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Paper 57
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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.

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.*

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background and Summary

Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 ("the challenged claims") 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."). Pursuant to 35 U.S.C. § 314, we granted the request and instituted *inter partes* review on July 9, 2019, as to the challenged claims on all grounds. Paper 18 ("Dec. Inst.").

Following institution, Patent Owner filed a Response (Paper 27, "PO Resp."), Petitioner filed a Reply (Paper 34, "Reply"), and Patent Owner filed a Sur-Reply (Paper 40,"Sur-reply"). Patent Owner objected to evidence submitted by Petitioner in its Petition and future filings (Papers 23, 35). With prior authorization (Paper 37), Patent Owner submitted a Supplemental Sur-Reply (Paper 41, "Supp. Sur-reply") related to the its objections and Petitioner submitted a Supplemental Sur-sur-reply (Paper 42, "Supp. Sur-sur-reply"). Patent Owner also filed a Motion to Exclude (Paper 38, "Mot. Excl."), Petitioner filed an Opposition to the Motion to Exclude (Paper 44, "Opp."), and Patent Owner filed a Reply to support the Motion to Exclude (Paper 48, "Mot. Reply").

A hearing was held on April 3, 2020, and a transcript of the hearing has been made part of the record. Paper 54; Ex. 1066.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons discussed below, we conclude that Petitioner has not shown by a preponderance of the evidence that the challenged claims of the '156 patent are unpatentable. We also deny Patent Owner's Motion to Exclude.

B. Related Matters

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-02738-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 also 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 panel denied institution in IPR2013-00504 and IPR2014-00487. IPR2013-00504, Paper 8 (PTAB February 13, 2014); IPR2014-00487, Paper 8 (PTAB September 11, 2014). In IPR2013-00506, the Board determined that claims 1–14, 19, 20, and 23–27 of the '156 patent were unpatentable. IPR2013-00506, Paper 47, 24 (PTAB February 11, 2015). The Federal Circuit vacated the decision in IPR2013-00506 and remanded for additional findings and explanation. *In re NuVasive,* 842 F.3d 1376, 1384 (Fed. Cir. 2016). On remand, the parties indicated that they had entered into a settlement agreement, and the panel granted a joint motion to terminate the proceeding. IPR2013-00506, Paper 57 (PTAB May 9, 2017).

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.

C. 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, codes (22), (45), (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.

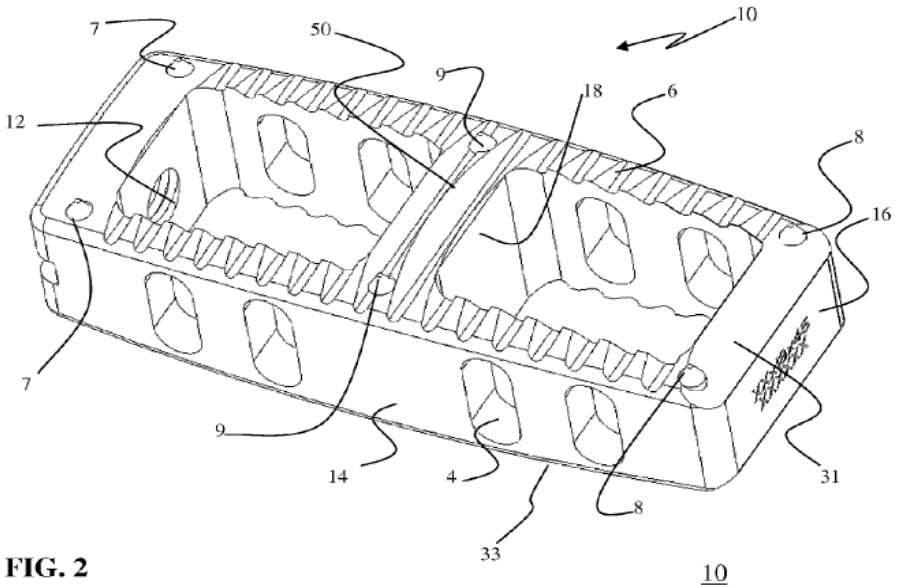


FIG. 2

Figure 2, above, 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 include 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 for lumbar fusion 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; *see id.* at 2:17–21.

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 that are "observable under X-ray and fluoroscopy[,] such that a surgeon may track the progress of the implant 10 during implantation and/or the placement of the implant 10 after implantation." *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.

D. 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*.

Id. at 12:32–67 (emphasis added).

E. Prior Art and Asserted Grounds

Petitioner asserted the following grounds of unpatentability in the Petition:

Claim(s) Challenged	35 U.S.C. §[1]	References/Basis
1–3, 5, 9, 10, 12–21, 23, 24, 27	§ 103	Brantigan[2], Baccelli[3], Berry[4]
9	§ 103	Brantigan, Baccelli, Berry, Michelson '973[5]

Pet. 21–22, 28–75.

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

To support its position, Patent Owner provides a Declaration of Jim A. Youssef, M.D. (Exs. 2013, 2055) and Carl R. McMillin, Ph.D. (Ex. 2057).

F. Real Parties in Interest

Petitioner identifies Alphatec Holdings, Inc. and Alphatec Spine, Inc. as the real parties in interest. Pet. 76. Patent Owner identifies NuVasive, Inc. as the real party in interest. Paper 4, 2.

[1] The Leahy-Smith America Invents Act ("AIA") amended 35 U.S.C. § 103. *See* Pub. L. No. 112-29, 125 Stat. 284, 285–88 (2011). As the application that issued as the '156 patent was filed before the effective date of the relevant amendments, the pre-AIA version of § 103 applies.
[2] Brantigan, U.S. Patent No. 5,192,327, issued March 9, 1993 (Ex. 1007, "Brantigan").
[3] Baccelli et al., U.S. Patent Application Publication No. US 2003/0028249 A1, published February 6, 2003 (Ex. 1008, "Baccelli").
[4] James L. Berry et al., *A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae*, 12 SPINE 362–67 (1987) (Ex. 1022, "Berry").
[5] Michelson, U.S. Patent No. 5,860,973, issued January 19, 1999 (Ex. 1032, "Michelson '973").

II. ANALYSIS

A. Estoppel Challenge

Petitioner states "Patent Owner's prior positions on Brantigan, Berry, and Michelson '973 are relevant and binding" in this proceeding and implies Patent Owner should be estopped from taking contrary positions in this proceeding. Pet. 25 (citing *Cardpool, Inc. v. Plastic Jungle, Inc.*, 817 F.3d 1316, 1323 (Fed. Cir. 2016); *Trustees in Bankr. of N. Am. Rubber Thread Co. v. United States*, 593 F.3d 1346, 1354–56 (Fed. Cir. 2010)). Specifically, Petitioner contends Patent Owner relied upon Brantigan and Berry in its Petitions for IPR2013-00206 and IPR2013-00208 (Exs. 1014–1015) concerning U.S. Patent 8,521,997 (Ex. 1021 or "Michelson '997"), which is a parent of Michelson '973 (Ex. 1032). *Id.* at 22. Petitioner quotes from statements in the Petition of IPR2013-00206 related to Brantigan (*id.* at 23–24) and states "[u]sing the understanding that as it pertains to spinal fusion implants, length is measured laterally, 'consistent with the direction of the insertion, from the "insertion end" to the "trailing end,"' the Federal Circuit affirmed." *Id.* at 24 (citing Ex. 1019, 5, 7, 9–10). Petitioner also contends Patent Owner told the Federal Circuit that several references, including Brantigan, disclose lateral insertion. *Id.* at 24–25 (citing Ex. 1035, 15). Petitioner asserts that Patent Owner presented evidence of "Berry showing [the] state of art." *Id.* at 24 (citing Ex. 1016, 15; Ex. 1047, 14–15); *see id.* at 25 (citing Ex. 1035, 43; Ex. 1022, 364[6]). Petitioner further states Patent Owner appealed a jury verdict of no invalidity of Michelson '997

[6] We refer to the actual pagination of the underlying document.

under a higher standard of review. *Id.* at 24 (citing Ex. 1035, 14, 27; Ex. 1046, 2, 5–7).

Patent Owner contends judicial estoppel does not apply in this proceeding. PO Resp. 44. Patent Owner argues that the issues are different. *Id.* Patent Owner asserts the Federal Circuit found that (1) the claims in Michelson '997 do not require Brantigan's implants to extend to the apophyseal ring or beyond a vertebral body's central region (*id.* (citing Ex. 1019, 6–7)); and (2) they need not determine whether Brantigan discloses a lateral approach (*id.* (citing Ex. 1019, 9). Patent Owner further argues its position is consistent with that taken in the prior proceeding, which included that laterally-inserted implants in Brantigan should occupy substantially—not entirely—the transverse width of a vertebra so as to fit within the annulus fibrosis. *Id.* at 45–46 (reproducing annotated Figure 10 of Brantigan found in Ex. 1015, 29) (citing Ex. 1019, 19[7]; Ex. 1007, 2:26–28, 2:63–64, 6:25–32, 6:61, Fig. 11; Ex. 2055 ¶¶ 51–53; Ex. 2057 ¶¶ 21–26). Citing to *Trustees in Bankr. of N. Am. Rubber Thread Co.*, Patent Owner argues Petitioner has not shown Patent Owner "succeeded in maintaining a position that is contrary to its positions herein, that any alleged change in position is premised only on an alleged changed interests, or that Petitioners qualify as a party that 'acquiesced in the position formerly taken.'" *Id.* at 44.

Having considered the parties' arguments and cited evidence, we agree with Patent Owner (*see* PO Resp. 44) that the issues in the proceedings noted by Petitioner are not relevant to the instant proceeding. For example, this proceeding concerns the '156 patent, whereas IPR2013-00206 and

[7] We located the figure in Exhibit 1015, 29.

IPR2013-00208 (Exs. 1014–1015) concern U.S. Patent 8,521,997 (Ex. 1021) or Michelson '997. Also, the '156 patent's claims and specification differ from those in Michelson '997. *Compare* Ex. 1001, *with* Ex. 1021.

Thus, we are not persuaded that Patent Owner's statements made concerning Michelson '997 and its claims in IPR2013-00206 and IPR2013-00208 (Exs. 1014–1015, 1047) or in its briefing to the Federal Circuit (Ex. 1035) or the Federal Circuit decision (Ex. 1019) related to IPR2013-00206 and IPR2013-00208 should be binding on Patent Owner in this proceeding concerning the '156 patent. Similarly, cited Exhibit 1046 (Pet. 24) is a Federal Circuit opinion concerning patents (e.g., Michelson '973) other than the '156 patent. Granted, the Federal Circuit discusses Brantigan (Ex. 1007) in the opinion. *See* Ex. 1046, 6–7. But, the record's evidence differs from this proceeding, and Petitioner has not identified any pertinent binding statements made by Patent Owner in the opinion related to Brantigan or the '156 patent. *See* Pet. 24 (stating only "Patent Owner unsuccessfully appealed a jury verdict of no invalidity of Michelson '973 under a higher clear error standard") (citing Ex. 1046, 2, 5–7).

Also, Petitioner has not persuasively shown that Patent Owner's position in this proceeding is clearly inconsistent with a position taken in the noted proceedings or that Patent Owner succeeded in maintaining such a position. *See Trustees in Bankr. of N. Am. Rubber Thread Co.*, 593 F.3d at 1353–54. For example, Petitioner asserts that Patent Owner has taken a position asserting the "length is measured laterally" and "consistent with the direction of insertion, from the 'insertion end' to the 'trailing end.'" Pet. 24. However, the Federal Circuit decision arrived at their understanding of "length" based on Michelson '997's claim 1 itself. Ex. 1019, 5 (citing Ex.

1021, 23:24–26 (claim 1). Moreover, the quoted passage from the Federal Circuit opinion (Pet. 24) concerns Warsaw's, not Patent Owner's, argument related to Brantigan. *See id.* (citing Ex. 1019, 9) (stating "the record belies *Warsaw*'s argument that the Brantigan implants were not designed for lateral implantation) (emphasis added).

Additionally, Patent Owner in this proceeding discusses inserting Brantigan's implant laterally. *See* PO Resp. 24 (stating "laterally-inserted Brantigan implant.") We thus agree with Patent Owner that any purported discussion to the Federal Circuit concerning "several references . . . disclose lateral insertion" (Pet. 24 (quoting Ex. 1035, 15)) is consistent with Patent Owner's present position. *See* PO Resp. 45.

As for Berry, Petitioner does not explain sufficiently what prior position taken by Patent Owner concerning this reference is "relevant and binding." Pet. 25; *see id.* at 22–25. At best, Patent Owner cites Exhibit 1016, stating "Berry show[s the] state of art in 1995." *Id.* at 24 (citing Ex. 1016, 15). Although Exhibit 1016 is a document submitted by Patent Owner in IPR2013-00206, the cited portion does not appear to discuss Berry and only states "sequential dilation was already well known before 1995." Ex. 1016, 15.

Based on the record, Petitioner has not established Patent Owner is estopped from taking any specific position in this proceeding.

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 different qualifications for a person of ordinary skill in the art ("POSA"). *See* PO Resp. 9. However, Patent Owner contends "a POSA would not be familiar with developments in the art that came after the relevant time, such as XLIF."[8] *Id.*

Our analysis below does not hinge on whether a POSA would be familiar with XLIF technology or developments in the art that would have come after the relevant time. As such, we adopt Petitioner's unchallenged assessment of the qualifications as the level of ordinary skill in the art.

Dr. Branch, Petitioner's expert, has completed residencies and a fellowship in neurosurgery departments between 1985–1987, has taught spinal surgery since 1987, focusing his practice and research on spinal diseases and injuries (e.g., minimally invasive lumbar interbody fusion techniques), and has obtained various patents related to spinal surgery, spinal implants, and spinal surgical instrumentation. Ex. 1002 ¶¶ 5–13; Ex. 1003. Dr. Branch's qualifications are sufficient as a person of skill in the art for purposes of this proceeding.

