Trials@uspto.gov
571-272-7822

Paper 58
Date: July 8, 2020

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.

IPR2019-00546
Patent 8,187,334 B2

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

JUNG, *Administrative Patent Judge*.

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

I. INTRODUCTION

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

A. Background and Summary

Alphatec Holdings, Inc., and Alphatec Spine, Inc., (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claim 16 of U.S. Patent No. 8,187,334 B2 (Ex. 1001, "the '334 patent"). NuVasive Inc. ("Patent Owner") filed a Preliminary Response. Paper 10. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '334 patent. Paper 17 ("Dec. to Inst."). In particular, we instituted review of claim 16 on all presented challenges. Dec. to Inst. 2, 26, 33, 35.

After institution, Patent Owner filed a Response (Paper 27, "PO Resp."), to which Petitioner filed a Reply (Paper 35, "Pet. Reply"). Patent Owner thereafter filed a Sur-Reply (Paper 41, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 39, "Mot."), and Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 45, "Opp."), to which Patent Owner filed a Reply (Paper 49, "Mot. Reply"). In an Order (Paper 38), we authorized Patent Owner to file a Supplemental Sur-Reply, which was filed (Paper 42) and Petitioner to file a Supplemental Sur-Sur-Reply, which was also filed (Paper 43). An oral hearing in this proceeding was held on April 3, 2020; a transcript of the hearing is included in the record (Paper 55, "Tr."). *See also* Exs. 1066, 2062 (parties' errata sheets for the transcript).

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claim 16 of the '334 patent is unpatentable. We also deny Patent Owner's Motion to Exclude.

B. Real Parties in Interest

Petitioner states that "Alphatec Holdings, Inc. and Alphatec Spine, Inc. are the real-parties-in-interest for purposes of this proceeding." Pet. 70. "In accordance with 37 C.F.R. § 42.8(b)(1), Patent Owner identifies NuVasive, Inc. as the real party-in-interest." Paper 4, 2.

C. Related Matters

The parties indicate that the '334 patent has been asserted in *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.) and *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-002738-CAB-MDD (S.D. Cal.). Pet. 70; Paper 4, 2. The parties also indicate that the '334 patent is the subject of IPR2019-00361. Pet. 70; Paper 4, 2.

Patent Owner additionally notes that the '334 patent was previously challenged in Cases IPR2013-00507 and IPR2013-00508. Paper 4, 2 (citing *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016)); *see also* Pet. 1 (stating that "the Federal Circuit affirmed the Board's finding in IPR2013-00507 (Ex. 1004) that sole independent claim 1 of the '334 patent and eighteen dependent claims (2–5, 10, 11, 14, 15, and 19–28) are invalid"). A related patent, U.S. Patent No. 8,361,156 B2, is challenged in IPR2019-00362. Pet. 70; Paper 4, 2.

D. The '334 Patent (Ex. 1001)

The '334 patent issued May 29, 2012, from an application filed 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), 1:7–13.

The '334 patent particularly 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 1:18–21. Figure 2 of the '334 patent is reproduced below.

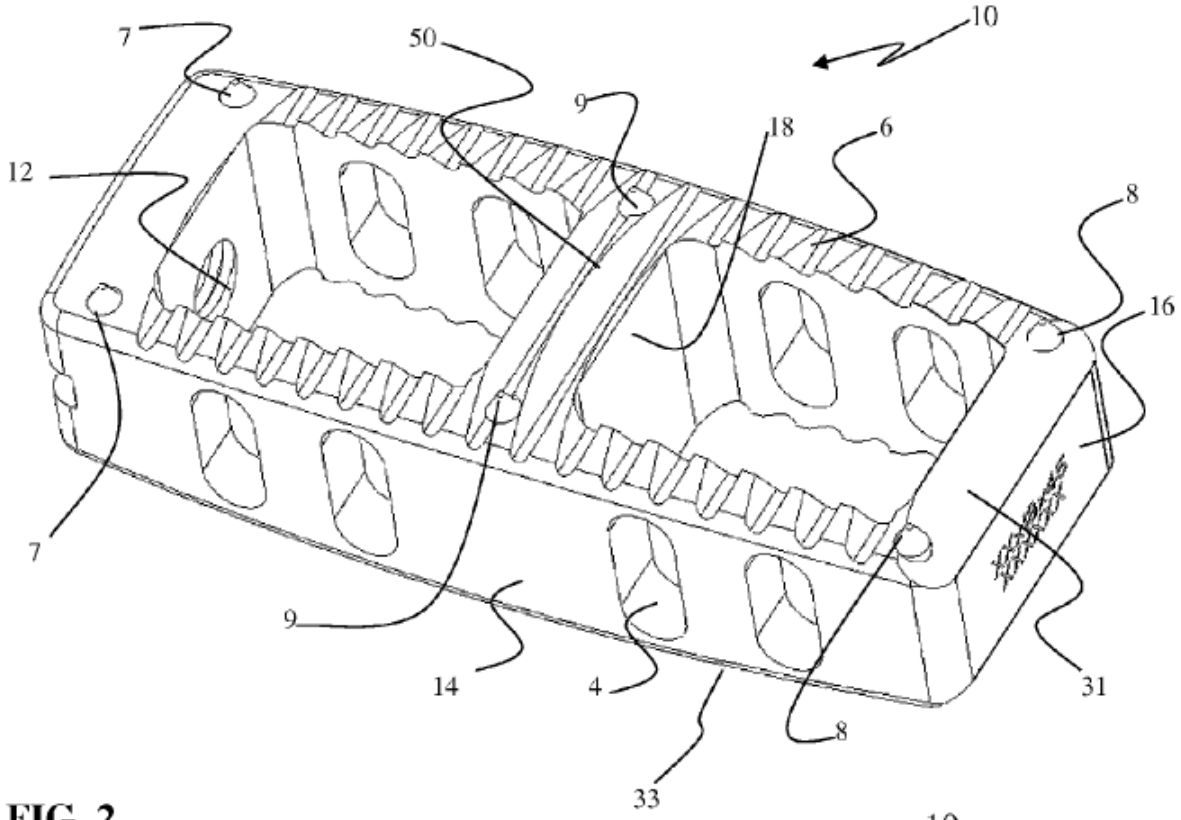


FIG. 2 10

Figure 2 shows a perspective view of a lumbar fusion implant. *Id.* at 3:36. The spinal fusion implant is introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach, and is made from a radiolucent material, such as PEEK (poly-ether-ether-ketone). *Id.* at 5:10–15, 5:29–33.

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

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

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

E. Sole Challenged Claim

The '334 patent has 28 claims, and claims 1–5, 10, 11, 14, 15, and 19–28 were cancelled in IPR2013-00507. Ex. 1001, 34. Petitioner challenges claim 16, which depends from cancelled claim 1. Claims 1 and 16 are 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, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;
>
> wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;
>
> wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion

of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times 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 three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

16. The spinal fusion implant of claim 1, further comprising a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker.

Ex. 1001, 12:32–13:4, 13:51–14:3.

F. Asserted Prior Art and Proffered Testimonial Evidence

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

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

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

(3) U.S. Patent Application Publication No. US 2002/0165550 A1, published November 7, 2002 (Ex. 1040, "Frey");

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

(5) James L. Berry et al., *A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae*, 12 Spine 362–367 (1987) (Ex. 1022, "Berry").

In support of its challenges, Petitioner provides a Declaration of Charles L. Branch, Jr., M.D. (Ex. 1002). *See* Pet. 22, 26–70. Patent Owner proffers a Declaration of Jim A. Youssef, M.D. (Ex. 2055), Declaration of Carl R. McMillan, Ph.D. (Ex. 2057), and Declaration of Matthew Link (Ex. 2059). Deposition transcripts for Dr. Branch (Ex. 2022), Dr. Youssef (Ex. 1050), Dr. McMillan (Ex. 1051), and Mr. Link (Ex. 1052) were filed.

G. Asserted Grounds

Petitioner asserts that claim 16 would have been unpatentable on the following grounds:

Claim Challenged	35 U.S.C. §[1]	References/Basis
16	103	Frey, Michelson, Baccelli
16	103	Brantigan, Baccelli, Berry, Michelson

Pet. 22, 26–70.

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the '334 patent issued was a continuation of an application filed before that date and claims the benefit of a filing date of provisional application also filed before that date, our citations to Title 35 are to its pre-AIA version. *See* Ex. 1001, codes (60), (63), 1:7–12.

II. ANALYSIS

A. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Exhibits 1041, 1042, 1053–1056, 1059–1062, 1064, and 1065. Mot. 1, 5–8 (discussing Ex. 1064 along with other exhibits). Patent Owner indicates that objections to these exhibits were previously filed. *Id.* at 1 (citing Papers 23, 36). 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 1041 and 1042

Exhibits 1041 and 1042 are declarations by Richard Hynes, M.D. filed in IPR2013-00507 and IPR2013-00508, respectively. Patent Owner argues that these exhibits should be excluded as irrelevant under Rules 401 and 402 of Federal Rules of Evidence ("FRE"). Mot. 2.

Patent Owner contends that "Petitioner relies on these exhibits solely to support the assertion that it is presenting a materially different theory compared to what was presented in these earlier proceedings." *Id.* at 1 (citing Pet. 25–26). Patent Owner agrees that a different theory has been presented and argues that the agreement "should be considered a stipulated fact," so that Exhibits 1041 and 1042 should be excluded. *Id.* at 2.

Petitioner responds that Exhibits 1041 and 1042 demonstrate that claim 18 is unpatentable based on a combination of references not previously presented in IPR2013-00507 and IPR2013-00508 and are relevant to § 325(d) issues. Opp. 1. Patent Owner replies that Petitioner's assertions undermines its collateral estoppel arguments and states that "[t]o the extent the materially different nature of Petitioner's current Petition and the prior IPRs is deemed an admission of fact, these exhibits should be excluded." Mot. Reply 1.

Patent Owner's basis for moving to exclude Exhibits 1041 and 1042 is that they support Petitioner's contention, and Patent Owner agrees with that contention. The mere fact that an exhibit supports the parties' agreement does not demonstrate a reason to exclude it from the record.

Accordingly, we deny Patent Owner's Motion to Exclude with respect to Exhibits 1041 and 1042.

2. Exhibits 1053 and 1054

Exhibit 1053 is U.S. Patent No. 6,241,770 B1 to Michelson, 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 as irrelevant to a ground of review, likely to cause confusion, and prejudicial. Mot. 2–5.

In particular, Patent Owner contends that "Petitioner cites these exhibits in support of a *prima facie* case of obviousness raised for the first time in Petitioner's Reply" and to fill a gap identified in the Patent Owner Response. *Id.* at 2–4 (citing Pet. 4–5, 30, 45, 47–48; PO Resp. 20–23; Pet. Reply 10). Petitioner responds that Exhibits 1053 and 1054 are proper rebuttal evidence. Opp. 2. Petitioner also identifies which of Patent Owner's arguments that the exhibits rebut and how they respond to those arguments. *Id.* at 2–4 (citing PO Resp. 9, 30; Pet. Reply 2–4, 10, 15–16). Patent Owner replies that "Petitioner does not contest that it could have presented them 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 2. Patent Owner reiterates its arguments that Exhibits 1053 and 1054 support a new rationale for combining the references. *Id.* at 2–4 (citing

Pet. 4–5, 31–32, 41–42; Opp. 3–4). Patent Owner also argues that these exhibits fail to support the theory presented in the Petition. *Id.* at 4 (citing Pet. 30; Opp. 3–4).

