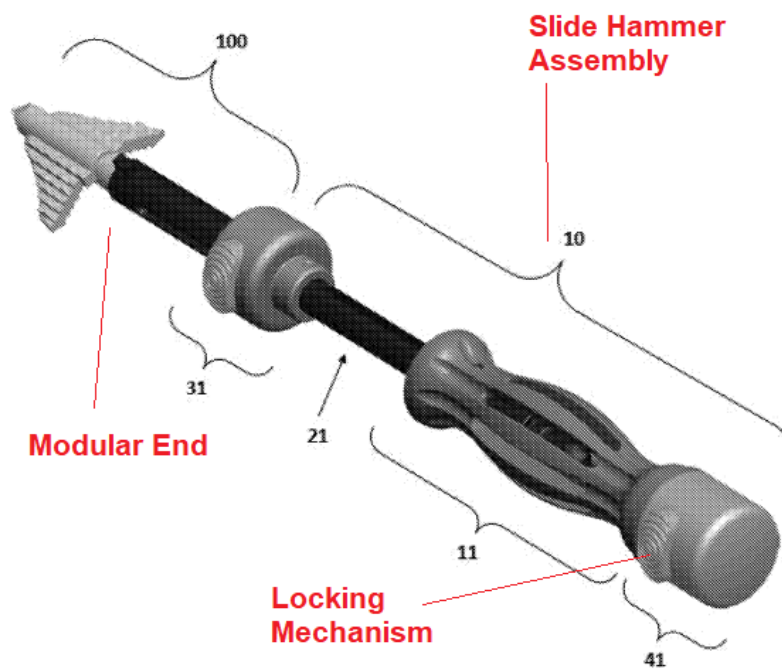
on December 13, 2013 and published on June 19, 2014 (hereinafter, “Sharma”). Sharma et al. qualifies as prior art under AIA 35 U.S.C. § 102(a)(1) because its publication date of April 28, 2005 significantly earlier than the earliest claimed priority date of the ‘129 patent, which is October 4, 2019.

99. 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).

100. An exemplary universal impactor and slap hammer tool 10 is

shown in Fig. 1 below, and 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



101. 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 49 of the impaction end 41 can be struck with a mallet to hammer the surgical instrument 100 into bone during surgery.

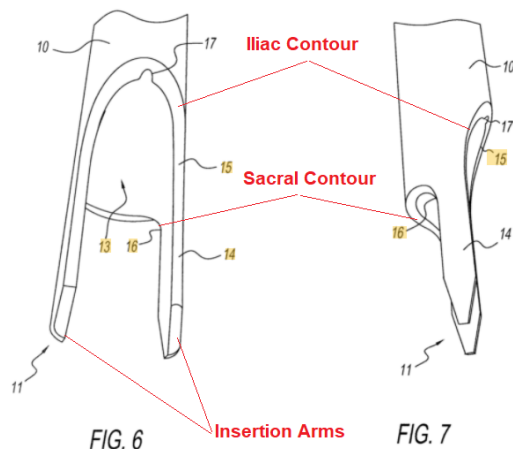
of the references described above, as well as many others that were part of the general background knowledge of a person of skill in this area. Indeed, any differences from these prior references and the claimed combination of features in the ‘129 patent are merely common sense and predictable arrangements of these well-known features which obtain predictable results, namely a posterior approach for a sacroiliac fusion surgery, utilizing a cannula having distal tangs for insertion into the joint with contours for accommodating the anatomy of the ilium and sacrum, and utilizing a slide hammer tool with a box chisel-style cutting head having rasping surfaces on the outside of the chisel to create an implant void in the sacroiliac joint. Therefore, in view of the various predictable and commonsense combinations of the prior art discussed above, it is my opinion that a POSITA would understand the steps and instruments set out in the claims of the ‘129 patent because each combination merely involves the exercise of ordinary skill in the art as of the filing date of the ‘129 patent.

105. To illustrate, the only discussion regarding the patentability of the challenged claims is found in the 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*

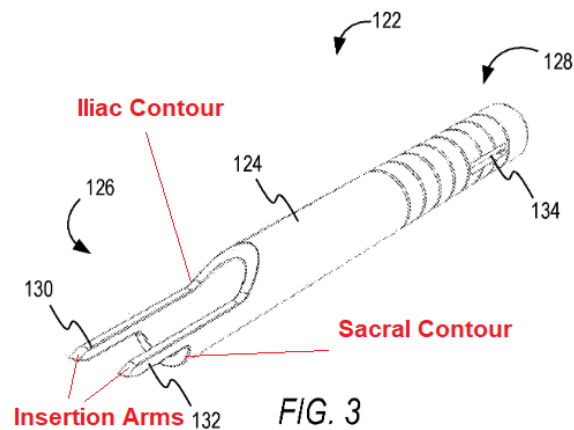
and iliac/sacral contours and introducing abrading device including open tip and slap hammer”. (Ex 1002, 46; emphasis added).