Dr. Youssef, Patent Owner's expert, is an orthopedic surgeon, has been a practicing spine surgeon for over two decades, including treating spinal injuries and performing spine surgery, is a member or fellow of various organizations related to surgery, orthopedics, and the spine, has written articles related to the spine, treatments, and surgery, and is a named

[8] eXtreme Lateral Interbody Fusion (XLIF) technology. Ex. 2013 ¶ 1.

inventor on patents related to spine implants and fixations systems. Ex. 2055 ¶¶ 1–12; Ex. 2056. Dr. McMillin, another of Patent Owner's experts, has a B.S. in mechanical engineering and Ph.D. in Macromolecular Science, has experience in the field of biomedical engineering beginning in 1974, including designing orthopedic products for the spine, and has served on various committees or advisory boards in the biomedical industry. Ex. 2057 ¶¶ 1–7; Ex. 2058. Both, Dr. Branch's and Dr. McMillin's qualifications are sufficient as persons of skill in the art for purposes of this proceeding.

C. 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. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This Petition was filed after the effective date of the rule change, November 13, 2018, so we apply *Phillips*-type[9] claim construction here. *Id.*; *see* Pet. 26 (stating that the "Board applies 'the standard used in federal courts . . . '" (quoting 83 Fed. Reg. at 51,343)); Paper 5, 1 (according filing date of December 13, 2018 to the Petition).

Petitioner stated in the Petition that each term "should be given its plain and ordinary meaning" and that "no express construction is needed to resolve the issues in this Petition." Pet. 26. Patent Owner presented a claim construction for the phrases "longitudinal length," "medial plane," and

[9] *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

"position proximate to said medial plane." Prelim. 8–10. We preliminarily construed each of these terms in the Decision to Institute based on the record then before us. Dec. Inst. 13–14. In its Response and Sur-reply, Patent Owner contends Petitioner relies on "unconventional meanings" (PO Resp. 4) for the phrases "longitudinal length" and "medial plane" that ignore their plain meanings. *Id.* at 3–9; *see* Sur-reply 2–3. Petitioner responds, reiterating what was stated regarding the phrases "longitudinal length" and "medial plane" in the Decision to Institute. Reply 5–6 (citing Dec. Inst. 13–14).

1. "Longitudinal Length"

Claim 1 recites "said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall." Ex. 1001, 12:45–47.

> In the Decision to Institute ("Dec. Inst."), we determined
>
> no express construction is required for ["longitudinal length"] 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.

Dec. Inst. 13.

In its Response, Patent Owner contends that "longitudinal length" means "the longest dimension." PO Resp. 5; *see id.* at 4–8 (citing Ex. 1001, 2:17–21, Fig. 2; Ex. 1007, 4:15–22, Fig. 1; Ex. 1040 ¶¶ 147, 159, Figs. 55, 63; Ex. 2022, 51:11–17, 76:7–12, 88:5–13, 89:15–22 (Branch Deposition); Ex. 2055 ¶¶ 31–34; Ex. 2023, 1204[10]; Exs. 2009, 2024–2027).

[10] We refer to the original pagination here.

As discussed in the Decision to Institute (Dec. Inst. 13), claim 1 requires that the "longitudinal length is greater than said maximum lateral width." *See* Ex. 1001, 12:50–51. The requirement that the longitudinal length is greater than the width is consistent with the plain and ordinary meaning of the term. Considering the entire record, the evidence amply supports the plain and ordinary understanding for "longitudinal length" as a dimension that is the longer dimension of an object.

First, although the '156 patent does not use the term "longitudinal" other than in the claims, it describes an implant having a width between 9 and 18 mm and a length ranging between 25 and 45 mm. Ex. 1001, 2:17–21. Figures 2 and 3 of the '156 patent also show an implant having one dimension longer (e.g., from left to right in Figure 3) than another dimension (e.g., from bottom to top in Figure 3). *See id.*, Figs. 2–3. Second, as Dr. Youssef testifies, other patents use the term "longitudinal" in the context of an implant's length or longer dimension. *See* Ex. 2055 ¶¶ 33–34 (citing Ex. 1007, 4:15–16, Fig. 1 (describing "ridges 12 are formed longitudinally across the end faces 11c"); Ex. 1040 ¶¶ 147 (describing "implant 1000 has an axis C extending through its center longitudinally"), 159, Fig. 55). Third, one definition of "longitudinal" includes "[p]arallel to the long axis of the body or part" (Ex. 2023[11], 1204), and one definition of "length" includes "the longer or longest dimension of an object."[12] Other provided medical dictionaries further support that "longitudinal" means "pertaining to a

[11] *Longitudinal*, Taber's Cyclopedic Medical Dictionary (2001).
[12] *Length*, The Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/length (def. 1a) (last visited June 1, 2020).

measurement in the direction of the long axis of an object, body, or organ" (Ex. 2024[13], 1020; *see also* Exs. 2026–2027) or "[r]unning lengthwise" (Ex. 2025[14], 995; *see also* Exs. 2009, 2026–2027). Fourth, Patent Owner's expert, Dr. Youssef, testifies "that the plain and ordinary meaning of the term longitudinal length is the longest dimension of the object. For the implant, the longitudinal length is the longest dimension of the implant." Ex. 2055 ¶ 32 (citing Ex. 1001, 12:44–64); *see id.* ¶¶ 33–34.

In contrast, Petitioner's expert, Dr. Branch, appears to use a "'convention' [that] is inconsistent with the plain meaning" (PO Resp. 6–7) of longitudinal length. *See id.* at 4–7 (citing Ex. 2022, 51:11–17, 52:5–56:9, 76:7–12, 88:5–13, 89:15–22, 114:3–19, 116:4–15, 117:3–4); *see also* Sur-reply 2–3 (citing Ex. 2022, 52:5–56:9, 114:3–19, 116:4–14, 117:2). Only as part of his testimony in support of obviousness does Dr. Branch testify that a person of ordinary skill in the art would have understood Brantigan's implants to "have a longitudinal length that is *measured relative to the direction in which it is inserted* from the proximal end that contains the tool receiving recess or mechanism to the distal end opposite the insertion end." Ex. 1002 ¶ 122 (emphasis added). Similarly, Dr. Branch had the following dialogue related to his convention:

> Q. And in this case, the 22 millimeter depth refers to the longest length of the implant, correct?
> A. Correct.

[13] *Longitudinal*, Mosby's Medical, Nursing, & Allied Health Dictionary (2002). We refer to the original pagination.
[14] *Longitudinal*, PDR® Medical Dictionary (1995). We refer to the original pagination.

> Q. And you are saying that that longest length of the implant is the longitudinal length of the implant?
> A. If we -- if we used the convention, which is proximal end is where the inserter is and the distal end is the leading end or the end that is furthest away from the inserter, then this term depth is equivalent to longitudinal length.
>
> Q. If the -- if the inserter for this implant was positioned in the middle of its longest dimension, is it your opinion that the longitudinal length of the implant would be the 8 millimeter width?
> A. By convention, the length is from the -- where the inserter attaches to the device. So if this device actually had an insertion or configuration that the inserter handle came in perpendicular to the -- what we see here is the longitudinal -- and came in perpendicular to this, attach and inserted it that way, then by convention the length would be this shorter distance and the width would be the longer distance.
>
> Q. And the shorter distance would be what you would call the longitudinal length?
> A. Correct.

Ex. 2022, 53:22–54:24.

Dr. Branch's interpretation of "longitudinal length" is inconsistent with the claim language and has no support in the Specification. The record also has inadequate support for Dr. Branch's interpretation. *See* Ex. 1002 ¶ 122; 37 C.F.R. § 42.65(a). On the other hand, Dr. Youssef's testimony, as discussed above, (1) provides support for and explanation why the plain and ordinary meaning of the term should be used (*see* Ex. 2055 ¶¶ 31–34) and (2) is consistent with (a) the claim language itself, (b) the Specification, (c) other references in the same field of art, and (d) an ordinarily skilled artisan's understanding.

Based on the entire record, we determine "longitudinal length" means an object's longer dimension. In the context of claim 1, we further determine "a longitudinal length" is the implant's longer dimension "extending from a proximal end of said proximal wall to a distal end of the said distal wall" and "is greater than said [implant's] maximum lateral width." Ex. 1001, 12:45–47, 12:50–51.

2. "Medial Plane" and "Proximate to Said Medial Plane"

Claim 1 also recites "a medial plane that is generally perpendicular to said longitudinal length" and "a position proximate to said medial plane." Ex. 1001, 12:49–50, 12:65, 12:67.

In the Decision to Institute, we preliminarily determined "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, 215[]; *see* Prelim. Resp. 9 (citing Ex. 1033; Ex. 2010)." Dec. Inst. 14 (omitting footnote 5 referring to *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CABMDD (S.D. Cal.), App'x B1, Joint Claim Construction Worksheet).

In its Response, Patent Owner agrees with our construction. PO Resp. 8 (citing Dec. Inst. 14). Dr. Youssef also states "it is my opinion that the plain and ordinary meaning of term 'medial' refers to the middle or midpoint of an object" "[b]ased on [his] knowledge and years of experience as a spine surgeon." Ex. 2022 ¶ 35. Petitioner reiterates our determination in the Decision to Institute. Reply 5–6. Upon review of the entire record, we determine that the "medial plane" in the context of claim 1 is located approximately at the midpoint of the longitudinal length consistent with our understanding of "longitudinal length" discussed in Section II.C.1.

In the Decision to Institute, we further determined the term "proximate" within the phrase "a position proximate said medial plane" means "near." Dec. Inst. 14 (citing Prelim. Resp. 10; Ex. 2009, 6).

Other than quoting from the Decision to Institute determining that the "'medial plane' is located approximately at the midpoint of the longitudinal length" (PO Resp. 9 (quoting Dec. Inst. 14)), Patent Owner provides no arguments related to the term "proximate" and our construction. *See id.* at 8–9. Petitioner reiterates our determination in the Decision to Institute. Reply 5–6. Upon review of the entire record, we determine that the term "proximate" means "near" and that the phrase "proximate to said medial plane" means near or approximately at the midpoint of the longitudinal length consistent with our understanding of "longitudinal length" discussed in Section II.C.1.

3. Other Terms

Although Patent Owner proposes the construction of additional claim terms (PO Resp. 4–9), we determine that it is not necessary to provide an express interpretation of any other term of the claims because it is not necessary to resolve any issue or dispute. *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. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

D. Legal Standards

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). "To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal of obviousness." *In re Magnum Oil Tools Int'l, Ltd*., 829 F.3d 1364, 1380 (Fed. Cir. 2016). We analyze the asserted ground with the principles stated above in mind.

E. Ground 1: Obviousness of Claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 over Brantigan, Baccelli, and Berry

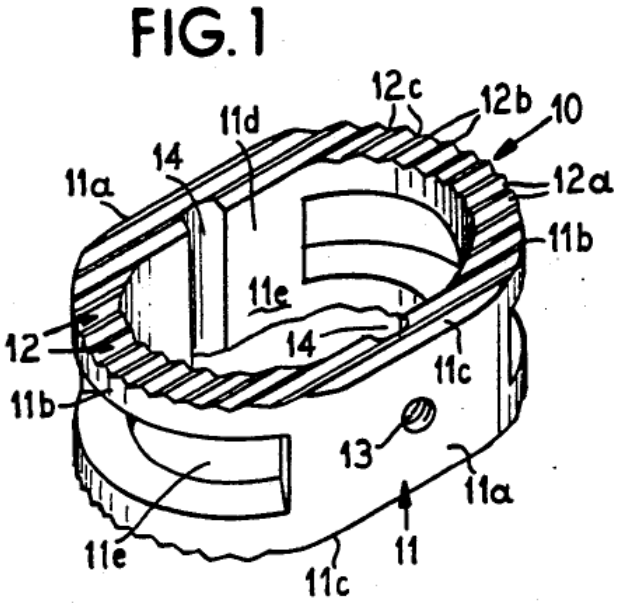
1. Brantigan (Ex. 1007)

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 1:13–18.

Brantigan provides "biologically acceptable, but inert rigid annular prosthesis units . . . 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.

Below, Figure 1 of Brantigan shows a full oval prosthetic device.



Id. at 3:21–22. Above Figure 1 shows oval ring plug 11 having opposed sides 11*a*, ends 11*b*, ridged top and bottom faces 11*c*, and central upstanding aperture 11*d*.[15] *Id.* at 4:5–10. Top and bottom faces 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 internally threaded hole 13 for receiving a mounting tool (e.g., element 73

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

shown in Figure 13), and interiors of side walls 11*a* have grooves 14 for mounting rectangular connecting bar 15. *Id.* at 4:20–27, 6:66–68, Figs. 1, 3, 4, 13. 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 3:30–32, 4:50–53, Figs. 1, 3, 4; *see also id.* at 2:15–18 (describing placement of bone graft material).

Figure 6 of Brantigan is reproduced below.

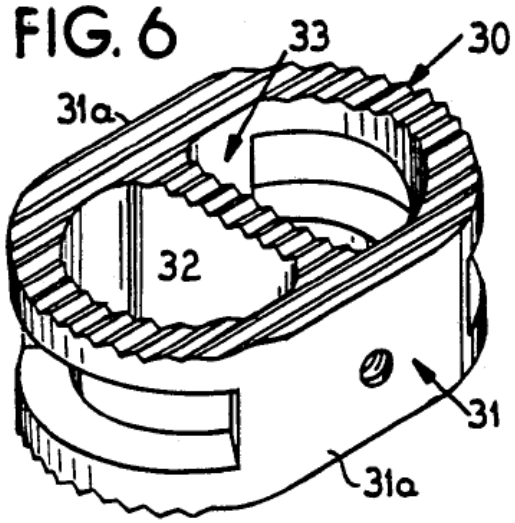


Figure 6 shows a perspective view of a modified device with an integral cross bar. *Id.* at 3:36–37, Fig. 6. Modified device 30 is plug 31 with the same shape as plug 11 but has reinforcing bar 32 integral with side walls 31*a*. Integral internal partition 32[16] bisects hollow interior 23[17] (not shown) forming "side-by-side apertures through the plug adapted to receive bone graft material." *Id.* at 5:37–43, Fig. 6.

[16] 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.
[17] Brantigan previously describes element "23" as a receiving recess. *Id.* at 5:1–2, 5:32–33. In context, it appears that Brantigan intended to refer to element "33" in Figure 6. *See id.,* Fig. 4.

"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), Figs. 4, 8, 10, 11, 13, 14.

"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.

2. Baccelli (Ex. 1008)

Baccelli "relates to intervertebral implant[s]." Ex. 1008 ¶ 1. Figures 1 (top) and 2 (bottom) of Baccelli are reproduced below.

