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Paper 9
Entered: February 23, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOFIX MEDICAL INC.,
Petitioner,

v.

SPINE HOLDINGS, LLC,
Patent Owner.

IPR2020-01411
Patent 9,649,203 B2

Before JAMES A. TARTAL, ZHENYU YANG, and JOHN P. PINKERTON, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Orthofix Medical Inc. ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–20 of U.S. Patent No. 9,649,203 B2 (Ex. 1001, "the '203 patent"). Spine Holdings, LLC ("Patent Owner") filed a Preliminary Response (Paper 6 ("Prelim. Resp.")). With our authorization, Petitioner filed a Reply (Paper 7), and Patent Owner filed a Sur-Reply (Paper 8).

We have authority under 35 U.S.C. § 314, which provides that 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." 35 U.S.C. § 314(a). The Federal Circuit has interpreted the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition." *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, we institute an *inter partes* review of claims 1–20 of the '203 patent on all grounds.

A. Related Matters

According to the parties, Patent Owner asserted the '203 patent against Petitioner in *Spine Holdings, LLC. v. Orthofix Medical Inc.*, No. 4-20-cv-00077 (E.D. Tex.). Pet. 1–2; Paper 4, 2. That case has been stayed. Pet. 2; Paper 4, 2.

In the same district court case, Patent Owner also asserted against Petitioner U.S. Patent No. 9,216,096. Pet. 2; Paper 4, 2. Petitioner filed IPR2020-01412, seeking *inter partes* review of claims of that patent. Pet. 2; Paper 4, 2.

B. The '203 Patent

The '203 patent relates to spinal fusion, specifically, to spinal implants. Ex. 1001, 1:19–21. The '203 patent explains that "[i]ntervertebral discs can degenerate or otherwise become damaged over time." *Id.* at 1:23–24. It was known that "an intervertebral implant can be positioned within a space previously occupied by a disc" to "help maintain a desired spacing between adjacent vertebrae and/or promote fusion between adjacent vertebrae." *Id.* at 1:24–28. It was also known that "[t]he use of bone graft and/or other materials within spinal implants can facilitate the fusion of adjacent vertebral bodies." *Id.* at 1:28–30. The '203 patent states that there is a need for "an improved intervertebral implant, as well as related instrumentation, tools, systems and methods." *Id.* at 1:30–32.

The spinal implant of the '203 patent comprises at least one internal chamber defined by four walls (an anterior wall, a posterior wall, a first lateral wall and a second lateral wall) and two surfaces (a top surface and a bottom surface). *Id.* at 1:36–50. The top surface is configured to at least partially engage a lower surface of a first vertebral body and the bottom surface is configured to at least partially engage an upper surface of a second vertebral body. *Id.* at 1:44–50. The two vertebral bodies are adjacent to each other. *Id.* at 1:49–50.

According to the ’203 patent,

> The implant further comprises at least one opening extending through the anterior wall, wherein such an opening is in fluid communication with the internal chamber. In some embodiments, the spinal implant additionally comprises at least one access port located in the anterior wall, the first lateral wall and/or the second lateral wall. In some embodiments, the implant is configured to releasably secure to an insertion tool using the access port.

Id. at 1:53–60.

The ’203 patent discloses a method for promoting spinal fusion. *Id.* at 3:22–36. The method comprises providing a spinal implant, positioning the spinal implant between two adjacent vertebral bodies or vertebrae of a patient, and directing at least one graft material into at least one internal chamber through a port of the implant. *Id.* at 3:22–29. The ’203 patent also discloses that excess graft material is configured to exit the at least one internal chamber through one or more openings of the anterior wall. *Id.* at 3:29–36. According to the ’203 patent, excess graft “can generally fill any gap that exists between the vertebral endplates and the adjacent surfaces of the implant,” resulting in improved spinal fusion. *Id.* at 24:38–53.

C. Illustrative Claim

Claims 1 and 11 of the ’203 patent are independent. Claim 11 is broader than claim 1. Claim 11 is illustrative and is reproduced below:

> 11. A method of promoting spinal fusion within a spine of a patient, comprising:
>
> advancing an implant through an anatomy of a patient, the implant comprising at least one internal chamber;

positioning the implant between a first vertebra and a second vertebra of a patient, the first and second vertebrae being immediately adjacent to one another; and

directing graft material into the at least one internal chamber of the implant through an access port of the implant to fill the at least one internal chamber of the implant, after positioning the implant between the first and second vertebrae, such that the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae, and wherein the graft material is contained within the at least one internal chamber;

wherein the at least one internal chamber of the implant, after implantation, extends from or near an endplate of the first vertebra to or near an endplate of the second vertebra such that the graft material directed into the at least one internal chamber can be substantially retained between the first and second vertebrae.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §[1]	References
1–5, 9–15, 19, 20	103	Alfaro,[2] Frey[3]
6–8, 16–18	103	Alfaro, Frey, Perez-Cruet[4]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102, 103, and 112, effective March 16, 2013. On the face of the '203 patent, the earliest priority of the challenged claims is before the effective date of the AIA. Ex. 1001, code (60). Thus, pre-AIA version of §§ 102, 103, and 112 applies.