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, but rather should have been filed as a motion to strike because they seek to exclude belatedly presented evidence that Patent Owner contends exceeds the proper scope of reply. In any event, because the dispute has been presented (*see* Papers 38, 42, 43), and the exhibits at issue support a proper rebuttal argument, we deny Patent Owner's Motion to Exclude with respect to Exhibits 1053 and 1054.

3. 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. Patent Owner argues that Exhibit 1055 should be excluded under Rules 401–403 because it is cited in Petitioner's Reply with no substantive discussion and no explanation of its significance. Mot. 5.

Exhibit 1056 is an excerpt from a transcript in related litigation. The excerpt contains Dr. Brantigan's direct testimony regarding implants. *See* Ex. 1056, 2–9. Patent Owner argues that Exhibit 1056 should be excluded under Rules 106 and 401–403 because it is "more likely to cause confusion and unreasonable prejudice than add probative value." Mot. 5. 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 5–6. Patent Owner also argues that,

because Exhibit 1056 is an excerpt, it is confusing and fails to provide context. *Id.* at 6.

Petitioner responds that Exhibits 1055 and 1056 were offered to rebut Dr. Youssef's testimony. Opp. 6. Petitioner argues that the exhibits are, thus, relevant and their relevance outweighs any risk of confusion. *Id.* 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.* (citing Ex. 2029; Ex. 2030; Ex. 2060, 27–29, 51).

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 5 (citing Opp. 6). 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.* (citing Mot. 5–8; Opp. 6).

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. Pet. Reply 4–5. Some of Patent Owner's arguments are again not properly the subject of a motion to exclude based on inadmissibility because they seek to exclude belatedly presented evidence that Patent Owner contends exceeds the proper scope of reply. In any event, 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 are properly presented as rebuttal evidence to aid in determining what weight we should afford to 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 credence 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.

4. Exhibits 1059 and 1064

Exhibit 1059 is an excerpt from a transcript of the deposition 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 because they are "more likely to cause confusion and unreasonable prejudice than add probative value." Mot. 5.

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 5–6. 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 likely to cause undue prejudice. *Id.* at 6, 8; *see also id.* at 6–7 (arguing that Dr. Branch has also provided consulting services). Petitioner responds that they were offered "to demonstrate the bias associated with Dr. Youssef's opinions." Opp. 7–8. Petitioner also describes Dr. Branch's consulting arrangement with Medtronic and other companies. *Id.* at 8.

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. 6–7; Opp. 8). 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.

5. 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 Mr. 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. 5. As discussed below, Patent Owner also argues that Exhibit 1060 should be excluded under Rules 401 and 402 for other reasons. *See id.* at 8.

In particular, Patent Owner argues that Exhibits 1060, 1061, and 1065 are incomplete documents from other proceedings, omits other information that should be considered, and are irrelevant to this proceeding. *Id.* at 5–6. Patent Owner also argues that, because these exhibits are excerpts, they are confusing and fail to provide context. *Id.* at 6. For Exhibits 1061 and 1065, Petitioner responds that they "were offered to rebut Patent Owner's evidence of secondary indicia of non-obviousness." Opp. 7. For Exhibit 1060, Petitioner does not provide a response. *See id.* at 7–8 (arguments under the

heading "Exhibits 1059–1061, 1064–1065"). Patent Owner does not provide a reply specific to these exhibits. *See* Mot. Reply 5.

Because we do not rely on Exhibit 1060, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibit 1060. For the reasons discussed below, we do not reach Patent Owner's asserted objective indicia for nonobviousness and do not consider evidence thereof. Therefore, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibits 1061 and 1065.

6. Exhibits 1060 and 1062

Exhibits 1060 is an excerpt of Petitioner's Reply to Patent Owner's Response in IPR2013-00206, and Exhibit 1062 is an order regarding a motion to dismiss counts in related litigation. Patent Owner argues that these exhibits should be excluded under Rules 401 and 402. Mot. 8. 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 we do not rely on Exhibits 1060 and 1062 in our analysis, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibits 1060 and 1062.

B. Legal Standards

In an *inter partes* review, Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

As discussed below, the parties' disputes are related to each of the above-listed underlying factual determinations. After reviewing the complete record, we conclude that Petitioner has not shown by a preponderance of the evidence that one of ordinary skill in the art would have combined the asserted references in the manner asserted by Petitioner.

C. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "would have a medical degree with two or 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). In our Decision to Institute, we preliminarily adopted Petitioner's unopposed proposal. Dec. to Inst. 13.

Patent Owner responds that Petitioner "fails to view the art through the knowledge of a [person of ordinary skill in the art] at the time" because, as an example, the person of ordinary skill in the art "would not be familiar

with developments in the art that came after the relevant time, such as XLIF." [2] PO Resp. 9 (citing Ex. 2055 ¶¶ 28–29). However, Patent Owner does not dispute Petitioner's asserted qualifications for one of ordinary skill in the art and applies those qualifications. *See* Tr. 27:19–28:9.

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

Based on the full record before us, we see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Patent Owner does not expressly provide its own definition of a level of ordinary skill in the art. *See* PO Resp. 9. Patent Owner also applies Petitioner's asserted qualifications for one of ordinary skill in the art. *See* Tr. 27:19–28:9. Accordingly, we maintain and reaffirm that one of ordinary skill in the art "'would have a medical degree with two or 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.'" Dec. to Inst. 13 (citing Pet. 28; Ex. 1002 ¶ 18). This level

[2] Mr. Link indicates that XLIF is an abbreviation for "eXtreme Lateral Interbody Fusion." Ex. 2059 ¶ 3. Patent Owner also describes XLIF is an "XLIF product line, including CoRoent® XL implants" and "a minimally invasive surgical approach to spinal fusion surgery that . . . accesses the disc space from the lateral aspect of the patient." PO Resp. 66 (citing Ex. 2059 ¶¶ 4–8).

of skill in the art is consistent with the disclosure of the '334 patent and the prior art of record. Also, our analysis below does not hinge on whether one of ordinary skill in the art would have been familiar with XLIF technology or developments in the art that come after the relevant time.

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 inventor on patents related to spine implants and fixations systems. Ex. 2055 ¶¶ 1–12. 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.

D. Claim Construction

On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This rule change applies to petitions filed on or after November 13, 2018, so the revised claim construction standard applies to this proceeding. *Id.*; *see* Pet. 26 (stating that the "Board applies 'the standard used in federal courts . . . '" (quoting 83 Fed. Reg. at 51343)); Paper 3, 1 (according filing date of January 10, 2019 to the Petition).

Petitioner states that "no express construction is needed to resolve the issues in this Petition." Pet. 26. In our Decision to Institute, we stated that "[w]e interpret 'longitudinal length' and 'longitudinal aperture length' consistent with the claim language, and further express interpretation is not required for purposes of this Decision." Dec. to Inst. 12. We also determined that no express interpretation of any claim term was required at that stage of the proceeding. *Id.* at 12–13.

Patent Owner proposes interpretations for "longitudinal length," "longitudinal aperture length," and "central region." PO Resp. 4–8. For the reasons discussed below, a preponderance of the evidence does not persuade us that one of ordinary skill in the art would have made Petitioner's proposed combination of Frey, Michelson, and Baccelli or Brantigan, Baccelli, Berry, and Michelson. Our determination does not depend on a particular interpretation for "longitudinal length," "longitudinal aperture length," and "central region."

Accordingly, we do not need to provide express claim interpretations for any claim term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

E. Ground Based on Frey, Michelson, and Baccelli

Petitioner argues that Frey and Michelson were previously determined to teach or suggest all the limitations of claim 1 and that Baccelli teaches or suggests the further limitations recited by dependent claim 16. Pet. 31, 32–38. Petitioner also argues that one of ordinary skill in the art would have been motivated to combine Frey as modified by Michelson with the further teachings of Baccelli. *Id.* at 29, 38.

Patent Owner responds the asserted references do not teach all the limitations of claims 1 and 16, Petitioner fails to provide a motivation to combine the references, and Petitioner fails to show collateral estoppel should be applied to the limitations of claim 1 incorporated in claim 16 by dependency. PO Resp. 19–25, 27–31, 34–55. Patent Owner also presents objective indicia of non-obviousness. *Id.* at 55–59.

For the reasons below, Petitioner does not persuade us by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to combine Frey as modified by Michelson with the teachings of Baccelli.

1. Scope and Content of the Asserted Prior Art

a) Frey (Ex. 1040)

Frey relates to "implants insertable in the spinal disc space," and specifically relates to "implants, methods and instruments for use in a

posterior lateral approach to the disc space, including a transforaminal approach." Ex. 1040 ¶ 2. Figure 55 of Frey is reproduced below.

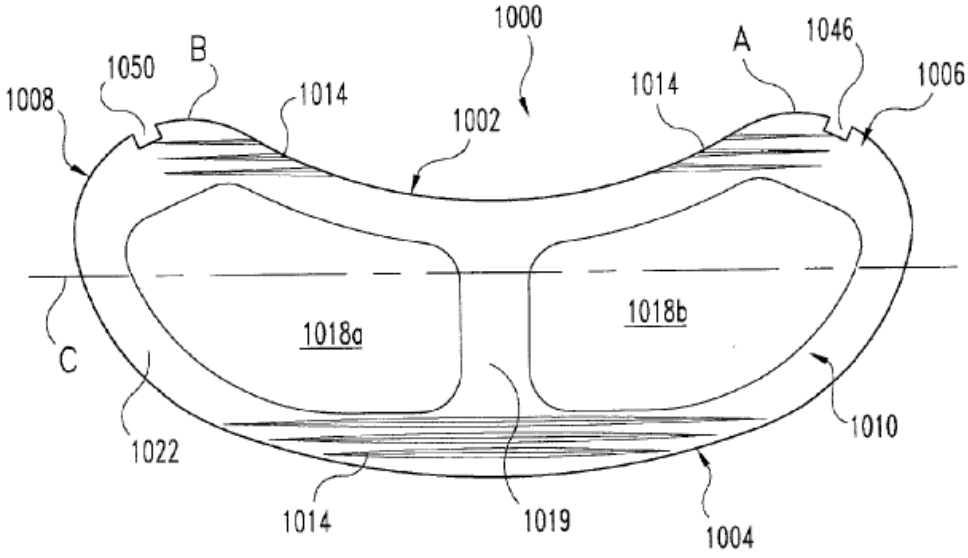


Fig. 55

Figure 55 is a plan view of an implant. *Id.* ¶¶ 66, 67. "Implant 1000 is an interbody fusion device or cage that can be packed with bone growth material or other known substance and inserted into disc space D1 to promote bony fusion between vertebrae V1 and V2." *Id.* ¶ 140. It has a "boomerang or banana shape." *Id.*

Implant 1000 also "includes a concave posterior wall 1002 and an opposite convex anterior wall 1004," "an arcuate leading end wall 1006 and an arcuate trailing end wall 1008" that "connect posterior wall 1002 and anterior wall 1004," and grooves 1014, 1016 that "engage the vertebral endplates to resist posterior and anterior migration of implant 1000 in the disc space." *Id.* ¶¶ 141, 143. Implant 1000 has "upper openings 1018*a* and 1018*b* separated by an upper strut 1019." *Id.* ¶ 144. "Implant 1000 can be made from titanium, surgical grade stainless steel, or other bio-compatible

material using fabricating techniques known in the art," such as PEEK. *Id.* ¶¶ 149, 181.