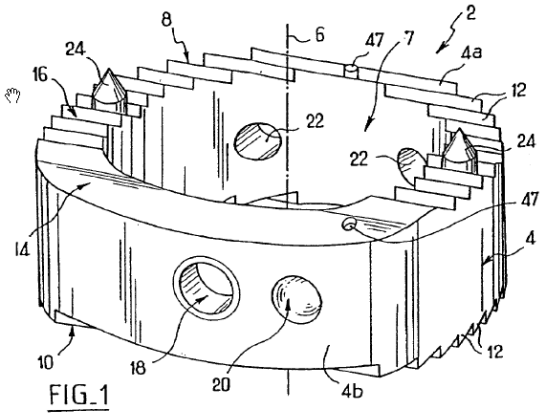


FIG_1

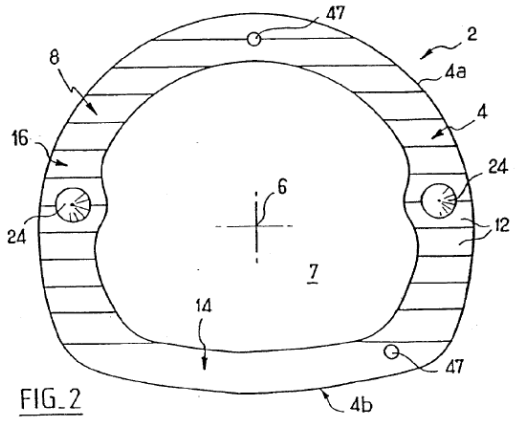


FIG_2

Above Figures 1 (top) and 2 (bottom) show perspective and plan views of implant 2. *Id.* ¶¶ 29, 33. 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 in shape, superior main face 8, and inferior main face 10 opposite face 8. *Id.* ¶¶ 33–35. Second portion or side 4b "is the anterior or front side of the cage." *Id.* ¶ 34. 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 that "are disposed symmetrically to each other about the sagittal midplane" and "extend in the frontal midplane containing the axis 6." *Id.* ¶ 41, Figs. 1–5.

Fitting tool 40 puts the cage into place between two vertebrae. *Id.* ¶¶ 44–45, Figs. 8– 9. Baccelli states "the cage is put into place between the vertebrae from behind." *Id.* ¶ 45. An endpiece of fitting tool 40 is suitable for threaded engagement with mounting orifice 18 of the cage. *Id*. ¶ 44.

"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, Figs. 1–2. "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 (bolding 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).

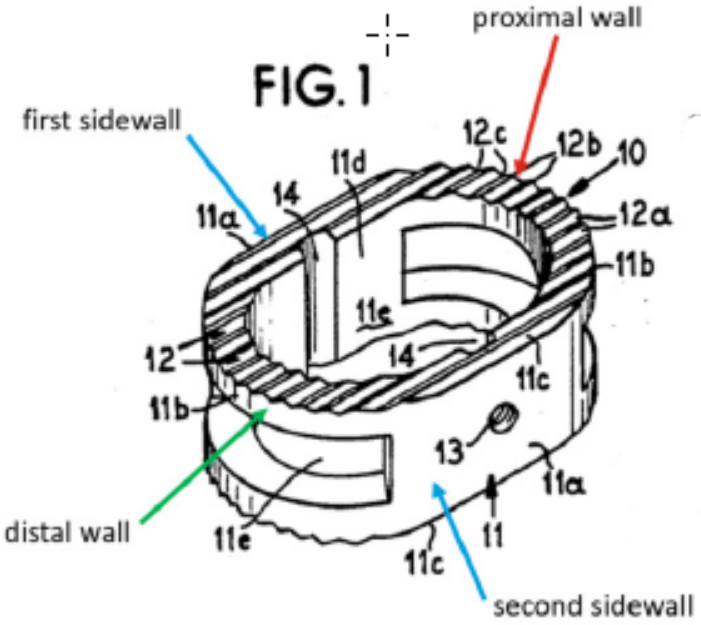
4. Analysis

As discussed below, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 are unpatentable over Brantigan, Baccelli, and Berry. For this reason, we only address certain limitations found in claim 1 in this section.

> *a. "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" ("the claimed implant dimensional features")*

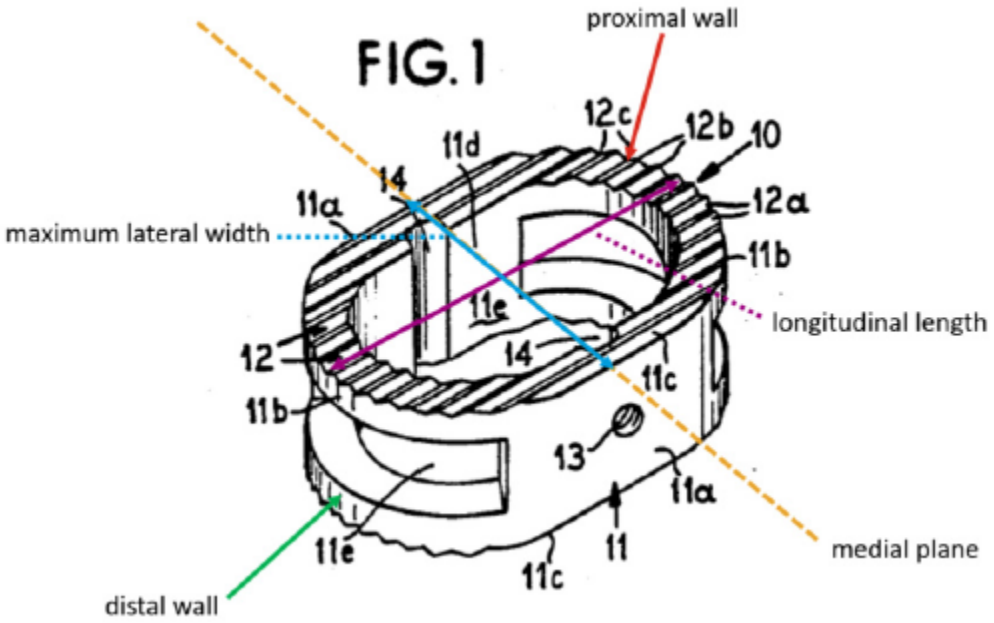
i. Petitioner's Contentions

Petitioner contends Brantigan teaches the claimed implant dimensional features. Pet. 41–46; *see id.* at 41 (referring to "§ XI.C.2.c" found at Pet. 41–44). In identifying the above features in claim 1, Petitioner annotates Brantigan's Figure 1 as follows:



Id. at 40 (reproducing Ex. 1007, Fig. 1 (annotated)). Under Petitioner's interpretation, the above annotated Figure 1 shows the implant's proximal wall in red (right), the implant's distal wall in green (left), and the implant's first and second sidewalls in blue (top and bottom roughly). *See id.* Petitioner contends Brantigan teaches "[o]ne side wall 11a of plug 11" (*id.* at 37 (citing Ex. 1007, 4:20–22)) or "Brantigan's 'opposed sides 11*a'* of the 'oval shaped' spinal fusion implants are the first and second sidewalls" (*id.* at 39 (citing Ex. 1007, 4:5–10; Ex. 1002, ¶ 151)) as recited in claim 1. Petitioner further contends "Brantigan's 'ends 11b' are a distal wall and a proximal wall" as recited in claim 1. *Id.* at 40 (citing Ex. 1007, 4:5–10; Ex. 1002, ¶ 151).

In identifying the claimed implant dimensional features, Petitioner further annotates Brantigan's Figure 1 as follows:

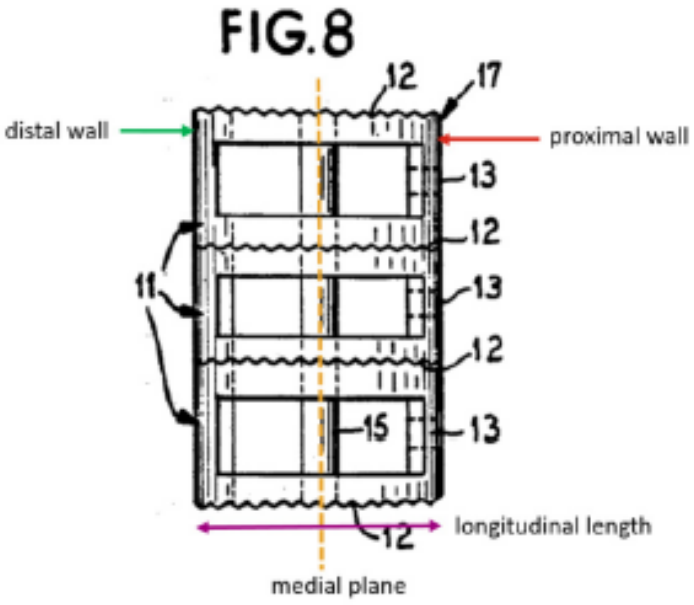


Id. at 44 (reproducing Ex. 1007, Fig. 1 (annotated)). The above annotated Figure 1 shows the implant's longitudinal length in purple running roughly from left to right, the implant's maximum lateral width in blue running roughly from bottom to top, the implant's medial plane in dotted orange running through the maximum lateral width, the implant's proximal wall in red (right), and the implant's distal wall in green (left). *See id.*

Petitioner contends Brantigan discloses an implant with "a longitudinal length extending from a proximal end of the proximal wall to a distal end of the distal wall" as claim 1 recites. *Id.* at 41–43 (citing Ex. 1002 ¶ 158; Ex. 1019, 6–9) (reproducing Ex.1007, Figs. 8, 10 (annotated)). Petitioner further contends Brantigan discloses "a maximum lateral width extending from the first sidewall to the second sidewall along a medial plane generally perpendicular to the longitudinal length" as claim 1 recites. *Id.* at 43 (citing Ex. 1002 ¶¶ 160–162). Petitioner asserts Brantigan also teaches its implants "are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies" (Ex.

1007, 1:19–21) to demonstrate the recited "maximum lateral width" feature in claim 1. *Id.* at 44 (citing Ex. 1002 ¶ 163; Ex. 1007, 1:19–21); *see id.* at 46 (quoting Ex. 1007, 1:19–21) (citing Ex. 1002 ¶¶ 174–175). Along with noting Brantigan's teachings related to the implant's oval shape, Petitioner quotes from Brantigan that its "implants are 'generally oval shaped to conform with the general outline perimeter of the vertebrae.'" *Id.* at 45 (quoting Ex. 1007, 2:2–4).

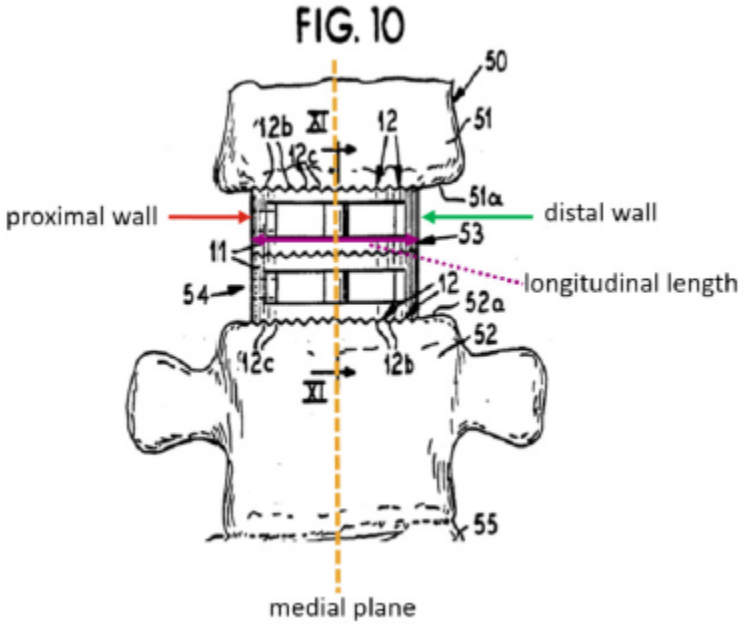
Additionally, Petitioner contends Brantigan's Figure 8 shows the recited "distal wall," "proximal wall," "first sidewall," "second sidewall," "longitudinal length," and "maximum lateral width" features in claim 1. *Id.* at 37–43. Petitioner annotates Brantigan's Figure 8 as follows.



Id. at 42 (reproducing Ex. 1007, Fig. 8 (annotated)). Under Petitioner's interpretations, above annotated Figure 8 shows a distal wall in green (left), a proximal wall in red (right), a medial plane in orange (dotted) running from bottom to top, and the longitudinal length in purple running from left to right. *See id.* Petitioner contends its annotated Figure 8 shows "the

longitudinal length of the laterally-inserted Brantigan implant that extends from the proximal end of the proximal wall (with threaded insertion hole 13) to the distal end of the distal wall." *Id.; see id.* at 37–38 (stating "[t]he wall of an implant containing the threaded insertion hole or recess for receiving a mounting tool is referred to as the 'proximal wall'" and "[o]pposite the proximal wall is the 'distal wall'—the wall of the implant that is inserted into the disc space first . . ."") (citing Ex. 1002 ¶¶ 147–148; Ex. 1019, 5).

Petitioner further contends Brantigan's Figure 10 (annotated) shows the same features. *Id.* at 38–39, 42–43 (citing Ex. 1002 ¶¶ 149 158). Petitioner annotates Brantigan's Figure 10 as follows.



Id. at 43 (reproducing Ex. 1007, Fig. 10 (annotated)) (citing Ex. 1002 ¶ 158). Under Petitioner's interpretations, annotated Figure 10 shows a distal wall in green (right), a proximal wall in red (left), a medial plane in orange (dotted) running from bottom to top, and the longitudinal length in purple running from left to right. *See id.*

For the recited "longitudinal length is greater than said maximum lateral width" in claim 1, Petitioner turns to Brantigan in combination with Berry. *Id.* at 44–46. Petitioner contends Berry reflects the knowledge of a skilled artisan concerning implants, including the teaching of (1) the average, known length and width of human vertebrae 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).

