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Paper No. 36
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00395
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 1–6 ("the challenged claims") of U.S. Patent No. 8,444,696 B2 ("the '696 patent"). Paper 7 ("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 1-6 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 12 ("Institution Decision"; "Dec. Inst.").

Patent Owner filed a Response (Paper 24, "PO Resp."), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 25 ("Reply"). An oral hearing was held on July 31, 2014. The transcript of the hearing has been entered into the record. Paper 35.

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 1–6 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, IPR2013-00396, involves claims 7–12 of the patent. Petitioner indicates further that Patent Owner has asked the district 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. 1002, 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 adjacent to the area of the disc removal.” *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 ’696 patent teaches further that the “upper and lower surfaces conforming to the contours of the vertebral endplates, which contours include but are not limited to being relatively flat or convex.” *Id.* at 2:52–55. 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:

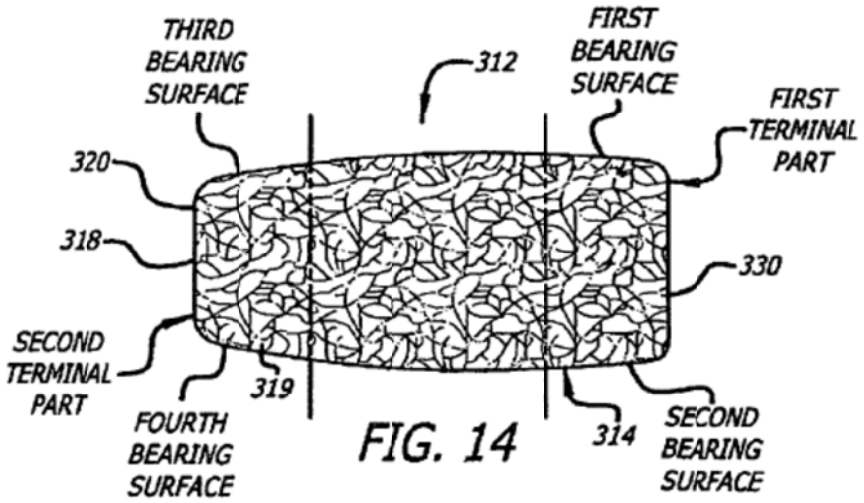

FIG. 14

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:

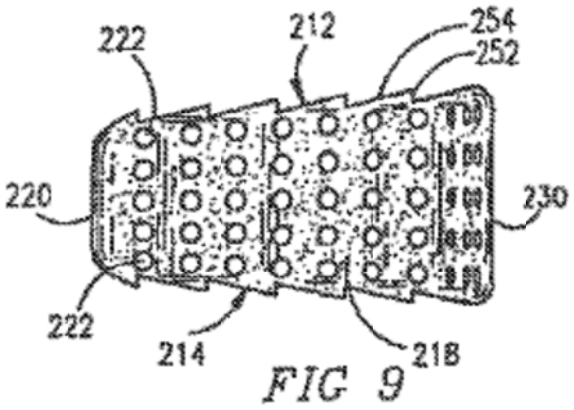

Figure 9 is a side elevational view of a lordotic interbody spinal fusion implant. *Id.* at 4:63:67. As seen in Figure 9, the ratchetings are oriented in the direction of the insertion end, 220, allowing for one-way insertion of the implant, and the bone engaging end, 252, prevents the implant from backing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

D. Illustrative Claim

Petitioner challenges claims 1–6 of the ’696 patent. Claims 1 and 4 are independent claims. Claim 1 is illustrative, and reads as follows:

1. A 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,

said trailing face having a recessed portion and a threaded opening configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

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, the width of said implant being greater than the height 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;

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 surfaces each 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;
>
> 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 Challenges

Claims	**Basis**	**References**
1, 3, 4, and 6	§ 103(a)	Senter[1] and Brantigan ’035[2]
2 and 5	§ 103(a)	Senter, Brantigan ’035, and Brantigan ’327[3]
1–6	§ 103(a)	Michelson ’037,[4] Wagner,[5] and Brantigan ’035

[1] Senter (“Senter”), WO 93/01771, published February 4, 1993 (Ex. 1007).
[2] Brantigan (“Brantigan ’035”), WO 89/09035, published October 5, 1989 (Ex. 1005).
[3] Brantigan (“Brantigan ’327”), US 5,192,327, issued March 9, 1993 (Ex. 1006).
[4] Michelson (“Michelson ’037”), WO 90/00037, published January 11, 1990 (Ex. 1008).
[5] Wagner (“Wagner”), US 5,306,309, issued April 26, 1994 (Ex. 1009).

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 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 only need to construe the following claim terms.

1. "opening"

Independent claims 1 and 4 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. 15–16. Petitioner responds that Patent Owner's interpretation is overly narrow. Reply 1.

