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Paper 18
Entered: July 9, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2019-00362
Patent 8,361,156 B2

Before DENISE M. POTHIER, HYUN J. JUNG, and SHEILA F. McSHANE, *Administrative Patent Judges.*

POTHIER, *Administrative Patent Judge.*

DECISION TO INSTITUTE
35 U.S.C. § 314

I. INTRODUCTION

Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of U.S. Patent No. 8,361,156 B2 (Ex. 1001, "the '156 patent"). NuVasive Inc. ("Patent Owner") filed a Preliminary Response (Paper 11, "Prelim. Resp."). Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and Preliminary Response and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We institute an *inter partes* review of all challenged claims on all presented challenges and, thus, institute an *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the '156 patent has been asserted in *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.) and *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-002738-CAB-MDD (S.D. Cal.). Pet. 76–77; Paper 4, 2. Petitioner indicates the latter litigation was settled on July 27, 2016. Pet. 77.

The parties additionally note that the '156 patent was previously challenged in Cases IPR2013-00504, IPR2013-00506, and IPR2014-00487.

Pet. 16, 21; Paper 4, 2 (citing *In re NuVasive, Inc.*, 842 F.3d 1376 (Fed. Cir. 2016)).

The parties also state that a related patent, U.S. Patent 8,187,334, is challenged in Cases IPR2019-00361 and IPR2019-00546. Pet. 77; Paper 4, 2 (further citing Cases IPR2013-00507 and IPR2013-00508 and *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016)); Paper 7, 2.

B. The '156 Patent (Ex. 1001)

The '156 patent issued January 29, 2013, from an application filed April 6, 2012, which is a continuation of an application filed on April 5, 2012, which is a continuation of an application filed on April 4, 2011, which is a continuation of an application filed on March 29, 2005, and claims priority to a provisional application filed on March 29, 2004. Ex. 1001, (22), (60), (63), 1:6–15.

The '156 patent relates to "a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction . . . to introduce the spinal fusion implant into any of a variety of spinal target sites." *Id.* at 1:21–25. Figure 2 of the '156 patent is reproduced below.

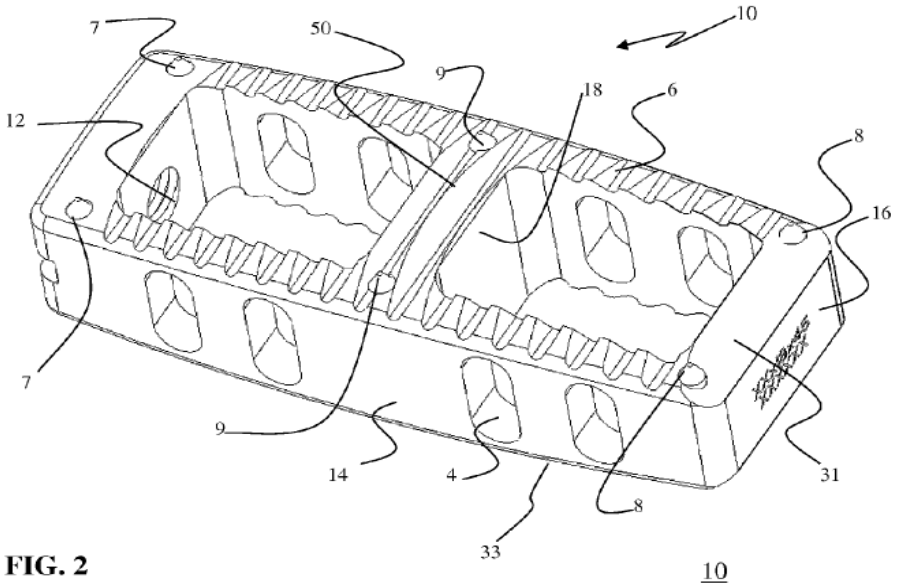

FIG. 2

The above Figure 2 shows a perspective view of a lumbar fusion implant. *Id.* at 3:36. The spinal fusion implant is introduced into a lumbar disc space through a lateral, a posterior, an anterior, an antero-lateral, or a postero-lateral approach to the spine. *Id.* at 5:29–35. The implant is made from a radiolucent material, such as poly-ether-ether-ketone (PEEK). *Id.* at 5:10–15.

Common attributes of the various embodiments of spinal fusion implant 10 includes top surface 31, bottom surface 33, lateral sides 14, proximal side 22, and distal side 16. *Id.* at 6:6–9, Figs. 2–3. By way of example, spinal fusion implant 10 may have "a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm." *Id.* at 5:15–19.

Spinal fusion implant 10 also preferably includes anti-migration features, such as ridges 6 and spike elements 7–9, designed to increase friction between spinal fusion implant 10 and adjacent contacting surfaces of vertebral bodies. *Id.* at 6:21–32, Figs. 2–3. Spike elements 7–9 are preferably made from materials having radiopaque characteristics. *Id.* at 6:35–38.

Spinal fusion implant 10 has fusion apertures 2, separated by medial support 50, extending through top surface 31 and bottom surface 33. *Id.* at 6:57–59, Figs. 2–3. "[F]usion apertures 2 function primarily as an avenue for bony fusion between adjacent vertebrae." *Id.* at 6:59–61.

C. Illustrative Claim

The '156 patent has 27 claims. Ex. 1001, 12:32–14:43. Petitioner challenges claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27. Claim 1 is the only independent claim and is reproduced below.

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:
>
> an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first sidewall, wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;
>
> wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, *said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length*, and said longitudinal length is greater than said maximum lateral width;
>
> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and
>
> *at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane*.

Ex. 1001, 12:32–67 (emphases added).

D. Evidence Relied Upon

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

(1) U.S. Patent No. 5,192,327, issued March 9, 1993 (Ex. 1007, "Brantigan");

(2) U.S. Patent No. 5,860,973, issued January 19, 1999 (Ex. 1032, "Michelson");

(3) U.S. Patent Application Publication No. US 2003/0028249 A1, published February 6, 2003 (Ex. 1008, "Baccelli"); and

(4) James L. Berry et al., *A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae*, 12 SPINE 362–67 (1987) (Ex. 1022, "Berry").

In support of its challenges, Petitioner provides a Declaration of Charles L. Branch, Jr., M.D. (Ex. 1002). *See* Pet. 21–22, 26–28.

E. Asserted Grounds

Petitioner challenges the patentability of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent on the following grounds:

Claim(s) Challenged	Statutory Basis	Reference(s)
1–3, 5, 9, 10, 12–21, 23, 24, 27	§ 103	Brantigan, Baccelli, and Berry
9	§ 103	Brantigan, Baccelli, Berry, and Michelson

Pet. 21–22, 28–75.

III. 35 U.S.C. § 325(d)

Patent Owner requests denial of institution under 35 U.S.C. § 325(d) because the Office has previously considered the same or substantially the same prior art or arguments (Prelim. Resp. 10) and Petitioner incorrectly argues that its presented grounds are not cumulative to references applied during prosecution of the '156 patent (*id.* at 15–16 (citing Pet. 25–26)). *See id.* at 10–20. Patent Owner provides a summary of the prosecution histories of the application that issued as the '156 patent and its parent applications. *Id.* at 10–14.

Patent Owner also provides its analysis of the factors identified in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 16–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) ("*Becton, Dickinson*"). Patent Owner's analysis focuses on, *inter alia*, the extensive consideration of Brantigan, Berry and Michelson during prosecution of the '156 patent and other related patents; the cumulative nature of Brantigan and Baccelli; the overlap of Petitioner's radiopaque marker configuration with arguments considered during prosecution; Petitioner's failure to identify Examiner error; and Petitioner's failure to provide new evidence to warrant reconsideration. *See* Prelim. Resp. 10–20.