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). Petitioner asserts "Berry . . . conducted 'a morphometric study of selected human vertebrae undertaken to provide data for implant design.'" *Id.* at 45 (quoting Ex. 1022, 362); *see also id.* at 29–30. Petitioner asserts "Berry measured 'major body diameter' (vertebral transverse width) and 'minor body diameter' (vertebral depth) at three different points from 240 different vertebrae." *Id.* (quoting Ex. 1022, 362–363, Fig. 1) (citing Ex. 1002 ¶ 169). Referring to Berry's Table 1, Petitioner asserts that a POSA "would have been motivated to turn to Berry when developing the implants of Brantigan" (*id.* at 30) and would have known that a "vertebral transverse width would be greater than the vertebral depth for all of Brantigan's thoracic or lumbar implants." *Id.* at 45–46 (citing Ex. 1022, Table 1; Ex. 102 ¶¶ 174–175).

ii. Patent Owner's Response

Although Patent Owner argues Brantigan does not teach an implant that spans the full transverse width of a vertebra (PO Resp. 17), Patent Owner does not dispute Brantigan teaches the claimed implant dimensional features recited in claim 1. Having considered the parties' positions and the cited evidence, we are persuaded Brantigan teaches the implant dimensional features as previously discussed. Notably, Patent Owner argues Baccelli's longitudinal length, as identified in the Petition, is not greater than the maximum lateral width as claim 1 recites. *Id.* at 21–22 (citing Pet. 31; Ex. 1002 ¶¶ 189–192) (reproducing in part Ex. 1002 ¶¶ 189, 191 (annotating Ex. 1008, Figs. 1–5)).

iii. Parties' Reply Arguments

In the Reply, Petitioner asserts it "relies on Brantigan and Berry to disclose the dimensional limitations," including the recited "longitudinal length that is greater than its maximum lateral width" recited in claim 1, but not Baccelli. Reply 7. Patent Owner does not further address the claimed implant dimensional features in the Sur-reply. *See generally* Sur-reply.

iv. Brantigan and Berry Teach or Suggest the Claimed Implant Dimensional Features Having considered the parties' positions and the cited evidence, we are persuaded Brantigan and Berry teach "said longitudinal length is greater than said maximum lateral width" under the adopted claim construction of "longitudinal length." See *supra* Section II.C.1. In particular, we are persuaded that Brantigan's Figure 1 (annotated above and at Pet. 40, 44) shows a vertebrae prosthesis device (Ex. 1007, 4:2) taking the form of an oval ring plug 11 (*id.* at 4:6) (e.g., the recited "spinal fusion implant") having "a longitudinal length" (in purple) extending from ends

11*b* (e.g., a "distal wall" (in green) and a "proximal wall" (in red) (*see* Pet. 44), such that the "longitudinal length extend[s] from a proximal end of the said proximal wall to a distal end of said distal wall" as recited in claim 1. *See* Ex. 1007, 4:1–14, Fig. 1. We also are persuaded that Brantigan's Figure 1 (annotated above and at Pet. 40, 44) shows the same implant has "a medial plane" (in dotted orange) and "a maximum lateral width" (in blue) (*see* Pet. 44) extending from opposed sides 11*a* (e.g., a "first sidewall" and a "second sidewall" (both in blue) (*see id.* at 40)), such that the "maximum lateral width extend[s] from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length" (*see id.* at 44) as claim 1 recites. *See* Ex. 1007, 4:1–14, Fig. 1.

However, we are not persuaded Brantigan's Figure 8 and 10, as annotated by Petitioner (*see supra*; *see also* Pet. 42–43), show "a longitudinal length" as claim 1 recites. We find the Petition's annotated Figures 8 and 10 problematic. As discussed above under Section II.C.1, a POSA would not have understood the implant's "longitudinal length" in claim 1 "is *measured relative to the direction in which [the implant] is inserted* from the proximal end that contains the tool receiving recess or mechanism to the distal end opposite the insertion end." Ex. 1002 ¶ 122 (emphasis added). As such, we are not persuaded that the implant's "longitudinal length" is necessarily located as labeled in annotated Brantigan's Figures 8 and 10, which defines the "length" relative to the location of internally threaded hole 13 on the implant's right (Fig. 8) or left side (Fig. 10). *See* Pet. 42–43. Also, based on our claim construction, the labeled "longitudinal length" in Brantigan's annotated Figures 8 and 10 (*see id.*) does not mark the implant's longer dimension or the dimension that

extends lengthwise but rather depicts the implant's width. *See id.* That is, the perspective of Brantigan's Figures 8 and 10 (*see id*.) differs from Brantigan's Figure 1's (*see id.* at 44) side perspective and appears as a straight-on view from one of ends 11*b* showing one of long horizontal slots 11*e*. *Compare* Ex. 1007, 3:46–50, Figs. 8, 10*, with id.* at 3:21–22, 4:10–14, Fig. 1. Additionally, even though Brantigan's Figure 8 shows "the stack devices of FIG. 4" (*id.* at 3:40–41), connecting bar 15 in Brantigan's Figures 8 and 10 are arranged in the opposite direction (e.g., spanning the implant's length) from the same connecting bar in Brantigan's Figure 4 (e.g., arranged in vertical grooves 14 and spanning the implant's width). *Compare id.*, Figs. 8, 10, *with id.*, Fig. 4.

Based on Petitioner's mapping to and annotations of Brantigan's Figure 1 (but not those annotated in Figures 8 and 10), we also are persuaded that Brantigan's implant has a "longitudinal length [that] is greater than said maximum lateral width" as claim 1 recites. *See* Pet. 44 (reproducing Ex. 1007, Fig. 1 (annotated)) (labeling the "longitudinal length" in purple and "maximum lateral width" in blue). As Petitioner points out (*id.* at 44–45), Brantigan shows and describes its "ring-like prosthetic plugs . . . are preferably *oval* shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies." Ex. 1007, 1:13–21 (emphasis added), Fig. 1. Dr. Brantigan verified this position during a deposition. Ex. 2060, 1493 (discussing Ex. 1007 and stating the implants "were sized and shaped to match the size and shape of the normal disc space and intervertebral body"). Dr. Youssef does not disagree. Ex. 2055 ¶ 51 (quoting the above passage and stating "Brantigan . . . suggests that the

length and width ratio of implants should match those of normal vertebral bodies").

Berry states it conducted "a morphometric study of selected human vertebrae undertaken to provide data for implant design" (Ex. 1022, 362), including examining various vertebral measurements in the lumbar and thoracic regions (*id.*, 363–364). Specifically, Berry's Figure 1 shows and Table 1 provides various vertebrae's (e.g., T2, T7, T12, L1–5) "[m]ajor body diameter" measurements (e.g., A–C) and "[m]inor body diameter" (e.g., D–F) measurements. *Id.* Dr. Branch also explains Berry's (1) A–C measurements of the "'major body diameter' correspond[] . . . with the 'longitudinal length' element claimed in the '156 patent" (Ex. 1002 ¶ 169) and "the longitudinal length of the spinal fusion implant described in Brantigan" (*id.* ¶ 170) and (2) D–F measurements of the "'minor body diameter' correspond[] with the 'maximum lateral width' element claimed in the '156 patent" (*id.* ¶ 169) and "the maximum lateral width of a spinal fusion implant described in Brantigan" (*id.* ¶ 170). For example, in Table 1, Berry provides A-C dimensions for a T2 vertebra of 29.8±2.4–33.5±2.9 and D-F dimensions for a T2 vertebra of 18.1±1.5–19.0±1.6. Ex. 1022, 364, Table 1. Dr. Branch also testifies that the "longitudinal length" in Berry (e.g., measurement A of 29.8 mm) is greater than the "maximum lateral width" in Berry (e.g., measurement D of 18.1 mm) for a T2 vertebrae. Ex. 1002 ¶ 174 (citing Ex. 1022, Table 1).

Thus, Brantigan and Berry collectively teach and suggest Brantigan's oval implant, shown in Figure 1 (Ex. 1007, Fig. 1), can be shaped with its medial-lateral dimension (e.g., the recited "longitudinal length") longer than and its anterior-posterior dimension (e.g., the recited "maximum lateral

width") to match the same ratio as normal vertebral bodies, such as those discussed and shown in Berry (e.g., dimensions A–C and dimensions D–F respectively). We therefore determine Brantigan and Berry collectively teach and suggest to a POSA that Brantigan's oval implant would have a "longitudinal length [] greater than said maximum lateral width" as claim 1 recites.

Patent Owner asserts that "[t]he petition mischaracterizes Berry by equating the size of vertebral bodies with the size of lumbar implants and fails to consider the space occupied by soft tissue . . . , such as the annulus" (PO Resp. 16 (citing Pet. 56, 74–75; Ex. 1022, 362; Ex. 2055 ¶¶ 47–49; Ex. 2057 ¶¶ 17–20)) and "Petitioner's proposed implant's width at the T1/T2 disc space "should be smaller than the depth of the adjacent vertebrae" so as "to leave [] room for the soft tissue" (*id.* at 29). Patent Owner arguments refer to portions of the Petition addressing dependent claim 9's limitations—not independent claim 1's limitations. *Compare* Pet. 56, 74–75, *with id.* at 44–46.

When addressing claim 1 (*see id.* at 29–30, 44–46), the Petition cites to (1) Brantigan's teaching that its implant is generally oval shaped to conform with the vertebrae's outline perimeter (Ex. 1007, 2:2–4) and to have its medial-lateral and anterior-posterior implant dimensions in the same *ratio* as a normal vertebral body (*id.* at 1:19–21) and (2) Berry's teaching related to vertebral measurements. *See* Pet. 44–46. Additionally, Exhibit 2029,[18] which is authored by Dr. Brantigan (see "Surgeon" signature and "Print Name" (Ex. 2029, 2–6, 8)), shows a similar implant to Brantigan's Figure 6.

[18] Exhibit 2029 is entitled "AcroMed Corporation, Request for Individual Custom Device."

Compare id. at 8, *with* Ex. 1007, Fig. 6. Also, similar to Brantigan, Exhibit 2029 states "I feel that the *ratio* of dimension of the cages should duplicate the known average dimensions of lumbar vertebrae. For simplicity, the different sizes should maintain about the same *ratio*." *Id.* at 7 (emphasis added). Thus, the evidence of record indicates Brantigan's implants (e.g., lumbar implants) are arranged to conform with vertebral bodies.

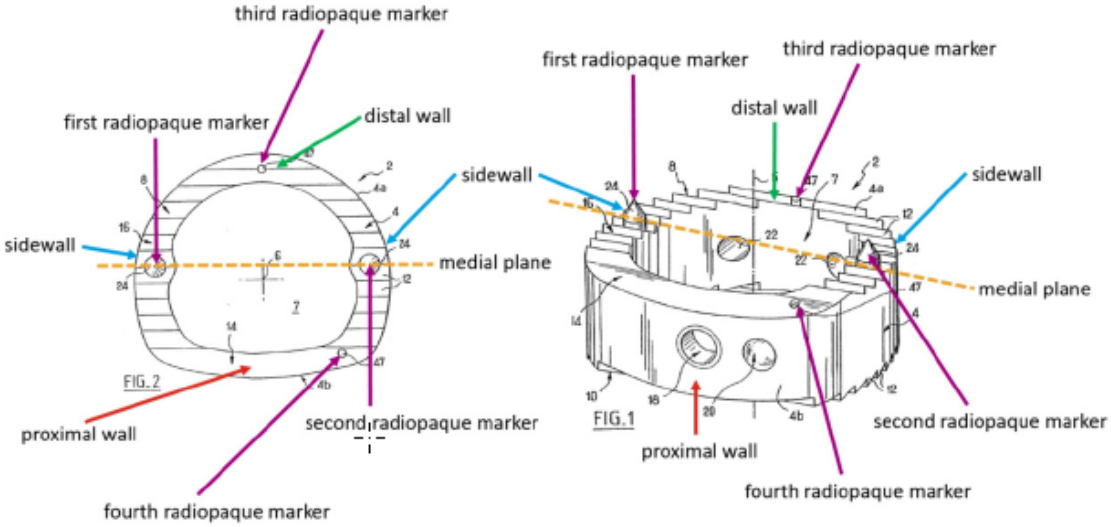
As such, having considered the parties arguments and the evidence in its entirety, Brantigan and Berry teach or suggest to a POSA that Brantigan's implant maintain its medial-lateral (i.e., the recited "longitudinal length") and anterior-posterior (i.e., the recited "maximum lateral width") dimensions in the same ratio as a normal vertebral body, which includes an implant having a "longitudinal length [] greater than said maximum lateral width" as claim 1 recites.

> b. *"at least first and second radiopaque markers . . ., 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"* ("the claimed marker limitation")

i. Petitioner's Contentions

Petitioner contends that Brantigan does not mention radiopaque markers in the middle of the implant's sidewalls but that Baccelli teaches the claimed marker limitation. Pet. 30, 49–52. Petitioner asserts "[w]ithout radiopaque markers, surgeons would have difficulty identifying the position and presence of the implant during and after surgery." *Id.* at 30 (citing Ex. 1002 ¶ 123). Petitioner further argues a POSA would have been motivated to combine Baccelli's teaching with Brantigan's implant. *Id.* at 30–33.

Specifically, Petitioner maps Baccelli's spikes 24 to the recited first and second radiopaque markers that extend into the sidewalls proximate the medial plane. *Id.* at 49 (citing Ex. 1008 ¶¶ 41, 50–51; Ex. 1002 ¶¶ 187, 189). In identifying Baccelli's markers, Petitioner annotates Figures 1 (right) and 2 (left) as follows:



Id. at 10, 31, 50 (reproducing Ex. 1008, Figs. 1–2) (annotating Ex. 1008, Figs. 1–2). Both annotated Figures 1 (right) and 2 (left) label (1) the "first radiopaque marker" and the "second radiopaque marker" in purple, (2) the "distal wall" (top) in green (also labeled 4a), (3) the "proximal wall" (bottom) in red (also labeled 4b), (4) each "sidewall" (right and left) in blue, and (5) the "medial plane" (extending between spikes 24) in dotted orange. *See id.* at 50. Also, the labels "first radiopaque marker" and "second radiopaque marker" in annotated Figures 1 and 2 point to spikes 24 (left and right respectively). *See id.*

Petitioner argues proximal wall 4b has mounting orifice 18 for fitting tool 40 as shown in Baccelli's Figures 3, 8, and 9. *Id.* (citing Ex. 1008 ¶ 44, Figs. 3, 8–9; Ex. 1002 ¶ 191). Referring to Baccelli's annotated Figures 4

and 5, Petitioner argues Baccelli discloses a distal wall (shown in green in annotated Fig. 4), a proximal wall opposite the distal wall (shown in red in annotated Fig. 3), and first and second sidewalls extending between the proximal and distal walls (shown in blue in annotated Figs. 3–5). *Id.* at 50–51 (citing Ex. 1008 ¶¶ 33–34, Figs. 3–5; Ex. 1002 ¶ 191) (reproducing Ex. 1008, Figs. 3–5 (annotated)). Petitioner further contends:

> Baccelli discloses that the radiopaque markers "are disposed symmetrically to each other about the sagittal midplane," defined as the plane parallel to axis 6 and perpendicular to front (proximal) wall 4b. Ex. 1008, [0036], [0041], [0050]–[0051], Figs. 3–5; Ex. 1002, ¶ 192. The spikes also "extend in the frontal midplane containing axis 6." *Id.*, [0041].