A dual lobe implant such as implant 1000, "is placed in the disc space D1 and has a length sufficient to span the disc space from the distal portion 37 to the proximal portion 41." *Id.* ¶ 130. Figure 63 of Frey is reproduced below.

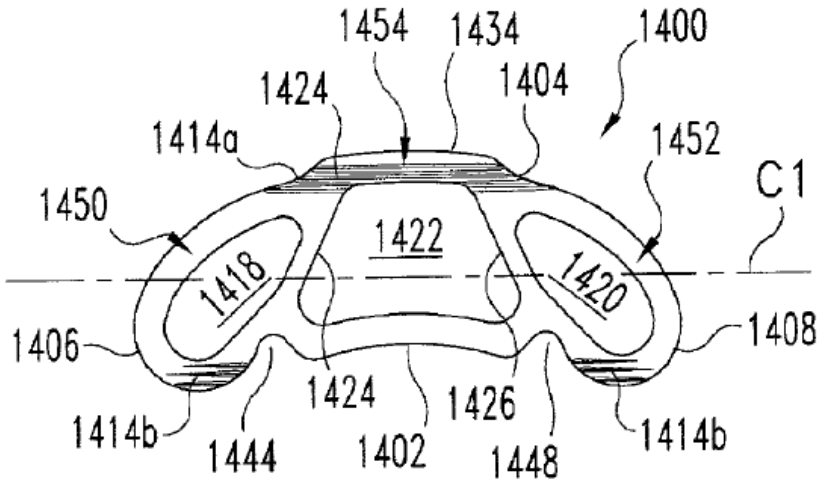


Fig. 63

Figure 63 is a plan view of another embodiment of an implant. *Id.* ¶¶ 71, 75. "Implant 1400 is an interbody fusion device or cage that can be packed with bone growth material or other known substance and inserted into disc space D1 to promote bony fusion between adjacent vertebrae V1 and V2." *Id.* ¶ 150. "Implant 1400 includes a body having a leading end portion 1450, a trailing end portion 1452, and a middle portion 1454 therebetween." *Id.* ¶ 151.

"In order to provide avenues for bone growth through implant 1400, . . . leading end portion 1450 includes first chamber 1418 and trailing end portion 1452 includes second chamber 1420." *Id.* ¶ 154. "Middle portion 1454 includes a middle chamber 1422." *Id.*

"A first strut 1424 is located between first chamber 1418 and third chamber 1422 and extends between posterior wall 1402 and anterior wall 1404," and a "second strut 1426 is located between second chamber 1420 and third chamber 1422 and extends between posterior wall 1402 and anterior wall 1404." *Id.*

Also, "[a] number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body," and "[s]uch markers are particularly useful for an implant 1400 made from radiolucent material." *Id.* ¶ 156. Frey describes that "markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434" and "at the posterior-most points of trailing end wall 1408 and leading end wall 1406." *Id.* "Positioning markers 1438 at these locations provides an indication of the anterior and posterior placement of implant 1400 in the disc space, and also an indication of the lateral placement of implant 1400 in the disc space." Frey also states that "[a]lignment of the end wall markers 1438 in a lateral X-ray indicates proper orientation of implant 1400 in the disc space in the A-P direction." *Id.*

b) Michelson (Ex. 1032)

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

Figures 18 and 19 of Michelson are reproduced below.

FIG. 18

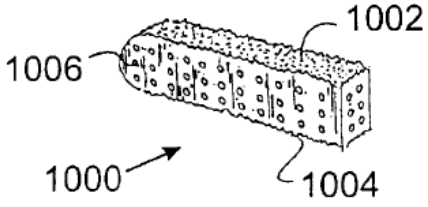


FIG. 19

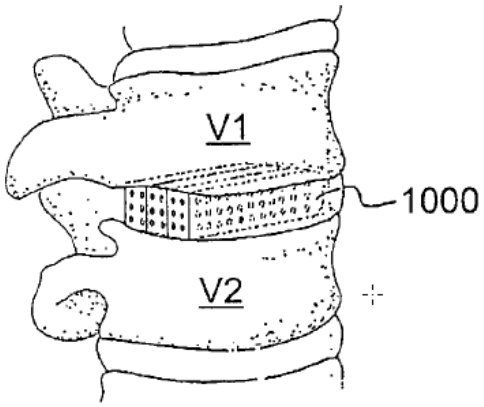


Figure 18 is a perspective side view of a spinal fusion implant, and Figure 19 is a perspective lateral anterior view of a segment of the spinal column with the implants shown in Figure 18 "inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the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

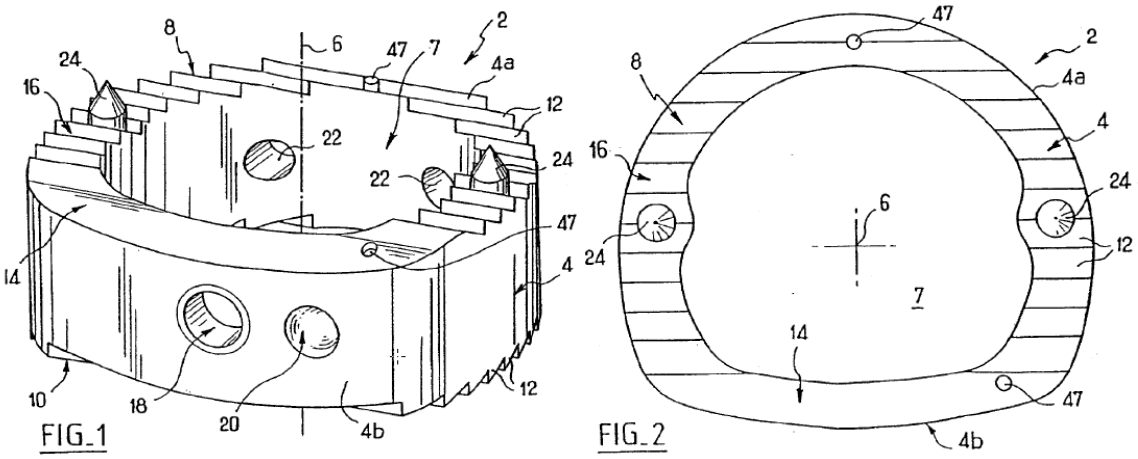
Michelson's implant "is dimensioned to fit within the disc space created by the removal of disc material between two adjacent vertebrae," "has a length that is substantially greater than the depth of the vertebrae and a width that approximates the depth of the vertebrae," "has more surface area of contact and thus permits greater stability," and "may be inserted into the disc space through a hollow tube." *Id.* at 3:34–40, 3:51–52. 3:61–63. The dimensions of the implant "permit[] a single implant to be inserted by a single procedure into the spine." *Id.* at 3:46–50.

Spinal implant 1000 "has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for

insertion within the disc space D between the adjacent vertebrae." *Id.* at 10:50–55. Spinal implant 1000 is an alternative embodiment of a preferred embodiment that has "a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." *Id.* at 10:42–47, Fig. 17. Michelson also claims an implant "having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae." *Id.* at 11:21–26.

c) Baccelli (Ex. 1008)

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



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

"The cage can be made of a material that is transparent to X-rays" and "can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or presence of the implant when X-rays are taken during or after the operation." *Id.* ¶ 50. "The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage." *Id.* ¶ 51. "They too can be made of a material that is opaque to X-rays." *Id.*

2. Claim 16

Claim 16 depends from claim 1 and recites "a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker." Ex. 1001, 13:51–14:3.

Petitioner relies on Baccelli for teaching the limitations of claim 16. Pet. 32–36 (citing Ex. 1002 ¶¶ 162–165; Ex. 1008 ¶¶ 36, 41, 44, 50, 51, Figs. 1–5, 8, 9). In particular, Petitioner argues that Baccelli's implant has four radiopaque markers, "one at least partially positioned in the distal wall, a second at least partially positioned in the proximal wall, a third at least partially positioned in the central region, and a fourth positioned in the central region at a position spaced apart from the third radiopaque marker." *Id.* at 32–33 (citing Ex. 1002 ¶¶ 162–164; Ex. 1008 ¶¶ 41, 50–51).

Petitioner also argues that one of ordinary skill in the art would have been motivated to combine Frey and Michelson, as the Board and the Federal Circuit concluded previously. Pet. 29 (citing Ex. 1002 ¶¶ 142–143, 147–149; Ex. 1005, 14–17). According to Petitioner, the combination of Frey and Michelson further modified by Baccelli would have rendered obvious claim 16. *Id.* at 38 (citing Ex. 1002 ¶ 168).

In particular, Petitioner contends that "Frey describes a number of radiopaque markers in an implant." *Id.* at 36 (citing Ex. 1040 ¶ 156).

Petitioner also argues that Frey teaches the use of radiographic markers in implants, does not limit the number of markers included in an implant, and teaches that alignment of markers indicates proper orientation of an implant. *Id.* at 29 (citing Ex. 1002 ¶ 161; Ex. 1040 ¶ 156). Petitioner, thus, argues that "it would have been obvious . . . to add a fourth radiopaque marker, like Baccelli teaches, to the Frey implant to give surgeons additional information," such as "proper orientation of the implant in the disc space in the saggital plane that bisects the patient into left and right through the spinous process." *Id.* at 36–37 (citing Ex. 1002 ¶ 161). Petitioner also argues that a fourth radiopaque marker would allow surgeons to determine the position of the implant from anterior-to-posterior and lateral X-rays. *Id.* at 37 (citing Ex. 1002 ¶ 166).

Petitioner further relies on Baccelli for teaching the placement of markers in the distal wall, proximal wall, and central region of a radiolucent spinal fusion implant. *Id.* at 30 (citing Ex. 1008, Figs. 1–5, 8, 9). Petitioner, thus, contends that one of ordinary skill in the art "would have been motivated to include radiopaque markers in all four walls of the radiolucent Frey lateral implant to enable surgeons to visualize orientation and location of the implant during and after surgery." *Id.* (citing Ex. 1002 ¶¶ 161, 166; Ex. 1040, Figs. 55, 59).

Petitioner also argues that it would have been obvious "to position markers in the middle (*e.g.*, the midline of the anterior wall and the midline of the posterior wall) of Frey's sidewalls, as well as in the leading and trailing ends of the implant" because such positioning "allow[s] surgeons to align the markers with the spinous process and the lateral ends of the vertebrae" and the alignment of markers in the sidewalls "indicates proper orientation of the implant in the disc space in the saggital plane . . . ." *Id.* at

30–31 (citing Ex. 1002 ¶ 161). Petitioner further argues that combining Frey, Michelson, and Baccelli "amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." *Id.* at 31 (citing Ex. 1002 ¶¶ 143–144, 148–150).

a) Patent Owner's Response

Patent Owner responds that the "Federal Circuit expressly acknowledged that motivation to combine length and width dimensions from different references was not considered and was not necessary to the judgment in IPR2013-00507." PO Resp. 27 (citing Pet. 29; Ex. 1005, 14–17). Patent Owner also argues that any previous motivation to combine "would not [be] applicable to the different obviousness theories advanced here." *Id.* at 27–28 (citing Pet. 26).

