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Paper 33
Date: May 24, 2023

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*.

Opinion for the Board filed by *Administrative Patent Judge* WOODS.

Opinion Dissenting-in-part filed by *Administrative Patent Judge* WORTH.

WOODS, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Revised Motion to Amend
35 U.S.C. § 318(a)

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. We issued a decision to institute an *inter partes* review of these claims. Paper 7 ("Institution Decision" or "Inst. Dec.").

Patent Owner, Orthocision, Inc., *did not* file a response to the Petition. In our Scheduling Order, we notified the parties that "Patent Owner is cautioned that any arguments not raised in the response may be deemed waived." Paper 8, 9 (emphasis omitted); *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide 66 (Nov. 2019) ("Practice Guide" or "CTPG") ("The patent owner response . . . should identify all the involved claims that are believed to be patentable and state the basis for that belief."). Accordingly, Patent Owner has waived any argument to the Challenged Claims. Petitioner nevertheless filed a Reply (Paper 14, "Pet. Reply"), as permitted under our Practice Guide. CTPG 73 ("the Board will permit the petitioner, in its reply brief, to address issues discussed in the institution decision").

Patent Owner filed, however, an initial Motion to Amend (Paper 9), to which Petitioner filed an Opposition (Paper 13, "Opp."). At Patent Owner's request, we issued Preliminary Guidance (Paper 16) in response to Patent Owner's initial Motion to Amend.

Following the Preliminary Guidance, Patent Owner filed a Revised Motion to Amend, replacing the initial Motion to Amend, seeking entry of Substitute Claims 32–35 ("Substitute Claims"). Paper 17 ("Motion" or "RMTA"). Petitioner filed an Opposition to the Revised Motion to Amend

(Paper 19, "RMTA Opp."), Patent Owner filed a Reply to Petitioner's Opposition (Paper 28, "RMTA Reply"), and Petitioner filed a Sur-reply to Patent Owner's Reply (Paper 29, "RMTA Sur-reply").[1]

Oral argument was held on March 29, 2023, and the transcript of the hearing has been entered as Paper 32 ("Transcript" or "Tr.").

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 26–28 and 31 of the '539 patent are unpatentable. We further conclude that Petitioner has shown by a preponderance of the evidence that proposed Substitute Claims, claims 32–35, are also unpatentable. Therefore, the RMTA is denied.

[1] Petitioner filed a motion to strike (Paper 24) seeking to strike Patent Owner's *initial* reply to Petitioner's Opposition to the Revised Motion to Amend. Paper 24. We granted the motion. Paper 27 ("Order"). In our Order, we struck from the record Paper 23 and granted Patent Owner permission to file a *revised* Reply to Petitioner's Opposition and a *revised* claim appendix. *See* Paper 27. Patent Owner filed a revised claim appendix (Ex. 2004, "App. A") and a revised Reply to Petitioner's Opposition (Paper 28, "RMTA Reply").

A. Related Proceedings

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

We further note the following matters appear related, as they involve U.S. Patent No. 11,083,511, which is related to the '539 patent: (1) *Omnia Medical, LLC v. PainTEQ, LLC*, Case No. 8:22-cv-00145-VMC-TGW (M.D. Fla.); IPR2023-00477; and IPR2023-00451.

The parties are reminded of their continuing obligation to update their mandatory notice information "within 21 days of a change of the information." 37 C.F.R. 42.8(a)(3).

B. Real Parties In Interest

The parties identify PainTEQ, LLC, Orthocision, Inc., and Omnia Medical, LLC, as the real parties in interest. Pet. 7; Paper 6, 2.

C. The '539 Patent (Ex. 1001)

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)).[2] "The sacroiliac joint is located in the lower back at the juncture of the ilium, the upper bone of the pelvis, and the sacrum at the base of the spine." *Id.* at 1:21–23. To illustrate the

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

sacroiliac joint and an implant used to fuse the joint, we reproduce Figure 55 from the '539 patent, below:

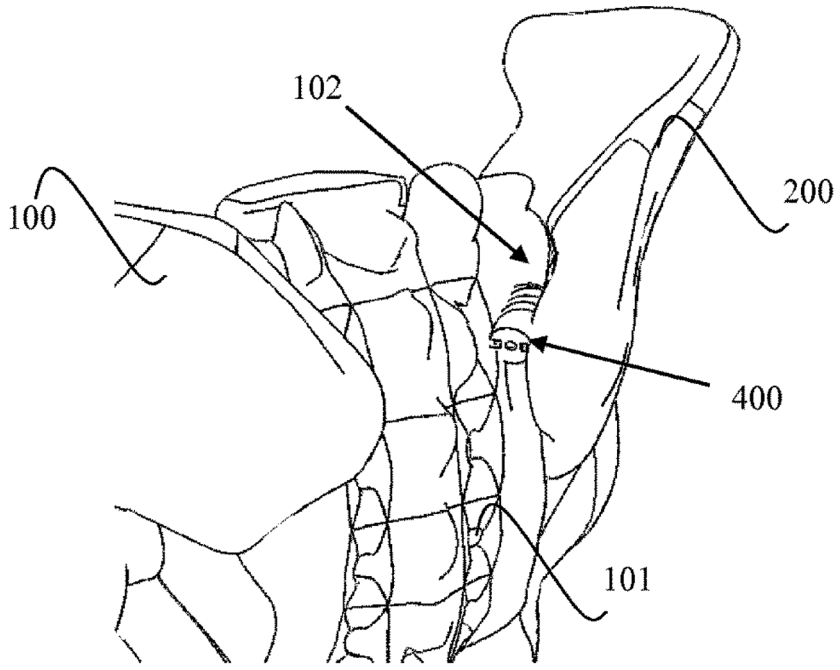

FIG. 55

Figure 55, reproduced above, "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.

D. Illustrative Claim

Of the Challenged Claims, claim 26 is independent. *See* Ex. 1001, 44:25–64. We reproduce that claim, below, adding formatting and 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.

E. 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 Sept. 27, 2016	1015

F. Alleged Grounds of Unpatentability

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

Ground	Claim(s) Challenged	35 U.S.C. §[3]	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(a)	Stark, Stoffman
5	26–28, 31	103(a)	Stark, McCormack
6	26–28, 31	103(a)	Vestgaarden, McCormack

Petitioner supports its challenge with a declaration from Dr. Jeffrey Henn (Ex. 1002). *See, e.g.*, Pet. 6. We find that 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 infra* § II.A; *see also* Ex. 1002 ¶¶ 13–15.

Patent Owner supports its Revised Motion to Amend with the declaration from Dr. Victor Zaporojan (Ex. 2001). *See, e.g.*, RMTA 10. We find that Dr. Zaporojan is also competent to testify on the understanding of a POSITA. *See infra* § II.A; *see also* Ex. 2001 ¶¶ 10–16.

[3] The pre-AIA version of 35 U.S.C. applies. *See* Ex. 1001, code (63) (claiming priority to a patent application filed March 15, 2013).

II. ANALYSIS

A. 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.*

In the Petition, Petitioner contends 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).

In our Institution Decision, we declined to adopt the definition of the level of ordinary skill in the art proposed by Petitioner. *See* Inst. Dec. 7. We explained that we were not persuaded that the level of skill would have required a Doctor of Medicine, and explained that Petitioner failed to sufficiently explain what a "related degree" might be. *Id.* Rather, we determined 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. *Id.* at 8. Also in our Institution Decision, we invited the parties to further brief this issue. *Id.*

In the Revised Motion to Amend, Patent Owner proposes that

> [a] person of ordinary skill in the art (POSITA) with respect to the subject matter of the '539 patent would typically have had at least a Bachelor's of Science in Mechanical, Biomechanical, or Biomedical engineering, or a related field of science, as well as at least three to seven years of experience in the field of orthopedic implants. . . . Such a POSITA would have at least had knowledge of spinal joint fusion implants, surgical instruments for spinal fusion surgeries, and the application of fusion implants in spinal fusion procedures and/or sacroiliac fusion procedures.

RMTA 10 (citing Ex. 2001 ¶ 17).

Petitioner does not address our initial definition or dispute Patent Owner's proposed definition. *See generally* RMTA Opp.; *see also generally* Pet. Reply.

We adopt Patent Owner's definition of a POSITA, which is supported by the testimony of its expert and consistent with the '539 patent and cited references. RMTA 10. We further find that Petitioner's expert, Dr. Henn, and Patent Owner's expert, Dr. Zaporojan, are persons of ordinary skill in the art. *See* Ex. 1002 ¶¶ 10–12 (listing Dr. Henn's qualifications); *see also* Ex. 1003 (curriculum vitae of Dr. Henn); *see also* Ex. 2001 ¶¶ 10–16 (listing Dr. Zaporojan's qualifications); *see also* Ex. 2002 (curriculum vitae of Dr. Zaporojan).

B. Claim Construction

1. Background

As set forth in *Phillips*, 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, 1312–1317 (Fed. Cir. 2005) ("*Phillips*").

In our Institution Decision, we determined that there were no terms that require express construction for the purposes of instituting trial. Inst. Dec. 8–9 (citing *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)).

In Petitioner's Reply, Petitioner addresses the deposition testimony of Patent Owner's expert, but does not otherwise propose that any term requires express construction. *See* Pet. Reply 1–2 (submitting only that the deposition testimony of Patent Owner's expert (from the Related Litigation) "confirms that, under either construction, Stark's screw-type fusion implant has a 'fixation element,' and that Stark II anticipates claims 26 and 28.").

We determine that the only term that requires express construction is the term "embed," which is recited in Patent Owner's revised amended claims. *See, e.g.*, App. A, 3 (Ex. 2004).

2. Embed

Petitioner submits that the term "embed" should be defined as "to be or become fixed or incorporated, as into a surrounding mass." RMTA Opp. 11 (citing Ex. 1026). Patent Owner agrees with this definition. RMTA Reply 7 ("The definition provided by Petitioner is 'to be or become fixed or incorporated, as into a surrounding mass'. *Patent Owner agrees with this definition*") (emphasis added). We adopt the parties agreed-upon definition of this term.

C. 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*, 800 F.3d at 1378.

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.

D. Ground 1: Anticipated by McCormack

Petitioner contends that claims 26–28 and 31 are anticipated by McCormack. Pet. 41.

1. McCormack (Ex. 1012)

McCormack is titled "Facet Joint Implants and Delivery Tools" (Ex. 1012, code (54)) and describes a "spinal joint distraction system" that includes a "delivery device, a driver assembly, and an internal actuator, where the driver assembly is adapted to [] hold an implant and be sleevably inserted into the delivery device" (*id.* at code (57)). We reproduce Figure 63A of McCormack, below:

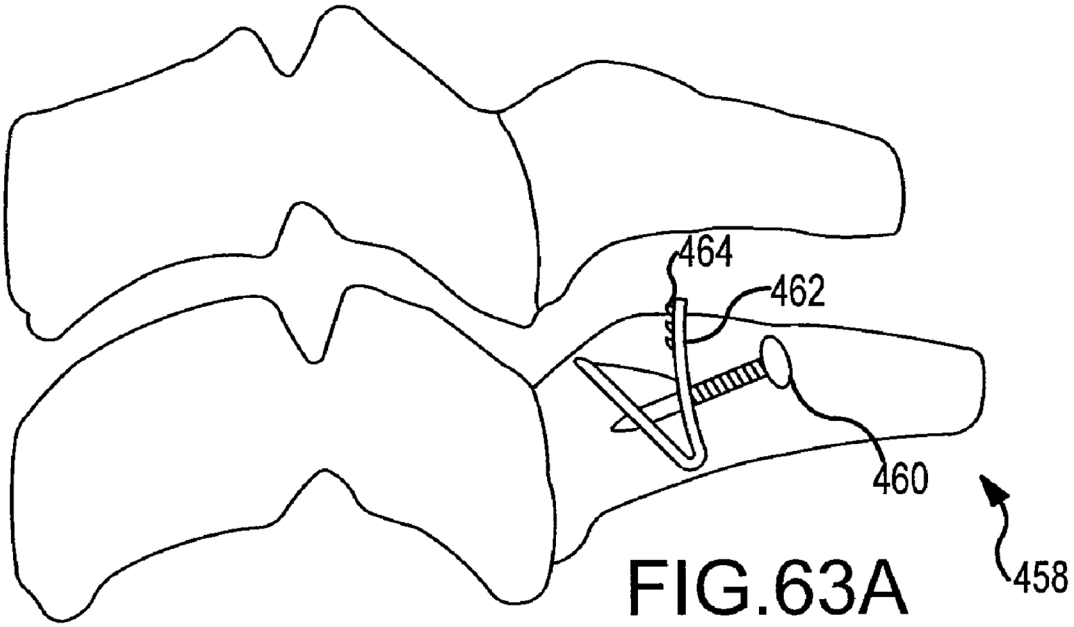

Figure 63A depicts a side view of an implant according to a particular embodiment. Ex. 1012, 11:36–37. In particular, Figure 63A depicts

triangular-shaped implant 458 for insertion into the *facet joint*. *Id.* at 30:63–66. Implant 458 includes anchoring screw 460 inserted through implant 458 and into the inferior lateral mass. *Id.* at 31:1–3. Metal flap 462 and inferior screw 460 may provide fixation of implant 458 "to enable permanent distraction of the facet and immobilization of the joint facilitating permanent fusion of the joint." *Id.* at 31:7–10.

We further reproduce Figure 63B, below:

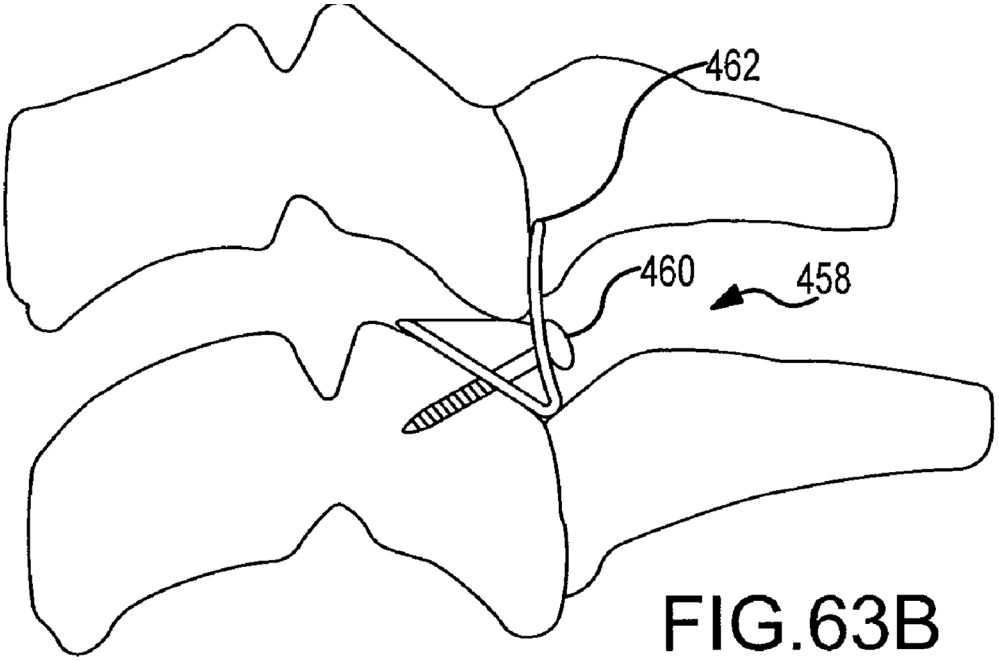

Figure 63B is similar to Figure 63A, further depicting metal flap 462 and inferior screw 460 fixated to a *facet joint*. *See id.* at 31:7–10.

2. Claim 26

Claim 26 recites "[a] method for repairing a *sacroiliac joint*." Ex. 1001, 44:25–44 (emphasis added). Even if we do not treat the preamble as limiting, the claim recites the steps of:

> **[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.

Id. (emphases added); *see also* Pet. 39–40 (adopting Petitioner's nomenclature).

To address the limitations recited in claim 26, Petitioner submits the following:

- "In McCormack, several embodiments of the system result in fusion of the *spinal facets*" (Pet. 41–42, (addressing the preamble, emphasis added));
- "McCormack explains that, [o]nce an access path is created, the chisel 108 . . . 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*" (Pet. 42 (internal quotation omitted, addressing element [b.1], emphasis added));
- "[t]he forks 112 of the delivery device 104 may be holding the *facet joint* slightly distracted" (Pet. 43

(internal quotation omitted, addressing element [b.2], emphasis added));

- "[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*" (Pet. 43 (addressing element [c], emphasis added));
- "the implant 154, in its flat and parallel position, may slide relatively easily into the *facet joint*" (Pet. 44 (quotation omitted, addressing element [d.1], emphasis added));
- "teeth, cleats, or keels 232 may engage the facet surfaces and provide acute fixation of the body 220 within the *facet joint*" (Pet. 45 (quotation omitted, addressing element [d.2], emphasis added)); and
- "Once the implant is inserted into the *facet joint* and secured . . ." (Pet. 46 (addressing element [d.4], emphasis added)).

As shown above, Petitioner cites extensively to McCormack's disclosure of a system and method for fusing a *facet joint*. A facet joint, however, is not a sacroiliac joint, as recited in claim 26. We are not persuaded that McCormack's method for fusing a facet joint, with a triangular-shaped implant uniquely shaped for fusing the facet joint (*see, e.g.*, Ex. 1012, Fig. 63B), anticipates the "method for repairing a sacroiliac joint," recited in claim 26.

We further note that, even though Patent Owner did not file a Patent Owner response to the Petition, we nevertheless review the Petition on the merits. *See Reactive Surfaces Ltd. v. Toyota Motor Corp.*, IPR2017-00572, Paper 32 (PTAB July 13, 2017) (citing 37 C.F.R. §§ 42.108(c), 120(a) (construing the Rules to allow the Board to review a challenged patent even in the absence of patent owner participation)). Indeed, *inter partes* review "is an act by the agency in reconsidering its own grant of a public franchise."

