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Paper 19
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

NUVASIVE, INC.,
Patent Owner.

Case 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.*

DECISION TO INSTITUTE
35 U.S.C. § 314

I. INTRODUCTION

Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 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, "Prelim. Resp."). Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and Preliminary Response and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. In particular, we institute an *inter partes* review of all challenged claims on all presented challenges, and thus, institute an *inter partes* review of claims 6–9 and 18 of the '334 patent.

II. BACKGROUND

A. Related Proceedings

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

Patent Owner additionally notes that the '334 patent was previously challenged in Cases IPR2013-00507 and IPR2013-00508. Paper 4, 2 (citing *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016)); *see also* Pet. 1 (stating that "the Federal Circuit affirmed the Board's finding in IPR2013-00507

(Ex. 1004) that sole independent claim 1 of the '334 patent and eighteen dependent claims (2–5, 10, 11, 14, 15, and 19–28) are invalid"). The parties also state that a related patent is challenged in Case IPR2019-00362. Pet. 75; Paper 4, 2.

B. 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, [22], [45], [60], [63], 1:7–13.

The '334 patent particularly relates to "a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction . . . to introduce the spinal fusion implant into any of a variety of spinal target sites." *Id.* at 1:18–21. Figure 2 of the '334 patent is reproduced below.

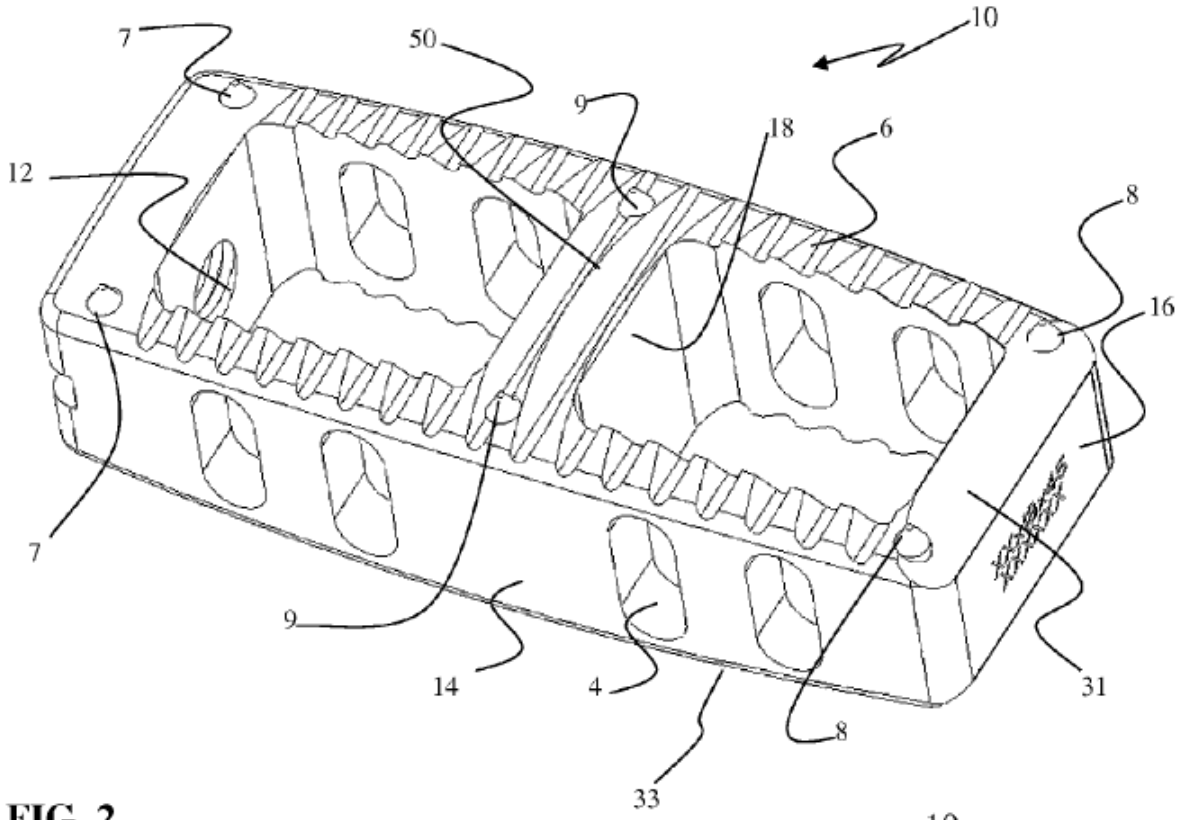


FIG. 2 10

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

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

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

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

C. Illustrative Claim

The '334 patent has 28 claims and its claim 18 was found patentable and claims 1–5, 10, 11, 14, 15, and 19–28 were cancelled in IPR2013-00507. 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 (emphases added), 13:17–19, 14:11–13.

D. Evidence Relied Upon

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

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

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

(3) U.S. Patent Application Publication No. US 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, 27–28.

E. Asserted Grounds

Petitioner challenges, under 35 U.S.C. § 103, claims 6–9 and 18 as unpatentable over (1) Frey, Michelson, and Berry; and (2) Brantigan, Baccelli, Berry, and Michelson. Pet. 21–22, 29–74.

III. 35 U.S.C. § 325(d)

Patent Owner requests denial of institution under 35 U.S.C. § 325(d) because Petitioner incorrectly argues that its presented grounds are not cumulative. Prelim. Resp. 15 (citing Pet. 25–26), 23. Patent Owner provides a summary of the prosecution history of the application that issued as the '334 patent, its parent application, and a related application. *Id.* at 12–15.

Patent Owner also provides its analysis of the factors identified in *Becton, Dickinson & Co. v. B. Braun Melsungen AG,* Case IPR2017-01586, slip op. at 16–18 (PTAB Dec. 15, 2017) (Paper 8) (informative). *Id.* at 15–23. Patent Owner's analysis is based on, *inter alia*, the alleged extensive consideration of Brantigan, Berry, and Michelson; the cumulative nature of Brantigan, Baccelli, and Frey; the overlap of Petitioner's radiopaque marker configuration arguments with arguments considered during prosecution; Petitioner's failure to identify Examiner error; and Petitioner's failure to provide new evidence to warrant reconsideration. *See id.*

The bases for Patent Owner's arguments relate to radiopaque markers. *See* Prelim. Resp. 16 (arguing that "the Patent Office considered multiple references discussing the use of radiopaque markers on radiolucent spinal implants" and that "Baccelli and Frey '550 are cumulative to Kuntz, Garcia, Villiers because none of these references discloses the claimed marker configuration for the claimed implant"), 19 (arguing "[n]either [Brantigan nor Michelson '973] provides any reason to adopt a marker configuration from either Baccelli or Frey '550 for the type of implant claimed in the challenged claims"). The portions of prosecution histories from related applications and the application that issued as the '334 patent upon which

Patent Owner relies also relate to radiopaque markers. *See id.* at 19–20 (citing Ex. 1020, 97, 108–110, 224–226, 230, 245, 247–250, 271, 273–275; Ex. 1023, 212–213, 215–216, 219, 222, 226), 21 (citing Ex. 1025, 104, 112), 22 (citing Ex. 1023, 212–213). The challenged dependent claims, however, relate to a medial support, a second fusion aperture, or a maximum lateral width. *See* Ex. 1001, 13:17–29, 14:11–13. The record does not indicate that the same or substantially the same arguments for the medial support and second fusion aperture were presented previously to the Office. And claim 18 was previously challenged, but it recites a maximum lateral width, which is not related to the radiopaque markers issues that Patent Owner argues.