Id. at 51. Petitioner argues Baccelli states spikes "can be inserted and fixed rigidly in the ducts" (Ex. 1008 ¶ 51) and "a POSA would have understood that the radiopaque markers extend into the first and second sidewalls." *Id.* at 51–52 (citing Ex. 1002 ¶¶ 192–193). Based on its illustrations, Petitioner argues Baccelli teaches the claimed marker limitation in claim 1. *Id.* at 51 (citing Ex. 1002 ¶¶ 192–193).

Petitioner also asserts Baccelli teaches including markers in radiolucent spinal fusion implants. *Id.* at 9, 30. Petitioner states Baccelli teaches because the markers "'are opaque to X-rays,' the 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 9–10, 30 (quoting Ex. 1008 ¶¶ 50–51); Reply 6 (citing Pet. 31–33; Ex. 1002 ¶¶ 123–126). Petitioner asserts the '156 patent includes text similar to Baccelli in this regard. *Id.* at 30 (citing Ex. 1001, 2:56–62). Based on Baccelli's teaching, Petitioner argues "a POSA would have been motivated to include the

radiopaque markers of Baccelli in the anterior and posterior sidewalls of the radiolucent Brantigan lateral implant" and "a POSA [would] have found it obvious to position two markers in the middle (widest portion) of Brantigan's sidewalls 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).

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, *quoted in* Pet. 29. Petitioner further asserts "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." Pet. 31 (citing Ex. 1002, ¶¶ 125–126, 257). To support these assertions, Petitioner argues Brantigan's connecting bar 15 "runs along the medial plane" and "sits directly in front of the spinous process." *Id.* (citing Ex. 1002 ¶ 125); *see id.* at 32 (reproducing Ex. 1007, Fig. 8 (annotated)). Petitioner contends that adding Baccelli's radiopaque markers to Brantigan's sidewalls "along connecting bar 15 would have allowed surgeons 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). Petitioner also contends:

> A lateral (side) X-ray of the same implant would allow the surgeon identify the position of the posterior sidewall of Brantigan relative to the posterior edge of the vertebral body (bordering the spinal canal) and the anterior sidewall of Brantigan relative to the anterior edge of the vertebral body (bordering the aorta and vena cava).

Id. at 32–33 (citing Ex. 1002 ¶ 125) (reproducing a vertebral body figure[19] from Ex. 1002 ¶ 125).

Petitioner further argues a POSA would have had a reasonable expectation of success of combining Brantigan with Baccelli and Berry to: (1) size implants for lateral insertion, (2) locate radiopaque markers "at the medial plane of the implant" (e.g., the middle of the anterior and posterior sidewalls), and (3) use an X-ray to determine the implant's location and spatial orientation because a POSA would have known radiopaque markers in a radiolucent implant can be seen in an X-ray "and the consequences were predictable." *Id.* at 33. Lastly, Petitioner asserts "surgeons had a reasonable expectation that they would be able tell how the otherwise translucent implant was arranged inside the patient." *Id.* (citing Ex. 1004, 13 (Final Written Decision in IPR2013-00506); Ex. 1002 ¶ 126).

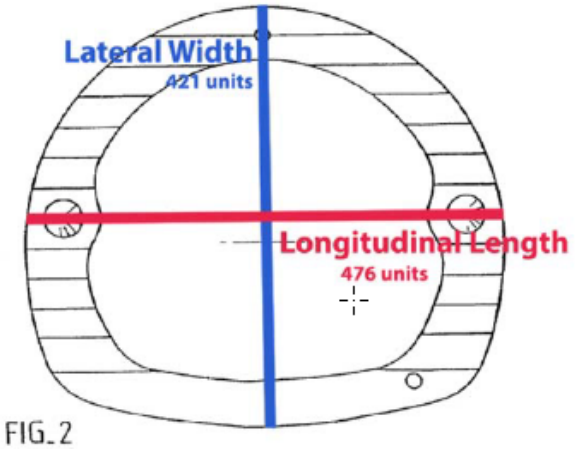
ii. Patent Owner's Response

Patent Owner argues "none of Brantigan, Baccelli, and Berry teach first and second radiopaque markers proximate the medial plane." PO Resp. 19; *see id.* at 19–24. Patent Owner highlights various statements made in the Decision to Institute (Paper 18) concerning Baccelli, asserting Baccelli lacks the claimed marker limitation in claim 1 and Petitioner has not made its required showing. *Id.* at 20–21 (quoting Dec. Inst. 26–27, 27 n.12); Sur-reply 4–5 (same). In particular, Patent Owner asserts Baccelli's longitudinal length identified in the Petition is not greater than the maximum lateral width. PO Resp. 21–22 (citing Pet. 31; Ex. 1002 ¶¶ 189–192) (reproducing

[19] According to Dr. Branch, the reproduced vertebral body is a "lumbar" vertebral body. Ex. 1002 ¶ 27.

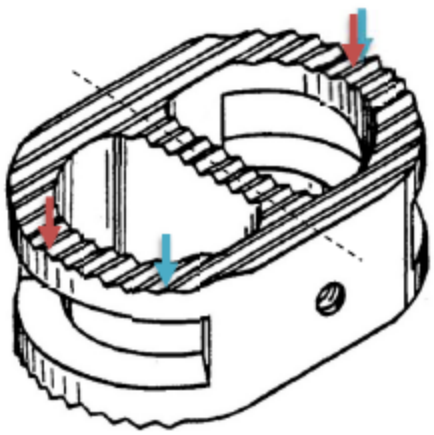
Ex. 1008, Figs. 1–2, 5 (annotated)). Patent Owner further argues Petitioner's expert, Dr. Branch, incorrectly labels the medial plane in Baccelli and what Dr. Branch indicates as the medial plane "is parallel to the longitudinal length." *Id.* at 14 (citing Ex. 1002 ¶ 125; Ex. 1001, claim 1); *see id.* at 15 (reproducing Ex. 1008, Fig. 2 (annotated)).

According to Patent Owner's expert, Dr. Youssef, Patent Owner contends the longitudinal length of Baccelli's implant "is measured sidewall to sidewall" as follows:



Id. at 15 (reproducing Ex. 1008, Fig. 2 (annotated)) (citing Ex. 2055 ¶¶ 60–66); *id.* at 23 (reproducing the same). Above annotated Figure 2 in Baccelli shows a "Longitudinal Length" in red extending horizontally between spikes (*see id.* at 23) and a "Lateral Width" in blue extending vertically and intersecting with the "Longitudinal Length" approximately at the center of the implant. *See id.* at 15, 23; *see also* Ex. 2055 ¶¶ 61, 65. Patent Owner argues, as annotated above, "spikes 24 [of Baccelli] are on a plane parallel to the longitudinal length" (PO Resp. 23) and thus Baccelli does not teach "two radiopaque markers proximate the medial plane" as required by claim 1 (*id.* at 24). *See id.* at 25 (citing Ex. 2055 ¶¶ 116–118, 121).

Patent Owner further argues, if Baccelli's teachings are applied to Brantigan's implant, a POSA would not arrive at the implant as recited. *Id.* at 24. Specifically, Patent Owner argues Baccelli teaches "placing the spikes such that they are 'disposed symmetrically to each other about the sagittal midplane.'" *Id.* at 16 (quoting Ex. 1008 ¶ 41); *see id.* at 24 (citing Ex. 1008 ¶ 41). Patent Owner also contends "[p]lacing markers 47 at the leading and trailing ends of a laterally-inserted Brantigan implant results in markers 47 at the distal and proximal walls." *Id.* at 24 (citing Ex. 1008 ¶ 41). Based on these assertions, Patent Owner contends markers 47 and spikes 24 in Baccelli would result in the following annotated Figure 1 in Brantigan:



Id. at 24 (reproducing Ex. 1007, Fig. 1 (annotated)). Above annotated Brantigan's Figure 1 shows the resulting spike 24 locations as red arrows and the resulting marker 47 locations as blue arrows. *See id*. Patent Owner argues there will be "no radiopaque markers proximate the medial plane." *Id.*

Patent Owner further argues "[t]he petition fails to establish motivation to place two markers on Brantigan proximate the medial plane, whether to align the markers with the spinous process or otherwise." *Id.* at

25; *see id*. at 20, 25–26. Specifically, Patent Owner argues that Dr. Youssef explains there is no reason to align markers with the spinous process found in Brantigan, Baccelli, or Berry. *Id.* at 25 (citing Ex. 2055 ¶¶ 116–117, 121). Patent Owner also argues Petitioner's "stated motivation" recycles an argument rejected by the Federal Circuit. *Id.* at 25–26 (quoting *In re NuVasive, Inc.*, 842 F.3d 1376, 1384 (Fed. Cir. 2016)) (citing Ex. 2017, 7:9–8:13 (oral hearing identifying Dr. Yuan as the argument's source)); Sur-reply 6. More specifically, Patent Owner contends Petitioner's reason to combine Baccelli with Brantigan to arrive at the claimed markers relies on its expert, Dr. Branch, similar to Dr. Yuan in *In re NuVasive*, to present the "alignment" motivation without supporting evidence and thus relies on hindsight. PO Resp. 25–26 (citing Ex. 2028 ¶ 60); Sur-reply 6 (same).

iii. Parties' Reply Arguments

In the Reply, Petitioner contends that the phrase "medial plane" in claim 1 should be construed based on claim 1's express language, which recites the longitudinal length "extend[s] from a proximal end of said proximal wall to a distal end of said distal wall" and the maximum lateral width "extend[s] from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length." Reply 7 (quoting Ex. 1001, claim 1) (alterations in original) (citing Dec. Inst. 13). Petitioner asserts "the language describing the length, width, and medial plane coordinates is separate from the language explaining how those coordinates interrelate." *Id.* "Given these coordinates," Petitioner asserts Baccelli teaches the recited radiopaque markers. *Id.* (citing Pet. 50–51). Petitioner contends Patent Owner has overlooked Brantigan's teaching that its implants are suitable for "anterior, posterior, or lateral placement in any

area of the spine" when arguing about applying Baccelli's marker configuration to Brantigan's implant. *Id.* at 7–8 (quoting Ex. 1007, 2:57–59) (citing PO Resp. 24). More specifically, Petitioner points to Brantigan's annotated Figures 8 and 10, which Petitioner asserts illustrates "the implant is laterally inserted" and "does 'not require mounting apertures in the end faces of the plugs,'" to demonstrate the claimed marker configuration. *Id.* at 8 (quoting Ex. 1007, 7:5–6) (citing Pet. 42–44).

As for the motivation to combine Baccelli's teaching with Brantigan, Petitioner refers to the Petition and Dr. Branch's explanation. *Id.* at 6 (citing Pet. 30–33; Ex. 1002 ¶¶ 123–126). Petitioner also replies that "reported lateral (C) and antero-posterior (D) radiographs of a transversely oriented BAK[20] cage show that POSAs knew the benefits of 'aligning markers with the spinous process and the lateral ends of the vertebrae' before the '156 patent without 'impermissible hindsight.'" *Id.* at 3 (citing Ex. 1054,[21] Fig. 1) (reproducing Ex. 1054, Fig. 1 (images (C) and (D)); *see also id.* at 6 (citing Ex. 1054, 6). Petitioner asserts these images "show the BAK cage emitting stronger signals at its center and lateral ends (thereby serving as markers)." *Id.* at 3 (citing Ex. 1054, Fig. 1). Petitioner further argues McAfee "report[s] lateral and antero-posterior radiographs of the transversely-oriented BAK cages to illustrate the benefits of 'aligning

[20] Bagby and Kuslich (BAK).
[21] Paul G. McAfee et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine, Emphasis on the Lateral BAK*, 23 Spine 1476–1484 (1998) ("McAfee"). This document includes page numbers 1 through 10 (bottom center). *See* Ex. 1054. We refer to pages 1 through 10 for consistency with Petitioner.

makers with the spinous process and lateral ends of the vertebrae'" and is not relying on impermissible hindsight. *Id*. at 6 (citing Ex. 1054, Fig. 4).

In its Sur-reply, Patent Owner argues Petitioner has not responded to various flaws identified by Patent Owner in its Response. Sur-Reply 1, 5–7. Patent Owner also argues Petitioner "pivots to a new reference that has no relevance to radiopaque markers." *Id.* at 1; *see id*. at 7 (citing Reply 13). Patent Owner disagree with Petitioner's assertion that "what Baccelli teaches is somehow related to the direction in which Brantigan's implants are inserted," contending that Baccelli instead teaches disposing spikes 24 symmetrically about the sagittal midplane, which "is agnostic as to the direction of insertion of any implant." *Id.* at 6 (citing Reply 7–8; Ex. 1007[22] ¶ 41; Ex. 1002 ¶¶ 29–30); *see id.* at 7.

Patent Owner also asserts Petitioner pivots to new arguments based on general knowledge and McAfee not discussed in the Petition to teach the claimed marker configuration, which is improper. *Id.* at 7–8 (citing Reply 13; *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016); *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011); *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1329-31 (Fed. Cir. 2019); *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015)); *see also* Supp. Sur-reply 1. Patent Owner also contends "McAfee does not teach placement of markers proximate the medial plane or anywhere else" (Sur-reply 8) and "is a post-operative image that was not used to position the implant and does not demonstrate alignment with the

[22] Perhaps, Appellant intended to refer to Exhibit 1008.

spinous process" (*id.* at 8–9 (citing Ex. 1054, 3, Fig. 1)). *See also* Supp. Sur-reply 6–7.