Saint Regis Mohawk Tribe v. Mylan Pharm. Inc., 896 F.3d 1322, 1328 (Fed. Cir. 2018).

Accordingly, even in the absence of any argument from Patent Owner, Petitioner fails to demonstrate by a preponderance of the evidence that McCormack anticipates claim 26.

3. Claim 27, 28, and 31

For the same reasons that Petitioner fails to demonstrate that McCormack anticipates the method recited in independent claim 26, Petitioner also fails to demonstrate that McCormack anticipates the methods recited in dependent claims 27, 28, and 31. *See* Pet. 46–50 (relying on McCormack's method for fusing a facet joint in addressing the additional limitations of claims 27, 28, and 31).

4. Summary of Ground 1

Petitioner fails to demonstrate by a preponderance of the evidence that McCormack anticipates claims 26–28 and 31.

E. 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:

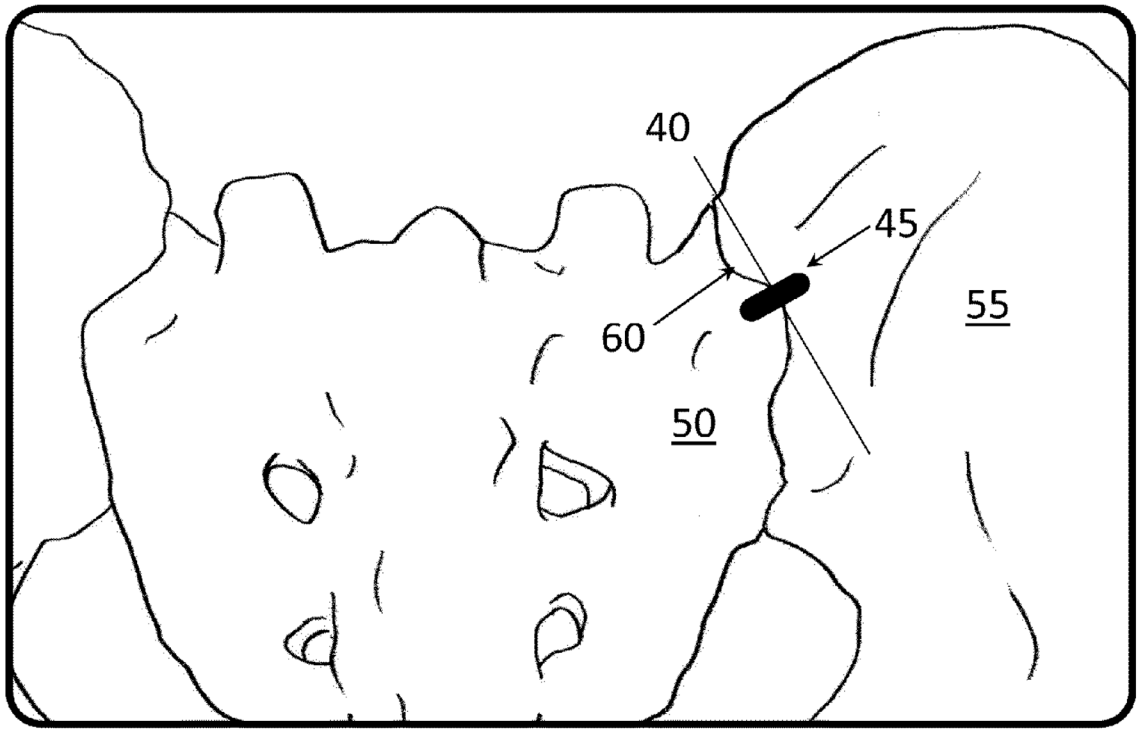

FIG. 3A

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:

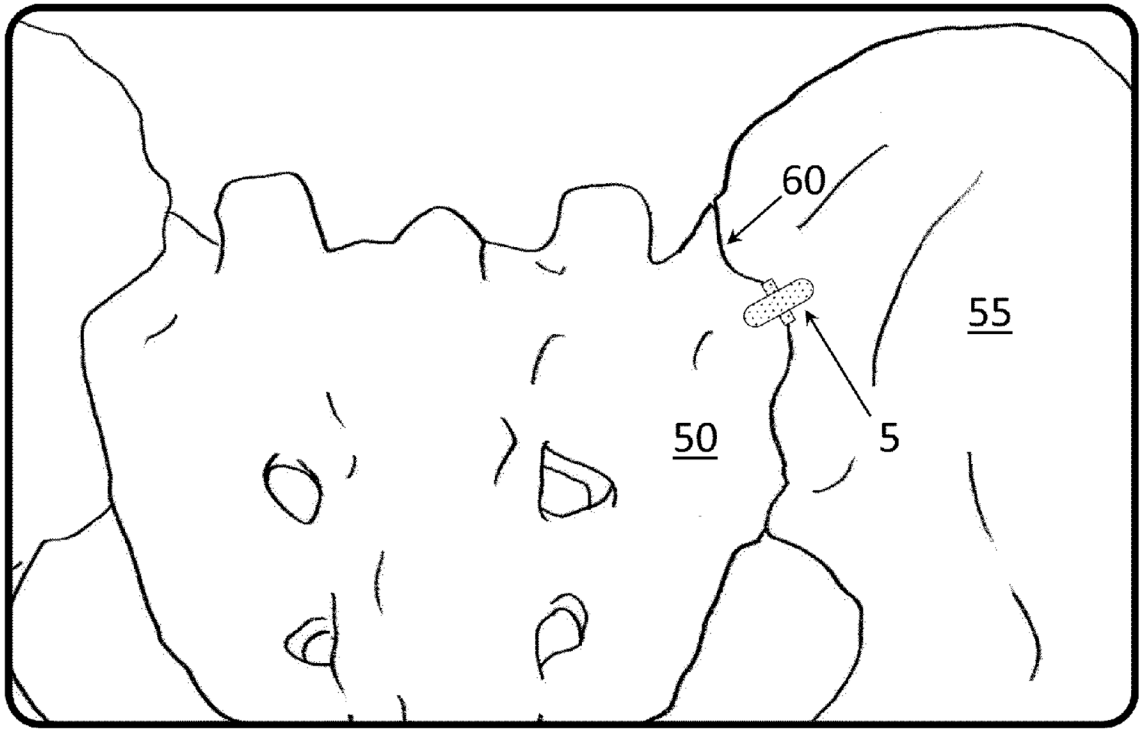

FIG. 3B

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"

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).

Patent Owner did not file a response to the Petition and waived any arguments that may have been made. *See* Paper 8, 9 ("**Patent Owner is cautioned that any arguments not raised in the response may be deemed waived**"); *see also In re NuVasive, Inc.*, 842 F.3d 1376, 1381 (determining that an argument not raised in a patent owner response was waived).

Without determining whether the preamble is limiting, Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the limitations recited in the preamble. *See* Ex. 1013, 1:6–9, 1:48–52.

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).

We find persuasive Dr. Henn's testimony 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).

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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. 51–52 (citing in part Ex. 1013, Fig. 17). We reproduce Vestgaarden's Figure 17, below:

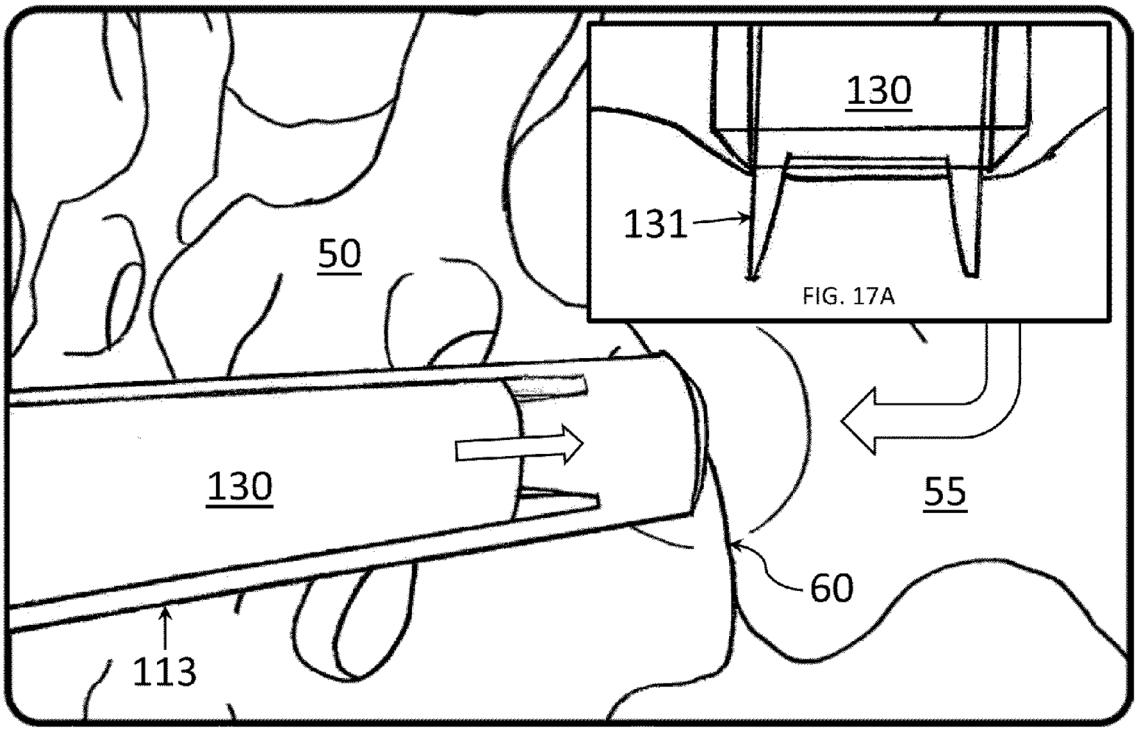

FIG. 17

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.

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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 testifies 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.*

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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).

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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).

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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:

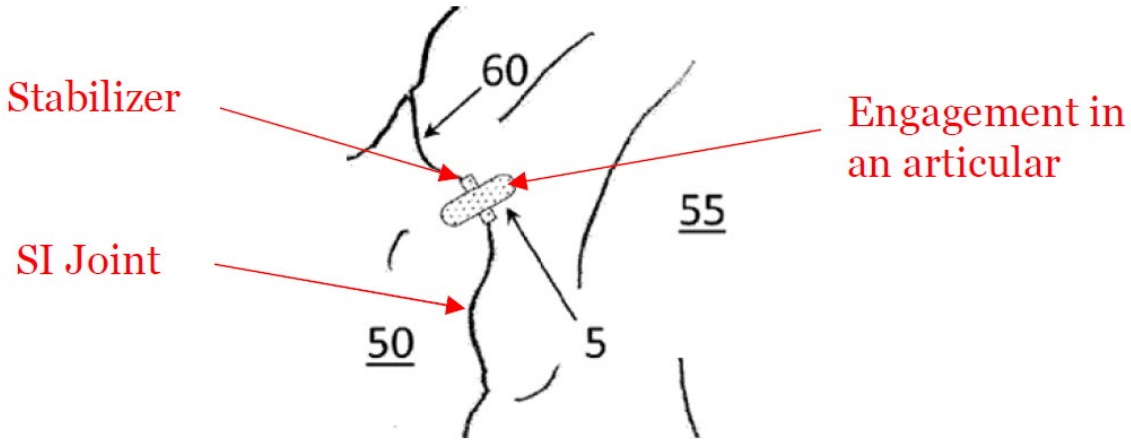

Figure 3B is a close-up perspective view of the SI joint and stabilization implant in the final position in the SI joint. Ex. 1013, 3:24–26. Petitioner provides red annotations to illustrate the "stabilizer," pointing to implant 5, SI joint, and the location where the "engagement with bone tissue in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

Petitioner also refers to two particular implant embodiments disclosed in U.S. Patent No. 8,162,981 B2 (Ex. 1016, "the '981 patent" or "Vestgaarden III"), which is incorporated by reference in Vestgaarden. *See id.*; *see also* Ex. 1001, 4:10–14 (incorporating by reference the '981 patent, which discloses sacroiliac stabilization implants). We reproduce those embodiments, below:

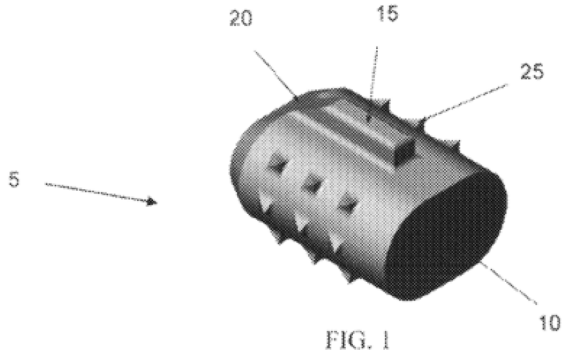

FIG. 1

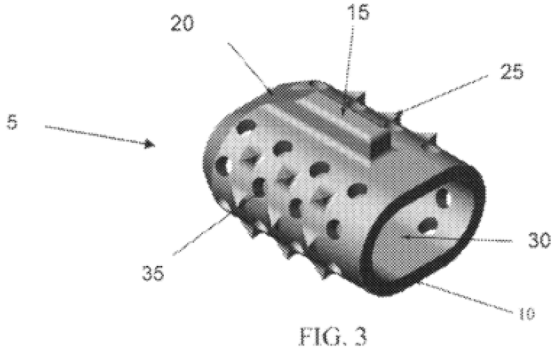

FIG. 3

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 established by a preponderance of the evidence 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), 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 demonstrated by a preponderance of the evidence that Vestgaarden discloses "fixation elements."

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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"

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).

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the 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 Vestgaarden 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.

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden satisfies the limitations recited in [d.4].

j. Summary of Claim 26

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden anticipates claim 26.

3. 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.*

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden anticipates claim 27.

4. 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:

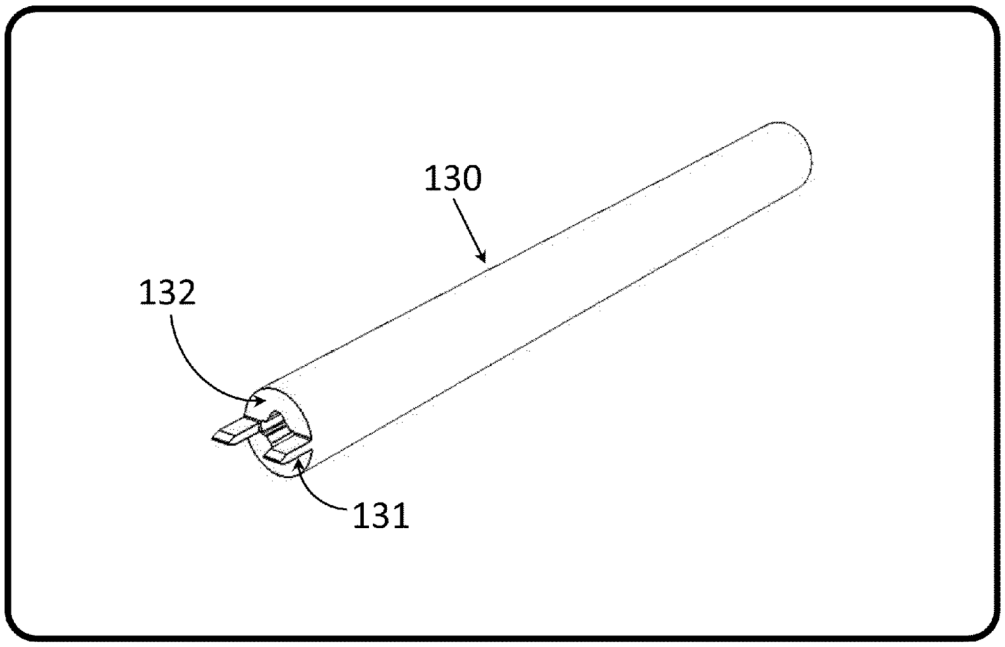

FIG. 8

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.

We agree with Petitioner and find that Vestgaarden's cannula teeth 131 satisfy the recited "at least one tang protruding from a distal end of the working channel."

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden anticipates claim 31.

5. Summary of Ground 2

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden anticipates claims 26, 27, and 31. Patent Owner did not file a response to the Petition and waived any arguments that may have been made. *See* Paper 8, 9; *see also NuVasive*, 842 F.3d at 1381.

F. Ground 3: Anticipated by Stark

Petitioner contends that claims 26–28 and 31 are anticipated by Stark. Pet. 41.

1. Stark (Ex. 1014)

Stark is a U.S. Patent titled "Tools for performing Less Invasive Orthopedic Joint Procedures" (Ex. 1014, code (54)) and describes a "tool set for preparing a joint, inserting an implant or removing an implant from a joint" (*id.* at code (57)).