[2] Alfaro et al., U.S. Patent App. Pub. No. 2010/0262245 A1, published Oct. 14, 2010 (Ex. 1008).

[3] Frey et al., U.S. Patent No. 6,764,491, issued July 20, 2004 (Ex. 1005).

[4] Perez-Cruet et al., U.S. Patent App. Pub. No. 2008/0172128 A1, published July 17, 2008 (Ex. 1004).

In support of their respective positions, Petitioner relies on the Declaration of Michael Sherman (Ex. 1003), and Patent Owner relies on the Declarations of the co-inventors Jim R. Lynn (Ex. 2006) and Russell W. Nelson, M.D. (Ex. 2007), as well as Anna Green (Ex. 2008), Daniel M. Cislo (Ex. 2009), and Baron Lonner, M.D. (Ex. 2010).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b) (2019). Under that standard, the words of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

On this record and for purposes of this Decision, we see no need to construe any term expressly. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (stating that claim terms need only be construed to the extent necessary to resolve the controversy).

B. Obviousness over Alfaro and Frey

Petitioner asserts that claims 1–5, 9–15, 19, and 20 of the '203 patent would have been obvious over the combination of Alfaro and Frey. Pet. 16–71. Based on this record, we determine Petitioner has established a

reasonable likelihood that it would prevail in this assertion, at least with regard to claim 11.

1. Prior Art Disclosures

a. Alfaro

Alfaro relates to surgical devices for insertion of intervertebral spacer implants and delivery of bone grafting material into intervertebral spaces in surgical procedures. Ex. 1008 ¶ 4.

Alfaro teaches that, to correct various spinal defects, it is often necessary to place exogenous devices between vertebrae in an effort to fuse adjacent vertebrae to each other. *Id.* ¶ 5. One way to achieve this is to introduce and pressure-fit a solid material into the vertebral space between the opposing vertebral bodies. *Id.* Alfaro explains that

> The intervertebral spacer usually contains voids that are packed with an osteoconductive and/or osteoinductive material ("biologic", "biologic materials" or "bone grafting materials" herein) prior to insertion into the intervertebral space. The biologic material facilitates fusion of the two vertebrae to the spacer by the formation of bone to and through the intervertebral spacer from one vertebral body to the opposite vertebral body. It is important that the end plates of the superior and inferior vertebrae make good contact to the biologic material since bone does not span a gap or voids without the assistance of a conductive and inductive bridge.

Id.

According to Alfaro, when a spacer has been pre-loaded prior to insertion, there are certain difficulties that prevent a complete and total fusion. *Id.* ¶ 9. For example, the biologic material may fall out of the spacer. *Id.* In addition, the irregularity of the surfaces of the vertebral end plates may

cause gaps between the vertebral end plates, the biologic material and the intervertebral spacer. *Id.*

Alfaro teaches "a delivery system in the form of a unitary device which comprises a spacer disengagingly attached to a hollow handle." *Id.* ¶ 11. According to Alfaro,

> The handle facilitates the introduction of the spacer by the surgeon into the intervertebral space. The handle comprises a chamber for delivery of appropriate biologic material, and material-advancing means within the chamber for introducing the bone grafting material from the chamber into and around the spacer and the intervertebral spaces.

Id.

Alfaro teaches the spacer may be any intervertebral spacer, as long as it is attachable and detachable to the handle. *Id.* ¶ 12. The spacer comprises "voids and spaces which communicate with the chamber of the handle on the one hand and with the intervertebral spaces on the other." *Id.* "Thus, there is a direct line of flow through the handle into the voids of the spacer and out into the vertebral space." *Id.*

Alfaro teaches that

> In practice, the spacer is inserted surgically into the vertebral space and properly positioned therein using the handle as the inserter. The handle contains biologic material located in the chamber of the hollow handle. This material is then expressed via the material-advancing means, pushed through the chamber into the voids of the spacer and out into the intervertebral space. The excess material floods the space including the space between the surfaces of the spacer and the vertebrae giving a complete coverage or permeation of the interfaces. The handle is then

> disengaged from the spacer and the surgery appropriately terminated in the usual way.

Id. ¶ 19.

b. Frey

Frey relates to methods and instruments for performing disc space preparation and implant insertion from a unilateral approach to the spine through a posterior lateral opening to the disc space. Ex. 1005, Abstract.

Figure 55 of Frey is reproduced below:

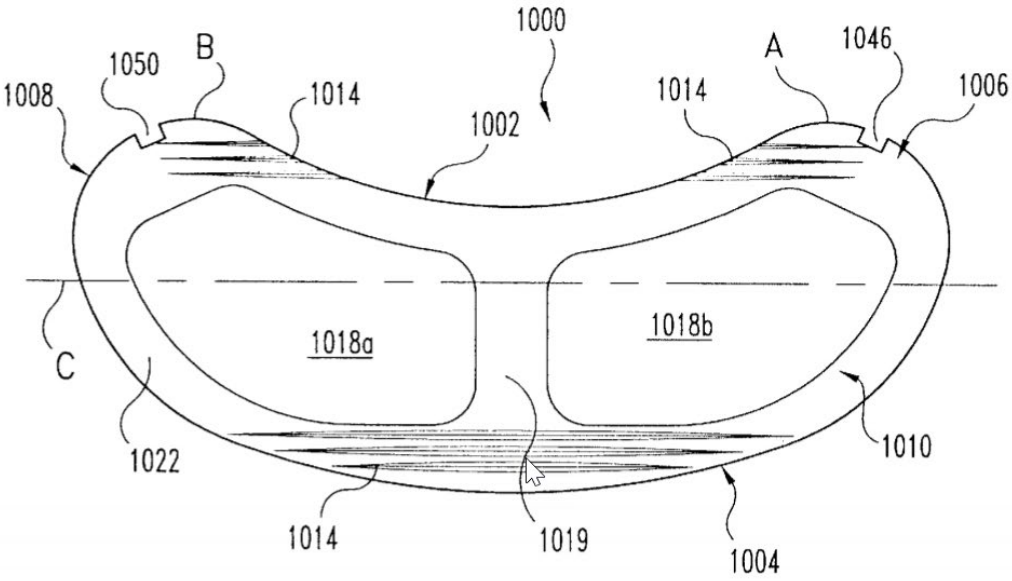


Fig. 55

Figure 55 is a top plan view of an implant according to one aspect of Frey. *Id.* at 5:3. "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.* at 19:18–21. Implant 1000 includes a concave posterior wall 1002, an opposite convex anterior wall 1004, an arcuate leading end wall 1006, and

an arcuate trailing end wall 1008. *Id.* at 19:43–46. It further includes an upper bearing member 1010 and a lower bearing member 1012 extending between and connecting walls 1002, 1004, 1006 and 1008. *Id.* at 19:50–52.

Figure 54 of Frey is reproduced below:

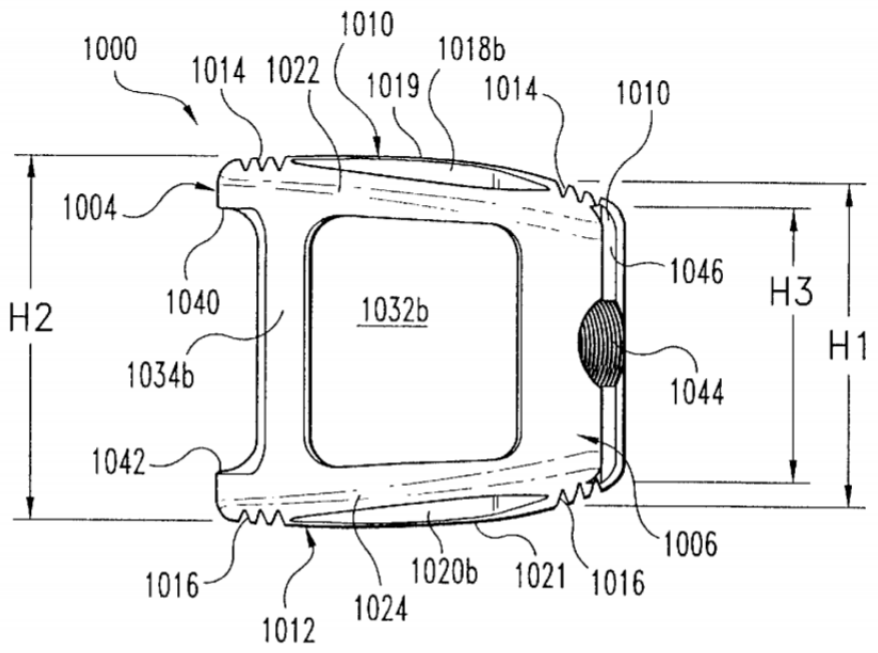


Fig. 54

Figure 54 is an end elevational view of the same implant shown in Figure 55. *Id.* at 5:1–3. According to Frey,

> Implant 1000 has a height H1 at the medial portion of posterior wall 1002 and a second height H2 at the medial portion of anterior wall 1004. Upper bearing member 1010 and lower bearing member 1012 have a slight convexity between the anterior and posterior walls 1002, 1004 and height H2 is preferably greater then H1 in order to correspond to the anatomy of the vertebral endplates at the posterior portion of disc space D1.

Id. at 19:53–60.

Frey also teaches that upper bearing member 1010 and lower bearing member 1012 can further be provided with a number of grooves 1014 and 1016, respectively. *Id.* at 20:6–8. "Grooves 1014 and 1016 can engage the vertebral endplates to resist posterior and anterior migration of implant 1000 in the disc space." *Id.* at 20:8–11.

2. Analysis

a. Prior Art Status of Alfaro

The '203 patent issued from an application that claims priority to a series of applications, including two provisional applications filed on March 16, 2010, and October 4, 2010, respectively. *See* Ex. 1001, codes (60), (63). Alfaro is a published U.S. patent application that was filed on February 17, 2010.[5] Ex. 1008, code (22). Thus, Petitioner asserts that Alfaro is prior art under 35 U.S.C. § 102(e). Pet. 15.

Patent Owner has produced evidence to antedate Alfaro. Exs. 2001–2010. Patent Owner argues that the inventors of the '203 patent conceived the claimed subject matter before the effective date of Alfaro, and diligently reduced the invention to practice during the critical period. Prelim. Resp. 10–26; Sur-Reply 1–5.

