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Paper 9
Date: February 25, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOFIX MEDICAL INC.,
Petitioner,

v.

SPINE HOLDINGS, LLC,
Patent Owner.

IPR2020-01412
Patent 9,216,096 B2

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

PINKERTON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Orthofix Medical Inc. ("Petitioner") filed a petition for *inter partes* review of claims 1–20 of U.S. Patent No. 9,216,096 B2 (Ex. 1001, "the '096 patent"). Paper 2 ("Pet."). Spine Holdings, LLC ("Patent Owner") filed Patent Owner's Mandatory Notices (Paper 4, "PO Notices") and a Preliminary Response (Paper 6 ("Prelim. Resp.")). Pursuant to our authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 7 ("Reply")), and Patent Owner filed a Sur-Reply (Paper 8 ("Sur-reply")).

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that 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) (2018); *see* 37 C.F.R. § 42.108 (2019). Upon consideration of the Petition, the Preliminary Response, and the associated evidence, we conclude that the information presented shows that there is a reasonable likelihood Petitioner would prevail in establishing the unpatentability of at least one challenged claim of the '096 patent.

A. Related Matters

The parties identify the following district court action that would affect, or be affected by, a decision in this proceeding: *Spine Holdings, LLC. v. Orthofix Medical Inc.,* No. 4-20-cv-00077 (E.D. Tex.) ("the district court litigation"). Pet. 2; PO Notices, 2; *see* 37 C.F.R. § 42.8(b)(2). Petitioner states that the '096 patent is related to U.S. Patent No. 9,649,203 B2 ("the '203 patent"). Pet. 2. Patent Owner states it owns the '203 patent, that the '203 patent is included in the complaint in the

district court litigation, and that the '203 patent is the subject of a petition for *inter partes* review in IPR2020-01411, filed on August 25, 2020. PO Notices, 2.

B. The '096 Patent

The '096 patent is titled "Intervertebral Implants and Related Tools." Ex. 1001, code (54). The '096 patent "generally relates to spinal fusion, and more specifically, to spinal implants and related systems, tools and methods." *Id.* at 1:18–21. The '096 patent Specification describes the invention in three sections primarily, which are designated as follows: "Spinal Implant" (*see id*. at 7:1–17:26); "Implantation into Targeted Intervertebral Space" (*see id*. at 17:27–21:4); and, "Filling of the Implant" (*see id*., 21:5–26:50). Figure 1A of the '096 patent, as annotated by Petitioner, is reproduced below.