Independent claim 1 requires that the implant have a first side and a second, opposite side, with the remaining two sides of the implant defined

by the claims as having the upper and lower bearing surfaces. The claims, thus, define the first and second sides as being the horizontal sides. 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. "upper and lower bearing surfaces"

Independent claims 1 and 4 require "upper and lower bearing surfaces each 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." Patent Owner contends that, in view of the disclosure of the '696 patent, the upper and lower bearing surfaces should be construed as "upper and lower surfaces for bearing against the anatomic endplates of the adjacent vertebrae." PO Resp. 17. In particular, Patent Owner contends that the "upper and lower bearing surfaces" should be construed as having "a length measured parallel to the longitudinal axis of the spinal fusion implant, have portions proximate each of the first and second sides, and are convexly curved along the entire length thereof relative to the second plane in a direction parallel to the longitudinal

axis, the convex curvatures conforming to the anatomic endplates of the adjacent vertebrae along the entire length thereof." *Id.*

As demonstrated by the embodiment shown in Figure 14, reproduced above, however, there may be more than a single bearing surface. The claim language only requires that those bearing surfaces be convex. We agree, therefore, with Petitioner that the claim language does not require that the convexity be along the entire length of the implant. Moreover, independent claims 1 and 4 only require that the "upper and lower bearing surfaces . . . being convex along the entire length of said upper and lower bearing surfaces." There is nothing in the claim language that requires that the convexity conform to the anatomic endplates of the adjacent vertebrae. The Specification does not provide a definition of convexity as conforming to the anatomic endplates of the adjacent vertebrae with reasonable clarity, deliberateness, and precision. We decline, therefore, to construe the convexity of the bearing surfaces as requiring that the convexity conform to the anatomic endplates of the adjacent vertebrae.

Thus, we construe "upper and lower bearing surfaces" as requiring that the bearing surface itself must be convex along the entire length of the bearing surface, but as the implant may have more than one upper bearing surface, as well as more than one lower bearing surface, the convexity need not be along the entire length of the implant. Moreover, the convexity need not conform to the anatomic endplates of the adjacent vertebrae.

3. "ratchetings"

Independent claims 1 and 4 require "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." 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. 18 (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. We note, however, that the claim does not require any specific directionality of the ratchets, such as, allowing for easier movement in the direction of insertion.

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. Secondary Considerations

Patent Owner contends that Dr. Michelson is a prolific inventor, and his "spinal implants are the preferred implants of choice for many surgeons performing spinal fusion surgeries." PO Resp. 24. According to Patent Owner:

> The widespread adoption of Dr. Michelson's spinal fusion implants is evidenced by the commercial success thereof. In particular, sales of spinal fusion implants by Medtronic (e.g., CLYDESDALE® Spinal System (Ex. 2011)) that are covered by independent claims 1 and 4 have totaled more than $80 million from inception to present and $15 million in fiscal year

> 2013 alone. (Ex. 2010) Warsaw submits that the commercial success of the spinal fusion implants covered by independent claims 1 and 4 support a finding of nonobviousness.

Id. Patent Owner contends further that Petitioner's expert, Dr. Brantigan, "agrees that there has been significant adoption of spinal fusion implants that appear to fall within the scope of the '696 patent." *Id.* (citing Ex. 2009. 172:15–173:2).

Before we can determine that the obviousness determinations above render the challenged claims unpatentable, we must consider the evidence of obviousness anew in light of any evidence of secondary considerations of nonobviousness presented by Patent Owner. *See Graham*, 383 U.S. at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) ("This objective evidence must be 'considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art.'") (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).

"Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In order to establish a proper nexus, the patent

owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. *See Microsoft v. Proxyconn, Inc.*, IPR2012-00026, slip op. at 4 (PTAB Mar. 8, 2013) (Paper 32).

Patent Owner, however, has not attempted to establish a nexus between the claims of the '696 and the CLYDESDALE® Spinal System. Thus, Patent Owner's arguments and evidence as to commercial success are entitled to little or no weight.

3. Obviousness under 35 U.S.C. § 103(a) of claims 1, 3, 4, and 6 over the Combination of Senter and Brantigan '035

Petitioner contends that the combination of Senter and Brantigan '035 would have rendered obvious independent claims 1 and 4, as well as dependent claims 3 and 6. Pet. 14–19. Petitioner sets forth a claim chart demonstrating where each element of the claims is taught by the combination (Pet. 34–47), and relies, initially, on the Declaration of Dr. John W. Brantigan (Ex. 1001). Patent Owner disagrees with Petitioner's assertions (PO Resp. 25–46), 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. Senter (Ex. 1007)

Senter is drawn to an implant that is placed between two vertebrae to fuse the vertebrae together. Ex. 1007, 1:4–7.[6] The posterior ledge of the implant is tapered inward preferably to permit the implant to be inserted between the vertebrae during a surgical procedure. *Id.* at 5:34–37. Senter

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

teaches further that the "surface of the intermediate ridge is preferably smooth for the same reason." *Id.*at 5:37–6:2. As taught by Senter, the "anterior platform and/or the posterior ledge and/or the ridge can be bowed outwardly slightly to match the shape of the contacted vertebrae more precisely." *Id.* at 6:13–16.