Although Brantigan, Michelson, and Berry were cited during prosecution of the '156 patent on an extensive information disclosure statement (*see* Ex. 1013, 207–217; *see* Ex. 1001, 2–3), there is no evidence in the record that Baccelli was considered. Ex. 1001, 1–3; Pet. 16 (stating "[t]he [E]xaminer never had Baccelli"). As such, any arguments previously made, including during prosecution of the '156 patent, differ from the

arguments presented by Petitioner at least as far as Baccelli is concerned. Also, as Petitioner and Patent Owner indicate, no substantive rejection was presented during the prosecution of the '156 patent or the other noted related applications, such as U.S. Application Nos. 13/079,645 and 13/440,062.[1] Pet. 16 (citing Ex. 1013, 191–194; Ex. 1023, 206–214; Ex. 1025, 106–110); *see* Prelim. Resp. 10–14, 19 (stating that Brantigan, Michelson, and Berry were "considered" by the Examiner and indicating the claims of the '156 patent were not rejected based on prior art). Moreover, during prosecution of the '156 patent, the Examiner did not discuss Brantigan, Michelson, or Berry but rather discussed the "prior art" generally when addressing the reasons for allowance. Ex. 1013, 193. Thus, the first and third *Becton, Dickinson* factors (*see* Prelim. Resp. 15, 19) disfavor denying institution. Also, the fourth and fifth *Becton, Dickinson* factors (*see id.* at 19–20) weigh neither for nor against institution. Specifically, given that there were no arguments presented during examination and the Examiner did not consider Baccelli, Petitioner could not have pointed out the Examiner's error in evaluating the asserted prior art.

Patent Owner's arguments under *Becton, Dickinson*'s second and sixth factors relate to radiopaque markers. *See* Prelim. Resp. 15–16 (arguing that "the [E]xaminer considered at least three references discussing the use of radiopaque markers on radiolucent spinal implants" and that "Brantigan and Baccelli are cumulative to the references . . . because they too do not disclose the claimed marker configuration for the claimed implant"), 20. Patent Owner directs our attention to portions of prosecution histories

[1] These applications matured into U.S. Patent Nos. 8,187,334 and 8,246,686 respectively.

from related applications and the application that issued as the '156 patent concerning radiopaque markers. *See id.* at 16–18 (citing Ex. 1013, 190–193, 196, 201; Ex. 1020, 97, 108–110, 224–226, 230, 245, 247–250, 271–275; Ex. 1023, 212–213, 215–216, 219, 222, 226; Ex. 1025, 104, 112, 114; Ex. 2005, 7:56–60; Ex. 2007 ¶¶ 60, 74, 76, 90, Figs. 7–8; Ex. 2008 ¶ 19; Pet. 15–16). But, as explained in more detail below in addressing the proposed grounds, Baccelli at least raises issues relating to radiopaque marker arrangements on an implant which differ from the previously considered prior art. As such, there is a material difference between the asserted art in this Petition and previously considered art. *Compare, e.g.*, Ex. 1008 ¶¶ 41, 50, 51, Figs. 1–2, 8 (Baccelli), *with e.g.*, Ex. 1001, 1–4; *see* Ex. 1013, 190–193 (the prosecution history of the '156 patent). At this stage, we disagree that Baccelli is cumulative to references considered during prosecution of the '156 patent. Moreover, the challenged claims do not recite a lateral, lumbar implant as discussed by Patent Owner (*see* Prelim. Resp. 16). *See* Ex. 1001, 12:32–67. As a result, the second and sixth *Becton, Dickinson* factors disfavor denying institution.

When considering all the factors for and against institution, the particular circumstances of this case do not indicate that we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution.

IV. 35 U.S.C. § 314(a)

Patent Owner also urges us to exercise our discretion under 35 U.S.C. § 314 to deny institution. Prelim. Resp. 21–34. Patent Owner asserts that this is the fourth *inter partes* review ("IPR") petition challenging the '156 patent and instituting review

> would not be an efficient use of Board resources because the Petition contradicts, without adequate justification, prior findings of the Board that were affirmed by the Federal Circuit and because the Petition fails to address major defects in its case despite having improperly obtained strategic advantage by reviewing NuVasive's briefing in prior IPRs challenging this very same patent using many of the same references.

Id. at 21. Cases IPR2013-00504 and IPR2013-00487, filed by Medtronic, Inc., were not instituted. *See* Prelim. Resp. 21; Ex. 1033; Ex. 1044. Case IPR2013-00506, also filed by Medtronic, Inc., was instituted. Ex. 1031. In the latter case, Case IPR2013-00506, the challenged claims were held to be unpatentable by the Board, but on appeal, the Federal Circuit vacated the Board's final written decision and remanded for further consideration. The case was then settled before a decision on remand issued. *See* Prelim. Resp. 21–23; Pet. 16–21.

Patent Owner also applies the factors identified in *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) (precedential) to the facts of this case and contends that the factors favor denying the Petition. Prelim. Resp. 27–34. Patent Owner asserts although Petitioner has not previously filed a petition challenging the '156 patent, discretion under § 314 is not limited to the same petitioner filing multiple petitions. *Id.* at 28. Patent Owner argues that (1) Petitioner's employees recently departed from NuVasive, Patent Owner, (2) claims 1–14, 19, 20, and 23–27 of the '156 patent were previously challenged in three prior petitions (IPR2013-00504, IPR2013-00506, and

IPR2014-00487[2]), (3) many of the issues and arguments in this Petition are the same as the prior petitions, (4) the references were previously asserted or cited in the prosecution of the '156 patent, and (5) no justification has been given for the delay in filing the instant Petition years after the prior IPRs were instituted. *See id.* at 27–34.

We have considered the parties' respective arguments and decline to exercise our discretion under § 314(a) to deny the present Petition. Our precedent indicates that application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same petitioner, and that relationships between different petitioners are to be considered in weighing the factors. *Valve Corp. v. Elec. Scripting Prods., Inc.*, Case IPR2019-00062, -00063, -00084, slip op. at 9 (PTAB Apr. 2, 2019) (Paper 11) (precedential). Potentially relevant to factors 1 and 3 of the *General Plastic* factors, Patent Owner argues here that "the lack of identity between prior and current petitioners" weighs against institution. Prelim. Resp. 29. Additionally, Patent Owner asserts the employees of the instant Petitioner are recently departed employees of "NuVasive" (*id.*), which is Patent Owner's company. Patent Owner, however, does not identify the nature of any relationship of these former employees with previous petitioners (e.g., Medtronic, Inc.) or provide any support for such a relationship. *See* Prelim. Resp. 29 (citing Ex. 2003, 1–5; Ex. 2018). Thus, *General Plastic* factors 1 and 3 weigh against exercising our discretion to deny institution.

[2] Petitioner asserts Medtronic filed this petition "to remedy deficiencies in IPR2013-00504." Pet. 21.

Additionally, with respect to the remaining *General Plastic* factors, we acknowledge that the Board has considered challenges to the '156 patent, and the Board has previously addressed one of those challenges, IPR2013-00506, in a final written decision. *See* Ex. 1004. Although we understand the purpose of § 314(a) regarding repeated challenges, we also recognize the purpose of the availability of *inter partes* review to parties accused of infringement. Patent Owner's complaint about the multiple *inter partes* review petitions filed against the '156 patent is not persuasive as the respective filings appear to be a direct result of its litigation activity. *See supra* Section II.A. Moreover, claims 15–18 of the '156 patent challenged in this Petition have not been previously challenged in the noted IPRs. Prelim. Resp. 27 (stating the prior petitions challenged claims 1–14, 19, 20, and 23–27 of the '156 patent).

