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Paper 7
Date: June 2, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

IPR2022-00335
Patent 10,426,539 B2

Before JAMES A. WORTH, MICHAEL L. WOODS,
and MICHAEL A. VALEK, *Administrative Patent Judges.*

WOODS, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner, PainTEQ, LLC, filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 26–28 and 31 ("the Challenged Claims") of U.S. Patent No. 10,426,539 B2 (Ex. 1001, "the '539 patent"). *See* Pet. 1. Patent Owner, Orthocision, Inc., did not file a Preliminary Response nor was it required to do so. Pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a), we have authority to determine whether to institute review.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that Petitioner has shown a reasonable likelihood it will prevail in establishing the unpatentability of at least one of the Challenged Claims. We, therefore, institute *inter partes* review.

A. RELATED MATTERS

The parties identify *PainTEQ, LLC v. Omnia Medical, LLC, Case No. 8:20-cv-02805-VMC-AAS* ("Related Litigation") as a related matter. Pet. 1; Paper 6, 2.

B. THE '539 PATENT

The '539 patent is titled "Method and Implant System for Sacroiliac Joint Fixation and Fusion" (Ex. 1001, code (54)) and purports to describe "[a]n improved method of fusing the sacroiliac joint and tools for

accomplishing the same" (*id.* at code (57)).[1] To illustrate the sacroiliac joint and an implant used to fuse the joint, we reproduce Figure 55 from the '539 patent, below:

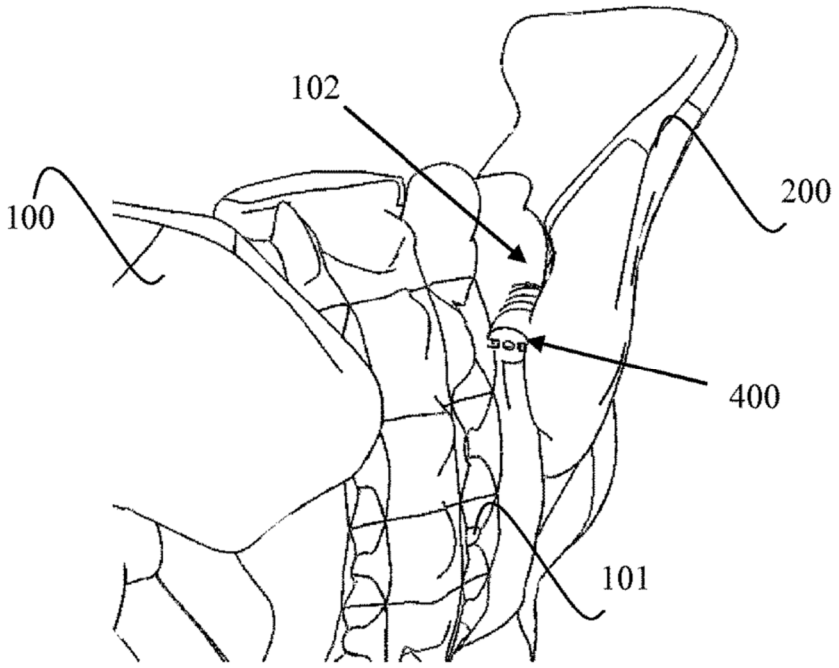


FIG. 55

Figure 55 "is an oblique, posterior view of the sacroiliac joint with a fusion implant having helical fixation elements placed in the sacroiliac joint through a posterior approach." Ex. 1001, 7:45–48. In particular, Figure 55 depicts ilium/iliac wing 100, iliac crest 200, and sacrum 101, with the sacroiliac joint ("SI joint" 102) defined between ilium 100 and sacrum 101, and with fusion implant 400 in its desired operative position in joint 102. *Id.* at 12:49–59, 23:66–67.

[1] Throughout this Decision, our quotations from the '539 patent and the other U.S. patent documents omit bold emphasis added to reference numerals.

C. CHALLENGED CLAIMS

Of the Challenged Claims, claim 26 is independent. *See* Ex. 1001, 44:25–64. We reproduce that claim, below, and add brackets with alphanumeric references that correspond to Petitioner's alphanumeric references of the claimed limitations (Pet. 39–40):

> 26. **[pre]** A method for repairing a sacroiliac joint of a patient, comprising:
>
> **[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;
>
> **[b.1]** inserting a working channel into said incision and
>
> **[b.2]** spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;
>
> **[c]** creating a void in said posterior portion of the sacroiliac joint; and
>
> **[d.1]** inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint,
>
> **[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,
>
> **[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
>
> **[d.4]** no further implants or fusion devices are introduced into the sacroiliac joint or surrounding tissues.