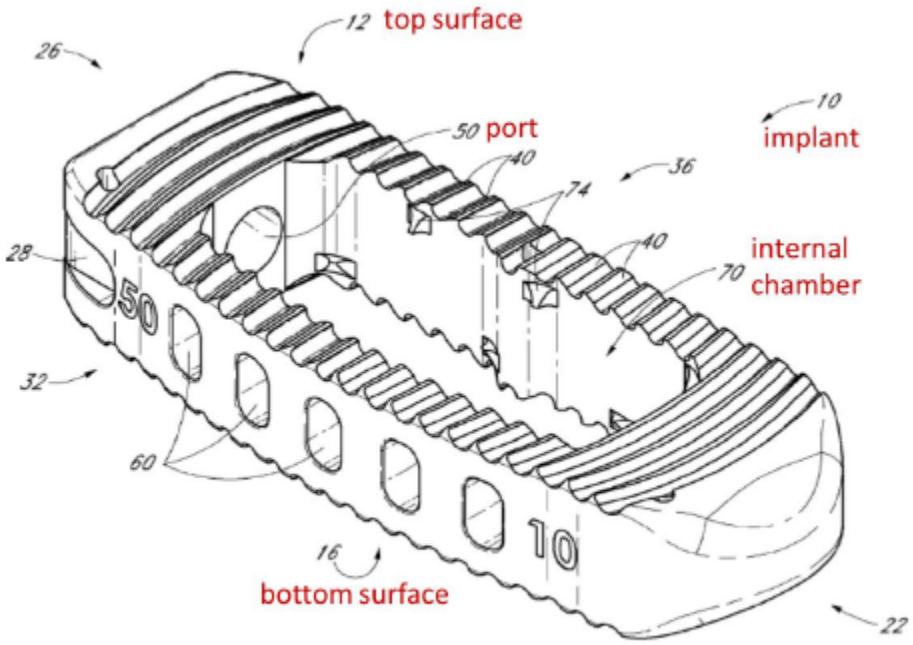

FIG. 1A

See id. at Fig. 1A; Pet. 6. Annotated Figure 1A illustrates a front perspective

view of spinal implant 10 according to one embodiment. Ex. 1001, 5:63–64. As depicted in Figure 1A, top surface 12 and bottom surface 16 of implant 10 comprise one or more teeth 40 or protruding members that are sized, shaped, and configured to contact and engage adjacent surfaces of the vertebral endplates once the implant has been positioned within the intervertebral space. *Id.* at 7:26–31. Such teeth or other engagement features 40 can help ensure that implant 10 does not migrate or otherwise undesirably move after implantation. *Id.* at 8:4–6. Implant 10 has left lateral end 26 and right lateral end 22, the exterior of which can be either generally planar (e.g., flat) or rounded, as desired or required. *Id.* at 7:60–61, 9:29–31. As shown in Figure 1A, right lateral end 22 includes both a vertical taper and a rounded profile when viewed from the top, which can facilitate insertion of implant 10 within the target intervertebral space. *Id.* at 9:5–10. Insertion tool receiving port 50 is positioned along lateral end 26 of implant 10 and is configured to releasably engage a corresponding insertion tool using a threaded connection. *Id.* at 9:34–40, 9:52–54.

Figure 11 of the ’096 patent is reproduced below.

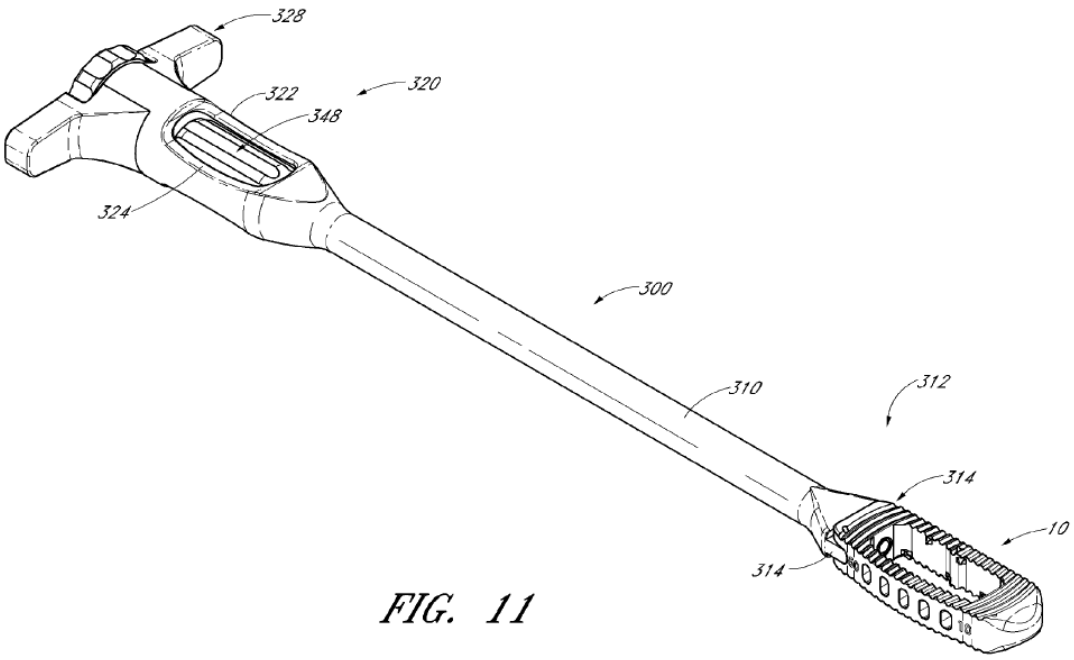

FIG. 11

Figure 11 illustrates a perspective view of insertion tool assembly 300 attached to spinal implant 10. *Id.* at 6:28–30; 19:47–50. Proximal portion 320 of insertion tool assembly 300 includes handle 322 and flared end 328. *Id.* at 19:63–65. Insertion tool assembly 300 includes outer elongated member 310 having distal end 312 adapted to releasably engage implant 10. *Id.* at 19:51–54. Outer member 310 can include inner passage 316 that extends from proximal end 320 to distal end 312 of insertion tool assembly 300 and that can receive a threaded rod 340, comprising main elongated portion 344 having distal end 346 to engage port 50 of implant 10. *Id.* at 19:59–62; 20:20:4–11; 20:45–48; *see also* Fig. 12A. Proximal end of threaded rod 340 has cylindrical thumbwheel 348, which is accessible through window(s) 324 of outer member 310, permitting a surgeon to selectively rotate thumbwheel 348 while grasping insertion tool assembly 300 to engage or release implant 10

from the assembly's distal end. *Id.* 20:19–29. Once implant 10 has been secured to distal end of insertion tool assembly 300, the surgeon can drive implant 10 into the targeted intervertebral space by impacting the proximal end of assembly 300 with a slap hammer assembly, a mallet or other tool or instrument. *Id.* at 20:54–61.