[5] Patent Owner states that "solely for the purposes of this Preliminary Response and without making any admission, [Patent Owner] treats Alfaro as having an effective filing date of its provisional application (February 18, 2009)." Prelim. Resp. 10; Ex. 1008, code (60). For purposes of this Decision, we do the same.

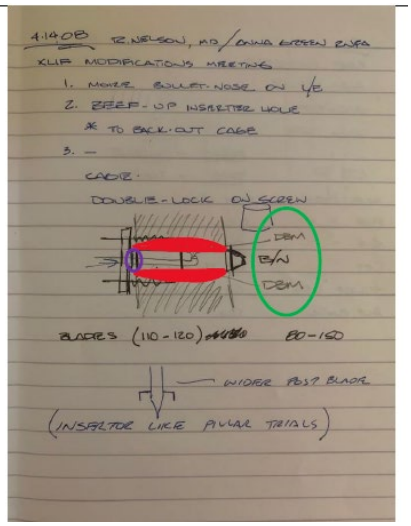
Petitioner challenges the sufficiency of Patent Owner's antedation arguments and evidence. Reply 3–8. Based on the current record, we find Petitioner's arguments sufficiently persuasive to support a reasonable likelihood of prevailing.

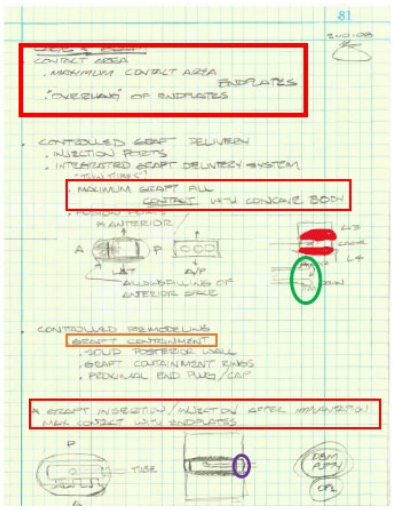
An inventor may antedate a § 102(e) reference by showing that the invention was conceived before the effective date of the reference, followed by reasonably continuous diligence until the constructive reduction to practice. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). Issues of diligence concern the period just preceding the effective date of the adverse reference, to the constructive reduction to practice. *In re Steed*, 802 F.3d 1311, 1317 (Fed. Cir. 2015). In this case, we agree with Patent Owner that it must show conception before February 18, 2009, the filing date of Alfaro's provisional application, and reasonably continuous diligence in reducing the invention to practice "from February 17, 2009 (the day prior to Alfaro's provisional filing date) to October 10, 2010 (the filing date of Applicant's Provisional Application No. 61/389,671 that resulted in the '203 Patent)." *See* Prelim. Resp. 10, 19.

Patent Owner relies on the declarations of both co-inventors, Mr. Lynn and Dr. Nelson (Exs. 2006, 2007), corroborating evidence including notebook pages of Mr. Lynn (Ex. 2002), other contemporaneous documents (Exs. 2001, 2003–2005), and declarations of a staff member and patent prosecution attorney (Exs. 2008, 2009), as well as the declaration of its expert, Dr. Lonner (Ex. 2010).

Specifically, Patent Owner argues that the co-inventors of the '203 patent started working to create a post-fill spinal implant in early 2008. Prelim. Resp. 11 (citing Ex. 2006 ¶ 7; Ex. 2007 ¶ 7). Patent Owner points to Mr. Lynn's notebook pages dated February 10, 2008 and April 14, 2008. *Id.* at 11–15; Ex. 2002, 1–5; Ex. 2006 ¶¶ 60–61; Ex. 2007 ¶¶ 56–57; Ex. 2010 ¶¶ 146–147. According to Patent Owner, "[b]y April 14, 2008, the inventors possessed a definite and permanent idea for at least all of the elements of claims 1 and 11." Prelim. Resp. 15.

We focus our analysis on the limitation "directing graft material into the at least one internal chamber of the implant through an access port of the implant to fill the at least one internal chamber of the implant . . . such that the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae." The co-inventors and Dr. Lonner provide identical testimony regarding this limitation. Ex. 2006 ¶¶ 60–61; Ex. 2007 ¶¶ 56–57; Ex. 2010 ¶¶ 146–147. They all rely on the same notebook pages of Mr. Lynn, reproduced below.





The figures above are the annotated notebook pages that Patent Owner relies on to show the conception of the limitation-at-issue. Ex. 2006 ¶¶ 60–61; Ex. 2007 ¶¶ 56–57; Ex. 2010 ¶¶ 146–147. The page on the left is dated April 14, 2008, and the one on the right is dated February 10, 2008.

The co-inventors and Dr. Lonner all testify that

> Because intervertebral bodies are naturally curved, there is [] generally some space between the implant and the intervertebral members. The sketches illustrate that there should be "maximum graft fill" and "maximum contact" with the endplates of the intervertebral members. Thus, i[t] i[s] inherent that the "maximum graft fill" and "maximum contact" result[] in the graft material being in flush contact with the vertebral members.
>
> The February 10, 2008 sketch describes "graft containment" when the graft material is directed into the implant. Thus, it is inherent in the February 10, 2008 sketch that the graft material is contained within the at least one internal chamber.

Ex. 2006 ¶¶ 60–61; Ex. 2007 ¶¶ 56–57; Ex. 2010 ¶¶ 146–147.

