Paper No. 35 Filed: December 17, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC., Petitioner,

v.

WARSAW ORTHOPEDIC, INC., Patent Owner.

Case IPR2013-00396 Patent 8,444,696 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges*.

GREEN, Administrative Patent Judge.

FINAL WRITTEN DECISION 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Petitioner, NuVasive Inc. ("NuVasive"), filed a Corrected Petition requesting *inter partes* review of claims 7–12 ("the challenged claims") of U.S. Patent No. 8,444,696 B2 ("the '696 patent"). Paper 5 ("Pet."). Patent Owner, Warsaw Orthopedic, Inc. ("Warsaw"), did not file a Patent Owner

Preliminary Response. We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 7-12 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on December 20, 2013, as to the challenged claims of the '696 patent. Paper 11 ("Institution Decision"; "Dec. Inst.").

Patent Owner filed a Response (Paper 23, "PO Resp."), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 24 ("Reply"). An oral hearing was held on July 31, 2014. The transcript of the hearing has been entered into the record. Paper 34.

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a). Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 7–12 of the '696 patent are unpatentable.

B. Related Proceedings

Petitioner filed concurrently with the instant Petition another petition for an *inter partes* review of the '696 patent. That proceeding, IPR2013-00395, involves claims 1–6 of the patent. Petitioner indicates further that Patent Owner has asked the court for permission to add the '696 patent to the case *Warsaw Orthopedic, Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB (S.D. Cal.). Pet. 1.

C. The '696 Patent

The '696 patent issued on May 21, 2013, with Gary Karlin Michelson as the listed inventor. The '696 patent is drawn to an interbody spinal fusion implant that is "configured to restore and maintain two adjacent vertebrae of the spine in correct anatomical angular relationship." Ex. 1102, 1:20–23.

As taught by the '696 patent, the cervical and lumbar areas of the human spine are lordotic in a healthy state, that is, they are "curved convex forward." *Id.* at 1:25–27. In degenerative conditions of the spine, the lordosis may be lost. *Id.* at 1:27–28. Surgical treatment of such degenerative conditions often involves spinal fusion, where adjacent vertebrae are joined together through an area of shared bone. *Id.* at 1:36–40.

The '696 patent discloses spinal implants that are sized to fit within the disc space that is created when the disc material between two adjacent vertebrae is removed, and that conform "wholly or in part to the disc space created." *Id.* at 1:61–64. The implants have upper and lower surfaces that form a support structure for the adjacent vertebrae, and, in a preferred embodiment, the upper and lower surfaces "are disposed in a converging angular relationship to each other such that the implants of the present invention have an overall 'wedged-shape' in an elevational side view." *Id.* at 1:67–2:4.

As taught by the '696 patent, the various faces of the implant may be curved to allow the implant "to conform to the shape of the vertebral surfaces." *Id.* at 2:23–25. That is, "the upper and/or lower surfaces may be convex, and/or the front and/or rear surfaces may be convex." *Id.* at 2:26–27. The surfaces of the implants may have openings, which may or may not pass all the way through the implant, but that connect through a central chamber. *Id.* at 2:27–31. The opening may be of random size, shape, and/or distribution. *Id.* at 2:31–32.

Figure 14 of the '696 patent is reproduced below:

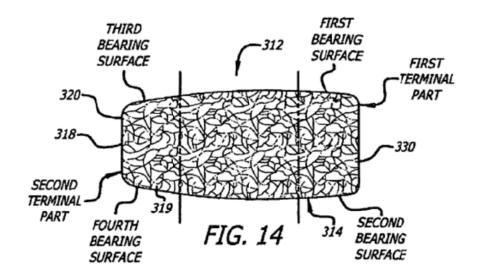


Figure 14, above, is a left side elevational view of a lordotic interbody spinal fusion implant. *Id.* at 5:11–12. The implant shown in Figure 14 has insertion end 320 and trailing end 330. *Id.* at 9:18–19. In addition,

the implant ... includes a first terminal part defining a first bearing surface adapted to bear against an endplate of the vertebrae V_1 , and an opposite second bearing surface adapted to bear against an endplate of the vertebrae V_2 . The implant ... also includes a second terminal part opposite the first terminal part. The second terminal part defines a third bearing surface adapted to bear against the endplate of the vertebrae V_1 and a fourth bearing surface adapted to bear against the endplate of the vertebrae V_2 .

Id. at 9:20-29.

