

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

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

GREEN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

NuVasive, Inc. (“NuVasive”) filed a corrected petition (“Pet.”) requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 8,444,696 (Ex. 1002, the “’696 patent”) on July 9, 2013. Paper 7. Patent Owner, Warsaw Orthopedic, Inc. (“Warsaw”), did not file a preliminary response. We have jurisdiction under 35 U.S.C. §§ 6(b) and 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

THRESHOLD. -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Inter partes review is instituted only if the petition supporting the ground demonstrates “that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.” 37 C.F.R. § 42.108(c).

Upon consideration of the Petition, we conclude that NuVasive has established a reasonable likelihood that it would prevail with respect to claims 1–6 of the ’696 patent. Accordingly, we grant the Petition, and institute an *inter partes* review of claims 1–6 of the ’696 patent.

A. *Related Proceedings*

NuVasive indicates that it has filed concurrently another petition for an *inter partes* review of the ’696 patent. Pet. 1. NuVasive indicates further that Warsaw has asked the court for permission to add the ’696 patent to the litigation titled

Warsaw Orthopedic, Inc. v. NuVasive Inc., Case No: 3:12-cv-02738-CAB (S.D. Cal.). *Id.*

B. The '696 Patent (Ex. 1002)

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. The spinal implants are sized to fit within the disc space that is created when the disc material between two adjacent vertebrae is removed, and 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 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.

Figure 14 of the '696 patent is reproduced below:

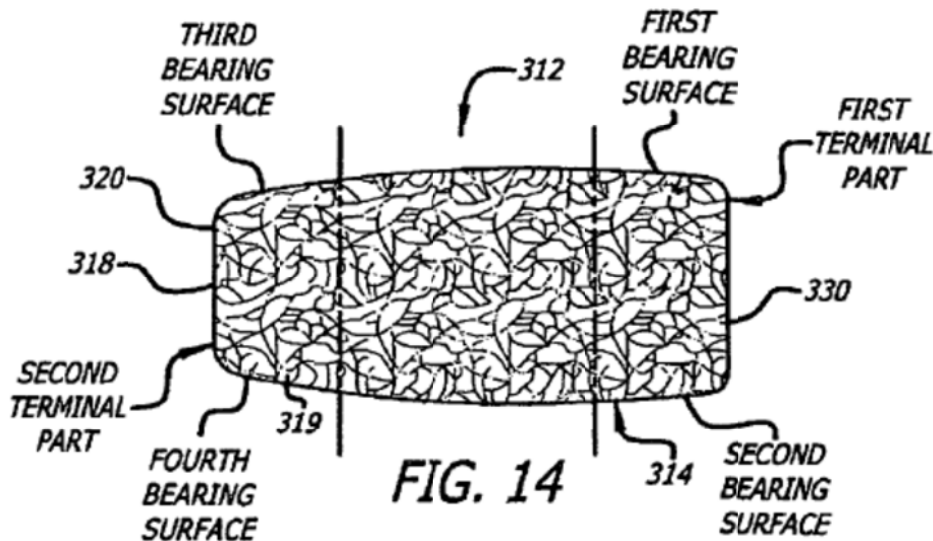


Figure 14, above, is a left side elevational view of a lordotic-interbody-spinal fusion implant. *Id.* at 5:11–12.

The implant shown in Figure 14 has insertion end 320 and trailing end 330. *Id.* at 9:18–19. In addition,

the implant **300** 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 **300** 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.

C. Representative Claims

NuVasive challenges claims 1–6 of the '696 patent. Claims 1 and 4 are independent claims. Claim 1 is representative, 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.

D. Prior Art Relied Upon

NuVasive relies upon the following prior art references:

Kim *et al.* (“Kim”), US 5,645,596, issued July 8, 1997 (Ex. 1004).

Brantigan (“Brantigan ’327”), US 5,192,327, issued March 9, 1993 (Ex. 1006).

Wagner *et al.* (“Wagner”), US 5,306,309, issued April 26, 1994 (Ex. 1009).

Brantigan (“Brantigan ’035”), WO 89/09035, published October 5, 1989 (Ex. 1005).

Senter et al. (“Senter”), WO 93/01771, published February 4, 1993 (Ex. 1007).

Michelson (“Michelson ’037”), WO 90/00037, published January 11, 1990 (Ex. 1008).

E. The Asserted Grounds of Unpatentability

NuVasive challenges the patentability of claims of the ’696 patent on the following grounds. Pet. 2–3.