Figure 7A of the '096 patent is reproduced below.

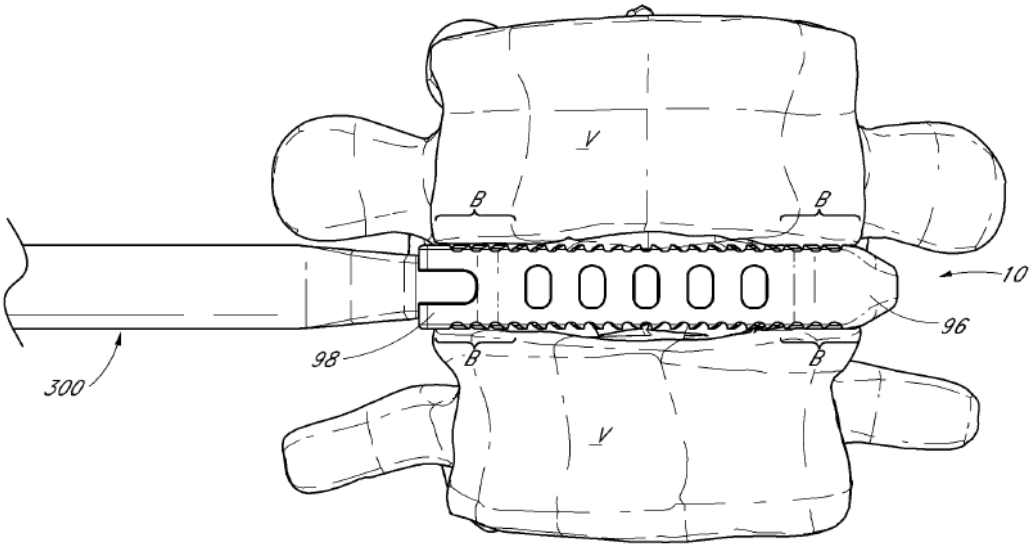

FIG. 7A

Figure 7A illustrates an anterior side view of implant 10 within a targeted intervertebral space between vertebrae V and secured to insertion tool assembly 300. *Id.* at 6:15–17; 15:21–26.

According to some embodiments of the '096 patent, once implant 10 has been properly implanted, insertion tool assembly 300 is decoupled from implant 10 and removed. *Id.* at 21:41–44. Subsequently, a fill tool assembly, comprising a catheter, tube, syringe or other conduit, can be positioned through, for example, port 50 to engage the implant and

selectively delivery graft material into the implant's internal chamber(s). *Id.* at 21:44–54. In other embodiments, insertion tool assembly 300 can be used to both deliver implant 10 to its proper intervertebral position and to subsequently fill the interior chamber(s) of implant 10 with graft material. *Id.* at 24:44–48. For example, internal passage 341 of cannulated threaded rod 340 can be sized, shaped, and configured to receive a flexible tube, catheter or other conduit of a syringe assembly to fill the chamber(s) of implant 10 with graft material. *Id.* at 24:48–52; *see also* Fig. 18.

C. Illustrative Claim

Among the challenged claims, claims 1 and 16 are independent. Claim 1 is illustrative of the subject matter of the challenged claims and reads as follows (with numbering added to identify the preamble and claim limitations consistent with those used by Petitioner):

> 1. [1.0] A spinal fusion system for placing an implant and graft material within a target intervertebral space, the system comprising:
>
> [1.1.1] (i)[1] an implant comprising: a first wall and a second wall, the second wall being generally opposite of the first wall;
>
> [1.1.2] [the implant comprising:] first and second side walls configured to extend between the first wall and the second wall;

[1] Following the preamble, claim 1's limitations are organized, in part, into three groups, designated as follows: "(i) an implant comprising," "(ii) an implant insertion tool," and "(iii) a graft material delivery system." Consistent with claim 1's designation for "an implant," we add the designation "(i)" to Petitioner's numbering scheme for limitation [1.1.1].

[1.1.3] [the implant comprising:] a top surface configured to at least partially engage a lower surface of a first vertebral body; [and] a bottom surface;

[1.1.4] [the implant comprising:] at least one internal chamber defined, at least in part, by the first wall, the second wall, the first side wall and the second side wall, wherein the at least one internal chamber extends from the top surface to the bottom surface of the implant; and

[1.1.5] [the implant comprising:] an access port extending through the first wall and being in fluid communication with the at least one internal chamber;

[1.1.6] wherein graft material is configured to be passed through the access port so at least a volume of graft material is selectively delivered into the at least one internal chamber;

[1.2] (ii) an implant insertion tool sized and configured to position the implant to a target intervertebral space;

[1.3] (iii) a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, 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;

[1.4] wherein, after delivery of the implant within the target intervertebral space, the first and second walls and the first and second sidewalls of the implant are configured to extend between superior and inferior vertebral members adjacent the target intervertebral space; and

[1.5.1] wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the at least one chamber upon implantation into the target intervertebral space

[1.5.2] such that the at least one chamber contains graft material delivered through the access port, thereby enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.