On balance, we determine it is not appropriate to exercise our discretion under 35 U.S.C. § 314(a) to deny institution in this case.

V. CHALLENGES UNDER 35 U.S.C. § 103

A. Claim Construction

On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change applies to petitions filed on or after November 13, 2018. Thus, the revised claim construction standard applies this proceeding. *Id.*; *see* Pet. 26 (stating that the "Board applies 'the standard used in federal courts . . . '" (quoting 83

Fed. Reg. at 51343)); Paper 5, 1 (according filing date of December 13, 2018 to the Petition).

Petitioner states that "no express construction is needed to resolve the issues in this Petition." Pet. 26.

According to Patent Owner, claim 1 defines "longitudinal length" to mean "'a dimension of the implant that extends lengthwise and is greater than the maximum lateral width of the implant.'" Prelim. Resp. 8 (citing Ex. 2009, 424 (a dictionary definition for "longitudinal")). At this stage of the proceeding, no express construction is required for this term other than that required under the express language of claim 1, which is: "a longitudinal length" "extend[s] from a proximal end of said proximal wall to a distal end of said distal wall" where "said longitudinal length is greater than said maximum lateral width." Ex. 1001, 12:45–47, 50–51.

Patent Owner additionally proposes interpreting "medial plane." Prelim. Resp. 8–9. Patent Owner proposes "a medial plane" to mean "a plane that intersects the implant approximately at the midpoint of the longitudinal length" with Patent Owner providing support from the language of claim 1, a dictionary definition, a prior Board determination regarding "medial plane," and Petitioner's proposed interpretation in related litigation. *Id.* at 8–9 (citing Ex. 2009, 5; Ex. 1033,[3] 5, 8; Ex. 2010, 21, 23 respectively). At this stage of the proceeding, we construe this term in accordance with the express language of claim 1 which recites that the medial plane "is [a plane]

[3] Patent Owner appears to err in citing to Exhibit 1041 when referring to "the Board's non-institution decision in IPR2013-00504." Prelim. Resp. 9. Exhibit 1033 is the "Decision Denying Institution for Inter Partes Review" for IPR2013-00504.

generally perpendicular to said longitudinal length." Ex. 1001, 12:49–50. Further, the plain and ordinary meaning of the term "medial" includes "being or occurring in the middle" and "extending toward the middle, especially: lying or extending toward the median axis of the body."[4] Thus, in the context of claim 1, the "medial plane" is located approximately at the midpoint of the longitudinal length. *See* Ex. 1033, 8; *see* Ex. 2010, 21[5]; *see* Prelim. Resp. 9 (citing Ex. 1033; Ex. 2010).

Patent Owner further proposes interpreting the phrase "position proximate to said medial plane" in claim 1. Prelim. Resp. 10; Ex. 1001, 12:65, 67. Patent Owner proposes "proximate" to mean "near" with support from a dictionary definition, and the phrase "position proximate to said medial plane" to mean a "position near the medial plane." Prelim. Resp. 10; Ex. 2009, 6. At this stage of the proceeding, the express language of claim 1 and the dictionary definition support Patent Owner's proposed interpretation of "proximate" to mean "near." Further express interpretation is not required for purposes of this Decision.

For purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, we determine that no other express interpretation is required for any claim term. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy); *see also Nidec Motor Corp. v.*

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[4] *Medial*, The Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/medial (defs. 2a and 2b) (last visited June 15, 2019).

[5] *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.), App'x B1, Joint Claim Construction Worksheet.

Zhongshan Broad Ocean Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "'would have a medical degree with two to three years' experience performing procedures using interbody spinal fusion implants'" or "'would have a mechanical or biomechanical engineering degree with at least two years' experience working in developing implant devices and associated instruments with significant access to orthopedic surgeons or neurosurgeons.'" Pet. 28 (quoting Ex. 1002 ¶ 18). Patent Owner does not assert a different skill level than Petitioner. Prelim. Resp. 3 n.1.

We preliminarily adopt Petitioner's unchallenged, asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition.

C. Challenge Based on Brantigan, Baccelli, and Berry (Ground 1)

1. Brantigan (Ex. 1007)

Brantigan "relates to inert rigid vertebral prosthetic devices and methods for implanting the devices between adjacent vertebrae." Ex. 1007, 1:7–9. Brantigan specifically "deals with ring-like prosthetic plugs or discs used singly or stacked together between vertebrae to form support [struts] in the spinal column and having rigid surfaces facilitating anchoring and providing valleys for bone ingrowth from adjoining vertebrae." *Id.* at 1:14–18.

Brantigan provides a "biologically acceptable, but inert rigid annular prosthesis units [that] are provided to support and fuse with adjacent

vertebrae in both the cervical, thoracic spine and lumbar portions of a human vertebral column." *Id.* at 1:64–68. "The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies . . . ." *Id.* at 1:18–21. They "are generally oval shaped to conform with the general outline perimeter of the vertebrae." *Id.* at 2:2–4. Figure 1 of Brantigan is reproduced below.

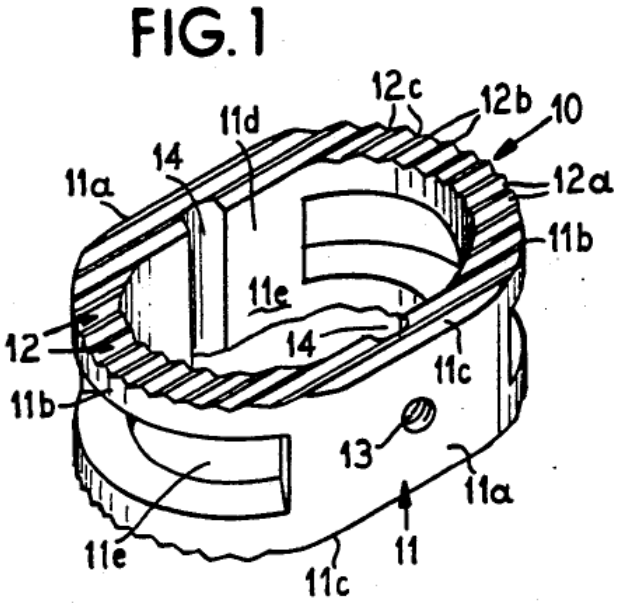


Figure 1 shows a perspective view of a full oval prosthetic device. *Id.* at 3:21–22. Oval ring plug 11 has opposed sides 11*a*, ends 11*b*, top and bottom surfaces 11*c*, and central upstanding aperture 11*d*.[6] *Id.* at 4:5–10. Top and bottom surfaces 11*c* have ridges 12 for engaging adjacent vertebrae. *Id.* at 4:15–16, 5:22–26; *see also id.* at 6:5–16 (describing stack of plugs 11 between vertebrae). One of side walls 11*a* has an internally threaded hole

[6] The '156 patent also describes element "11*d*" as a central aperture and a hollow interior. *Id.* at 4:50, 6:37, Figs. 1–2, 11 (showing reference numeral 11).

13 for receiving a mounting tool, and interiors of side walls 11*a* have grooves 14 for mounting rectangular connecting bar 15. *Id.* at 4:20–27. Figs. 1, 3, 4. In one embodiment, bar 15 separates central aperture 11*d* into two chambers that can be "packed with bone graft material to expedite the fusion of the prosthesis device in the spinal column." *Id.* at 4:50–53, Figs. 1, 3; *see also id.* at 2:15–18 (describing placement of bone graft material).