Relying on the testimony of its expert, Mr. Sherman, Petitioner contends that such evidence fails to demonstrate conception of directing graft material "to fill the at least one internal chamber of the implant . . . such that graft material is in flush contact." Reply 4 (citing Ex. 1024 ¶¶ 12–16). According to Mr. Sherman, Patent Owner "fails to consider and address the claimed requirement of 'directing graft material into' the implant 'to fill the internal chamber of the implant.'" Ex. 1024 ¶ 12.

Mr. Sherman explains that in the '203 patent, "it is the 'excess graft' (graft exceeding the volume of the internal chamber) that flows out of the internal chamber once the graft volume 'exceeds the internal capacity.'" *Id.*

(citing Ex. 1001, 24:20–53). He opines that, in contrast, Patent Owner's evidence shows "CONTROLLED GRAFT DELIVERY" accomplished by "directing graft material out of an empty internal chamber through 'FUSION PORTS' in the cage which 'ALLOWS FILLING OF ANTERIOR SPACE' outside of the cage and graft to be directly positioned by the right-angle nozzle above and below the cage." *Id.* (quoting Ex. 2002, 2), *see also id.* ¶ 14 ("The images illustrate depositing of graft above and below the implant without illustrating or discussing any graft in the internal chamber."), ¶ 15 ("[I]t is not the filling of the internal chamber that forces the graft material into contact with the endplates but directing the graft material by positioning the output of the nozzle of the fill tube.").

Mr. Sherman further testifies that

> [E]ven if one were to assume for the sake of argument that graft material would flow backwards over the right-angle graft delivery tube and begin to fill the internal chamber of the implant, neither the inventors nor Dr. Lonner provide any explanation of how the volume of bone graft that was directed outside the cage could fill the space inside the cage without reducing the volume of bone graft outside the cage (the bone graft that is supposed to be in "flush contact" with the endplate).

Id. ¶ 16.

Patent Owner does not directly address these criticisms. Instead, Patent Owner only counters a related but separate argument that the withdrawal of the angled tube would leave a void. Sur-Reply 4.

Petitioner also presents other arguments challenging Patent Owner's evidence on conception. Reply 4–5 (citing Ex. 1024 ¶¶ 10, 16–19, 21, 22, 24). Petitioner further contends that Patent Owner has not demonstrated

reasonably continuous diligence in reduction to practice. *Id.* at 5–8. Because we find that, on this record, Patent Owner has not sufficiently shown conception of directing graft material "to fill the at least one internal chamber of the implant . . . such that the graft material is in flush contact endplate surfaces" of the vertebrae, we do not reach those arguments.

In sum, based on the current record and for purposes of this Decision, we determine Petitioner has shown sufficiently that Alfaro qualifies as prior art under § 102(e). During trial, Patent Owner may, if it wishes to do so, further develop its antedation evidence and arguments, and Petitioner will have the opportunity to cross-examine Patent Owner's witnesses on this issue.

b. Obviousness over Alfaro and Frey

Petitioner contends that the combined teachings of Alfaro and Frey render obvious the subject matter of claims 1–5, 9–15, 19, 20. Pet. 25–71. At this stage of the proceeding, Patent Owner only disputes the prior art's teaching of

> wherein the graft material is contained within the at least one internal chamber;
>
> wherein the at least one internal chamber of the implant, after implantation, extends from or near an endplate of the first vertebra to or near an endplate of the second vertebra such that the graft material directed into the at least one internal chamber can be substantially retained between the first and second vertebrae.

Indeed, Patent Owner argues that "Alfaro and Frey do not teach an internal chamber that extends from or near a first vertebra, to or near a

second vertebra, and allows for retaining graft material between the vertebral bodies" (Prelim. Resp. 29), and that "neither can contain or retain graft material within an internal chamber"[6] (*id.* at 27).

Patent Owner does not yet challenge, and we agree, that Petitioner has sufficiently shown that Alfaro teaches the other limitations of claim 11. Based on the current record, and for purposes of this Decision, we adopt Petitioner's analyses of those limitations as our own. *See* Pet. 25–40. We focus our analysis on the two "wherein" clauses that Patent Owner disputes.

Petitioner argues that Alfaro teaches "placing the spacer '*near'* the adjacent endplates." *Id.* at 45. According to Petitioner, Alfaro teaches the claimed implant in the form of an intervertebral spacer. *Id.* at 27. Alfaro also teaches implanting the spacer between adjacent vertebrae in a patient. *Id.* at 28–29, 32. Referring to Figures 1, 2, 8, and 9 of Alfaro, Petitioner asserts that Alfaro teaches "spacers having one or two internal compartments or '*chambers*.'" *Id.* at 29. Figure 9 of Alfaro is reproduced below.

[6] Here and elsewhere, Patent Owner appears to use the terms "contain" and "retain" interchangeably. *See* Prelim. Resp. 27 (arguing "neither can contain or retain graft material within an internal chamber"), 47 (arguing that Alfaro "does not teach the containment and/or retainment of graft material within the internal chamber of the implant"). The challenged claims, however, require that "the graft material is *contained within the at least one internal chamber*," and "can be substantially *retained between the first and second vertebrae*." Ex. 1001, claims 1, 11 (emphases added).