We reproduce Figure 3 of Stark, below:

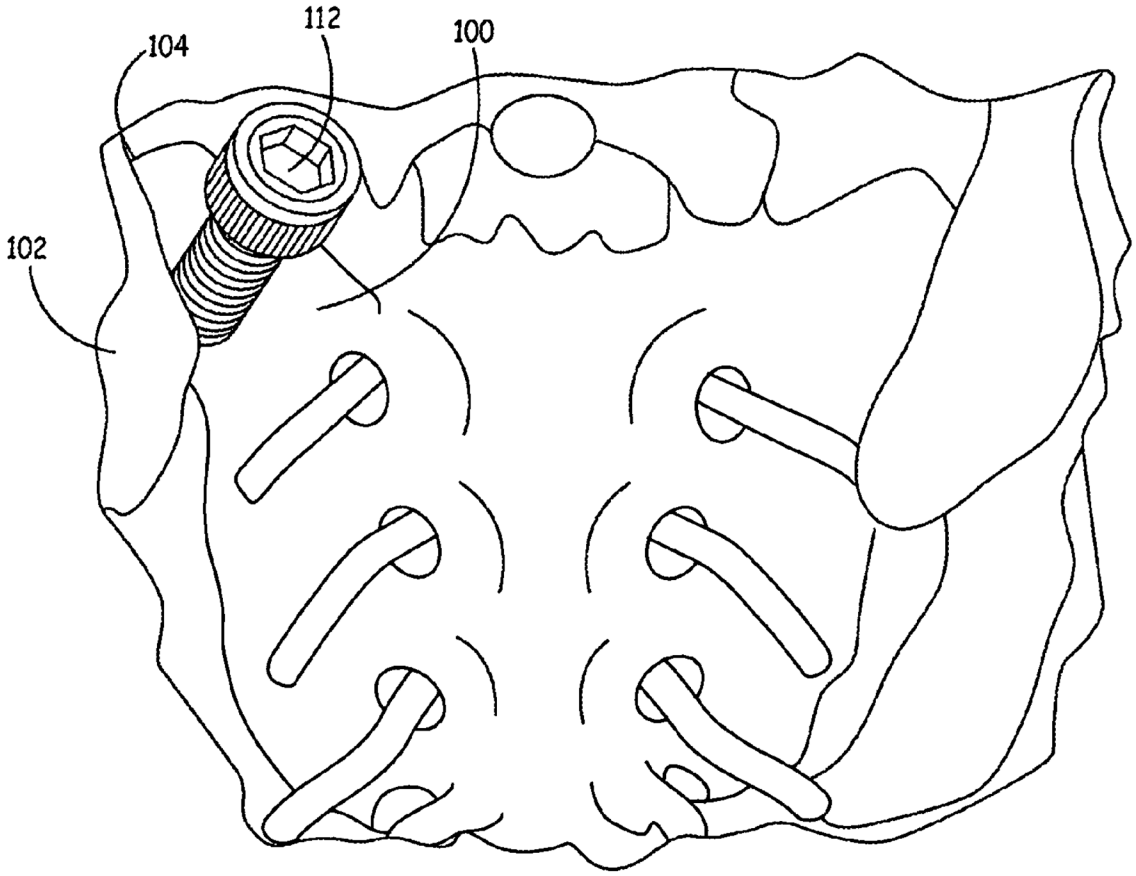

FIG. 3

Figure 3 "is a front view of a model of the sacroiliac joint immobilized with a screw." Ex. 1014, 2:45–46. In particular, Figure 3 depicts sacroiliac joint 103 between sacrum 100 and ilium 102, with simple screw 112 used to immobilize the joint. *Id.* at 8:14–17.

2. Claim 26

a. [pre] "A method for repairing a sacroiliac joint of a patient"

Petitioner cites to Stark's disclosure that its "invention relates to less invasive approaches for the immobilization or fusion of joints, such as the sacroiliac joint, and apparatuses for facilitating the procedures." Pet. 56 (citing Ex. 1014, 1:6-8).

Without determining whether the preamble is limiting, Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in the preamble.

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 Stark's disclosure that "[t]he 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." Pet. 57 (quoting Ex. 1014, 4:18–22). Petitioner further cites to Stark's disclosure that "a plurality of tools that can be delivered into the joint through a small incision." *Id*. (quoting Ex. 1014, 4:59–60).

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in [a].

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

Petitioner submits that Stark's "working channel is identified as an inner cannula (320)" and that "[t]his and other instruments are delivered into the SI Joint through the posterior incision." Pet. 57 (citing Ex. 1014, 4:57–5:5).

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in [b.1].

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

To address this limitation, Petitioner submits copies of Stark's Figures 9 and 10 (Pet. 57), a copy of which we reproduce, below:

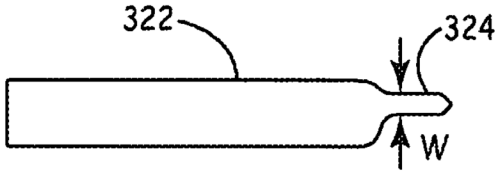

FIG. 9

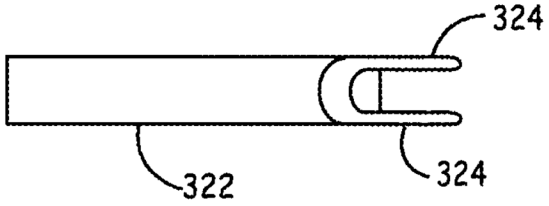

FIG. 10

Figure 9 (top) "is a first side view of a cannula with two tangs." Ex. 1014, 2:61. Figure 10 (bottom) "is a second side view of the cannula of FIG. 9 with the view rotated 90 degrees around the axis of the cannula relative to the view in FIG. 9." *Id.* at 2:65–66. Petitioner submits that these figures

teach "the use of an inner cannula . . . having a body portion (322) and tangs (324) projecting from the distal end." Pet. 57.

Stark discloses,

> [t]he 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.

Ex. 1014, 12:6–7. Petitioner submits that "[t]hese 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." Pet. 58 (citing Ex. 1018, 210). Petitioner further explains, "[f]orcibly 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." *Id.* at 59 (citing Ex. 1002 ¶ 116).

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in [b.1].

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

Petitioner submits that Stark's "instrument set . . . includes a cutting component." Pet. 59. Petitioner cites to Stark's disclosure that "the cutting component can open up a hole or passageway for insertion of an implant and/or implantation material." *Id.* (citing Ex. 1014 13:43–45). Petitioner further cites to Stark's disclosure that "a drill bit generally is used to cut away the bone to create a passageway for the cannula and/or implant." *Id.* (citing Ex. 1014, 13:57-59). Stark further discloses that "[t]he drilling

procedure prepares a hole or otherwise decorticates the bone around the joint as a site for placement of immobilization elements." Ex. 1014, 19:26–28.

Petitioner submits that Stark's "passageway, or hole, is the void." Pet. 59.

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the 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 cites to Stark's disclosure 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." Pet. 59 (quoting Ex. 1014, 9:27–29). Petitioner explains that 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 59–60 (citing Ex. 1014 13:15–18, Figs. 21–26).

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the 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"

Petitioner explains that if the term "fixation element" is construed broadly to "include threads on a screw that grip the articular surfaces of the sacrum and ilium inside the SI joint," then Stark anticipates this limitation. Pet. 60 (citing Ex. 1002 ¶ 119).

Based on this interpretation, Petitioner cites to Stark's disclosure that "[s]crews can be effectively used based anchoring the screw within the joint.

Suitable screws can be solid, cannulated or hollow . . . ." Pet. 60 (quoting Ex. 1014, 6:42–44). Petitioner further cites to Stark's disclosure that "[t]he threads of the screw grip the bone on either side of the joint to further the immobilization of the joint." *Id.* (quoting Ex. 1014, 6:46–49). Stark further discloses that an "improved implant for the sacroiliac joint is a tapered screw." Ex. 1014, 16:15–16.

We agree that the recited "fixation element" is broad enough to include the screws disclosed in Stark. We further agree that Stark's screw threads "grip the articular surfaces of the sacrum and ilium inside the SI joint," further meeting the language recited in the claim. *See* Pet. 60. Accordingly, Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the 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"

Based on the interpretation of "fixation element" discussed above in connection with element [d.2], Petitioner submits that Stark discloses this element. *See* Pet. 61.

Petitioner cites to Stark's disclosure that its "threads of the screw grip the bone on either side of the joint to further the immobilization of the joint." *Id.* (quoting Ex. 1014, 6:46–49).

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in [d.3].

i. [d.4] "wherein said at least one fixation element engages with said articular surface of at least one of said ilium and said sacrum"

Petitioner submits that Stark satisfies this limitation, citing Stark's disclosure 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." Pet. 61 (quoting Ex. 1014, 9:27–29). Petitioner explains that Stark thereby "expressly teaches an embodiment that uses a single implant with no other implants or fusion devices introduced into the SI Joint." *Id.*

Petitioner has demonstrated by a preponderance of the evidence that Stark satisfies the limitations recited in [d.4].

j. Summary of Claim 26

Petitioner has demonstrated by a preponderance of the evidence that Stark anticipates claim 26.

3. Claim 27

Claim 27 depends from the method of claim 26 and further comprises the step 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 submits that Stark teaches this claim. Pet. 61–62. Petitioner cites to Stark's disclosure that the "implant can be a nail, a wedge, a shim, a cage, or other similar structures." *Id.* at 62 (citation omitted).

Stark discloses,

> [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.

Ex. 1014, 6:37–42.

Petitioner explains that "[e]ach of these are not threaded members, and they would therefore have to be driven into the SI Joint void using an impactor." Pet. 62 (citing Ex. 1002 ¶ 123).

Petitioner explains that, "[f]or 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.* (citing Ex. 1002 ¶ 124).

Petitioner has demonstrated by a preponderance of the evidence that Stark anticipates claim 27.

4. Claim 28

Claim 28 depends from claim 26 and further recites, "wherein driving said fusion implant into said void comprises rotating said fusion implant or a portion thereof having said at least one fixation element thereon." Ex. 1001, 44:49–52.

Petitioner submits that Stark "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 above in connection with element 26 [d.1]. *See* Pet. 62. Petitioner further explains that Stark incorporates by reference another patent (Ex. 1017), which discloses that "[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 63 (quotation omitted).

Petitioner has demonstrated by a preponderance of the evidence that Stark anticipates claim 28.

5. 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.

In challenging claim 31, Petitioner explains,

> [a]fter 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 . . . inherently discloses using the tangs for securing a position of the working channel in the SI Joint.

Pet. 64 (citing Ex. 1002 ¶ 129).

Petitioner has demonstrated by a preponderance of the evidence that Stark anticipates claim 31.

6. Summary of Ground 3

Petitioner has demonstrated by a preponderance of the evidence that Stark anticipates claims 26–28 and 31. Patent Owner did not file a response to the Petition and waived any arguments that may have been made. *See* Paper 8, 9; *see also NuVasive*, 842 F.3d at 1381.

G. Ground 4: Obvious over Stark and Stoffman

Petitioner submits that claims 26, 28, and 31 are unpatentable over Stark in view of Stoffman. Pet. 64.

1. Stoffman (Ex. 1015)

Stoffman is a U.S. Patent titled "Percutaneous Sacroiliac Joint Implant and Methods for Surgically Inserting and Securing the Implant into the Sacroiliac Joint." Ex. 1015, code (54). Stoffman discloses an "implantable device including a tapered body . . . [with first and second] ancillary member[s] operatively arranged to be inserted through" openings. *See id.* at code (57). We reproduce Figure 5 of Stoffman, below:

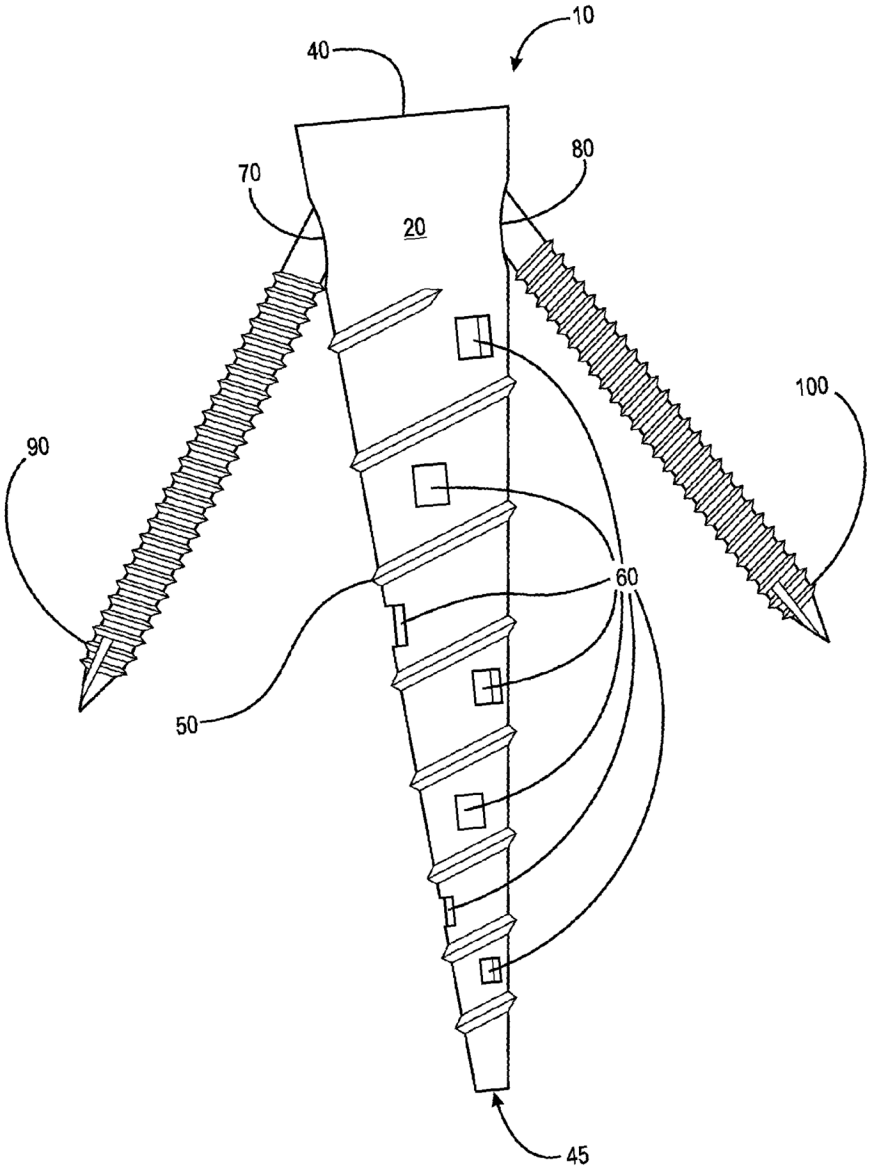

Fig. 5

Figure 5, reproduced above, depicts a front view of Stoffman's invention. Ex. 1015, 4:61. In particular, Figure 5 depicts SI joint fusion device including body 20 with ends 40, 45. *See id.* at 6:61–7:3. First and second ancillary members 90, 100 are arranged to extend through body 20. *Id.* at 6:5–6.

2. Combination of Stark and Stoffman

In presenting this alternative challenge and combining Stark with Stoffman, Petitioner reasons that 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 . . . to reach the same result as that of the Challenged Claims." Pet. 64 (citing Ex. 1002 ¶ 130).

Petitioner submits that Stark "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.'" *Id.* (citing Ex. 1014, 6:46–49). Petitioner cites to Stark's disclosure that "[i]n 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*. (citing Ex. 1014, 6:51–54). Based on these teachings, Petitioner submits that Stark "teaches that a tapered, threaded implant is advantageous for gripping the articular bone surfaces inside the SI Joint." *Id.* at 64–65.

As to Stoffman, Petitioner explains that "Stoffman improves on Stark . . . by adding fixation elements (the ancillary members (90, 100)) to further secure the fusion implant in the SI Joint." *Id.* at 65 (citing Ex. 1015, 6:58–60, 9:35–43).

Based on Stoffman's and Stark's teachings, Petitioner reasons that a skilled artisan would have combined Stoffman's teachings with Stark. *See id.* at 65–66 (citations omitted). Petitioner explains that a skilled artisan would have used the additional fixation elements (i.e., Stoffman's ancillary members 90, 100) with Stark "to further secure the fusion implant in Stark." *Id.* (citing in part Ex. 1002 ¶ 132).

3. Claim 26

a. Elements [pre], [a], [b.1], [b.2], [c], [d.1], and [d.4]

Petitioner cites to its challenge under Ground 3, in which Stark anticipates claim 26, and relies on these same findings in addressing limitations under Ground 4. *See* Pet. 66 ("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.").

Without determining whether the preamble is limiting, Petitioner has demonstrated by a preponderance of the evidence that Stark, as modified based on Stoffman's teachings, satisfy the preamble and limitations [a], [b.1], [b.2], [c], [d.1], and [d.4].

b. [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"

Petitioner submits that Stark, as modified by Stoffman, satisfies the limitations recited in element d.2. *See* Pet. 66–68. Petitioner reasons that "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.* at 68 (citing Ex. 1002 ¶ 135). Dr. Henn testifies that "driving of the ancillary members continues to draw the sacrum and ilium together." Ex. 1002 ¶ 135.

Petitioner has demonstrated by a preponderance of the evidence that Stark, as modified to include Stoffman's ancillary members, satisfies the limitations recited in [d.2].

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

Petitioner cites to the discussion in connection with Ground 3, in which claim 26 is anticipated by Stark. *See* Pet. 68.

In its challenge under Ground 3, Petitioner submits that Stark discloses this element. *See id.* at 61.

Petitioner cites to Stark's disclosure that its "threads of the screw grip the bone on either side of the joint to further the immobilization of the joint." *Id.* (quoting Ex. 1014, 6:46–49).

Petitioner has demonstrated by a preponderance of the evidence that Stark, as modified by Stoffman, satisfies the limitations recited in [d.3].

d. Summary of Claim 26

Petitioner has demonstrated by a preponderance of the evidence that Stark, as modified by Stoffman, renders obvious claim 26.

4. Claim 28

Claim 28 depends from claim 26 and further recites, "wherein driving said fusion implant into said void comprises rotating said fusion implant or a

portion thereof having said at least one fixation element thereon." Ex. 1001, 44:49–52.

Petitioner submits that "Stoffman teaches rotating the portion of the fusion implant having at least one fixation element thereon." Pet. 68. Petitioner explains that "Stoffman teaches driving ancillary members (90, 100) into the sacrum and ilium." *Id.* (citing Ex. 1015, 7:36–54).