"The individual plugs or the stack of plugs can be introduced anteriorly, laterally or posteriorly depending upon conditions . . . ." *Id.* at 5:30–32; *see also id.* at 2:34–38 (describing implants of varying height achieved by stacks of rings of varying height), 2:55–66 (describing placement and insertion), 6:61–7:6 (describing insertion of plugs 11). Brantigan further discusses the devices "are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae . . . is damaged," and "[t]wo such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation." *Id.* at 2:2–8, 3:24–25, Fig. 2.

"The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek', (polyetherether ketone) . . . ." *Id.* at 3:9–11. Figure 6 of Brantigan is reproduced below.

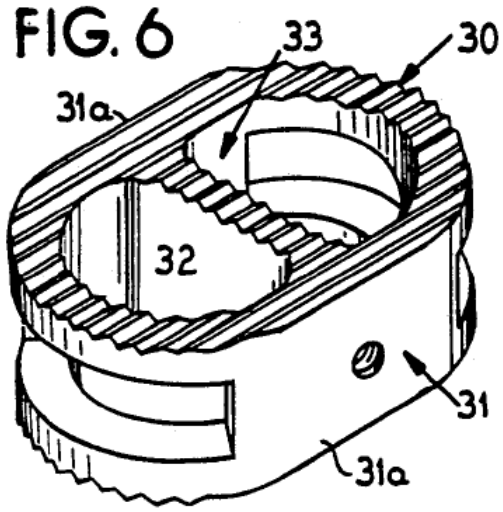


Figure 6 shows a perspective view of a modified device with an integral cross bar. *Id.* at 3:36–37, Fig. 6. Modified device 30 is plug 31 with the same shape as plug 11 but has reinforcing bar 32 integral with side walls 31*a*. Integral internal partition 32[7] bisects hollow interior 23[8] (not shown) forming "side-by-side apertures through the plug adapted to receive bone graft material." *Id.* at 5:37–43, Fig. 6.

2. Baccelli (Ex. 1008)

Baccelli "relates to intervertebral implant." Ex. 1008 ¶ 1. Figures 1 and 2 of Baccelli are reproduced below.

[7] Brantigan describes element "32" as an internal cross bar, a reinforcing bar, and internal partition. *Id.* at 3:36–37, 5:37–43, Fig. 6.
[8] Brantigan previously describes element "23" as a receiving recess. *Id.* at 5:1–2, 5:32–33.

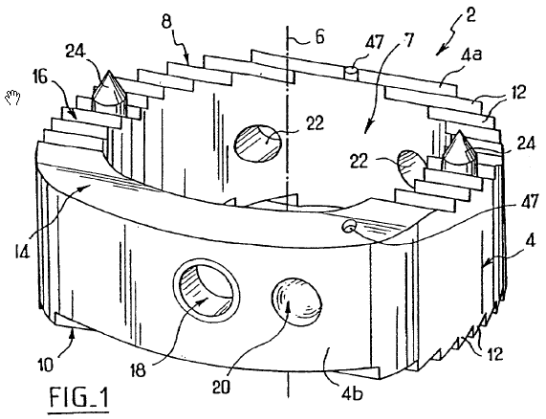


FIG_1

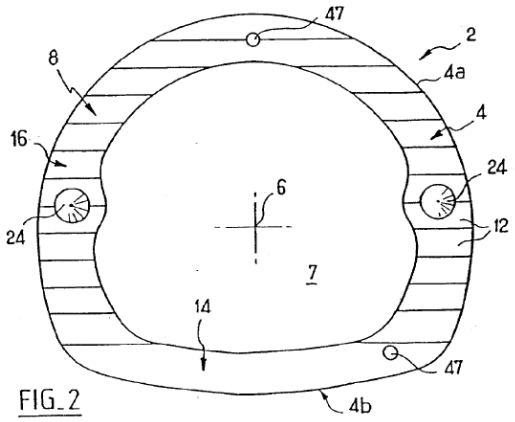


FIG_2

Figures 1 and 2 show perspective and plan views of an implant. *Id.* ¶ 29. Implant 2 is made up of a cage having wall 4 with first portion 4a that is horseshoe shaped and joined to second portion 4b that is cylindrical, superior main face 8, and inferior main face 10 opposite face 8. *Id.* ¶¶ 33–35. Wall 4 defines hole 7 that extends between faces 8, 10. *Id.* ¶¶ 34–35. Faces 8 and 10 have a toothed profile forming teeth 12. *Id.* ¶¶ 36–37. The cage has spikes 24 on faces 8, 10. *Id.* ¶ 41, Figs. 3–5. Fitting tool 40 puts the cage into place between two vertebrae. *Id.* ¶¶ 44–45, Fig. 9.

"The cage can be made of a material that is transparent to X-rays" and "can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation." *Id.* ¶ 50. "The

spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage" and "can be made of a material that is opaque to X-rays." *Id.* ¶ 51.

3. Berry (Ex. 1022)

Berry presents "results of a morphometric study of selected human vertebrae undertaken to provide data for implant design." Ex. 1022, 362 (emphasis omitted). Berry states that "[a]ccurate anatomic descriptions of vertebral shape are necessary for the development of implantable devices and spinal instrumentation" and that the "current study was undertaken due to a lack of information needed for design projects involving instrumentation for the lumbar and thoracic vertebrae." *Id.* "[V]irtually the entire geometry of the vertebrae was quantified by recording a total of 27 measurements per vertebra." *Id.* "The means and standard deviations of the dimensional data for all 240 vertebrae are presented in Table 1." *Id.* at 363; *see also id.* at 364 (presenting Table 1).

4. Claims 1, 5, 10, 12–21, 23, 24, and 27

Petitioner argues that Brantigan teaches or suggests most of the limitations of claim 1. Pet. 8–9, 28–48 (citing Ex. 1002 ¶¶ 30, 122–126, 129–135, 137–138, 142–152, 154–155, 158, 160–163, 165–183, 185, 187, 189, 191–193, 202, 209–211, 241, 257; Ex. 1004, 13; Ex. 1007, Abstract, 1:7–12, 1:14–15, 1:18–29, 1:41–47, 1:54–56, 1:64–24, 2:15–23, 2:34–38, 2:56–62, 3:9–12, 4:3–10, 4:15–18, 4:20–22, 4:50–53, 5:22–26, 5:30–43, 5:59–66, 6:5–16, 6:61–7:6, 7:29–34, Figs. 1, 6, 8, 10, 11, 13, 14; Ex. 1014, 24–25; Ex. 1015, 32–33; Ex. 1019, 5–9, Ex. 1035, 49). Petitioner relies on Berry to reflect the knowledge of a skilled artisan concerning implants, including to teach (1) the average, known length and width of human vertebrae before March 2004 and (2) one skilled in the art would have

recognized that accurate descriptions of vertebral shape would have been necessary to develop implantable devices. *Id.* at 10–11, 29–30 n.7 (citing Ex. 1002 ¶¶ 102, 123, 169–172; Ex. 1022, 362–364, Table 1), 45–46 (citing Ex. 1002 ¶¶ 169, 174–175; Ex. 1022, 362–363, Fig. 1, Table 1). Petitioner also relies on Baccelli for teaching or suggesting the limitations related to radiopaque markers. *Id.* at 9–10, 30–33 (citing Ex. 1002 ¶¶ 122–126, 257; Ex. 1004, 13; Ex. 1008 ¶¶ 12–13, 33–34, 45, 50–51, Figs. 1–5, 8, 9), 49–52 (citing Ex. 1002 ¶¶ 189, 191–193; Ex. 1008 ¶¶ 36, 41, 44, 50–51, Figs. 1–5, 8, 9).