Patent Owner also responds that (1) Petitioner misapprehends the teachings of Baccelli (*id.* at 28 (citing Ex. 1008 ¶ 41)); (2) Petitioner does not provide a reason to import the proposed marker configuration into Frey (*id.*); and (3) the asserted motivation is conclusory, nonsensical, and was rejected by the Federal Circuit as impermissible hindsight (*id.* at 28–31 (citing Pet. 29, 31; Ex. 1002 ¶ 161; Ex. 2017, 7:9–8:13; Ex. 2022, 124:14–125:13; Ex. 2028 ¶ 60; Ex. 2055 ¶¶ 104–123)). In particular, Patent Owner argues that Petitioner "fails to explain how adding an additional marker would enable locating the implant when Frey teaches that the existing positioning of the markers already provides an indication of A-P and lateral placement as well as implant orientation," "the proposed modification would not assist the surgeon in locating the implant," and the proposed modification "would undermine the stated motivation." *Id.* at 29 (citing Ex. 2055 ¶¶ 114–123).

According to Patent Owner, "the proposed modification would only decrease the surgeon's ability to confirm the implant was properly oriented" because a fourth radiopaque marker would result in ambiguous X-ray images. *Id.* at 29 (citing Ex. 2022, 124:14–125:13; Ex. 2055 ¶¶ 121–123). Patent Owner contends that, on a lateral X-ray, the proposed fourth marker in addition to two markers 1438 positioned at the posterior-most points of walls 1406, 1408 would result in two images of markers near the posterior edge of the implant. *Id.* at 30 (citing Ex. 2055 ¶¶ 121–123). The two images of markers can mean either proper placement because the X-ray would show the fourth marker separated from markers 1438 or improper alignment because the X-ray would show the fourth marker and one of markers 1438 separated from the other marker 1438. *Id.* at 30 (citing Ex. 2055 ¶¶ 121–123).

b) Parties' Reply Arguments

Petitioner replies that it "does not rely on Baccelli for the 'central region' limitation" and "relies on the orientation disclosed in Baccelli of four radiopaque markers." Pet. Reply 9 (citing PO Resp. 19–22). Petitioner also argues that Patent Owner "read[s] the prior art in i[]solation disconnected from the relevant state-of-art." *Id.* (citing PO Resp. 29–30).

Patent Owner replies that "Petitioner admits that the theory of unpatentability is different here that in IPR2013-00507." PO Sur-reply 11 (citing Pet. 26, 29; PO Resp. 27–28; Pet. Reply 7). Patent Owner also argues that Petitioner abandons the marker positioning of Baccelli, "offers no meaningful response," and relies on a "mischaracterization of Baccelli as teaching placing two radiopaque markers in the claimed central region." *Id.* at 15–17 (citing Pet. 30–31, 34–35, 40; PO Resp. 18–23, 28–31; Pet. Reply 10; Ex. 1002 ¶¶ 29–30; Ex. 1008 ¶ 41, Figs. 1, 5; Ex. 2017, 7:9–8:13;

Ex. 2028 ¶ 60). According to Patent Owner, Petitioner pivots to a new reference. *Id.* at 17–18 (citing Pet. Reply 2–3; Ex. 1054, 3)

c) Insufficient Reason to Combine the References

Petitioner relies on Frey for describing "a number of radiopaque markers in an implant." Pet. 36 (citing Ex. 1040 ¶ 156). Specifically, Petitioner contends that Frey teaches markers 1438, their positions in an implant, and how markers 1438 provide an indication of anterior and posterior placement, lateral placement, and proper orientation in the disc space. *Id.* (citing Ex. 1040 ¶ 156).

We find that paragraph 156 of Frey teaches that a "number of radiographic markers 1438 can be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in a patient's body," and that "markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434" and "at the posterior-most points of trailing end wall 1408 and leading end wall 1406." Ex. 1040 ¶ 156. We also find that "[p]ositioning markers 1438 at these locations provides an indication of the anterior and posterior placement of implant 1400 in the disc space, and also an indication of the lateral placement of implant 1400 in the disc space." *Id.* According to Frey, "[a]lignment of the end wall markers 1438 in a lateral X-ray indicates proper orientation of implant 1400 in the disc space in the A-P direction." *Id.*

The parties' declarants agree as to what Frey teaches in paragraph 156, and we credit their testimony because the record supports it. Ex. 1002 ¶ 161; Ex. 1040 ¶ 156; Ex. 2055 ¶¶ 119, 120. We, thus, find that Frey teaches that its placement of markers 1438 in implant 1400 provides, in a lateral X-ray, indications of "the anterior and posterior placement of implant 1400 in the disc space," "the lateral placement of implant 1400 in the disc

space," and "proper orientation of implant 1400 in the disc space in the A-P direction." Ex. 1002 ¶ 161; Ex. 1040 ¶ 156; Ex. 2055 ¶¶ 119, 120.

According to Petitioner, one of ordinary skill in the art would have been motivated to add a fourth radiopaque marker to Frey's implant "to enable surgeons to visualize the orientation and location of the implant during and after surgery," "to allow surgeons to align the markers with the spinous process and the lateral ends of the vertebrae," and "to give surgeons additional information." Pet. 30–31 (citing Ex. 1002 ¶¶ 161, 166; Ex. 1040, Figs. 55, 59), 31 (citing Ex. 1002 ¶ 161), 36 (citing Ex. 1002 ¶ 161). Petitioner argues that the fourth radiopaque marker would provide, for example, "proper orientation of the implant in the disc space in the sagittal plane that bisects the patient into left and right through the spinous process" (*id.* at 31 (citing Ex. 1002 ¶ 161)) and "alignment of markers at the midline of both the anterior and posterior walls in an anterior X-ray indicates proper orientation of the implant in the disc space in the sagittal plane that bisects the patient into left and right through the spinous process" (*id.* at 36–37 (citing Ex. 1002 ¶ 161)).

Petitioner cites paragraphs 161 and 166 of Dr. Branch's declaration for support. *See* Pet. 30, 31, 36–37. Dr. Branch opines that the

> addition of a fourth radiopaque marker—as described by Baccelli—would provide additional, valuable information to surgeons because, for example, alignment of markers at the midline of both the anterior and posterior walls in an anterior X-ray indicates proper orientation of the implant in the disc space in the sagittal plane that bisects the patient into left and right through the spinous process.

Ex. 1002 ¶ 161. Dr. Branch also opines that markers in the proximal, distal, and central region of Frey's implant would "assist a surgeon in locating the spinal fusion implant during and after surgery." *Id.* ¶ 166. Dr. Branch

testifies that "a total of four radiopaque markers in an implant would have allowed surgeons to see in an anterior-to-posterior (front) X-ray whether the implant is askew relative to the spinous process and the lateral edges of the vertebrae during and after lateral insertion" and that a

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

Id. Paragraphs 161 and 166 do not cite to any supporting evidence. Also, Dr. Branch confirms that the fourth radiopaque marker would be added at the "most concave portion of" implants 1000 and 1400. Ex. 2022, 124:14–125:13.

Patent Owner provides testimony from its declarant to argue that Petitioner presents an insufficient reason for modifying Frey in view of Baccelli. PO Resp. 29 (citing Ex. 2055 ¶¶ 114–123). Dr. Youssef testifies that "Frey explains that the placement of markers 1438 on the anterior- and posterior-most positions on the implant serve to identify anterior/posterior positioning and proper alignment in the disc space." Ex. 2055 ¶ 120 (citing Ex. 1040 ¶ 156). As discussed above, we find that Frey teaches placing markers 1438 provides in a lateral X-ray indications of anterior-to-posterior placement, lateral placement, and proper orientation of the implant in the disc space in the anterior-to-posterior direction. Ex. 1002 ¶ 161; Ex. 1040 ¶ 156; Ex. 2055 ¶¶ 119, 120.

Frey also supports Dr. Youssef's statement that "when positioned in the disc space, a lateral X-ray will show an image of the anterior marker and, if properly aligned, a single image for the two posterior markers." Ex. 2055

¶¶ 119, 120; Ex 1002 ¶ 161; Ex. 1040 ¶ 156. Reproduced below is an annotated Figure 63 of Frey from Dr. Youssef's declaration.

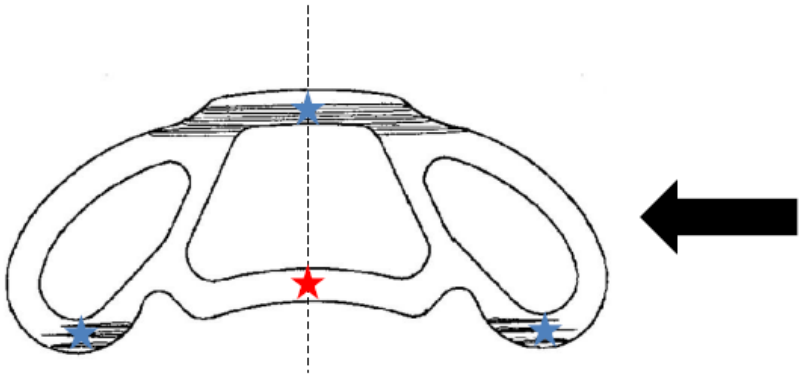


Figure 63 is a plan view of an embodiment of Frey's implant and has been annotated with blue stars representing the positions of markers 1438 and a red star representing Petitioner's proposed fourth marker. Ex. 1040 ¶¶ 71, 75; Ex. 2022, 124:14–125:13; Ex. 2055 ¶ 122. Dr. Youssef explains that "[o]n a lateral X-ray, as disclosed by Frey, the additional marker confuses interpretation of the implant position" because "[f]or example, two radiopaque signals on the posterior edge could mean either proper placement of the implant (alignment of both blue markers) or that the implant is not properly aligned (alignment of a red and blue marker)." Ex. 2055 ¶ 123. Dr. Youssef concludes that "[n]o other marker [other than those already disclosed in Frey] is necessary to determine proper placement of Frey." *Id.* ¶ 122.

Frey supports Dr. Youssef's testimony, and the parties do not dispute, that a lateral X-ray would show alignment of markers 1438 when Frey's implant is properly aligned in the disc space. Ex 1002 ¶ 161; Ex. 1040 ¶ 156; Ex. 2055 ¶¶ 119, 120. Frey also implicitly supports that a lateral X-ray would show markers 1438 not aligned with each other when Frey's implant is not properly aligned in the disc space. Ex. 1040 ¶ 156. There is

no dispute that the proposed fourth radiopaque marker would show in a lateral X-ray, and Petitioner does not address Patent Owner's argument that a fourth radiopaque marker would make a lateral X-ray ambiguous. *See* Pet. Reply 8–9 (arguing under "Motivation to combine" that other references teach a "central region" and Patent Owner reads the references in isolation). In view of the full record before us, we credit Dr. Youssef's testimony (Ex. 2055 ¶¶ 114–123) over Dr. Branch's testimony (Ex 1002 ¶¶ 161, 166) because Dr. Youssef's opinion is more consistent with the teachings of Frey. Ex. 1040 ¶ 156.