Regarding the asserted failure to identify Examiner error, the previous proceeding IPR2013-00507 cancelled claim 1, thereby determining that the claim should not have been allowed to issue and indicating an error in evaluating the prior art. As for the argument that new evidence has not been submitted to warrant reconsideration, Petitioner's evidence in this proceeding is directed to the recited medial support, second fusion aperture, and maximum lateral width, not the radiopaque marker limitation of cancelled claim 1. Petitioner's evidence, and its arguments arising therefrom, have not been previously considered for, at least, challenged claims 6–9.

For the above reasons, the particular circumstances of this case do not indicate that we should exercise our discretion under 35 U.S.C. § 325(d) to deny instituting review of all presently challenged claims.

IV. 35 U.S.C. § 314(a)

Patent Owner also urges us to exercise our discretion under 35 U.S.C. § 314 to deny institution. Prelim. Resp. 23–37. Patent Owner asserts that instituting review "would not be an efficient use of Board resources because the Petition contradicts, without justification, prior findings of the Board that were affirmed by the Federal Circuit and fails to address major defects in its case despite having strategic advantage from reviewing NuVasive's briefing in prior IPRs." *Id.* at 23.

Patent Owner argues that, in IPR2013-00507 and IPR2013-00508, the Board determined that Frey did not disclose inherently an implant longer than 40 mm and that Michelson does not disclose an implant with a length greater than 40 mm and a width of 18 mm, as required by claim 18. *Id.* at 23–26 (citing Ex. 1023, 104, 105, 115–117, 124, 129–157; Ex. 1033, ii; Ex. 1034, ii). Patent Owner also notes that the Board concluded that one of ordinary skill in the art would not have expanded Michelson to 26 mm. *Id.* at 26 (citing Ex. 1023, 117). Patent Owner summarizes the Federal Circuit's determinations and notes that the Federal Circuit affirmed the Board's conclusion that Michelson does not disclose the length and width required by claim 18. *Id.* at 26–27 (citing Ex. 1023, 1–4, 16–19, 21).

Patent Owner also asserts its application of the factors identified in *General Plastic Industries Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) (precedential) to the facts of this case and contends that the factors favor denying the petition. *Id.* at 28–37. Patent Owner argues that, although Petitioner has not previously filed a petition challenging the '334 patent, discretion under § 314 is not limited to the same petitioner filing multiple petitions. *Id.* at 28. Patent Owner points

to (1) the recent departure of Petitioner's employees from Patent Owner's company, (2) substantially the same challenge being brought against claim 18, (3) the references having been previously asserted or cited in prosecution, (4) Petitioner having reviewed the previous Board decisions and filings, (5) no justification being given for the delay in filing, and (6) no reasons being given to revisit unpersuasive arguments. *See id.* at 29–37.

As noted by Patent Owner, the present Petition challenges claim 18, which was at issue in IPR2013-00507 and IPR2013-00508, and challenges claims 6–9, which were not previously challenged. *See* Prelim. Resp. 24. We acknowledge that, including the instant case, the Board has been presented thus far with multiple challenges to the '334 patent. Although we understand the purpose of § 314(a) regarding repeated challenges, we also recognize the purpose of the availability of *inter partes* review to parties accused of infringement. Patent Owner's complaint about the multiple *inter partes* review petitions filed against the '334 patent is not persuasive when the respective filings appear to be a direct result of its own litigation activity. *See supra* Section II.A. The discretion to deny petitions is for the panel to exercise under certain conditions, but not in every situation where a Patent Owner complains of repeated challenges against its patent.

Notably, our precedent indicates the application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same petitioner but considers any relationship between different petitioners. *Valve Corp. v. Elec. Scripting Prods., Inc*., Case IPR2019-00062, -00063, -00084, slip op. at 9 (PTAB Apr. 2, 2019) (Paper 11) (precedential). Here, potentially relevant to factors 1 and 3 of the *General Plastic* factors, Patent Owner argues that some of Petitioner's

employees were previously employees of "NuVasive" (Prelim. Resp. 29, 31–32), which is the Patent Owner of the '334 patent. The former employees were not previously a petitioner for another petition directed to the same claims of the same patent. Patent Owner also fails to direct us to sufficient evidence indicating that present Petitioner's companies have a relationship with any previous petitioners, or that the noted former employees have such a relationship. *See id.* at 29, 31–32. Thus, factors 1 and 3 weigh against exercising our discretion to deny institution.

Additionally, for the remaining factors, we are not persuaded for claims 6–9 that Petitioner's potential review of papers in IPR2013-00507 and IPR2013-00508 amounts to a petitioner receiving the benefit of a preliminary response or decision on institution before filing a second petition challenging the same patent, which were the circumstances addressed by the *General Plastic* factors. Given that claims 6–9 were not challenged in the previous proceedings, the additional use of Board resources to consider claim 18 in this proceeding along with the consideration of claims 6–9 does not amount to an inefficient use of Board resources. *See also* Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (explaining that "the PTAB will institute as to all claims or none" and "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

Thus, for the foregoing reasons, we do not exercise our discretion under 35 U.S.C. § 314(a) to deny institution.

V. CHALLENGES UNDER 35 U.S.C. § 103

A. Claim Construction

On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change applies to petitions filed on or after November 13, 2018, 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. According to Patent Owner, claim 1 defines "longitudinal length" to mean "a dimension of the implant that extends lengthwise and is greater than the maximum lateral width of the implant." Prelim. Resp. 9 (citing also Ex. 2009, 424 (dictionary definition for "longitudinal")). Patent Owner also contends that claim 1 defines "longitudinal aperture length" to mean "a dimension of the aperture that runs lengthwise and is greater than the lateral aperture width that extends between the first sidewall and the second sidewall." *Id.*

We agree with Patent Owner that claim 1 recites limitations regarding "longitudinal length" and "longitudinal aperture length." *See* Ex. 1001, 12:44–46, 12:59–61. At 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 length extending generally parallel to the longitudinal length of said implant," as recited by claim 1. *Id.* Further express interpretation is not required for purposes of this Decision.

Patent Owner additionally proposes interpreting "medial support" to mean "a supporting wall that intersects the sidewalls of the implant approximately at the midpoint of its longitudinal length" with support from the Specification, a dictionary definition, a prior Board determination regarding "medial plane," and a joint proposed interpretation of "medial plane" in related litigation. *Id.* at 10–11 (citing Pet. 75; Ex. 1001, 6:57–59, Figs. 2–5; Ex. 1013, 130–133; Ex. 2009, 446; Ex. 2010, 21, 23).