Stoffman discloses that its "[f]irst and second ancillary members 90 and 100 are typical screws such as, preferably, a Phillips oval head." Ex. 1015, 7:36–39; *see also id.* at Fig. 6. Based on this teaching, Dr. Henn testifies that 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.

Petitioner has demonstrated by a preponderance of the evidence that Stark, as modified by Stoffman, renders obvious claim 28.

5. 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.

In challenging claim 31, Petitioner relies on the same analysis presented for claim 26. *See* Pet. 69 ("Since the combination of Stark . . . and Stoffman obviates claim 26 as discussed above, claim 31 is also obviated by the same combination of references.").

Petitioner has demonstrated by a preponderance of the evidence that the proposed Stark and Stoffman combination renders obvious claim 31.

6. Summary of Ground 4

Petitioner has demonstrated by a preponderance of the evidence that the proposed combination of Stark and Stoffman renders obvious claims 26, 28, and 31. Patent Owner did not file a response to the Petition and waived any arguments that may have been made. *See* Paper 8, 9; *see also NuVasive*, 842 F.3d at 1381.

H. Ground 5: Obvious over Stark and McCormack

Petitioner submits that claims 26–28 and 31 are unpatentable over Stark in view of McCormack. *See* Pet. 69–70.

Under this challenge, Petitioner submits that a POSITA would have been motivated to combine these references because "[b]oth Stark . . . and McCormack describe the importance of securing the fusion implant inside the SI Joint to promote distraction and fusion." Pet. 70.

As explained under Ground 1, McCormack focuses on the facet joint, rather than teaching distracting or fusing the *SI Joint*. *See supra* § II.D. Similarly, we disagree with Petitioner's assertion that "McCormack describe[s] the importance of securing the fusion implant inside the SI Joint to promote distraction and fusion." Pet. 70. For this reason, Petitioner has not articulated sufficient reasoning for combining the references.

Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that Stark in view of McCormack renders claims 26–28 and 31 obvious.

I. Ground 6: Obvious over Vestgaarden and McCormack

Petitioner submits that claims 26–28 and 31 are unpatentable over Vestgaarden in view of McCormack. *See* Pet. 73–75.

Under this challenge, Petitioner reasons that

> [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 . . . to reach the same result as that of the Challenged Claims. First, Vestgaarden . . . , which is directed to SI Joint fusion and entitled "Method for Deploying a Fusion Device for Sacroiliac Joint Fusion," incorporates by reference Vestgaarden . . . , which is directed to spinal facet fusion and entitled "Method and Apparatus for Spinal Facet Fusion." Thus, a POSITA familiar with Vestgaarden . . . would find it obvious, and would be motivated, to consider art from spinal facet fusion, such as McCormack. . . .

Pet. 73–74 (citing Ex. 1002 ¶ 153).

Petitioner further reasons,

> [s]econd, Vestgaarden . . . and McCormack both teach posterior methods of fusing the articular surfaces of spinal bone structures. . . . Vestgaarden . . . , by incorporation of Vestgaarden . . . , teaches a fusion implant having surface barbs to prevent retraction of the implant from the facet joint. . . . To improve this anti-retraction feature, it would be well within the s[k]ill of a POSITA to use the fusion implants from McCormack in the SI Joint fusion system and method of Vestgaarden . . . . McCormack provides a variety of embodiments to do so. . . . A POSITA would be motivated to make this combination to achieve the improved result delivered by the combination of Vestgaarden . . . and McCormack. . . .
>
> The combination of incorporating McCormack into Vestgaarden . . . would have been well within a POSITA's ability at the time of the alleged invention of the challenged claims. . . . 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. . . . Again, this is demonstrated by Vestgaarden . . . incorporating by reference the implants in Vestgaarden . . . .
>
> Fusion implants having surface anti-migration features were well known in the art at the time of the alleged 539 Patent invention. . . . The combination of McCormack and Vestgaarden . . . would have led a POSITA to a predictable result, namely, better securement of the fusion implant inside the SI Joint. . . .
>
> Finally, adding McCormack to Vestgaarden . . . would have been an obvious design choice since McCormack teaches to do so. The surgical procedures described in McCormack and Vestgaarden . . . are highly similar, which is unsurprising since the both are directed to a posterior approach for fusing articular surfaces of a spinal joint. . . . 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 . . . .

Pet. 74–75 (emphases added).

We are not persuaded by Petitioner's analysis.

Neither Petitioner nor Dr. Henn sufficiently explains how Vestgaarden and McCormack are being combined. We do not see how McCormack's teaching of a triangular-shaped implant 458 (Ex. 1012, Figs. 63A, 63B) would have led a skilled artisan to modify Stark's screw 112 (Ex. 1014, Fig. 3). We do not see how the modification would have satisfied the claim limitations. Petitioner's general statements regarding obvious design choice (Pet. 73–75) are not enough.

Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that Vestgaarden in view of McCormack renders claims 26–28 and 31 obvious.

III. REVISED MOTION TO AMEND[4]

As discussed above, Patent Owner filed a contingent Revised Motion to Amend, presenting substitute claims 32–35 ("the Substitute Claims"). RMTA; *see also* Paper 9, 1 (explaining in the initial Motion to Amend that the new claims replace the Challenged Claims on a contingent basis). Because we conclude that Petitioner shows, by a preponderance of the evidence, that each of challenged claims 26–28 and 31 is unpatentable, we consider Patent Owner's Revised Motion to Amend with respect to the Substitute Claims.

"Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121." *See Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Patent Owner bears the burden of persuasion to show, by a preponderance of the evidence, that the motion to amend complies with these requirements. 37 C.F.R. § 42.121(d)(1). Specifically, a patent owner must provide a claim listing reproducing each proposed substitute claim, and must make an initial showing to demonstrate the following: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial; and (3) the amendment does not seek to enlarge the

[4] In opposing Patent Owner's Revised Motion to Amend, Petitioner refers to the Board's Preliminary Guidance as well as its initial Opposition to Patent Owner's first Motion to Amend. *See, e.g.*, RMTA Opp. 11–25. Throughout this Decision, we refer to our initial Preliminary Guidance (Paper 16) as well as arguments made by Petitioner in the original Opposition (Paper 13).

scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

As also provided under our Rules, a petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claim is unpatentable. 37 C.F.R. § 42.121(d)(2).

As explained below, Patent Owner has met its burden of persuasion to show that the amendments comply with the requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. As also explained below, however, Petitioner has demonstrated by a preponderance of the evidence that each of the Substitute Claims is unpatentable over the prior art under 35 U.S.C. §§ 102, 103(a).

A. Proposed Substitute Claims

Patent Owner proposes to amend the '539 patent by adding new claims 32–35 as respective substitutes for original claims 26–28 and 31. *See* RMTA 1; *see also* App. A (Ex. 2004). Claim 32 is proposed as a substitute for original claim 26 and is reproduced below:[5]

> [~~26.~~32.] 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. inserting a working channel into ~~said~~the incision and spreading ~~said~~the posterior portion of the sacroiliac joint with an inserted end of ~~said~~the working channel;

[5] Underlined language reflects subject matter added to original claims 26–28 and 31, and strike-through indicates deletion. Claims 32–35 correspond to original claims 26–28 and 31, respectively.

c. creating a void in ~~said~~the posterior portion of the sacroiliac joint; ~~and~~

d. inserting a single fusion implant into ~~said~~the void along a path that is substantially parallel to articular surfaces of the sacroiliac joint~~, said~~ and no further implants, fusion devices, or implant components are introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant; and

e. rotating the fusion implant or a portion thereof in the void, the single fusion implant having at least one fixation element ~~for engagement with~~that penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum in ~~said sacroiliac joint~~the sacroiliac joint as the fusion implant or a portion thereof is rotated thereby fixing the ilium and sacrum in relative lateral positions and the fusion implant in the sacroiliac joint.

RMTA 27–28.

Claim 33 is proposed as a substitute for original claim 27 and is reproduced below:

~~27.~~ 33. The method of claim ~~26~~32, ~~further comprising driving said fusion implant into said void with an impactor,~~ wherein ~~driving said fusion implant engages said~~the at least one fixation element includes a plurality of flukes, claws, or hooks that penetrate and embed in the cancellous bone tissue of articular surfaces of the ilium and sacrum and pull the sacrum and ilium together as the single fusion implant is rotated, thereby ~~with~~ compressing the sacroiliac joint and securing the single fusion implant in the sacroiliac joint~~said bone tissue~~.

RMTA 28.

Claim 34 is proposed as a substitute for original claim 28 and is reproduced below:

~~28.~~34. The method of claim ~~26~~32, wherein said at least one fixation element includes a first fixation element having a first cutting edge at a distal end thereof and a second fixation

> element having a second cutting edge at a distal end thereof, wherein said step of inserting said single fusion implant into the void includes positioning said first cutting edge in proximity to an articular surface of said ilium and positioning said second cutting edge in proximity to an articular surface of said sacrum and said step of ~~driving said fusion implant into said void comprises~~ rotating ~~said~~the single fusion implant or a portion thereof draws the articular surfaces of the sacroiliac joint together to compress the sacroiliac joint and secure the fusion implant in the sacroiliac joint~~having said at least one fixation element thereon.~~

RMTA 28.

Claim 35 is proposed as a substitute for original claim 31 and is reproduced below:

> ~~31.~~35. The method of claim ~~26~~ 32 wherein ~~said~~the working channel includes ~~at least one tang~~two tangs protruding from a distal end of the working channel for securing a position of ~~said~~the working channel in ~~said sacroiliac joint~~the sacroiliac joint, the working channel has an oblong cross-sectional shape, and the tangs are positioned on opposite sides of the longest cross-sectional diameter of the working channel.

RMTA 28.

B. Requirements for Amendment

As explained below, Patent Owner has shown that proposed substitute claims 32–35 meet the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

1. Reasonable Number of Substitute Claims

A motion to amend must "propose a reasonable number of substitute claims." 35 U.S.C. § 316(d)(1)(B); *see also* 37 C.F.R. § 42.121(a)(3) ("A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims."). "There is a rebuttable presumption that a

reasonable number of substitute claims per challenged claim is one (1) substitute claim." *Lectrosonics*, Paper 15 at 4; *see also* 37 C.F.R. § 42.121(a)(3). Here, Patent Owner proposes no more than one substitute claim for each challenged claim. App. A; *see also supra* § III.A. Petitioner does not contend that the number of substitute claims is unreasonable. *See generally* RMTA Opp.

Thus, this requirement is met.

2. Responsive to Ground of Unpatentability

"A motion to amend may be denied where. . . [t]he amendment does not respond to a ground of unpatentability involved in the trial." 37 C.F.R. § 42.121(a)(2)(i). The Petition asserts that claims 26–28 and 31 are unpatentable over prior art. Pet. 8. As shown above, through the Revised Motion to Amend, Patent Owner has sought to change the substantive features of challenged independent claim 26. *See* RMTA 27–28. The proposed amendments to the other challenged dependent claims make them depend, directly or indirectly, on the proposed substitute independent claims. *Id.* Petitioner does not contend that the proposed amendments fail to respond to a ground of unpatentability in this trial. *See generally* RMTA Opp.

Thus, this requirement is met.

3. Enlarge Scope

An amendment may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). Patent Owner asserts that the Substitute Claims (claims 32–35) do not enlarge the scope, but rather narrow the scope of claims 26–28 and 31. RMTA 2.

Petitioner does not contend that any proposed substitute claim enlarges the scope of any challenged patent claim. *See generally* RMTA Opp.

Thus, this requirement is met.

4. New Matter

An amendment may not introduce new matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). New subject matter is any addition to the claims that lacks sufficient support in the subject patent's original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When [an] applicant adds a claim . . . , the new claim[] . . . must find support in the original specification."). Patent Owner also is required to show written description support in "the original disclosure of the patent for each claim that is . . . amended," and in "an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought." 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2).

Petitioner argues that Patent Owner has failed to sufficiently identify written description support for the Substitute Claims. *See* RMTA Opp. 1–5. We address Petitioner's arguments in the order presented.

a. "inserting . . . along a path that is substantially parallel to articular surfaces of the sacroiliac joint"

Petitioner asserts that "inserting a single fusion implant into the void along a path that is substantially parallel to articular surfaces of the sacroiliac joint" specifies a direction during insertion of the implant, but the term "parallel" describes an "orientation of the implant after it is

positioned." RMTA Opp. 2. According to Petitioner, there is no support for the "inserting" action. *Id.* at 2–3.

We disagree.

Patent Owner relies, in part, on the following disclosure: "the body 801 may be roughly parallel to or aligned with the plane of the SI joint between the articular surfaces when the fusion implant 800 is inserted into the SI joint." RMTA 5 (quoting Ex. 1001, 29:61–65). Based on this and other disclosure cited by Patent Owner, we find that the limitation "inserting a single fusion implant into the void along a path that is substantially parallel to articular surfaces of the sacroiliac joint" has adequate written description support. Petitioner's argument otherwise is not persuasive.

b. "flukes, claws, or hooks that . . . pull the sacrum and ilium together . . . thereby compressing the sacroiliac joint" and "the step of rotating . . . draws the articular surfaces of the sacroiliac joint together to compress the sacroiliac joint"

Petitioner also asserts that "none of the cited passages mentions anything pertaining to pulling the ilium and sacrum together thereby compressing the SI joint," or rotating "to compress the SI joint" RMTA Opp. 3.

We disagree.

Patent Owner cites, *inter alia*, the '539 patent's description that "[a]s 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." RMTA 8 (citing Ex. 1001, 25:16–23) (emphasis added). This provides adequate written description support for these limitations.

c. "embed"

Petitioner asserts that "Patent Owner introduced a new term 'embed' into substitute claims 32 and 33." RMTA Opp. 11. Although Petitioner does not assert that "embed" introduces new matter, because the term "embed" is not found in the '539 patent, we review the Revised Motion to Amend to determine whether embed is consistent with the parties' definition of this term, i.e., "to be or become fixed or incorporated, as into a surrounding mass." *See supra* § II.B.2 (construing the term "embed").

Patent Owner relies on several sections of the '539 patent to provide support for "embed." RMTA 5–6. Notably, the '539 patent describes, "hooks to engage (hook into) the tissue in the SI joint as the central axle is rotated," and that flukes "may provide additional bite and purchase into the bone tissue," and further that "[t]he hooking edges may facilitate penetration of the flukes into the bone tissue (e.g., cortical and/or cancellous/spongy bone tissue) of the articular surfaces of the ilium and sacrum when the central axle is rotated." Ex. 1001, 30:18–34. Because the '539 patent discloses fixation devices, including hooks and flukes that "engage (hook into) the tissue" that "provide additional bite and purchase into the bone tissue," and "facilitate penetration of the flukes into the bone tissue," we agree with Patent Owner that there is support for the term "embed" that is consistent with the parties' definition of "to be or become fixed or incorporated, as into a surrounding mass." RMTA Reply 7.

d. Written Description Support Summary

Having considered Petitioner's contrary position, we find Patent Owner has sufficiently set forth adequate written description support for proposed substitute claims 32–35 in the '539 patent. Petitioner notes that 37

C.F.R. § 42.121(b)(1) provides that the motion to amend must set forth "support in the original disclosure of the patent," which is the disclosure in U.S. Application No. 14/668,982 ("the '982 Application") (RMTA Opp. 2), whereas Patent Owner only cites to the '539 Patent. RMTA 4–10. Because our review of the '982 Application does not discern any distinction from the disclosure of the '539 patent, as noted in the Preliminary Guidance, we view this omission as harmless error. Patent Owner's omission does not prevent Petitioner from understanding Patent Owner's position or the Board from discerning whether sufficient written description support exists.

For these reasons, we determine that each proposed substitute claim is supported by the '539 patent and does not introduce new matter.

C. Indefinite

Patent Owner met its burden of persuasion to show that the amendments comply with the requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

The burden of persuasion now lies with Petitioner to show, by a preponderance of the evidence, that any proposed substitute claim is unpatentable. 37 C.F.R. § 42.121(d)(2).

The Supreme Court interprets the definiteness requirement of 35 U.S.C. § 112(b) "to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instr., Inc.*, 134 S. Ct. 2120, 2129 (2014). "The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *Interval Licensing, LLC v. AOL,*

Inc., 766 F.3d 1364, 1371 (Fed. Cir. 2014) (emphasis added). That is, "the dispositive question in an indefiniteness inquiry is whether the 'claims,' not particular claim terms" satisfy the definiteness standard. *Cox Commc'ns, Inc. v. Sprint Commc'n Co.*, 838 F.3d 1224, 1231 (Fed. Cir. 2016).

Petitioner argues that the claims are indefinite, presenting three sub-arguments addressing: (1) the term "the bone tissue"; (2) the term "a portion thereof"; and (3) supposed lack of antecedent basis and supposed use of inconsistent terminology. *See* RMTA Opp. 5–11. We address each of these sub-arguments in turn.

1. "the bone tissue"

Petitioner contends that "the lack of antecedent basis with respect to the limitations 'the bone tissue' and 'the cancellous bone tissue' materially obfuscates the scope of claim 32." RMTA Opp. 6. According to Petitioner, the lack of antecedence leads to two interpretations: (1) that both phrases have identical scope; and (2) that "cancellous tissue" is limited to that tissue, whereas "bone tissue" is "*any* bone tissue." *Id.*

We do not believe the meaning of these terms is unclear.

Independent claim 32 recites, "the fusion implant having at least one fixation element that penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum." App. A, 3. The term "cancellous bone tissue" is in dependent claim 33, which recites, "the at least one fixation element includes a plurality of flukes, claws, or hooks that penetrate and embed in the cancellous bone tissue of articular surfaces of the ilium and sacrum." *Id.* at 5.

