UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

Patent No. 10,426,539
Issue Date: October 1, 2019
Title: METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION

Inter Partes Review No. IPR2022-00335

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,426,539

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I. INTRODUCTION

PainTEQ, LLC ("PainTEQ" or "Petitioner") requests *Inter Partes* Review ("IPR") of claims 26-28, and 31 of U.S. Patent No. 10,426,539 (Exhibit 1001), assigned to Orthocision, Inc. ("Orthocision" or "Patent Owner").

This petition shows a reasonable likelihood that claims 26-28 and 31 are unpatentable. 35 U.S.C. § 314(a).

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

Litigation: Petitioner brought an action against Patent Owner's allegedly exclusive licensee, Omnia Medical, LLC ("Omnia"). Omnia asserted a counterclaim alleging infringement of U.S. Patent No. 10,426,539 ("539 Patent") in *PainTEQ, LLC v. Omnia Medical, LLC*, Case No. 8:20-cv-02805-VMC-AAS (the "Litigation").

C. Lead And Backup Counsel And Service Information

Lead Counsel	Stephen E. Kelly, Reg. No. 59,973
Backup Counsel	Thomas J. Banks, Reg. No. 77,913

Service Information	Email: Stephen.Kelly@hwhlaw.com Thomas.banks@hwhlaw.com Post and Hand Delivery: HILL WARD HENDERSON, P.A. 101 East Kennedy Boulevard Suite 3700 Tampa, Florida 33602 Tel: (813) 221-3900 Fax: (813) 221-2900

III. PAYMENT OF FEES

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

IV. STANDING

Petitioner certifies that the 539 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the grounds identified herein.

V. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests institution of IPR of claims 26-28 and 31 ("Challenged Claims") of the 539 Patent, and the each of the Challenged Claims be held unpatentable based on the following grounds:

Ground	Claims	Statute	Prior Art
1	26-28, 31	§ 102	McCormack
2	26-27, 31	§ 102	Vestgaarden II
3	26-28, 31	§ 102	Stark II

4	26, 28, 31	§ 103(a)	Stark II and Stoffman
5	26-28, 31	§ 103(a)	Stark II and McCormack
6	26-28, 31	§ 103(a)	Vestgaarden II and McCormack

VI. REQUEST FOR *INTER PARTES* REVIEW OF CLAIMS 26-28 AND 31 OF THE 539 PATENT

A. Overview Of The 539 Patent

The 539 Patent is directed to instruments and methods for fusing a sacroiliac joint ("SI Joint") to repair the joint or to alleviate pain in the pelvis or spine. (Ex. 1001, 1:14-43; 1:2:20-40). The SI Joint is characterized by a relatively planar interface between the articular surfaces of the sacrum bone and an ilium bone in the pelvic area. The 539 Patent discloses various embodiments of a set of instruments for installing a fusion implant into the SI Joint. (*Id*., 2:19-40). The fusion implant facilitates joint fusion by retaining the sacrum and ilium in a fixed relation to promote bone fusion across the SI Joint, thereby repairing the joint by permanently immobilizing it. (*Id*., 2:41-49).

One embodiment of the method of repairing the SI Joint begins by creating an incision in the patient's skin proximal to the patient's sacroiliac joint. (*Id*., 4:13-15). A working channel is inserted "into the [] incision and spread[s] the sacroiliac joint with an inserted end of the [] working channel." (*Id*., 4:15-17). A void is created in the SI Joint, and a fusion implant is inserted into the void in a path that is substantially parallel to the articular surfaces of the SI Joint. (*Id*., 4:18-19, Figs. 71-

93). "[T]he fusion implant ha[s] at least one fixation element for engagement with bone tissue in the articular surfaces of the sacrum and the ilium in the sacroiliac joint. (*Id*., 4:19-22). Once the fusion implant is properly seated in the void, all instruments are removed from the surgical site, and the incision is closed. (*Id*., 5:10-11).

The fixation elements are components of the fusion implant that penetrate the articular surfaces of either the sacrum, the ilium, or both, thereby fixing the position of the fusion implant in the SI Joint. (*See, e.g., id*., 5:23-29). The 539 Patent discloses six embodiments of fixation elements, which are helical anchors, lateral blades, flukes, claws, hooks, and screw structures.

Claws are not clearly described in the 539 Patent. The other five embodiments, and the manner in which they engage the SI Joint articular surfaces, are described in the 539 Patent specification and summarized in Table 1 as follows:

Fixation Element	**Figure Depicting the Embodiment**	**For engagement with bone tissue**	**Engages with said articular surface**
Helical anchors (403, 404)	Figs. 49-54	"Each of the helical anchors 403 and 404 may have a distal cutting edge 405 that may be operable to penetrate bone tissue in joint targeted for fusion." Ex. 1001, 22:11-13, s*ee also, id.* at 22:32-35-41, and 22:52	"[C]utting edges [are placed] in close proximity to the targeted articular surfaces such that they engage and penetrate the articular surfaces immediately upon rotation of the inserter." Ex. 1001, at 22:11-13 & 23:8-10.

Fixation Element	**Figure Depicting the Embodiment**	**For engagement with bone tissue**	**Engages with said articular surface**
		to 23:16.	
Lateral flukes (503, 504)	Figs. 56-57	"Each of the lateral flukes 503 and 504 may have a distal hooking ends 505 that may be operable to penetrate bone tissue in joint targeted for fusion. The distal cutting edges of each of the lateral flukes 503 and 504 may be on opposite sides of the fusion implant 500 such that as the fusion implant is advanced into the SI joint, the lateral fluke 503 engages the ilium and lateral fluke 504 engages the sacrum . . . ." *Id.* at 24:22-39.	"As the fusion implant 500 is rotated, the sacrum and ilium bones may be pulled towards each other and the sacroiliac joint may be compressed and stabilized. Hooking ends 505 may pierce the bone tissue [] of the sacrum and ilium. As shown in FIGS. 56-57, but without limitation, the lateral flukes 503 and 504 may be aligned with the notches 502 for receiving the inserter tool." *Id*. at 25:3-25.
Screw (603, 604)	Figs. 59-61	"[T]he surgical screw 603 and 604 may be self-drilling screws that can penetrate the bone tissue [] of the articular surface." *Id.* at 26:21-22.	"As the surgical screws 603 and 604 are advanced into the bone tissue of the sacrum and ilium, the sacrum and ilium bones may be pulled towards each other and the sacroiliac joint may be compressed and stabilized." *Id.* at 27:1-6.
Lateral	Figs. 63-66	The lateral blades may	"As the fusion implant 700

Fixation Element	**Figure Depicting the Embodiment**	**For engagement with bone tissue**	**Engages with said articular surface**
blades (703, 704)		have an outer edge 705 for engagement with bone tissue of the sacrum and ilium. The outer edge may have varying geometry to facilitate entry into and compression of the sacrum and ilium. *Id*. at 27:60-62. *See also*, *id*. at 27:51 to 28: 10.	is advanced into the SI joint, the lateral blades 703 and 704 are driven into and penetrate the bone tissue of the sacrum and ilium, and the blades 703 and 704 may act to draw in the sacrum and ilium bones and the sacroiliac joint may be compressed and stabilized." *Id.* at 28:46-51.
Flukes (803, 804)	Figs. 68-70	"the hooking edges of the flukes may have a sharp cutting edge which can penetrate the bone tissue . . . . The hooking edges may facilitate penetration of the flukes into the bone tissue [] of the articular surfaces of the ilium and sacrum when the central axle is rotated." *Id*. at 30:22-34; s*ee also*, *id.* at 30:12-37.	"The consistent orientation of all of the flukes allows all of the hooks to engage (hook into) the tissue in the SI joint as the central axle is rotated." *Id*. at 30:17-19.

Table 1

B. Prosecution History

The application for the 539 Patent was filed on March 26, 2015. On April 25, 2017, the USPTO issued a non-final rejection of all claims. (Ex. 1004, at 266).

Claim 32, submitted in a Preliminary Amendment on the filing date, is representative of the pending claims:

> 32. (Original) A method for repairing a sacroiliac joint of a patient, comprising:
>
> a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;
>
> b. inserting a working channel into said incision and spreading said sacroiliac joint with an inserted end of said first working channel;
>
> c. creating a void in said sacroiliac joint; and
>
> d. inserting a fusion implant into said void, said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint.

(*Id*., at 1141). Original claim 49 was substantially similar to claim 32, adding only the limitation of "driving said fusion implant into said void such that said at least one fixation element engages with said bone tissue, and said fusion implant fixes relative positions of said sacrum and said ilium." Notably, neither claim 32 nor claim 49 recited compression of the SI Joint.

Claim 32 was rejected as anticipated by U.S. Patent Application Publication No. 2010/0131011 ("Stark I"). (*Id*., at 271). Stark I teaches a method of posterior

SI Joint fusion to repair the joint by inserting an immobilization element into the plane of the joint. (Ex. 1009, at [0005]-[0012]; Fig. 3). The immobilization element could be one of pins, nails, screws, darts, wedges, shims, and hardening material. (*Id*., abstract).

The office action further rejected original claims 47 (dependent from claim 32) and 67 (dependent from claim 49) over Stark I in view of U.S. Patent Application Publication No. 2012/0271351 ("Vestgaarden I"). Claims 47 and 67 recited a mechanism for inserting the fusion implant into the SI Joint. (Ex. 1004, at 1143, 1146). Vestgaarden I teaches "a novel spinal facet fusion implant for disposition between opposing articular surfaces of a facet joint to immobilize the facet joint and facilitate fusion between the opposing facets." (Ex. 1010, at [0013]). The implant is inserted through a posterior approach, which has been familiar to surgeons for many years. (*Id*., at [0090]). A surgical cannula provides access to the facet joint. (*Id*., at [0103]; Fig. 11). The cannula has arms (or tangs) extending from the distal end, and the arms are inserted into the facet joint to provide an alignment in the plane of the articular surfaces of the facet joint. (*Id*.). This enables in-plane orientation of the other instruments (such as drills and inserters), and the arms maintain distraction of the joint during the insertion process. (*Id*.). Because of this alignment of the cannula, the cavity (or void) in the joint is formed by a drill in an orientation

substantially parallel to the SI Joint. (*Id*., at [0099]). The implant is delivered into the cavity in the same in-plane orientation. (*Id*.).

The office action further rejected original claim 51 (dependent from claim 49) over Stark I in view of U.S. Patent Application Publication No. 2002/0055737 ("Lieberman"). (Ex. 1004, at 278). Claim 51 recited a fixation element comprising a helical anchor. (*Id*.). Lieberman teaches a helical anchor for fusing bone in a patient's spine or pelvis. (Ex. 1011, at [0002] & [0052]-[0053]). Lieberman notes, "[i]t should be understood that the apparatus 10 could be implanted into any vertebral body, including the sacrum." (*Id*., at [0053]).

In response to the office action, on July 25, 2017 the applicant submitted claim amendments, including an amendment to the last paragraph of claim 32 as follows:

> d. inserting a fusion implant into said void, said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint, and said fusion implant compresses the sacroiliac joint.

(Ex. 1004, at 226). Similarly, claim 49 was amended as follows: "driving said fusion implant into said void such that said at least one fixation element engages with said bone tissue, and said fusion implant fixes relative positions of said sacrum and said ilium and compresses the sacroiliac joint." (*Id*., at 229).

The applicant supported patentability of these amendments by arguing that Stark I teaches only distracting immobilization elements that "are not operable to compress the SI joint." (*Id*., at 235-36). The applicant argued that neither Vestgaarden I nor Lieberman teach or suggest an implant with a fixation element that compresses the SI Joint, and therefore the combination of cited references could not make a proper rejection of the claims. (*Id*., at 237-39). Notably, the applicant did not object to either Vestgaarden I or Lieberman as non-analogous art.

Later, in an office action dated November 30, 2018, the examiner issued a claim interpretation notice that the language in claims 32 and 49 reciting "at least one fixation element for engagement with bone tissue" was being interpreted under 35 U.S.C. Section 112(f). (*Id*., at 111-12). The examiner determined, based on the specification, that a "helical anchor or functional equivalents thereof" was the "structure determined to perform the function of fixation and engaging with bone tissue." (*Id*., at 112).

In its April 1, 2019 response, the applicant argued that

> [t]here are several forms of fixation elements disclosed and described in the present application in addition to helical anchors. Such fixation elements include lateral blades, flukes, claws, hooks, and screws (see, e.g., paragraphs 202-228 FIGS. 56-70 of the present application). Clearly, the description of fixation elements for engagement with bone tissue is not limited to helical anchors and equivalents thereof. One of

> ordinary skill in the art would understand that the lateral blades, flukes, claws, hooks, and screws structures shown in FIGS. 56-70 and described in paragraphs [0202]-[0228] will perform the function of engaging with bone tissue.