Claims 6, 7, and 9, respectively, require "a medial support extending between the first and second sidewalls," "said medial support is positioned along said central region," and a medial support separating first and second fusion apertures. Ex. 1001, 13:17–21, 13:27–29. Patent Owner points to a portion of the Specification that states that the "spinal fusion implant 10 has two large fusion apertures 2, separated by a medial support 50, extending in a vertical fashion through the top surface 31 and bottom surface 33." *Id.* at 6:57–59. Patent Owner also points to Figures 2–5, which show one embodiment, but the '334 patent is not limited to what is shown in those figures. *See id.* at 3:32–56, 12:12–20. At this stage of the proceeding, the express language of the claims and the relied-upon portions of the Specification do not indicate that interpreting "medial support" requires it to be "at the midpoint of its longitudinal length," as proposed by Patent Owner.

At this stage, the dictionary definition and prior Board determination regarding "medial plane" also do not support persuasively Patent Owner's proposed interpretation of "medial support." Patent Owner also points to the joint proposed interpretations in related litigation, but those interpretations relate to patents that are not at issue in this proceeding.

Thus, we analyze whether the asserted references teach or suggest "a medial support extending between the first and second sidewalls," "positioned along said central region," and separating first and second fusion apertures, as required by challenged claims 6, 7, and 9, to determine whether Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims. After the record has been developed, we may revisit whether "medial support" needs to be interpreted expressly.

For the reasons above and for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, we determine that no express interpretation is required for any claim term. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "'would have a medical degree with two 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). Patent Owner does not yet propose a level of ordinary skill.[1]

We preliminarily adopt Petitioner's unchallenged, asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition.

C. Challenge Based on Frey, Michelson, and Berry

1. 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.

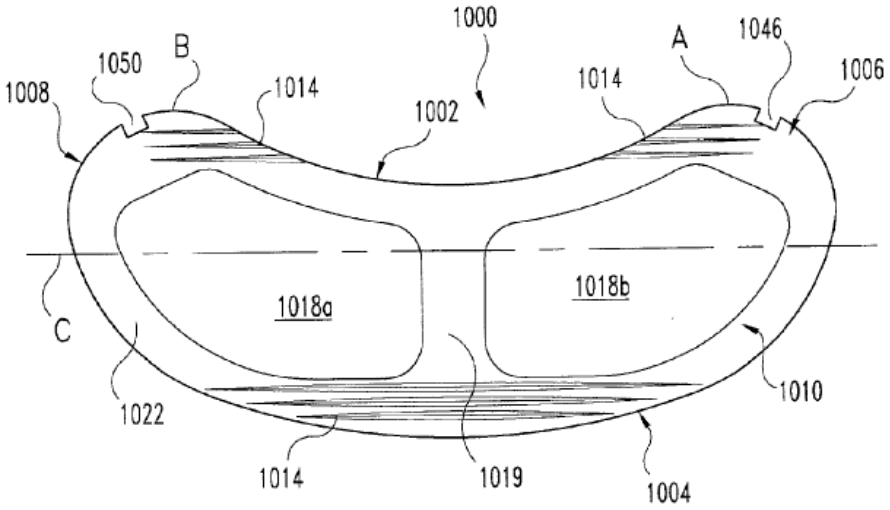


Fig. 55

[1] We note that, in the related IPR2019-00362 which addresses a continuation of the '334 patent and similar prior art, Patent Owner does not assert a different skill level than Petitioner.

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.

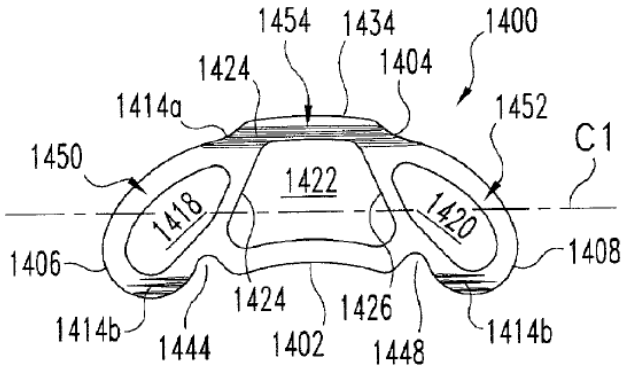


Fig. 63

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.*

2. Michelson (Ex. 1032)

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

FIG. 18

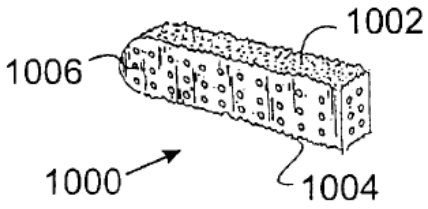


FIG. 19

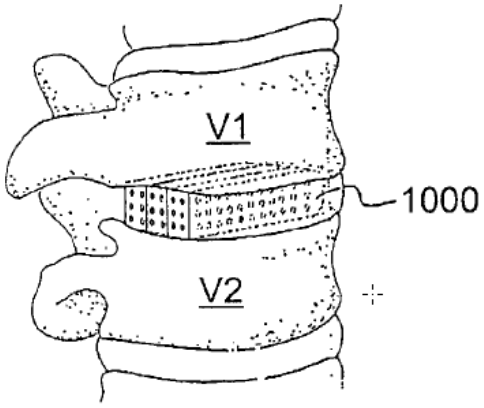


Figure 18 is a perspective side view of a spinal fusion implant, and Figure 19 is a perspective lateral anterior view of a segment of the spinal column with the implants shown in Figure 18 "inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the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

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

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

insertion within the disc space D between the adjacent vertebrae." *Id.* at 10:50–55. Spinal implant 1000 is an alternative embodiment of a preferred embodiment that has "a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." *Id.* at 10:42–48, Fig. 17. Michelson also claims an implant "having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae." *Id.* at 11:21–26.

3. Berry (Ex. 1022)

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

4. Claim 1

The challenged claims, claims 6–9 and 18, depend from cancelled claim 1. Ex. 1001, 13:17–29, 14:11–13. Petitioner states that "the Board determined that all limitations of claim 1 'are taught or suggested by the combination of Frey and Michelson'" and that the "Federal Circuit affirmed

the Board's decision." Pet. 32 (citing Ex. 1001; Ex. 1004, 5, 13; Ex. 1005, 17). Petitioner, thus, contends that "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'" and "estopped from arguing that claim 1 renders any dependent claim patentable over Frey and Mich[]elson as those references have been definitively established as rendering claim 1, among others, unpatentable." *Id.*

The Preliminary Response presents arguments that are based on limitations of claim 1 that are incorporated in the dependent claims asserted to be unpatentable over Frey, Michelson, and Berry. Prelim. Resp. 37–40. We address those arguments here for clarity instead of below with arguments related to the subject matter of claims 6–9 and 18.

Patent Owner responds that Petitioner fails to map adequately the prior art to the elements of claim 1, thereby violating 37 C.F.R. § 42.104(b)(4). Prelim. Resp. 37–38. Patent Owner argues that Petitioner's reliance on the cancellation of claim 1 does not relieve Petitioner from "demonstrating that each challenged claim ***as a whole*** would have been obvious, including the elements incorporated from claim 1." *Id.* at 38.