Reference(s)	Basis	Claims challenged
Kim and Brantigan ’035	§ 103	1, 3, 4, and 6
Kim, Brantigan ’035, and Brantigan ’327	§ 103	2 and 5
Senter and Brantigan ’035	§ 103	1, 3, 4, and 6
Senter, Brantigan ’035, and Brantigan ’327	§ 103	2 and 5
Michelson ’037, Wagner, and Brantigan ’035	§ 103	1–6

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning in view of the specification as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the

specification with reasonable clarity, deliberateness, and precision. *In re Paulson*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Independent claims 1 and 4 recite (emphasis added) “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.” The claims also require (emphasis added) “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.”

NuVasive contends that the broadest reasonable interpretation of the term “‘substantially flat’ in relation to the ‘first side’ and the ‘second side’ of the implant . . . is interpreted to include sides that are either planar or outwardly bowed.” Pet. 3 (emphasis removed). NuVasive acknowledges that the examples provided in the Specification of the ’696 patent all have flat sides, but that the use of the modifier “substantially” allows this construction. *Id.*

Claims 1 and 4 require only that portions of the first and second side are substantially flat, and do not define how much of the side is substantially flat. In addition, the substantially flat portions intersect a second plane that is perpendicular to a first plane, and are symmetrical about the first plane. Thus, what appears to be required by the claims is that there is some substantially flat portion on each of the first and second sides, and that they are symmetrical about the first plane and intersect the second plane. Thus, we agree with NuVasive that the claim language encompasses sides that are outwardly bowed, with the proviso that there is some small portion on each side that is “substantially planar.”

NuVasive contends further that the limitation required by independent claims 1 and 4 of “upper and lower bearing surfaces having portions . . . being convex along the entire length of said upper and lower bearing surfaces” does not require that the convexity is along the entire length of the implant. Pet. 4 (emphasis removed). Rather, NuVasive contends, the convexity “need only be ‘along the entire length of said upper and lower bearing surfaces,’” including the gearing surface portions that are between the two vertical lines shown in Figure 14. *Id.* (emphasis removed).

As demonstrated by the embodiment shown in Figure 14, reproduced above, there may be more than a single bearing surface. The claim language only requires that those bearing surfaces be convex. Thus, we agree with NuVasive that the claim language does not require that the convexity be along the entire length of the implant.

We note that in its Patent Owner Response, Warsaw has the opportunity to inform the Board as to its construction of the claim limitations, and how those claim limitations are supported in the Specification of the ’696 patent. If Warsaw declines to exercise that opportunity, it will leave the Board recourse only to the intrinsic record, as well as NuVasive’s proposed construction of the claim limitations.

B. Obviousness over Senter (Ex. 1007) and Brantigan ’035 (Ex. 1005).

NuVasive contends that claims 1, 3, 4, and 6 are rendered obvious under 35 U.S.C. § 103 by the combination of Senter and Brantigan ’035. *See, e.g.*, Pet. 14–17. NuVasive also contends that claims 2 and 5 are rendered obvious under 35 U.S.C. § 103 by the combination of Senter, Brantigan ’035, and Brantigan ’327. Pet. 18–19.

Senter is drawn to an implant that is placed between two vertebrae to fuse the vertebrae together. Ex. 1007, 1:4–7.¹ 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. 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:

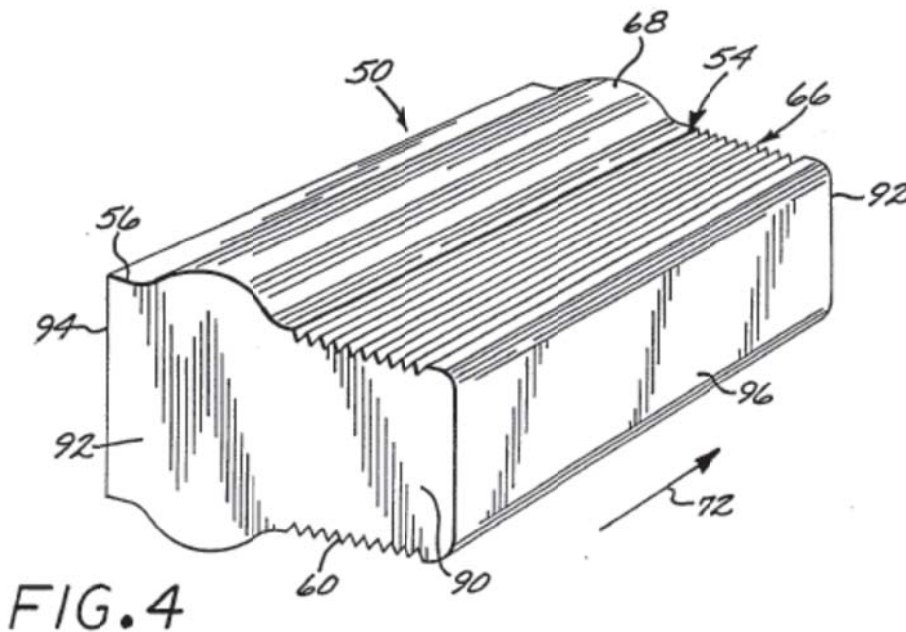


Figure 4, above, shows a perspective view of an embodiment of the spinal implant of Senter. *Id.* at 8:6–9.

The implant 50 as shown in the figure 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

¹ Page numbers refer to the numbers at the top of each page rather than those on the bottom.

cancellous bone of the vertebrae to inhibit dislocation (movement) of the implant 50 relative to the vertebrae after implantation.” *Id.* at 11:17–20.

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, 1:3–8.² 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 that is fitted into the wings or slots. *Id.* at 5:16–18.

NuVasive 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. NuVasive 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. NuVasive asserts that those features were known widely and used conventionally in spinal implants, as evidenced by Brantigan ’035. *Id.*

Specifically, according to NuVasive, 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. NuVasive 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,

² Page numbers refer to the numbers at the top of each page rather than those on the bottom.

which then may grow into the bone tissue of the adjacent vertebrae. *Id.* Similarly, NuVasive 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 Nuvasive, 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 Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)).

We have considered the arguments and evidence presented by NuVasive, and we are persuaded that NuVasive has demonstrated a reasonable likelihood that independent claims 1 and 4 are rendered obvious by the combination of Senter and Brantigan '035. We have considered NuVasive’s arguments and evidence, moreover, as to the obviousness of dependent claims 3 and 6, and are persuaded that NuVasive has demonstrated a reasonable likelihood that it will prevail as to those claims as well. Accordingly, we institute *inter partes* review of claims 1, 3, 4, and 6 for obviousness over Senter and Brantigan '035.

NuVasive cites Brantigan '327 to meet the limitations of dependent claims 2 and 5, Pet. 18–19, and provides a detailed claim chart showing where the additional limitations may be found, *id.* at 47–48. NuVasive also provides reasons as to why the ordinary artisan would have combined Brantigan '327 with Senter and Brantigan '035. Upon consideration of the evidence and arguments provided by NuVasive, we are persuaded that NuVasive has demonstrated a reasonable likelihood that claims 2 and 5 are rendered obvious by the combination of Senter, Brantigan '035, and Brantigan '327. Accordingly, we institute *inter partes* review of claims 2 and 5 for obviousness over Senter, Brantigan '035, and Brantigan '327.

C. Obviousness over Michelson '037 (Ex. 1008), Wagner (Ex. 1009), and Brantigan '035 (Ex. 1005).

NuVasive contends that claims 1–6 are rendered obvious under 35 U.S.C. § 103 by the combination of Michelson '037, Wagner, and Brantigan '035. *See, e.g.,* Pet. 19–22.

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, 1:2–4.³ 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.

³ 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:

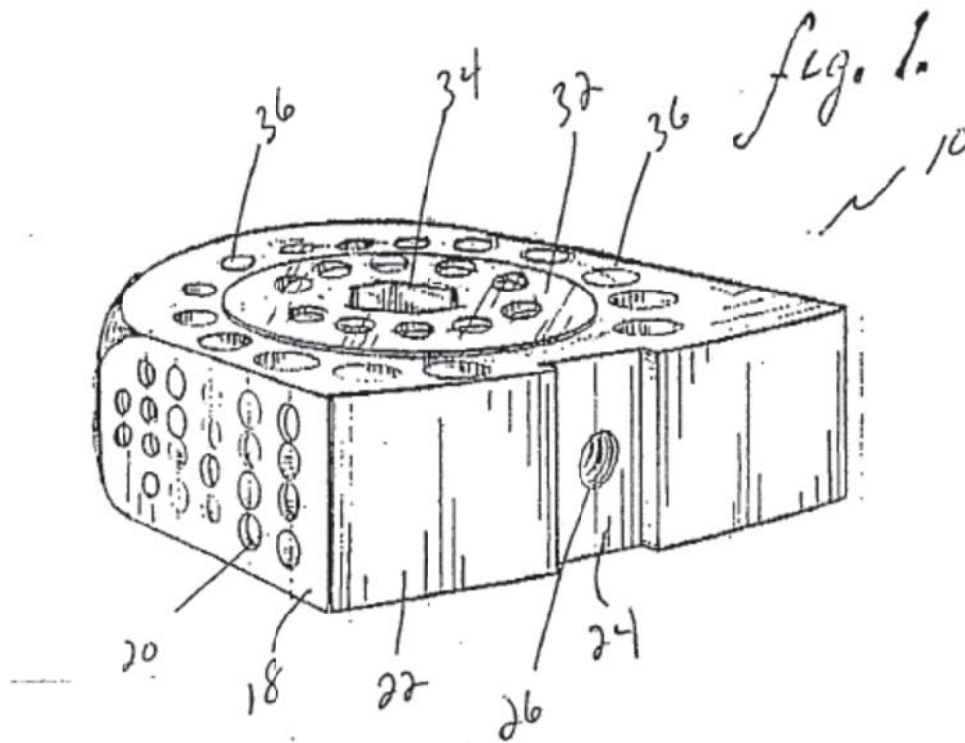


Figure 1, above, is a top right perspective view of the implant of Michelson '037.
Id. at 10:13–14.

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, 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.

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.

Brantigan '035 (Ex. 1005) is discussed above.

NuVasive asserts that Michelson '037 discloses almost all the limitations of independent claims 1 and 4, Pet. 19, and provides a detailed claim chart demonstrating where each of the limitations may be found, *id.* at 48–59. NuVasive 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. NuVasive 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 NuVasive, 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 NuVasive, 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).

We have considered the arguments and evidence presented by NuVasive, and we are persuaded that NuVasive has demonstrated a reasonable likelihood that independent claims 1 and 4 are rendered obvious by the combination of Michelson '037, Wagner, and Brantigan '035. Moreover, we have considered NuVasive's arguments and evidence as to the obviousness of dependent claims 2, 3, 5, and 6, and are persuaded that NuVasive has demonstrated a reasonable likelihood that it will prevail as to those claims as well. Accordingly, we institute *inter partes* review of claims 1–6 for obviousness over Senter and Brantigan '035.

Other Challenges

Upon review of the other challenges asserted by NuVasive against claims 1–6, we conclude that they are redundant in light of the grounds on the basis of which we institute review.⁴

III. CONCLUSION

For the foregoing reasons, we determine that NuVasive has demonstrated a reasonable likelihood that it will prevail on its challenges of claims 1–6 of the '696 patent.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim.

IV. ORDER

It is

ORDERED that the petition is *granted* as to claims 1–6 with respect to the following grounds:

Claims 1, 3, 4, and 6 as obvious under 35 U.S.C. § 103 by the combination of Senter and Brantigan '035;

Claims 2 and 5 as obvious by the combination of Senter, Brantigan '035, and Brantigan '327; and

⁴ We acknowledge Petitioner's statement that the "three sets of obviousness grounds for claims 1–6 are not cumulative, but instead all rely upon different primary references that individually assert unique benefits to the patient, the practitioner, or both, address the dependent claims in different ways, and one reference (Kim) may be removed if sworn behind." Pet. 8. Except for stating that Kim may be removed if sworn behind, Petitioner does not provide further explanation why the grounds are not redundant.

Claims 1-6 as obvious under 35 U.S.C. § 103 by the combination of
Michelson '037, Wagner, and Brantigan '035;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '696 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial;

FURTHER ORDERED that all other grounds presented in NuVasive's petition are *denied*, and no ground other than those specifically granted above is authorized for the *inter partes* review as to claims 1–6; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2:00 pm Eastern Time on January 16, 2014. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

Case IPR2013-00395

Patent 8,444,696

Petitioner:

Stephen Schaefer

Michael Hawkins

Fish & Richardson P.C.

schaefer@fr.com

hawkins@fr.com

Patent Owner:

Thomas Martin

Wesley Meinerding

MARTIN & FERRARO, LLP

tmartin@martinferraro.com

wmeinerding@martinferraro.com