(*Id*., at 91-92). In a notice of allowance and examiner's amendment dated July 10, 2019, the examiner allowed claim 32 (issued claim 1) and claim 49 (issued claim 12). (*Id*., at 36-37). The examiner specifically explained:

> Regarding the "at least one fixation element for engagement with bone tissue" in claims 32, 49 and now claims 85 and 91, the interpretation of these claims under 35 U.S.C. 112(f) is maintained. However the structure corresponding to the function of fixation and engagement with bone tissue will include those elements disclosed and described in the application as listed by the applicant in the Arguments/Remarks of 4/1/2019.

(*Id*., at 36). Claim 91 issued as claim 26.

C. Summary of Challenged Claims

1. Independent Claim 26.

Claim 26 of the 539 Patent claims a method of installing a single fusion implant from a posterior approach. (Ex. 1001, at 44:24-43). The implant is inserted into the SI Joint along a plane that is substantially parallel to the plane defined by the SI Joint interface. (*Id*.). The fusion implant comprises a fixation element that engages with bone tissue in an articular surface of the ilium or the sacrum. (*Id*.).

The fixation element could be any of the embodiments listed in Table 1 above. Like original claims 32 and 49, issued claim 26 does not recite compression of the SI Joint. (*See* Section VI.B.). Consequently, and as demonstrated below, claim 26 is vulnerable to anticipation and obviousness for the same reasons as those cited by the examiner during examination of original claims 32 and 49.

2. Dependent Claim 27.

The 539 Patent specification describes "driving" as either linear motion or angular motion. For example, linear driving is described as "an impactor or other driving tool may be used to drive the fusion implant 700 into the bone tissue and into position in the SI joint," thus causing the lateral blades 703 and 704 to "penetrate the bone tissue of the sacrum and ilium." (*Id*., at 28:45-51, 57-59). Alternately, angular driving, or rotation, is also described as causing the fixation element to engage the bone tissue:

> the inserter may be subsequently rotated to engage the helical anchors with the bone tissue of the articular surfaces of the sacrum and ilium. For example, and without limitation, a driving tool may be attached to the inserter to aid in rotating the inserter. As the fusion implant is rotated, the sacrum and ilium bones may be pulled towards each other and the sacroiliac joint may be compressed and stabilized.

(*Id.*, at 22:52-59).

3. Dependent Claim 28.

In claim 28, driving the fusion implant comprises either rotation of the implant itself, or rotation of the portion of the implant that comprises the fixation element. For example, in the embodiment of the helical anchor, the entire fusion implant is rotated to drive the tips of the anchor into the articular surfaces of the ilium or sacrum, as described above in relation to claim 27.

In an embodiment shown in Fig. 59 and 60, where the fusion implant comprises screws 604, 605, the fusion implant itself is not rotated inside the SI Joint.

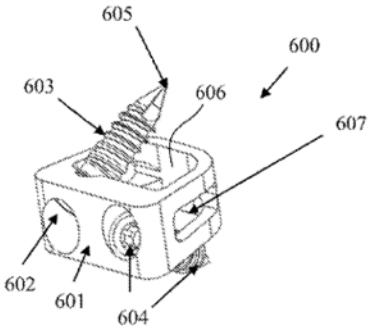


FIG. 59

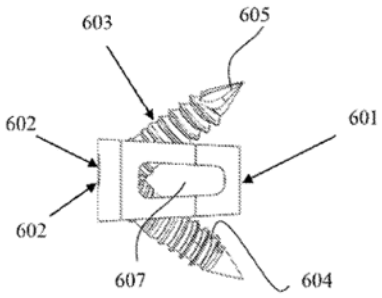


FIG. 60

Instead, the fusion implant has a box-like body that slides into the void created in the SI Joint.

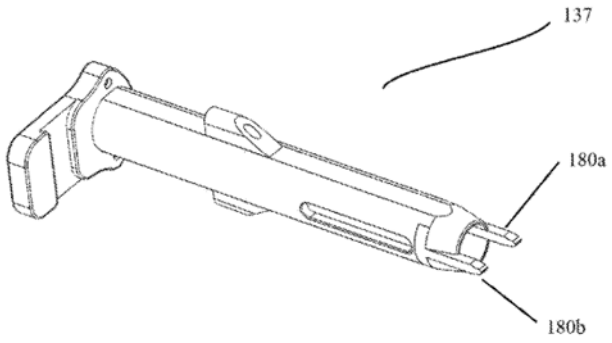
> The body 601 may be designed such that a central plane of the body 601 bisecting the proximal end of the body 601 and bisecting screw holes 602a and 602b may be roughly aligned with the plane of the SI joint between the articular surfaces when the fusion implant is inserted into the SI joint. The box-like geometry of the fusion implant 600 may resist torsional stress applied by movement of the SI joint.

(*Id*., at 25:60-67). The screws 604 and 605 are rotatable separately from the body, and the screws may be self-drilling. (*Id*., at 26:20-36). Thus, rotation of the fixation element itself causes the fixation element to engages with bone tissue in an articular surface of the sacrum or the ilium. (*Id*.).

4. Dependent Claim 31.

Claim 31 adds the limitation that the working channel includes at least one tang protruding from the distal end of the working channel. (*Id*., at 44:60-64). The tangs are depicted as elements 180a and 180b in Fig. 30, as shown below:

FIG. 30



D. Overview of The Prior Art

1. McCormack (Ex. 1012)

McCormack was filed on June 5, 2009 and issued on January 29, 2013. McCormack discloses an instrument set and several embodiments of implants for distracting a spinal facet joint. (Ex. 1012, abstract). Several embodiments of the system result in fusion of the spinal facets, causing permanent immobilization of the

joint. (*Id*., at 25:41-47, 26:2-6, 29:45-50, 31:5-10).

The instrument set includes a delivery device 104 having a tubular shaft 114 (a surgical cannula) that has forks 112 (or tangs) at the distal end for insertion into, and distraction of, the spinal facet joint. (*Id*., at 14:14-18, 22:15-16). Fig. 2 depicts the distal end as follows:

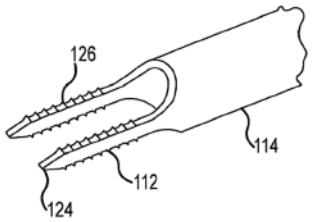


FIG.2

In one embodiment, a chisel (or internal dilator) is inserted into the surgical cannula, and the combined device is inserted through an incision toward the spinal facet joint from a posterior approach. (*Id*., at 21:62-66). The combined forks and chisel blade are inserted into the joint, where the forks distract (or spread) the joint and stabilize the surgical cannula. (*Id*., at 22:15-16).

A decorticator, such as the one depicted in Fig. 4, is then inserted into the cannula and advanced to the joint. (*Id*., at 15:61-67). The decorticator is rotated inside the cannula to decorticate the articular surfaces of the facet joint, as depicted in Fig. 6. (*Id*.).

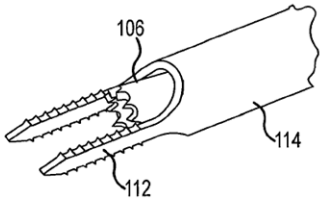


FIG.4

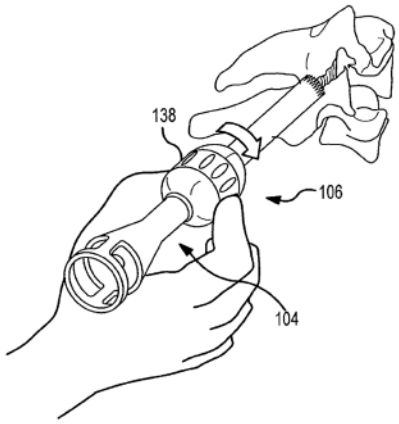
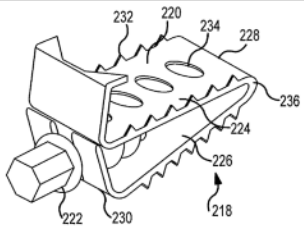
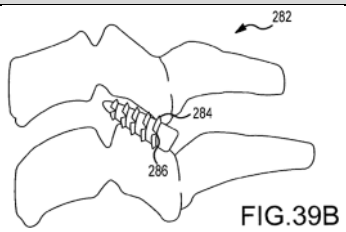
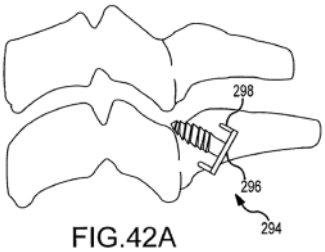
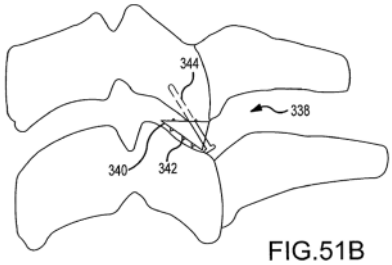
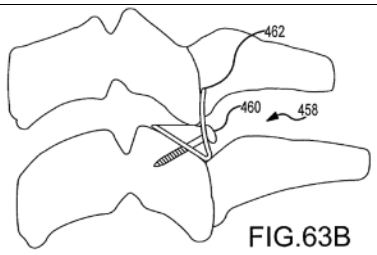
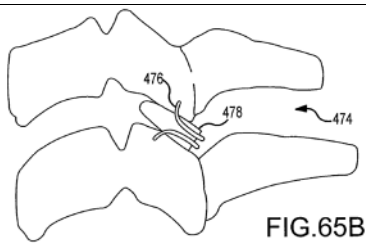


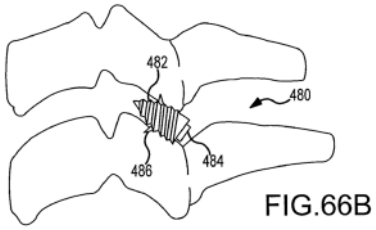
FIG.6

As the decorticator is rotated, its serrated teeth on the decorticator remove cortical bone in the articular surfaces of the spinal facets, thereby creating a void for location of the implant. (*Id*., at 15:48-67). The decorticator is then removed from the cannula, and the implant is advanced into the void in the spinal facet joint by a variety of driver assembly mechanisms. (*Id*., at 22:17-20, 39-45).

McCormack teaches a variety of implants that are suitable for repairing, distracting, and fusing the spinal facet joint. (*Id*., at 22:45-46). Seven examples of these embodiments for analysis of the 539 Patent:

Embodiment Designation	Figures	Representative Depiction
I	30	 FIG.30

Embodiment Designation	Figures	Representative Depiction
II	39A-D	 FIG.39B
III	42A-F (variations shown in Figs. 43A-C, 44A-D, & 45A-D)	 FIG.42A
IV	51A-B	 FIG.51B
V	63A-C	 FIG.63B
VI	65A-	 FIG.65B

Embodiment Designation	Figures	Representative Depiction
VII	66A-C	 FIG.66B

For example, in Embodiment I, shown in Fig. 30, McCormack explains:

> The faces may include teeth 232 and the trailing end 230 of the upper face 224 may be formed to project towards the leading end, both of these features assisting in the implant 218 anchoring to the bone facet surfaces. Holes 234 may exist in the faces 224, 226 such that when the screw 222 is received in the body 220, the thread edges of the screw 222 may project through the holes 234 to bite into the facet surfaces.

(*Id*., at 22:61 – 23:1).

> As the body 220 expands, sharp directional teeth, cleats, or keels 232 on the opposing (superior & inferior) surfaces or faces 224, 226 of the body 220 may become anchored in the cortical bone of the opposing facet surfaces. These teeth, cleats, or keels 232 may engage the facet surfaces and provide acute fixation of the body 220 within the facet joint. The teeth, cleats, or keels 232 may be included on only one surface 224, 226 as opposed to both surfaces 224, 226 so as to allow for a movement of the joint after placement of the implant 218.

(*Id*., at 23:13-22). Exemplary depictions of Embodiment I are as follows:

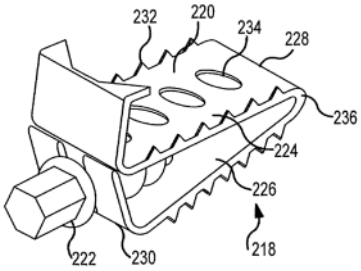


FIG.30

In Embodiment II, the implant (282) is a screw-like structure with threads (284) that penetrate the bone as the implant (282) is inserted into the joint.