Figure 4 of Senter is reproduced below:

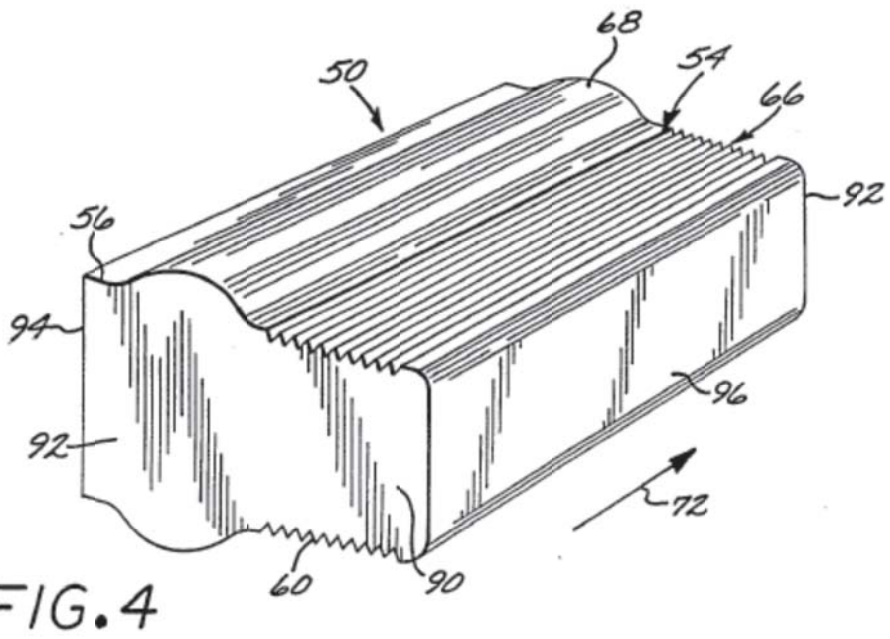

FIG. 4

Figure 4, above, shows a perspective view of an embodiment of the spinal implant of Senter. *Id.* at 8:6–9. Implant 50, as shown in Figure 4, has four sides, and "a pair of spaced-apart, opposed parallel bases 92." *Id.* at 10:2–4. The implant includes pattern of serrations 66, which may be small teeth, continuous small ridges, bumps, or equivalent structures. *Id.* at 11:12–17. The serrations "interlock with the cancellous bone of the vertebrae to inhibit dislocation (movement) of implant 50 relative to the vertebrae after implantation." *Id.* at 11:17–20.

Senter teaches:

> Dislocation (movement) of any spinal implant is a serious concern, and the present implant 50 is designed to avoid such movement. Dislocation of the implant 50 posteriorly toward the foramen 38 is of particular concern, because such dislocation could result in the implant 50 impinging against the spinal cord. The combination of the ridge 68, the serrations 66, and the slightly wedge-shaped configuration of the implant 50 all aid in avoiding dislocation of the implant 50, and particularly in avoiding dislocation in the direction of the spinal cord.

Id. at 11:33–12:7.

The implant of Senter is implanted surgically by grinding a groove into the superior and inferior vertebrae. *Id.* at 15:35–37. The groove is positioned so as to provide a flush placement of the implant, such that close contact between the ridge of the implant and the groove ground into the vertebrae is achieved. *Id.* at 16:3-10. As taught by Senter, typically, the spine is distended to ease insertion of the implant. *Id.* at 16:20–22.

b. Brantigan '035 (1005)

Brantigan '035 is drawn to an implant, in the form of inert plugs, to be placed in prepared sites between opposed faces of adjacent vertebrae. Ex. 1005, 1:3–8.[7] The plugs may have barbs to bite into the vertebrae, as well as slots for carrying bone graft material. *Id.* at 1:16–17.

The plugs are mounted endwise on a tool to facilitate insertion. *Id.* at 1:12–13. Specifically, the plugs may have at one end an internally threaded axial hole, and wings or slots radiating from the hole. *Id.* at 5:13–16. An insertion tool then may be threaded into the hole and surrounded by a sleeve

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

that is fitted into the wings or slots. *Id.* at 5:16–18. Brantigan '035 teaches the use of "[b]ristle or prong surfaces," which may be shaped to facilitate insertion and resist retraction. *Id.* at 6:13–15. The implant also may have horizontal or vertical slots that are packed with bone graft material. *Id.* at 7:10–15.

c. Analysis

Petitioner asserts that Senter discloses almost all the limitations of independent claims 1 and 4, Pet. 14, and provides a detailed claim chart demonstrating where each of the limitations may be found, *id.* at 34–47. Petitioner notes, however, that Senter may "not disclose (i) 'a recessed portion and a threaded opening' of the trailing face, (ii) 'an opening' for the growth bone, or (iii) the 'ratchetings.'" *Id.* at 14. Petitioner asserts that those features were known widely and used conventionally in spinal implants, as evidenced by Brantigan '035. *Id.*

Specifically, according to Petitioner, the ordinary artisan would have included a recessed portion and threaded opening, as taught by Brantigan '035, in order to provide a convenient process to insert and remove the insertion instrument without disturbing the mounting. *Id.* at 15. Petitioner also asserts that the ordinary artisan also would have incorporated at least one opening into the implant, and Brantigan '035 teaches that the opening may be filled with strips of bone implant, which then may grow into the bone tissue of the adjacent vertebrae. *Id.* Similarly, Petitioner also argues that the ordinary artisan would have included ratchetings on the upper and lower bearing surfaces, as Brantigan '035 discloses that such ratchetings inhibit dislocation of the implant once it has been placed. *Id.* at 16. According to Petitioner, combining Senter and Brantigan 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 17 (citing *KSR*, 550 U.S. at 417).