Ex. 1001, 44:25–44; Pet. 39–40.

D. REFERENCES RELIED UPON

Petitioner's challenges rely on the following references (Pet. 3):

Name	Reference	Ex. No.
McCormack	US Patent No. 8,361,152 B2, issued Jan. 29, 2013	1012
Stark	US Patent No. 8,740,912 B2, issued June 3, 2014	1014
Vestgaarden	US Patent No. 8,882,818 B1, issued Nov. 11, 2014	1013
Stoffman	US Patent No. 9,451,986 B2, issued Sep. 27, 2016	1015

E. ASSERTED GROUNDS

Petitioner contends that the Challenged Claims are unpatentable based on the following grounds (Pet. 8–9):

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	26–28, 31	102	McCormack
2	26, 27, 31	102	Vestgaarden
3	26–28, 31	102	Stark
4	26, 28, 31	103	Stark, Stoffman
5	26–28, 31	103	Stark, McCormack
6	26–28, 31	103	Vestgaarden, McCormack

Petitioner supports its challenge with a declaration from Dr. Jeffrey Henn (Ex. 1002). *See, e.g.*, Pet. 6. At this stage of the proceeding, Dr. Henn is competent to testify on the understanding of a person having ordinary skill in the art at the time of the alleged invention ("POSITA"). *See* Ex. 1002 ¶¶ 13–15.

II. ANALYSIS

A. PRINCIPLES OF LAW

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Petitioner's challenge is based on anticipation and obviousness. Pet. 8–9.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). To establish anticipation, "all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and, when

presented, (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

We analyze the asserted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, we may consider certain factors, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.*

Petitioner contends, and is supported by the accompanying declaration testimony of Dr. Henn, that a 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." Pet. 38 (citing Ex. 1002 ¶ 13; Ex. 1003).

For purposes of this Decision, we decline to adopt the definition of the level of ordinary skill in the art proposed by Petitioner. At this stage of the proceeding, we are not persuaded that the level of skill would have required a Doctor of Medicine, nor has Petitioner explained what a "related degree" might be in this context.

Having reviewed the '539 patent and the references relied on by Petitioner, we determine that a POSITA would have had at least some working experience and/or educational training in joint or spinal fusion, with more experience making up for less educational training, and vice versa. If either party disagrees with our definition of the ordinarily skilled artisan, that party is encouraged to develop the issue at trial.

C. CLAIM CONSTRUCTION

Claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc).

Petitioner submits that the parties have submitted claim construction briefs in the Related Litigation, and explains the "parties have stipulated to plain and ordinary meaning of all claim terms in claim 26[] with the exception of three terms," i.e., "fixation element," "for engagement with bone tissue in an articular surface," and "engages with said articular surface." Pet. 36–37. Petitioner further submits that, despite the disagreement in construction of these claim terms, the applied references anticipate and render obvious the Challenged Claims under either Patent Owner's or Petitioner's proposed constructions in the Related Litigation. *See id.* at 37.

At this stage of the proceeding, we determine that there are no terms that require express construction for the purposes of instituting trial. *See*

Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

D. GROUND 2: ANTICIPATED BY VESTGAARDEN

Petitioner contends that claims 26, 27, and 31 are anticipated by Vestgaarden. Pet. 41.

1. Vestgaarden (Ex. 1013)

Vestgaarden is titled "Method for Deploying a Fusion Device for Sacroiliac Joint Fusion" (Ex. 1013, code (54)) and describes "[a] method for fusing a spinal sacroiliac joint and a surgical kit" (*id.* at code (57)). We reproduce Figure 3A of Vestgaarden, below:

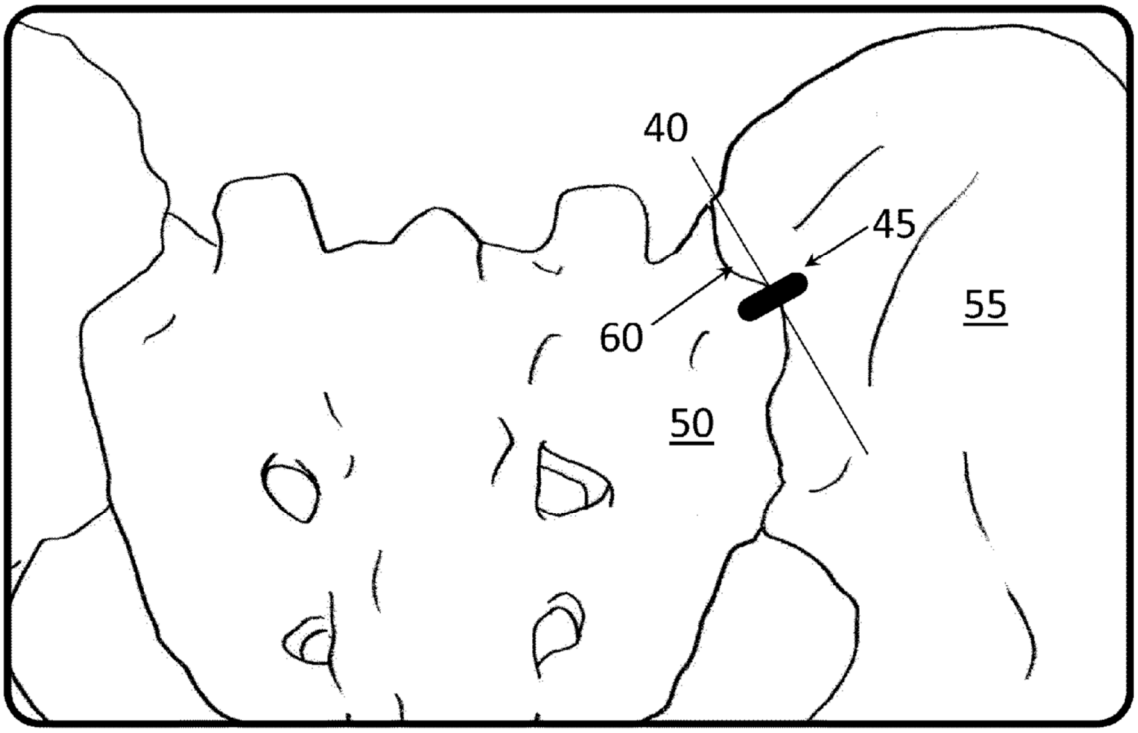


FIG. 3A

Figure 3A "is a close-up perspective view of said sacroiliac joint and a drilled, bored, punched, or cut cavity." *Id.* at 3:22–23. In particular, Figure

3A depicts sacroiliac joint 60 with cavity 45 formed across plane 40 so that one-half of cavity 45 is formed in sacrum 50 and one-half is formed in ilium 55. *Id.* at 4:63–65.

We also reproduce Vestgaarden's Figure 3B, below:

FIG. 3B

Figure 3B "is a close-up perspective view of said sacroiliac joint and said stabilization implant in the final position in the sacroiliac joint." *Id.* at 3:24–26. Specifically, Figure 3B depicts stabilization implant 5 inserted into cavity, which is preferably slightly oversized relative to cavity 45 so as to create a press fit. *Id.* at 5:1–7.

2. Claim 26

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

Petitioner treats the preamble as limiting, arguing that Vestgaarden discloses a method for repairing a sacroiliac joint. *See* Pet. 50–51.

Petitioner cites to Vestgaarden's disclosure that its "invention relates to surgical methods and apparatus in general, and more particularly to surgical methods and apparatus for fusing sacroiliac joints." *Id.* at 50 (citing Ex. 1013, 1:6–9). Petitioner also cites to Vestgaarden's disclosure that "a general objective of [Vestgaarden's] invention [is] to provide a method to deliver a device for correcting symptomatic sacroiliac joint dysfunction or instability." *Id.* at 50–51 (citing Ex. 1013, 1:48–52).

At this stage of the proceeding, and without determining whether the preamble is limiting, Petitioner has shown a reasonable likelihood that Vestgaarden discloses the recited limitations.

b. [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"

Petitioner cites to Vestgaarden's disclosure that "[s]tabilization implant 5 is inserted into a sacroiliac joint using a posterior approach." Pet. 51 (citing Ex. 1013, 4:34–37) (alteration in original). Petitioner also cites to Vestgaarden's disclosure that "[a] path through soft tissue to the sacroiliac joint is . . . created via surgeon's preference, such as open, minimally-invasive, percutaneous, or arthroscopic." *Id.* (citing Ex. 1013, 5:23–26) (first alteration in original).