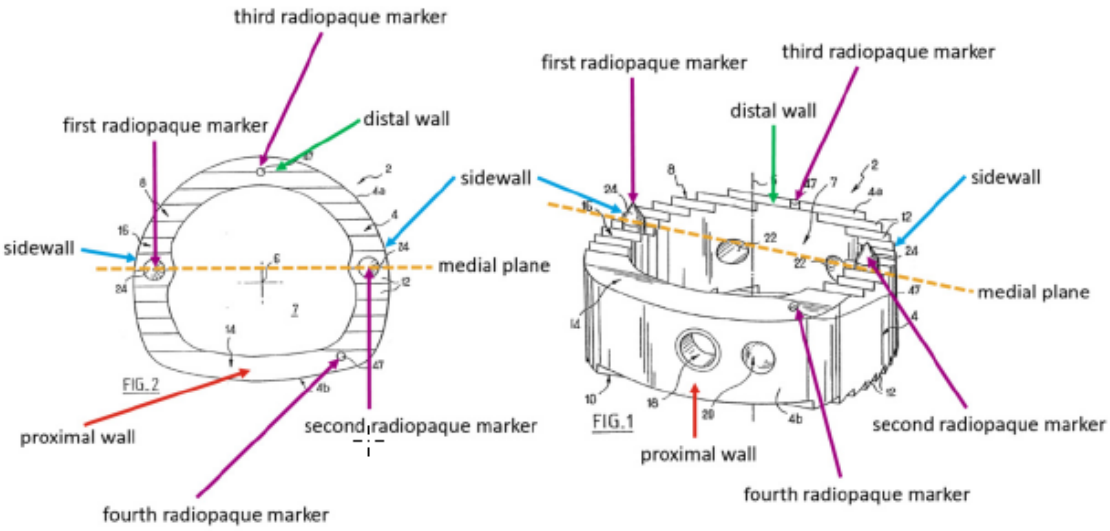
iv. *Baccelli's Asserted Medial Plane and Marker Locations Position Proximate the Medial Plane*

Having considered the parties' arguments and cited evidence, we are not persuaded by a preponderance of evidence that Baccelli when applied to Brantigan's implant teaches or suggests "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" as recited in claim 1. As indicated in Sections II.C.1–2, the phrase "medial plane" means near or approximately at the midpoint of the longitudinal length,[23] such that as claimed, the radiopaque markers extends in the sidewalls at a position near or approximately at the midpoint of the implant's longer dimension. Accordingly, although we agree with Petitioner that the recited "medial plane" should be construed based on claim 1's express language (Reply 7), we are not persuaded that "medial plane" under its plain and ordinary meaning in the context of the claim is measured relative to the direction from which the implant is inserted (*see id.*) as previously explained in Section II.C.1.

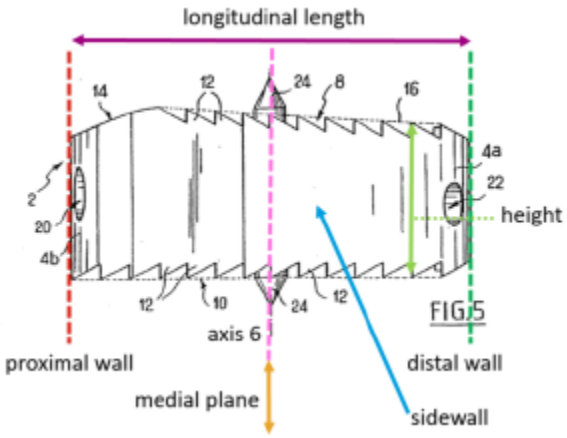
Based on our construction of "medial plane," we are not persuaded that, as argued by Petitioner (*see* Pet. 50–51), Baccelli teaches or shows spikes 24 in the implant's sidewall "at a position proximate to said medial plane," which "is generally perpendicular to said longitudinal length" as

[23] We previously determined "a longitudinal length" means a dimension that is the longer dimension of an object. *See supra*, Section II.C.1.

recited in claim 1 (Ex. 1001, 12:49–50, 12:63–67). As stated in the Decision to Institute, "Petitioner fails to demonstrate sufficiently that Baccelli's medial plane is located as recited in claim 1" (Dec. Inst. 26), including "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." Dec. Inst. 27; *see id.* n.12. Petitioner's mapping to Baccelli's "medial plane" is shown in annotated Figures 1 (right) and 2 (left) below.

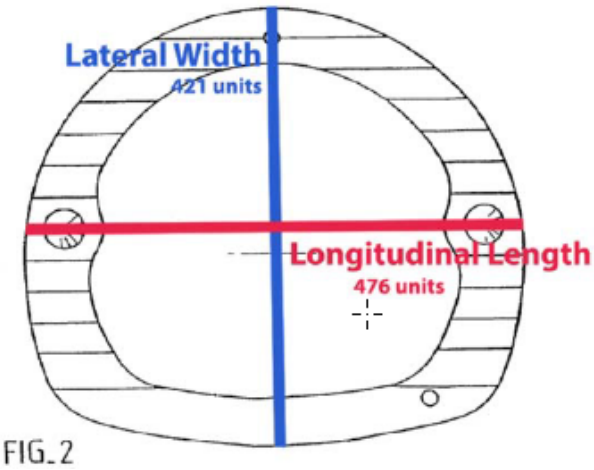


Pet. 50 (reproducing Ex. 1008, Figs. 1–2 (annotated)). Baccelli's Figure 1 (right) is "a perspective view" of its implant; Baccelli's Figure 2 (left) is "a plan view" of its implant. Ex. 1008 ¶ 29. Additionally, Petitioner's mapping to Baccelli's "longitudinal length" is shown annotated Figure 5 below.



Pet. 51 (reproducing Ex. 1008, Fig. 5 (annotated)). Baccelli's Figure 5 is "a right-hand view" of its implant (Ex. 1008 ¶ 29), labeling the "longitudinal length" in purple.

As shown above, annotated Baccelli's Figures 1 (right) and 2 (left) show the medial plane (marked in dotted orange) extending *lengthwise* along Baccelli's implant (*see id.* at 50), which conflicts with claims 1's requirement that the recited "longitudinal length"—not the "medial plane"—is the longer dimension of the implant. Dr. Youssef makes similar findings (Ex. 2055 ¶ 65), including providing the following annotated Figure 2 from Baccelli:



PO Resp. 15 (reproducing Ex. 1008, Fig. 2 (annotated)) (citing Ex. 2055 ¶¶ 60–66). As illustrated in annotated Figure 2 above, Dr. Youssef states "what Dr. Branch indicates as the medial plane of Baccelli, is parallel to the longitudinal length." Ex. 2055 ¶ 65 (reproducing Ex. 1008, Fig. 2 (annotated)). Also, although the Petition indicates in its annotated Figures 1, 2, and 5 of Baccelli's that the "medial plane is generally perpendicular to said longitudinal length" as claim 1 requires (Ex. 1001, 12:49–50), its annotated Figure 5 above (*see* Pet. 51) shows the "longitudinal length" extending along its implant's shorter dimension instead of its longer dimension (*see id.*).

Brantigan, Baccelli, and Berry collectively further support that the "medial plane" of Baccelli's implant would not be located as annotated by Petitioner in Baccelli's Figures 1, 2, and 5. As previously discussed, Brantigan teaches its implants are: (1) "especially well suited for anterior cervical and lumbar fusion" (Ex. 1007, 1:46–47), (2) "preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebrae bodies" (*id.* at 1:19–22; *see* Ex. 1002 ¶ 165), and (3) "generally oval shaped to conform with the general outline perimeter of the vertebrae (Ex. 1007, 2:2–4). Dr. Branch testifies "medial-lateral dimensions of a spinal fusion implant refer to the length of the implant" and "anterior-posterior depth of the spinal fusion implant refers to the width of the implant." Ex. 1002 ¶ 166. Baccelli further teaches its implant is a "cervical implant" (Ex. 1008 ¶ 24; *see id.* ¶ 42) that is "disposed symmetrically about the sagittal midplane" (*id.* ¶ 40). *See* Ex. 1002 ¶¶ 29–30 (showing the sagittal midplane and stating this "plane . . . divides the body into left and right"). Dr. Branch's testimony includes the shape of a

cervical vertebra (top figure) being oval, where its medial-lateral dimension is greater than its anterior-posterior dimension. *See* Ex. 1002 ¶ 27. Berry also shows an oval shaped vertebra, where its medial-lateral dimension (i.e., extending along the "longitudinal length") is greater than its anterior-posterior (i.e., extending along the "medial plane"). Ex. 1022, 363 (Fig. 1).

Baccelli does not demonstrate the recited "medial plane" at the location proposed by Petitioner when considering (1) the collective record related to the medial plane, (2) claim 1's language, and (3) the plain and ordinary meaning of a medial plane as discussed in Section II.C. Accordingly, Baccelli alone does not teach or suggest the claimed marker limitation as set forth in claim 1

v. Collective Teachings Concerning the Claimed Marker Limitation

As recognized in Decision to Institute (Dec. Inst. 27), Petitioner states it is not looking to Baccelli but rather "relies on Brantigan and Berry to disclose the dimensional limitations," including the "longitudinal length that is greater than its maximum lateral width," which is located "along a medial plane that is generally perpendicular to said longitudinal length," (Ex. 1001, 12:47–51) recited in claim 1. *See* Reply 7. Even so, as stated in the Decision on Institution, we determined Petitioner would need "to show Baccelli at least suggests placing 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." Dec. Inst. 27 n.12.

At the Decision to Institute stage, we further stated 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 27 (citing Pet. 31–33).

Along these lines, Petitioner argues Brantigan's and Baccelli's collective teachings would result in the claimed marker limitation, including the recited "first radiopaque marker" and "second radiopaque maker" "proximate to said medial plane." Reply 7–8. More specifically, Petitioner contends that Brantigan's implants can be placed in the spine anteriorly, posteriorly, or laterally (*id.* at 7–8 (quoting Ex. 1007, 2:57–59)) and points to Brantigan's annotated Figures 8 and 10, which Petitioner asserts illustrates "the implant is laterally inserted" and "does 'not require mounting apertures in the end faces of the plugs,'" to demonstrate the claimed marker configuration (*id.* at 8 (quoting Ex. 1007, 7:5–6)) (citing Pet. 42–44).

Upon reviewing the record, we are not persuaded by a preponderance of the evidence that Brantigan provides a sufficient teaching to apply Baccelli's marker teachings to Brantigan according to the claimed marker limitation. *See* Pet. 29–31. First, the Petitioner relies on Baccelli—not Brantigan—to teach the marker configuration, including that the markers are arranged "at a position proximate the medial plane" as claim 1 requires. *Id.* at 49–52 (discussing only Baccelli). Second, Baccelli teaches markers 47—not spikes 24 mapped to the radiopaque markers (*see id.*)—are used "to identify the position and/or presence of the implant when X-rays are taken during or after the operation." Ex. 1008 ¶ 50. Although one of markers 47 in Baccelli (labeled "third radiopaque marker" in Baccelli's annotated Figures 1 and 2 *supra* (*see also* Pet. 31)) is located proximate to the medial

plane, contrary to Patent Owner's contention (*see* PO Resp. 24), the other marker (labeled "fourth radiopaque marker" in Baccelli's annotated Figures 1 and 2 *supra*) is closer to a "sidewall" than to the medial plane.

Third, to the extent that Baccelli suggests spikes 24 can also be located in other places on a spinal implant to identify an implant's position and presence when taking X-rays (*see id.* ¶¶ 50–51) and "to visualize the orientation and location of the implant during and after surgery" (Pet. 31 (citing Ex. 1002 ¶¶ 122–126, 257)), we are not persuaded that the collective teachings of Baccelli, Brantigan, and Berry provide sufficient support for making specific modifications to arrive at the claimed marker limitation in claim 1. *See id.* at 31–33 (citing Ex. 1002 ¶¶ 122–126, 257; Ex. 1004, 13; Ex. 1007, Figs. 8, 10). Brantigan teaches that implants are suitable for anterior, posterior, and lateral insertion (Ex. 1007, 2:57–59) but does not address placing markers on the implant (*see generally id*.). Baccelli teaches placing markers in the spinal implant (Ex. 1008 ¶¶ 50–51) but does not specifically "instruct[] a POSA to include radiopaque markers in the middle of the implant sidewalls relative to the direction in which the implant is inserted" as Petitioner contends. Pet. 31; *see* Ex. 1002 ¶ 125. Instead, Baccelli states spikes 24, mapped to the recited "radiopaque markers" (*see* Pet. 49–51), are "disposed symmetrically to each other about the sagittal midplane" (Ex. 1008 ¶ 41; *see* Ex. 1002 ¶¶ 29–30), which is "agnostic" (Sur-reply 6) to the insertion direction.

Fourth, neither Brantigan nor Baccelli discuss using markers to align with the spinous process as Petitioner argues. Pet. 31; Ex. 1002 ¶ 125. For example, Baccelli's spikes 24 are "disposed symmetrically to each other about the sagittal midplane" (Ex. 1008 ¶ 41), which would not be located so

as to align with the spinous process. That is, Dr. Branch and Berry show the location of the spinous process of various vertebrae. *See* Ex. 1002 ¶ 27; *see* Ex. 1022, 363 (Figs. 1–3). Dr. Branch also shows the sagittal plane's locations relative to the human body. *See* Ex. 1002 ¶ 29. Thus, when the above vertebra are located in the human body, they will be located approximately along the sagittal plane (*see* Ex. 1002 ¶¶ 27, 29; *see* Ex. 1022, 363; *see* Ex. 2001, 511 (stating "[t]he spinous process (spine) projects dorsally") (emphasis omitted)), whereas Baccelli's spikes 24 will be located symmetrically *about* the sagittal midplane (Ex. 1008 ¶ 41).