As Patent Owner correctly notes, a person of ordinary skill in the art would know that "the articular surfaces of the ilium and sacrum necessarily

have both bone tissue generally and cancellous bone tissue deep to the superficial cortical bone tissue." RMTA Reply 6. Indeed, the '539 patent discloses "penetrat[ing] the bone tissue (e.g., cortical and/or cancellous/spongy bone tissue) of the articular surface." Ex. 1001, 26:21–23. Given the known difference in density and hardness of cortical and cancellous tissue, and that a POSITA would "have at least had knowledge of spinal joint fusion implants, surgical instruments for spinal fusion surgeries, and the application of fusion implants in spinal fusion procedures and/or sacroiliac fusion procedures" (*see supra* § II.A), a skilled artisan would know with reasonable certainty the particular tissue the claims refer to. Thus, when read in light of the specification, reference to "the bone tissue" in claim 32 and "the cancellous bone tissue" in claim 33 is not unclear, because an ordinary artisan would know that claim 32 refers to cortical and/or cancellous bone tissue, whereas dependent claim 33 refers to only cancellous bone tissue.

2. "a portion thereof"

Petitioner points out that claim 32 recites, "rotating the fusion implant or *a portion thereof*" and "the fusion implant or *a portion thereof* is rotated." RMTA Opp. 8 (citing RMTA 26) (emphasis replaced). Petitioner contends that the article "a" is unclear, as it is not clear "whether both instances refer to the same portion of the implant or two different portions." *See id.*

> We disagree. In full context, the claim limitation recites,
>
> *rotating the single fusion implant or a portion thereof* in the void, the fusion implant having at least one fixation element that penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum in the sacroiliac joint *as the fusion implant or a portion thereof is rotated*

> thereby fixing the ilium and sacrum in relative lateral positions and the fusion implant in the sacroiliac joint.

App. A 3 (emphasis added). To paraphrase, the claim recites, "rotating the single fusion implant or a portion thereof . . . as the fusion implant or a portion thereof is rotated." *Id.*

An ordinary artisan would know with reasonable certainty that the second recitation of "a portion thereof" is clearly in reference to the first recitation of "a portion thereof."

The limitation is sufficiently clear.

3. Antecedent Basis and Inconsistent Terminology

Third, Petitioner asserts the claims are indefinite because "the lack of proper antecedent basis for multiple limitations and inconsistent usage of various claim terms result in incoherent claims that do not reasonably inform a POSA as to their scope." RMTA Opp. 11.

We are not persuaded, as it is not clear to us what Petitioner argues, and we perceive no apparent indefiniteness issues on the face of the Substitute Claims.

The Patent Rules require more substantive arguments than a naked assertion that a claim is indefinite. 37 C.F.R. § 42.22. We find that Petitioner's conclusory statement does not point out, with any specificity, missing limitations or improper antecedence not already addressed. We agree with Patent Owner that Petitioner has not established indefiniteness because the terms discussed "would cause no confusion to a POSITA." *See* RMTA Reply 7.

4. Summary of Indefiniteness Arguments

Petitioner fails to demonstrate by a preponderance of the evidence that any of claims 32–35 is indefinite.

D. Unpatentable Over the Prior Art

Petitioner contends that the Substitute Claims are unpatentable based on the following grounds (RMTA Opp.):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
32[6]	102	Stark
32–34	103(a)	Lieberman,[7] Stark
32	102	Vestgaarden
32	103(a)	Vestgaarden
32, 34, 35	103(a)	Vestgaarden, Vishnubholta[8]
32, 34	103(a)	Stark, Stoffman

1. Anticipated by Stark

Petitioner submits that claim 32 is anticipated by Stark. RMTA Opp. 11; *see also supra* n.5.

[6] Although the heading of the challenge also lists claim 35 as anticipated by Stark, we understand this to be a typographical error, as Petitioner does not substantively address claim 35 in its argument (*see* RMTA Opp. 11–13) and Petitioner does not list claim 35 as anticipated by Stark in its Sur-Reply to the Revised Motion to Amend (*see* RMTA Sur-reply 9–10).
[7] U.S. Patent Number 6,468,309 B1, issued Oct. 22, 2002 (Ex. 1020, "Lieberman").
[8] U.S. Patent Number 8,979,933 B2, issued Mar. 17, 2015 (Ex. 1025, "Vishnubholta").

Claim 32 was amended from original claim 26, which is anticipated by Stark. *See supra* § II.F.2; *see also* App. A, 1–5. Claim 32 differs from claim 26 in that claim 32 recites, *inter alia*,

> rotating the single fusion implant or a portion thereof in the void, the fusion implant having at least one *fixation element that penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum* in the sacroiliac joint as the fusion implant or a portion thereof is rotated thereby.

See RMTA 27–28 (emphasis added).

Patent Owner argues that Stark's "fixation elements" do not "embed" in the bone tissue, as required by claim 32. *See* RMTA 12 ("Stark []does not disclose penetrating and *embedding* in the bone tissue, as recited in Revised Replacement Claim 32."). Patent Owner explains that "[t]he threading of [Stark's] screw may establish some purchase in the bone tissue, but only in a superficial manner in the cortical bone tissue without embedding itself in the bone." *Id.* Patent Owner acknowledges that Stark discloses self-tapping screws, but contends that Stark "does not provide such an example or suggest[ion] that such self-tapping screws when inserted parallel to the articular surfaces of the SI Joint would embed in the bone tissue." *Id.* at 13 (citing in part Ex. 2001 ¶ 37). Patent Owner's expert, Dr. Zaporojan, testifies that "Stark [] fails to disclose . . . at least one fixation element that penetrates bone tissue in an articular surface . . . in the sacroiliac joint." Ex. 2001 ¶ 37.

Petitioner contends that Patent Owner's argument is contradicted by its own expert's testimony. *See* RMTA Opp. 12 (citing Ex. 1021, 98:8–10, 105:15–16, 107:10–15).

We agree with Petitioner. Stark's self-tapping screws satisfy the limitation. *Id.* at 11–12.

Stark discloses "immobilization of the SI joint 104 using a simple screw 112. The screw 112 is inserted into the SI joint 104 between the sacrum 100 and the ilium 102." Ex. 1014, 8:14–17. Stark also discloses that "threads of the screw grip the bone on either side of the joint to further the immobilization of the joint," and that "[a] self-tapping screw with one or more flutes or the like can be used." *Id.* at 6:42–56.

To further illustrate, we reproduce Figure 26 of Stark, below:

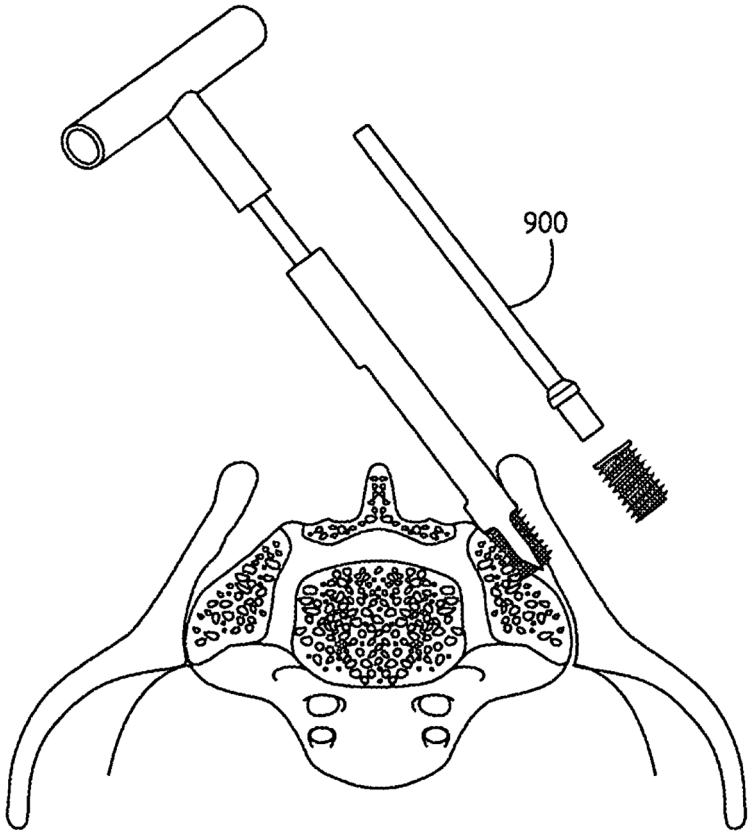

FIG. 26

Figure 26 depicts "an inserter being used to implant the immobilization element into the sacroiliac joint." Ex. 1014, 3:31–32. As mentioned above,

Stark discloses that a "self-tapping screw with one or more flutes or the like can be used." *Id.* at 6:54–56; *see also id.* at 7:43–45 (describing self-tapping screws).

Stark's disclosure of self-tapping screws and Figure 26 depicting a screw penetrating and embedding in bone tissue supports Petitioner's position. Furthermore, because Stark discloses that using various types of "thread can improve the gripping while providing for effective implantation of the screw" (Ex. 1014, 6:50–51), an ordinary artisan would also understand that gripping the bone to provide effective implantation of the screw includes penetration and embedding into the bone.

Finally, we agree with Petitioner that the testimony of Patent Owner's expert, Dr. Zaporojan, supports Petitioner's position that Stark's self-tapping screw penetrates the bone tissue. *See, e.g.*, Ex. 1021, 107:13–15 ("Q. And [Stark's self-tapping] screws would penetrate the bone, correct? A. Those would penetrate into the bone, yeah") (emphasis omitted). Dr. Zaporojan's cross-examination testimony contradicts Patent Owner's argument in the RMTA that Stark's self-tapping screws do not "embed" into the bone tissue as recited in claim 32.

Accordingly, Petitioner has shown, by a preponderance of the evidence, that claim 32 is anticipated by Stark.

2. Obvious Over Lieberman and Stark

Petitioner contends that claims 32–34 would have been obvious over Lieberman in view of Stark. RMTA Opp. 13.

a. Lieberman (Ex. 1020)

Lieberman is a U.S. Patent titled "Method and Apparatus for Stabilizing Adjacent Bones." Ex. 1020, code (54). We reproduce Figure 1 of Lieberman, below:

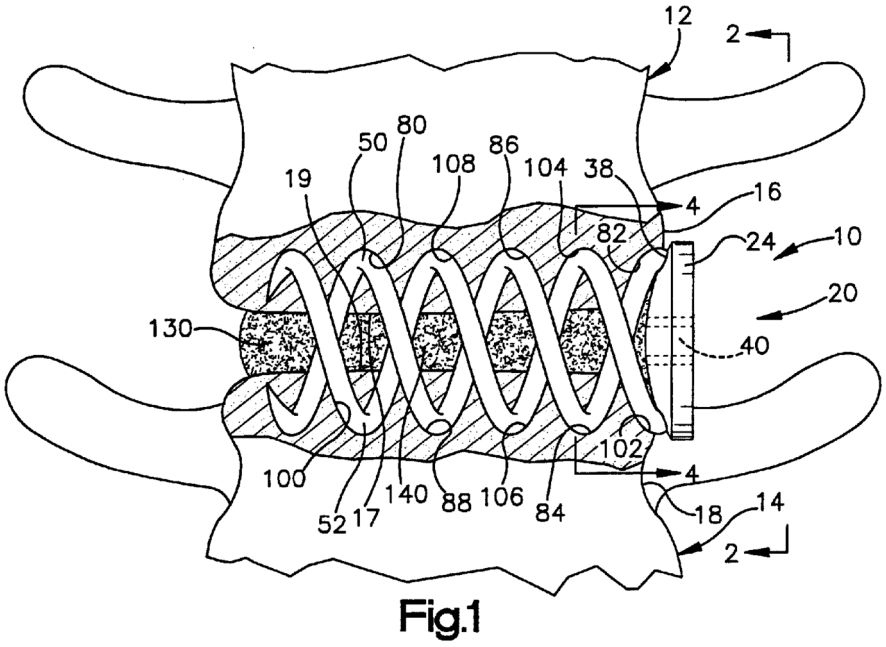

Fig.1

Figure 1 "is a schematic anterior view of an apparatus implanted in an adjacent pair of vertebral bodies." Ex. 1020, 2:57–59. Lieberman describes apparatus 10 implanted into an adjacent pair of lumbar vertebrae 12, 14. *Id.* at 3:17–18. Apparatus 10 includes interbody stabilizer 20 including platform 24 with axial passage 40. *See id.* at 3:39–40. First spike 50 and second spike 52, which resemble a pair of intertwined corkscrews, project from end surface 38 of platform 24. *See id.* at 3:43–45.

Lieberman also discloses a method for fusing the vertebral bodies together, including the steps of: removing disc material disposed between the vertebral bodies to create an interbody space and inserting the interbody stabilizer into that space. *See id.* at 2:25–33. Lieberman discloses that its

interbody spacer can be inserted in an open surgical procedure or endoscopically with a typical cannula. *See id.* at 3:54–56, 3:61–62.

b. Petitioner's Challenge

Petitioner asserts that "Lieberman discloses that the implant has 'at least one helical spike for embedding into each of the adjacent pair of vertebral bodies upon rotation of the platform to attach the at least one helical spike to each of the vertebral bodies and thus fasten (pin) the vertebral bodies together.'" Opp. 15 (citing Ex. 1020, 2:3–7) (emphasis omitted). Based on this disclosure, Petitioner submits that

> Lieberman teaches an implant having fixation elements (helical spikes) configured to penetrate bone tissue when the implant is rotated, thereby stabilizing the adjacent bones (fixing their relative positions) and fastening/pinning the articular surfaces of the joint together (i.e., pulling the articular surfaces together, thereby compressing the joint).

Id. (emphasis omitted).

Petitioner points out that Lieberman teaches that its implant can be implanted endoscopically through a cannula into a void formed in the joint, but acknowledges that Lieberman "does not provide specific details regarding the insertion method and associated surgical tools." Opp. 16 (citing Ex. 1020, 3:54–56, 5:8–20).

To address these shortcomings, Petitioner relies on Stark. *See id.* Petitioner finds that Stark "discloses a method and tools for creating a void within an SI joint and inserting an implant through a cannula." *Id.* (citing Ex. 1014, code (57)).

In combining Lieberman with Stark, Petitioner reasons that "a POSA had a good reason for combining the implant disclosed in Lieberman with

the method and tools for immobilizing an SI joint disclosed in Stark II and would have had a reasonable expectation of success of this combination." *Id.*

c. Claim 32

Claim 32 is amended from claim 26 and further recites, *inter alia*, "at least one fixation element . . . penetrates and *embeds* in the bone tissue." RMTA 28 (emphasis replaced). According to Petitioner, "Lieberman expressly teaches this limitation by describing an implant having 'at least one helical spike for embedding into each of the adjacent pair of [bones] upon rotation.'" RMTA Opp. 13 (citing Ex. 1020, 2:3–7) (emphasis omitted).

We agree with Petitioner, as Lieberman discloses that its apparatus includes "at least one helical spike for embedding into each of the adjacent pair of vertebral bodies upon rotation of the platform to attach the at least one helical spike to each of the vertebral bodies and thus fasten (pin) the vertebral bodies together." Ex. 1020, 2:3–7. We also find that the articulated combination of Lieberman and Stark teaches or suggests all of the limitations of claim 32.

Patent Owner presents several arguments in contesting the challenge under Lieberman and Stark.

First, Patent Owner argues that "Petitioner has not articulated a rationale for combining the implant of Lieberman with the methods and instruments of Stark." RMTA Reply 9; *see also* RMTA 16 ("the proposed combination of the implant of Lieberman with the method of Stark . . . is a product of hindsight bias"). Patent Owner submits that Petitioner fails to provide a reason for combining the references. *See* RMTA Reply 9

("Petitioner's arguments rest on an assumption that a POSITA would be motivated to make such a combination without providing a reason as to why.").

We determine that Petitioner has articulated a sufficient rationale for this prior art combination. Thus, Patent Owner's first argument is not persuasive.

In combining Lieberman with Stark, Petitioner relies on Lieberman's *device* and on Stark's disclosure of the surgical *steps* recited in claim 32. *See* RMTA Sur-reply 10 ("Lieberman teaches an implant for 'stabiliz[ing] other adjacent bones,' but does not teach surgical tools or the complete implantation procedure"); *see also* Opp. 16 (explaining the proposed combination of Stark and Lieberman). These steps include, *inter alia*, "creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint . . . ," "inserting a working channel into the incision . . . ," "creating a void . . . ," "inserting a single fusion implant into the void . . . ," and "rotating the fusion implant . . . ." *See* RMTA 27–28. As discussed above, Stark discloses these steps. *See supra* § III.D.1. Stark provides express disclosure for surgical steps that Lieberman itself suggests, but does not expressly disclose.

Indeed, Lieberman expressly suggests that its device can be deployed to the sacroiliac joint. That is, Lieberman discloses that its "method and apparatus . . . could be used to attach and stabilize other adjacent bones, not just bones in the spine or pelvis." Ex. 1020, 9:39–42. This disclosure suggests the step of "creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint," as the sacroiliac joint connects the spine to the pelvis. *See, e.g.*, Ex. 1001, 1:21–23 ("The sacroiliac joint is

located in the lower back at the juncture of the ilium, the upper bone of the pelvis, and the sacrum at the base of the spine.").

Additionally, Lieberman discloses that its surgical method may be used in "open surgical procedure[s]" or less-invasive procedures with the use of a "typical cannula." Ex. 1020, 3:54–62. This disclosure teaches the step of "inserting a working channel into an incision."

Furthermore, Lieberman discloses that

> [t]he method comprises the step of removing disc material disposed between the vertebral bodies to create an interbody space and the step of providing an interbody stabilizer for insertion into the interbody space by implanting the interbody stabilizer into both of the adjacent pair of vertebral bodies.