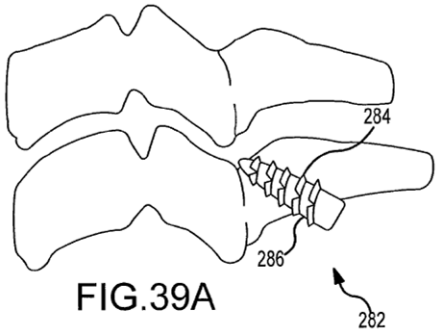


FIG.39A

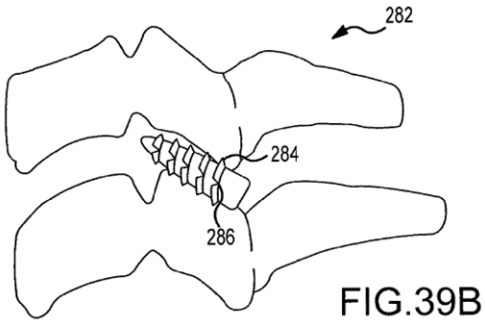


FIG.39B

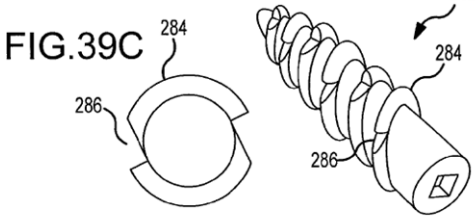


FIG.39C

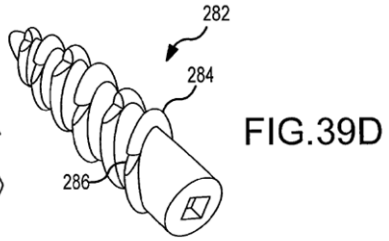


FIG.39D

McCormack describes this embodiment as follows:

> FIGS. 39A-D show another embodiment of an implant 282. In this embodiment, a screw like implant 282 may be inserted between the facet. The insertion of this screw may serve to distract the joint surfaces resulting in a decompression of the nerve root. Additionally, the threads 284 of the screw may include V-shaped notches 286 in the threads 284 spaced throughout the length of the screw creating serrated teeth. As the screw implant 282 is threaded progressively further

> anterior, the serrated teeth may cut/bore into the cortical bone of the opposing facet surfaces. The defect in the bone these serrations produce may prevent the implant 282 from backing out posteriorly or migrating medial/lateral because the threads 284 are configured with the serrated teeth to allow the implant 282 to catch or "bite" in the bone if any posterior withdraw or backing out occurs.

(*Id*., at 25:1-15).

Embodiment III is shown in Figs. 42A-F, with variations shown in Figs. 43A-C, 44A-D, & 45A-D. McCormack describes this embodiment as follows:

> The screw may have a washer or extra broad head 296 with sharp protrusions 298 on the distal surface of the head 296 that engage the superior and inferior lateral mass surfaces as the screw is inserted into the facet joint. The engagement of the sharp protrusions 298 may occur as a result of both the longitudinal translation of the screw together with the rotational motion causing the sharp protrusions 298 to cut into the lateral mass surface as the screw is advanced and rotated. As the washer 296 rotates, the sharp protrusions 298 roughen the lateral masses and create a fracture environment. This fracture environment causes osteoblastic activity that will lead to bone production and assist in fusion of the joint at the lateral mass. Moreover, the moat created by the rotating and cutting protrusions 298 may begin to lock the facet surfaces together.

(*Id*., at 25:33-47. Exemplary depictions of Embodiment III are as follows:

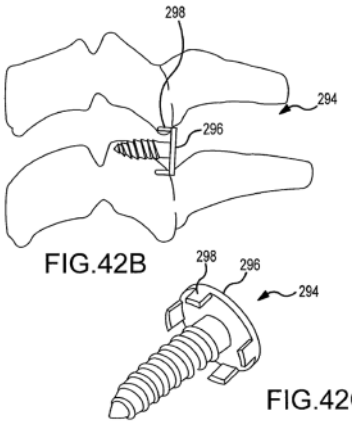


FIG.42B

FIG.42C

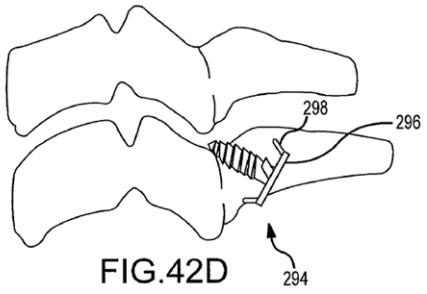


FIG.42D

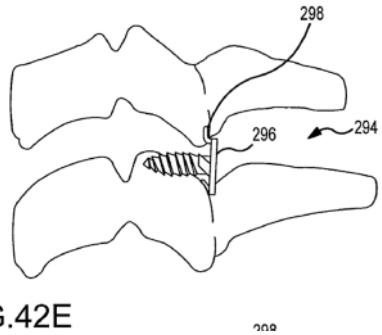


FIG.42E

Embodiment IV is shown in Figs. 51A-B, and McCormack describes it as follow:

> The surfaces of this implant 338 may include teeth, spikes, cleats, surface roughening, and/or keels 342 to help prevent migration or backout. In another configuration of this embodiment, as shown in FIGS. 51A-B, the wedge shaped or triangular implant 338 may be anchored in position by one or two (one shown in FIG.) lateral mass screws/nails 344 that would connect the superior & inferior aspects of the implant 338 to the corresponding superior & inferior lateral masses of the affected segment.

(*Id*., at 27:42-50). Exemplary depictions of Embodiment IV are as follows:

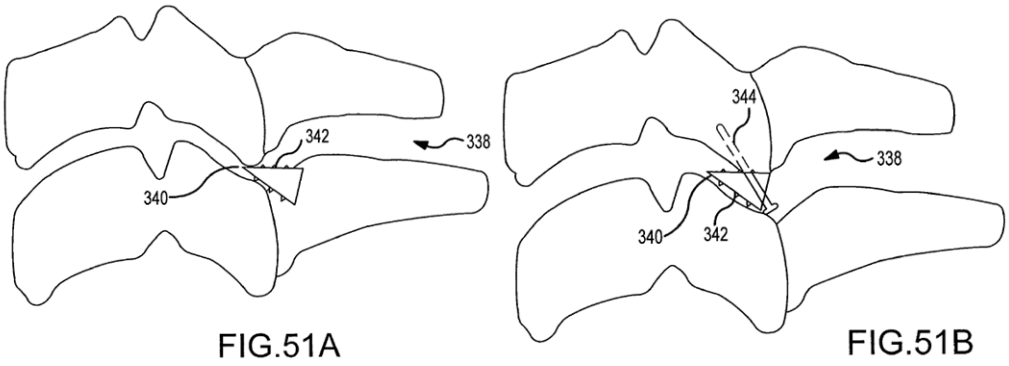


FIG.51A FIG.51B

Embodiment V is depicted in Figs. 63A-C, and McCormack describes this embodiment as follows:

> In this embodiment, a triangular shaped implant 458 including a bent plate and a filler wedge may be inserted in the facet joint. As the triangular implant 458 is inserted progressively more anterior, the joint may be distracted to an optimal level. Once the desired distraction is achieved, an anchoring screw 460 may be inserted through the implant 458 and into the inferior lateral mass. The superior aspect of the implant 458 may include a metal flap 462 with teeth, spikes, or cleats 464. This maleable flap 462 may be contoured to the superior lateral mass and anchored using its teeth, spikes, or cleats 464. The metal flap 462 and inferior screw 460 may provide permanent fixation of the triangular implant 458 to enable permanent distraction of the facet and immobilization of the joint facilitating permanent fusion of the joint.

(*Id*., at 30:63 – 31:10). Exemplary depictions of Embodiment V are as follows:

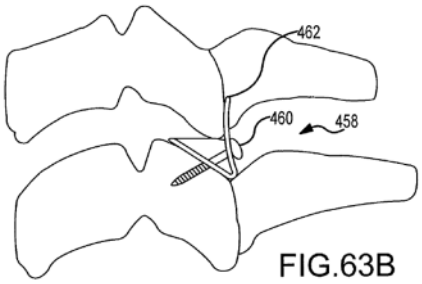


FIG.63B

Exemplary depictions of Embodiment V are as follows:

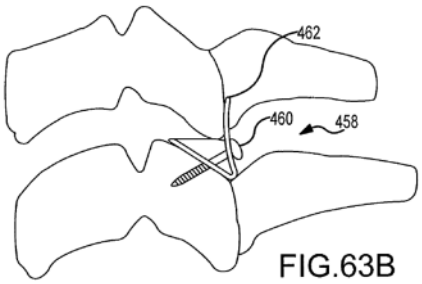


FIG.63B

In Embodiment VI, shown in Figs. 65A-C, the fusion implant comprises nitinol hooks (476), as shown below:

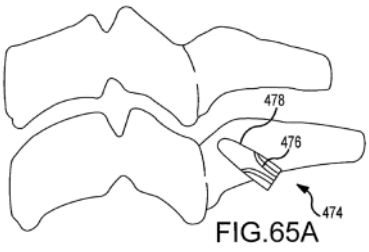


FIG.65A

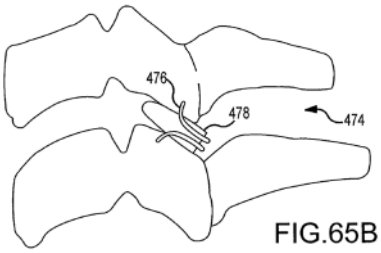
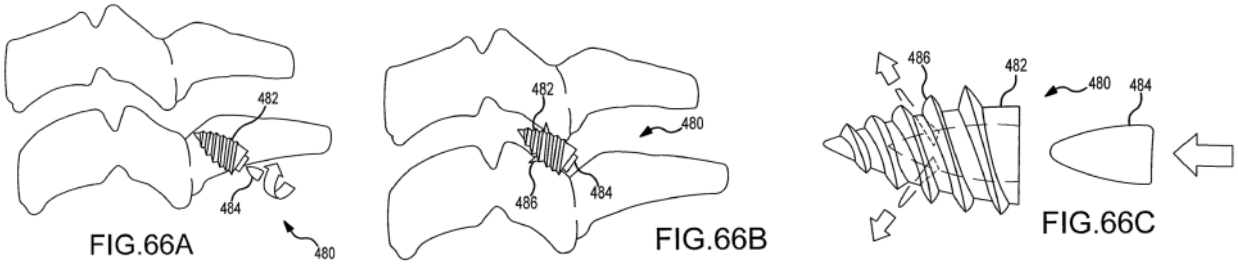


FIG.65B

> The hooks 476 may be flattened and inserted through a delivery system 478. The delivery system 478 may be placed in a facet joint. Once inserted within the facet, the nitinol hooks 476 may be activated via temperature, force, or other activation means causing them to assume their original (pre-flattened) shape and hook into the opposing facet surfaces.

(*Id*. at 31:26-37).

Embodiment VII, shown in Figs. 66A-C, the fusion implant comprises a wedge (484) that actuates barbs (482), as shown below:



> A wedge 484 may then be placed within the hollow screw sleeve 482 causing it to expand and distract the joint. Additionally, the screw sleeve 482 may include sharp barbs 486 having a retracted position and a ejected position. As the wedge 484 is inserted, the wedge 484 displaces the sharp barbs 486 causing them to be ejected through the screw sleeve 482 and engage the facet surfaces. These barbs 486 may provide acute fixation of the implant 480 to the joint and prevent migration of the implant 480.

(*Id*. at 31:37-50).

2. Vestgaarden II (Ex. 1013)

Vestgaarden II was filed on June 5, 2009 and issued on November 11, 2014. Vestgaarden II discloses an instrument set and several embodiments of implants for fusing an SI Joint. (Ex. 1013, abstract, 1:48-52, 2:28-33). Vestgaarden II explains, "[f]usion is a surgical treatment to relieve pain generated from joint dysfunction." (*Id*., at 1:46-47).

The method taught by Vestgaarden II is a posterior approach, which "is familiar to spine surgeons, thereby providing an increased level of comfort for the surgeon." (*Id*., at 4:34-37). A directional surgical cannula having teeth (or tangs) is inserted into the posterior incision until the teeth penetrate the SI Joint, thereby aligning the directional cannula with the plane of the joint. (*Id*., at 2:7-11, 4:38-43, 5:51-56). A drill is used to form a cavity in the SI Joint for receiving the implant, and the implant is driven into the cavity. (*Id*., at 2:12-24, 4:60-65, 6:28-36). All instruments are then removed from the surgical site, and the incision is closed. (*Id*., at 6:37-40).