The '696 patent also discloses an embodiment with ratcheting. Figure 9 of the patent is reproduced below:

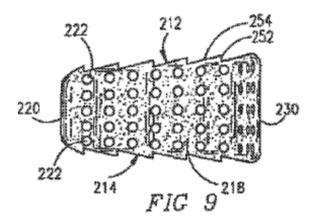


Figure 9 is a side elevational view of a lordotic interbody spinal fusion implant. *Id.* at 4:63–67. As seen in the Figure, the ratchetings are oriented in the direction of insertion end, 220, allowing for one-way insertion of the implant, and bone engaging end, 252, prevents the implant from backing out once implanted. *Id.* at 8:40–49.

The '696 patent teaches further that when a posterior lumbar interbody fusion is performed, it is not possible to replace the removed portions of the disc with a single, large implant. *Id.* at 2:35–38. In such cases, a "modular implant[]" may be used. *Id.* at 2:40–42. The modular implants are as long as the length of the disc material that is removed, but are narrower, and thus, can be "introduced into the disc space from the posterior aspect to either side of the dural sac, and then aligned side to side within the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed." *Id.* at 2:42–50.

According to the '696 patent, because the disc spaces in the lumbar spine are generally lordotic, the modular implants would be taller at the insertion end than at the trailing end. *Id.* at 2:55–58. As the insertion of such implants may be problematic, the implant may incorporate a mechanism that engages an insertion instrument at its trailing end, such as a box and threaded opening, which allows the modular implant to be rotated ninety degrees to its fully upright position after insertion. *Id.* at 2:59–62, 3:7–26.

D. Illustrative Claim

Petitioner challenges claims 7–12 of the '696 patent. Claims 7 and 10 are independent claims. Claim 7 is illustrative, and reads as follows:

7. A lordotic spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first

terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane, said implant being adapted to be inserted between the first vertebra and the second vertebra with said first side and said second side of said implant being oriented toward the first endplate and the second endplate, respectively, and then rotated ninety degrees into an upright position, said trailing face having a recessed portion intersecting each of said first and second sides and being configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing each surfaces having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides, said upper and lower bearing surfaces being disposed in a converging angular relationship toward each other such that said implant appears wedge-shaped from a side view,

the converging angular relationship of said upper and lower bearing surfaces maintaining the first vertebra and the second vertebra adjacent to said upper and lower bearing surfaces in an angular relationship to maintain the desired lordosis between the first vertebra and the second vertebra;

ratchetings on each of said upper and lower bearing surfaces adapted to engage the first vertebra and the second vertebra, respectively, each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction; and

said implant being adapted to hold bone fusion promoting materials.

E. Instituted Challenge

Claims	Basis	References
7–12	§ 103(a)	Steffee, ¹ Michelson '037, ² and Kim ³

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms also are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the

¹ Steffee ("Steffee"), US 5,443,514, issued August 22, 1995 (Ex. 1108).

² Michelson ("Michelson '037"), WO 90/00037, published January 11, 1990 (Ex. 1109).

³ Kim ("Kim"), US 5,645,596, issued July 8, 1997 (Ex. 1110).

context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). For purposes of this Decision, we need only construe the following claim terms.

1. "opening"

Independent claims 7 and 10 each require "an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra." Patent Owner argues that "opening" "requires a hole that necessarily extends through the spinal fusion implant from proximate the top thereof to proximate the bottom thereof in the space between the trailing face, the insertion face, and the first and second sides of the spinal fusion implant." PO Resp. 15. Petitioner responds that "[t]here is no language in claims [7] and [10] that would require the claimed "opening" to be oriented in a specific direction (e.g., vertically oriented from the lower to upper surface)." Reply 2.

Independent claim 7 requires that the implant have a first side and an opposite second side, wherein "said first side and said second side of said implant being oriented toward the first endplate and the second endplate, respectively, and then rotated ninety degrees into an upright position." Independent claim 10 has the same limitation. The remaining two sides of the implant are then defined by the claims as becoming the upper and lower bearing surfaces. The claims, thus, define the first and second sides as being the horizontal sides after the implant is placed and rotated 90 degrees. The

claim then requires that the opening be "between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra." Thus, we construe "opening," consistent with the language of the claims, as a hole that extends from the upper bearing surface to the lower bearing surface that is of sufficient size to permit growth of bone therethrough.