Id. at 2:28–34. By "removing disc material disposed between the vertebral bodies to create an interbody space" and "insert[ing] into the interbody space by implanting the interbody stabilizer," Lieberman also suggests, without expressly disclosing, the step of "creating a void in the posterior portion of the sacroiliac joint" and "inserting a single fusion implant into the void," as also required by claim 32. RMTA 27.

Lieberman's disclosure focuses on the structure of its interbody implant, whereas Stark provides a detailed explanation of the surgical steps performed during fusion of the sacroiliac joint. We agree with Petitioner that a skilled artisan would have been motivated to deploy Lieberman's implant to fuse the sacroiliac joint using the surgical methods disclosed in Stark. *See* Opp. 16. In particular, we agree with Petitioner that "Lieberman's implant and Stark's surgical tools would have predictably performed their known and intended functions, and [a] POSA would have had a reasonable expectation of success of achieving joint fusion—which is the common objective of both Lieberman and Stark." RMTA Opp. 17.

We are unaware of any reason why Lieberman's implant could not be deployed in a sacroiliac joint using Stark's method, or that the insertion would be unpredictable. The Supreme Court has repeatedly held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 415–416. In addition, the teaching of prior art is not limited to particular examples, but rather extends to all that is disclosed, and is good for all that it would have fairly "suggested to one of ordinary skill in the art at the time [of] the invention." *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (internal citation omitted); *see also In re Fracalossi*, 681 F.2d 792, 794 n.1 (CCPA 1982) (holding that a prior art's disclosure is not limited to its examples); *see also In re Boe*, 355 F.2d 961, 965 (CCPA 1966) (explaining that all of the disclosures in a prior art reference "must be evaluated for what they fairly teach one of ordinary skill in the art").

Second, Patent Owner argues that "the implant of Lieberman is not particularly compatible with the objectives and method of Stark . . ., as it cannot distract the SI joint." RMTA 15. Patent Owner explains that "Lieberman would compress the SI Joint" and "compression of the SI Joint is at odds with the method and purpose of Stark." RMTA Reply 10. Patent Owner explains that the proposed modification would render Stark unsatisfactory for its intended purpose, because the modification "would defeat the stated purpose of distracting the SI Joint." *See id.* (citing MPEP § 2143.01(V) (citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984))).

As to Patent Owner's second argument that Stark's "intended purpose" is "distraction," whereas Lieberman's purpose is "compression," and that the proposed combination would "defeat the stated purpose of

distracting the SI joint" (*see* RMTA Reply 10), we disagree. Patent Owner's argument is premised on a false dichotomy that distracting the space within a joint to deploy an implant conflicts with an implant that, once deployed, pulls adjacent bones together. *See id.* Patent Owner's assumption is unsupported and, in fact, contrary to the evidence of record.

For example, Vishnubholta (Ex. 1025) teaches an implant in which the endplates of adjacent bones are "pull[ed] . . . together" after deployment (Ex. 1025, 6:37–38), while also teaching that the joint space is "distract[ed]" during insertion (*see id.* at 6:3–5). Indeed, upon reviewing the record, we understand that the space in which the implant is deployed is "distract[ed]" to accept insertion of the implant, even if the implant, once inserted, ultimately "compresses" or "pulls . . . together" adjacent bones. *Id.* at 6:3–5, 6:37–38. As taught by the cited art, the steps are not mutually exclusive and Patent Owner's attempt to draw a distinction between Stark's step of distraction and the implant of Lieberman is without merit.

We also disagree with Patent Owner's suggestion that the intended purpose of Stark's invention is "distraction," whereas Lieberman's intended purpose is "compression." *See* RMTA Reply 10. Rather, Stark and Lieberman share the same purpose of fusing the joint between the spine and pelvis. *See, e.g.*, Ex. 1014, 1:6–8; *see also, e.g.*, Ex. 1020, code (54), 9:40–42.

Finally, we respectfully disagree with our colleague's dissenting opinion. We appreciate the thoughtful analysis provided in the dissent, but note that Patent Owner did not present arguments corresponding to much of the dissent's analysis. For example, Patent Owner did not dispute Petitioner's argument that Lieberman's implant can be used to stabilize the

sacroiliac joint. *See* RMTA Reply 9–10. As another example, Patent Owner did not argue that bones "in the spine or pelvis" (Ex. 1020, 9:39–42) refers to the *symphysis pubis* joint, and not the sacroiliac joint (*see generally* RMTA Reply 9–10). Patent Owner was on notice that any argument not raised may be deemed waived. *Cf.* Paper 8, 9; *cf. NuVasive*, 842 F.3d at 1381.

We appreciate that Petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claim is unpatentable. 37 C.F.R. § 42.121(d)(2). Here, Petitioner has met that burden by pointing to the teaching in Lieberman and arguing that it reasonably suggests the use of the implant in the sacroiliac joint. Patent Owner did not dispute this point. Therefore, we respectfully disagree with our colleague's dissenting opinion and find that Lieberman's teaching of stabilizing bones "in the spine or pelvis" (Ex. 1020, 9:40–42) would have led a skilled artisan to consider Lieberman in the fusion of a sacroiliac joint, which is the joint that connects the spine to the pelvis (*see, e.g.*, Ex. 1001, 1:21–23).

Accordingly, Petitioner has shown, by a preponderance of the evidence, that the limitations of proposed substitute claim 32 would have been obvious over the teachings of Lieberman and Stark.

d. Claim 33

Claim 33 is amended from claim 27 and further recites, *inter alia*,

> at least one fixation element includes a *plurality of flukes, claws, or hooks* that penetrate and embed in the cancellous bone tissue of articular surfaces of the ilium and sacrum and pull the sacrum and ilium together as the single fusion implant is

> rotated, thereby with compressing the sacroiliac joint and securing the single fusion implant in the sacroiliac joint.

RMTA 28 (emphasis added); *see also* App. A, 5 (providing clean listing of claim 33).

According to Petitioner, "Lieberman discloses that as the implant is rotated within a joint, 'the tip portion 58 of the first helical spike 50 penetrates the cancellous bone,'" thereby meeting the limitations recited in claim 33. RMTA Opp. 14 (citing Ex. 1020, 5:51–52) (emphasis omitted).

Patent Owner does not contest Petitioner's challenge of claim 33 apart from its general contentions addressing the combination of Lieberman and Stark (*see* RMTA 14–16; *see also* RMTA Reply 9–10), which we find unavailing for the reasons set forth above.

We agree with Petitioner.

Lieberman discloses that

> [a]s the interbody stabilizer 20 is rotated, the tip portion 58 of the first helical spike 50 penetrates the cancellous bone in the vertebrae 12 and cuts a first helical segment 82 of a first tunnel 80 (FIG. 1) in the vertebrae 12. Simultaneously, the tip portion 58 of the second helical spike 52 penetrates the cancellous bone of the vertebrae 14 and cuts a first helical segment 102 of a second tunnel 100 in the vertebrae 14.

Ex. 1020, 5:51–57; *see also id.* at Fig. 1 (depicting cork-screw like helical spikes 50 within the bone of two adjacent vertebral bodies). This disclosure satisfies the additional limitations of claim 33.

Accordingly, Petitioner has shown, by a preponderance of the evidence, that the limitations of proposed substitute claim 33 would have been obvious over Lieberman and Stark.

e. Claim 34

Claim 34 is amended from claim 28 and recites, *inter alia*,

> at least one fixation element includes a plurality of flukes, claws, or hooks that penetrate and embed in the cancellous bone tissue of articular surfaces of the ilium and sacrum and pull the sacrum and ilium together as the single fusion implant is rotated, thereby with compressing the sacroiliac joint and securing the single fusion implant in the sacroiliac joint.

RMTA 28 (emphasis omitted); *see also* App. A, 6 (providing a clean listing of claim 34).

According to Petitioner,

> Lieberman discloses that the implant has two helical spikes with "sharp pointed tip[s]" and further describes a "self-tapping configuration for the tip portions 58 which includes a planar surface 66 for driving into the [bones], in the same manner that a wood chisel turned upside-down drives into wood."

RMTA Opp. 14 (quoting Ex. 1020, 5:2–6) (emphasis omitted).

Petitioner further submits that claim 34

> further requires that the cutting edges of the fixation elements must be placed in proximity to the articular surfaces of the sacrum and ilium. . . . With respect to this limitation, Lieberman discloses that "the tip portions 58 illustrated in FIGS. 1-5 may be able to punch through the cortical bone upon rotation of the interbody stabilizer 20."

Id. (quoting Ex. 1020, 5:24–28) (emphasis omitted).

Patent Owner does not contest Petitioner's challenge of claim 34 apart from its general contentions addressing the combination of Lieberman and Stark, which we find unavailing for the reasons set forth above. *See* RMTA 14–16; *see also* RMTA Reply 9–10.

We agree with Petitioner. As shown in Lieberman's Figure 1, for example, Lieberman discloses two helical spikes, which satisfy the recited "fixation elements," having cutting edges on their distal ends "that penetrate and embed in the cancellous bone tissue" and "pull the sacrum and ilium together as the single fusion implant is rotated," as required by claim 34.

Accordingly, Petitioner has shown, by a preponderance of the evidence, that the limitations of proposed substitute claim 34 would have been obvious over the teachings of Lieberman and Stark.

f. Summary of Lieberman in view of Stark

Petitioner has demonstrated by a preponderance of the evidence that the proposed combination of Lieberman and Stark renders claims 32–34 obvious.

3. Anticipated by Vestgaarden

Petitioner submits that Vestgaarden anticipates claim 32. RMTA Opp. 18.

Claim 32 was amended from original claim 26, which we find is anticipated by Vestgaarden. *See supra* § II.E; *see also* App. A, 1–5. Claim 32 differs from claim 26 in that claim 32 recites, *inter alia*,

> inserting a single fusion implant into the void along a path that is substantially parallel to articular surfaces of the sacroiliac joint and *no further implants*, fusion devices, *or implant components* are introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant,
>
> rotating the single fusion implant or a portion thereof in the void, the fusion implant having at least one fixation element that *penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum* in the sacroiliac

> joint as the fusion implant or a portion thereof is rotated thereby fixing the ilium and sacrum in relative lateral positions and the fusion implant in the sacroiliac joint . . .

See RMTA 27–28 (emphases added); *see also* App. A, 1–5.

To address claim 32, Petitioner relies on the embodiment shown in Figures 58–60 of U.S. Patent No. 8,162,981 B2, also to Vestgaarden ("Vestgaarden III"), which is incorporated by reference in Vestgaarden. RMTA Opp. 18.

We reproduce Figure 58 of Vestgaarden III, below:

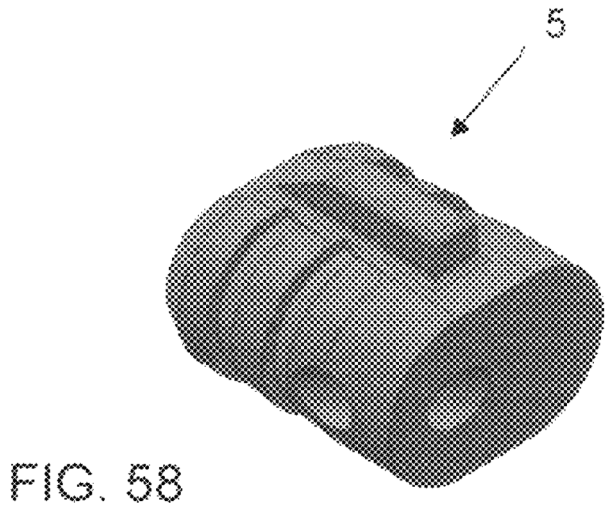

FIG. 58

Figure 58, reproduced above, depicts an embodiment of a fusion implant. Ex. 1014, 4:14–15. In particular, Figure 58 depicts fusion implant 5 comprising a hole for attaching the implant to a facet joint, with a "K-Wire, suture, staple, *screw* or other fixation device." *Id.* at 8:19–23 (emphasis added).

Petitioner further cites to the embodiment depicted in Vestgaarden III's Figures 65–68, which Petitioner submits disclose a "screw for attaching the fusion implant to the joint." Opp. 21. We reproduce Figure 68, below:

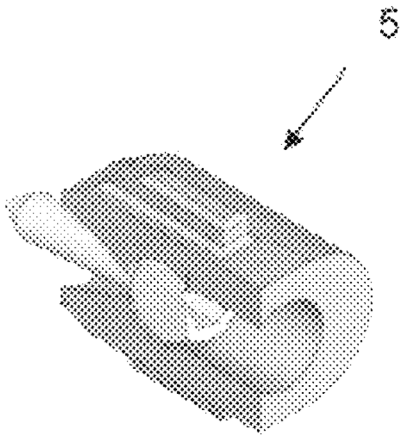

FIG. 68

Figure 68, reproduced above, depicts fusion implant 5 with a hole for attachment to a facet joint, which "may be effected by an *integrated screw*." Ex. 1016, 8:30–34 (emphasis added).

As to the embodiments of Figures 58–60, Patent Owner argues that "[o]nly after the implant 5 is inserted into the SI joint would the additional screw be inserted through the oblique hole in the implant shown in FIGS. 58-60." RMTA 19 (citing Ex. 1016, 8:19–23). Patent Owner further explains that "[t]he additional screw is a separate component or fusion device that is not inserted as part of a single fusion implant along a path that is substantially parallel to articular surfaces of the SI joint." *Id.*

Regarding the embodiments of Figures 65–68, Patent Owner points out that "implant 5 . . . includes an axially placed screw passing through the center of the implant." *Id.* (citing Ex. 1016, 8:30–34). Patent Owner asserts that "[b]ecause the screw is axially positioned in the implant, the screw would be positioned in parallel with articular surfaces of the SI joint." *Id.* at 19–20.

Patent Owner's arguments are persuasive to undermine Petitioner's challenge.

As to the embodiments shown in Vestgaarden III's Figures 58–60, we agree with Patent Owner that the non-integrated screw does not satisfy the limitations of claim 32. *See* RMTA Reply 11 ("The anchor screws are separate devices that are inserted into the joint and the implant after the implant is in position in the SI joint."). Claim 32 recites, *inter alia*, "no further implants, fusion devices, *or implant components* are introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant." App. A, 2 (emphasis added). Based on the record, we find that the anchor screws described with the Figures 58–60 of Vestgaarden III are "implant components [that] are introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant." *Id.*

As to the embodiments shown in Vestgaarden III's Figures 65–68, we agree with Patent Owner that the integrated screw passes through the center of the implant, and we are not persuaded that the screw would—"penetrate[] and embed[] in the bone tissue in an *articular surface* of at least one of an ilium and a sacrum," as required by claim 32. *See* App. A, 2 (emphasis added). Upon reviewing Figures 65–68 of Vestgaarden III, we do not see how the integrated screw would either penetrate or embed within either the ilium or sacrum once implant 5 is inserted into the sacroiliac joint.

Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that Vestgaarden anticipates claim 32.

4. Obvious over Vestgaarden

Petitioner argues, *in the alternative*, that based on Vestgaarden III's teaching of an *integrated* fixation screw, a skilled artisan would have been motivated to modify Vestgaarden's fusion implant to satisfy the limitations recited in claim 32. *See* RMTA Opp. 19–20 (citing Ex. 1016, 8:19–23, 8:30–34). In particular, Petitioner reasons that

> [b]ecause the implant with an integrated screw has fewer discrete parts (which are less prone to become misplaced) and can be inserted more efficiently in one step, POSA would have been motivated to integrate the fixation screw into the implant body. The resultant implant would be inserted as a single unit via the working channel along a path that is substantially parallel to the SI joint, thus rendering obvious the contested limitations of claim 32, even under Patent Owner's erroneous interpretation.

Id.

Patent Owner does not respond to Petitioner's argument that it would have been obvious to modify Vestgaarden's fusion implant to have an integrated screw. *See generally* RMTA; *see also generally* RMTA Reply; *see also* RMTA Sur-reply 12 ("there is no dispute in the record that integrating the screw into the implant would have been obvious.").

We agree with Petitioner.

Based on the Vestgaarden III's teachings, which are incorporated by reference in Vestgaarden (*see* Ex. 1013, 4:10–14), we agree that a skilled artisan would have been motivated to modify the embodiment of Figures 58–60 (which includes a hole for receiving a separate screw) to make the screw integrated (as taught by the embodiment of Figures 65–58) because that modification would have improved upon the implant shown in Figures 58–60 by resulting in an implant with "fewer discrete parts" that would be

"less prone to becom[ing] misplaced," as Petitioner reasons. RMTA Opp. 19–20. Patent Owner does not dispute or otherwise challenge this modification or the rationale for making it. *See generally* RMTA Reply.

We further note that the integrated screw, positioned at the angle shown in Figure 58, would have satisfied the limitations of claim 32, including that no further "implant components are introduced" and that the screw "penetrates and embeds in the bone tissue in an articular surface of at least one of an ilium and a sacrum," which were shortcomings of Petitioner's anticipation challenge discussed above.

Petitioner has demonstrated by a preponderance of the evidence that Vestgaarden renders obvious the limitations recited in substitute claim 32.