106. However, US 10,219,841 (Compton et al., of record in the ‘129 Patent – Ex. 1004 herein) discloses a cannula having arms and contours that are nearly identical to those of the cannula disclosed and illustrated in the ‘129 Patent. FIG. 3 of Compton et al. 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. FIGS. 6-7 of the ‘129 Patent provide close-up views of the distal end of the cannula 10, the features of which closely resemble the contours and arms of cannula of Compton et al.

‘129 Patent



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



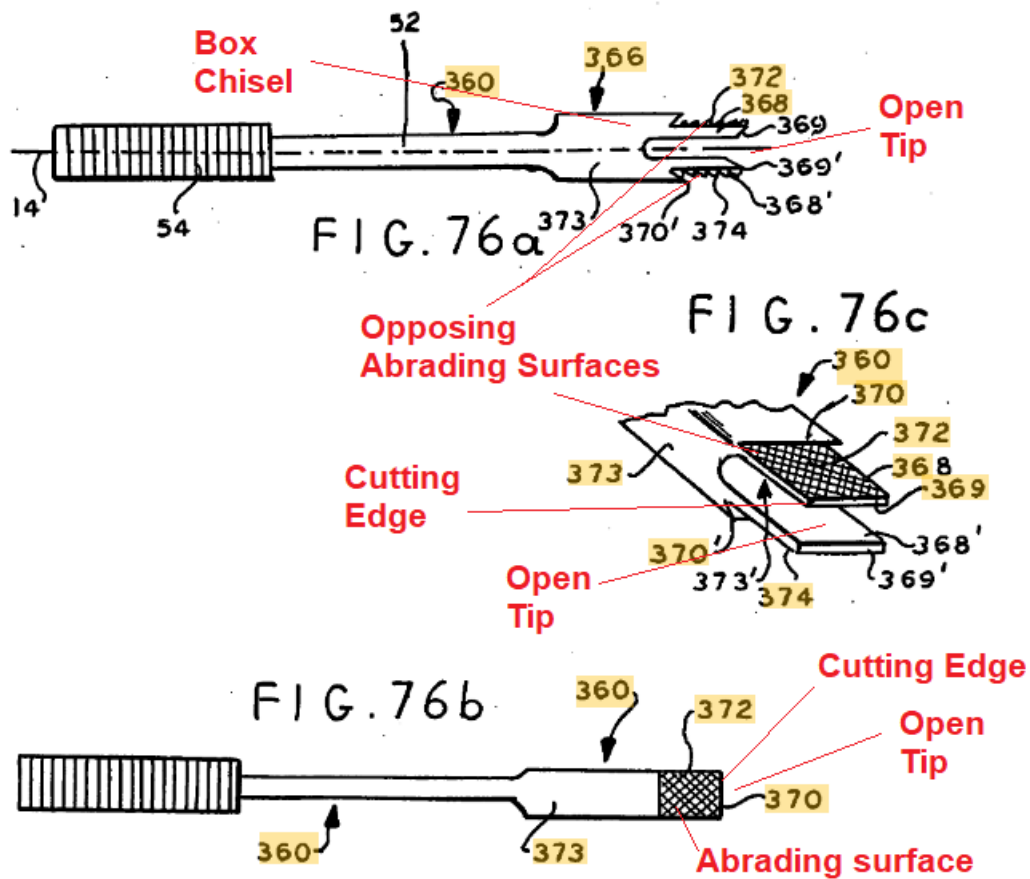
107. Additionally, multiple prior art references disclose an “abrading device having an open tip”, including the following references relied on in this petition: US Pat. Publ. No. 2005/0090829 (Martz et al.), (Ex. 1008) US

Declaration of Troy D. Drewry

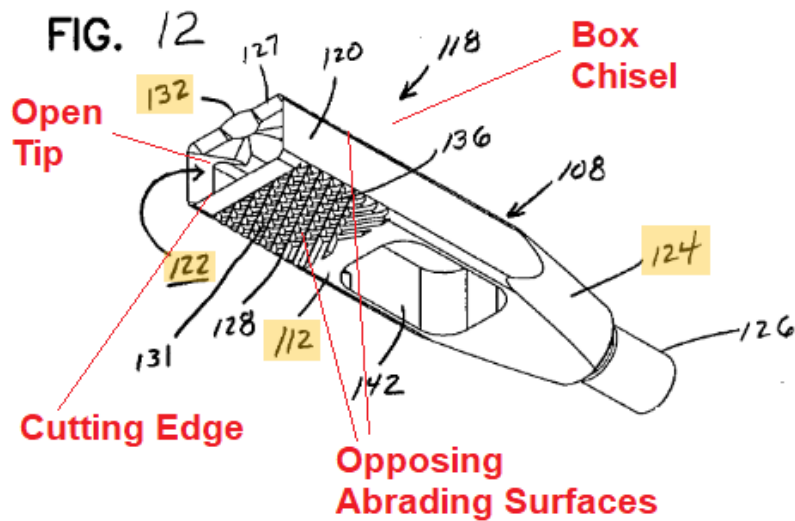
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