Petitioner also argues that combining Frey, Michelson, and Baccelli "amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." Pet. 31 (citing Ex. 1002 ¶¶ 143–144, 148–150). Even if we were to agree that Petitioner's proposed combination is a rearrangement of known mechanical elements, as discussed above, placing Petitioner's a fourth marker at the location that Petitioner proposes would result in an ambiguous lateral X-ray, and the record provides no other support that one of skill in the art would have made this rearrangement.

Accordingly, for the reasons above and based on the full record before us, we determine that Petitioner does not present a sufficient reason why one of ordinary skill in the art would have modified Frey in view of Michelson and Baccelli.

F. Ground Based on Brantigan, Baccelli, Berry, and Michelson

Petitioner argues that Brantigan, Baccelli, Berry, and Michelson teach or suggest the limitations of claims 1 and 16. Pet. 42–69. Petitioner also argues that one of ordinary skill in the art would have been motivated to combine these references. *Id.* at 38–42.

Patent Owner responds that the asserted references do not teach all the limitations of claims 1 and 16, and that Petitioner fails to provide a motivation to combine the references. PO Resp. 25–27, 31–34. Patent Owner also presents objective indicia of non-obviousness. *Id.* at 55–59.

For the reasons below, Petitioner does not persuade us by a preponderance of the evidence that the asserted reason for combining Brantigan, Baccelli, Berry, and Michelson has rational underpinnings, and, for separate reasons, that there is a motivation to combine the references.

1. Scope and Content of the Asserted Prior Art

Michelson (Ex. 1032) and Baccelli (Ex. 1008) are discussed above.

a) Brantigan (Ex. 1007)

Brantigan "relates to inert rigid vertebral prosthetic devices and methods for implanting the devices between adjacent vertebrae." Ex. 1007, 1:7–9. Brantigan specifically "deals with ring-like prosthetic plugs or discs used singly or stacked together between vertebrae to form support [struts] in the spinal column and having rigid surfaces facilitating anchoring and providing valleys for bone ingrowth from adjoining vertebrae." *Id.* at 1:14–15.

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" and "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. "Each of the oval implants is sized to match the height of an average disc and thus, can vary

from 10 to 15 mm for the lumbar area and from 7-11 mm for the cervical area." *Id.* at 2:20–23. Figure 1 of Brantigan is reproduced below.

FIG. 1

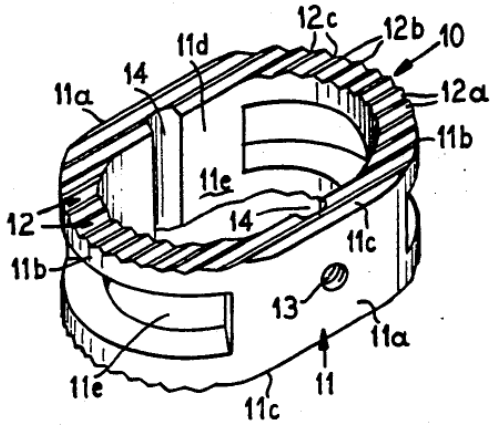


Figure 1 shows a perspective view of a full oval prosthetic device. *Id.* at 3:21–22. Oval ring plug 11 has opposed sides 11*a*, ends 11*b*, top and bottom surfaces 11*c*, and central upstanding aperture 11*d*.[3] *Id.* at 4:5–10. Top and bottom surfaces 11*c* have ridges 12 for engaging adjacent vertebrae. *Id.* at 4:15–16, 5:22–26; *see also id.* at 6:5–16 (describing stack of plugs 11 between vertebrae). One of side walls 11*a* has an internally threaded hole 13 for receiving a mounting tool, and interiors of side walls 11*a* have grooves 14 for mounting rectangular connecting bar 15. *Id.* at 4:20–27. Bar 15 separates central aperture 11*d* into two chambers that can be "packed with bone graft material to expedite the fusion of the prosthesis device in the spinal column." *Id.* at 4:50–53; *see also id.* at 2:15–19 (describing placement of bone graft material).

"The individual plugs or the stack of plugs can be introduced anteriorly, laterally or posteriorly depending upon conditions . . . ." *Id.* at

[3] Brantigan also describes "11*d*" as a central aperture (Ex. 1007, 4:13–14, 4:50) and a hollow interior (*id.* at 6:37). *See also id.*, Figs. 1, 11 (showing reference number 11).

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

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

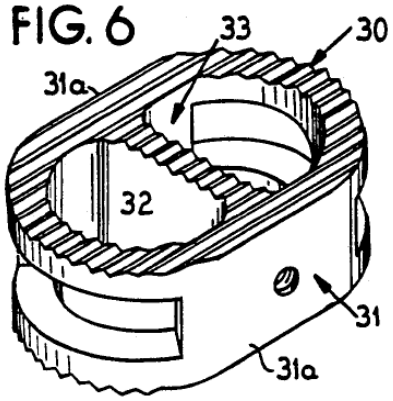


Figure 6 shows a perspective view of a modified device with an integral cross bar. *Id.* at 3:21–22, 3:36–37, Fig. 6. Modified device 30 is plug 31 with the same shape as plug 11 but has reinforcing bar 32 integral with side walls 31*a*. Integral internal partition 32[4] bisects hollow

[4] Brantigan describes element "32" as a cross bar, a reinforcing bar, and internal partition. *Id.* at 3:36–37, 5:37–43, Fig. 6.

interior 23[5] (not shown) forming "side-by-side apertures through the plug adapted to receive bone graft material." *Id.* at 5:37–43, Fig. 6.

b) Berry (Ex. 1022)

Berry presents "results of a morphometric study of selected human vertebrae undertaken to provide data for implant design." Ex. 1022, 362. 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.*

"With present and future applications in mind, virtually 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).

2. Claim 1

Petitioner does not assert that Patent Owner is estopped from arguing the patentability of claim 1 over the asserted combination of Brantigan, Baccelli, Berry, and Michelson. *See generally* Pet.; *see also id.* at 32 (arguing that "Patent Owner is therefore estopped from arguing that claim 1 renders any dependent claim patentable over *Frey and Michaelson* [sic.] as those references have been definitively established as rendering claim 1, among others, unpatentable") (emphasis added).

[5] Brantigan also describes element "23" as a tool receiving recess (*id.* at 5:1–2, 5:32–33).

For our analysis below, we need only address the limitation "wherein said longitudinal length is at least two and half times greater than said maximum lateral width" of claim 1, which is an element of claim 16 due to its dependency.

> *a) wherein said longitudinal length is at least two and half times greater than said maximum lateral width;*

Petitioner contends that Brantigan teaches substantially all the limitations of claim 1 with citations to Brantigan and Dr. Branch's declaration. Pet. 42–54, 57–60. Specifically, for "said longitudinal length is at least two and half times greater than said maximum lateral width," Petitioner argues that Brantigan teaches "an implant with a longitudinal length that is greater than 40 mm." *Id.* at 54 (citing Ex. 1002 ¶ 204; Ex. 1019, 6–9).

Petitioner turns to Michelson for "express[ly] teaching to make the implant 'narrower' so that they 'may be combined in a modular fashion for insertion within the disc space D between adjacent vertebrae.'" *Id.* at 54 (citing Ex. 1032, 10:50–55). Petitioner contends 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.* at 54–55 (citing Ex. 1032, 3:61–65; Ex. 1002 ¶ 221).

According to Petitioner, Michelson teaches that spinal fusion implant 900 "has 'a length in the range of 32 mm to 50 mm' and 'a width that approximates the depth of the vertebrae'" and that spinal fusion implant 1000 "is similar to the spinal fusion 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 between the adjacent vertebrae." *Id.* at 55–56 (citing Ex. 1032, 10:32–59, Figs. 18, 19). In

Petitioner's view, both Brantigan and Michelson teach modularity, both are directed to "laterally-inserted implants that are sized to span the full transverse width of the lumbar vertebra," and "Brantigan teaches modifying the width in the direction of insertion of a spinal fusion implant in the same way Michelson teaches." *Id.* at 55 (citing Ex. 1007, 1:18–21, 1:65–68, 2:2–11, 2:55–66, 4:5–8, 5:30–35; Ex. 1032, 3:1–10, 3:35–53, 10:50–55, claim 1).

Petitioner contends that Michelson expressly teaches preferred dimensions for spinal fusion implant 900 "but does not specify what region of the lumbar spine those dimensions pertain to." *Id.* at 56 (citing Ex. 1002 ¶ 225). Petitioner argues that "in modifying Brantigan in view of Michelson's long-and-narrow modular teaching for a fusion between L4 and L5, for example," one of ordinary skill in the art "would have referred to Berry" because Berry provides mean widths of human vertebrae that can be between 31.9 mm at L1 and 35.1 mm at L5. *Id.* at 56 (citing Ex. 1002 ¶¶ 176, 225, 226; Ex. 1022, 362–364, Table 1). Petitioner argues that, "[a]pplying the standard deviations reported in Berry," one of ordinary skill in the art "would have been motivated to modify Michelson's long-and-narrow implants to have widths ranging from 14.1 mm L1 to 18.95 mm for L5" and, thus when modifying Brantigan in view of Michelson, "to have widths ranging from 16.15 mm to 18.95 mm." *Id.* at 56–57 (citing Ex. 1002 ¶¶ 226, 227; Ex. 1022, 364, Table 1).

Petitioner, thus, asserts that one of ordinary skill in the art "would have been motivated to design an L5 spinal fusion implant that was 'approximately 18 mm wide'" and that, "[a]pplying the standard deviations of Berry, an implant for spinal fusion between L4 and L5 . . . would be at least 46.3 mm in longitudinal length, which is more than two and a half

times greater than approximately 18 mm in maximum lateral width." *Id.* at 57 (citing Ex. 1002 ¶ 227). Therefore, according to Petitioner, "Brantigan in view of Berry and Michelson further disclose[s] that the length is at least two and a half times greater than the maximum lateral width." *Id.* at 54 (citing Ex. 1002 ¶¶ 216–227).

Under "Motivation to Combine Brantigan with Baccelli, Berry, and Michelson" (*id.* at 38–42), Petitioner contends that Brantigan teaches implants that are introduced laterally with dimensions appropriate for the space between vertebrae. *Id.* at 38–39 (citing Ex. 1007, 1:20–21, 2:2–4, 4:3–4, 4:6–7, 5:30–35, Figs. 8, 10). Petitioner argues that one of ordinary skill in the art "would have known the average dimensions of the human vertebrae" from, for example, Berry. *Id.* at 39.

Petitioner also argues that "Michelson explains the benefits associated with lateral insertion of the Brantigan implant: increased safety, decreased patient discomfort, and increased structural support that an 'oversized' implant provides" and that Michelson teaches "these benefits can be accomplished by inserting the long-and-narrow implant of Figures 18–19 modularly, allowing a narrower implant to be inserted through a hollow tube, thereby decreasing patient surgical discomfort by reducing incision size." *Id.* at 40–41 (citing Ex. 1032, Abstract, 2:19–67, 3:56–4:24, 10:20–59, Figs. 18–19; Ex. 1002 ¶ 175). Petitioner further 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.* at 54–55 (citing Ex. 1002 ¶ 221; Ex. 1032, 3:61–65).