5. Obvious Over Vestgaarden and Vishnubholta

Petitioner contends that claims 32, 34, and 35 would have been obvious over Vestgaarden in view of Vishnubholta. RMTA Opp. 21.

a. Vishnubholta (Ex. 1025)

Vishnubholta is a U.S. Patent titled "Stand-Alone Interbody Fixation System." Ex. 1025, code (54). Vishnubholta teaches an implant having rotatable blades "designed to penetrate bone with a sharp tip feature." *Id.* at 7:50:52. We reproduce Figure 2 of Vishnubholta, below:

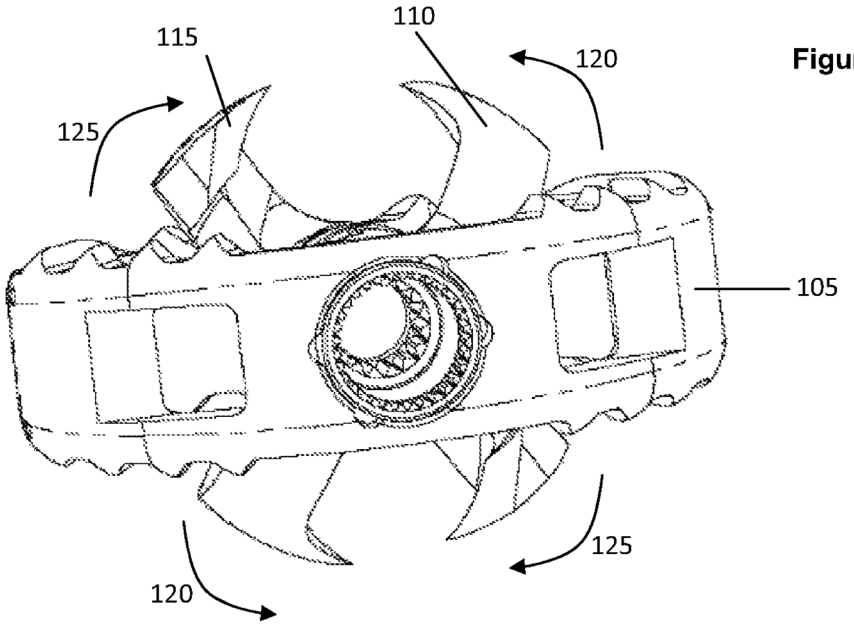

Figure 2

Figure 2 "shows a perspective view of . . . a stand-alone interbody fixation system having a rachet teeth locking feature, wherein blades are in a deployed position." *Id.* at 4:65–67. In particular, Figure 2 depicts cage 105 with anterior fixation blade 110 and posterior fixation blade 115. *See id.* at 2:41–44 (describing another view of the implant in Figure 1A).

Vishnubholta discloses that "[s]ome embodiments of the blade shape geometry may also pull the endplates together when deployed." *Id.* at 6:37–38.

b. Petitioner's Challenge

Petitioner submits that claims 32, 34, and 35 would have been obvious over Vestgaarden in view of Vishnubholta. RMTA Opp. 21; *see also* Opp. 22–24.

Petitioner submits that Vestgaarden teaches that its method and system can be used in conjunction with various spinal fusion implants, and that a skilled artisan would have understood that the method and tools taught

by Vestgaarden for fusing the sacroiliac joint could have been readily combined with other spinal fusion implants, including that taught in Vishnubholta. *See* Opp. 23 (citing Ex. 1013, 4:10–14). Petitioner reasons, "[b]ecause immobilization of a joint is an objective recited in Vestgaarden . . . , a POSA had a good reason to combine Vestgaarden's method and tools for repairing an SI joint with Vishnubholta's fusion implant, with a reasonable expectation of success in this combination." *Id.*

Petitioner asserts that Vestgaarden's implant "is 'shaped in a way that would be prone to motion, to movement' and may not 'stay in place long enough to provide the fusion that's needed.'" RMTA Opp. 21–22 (quoting Ex. 1021, 92:19–93:13). Petitioner explains that "Vishnubholta addresses this issue by disclosing an implant with 'blades [] capable of penetrating the [bone],' thereby alleviating concerns of the implant migrating within the joint." *Id.* at 22 (quoting Ex. 1025, 3:52–53). Petitioner submits that "Vishnubholta teaches that its implant 'provides a solid fixation in all aspects (flexion, extension, torsion, rotation, migration),' which perfectly complements Vestgaarden's general objective 'to provide a method to deliver a device for . . . enhancing stability for purposes of immobilizing a joint.'" *Id.* (quoting Ex. 1025, 6:1–3; citing Ex. 1013, 1:48–52). Based on these teachings and evidence, Petitioner reasons that a "POSA had motivation to combine Vestgaarden's surgical tools and method with Vishnubholta's implant, and this combination would have yielded a predictable result with known components performing their intended functions." *Id.*

c. Claim 32

Claim 32 is amended from claim 26 and further recites, *inter alia*, "at least one fixation element . . . penetrates and *embeds* in the bone tissue." RMTA 28 (emphasis replaced); *see also* App. A, 1–5.

According to Petitioner, Vishnubholta discloses these limitations. *See* RMTA Opp. 21 (citing Ex. 1025, 7:50–55). Vishnubholta discloses:

> [F]ixation blade 110 includes blade tips 135 that are designed to penetrate bone with a sharp tip feature and continue to a leading edge or cutting edge 140, similar to a sickle. The blade tips 135 positioned at the outer perimeter of an anterior fixation blade 110 diameter facilitate immediate bone engagement at initial deployment.

Ex. 1025, 7:50–55. We agree with Petitioner that Vishnubholta's disclosure of a fixation blade with blade tips that penetrate bone satisfies the recited "fixation element" that "penetrates and embeds" in bone tissue. We also find that the articulated combination of Vestgaarden and Vishnubholta teaches or suggests all of the limitations of claim 32.

In contesting Petitioner's challenge, Patent Owner argues that "there does not appear to be any good reason to modify the method of Vestgaarden . . . with the implant of Vishnubholta." RMTA 22. Patent Owner explains that "[i]t is not clear how the implant of Vishnubholta would be incorporated into [Vestgaarden's] process, since the blades 110 and 115 of Vishnubholta would not be oriented to the articular surfaces of the SI joint if inserted into cavity 45." *Id.*

We determine that Petitioner has articulated a sufficient rationale for this prior art combination. Thus, Patent Owner's first argument is not persuasive.

In Petitioner's Opposition to the Revised Motion to Amend, Petitioner explains that the implant taught in Vestgaarden may be susceptible to movement by way of migration after implantation. *See* RMTA Opp. 21–22 (citing Ex. 1021, 92:19–93:13). This explanation is supported by the testimony of Patent Owner's expert. On cross-examination, Dr. Zaporojan testifies that Vestgaarden III's implant, without a screw, is "just not going to stay in place." Ex. 1021, 92:19–3:4; *see also id.* at 92:4–7 (questioning implant 5 from Vestgaarden III). Dr. Zaporojan further explains that "the surface is very smooth" and "[i]t's also got this cruciform design, and you see that it's shaped in a way that would be prone to motion, to movement, and I don't think it's going to stay in place long enough to provide the fusion that's needed." *Id.* at 93:8–13.

Based on the perceived shortcomings of Vestgaarden's fusion implants (without a screw), Petitioner turns to Vishnubholta's implant. *See* RMTA Opp. 21–24. Petitioner explains, "Vishnubholta addresses [Vestgaarden's movement] issue by disclosing an implant with 'blades [] capable of penetrating the [bone],' thereby alleviating concerns of the implant migrating within the joint." *Id.* at 22 (quoting Ex. 1025, 3:52–53). Petitioner further explains, "Vishnubholta teaches that its implant "provides a solid fixation in all aspects (flexion, extension, torsion, rotation, migration)," which perfectly complements Vestgaarden's general objective "to provide a method to deliver a device for . . . enhancing stability for purposes of immobilizing a joint." *Id*. (quoting Ex. 1025, 6:1–3; quoting *also* Ex. 1013, 1:48–52). Petitioner reasons that a "POSA had motivation to combine Vestgaarden's surgical tools and method with Vishnubholta's

implant, and this combination would have yielded a predictable result with known components performing their intended functions." *Id.*

Notably, Patent Owner *does not address* Petitioner's reasoning in Petitioner's Opposition to the Revised Motion to Amend, in which Petitioner explains that replacing Vestgaarden's implants with Vishnubholta's implant would have improved fusion of the sacroiliac joint by reducing movement (i.e., migration) of Vestgaarden's implant. *See* RMTA Reply 12 (failing to present additional argument in Patent Owner's Reply); *see also* RMTA Opp. 22 (explaining that "Vishnubholta addresses [Vestgaarden's shortcoming] by disclosing an implant with 'blades [] capable of penetrating the end plate [of the bone],' thereby alleviating concerns of the implant migrating within the joint." (quoting Ex. 1025 at 3:52-53)). Both the teachings in Vishnubholta (Ex. 1025, 6:1–3, 3:52–53) and the testimony of Patent Owner's expert (Ex. 1021, 92:19–93:13) provide rational underpinning for Petitioner's unrebutted reasoning, which is that the modification would have reduced undesirable implant migration (*see* RMTA Opp. 22).

Second, Patent Owner argues, "[i]t is not clear how the implant of Vishnubholta would be incorporated into this process, since the blades 110 and 115 of Vishnubholta would not be oriented to the articular surfaces of the SI Joint if inserted into cavity 45." RMTA 22. Patent Owner points out Vestgaarden's implant 5 has a crucifix, or cruciform, shape. *Id.* Patent Owner contends that "the implant of Vishnubholta would not have a structure like stabilizer 15 of Vestgaarden . . . to *distract the SI Joint*," urging that "it is not apparent that the implant of Vishnubholta can be incorporated into the method of Vestgaarden . . . to accomplish the goal of

distracting the SI joint without significantly redesigning the method of Vestgaarden." *Id.* at 22–23 (emphasis added).

We disagree with Patent Owner's second argument.

As Petitioner correctly asserts, Patent Owner's argument is based on overly "constricted interpretation of Vestgaarden . . . and directly contradicts the 'expansive and flexible approach to the obviousness question' mandated in *KSR*." RMTA Opp. 22 (citing *KSR*, 550 U.S. at 401). A skilled artisan is not an automaton. *KSR*, 550 U.S. at 401. To the contrary, an appropriate obviousness analysis takes "account of the inferences and creative steps that a person of ordinary skill in the art would employ," which here would have involved creating a void in an SI joint based on the cross-sectional shape of Vishnubholta's implant—not Vestgaarden's implants—if that artisan were to deploy Vishnubholta's device in the joint. *See In re Translogic Technology, Inc.*, 504 F.3d 1249, 1262 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418). Contrary to Patent Owner's logic, a skilled artisan would not create a cruciform shape in the bone tissue to accommodate an implant that does not in fact have a cruciform shape. *See In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (rejecting non-obviousness argument that "presumes stupidity rather than skill" from the skilled artisan). Moreover, that skilled artisan would have oriented the implant such that the upper surface is aligned with the ilium or sacrum, while the lower surface is aligned with the other bone, as it is the upper and lower surfaces of Vishnubholta's implant that are configured to engage the surfaces of adjacent bones. Indeed, this is expressly taught in Vishnubholta. *See, e.g.*, Ex. 1025, 9:24–27 ("The cage 105 is annular in configuration having an upper surface 205 and an opposed lower surface 210 configured to engage Superiorly and inferiorly the end

plates of adjacent vertebrae"); *see also id.* at Fig. 9C (depicting a similar embodiment with upper surface 205 and lower surface 210). Upon proper orientation of Vishnubholta's implant within the sacroiliac joint, fixation blades 110, 115 would be rotated (*see, e.g.*, *id.* at 6:13–15) to

> penetrate[] and embed[] in the bone tissue in an articular surface of at least one of an ilium and a sacrum in the sacroiliac joint as the fusion implant or a portion thereof is rotated thereby fixing the ilium and sacrum in relative lateral positions and the fusion implant in the sacroiliac joint,

as required by claim 32. App. A, 3.

Moreover, Patent Owner's attempt to distinguish Vestgaarden from Vishnubholta by focusing on Vestgaarden's "distraction" also fails. *See* RMTA 22. Notably, Vishnubholta expressly discloses a method that *distracts* the space between adjacent bones. *See* Ex. 1025, 6:3–5 ("In many embodiments, the system 100 is configured to use a single instrument to distract, insert and deploy the system"). We further point out that Vishnubholta's implant is wedge-shaped, with the insertion end being narrow, and that insertion would apparently distract the space upon insertion. *See, e.g.*, *id.* at Figs. 5A, 9E, 9F; *see also id.* at 6:8–9 ("In many embodiments, the design includes a tapered leading portion that allows smooth insertion and deployment"). Accordingly, Patent Owner's assertion that "the implant of Vishnubholta would not have a structure like stabilizer 15 of Vestgaarden . . . to distract the SI Joint" is contradicted by the express teachings of Vishnubholta. *See* RMTA 22.

Finally, we respectfully disagree with our colleague's thoughtful dissenting opinion. Although Patent Owner argued against the combinability of Vestgaarden and Vishnubholta, Patent Owner's arguments, addressed above, were premised on a misunderstanding that the "goal" of

Vestgaarden was to "distract" the SI joint, and that using Vishnubholta's implant, *which does not distract*, would result in the "significant redesign" of Vestgaarden's method. *See* RMTA 22–23. As explained above, and contrary to Patent Owner's understanding, Vestgaarden's goal is not distraction, and even if it was, Vishnubholta discloses *distracting* the space between adjacent bones. *See* Ex. 1025, 6:3–5

Furthermore, we reiterate that Patent Owner *did not address* Petitioner's reasoning that replacing Vestgaarden's implants with Vishnubholta's implant would have improved fusion of the sacroiliac joint by *reducing migration* of the implant. *Compare* RMTA Reply 12, *with* RMTA Opp. 22. If Patent Owner disagreed with Petitioner's reason for combining Vishnubholta with Vestgaarden, Patent Owner should have explained why in its Reply to the Revised Motion to Amend. Patent Owner did not. *See* RMTA Reply 12. Patent Owner was on notice that any argument not raised may be deemed waived. *Cf.* Paper 8, 9; *cf. NuVasive*, 842 F.3d at 1381. In this instance, and in the absence of any argument by Patent Owner, Petitioner's reasoning for combining Vishnubholta with Vestgaarden is supported by rational underpinnings, specifically, the teachings in Vishnubholta (Ex. 1025, 6:1–3, 3:52–53) and the cross-examination testimony of Patent Owner's expert (Ex. 1021, 92:19–93:13).

Petitioner has shown, by a preponderance of the evidence, that claim 32 would have been obvious over Vestgaarden in view of Vishnubholta.

d. Claim 34

Claim 34 is amended from claim 28 and recites,

> at least one fixation element includes a first fixation element having a first cutting edge at a distal end thereof and a second

> fixation element having a second cutting edge at a distal end thereof, wherein said step of inserting said single fusion implant into the void includes positioning said first cutting edge in proximity to an articular surface of said ilium and positioning said second cutting edge in proximity to an articular surface of said sacrum and said step of rotating the single fusion implant or a portion thereof draws the articular surfaces of the sacroiliac joint together to compress the sacroiliac joint and secure the fusion implant in the sacroiliac joint.

RMTA 28 (underlining and strike-through omitted); *see also* App. A, 6–7 (providing a clean listing of claim 34).

According to Petitioner, Vishnubholta discloses this feature when its fixation blades are rotated. *See* Opp. 23–24; *see also* RMTA Opp.

Other than those arguments discussed above in connection with claim 32, Patent Owner does not present separate arguments in response to Petitioner's challenge of claim 34 as obvious over Vestgaarden and Vishnubholta. *See* RMTA 21–23.

We agree with Petitioner.

Upon insertion of Vishnubholta's implant into the sacroiliac joint, Vishnubholta's fixation blades 110, 115 would be rotated and would "draw[] the articular surfaces of the sacroiliac joint together to compress the sacroiliac joint and secure the fusion implant in the sacroiliac joint," as recited in claim 34 (emphasis added). Indeed, Vishnubholta discloses that "[s]ome embodiments of the blade shape geometry may also *pull the endplates together* when deployed." Ex. 1025, 6:37–38 (emphasis added).

Petitioner has shown, by a preponderance of the evidence, that claim 34 would have been obvious over Vestgaarden in view of Vishnubholta.

e. Claim 35

Claim 35 is amended from claim 31 and recites,

> wherein the working channel includes two tangs protruding from a distal end of the working channel for securing a position of said working channel in said sacroiliac joint, the *working channel has an oblong cross-sectional shape* and the tangs are positioned on opposite sides of the longest cross-sectional diameter of the working channel.

RMTA 28 (underlining and strike-through omitted, emphasis added); *see also* App. A, 7–8 (providing a clean listing of claim 35).

According to Petitioner, Vestgaarden discloses these limitations, including a cannula, or "working channel," with an oval cross section (i.e., having an "oblong cross-sectional shape"). *See* RMTA Opp. 24.

Other than those arguments discussed above in connection with claim 32, Patent Owner does not present separate arguments in response to Petitioner's challenge of claim 35 as obvious over Vestgaarden and Vishnubholta. *See* RMTA 21–23.

We agree with Petitioner.

Vestgaarden discloses, "aligning the teeth located on the distal end of the cannula with the plane of the joint." *See* Ex. 1013, 2:7–11. Vestgaarden also discloses that its cannula may have an "oval cross section, rectangular cross section or other desired shape that provides the desired guide channel to deliver a stabilization device into [the] cavity." *Id.* at 4:57–59. A skilled artisan, utilizing Vestgaarden's cannula for deploying Vishnubholta's implant, would have selected a cannula with an oval or rectangular cross-section that matches the cross-sectional shape of Vishnubholta's implant. *See, e.g.*, Ex. 1025, Figs. 5B, 9C, 9D (depicting front or rear views of

Vishnubholta's cage with a rectangular cross-section, which is the cross section of the implant upon delivery).

Accordingly, Petitioner has shown, by a preponderance of the evidence, that claim 35 would have been obvious over Vestgaarden in view of Vishnubholta.

f. Summary of Vestgaarden in view of Vishnubholta

Petitioner has demonstrated by a preponderance of the evidence that claims 32, 34, and 35 would have been obvious over Vestgaarden and Vishnubholta.

