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Paper 59
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.

IPR2019-00361
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 Some Challenged Claims 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 claims 6–9 and 18 of U.S. Patent No. 8,187,334 B2 (Ex. 1001, "the '334 patent"). NuVasive Inc. ("Patent Owner") filed a Preliminary Response (Paper 12). Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '334 patent. Paper 19 ("Dec. to Inst."). In particular, we instituted review of claims 6–9 and 18 on all presented challenges. Dec. to Inst. 2, 24, 25, 26, 29, 30, 38, 41, 43.

After institution, Patent Owner filed a Response (Paper 28, "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 56, "Tr."). *See also* Exs. 1066, 2062 (parties' transcript errata sheets).

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 6–9, but not claim 18, of the

'334 patent are 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. 75. "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. 75; Paper 4, 2. The parties also indicate that the '334 patent is the subject of IPR2019-00546. Paper 4, 2; Paper 6, 2.

Patent Owner additionally notes that the '334 patent was previously challenged in 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. 75; Paper 4, 2; Paper 6, 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.

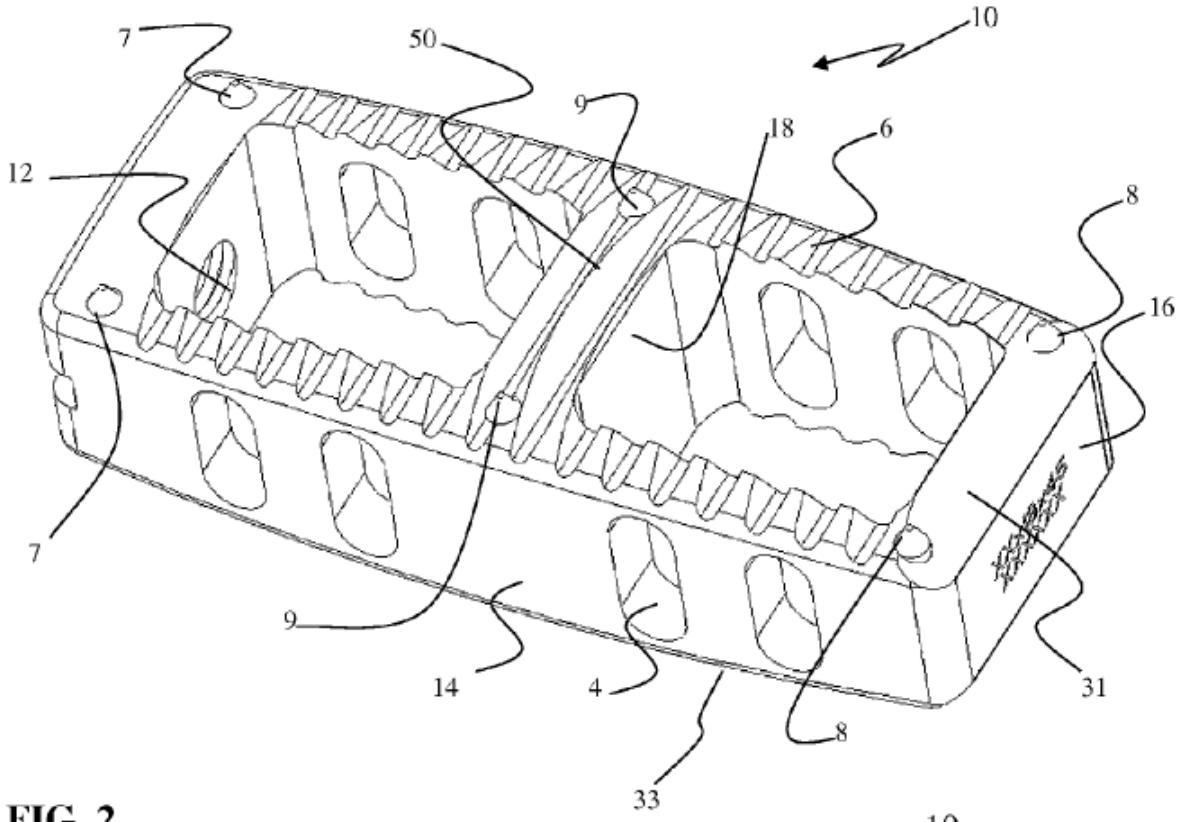


FIG. 2

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. Illustrative Claims

The '334 patent has 28 claims. In IPR2013-00507, claim 18 was found to be "patentable," and claims 1–5, 10, 11, 14, 15, and 19–28 were cancelled. Ex. 1001, 34. Petitioner challenges claims 6–9 and 18, all of which ultimately depend from cancelled claim 1. Claims 1, 6, and 18 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.

6. The spinal fusion implant of claim 1, further comprising a medial support extending between the first and second sidewalls.

18. The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.

Ex. 1001, 12:32–13:4, 13:17–19, 14:11–13.

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. 21, 29–74. Patent Owner proffers a Declaration of Jim A. Youssef, M.D. (Ex. 2055), Declaration of Carl R. McMillin, Ph.D. (Ex. 2057), and Declaration of Matthew Link (Ex. 2059). Deposition transcripts for Dr. Branch (Ex. 2022), Dr. Youssef (Ex. 1050), Dr. McMillin (Ex. 1051), and Mr. Link (Ex. 1052) were filed.

G. Asserted Grounds

Petitioner asserts that claims 6–9 and 18 would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §[1]	References/Basis
6–9, 18	103	Frey, Michelson, Berry
6–9, 18	103	Brantigan, Baccelli, Berry, Michelson

Pet. 21–22, 29–74.

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. Patent Owner indicates that objections to these exhibits, except for Exhibit 1064, were previously filed. *Id.* (citing Papers 24, 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.

[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.

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 undermine its collateral estoppel arguments and states that "[t]o the extent the materially different nature of Petitioner's 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. 2–4.

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 3–4 (citing Pet. 4–5, 30, 45, 47–48; PO Resp. 19–20, 55; Pet. Reply 10). Petitioner responds that Exhibits 1053 and 1054 are proper rebuttal evidence. Opp. 1–2. Petitioner also identifies which of Patent Owner's arguments that the exhibits rebut and how they respond to those arguments. *Id.* at 2–5 (citing PO Resp. 9, 13, 62; 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 1–2. Patent Owner reiterates its argument that Exhibits 1053 and 1054 support a new rationale for combining the references. *Id.* at 2–3 (citing Pet. 4–5, 30, 47–58; Opp. 3–4). Patent Owner also argues that these exhibits fail to support the theory presented in the Petition. *Id.* at 4 (citing Pet. 45; 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 possible 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. 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 1055 should be excluded under Rules 401–403 of FRE because it is cited in Petitioner's Reply with no substantive discussion and no explanation of its significance and Exhibit 1056 should be excluded under Rules 106 and 401–403 of the FRE because it is "more likely to cause confusion and unreasonable prejudice than add probative value." Mot. 5. More 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. 5–6. Petitioner argues that the exhibits are, thus, relevant and their relevance outweighs any risk of confusion. *Id.* at 6. Petitioner also contends that Patent Owner relied on Exhibit 1055 in previous litigation and relies on exhibits from the same litigation to support arguments in this proceeding. *Id.* (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. Patent Owner also replies that "Petitioner

approved of NuVasive's filing of EX2060 as a complete version of the transcript Petitioner filed as EX1056," which Patent Owner argues is incomplete, and that Petitioner "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 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, omit 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, and 1065"). Patent Owner does not provide a reply specific to these exhibits. *See* Mot. Reply 5.

Because we do not rely on Exhibit 1060 for our analysis, we deny as moot Patent Owner's Motion to Exclude with respect to Exhibit 1060. Also, for the reasons discussed below, we consider Exhibits 1061 and 1065 to be proper rebuttal evidence to Patent Owner's asserted objective indicia for nonobviousness and, thus, we deny 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 in a 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 and for the reasons below, we conclude that Petitioner has shown by a preponderance of the evidence that claims 6–9 would have been unpatentable over Frey, Michelson, and Berry. Petitioner, however, does not show by a preponderance of the evidence that claim 18 would have been unpatentable.

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. 28–29 (quoting Ex. 1002 ¶ 18). In our Decision to Institute, we preliminarily adopted Petitioner's unopposed proposal. Dec. to Inst. 15.

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. 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. Patent Owner's declarants also state that

[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).

they applied Petitioner's asserted level of ordinary skill. *See* Ex. 2055 ¶¶ 28–29; Ex. 2057 ¶ 14.

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; Ex. 2055 ¶¶ 28–29; Ex. 2057 ¶ 14.

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. 14–15 (citing Pet. 28–29; Ex. 1002 ¶ 18). This level 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. Youssef'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 5, 1 (according filing date of December 21, 2018 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 determined that "[a]t this stage of the proceeding, analyzing whether Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims only requires determining if the asserted references teach or suggest 'a longitudinal length . . . extending from a proximal end of said proximal wall to a distal end of said distal wall' and 'a longitudinal aperture extending generally parallel to the longitudinal length of said implant,' as recited by claim 1" and that "[f]urther express interpretation is not required." Dec. to Inst. 12–13.

Patent Owner proposes interpretations for "longitudinal length," "longitudinal aperture length," and "medial support," to which the parties provide reply arguments. PO Resp. 4–9; Pet. Reply 5–6; PO Sur-reply 15–17. For the reasons discussed below, our analysis does not depend on a particular interpretation for "longitudinal length," "longitudinal aperture length," and "medial support."

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 Berry

1. The Limitations of Claim 1 Incorporated into Claims 6–9 and 18

a) Petitioner's Assertions

Petitioner states that "the Board determined that all limitations of claim 1 'are taught or suggested by the combination of Frey and Michelson" and the "Federal Circuit affirmed the Board's decision." Pet. 32 (citing Ex. 1004, 5, 13; Ex. 1005, 17[3]). Petitioner argues that "Patent Owner is therefore estopped from arguing that claim 1 renders any dependent claim patentable over Frey and Michaelson as those references have been definitively established as rendering claim 1, among others, unpatentable." *Id.*

b) Patent Owner's Response

Patent Owner responds that Petitioner appears to rely on common law collateral estoppel to argue that Patent Owner is estopped from arguing claim 1 renders a dependent claim patentable. PO Resp. 21.

Patent Owner argues that "Petitioner has failed to satisfy its burden of showing the required elements of collateral estoppel are satisfied here and effectively admits they are not met." *Id*. at 24. According to Patent Owner,

[3] Like Petitioner, we refer to the exhibit page numbers in the lower, right corner of Exhibit 1005, not the page numbers of the slip opinion at the top. Petitioner cites Exhibit 1005, which is the slip opinion from the Federal Circuit addressing the appeal of the Final Written Decisions of IPR2013-00507 and IPR2018-00508 corresponding to *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016). Like Petitioner, we refer to the exhibit page numbers affixed in the lower, right corner of Exhibit 1005, not the page numbers of the slip opinion at the top.

Petitioner acknowledges that the unpatentability issues raised are different from the issues litigated and essential to the Final Written Decision of IPR2013-00507, and thus, Patent Owner could not have had a full and fair opportunity to litigate the different issues. *Id.* at 25; *see also id.* at 29–31 (explaining why Patent Owner could not have had a full and fair opportunity to litigate the different issues presented in this proceeding) (citing Pet. 2–5; Ex. 1004, 9; Ex. 1005, 7–8, 14–15; Ex. 2045, 27:13–18, 28:8–14, 32:16–22).