According to Petitioner, Michelson explains the benefits of lateral insertion achieved through inserting long-and-narrow implants. *Id.* at 40–41 (citing Ex. 1002 ¶ 175; Ex. 1032, Abstract, 2:19–67, 3:56–4:24, 10:20–59,

Figs. 18, 19). Petitioner thus contends that one of ordinary skill in the art would have been motivated to make Brantigan's implant narrower in view of Michelson's teachings and the dimensions taught by Berry. *Id.* at 41 (citing Ex. 1002 ¶ 176; Ex. 1022, 364; Ex. 1032, 3:61–65, 10:20–59, Figs. 18, 19).

Petitioner argues that one of ordinary skill in the art "would have been motivated to make Brantigan's laterally-inserted lumbar spinal fusion implants 'narrower' for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness." *Id.* at 41 (citing Ex. 1032, 3:61–65); *see also id.* at 54 (arguing that one of ordinary skill in the art "would have been motivated to modify the width of the Brantigan implant, which has 'medial-lateral and anterior-posterior dimensions in the same ratios as normal vertebral bodies' (Ex. 1007, 1:20–21) according to Michelson's express teaching to make the implant 'narrower' so that they 'may be combined in a modular fashion for insertion within the disc space D between adjacent vertebrae'") (citing also Ex. 1032, 10:50–55). Petitioner additionally contends that one of ordinary skill in the art would have had a reasonable expectation of success in modifying the references in the manner asserted. *Id.* at 41–42 (citing Ex. 1002 ¶ 177).

(1) Patent Owner's Response

Patent Owner responds that one of ordinary skill in the art would not have been motivated to combine Brantigan, Baccelli, Berry, and Michelson. PO Resp. 31–34. Specifically, Patent Owner argues that Petitioner's proposed modification "to make Brantigan bigger according to Berry" is "nonsensical" because "Brantigan did modify his implants according to Berry." *Id.* at 32 (citing Ex. 2029, 7; Ex. 2057 ¶¶ 15, 21–27).

Patent Owner also responds that Petitioner fails to explain how "mak[ing] Brantigan . . . modular according to Michelson" "would increase

patient safety or minimize invasiveness." *Id.* (citing Ex. 2055 ¶¶ 89–95). According to Patent Owner, "neither Michelson nor Brantigan disclose sequential insertion of modular members into the disc space but they instead teach assembly prior to insertion." *Id.* (citing Ex. 1007, Abstract, 1:18–21, 1:59–61, 2:2–11, 2:34–43, 3:25–31, 4:23–49, 5:18–21, Figs. 1, 3, 4; Ex. 1011, 8; Ex. 1032, 3:46–49, 10:50–53; Ex. 2055 ¶¶ 41–47, 55–64; Ex. 2057 ¶¶ 16, 37–48).

Patent Owner further responds that, because of the anti-migration elements of Brantigan, sequential insertion of the proposed modular Brantigan implants would have decreased safety and increased invasiveness. *Id.* at 32–34 (citing Ex. 1007, 5:22–26, 6:14–16, Fig. 1; Ex. 1032, 8:20–22; Ex. 1040 ¶¶ 116, 139, 140, Figs. 29, 53; Ex. 2022, 69:22–70:7, 70:15–24, 85:21–24, 97:10–98:24; Ex. 2055 ¶¶ 46–49, 124–132; Ex. 2057 ¶¶ 46–49). Patent Owner argues that the proposed modification to use two modular implants would be riskier, more invasive, and result in less stability. *Id.* at 34 (citing Ex. 2055 ¶ 129; Ex. 2057 ¶¶ 44–46). Patent Owner also argues that two implants would "make it more difficult to interpret radiopaque markers placed on the implants." *Id.* (citing Ex. 2055 ¶ 133).

(2) Petitioner's Reply

Petitioner replies that it did not argue that modular implants would be assembled within the disc space. Pet. Reply 1 (citing PO Resp. 12). Petitioner argues that it is undisputed that Brantigan and Michelson teach modular implants and "[n]one requires assembly." *Id.*; *see also id.* at 1–2 (citing Ex. 1054, 2, 5, 6, 9, Figs. 4–5) (asserting the use of "two parallel transverse interbody cages" was known), 4 (citing Ex. 1053, 2:20–37) (arguing that side-by-side implants were known).

Petitioner also replies that Michelson teaches a narrow implant consistent with the modularity of Brantigan and Michelson. *Id.* at 9 (citing Pet. 54–55; Ex. 1002 ¶¶ 204, 216–227; Ex. 1007, 1:20–21, 2:4–11; Ex. 1019, 6–9; Ex. 1032, 3:61–65, 10:50–55). Petitioner further replies that "Brantigan and Michelson are directed to implants that span the width of the lumbar vertebra" and one of ordinary skill in the art "would look to Berry to size Brantigan in view of Michelson." *Id.* at 9–10 (citing Pet. 55–57; Ex. 1022, 1–3).

(3) Patent Owner's Sur-Reply

Patent Owner replies that Petitioner fails to justify why one of ordinary skill in the art would make a modular implant or why modularity would increase safety and minimize invasiveness. PO Sur-reply 12 (citing Pet. 54–57). Patent Owner contends that neither Brantigan nor Michelson teach "sequential insertion of modular members" and argues that Patent Owner's evidence shows that one of ordinary skill in the art would have expected modular implants to decrease safety and increase invasiveness. *Id.* (citing PO Resp. 32–34; Ex. 2022, 69:22–70:24, 97:10–99:24; Ex. 2055, 41–49, 124–133; Ex. 2057, 15–16, 21–27, 37–49).

Patent Owner also replies that Petitioner does not address its argument that a "modular approach would make it more difficult to interpret radiopaque markers placed on the implants." *Id.* at 13. According to Patent Owner, Petitioner's declarant understood that Michelson teaches sequential insertion. *Id.* (citing Ex. 2022, 121:15–122:7). Patent Owner argues that "Petitioner provides no meaningful rebuttal and fails to substantiate that the proposed modification would increase safety and minimize invasiveness." *Id.* (citing PO Resp. 32–34).

Patent Owner further replies that Petitioner incorrectly and without support contends that Brantigan and Michelson teach modular implants. *Id.* at 13–14 (citing Pet. 11; PO Resp. 17–18). According to Patent Owner, the Petition argued that a person of ordinary skill in the art "would have been motivated to modify the full-oval Brantigan device (*i.e.*, plug 11 or 30) . . . not the hemi-oval device." *Id.* at 14 (citing Pet. 38–41). Patent Owner argues that "there is no dispute that Petitioner points to Michelson Figs. 18–19 and associated text as teaching a modular implant." *Id.* (citing Pet. 2–4, 14, 41, 54; PO Resp. 14–15). Patent Owner also argues that "[b]oth Michelson and Brantigan teach assembly of modular implants as NuVasive explained in detail in its response." *Id.* (citing PO Resp. 14–15, 17–18, 53; Ex. 1032, 10:53–54; Ex. 1051, 49:18–50:5; Ex. 2055 ¶¶ 59–62; Ex. 2057 ¶¶ 35–40).

Patent Owner further argues that it presented corroborating evidence that the Brantigan implants were sized to fit within the annulus fibrosis in the present and past proceedings. *Id.* at 14–15 (citing Pet. Reply 4; Ex. 1007; Ex. 1056; Ex. 2029, 8; Ex. 2060, 19:20–20:8, 23:12–18, 24:4–25:4, 26:21–27:3, 34:23–37:21, 40:8–23, 41:13–23, 47:15–22, 47:23–48:9, 49:10–15, 69:12–25; Ex. 2061). Patent Owner also contends that arguments relying improperly on Exhibits 1053 and 1054 "have nothing to do with the modularity of Michelson." *Id.* at 15 (citing Pet. Reply 1–4).

(4) Insufficient Reason for Modifying Brantigan in view of Michelson

(a) Michelson Teaches Inserting a Single Implant by a Single Procedure

According to Petitioner, "Michelson teaches 'spinal fusion implant 1000'" that "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.'" Pet. 55–56 (quoting from Ex. 1032, 10:48–59). In response, Patent Owner points to column 10, lines 50–53 of Michelson, paragraphs 41–47 and 55–64 of Dr. Youssef's declaration, and paragraphs 16 and 37–48 of Dr. McMillan's declaration. PO Resp. 32. Dr. Youssef and Dr. McMillin point us to column 3, lines 46–49 and column 10, lines 50–53 of Michelson. Ex. 2055 ¶¶ 46, 47; Ex. 2057 ¶¶ 33, 34.

The first of these cited portions states that "[t]he dimensions of the translateral spinal fusion implant of the present invention permits a *single implant* to be inserted by a single procedure into the spine and to engage more of the adjacent vertebrae." Ex. 1032, 3:46–49 (emphasis added); *see also* Ex. 1002 ¶ 113 (citing Ex. 1032, 3:47–53) (Petitioner's declarant Dr. Branch stating that "Michelson explains how '[t]he dimensions of the translateral spinal fusion implant of the present invention permits a single implant to be inserted by a single procedure into the spine and to engage more of the adjacent vertebrae'"), ¶ 217 (quoting Ex. 1032, 3:35–53); Ex. 2022, 105:11–17 (Dr. Branch agreeing that Michelson describes a single implant inserted in a single procedure). We find that column 3, lines 46–49 of Michelson teaches inserting a single implant by a single procedure, and not inserting modular components of an implant to be assembled in the spine. Ex. 2055 ¶ 47; Ex. 2057 ¶ 33.

Our finding is supported by the immediately following sentence in Michelson that states "[a]s a result, the translateral spinal fusion implant of the present invention has more surface area of contact and thus permits greater stability so as to withstand torque." Ex. 1032, 3:49–52; *see also* Ex. 2022, 105:18–106:2 (Dr. Branch agreeing that Michelson's single implant

has more surface area of contact and permits greater stability). Together with the "single implant . . . to engage more of the adjacent vertebrae" described in the previous sentence, we determine that a "single implant," even if it is made up of modular components, must already be assembled to be the "single implant" that "engage[s] more of the adjacent vertebrae," "has more surface area of contact," and "permits greater stability." *See* Ex. 1032, 3:46–52. Stated differently, although Michelson describes that 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," based on the teachings of Michelson, the modular components of implant 1000, collectively, in an assembled fashion, constitute the "single implant" that "engage[s] more of the adjacent vertebrae" "has more surface area of contact," and "permits greater stability." Ex. 1032, 3:46–52, 10:51–54.

We credit Dr. Youssef's testimony that "a benefit of [Michelson's] implant is that only a single implant is needed for stability" because the above-discussed portions of Michelson support it. Ex. 2055 ¶ 45 (citing Ex. 1032, 3:46–49). The full record also supports Dr. Youssef's testimony that Michelson teaches "combining modular components *for* insertion in the disc space—it does not describe combining components in the disc space *after* serial insertion." Ex. 2055 ¶ 47.

We also credit Dr. McMillin's testimony that "Michelson does not disclose inserting implants into the disc space piece-by-piece." Ex. 1032, 3:46–52; Ex. 2057 ¶ 33. The full record supports Dr. McMillin's testimony that "such an insertion method would be contrary to what Michelson describes as a benefit of the inventive implants—that is, the invention permits using a single implant inserted in a single procedure." Ex. 2057 ¶ 33

(citing Ex. 1032, 3:46–49); *see also* Ex. 2022, 69:22–70:7 (Dr. Branch indicating that revising the position of an implant with antimigration elements "is not the optimal technique" because "pulling it back against antimigration elements . . . injures the endplate and might actually obligate you to put in a different size implant").