Patent Owner contends that Senter does not teach or suggest the limitation of claims 1 and 4 that the upper and lower bearing surfaces are convex. PO Resp. 26. According to Patent Owner, Petitioner relies on features 68 and 68a of Senter as the upper and lower bearing surfaces of independent claims 1 and 4. *Id.* at 29. Senter teaches cutting away portions of the endplates of the superior and inferior vertebrae, 22a and 22b, and, therefore, Patent Owner contends that “the intermediate ridges 68, 68a do not conform to the anatomic endplates of the superior and inferior vertebrae 22a and 22b, but instead, conform to the grooves 80.” *Id.*

As construed above (*see* Section II(A)(2), above), the convexity of the upper and lower bearing surfaces need not extend along the entire length of the implant, and also need not conform to the anatomic endplates of the adjacent vertebrae. It is irrelevant, therefore, that the convex surfaces of Senter conform to grooves cut into the endplates of the superior and inferior vertebrae, rather than to the anatomic endplates of the superior and inferior vertebrae. As Senter teaches upper and lower bearing surfaces that are convex, it meets that limitation of challenged independent claims 1 and 4.

Patent Owner argues further that that the ordinary artisan would not have modified Senter to include ratchetings. PO Resp. 30. Patent Owner contends that Senter is concerned about movement of the spinal disk implant towards the spinal cord, and is configured to prevent forward movement of the implant. *Id.* at 33–34 (citing Ex. 1007, 11:35–12:2). The nubs of Brantigan ’035, Patent Owner argues, accommodate movement in the

direction of insertion, and prevent movement in the opposite direction. *Id.* at 33 (citing Ex. 1005, 20:30–21:3). According to Patent Owner, because the nubs of Brantigan '035 would afford forward movement of the implant, Senter teaches away from their use by its use of an implant that is configured to prevent forward movement. *Id.* at 34.

Petitioner responds that "[d]uring implantation the vertebrae are distracted (i.e., spread apart) to allow for insertion of the implant." Reply 4 (citing Ex. 1017 ¶¶ 7, 18; Ex. 1018, 69–70). Although the ratchets may accommodate movement in one direction during insertion, once implanted, the ratchets would resist both forward and backward movement, as well as side-to-side movement, due to the ratchets digging into the surrounding vertebrae. *Id.* (citing Ex. 1017 ¶¶ 4–9). Petitioner asserts further that the ratchets do not propel movement of the implant in any direction. *Id.* (citing Ex. 1017 ¶ 5). Thus, Petitioner contends that Senter does not teach away from the combination with Brantigan '035.

We credit the Declaration of Dr. Brantigan that the two adjacent vertebrae may be distracted upon insertion of the implant. Ex. 1017 ¶¶ 7, 1; *see also* ex. 1007, 16:20–22 (noting that the spine is distended typically to ease insertion of the implant). In fact, Patent Owner's expert, Dr. Branch, agreed that if serrations were put on the convex surfaces of the device of Senter, and the vertebral bodies were distracted sufficiently, the ratchets would not contact the vertebral bodies upon insertion. Ex. 1018, 69–70.

Moreover, as taught by Brantigan '035, the sharp apexes of the nubs bite into the vertebrae bone, and, thus, once the implant is in the proper position, it will not shift from that position. Ex. 1005, 21:1–5. We, thus, credit Dr. Brantigan's testimony that the ratchetings would not propel an

implant forward, but would resist forward movement of the implant, as well as back-out of the implant, after implantation. Ex. 1017 ¶ 18. Thus, we agree with Petitioner that Senter does not teach away from the combination with Brantigan '035.

Patent Owner argues further that modifying Senter with Brantigan '035, as suggested by Petitioner, would undermine the function of the Senter implant. PO Resp. 34 In particular, Patent Owner contends that adding the nubs of Brantigan '035 to the intermediate ridges 68 and 68a of Senter would not only facilitate movement of the spinal disk implant in the direction of insertion, they would also interfere with the function of the intermediate ridges. *Id.* at 35 (citing Ex. 2005 ¶ 88). Senter teaches that the ridges are preferably smooth, without serration, to allow for surgical implantation. *Id.* (citing Ex. 1007, 11:30–31). Providing the ridges with serrations would interfere with insertion. *Id.* at 36–38 (citing Ex. 2005 ¶¶ 90, 91).