Patent Owner contends that, according to Petitioner, the grounds in this proceeding are not cumulative to previous grounds and are based on different combinations. *Id.* at 25–26 (citing Pet. 25–26). Patent Owner also points to differences regarding the first fusion aperture limitation and the motivation to modify Frey. *Id.* at 26–27 (citing Pet. 17, 37–40; Ex. 1005, 15; Ex. 1023, 2, 21; Ex. 1033, 26–27[4]). Patent Owner further points to the different mapping for claims 6–9 and the narrowing of scope by claims 6–9 and 18. *Id.* at 27–29 (citing Pet. 25, 33–43).

Patent Owner also argues that it would inequitable to apply collateral estoppel in this proceeding because arguments based on the modularity of Michelson were presented in reply in IPR2013-00507 without adequate opportunity to respond to those arguments. *Id.* at 31–33 (citing Ex. 1005, 5, 7–8, 11–12, 15, 17; Ex. 1023, 18–19, 104, 117; Ex. 2045, 30:7–20, 31:9–14). Patent Owner further argues changes in law and procedure make collateral estoppel inapplicable, specifically pointing to filing of a sur-reply as a matter of right, change in claim construction standard, presumption of nexus for objective indicia of nonobviousness, and the changes from *SAS*

[4] Like the parties, we refer to the exhibit page numbers in the lower, right corner of Exhibit 1033, not the page numbers of the petition from IPR2013-00507.

Inst., Inc. v. Iancu, 138 S. Ct. 1348 (2018). *Id.* at 33–39. Finally, according to Patent Owner, Petitioner fails to justify applying judicial estoppel, and the Board cannot cancel claims based on collateral estoppel. *Id.* at 39–41.

c) Petitioner's Reply

Petitioner replies that whether the combinations of references asserted in the Petition were not previously considered is inapplicable to whether claim 1 should be relitigated on the grounds asserted in IPR2013-00507. Pet. Reply 6. Petitioner also argues that the issue was litigated, resolution was essential to the final judgment, and Patent Owner had a full and fair opportunity to litigate and to avail themselves of the opportunity to argue the issues. *Id.* at 7 (citing Ex. 1004, 5; Ex. 1005). Petitioner further argues that equities favor preclusion with support from case law. *Id.* at 7–8 (citing also Ex. 1004, 11; Ex. 1005, 15).

d) Patent Owner's Sur-Reply

Patent Owner replies that Petitioner should have addressed the elements of collateral estoppel in the Petition. PO Sur-reply 3. Patent Owner argues it does not seek to relitigate claim 1, Petitioner's grounds are not the same as in IPR2013-00507, Petitioner does not meet its burden of showing how the references teach the challenged claims, and the dispute concerns whether Petitioner's combination of Frey and Michelson was actually litigated in IPR2013-00507. *Id.* at 4–5 (citing Pet. 25–26; PO Resp. 22–24; Pet. Reply 6–8). Patent Owner also replies that Petitioner has the burden for construing claim terms, does not address the change in claim interpretation, and concedes that objective indicia must be relitigated. *Id.* at 5–6 (citing Pet. 26; Pet. Reply 6–8).

e) Issue Preclusion Applies to Frey and Michelson Teaching or Suggesting the Limitations of Claim 1 Incorporated into Claims 6–9 and 18 by Dependency

"It is well established that collateral estoppel, also known as issue preclusion, applies in the administrative context." *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (citations omitted); *Webpower, Inc. v. Wag Acquisition, LLC*, IPR2016-01239, Paper 21 at 26–28 (PTAB Dec. 26, 2017). A patentee is estopped from asserting the validity of a patent that has been declared invalid in a prior suit against a different defendant, unless patentee demonstrates that he did not have full and fair opportunity, procedurally, substantively, and evidentially, to litigate the validity of his patent in the prior suit. *MaxLinear, Inc.*, 880 F.3d at 1377 (citing *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971) (finding collateral estoppel applies to a patentee who had a full and fair opportunity to litigate the validity of a patent in a prior federal case.)). Thus, as to a different petitioner, when the prior decisions finding claims unpatentable have "subsequently been affirmed by [the Federal Circuit] those prior decisions, having been affirmed by [the Federal Circuit], are binding in this proceeding, as a matter of collateral estoppel." *Id.* at 1376.

Medtronic, Inc. ("Medtronic"), Petitioner in IPR2013-00507, challenged claims 1–5, 10, 11, and 14–28 of the '334 patent based on several grounds. Ex. 1033, 7. The references referred to as Frey and Michelson in IPR2013-00507 are the same references asserted in this proceeding. *Compare id.* at 7, *with* Exs. 1032, 1040. Medtronic challenged claim 1 as anticipated by Frey, rendered obvious by Frey in view of Michelson, rendered obvious by Frey in view of Baccelli, and rendered obvious by Frey in view of other references not asserted in this proceeding. Ex. 1033, 7, 20–

28, 40–41, 48–49, 52–56, 58–60. Claim 18 was challenged only based on Frey and Michelson. *Id.* at 7, 56–58.

In the challenge based on Frey and Michelson, Medtronic referred to its earlier arguments that Frey anticipates claim 1 for all the limitations of claim 1 except for "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." *Id.* at 56. Medtronic additionally relied on Michelson's teaching at column 10, lines 41–46 that "spinal fusion implant 900 has a . . . length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." *Id.* at 53, 60. Medtronic argued that "combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results." *Id.* at 56.

The Final Written Decision in IPR2013-00507 determined that Frey and Michelson teach or suggest all the limitations of claims 1–5, 10, 11, 14, 15, and 19–28. Ex. 1004, 5. The Final Written Decision also stated that column 10, lines 40–41 and 44–47 of "Michelson expressly discloses an implant 'with 42 mm being the preferred length' and a width that 'approximates the depth of the vertebrae,' that measures 'in the range of 24 mm to 32 mm,' with 'the preferred width being 26 mm.'" *Id.* at 9. The Final Written Decision also determined that "it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1." *Id.* The Final Written Decision also found that that there had been no showing that dependent claim 18 of the '334 patent was unpatentable as obvious over Frey and Michelson. *Id*. at 9–11.

On appeal, the Federal Circuit "affirm[ed] the Board's final written decision in IPR2013-507, invalidating claims 1–5, 10, 11, 14, 15, and 19–

28."[5] *NuVasive*, 841 F.3d at 974. In analyzing the Final Written Decision of IPR2013-00507, the Federal Circuit determined in relevant part that

> [s]ubstantial evidence supports the Board's specific findings that (1) "a spinal implant measuring up to 45 mm in length" would not render Frey "inoperable" for its intended purpose, even if Frey were limited to use in transforaminal lumbar interbody fusion (TLIF) procedures . . . ; (2) an implant could be longer than 40 mm and not violate the teaching of Frey that it fit within the inner-annulus region . . .; and (3) Michelson in fact teaches the relevant long-and-narrow implants.

Id. The Federal Circuit also determined that:

> [a]s to reasons to combine: The Board did not have to find a reason that a relevant artisan would combine the length of an implant from one prior-art reference with the length-to-width ratio of an implant from another reference, because it found that Michelson disclosed an implant meeting both limitations.

Id.

"A party seeking to apply collateral estoppel based on a prior action must show that (1) the identical issue was actually litigated; (2) the issue was actually decided in a final decision on the merits; (3) the issue was necessary to the final decision; and (4) the party being estopped was adequately represented in the prior action." *United Access Techs., LLC v. CenturyTel Broadband Services LLC*, 778 F.3d 1327, 1331 (Fed. Cir. 2015)); *see also* PO Resp. 24–25 (stating that "collateral estoppel, also known as issue preclusion, requires '(1) identity of the issues in a prior proceeding; (2) the issues were actually litigated; (3) the determination of the issues was necessary to the resulting judgment; and, (4) the party defending against preclusion had a full and fair opportunity to litigate the issues'") (citing

[5] The Federal Circuit appeal did not address claim 18 of the '334 patent. *See generally*, *In re NuVasive, Inc.*, 841 F.3d 966.

Soverain Software v. Victoria's Secret Brand, 778 F.3d 1311, 1315 (Fed. Cir. 2015)).

Petitioner contends that "the Board determined that all limitations of claim 1 'are taught or suggested by the combination of Frey and Michelson.'" Pet. 32. Petitioner relies only on the previous determination regarding the specific issue of whether Frey and Michelson teach or suggest the limitations of claim 1. *See id.* We, thus, focus on whether that particular issue meets the requirements identified above for the application of collateral estoppel.

Regarding the first three elements of collateral estoppel, the prior action determined that Frey and Michelson teach or suggest all the limitations of, at least, claim 1. Ex. 1004, 5. The determination was made in a Final Written Decision, and the same determination that these references teach or suggest all the limitations of claim 1 would have been necessary for the conclusion that Frey and Michelson would have rendered obvious claim 1. Ex. 1004, 5, 9, 13. The Federal Circuit also determined that Frey and Michelson teach or suggest an implant greater than 40 mm in length and a long-and-narrow implant. *See NuVasive*, 841 F.3d at 974 ("This was sufficient to make an affirmative, supported case for the obviousness of the challenged '334 claims, given the limited arguments presented by NuVasive."). Petitioner presents the same issue to us. *See* Pet. 32. Thus, "(1) the identical issue was actually litigated; (2) the issue was actually decided in a final decision on the merits; [and] (3) the issue was necessary to the final decision." *United Access*, 778 F.3d at 1331.

As for the final element of collateral estoppel, the record does not reflect, nor does Patent Owner direct us to evidence indicating that Patent Owner was not adequately represented in the prior action or did not have a

full and fair opportunity to litigate issues related to what Frey and Michelson teach or suggest. The fact that Petitioner asserts additional references or an additional embodiment in this proceeding does not provide support that we should not apply issue preclusion to whether Frey and Michelson teach or suggest the limitations of claim 1. *See* PO Resp. 25–27. Also, in our analysis below, we are not applying issue preclusion to Petitioner's asserted rationale for combining the references for the challenged dependent claims. *See id.* at 26–29. Furthermore, the fact that certain teachings were not contested because Patent Owner did not present arguments in the prior action, does not provide a reason that issue preclusion should not be applied. *See NuVasive*, 841 F.3d at 974 ("Although the Board did not make findings as to whether any of the other claim limitations (such as fusion apertures or anti-migration teeth) are disclosed in the prior art, it did not have to: NuVasive did not present arguments about those limitations to the Board.").

Therefore, we determine that, under the applicable legal standard, issue preclusion applies to the unpatentability of claim 1. *See* Pet. 32 (citing Ex. 1004, 5, 13; Ex. 1005, 17). Thus, for our analysis below, we apply issue preclusion to arguments specifically regarding whether Frey and Michelson teach or suggest the limitations of claim 1. Further, Patent Owner is precluded from relitigating here whether Frey and Michelson teach all the limitations of claim 1, as arranged in the claim, including for purposes of determining the patentability of dependent claims 6–9 and 18.

Dependent claims 6–9 have not been finally adjudicated as unpatentable in any previous case. In the prior proceedings, Medtronic did not challenge the patentability of claims 6–9. Ex. 1033, 7. Accordingly, the Federal Circuit could not have addressed the additional limitations of these claims. *See generally NuVasive*, 841 F.3d 966; Ex. 1033; *see also* PO Resp.

27–29 (arguing that differences in claims 6–9 present a different theory). Nor has claim 18 been finally adjudicated as unpatentable in any previous proceeding. Claim 18 was not found to be unpatentable as obvious over Frey and Michelson, however, the grounds here include additional prior art directed to the additional limitation of claim 18. *See* Pet. 22. We, therefore, analyze the parties' arguments and evidence below regarding the additionally recited limitations of claims 6–9 and 18 under Frey, Michelson, and Berry.[6] This analysis includes consideration of the rationale to combine the prior art for the dependent claims, as well as consideration of asserted objective indicia of nonobviousness.