For purposes of institution, we agree with Dr. Henn that the surgical procedures disclosed in Vestgaarden involve creating an incision in the patient in a position proximal to the patient's sacroiliac joint, as recited in the claim. *See* Ex. 1002 ¶ 97; *see also* Pet. 51 (citing the same).

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [a].

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

Petitioner submits that the "working channel" in Vestgaarden is directional cannula 130. Pet. 51 (citing in part Ex. 1013, Fig. 17). We reproduce Vestgaarden's Figure 17, below:

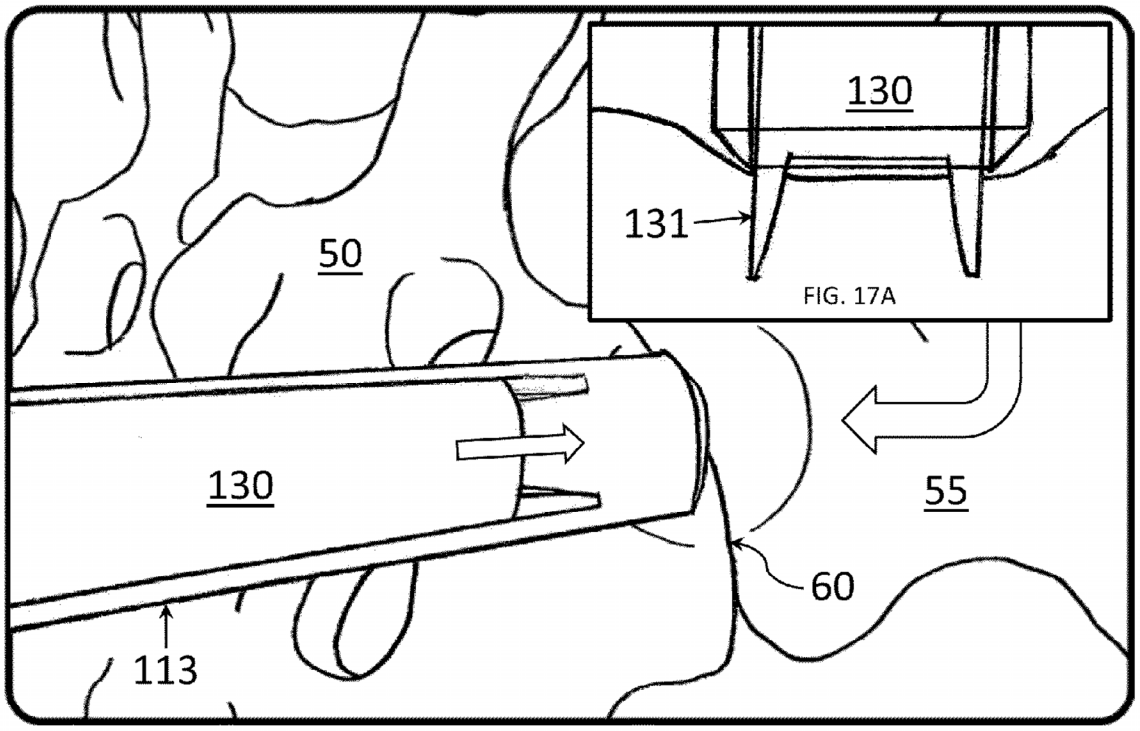


FIG. 17

Figure 17 "is a perspective view of said directional cannula." Ex. 1013, 3:50. In particular, Figure 17 depicts "directional cannula 130 . . . inserted into the lumen of dilation tube 113 until a distal end of cannula 130 engages sacroiliac joint 60." *Id.* at 5:49–51.

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [b.1].

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

Petitioner cites to Vestgaarden's disclosure that "[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)." Pet. 52 (quoting Ex. 1013, 5:51–56) (alteration in original).

Dr. Henn testifies that "[t]he 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; *see also* Pet. 52 (citing the same). Dr. Henn further explains that "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. 1002 ¶ 99 (quoting Ex. 1013, 2:7–11). Dr. Henn testifies that "tapping the directional cannula (130) to force the teeth (131) into the joint causes distraction, or spreading, of the SI Joint" and that Vestgaarden "inherently discloses spreading the posterior portion of the SI Joint with an insertion end of the working channel." *Id.*

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [b.2].