Although Dr. Branch quotes column 3, lines 46–52 of Michelson in several paragraphs related to the challenge based on Brantigan, Baccelli, Berry, and Michelson, he does not explain how this portion or any other part of Michelson teaches or suggests a sequential insertion of modular components. *See, e.g.*, Ex. 1002 ¶¶ 113, 208, 217. For the reasons above, we credit Drs. Youssef's and McMillan's testimony over Dr. Branch's testimony regarding the single implant of Michelson and that Michelson does not teach sequential insertion of implants.

For the reasons above, based on the full record before us, we determine that Michelson teaches inserting a single implant by a single procedure. Ex. 1032, 3:46–52, 10:48–54; Ex. 2055 ¶¶ 45–47; Ex. 2057 ¶¶ 33, 34; Ex. 2022, 105:11–106:2. The full record does not persuade us that Michelson teaches inserting implants in a sequential manner, as argued by Petitioner.

(b) Michelson Teaches Combining Modular Components before Insertion

Petitioner argues that one of ordinary skill in the art "would have been motivated to make Brantigan's laterally-inserted lumbar spinal fusion implants 'narrower' for insertion *in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness." Pet. 41 (emphasis added) (citing Ex. 1002 ¶ 176; Ex. 1022, 364; Ex. 1032, 3:61–65, 10:20–59, Figs. 18, 19); *see also id.* at 54 (citing Ex. 1007, 1:20–21; Ex. 1032, 10:50–

55). Dr. Branch also uses the phrase "for insertion in a modular fashion" in his declaration. *See* Ex. 1002 ¶ 176 (Dr. Branch stating that a person of ordinary skill in the art "would have been motivated to achieve the benefits of Michelson by making Brantigan's laterally-inserted lumbar spinal fusion implants 'narrower' for *insertion in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness") (emphasis added). Petitioner does not specifically contend if the modified narrower Brantigan implants would be combined before insertion or after insertion. *See* Pet. 41, 54; Ex. 1002 ¶ 176. Petitioner, however, replies that it did not argue that modular implants would be assembled within the disc space. Pet. Reply 1 (citing PO Resp. 12).

Patent Owner contends that Michelson teaches combining before, not after, insertion, and thus, cannot teach sequential insertion of modular members. PO Resp. 32 (citing Ex. 1007, Abstract, 1:18–21, 1:59–61, 2:2–11, 2:34–43, 3:25–31, 4:23–49, 5:18–21, Figs. 1, 3, 4; Ex. 1011, 8; Ex. 1032, 3:46–49, 10:50–53; Ex. 2055 ¶¶ 41–47, 55–64; Ex. 2057 ¶¶ 16, 37–48). As discussed above, we find that Michelson teaches inserting a single implant by a single procedure, not inserting modular members of an implant to be assembled in the spine, because a single implant provides stability and insertion in a single procedure. Ex. 1032, 3:46–52; Ex. 2055 ¶¶ 45–47; Ex. 2057 ¶¶ 33, 34; *see also* Ex. 2022, 105:18–106:2 (Dr. Branch agreeing that Michelson's single implant has more surface area of contact and permits greater stability).

Also, as discussed above, Michelson describes that 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." Ex. 1032, 10:51–54 (emphasis added).

Dr. Branch does not explain how this portion of Michelson teaches or suggests a sequential insertion of modular components. *See* Ex. 1002 ¶¶ 110–117 (opining as to what Michelson teaches), 118 (quoting from Ex. 1032, 10:50–55 without further explanation), 169–245 (opining that Brantigan, Baccelli, Berry, and Michelson would have rendered obvious claims 1 and 16). Dr. McMillin states that a person of ordinary skill in the art "would have understood Michelson to disclose what is stated expressly—the implant is assembled prior to insertion thereby retaining the benefits of using a single implant inserted through a single procedure." Ex. 2057 ¶ 34 (quoting Ex. 1032, 10:50–53).

We credit Dr. McMillin's testimony because column 10, lines 50–53 of Michelson supports it. We also find Dr. McMillan's testimony more credible than Dr. Branch's testimony regarding this particular portion of Michelson. Ex. 1002 ¶ 118 (quoting from Ex. 1032, 10:50–55 without further explanation); Ex. 2057 ¶ 34 (quoting from Ex. 1032, 10:50–53 and explaining that assembly prior to insertion retains Michelson's disclosed benefit).

Dr. Branch also opines that a person of ordinary skill would have modified Brantigan's laterally-inserted spinal fusion implants to be narrower or long-and-narrow in view of Michelson "for insertion in a modular fashion." Ex. 1002 ¶¶ 176, 224. Dr. Branch further opines that Brantigan describes a similar modularity concept. *Id.* ¶ 96 (citing Ex. 1007, 1:13–16, 2:4–5), ¶ 222 (citing Ex. 1007, 2:4–11).

Based on the full record, even if Brantigan teaches inserting implants in a modular fashion, Michelson teaches inserting a single implant in a single procedure to engage more of the adjacent vertebrae and permit greater stability to withstand torque. Ex. 1032, 3:46–54, 3:61–65, 10:50–54;

Ex. 2055 ¶¶ 45–47; Ex. 2057 ¶¶ 33, 34. Petitioner does not address why one of ordinary skill in the art would insert Brantigan's implant in a modular fashion in view of Michelson's teaching to insert a single implant in a single procedure. *See* Pet. 38–69; Pet. Reply 9–12; Ex. 1032, 3:46–52; *see also* Ex 2022, 69:22–70:7 (Dr. Branch indicating that revising the position of an implant with antimigration elements "is not the optimal technique" because "pulling it back against antimigration elements . . . injures the endplate and might actually obligate you to put in a different size implant"), 105:18–106:2 (Dr. Branch agreeing that Michelson's single implant has more surface area of contact and permits greater stability).

Patent Owner also contends that inserting modular implants would be less safe and would increase invasiveness, contrary to Petitioner's reason for the modification, because of the anti-migration elements of Brantigan prevent moving a first implant to add another implant. PO Resp. 32–34 (citing Ex. 1007, 5:22–26, 6:14–16, Fig. 1; Ex. 1032, 8:20–22; Ex. 1040 ¶¶ 116, 139, 140, Figs. 29, 53; Ex. 2022, 69:22–70:7, 70:15–24, 85:21–24, 97:10–98:24; Ex. 2055 ¶¶ 46–49, 124–132; Ex. 2057 ¶¶ 46–49).

Based on Petitioner's Reply and our determinations above, Petitioner's proposed modification "for insertion in a modular fashion" would include two Brantigan implants modified to be long and narrow as taught by Michelson and assembled before insertion. *See* Pet. 40–41, 54–57; *see also* Pet. Reply 4 (arguing that one of ordinary skill in the art would have known of implants "inserted across the disc space in side-by-side pairs"). Thus, the two modified Brantigan implants, in view of Michelson's teaching of a single implant assembled before insertion, would have to be larger than any one of the non-modified Brantigan implants, and require a larger

insertion pathway, which is contrary to Petitioner's contention that the proposed modification would "minimize invasiveness" (Pet. 41).

We note that, if modified implants were to be assembled after insertion, then we would agree with Petitioner that its proposed modification would minimize invasiveness because the proposed modification would be able to take advantage of the narrower implants. The full record shows, however, that inserting narrower implants would not necessarily increase safety because Michelson does not teach sequential insertion of modular components let alone that sequential insertion of modular components would make the procedure safe and simple. Ex. 1032, 3:46–49, 3:61–65, 10:50–54; Ex. 2055 ¶¶ 90–96 (Dr. Youssef testifying that implementing Michelson's modularity concept would be more invasive and less safe); Ex. 2057 ¶ 16 (Dr. McMillan testifying that serial insertion of modular members would be unsafe and more invasive).

Thus, based on the full record, we find that Michelson teaches that 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," that one of ordinary skill in the art would have understood Michelson to be teaching combining implants 1000 before insertion when Michelson states "combin[ing] in a modular fashion for insertion," and that one of ordinary skill in the art would not have understood that Michelson to be teaching the sequential insertion of modular components to be combined after insertion. Ex. 1032, 3:46–54, 3:61–65, 10:50–54; Ex. 2055 ¶¶ 45–47, 90–96; Ex. 2057 ¶¶ 16, 33, 34.

(c) Michelson Teaches Inserting Through a Tube Making a Procedure Safe and Simple

The parties do not dispute that the modified implant would be inserted through a tube. *See* Pet. 41; PO Resp. 31–34; Pet. Reply 9–11; PO Sur-reply 12–15. The parties also do not dispute that Michelson teaches engaging a hollow tube to the lateral aspect of the spine through a lateral, anterior, or anterolateral incision. *See* PO Resp. 31–34; Pet. Reply 9–11; PO Sur-reply 12–15; *see also* Ex. 1002 ¶ 112 (testifying that Michelson's implant is inserted in a translateral approach to the spine).

Michelson teaches that "[t]he translateral spinal fusion implant of the present invention may be inserted into the disc space through a hollow tube which is engaged to the lateral aspect of the spine through a lateral, anterior, or anterolateral incision making the procedure safe and simple." Ex. 1032, 3:61–65.

Based on the full record, we find that Michelson teaches inserting a single translateral spinal fusion implant into the disc space through a hollow tube, which is engaged to the lateral aspect of the spine through, at least, a lateral incision makes the procedure safe and simple. *See* Ex. 1032, 3:46–49, 3:61–65; Ex. 1002 ¶ 114 (quoting from Ex. 1032, 3:56–60) (testifying that Michelson's translateral implants are safer than implants inserted from the front or back), ¶ 115 (quoting from Ex. 1032, 3:61–65) (testifying that Michelson's lateral approach maximizes safety).

Thus, based on the full record, we find that Michelson does not teach that "insertion in a modular fashion" makes a procedure safe and simple or that safety arises necessarily from making an implant long and narrow. Pet. 41; Ex. 1002 ¶¶ 112, 114, 115; Ex. 1032, 3:46–49, 3:61–65; Ex. 2055

¶¶ 90–96; Ex. 2057 ¶¶ 16, 35–43; *see also* Ex. 2022, 97:10–98:24 (Dr. Branch discussing the considerations for inserting a second implant).

(d) Petitioner does not rely on Baccelli or Berry for a Reason to Make an Implant Narrower for Insertion in a Modular Fashion

As discussed above, Petitioner modifies Brantigan's implant in view of Baccelli, Berry, and Michelson. Pet. 38–42. Petitioner relies on Baccelli for teaching "one or more—and in particular, four—markers in a radiolucent spinal fusion implant." *Id.* at 39 (citing Ex. 1002 ¶ 172; Ex. 1008 ¶ 50). Petitioner relies on Berry only for "the average dimensions of the human vertebrae" known to ordinary skilled artisans at the time of invention, which is not related to modularity. *Id.*

We determine that neither Baccelli nor Berry provide support for making a narrower implant "for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness." *Id.* at 41.