2. "ratchetings"

Independent claims 7 and 10 require "ratchetings on each of said upper and lower bearing surfaces . . . each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction." An embodiment of the ratchetings can be seen in Figure 9 of the '696 patent, reproduced above in Section I(C).

Patent Owner argues that ratchetings should be construed as "facets that are angled to afford forward movement of the spinal fusion implant in one direction and facets that are angled to prevent the spinal fusion implant from backing out in the opposite direction." PO Resp. 17 (citing Ex. 2005 ¶ 38). Petitioner does not present an alternate construction. We determine that Patent Owner's construction is consistent with the Specification and the language of the claim itself, and, thus, we adopt that construction.

B. Patentability

1. Principles of Law

To prevail on its challenges to the patentability of claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *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 (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). The level of ordinary skill in the art usually is evidenced by the references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

Prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). Moreover, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see In re Translogic Tech.*, *Inc.*, 504 F.3d. at 1259.

2. Obviousness under 35 U.S.C. § 103(a) of claims 7–12 over the Combination of Steffee, Michelson '037, and Kim

Petitioner contends that the combination of Steffee, Michelson '037, and Kim renders obvious independent claims 7 and 10, as well as dependent claims 8, 9, 11, and 12. Pet. 14–19. Petitioner sets forth a claim chart demonstrating where each element of the claims is taught by the reference (*Id.* at 47–60), and relies, initially, on the Declaration of Dr. John W. Brantigan (Ex. 1101). Patent Owner disagrees with Petitioner's assertions (PO Resp. 23–46), and relies on the Declaration of Dr. Charles L. Branch, Jr. (Ex. 2005) as evidence that the asserted combination does not render obvious the challenged claims.

a. Steffee (Ex. 1108)

Steffee is drawn to a spinal implant, as well as methods of using the implant, to fuse adjacent vertebrae of the spine together. Ex. 1108, 1:5–7. In order to place the implant, at least a portion of the spinal disc is removed from between the adjacent vertebrae. *Id.* at 1:32–35. The implant is inserted between the adjacent vertebra, "with the first and second substantially parallel side surfaces facing the adjacent vertebrae." *Id.* at 1:35–38. The implant is then rotated ninety degrees so that the upper and lower surfaces can engage the adjacent vertebrae. *Id.* at 1:38–42.

Figure 2 of Steffee is reproduced below:

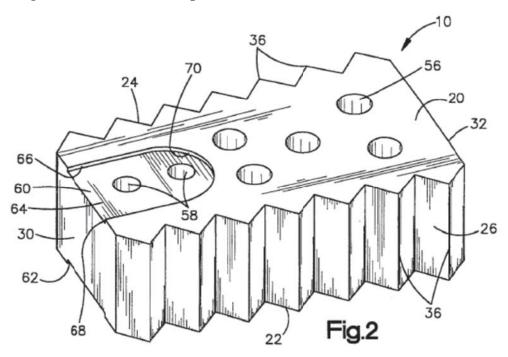


Figure 2, above, shows a perspective view of an embodiment of the spinal implant of Steffee. *Id.* at 1:55–56. Implant 10, as shown in the figure, has "parallel side surfaces 20 and 22." *Id.* at 2:32–33. The implant also has upper surface 24, and lower surface 26, that engage the adjacent vertebrae, and plurality of triangular-shaped teeth 36 for engaging the vertebrae. *Id.* at 2:33–34, 44–47. Specifically, Steffee teaches:

The surface 40 of the tooth 36 extends at an acute angle x to the plane 48. The surface 42 of the tooth 36 extends at an acute angle y to the plane 48. Preferably, the angles x and y are equal and have a value of 45° so that surfaces 40 and 42 extend perpendicular to each other. Therefore, the teeth 36 are not preferential. The teeth 36 prevent the spinal implant 10 from moving toward the anterior portion of the spinal column 16 as much as they prevent the spinal implant from moving toward the posterior portion of the spinal column 16.

Id. at 2:54–63.

The implant also has a plurality of openings 56 and 58 that extend between the side surfaces to allow for blood flow, as well as bone growth from one side of the implant to the other. *Id.* at 2:64–67. The implant may be implanted using any instrument or tool that firmly holds the implant, and also allows the implant to be rotated into position. *Id.* at 3:24–26.

b. Michelson '037 (Ex. 1109)

Michelson '037 is drawn to an implant to be placed into the space between two vertebrae after a damaged spinal disc has been removed. Ex. 1109, 1:2–4.⁴ The implant allows for bone fusion across the intervertebral space, and may contain a plurality of cells or openings of 1-3 mm, into which fusion promoting materials may be placed, allowing a bony bond between the adjacent vertebrae to each other, as well as to the implant. *Id.* at 8:10–21.