Pat. Publ. No. 2005/0080422 (Otte et al.) (Ex. 1007), and US Pat. Publ. No. 2018/0036017 (Donner et al.). (Ex. 1006). Figures from the foregoing references are provided below to illustrate the abrading devices they disclose.

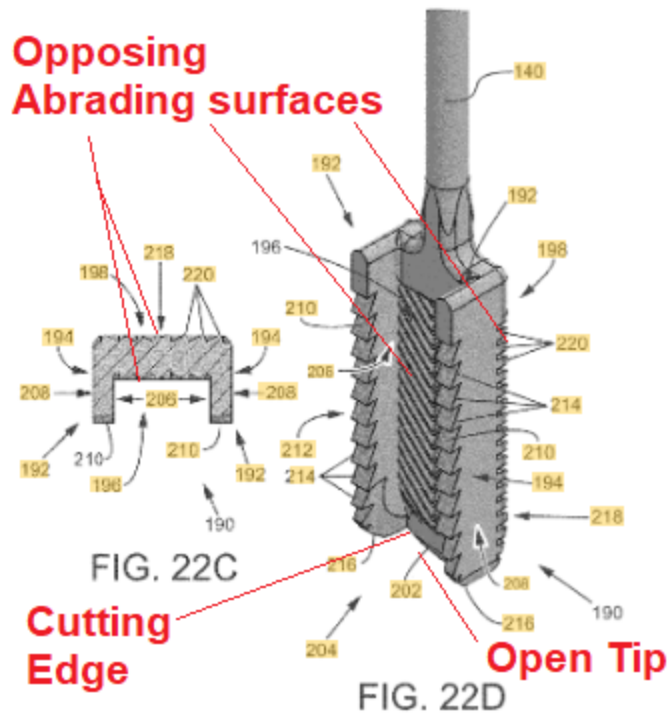
US Pat. Publ. No. 2005/0090829 (Martz et al.)



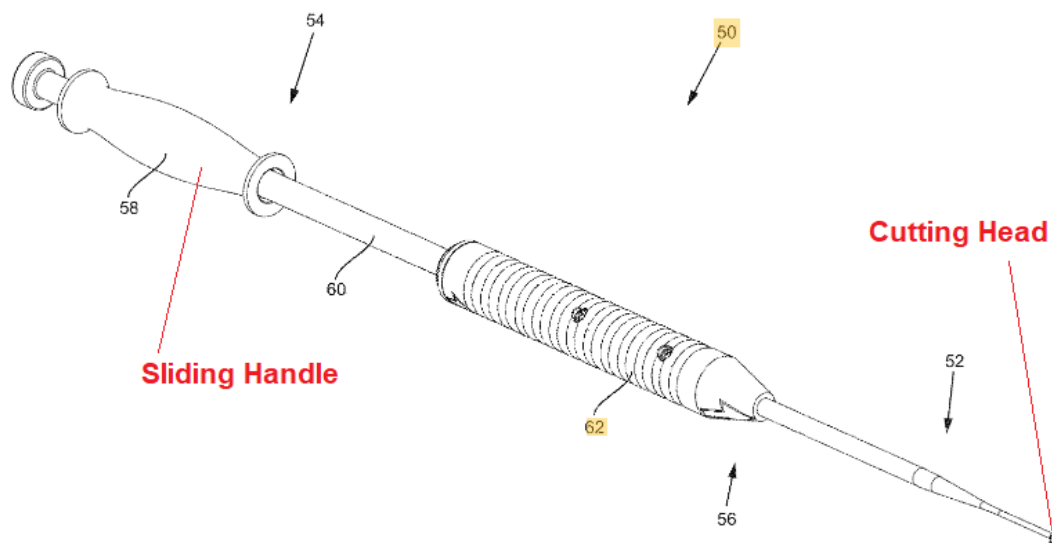
US Pat. Publ. No. 2005/0080422 (Otte et al.)



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



108. Furthermore, Donner et al. discloses a joint preparation tool 50 that includes a slap hammer assembly 54 and a cutting tool assembly 56, as shown in FIGS. 6-7 provided below. (Ex.1006, ¶[0164]). 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]).



109. The joint preparation tool 50 is configured to be used with a variety of interchangeable tooling heads 52, including the rasping, joint cutting tool shown above FIGS. 22C-22D of Donner et al. provided above. (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. 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.