Petitioner responds that the convex ridges of Senter would have prevented movement of the implant after implantation if they were modified to include conventional ratcheting. Reply 5 (citing Ex. 1001 ¶¶ 36–38). Moreover, Petitioner argues that including ratchetings on the convex ridges of Senter would provide "a 'belt-and-suspenders' approach" to prevent migration after implantation. *Id.* at 6 (citing Ex. 1017 ¶¶ 7–9, 31–36). Thus, Petitioner asserts that providing ratchets on the convex ridges of Senter "would not undermine the function of the Senter implant." *Id.* Petitioner notes further that Patent Owner argues that the ratchets would interfere with forward movement during insertion (PO Resp. 36), but then argues that the

ratchets would afford movement, and thus encourage dislocation after implantation (PO Resp. 38). Reply 6.

Initially, we agree with Petitioner that Patent Owner is, to a certain extent, taking inconsistent positions. That is, Patent Owner argues that "providing the ratchetings such as the nubs 122 of Brantigan '035 on the intermediate ridges 68, 68a would also interfere with the insertion of the spinal disk implant 50 of Senter between the adjacent vertebrae," (PO Resp. 36), but then argues **"**rather than inhibiting dislocation thereof, providing the intermediate ridges 68, 68a with ratchetings such as the nubs 122 of Brantigan '035 would afford movement of the modified spinal disk implant 50 of Senter between the superior and inferior vertebrae 22a and 22b in the direction of insertion" (*id.* at 38). Thus, Patent Owner appears to be arguing that if ratcheting were added to the intermediate ridge of Senter, the ratchetings would impede insertion, but then would afford the implant the ability to move after insertion.

Moreover, Senter teaches:

> The posterior ledge is preferably, although not necessarily, tapered inwardly to permit the implant to be inserted between the vertebrae during the surgical procedure. The surface of the intermediate ridge is preferably smooth for the same reason.

Ex. 1007, 5:34–6:2. Although Senter teaches that it may be preferred that the surface of the intermediate ridge be smooth for ease of insertion, 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 Laboratories 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.'"). By noting that the surface of the intermediate ridge is preferably smooth, the ordinary artisan would understand that Senter contemplates embodiments in which that ridge is not smooth. The ratchets of Brantigan '035, if added to the intermediate ridges of Senter, would then provide an additional mechanism of ensuring that the implant would not move after implantation. We determine, therefore, that the ordinary artisan would have had a reason to add the ratchets of Brantigan '035 to the intermediate ridges of Senter.

Patent Owner contends further that the ordinary artisan would not have modified the implant of Senter to include the opening of Brantigan '035. PO Resp. 39–42. The implant of Senter is made preferably from a material that bonds to the bone, and thus the implant of Senter "is used in a spinal fusion process, but is not itself a spinal fusion implant." *Id.* at 41.

According to Patent Owner, modifying the implant of Senter to include an opening would not result in an effective spinal fusion implant. *Id.* at 43–46. Patent Owner argues that if bone were used to fill the void created by the opening, the bone would extend above and below the surfaces of the anterior platforms 56, 56a and the posterior ledges 60, 60a. *Id.* at 44. The bone filling would then be subject to dislodgement on insertion through contact with the superior and inferior vertebrae. *Id.* Moreover, Patent Owner contends, if the bone did not fill the void completely, it would be protected by the leading end, but it would be separated from the superior and inferior vertebrae by a significant gap. *Id.* at 45. Such contact is required for fusion to occur. *Id.*

Petitioner responds that Senter specifically teaches that a purpose of its implant "is to 'improve the fusion of the adjacent vertebrae,'" and, is thus, a fusion implant. Reply 7 (quoting Ex. 1007, 17:15–17). Petitioner responds further that Patent Owner's asserted problem of providing the implant of Senter with an opening is not actually a problem, as the ordinary artisan would have understood that placing vertical holes in spinal implants, which may then be filled with fusion-promoting material, was a well-known feature. *Id.* at 7–8. Moreover, as discussed previously, the two adjacent vertebrae are distracted during insertion, thus minimizing the possible loss of graft material. *Id.* at 8. Moreover, a spinal surgeon of ordinary skill would have understood that the opening need not be filled to the very top with the fusion-promoting material, and that minor dislodgment of the material would be tolerable. *Id.* at 8–9 (citing Ex. 1017 ¶ 11).

Senter teaches an implant "that is implanted between two vertebrae during a procedure in which two vertebrae are fused together." Ex. 1007, 4:15–17. Brantigan '035 teaches an implant that has

> vertical or horizontal slots therethrough or intersecting vertical and horizontal slots, packed with bone graft material, such as strips of bone excised from the iliac crest of the pelvis. This implant material provides a block of livng bone that grows all around and through the implant plug into the bone of the vertebrae.

Ex. 1005, 9:12–18. We credit the Declaration of Dr. Brantigan that the ordinary artisan at the time of invention would have understood how to deal with any potential dislodgement of the bone graft material during insertion. Ex. 1017 ¶ 11. We determine that Petitioner has shown that the ordinary artisan would have included the slots of Brantigan '035, including the vertical slots, to further aid in the fusion process taught by Senter.