The implant (5) has two stabilizers (15a, 15b) for stabilizing the implant in the SI Joint, as shown in Figs. 1 and 3B below:

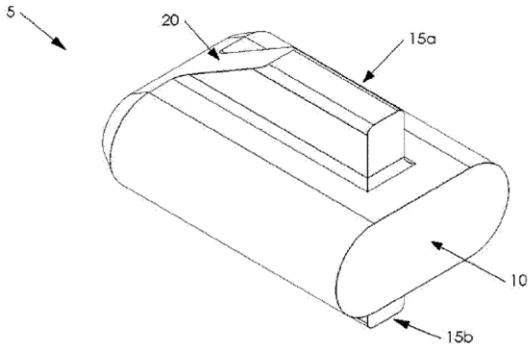


Fig. 1

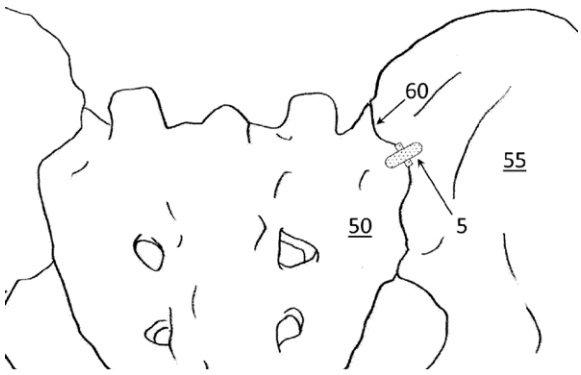
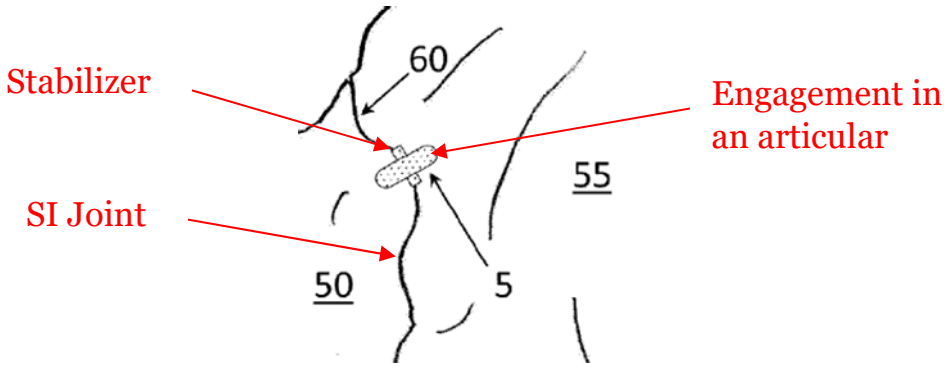
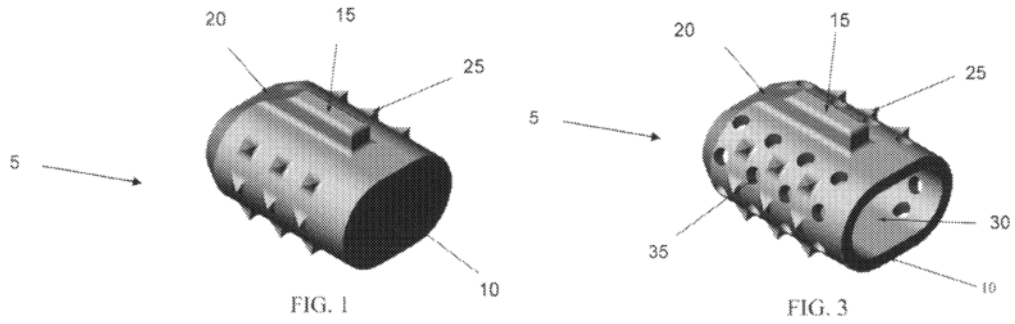


Fig. 3B

An enlargement of Fig. 3B clarifies the orientation of the implant (5) in the SI Joint, as annotated below:



Finally, Vestgaarden II incorporates by reference the spinal facet implants disclosed in U.S. Patent No. 8,162,981 ("Vestgaarden III"). (*Id*., at 4:10-14). Exemplary embodiments of implants taught in Vestgaarden III are depicted as follows:



These embodiments include barbs (25) to resist retraction of the implant (5) from the facet joint. (Ex. 1016, at 4:35-37).

3. Stark II (Ex. 1014)

Stark II was filed on February 27, 2008 and issued on June 3, 2014. Stark II discloses an instrument set and several embodiments of implants for posterior fusion of an SI Joint. (Ex. 1014, abstract, 1:6-8, 4:18-22). In one embodiment, the surgery is performed through a cannula having "projections/tangs that extend from the distal

end of the cannula for insertion into the joint." (*Id*., at 11:8-10). "The tangs can have a projected width in side view from about 3 mm to about 15 mm." (*Id*., at 12:6-7). "A mallet or the like can be used to hammer on the filler to drive the filler and the corresponding cannula(e) into the SI joint." (*Id*., at 13:36-38). Once the cannula is placed, a passageway (or void) is formed in the SI Joint for receiving the implant. (*Id*., at 13:43-45, 13:57-59). One or more implants are then inserted into the passageway to facilitate joint fusion. (*Id*., at 9:27-29). The implants are inserted in a trajectory that is substantially parallel to the plane of the articular surfaces of the SI Joint, as depicted in Fig. 26 of Stark II:

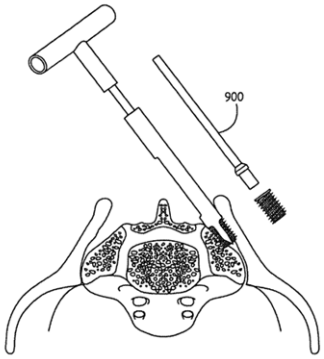


FIG. 26

Stark II describes the implant, or immobilization element, as follows:

> A wide range of immobilization elements is suitable for immobilizing the joint, e.g., SI joint, either alone or in combination. For example, the immobilization element can be a nail, a screw, a dart, a wedge, a shim, a cage, agglomerated inorganic and/or organic material, or the like or combinations thereof. Screws can be effectively used based anchoring the screw within the joint . . . . The threads of the screw grip the bone

> on either side of the joint to further the immobilization of the joint. Thus, screws with sharp and/or pointed threads can be effective. Similarly, a non-uniform thread can improve the gripping while providing for effective implantation of the screw. In some embodiments, a screw can be tapered along the threads by about 2 degrees to about 10 degrees or more to facilitate implantation and/or the gripping function. A self-tapping screw with one or more flutes or the like can be used, such that pre-drilling or tapping may not be used.

(*Id*., at 6:37-56). Stark II discloses that the screw can be tapered. (*Id*., at 16:15-16).

4. Stoffman (Ex. 1015)

Stoffman was filed on January 24, 2013 and issued on September 27, 2016. Stoffman discloses a SI Joint fusion implant having a tapered body and first and second ancillary members (e.g., screws) for securing the device inside the SI Joint. (Ex. 1015, at 5:56 - 6:5). Representative depictions of the fusion implant are shown below:

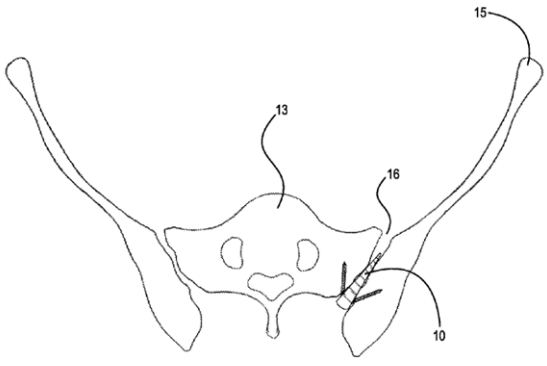


Fig. 2

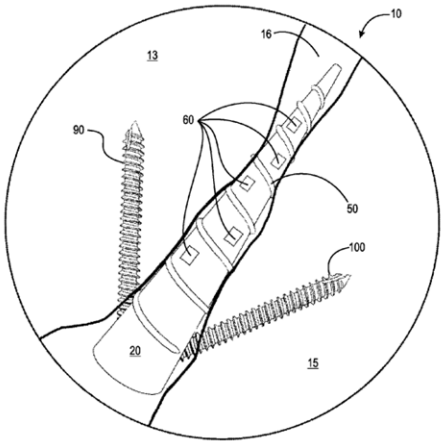


Fig. 4

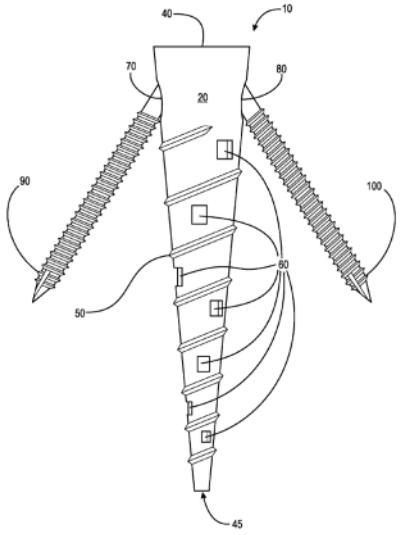


Fig. 5

Figs. 2 and 3 show the fusion device installed in a SI joint, and Fig. 5 shows relevant detail of the device. Stoffman further describes the fusion device as follows:

> SI joint fusion device 10 . . . comprises body 20 and first and second ancillary members 90 and 100, respectively, protruding outwardly from body 20. In the preferred embodiment, body 20 is tapered and frusto-conical . . . . [B]ody 20 could be a non-tapered cone, a cylinder, a tapered cylinder, or a square-based or triangular-based pyramid.

(*Id*., at 6:16-24). "[T]hreading 50 has a helical shape . . . . [I]t should be appreciated, that threading 50 could take any form and need not be continuous. For example, threading 50 could be segmented or threading 50 could comprise a plurality of protrusions." (*Id*., at 6:48-57).

"Alternatively, first and second ancillary members 90 and 100 could have no threading at all and have some other secure means such as, a rod or a pin." (*Id*., at

7:54-56). As shown in Figs. 2 and 4 above, "[f]irst ancillary member 90 is secured within sacrum 13 and second ancillary member 100 is secured within right ilium bone 15." (*Id*., at 6:58-60). "[A] surgeon taps and places ancillary screw members 90 and 100, respectively, into right ilium bone 15 and sacrum 13, respectively." (*Id*., at 9:35-37).

VII. CLAIM CONSTRUCTION

A. Overview.

In the Litigation, the parties have fully briefed claim construction, but the court has not yet set a date for a *Markman* hearing or issued a ruling. The parties have stipulated to plain and ordinary meaning of all claim terms in claim 26, with the exception of three terms. The parties' proposed claim constructions for the three disputed terms is as follows:

U.S. Patent No. 10,426,539 (Claim 26)	**Omnia's Proposed Construction** **("Omnia Claim Construction"**	**PainTEQ's Proposed Construction** **("Petitioner Claim Construction")**
Fixation element	Stabilization part	Helical anchors, lateral blades, flukes, claws, hooks, and screws structures, which fix the position of the fusion implant and provide for compression across the sacroiliac joint

For engagement with bone tissue in an articular surface	Configured to move the fixation element into position so as to come into operation with the bone tissue in the articular surface	Configured for interlocking with bone tissue in the articular surface in a piercing or penetrating manner
Engages with said articular surface	The fixation element comes into operation with the bone tissue in the articular surface	Interlocks with bone tissue in the articular surface

For the Board's convenience, Omnia's claim construction brief is attached as Exhibit 1008, Petitioner's claim construction brief is attached as Exhibit 1009, and Omnia's claim construction reply brief is attached as Exhibit 1010.

For the purposes of this proceeding, Petitioner submits that the Challenged Claims are invalid under either of the parties' proposed claim constructions, as will be demonstrated herein. While Petitioner does not agree with the Omnia Claim Construction, the prior art discussed below anticipates and obviates each of the Challenged Claims under this construction.

The Petitioner's Claim Construction is supported by *Phillips*, the 539 Patent specification, and its prosecution history. *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). To obtain the 539 Patent, the applicant established lexicography of the terms "fixation element" and engagement in an articular surface. (Ex. 1006, at 9-12, 16-17). The applicant argued this construction to the USPTO in

order to obtain the patent. (*Id.* at 12-16, 17-19). The Petitioner Claim Construction properly accounts for this lexicography and disavowal.

B. Means Plus Function (Section 112(f)).

As discussed in Section VI.B. above, in an office action dated November 30, 2018, the examiner interpreted under 35 U.S.C. Section 112(f). (Ex.1004, at 111-12). The Petitioner Claim Construction accounts for the Section 112(f) interpretation under which the 539 Patent was examined. The Omnia Claim Construction does not. Thus, under *Phillips*, the Petitioner Claim Construction is the proper one, even though the Challenged Claims are invalid under either construction, as demonstrated below.

VIII. THE LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") at the time of the alleged invention of 539 Patent would have a Doctor of Medicine or related degree and at least 4 years working experience in joint or spinal fusion. (Ex. 1002, ¶13; Ex. 1003).

IX. PRIORITY DATE OF THE '539 PATENT

The 539 Patent was filed on March 26, 2015 and is a continuation of U.S. Patent No. 10,993,757, which was filed on March 25, 2015 as a continuation-in-part of U.S. Patent No. 9,119,732, filed on March 15, 2013. Because of the new matter added to the 539 Patent, the USPTO properly examined the application under the AIA. (Ex. 1004, at 268).

The Challenged Claims recited "engagement with bone tissue in an articular surface" of the SI Joint. This claim limitation is not supported by the specification filed on March 15, 2013. Therefore, the earliest priority date of the Challenged Claims is March 25, 2015. Regardless, all prior art references relied upon in this Petition predate the 539 Patent's earliest possible priority date of March 15, 2013.