110. Thus, it is my opinion that a POSITA would have found methods and instruments utilized in spinal orthopedic procedures, including interbody fusion and sacroiliac fusion methods, and general instruments used in orthopedic procedures (e.g., cannulas, slide hammers, chisels, and rasps) to be highly related to the claimed methods of the '129 patent and that a POSITA would look to such related procedures in devising a posterior sacroiliac fusion approach like that disclosed in the '129 patent with reasonable expectations of success. Specifically, it is my opinion that claims 1, 2, and 9-10 are obvious over Compton combined with Donner (Ex. 1010), Otte (Ex. 1007), and Sharma as well as the generally well-known aspects of the background knowledge of a POSITA. It is also my opinion that claims 1, 2, and 9-10 are obvious over Schifano (Ex. 1003) combined with Compton (Ex. 1004), Martz (Ex. 1008), and Sharma (Ex. 1009) as well as the

generally well-known aspects of the background knowledge of a POSITA. It is also my opinion that claims 1, 2, and 9 are obvious over Compton combined with Martz and Sharma as well as the generally well-known aspects of the background knowledge of a POSITA. It is also my opinion that claims 1, 2, and 9-10 are obvious over Black (Ex. 1005) combined with Martz and Sharma as well as the generally well-known aspects of the background knowledge of a POSITA. It is also my opinion that claims 1, 2, and 9-10 are obvious over Black combined with Donner, Martz, and Sharma as well as the generally well-known aspects of the background knowledge of a POSITA. Appendix A provides a table comparing the disclosures of various references.

a. 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

111. 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 as they are closely related. 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. Thus, the methods and instruments of Compton and Donner are closely related and have significant overlap in both instrumentation and methodology. 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. 1006, ¶[0190]). Additionally, the joint preparation tool of Donner includes a slap hammer portion, and thus provides a single tool that 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.

112. 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. 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.

113. 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.1009, Abstract; p.19, ll.15-18). 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). 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.

2. Independent Claim 1

i) *Preamble*

114. Compton teaches a method that includes forming an implant void in an SI Joint. (Ex.1004, 4:14-22).

115. 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]).

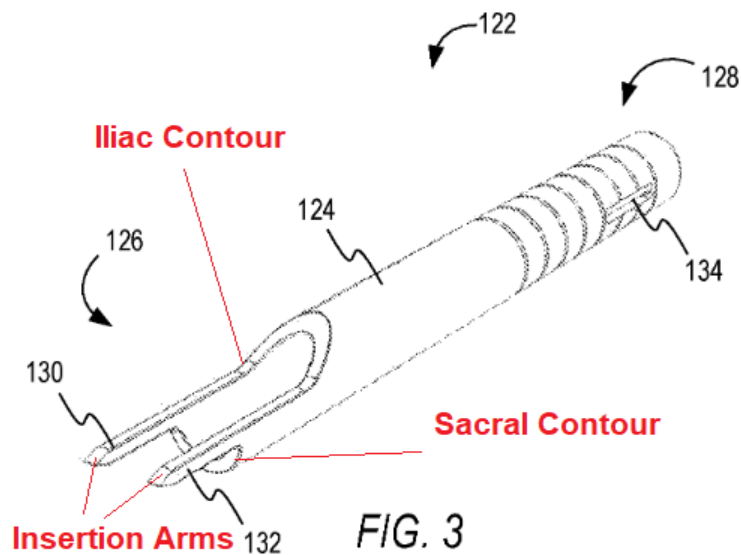
ii) (1(a)) *Locating insertion point*

11666. 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*

117. 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). 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.



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

118. 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).

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

119. 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 1004, 5:1-25). The broach 148 is inserted into the SI Joint through the retraction guide 122 (working channel). (Ex 1004, 20:3-20).

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

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

121. 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]).

122. 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*

123. 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. 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.

124. 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]).

125. 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.C.1. herein, it would be obvious to combine the slide hammer of Sharma with the methods of Compton and Donner.

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

126. 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 1004, 5:12-25; 7:42-53).

127. 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]). 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. (*Ibid.*) Drills are discussed in Donner as alternative embodiments to non-rotary cutting elements. (Ex 1006, ¶[0270]).

3. Dependent Claim 2

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

128. 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*

129. 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*

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

b. 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

131. A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9 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.

132. 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. 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). 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. 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.

133. 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]).

Thus, the methods and instruments of Schifano, Compton, and Martz are highly related and have significant overlap.

134. 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.1008, ¶[0305]). The box chisel tool of Martz predictably improves the efficiency of the method of Schifano. 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. 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.