(1) 37 C.F.R. § 42.73(d)(3)(i)

Petitioner cites 37 C.F.R. § 42.73(d)(3)(i) to argue that for claim 1, "Patent Owner is precluded from taking any 'action inconsistent with the adverse judgment,' including obtaining any claims that are 'not patentably distinct from a finally refused or canceled claim.'" Pet. 32. Patent Owner responds that the rule "does not preclude an owner from defending the patentability of existing claims in an IPR," and Patent Owner is not attempting to obtain any challenged claim that are not patentably distinct from a canceled claim. PO Resp. 21. Patent Owner also contends that the rule "only applies to prevent recapture of claimed subject matter that was previously lost," and Patent Owner is not attempting to recapture claim 1. *Id.* at 22. Petitioner does not reply to Patent Owner's argument regarding 37

[6] Contrary to Patent Owner's argument, issue preclusion does not alone decide the patentability of any of the challenged dependent claims. *See* PO Resp. 40–41 (arguing that the Board does not have authority to cancel claims based on estoppel).

C.F.R. § 42.73(d)(3)(i). *See generally* Pet. Reply. Patent Owner replies that "Petitioner . . . abandons rule 42.73(d)(3)(i)." PO Sur-reply 3.

Even if we were to agree with Patent Owner that the express terms of 37 C.F.R. § 42.73(d)(3)(i) do not apply, as discussed above, Petitioner is not required to demonstrate in this proceeding that Frey and Michelson teach or suggest the limitations of claim 1 in the challenged dependent claims due to their ultimate dependency on claim 1.

(2) Asserted Treatment of Claim 1 as Prior Art

Patent Owner argues that "it remains Petitioner's burden to demonstrate obviousness of each challenged claim over the printed publication prior art asserted in the petition ***as the art was asserted in the petition***," which "includes demonstrating all elements of the challenged claims (including elements incorporated by virtue of dependency) are found in the cited prior art, rationale to combine and reasonable expectation of success." PO Resp. 22–23. According to Patent Owner, "Petitioner's argument lacks authority under the statute, attempts to sidestep its responsibilities, and improperly attempts to shift Petitioner's burden of proof onto the patent owner to prove the challenged claims are patentable." *Id.* at 23.

Patent Owner also argues that "Petitioner's argument that the elements of the challenged claims incorporated from claim 1 must be ignored improperly treats a cancelled claim as if it somehow became printed publication prior art" and "is not permitted." *Id.* Patent Owner further argues that "the relevant question is not solely limited to whether only the additional limitations can be found in the prior art, but whether petitioner's 'case-in-chief' for each dependent claim is sufficient" and "[r]egardless of the cancellation of claim 1, the Board thus must evaluate whether the prior

art as argued in the present petition demonstrates the unpatentability of each challenged claim ***as a whole***." *Id.* at 24.

Petitioner does not reply to Patent Owner's argument summarized above. *See generally* Pet. Reply. Patent Owner replies that Petitioner "cites no authority for treating a cancelled claim as prior art." PO Sur-reply 3.

We do not agree that applying a previous determination that Frey and Michelson teaches or suggests all the limitations of claim 1 is the same as treating claim 1 as prior art. Instead, the Federal Circuit analyzed whether the asserted prior art Frey and Michelson teach or suggest the limitations of claim 1 for the reasons given in the Final Written Decision of IPR2013-00507. *See NuVasive*, 841 F.3d at 974.

2. 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.

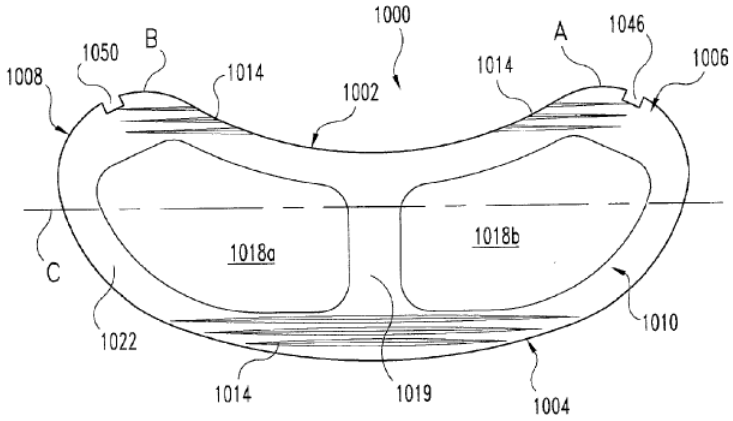


Fig. 55

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.

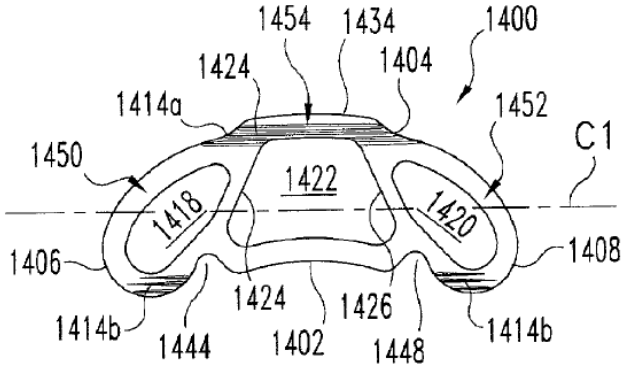


Fig. 63

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.*

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

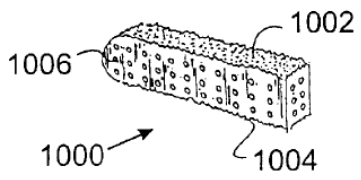


FIG. 19

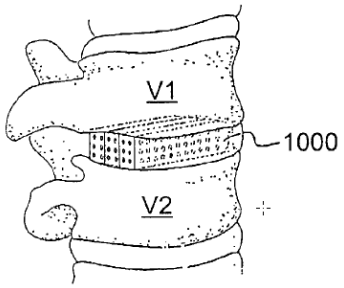


Figure 18 is a perspective side view of a spinal fusion implant, and Figure 19 is a perspective lateral anterior view of a segment of the spinal

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." *Id.* at 3:34–40.

Michelson 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." *Id.* at 3:46–49. "As 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, and in the case of a threaded implant, increases the depth which any threads are able to penetrate the vertebrae." *Id.* at 3:49–54. Michelson also states 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." *Id.* at 3:61–65.

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) 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).

3. Analysis of Challenged Claim 6

Claim 6 depends from claim 1 and recites "further comprising a medial support extending between the first and second sidewalls." Ex. 1001, 13:17–19. Petitioner argues that Frey teaches the limitations of claim 6. Pet. 33–35 (citing Ex. 1002 ¶¶ 162, 165, 166; Ex. 1040 ¶¶ 144, 149, 154, 181, Figs. 55, 59, 63).

We find that the relied-upon portions of Frey teach that "first strut 1424 is located between first chamber 1418 and third chamber 1422 and

extends between posterior wall 1402 and anterior wall 1404" and "second strut 1426 is located between second chamber 1420 and third chamber 1422 and extends between posterior wall 1402 and anterior wall 1404." Ex. 1040 ¶ 154; *see also id.* ¶ 144 (describing that "upper openings 1018a and 1018b [are] separated by an upper strut 1019" and "upper bar 1022 forming the perimeter of upper bearing member 1010 has a boomerang shape, and surrounds upper openings 1018a, 1018b and is connected to strut 1019" shown in Figure 55). We also find that Figures 59 and 63 show first and second struts 1424, 1426 extending between walls. Figure 59 is reproduced below.

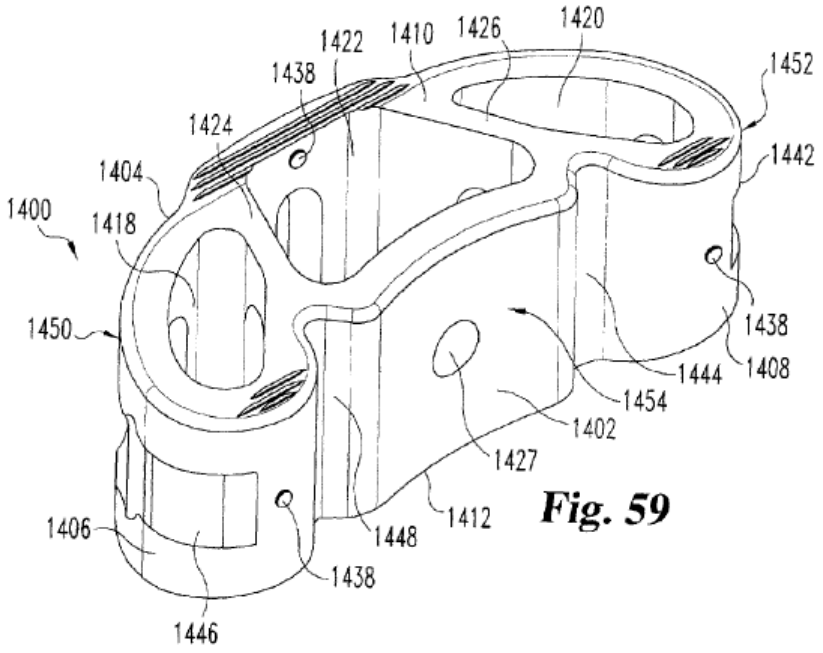


Fig. 59

Figure 59 is "a perspective view looking toward the posterior wall" an embodiment of Frey's implant. Ex. 1040 ¶ 71. We further credit Dr. Branch's testimony regarding how Frey teaches or suggests the limitations of claim 6 because the cited evidence supports it. Ex. 1002 ¶ 162 (citing Ex. 1040, Fig. 63).

Patent Owner responds that Frey's implant 1000 does not have a medial support separating first and second fusion apertures because the asserted fusion apertures do not extend from upper to lower surfaces. PO Resp. 47–49 (citing Ex. 1040 ¶ 144, 149, Fig. 57; Ex. 2022, 75:5–22, 94:7–96:9; Ex. 2055 ¶¶ 121–124, 129). Patent Owner also argues that upper strut 1019 does not extend between walls because it extends across member 1010 which is not a sidewall. *Id.* at 49 (citing Ex. 1040 ¶ 141, Figs. 56–57; Ex. 2055 ¶¶ 125–128).

Regarding Frey's embodiment shown in Figure 59, Patent Owner contends that "a medial support must be located approximately at the midpoint of the longitudinal length of the implant" and "Petitioner incorrectly identifies first strut 1424 and second strut 1426 as the medial support . . . because they do not extend between the sidewalls of the implant at approximately the midpoint of its longitudinal length." *Id.* at 50–51 (citing Pet. 2–3, 8, 33–36, 39; Ex. 1040 ¶ 156, Fig. 59; Ex. 2055 ¶¶ 130–136).

Petitioner replies that the '334 patent "patent does not define 'medial support' as 'approximately the midpoint'" and "because struts 1424 and 1426 lie adjacent to middle portion and middle chamber, a [person of ordinary skill in the art] would understand these struts to be located at 'approximately the midpoint.'" Pet. Reply 12 (citing PO Resp. 49, 50; Ex. 1040 ¶ 154). Patent Owner summarizes the parties' arguments and replies that Petitioner for the first time asserts that it does not rely on a specific embodiment and that Petitioner presents new arguments that lack merit. PO Sur-reply 18–20 (citing Pet. 32–43; PO Resp. 46–51; Pet. Reply 11–12; Ex. 2022, 94:7–96:9; Ex. 2055 ¶¶ 36–37, 121–132).