We agree with Petitioner at this stage that Patent Owner is estopped from arguing that limitations of claim 1 render the challenged dependent claims patentable over Frey and Michelson because of the determination in IPR2013-00507 that those references rendered claim 1 obvious. *See* Pet. 32. Patent Owner fully participated in the prior proceeding, and the prior proceeding reached a final written decision that determined that claim 1 was shown to be unpatentable over Frey and Michelson. That final written

decision was appealed, and the determination that claim 1 is unpatentable over Frey and Michelson was affirmed. An "Inter Partes Review Certificate" that cancelled claim 1 was issued, thus indicating that further judicial review was not sought. Ex. 1001, 33–34.

If Patent Owner intends to reassert this argument during trial, Patent Owner should explain why it is not estopped from arguing that the limitations of claim 1 incorporated into challenged claims 6–9 and 18 demonstrate patentability over Frey, Michelson, and Berry, when those same limitations were determined to be unpatentable over Frey and Michelson.

Moreover, we do not understand Petitioner to be challenging claim 1, and thereby implicating the requirements of 37 C.F.R. § 42.104(b)(4), because claim 1 was cancelled by IPR2013-00507. Petitioner has submitted evidence from IPR2013-00507 that supports the determination that claim 1 was unpatentable over Frey and Michelson. In view of the circumstances of this case where the patentability of claim 1 has been fully decided with no further judicial review possible, and the evidence from the previous case has been filed, we discern no need for Petitioner to argue with particularity the limitations of claim 1, even to the extent they are included in the challenged claims by the virtue of dependency.

Turning to Patent Owner's arguments based on limitations in cancelled claim 1, claim 1 recites, *inter alia*, "said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant . . . wherein the longitudinal aperture length is greater than the lateral aperture width." Ex. 1001, 12:59–64. Patent Owner responds that Petitioner fails to establish that Frey's implant has apertures with "a longitudinal aperture length extending generally

parallel to the longitudinal length of said implant" that is "greater than the lateral aperture width" between first and second sidewalls. Prelim. Resp. 38. Patent Owner contends that Petitioner does not provide a rationale for modifying Frey's implant to have such dimensional limitations. *Id.*

Patent Owner also contends that Petitioner's asserted longitudinal lengths are not parallel to each other or to the longitudinal length of the implant. *Id.* at 38–39. Patent Owner argues that Petitioner's asserted fusion apertures do not satisfy the requirements of claims 6–9. *Id.* at 39 (citing Pet. 33–40) (providing annotated Ex. 1040, Figs. 55, 63). Patent Owner also argues that Frey teaches axis C1 extending longitudinally through the implant's center and the asserted fusion apertures are not parallel to the axis. *Id.* at 40 (quoting Ex. 1040 ¶ 159).

As discussed above, we agree with Petitioner that Patent Owner is estopped from arguing that Frey would not have rendered obvious claim 1 because claim 1 was shown to be unpatentable over Frey and Michelson in a prior proceeding. *See* Pet. 32. Also, as indicated above, if Patent Owner intends to reassert this argument during trial, Patent Owner should explain why it is not estopped from arguing limitations of claim 1, even if it is in the context of arguing for the challenged dependent claims.

Moreover, even if we were to consider Patent Owner's arguments regarding "longitudinal aperture length," claim 1 does not require that the fusion aperture have a longitudinal aperture length along its longest dimension. Claim 1 only requires "a longitudinal aperture length extending generally parallel to the longitudinal length of said implant."

5. Claims 6–9

Petitioner contends that Frey teaches the limitations of claims 6–9. Pet. 33–40. Relevant to the parties' dispute at this stage are limitations related to a medial support. In particular, claim 6, which depends from claim 1, recites "further comprising a *medial support* extending between the first and second sidewalls." Ex. 1001, 13:17–19 (emphasis added). Claim 7, which depends from claim 6, recites "wherein said *medial support* is positioned along said central region." *Id.* at 13:21–22 (emphasis added). Claim 9, which depends from claim 1 via claim 8, recites "wherein said second fusion aperture is separated from said first fusion aperture by a *medial support*." *Id.* at 13:27–29 (emphasis added).

Petitioner contends that Frey teaches the medial support of claims 6, 7, and 9. Pet. 33–35 (citing Ex. 1002 ¶¶ 162, 165, 166; Ex. 1040 ¶¶ 144, 149, 154, 181, Figs. 55, 59, 63), 35–36 (citing Ex. 1002 ¶¶ 168–171, Ex. 1040 ¶¶ 144, 154, Figs. 55, 59, 63), 38–40 (citing Ex. 1002 ¶¶ 177–179; Ex. 1040 ¶¶ 144, 149, 154, Figs. 55, 63). We reproduce below Petitioner's annotated Figures 55 and 63 of Frey that depict Petitioner's positions regarding the medial support.

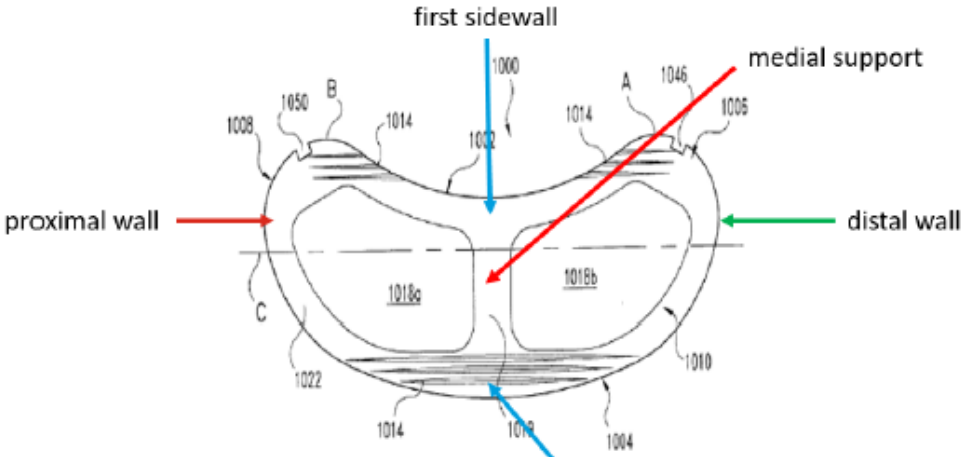


Fig. 55

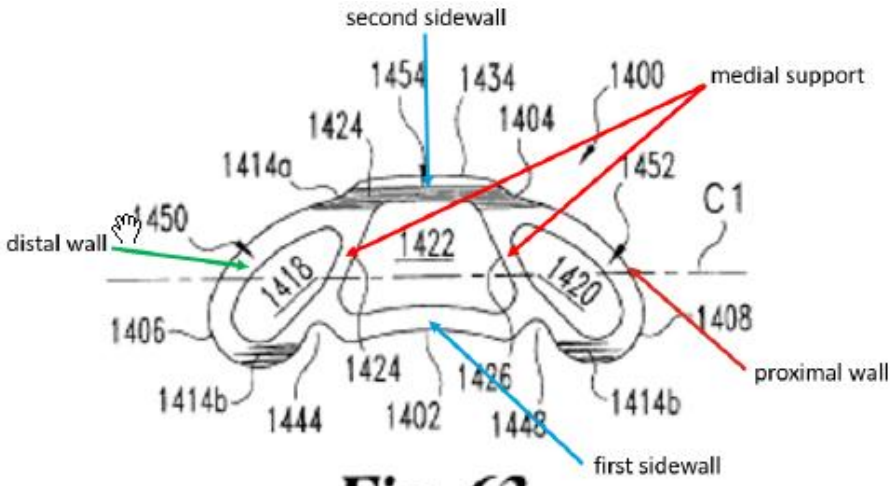


Fig. 63

Id. at 35–36; *see also id.* at 39–40 (providing Figs. 55, 63 with similar annotations to support arguments for claim 9).