Additionally, Brantigan does not discuss using markers at all or using them along the spinous process. *See generally* Ex. 1007. Moreover, although Petitioner relies Brantigan's Figure 10 to provide a reason to add radiopaque markers "at a position proximate said medial plane," as we previously noted, its configuration as disclosed does not comport with the placement of markers consistent with Petitioner's assertions. Pet. 31–32 (citing Ex. 1007, Figs. 8, 10). For example, Petitioner contends Brantigan's implant is inserted laterally. *See id.* at 29 (stating "[o]nce inserted laterally into the interbody space") (citing Ex. 1007, Figs. 8, 10), 31 (stating "Brantigan lateral implant") (citing Ex. 1007, Figs. 8, 10). Brantigan's Figures 8 and 10 show hole 13 for receiving a mounting tool (e.g., 73) (*id.* at 4:20–22, 6:66–68, Figs. 8, 10, 13) and thus, stack 53 (e.g., an implant) appears to be inserted laterally in between disc space 54 adjacent vertebrae 51 and 52 (*see id.* at 5:30–35, 6:5–9). However, if the implant is inserted as Petitioner contends (*id.* at 29, 31), ends 11e of Brantigan's implant, which are labeled as the implant's distal and proximal wall (*see id.* at 40), would be located adjacent the anterior and posterior of the vertebra (*see* Ex. 1002 ¶ 27;

see Ex. 1022, 363; *see* Ex. 2017, 8:1–2 (stating "the spinous process . . . is basically the bony ridge down the posterior surface of your back")).

More specifically, as proposed by Petitioner (Pet. 31–33), the Brantigan implant's longer dimension in Figure 10 would extend approximately in an anterior-posterior direction and in the direction of the spinous process. *See* Ex. 1007, Fig. 10; *see* Ex. 1002 ¶ 27; *see* Ex. 1022, 363. This, however, runs contrary to other teachings in Brantigan, suggesting the implant has the dimensions in the same ratio as a vertebra or conforms to the general outline perimeter of the vertebrae (*see* Ex. 1007, 1:18–22, 2:2–4). *See* Ex. 1002 ¶ 27 (showing shapes of various vertebra); *see also* Ex. 2029, 7 (stating "I feel that the ratio of [the] dimension of the cages should duplicate the known average dimension of lumbar vertebrae."). We therefore are not persuaded that, once the implant is inserted laterally as shown in Brantigan's Figure 10, "Brantigan's [implant] length spans the full transverse width of the vertebra such that its sidewalls are located along the anterior and posterior portions of the vertebra." Pet. 29 (citing Ex. 1007, Figs. 8, 10).

In reply, Petitioner further contends Brantigan's Figures 8 and 10 show "the implant is laterally inserted, which does 'not require mounting apertures in the end faces of the plugs.'" Reply 8 (quoting Ex. 1007, 7:5–6) (citing Pet. 42–44). Brantigan teaches "[t]ools such as 73 and 75 may also be replaced with other gripping tools which do not require amounting apertures in the end faces of the plugs." Ex. 1007, 7:4–6. However, the record supports that for the teaching of the Figure 10 embodiment, tool 73 would have been used; that is, Brantigan discloses the implant is "a two-unit stack 53 composed of the plugs 11 illustrated in detail in FIGS. 1, 4, and 8"

(*id.* at 6:5–8), which include holes 13 for tool 73 (*see id.* at 4:20–22, 6:65–68, Figs. 1, 4, 8, 10).

Petitioner further contends Baccelli's spikes 24 would be located in the anterior and posterior "sidewalls" of the "Brantigan lateral implant" and along where the rectangular connecting bar runs in Brantigan's Figures 8 and 10 (*see* Pet. 31) so as to "to align the markers with the spinous process . . . after the implant is inserted laterally." *Id.* (citing Ex. 1002 ¶ 125). Yet, following from the above explanation, the longitudinal length of Brantigan's implant in Figure 10 runs along ends 11e (*see* Ex. 1007, Figs. 1, 4, 10), such that adding spikes 24 as taught by Baccelli to Brantigan as proposed (*see* Pet. 31–32) would result in the spikes being located "along where the rectangular connecting bar runs in Brantigan's Figures 8 and 10" (*id.* at 31), which would extend between the labeled "proximal wall" and "distal wall" (*see id.* at 44 (reproducing Ex. 1007, Figs. 1, 6 (annotated)) rather than "proximate said medial plane," which is "generally perpendicular to the longitudinal length" as claim 1 recites. Ex. 1001, 12:45–47, 12:49–50, 12:63–67. We therefore disagree with Dr. Branch's findings in this regard. Ex. 1002 ¶ 125.

Also, as previously explained, we are not persuaded that the longitudinal length of Brantigan (or Baccelli) should be "measured relative to the direction in which it is inserted from the proximal end that contains the tool receiving recess or mechanism to the distal end opposite the insertion end." *Id.* Brantigan provides a more general teaching that its "vertebral prosthetic implant devices [are] suitable for anterior, posterior or lateral placement in any area of the spine requiring replacement of disc or vertebral body" (Ex. 1007, 2:55–59) and this placement can be achieved

"with other gripping tools which do not require amounting apertures in the end faces of the plugs" (*id.* at 7:4–6). *See id.* at 2:64–66, 6:63–68. Brantigan also states "the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column." *Id.* at 5:30–35. As such, Brantigan's more general teachings support that its implant may be inserted in a configuration where its "medial-lateral" dimension (*id.* at 1:20) match the recited "longitudinal length" in claim 1, including that shown in Figure 11. *See id.* at 6:25–32 Fig. 11; *see id.* at 1:20–21 (discussing an oval shaped implant having "medial-lateral . . . dimensions in the same ratio as normal vertebral bodies"); *see id.* at 2:2–4 (discussing the implant "conform[s] with the general outline perimeter of the vertebrae"). This general teaching supports "that Brantigan's [implant] length spans the full transverse width of the vertebra such that its sidewalls are located along the anterior and posterior portions of the vertebra." Pet. 29.

Baccelli also provides a general teaching to "have one or more markers . . . serving . . . to identify the position and/or the presence of the implant when X-rays are taken during or after the operation." Ex. 1008 ¶ 50, *quoted in* Pet. 30. Petitioner contends more generally "[f]ollowing Baccelli, a POSA would have been motivated to include the radiopaque markers of Baccelli in the anterior and posterior sidewalls of the radiolucent Brantigan lateral implant to enable surgeons to visualize the orientation and location of the implant during and after surgery." Pet. 31. Petitioner also asserts, in particular, that adding Baccelli's markers to Brantigan's implant "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 . . . insertion" (*id.* at 32 (citing Ex. 1002 ¶ 125); *see id.* at 31) and with a lateral X-ray, "would allow the surgeon [to] identify the position of the posterior sidewall of Brantigan relative to the posterior edge of the vertebral body (bordering the spinal canal) and the anterior sidewall of Brantigan relative to the anterior edge of the vertebral body (bordering the aorta and vena cava)" (*id.* at 32–33 (citing Ex. 1002 ¶ 125); *see id.* at 31).

The above rationale to combine the teachings of Brantigan and Baccelli is deficient. Baccelli's general teaching does not provide a specific reason to place "said first radiopaque marker extend[ing] into said first sidewall at a position proximate to said medial plane" or "said second radiopaque marker extend[ing] into said second sidewall at a position proximate to said medial plane" as claim 1 requires. *See id.; see also id*. at 49. As to the noted reasons, when Brantigan is inserted such that its longitudinal length runs along the vertebra's medial-lateral dimension (e.g., as shown in Brantigan's Figure 11), we agree that the implant's connecting bar 15 would be located near the spinous process as Dr. Branch discusses. *See* Ex. 1002 ¶ 125. However, neither Brantigan nor Baccelli provide the Petitioner's specifically stated explanation for why a POSA would have placed the markers "at a position proximate said medial plane" as opposed to another location on the implant to achieve the same aim of allowing the surgeon to see whether an implant is askew during and after insertion or to identify the implant's posterior or anterior sidewall relative to the vertebral bodies' edges. *See generally* Exs. 1007–1008; *see* Ex. 2055 ¶¶ 116–117. In fact, as previously discussed, Baccelli's teaching indicates placing spikes 24 about the sagittal plane (*see* Ex. 1008 ¶ 41) rather than the medial plane of an implant like Brantigan's Figure 11.

Petitioner's reasoning also relies on Dr. Branch's testimony, which is deficient. Pet. 31–32 (citing Ex. 1002 ¶ 125). Other than relying on Brantigan's Figures 8 and 10, as discussed above, and reproducing the anatomy of a vertebral body, Dr. Branch has not provided supporting evidence for his conclusory statements. *See* Ex. 1002 ¶ 125; *see id*. ¶ 49.

Moreover, Petitioner's rationale to combine suggests the use of impermissible hindsight. More specifically, the CoRoent® XL implant (Ex. 2039) is associated with the '156 patent at issue in this proceeding and is assigned to NuVasive. *Compare* Ex. 1001, code (73) (indicating the '156 patent is assigned to NuVasive, Inc.), Figs. 2–6, *with* Ex. 2039, 1, 4–5 (NuVasive brochure for the CoRoent® XL implant). Concerning this implant, Dr. Yuan testified (Ex. 2028 (a declaration submitted in IPR2013-00506)) that NuVasive's CoRoent® XL implant permits "a surgeon [to] align both markers with the spinous process to better align the implant" and "[h]aving two radiopaque markers also allows a surgeon to see in an anterior-to-posterior x-ray view whether the implant is askew and the degree to which the implant is askew." *Id.* ¶ 60. In this context, Petitioner's rationale for combining Brantigan and Baccelli resembles the advantages of the CoRoent® XL implant noted previously by Dr. Yuan, which is suggestive of improper hindsight. *Compare id.*, *with* Pet. 32 (stating "Adding Baccelli's radiopaque markers to Brantigan's sidewalls along connecting bar 15 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 . . . A lateral (side) X-ray of the same implant would allow the surgeon identify the position of the posterior sidewall of Brantigan relative to the posterior edge

of the vertebral body . . . and the anterior sidewall of Brantigan relative to the anterior edge of the vertebral body . . . .").

Because Petitioner's reasons to combine are not supported by Baccelli and Brantigan, Petitioner's noted reason to combine the references to arrive at the claimed marker limitation at best come from alleged common knowledge. *See, e.g.,* Ex. 1002 ¶¶ 47 (stating "[i]ncorporation of these [radiopaque] markers into various locations in the implant, e.g., anterior and posterior sidewalls, allowed a surgeon to determine whether the implant was properly seated in the vertebral space"), 49 (stating "[f]or a laterally inserted implant, it was known that location of a marker centrally along the length of the implant would enable a surgeon to properly align the implant relative to the spinous process" and "[a]s the shape and structures of the human spine were known, as was the ability to see radiopaque materials in an X-ray, a POSA would have had a reasonable expectation that including radiopaque markers in the center of the anterior and posterior walls of a lateral implant, for example, would provide specific beneficial information to the surgeon"), 125 (stating "[a] POSA would also have known that inclusion of radiopaque markers in the anterior and posterior walls would have enabled the surgeon to see if the implant is properly aligned with the anterior and posterior edges of the vertebral body."). However, this is insufficient support of a rationale to combine. *See In re NuVasive*, 842 F.3d at 1383–84 ("the PTAB cannot rely solely on common knowledge or common sense to support its findings" and instead needs to "explain the reason why a [POSA] would have been motivated to modify [the Brantigan] implant[], in light of Baccelli, to place radiopaque markers 'proximate to said medial plane.'"); *see also Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361-63, 1366 (Fed. Cir. 2016). Dr.

Branch's testimony (*see* Ex. 1002 ¶¶ 47, 49) does not disclose the underlying facts to support his opinion in this regard and thus is entitled to little weight. *See* 37 C.F.R. § 42.65(a).

Petitioner further discusses McAfee in its Reply to explain why a POSA would place the radiopaque markers as recited in claim 1. Reply 2–3, 6 (citing Ex. 1054, 6, Figs. 1, 4). Petitioner specifically states "McAfee also reported lateral and antero-posterior radiographs of the transversely-oriented BAK cages to illustrate the benefits of 'aligning markers with the spinous process and lateral ends of the vertebrae.'" *Id*. at 6 (citing Ex. 1054, Fig. 4). However, McAfee fails to show or discuss markers or the spinous process, let alone aligning markers with the spinous process and lateral ends of the vertebrae as Petitioner asserts. *See* Ex. 1054, 3 (Fig. 1), 6, 8 (Fig. 4); *see* Sur-reply 8 (noting McAfee's cage is radiopaque and has no radiopaque markers). Rather, as Patent Owner notes (*see* Supp. Sur-reply 6–7), McAfee shows a radiopaque implant having "areas of differing intensity" (*see* Ex. 1054, Fig. 1) instead of radiopaque markers arranged in the claimed marker configuration. As such, this evidence does not provide a sufficient reason to place radiopaque markers on in implant, including "at a position proximate said medial plane" as claim 1 recites. *See id.* at 8; *see also* Supp. Sur-Reply 1, 4–7.

Accordingly, upon review of the entire record, the evidence of record is insufficient to support the Petitioner's stated rationale for combining Brantigan, Baccelli, and Berry to arrive at the claimed marker limitation in claim 1.

Patent Owner presents various evidence related to objective indicia of non-obviousness. PO Resp. 39–43. Based on the foregoing discussion, we

need not reach the issue of whether the secondary evidence supports a conclusion of non-obviousness.

5. Conclusion for Ground 1

For the foregoing reasons, Petitioner has not shown by a preponderance of the evidence that claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 are unpatentable over Brantigan, Baccelli, and Berry.

F. Ground 2: Obviousness of Claim 9 over Brantigan, Baccelli, Berry, and Michelson '973

1. Michelson '973 (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 3:3–57(describing translateral approach). Figures 18 and 19 of Michelson '973 are reproduced below.

FIG. 18

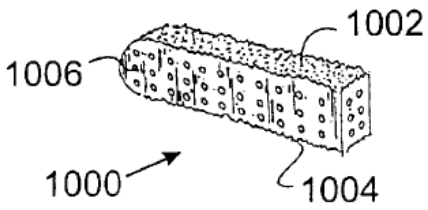


FIG. 19

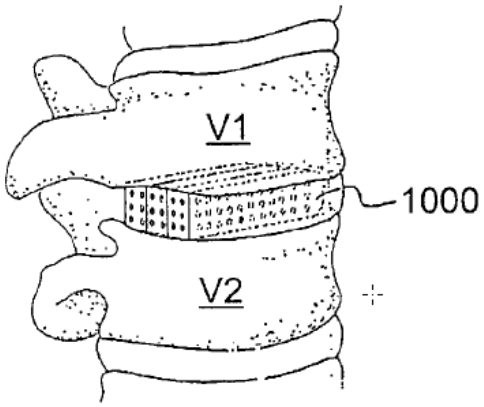


Figure 18 is a perspective side view of a spinal fusion implant 1000, and Figure 19 is a perspective lateral anterior view of a segment of the spinal column with the implants shown in Figure 18 "inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the transverse width of the vertebrae." *Id.* at 5:31–39. 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; *see id.* at 10:56–59, Fig. 19.