135. Martz also discloses preparing articulating bone surfaces using the box chisel, rasp combination tool without the use of a drill. The bone surfaces of intervertebral discs are analogous in their structure to the articular surfaces of the sacrum and ilium in the sacroiliac joint. 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 predictable results. 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.

136. 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.1009, Abstract; p.19, ll.15-18). The slap hammer device of Sharma is designed for general use in orthopedic procedures. (Ex. 1009, Abstract). 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. (Ex.1003, 19:40-50, 15:21-34, 19:66-20:2). 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 improve the efficiency of the procedure of Schifano.

2. Independent Claim 1

i) Preamble

137. Schifano et al. discloses methods of a posterior surgical approach for sacroiliac fusion. (Ex 1003, at Abstract). The methods include creating an incision and a void in a patient's sacroiliac joint. *Ibid.*

138. 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*

139. 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; 18:52 – 19:16).

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

140. 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).

141. As explained above in section VIII.C.a.2.iii. herein, Compton discloses the limitations of claim designation 1(b).

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

142. 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 1003, 1:11-16; 2:51-60; 3:59-65; 7:4-15).

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

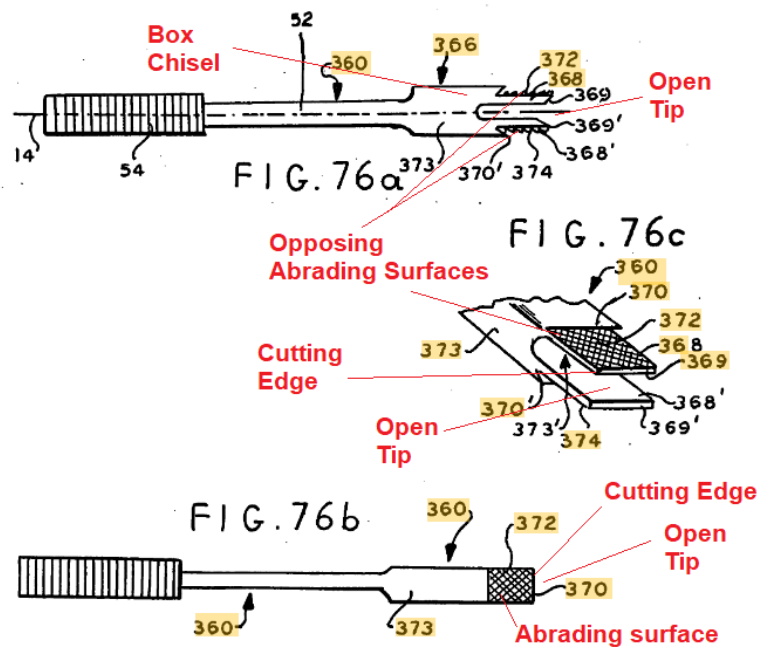
143. Schifano discloses a rasp (abrading device) having a distal tip having teeth on opposing sides thereof for preparing the bone tissue in the SI Joint for fusion. (Ex 1003, 20:3-20). The rasp is inserted into the SI Joint through the working channel. (Ex 1003, 20:3-20).

viii) (1(d)(i)(b)) “an open tip / cutting edge”

144. 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).

145. 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.

146. 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:



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

147. As explained above in section VIII.C.a.2.ix herein, Sharma discloses the limitations of claim designation 1(d)(i)(c). As further explained above in section VIII.C.1. herein, it would be obvious to combine the slide hammer of Sharma with the methods of Schifano and Compton.

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

148. 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).

149. 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]).

3. Dependent Claim 2

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

150. As explained above in Section VIII.C.a.3 herein, Sharma et al. discloses the limitations of Claim 2.

4. Dependent Claim 9

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

151. 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*

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

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

1. Motivation to combine

153. As previously explained in Section VIII.C.a.1., 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.

154. As explained above in section VIII.D.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. Also explained above in Section VIII.D.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.

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*”

155. As explained above in section VIII.C.a.2.i., Compton teaches the limitations of the preamble, except for the absence of rotary cutting tools.

156. 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]).

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

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

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

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

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

159. As explained above in section VIII.C.a.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*

160. As explained above in section VIII.C.a.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*

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

162. As explained above in section VIII.C.a.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*

163. As explained above in section VIII.C.b.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).

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

164. 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).

165. 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 VIII.C.b.2.x.

3. Dependent Claim 2

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

166. As explained above in Section VIII.C.a.3, Sharma discloses the limitations of Claim 2.

4. Dependent Claim 9

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

167. As explained in section VIII.C.a.4, Compton discloses the limitations of Claim 9.

5. Dependent Claim 10

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

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

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

1. Motivation to combine

169. 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. 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]).