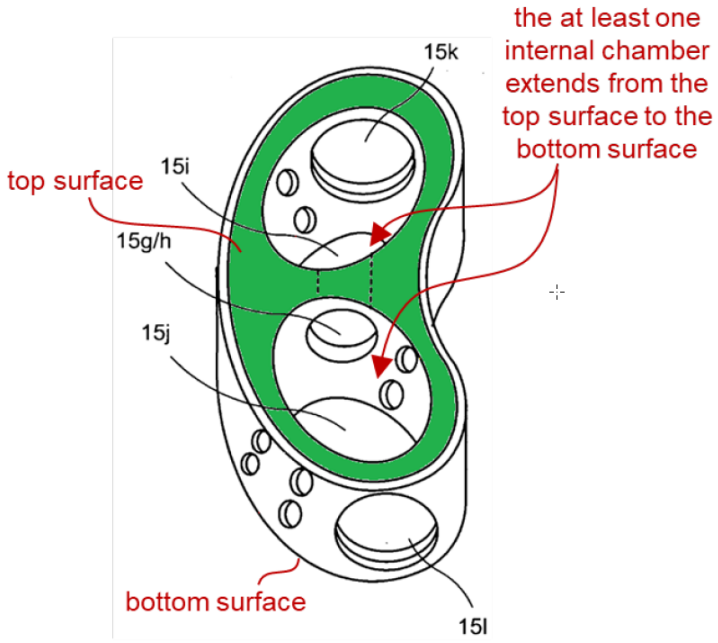
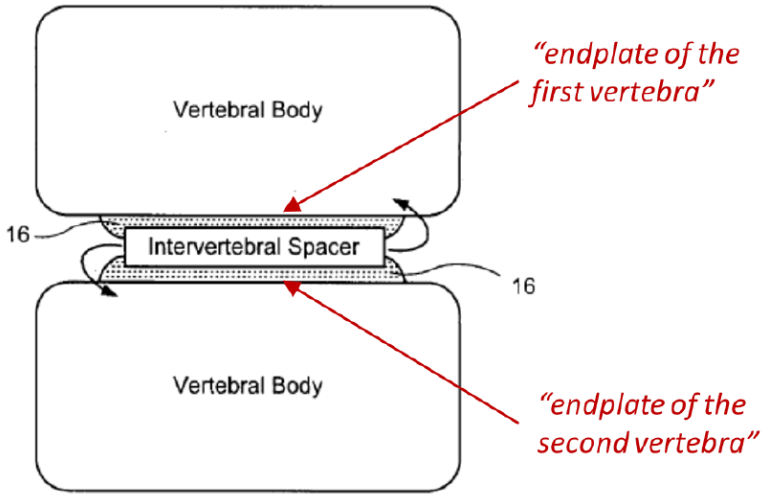


Figure 9 above shows a three dimension perspective view of the spacer of Alfaro, as annotated by Petitioner. Pet. 44; Ex. 1008 ¶ 27. Petitioner refers to Alfaro for teaching that the spacer of Figure 9 comprises two compartments, "open at the top of the spacer and at the bottom at 15(i) and 15(j) (in FIG. 9)," "are **adapted to contain DBM [demineralized bone matrix] or any other suitable biologic** and communicate with the opposing vertebral surfaces to allow the biologic to flow into the space." Pet. 41–42 (quoting Ex. 1008, ¶ 29, emphasis added by Petitioner), *see also id.* at 41 (arguing that the compartments in Figure 1 of Alfaro are "**shown to contain DBM**") (quoting Ex. 1008 ¶ 29, emphasis added by Petitioner). As a result, Petitioner argues that Alfaro teaches compartments that "contain" graft material. *Id.* at 42.

Again referring to Figure 9 of Alfaro, Petitioner argues that the curvilinear shaped spacer approximates the shape of a vertebral body,

"confirming that the top and bottom surfaces are adjacent to vertebral surfaces." *Id.* at 44 (citing Ex. 1003 ¶ 185); *see also* Ex. 1008 ¶ 20 ("[T]he spacer is shaped in a curvilinear fashion to approximate the shape of the vertebral body.").

Petitioner further refers to Figure 6 of Alfaro, reproduced below.



F I G. 6

Figure 6 above shows an elevation view of Alfaro's approach for delivering a biologic into the intervertebral spaces, as annotated by Petitioner. Pet. 45; Ex. 1008 ¶ 26. Petitioner points out that the spacer is "**pressure-fit into place between the opposing vertebral bodies so as to fix the device in place**." Pet. 44 (quoting Ex. 1008 ¶ 5, emphasis added by Petitioner). Thus, Petitioner argues that Alfaro teaches at least one internal chamber of an implant near the adjacent endplates of two opposing vertebrae. *Id.* at 45.

Alternatively, Petitioner argues that the combination of Alfaro and Frey teaches at least one internal chamber of an implant extends from an

endplate of the first vertebra to an endplate of the second vertebra. *Id.* at 45–47. According to Petitioner, Frey teaches an implant similar to the spacer of Alfaro. *Id.* at 45. The implant of Frey has upper and lower bearing members with grooves configured for directly engaging vertebral endplates to resist migration of the implant in the disc space. *Id.* at 45–46 (citing Ex. 1005, 19:50–52, 20:6–11).