Michelson '973 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 '973'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. Spinal fusion implant 900, which is an alternative embodiment to spinal implant 1000, 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 10:42–47, Fig. 17. Michelson '973 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. Analysis

Claim 9 depends from claim 1 and further recites "said maximum lateral width of said implant of approximately 18 mm." Ex. 1001, 13:26–27. For Ground 2, Petitioner proposes claim 9 would have been rendered obvious by Brantigan, Baccelli, Berry, and Michelson '973. Pet. 69–75.

Petitioner asserts Michelson '973 teaches spinal fusion implant 900 (1) is rectangular with top and bottom surfaces 902, 904, (2) is implanted from the spine's lateral aspect into disc space D between two adjacent vertebrae along the vertebra'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). Petitioner further discusses that Michelson '973 "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 '973 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[24]). Petitioner discusses spinal fusion implant 1000 in Michelson '973 that 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.* (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

[24] We presume Petitioner intended to refer to column 10 here.

opposite side.' [Ex. 1007], 2:7-11." *Id.* at 73 (first alteration in original). 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 '973'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 to 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 recited implant in claim 9 that is "'approximately 18 mm wide.'" *Id.* at 74–75 (citing Ex. 1002 ¶¶ 275–285; Ex. 1022, 364, Table 1).

Patent Owner argues that Petitioner's arguments and evidence fail on Ground 2. PO Resp. 32–39.

Having considered the parties' arguments and evidence, we are not persuaded by a preponderance of evidence that Petitioner has shown Michelson '973 remedies the deficiencies of the teachings of Brantigan, Baccelli, and Berry, discussed above in Section II.E.4.b, relating to the

claimed marker limitation of claim 1. Petitioner does not address the claimed marker limitation or radiopaque marker features when discussing Michelson '973 (*see* Pet. 69–75), but rather relies on its evidence and argument related to claim 1. *Id.* at 70 (stating "Brantigan, Baccelli, and Berry render the spinal fusion implant of claim 1 obvious. *Supra* § XI.C.2."). Moreover, Michelson '973 fails to discuss radiopaque markers, let alone a radiopaque marker proximate to the medial plane as claim 1 recites. *See generally* Ex. 1032.

Also, Michelson '973 discusses the vena cava and aorta, recognizing "translateral implants . . . are safer to use than implants inserted from the front or back as the aorta and vena cava lie anterior to the spine and the dural sac and nerves posteriorly, all of which structures are simply avoided in the lateral approach." Ex. 1032, 3:56–60. Yet, Petitioner does not explain how this teaching in Michelson '973 (Pet. 69–75) would have suggested to a POSA the claimed marker limitation in claim 1 for "allow[ing] the surgeon [to] identify the position of the posterior sidewall of Brantigan relative to the posterior edge of the vertebral body (bordering the spinal canal) and the anterior sidewall of Brantigan relative to the anterior edge of the vertebral body (bordering the aorta and vena cava)" as discussed in Ground 1. Pet. 32–33 (citing Ex. 1002 ¶ 125).

Having considered the parties' arguments and cited evidence, we are not persuaded Michelson '973 provides a sufficient teaching missing from Ground 1 to teach or suggest the claimed features in dependent claim 9, which include the features of claim 1.

3. Conclusion for Ground 2

For the foregoing reasons, Petitioner has not shown by a preponderance of the evidence that claim 9 is unpatentable over Brantigan, Baccelli, Berry, and Michelson '973.

G. Patent Owner's Motion to Exclude Evidence

In *inter partes* review proceedings, documents are admitted into evidence subject to an opposing party asserting objections to the evidence and moving to exclude the evidence. 37 C.F.R. § 42.64. Patent Owner moves to exclude certain exhibits to which they previously objected. Mot. Excl. 1 (citing Paper 35). In particular, Patent Owner moves to exclude Exhibits 1053–1056, 1059–1062, 1064,[25] and 1065. *Id.* at 1–7. Patent Owner, as the "moving party," "has the burden of proof to establish that it is entitled to the requested relief." 37 C.F.R. § 42.20(c).

1. Exhibits 1053 and 1054

Exhibit 1053 is U.S. Patent No. 6,241,770 B1 to Michelson (Michelson '770), issued June 5, 2001, and Exhibit 1054 is an article titled "Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine" by Paul C. McAfee et al., from pages 1476–1484 of volume 23, number 13 of Spine, published in 1998. Patent Owner argues that these exhibits should be excluded under Rules 401–403 of the Federal Rules of Evidence (FRE) as irrelevant to a ground of review, likely to cause confusion, and prejudicial. Mot. Excl. 1–3.

In particular, Patent Owner contends that "Petitioner cites these exhibits in support of a *prima facie* case of obviousness raised for the first

[25] Although this exhibit is not listed on page 1, Exhibit 1064 is discussed on pages 4 and 5. Mot. Excl. 4.

time in Petitioner's Reply" (*id.* at 1) and to fill a gap identified in the Patent Owner Response (*id.* at 2–3 (citing Pet. 4–5, 30, 45, 47–48; PO Resp. 21–26, 55[26]; Reply 10)). Petitioner responds that Exhibits 1053 and 1054 are proper rebuttal evidence. Opp. 1–2. Petitioner also identifies which of Patent Owner's arguments that the exhibits rebut and how they respond to those arguments. *Id.* at 2–5 (citing PO Resp. 9, 13, 25; Reply 1–5, 10). Patent Owner replies that "Petitioner does not contest that it could have presented the[exhibits] with the Petition" and "concedes that it is improper in reply to rely on a new rationale to combine the prior art references." Mot. Reply 1. Patent Owner reiterates its arguments that Exhibits 1053 and 1054 support a new rationale for combining the references. *Id.* at 2–4 (citing Pet. 14, 31, 69–70, 72–75; Opp. 2–4). Patent Owner also argues that these exhibits fail to support the theory presented in the Petition. *Id.* at 3–4 (citing Pet. 31; Opp. 3).

We have reviewed the record. The parties dispute whether Exhibits 1053 and 1054 support rebuttal arguments or are new arguments. Patent Owner's arguments are not properly the subject of a motion to exclude based on inadmissibility. Rather, Patent Owner should have filed a motion to strike because it seeks to exclude belatedly presented evidence that Patent Owner contends exceeds the proper scope of reply. In any event, because we find that the exhibits are proper rebuttal evidence, we deny Patent Owner's Motion to Exclude with respect to Exhibits 1053 and 1054.

[26] Notably, there are only fifty-three pages in the Response.

2. Exhibits 1055 and 1056

Exhibit 1055 is an article titled "A Carbon Fiber Implant to Aid Interbody Lumbar Fusion" by John W. Brantigan, M.D. and Arthur D. Steffee, M.D., from pages 2106–2117 of volume 18, number 14 of Spine, published in 1993. Exhibit 1056 is an excerpt from a transcript in related litigation. The excerpt contains a portion of Dr. Brantigan's direct testimony. *See* Ex. 1056, 2–9[27]. Patent Owner argues that Exhibit 1055 should be excluded under Rules 401–403 of FRE because it is cited in Petitioner's Reply with no substantive discussion and no explanation of its significance. Mot. Excl. 4. Patent Owner also argues that Exhibit 1056 should be excluded under Rules 106 and 401–403 of FRE because it is "more likely to cause confusion and unreasonable prejudice than add probative value." *Id*.

Specifically, Patent Owner argues that Exhibit 1056 is an incomplete document from another proceeding, omits other information that should be considered, and is irrelevant to this proceeding. *Id.* at 4–5. Patent Owner also argues that, because Exhibit 1056 is a partial transcript, it is confusing, and fails to provide context. *Id.* at 5. Petitioner responds that Exhibits 1055 and 1056 were offered to rebut Dr. Youssef's testimony. Opp. 5–6. Petitioner argues that the exhibits are, thus, relevant and their relevance outweighs any risk of confusion. *Id.* at 5– 6. Petitioner also contends that Patent Owner relied on Exhibit 1055 in previous litigation and relies on exhibits from the same litigation to support arguments in this proceeding. *Id.* at 5–6 (citing Ex. 2029; Ex. 2030; Ex. 2060, 27–29, 51).

[27] We refer to the Exhibit's pagination here. Unless otherwise indicated, we refer to the exhibits pagination, as does Petitioner, throughout the decision.

Patent Owner replies that Petitioner "improperly attempt[s] to back-fill arguments regarding Exhibit 1055" and the arguments are "belated and non-responsive." Mot. Reply 4. Patent Owner also replies that "Petitioner approved of NuVasive's filing of EX2060 as a complete version of the transcript Petitioner filed as EX1056" and "fails to establish the admissibility of its exhibits." *Id.* at 5 (citing Mot. Excl. 4–7; Opp. 5).

Petitioner cites Exhibits 1055 and 1056 in its Reply in support of its argument that Dr. Youssef was unaware of Patent Owner's reliance on Brantigan. Reply 5. We do not agree with Patent Owner that the explanation of its significance is insufficient or that these exhibits are irrelevant. The exhibits at issue aid in determining what weight we should afford Dr. Youssef's testimony in this proceeding. These exhibits inform us about Dr. Youssef's knowledge about a reference asserted in this proceeding which, in turn with all other record evidence, may or may not affect the weight we give to Dr. Youssef's opinion of the asserted reference.

Accordingly, Patent Owner has not satisfied its burden to show that Exhibits 1055 and 1056 should be excluded, and thus, we deny Patent Owner's Motion to Exclude with respect to Exhibits 1055 and 1056.

3. Exhibits 1059 and 1064

Exhibit 1059 is an excerpt from a deposition transcript of Dr. Youssef in related litigation, and Exhibit 1064 is open payments data for Dr. Youssef. Patent Owner argues that these exhibits should be excluded under Rules 106 and 401–403 of the FRE because they are "more likely to cause confusion and unreasonable prejudice than add probative value." Mot. Excl. 4.

In particular, Patent Owner argues that Exhibit 1059 is an incomplete document from another proceedings, omits other information that should be

considered, and is irrelevant to this proceeding. *Id.* at 4. According to Patent Owner, Exhibits 1059 and 1064 support that Dr. Youssef has been compensated for consulting services provided to Patent Owner beyond this proceeding and the partial record is confusing, provides minimal context, and is likely to cause undue prejudice. *Id.* at 6; *see also id.* at 5–6 (arguing that Dr. Branch has also provided consulting services). Petitioner responds that the exhibits were offered "to demonstrate the bias associated with Dr. Youssef's opinions." Opp. 7. Petitioner also describes Dr. Branch's consulting arrangement with Medtronic and other companies. *Id.*

Patent Owner replies that "Petitioner's use of [Exhibit 1064] is misleading and incomplete because Dr. Branch testified during his deposition in the district court case that he was paid several million dollars as a consultant for Medtronic and that this range of compensation reflected fair market value" and that "Petitioner does not contest the authenticity or veracity of Dr. Branch's testimony." Mot. Reply 5 (citing Mot. Excl. 5–6; Opp. 7). Patent Owner does not provide a reply specific to Exhibit 1059. *See id.*

Dr. Youssef's testimony (Ex. 1059) and open payments data (Ex. 1064) would aid in determining bias, if any, that may have affected his opinion in this proceeding. Because these exhibits aid in determining what weight we should give to his testimony, we deny Patent Owner's Motion to Exclude with respect to Exhibits 1059 and 1064.

4. Exhibits 1060, 1061, and 1065

Exhibits 1060, 1061, and 1065 are, respectively, an excerpt of Petitioner's Reply to Patent Owner's Response in IPR2013-00206, an excerpt of an expert report regarding damages in related litigation, and a

declaration by Matthew Link in support of a motion for preliminary injunction in related litigation. Patent Owner argues that these exhibits should be excluded under Rules 106 and 401–403 of the FRE because they are "more likely to cause confusion and unreasonable prejudice than add probative value." Mot. Excl. 4.

In particular, Patent Owner argues that Exhibits 1060, 1061, and 1065 are incomplete documents from other proceedings, omit other information that should be considered, and are irrelevant to this proceeding. *Id.* at 4–5. Patent Owner also argues that, because these exhibits are excerpts, they are confusing and fail to provide context. *Id.* For Exhibits 1061 and 1065, Petitioner responds that they "were offered to rebut Patent Owner's evidence of secondary indicia of non-obviousness." Opp. 6. For Exhibit 1060, Petitioner does not provide a specific response. *See id.* at 6–7 (arguments under the heading "Exhibits 1059–1061, 1064, and 1065"). Patent Owner does not provide a reply specific to these exhibits. *See* Mot. Reply 5.

For the reasons discussed below, we do not reach Patent Owner's asserted objective indicia for nonobviousness and we therefore have not considered this evidence. Therefore, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibits 1061 and 1065.

As for Exhibit 1060, Patent Owner also argues that this exhibit should be excluded under Rules 401 and 402 of FRE because it is not cited in the brief. Mot. Excl. 7. Because we do not rely on Exhibit 1060 in this decision, we deny Patent Owner's Motion to Exclude with respect to Exhibit 1060 as moot.

5. Exhibit 1062

Exhibit 1062 is an order regarding a motion to dismiss counts in related litigation. Patent Owner argues that Exhibits 1060 and 1062 should be excluded under Rules 401 and 402 of the FRE. Mot. Excl. 7. Patent Owner contends that the exhibits were filed with Petitioner's Reply but were not cited and are, thus, not relevant to the proceeding. *Id.* Petitioner does not respond to these arguments. *See generally* Opp.

Because Petitioner does not point to where in the record Exhibit 1062 is cited to support an argument, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibit 1062.

III. CONCLUSION

Petitioner has not shown by a preponderance of the evidence that claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent have not been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied;

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.

In summary:

Claims	35 U.S.C. §	References/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 5, 9, 10, 12–21, 23, 24, 27	103	Brantigan, Baccelli, Berry		1–3, 5, 9, 10, 12–21, 23, 24, 27
9	103	Brantigan, Baccelli, Berry, Michelson '973		9
Overall Outcome				1–3, 5, 9, 10, 12–21, 23, 24, 27

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