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

Petitioner submits that "Vestgaarden . . . describes using a drill to create a fusion implant cavity in both the sacrum and the ilium." Pet. 53 (citing Ex. 1013, 5:57–6:27).

Vestgaarden discloses "directional cannula 130 is inserted into the lumen of dilation tube 113 until a distal end of cannula 130 engages sacroiliac joint" (Ex. 1013, 5:49–51, Fig. 17) and that a "drill bit 150 is inserted into guide hole 141 and used to drill a cavity in iliac bone 55." Ex. 1013, 5:64–65.

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [c].

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

Petitioner submits that "[w]hen 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." Pet. 53 (citing Ex. 1013, 2:7–11). Petitioner further submits, "[a]fter 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." *Id.* (citing Ex. 1013, 2:12–24, 4:60–65, 6:28–36).

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [d.1].

g. [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"

To address limitation [d.2], Petitioner submits an annotated version of Vestgaarden's Figure 3B (Pet. 54), a copy of which we reproduce, below:

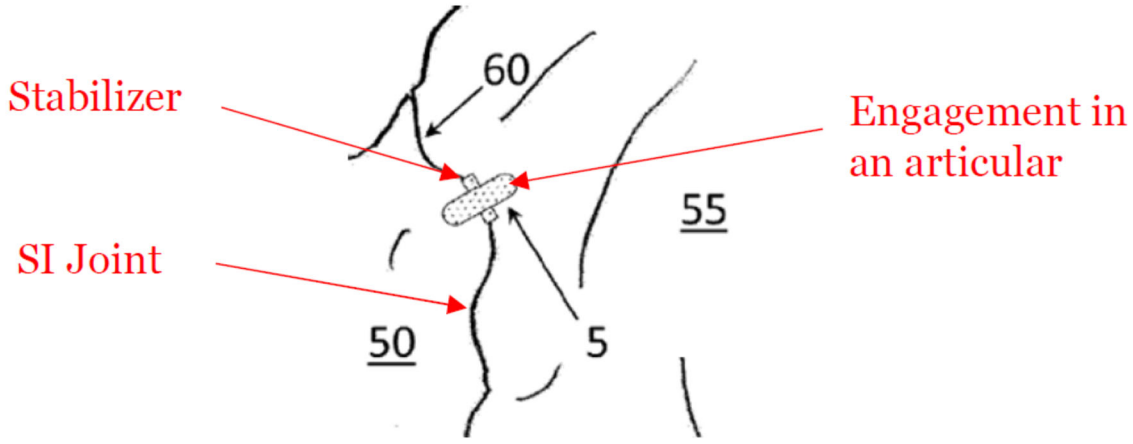
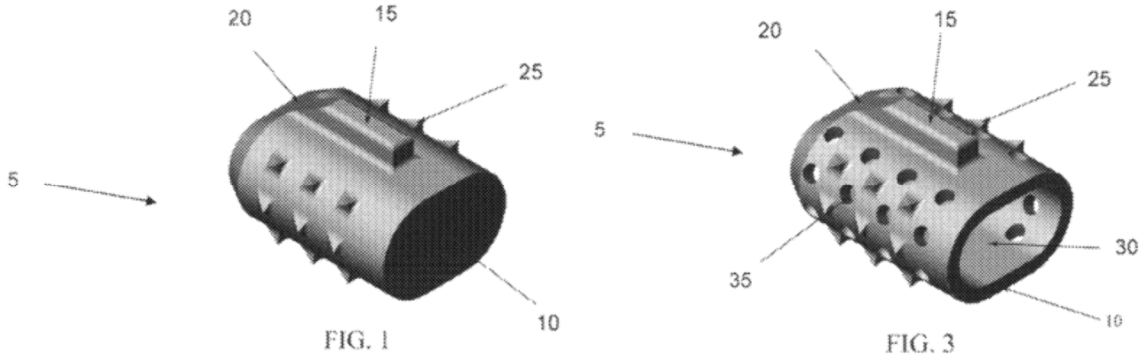


Figure 3B is a close-up perspective view of the SI joint and stabilization implant in the final position in the SI joint. Ex. 1013, 3:24–26. Petitioner provides red annotations to illustrate the "stabilizer," pointing to implant 5, SI joint, and the location where the "engagement with bone tissue in an articular surface." Pet. 53.