X. GROUNDS FOR UNPATENTABILITY FOR EACH CLAIM

For the purposes of the analysis below, the limitation of the Challenged Claims are referenced as follows:

Ref.	539 Patent – Claim 26
[26 pre]	A method for repairing a sacroiliac joint of a patient, comprising:
[26.a.]	a. creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;
[26.b.1.]	b. inserting a working channel into said incision and
[26.b.2.]	spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;
[26.c.]	c. creating a void in said posterior portion of the sacroiliac joint; and
[26.d.1.]	d. inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint,
[26.d.2.]	said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint,
[26.d.3.]	wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum and

[26.d.4.]	no further implants or fusion devices are introduced into the sacroiliac joint or surrounding tissues.

Ref.	**539 Patent – Claim 27**
[27 pre]	The method of claim 26, further comprising:
[27.a.]	driving said fusion implant into said void with an impactor,
[27.b.]	wherein driving said fusion implant engages said at least one fixation element with said bone tissue.

Ref.	**539 Patent – Claim 28**
[28 pre]	The method of claim 26, wherein driving said fusion implant into said void comprises
[28.a.]	rotating said fusion implant or
[28.b.]	a portion thereof having said at least one fixation element thereon.

Ref.	**539 Patent – Claim 31**
[31 pre]	The method of claim 26 wherein
[31.a.]	said working channel includes at least one tang protruding from a distal end of the working channel
[31.b.]	for securing a position of said working channel in said sacroiliac joint.

The grounds asserted for invalidating the Challenged Claims are as follows:

Ground	**Claims**	**Statute**	**Prior Art**
1	26-28, 31	§ 102	McCormack
2	26-27, 31	§ 102	Vestgaarden II

3	26-28, 31	§ 102	Stark II
4	26, 28, 31	§ 103(a)	Stark II and Stoffman
5	26-28, 31	§ 103(a)	Stark II and McCormack
6	26-28, 31	§ 103(a)	Vestgaarden II and McCormack

Regarding relative strength of these grounds, if the Board adopts the Petitioner Claim Construction, the Grounds 1, 4, and 5 are considered the strongest. Grounds 1 and 5 seek invalidation of all Challenged Claims, and Ground 4 seeking invalidation of only claims 26, 28, and 31. If the preamble of claim 26 is determined to be non-limiting on the claim, then Ground 1 is the strongest because it anticipates claim 26. Petitioner submits that the preamble should be non-limiting, as was determined by the examiner in the initial rejection of original claims 32 and 49 over the spinal facet fusion taught in Vestgaarden I, as discussed above. Indeed, the preamble does not "breathe life" into the claim, and should not be limiting.

By contrast, if the preamble of claim 26 is determined to be limiting on the claim, then Grounds 4 and 5 are the strongest. Finally, if the Board adopts the Omnia Claim Construction, then Grounds 2, 3, and 6 are considered equally strong, and Petitioner respectfully request their consideration by the Board.

A. Anticipation of Claims 26-28 and 31 by McCormack (Ex. 1012)

1. Independent Claim 26

a) [26 pre] A method for repairing a sacroiliac joint of a patient, comprising:

In McCormack, several embodiments of the system result in fusion of the

spinal facets, causing permanent immobilization of the joint. (Ex. 1012, at 25:41-47, 26:2-6, 29:45-50, 31:5-10). For example, the description of Embodiment V explains, "[t]he metal flap 462 and inferior screw 460 may provide permanent fixation of the triangular implant 458 to enable permanent distraction of the facet and immobilization of the joint facilitating permanent fusion of the joint." (Ex. 1012, at 31:7-10).

b) [26.a.] "creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint"

In McCormack, the surgery is posterior: "[i]nitially an incision may be made in the patients back. Tools known in the art may be used to create this incision and to open an access path through the tissues of the back to access the spine." (*Id*., at 21:59-62; Ex. 1002, ¶76).

c) [26.b.1.] "inserting a working channel into said incision"

McCormack explains that, "[o]nce an access path is created, the chisel 108 described above may be inserted into the delivery device 104 and the two of them may be inserted through the incision and the distal tip 130 may be positioned adjacent the target facet joint. (Ex. 1012, at 21:62-66). In this description, the delivery device 104 is the working channel.

d) [26.b.2.] "spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel"

Once the forks (112) are inserted into the SI Joint and before the implant is inserted into the joint, "[t]he forks 112 of the delivery device 104 may be holding the facet joint slightly distracted." (*Id*., at 22:15-16). Thus, the posterior portion of the joint is spread using the inserted end of the working channel.

e) [26.c.] "creating a void in said posterior portion of the sacroiliac joint"

McCormack teaches the use of a decorticator to create a void in the joint for seating the implant. For example, "[t]he decorticator may be used as shown in FIGS. 6B and 6C to rotationally scrape or longitudinally penetrate the lateral mass of a facet joint. A driving member may be used to assist the decorticating process." (*Id*., at 16:19-22). This decortication inherently removes bone tissue from the articular surfaces of the joint, namely, removal of the cortical bone tissue. (Ex. 1002, ¶79). Without removal of cortical bone tissue, the healing, osteoblastic process will not be triggered to cause bone fusion. (*See also*, Ex. 1012, at 25:41-45; Ex. 1009, at [0065]). Thus, the McCormack decortication processes using the decorticators shown in Figs. 4 and 6 of McCormack inherently creates a void for receiving the implant. (Ex. 1002, ¶79).

Notably, the decorticator shown in McCormack Fig. 4 is inserted inside the surgical cannula, and the distal serrated teeth are actuated by rotation (shown in Fig. 6) to decorticate the implant insertion point. (Ex. 1012, at 15:48-66, 16:41-48).

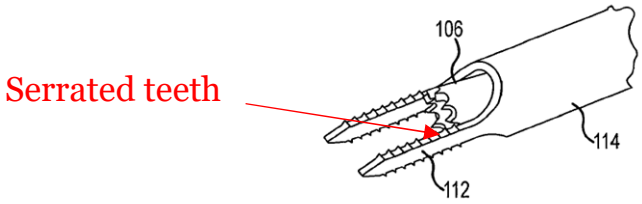


FIG.4

Thus, the serrated teeth in Fig. 4 act as a rotary cutting instrument in a manner equivalent to that of the void-forming drill disclosed in the 539 Patent. (Ex. 1002, ¶80).

f) [26.d.1.] "inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint"

The forks (112) in McCormack align the tubular shaft (114) with the plane of the facet joint. Consequently, "the implant 154, in its flat and parallel position, may slide relatively easily into the facet joint." (Ex. 1012, at 22:16-18). The fusion implant is delivered to the facet joint in a trajectory substantially parallel to the articular surfaces because the delivery device is positioned substantially parallel to the articular surfaces, and the implant is delivered through the delivery device (*Id*., at 47:36-39). A single fusion implant is taught throughout McCormack, such as in Embodiments I – VII.

g) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

McCormack teaches that its method can be performed using any of

Embodiments I – V discussed above. Each of these Embodiments comprises a fixation element that penetrates the articular surfaces of the spinal facets that form the facet joint being repaired, which is discussed in detail above. *See* Section VI.D.1. The McCormack fixation elements include "teeth, cleats, or keels 232 may engage the facet surfaces and provide acute fixation of the body 220 within the facet joint," (Embodiment I), "serrated teeth may cut/bore into the cortical bone of the opposing facet surfaces" (Embodiment II), "sharp protrusions 298 [that] cut into the lateral mass surface as the screw is advanced and rotated" (Embodiment III), screws/nails 344 that penetrate the articular surfaces of the superior & inferior lateral masses of the affected segment (Embodiment IV), and "an anchoring screw 460 [that] may be inserted through the implant 458 and into the inferior lateral mass" (Embodiment V); nitinol hooks that "hook into the opposing facet surfaces" (Embodiment VI); and barbs that engage the facet surfaces (Embodiment VII). (Ex. 1012, at 23:13-22, 25:1-15, 25:33-47, 27:42-50, 30:63 – 31:10, 31:26-37, and 31:37-50). Notably, when Embodiment IV uses two screws (not shown in Fig. 51A), the device provides a structure that is functionally equivalent to the to the fusion implant embodiment shown in Figs. 59 and 60 in the 539 Patent. (Ex. 1002, ¶82). In a two-screw version of Embodiment IV, the screws connect to opposing articular surfaces to compress the joint in a manner equivalent to that of the structure in Figs. 59 and 60 of the 539 Patent. (*Id*.).

h) [26.d.3.] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

McCormack teaches this claim limitation in combination with the teachings of the fixation element embodiments discussed above in relation to *[26.d.2.]*. Section X.A.1.(g).

i) [26.d.4.] "no further implants or fusion devices are introduced into the sacroiliac joint or surrounding tissues"

McCormack teaches use of a single fusion implant for Embodiments I – VII. Once the implant is inserted into the facet joint and secured, "[t]he injector 202 may then be removed. The delivery device 104 may also be removed and the incision closed," thus precluding use of any other fusion implants or fusion devices. (Ex. 1012, at 22:36-38).

2. Dependent Claim 27

a) [27 pre] "The method of claim 26, further comprising"

See analysis of claim 26 above. Section X.A.1.

b) [27.a.] "driving said fusion implant into said void with an impactor"

McCormack explains, "to properly position the driver assembly 142 and the implant 154, some force may be required via a mallet or other member driving member." (Ex. 1012, at 18:25-41). "[T]he proximal end of the driver assembly 142 may be tapped to properly advance and position the implant 154." (*Id*., at 22:16-

20). Thus, McCormack teaches tapping the driver assembly with a mallet or other impactor to properly position the fusion implant. (Ex. 1002, ¶86).

c) [27.b.] "wherein driving said fusion implant engages said at least one fixation element with said bone tissue"

In, McCormack, the fixation elements of Embodiment I anchor the fusion implant to the bone facet surfaces. (Ex. 1012, at 22:61-65). In instances where the facet joint is not sufficiently distracted, the fusion implant (218) is tapped into position in the facet joint. (*Id*., at 22:16-20). This tapping (or driving) necessarily causes the teeth (232) to anchor to the bone facet surfaces. (*Id*., at 22:61-65). (Ex. 1002, ¶87). Thus, McCormack teaches a fusion implant having a fixation element where driving the implant into the joint causes the fixation element to engage with the bone tissue of the articular surface of the facet joint. (*Id*.).

Embodiments II and III discuss how driving the screw-like implants of these embodiments causes their respective fixation elements to engage with bone tissue. For example, Embodiment II is summarized "the threads may be notched along the length of the implant creating serrations for cutting into the articular surfaces of a facet joint." (Ex. 1012, at 3:44-47). More particularly, "[a]s the screw implant 282 is threaded progressively further anterior, the serrated teeth may cut/bore into the cortical bone of the opposing facet surfaces." (*Id*., at 25:8-10). In addition, Embodiment II comprises "sharp protrusions 298 [that] cut into the lateral mass

surface as the screw is advanced and rotated." (*Id*., at 25:36-41). In other words, as these screw-like fusion implants are driven into the joint, their respective fixation elements cut into the articular surfaces of the opposing facets of the joint. (Ex. 1002, ¶88).

Also, in Embodiment VII, the wedge (484) is driven by an axial force to actuate the barbs for penetration into the articular surfaces of the facet joint, as shown below:

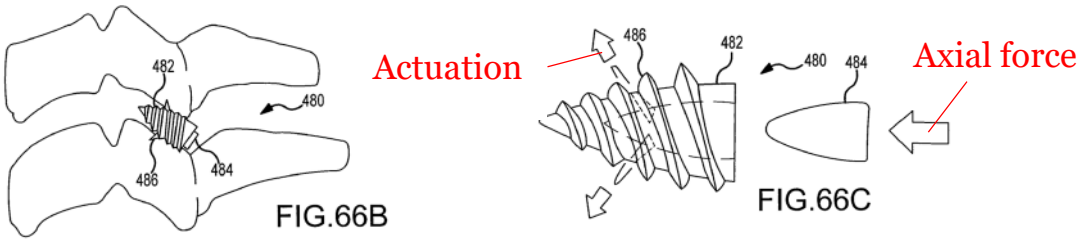


Fig. 66B shows that upon actuation, the barbs (482) penetrate the articular surfaces.

Thus, McCormack teaches a fusion implant having a fixation element where driving the implant into the joint causes the fixation element to engage with the bone tissue of the articular surface of the facet joint. (*Id*., at 90).

3. Dependent Claim 28

a) [28 pre] "The method of claim 26, wherein driving said fusion implant into said void comprises"

As discussed in relation to [27.b.] above, McCormack teaches several embodiments of fusion implants being driven into the void. Section X.A.2.(c).

b) [28.a.] "rotating said fusion implant"

Embodiment II comprises "sharp protrusions 298 [that] cut into the lateral mass surface as the screw is advanced and rotated." (Ex. 1012, at 25:36-41). In other words, as these screw-like fusion implants are driven into the joint, their respective fixation elements cut into the articular surfaces of the opposing facets of the joint. (Ex. 1002, ¶92).

c) [28.b.] "or a portion thereof having said at least one fixation element thereon".