⁴ Page numbers refer to the numbers at the top of each page rather than those on the bottom.

Figure 1 of Michelson '037 is reproduced below:

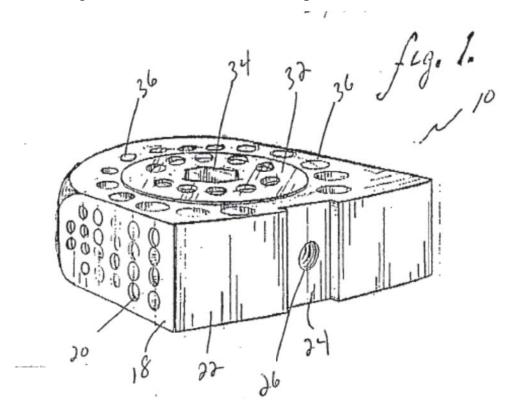


Figure 1, above, is a top right perspective view of the implant of Michelson '037. *Id.* at 10:13–14. As seen in the above Figure, the front wall, 22, of the implant, is slightly convex, and has depressed portion 24 that has central threaded opening 26 that can receive the engaging end of a driving member. *Id.* at 11:38–40. As seen also in the Figure, the recessed portion intersects the sides of the implant that face the vertebrae during the insertion step, such that restriction members of the inserter tool act as a stop when they abut the vertebrae, thus preventing over insertion of the implant. *Id.* at 12:38–13:3.

c. Kim (Ex. 1110)

Kim is drawn to an implant that may be used "as a substitute for one or more intervertebral disks that have been resected in a resection

operation." Ex. 1110, 1:7–10. According to Kim, the "contact surface of the vertebra body with the intervertebral disk is macroscopically a concave surface." *Id.* at 2:31–33. The vertebrae prosthesis is, thus, provided with a convex surface that corresponds to the concave surface of the vertebra, allowing for multiple advantages, such as ease of insertion, increase in stability, etc. *Id.* at 2:33–41.

d. Analysis

Petitioner asserts that Steffee discloses almost all the limitations of independent claims 7 and 10, Pet. 17–18, and provides a detailed claim chart demonstrating where each of the limitations may be found, *id.* at 47–60. Petitioner notes, however, that Steffee may "not expressly describe the claimed features of (i) the 'trailing face having a recessed portion intersecting each of said first and second sides[of the trailing face],' or (ii) the upper and lower bearing portions being 'convex.'" *Id.* at 18. NuVasive asserts, however, that those features were widely known and conventionally used in spinal implants, as evidenced by Michelson '037 and Kim. *Id.* at 18–21.

Specifically, according to Petitioner, the ordinary artisan would have included a recessed portion and threaded opening that engages an insertion tool, as taught by Michelson '037, in order to provide a convenient process to insert and remove the insertion tool "while maintaining the established orientation of the implant." *Id.* at 19. Petitioner also asserts that the ordinary artisan would have convexly bowed the upper and lower bearing surfaces outward, as taught by Kim, in order conform to the contours of the vertebral endplates. *Id.* at 20–21. According to Petitioner, combining Steffee, Michelson '037, and Kim to arrive at the implant claimed by the

'696 patent, is "merely [the] use of known technique[s] to improve similar devices in the same way." *Id.* at 21 (citing *KSR*, 550 U.S. at 417).

Moreover, Petitioner contends that, to the extent that Steffee does not disclose a vertical opening, that configuration is disclosed by Michelson '037, whose opening serves the same purpose as the opening of Steffee, that is, "to promote bone ingrowth between the implant and the adjacent vertebrae." Reply 5 (quoting Ex. 1109, 13).

Patent Owner contends that Steffee does not teach or suggest ratchetings, as suggested by Petitioner. PO Resp. 24–30. In particular, Patent Owner contends that the teeth of Steffee are not preferential—that is, they resist movement equally in the anterior and posterior directions. *Id.* at 25 (citing Ex. 1108, 2:59–63). The ratchetings used on the implant of the challenged claims, however, allow for forward direction during insertion, but prevent the implant from backing out after insertion. *Id.* (citing Ex. 1102, 8:42–47). Thus, Patent Owner contends, the teeth of Steffee do not correspond to the claimed ratchetings. *Id.* at 26.