Because Frey teaches first and second struts 1424, 1426 extending between walls 1402, 1404, and claim 6 only requires a medial support extending between sidewalls, Petitioner persuades us that Frey teaches or suggests "a medial support extending between the first and second sidewalls," as recited by claim 6. We determined above that Frey and Michelson teach or suggest the limitations of claim 1 from which claim 6 depends. *See also* Ex. 1002 ¶¶ 127–160 (opining how at least Frey and Michelson teach or suggest the limitations of claim 1). Petitioner, therefore, persuades us that Frey and Michelson teach or suggest all the limitations of claim 6.

Petitioner also asserts that one of ordinary skill in the art would have been motivated to modify Frey's implant to be long and narrow in view of Michelson and Berry. Pet. 29–31. Petitioner also asserts that there would have been motivation "to combine the structural features of Frey and Michelson because both disclose, for example, implants having apertures for holding bone growth material to facilitate fusion." *Id*. at 31 (citing 1040 ¶ 130). Petitioner further argues that "combining the elements of Frey and Michelson amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." *Id.* at 31. Based on the full record, at least Frey evidences that a medial support was a known mechanical element.

Patent Owner responds to Petitioner's asserted motivation to combine on several issues, but does not address whether the subject matter of claim 6 represents "rearranging known mechanical elements to achieve a predictable result." *See* PO Resp. 42–45. Frey provides evidence that struts 1424, 1426 between walls 1402, 1404 were known mechanical elements for implants. Based on the full record before us, because Frey evidences that a medial

support was a known mechanical element, we determine that Frey and Michelson teach or suggest all the limitations of claim 6 and that the spinal fusion implant of claim 6 represents "rearranging known mechanical elements to achieve a predictable result." *See KSR*, 550 U.S. at 416 (The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results).

Also, because Frey shows a strut between walls, we determine that placing a medial support between sidewalls would have been within ordinary skill and one of ordinary skill in the art would have had a reasonable expectation of success in implementing such a medial support. Further, our determination would be the same even if we applied Patent Owner's proposed interpretation of "medial support" as something in the middle or midpoint of an object because a person of ordinary skill in the art would have understood Frey's strut to be in the middle or midpoint. *See* PO Resp. 8–9.

4. Analysis of Challenged Claim 7

Claim 7 depends from claim 6 and recites "wherein said medial support is positioned along said central region." Ex. 1001, 13:20–21. Petitioner argues that Frey teaches the limitations of claim 7, and thus, the proposed combination of references would have rendered obvious claim 7. Pet. 35–36 (citing Ex. 1002 ¶¶ 168–171; Ex. 1040 ¶¶ 144, 154, Figs. 55, 59, 63).

As discussed for claim 6, we find that Frey teaches or suggests first and second struts 1424, 1426 extending between walls 1402, 1404. Ex. 1002 ¶ 162; Ex. 1040 ¶ 154, Figs. 59, 63. Frey also teaches or suggests upper strut 1019 and shows that upper strut 1019 is positioned along a central region of an implant. *Id.* ¶ 144, Fig. 55. We credit Dr. Branch's

testimony regarding how Frey teaches or suggests the limitations of claim 7 because the cited evidence supports it. Ex. 1002 ¶¶ 168–171 (citing Ex. 1040 ¶¶ 144, 154, Figs. 55, 59, 63). In particular, Dr. Branch states that "[u]pper strut 1019 is a medial support positioned along the central region." *Id.* ¶ 170 (citing Ex. 1040, Fig. 55).

Patent Owner responds with the same arguments summarized above for claim 6 that Frey's implant 1000 does not have a medial support separating fusion apertures because the asserted fusion apertures do not extend from upper to lower surfaces, upper strut 1019 does not extend between walls because it extends across member 1010 which is not a sidewall, "a medial support must be located approximately at the midpoint of the longitudinal length of the implant," and "Petitioner incorrectly identifies first strut 1424 and second strut 1426 as the medial support . . . because they do not extend between the sidewalls of the implant at approximately the midpoint of its longitudinal length." PO Resp. 47–51 (citing Pet. 2–3, 8, 33–36, 39; Ex. 1040 ¶¶ 141, 144, 149, 156, Fig. 56, 57, 59; Ex. 2022, 75:5–22, 94:7–96:9; Ex. 2055 ¶¶ 121–136). Patent Owner also argues that "struts 1424 and 1436 are not 'positioned along said central region' as required by claim 7" because they "are not on a course parallel to the central region and are therefore not positioned along said central region." *Id.* at 51 (citing Ex. 2041; Ex. 2042; Ex. 2055 ¶¶ 133–134).

Petitioner replies that the "claimed '***central region***' is not a ***point*** per claim 1" and the claimed fusion apertures can be any suitable shape. Pet. Reply 12 (citing PO Resp. 51; Ex. 1001, 6:61–65). Petitioner argues that, in embodiments with fusion apertures having a non-rectangular shape, "the medial support would not be 'on a course parallel to the central region.'" *Id.* at 13. Petitioner also argues that "[t]here is also no requirement that a

'medial support must separate the two fusion apertures from the upper surface to the lower surface' completely." *Id.* (citing PO Resp. 48–49).

Patent Owner replies that Petitioner admits that Frey's struts are not positioned along the central region. PO Sur-reply 21 (citing Pet. Reply 13). Patent Owner also argues that Petitioner's contention about completely separating the fusion apertures is unsupported and has been rebutted. *Id.* at 21–22 (citing PO Resp. 8–9; Pet. Reply 13; Ex. 2055 ¶¶ 36–37, 121–129).

Because Frey teaches first and second struts 1424, 1426 around a central region and teaches strut 1019 in a central region, Petitioner persuades us that Frey teaches or suggests "wherein said medial support is positioned along said central region," as recited by claim 7. We determine above that Frey and Michelson teach or suggest the limitations of claims 1 and 6, from which claim 7 depends. *See also* Ex. 1002 ¶¶ 127–160 (opining how at least Frey and Michelson teach or suggest the limitations of claim 1). Petitioner, therefore, persuades us that Frey and Michelson teach or suggest all the limitations of claim 7.

Also, as discussed above for claim 6, Petitioner argues that "combining the elements of Frey and Michelson amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." Pet. 31 (citing *KSR*, 550 U.S. at 418; Ex. 1002 ¶¶ 143–144, 148–150). Based on the full record, at least Frey evidences that a medial support was a known mechanical element that was known to be in the center of an implant.

Patent Owner does not specifically address whether the subject matter of claim 7 represents "rearranging known mechanical elements to achieve a predictable result." *See* PO Resp. 42–45. Based on the full record before us, we determine that Frey and Michelson teach or suggest all the limitations of

claim 7 and that the spinal fusion implant of claim 7 represents "rearranging known mechanical elements to achieve a predictable result."

Also, because Frey shows a strut in the center of an implant, we determine that positioning a medial support in a central region is within ordinary skill and one of ordinary skill in the art would have had a reasonable expectation of success in such placement. Further, our determination would be the same even if we applied Patent Owner's proposed interpretation of "medial support" because a person of ordinary skill in the art would have understood Frey's strut to be in the middle or midpoint of the implant under Patent Owner's proposed interpretation. *See* PO Resp. 8–9.

5. Analysis of Challenged Claim 8

Claim 8 depends from claim 1 and recites "further including a second 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." Ex. 1001, 13:22–26. Petitioner argues that Frey teaches the limitations of claim 8, and thus, the proposed combination of references would have rendered obvious claim 8. Pet. 36–38 (citing Ex. 1002 ¶¶ 173–175; Ex. 1040 ¶¶ 144, 149, 154, Figs. 55, 63).

We find that the relied-upon portions of Frey teach that "[u]pper bearing member 1010 includes upper openings 1018a and 1018b separated by an upper strut 1019" and "leading end portion 1450 includes first chamber 1418 and trailing end portion 1452 includes second chamber 1420." Ex. 1040 ¶¶ 144, 154. Frey also teaches that "[i]n order to provide avenues for bone growth through implant 1400, the walls of implant 1400 form a number of chambers." *Id.* ¶ 154. We also find that Figure 63 shows first

and second chambers 1418 and 1420. We further credit Dr. Branch's testimony regarding how Frey teaches or suggests the limitations of claim 8 because the cited portions of Frey support it. Ex. 1002 ¶¶ 173–174 (citing Ex. 1040 ¶¶ 144, 154, Figs. 55, 63).

Patent Owner responds that Frey's implant 1000 does not have first and second fusion apertures that extend from upper to lower surfaces. PO Resp. 47–49 (citing Ex. 1040 ¶ 144, 149, Fig. 57; Ex. 2022, 75:5–22, 94:7–96:9; Ex. 2055 ¶¶ 121–124, 129). Petitioner replies that the challenged claims "do not require the fusion apertures to be bounded on four sides." Pet. Reply 13. Patent Owner replies that

> Petitioner fails to demonstrate that upper strut 1019 separates a first fusion aperture that extends from the upper surface of the implant to the lower surface of the implant from a second fusion aperture that extends from the upper surface of the implant to the lower surface of the implant, as required by the claim.

PO Sur-reply 21–22.

Because Frey teaches first and second chambers 1418, 1420 for allowing bone growth through implant 1400, Petitioner persuades us that Frey teaches or suggests "a second 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," as recited by claim 8. We determine above that Frey and Michelson teach or suggest the limitations of claim 1, from which claim 8 depends. *See also* Ex. 1002 ¶¶ 127–160 (opining how at least Frey and Michelson teach or suggest the limitations of claim 1). Petitioner, therefore, persuades us that Frey and Michelson teach or suggest all the limitations of claim 8.

As summarized above, Petitioner argues that "combining the elements of Frey and Michelson amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." Pet. 31 (citing *KSR*, 550 U.S. at 418; Ex. 1002 ¶¶ 143–144, 148–150). Based on the full record, at least Frey evidences that a second path through the entirety of an implant for bone growth was a known mechanical element. Patent Owner does not specifically address whether the subject matter of claim 8 represents "rearranging known mechanical elements to achieve a predictable result." *See* PO Resp. 42–45.

Based on the full record before us, we determine that Frey and Michelson teach or suggest all the limitations of claim 8 and that the spinal fusion implant of claim 8 represents "rearranging known mechanical elements to achieve a predictable result." Also, because Frey shows a second path through an implant for bone growth from top to bottom of the implant, we determine that providing a second fusion aperture as required by claim 8 is within ordinary skill and one of ordinary skill in the art would have had a reasonable expectation of success in providing such an aperture.

6. Analysis of Challenged Claim 9

Claim 9 depends from claim 8 and recites "wherein said second fusion aperture is separated from said first fusion aperture by a medial support." Ex. 1001, 13:27–29. Petitioner argues that Frey teaches the limitations of claim 9, and thus, the proposed combination of references would have rendered obvious claim 9. Pet. 38–40 (citing Ex. 1002 ¶¶ 177–179; Ex. 1040 ¶¶ 144, 149, 154, Figs. 55, 63).

As discussed above, we find that Frey teaches or suggest a second fusion aperture and a medial support. Ex. 1040 ¶¶ 144, 149, 154, Figs. 55, 63. We also credit Dr. Branch's testimony regarding how Frey teaches or

suggests the limitations of claim 8 because the cited evidence supports it. Ex. 1002 ¶¶ 177–178 (citing Ex. 1040 ¶¶ 144, 149, 154, Figs. 55, 63).