Petitioner contends that it would have been obvious to modify the top and bottom surfaces of Alfaro's spacer to include Frey's grooves "to better resist migration of the intervertebral spacer in the intervertebral space to ensure that the implant achieves Alfaro's teaching that the intervertebral spacer 'remains in place at the correct site between the vertebrae.'" *Id.* at 46–47 (citing Ex. 1008 ¶ 31). As modified, Petitioner continues, the top and bottom surfaces of Alfaro's spacer are configured to directly engage the endplates of the first and second vertebrae. *Id.* at 47 (citing Ex. 1003 ¶ 192). As a result, Petitioner concludes that modified Alfaro's compartments, "which extend from the top surface to the bottom surface of Alfaro's intervertebral spacer, likewise extend from the endplate of the first vertebra to the endplate of the second vertebra." *Id.* (citing Ex. 1003 ¶ 193).

Petitioner further refers to Alfaro for teaching that "[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels . . . the DBM flow[s] through the compartments and into the vertebral spaces shown in FIG. 6 at 16." *Id.* at 48 (citing Ex. 1008 ¶ 31). According to Petitioner, this teaching, together with Figure 6 of Alfaro, shows that the graft material is

substantially retained between the adjacent vertebrae, as claim 11 requires. *Id.* (citing Ex. 1008, FIG. 6).

Relying on the declaration of Dr. Lonner, Patent Owner asserts that Alfaro does not contain graft material within an internal chamber. Prelim. Resp. 27 (citing Ex. 2010 ¶¶ 85–90, 92), 47 (citing Ex. 2010 ¶¶ 136–137). Dr. Lonner's testimony, however, does not support this argument. Indeed, Dr. Lonner only testifies that "there can be no containment or retainment of graft material in an internal chamber []as Frey is completely open." Ex. 2010 ¶ 90. Although he later states that Alfaro does not teach containment of graft material within at least one chamber, he either only cites Frey (*id.* ¶ 92 (citing Ex. 1005, 19:16–21)) or provides no support for his opinion.

Based on the current record, and especially in view of Alfaro's explicit teaching that the compartments "are adapted to contain DBM or any other suitable biologic," or are "shown to contain DBM" (Ex. 1008 ¶ 29), we are persuaded that Petitioner has met its burden regarding the limitation "the graft material is contained within the at least one internal chamber."

Patent Owner argues that Petitioner "falsely claims that Alfaro teaches an engagement, or interfacing of the implant and the vertebral bodies." Prelim. Resp. 28. We disagree with Patent Owner's characterization of Petitioner's argument. As discussed above, Petitioner contends that, not Alfaro by itself, but Alfaro as modified by Frey, teaches an engagement of the implant and the vertebrae (Pet. 47). *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981) ("[O]ne cannot show non-obviousness by attacking references

individually where, as here, the [challenges] are based on combinations of references.").

Regarding the combination of Alfaro and Frey, Patent Owner contends that the two references teach different implant styles for different purposes, and "Frey would defeat the purpose of Alfaro because of its open change [*sic*] design which would prevent graft material from ever generating a flush contact." Prelim. Resp. 27 (citing Ex. 2010 ¶¶ 85–90, 92).[7] Based on the current record, we are not persuaded by this argument.

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference." *Keller*, 642 F.2d at 425. "Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Id.* Here, Petitioner argues that (1) Alfaro teaches its spacer must "remain[] in place at the correct site between the vertebrae" (Pet. 46–47 (citing Ex. 1008 ¶ 31)); (2) Frey teaches grooves on the upper and lower bearing members engage the vertebral endplates to resist migration of the implant in the disc space (*id.* at 45–46 (citing Ex. 1005, 19:50–52, 20:6–11)); and (3) the combination of Alfaro and Frey would have suggested to an ordinarily skilled artisan to modify the top and bottom surfaces of

[7] Patent Owner also argues that "the combination would be improper because neither can contain or retain graft material within an internal chamber." Prelim. Resp. 27. It appears this argument relates to whether the combination teaches the limitation, rather than whether the teachings can be combined.

Alfaro's spacer to include Frey's grooves to better resist migration of the spacer (*id.* at 46–47 (citing Ex. 2003 ¶¶ 192, 193)). Patent Owner does not present sufficient evidence or argument to persuade us that Frey's open cage design would have changed this analysis.

Patent Owner also contends that Alfaro teaches away from Frey because the Alfaro's implant must include a compartment that is empty of graft material before insertion, whereas Frey teaches an implant with an open cage design. Prelim. Resp. 29 (citing Ex. 2010 ¶¶ 93–97, 138). Based on the current record, we are not persuaded by this argument either.

A reference teaches away "if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Although Alfaro points out the difficulty with spacers pre-loaded before insertion (Ex. 1008 ¶ 9), it does not address, let alone "criticize, discredit, or otherwise discourage," having grooves on the spacer's top and bottom surfaces. Thus, we are not persuaded that Alfaro teaches away from Frey.

Patent Owner further asserts that Alfaro is not enabled. Prelim. Resp. 28–29. According to Patent Owner,

> As shown in Figure 6 of Alfaro it is seen that there is the layer of graft material between the vertebral bodies and the implant, which illustrations [*sic*] that the internal chamber does not extends from or near a first vertebra to or near a second vertebra and retain graft material between the vertebral bodies.