Patent Owner notes that Petitioner relies on the teaching of Steffee that the orientation of the teeth is achieved by selecting the surface angle 'x' and 'y,' wherein 'x' and 'y' are limited to acute angles. *Id.* at 27 (citing Pet. 54, 59). Patent Owner contends that, according to Petitioner, "so long as the angles are acute, the angles x and y can vary with respect to one another within a selected range, and that the angles x and y could be selected that result in teeth 36 that are ratchetings." *Id.* Patent Owner asserts that reading of Steffee is incorrect, as the portions of Steffee relied upon must be read in association with the remainder of the disclosure of Steffee, which indicates

that the teeth are configured to prevent movement in two directions. *Id.* at 27–28.

Moreover, Patent Owner argues that the ordinary artisan would not have modified the teeth of Steffee, which prevent movement in two directions, to ratchetings, which allow forward movement during insertion, but prevent backward movement. *Id.* at 29. Specifically, Patent Owner argues that the spacer implants of Steffee are inserted linearly between adjacent vertebrae, and then rotated 90 degrees. *Id.* The teeth are not oriented towards the adjacent vertebrae during insertion, but only contact the vertebrae after insertion and rotation. *Id.* Thus, Patent Owner contends, there would be no reason to modify the teeth of Steffee to ratchetings, which allow forward movement and prevent backward movement. *Id.* at 30 (citing Ex. 2005 ¶ 73; Ex. 2009, 124:21–125:11).

Petitioner responds that embodiments with one-way ratchetings were contemplated by Steffee. Reply 2–3 (citing Ex. 1101 ¶ 52; Ex. 1117, 42–47, 50; Ex. 1116 ¶¶ 26–27). Petitioner asserts further that using unequal angles for 'x' and 'y' for the teeth of Steffee would not hinder the stated purpose of the teeth of Steffee—preventing movement of the spinal implant. *Id.* at 3 (citing Ex. 1108, 2:60–63). According to Petitioner, "[a]lthough angling the teeth in a particular direction would afford slightly easier mobility in one direction over another during insertion/manipulation by the surgeon using an inserter tool, the implant would still resist movement in both forward and backward directions (just like any traditional ratchetings that bite into the bone after reaching the final position) after implantation." *Id*.

We determine that Steffee discloses teeth that would be encompassed by the ratchetings of challenged independent claims 7 and 10. In particular, while we agree that the preferred embodiment of Steffee is one in which the angles 'x' and 'y' are equal, having a value of 45°, a reference is not limited to its preferred embodiment, but is available for all that it discloses and suggests to the ordinary artisan. *In re Applied Mat'ls, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012); *see also Merck & Co. Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("[I]n a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.""). Steffee teaches that the angles 'x' and 'y' are limited to acute angles, and further states that, in a preferred embodiment, the angles 'x' and 'y' are equal. As explained by Dr. Brantigan, the selection of angles 'x' and a 'y' that are not equal "would, by nature, afford preferential movement of the implant in one direction over the opposite direction." Ex. 1116 ¶ 26. Thus, while the use of teeth in which the angles 'x' and 'y' are equal is preferred by Steffee, the disclosure of Steffee is not so limited.

In addition, Patent Owner acknowledges that ratchetings were known in the art at the time of Steffee. In particular, Patent Owner argues that Steffee cites Brantigan '757 (Ex. 2003), which discloses nubs, or ratchetings. PO Resp. 31. Steffee, Patent Owner asserts, does not adopt the nubs of Brantigan '757, which "reinforces that one of ordinary skill would not have modified the teeth 36 to be ratchetings." *Id.* We disagree. Steffee's use of 'x' and 'y' to define the angles, and Steffee's statement that, in a preferred embodiment, angles 'x' and 'y' are equal, demonstrate that Steffee was not excluding the nubs of Brantigan '757, which would provide preferential movement in one direction. *See, e.g.*, Ex. 2003, Figs. 7, 8 (showing angled nubs), 6:40–50 (describing the angled nubs).