Patent Owner responds that Frey's implant 1000 does not have a medial support separating first and second fusion apertures because the asserted fusion apertures do not extend from upper to lower surfaces. PO Resp. 47–49 (citing Ex. 1040 ¶ 144, 149, Fig. 57; Ex. 2022, 75:5–22, 94:7–96:9; Ex. 2055 ¶¶ 121–124, 129). Patent Owner also argues that upper strut 1019 does not extend between walls because it extends across member 1010 which is not a sidewall. *Id.* at 49 (citing Ex. 1040 ¶ 141, Figs. 56–57; Ex. 2055 ¶¶ 125–128). Patent Owner further responds that "Petitioner incorrectly identifies first strut 1424 and second strut 1426 as the medial support . . . because they do not extend between the sidewalls of the implant at approximately the midpoint of its longitudinal length." *Id.* at 50–51 (citing Pet. 2–3, 8, 33–36, 39; Ex. 1040 ¶ 156, Fig. 59; Ex. 2055 ¶¶ 130–136). The parties' reply arguments regarding the medial support and second fusion apertures are summarized above in our analysis of claims 6–8.

Because Frey teaches first and second struts 1424, 1426 between first and second chambers 1418, 1420 that allow bone growth through an implant, Petitioner persuades us that Frey teaches or suggests "wherein said second fusion aperture is separated from said first fusion aperture by a medial support," as recited by claim 9. We determine above that Frey and Michelson teach or suggest the limitations of claim 1 from which claim 8 depends and Frey teaches or suggests the limitations of claim 8, from which claim 9 depends. *See also* Ex. 1002 ¶¶ 127–160 (opining how at least Frey and Michelson teach or suggest the limitations of claim 1). Petitioner, therefore, persuades us that Frey and Michelson teach or suggest all the limitations of claim 9.

Petitioner argues that "combining the elements of Frey and Michelson amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." Pet. 31 (citing *KSR*, 550 U.S. at 418; Ex. 1002 ¶¶ 143–144, 148–150). Patent Owner does not specifically address whether the subject matter of claim 8 represents "rearranging known mechanical elements to achieve a predictable result." *See* PO Resp. 42–45.

Based on the full record before us, we determine that Frey and Michelson teach or suggest all the limitations of claim 9 and that the spinal fusion implant of claim 9 represents "rearranging known mechanical elements to achieve a predictable result." Also, Frey provides evidence that separating fusion apertures with a medial support is within ordinary skill, and thus, one of ordinary skill in the art would have had a reasonable expectation of success in doing so.

7. Analysis of Challenged Claim 18

Claim 18 depends from claim 1 and recites "wherein said maximum lateral width of said implant is approximately 18 mm." Ex. 1001, 14:11–13. Petitioner argues that one of ordinary skill in the art would have been motivated to combine Frey, Michelson, and Berry. Pet. 29–32.

In particular for claim 18, Petitioner contends that Michelson teaches "'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.'" *Id.* at 41 (citing Ex. 1002 ¶ 183; Ex. 1032, 10:32–47). Petitioner also argues that a "narrower implant for lateral insertion would be easier to fit within the hollow tube Michelson describes to facilitate a minimally-invasive insertion into the disc space." *Id.* (citing Ex. 1002 ¶ 190; Ex. 1032, 3:61–65). Specifically for claim 18, Patent Owner responds that Petitioner fails to

show a motivation to combine the references (PO Resp. 42–45) and fails to show a maximum lateral width of approximately 18 mm (*id.* at 51–52).

Based on the full record, for the reasons below, Petitioner does not persuade us that claim 18 is unpatentable over Frey, Michelson, and Berry.

a) IPR2013-00507

Medtronic challenged claim 18 as obvious in view of Frey and Michelson. Ex. 1033, 7, 56–58. Patent Owner in IPR2013-00507 argued that Michelson does not disclose an implant that is both longer than 40 mm and 18 mm wide. Ex. 1004, 9. The Final Written Decision in IPR2013-00507 determined that:

> even if the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12–30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified Michelson's implant to have a length greater than 40 mm and a maximum width of 18 mm.

Id. at 10. On appeal, the Federal Circuit "affirm[ed] the Board's final written decision in IPR2013-507, . . . upholding claim 18." 841 F.3d at 974.

b) Petitioner Presents an Insufficient Reason for Combining Frey, Michelson, and Berry

Relevant to our analysis below, in deciding the appeal of IPR2013-00507, the Federal Circuit determined that

> [s]ubstantial evidence supports the Board's specific findings that (1) 'a spinal implant measuring up to 45 mm in length" would not render Frey "inoperable" for its intended purpose, even if Frey were limited to use in transforaminal lumbar interbody fusion (TLIF) procedures . . . ; (2) an implant could be longer than 40 mm and not violate the teaching of Frey that it fit within

> the inner-annulus region . . .; and (3) Michelson in fact teaches the relevant long-and-narrow implants.

NuVasive, 841 F.3d at 974. The Federal Circuit also determined that:

> [a]s to reasons to combine: The Board did not have to find a reason that a relevant artisan would combine the length of an implant from one prior-art reference with the length-to-width ratio of an implant from another reference, because it found that Michelson disclosed an implant meeting both limitations.

Id. The Federal Circuit further determined that Patent Owner did not present arguments

> (1) that a skilled artisan would never have made a long-and-narrow implant for any use other than as a component to be assembled into a single, oversized, modular implant; (2) that, given the state of modular implants at the time of the invention, no one would have tried to make one; and (3) that the boomerang-shaped Frey implant would not have been suitable to be modified to be modular.

Id. The Federal Circuit did not fault the Board for not considering these arguments because Patent Owner did not present them to the Board. *Id.*

According to Petitioner, one of ordinary skill in the art would have been motivated to combine Frey, Michelson, and Berry. Pet. 29–31. In particular, Petitioner argues that:

> To achieve the benefits of Michelson for a lumbar fusion, a [person of ordinary skill in the art] would have been motivated to make Frey's laterally-inserted spinal fusion implants long-and-narrow as taught by Michelson *for insertion in a modular fashion* through a hollow tube *to increase patient safety and minimize invasiveness*.

Id. at 30 (emphases added) (citing Ex. 1002 ¶ 150); *see also id.* at 29 (arguing the Federal Circuit concluded a person of ordinary skill in the art would have been motivated to combine Frey and Michelson) (citing Ex. 1002 ¶¶ 143–144, 148–150; Ex. 1005, 14–17), 29–30 (arguing that Frey

and Michelson are directed to and disclose spinal fusion implants) (citing Ex. 1002 ¶¶ 134, 136; Ex. 1032, 3:1–10, 3:33–53, 10:32–59, Fig. 18, 19, claim 1; Ex. 1040 ¶¶ 130, 150, 184, Fig. 47).

According to Petitioner, one of ordinary skill in the art "would have known the average length and width of human vertebrae," "would have been motivated to turn to Berry when developing the implants of Frey and Michelson," and "would have been motivated to reduce the width by half (for example) to make the implants modular, while maintaining the overall length that provides enhanced structural support." *Id.* at 30–31 (citing Ex. 1002 ¶ 202; Ex. 1022, 362–364; Ex. 1032, 10:20–59). Petitioner also argues that one of ordinary skill in the art "would have been motivated to combine the structural features of Frey and Michelson because both disclose, for example, implants having apertures for holding bone growth material to facilitate fusion" and "[t]hus, combining the elements of Frey and Michelson amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." *Id.* at 31 (citing Ex. 1002 ¶¶ 143–144, 148–150; Ex. 1032, claims 61, 69; Ex. 1040 ¶ 130).

(1) Patent Owner's Response

Patent Owner responds that Petitioner "fails to explain how inserting Frey's implant through a hollow tube—instead of as Frey's implants were designed—would increase patient safety and minimize invasiveness." PO Resp. 42 (citing Ex. 2055 ¶¶ 106–116). Patent Owner also responds that one of ordinary skill in the art "would not have been motivated to adopt the vertebral body dimensions of Berry as the implant dimensions for Frey's implant" because "Frey discloses that its implants fit within the annulus fibrosis" and one of ordinary skill in the art "would have understood Frey's implants should be smaller than 40 mm in length and smaller than

approximately 18 mm in width." *Id.* (citing Ex. 1040, Figs. 47, 55; Ex. 2040, Fig. 2; Ex. 2057 ¶¶ 16–19, 31–32). Patent Owner argues that "[t]rying to fit two 18 mm wide implants into the disc space is simply absurd." PO Resp. 43 (citing Ex. 2057 ¶ 19).

Turning to Petitioner's asserted reason for combining the references, Patent Owner responds that "Michelson does not disclose sequential insertion of modular members into the disc space but instead teaches assembly prior to insertion" and "discloses that the advantage of lateral implants is using a single implant and inserting it through a single procedure." *Id.* (citing Ex. 1032, 3:46–49). Patent Owner contends that "Michelson thus teaches that modular members can be 'combined in a modular fashion for insertion within the disc space'" and that "the modular members are combined before insertion into the disc space, not after." *Id.* (citing Ex. 1032, 10:50–53; Ex. 2055 ¶¶ 46–47; Ex. 2057 ¶¶ 32–34, 38).

Patent Owner also argues that "the proposed modification [to Frey] would undermine the proposed motivation" because "the proposed modification would only decrease safety and increase invasiveness." *Id.* at 43. Patent Owner asserts that "inserting Frey's implants through a hollow tube would require changing from a curved insertion path to a linear insertion path and would impair the integrity of Frey's implants during insertion, leading to unwanted breakage." *Id.* at 43–44 (citing Ex. 1032, 8:20–22; Ex. 1040 ¶ 139; Ex. 2022, 86:7–87:11, 119:10–13; Ex. 2055 ¶¶ 49, 90–96, 111–112; Ex. 2057 ¶¶ 16, 44–47). Patent Owner also asserts that employing a tube with a linear insertion pathway "would require increasing the diameter of the surgical pathway" and "a surgical path that matches the total distance between the anterior-most and posterior-most portions of the

implants." *Id.* at 44 (citing Ex. 1040 ¶¶ 116, 139, Figs. 29, 53; Ex. 2022, 85:21–24; Ex. 2055 ¶¶ 49, 112–113).

Patent Owner further asserts that "[i]nserting two implants through a single surgical path would result in the first implant blocking the pathway of the second implant" and "risk damaging the vertebral endplates." PO Resp. 44–45 (citing Ex. 1040 ¶¶ 140, 153). Patent Owner argues that a surgeon would not insert implants in such a manner and thus, would have to use two surgical pathways, which is more invasive. *Id.* at 45 (citing Ex. 2022, 97:10–98:24; Ex. 2055 ¶¶ 113–114).

Patent Owner additionally asserts that Frey's implants are not well-suited for nesting or coupling because of their concavity, "would not provide a stable and even support for the vertebral bodies," and "would alter the natural curvature of the spine." *Id.* (citing Ex. 2055 ¶¶ 115–116).

(2) Petitioner's Reply

Petitioner replies that Frey "expressly teaches that '[i]nserter instrument 1500 can also be used to position ***multiple implants at various locations in the disc space***, and also for ***insertion of one or more implants*** from other approaches to the disc space,' including laterally" and "it is contemplated that the ***implants***, instruments and methods ***may be used through guide sleeves or tubes*** to provide greater protection to adjacent tissues, to reduce the size of access incisions, to provide direct visualization of the surgical site, and/or to provide greater control of the method." Pet. Reply 9 (emphases in original) (responding to PO Resp. 42, 43; Ex. 1051, 40:20–41:7; Ex. 2055 ¶ 109; Ex. 2057 ¶ 109) (citing Ex. 1040 ¶¶ 150, 160, 183, 184). Petitioner also replies that it never suggested inserting an implant up to 37.9 mm wide, as stated by Patent Owner's declarant. *Id.* at 9–10

(responding to PO Resp. 42; Ex. 1051, 15:7–16, 38:4–10, 53:6–23, 54:2–13; Ex. 2057 ¶ 19).