Notwithstanding Patent Owner's arguments, which we address below, on the present record including the preliminary evidence of objective indicia of non-obviousness discussed below, Petitioner shows a reasonable likelihood of prevailing in its challenge of claims 6–9 as unpatentable over Frey, Michelson, and Berry. We, thus, institute *inter partes* review.

Patent Owner argues that Petitioner fails to show that Frey teaches the medial support of claims 6, 7, and 9. According to Patent Owner, upper strut 1019 is not the claimed medial support because it "is not a wall, does not extend from upper surface to lower surface, and does not separate the first fusion aperture from the second fusion aperture." Prelim. Resp. 43 (citing Pet. 34; Ex. 1040 ¶¶ 66–70, Figs. 54, 56, 57). Patent Owner asserts that these differences were pointed out during prosecution. *Id.* at 44 (citing Ex. 1020, 264).

Claims 6, 7, and 9 only require the medial support extend between first and second sidewalls, be positioned along said central region, and

separate first and second apertures. *See* Ex. 1001, 13:17–21, 13:27–29. The claims do not require the medial support to be a wall or to extend from an upper surface to a lower surface, as argued by Patent Owner. *See id.* Petitioner sufficiently shows that its asserted medial support separates its asserted first and second apertures at least partially. Petitioner's position appears to be that claims 8 and 9 do not require the medial support to separate the first and second fusion apertures entirely. At this stage of the proceedings, we find Petitioner's argument and evidence to be sufficient.

Further, for the reasons discussed in Section V.A., the present record does not support persuasively Patent Owner's proposed interpretation of "medial support" to mean "a supporting wall that intersects the sidewalls of the implant approximately at the midpoint of its longitudinal length."

Patent Owner also contends that first strut 1424 and second strut 1426 combined together do not teach or suggest the claimed medial support because they "are not disposed in the middle of the implant." Prelim. Resp. 44–45 (citing Pet. 39; Ex. 1040 ¶¶ 45, 156, Fig. 59).

Patent Owner's argument appears to pertain only to claim 7 because it recites "wherein said medial support is positioned along said central region." Ex. 1001, 13:20–21. On the present record, the other challenged claims do not expressly limit the medial support to the middle of the implant. At this stage of the proceedings, Petitioner provides sufficient argument and evidence to support that struts 1424 and 1426 are "along said central region." *See* Pet. 35 (citing Ex. 1002 ¶¶ 168–169; Ex. 1040 ¶ 154, Figs. 59, 63).

For the reasons above, in view of the arguments and evidence in this record, we determine that Petitioner has shown that there is a reasonable

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

6. Claim 18

Cancelled claim 1 recites "a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall," "a *maximum lateral width* of said implant extending from said first sidewall to said second sidewall," and "wherein said longitudinal length is at least two and half times greater than said *maximum lateral width*." Ex. 1001, 12:44–46, 12:50–52 (emphasis added), 12:63–64 (emphasis added). Claim 18 depends from cancelled claim 1 and recites "wherein said *maximum lateral width* of said implant is approximately 18 mm." *Id.* at 14:11–13 (emphasis added).

Petitioner contends that Michelson teaches spinal fusion embodiments with "a length in the range of 35 mm to 50 mm" and a narrow width so that implants can be combined for insertion, but that Michelson "does not specify what region of the lumbar spine those dimensions pertain to." *Id.* at 41 (citing Ex. 1002 ¶¶ 183, 189, 191; Ex. 1032, 10:32–59, Figs. 18, 19). Petitioner 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).

According to Petitioner, one of ordinary skill in the art would have referred to Berry because it "teaches 'direct dimensional measurements' of human vertebrae." *Id.* at 41–42 (citing Ex. 1002 ¶¶ 191–192; Ex. 1022, 362–364, Table 1). Petitioner contends that, "[a]pplying the standard deviations reported in Berry, a [person of ordinary skill in the art] would have been motivated to modify Michelson's long-and-narrow implants to have widths ranging from 14.1 mm LI to 18.95 mm for L5," "from 16.15 mm to 18.95 mm," or "approximately 18 mm wide," as recited by claim 18. *Id.* at 42 (footnotes omitted) (citing Ex. 1002 ¶¶ 192–194; Ex. 1022, 364, Table 1). Petitioner also contends that "Berry teaches mean transverse widths of L4 (lower surface) and L5 (upper surface) to be 50.9 mm and 53.4 mm, respectively," and thus, "[a]pplying the standard deviations of Berry, an implant for spinal fusion between L4 and L5 would, therefore, be at least 46.3 mm, which is more than two and a half times greater than approximately 18 mm." *Id.* (citing Ex. 1002 ¶¶ 153, 193; Ex. 1022, 363–364, Table 1).

Petitioner further contends that one of ordinary skill in the art "would have been motivated to nest the curved modular implants of Frey to approximate better the 'depth of the vertebra'—which is curved anteriorly—as taught by Michelson." *Id.* at 42–43 (citing Ex. 1002 ¶ 188; Ex. 1032, 10:32–47). Petitioner also argues that "Frey teaches a special inserter that may 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.* at 43 (citing Ex. 1002 ¶ 187; Ex. 1040 ¶ 160).

Petitioner argues that Frey and Michelson are both directed to and disclose similar subject matter. *Id.* at 29–30 (citing Ex. 1002 ¶¶ 134, 136; Ex. 1032, 3:1–10, 3:33–53, claim 1; Ex. 1040 ¶¶ 130, 150, 184, Fig. 47). Petitioner asserts that one of ordinary skill in the art would have been motivated to combine Frey and Michelson for the reasons previously determined by the Board and affirmed by the Federal Circuit. *Id.* at 29 (citing Ex. 1002 ¶¶ 143–144, 148–150; Ex. 1005, 14–17).

Petitioner also contends that Michelson teaches embodiments with "a length in the range of 32 mm to 50 mm," "a width that approximates the depth of the vertebrae," and "a narrower width such that more than one spinal implant 1000 may be combined in a modular fashion." *Id.* at 30 (quoting from Ex. 1032, 10:32–59) (citing also Figs. 18, 19). Petitioner, thus, argues 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." *Id.* (citing Ex. 1002 ¶ 150).

Petitioner further contends that one of ordinary skill in the art "would have known the average length and width of human vertebrae" because of Berry and "would have been motivated to turn to Berry when developing the implants of Frey and Michelson." *Id.* at 30–31 (citing Ex. 1022, 362–364). Petitioner, thus, argues that one of ordinary skill in the art "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 31 (citing Ex. 1002 ¶ 122; Ex. 1022, 364, Table 1; Ex. 1032, 10:20–59).