170. As explained above in section VIII.D.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.

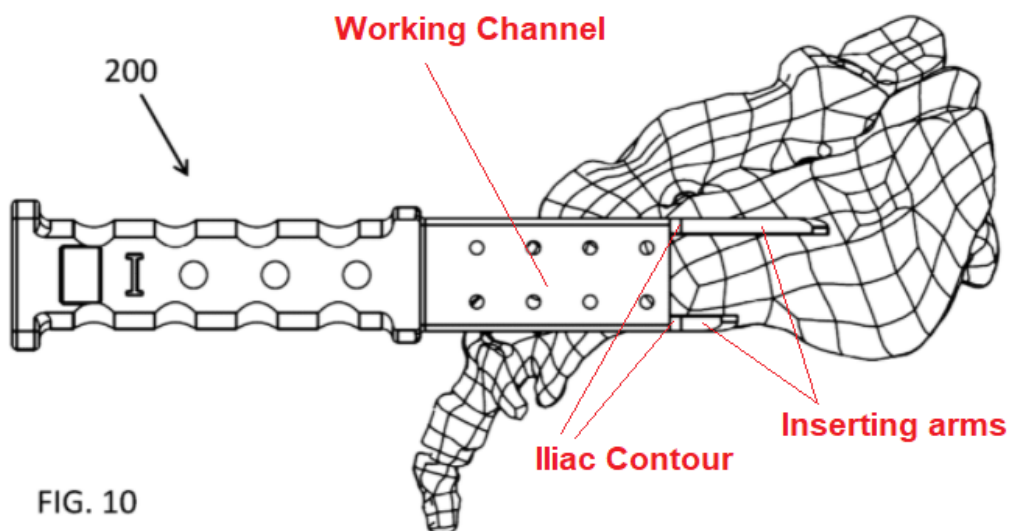
171. Black discloses a SI joint fusion procedure that includes the use of an impactor and tools that are conventionally used with slap hammers, such as a box chisel or rasp. (Ex. 1005, ¶¶[0073]-[0077]). As explained above in Section VIII.C.b.1. herein, it would be obvious to use the universal impactor 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. Therefore, it would be obvious to a

POSITA to modify the method of Black to utilize the universal impactor tool of Sharma.

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”*

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



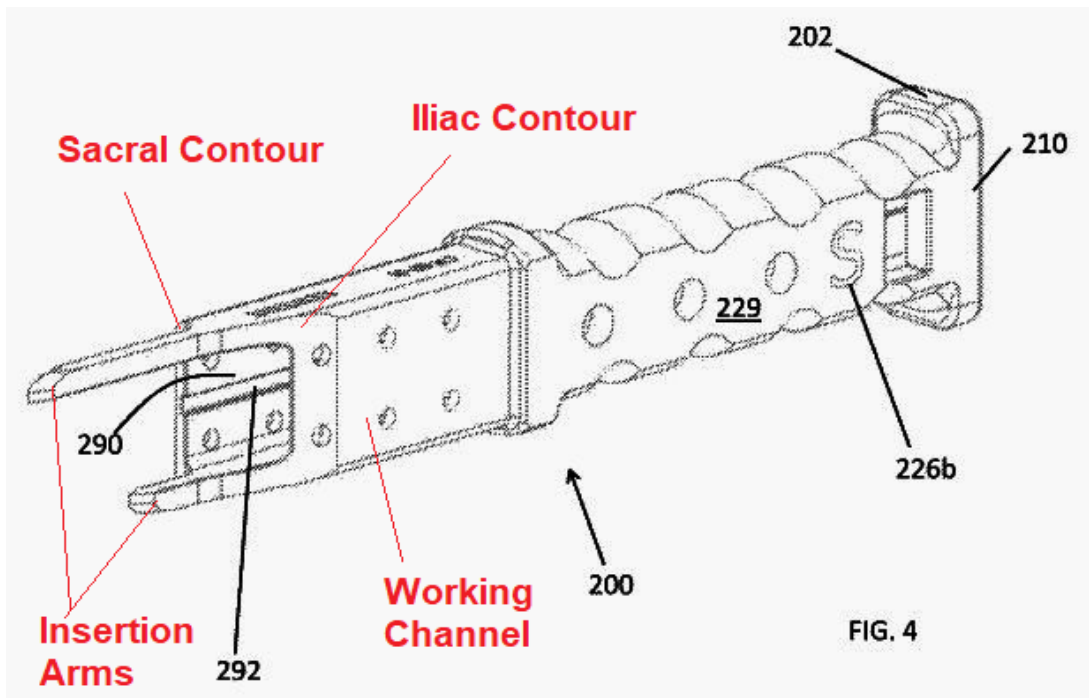
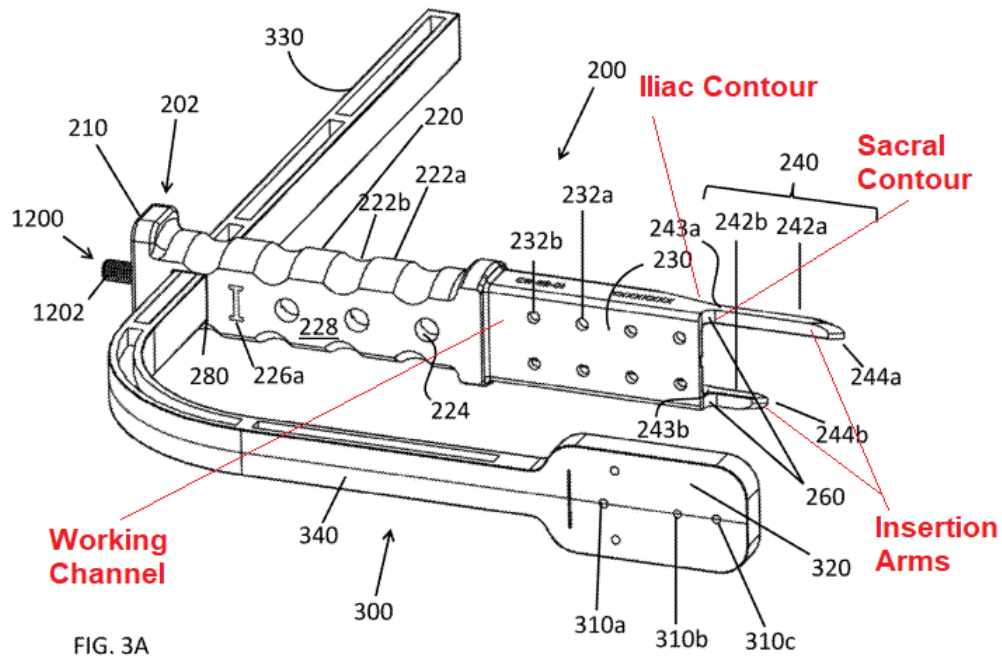
173. Martz discloses a method that utilizes a spinal implant chisel tool used to prepare an intervertebral disc space for implant insertion without the use of a drill. (Ex 1008, ¶¶[0002], [0025], [0093, and [0305]-[0306]).