Petitioner contends that an ordinary artisan would have been motivated to combine Brantigan with Baccelli and Berry. *Id.* at 28. More specifically, Petitioner alleges that one skilled in the art would have known the average length and width of vertebrae based on Berry's teachings and would have turned to Berry when developing Brantigan's implant. *Id.* at 29–30 (citing Ex. 1022, 362–364). Additionally, Petitioner contends that one skilled in the art would have been motivated to include radiopaque markers in the middle of Brantigan's sidewalls based on Baccelli's teachings "to enable surgeons to visualize the orientation and location of the implant during and after surgery" and "to allow surgeons to align the markers with the spinous process during and after the implant is inserted laterally." *Id.* at 31 (citing Ex. 1002 ¶¶ 122–126, 257; Ex. 1007, Figs. 8, 10); *id.* at 31–33 (citing Ex. Ex. 1002 ¶¶ 125–126; Ex. 1004, 13; Ex. 1007, Figs. 8, 10 (annotated)).

More specifically, Petitioner asserts the radiopaque "markers enable surgeons 'to identify the position and/or presence of the implant when X-rays are taken during or after the operation'" (*id.* at 30 (quoting Ex. 1008

¶ 50)), suggesting that "[w]ithout radiopaque markers, surgeons would have difficulty identifying" the implant's position and presence "during and after surgery" (*id.* (citing Ex. 1002 ¶ 123)). Petitioner also asserts Brantigan discloses spinal fusion implants "can be introduced anteriorly, laterally or posteriorly depending upon conditions[,] and the tool receiving recesses . . . can thus be positioned to meet the particular type of insertion into the vertebral column." Ex. 1007, 5:30–35, *cited in* Pet. 29. Petitioner further asserts "Baccelli instructs a POSA[9] to include radiopaque markers in the middle of the sidewalls of the implant relative to the direction in which the implant is inserted" (Pet. 31 (citing Ex. 1002, ¶¶ 125–126, 257)), and "[a]dding Baccelli's radiopaque markers to Brantigan's sidewalls . . . would have allowed surgeons to see in an anterior-to-posterior (front) X-ray whether and to what degree the implant is askew relative to the spinous process during and after lateral insertion" (*id.* at 32 (citing Ex. 1002, ¶ 125)). *See id.* at 31–32.

On the present record, we determine that Petitioner provides sufficient support for its challenge of claim 1 as unpatentable over Brantigan, Baccelli, and Berry.

Patent Owner responds that Petitioner misinterprets Baccelli. Prelim. Resp. 34–36 (citing Pet. 10, 50–51; Ex. 1008 ¶¶ 29–31, 50, Figs. 1–5, 8, 9). According to Patent Owner, Petitioner misinterprets the spikes in Baccelli (elements 24) as markers. Prelim. Resp. 34. Patent Owner argues "Baccelli discloses an implant having two (not four) radiopaque markers, each marker [47] being disposed in ducts along the distal and proximal walls–not in the

[9] Person of Ordinary Skill in the Art.

middle of the sidewalls." *Id.* at 35 (citing Ex. 1008 ¶ 50). More specifically, Patent Owner contends spikes 24 are not (a) markers, (b) radiopaque, or (c) located in the sidewalls proximate the medial plane as recited. *Id.* at 35–38 (citing Pet. 10, 50; Ex. 1008 ¶¶ 16–17, 24, 29–31, 42–43, 50–51, Figs. 1–9; Ex. 2001, 518, Fig. 6.97) (reproducing Ex. 1008, Fig. 2 (annotated); Ex. 2001, 518, Fig. 6.97 (annotated)), 41–43 (asserting markers would be located at the proximal and distal ends of the implant relative to the insertion direction or the distal end's middle and proximal end's left side[10]). Patent Owner further asserts Baccelli teaches only spikes 24 placed in ducts can be radiopaque and not those shown in Figures 1–5, 8, and 9. *Id.* at 38–39 (citing Ex. 1008 ¶¶ 2–3, 21, 45, 51). Patent Owner additionally argues that Baccelli and other references teach that the radiopaque markers "should be located on the ***proximal and distal ends***, not along the ***medial plane*** as is claimed in the '156 patent." *Id.* at 40–41.

Patent Owner further argues that Baccelli's longest length extends laterally, not in the anterior-posterior direction. *Id.* at 36–37 (citing Pet. 51; Ex. 1008 ¶¶ 16–17, 24, 30, 42–43, Figs. 1–5, 8, 9; Ex. 2001, 518, Fig. 6.97). Patent Owner also argues that "Baccelli does not teach or suggest that its marker placement is appropriate for lateral implants, for thoracic or lumbar implants, or for implants (like the claimed implant) that are elongated relative to their direction of insertion." *Id.* at 41 (citing *NuVasive*, 842 F.3d

[10] Patent Owner appears to switch its mapping of the implant's proximal and distal ends in the prior art. *Compare* Prelim. Resp. 42 n.4 (discussing Baccelli's *spikes 24* "would be located on the distal and proximal ends of the implant"), *with id.* at 42 (stating combining Baccelli with Brantigan teaches one of radiopaque *markers 47* "disposed near the middle of the distal end of the Brantigan implant"). We request clarification.

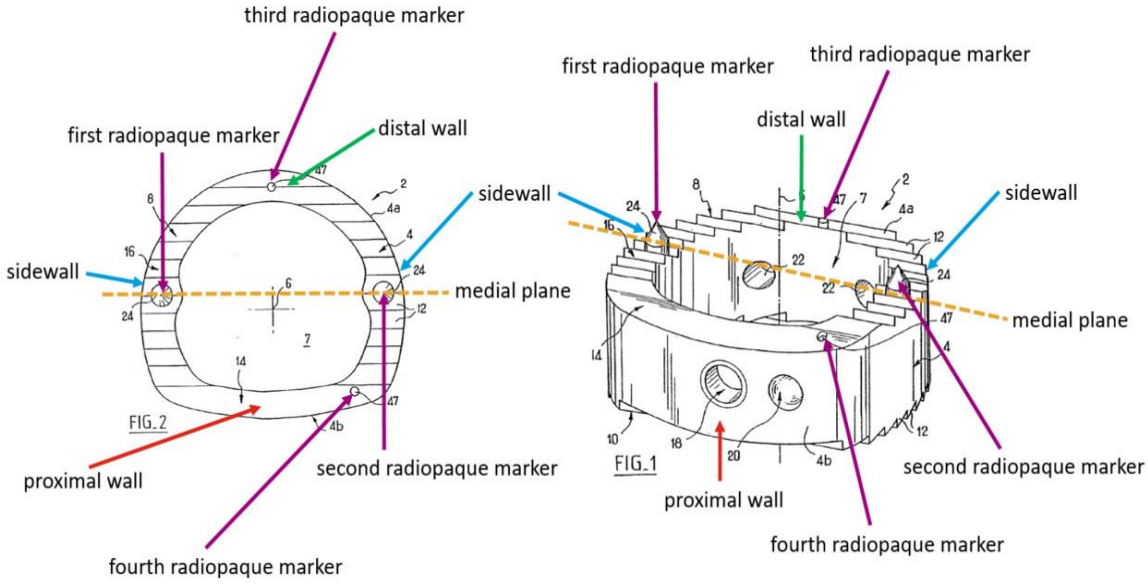
at 1384–85). Patent Owner argues Baccelli only teaches including markers with an implant inserted anteriorly and does not teach or suggest placing radiopaque markers to align with the spinous process or orthogonal to the insertion direction. *Id.* at 40 (citing Pet. 10, 50; Ex. 1008 ¶¶ 24, 30, 34, 39, 42–45, Figs. 1–4, 8, 9), 45. For these reasons, Patent Owner asserts that Petitioner failed to establish a motivation to employ Baccelli's markers on (a) a lateral, lumbar implant or (b) an implant elongated in the insertion direction. *Id.* at 39–41 (citing *id.* § I.A (*id.* at 5–6)).