Patent Owner argues that Petitioner "appears to have cherry picked" the features of Senter and Brantigan '035 and arranged those features in a manner that never existed prior to Dr. Michelson." PO Resp. 25 (citing Ex. 2009, 175:13–20). Specifically, Patent Owner argues that the implants of Senter and Brantigan '035 are very different. PO Resp. 42–43. Patent Owner thus contends "[w]ithout hindsight it is difficult to reconcile the differences between the teachings of Senter and Brantigan '035 embodied in the differences between the spinal disk implant 50 of Senter and the plug implants 111 of Brantigan '035." *Id.* at 43

We disagree. Although the Supreme Court has cautioned that it may be valuable to identify a particular reason to combine 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.* As discussed above, the combination of Senter and Brantigan '035 is no more "than the predictable use of prior art elements according to their established functions." *Id.*

d. 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 1and 4 are unpatentable under 35 U.S.C. § 103(a) over the combination of Senter and Brantigan '035. Patent Owner presents no additional argument as to dependent claims 3 and 6.

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 Senter and Brantigan ’035.

4. Obviousness of Claims 2 and 5 over the Combination of Senter (1007), Brantigan ’035, and Brantigan ’327

Petitioner contends that claims 2 and 5 are rendered obvious by the combination of Senter, Brantigan ’035, and Brantigan ’327 (Pet. 18–19, 47–48). Patent Owner presents no argument, other than those already discussed as to independent claims 1 and 4, that Petitioner’s contentions are incorrect. PO Resp. 46. Upon review of claims 2 and 5, 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 unpatentable by the combination of Senter, Brantigan ’035, and Brantigan ’327.

5. Obviousness of Claims 1–6 over the Combination of Michelson ’037, Wagner, and Brantigan ’035

Petitioner contends that the combination of Michelson ’037, Wagner, and Brantigan ’035 teaches all the limitations of the challenged claims (Pet. 19–22). Petitioner sets forth a claim chart demonstrating where each element of the claims is taught by the reference (Pet. 48–59), and relies, initially, on the Declaration of Dr. Brantigan (Ex. 1001). Patent Owner disagrees with Petitioner’s assertions (PO Resp. 46–56), and relies on the Declaration of Dr. Branch (Ex. 2005) as evidence that the asserted combination does not render obvious the challenged claims.

a. Michelson '037 (Ex. 1008)

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. 1008, 1:2–4.[8] The implant allows for bone fusion across the intervertebral space, and may contain cells or openings, into which fusion promoting materials may be placed. *Id.* at 8:10–21. The implant may have texturizing on its surface to allow for bone ingrowth. *Id.* at 8:21–25.

Figure 1 of Michelson '037 is reproduced below:

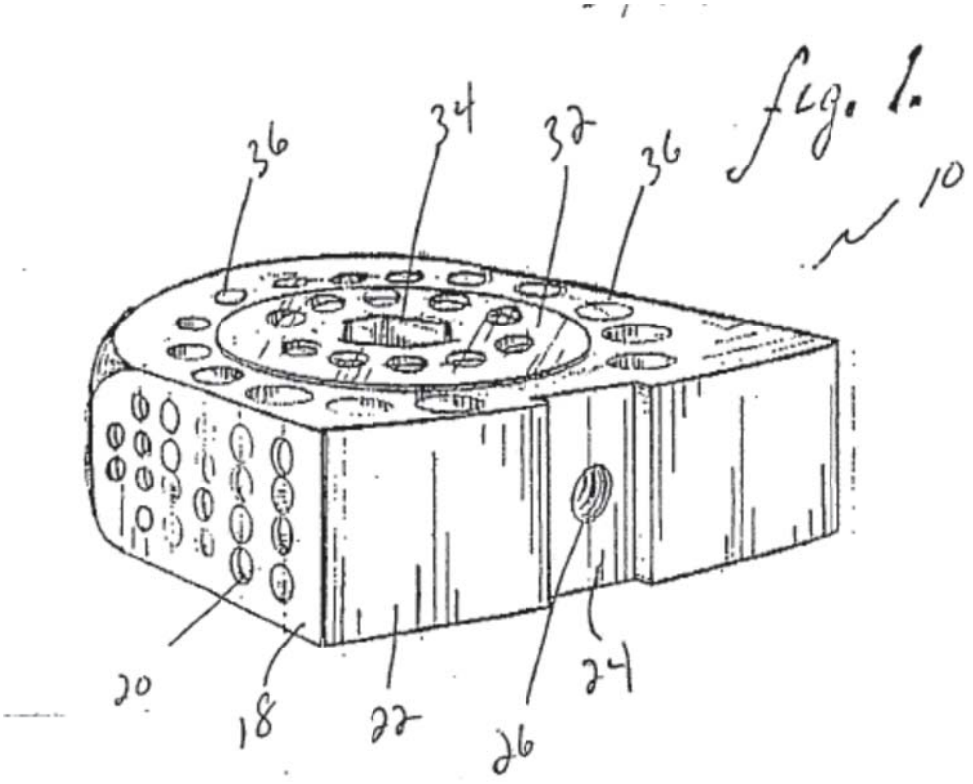

Figure 1, above, is a top right perspective view of the implant of Michelson '037. *Id.* at 10:13–14. The implant shown in Figure 1 has a substantially rectangular hollow configuration, and has a tapered forward portion. *Id.* at 11:30–32. Front wall 22 of the implant, is slightly convex,