Embodiment I comprises a fusion implant that receives a screw or bolt, which causes the implant to expand as the screw or bolt is threaded into the implant. (Ex. 1012, at 23:9-11). "As the body 220 expands, sharp directional teeth, cleats, or keels 232 on the opposing (superior & inferior) surfaces or faces 224, 226 of the body 220 may become anchored in the cortical bone of the opposing facet surfaces." (*Id*., at 23:13-16). This is also taught in Embodiments IV and V, discussed above, where the fixation element is a threaded screw that is rotatably driven into the articular surfaces. *See* Section VI.D.1.

4. Dependent Claim 31

a) [31.a.] "said working channel includes at least one tang protruding from a distal end of the working channel"

In McCormack, the "working channel" is the delivery device (104). (Ex. 1002, ¶94). "The delivery device 104 may include a receiving assembly 110 at a proximal end, anchoring forks 112 at a distal end, and a generally tubular shaft 114

defining a longitudinal axis and extending between the receiving assembly 110 and the anchoring forks 112." (Ex. 1012, at 14:14-18). The anchoring forks (112) are the "tangs," and they are shown in Fig. 2 below:

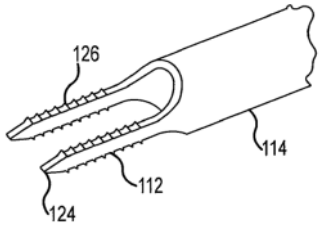


FIG.2

b) [31.b.] "for securing a position of said working channel in said sacroiliac joint"

The purpose of the forks (112) is to anchor the delivery device (104) in the facet joint. (*Id*., at 14:62 – 15:13). In one embodiment, the forks (112) comprise "serrations on the opposing surfaces of the forks 112 [that] aid in anchoring the delivery device 104 in the joint and preventing dislodgement." (*Id*., at 15:9-12, 16:36-40).

B. Anticipation of Claims 26, 27, and 31 by Vestgaarden II (Ex. 1013)

1. Independent Claim 26

a) [26 pre] A method for repairing a sacroiliac joint of a patient, comprising:

As Vestgaarden II explains, "[t]his invention relates to surgical methods and apparatus in general, and more particularly to surgical methods and apparatus for fusing sacroiliac joints. (Ex. 1013, at 1:6-9). More specifically, "it is a general

objective of this invention to provide a method to deliver a device for correcting symptomatic sacroiliac joint dysfunction or instability, for enhancing stability for purposes of immobilizing a joint, and for fusing two opposed bone structures across the joint." (*Id*., at 1:48-52). Thus, Vestgaarden II teaches methods of repairing an SI Joint.

b) [26.a.] "creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;"

In Vestgaarden II, "[s]tabilization implant 5 is inserted into a sacroiliac joint using a posterior approach. The posterior approach is familiar to spine surgeons, thereby providing an increased level of comfort for the surgeon." (*Id*., at 4:34-37). To being the procedure, "[a] path through soft tissue to the sacroiliac joint is then created via surgeon's preference, such as open, minimally-invasive, percutaneous, or arthroscopic." (*Id*., at 5:23-26). These procedures necessarily involve creating an incision in the patient's skin in a position proximal to the patient's SI Joint, thereby enabling access to the posterior portion of the SI Joint. (Ex. 1002, ¶97).

c) [26.b.1.] "inserting a working channel into said incision and"

In Vestgaarden II, the working channel is called a "directional cannula (130)." Vestgaarden II, explains, "[a] set of dilation tubes 110-113 (FIG. 13) having increasing diameters is then inserted into the soft tissue opening in sequence of increasing diameters to sufficiently retract the soft tissue exposing a graft site. (Ex.

1013, at 5:27-30). "Next, directional cannula 130 is inserted into the lumen of dilation tube 113 until a distal end of cannula 130 engages sacroiliac joint 60 (FIG. 17)." (*Id*., at 5:49-51). Thus, the directional cannula (130) is inserted into the incision by way of the dilation tube (113).

d) [26.b.2.] "spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;"

Once the directional cannula (130) is inserted into the incision, as referenced in relation to [26.b.1.] above, "[d]irectional cannula teeth 131 are then aligned with plane 40 of sacroiliac joint 60. Once teeth 131 of cannula 130 are aligned with plane 40, directional cannula 130 is lightly tapped to insert cannula teeth 131 into sacroiliac joint 60 until positive stop 132 engages sacroiliac joint 60 (FIG. 17A)." (*Id*., at 5:51-56). The teeth (131) are tapped into the SI Joint because they are too wide to slide into the joint without the application of axial force. (Ex. 1002, ¶99). Moreover, the teeth have to be wide enough so that when they are driven into the SI Joint, the compressive force of the sacrum and ilium on the teeth is enough to "secure the alignment teeth into the sacroiliac joint." (Ex. 1013, at 2:7-11). Therefore, tapping the directional cannula (130) to force the teeth (131) into the joint causes distraction, or spreading, of the SI Joint. (Ex. 1002, ¶99). Consequently, Vestgaarden II inherently discloses spreading the posterior portion of the SI Joint with an insertion end of the working channel. (*Id*.).

e) [26.c.] "creating a void in said posterior portion of the sacroiliac joint"

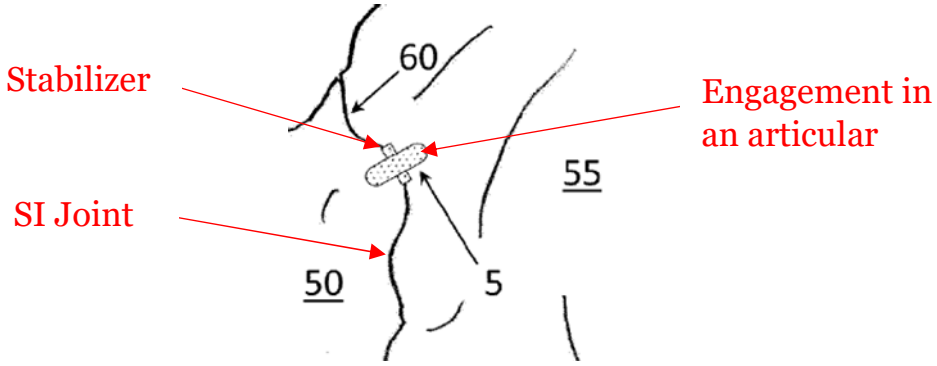
Vestgaarden II describes using a drill to create a fusion implant cavity in both the sacrum and the ilium. (Ex. 1013, at 5:57 to 6:27).

f) [26.d.1.] "inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint"

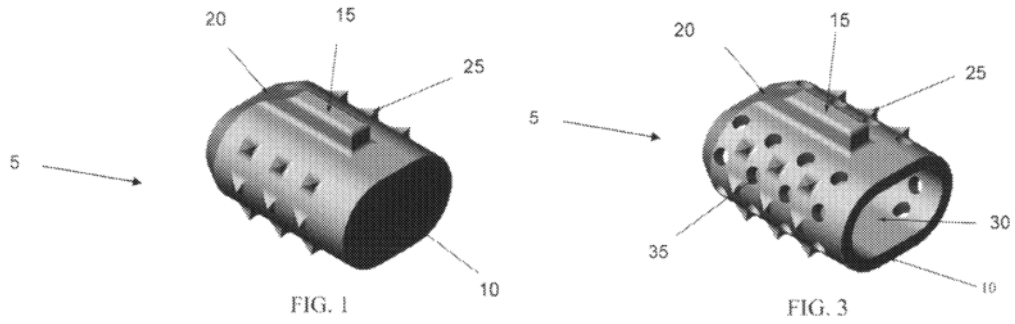
When the directional cannula (130) is inserted into the SI Joint as described above, the teeth are aligned with the plane of the SI Joint, thereby aligning the directional cannula with the same plane. (*Id*., at 2:7-11). After the drill is used to form the cavity in the SI Joint for receiving the implant, the implant passed through the directional cannula (130) and driven into the cavity along the plane of the SI Joint. (Ex. 1013, at 2:12-24, 4:60-65, 6:28-36).

g) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

The implant in Vestgaarden II is oriented so that the implant protrudes into the sacrum and into the ilium, thus providing engagement in an articular surface as shown below:



Notably, Vestgaarden II incorporates by reference the spinal facet implants disclosed in U.S. Patent No. 8,162,981 ("Vestgaarden III"). (*Id*., at 4:10-14). Exemplary embodiments of implants taught in Vestgaarden III are depicted as follows:



These embodiments include barbs (25) to resist retraction of the implant (5) from the facet joint. (Ex. 1016, at 4:35-37). Because of the orientation of the implant in the cavity, the barbs (25) are placed in direct contact with the walls of the cavity in the bone tissue exposed by formation of the cavity. Therefore, these barbs (25) are further fixation elements that engage the bone tissue in an articular surface of the sacrum and in the ilium.

h) [26.d.3.] "wherein said at least one fixation element

engages with said articular surface of at least one of said ilium and said sacrum"

See discussion for [26.d.2.] above.

i) [26.d.4.] "and no further implants or fusion devices are introduced into the sacroiliac joint or surrounding tissues"

Vestgaarden II teaches insertion of a single implant. For example, at the end of the surgical method, "implant positioner 160 and directional cannula 130 are removed from the lumen of dilation tube 113. Dilation tube 113 is then removed from the soft tissue and the incision is closed," with no other implants or fusion devices introduced into the SI Joint or surrounding tissue. (Ex. 1013, at 6:37-40).

2. Dependent Claim 27

a) [27.a.] "driving said fusion implant into said void with an impactor"

"[I]mplant positioner 160 is lightly tapped to drive implant 5 into cavity 45 created laterally across sacroiliac joint 60 (FIG. 23)." (*Id*., at 33-35).

b) [27.b.] "wherein driving said fusion implant engages said at least one fixation element with said bone tissue"

Driving the implant, as described above in Section X.B.2. for [27.a.], engages barbs (25) in the bone tissue exposed by formation of the cavity in the sacrum and in the ilium, as described above in Section X.B.1.(g) for [26.d.2.].

3. Dependent Claim 31

a) [31.a.] "said working channel includes at least one tang protruding from a distal end of the working channel"

The directional cannula (130) comprises teeth (131) at the distal end of the directional cannula(130), as shown in Fig. 8 below:

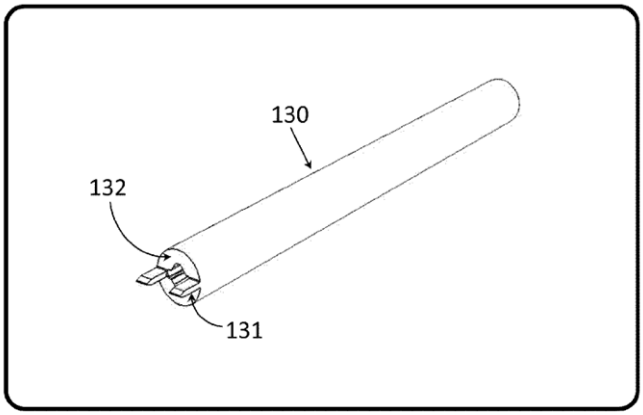


FIG. 8

b) [31.b.] "for securing a position of said working channel in said sacroiliac joint".

As discussed above in Section X.B.1.(d) for [26.b.2.], Vestgaarden describes orienting the directional cannula with the plane of the SI Joint by "secur[ing] the alignment teeth into the sacroiliac joint." (*Id*., at 2:7-11).

C. Anticipation of Claims 26-28 and 31 by Stark II

1. Independent Claim 26

a) [26 pre] A method for repairing a sacroiliac joint of a patient, comprising:

In Stark II, "[t]he invention relates to less invasive approaches for the immobilization or fusion of joints, such as the sacroiliac joint, and apparatuses for facilitating the procedures." (Ex. 1014, at 1:6-8). A POSITA would understand this to mean a method for repairing an SI Joint of a patient.

b) [26.a.] "creating an incision in the patient's skin in a

position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;"

Stark II expressly discloses a posterior incision: "The opening of the sacroiliac joint can be approached through an incision in the patient's back to provide an approach with less risk of damaging nerves and blood vessels passing from the torso to the lower extremities." (*Id*., at 4:18-22). Further "a plurality of tools that can be delivered into the joint through a small incision." (*Id*. at 4:59-60).

c) [26.b.1.] "inserting a working channel into said incision and"

In Stark II, the working channel is identified as an inner cannula (320). This and other instruments are delivered into the SI Joint through the posterior incision. (*Id*., at 4:57 to 5:5).

d) [26.b.2.] "spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;"

Stark II teaches the use of an inner cannula (320) having a body portion (322) and tangs (324) projecting from the distal end, as shown in Figs. 9 and 10 below:

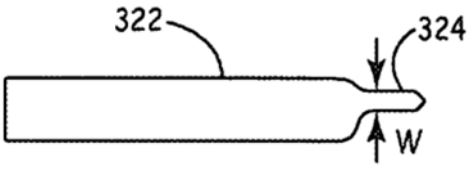


FIG. 9

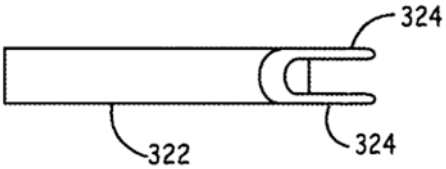


FIG. 10

Stark II explains, "cannulae can comprise projections/tangs that extend from the distal end of the cannula for insertion into the joint." (*Id*., at 11:8-10).