6. Obvious Over Stark and Stoffman

Petitioner contends that claims 32 and 34 would have been obvious over Stark in view of Stoffman. RMTA Opp. 24.

a. Stoffman (Ex. 1015)

As previously discussed (*see supra* § II.G.1), Stoffman is a U.S. Patent titled "Percutaneous Sacroiliac Joint Implant and Method for Surgically Inserting and Securing the Implant into the Sacroiliac Joint." Ex. 1015, code (54). We reproduce Figure 5 of Stoffman, below:

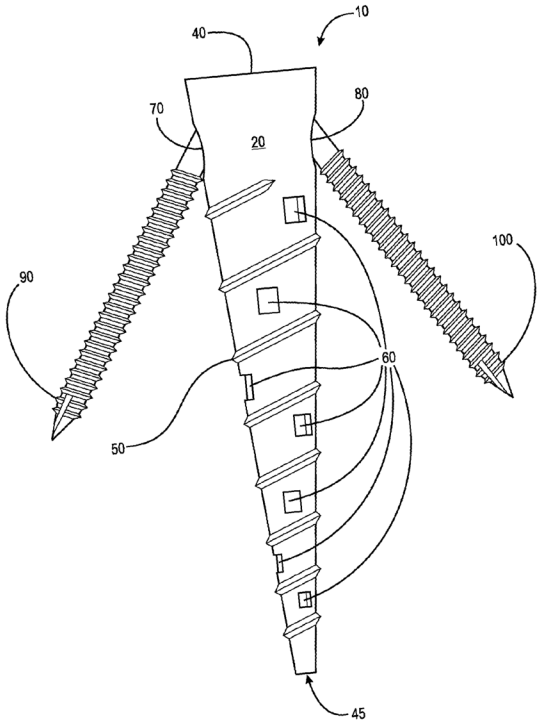

Fig. 5

Figure 5 depicts SI joint fusion device 10 with body 20 open at ends 40 and 45. *See id.* at 6:61–7:4. First ancillary member 90 and second ancillary member 100 are self-tapping screws that extend through body 20. *Id.* at 7:5–6, 7:43–45.

In fusing the sacroiliac joint, body 20 is first advanced by a guide wire or guide tube until it is located in the SI joint. *See id.* at 9:26–31. "Thereafter, a surgeon removes the guide wire and drills holes . . . for placement of ancillary screw members 90 and 100 into right ilium bone 15 and sacrum 13." *Id.* at 9:31–35; *see also id.* at Fig. 2 (depicting the fusion device between sacrum 13 and ilium 15). Once fusion device 10 is positioned satisfactorily, "the surgeon tightens ancillary screw members 90 and 100" to fuse the sacroiliac joint. *Id.* at 9:48–51.

b. Petitioner's Challenge

Petitioner submits that claims 32 and 34 would have been obvious over Stark in view of Stoffman. *See* RMTA Opp. 24–25 (challenging only substitute claims 32 and 34); *see also* Opp. 24–25 (challenging initially-amended claims 32, 34, and 35).

In combining Stark with Stoffman, Petitioner proposes to "use the method and tools taught in Stark . . . to implant the SI joint implant disclosed in Stoffman." Opp. 24.

Patent Owner argues that "Revised Substitute Claim 32 includes the limitation that no further implants, fusion devices, or implant components are introduced into the SI joint or surrounding tissues after the insertion of the single fusion implant." RMTA 24. Patent Owner argues that Stoffman's ancillary screws are separate fixation elements that fail to meet this limitation. *Id.*

In response to Patent Owner's argument, Petitioner contends that Patent Owner's "argument ignores that Stoffman teaches that the implant body and axillary screws collectively form a 'single' fusion implant (as clearly shown in Figures 3 and 4 of Stoffman)." RMTA Opp. 25 (emphasis omitted).

We agree with Patent Owner.

Contrary to Petitioner's assertion, nothing in Stoffman's Figures 3 and 4 supports Petitioner's position.

Independent claim 32 recites, *inter alia*, "no further implants, fusion devices, or *implant components* are introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant." App. A, 2 (emphasis added). As explained above, Stoffman describes ancillary

members 90 and 100 as being placed within the SI joint *after* body 20 is guided into the joint. *See* Ex. 1015, 9:26–37. We credit Patent Owner's expert, Dr. Zaporojan, that

> Stoffman discloses fusion device 10 with *three separate fusion elements*, including a frustoconical, wedge-like body 20 having a tapered sidewall and ancillary members 90 and 100 (surgical screws) that are inserted through body 20 *after* it is placed in the sacroiliac joint.

Ex. 2001 ¶ 47 (citing Ex. 1015, 9:30–37) (emphasis added).

Accordingly, Stoffman's ancillary screws 90, 100 are "implant components" that are "introduced into the sacroiliac joint or surrounding tissues after the insertion of the single fusion implant," or Stoffman's body 20. As such, Stoffman's structure does not satisfy the limitations recited in independent claim 32 and incorporated by reference into dependent claim 34.

Petitioner fails to demonstrate by a preponderance of the evidence that Stark in view of Stoffman renders obvious claims 32 and 34.

IV. CONCLUSION

As to the Challenged Claims, and after weighing the evidence of the disclosure of the references, the testimony, and the reasoning to combine the references, we determine that Petitioner has shown by a preponderance of the evidence Challenged Claims 26–28 and 31 of the '539 patent are unpatentable.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
26–28, 31	102	McCormack		26–28, 31
26, 27, 31	102	Vestgaarden	26, 27, 31	
26–28, 31	102	Stark	26–28, 31	
26, 28, 31	103	Stark, Stoffman	26, 28, 31	
26–28, 31	103	Stark, McCormack		26–28, 31
26–28, 31	103	Vestgaarden, McCormack		26–28, 31
Overall Outcome			26–28, 31	

As to the Substitute Claims, and after weighing the evidence of the disclosure of the references, the testimony, and the reasoning to combine the references, Petitioner has shown by a preponderance of the evidence that proposed Substitute Claims (claims 32–35) would also be unpatentable and therefore Patent Owner's RMTA is denied.

Substitute Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
32–35	112(a)	Written Description		32–35
32–35	112(b)	Indefinite		32–35
32	102	Stark	32	
32–34	103	Lieberman, Stark	32–34	
32	102	Vestgaarden		32
32	103	Vestgaarden	32	
32, 34, 35	103	Vestgaarden, Vishnubholta	32, 34, 35	
32, 34	103	Stark, Stoffman		32, 34
Overall Outcome			32–35	

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	32–35
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	32–35
Substitute Claims: Not reached	

V. ORDER

Accordingly, it is:

ORDERED that claims 26–28 and 31 of the '539 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend is *denied* as to proposed substitute claims 32–35; and

FURTHER ORDERED that any party seeking judicial review must comply with the notice and service requirements of 37 C.F.R. § 90.2.[9]

[9] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

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.*

WORTH, *Administrative Patent Judge, Dissenting-in-part.*

I would determine that Petitioner has not demonstrated a reasonable expectation of success in using certain devices intended for use in the disk joints of the spine (for spinal fusion) in a different kind of joint (the sacroiliac joint) because Petitioner has not provided sufficient evidence that it would have been predictable to do so.

Ground of Obviousness of Proposed Substitute Claims 32–34 Over Lieberman and Stark

Petitioner reasons that "[b]ecause an SI joint comprises two adjacent bones and links the spine and pelvis together, a POSA had a good reason to

use Lieberman's implant to repair an SI joint, with a reasonable expectation of success." Paper 13 (Petitioner's Opposition to Contingent Motion to Amend), 16. Petitioner argues that "a POSA had a good reason for combining the implant disclosed in Lieberman with the method and tools for immobilizing an SI joint disclosed in Stark II and would have had a reasonable expectation of success of this combination." *Id.* Petitioner argues that "Lieberman's implant and Stark's surgical tools would have predictably performed their known and intended functions, and POSA would have had a reasonable expectation of success of achieving joint fusion—which is the common objective of both Lieberman and Stark II." Paper 19 (Petitioner's Opposition to Revised Motion to Amend, hereinafter "RMTA Opp."), 17.

Obviousness is a question of law based on underlying factual inquiries. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).[10] However, there is no expert testimony that Lieberman's device would have behaved in a predictable manner in the sacroiliac joint as opposed to being used in an

[10] *See also Intel Corporation v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (citing, e.g., *KSR*, 550 U.S. at 417) ("Similarly, 'if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.' This is the so-called 'known-technique' rationale. And if there's a known technique to address a known problem using 'prior art elements according to their established functions,' then there is a motivation to combine.")

intervertebral joint:

> COUNSEL FOR PETITIONER: So, Lieberman teaches an implant and says that it's applicable to other types of joints, including those joints that are not just in the spine or pelvis. The SI joint actually is the joint between the spine and the pelvis. And then when we look at the abstract of Stark, it provides the exact toolset for performing such a procedure with respect to SI joint. So, it would be a trivial matter to use Stark's tools to insert Lieberman's implant. And --
>
> JUDGE WORTH: And when you say "trivial" -- sorry. I'm sorry. Do you have expert testimony to support the idea that it's trivial?
>
> COUNSEL FOR PETITIONER: No, we do not. But Stark speaks for itself.

Paper 32 (Tr.), 44:8–16.

Lieberman devotes most of its disclosure to the use of its device for spinal fusion of two vertebrae. *See, e.g.*, Ex. 1020, Figs. 1, 2, 6, 8, col. 5:9–7:37, 7:57–8:28, 9:5–30. Figure 1 of Lieberman is reproduced below:

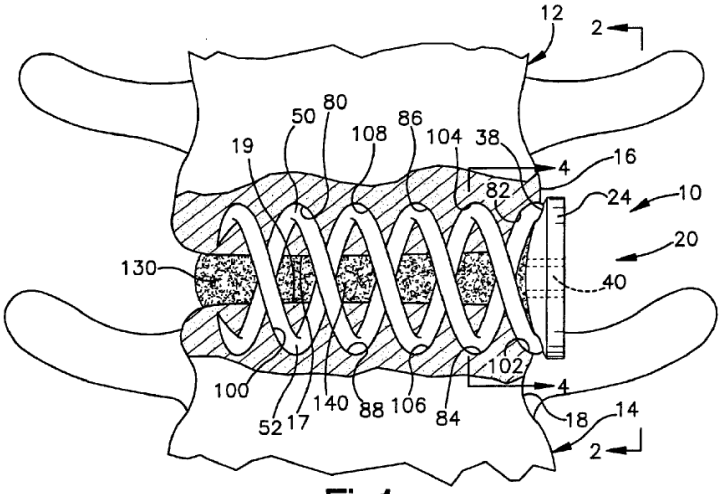

Fig.1

Figure 1 is a schematic anterior view of an apparatus implanted in an adjacent pair of vertebral bodies. Ex. 1020, 2:57–59. Figure 2 of Lieberman is reproduced below:

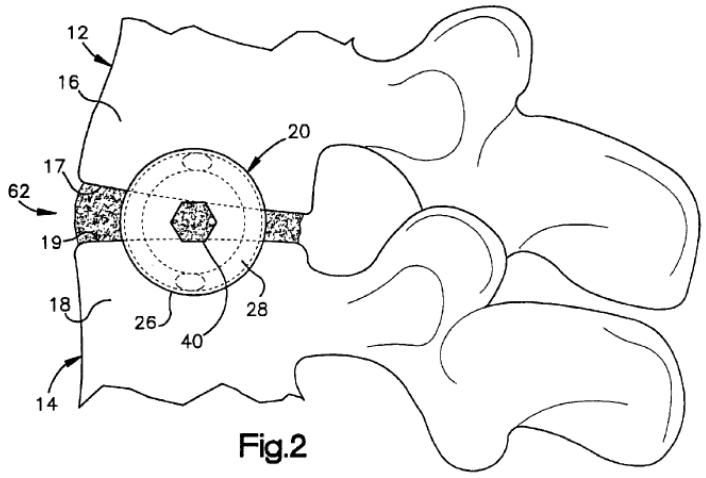

Fig.2

Figure 2 is a side view of the spine shown in Figure 1. *See id.* at 2:60. According to the method of Lieberman, the disk material is removed leaving interbody space 62. *Id.* at 5:8–13.

Spinal fusion of vertebrae occurs at a different type of joint than the sacroiliac joint. *See* Tr. 46:15–47:9. By contrast the sacroiliac joint is reproduced below, as depicted in Figure 71 of the '539 patent:

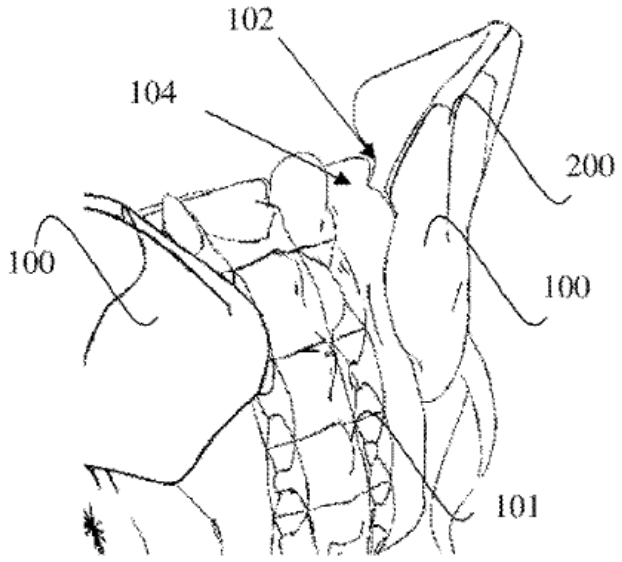

FIG. 71

This figure shows an oblique posterior view of sacroiliac joint 102. Ex. 1001, 8:31–34; 31:43–45. Thus, the intervertebral disk joint has a disk or an

interbody space that is not present in the sacroiliac joint.

The claimed invention is to push apart the bones to create a space before pulling them together. In particular, the claimed invention is to create a space ("a void") in the sacroiliac joint before rotating the fusion implant and its fixation element(s), thereby compressing the joint. *See* RMTA 27–28 (proposed substitute claim 32); Ex. 1001, 5:18–27 (creating a void in the sacroiliac joint by displacing a portion of the patient's ilium and a portion of the patient's sacrum and then compressing the patient's ilium to the patient's sacrum); 24:36–39 (the inserter turns the fusion implant to allow for the lateral flukes to pull the sacrum and ilium towards each other, creating compression).

That is why it is significant to this discussion that the sacroiliac joint lacks the disk or interbody space that is already present in the intervertebral disk joint.

Lieberman does state that "[i]t should be understood that the method and apparatus according to the present invention could be used to attach and stabilize other adjacent bones, not just bones in the spine or pelvis." Ex. 1020, 9:39–42. In this way, Lieberman does indicate that its device may be used not only in the spine but also in the pelvis. However, Lieberman is silent as to which bones and which joints it is referring to. For example, Lieberman is silent as to whether its device would be used in the sacroiliac joint or in another joint of the pelvis, such as the symphysis pubis. In my view, it is unclear that Lieberman is teaching that its device can be used in the sacroiliac joint. But that is what Petitioner seeks to do -- to "use Stark's surgical tools and method to endoscopically insert Lieberman's implant into an SI joint." RMTA Opp. 17.

Petitioner argues that "Patent Owner failed to articulate any rationale as to why Stark's surgical tools and method cannot be successfully used in a predictable manner to insert Lieberman's implant." *Id.* at 18. However, Petitioner's argument would flip the burden of proof, which stays with Petitioner. *See* 35 U.S.C. § 316(e).

Petitioner also argues that Stark would have been a "suitable" option, even if not the best option, to provide surgical tools to complete Lieberman's implantation procedure (*see* Paper 29, 10 (citing *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021)), but Petitioner does not explain why it would have been predictable to use Lieberman at the sacroiliac joint. Nor is it clear from Petitioner's argument how "Stark speaks for itself." Tr. 44:12–44:16.

Petitioner also argues that "[t]here is no dispute that the Lieberman-Stark combination would be functional to fuse an SI joint." Paper 29, 11. However, the question of obviousness is not whether an invention or combination is functional, but rather whether a person of ordinary skill would have sought to make the proposed combination absent hindsight. Further, Patent Owner does argue that incorporating Lieberman's device into Stark's method would "defeat the stated purpose of distracting the SI joint" and Patent Owner argues that a person of ordinary skill would not have combined the references. *See* Paper 28, 10. The burden rests with Petitioner to establish its case in chief in the first instance.

At some level this is a close case because the device is a mechanical device. However, we are dealing with the human body and a different type of joint. This is also not to say that Lieberman's device would not have behaved in a predictable manner. Only that Petitioner has not adduced

adequate evidence, in terms of expert testimony or documentary evidence, to show that the proposed combination would have been predictable, i.e., to support a conclusion of unpatentability in this context. Contrary to Petitioner, this is not a "trivial" matter.

In my view, Petitioner's argument that Lieberman could have been used with Stark in the sacroiliac joint in a predictable fashion is not supported by adequate evidence. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (rejecting attorney argument as unsupported by factual evidence); *see also In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence."). Accordingly, I would determine that Petitioner has not met its burden with respect to the ground of obviousness of proposed substitute claims 32–34 over Lieberman and Stark.

Ground of Obviousness of Proposed Substitute Claims 32, 34, 35 Over Vestgaarden and Vishnubholta

Petitioner reasons that a "POSA had motivation to combine Vestgaarden's surgical tools and method with Vishnubholta's implant, and this combination would have yielded a predictable result with known components performing their intended functions." RMTA Opp. 21–24. However, there is no expert testimony that Vishnubholta's device would have behaved in a predictable manner in the sacroiliac joint as opposed to an intervertebral joint.

Patent Owner addresses the proposed combination of Vestgaarden and Vishnubholta in its Revised Motion to Amend. *See* Paper 17, 21–23.

I would determine that Petitioner has not met its burden with respect to the ground of obviousness of proposed substitute claims 32, 34, and 35

over Vestgaarden and Vishnubholta for similar reasons as for the ground of obviousness over Lieberman and Stark.

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