Petitioner further replies that Patent Owner "mischaracterizes Michelson, which states that Figure 19 shows 'a ***plurality*** of the spinal ***implants*** of FIG 18 . . . inserted from the lateral aspect in a modular fashion in the disc space.'" Pet. Reply 10 (responding to PO Resp. 43) (citing Ex. 1032, 3:62–64, 5:34–39, 10:56–59). Petitioner contends that "[i]f modular components must be assembled before insertion, there is no use for implant 1000, which 'has a narrower width' than implant 900." *Id.* (citing Ex. 1032, 10:52). Petitioner argues that one of ordinary skill in the art would have known of implants in a side-by-side relationship so would have been able to insert Petitioner's proposed modified implant through a hollow tube. *Id.* at 10–11 (citing Ex. 1053, 10:10–16, Figs. 13B, 14B).

(3) Patent Owner's Sur-reply

Patent Owner replies that Petitioner does not explain why modularity would increase safety and minimize invasiveness. PO Sur-reply 6–7 (citing Pet. 2–3, 5, 12, 30, 41, 47, 62). Patent Owner asserts that although Dr. Branch's assumption is that Michelson teaches sequential insertion, Patent Owner argues, Michelson does not teach sequential insertion. *Id.* at 7 (citing PO Resp. 14–15; Ex. 2022, 121:15–122:7). According to Patent Owner, Michelson teaches inserting the modular implant as a single implant. *Id.* (citing Ex. 1032, 10:50–53).

Patent Owner also replies that increased safety and minimized invasiveness has not been shown and that "Petitioner provides no meaningful rebuttal." *Id.* at 7–8 (citing PO Resp. 43–45, 53–54; Ex. 2055 ¶ 109). Patent Owner argues that Petitioner incorrectly and without support

contends that Frey and Michelson teach modular implants. *Id.* at 8 (citing Pet. 5, 29–30; Pet. Reply 9; Ex. 1040, Fig. 46).

Patent Owner also replies that Petitioner's argument that there is no use for implant 1000 if assembling modular components before insertion is not supported by evidence and contradicted by Drs. McMillin and Youssef "who explained that modular implants were contemplated for assembling an implant with optimal dimensions by pre-insertion combination of off-the-shelf modules." PO Sur-reply 9 (citing Pet. Reply 10; Ex. 1007, 2:34–43; Ex. 1050, 45:23–46:9; Ex. 1051, 20:17–21:8). Patent Owner also contends that arguments relying improperly on Exhibit 1054 "has nothing to do with the modularity of Michelson." *Id.* at 10 (citing Pet. 5, 30, 47; Pet. Reply 10).

Patent Owner additionally argues that Petitioner improperly relies on Exhibits 1053 and 1054. Paper 42, 1.

(4) Petitioner's Asserted Reason to Combine Lacks a Rational Underpinning

Petitioner argues that one of ordinary skill in the art would have been motivated to modify Frey's implant "for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness." *See* Pet. 29–31 (presenting a "Motivation to Combine Frey and Michelson and Berry" in the section titled "Ground 1: claims 6–9 and 18 are rendered obvious by Frey in view of Michelson and Berry"); *see also* Pet. Reply 10 (arguing that Patent Owner mischaracterizes Michelson as not teaching sequential insertion).

Patent Owner argues that "Michelson does not disclose sequential insertion of modular members into the disc space but instead teaches assembly prior to insertion" and "discloses that the advantage of lateral

implants is using a single implant and inserting it through a single procedure." PO Resp. 43 (citing Ex. 1032, 3:46–49).

For the reasons below, because Michelson teaches the insertion of a single implant but does not teach the sequential insertion of several implants, we determine that Michelson does not teach sequential insertion of modular components of an implant. Therefore, we find that Petitioner's reason for combining Frey, Michelson, and Berry lacks a rational underpinning.

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

Turning first to whether Michelson teaches inserting a single implant, 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. 30 (quoting from Ex. 1032, 10:48–59). In response, Patent Owner points to column 10, lines 50–53, paragraphs 46–47 of Dr. Youssef's declaration, and paragraphs 32–34 and 38 of Dr. McMillan's declaration. PO Resp. 42–43.

Patent Owner's declarants Dr. Youssef and Dr. McMillin point 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 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'"), ¶ 143 (quoting Ex. 1032, 3:35–53); Ex. 2022, 105:11–17 (Petitioner's declarant 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. 1032, 3:46–49; 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 (Petitioner's declarant 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, 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 ¶ 46 (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 ¶ 48.

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 (Petitioner's declarant 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 Petitioner's declarant Dr. Branch quotes column 3, lines 46–52 of Michelson in several paragraphs related to the challenge based on Frey, Michelson, and Berry, 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 ¶¶ 136, 143, 183. 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 ¶¶ 46–48; 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 "to make Frey's laterally-inserted spinal fusion implants long-and-narrow as taught by Michelson *for insertion in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness." Pet. 30 (emphasis added) (citing Ex. 1002 ¶ 150). Dr. Branch also uses the phrase "for insertion in a modular fashion" in his declaration. *See* Ex. 1002 ¶ 150 (Dr. Branch stating that a person of ordinary skill in the art "would have been motivated to make Frey's laterally-inserted spinal fusion implants long-and-narrow as taught by Michelson for *insertion in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness") (emphasis added), ¶ 190 (Dr. Branch stating for claim 18 that a person of ordinary skill in the art "would have been motivated to make Frey's laterally-inserted spinal fusion implants long-and-narrow as taught by Michelson 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 long-and-narrow Frey implants would be combined before insertion or after insertion. *See* Pet. 30; Ex. 1002 ¶¶ 150, 190. However, in its Reply, Petitioner asserts that Patent Owner "mischaracterizes Michelson" because "Patent Owner argues that 'Michelson does not disclose sequential insertion of modular members into the disc space but instead teaches assembly prior to insertion.'" Pet. Reply 10 (citing PO Resp. 43; Ex. 1032, 3:62–64, 5:34–39, 10:56–59).

Patent Owner contends that Michelson teaches combining before, not after, insertion, and thus, cannot teach sequential insertion of modular members. PO Resp. 42. 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 ¶¶ 46, 48; Ex. 2057 ¶ 33; *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), 127–194 (opining that Frey, Michelson, and Berry would have rendered obvious claims 6–9 and 18). 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 follow the teachings of Frey to insert more than one Frey implant in a modular fashion." Ex. 1002 ¶ 148. The previous paragraph of Dr. Branch's declaration quotes the last sentence from Frey's paragraph 160 that states "[i]nserter instrument 1500 can also be used to position multiple implants at various locations in the disc space, and also for insertion of one or more implants from other approaches to the disc space." *Id.* ¶ 147 (citing Ex. 1040 ¶ 160); Ex. 1040 ¶ 160.

Patent Owner also contends that inserting Frey's implants in a modular fashion would be less safe and would increase invasiveness, contrary to Petitioner's reason for the modification, because the proposed modification increases the possibility that the implant would break, increases the diameter of the tube for insertion, and increases the risk of endplate damage. PO Resp. 43–45 (citing Ex. 1032, 8:20–22; Ex. 1040 ¶¶ 116, 139, 140, 153, Figs. 29, 53; Ex. 2022, 85:21–24, 86:7–87:11, 119:10–13; Ex. 2055 ¶¶ 49, 90–96, 111–113; Ex. 2057 ¶¶ 16, 44–47).

Based on the full record, even if Frey 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 ¶¶ 46–48; Ex. 2057 ¶¶ 33–34. Petitioner does not address why one of ordinary skill in the art would insert Frey's implant in a modular fashion in view of Michelson's teaching to insert a single implant in a single procedure. *See* Pet. 29–43; Pet. Reply 8–13; 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).

In view of the weight of the evidence, Petitioner does not persuade us that the inserting narrower implants would necessarily increase safety because we find that Michelson does not teach sequential insertion of modular components let alone that sequential insertion of modular components 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 was not done at the time, more invasive, and less safe); Ex. 2057 ¶ 16 (Dr. McMillan testifying that serial insertion of modular members would be unsafe and more invasive).

Even if Petitioner's proposed modification "for insertion in a modular fashion" were to include two Frey implants modified to be long and narrow as taught by Michelson and assembled *before* insertion, Petitioner does not persuade us that the proposed modification would necessarily "minimize invasiveness." *See* Pet. 29–31; *see also* Pet. Reply 10 (arguing that one of ordinary skill in the art would have known of implants "being used in a side-by-side relationship inserted generally laterally or anterolaterally into the spine." Petitioner implies that two modified Frey implants would be in a side-by-side relationship in the spine, but, if they were assembled before insertion, in view of Michelson's teaching of a single implant assembled before insertion, they would have to be larger than any one of the non-modified Frey implants, and require a larger insertion pathway, which is

contrary to Petitioner's contention that the proposed modification would "minimize invasiveness." Pet. 30.

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" and 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 ¶¶ 46–48, 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* PO Resp. 42 (arguing Petitioner "fails to explain how inserting Frey's implant through a hollow tube—instead of as Frey's implants were designed—would increase patient safety and minimize invasiveness"); Pet. Reply 11 (arguing that "Patent Owner's theory that a [Person of Ordinary Skill in the Art ("POSA")] would not be able to insert Frey in view of Michelson and Berry through a hollow tube is baseless"). 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. 42–45; Pet. Reply 9–11; PO Sur-reply 6–10; *see also* Ex. 1002 ¶ 112 (testifying that Michelson's implant is inserted in a translateral approach to the spine).

In support of the asserted motivation to combine, Petitioner points to paragraph 150 of Dr. Branch's declaration where Dr. Branch relies on column 3, lines 61–65 of Michelson. Pet. 30; Ex. 1002 ¶ 150. The relied-upon portion of Michelson states 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 a single translateral spinal fusion implant that may be inserted into the disc space through a hollow tube, which is engaged to the lateral aspect of the spine through, at least, a lateral incision making the procedure safe and simple. *See* Ex. 1032, 3:46–49, 3:61–65. We, thus, find that Michelson's safety arises from "insert[ing] 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." *See id.* at 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); *see also* Ex. 2057 ¶¶ 44–47 (describing problems with inserting modified Frey implants through a tube).

Therefore, based on the full record, we find that Michelson's "insertion in a modular fashion" is the feature that makes a procedure safe and simple or that safety arises necessarily from making an implant long and narrow. Pet. 30; Ex. 1002 ¶¶ 112, 114, 115; Ex. 1032, 3:46–49, 3:61–65; Ex. 2055 ¶¶ 90–96; Ex. 2057 ¶¶ 16, 44–47; *see also* Ex. 2022, 97:10–98:24 (Dr. Branch discussing the considerations for inserting a second implant).

Instead, as discussed above, Michelson's teachings on lateral insertion through a hollow tube is the feature that makes the implants safer.

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

As discussed above, Petitioner modifies Frey's implant in view of Michelson and Berry. Pet. 29–31. In the portions of Dr. Branch's declaration cited for support of the proposed modification, Dr. Branch states that one of ordinary skill in the art "would follow the teachings of Frey to insert more than one Frey implant in a modular fashion and nest the implants together to better fill the depth of the vertebral space." Ex. 1002 ¶ 148. Petitioner relies on Berry only for "the average length and width of human vertebrae" known to ordinary skilled artisans at the time of invention, which is not related to modularity. Pet. 30–31.

We determine that neither Frey nor Berry provide support for making "laterally-inserted spinal fusion implants long-and-narrow . . . for insertion in a modular fashion through a hollow tube to increase patient safety and minimize invasiveness." *Id.* at 30.