> The tangs can have a projected width in a side view from about 3 mm to about 15 mm, and in further embodiments from about 5 mm to about 10 mm. The projected width corresponds approximately with the spacing of the SI joint at the tang once the tang is inserted in the joint. The width "w" is marked in FIG. 9.

(*Id*., at 12:6-7). These teachings inherently disclose that the tangs at the distal end of the inner cannula spread the SI Joint because the average width of an SI Joint is approximately 3 mm in adults. (*See, e.g*., Ex. 1018, at 210 (stating that in 400 subjects tested, the average SI Joint width was 2.49±0.66 mm in subjects under 40 years of age and 1.47±0.21 mm in subjects over 40 years of age)). Therefore, insertion into the SI Joint of tangs having a width of greater than about 3 mm (such as 5mm, 10mm, or 15mm) necessarily spreads the SI Joint, which is inherently disclosed in Stark II. (Ex. 1002, ¶115).

This SI Joint distraction is reinforced in Stark II, which describes the force necessary to drive such wide tangs into the relatively narrow SI Joint. Stark II describes that the cannula must be impacted with such great force that the tangs could bend instead of being inserted into the SI Joint. (Ex. 1014, at 13:26-28). To avoid possible bending, Stark II teaches that a filler be inserted into the cannula to provide lateral support to the tangs before the tangs are hammered into the SI Joint.

(*Id*., at 13:26-28, 13:36-38, 18:60-62). Forcibly hammering relatively wide tangs into a relatively narrow SI Joint – with enough force to bend the metal tangs – necessarily distracts and spreads the SI Joint. (Ex. 1002, ¶116). Therefore, Stark II teaches spreading the posterior portion of the SI Joint with an inserted end of the working channel.

e) [26.c.] "creating a void in said posterior portion of the sacroiliac joint"

The instrument set in Stark II includes a cutting component. "[T]he cutting component can open up a hole or passageway for insertion of an implant and/or implantation material." (Ex. 1014, at 13:43-45). "For performing procedures within a cannula, a drill bit generally is used to cut away the bone to create a passageway for the cannula and/or implant." (*Id*., at 13:57-59). "The drilling procedure prepares a hole or otherwise decorticates the bone around the joint as a site for placement of immobilization elements." (*Id*., at 19:26-28). The passageway, or hole, is the void.

f) [26.d.1.] "inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint"

Stark II teaches that "[a] single or a plurality of alignment components can be used in a procedure to provide a single or plurality of implants within the SI joint." (*Id*., at 9:27-29). The single implant is inserted into the passageway created by the drill, and the insertion is along a path that is substantially parallel to the articular

surfaces of the SI Joint. (*Id*., at 13:15-18; Figs. 21-26). This is depicted in exemplary Fig. 26 below:

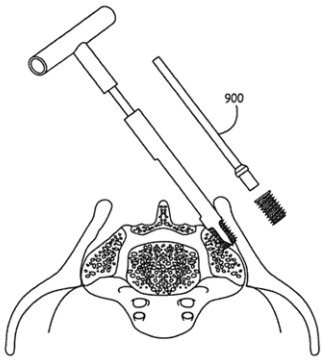


FIG. 26

g) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

Under the Omnia Claim Construction, "fixation element" is construed broadly enough to include threads on a screw that grip the articular surfaces of the sacrum and ilium inside the SI Joint. Stark II anticipates the fixation element under this construction. (Ex. 1002, ¶119). For example, "[s]crews can be effectively used based anchoring the screw within the joint. Suitable screws can be solid, cannulated or hollow . . . ." (Ex. 1014, at 6:42-44). "The threads of the screw grip the bone on either side of the joint to further the immobilization of the joint." (*Id*., at 6:46-49). Further, "[a]n improved implant for the sacroiliac joint is a tapered screw." (*Id*., at 16:15-16).

Under the Petitioner Claim Construction, Stark II does not expressly teach a fixation element that penetrates the articular surfaces in a manner that is capable of compressing the SI Joint. (Ex. 1002, ¶120).

h) [26.d.3.] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

Again, under the Omnia Claim Construction, Stark II explains that "[t]he threads of the screw grip the bone on either side of the joint to further the immobilization of the joint." (Ex. 1014, at 6:46-49). Thus, Stark II expressly teaches a gripping engagement of the articular surfaces of the sacrum and ilium inside the SI Joint.

i) [26.d.4.] "and no further implants or fusion devices are introduced into the sacroiliac joint or surrounding tissues"

Stark II expressly teaches that its method of fusing the SI Joint can be performed with a single implant. "A single or a plurality of alignment components can be used in a procedure to provide a single or plurality of implants within the SI joint." (*Id*., at 9:27-29). Thus, Stark II expressly teaches an embodiment that uses a single implant with no other implants or fusion devices introduced into the SI Joint.

2. Dependent Claim 27

a) [27.a.] "driving said fusion implant into said void with an impactor"

Stark II discloses that embodiments of the implant can be a nail, a wedge, a shim, a cage, or other similar structures. (*Id*., at 37-42). Each of these are not threaded members, and they would therefore have to be driven into the SI Joint void using an impactor. (Ex. 1002, ¶123).

b) [27.b.] "wherein driving said fusion implant engages said at least one fixation element with said bone tissue"

Under the Omnia Claim Construction, the driving of the implant causes the fixation element in Stark II to come into operation with the articular surfaces of the SI Joint. (*Id*., ¶124). For example, the wedges, shims, and cages distract the SI Joint as these fusion elements are driven deeper into the joint. The distraction is caused by these implants contacting, or coming into operation with, the articular surfaces of the SI Joint. (*Id*.).

3. Dependent Claim 28

a) [28 pre] "The method of claim 26, wherein driving said fusion implant into said void comprises"

Stark II teaches a variety of screws to be used as the fusion implant. These screws are inserted into the passageway or hole in the SI Joint created by the drill, as explained in reference to [26.d.1.] above.

b) [28.a.] "rotating said fusion implant"

Stark II incorporates by reference U.S. Patent Application No. 11/879,536 ("Stark III"). (Ex. 1014, at 4:8-11; Ex. 1017). Stark III teaches an embodiment of an implant shown in Fig. 1 below:

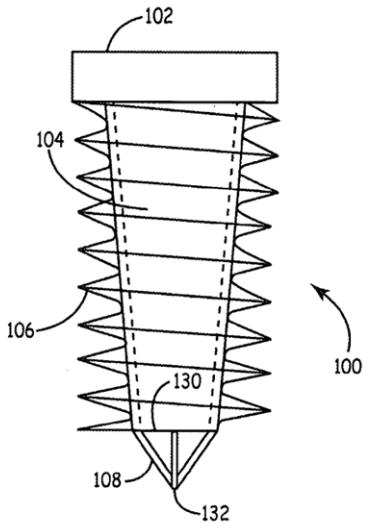


FIG. 1

Alternate embodiments are shown in Figs. 6-10. (Ex. 1017). Stark III explains, "[i]n order for the screw to grip more tightly as the screw advances, it can be desirable for the displacement of the screw to increase as the screw is driven into the bone/joint." (*Id*., at [0033]). This embodiment inherently requires rotation of the implant to drive the implant, and the driving action causes the threads of the implant to penetrate the bone in the articular surfaces of the SI Joint. (Ex. 1002, ¶126).

c) [28.b.] "or a portion thereof having said at least one fixation element thereon".

This aspect of claim 28 is not expressly disclosed in Stark II.

4. Dependent Claim 31

a) [31.a.] "said working channel includes at least one tang protruding from a distal end of the working channel"

See above analysis of [26.b.2.]. Section X.C.1.(d).

b) [31.b.] "for securing a position of said working channel in said sacroiliac joint".

See above analysis of [26.b.2.]. Section X.C.1.(d). After the tangs are hammered into the SI Joint, the compressive force that the SI Joint exerts on the tangs secures the position of the inner cannula (working channel). Thus, Stark II inherently discloses using the tangs for securing a position of the working channel in the SI Joint. (Ex. 1002, ¶129).

D. Obviousness of Claims 26, 28, and 31 Over Stark II in view of Stoffman

1. Motivation to combine Stark II and Stoffman

A POSITA would have found it obvious at the time of the alleged invention of the Challenged Claims to combine the implant of Stoffman with the system of Stark II to reach the same result as that of the Challenged Claims. (Ex. 1002, ¶130). Stark II explains that "[t]he threads of the screw grip the bone on either side of the joint to further the immobilization of the joint. Thus, screws with sharp and/or pointed threads can be effective." (Ex. 1014, at 6:46-49). "In some embodiments, a screw can be tapered along the threads by about 2 degrees to about 10 degrees or more to facilitate implantation and/or the gripping function." (*Id*., at 6:51-54). Accordingly, Stark II teaches that a tapered, threaded implant is advantageous for

gripping the articular bone surfaces inside the SI Joint. Thus, a POSITA would be motivated to combine Stoffman with Stark II because Stoffman teaches a fusion implant having a tapered, threaded body. (Ex. 1015, at 6:36-43; Ex. 1002, ¶130).

Both Stark II and Stoffman describe the importance of securing the fusion implant inside the SI Joint to promote distraction and fusion. Stoffman improves on Stark II by adding fixation elements (the ancillary members (90, 100)) to further secure the fusion implant in the SI Joint. (Ex. 1015, at 6:58-60, 9:35-43). A POSITA would be motivated to make this combination to achieve the improved result delivered by the combination of Stark II and Stoffman. (Ex. 1002, ¶131).

The combination of incorporating Stoffman into Stark II would have been well within a POSITA's ability at the time of the alleged invention of the challenged claims. (*Id*., at ¶132). Indeed, threaded fusion implants were well known in the art at the time of the alleged 539 Patent invention. (Ex. 1009, Ex. 1012, Ex. 1014, Ex. 1015). The combination of Stoffman and Stark would have led a POSITA to a predictable result, namely, better securement of the fusion implant inside the SI Joint. (*Id*., at ¶132). Finally, adding Stoffman to Stark II would have been an obvious design choice since Stoffman teaches to do so because the surgical procedure described at a high level in Stoffman is consistent with the more detailed approached described in Stark II. (Ex 1015, at 9:17-31; Ex. 1002, ¶132). A POSITA would have therefore had the design choice to use the additional fixation elements

(ancillary members) of Stoffman to further secure the fusion implant in Stark II. (Ex. 1002, at ¶132).