Petitioner additionally contends 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 the proposed combination "amounts to nothing more than rearranging known mechanical elements to achieve a predictable result." *Id.* (citing Ex. 1002 ¶¶ 143–144, 148–150; Ex. 1032, claims 61, 69; Ex. 1040 ¶ 130).

Patent Owner argues that Petitioner fails to establish that the total width of Petitioner's proposed modification of Frey's curved members results in a maximum lateral width of approximately 18 mm. Prelim. Resp. 51; *see also id.* at 50–52 (describing Pet. 35–36, 40–42). Patent Owner argues that, "because Frey's implants are curved, the total width of the implant relative to the vertebral body is necessarily larger than the maximum lateral width between sidewalls (anterior wall 1404 and posterior wall 1402) in the central region" and provides annotated Figures 55 and 63 to illustrate its argument. *Id.* at 52–54.

At this stage, Petitioner has provided sufficient evidence to demonstrate a reasonable likelihood of prevailing in its challenge of claim 18. Nevertheless, Patent Owner raises factual issues that may implicate expert testimony. Further, our determinations regarding Michelson may be further considered in view of previous Board findings from, at least, IPR2013-00507.

7. Conclusion

Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to its obviousness challenge over Frey, Michelson, and

Berry, and, thus, *inter partes* review of all challenged claims over this prior art is instituted.

D. Challenge Based on Brantigan, Baccelli, Berry, and Michelson

1. Brantigan (Ex. 1007)

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

Brantigan provides a "biologically acceptable, but inert rigid annular prosthesis units [that] are provided to support and fuse with adjacent vertebrae in both the cervical, thoracic spine and lumbar portions of a human vertebral column." *Id.* at 1:64–68. "The rings are bottomed on the opposing end faces of adjoining vertebrae" and "are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies . . . ." *Id.* at 1:18–21. They "are generally oval shaped to conform with the general outline perimeter of the vertebrae." *Id.* at 2:2–4. "Each of the oval implants is sized to match the height of an average disc and thus, can vary from 10 to 15 mm for the lumbar area and from 7-11 mm for the cervical area." *Id.* at 2:20–23. Figure 1 of Brantigan is reproduced below.

FIG. 1

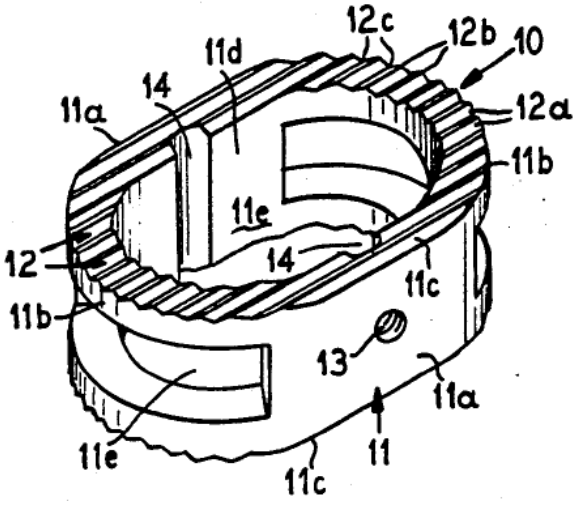


Figure 1 shows a perspective view of a full oval prosthetic device. *Id.* at 3:21–22. Oval ring plug 11 has opposed sides 11*a*, ends 11*b*, top and bottom surfaces 11*c*, and central upstanding aperture 11*d*.[2] *Id.* at 4:5–10. Top and bottom surfaces 11*c* have ridges 12 for engaging adjacent vertebrae.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

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

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

5:30–32; *see also id.* at 2:34–38 (describing implants of varying height achieved by stacks of rings of varying height), 2:55–66 (describing placement and insertion), 6:61–7:6 (describing insertion of plugs 11). Brantigan further discusses that the devices "are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae 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.

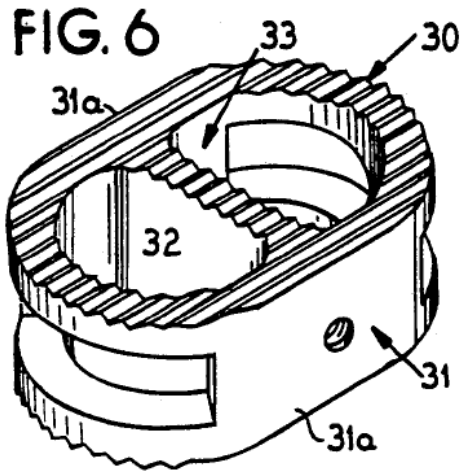


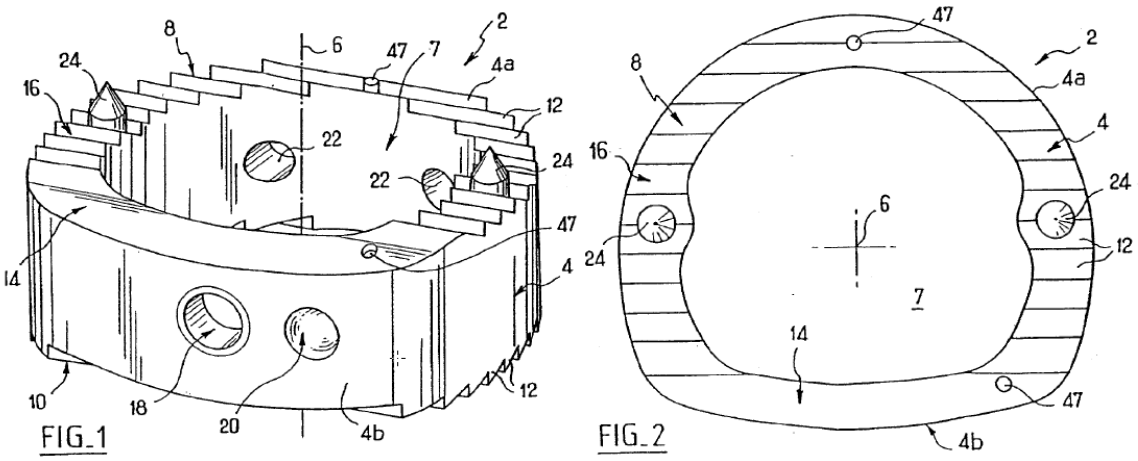
Figure 6 shows a perspective view of a modified device with an integral cross bar. *Id.* at 3:21–22, 3:36–37, Fig. 6. Modified device 30 is plug 31 with the same shape as plug 11 but has reinforcing bar 32 integral with side walls 31*a*. Integral internal partition 32[3] bisects hollow

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

interior 23[4] (not shown) forming "side-by-side apertures through the plug adapted to receive bone graft material." *Id.* at 5:37–43, Fig. 6.