(e) Determining Petitioner's Reason Lacks a Rational Underpinning

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 Frey's laterally-inserted spinal fusion implants long-and-narrow as taught by Michelson *for insertion in a modular fashion* through a hollow tube to increase patient safety and minimize invasiveness." Pet. 30 (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 Frey's implant long and narrow "*for insertion in a modular fashion* through a hollow tube *to increase patient safety* and minimize invasiveness." Pet. 30 (emphases added); Ex. 1032, 3:46–52, 10:48–54; Ex. 2055 ¶¶ 46–48; Ex. 2057 ¶¶ 33, 34; Ex. 2022, 105:11–106:2. Because Michelson does not teach sequential insertion of modular components to form the implant in the disc space, Michelson also does not support Petitioner's proposed modification to make Frey's implant long and narrow "for insertion in a modular fashion . . . increase[s] patient safety and minimize[s] invasiveness." Pet. 30; Ex. 1032, 3:46–54, 3:61–65, 10:50–54; Ex. 2055 ¶¶ 46–48, 90–96; Ex. 2057 ¶¶ 16, 33, 34.

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 for making Frey's implant long and narrow "for insertion in a modular fashion . . . to increase patient safety." Pet. 30; Ex. 1002 ¶¶ 112, 114, 115; Ex. 1032, 3:46–49, 3:61–65; Ex. 2055 ¶¶ 90–96; Ex. 2057 ¶¶ 16, 44–47. Additionally, neither Frey nor Berry provide, or are relied upon to provide, a rational underpinning for Petitioner's proposed modification. Pet. 29–31.

For the reasons above, the evidence in the full record does not support Petitioner's alleged motivation for the proposed modification. We, therefore, determine that Petitioner's rationale lacks a rational underpinning.

Furthermore, Petitioner's contention that the proposed combination is "nothing more than rearranging known mechanical elements to achieve a predictable result" does not provide a rationale for one of ordinary skill in the art to change the dimensions of known mechanical elements. Pet. 31. As discussed above, the disclosed dimensions of Frey and Michelson do not

teach or suggest an implant of greater than 40 mm with a maximum lateral width of approximately 18 mm, as recited by claim 18. Ex. 1004, 10 (stating "even if the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12–30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm"); Ex. 1005, 17 ("affirm[ing] the Board's final written decision in IPR2013-507 . . . upholding claim 18").

8. Objective Indicia of Nonobviousness

a) Nexus

For objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). "[T]here is no nexus unless the evidence presented is 'reasonably commensurate with the scope of the claims.'" *Id.* (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)).

A patentee is entitled to a presumption of nexus "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))). "[T]he purpose of the coextensiveness requirement is to ensure that nexus is only presumed when the product tied to the evidence of secondary considerations 'is the invention disclosed and claimed.'" *Id.* at 1374 (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)).

"[T]he degree of correspondence between a product and the patent claim falls along a spectrum. At one end of the spectrum lies perfect or near perfect correspondence. At the other end lies no or very little correspondence." *Id.* "A patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality." *Id.* at 1375.

However, "[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations." *Fox Factory*, 944 F.3d at 1375. "To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)); *see also Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020) (designated precedential) (applying the same two-step analysis of *Fox Factory*). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention," meaning that "there must be a nexus to some aspect of the claim not already in the prior art." *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original). On the other hand, there is no requirement that "objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, "that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id.* Ultimately, the fact

finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. *Id.* at 1331–32.

Petitioner states that it "is unaware of any secondary considerations that demonstrate nonobviousness" and contends that, in IPR2013-00507, the Board found no nexus between the challenged claims and the proffered evidence. Pet. 74–75 (citing Ex. 1004, 11–12).

Patent Owner states that the "CoRoent® XL implants are encompassed by the challenged claims and have overcome industry skepticism to achieve tremendous commercial success" and that "Petitioner has sought to take advantage of the market dominance of CoRoent® XL implants by marketing a blatant copy." PO Resp. 65–66; *see also id.* at 67 (arguing that CoRoent® XL implant falls within scope of challenged claims) (citing Ex. 2055 ¶¶ 172–174; Ex. 2059 ¶ 9). Patent Owner describes the development of the XLIF product line that includes CoRoent® XL implant. *Id.* at 66 (citing Ex. 2059 ¶¶ 4–8).

Petitioner replies that "success of XLIF is irrelevant because, as Patent Owner concedes, the CoRoent® XL implant is not coextensive with XLIF, and Patent Owner does not isolate the contribution owed to CoRoent® XL." Pet. Reply 18. According to Petitioner,

> Patent Owner's President Matthew Link defines XLIF as the products and technologies associated with a series of retractor systems; dilating tools associated with a retractor system; some components of an automatic nerve physiology system; instrumentation associated with spinal anatomy; and a number of interbody devices and fixation options for the lateral procedure

and "[e]xcept for CoRoent XL, none of these are tied to the challenged claims." *Id.* (citing Ex. 1052, 17:10–18:4, 20:14–21:3). Petitioner also

argues that an XLIF procedure includes access tools, implants, and neuromonitoring and "[i]t is undisputed that the challenged claims do not relate to access tools and neuromonitoring" so that unclaimed features are responsible for the success of XLIF. *Id.* at 18–19 (citing Ex. 1061, 2; Ex. 2055 ¶ 84).

Patent Owner replies that Petitioner has failed to show that the asserted commercial success was "driven by any of these factors." PO Sur-Reply 17–18 (citing PO Resp. 68; Pet. Reply 18–19). Patent Owner also argues that Petitioner "has admitted nexus between the CoRoent XL implant and the challenged claims, and that evidence alone is strong evidence of non-obviousness." *Id.* at 17.

Regarding whether the asserted objective evidence is tied to a specific product and whether the product embodies the claimed features and is coextensive with them, Patent Owner presents only the CoRoent XL implant as the specific product embodying claimed features and coextensive with the challenged claims. PO Resp. 65–66; 67 (citing Ex. 2055 ¶¶ 172–174; Ex. 2059 ¶ 9). Dr. Youssef states that the "CoRoent XL implant comes in various sizes, including those with a longitudinal length . . . of 40 mm, 45 mm, 50 mm, and 55 mm" and identifies only those implants with longitudinal length of 40 mm, 45 mm, 50 mm, and 55 mm as embodying the limitation "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," recited by claim 1. Ex. 2055 ¶ 173. Dr. Youssef identifies a subset of those for embodying "wherein said longitudinal length is at least two and half times greater than said maximum lateral width." *Id.* In particular, according to Dr. Youssef, "[t]he CoRoent XL implant comes in various sizes, including those where the maximum lateral width is 18 mm

and where the longitudinal length is at least two and half times greater than said maximum lateral width, such as 50 mm and 55 mm." *Id.* Dr. Youssef does not identify any other size of the CoRoent® XL implant for that particular limitation of claim 1. *See id.* Mr. Link refers to Dr. Youssef's testimony regarding whether the CoRoent® XL implant embodies features of the challenged claims and is coextensive with them. Ex. 2059 ¶ 9.

Based on Patent Owner's evidence, we determine that, because claims 6–9 include the limitations of claim 1 by dependency, only CoRoent® XL implants of 50 mm and 55 mm longitudinal length embody at least the features of claim 1 incorporated into claims 6–9 and are coextensive with them. As discussed above, for claim 18, Petitioner does not show that one of ordinary skill in the art would have combined Frey, Michelson, and Berry in the manner asserted for the reasons asserted by Petitioner. Thus, we turn to each of Patent Owner's asserted objective indicia of nonobviousness and further analyze nexus between claims 6–9 and each of the asserted indicia.

b) Skepticism

Patent Owner argues that there was skepticism regarding the CoRoent® XL implant because surgeons were concerned that a safe surgical window would not be large enough for an 18 mm wide CoRoent® XL implant and thus there was doubt about the safety and efficacy of XLIF products. PO Resp. 67 (citing Ex. 2036, 102:25–103:11; Ex. 2052 ¶ 7; Ex. 2059 ¶¶ 10–12).

Petitioner replies that "the 18 mm implant size, contrary to Patent Owner's suggestion, was smaller than several known and disclosed spinal implants," Patent Owner's "evidence cited is misplaced," "[t]o the extent it shows any doubt about the size of the implant, (it does not), that doubt

related to the ***access path***," and "Patent Owner cited no evidence showing skepticism tied directly to the 18 mm size." Pet. Reply 19.

Patent Owner replies that "Petitioner does not rebut testimony from its own employee that the industry was skeptical of an 18-mm wide lateral implant" and that an "implant having a maximum A-P dimension of 18 mm was simultaneously viewed as being too small to adequately support the full weight conveyed through the spine and also being too wide to be inserted through a direct lateral approach between the L4 and L5 vertebrae, as proposed by Petitioner." PO Sur-Reply 18 (citing Pet. Reply 19).

Claims 6–9 are directed towards an implant with a medial support positioned along a central region or an implant with a second fusion aperture separated from a first fusion aperture by a medial support. Ex. 1001, 13:17–29. They do not require any particular measurement for the width of the claimed implant. *See id.*

"Evidence of industry skepticism weighs in favor of nonobviousness." *WBIP*, 829 F.3d at 1335. An example of such evidence is "evidence that an audience of over 200 people at an industry workshop . . . expressed shock when" the results achieved by the claimed invention were announced, or that people told the inventor that "it was impossible to produce" the claimed invention. *Id.*

Here, the evidence of record regarding skepticism and CoRoent® XL implants of 50 mm and 55 mm length and 18 mm width is weak. For example, according to Dr. Youssef, however, CoRoent® XL implants of 50 mm and 55 mm length and 18 mm width embody the limitations of claim 1. Ex. 2055 ¶ 173. Even so, Patent Owner's evidence of skepticism is mostly directed to the procedure, not the implant itself and does not indicate widespread skepticism that an implant of the claimed structure and

dimension was impossible to produce or insert safely during surgery. *See* PO Resp. 67 (citing Ex. 2036, 102:25–103:11; Ex. 2052 ¶ 7; Ex. 2059 ¶¶ 10–12). Patent Owner points to Mr. Link's declaration. Paragraphs 10 and 11 of Mr. Link's declaration state that "many surgeons did not believe that spinal fusion surgery via a lateral, trans-psoas approach could be done safely and reproducibly" and that "surgeons were concerned that the safe surgical window was not sufficiently large to accommodate such a wide implant for lateral surgery." Ex. 2059 ¶¶ 10, 11 (citing Ex. 2036, 102:25–103:11). Paragraph 12 describes how the asserted skepticism was overcome. *Id.* ¶ 12. This proffered declaratory evidence is directed more at the skepticism regarding the approach and safe surgical window, not particularly directed at CoRoent® XL implants of 50 mm and 55 mm length and 18 mm width.

The remaining proffered testimonial evidence relate to the size of an implant and do not address specifically the features recited by claims 6–9, such as the medial support or second fusion aperture. The deposition of Mr. Link indicates that larger implants "would put more pressure on the nerves in that muscle that you're traversing." Ex. 2036, 102:25–103:11; *see also* Ex. 2059 ¶ 11 (quoting Ex. 2036, 102:25–103:11). Patent Owner also points to a declaration from IPR2013-00507 that states "NuVasive's XLIF solution was met with substantial skepticism within the spinal orthopedics community, including concern over the size of our implant." Ex. 2052 ¶ 7.

Further, even considering the size of the implants embodying claims 6–9, the testimonial evidence does not discuss in particular CoRoent® XL implants with longitudinal lengths of 40 mm, 45 mm, 50 mm, or 55 mm. Patent Owner does not show how the evidence of skepticism specifically relates to CoRoent® XL implants of 50 mm and 55 mm longitudinal length, which we determined above embody at least the features of claim 1

incorporated into claims 6–9 and are coextensive with them. The proffered testimonial evidence does not discuss any particular size of CoRoent® XL implants. Ex. 2052 ¶ 7.