Ex. 1001 at 27:16–63.

D. Asserted Grounds of Unpatentability

Petitioner contends that claims 1–20 of the '096 patent are unpatentable based on the following grounds (Pet. 15):

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–8, 10–20	103(a)	Alfaro,[2] Frey,[3] Perez-Cruet[4]
9	103(a)	Alfaro, Frey, Perez-Cruet, Fuss[5]

In its analysis, Petitioner relies on the declaration testimony of Michael Sherman (Ex. 1003, "Sherman Decl."). *See id*. at 17–90.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review based on a petition filed on or after November 13, 2018, we apply the same claim construction standard that would be used in a civil action under 35 U.S.C. § 282(b), following the standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b) (2019). In applying such standard, claim terms are generally given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention and in the context of the entire patent disclosure. *Phillips*, 415 F.3d at 1312–13. "In determining the meaning of the disputed claim

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[2] U.S. Patent Application Publication No. US 2010/0262245 A1 ("the '245 publication"), published October 14, 2010 (Ex. 1008).
[3] U.S. Patent No. 6,764,491, issued July 20, 2004 (Ex. 1005).
[4] U.S. Patent Application Publication No. US 2008/0172128 A1, published July 17, 2008 (Ex. 1004).
[5] U.S. Patent No. 6,562,072 B1, issued May 13, 2003 (Ex. 1022).

limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy"); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs.* in the context of an *inter partes* review).

Petitioner contends that express construction is required only for claim 1's limitation [1.1.3], which recites "graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, 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," and the corresponding limitation of claim 16, which is the same as limitation [1.1.3], except it does not recite "a volume of." Pet. 11–12. Petitioner argues that the "graft material delivery system" limitation is a means-plus-function limitation because, although it does not use the word "means," the presumption that it is not a means-plus-function limitation is overcome as (1) it recites the function of "delivering a volume of graft material into the at least one internal chamber of the implant" and (2) the term "graft material delivery system" is not understood in the art as referring to a specific

structure, and the only structure recited is a "conduit," which is not sufficient for performing the stated function. *Id.* at 12–13 (citing *Williamson v. Citrix Online, LLC,* 792 F.3d 1339, 1348–49 (Fed. Cir. 2015) (en banc); Ex. 1003 ¶ 118). In regard to the corresponding structure disclosed in the Specification for performing the recited function, Petitioner asserts that "[t]he term 'graft material delivery system' is used in only one short passage stating: 'In some arrangements, the graft material delivery system comprises a syringe, a sizing tool and a conduit configured to pass through the at least one access port of the spinal implant.'" *Id.* at 13 (citing Ex. 1001, 4:13–22). Petitioner also asserts that the Specification describes another structure for performing the function, comprising insertion tool 300 (as shown in Figure 18) using "a flexible tube, catheter or other conduit of a syringe assembly," including syringe 650 (having plunger 658, and barrel 652) and tubing 670 (as shown in Figures 13 and 15). *Id.* at 13–14 (citing Ex. 1001, 22:25–32, 22:41–44, 24:42–56; Figs. 13, 15, 18) (emphasis omitted). According to Petitioner, "it suffices here to identify only the structure for performing the claimed function of a syringe attached to a conduit, or a plunger configured to displace graft material within a conduit." *Id.* at 15 (citing Ex. 1003 ¶¶ 116–125).

In its Preliminary Response, Patent Owner does not dispute Petitioner's argument that the "graft material delivery system" limitation of claims 1 and 16 is a means-plus-function limitation or Petitioner's proposed construction. *See generally* Prelim. Resp. Neither does Patent Owner argue that any claim limitations should be construed nor propose a construction for any claim terms. *See id.* Moreover, Patent Owner does not present any specific arguments that the "graft material delivery system" limitation of

claims 1 and 16 is not taught or suggested by the prior art references. *See id.* at 38–41 (claim 1), 47–50 (claim 16). Thus, the parties have not presented a dispute as to the meaning of the "graft delivery material system" or any other limitation that we need to resolve for purposes of institution.

Because resolving the present controversy for purposes of this Decision does not require the express construction of any claim terms, we do not construe expressly any terms at this stage of the proceeding.