Patent Owner contends Petitioner's argued motivation lacks supporting evidence, is conclusory, and ignores Baccelli's teachings. *Id.* at 43–47 (citing Pet. 31–32, 51, 53; Ex. 1008 ¶¶ 41, 50–51, Figs. 1–4, 8, 9; *NuVasive*, 842 F.3d at 1383–84). Patent Owner asserts that Baccelli "does not teach or suggest placing radiopaque markers at any specific location other than in the ducts on the distal and proximal walls where the markers 47 are disposed in Baccelli's figures" (*id.* at 45) and Petitioner "ignore[s] Baccelli's teachings by proposing to move spikes 24 from being spaced symmetrically about the sagittal midplane so that they are instead located on the sagittal midplane" (*id.* at 46 (emphasis omitted)). Patent Owner, thus, argues that hindsight influences Petitioner's rationale. *Id.* at 41, 44, 46–47.

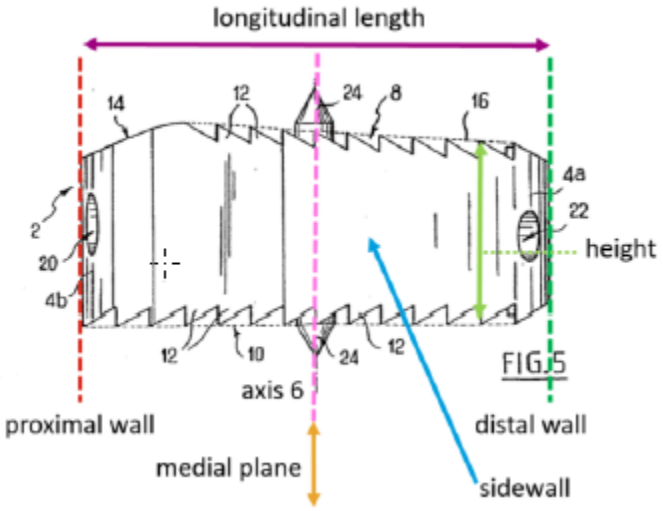
At this stage of the proceeding, Petitioner sufficiently shows that the combination of Brantigan/Berry/Baccelli teaches "at least first and second radiopaque markers" arranged as recited. *See* Pet. 31 (stating "Baccelli instructs a POSA to include radiopaque markers in the middle of the sidewalls of the implant relative to the direction in which the implant is

inserted") (citing Ex. 1002 ¶¶ 122–126,[11] 257; Ex. 1007, Figs. 8, 10). Notably, in one proposed embodiment (*see id.* at 49–51), Petitioner has not sufficiently demonstrated that Baccelli alone teaches that its "longitudinal length" is "greater than said maximum lateral width" as claim 1 requires. Nor has Petitioner shown sufficiently that Baccelli's "medial plane" is in the correct location—generally perpendicular to said longitudinal length—or that the radiopaque markers are proximate to the medial plane. *See id.* at 9–10 (discussing Baccelli's spikes location), 49–51 (same); *see* Ex. 1001, 12:49–50, 63–67.

More specifically, Petitioner reproduces annotated Figures 1, 2, and 5 (shown below) from Baccelli, marking the asserted implant's "longitudinal length" and "medial plane." *Id*. at 49–51 (citing Ex. 1002 ¶¶ 189, 191–192; Ex. 1008 ¶¶ 36, 41, 44, Figs. 1–5, 8, 9 (annotated)).



[11] Dr. Branch mistakenly refers to Ex. 1008 ¶ 50 as "Brantigan." Ex. 1002 ¶ 123.



Ex. 1008, Figs. 1, 2, 5 (respectively annotated) indicating the proposed longitudinal length and medial plane.

As shown in the annotated figures, Petitioner asserts spatial locations pertaining to both the recited "the longitudinal length" and "the medial plane" in Baccelli. *See id.* However, Petitioner provides no explanation why "the longitudinal length" and "the medial plane" are or should be located in Baccelli as shown. *See id*. (citing Ex. 1002 ¶¶ 189, 191–192; Ex. 1008 ¶¶ 36, 41, 44, Figs. 1–5, 8, 9 (annotated)). Petitioner's expert reproduces the same annotated figures without further explanation or support. *See* Ex. 1002 ¶¶ 189–192 (reproducing the same annotated figures with no further explanation); 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Petitioner fails to demonstrate sufficiently that Baccelli's medial plane is located as recited in claim 1—"generally perpendicular to said longitudinal length" and "is greater than

said maximum lateral width" that "extend[s] . . . along [the] medial plane"[12] (Ex. 1001, 47–51)—and thus that Baccelli's markers 24 (*see* Pet. 49–50 (citing Ex. 1008 ¶¶ 41, 50–51, Figs. 1–2 (annotated)) are located "proximate to said medial plane" (Ex. 1001, 12:63–67) as recited in claim 1.

Nevertheless, Petitioner also asserts that Brantigan, Berry, and Baccelli in combination sufficiently teaches the radiopaque markers limitation of claim 1. *See* Pet. 29–33. At this stage, we determine that Petitioner sufficiently shows the combined Brantigan/Berry/Baccelli spinal fusion implant can be introduced laterally (or in another direction) and its radiopaque markers can be oriented "proximate to said medial plane" as claim 1 recites, depending upon conditions, to allow a surgeon to identify the position and presence (e.g., the implant's alignment within the body) during or after an operation. *See id.* at 31–33. Petitioner also shows sufficiently a rationale for combining Brantigan, Berry, and Baccelli so that the proposed combination includes "'at least first and second radiopaque markers'" arranged as recited in claim 1. *See* Pet. 29–33. This rationale is supported by Dr. Branch testimony that a person of ordinary skill in the art would seek to position the markers as claimed to allow surgeon align the markers with the spinous process during and after the implant is inserted laterally. ; Ex. 1002 ¶¶ 46–49, 122–126, 257. We recognize however that

[12] Granted, Petitioner further asserts Brantigan discloses the recited feature of "said longitudinal length is greater than said maximum lateral width" in claim 1. *See* Pet. 44–45 (citing Ex. 1002 ¶ 167; Ex. 1007, 1:19–21, 1:65–68, 2:2–4, 4:5–8). Even so, Petitioner needs to show Baccelli teaches or suggests the recited radiopaque markers proximate the medial plane, which is (a) generally perpendicular to the longitudinal length and (b) along where the maximum lateral width extends as claim 1 recites. Ex. 1001, 12:47–51.

there may be differences in expert opinions, which implicate genuine issues of fact, and that it is more appropriate to resolve such issues in trial. 37 C.F.R. § 42.108(c) ("a genuine issue of material fact created by . . . testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review").

Patent Owner also contends that Petitioner's failure to address objective indicia of non-obviousness should weigh against institution. Prelim. Resp. 59–62. We refer to the below discussion related to objective indicia of non-obviousness.

For the reasons above, we determine that based on the present record Petitioner shows a reasonable likelihood of prevailing in its challenge of claim 1.