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

174. 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*

175. 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.



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

176. 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. (*Ibid.*) 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*

177. 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*

178. 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]).

179. 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.

180. As explained above in section X.C..b.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*

181. 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.

182. As explained above in section VIII.C.a.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).

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

183. 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]).

184. 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 VIII.C.b.2.x.

3. Dependent Claim 2

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

185. As explained above in Section VIII.C.a.3, Sharma discloses the limitations of Claim 2.

4. Dependent Claim 9

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

186. 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*

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

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

1. Motivation to combine

188. A POSITA would have found it obvious at the time of the alleged invention of Claims 1, 2, and 9-10 of the '129 Patent to modify the posterior SI Joint approach disclosed by Black in view of the instruments and method disclosed by Donner. Black discloses methods and instruments for a posterior approach for SI Joint fusion, as explained above in section VIII.C.d.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. 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. 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.

189. As explained above in section VIII.C.d.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.

190. As explained above in Section VIII.C.d.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.

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”*

191. As explained in section VIII.C.d.2.i., the combined teachings of Black and Martz meet the limitations of the Preamble of Claim 1.

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

192. As explained above in Section VIII.C.d.2.ii, Black discloses the limitations of Claim 2.

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

193. As explained above in Section VIII.C.d.2.iii, Black discloses the limitations of claim designation 1(b).

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

194. As explained above in Section VIII.C.d.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*

195. As explained above in Section VIII.C.d.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*

196. As explained above in section VIII.C.d.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*

197. As explained above in section VIII.C.d.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.

198. As explained above in section VIII.C.a.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.

199. As explained above in section VIII.C.a.2.ix., Sharma et al. discloses the limitations of claim designation 1(d)(i)(c).

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

200. As explained above in Section VIII.C.d.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.

201. 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]).

202. Martz also discloses the limitations of claim designation 1(e), as explained above in section VIII.C.b.2.x.

3. Dependent Claim 2

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

203. As explained above in Section VIII.C.b.3, Sharma discloses the limitations of Claim 2.

4. Dependent Claim 9

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

204. As explained above in section VIII.C.d.4., Black discloses the limitations of Claim 9.

5. Dependent Claim 10

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

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

IX. RIGHT TO SUPPLEMENT

206. The opinions herein are based upon my research and study to date. I reserve the right to supplement this declaration should additional information or evidence come to light relevant to my opinions provided herein, including any opinions, information, evidence, or other materials submitted by the Patent Owner. I reserve the right to amend my opinions and my declaration upon discovery of any additional information and I reserve the right to make such changes as may be deemed necessary.