Patent Owner contends further that the recitation of an opening in challenged independent claims 7 and 10 "makes it clear that the implants of independent claims 7 and 10 are spinal fusion implants." PO Resp. 32. Steffee is not drawn to a spinal fusion implant, but to a spacer implant or interbody support. *Id.* at 32–33. That is, Patent Owner asserts, "the spacer implants 10 of Steffee are used in a spinal fusion process, but are not themselves spinal fusion implants." Id. at 33. After the spacer implants of Steffee are positioned, the space between the implants is packed with bone graft material to promote fusion. *Id.* (citing Ex. 1108, 4:57–59). Once the implants of Steffee are positioned, Patent Owner notes that the openings of Steffee are oriented horizontally, away from the adjacent vertebrae, allowing for blood flow and bone growth from one side of the implant to the other, *Id*. at 34 (citing Ex. 1108, 2:65-67). Thus, Patent Owner contends, "fusion between the adjacent vertebrae 12 and 14 occurs via the bone graft bone, not growth of bone into and through the openings 56 and 58." *Id.* Thus, Patent Owner contends, the implants of Steffee do not meet the limitation of "an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra," as required by challenged independent claims 7 and 10. *Id.* at 35 (citing Ex. 2005 ¶ 79).

Petitioner responds that Steffee specifically teaches that the disclosed invention relates "to a spinal implant, and to a method of using the spinal implant *to fuse together adjacent vertebrae* of a spinal column." Reply 5 (quoting Ex. 1108, 1:5–7). Moreover, Steffee teaches that the horizontal openings allow for the growth of bone, as well as the flow of blood, and, thus, do not preclude the implant of Steffee from being a spinal fusion

implant. *Id.* Petitioner contends further that, to the extent that the opening of Steffee is not vertical, that limitation is disclosed by Michelson '037, and that opening serves the same purpose as the opening of Steffee, that is, "to promote bone ingrowth between the implant and the adjacent vertebrae." *Id.* (quoting Ex. 1109, 13).

The claim term "opening," as construed in Section II(A)(1), above, is a hole that extends from the upper bearing surface to the lower bearing surface that is of sufficient size to permit growth of bone therethrough. Stated differently, "opening," as required by challenged independent claims 7 and 10, requires that the hole be vertical in the implant as placed. While Steffee does not teach a vertical opening, it does teach that the implant has a plurality of horizontal openings that extend between the side surfaces to allow for blood flow, as well as bone growth from one side of the implant to the other. Ex. 1108, 2:64–67.

Michelson '037 also teaches an implant that may contain a plurality of cells or openings of 1–3 mm, into which fusion-promoting materials may be placed, allowing a bony bond between the adjacent vertebrae to each other, as well as to the implant. Ex. 1109, 8:10–21. Thus, the openings of Steffee and the opening of Michelson '037 serve the same purpose—that is, to allow the growth of bone to aid in bonding the implants to the adjacent vertebrae. The addition of vertical openings as taught by Michelson '037 to the implant of Steffee would have been a predictable use of an element taught by the prior art according to its established function. *KSR*, 550 U.S. at 417.

Patent Owner contends that Petitioner's expert, Dr. Brantigan, admits that no advantage would result by providing the openings of Michelson '037 on the implants of Steffee. PO Resp. 36 (citing Ex. 2009, 164:17–165:1).

Patent Owner argues further that Brantigan '757 (Ex. 2003), referenced by Steffee, includes both vertical and horizontal slots, but that Steffee does not adopt them. PO Resp. 39–40.

The obviousness inquiry, however, does not require an advantage or an improvement in properties. *See In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable, combination."); *see also In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("[a] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use."). Moreover, the fact that Brantigan '757, referenced by Steffee, discloses horizontal slots, but Steffee did not adopt them, does not amount to a teaching away from the use of horizontal slots. *See Fulton*, 391 F.3d at 1201 ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any . . . alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.").

Patent Owner argues also that the ordinary artisan would not have looked to Michelson '037 to modify the implant of Steffee because of the different fusion processes used by the two references. PO Resp. 35 (citing Ex. 2005 ¶ 114). For example, the bone graft material of Steffee is placed between the implants, whereas it is held within the central hollow portion of the Michelson '037 implant. *Id.* at 38 (citing Ex. 2005 ¶¶ 112–113). Moreover, Patent Owner argues that the footprint of the Michelson '037 implant, which is substantially the same size as the disc space, is

substantially larger than the footprint of the Steffee implant. *Id.* at 37 (citing Ex. 2005 ¶60; Ex. 2009, 129:25–130:3). As noted by Petitioner, however, both Steffee and Michelson teach the use of the implants "to support bone graft material or other fusion-promoting material between adjacent vertebrae to promote fusion of the vertebrae through bone growth." Reply 6. We determine that the ordinary artisan would have looked to the disclosure of Michelson '037 of a vertical opening in the implant to modify the implant of Steffee.