B. Level of Ordinary Skill

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Relying on the testimony of its declarant, Mr. Sherman, Petitioner asserts that a person of ordinary skill in the art of the '096 patent, at the time of filing the earliest provisional application,

> would have had at least a bachelor's degree in the field of Mechanical, Biomechanical or Biomedical engineering and at least five years of experience in designing and developing spinal implants and related systems, tools and methods. Furthermore, a person with more technical education but less experience could also meet the relevant standard for [persons of ordinary skill in the art]. Alternatively, a [person of ordinary skill in the art] could be a practicing orthopedic surgeon or neurosurgeon with experience designing spinal implants.

Pet. 11 (Ex. 1003 ¶¶ 22–25). Patent Owner does not dispute Petitioner's assertions regarding the level of ordinary skill in the art. *See generally* Prelim. Resp.

Petitioner's use of the phrase "at least" in its description of the level of ordinary skill is too open-ended. We determine, on the current record, that the level of ordinary skill proposed by Petitioner, except for the reference to "at least," is consistent with the challenged claims of the

'096 patent and the asserted prior art, and we, therefore, adopt that modified level for purposes of this decision.

C. Ground 1: Asserted Obviousness over Alfaro, Frey, and Perez-Cruet

Petitioner contends that claims 1–8 and 10–20 of the '096 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Alfaro, Frey, and Perez-Cruet. Pet. 17–87. Relying in part on the testimony of Mr. Sherman, Petitioner explains how the references allegedly teach or suggest the claim limitations and provides reasoning for combining the teachings of the references. *Id.* at 30–87. In its Reply, Petitioner addresses Patent Owner's attempt to "swear behind" Alfaro, and argues that Patent Owner's evidence fails. Reply 1–8.

Patent Owner argues that Alfaro is not prior art to the '096 patent because the inventors conceived of the claimed subject matter before the alleged priority date of Alfaro and, together with their prosecution counsel, exercised reasonable diligence to reduce the invention to practice during the critical period. Prelim. Resp. 1, 8–26, 28; Sur-reply 1–5. Patent Owner also argues that, even if Alfaro is prior art, it cannot be combined with Frey and Perez-Cruet (Prelim. Resp. 26–38), and the combination of references does not teach or suggest all of the limitations of claims 1–8 and 10–20 (*id.* at 38–52).

1. Overview of Alfaro

Alfaro's U.S. Patent Application No. 12/656,788, which was published as the '245 publication, is titled "Intervertebral Spacer." Ex. 1008, code (54). Alfaro relates to surgical devices for insertion of intervertebral spacer implants and delivery of bone grafting material into intervertebral spaces in surgical procedures. *Id.* ¶ 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,

> [t]he 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 that 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 also 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.

Figure 2 of Alfaro is reproduced below:

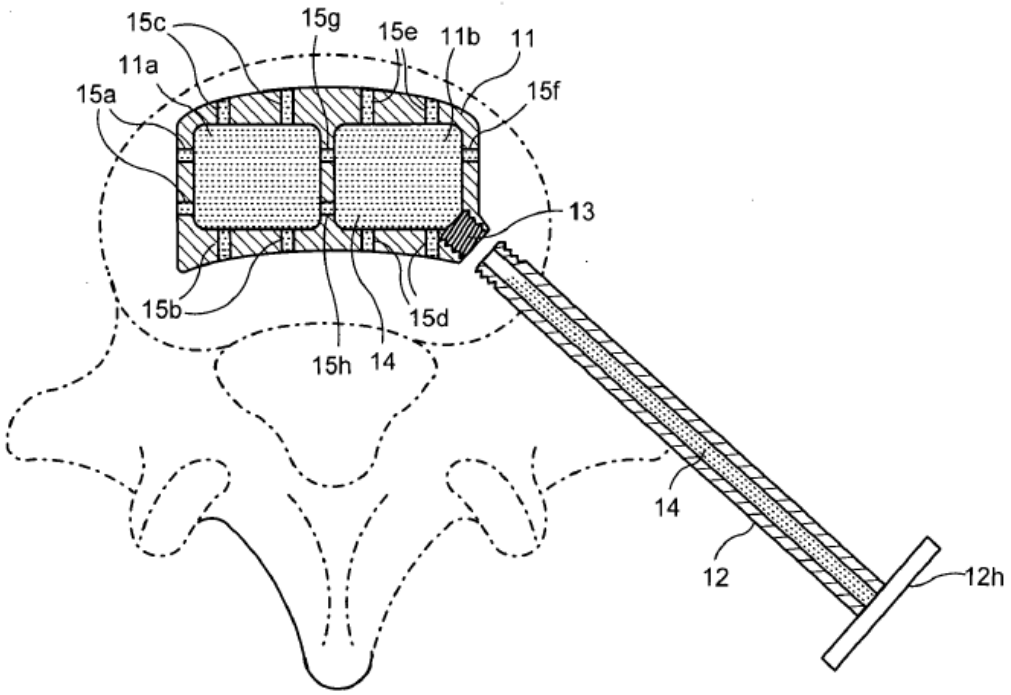

FIG. 2

Figure 2 is a plan view of an embodiment of Alfaro's delivery system containing biologic material and in place in the anatomy of a patient. *Id.* ¶ 24. Spacer 11 comprises compartments 11a and 11b, which are open at the top and bottom, and adapted to contain demineralized bone matrix (DBM). *Id.* ¶¶ 22, 28. Handle 12 screws into compartment 11b at 13. *Id.* ¶ 29. Handle 12 is shown to contain DBM 14 in the hollow portion of handle 12 and in compartments 11a and 11b. *Id.* Compartments 11a and 11b are connected by tunneling 15g and 15h to allow biologic material to flow from the compartment of introduction to the other compartment and out into the intervertebral space. *Id.*

2. Overview of Frey

Frey is U.S. Patent No. 6,764,491 titled "Devices and Techniques for a Posterior Lateral Disc Space Approach." Ex. 1005, code (54). 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. *Id.* at code (57).

Figure 55 of Frey is reproduced below:

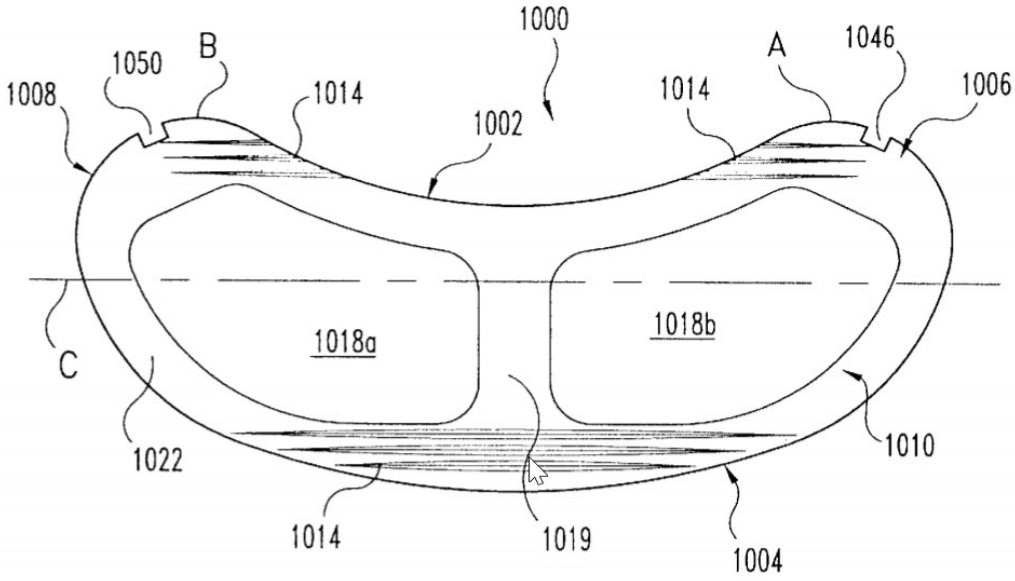

Fig. 55

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:

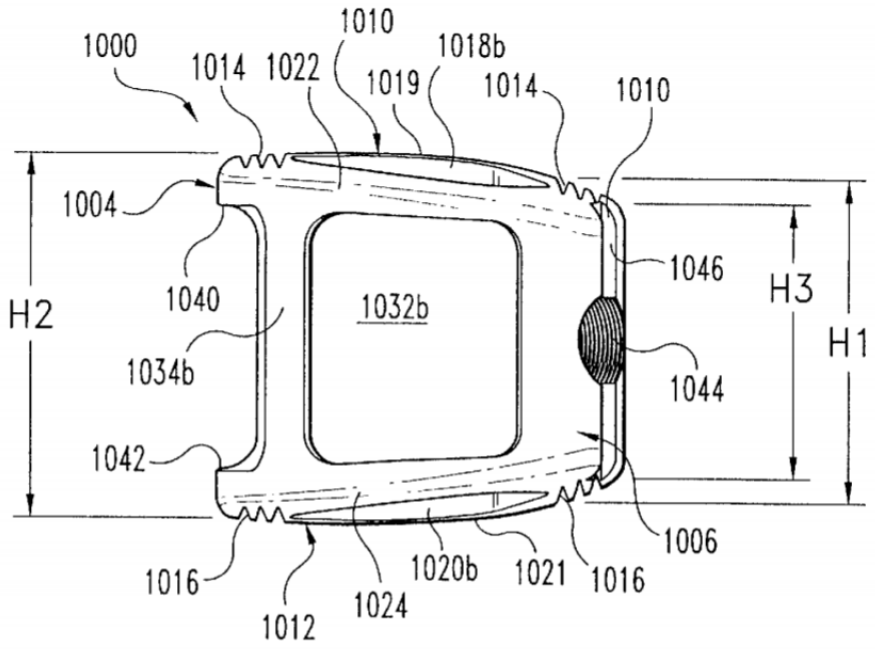

Fig. 54

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.