Id. at 29 (citing Ex. 2010 ¶¶ 128–131). Neither this sentence nor the cited paragraphs of Lonner Declaration appear to be related to the enablement

argument.[8] In any event, a prior-art reference is generally presumed to be enabled. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Patent Owner does not present sufficient evidence or argument to rebut this presumption.

In sum, based on the current record and for purposes of this Decision, Petitioner has met its burden in showing that the combination of Alfaro and Frey teaches each and every limitation (Pet. 25–49), an ordinarily skilled artisan would have had a reason to combine the teachings (*id.* at 23–25, 46–47), and such combination "represents combining prior art elements . . . according to known methods to yield the predictable result" (*id.* at 23–24). In other words, there is a reasonable likelihood that Petitioner would prevail in its challenge of claim 11 over Alfaro and Frey. Thus, we institute an *inter partes* review as to all challenges raised in the Petition. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019)[9] ("The Board will not institute on fewer than all claims or all challenges in a petition.").

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[8] To the extent this argument relates to whether Alfaro teaches an internal chamber extending "from or near an endplate of the first vertebra to or near an endplate of the first second vertebra," we observe that, as Petitioner noted, "[t]he term '*near*' is not defined in the specification of the '203 patent." Pet. 45. Moreover, as explained above, we are persuaded that the combined teachings of Alfaro and Frey suggest an internal chamber extending from an endplate of the first vertebra to an endplate of the first second vertebra.

[9] Available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf

C. Obviousness over Alfaro, Frey, and Perez-Cruet

Petitioner asserts that claims 6–8 and 16–18 of the '203 patent would have been obvious over the combination of Alfaro, Frey, and Perez-Cruet. Pet. 71–91. Based on this record, we determine Petitioner has established a reasonable likelihood that it would prevail in this assertion, at least with regard to claim 16.

1. Perez-Cruet

Perez-Cruet relates to a minimally invasive interbody device assembly that includes "an interbody device for restoring the disc space height between two adjacent vertebrae during minimally invasive spinal fusion surgery," and "an instrument for positioning the device in the disc space and delivering bone graft material to the disc space on both sides of the device." Ex. 1004 ¶ 3. Specifically, Perez-Cruet teaches an "interbody device assembly employing a syringe for delivering the bone graft material down the instrument." *Id.* ¶ 35, FIG. 21, *see also id.* ¶ 62 (the same).

2. Analysis

Claim 16 of the '203 patent depends from claim 11 and recites

> wherein directing the graft material into the at least one internal chamber comprises using a graft material delivery system, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit.

Petitioner argues that Alfaro teaches a "syringe-type of system" for moving graft material through the handle and into the spacer. Pet. 80 (citing Ex. 1008 ¶ 12); *see also* Ex. 1008 ¶ 32 (teaching syringes as means for delivering graft material). Petitioner acknowledges that "Alfaro does not

explicitly disclose the implementation details of its disclosed syringes and how they would interface with Alfaro's hollow handle" for delivering graft material. Pet. 80. According to Petitioner, an ordinarily skilled artisan "would have been motivated to look to other references for implementation details regarding the implementation of its disclosed syringes." *Id.* at 74–75.

Petitioner asserts that "Perez-Cruet provides an illustrated example of a syringe-type system, as suggested by Alfaro." *Id.* (citing Ex. 1003 ¶ 276; Ex. 1004 ¶ 62), *see also id.* at 74–75 (the same). "When utilized with Alfaro's handle," Petitioner continues, "Perez-Cruet's syringe directs graft material into an internal compartment of a spacer . . . by positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's handle 12." *Id.* at 76 (citing Ex. 1003 ¶ 266), *see also id.* at 82–83 (citing Ex. 1003 ¶ 279–281) (the same). Thus, Petitioner concludes that the combination of Alfaro and Perez-Cruet teaches the additional limitation of claim 6. *Id.* at 84.

Patent Owner presents similar argument here as those in addressing the ground involving Alfaro and Frey. For example, Patent Owner argues that the combination of the prior art here is improper because Perez-Cruet is "a vertically aligned cage" and "does not allow for fusion in the same manner or methods of Alfaro or Frey." Prelim. Resp. 37 (citing Ex. 2010 ¶¶ 111–113). As explained above, we are not persuaded by this line of argument because obviousness analysis does not require bodily incorporation. *See Keller*, 642 F.2d at 425.

Patent Owner also asserts that "the plate of Perez-Cruet prevents solid fusion between the two sides of the implant, and regardless of the graft delivery system, delivery to the at least one internal chamber is not possible." Prelim. Resp. 38 (citing Ex. 2010 ¶¶ 114–115). We accord this argument no weight because it is not supported by the cited Lonner Declaration.

In sum, based on the current record, we find Petitioner has presented sufficient evidence and arguments to carry its burden with regard to obviousness of claim 16 over Alfaro, Frey, and Perez-Cruet.

III. CONCLUSION

Based on the current record, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of any challenged claim. Our view with regard to any conclusion reached in the foregoing could change upon further development of the record during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted on all challenged claims of the '203 patent based on the asserted 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, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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