Petitioner also refers to two particular implant embodiments disclosed in U.S. Patent No. 8,162,981 ("the '981 patent"), which is incorporated by reference in Vestgaarden. *See id.*; *see also* Ex. 1001, 4:10–14 (incorporating by reference the '981 patent, which discloses a sacroiliac stabilization implants). We reproduce those embodiments, below:



Figures 1 and 3 depict fusion implants 5 with body 10 and stabilizer 15. Ex. 1016, 4:4–5, 4:21–24. Petitioner submits that "these embodiments include

barbs (25) to resist retraction of the implant (5) from the facet joint." Pet. 54 (citing Ex. 1016, 4:35–37). Petitioner explains, "[b]ecause 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." *Id.*

Petitioner has shown a reasonable likelihood that the barbs disclosed in the '981 patent—and incorporated by reference in Vestgaarden—are "fixation elements," as recited in the claim. Although we do not expressly construe whether a "fixation element" is one of a "helical anchor[], lateral blade[], fluke[], claw[], hook[], or screw[] structure[]" or simply a "stabilization part" (*see* Pet. 36), at this stage of the proceeding, we find Vestgaarden's "barbs" are *both* a "stabilization part" and a "claw." Indeed, the '981 patent discloses that its "Barbs . . . are designed to . . . impede retraction of [the] body" (Ex. 1016, 4:35–37) and the '539 patent describes that its fixation elements may be integrally-formed claws (*see, e.g.*, Ex. 1001, 2:33–34 (describing a "claw" as a "fixation element"); *see also, e.g., id.* at 11:46–48 (describing the fixation elements as being, for example, integrally-formed)). In other words, due to the similarity between the integrally-formed claws described as "fixation elements" in the '539 patent and the integrally-formed barbs shown in Vestgaarden (via the '981 patent), Petitioner has shown a reasonable likelihood that Vestgaarden discloses "fixation elements."

If Petitioner or Patent Owner disagrees that Vestgaarden's "barbs" are "fixation elements" *under that party's own construction*, that party shall submit a proposed claim construction and related analysis explaining its position in either the Patent Owner Response or Petitioner Reply.

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [d.2].

h. [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"

In addressing limitation [d.3], Petitioner refers to the discussion addressing limitation [d.2]. *See* Pet. 55. Petitioner explains that "barbs (25) are further fixation elements that engage the bone tissue in an articular surface of the sacrum and in the ilium." *Id.* at 54 (referencing the implant embodiments of the '981 patent).

Vestgaarden's barbs 25 would engage the articular surface of both the ilium and sacrum. *See* Ex. 1013, Fig. 35 (depicting implant 5 within the SI joint); *see also* Ex. 1016, Figs. 1, 3 (depicting the location of barbs 25, or "fixation elements," positioned at locations on implant 5 that would engage the articular surface of the ilium and sacrum).

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [d.3].

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

Petitioner submits that Vestegaarden teaches the use of a single implant, with "no other implants or fusion devices introduced into the SI Joint or surrounding tissue." Pet. 55 (citing Ex. 1013, 6:37–40).

Figures 3A and 3B of Vestgaarden depict a single implant 5 within the SI joint.

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in [d.4].

j. Summary of Claim 26

Petitioner has shown a reasonable likelihood that claim 26 is anticipated by Vestgaarden.

3. Dependent Claim 27

Claim 27 depends from claim 26 and further recites the steps of "driving said fusion implant into said void with an impactor, wherein driving said fusion implant engages said at least one fixation element with said bone tissue." Ex. 1001, 44:45–48.

Petitioner cites to Vestgaarden's disclosure that "[i]mplant positioner 160 is lightly tapped to drive implant 5 into cavity 45 created laterally across sacroiliac joint 60." Pet. 55 (quoting Ex. 1013, 6:33–35). Petitioner further submits that "[d]riving the implant . . . engages barbs (25) in the bone tissue exposed by formation of the cavity," as described above. *See id.*

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in dependent claim 27.

4. Dependent Claim 31

Claim 31 depends from claim 26 and further recites, "wherein said working channel includes at least one tang protruding from a distal end of the working channel for securing a position of said working channel in said sacroiliac joint." Ex. 1001, 44:61–64.