3. Overview of Perez-Cruet

Perez-Cruet's U.S. Patent Application No. 11/932,175, which was published as the '128 publication, is titled "Minimally Invasive Interbody Device Assembly." Ex. 1004, code (54). 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 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. *Id.* ¶ 3.

Figure 21 of Perez-Cruet is reproduced below:

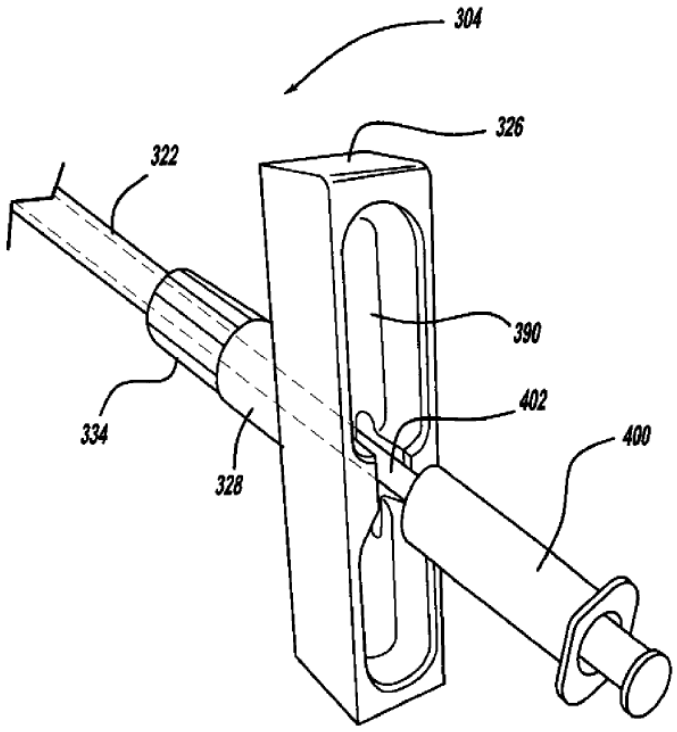

FIG - 21

Figure 21 is a perspective view of Perez-Cruet's assembly employing syringe 400 for delivering bone graft material down the instrument. *Id.* ¶ 35. Perez-Cruet explains that bone graft material is delivered through instrument 304 using syringe 400 having an extended tubular end portion 402. *Id.* ¶ 62.

4. Analysis

a. Is Alfaro prior art?

We first address Patent Owner's argument that Alfaro is not prior art under 35 U.S.C. § 102(e). Petitioner argues that "[b]ecause a patent is not presumed to be entitled to the benefit of any provisional application, *Dynamic Drinkware, LLC v. National Graphics, Inc*., 800 F.3d 1375, 1380 (Fed. Cir. 2015), the '096 Patent is entitled only to the filing date of its earliest non-provisional application of March 16, 2011."[6] Pet. 15. Nevertheless, Petitioner asserts that all of the references are prior art relative to the filing date of March 16, 2010, for even the earliest provisional application for the '096 patent.[7] *Id.* at 15–16.

Regarding Alfaro, Petitioner asserts that the patent application corresponding to the '245 publication was filed on February 17, 2010. *Id.* at 16 (citing Ex. 1008, code (22)). Petitioner also asserts that, should Patent Owner attempt to swear behind Alfaro, it will present evidence, among other things, that Alfaro is entitled to the benefit of U.S. Provisional Application

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[6] The '096 patent's earliest non-provisional application is U.S. Patent Application No. 13,049,693 ("the '693 application"), filed on March 16, 2011, now U.S. Patent No. 8,343,224. *See* Ex. 1001, code (63).

[7] The '096 patent's earliest provisional application is U.S. Provisional Patent Application No. 61/314,509 ("the '509 provisional"), filed on March 16, 2010. *See* Ex. 1001, code (60).

No. 61/207,912 ("the '912 provisional") (Ex. 1020), which was filed on February 18, 2009. *Id.* at 16–17 (citing Ex. 1003, App'xs. A, B).