Additionally, claims 5, 10, 12–21, 23, 24, and 27 depend directly or indirectly from claim 1. Patent Owner does not address Petitioner's evidence and arguments for these claims beyond the arguments advanced for claim 1. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions and determine that, for purposes of this institution decision, Petitioner has shown sufficiently that Brantigan, Baccelli, and Berry collectively teach or suggest the claimed subject matter of claims 5, 10, 12–21, 23, 24, and 27. Pet. 54–69 (citing Ex. 1002 ¶¶ 202–211, 217–218, 220–222, 224–226, 228–229, 233–238, 240–242, 244–245, 247–249, 251–253, 255–258, 260–261, 266, 268, 270–272; Ex. 1007, 1:19–21, 1:42–47, 1:65–68, 215–17, 2:19–22, 3:9–12, 4:5–8, 4:15–18, 4:20–27, 4:50–53, 5:22–26, 5:32–43, 5:48–52, 5:55–57, 5:65–6:1, 6:14–16, 6:37–40, 7:23–25, 8:38–53, Figs. 1, 3, 4, 6, 8, 10, 11; Ex. 1008 ¶¶ 2–3, 20–21, 51; Ex. 1014, 25; Ex.

1015, 33; Ex. 1022, 364, Table 1). Petitioner also has articulated a sufficient rationale for combining the teachings of the references to arrive at the claimed subject matter. *Id.*

Accordingly, we determine that on the present record Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge of claims 5, 10, 12–21, 23, 24, and 27 as obvious over Brantigan, Baccelli, and Berry.

Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Therefore, we institute *inter partes* review of all challenged claims on all presented challenges. *See* USPTO, *Guidance on the Impact of SAS on AIA Trial Proceedings* (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (explaining that "the PTAB will institute as to all claims or none" and "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

5. Claims 2 and 3

Claims 2 and 3 each depend from claim 1. Petitioner argues that the cited prior art discloses the limitations of claims 2 and 3. Pet. 52–54. Relevant to the parties' dispute at this stage, Petitioner contends that Baccelli teaches "first and second radiopaque markers are substantially equally spaced apart from the proximal end of the proximal wall by a first longitudinal distance" as claim 2 recites (*id.* at 52 (reproducing Fig. 5 (annotated)) and "a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall" as claim 3 recites (*id.* at 53 (reproducing Figs. 1–2 (annotated)). *Id.* at 52–54

(citing Ex. 1002 ¶¶ 195–197, 200–201; Ex. 1008 ¶¶ 36, 41, 50, Figs. 1–5 (annotated), 8, 9).

For claim 2, Patent Owner responds by referring to Section § IV.A. of the Preliminary Response, with reliance on similar arguments to those made for claim 1, including spikes 24 are not radiopaque markers. Prelim. Resp. 47–48. Patent Owner also argues that Baccelli's radiopaque markers 47 are located in the distal wall duct and "at the intersection of the proximal wall and its adjacent sidewall" and, thus, not equally spaced apart from the proximal wall. *Id.* at 47–48. For claim 3, Patent Owner repeats argument presented for claims 1 and 2. *Id.* at 48.

At this stage, for similar reasons to those discussed above for claim 1, Petitioner provides sufficient argument and evidence in support of the challenges of claims 2 and 3 for purposes of instituting review.

6. Claim 22

Petitioner does not request to institute an *inter partes* review for claim 22 at the Petition's outset. Pet. 1 (petitioning to institute *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent). However, on at least one occasion, as noted by Patent Owner (Prelim. Resp. 48), Petitioner requests institution for claim 22. *Id.* at 77 (requesting institution for claims 1–5, 9, 10, 12–24, and 27 of the '156 patent and canceling of the same claims).

Patent Owner argues Petitioner does not further discuss or specify any grounds for challenging claim 22. Prelim. Resp. 48. We agree. The Petition does not identify grounds on which the challenge of claim 22 would be based and evidence that supports any challenge as required by

35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.104(b)(2) and (4). *See generally* Pet. Rather, as understood, the inclusion of claim 22 at various parts of the Petition (Pet. 21, 77) appears to be typographical error.

Accordingly, to the extent intended, Petitioner does not provide sufficient arguments and evidence to institute claim 22's review.[13]

7. Claim 9

Claim 9 depends from claim 1 and recites "wherein said maximum lateral width of said implant is approximately 18 mm." Ex. 1001, 13:26–27.

Petitioner contends that Brantigan teaches implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column," "with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies," and "are generally oval shaped to conform with the general outline perimeter of the vertebrae." Pet. 56 (citing Ex. 1007, 1:20–21, 2:2–4, 4:5–8). Petitioner further asserts Berry teaches that one skilled in the art "would have been aware of . . . 'direct dimensional measurements' of human vertebrae and would have known that a Brantigan implant positionable within the interbody space at T2 would have a longitudinal length of approximately 29.8 mm and a lateral width of approximately 18.1 mm." *Id.* (citing Ex. 1002 ¶¶ 174, 213–215; Ex. 1022, 362, 364, Table 1). Petitioner concludes the cited prior art discloses claim 9's limitations. *Id.*

[13] Although not indicated by Patent Owner, Petitioner also requests institution and cancelation of claim 4 on at least one occasion. Prelim. Resp. 21, 77. However, Petitioner does not include and request claim 4 be part of the *inter partes* review at the Petition's outset and does not identify grounds on which to challenge claim 4. *Id.* at 1.

Patent Owner responds that Petitioner "necessarily refer[s] to the space between the T1 and T2 vertebrae" (Prelim. Resp. 49) and fails to provide evidence that "that the disc space between the T1 and T2 vertebrae has a depth of approximately 18 mm" (*id.* at 48).

At this stage of the proceeding, Petitioner provides sufficient argument and evidence for purposes of instituting review of claim 9. However, we recognize that the interpretation of Berry's Table 1's measurement A and D implicates genuine issues of fact and supporting expert testimony, which are more appropriately resolved at trial. Accordingly, we determine that based on the present record, Petitioner shows a reasonable likelihood of prevailing in its challenge of claim 9.

D. Challenge Based on Brantigan, Baccelli, Berry, and Michelson (Ground 2)

1. Michelson (Ex. 1032)

Michelson relates "particularly to spinal fusion implants for insertion from the side of a patient (translateral) across the transverse width of the spine and between two adjacent vertebrae." Ex. 1032, 1:16–19; *see also id.* at 3:3–5 (describing translateral approach). Figures 18 and 19 of Michelson are reproduced below.

FIG. 18

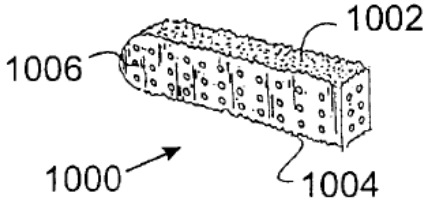


FIG. 19

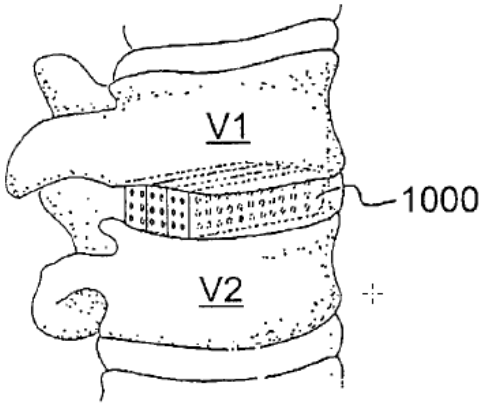


Figure 18 is a perspective side view of a spinal fusion implant, and Figure 19 is a perspective lateral anterior view of a segment of the spinal column with the implants shown in Figure 18 "inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the transverse width of the vertebrae." *Id.* at 5:31–39. Michelson states that the "transverse width of a vertebra is measured from one lateral aspect of the spine to the opposite lateral aspect" and that the "depth of a vertebra is measured from the anterior aspect to the posterior aspect of the spine." *Id.* at 3:7–10.