2. Independent Claim 26

As discussed above regarding anticipation by Stark II, all aspects of claim 26 are disclosed by Stark II with the exception of a fixation element as interpreted under the Petitioner Claim Construction. Thus, see above Section X.C.1. for a discussion of Stark II disclosures of [26 pre], [26.a.], [26.b.1.], [26.b.2.], [26.c.], [26.d.1.], and [26.d.4.].

a) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

Under the Petitioner Claim Construction, Stark II does not expressly disclose a fixation element that provides for engagement of bone tissue in the articular surfaces in the SI Joint. Stoffman discloses an SI Joint fusion device having a tapered body and first and second ancillary members (e.g., screws) for securing the device in the SI Joint. (Ex. 1015, at 5:56 - 6:5). Representative depictions of the device are shown below:

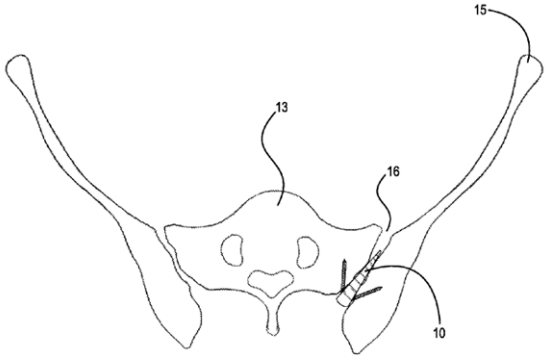


Fig. 2

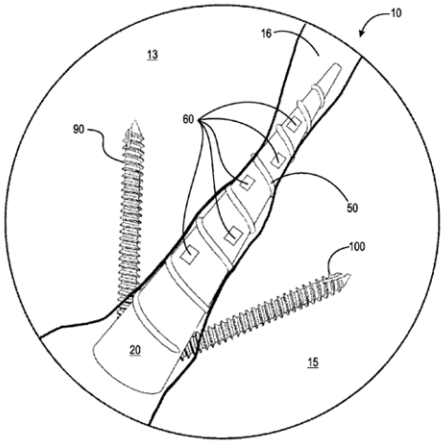


Fig. 4

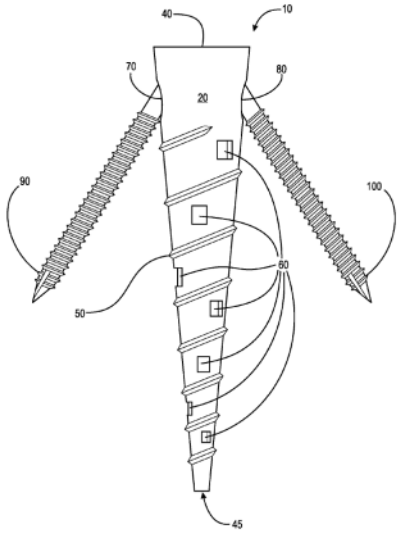


Fig. 5

Fig. 2 shows the Stoffman devices situated in the SI Joint where the ancillary members (90, 100) (fixation elements) are engaged in the articular surfaces of the sacrum and the ilium, with an enlarged view shown in Fig. 4. Further driving of the ancillary members continues to draw the sacrum and ilium together. Consequently, this configuration provides a compression across the SI Joint that is equivalent to the compression provided by the fusion element embodiment depicted in Figs. 59 and

60 of the 539 Patent. (Ex. 1002, ¶135). Therefore, at the time of the alleged invention of claim 26, it would have been obvious to a POSITA to provide a fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint. (*Id*.).

b) [26.d.3.] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

See discussion of [26.d.2.] above. Section X.C.1.(g).

3. Dependent Claim 28

As discussed above, Stark II discloses [28 pre] and [28.a.]. Since the combination of Stark II and Stoffman obviates claim 26 as discussed above, claim 28 is also obviated by the same combination of references.

a) [28.b.] "or a portion thereof having said at least one fixation element thereon"

To the extent that Stark II does not teach [28.a.], Stoffman teaches rotating the portion of the fusion implant having at least one fixation element thereon. Specifically, Stoffman teaches driving ancillary members (90, 100) into the sacrum and ilium. (Ex. 1015, at 7:36-54). In one embodiment, "[f]irst and second ancillary members 90 and 100 are typical screws such as, preferably, a Phillips oval head." (*Id*.). A POSITA would understand that a typical screw is rotated to drivingly engage the intended substrate, in this case, the bone tissue of the sacrum or the ilium. (Ex. 1002, ¶138).

4. Dependent Claim 31

As discussed above, Stark II discloses [31 pre], [31.a.], and [31.b.]. Section X.C.4. Since the combination of Stark II and Stoffman obviates claim 26 as discussed above, claim 31 is also obviated by the same combination of references.

E. Obviousness of Claims 26-28 and 30 over Stark in view of McCormack

1. Motivation to Combine Stark II and McCormack

A POSITA would have found it obvious at the time of the alleged invention of the Challenged Claims to combine McCormack with the system of Stark II to reach the same result as that of the Challenged Claims. (Ex. 1002, ¶140). Stark II teaches a tapered body having surface texture to prevent migration of the fusion implant. Stark II explains that "[t]he threads of the screw grip the bone on either side of the joint to further the immobilization of the joint. Thus, screws with sharp and/or pointed threads can be effective" for gripping the articular surfaces of the SI Joint. (Ex. 1014, at 6:46-49). "In some embodiments, a screw can be tapered along the threads by about 2 degrees to about 10 degrees or more to facilitate implantation and/or the gripping function." (*Id*., at 6:51-54). Accordingly, Stark II teaches that a tapered, threaded implant is advantageous for gripping the articular bone surfaces inside the SI Joint. (Ex. 1002, ¶140). Thus, a POSITA would be motivated to combine McCormack with Stark II because McCormack teaches a fusion implant

having a tapered body surface features for preventing migration. (Ex. 1012, at 27:42-44; Ex. 1002, ¶140). Specifically, "[t]he surfaces of this implant 338 may include teeth, spikes, cleats, surface roughening, and/or keels 342 to help prevent migration or backout." (Ex. 1012, at 27:42-44).

Both Stark II and McCormack describe the importance of securing the fusion implant inside the SI Joint to promote distraction and fusion. McCormack improves on Stark II by adding a variety of fixation elements to further secure the fusion implant in the SI Joint. (*Id*., at 23:13-22, 25:1-15, 25:33-47, 27:42-50, 30:63 - 31:10, 31:26-37, and 31:37-50). A POSITA would be motivated to make this combination to achieve the improved result delivered by the combination of Stark II and McCormack. (Ex. 1002, ¶141).

The combination of incorporating McCormack into Stark II would have been well within a POSITA's ability at the time of the alleged invention of the challenged claims. (Ex. 1002, ¶142). Indeed, a POSITA would be well versed in a variety of spinal surgeries for fusion, immobilization, distraction, and other repair of spinal and pelvic joints, all of which are within the skill set of a POSITA. (*Id*.). Fusion implants having threading and other surface anti-migration features were well known in the art at the time of the alleged 539 Patent invention. (Ex. 1009, Ex. 1012, Ex. 1014, Ex. 1015; Ex. 1002, ¶142). The combination of McCormack and Stark II would have led a POSITA to a predictable result, namely, better securement of the fusion

implant inside the SI Joint. Finally, adding McCormack to Stark II would have been an obvious design choice since McCormack teaches to do so. (Ex. 1002, ¶142). The surgical procedures described in McCormack and Stark II are highly similar, which is unsurprising since the both are directed to a posterior approach for fusing articular surfaces of a spinal joint. (*Id*.). A POSITA would have therefore had the design choice to use the additional fusion implants and fixation elements of McCormack to further secure the SI Joint, as described in Stark II. (*Id*.).

2. Independent Claim 26

As discussed above regarding anticipation by Stark II, all aspects of claim 26 are disclosed by Stark II with the exception of a fixation element as interpreted under the Petitioner Claim Construction. Thus, see above Section X.C.1. for a discussion of Stark II disclosures of [26 pre], [26.a.], [26.b.1.], [26.b.2.], [26.c.], [26.d.1.], and [26.d.4.].

a) [26.b.2.] "spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;"

The disclosure of spreading the SI Joint with an inserted end of the working channel is inherently disclosed in Stark II, as discussed above in Section X.C.1.(d). In addition, McCormack expressly discloses this feature, as demonstrated above in Section X.A.1.(d).

b) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an

articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

Under the Petitioner Claim Construction, Stark II does not expressly disclose a fixation element that provides for engagement in bone tissue of the articular surfaces in the SI Joint. McCormack discloses multiple embodiments of fusion implants that demonstrate these features, as summary of which is listed in Section VI.D.1. above.

c) [26.d.3.] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

McCormack teaches this claim limitation in combination with the teachings of the fixation element embodiments discussed in Section X.A.1.(i) above.

3. Dependent Claim 27

a) [27.a.] "driving said fusion implant into said void with an impactor"

See Section X.E.2.; X.C.2.(a).; X.A.2.(b).

b) [27.b.] "wherein driving said fusion implant engages said at least one fixation element with said bone tissue"

Stark II inherently teaches driving the implant with an impactor, as described in Sections X.C.2.(b). Additionally, McCormack expressly teaches these limitations, as discussed above in Section X.A.2(c).

4. Dependent Claim 28

As discussed above, Stark II discloses [28 pre] and [28.a.]. Section X.C.3.

Therefore, since the combination of Stark II and McCormack obviates claim 26 as discussed above, claim 28 is also obviated by the same combination of references. See Section X.E.2.

a) [28.b.] "or a portion thereof having said at least one fixation element thereon"

To the extent that Stark II does not teach [28.a.], McCormack teaches rotating the portion of the fusion implant having at least one fixation element thereon. See Sections X.A.3.(c).

5. Dependent Claim 31

See Sections X.A.4 and X.C.4 above.

F. Obviousness of Claims 26-28 and 31 Over Vestgaarden II in view of McCormack

1. Motivation to Combine Vestgaarden II and McCormack

A POSITA would have found it obvious at the time of the alleged invention of the Challenged Claims to combine McCormack with the system of Vestgaarden II to reach the same result as that of the Challenged Claims. First, Vestgaarden II, which is directed to SI Joint fusion and entitled "Method for Deploying a Fusion Device for Sacroiliac Joint Fusion," incorporates by reference Vestgaarden III, which is directed to spinal facet fusion and entitled "Method and Apparatus for Spinal Facet Fusion." Thus, a POSITA familiar with Vestgaarden II would find it

obvious, and would be motivated, to consider art from spinal facet fusion, such as McCormack. (Ex. 1002, ¶153).

Second, Vestgaarden II and McCormack both teach posterior methods of fusing the articular surfaces of spinal bone structures. (Ex. 1012, at 31:7-10, 14:10-12; Ex. 1013, at 2:28-33, 4:34-36). Vestgaarden II, by incorporation of Vestgaarden III, teaches a fusion implant having surface barbs to prevent retraction of the implant from the facet joint. (Ex. 1016, at 4:35-37). To improve this anti-retraction feature, it would be well within the sill of a POSITA to use the fusion implants from McCormack in the SI Joint fusion system and method of Vestgaarden II. (Ex. 1002, ¶154). McCormack provides a variety of embodiments to do so. (Ex. 1012, at 23:13-22, 25:1-15, 25:33-47, 27:42-50, 30:63 - 31:10, 31:26-37, and 31:37-50). A POSITA would be motivated to make this combination to achieve the improved result delivered by the combination of Vestgaarden II and McCormack. (Ex. 1002, ¶154).

The combination of incorporating McCormack into Vestgaarden II would have been well within a POSITA's ability at the time of the alleged invention of the challenged claims. (Ex. 1002, ¶155). Indeed, a POSITA would be well versed in a variety of spinal surgeries for fusion, immobilization, distraction, and other repair of spinal and pelvic joints, all of which are within the skill set of a POSITA. (*Id*.).

Again, this is demonstrated by Vestgaarden II incorporating by reference the implants in Vestgaarden III. (*Id*.).

Fusion implants having surface anti-migration features were well known in the art at the time of the alleged 539 Patent invention. (Ex. 1009, Ex. 1012, Ex. 1014, Ex. 1015). The combination of McCormack and Vestgaarden II would have led a POSITA to a predictable result, namely, better securement of the fusion implant inside the SI Joint. (Ex. 1002, ¶156).

Finally, adding McCormack to Vestgaarden II would have been an obvious design choice since McCormack teaches to do so. The surgical procedures described in McCormack and Vestgaarden II are highly similar, which is unsurprising since the both are directed to a posterior approach for fusing articular surfaces of a spinal joint. (*Id*., ¶157). Therefore, a POSITA would have had the design choice to use the additional fusion implants and fixation elements of McCormack to further secure the SI Joint, as described in Vestgaarden II. (*Id*.).

2. Independent Claim 26

As discussed above regarding anticipation by Vestgaarden II, all aspects of claim 26 are disclosed by Vestgaarden II. See Section VI.D.2. To the extent that Vestgaarden II fails to teach spreading the SI Joint with the inserted end of the working channel and fixation elements under the Petitioner Claim Construction, McCormack expressly teaches both.

a) [26.b.2.] "spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;"

These limitations are disclosed by McCormack. See Section X.A.1.(d).

b) [26.d.2.] "said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of an ilium and a sacrum in said sacroiliac joint"

These limitations are disclosed by McCormack. See Section X.A.1.(g).

c) [26.d.3.] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

These limitations are disclosed by McCormack. See Section X.A.1.(h).

3. Dependent Claim 27

These limitations are disclosed by McCormack. See Section X.A.2.

4. Dependent Claim 28

Vestgaarden II does not teach rotating the fusion implant or the portion thereof having the fixation implant. However, McCormack expressly teaches both of these embodiments. See Section X.A.3.

5. Dependent Claim 31

These limitations are disclosed by McCormack. See Sections X.A.4 and X.B.3.

XI. CONCLUSION

For the foregoing reasons, Petitioner respectfully request that the Board

institute IPR and find all Challenged Claims unpatentable.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

Pursuant to Rule 37 C.F.R. § 42.24(d), the undersigned hereby certifies that, based upon the word count of the word-processing system used to prepare this petition, the number of words in this petition complies with 37 C.F.R. § 42.24(a)(1)(i) and is 13,994. Pursuant to 37 C.F.R. § 42.24(a)(1), this word count does not include "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: December 20, 2021

/Steve Kelly/
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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of December, 2021, a copy of the attached **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,426,539**, together with all supporting materials (Exhibits 1001-1018) and all other papers filed therewith as indicated below on the Patent Owner and the attorneys of record in the co-pending litigation, at the following addresses:

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