2. Baccelli (Ex. 1008)

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



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

[4] 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.*

3. Claim 1

Petitioner argues that Brantigan teaches or suggests most of the limitations of claim 1. Pet. 48–61 (citing Ex. 1002 ¶¶ 32, 89, 204–210, 212–213, 217, 219–227, 229, 230, 238–241; Ex. 1007, Abstract, 1:44–47, 1:7–12, 1:14–15, 1:18–29, 1:64–68, 2:2–4, 2:20–23, 2:34–38, 2:59–66, 3:9–12, 4:5–10, 4:15–18, 4:20–22, 4:50–53, 5:22–26, 5:30–43, 6:5–16, 6:61–7:6, Figs. 1, 6, 8, 10; Ex. 1019, 5–9), 64–67 (citing Ex. 1002 ¶¶ 254–259; Ex. 1007, 1:41–43, 2:15–17, 4:8–10, Figs. 1, 6; Ex. 1022, 363–364, Table 1). Petitioner relies on Berry for teaching a longitudinal length "greater than 40 mm" for lumbar vertebrae. *Id.* at 57 (citing Ex. 1002 ¶ 236; Ex. 1022, 364, Table 1).

Petitioner proposes modifying Brantigan in view of Berry and Michelson so that a longitudinal length is at least two and a half times greater than a maximum lateral width. *Id.* at 61–62 (citing Ex. 1002 ¶¶ 242–253; Ex. 1007, 1:20–21, 2:4–11; Ex. 1032, 3:61–65, 10:50–55). Petitioner contends that Brantigan and Michelson are directed to spinal implants and that Michelson provides preferred dimensions. *Id.* at 62 (citing Ex. 1002 ¶¶ 251; Ex. 1007, 1:18–21, 1:65–68, 2:2–4, 2:55–66, 4:5–8, 5:30–35; Ex. 1032, 3:1–10, 3:35–53, 10:32–59, Figs. 18–19, claim 1). Petitioner also contends that one of ordinary skill in the art would have looked to Berry for vertebrae dimensions. *Id.* at 63 (citing Ex. 1002 ¶¶ 202, 251, 252; Ex. 1022, 362–364, Table 1). Petitioner thus argues that one of ordinary skill in the art would have been motivated to modify Brantigan to be "approximately 18

mm wide." *Id.* at 63–64 (citing Ex. 1002 ¶¶ 252, 253; Ex. 1022, 364, Table 1).

Relevant to the parties' disputes at this stage, Petitioner contends that Brantigan teaches a longitudinal length between ends 11b, as required by cancelled claim 1. *Id.* at 54 (citing Ex. 1002 ¶ 226; Ex. 1007, 4:5–10), 56 (referring also to arguments at Pet. 52–55). Petitioner also contends that Brantigan teaches a lateral aperture width that is parallel to the longitudinal width, as required by claim 1. *Id.* at 65–67 (citing Ex. 1002 ¶¶ 257–259; Ex. 1007, Figs. 1, 6; Ex. 1022, 363–364, Table 1) (referring also to arguments made at Pet. 64–65). Also, relevant to the disputes at this stage, Petitioner relies on Baccelli for teaching or suggesting the limitations related to radiopaque markers. *Id.* at 67–70 (citing Ex. 1002 ¶¶ 262, 263; Ex. 1008 ¶¶ 36, 41, 44, 50–51, Figs. 1–5, 8, 9).

Patent Owner asserts that Petitioner does not show that the longitudinal length of the first fusion aperture is parallel to the longitudinal length of the implant. Prelim. Resp. 40–41 (citing Pet. 55, 57, 65, 70, 72). Patent Owner also argues that Petitioner misinterprets Brantigan. *Id.* at 41–42 (citing Pet. 65, 72). Patent Owner contends that the longitudinal length of the apertures is not parallel to the longitudinal length of the implant. *Id.* at 42–43 (reproducing Pet. 7, annotated Fig. 2).

As discussed above for the challenge based on Frey, Michelson, and Berry, if Patent Owner intends to assert arguments during trial regarding limitations in cancelled claim 1, Patent Owner should explain why it is not estopped from arguing limitations of claim 1, even if it is in the context of arguing the dependent claims challenged based on references not presented in the previous proceeding.

Also, on this record, Petitioner sufficiently shows for purposes of institution that Brantigan teaches that the longitudinal length of the first fusion aperture is parallel to the longitudinal length of the implant. *See* Pet. 65–67 (citing Ex. 1002 ¶¶ 257–259; Ex. 1007, Figs. 1, 6; Ex. 1022, 363–364, Table 1) (referring also to arguments made at Pet. 64–65). Patent Owner's argument involves factual issues that implicate expert testimony, and the present record is devoid of supporting evidence.

Patent Owner also contends that Petitioner misinterprets Baccelli and that Baccelli shows two, not four, radiopaque markers. Prelim. Resp. 56–58 (citing Pet. 16, 45; Ex. 1008 ¶¶ 29–31, 50, Figs. 1–5, 8, 9). Patent Owner additionally argues that Baccelli's longest length extends laterally, not in the anterior-posterior direction. *Id.* at 58–60 (citing Pet. 16, 68–69; Ex. 1008 ¶¶ 16, 17, 24, 30, 42, 43, Figs. 1–5, 8, 9; Ex. 2001, 518, Fig. 6.97); *see also id.* at 62–63 (citing Pet. 16, 45; Ex. 1008 ¶¶ 24, 30, 34, 39, 42–45, Figs. 1–4, 8, 9). Patent Owner also contends that an alternative embodiment fails to teach or suggest the claimed radiopaque markers. *Id.* at 60–61 (citing Ex. 1008 ¶¶ 2, 3, 21, 45, 50, 51).

According to Patent Owner, "Baccelli does not teach or suggest its marker placement is appropriate for lateral implants, for thoracic or lumbar implants, or for implants (like the claimed implant) that are elongated relative to their direction of insertion." *Id.* at 63 (citing *In re NuVasive, Inc.*, 842 F.3d at 1384–85). Patent Owner argues that Baccelli also does not teach or suggest placing radiopaque markers in all four walls of an implant. *Id.* at 63–64 (citing Pet. 45). Patent Owner additionally asserts that Baccelli and other references teach that the radiopaque markers "should be located on the ***proximal and distal ends***, not in the central region." *Id.* at 62–63, 64–65

(annotating Ex. 1007, Fig. 10). Patent Owner further contends that Petitioner does not rely on Brantigan and Michelson for teaching or suggesting radiopaque markers. *Id.* at 61–62 (citing Pet. 5, 43–44).

Patent Owner asserts that Petitioner's argued motivation lacks supporting evidence, is conclusory, and ignores Baccelli's teachings. Prelim. Resp. 65–68 (citing *In re NuVasive, Inc.*, 842 F.3d at 1383, 1384; Pet. 45–46, 60, 68; Ex. 1008 ¶¶ 50, 51, Figs. 1–4, 8, 9). Patent Owner additionally asserts that Petitioner does not explain why two additional radiopaque markers would be added in the claimed locations. *Id.* at 68–69 (citing Pet. 45–46). Patent Owner, thus, argues that hindsight influences Petitioner's rationale. *Id.* at 69–70.

As discussed above, Patent Owner presents arguments regarding a limitation found in cancelled claim 1, and if Patent Owner intends to present arguments during trial regarding limitations in cancelled claim 1, Patent Owner should explain why it is not estopped from arguing limitations of claim 1, even if it is in the context of arguing the dependent claims challenged based on references not previously asserted.