Patent Owner contends that the ordinary artisan also would not have looked to Kim to modify Steffee. PO Resp. 40–46. The implant of Kim has a significantly larger footprint than the footprint of the implant of Steffee, and the upper and lower contact surfaces of the implant of Kim are convex to correspond to the macroscopically concave surfaces of the vertebra bodies. *Id.* at 40 (citing Ex. 1110, 2:31–37). The upper and lower contact surfaces uniformly spread the compression stress from the vertebra bodies, and limit the movement of the implant. *Id.* at 41.

In contrast, the implants of Steffee include teeth that are used to prevent movement. *Id.* at 43. Contact between the spacer of Steffee and the adjacent vertebra is concentrated on the edges and surfaces of the teeth. *Id.* Patent Owner contends that because Steffee and Kim use divergent approaches for maintaining the position of the implants, the ordinary artisan would not have looked to Kim to modify Steffee, and the modification suggested by Petitioner would undermine the ability of the spacer of Steffee to function, and also negate the advantages of the implant of Kim. *Id.* at 42–44. Patent Owner asserts that if the ordinary artisan were to adopt the curved configuration of Kim, the ordinary artisan would also adopt the

larger footprint of the implant of Kim. *Id.* at 45. Patent Owner argues that the larger footprint of Kim, however, would inhibit the insertion of the implant using the method of Steffee. *Id.*

Petitioner responds that the ordinary artisan "would have understood that the convex curvature of Kim's implant and the teeth 36 of Steffee's implant are merely two complimentary techniques for providing improved resistance to movement for a spinal implant." Reply 9–10 (citing Ex. 1116 ¶¶ 23–25; Ex. 2005 ¶82). Thus, modifying the implant of Steffee to include the convex curvature of Kim would increase the contact between the teeth of Steffee and the inferior and superior vertebrae. *Id*.

Kim teaches that providing a vertebral prosthesis with a convex surface that corresponds to the concave surface of the vertebra allows for multiple advantages, such as an increase in stability of the implant after implantation. Ex. 1110, 2:33–41. We, therefore, credit the Declaration of Dr. Brantigan, which states that adding the convexity of Kim to the implant of Steffee would increase the ability of the teeth to resist movement after implantation. Ex. 1116 ¶ 24. We determine, therefore, that the Petitioner has demonstrated that the ordinary artisan would have had a reason to add convexity as disclosed by Kim to the implant of Steffee.

Patent Owner contends also that, given the divergent teachings of Michelson '037 and Kim as compared to Steffee, Petitioner engaged in improper hindsight in combining Steffee with Michelson '037 and Kim to arrive at the implant of challenged independent claims 7 and 10. PO Resp. 46. We disagree. Although the Supreme Court has cautioned that it may be valuable to identify a particular reason to combine two references, the obviousness analysis is not limited to this inquiry. *See KSR*, 550 U.S. at

418–19. "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* 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." *Id.* The combination of Steffee, Michelson '037, and Kim is no more "than the predictable use of prior art elements according to their established functions." *Id.*

e. Conclusion

After considering Petitioner's and Patent Owner's positions, as well as their supporting evidence, we determine that Petitioner has shown by a preponderance of the evidence that claims 7 and 10 are unpatentable under 35 U.S.C. § 103(a) over the combination of Steffee, Michelson '037, and Kim. Patent Owner presents no additional argument as to dependent claims 8, 9, 11, and 12. PO Resp. 46. Upon review of those claims, as well as the contentions and evidence relied upon by Petitioner, we determine that the preponderance of the evidence of record demonstrates that those claims are rendered also unpatentable by the combination of Steffee, Michelson '037, and Kim.

C. Petitioner's Motion to Exclude (Paper 28)

Petitioner asks us to exclude Exhibits 2007 and 2008. As we did not rely on those exhibits in this Decision, we dismiss Petitioner's Motion to Exclude as moot.

III. CONCLUSION

Petitioner has shown by a preponderance of the evidence that claims 7–12 are unpatentable under 35 U.S.C. § 103(a) as rendered obvious by the combination of Steffee, Michelson '037, and Kim.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 7–12 of the '696 patent are unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *dismissed* as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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