To address the limitation, Petitioner reproduces Figure 8 of Vestgaarden (Pet. 56), a copy of which we reproduce, below:

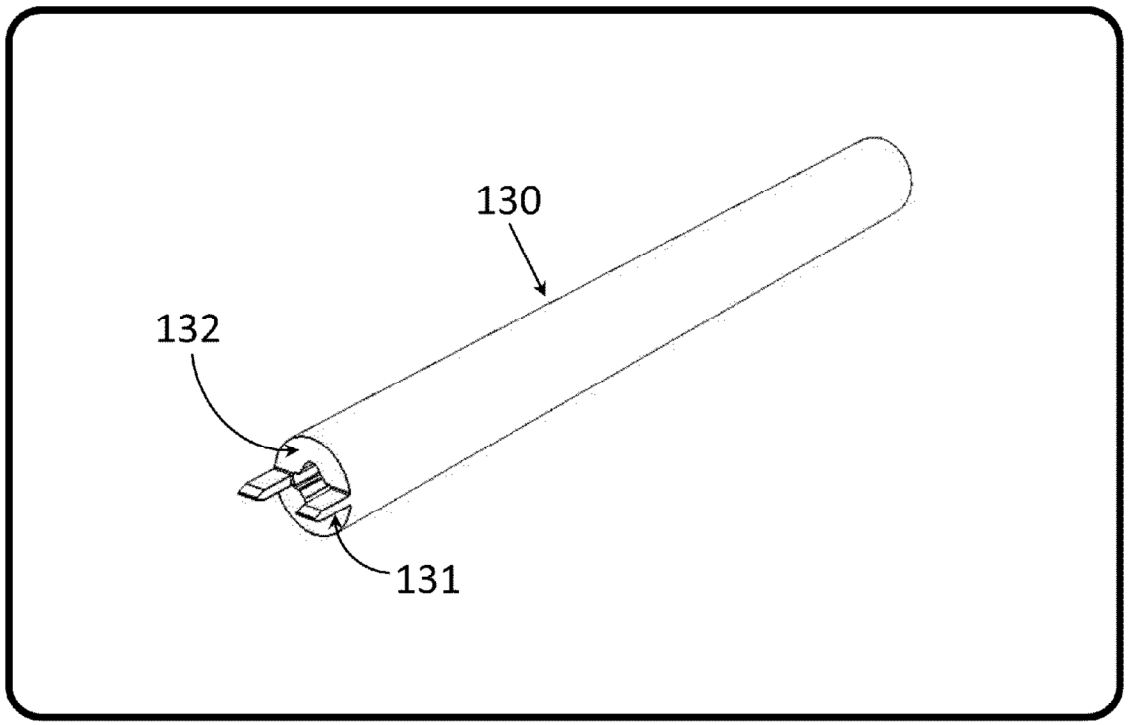


FIG. 8

Figure 8 depicts a directional cannula 130 with cannula teeth 131 that are insertable into a sacroiliac joint until positive stop 132 engages the joint. *See* Ex. 1013, 3:32; *see also id.* at 5:49–56.

For purposes of institution, we find that Vestgaarden's cannula teeth 131 satisfy the recited "at least one tang protruding from a distal end of the working channel."

At this stage of the proceeding, Petitioner has shown a reasonable likelihood that Vestgaarden discloses limitations recited in dependent claim 27.

5. Summary of Ground 2

Based on the present record, Petitioner has shown a reasonable likelihood that Vestgaarden anticipates claims 26, 27, and 31.

E. GROUNDS 1 AND 3–6

We do not need to determine whether Petitioner's showings under these additional grounds are sufficient in light of our determination regarding claims 26, 27, and 31 under Ground 2. Therefore, pursuant to USPTO policy implementing the decision in *SAS Inst., Inc. v. Iancu,* 138 S. Ct. 1348 (2018), we institute as to all claims challenged in the Petition and on all grounds in the Petition. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019),[2] 5–6, 64.

III. CONCLUSION

For the reasons discussed above, Petitioner has shown a reasonable likelihood of prevailing with respect to at least one claim. This decision does not reflect a final determination on the patentability of the claims. We have evaluated the parties' submissions and determine that the record supports institution.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '539 patent is instituted on all claims and all grounds set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

[2] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

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