Also, at this stage, Petitioner sufficiently shows that Baccelli teaches "one or more markers 47" that are "opaque to X-rays" and "identify the position and/or the presence of the implant" and "spikes 24" that "can be made of a material that is opaque to X-rays." Pet. 67 (quoting Ex. 1008 ¶¶ 50–51); *see also id.* at 68 (contending, with reference numbers switched, that "Baccelli discloses extending the radiopaque markers (24) and spikes (47) into the proximal and distal walls, as well as the sidewalls in the central region"), 69 (arguing "Baccelli's radiopaque markers (47) and spikes (24) are oriented parallel to the height of the implant along central axis 6");

Ex. 1002 ¶ 263; Ex. 1008 ¶¶ 50 (describing markers 47), 51 (describing spikes 24).

As determined above, Petitioner has shown sufficiently for purposes of institution that Brantigan, Baccelli, Berry, and Michelson would have rendered obvious claim 1.

4. Claims 6–9

Petitioner argues that Brantigan teaches the limitations of claims 6–9, with citations to Brantigan and its declarant testimony. Pet. 70–73. Patent Owner presents arguments related to limitations of cancelled claim 1, which we discuss above, and for the reasons discussed, we do not find persuasive. Patent Owner does not present arguments that the proposed combination of Brantigan, Baccelli, Berry, and Michelson fail to teach, suggest, or render obvious the subject matter of claims 6–9.

As determined above, Petitioner has shown in its challenge based on Frey, Michelson, and Berry that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, and, thus, *inter partes* review of all challenged claims on all presented challenges is instituted. At this stage of the proceeding, we are also satisfied that Petitioner shows a reasonable likelihood of prevailing in its challenge of claims 6–9 as unpatentable over Brantigan, Baccelli, Berry, and Michelson.

5. Claim 18

Petitioner argues that Brantigan in view of Baccelli, Berry, and Michelson would have rendered obvious "wherein said maximum lateral

width of said implant is approximately 18 mm," as recited by claim 18. Pet. 73–74 (citing Ex. 1002 ¶¶ 280–292; Ex. 1022, 363–364).

Patent Owner responds that Petitioner's arguments based on Michelson "are illogical, driven by nothing other than improper hindsight, and in direct conflict with interpretations of the same reference [in IPR2013-00507 and IPR2013-00508]," which determined that Michelson teaches that "24–32 mm . . . is the appropriate implant width to approximate the depth of the lumbar vertebrae." Prelim. Resp. 45–46; *see also id.* at 46–47 (discussing Ex. 1023, 19, 21, 104–105, 115–117, 124). Patent Owner also argues that Michelson "teaches that the dimension of the implant corresponding to the depth of the vertebrae still should be ***smaller*** than the average vertebral body depth" resulting in a maximum width of 32 mm and a modular member width of 18 mm. *Id.* at 47.

Patent Owner thus contends that Michelson, Berry, and other references known by one of ordinary skill in the art "consistently teach maximum implant widths too small[5] to satisfy claim 18." *Id.* at 47–48. Patent Owner also contends that Petitioner does not address the Board's previous determination that 26 mm should not be exceeded. *Id.* at 48 (citing Ex. 1023, 117). Patent Owner further contends that Petitioner cites Berry's dimensions for vertebral bodies, not the disc space, in conflict with a previous Board determination. *Id.* (citing Pet. 41, 63; Ex. 1023, 136).

[5] Claim 18, however, recites "said *maximum* lateral width of said implant is approximately 18 mm." In any event, we understand Patent Owner to be arguing that the identified references fail to teach or suggest the dimensional requirements of claim 18 and claim 1 from which it depends.

Patent Owner also asserts that Petitioner insufficiently shows that Brantigan's implant spans a disc space as recited. *Id.* at 49 (Ex. 1007, 6:23–25, Figs. 10, 11; Ex. 1023, 136). Patent Owner additionally argues that Berry's mean widths are too small to satisfy claim 18 and that Petitioner must resort to hindsight-driven use of standard deviations in contradiction to other references to meet the claim limitation to arrive at an implant larger than the average dimension of the largest vertebrae. *Id.* at 50 (citing Pet. 41–42, 63).

At this stage, Petitioner's arguments and evidence are sufficient for purposes of institution. For example, Petitioner sufficiently shows that Michelson supports its argument that lateral insertion of Brantigan's implant provides benefits that are accomplished with a long-and-narrow implant inserted modularly. *See* Pet. 47 (citing Ex. 1002 ¶ 201; Ex. 1032, Abstract, 2:19–67, 3:56–4:24, 10:20–59, Figs. 18, 19). Petitioner also sufficiently argues, and Michelson supports, that modular insertion increases patient safety and minimizes invasiveness. *See id.* at 47–48 (citing Ex. 1032, 3:61–65). Petitioner additionally argues, and Berry supports, that one of ordinary skill in the art would have been motivated to reduce the width of Brantigan's implant. *See id.* at 48 (citing Ex. 1002 ¶ 202; Ex. 1022, 364; Ex. 1032, 10:20–59, Figs. 18, 19).

Patent Owner further asserts that Petitioner's proposed modification of Brantigan in view of Michelson eliminates the claimed feature of a maximum lateral width extending between first and second sidewalls. Prelim. Resp. 54–55 (citing Pet. 31, 48, 61–62). Patent Owner also argues that Petitioner fails to explain how one of ordinary skill in the art would assemble two 18-mm-wide modular members into a single implant that

would then become 36 mm wide, thereby failing to show a reasonable expectation of success. *Id.* at 55–56.

We understand Petitioner to be pointing to a portion of Brantigan that describes "hemi-oval" implants to support its assertion that Brantigan and Michelson both disclose modularity. *See* Pet. 61–62 (citing Ex. 1007, 2:4–7). As indicated by other arguments, Petitioner, however, does not appear to be proposing to modify the "hemi-oval" implants of Brantigan. *See, e.g.*, Pet. 64–66 (providing annotated Figs. 1, 6 from Ex. 1007).

For the reasons above, at this stage of the proceeding, we are satisfied that Petitioner shows a reasonable likelihood of prevailing in its challenge of claim 18 as unpatentable over Brantigan, Baccelli, Berry, and Michelson.

E. Objective Indicia of Non-Obviousness

Petitioner states that it "is unaware of any secondary consideration that demonstrate nonobviousness" and contends that such evidence proffered in IPR2013-00507 did not show adequately a nexus between the claimed invention and the proffered evidence. Pet. 74–75 (citing Ex. 1004, 11–12).

Patent Owner contends that Petitioner should have known of and addressed testimony submitted by "Chairman and CEO, Patrick Miles." Prelim. Resp. 70 (citing Pet. 74; Ex. 2003, 1). Patent Owner argues that the testimony shows commercial success, industry praise, copying, skepticism, failure of others, and unexpected results. *Id.* at 71 (citing Ex. 2002 ¶¶ 1–2, 6–8, 11, 14). Patent Owner also argues that there is presumed nexus between the claims and its objective indicia of nonobviousness, particularly commercial success and copying. *Id.* at 71–72 (citing Pet. 74–75; Ex. 2002 ¶ 9; Ex. 2013; Ex. 2014, 7; Ex. 2015 ¶¶ 314–366).

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

VI. CONCLUSION

The Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one of claims 6–9 and 18 of the '334 patent is unpatentable.

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

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

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 6–9 and 18 of U.S. Patent No. 8,187,334 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,187,334 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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