(e) Determining Petitioner's Reason Lacks Rational Underpinnings

In view of our findings discussed above, Petitioner fails to persuade us by a preponderance of the evidence that one of ordinary skill in the art "would have been motivated to make Brantigan's laterally-inserted lumbar spinal fusion implants 'narrower' *for insertion in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness." Pet. 41 (emphasis added).

Because Michelson teaches that inserting a single implant through a tube makes the procedure safe and simple, Michelson does not support Petitioner's proposed modification to make Brantigan's implant narrower "*for insertion in a modular fashion* through a hollow tube *to increase patient*

safety and minimize invasiveness." Pet. 41; Ex. 1032, 3:46–52, 10:48–54; Ex. 2055 ¶¶ 45–47; Ex. 2057 ¶¶ 33, 34; Ex. 2022, 105:11–106:2.

Also, because Michelson teaches that inserting its implant through a hollow tube engaged to the lateral aspect of the spine through one of several listed incisions makes the procedure safe and simple, Michelson does not support Petitioner's proposed modification to Brantigan's implant "for insertion in a modular fashion . . . to increase patient safety." Pet. 41; Ex. 1002 ¶¶ 112, 114, 115; Ex. 1032, 3:46–49, 3:61–65; Ex. 2055 ¶¶ 90–96; Ex. 2057 ¶¶ 16, 44–47. Additionally, neither Baccelli nor Berry provide, or are relied upon to provide, a rational underpinning for Petitioner's proposed modification. Pet. 38–42.

For the reasons above, based on the full record, we find that Michelson does not support that Petitioner's proposed modification to Brantigan would increase patient safety and minimize invasiveness. We, therefore, determine that Petitioner's rationale lacks a rational underpinning.

3. Claim 16

Claim 16 depends from claim 1 and recites "a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker." Ex. 1001, 13:51–14:3. Petitioner contends that Baccelli teaches the subject matter of claim 16. Pet. 63–69 (citing Ex. 1002 ¶¶ 240–243; Ex. 1008 ¶¶ 36, 41, 44, 50, 51, Figs. 1–5, 8, 9).

Petitioner argues that, "[b]ecause Brantigan does not describe [or] mention radiopaque markers in the proximal and distal walls or the central region of the implant," it would have been obvious to include four markers in the proximal, distal, and side walls of Brantigan "to enable surgeons to visualize the orientation and location of the implant during and after

surgery" and "to allow surgeons to align the markers with the spinous process and the lateral ends of the vertebrae." *Id.* at 67 (Ex. 1002 ¶¶ 172–174). Petitioner also argues that adding radiopaque markers "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 and the lateral edges of the vertebrae during and after lateral insertion," as well as allow surgeons to identify the position of posterior sidewall relative to the posterior edge of the vertebrae or the position of the anterior sidewall relative to the anterior edge of the vertebrae. *Id.* at 68–69 (citing Ex. 1002 ¶ 174)). Petitioner, thus, contends that Brantigan, Baccelli, Berry, and Michelson would have rendered obvious claim 16. *Id.* at 69 (citing Ex. 1002 ¶ 245).

Also, in connection with limitations regarding "at least three radiopaque markers" recited by claim 1, Petitioner argues that Baccelli teaches at least three radiopaque markers with one each in the distal, proximal, and side walls. Pet. 60–63 (citing Ex. 1002 ¶¶ 236–238; Ex. 1008 ¶¶ 36, 41, 44, 50, 51, Figs. 1–5, 8, 9). Petitioner contends that, because "Brantigan's spinal fusion implant is radiolucent and transparent to X-rays" and because "Baccelli instructs a [person of ordinary skill in the art] to include four radiopaque markers in the implant," one of ordinary skill in the art "would have been motivated to include radiopaque markers in all four walls of the radiolucent Brantigan lateral implant to enable surgeons to visualize the orientation and location of the implant during and after surgery, including, for example, alignment with the spinous process and the lateral ends of the vertebrae." *Id.* at 39–40 (citing Ex. 1002 ¶¶ 172, 173; Ex. 1007, Figs. 8, 10; Ex. 1008 ¶¶ 50, 51, Figs. 1–5, 8, 9).

a) Patent Owner's Response

Patent Owner responds that Brantigan, Baccelli, Berry, and Michelson fail to teach third and fourth radiopaque markers in the "central region" as recited by claims 1 and 16. PO Resp. 19–23. Patent Owner also responds that Petitioner's reason why one of ordinary skill in the art would have modified Brantigan to have a radiopaque marker on each of the four walls of the implant should be rejected as improperly based on hindsight, "fails for the same reason as discussed above," and "is based on a misapprehension of the contents of Baccelli." *Id.* at 31–32 (citing Pet. 38–41, 54–57). As discussed above for claim 1, Patent Owner also responds that Petitioner's proposed modification does not increase patient safety or minimize invasiveness. *Id.* at 32–34.

b) Parties' Reply Arguments

Petitioner replies that Patent Owner's interpretation of "central region" is unsupported and that Petitioner does not rely on Baccelli for the required "central region" and instead relies on Baccelli for teaching the orientation of four radiopaque markers. Pet. Reply 5 (citing PO Resp. 19–23), 8–9 (citing PO Resp. 19–22). Petitioner also replies that one of ordinary skill in the art would have been motivated to include Baccelli's four radiopaque markers. *Id.* at 9 (citing Pet. 67–69). Petitioner further replies that its proposed combination teaches the limitations of claim 16 and one of ordinary skill in the art would have been motivated to combine the references to arrive at claim 16. *Id.* at 10–11 (citing Pet. 63–69; PO Resp. 19–22, 31–32; Ex. 1008 ¶¶ 36, 41, 44, 50, 51, Figs. 1–5, 8, 9).

Patent Owner replies that "Petitioner's marker configuration argument is based on impermissible hindsight." PO Sur-reply 1. Patent Owner also replies that Petitioner does not meaningfully respond to Patent Owner's

arguments, applies an incorrect interpretation of "central region," and misapprehends Baccelli's teachings. *Id.* at 1 (citing PO Resp. 2, 4–8, 18–23, 28), 9–10 (citing Pet. 2; Pet. Reply 5; PO Resp. 4–8, 18–23, 28), 10–11 (citing Pet. 30, 40; PO Resp. 18–23, 28–29), 15–17 (citing Pet. 30–31, 34–35, 40; PO Resp. 18–23, 28–31; Pet. Reply 10,11; Ex. 1002 ¶¶ 29–30; Ex. 1007 ¶ 41; Ex. 2017, 7:9–8:13; Ex. 2028 ¶ 60).

c) Insufficient Reason for Including a Fourth Radiopaque Marker

As discussed above in connection with claim 1, Petitioner contends that one of ordinary skill in the art would have been motivated to narrow the width of Brantigan's implant "so that they 'may be combined in a modular fashion for insertion within the disc space D between adjacent vertebrae.'" Pet. 54 (citing Ex. 1007, 1:20–21; Ex. 1032, 10:50–55); *see also id.* at 41 (arguing that one of ordinary skill in the art "would have been motivated to make Brantigan's laterally-inserted lumbar spinal fusion implants 'narrower' for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness") (citing Ex. 1032, 3:61–65). For the reasons discussed for claim 1, Petitioner does not persuade us that one of ordinary skill in the art would have made the proposed combination to render obvious claim 1, from which claim 16 depends. Petitioner's arguments for claim 16 do not remedy the deficiencies of claim 1.

Additionally, for claim 16, Petitioner contends that it would have been obvious "to include the four markers Baccelli teaches into the proximal, distal, and sidewalls of the radiolucent lateral Brantigan implant to enable surgeons to visualize the orientation and location of the implant during and after surgery." *Id.* at 67 (citing Ex. 1002 ¶ 173; Ex. 1007, Figs. 8, 10).

Based on the full record, Petitioner does not persuade us that one of ordinary skill in the art would have modified Brantigan's implant so that

they may be combined in a modular fashion for insertion and so that each one would have four radiopaque markers in each of their four walls. *See id.* at 41, 54, 67. The proposed modifications would result in the combination having at least eight total radiopaque markers. Petitioner's reason for "position[ing] markers in the middle (e.g., central region or widest portion) of Brantigan's sidewalls, as well as in the leading and trailing ends of the implant, to allow surgeons to align the markers with the spinous process and the lateral ends of the vertebrae" does not persuasively address why eight total radiopaque markers would be needed. *See id.* at 41, 54, 67; Ex. 1002 ¶ 173. As discussed above, when addressing the other proposed challenge, Frey provides evidence that its three markers 1438 provide indications of anterior-to-posterior placement, lateral placement, and proper orientation of the implant in the disc space in the anterior-to-posterior direction. Ex. 1002 ¶ 161; Ex. 1040 ¶ 156; Ex. 2055 ¶¶ 119, 120.

Petitioner does not present a sufficient reason, if three radiopaque markers were known to be sufficient for proper orientation of an implant in the disc space, why one of ordinary skill in the art would have included an additional fourth marker or make modular implants that would result in eight markers when the modular implants are combined for insertion. *See* Pet. 41, 54, 67.

Thus, when considering Petitioner's two proposed modifications together, we are not persuaded that Petitioner presents a sufficient reason that one of ordinary skill in the art would have modified Brantigan to have four radiopaque markers in modular implants that would be combined for insertion within the disc space.

G. Weighing the Graham *Factors*

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1361 (Fed. Cir. 2017). Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, and (3) any differences between the claimed subject matter and the prior art.

In particular, we find that Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, but Petitioner does not persuade us by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to combine Frey, Michelson, and Baccelli. Petitioner also does not persuade us by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to combine Brantigan, Baccelli, Berry, and Michelson

Petitioner, thus, does not persuade us by a preponderance of the evidence that claim 16 of the '334 patent is unpatentable over (1) Frey, Michelson, and Baccelli or (2) Brantigan, Baccelli, Berry, and Michelson.

H. Other Arguments

Patent Owner also argues that the asserted references fail to teach or suggest certain limitations of claim 16 (*see* PO Resp. 19–27), asserts that estoppel should not be applied (*see id.* at 34–55), and presents objective indicia of nonobviousness (*see id.* at 55–59). The parties provide reply arguments regarding these issues. Pet. Reply 6–8, 9, 11–14; PO Sur-reply 2–11, 15–23.

Because we determine that Petitioner does not present a sufficient reason for combining Frey, Michelson, and Baccelli or combining Brantigan, Baccelli, Berry, and Michelson, we do not reach these other arguments.

III. CONCLUSION

In summary:

Claim	35 U.S.C. §	References/Basis	Claim Shown Unpatentable	Claim Not Shown Unpatentable
16	103	Frey, Michelson, Baccelli		16
16	103	Brantigan, Baccelli, Berry, Michelson		16
Overall Outcome				16

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 16 of U.S. Patent No. 8,187,334 B2 has not been shown, by a preponderance of the evidence, to be unpatentable;

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

FURTHER ORDERED that, because this is a Final Written Decision, the 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.

FOR PETITIONER:

Jovial Wong
David P. Dalke
Nimalka R. Wickramasekera
WINSTON & STRAWN LLP
jwong@winston.com
ddalke@winston.com
nwickramasekera@winston.com

FOR PATENT OWNER:

Michael T. Rosato
Paul D. Tripodi II
Sonja R. Gerrard
Jad A. Mills
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
ptripodi@wsgr.com
sgerrard@wsgr.com
jmills@wsgr.com