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

and has a depressed portion, 24, that has a central threaded opening, 26, that can receive the engaging end of a driving member. *Id.* 11:38–40.

b. Wagner (Ex. 1009) and Brantigan '035 (Ex. 1005)

Wagner describes an implant that is placed between two vertebrae to fuse the vertebrae together. Ex. 1009, 1:6–10. The implant has a convexly curved anterior and a posterior face, which generally match the shape of the outer edge of the vertebrae. *Id.* at 3:13–16; 5:24–39. In addition, Wagner teaches the use of a convex engagement region on the transverse faces, wherein the engagement region "has three-dimensional features thereon." *Id.* at 3:38–41. In one embodiment, the three-dimensional features may be pyramids. *Id.* at 5:68–6:1.

The disclosure of Brantigan '035 is discussed above.

c. Analysis

Petitioner asserts that Michelson '037 discloses almost all the limitations of independent claims 1 and 4, and provides a detailed claim chart demonstrating where each of the limitations may be found. Pet. 19, 48–59. Petitioner notes, however, that Michelson '037 may "not expressly describe the two claimed features of (i) the upper and lower bearing surfaces being 'convex,' and (ii) the 'ratchetings.'" *Id.* at 19. Petitioner asserts that those features were known widely and used conventionally in spinal implants, as evidenced by Wagner and Brantigan '035. *Id.* at 19–20.

Specifically, according to Petitioner, the ordinary artisan would have bowed convexly the upper and lower bearing surfaces outward, as taught by Wagner, in order conform to the contours of the vertebral endplates. *Id.* at 20–21. The ordinary artisan also would have included ratchetings on the upper and lower bearing surfaces, as Brantigan '035 discloses that such

ratchetings inhibit dislocation of the implant once it has been placed. *Id.* at 21. According to Petitioner, combining Michelson '037, Wagner, and Brantigan '035 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 22 (citing *KSR* at 417).

Patent Owner argues that the ordinary artisan would not have modified Michelson '037 as suggested by Petitioner. PO Resp. 47–55. In particular, Patent Owner argues that because Michelson '037 discloses that its implants "are already 'self-stabilizing to resist dislodgement,' one of ordinary skill would not have been motivated to modify the spinal fusion implant 10 of Michelson '037 with the teachings of Wagner and Brantigan '035." *Id.* at 51 (quoting Ex. 2005 ¶ 103).

Petitioner responds that, again, "one of ordinary skill would have been motivated to employ a 'belt-and suspenders' approach to preventing movement of the implant by including Brantigan '035's ratchetings to "prevent retraction" of the implant after insertion and enhance Michelson '037's stated goal of 'resist[ing] dislodgement.'" Reply 11.

As noted by the U.S. Court of Appeals for the Federal Circuit, "[t]he normal desire of scientists or artisans [is] to improve upon what is already generally known." *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003). Thus, the fact that Michelson '037 teaches that its implant is self-stabilizing is not a persuasive argument that the ordinary artisan would not look to the prior art to determine ways in which that implant may be modified.

Patent Owner contends also that the spinal fusion implant of Michelson '037 and the spinal disk implant of Wagner are used to treat different types of spinal disease: The spinal fusion implant of Michelson

’037 is used to treat spinal disease when a degenerative disc has lost its bi-convex appearance, whereas the spinal disk implant of Wagner is used to treat spinal disease occurring where a degenerative disc has limited loss of its bi-convex appearance. PO Resp. 51–52 (citing Ex. 2005 ¶ 104). Thus, Patent Owner asserts, the ordinary artisan would not have modified the implant of Michelson ’037 to include the convexly-bowed transverse faces 68 and 70 of Wagner. *Id.* at 52.

Petitioner responds that Michelson ’037 is not limited to use for treatment of spinal disease due to a degenerative disc having lost its bi-convex appearance, as Michelson ’037 specifically “states that the disclosed implant device ‘will fit any patient, anywhere throughout the spine, *in any vertebral disc space, and without alteration of that interspace regardless of its natural size or shape*.’” Reply 9 (quoting Ex. 1008, 5:18–22). Petitioner notes further that Patent Owner’s expert, Dr. Branch, “agreed that the intent of the Michelson ‘037 implant ‘is to fit any patient’ and that the implant ‘certainly could fit any patient anywhere throughout the spine.’” *Id.* at 10 (quoting Ex. 1018, 113).

As noted by Petitioner, Michelson ’037 teaches that the disclosed implant device will fit any patient, anywhere throughout the spine. Ex. 1008, 5:18–22. Although Patent Owner relies on the Declaration of Dr. Branch to support its assertion that fusion implant of Michelson ’037 is used to treat spinal disease when a degenerative disc has lost its bi-convex appearance, Dr. Branch states only that the “configuration of the spinal fusion implant 10 of Michelson ‘037 implies its use in treatment of spinal disease occurring because of a degenerative disc having lost its bi-convex appearance,” but does not point to any support in Michelson ’037 for that

conclusion, and does not reconcile that conclusion within the quoted language of Michelson '037. Ex. 2005 ¶ 104. Thus, we disagree with Patent Owner that the ordinary artisan would not have looked to Wagner to modify the implant of Michelson '037 on the basis that the implants are used to treat different types of spinal disease.