X. CONCLUSION

207. For the foregoing reasons, claims 1-2 and 9-10 of the '129 Patent are invalid.

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

I hereby declare under penalty of perjury that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true. I understand that willfully false statements and the like are punishable by fine, imprisonment, or both under 18 U.S.C. §1001.

Executed on February 16, 2023 in Memphis, TN.

By: Troy D. Drewry
Troy D. Drewry

APPENDIX A

OVERVIEW OF PRIOR ART DISCLOSURES

Claim Designation	Ground 1 Compton Donner Otte Sharma	Ground 2 Schifano Compton Martz Sharma	Ground 3 Compton Martz Sharma	Ground 4 Black Martz Sharma	Ground 5 Black Donner Martz Sharma
Independent Claim 1 “Preamble”	Compton or Donner in view of Otte	Schifano, or Compton, in view of Martz	Compton in view of Martz	Black	Black
Limitation 1(a) “locating insertion point”	Compton or Donner	Schifano or Compton	Compton	Black	Black or Donner
Limitation 1(b) “introducing working channel”	Compton	Schifano or Compton	Compton	Black	Black
Limitation 1(c) “inserting arms”	Compton	Schifano or Compton	Compton	Black	Black
Limitation 1(d) “introducing abrading device comprising”	Compton	Schifano or Compton	Compton	Black	Black
Limitation 1(d)(i) “an abrading head”	Compton, Donner, or Otte	Schifano, Compton, or Martz	Compton or Martz	Black or Martz	Black, Donner, or Martz

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

Limitation 1(d)(i)(a) “abrading surfaces”	Compton, Donner, or Otte	Schifano, Compton, or Martz	Compton or Martz	Black or Martz	Black, Donner, or Martz
Limitation 1(d)(i)(b) “an open tip / cutting edge”	Donner or Otte	Martz	Martz	Martz	Donner or Martz
Limitation 1(d)(ii) “a slide hammer / released position / locked position / releasing means”	Sharma	Sharma	Sharma	Sharma	Sharma
Limitation 1(e) “advancing the abrading device”	Compton in view of Donner or Otte	Schifano or Compton, in view of Martz	Compton in view of Martz	Black in view of Martz	Black in view of Donner or Martz
Claim 2 “Preamble”	Sharma	Sharma	Sharma	Sharma	Sharma
Limitation 2(a) “unlocking slide hammer”	Sharma	Sharma	Sharma	Sharma	Sharma
Limitation 2(b) “dislodge abrading head”	Sharma	Sharma	Sharma	Sharma	Sharma
Claim 9 “Preamble”	Compton, Donner, or	Schifano, Compton, or	Compton or Martz	Black or Martz	Black, Donner, or

Declaration of Troy D. Drewry
Petition for Inter Partes Review of U.S. Patent No. 11,020,129

	Otte	Martz			Martz
Limitation 9(a) “forming rectangular shape”	Compton, Donner, or Otte	Schifano, Compton, or Martz	Compton or Martz	Black or Martz	Black, Donner, or Martz
Claim 10 Preamble 10(a)	Sharma, and Compton, Donner, or Otte	Sharma, and Schifano, Compton, or Martz	Sharma, and Compton or Martz	Sharma, and Black or Martz	Sharma, and Black, Donner, or Martz
Limitation 10(b) “unlocking slide hammer”	Sharma, and Compton, Donner, or Otte	Sharma, and Schifano, Compton, or Martz	Sharma, and Compton or Martz	Sharma, and Black or Martz	Sharma, and Black, Donner, or Martz
Limitation 10(c) “dislodge abrading head”	Sharma, and Compton, Donner, or Otte	Sharma, and Schifano, Compton, or Martz	Sharma, and Compton or Martz	Sharma, and Black or Martz	Sharma, and Black, Donner, or Martz

APPENDIX B

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. 11,083,511 (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. <i>How often is low back pain not coming from the back?</i> Spine (Philadelphia, PA 1976). 2009; 34(1): E27–E32.
1011	Cohen, Steven P. <i>Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis, and Treatment</i> . Anesth Analg 2005;101:1440–53.
1012	Falowski, Steven, Sayed, Dawood, Pope, Jason, Patterson, Denis, Fishman, Michael, Gupta, Mayank, Mehta, Pankaj. <i>A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain</i> . Journal of Pain Research 2020:13 3337–3348.
1013	Hamidi-Ravari, Behdad, Tafazoli, Sharwin, Chen, Hamilton, Perret, Danielle. <i>Diagnosis and Current Treatments for Sacroiliac Joint Dysfunction: A Review</i> . 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).

Declaration of Troy D. Drewry

Petition for Inter Partes Review of U.S. Patent No. 11,020,129

	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	Expert CV – Troy D. Drewry
1019	File history of U.S. Provisional Application No. 62/910,913