Michelson's implant "is dimensioned to fit within the disc space created by the removal of disc material between two adjacent vertebrae," "has a length that is substantially greater than the depth of the vertebrae and a width that approximates the depth of the vertebrae," "has more surface area of contact and thus permits greater stability," and "may be inserted into the disc space through a hollow tube." *Id.* at 3:35–40, 3:51–52. 3:61–63. The dimensions of the implant "permit[] a single implant to be inserted by a single procedure into the spine." *Id.* at 3:46–50.

Spinal implant 1000 "has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae." *Id.* at 10:50–55. Spinal implant 1000 is an alternative embodiment of a preferred embodiment that has "a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." *Id.* at 10:42–48, Fig. 17. Michelson also claims an implant "having a length that is greater than one

half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae." *Id.* at 11:21–26.

2. Claim 9

Petitioner additionally proposes claim 9 would have been rendered obvious by Brantigan, Baccelli, Berry, and Michelson, relying on its evidence and argument related to claim 1. Pet. 70 (citing *id.*, § XI.C.2). Relevant to the parties' dispute at this stage, Petitioner asserts Michelson teaches spinal fusion implant 900 (1) is rectangular with top and bottom surfaces 902, 904 with roughenings for engaging vertebrae and openings 906 to allow bone growth, (2) is implanted from the spine's lateral aspect into disc space D between two adjacent vertebrae along the vertebrae's transverse width, and (3) has a width that approximates the vertebrae's depth. *Id.* at 11–14, 70–72 (citing Ex. 1032, 3:1–7, 3:35–40, 3:47–53, 3:56–65, 10:6–16, 10:19–41, 10:50–55, Figs. 16–19). According to Petitioner, Michelson "provides a range of preferred dimensions of length, height, and width of spinal fusion implant 900, but does not specify what region of the lumbar spine those dimensions pertain to." *Id.* at 73. Petitioner also proposes one skilled in the art would turn to Berry's dimensional data in Table 1 when designing an implant for fusion between vertebrae, such as between L4 and L5. *Id.* at 73–74 (citing Ex. 1002 ¶¶ 281–282; Ex. 1022, 362, 364, Table 1; Ex. 1032, 10:42–47, 50–55, Fig. 19).

Petitioner proposes that Brantigan and Michelson both teach modifying the implant's width in the insertion direction of a spinal implant. *Id.* at 72–73 (citing Ex. 1007, 2:4–11; Ex. 1032, 50–55). Petitioner discusses spinal fusion implant 1000 in Michelson is similar to implant 900 but "has a narrower width such that more than one spinal fusion implant

1000 may be combined in a modular fashion for insertion within the disc space D." *Id.* at 72–73 (citing Ex. 1032, 10:50–59, Fig. 19). Petitioner contends Brantigan teaches using "'[t]wo such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retraced to each side in turn as the implant is placed on the opposite side.' [Ex. 1007], 2:7-11." *Id.* at 73. Petitioner proposes an ordinary skilled artisan would have been motivated to modify Brantigan's implant width, having "'medial-lateral and anterior-posterior dimensions in the same ratios as normal vertebral bodies' (Ex. 1007, 1:20–21)" (*id.* at 74), according to Michelson's teachings so that the implants are narrower and "'may be combined in a modular fashion for insertion within the disc space D between adjacent vertebrae.' Ex. 1032, 10:50–55." *Id.* Petitioner also argues that a "narrower implant for lateral insertion would be easier to fit within the hollow tube Michelson describes to facilitate insertion into the disc space" (*id.* (citing Ex. 1002 ¶ 283; Ex. 1032, 3:61–65)) as well as increase safety (*id.* at 69 (citing Ex. 1002 ¶¶ 113–115; Ex. 1032, Abstract, 2:19–67, 3:56–4:24)).

Petitioner further contends an artisan would turn to Berry's dimensions and half the width dimensions for various vertebrae implants based on Brantigan's teaching to make the implants modular. *Id.* at 69–70 (citing Ex. 1002 ¶¶ 277–284; Ex. 1022, 364, Table 1; Ex. 1032, 3:50–55). For the above reasons, Petitioner asserts a person of ordinary skill in the art would have arrived at the recited implant in claim 9 that is "'approximately 18 mm wide.'" *Id.* at 74–75 (citing Ex. 1002 ¶¶ 275–285; 1022, 364, Table 1).

Patent Owner argues Petitioner has not "establish a reasonable expectation of successfully making the 18 mm-wide modular members . . . in a way that would satisfy all limitations of claim 9." Prelim. Resp. 55. In particular, Patent Owner contends "cutting the Brantigan implant into longitudinal modular members narrow enough to satisfy claim 9 would separate the walls from one another" (*id.* at 56) and "would thus eliminate the claim element that the maximum lateral width of the implant extends from the first sidewall to the second sidewall along the medial plane" in claim 1 (*id.* at 57). Patent Owner further contends other elements in claim 1, from which claim 9 depends, would be missing, including "a second sidewall generally opposite from the first sidewall," "a lateral aperture width extending between said first sidewall to said second sidewall," and the implant having a radiopaque marker on each sidewall near the medial plane. *Id.* Patent Owner additionally contends Petitioner does not explain sufficiently how an ordinary artisan would assemble two 18-mm modular members into a single implant to satisfy claim 9's elements, including the recited maximum lateral width of approximately 18 mm and, thus, this ground lacks a reasonable expectation of success. *Id.* at 57–58.

At this stage of the proceedings, Petitioner provides sufficient support for purposes of instituting review for claim 9. We note that the issue of the reasonable expectation of the proposed combination successfully resulting in an implant having a "maximum lateral width of . . . approximately 18 mm" when modifying Brantigan's implants implicates issues of fact and expert opinions, and it is more appropriate to resolve such issues in trial.

Accordingly, we determine on the present record that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge of claim 9.

E. Objective Indicia of Non-Obviousness

Petitioner states that it "is unaware of any secondary considerations that demonstrate nonobviousness" and contends that such evidence proffered in IPR2013-00506 to show commercial success did not show adequately a nexus between the claimed invention and the proffered evidence. Pet. 75–76 (citing Ex. 1004, 20–22; Ex. 1043, 22, 65).

Patent Owner contends that Petitioner should have asked their "Chairman and CEO, Patrick Miles." Prelim. Resp. 60 (citing Pet. 74; Ex. 2003, 1). Patent Owner argues that the testimony shows commercial success, industry praise, copying, skepticism, failure of others, and unexpected result. *Id.* at 59–62 (citing Ex. 2002 ¶¶ 1–2, 6–9, 11, 14; Ex. 2013; Ex. 2014, 7; Ex. 2015 ¶¶ 314–366). Patent Owner also argues that there is presumed nexus between implant sales of NuVasive's CoRoent XL implant covered by the '334 patent and "those claims." *Id.* at 61 (citing Pet. 74–75).

At this stage, Patent Owner first presents its evidence of secondary considerations with the Preliminary Response, and Petitioner has not yet had an opportunity to respond to this evidence in this proceeding. Any genuine issue of material fact created by Patent Owner's testimony will be viewed in the light most favorable to the Petitioner for purposes of deciding whether to institute an *inter partes* review. *See* 37 C.F.R. § 42.108(c). As such, Petitioner's failure to address all the evidence of secondary considerations proffered by Patent Owner does not favor denying institution. We will

reconsider objective indicia of non-obviousness in our Final Written Decision based on the full trial record.

VI. CONCLUSION

The Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent is unpatentable.

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, we institute an *inter partes* review of all challenged claims on all presented challenges.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of U.S. Patent No. 8,361,156 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,361,156 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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