We are not persuaded by the asserted evidence of skepticism because it is not specific to the products embodying claims 6–9 nor is it sufficient to support that there was expert or industry skepticism of particular products. For the reasons above, we determine that Patent Owner does not sufficiently show a nexus between challenged claims 6–9 and the purported evidence of skepticism.

c) Commercial Success

Patent Owner argues that the CoRoent® XL implant is a commercial success because XLIF products were the "only minimally invasive lateral procedure commercially available to surgeons until 2006," "Patent Owner leads the minimally invasive lateral spinal fusion commercial market it created," and the CoRoent® XL implant generates about $400 million in revenue. PO Resp. 67–68 (citing Ex. 2052 ¶¶ 6, 9, 10; Ex. 2059 ¶¶ 13, 16).

Petitioner replies that "Patent Owner relies on the purported success of the XLIF procedure, which Dr. Youssef admits is due to several unclaimed features" and "much of XLIF's success is owed to Patent Owner's extensive surgeon education and training." Pet. Reply 19 (citing Ex. 1065, 2–5, 8). Patent Owner replies that it "provided sales figures specifically for the 18 mm wide CoRoent XL implant" and that "Petitioner has failed to demonstrate that the specific sales figures . . . are driven by any of these factors." PO Sur-Reply 17–18 (citing PO Resp. 68; Pet. Reply 18–19).

Claims 6–9 are directed towards an implant with a medial support positioned along a central region or an implant with a second fusion aperture

separated from a first fusion aperture by a medial support. Ex. 1001, 13:17–29. Patent Owner argues that commercial success was due to a "minimally invasive procedure" and the sale figures are related to the "18 mm wide CoRoent XL implant." *See* PO Resp. 67–68; PO Sur-reply 17–18. Patent Owner does not argue that commercial success was due to an implant with a medial support positioned along a central region or an implant with a second fusion aperture separated from a first fusion aperture by a medial support, as recited by claims 6–9. *See* PO Resp. 67–68; PO Sur-reply 17–18. Further, Patent Owner's evidence of commercial success does not discuss what portion of sales were for CoRoent® XL implants of 50 mm and 55 mm longitudinal length, which we determined above embody at least the features of claim 1 incorporated into claims 6–9 and are coextensive with them.

For the reasons above, Patent Owner does not show sufficiently a nexus between challenged claims 6–9 and the alleged evidence of commercial success.

d) Copying

Patent Owner contends that Petitioner offered around 2008 a very different lateral product that was designed to compete with XLIF but Petitioner's product did "gain[] any real traction in the market." PO Resp. 68 (citing Ex. 2059 ¶ 17). According to Patent Owner, "Petitioner changed its approach in 2017 and began marketing the Battalion™ Lateral Access System" that is "very similar to XLIF" and "encompassed by the challenged claims." *Id.* at 69 (citing Ex. 2055 ¶¶ 175–178; Ex. 2059 ¶¶ 18–21).

Patent Owner relies on paragraphs 175–178 of Dr. Youssef's declaration and paragraphs 17–21 of Mr. Link's declaration. *See* PO Resp. 68–69 (citing Ex. 2055 ¶¶ 175–178; Ex. 2059 ¶¶ 18–21). Dr. Youssef's testimony regarding the alleged copying analyzes whether

Petitioner's Battalion™ Lateral Access Spacer embodies claims 6–9 and 18 of the '334 patent. *See* Ex. 2055 ¶¶ 175–178. Mr. Link's testimony regarding alleged copying points to the hiring of Mr. Miles before launch of the Battalion™ Lateral Access System, similarities based on personal review, a side-by-side comparison of Petitioner's and Patent Owner's implants, and Dr. Youssef's testimony that Battalion™ Lateral Spacers are within the scope of claims 1 and 16. *See* Ex. 2059 ¶¶ 17–21.

Petitioner replies that Patent Owner's only evidence of copying are its infringement assertions, which are insufficient, and that "Patent Owner has no evidence Petitioner copied, which, in any case, cannot overcome the strong prima facie case of obviousness." Pet. Reply 19–20. Patent Owner replies that "Petitioner elected to market implants that are strikingly similar to the CoRoent XL implant," "no such implant is found in the prior art," and "Petitioner's copying of NuVasive's product provides strong evidence of nexus and of non-obviousness." PO Sur-Reply 18 (citing PO Resp. 68–69; Pet. Reply 19–20).

Based on the full record, Patent Owner has not pointed to any evidence showing that Petitioner copied Patent Owner's implant after expending great effort to develop their own solution. *See Pentec, Inc. v. Graphic Cntrls. Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985) (alleged copying is not persuasive of nonobviousness when the copy is not identical to the claimed product, and the other manufacturer has not expended great effort to develop its own solution); *Vandenberg v. Dairy Equip. Co., a Div. of DEC Int'l, Inc.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984) (evidence of copying found particularly persuasive where copyist had itself attempted for a substantial length of time to design a similar device, and failed). Further, a showing of copying requires evidence of efforts to replicate a specific product, which

may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product. *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004).

For the reasons above, we determine that the declaratory evidence submitted by Patent Owner are insufficient to establish that Petitioner copied Patent Owner's implant after expending great effort to develop their own solution.

9. 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, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Frey, Michelson, and Berry teach or suggest all the limitations of claims 6–9, (3) claims 6–9 represent "rearranging known mechanical elements to achieve a predictable result," and (4) there is insufficient demonstration of nexus to the alleged skepticism and commercial success and insufficient showing of copying after expending great effort. For claim 18, we determine that Petitioner's

reason for modifying Frey in view of Michelson and Berry lacks a rational underpinning. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claims 6–9, but not claim 18, of the '334 patent are unpatentable over Frey, Michelson, and Berry.

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

Petitioner does not assert estoppel based on the asserted combination of Brantigan, Baccelli, Berry, and Michelson over claim 1. *See generally* Pet.; *see also* PO Resp. 53 (stating that the "petition did not assert estoppel arising from the cancellation of claim 1 regarding Ground 2").

1. Scope and Content of the Asserted Prior Art

Michelson (Ex. 1032) and Berry (Ex. 1022) 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.

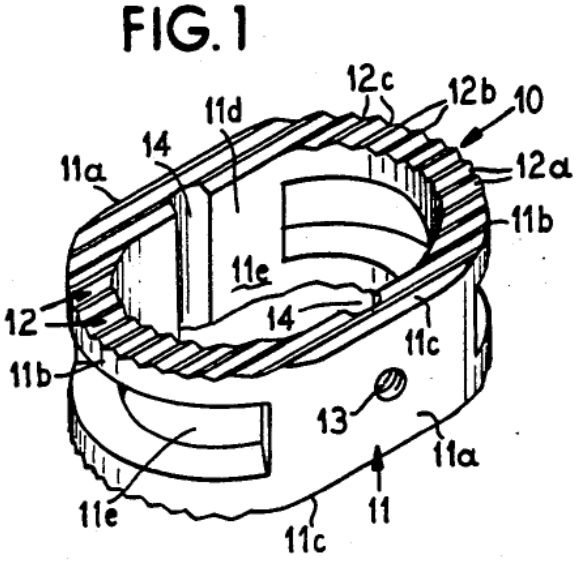


Figure 1 shows a perspective view of a full oval prosthetic device. *Id.* at 3:21–22. Oval ring plug 11 has opposed sides 11*a*, ends 11*b*, top and bottom surfaces 11*c*, and central upstanding aperture 11*d*.[7] *Id.* at 4:5–10. Top and bottom surfaces 11*c* have ridges 12 for engaging adjacent vertebrae. *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

[7] 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).

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 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.

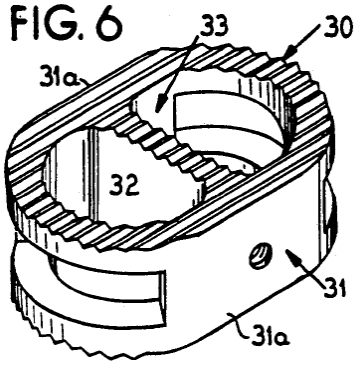
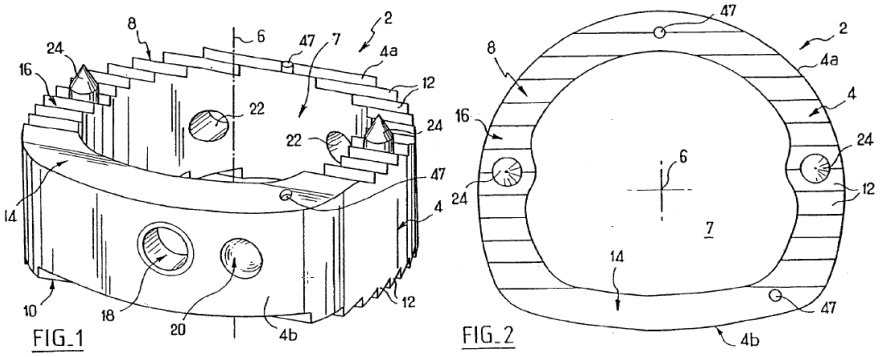


Figure 6 shows a perspective view of a modified device with an integral cross bar. *Id.* at 3:21–22, 3:36–37, Fig. 6. Modified device 30 is plug 31 with the same shape as plug 11 but has reinforcing bar 32 integral

with side walls 31*a*. Integral internal partition 32[8] bisects hollow interior 23[9] (not shown) forming "side-by-side apertures through the plug adapted to receive bone graft material." *Id.* at 5:37–43, Fig. 6.

b) 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

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

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. Analysis of Challenged Claims 6–9 and 18

Petitioner argues that Brantigan in view of Baccelli, Berry, and Michelson would have rendered obvious claims 6–9 and 18. Pet. 43–74. According to Petitioner:

> To achieve the benefits of Michelson, a [person 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 47–48 (emphases added) (citing Ex. 1002 ¶ 201; Ex. 1032, 3:61–65); *see also id.* at 43–48 (presenting a "Motivation to Combine Brantigan with Baccelli, Berry, and Michelson" in the section titled "Ground 2: Claims 6–9 and 18 are rendered obvious by Brantigan in view of Baccelli, Berry, and Michelson"). The arguments and evidence presented for the challenge based on Brantigan rely on Michelson in a manner substantially similar to that in the asserted motivation to combine Frey, Michelson, and Berry. *Compare id.* at 43–48, *with id.* at 29–31, 40–43.

Patent Owner argues that Petitioner "fails to explain how this would increase patient safety or minimize invasiveness and Brantigan does not disclose sequential insertion of modular members into the disc space but instead teaches assembly prior to insertion." PO Resp. 53 (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 ¶¶ 60–65, 144–147; Ex. 2057 ¶¶ 35–40). Patent Owner's responsive arguments and

evidence are similar to those presented for the challenge based on Frey. *Compare id.* at 53, *with id.* at 42–45.

For the reasons above, because we find that Michelson teaches the insertion of a single implant and does not teach the sequential insertion of several implants, we determine that Petitioner's reason for combining Brantigan, Baccelli, Berry, and Michelson also lacks a rational underpinning.

3. Weighing the Graham *Factors*

Based on full record before us and weighing our findings, 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 that its articulated reasoning for combining the asserted references has a rational underpinning. *Arctic Cat*, 876 F.3d at 1361.

Accordingly, Petitioner does not show by a preponderance of the evidence that claims 6–9 and 18 of the '334 patent are unpatentable over Brantigan, Baccelli, Berry, and Michelson.

III. CONCLUSION[10]

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
6–9, 18	103	Frey, Michelson, Berry	6–9	18
6–9, 18	103	Brantigan, Baccelli, Berry, Michelson		6–9, 18
Overall Outcome			6–9	18

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 6–9, but not claim 18, of U.S. Patent No. 8,187,334 B2 have 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.

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[10] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

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