Patent Owner argues further that Petitioner selects the convexly-bowed transverse faces of Wagner, ignoring the teachings of an engagement region located on those transverse faces. PO Resp. 52. The engagement regions of Wagner, Patent Owner asserts, have one or more three-dimensional pyramids for engaging the adjacent vertebrae. *Id.* at 53. As such, Wagner requires little, if any, preparation of the endplates of the adjacent vertebrae to receive the implant. *Id.* The implant of Brantigan '035, unlike the implants of Michelson '035 and Wagner, requires significant preparation of the adjacent vertebrae. *Id.* In addition, although the nubs formed on the plug implants of Brantigan '035 constrain the movement of the implant, as compared to the engagement regions with the pyramids of Wagner, the nubs of Brantigan '035 provide diminished capabilities. *Id.* Thus, Patent Owner contends, if the ordinary artisan would have adopted the convexly-bowed transverse faces of Wagner, they also necessarily would have included the pyramid shaped engagement features. *Id.* at 53–54.

Patent Owner asserts further that the nubs of Brantigan '035 provide diminished capabilities as compared to the pyramids of Wagner. *Id.* at 54–55. According to Patent Owner, the ordinary artisan would not have replaced "the multi-directional movement prevention afforded by the engagement region 74 with the pyramids 76 of Wagner with the nubs 122 of

Brantigan ‘035 that would be susceptible to forward and side to side movement and require a prepared space in the adjacent vertebrae." *Id.* at 55.

Petitioner responds that there is no legal requirement that if one feature of a reference is used in the combination, all of the features of that reference must also be incorporated. Reply 11–12. Thus, the ordinary artisan would understand that Wagner's convex surface could be incorporated without also incorporating the pyramids disclosed by Wagner. *Id.* Petitioner contends, moreover, that Wagner teaches that the engagement feature may be any three-dimensional feature extending above the bearing faces, and that the pyramids are just one example of such a three-dimensional structure. *Id.* at 12 (citing Ex. 1018, 118–119). Petitioner argues also that "the ratchetings of Brantigan ‘035 do not cause ‘forward and side to side movement' of the implant, but rather prevent movement in all directions, with a slightly higher resistance to movement in a backward direction compared to other directions." *Id.* In particular, Petitioner argues that the ordinary artisan would understand that the convex surface of Wagner and the ratchetings of Brantigan ’035 are complementary options for meeting the goal of Michelson ’037 of resisting dislodgement. *Id.* (citing Ex. 1008, 7:17–19).

As noted by Petitioner, Wagner teaches an engagement region containing three-dimensional features, with one embodiment being pyramids. Thus, the ordinary artisan would not read Wagner as being limited to using pyramids. In addition, "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Thus, we disagree with Patent Owner that, if the ordinary artisan had adopted the convexly-bowed transverse faces of Wagner, they also necessarily would have included the pyramid shaped engagement features. Rather, the ordinary artisan would have understood that the ratchetings of Brantigan '035 would meet the requirement of a three-dimensional feature on the convex surface Wagner. *See* Ex. 1018, 118:8–21 (Dr. Branch, Patent Owner's experts, agreeing that the nubs are three-dimensional features).

We disagree also with Patent Owner that one would not have used the nubs of Brantigan '035, because they provide diminished capacities compared to the pyramids of Wagner. Brantigan '035 teaches that the sharp apexes of the nubs bite into the vertebrae bone, and, thus, once the implant is in the proper position, it will not shift from that position. Ex. 1005, 21:1–5. Thus, the ordinary artisan would understand that the nubs of Brantigan '035 would aid in preventing movement of the implant after placement. Moreover, the obviousness inquiry 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, 554 (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.").

Patent Owner argues again that Petitioner has "cherry-picked" the features of Michelson '037, Wagner, and Brantigan '035, and combined them in a way "that never existed prior to Dr. Michelson without regard to the teachings of these references." PO Resp. 50 (citing Ex. 2009, 175:13–20). According to Patent Owner, the ordinary artisan would not have combined the references as suggested by Petitioner given the diminished capabilities provided by the nubs of Brantigan '035.

We disagree. As noted above with respect to the combination of Senter and Brantigan '035, the combination of Michelson '037, Wagner, and Brantigan '035 is no more "than the predictable use of prior art elements according to their established functions." *Id.*

d. 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 independent claims 1 and 4 are unpatentable under 35 U.S.C. § 103(a) over the combination of Michelson '037, Wagner, and Brantigan '035. Patent Owner presents no additional argument as to dependent claims 2, 3, 5 and 6. PO Resp. 56. 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 Michelson '037, Wagner, and Brantigan '035.

C. Petitioner's Motion to Exclude Evidence (Paper 29)

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 1–6 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Senter and Brantigan ’035; and

Petitioner has shown by a preponderance of the evidence that claims 1–6 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Michelson ’037, Wagner, and Brantigan ’035.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–6 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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