Patent Owner argues that, because it has not been determined Alfaro is entitled to the benefit of its provisional application filed on February 18, 2009, Alfaro is entitled to the benefit of only its earliest non-provisional application filed on February 17, 2010. Prelim. Resp. 9. Patent Owner asserts, however, that solely for purposes of its Preliminary Response, and without making any admission, Patent Owner treats Alfaro as having an effective filing date of February 18, 2009, the filing date of the '912 provisional. *Id.* at 10.

(1) Applicable Law

The burden to show that Alfaro is prior art to the '096 patent rests with Petitioner. *Dynamic Drinkware,* 800 F.3d at 1379. Petitioner presents evidence that Alfaro was filed on February 17, 2010, prior to the filing date of March 16, 2011, for the '693 application, the earliest non-provisional application for the '096 patent, and therefore qualifies as prior art under 35 U.S.C. § 102(e). *See* Pet. 15–16 (citing Ex. 1008).[8] Thus, the burden of production shifts to Patent Owner to come forward with evidence showing that Alfaro is not prior art. *Dynamic Drinkware,* 800 F.3d at 1380.

A patent owner may remove a reference as prior art by "swearing behind" the reference, i.e., demonstrating an invention date prior to the filing date of the reference. *Taurus IP, LLC v. DaimlerChrysler Corp.,* 726 F.3d 1306, 1323 (Fed. Cir. 2013); *see, e.g.*, *Loral Fairchild Corp. v. Matsushita*

[8] As discussed *supra*, the parties agree, for purposes of this Decision, that Alfaro's effective filing date is February 18, 2009, the filing date of the '912 provisional.

Elec., 266 F.3d 1358, 1362 (Fed. Cir. 2001). To establish an earlier date of invention, a patent owner must prove either "(1) a conception and reduction to practice before the filing date of the [prior art] patent or (2) a conception before the filing date of the [prior art] patent combined with diligence and reduction to practice after that date." *Taurus IP*, 726 F.3d at 1323. An inventor's testimony, standing alone however, is insufficient to prove conception and diligence, as some form of corroboration is required. *Mahurkar v. C.R. Bard, Inc.,* 79 F.3d 1572, 1577 (Fed. Cir. 1996); *Price v. Symsek,* 988 F.2d 1187, 1194 (Fed. Cir. 1993). Corroboration is not required where a party seeks to prove conception through the use of physical exhibits because "the trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art." *Mahurkar,* 79 F.3d at 1577–78.

(2) Patent Owner's Arguments

Patent Owner argues Alfaro is not prior art because its evidence demonstrates (1) conception of the claimed subject matter of the '096 patent "no later than April 14, 2008, which is before the February 18, 2009 filing date" of Alfaro's '912 provisional (Prelim. Resp. 10–19) and (2) reasonable diligence in constructively reducing the invention of the '096 patent to practice during the critical period from February 17, 2009 (i.e., the day prior to Alfaro's effective filing date), to the filing on October 4, 2010 of the second provisional application for the '096 patent, U.S. Provisional Patent Application No. 61/389,671 ("the '671 provisional"), which "served as constructive reduction to practice" (*id.* at 19–26). *See* Ex. 1001, code (60).

Patent Owner's evidence includes the following: the declaration of Baron Lonner, M.D. (Ex. 2010 ("the Lonner Decl.")), who Patent Owner

asserts is "a premier spinal surgeon and designer of spinal implants" (*see* Prelim. Resp. 2); the declaration of Russell W. Nelson, M.D. (Ex. 2007 ("the Nelson Decl.")), who Patent Owner asserts is "a former spinal surgeon and co-inventor of the '096 Patent" (*see* Prelim. Resp. 2); the declaration of Anna Green (Ex. 2008 ("the Green Decl.")), who Patent Owner asserts is "Dr. Nelson's former surgical nurse and corroborating witness for conception and due diligence" (*see* Prelim. Resp. 2); the declaration of Daniel M. Cislo (Ex. 2009 ("the Cislo Decl.")), who Patent Owner states is "the inventors' prosecution counsel for their first provisional patent application that resulted in the '096 Patent" (*see* Prelim. Resp. 2); and, the declaration of Jim R. Lynn (Ex. 2006 ("the Lynn Decl.")), who states he is a co-inventor of the subject matter of the '096 patent (*id.* ¶ 4) and who is described by Patent Owner as Dr. Nelson's "spinal implant representative" (*see* Prelim. Resp. 11).

Patent Owner's evidence also includes Exhibit 2002, which has four pages with sketches, two pages of which are dated February 10, 2008 (Ex. 2002, 2, 3), and one page of which is dated April 14, 2008 (*id.* at 5). Mr. Lynn states that Dr. Nelson approached him about the possibility of making a post-fill spinal implant and that, "[b]eginning in early 2008, Dr. Nelson and I began to work together to create a post-fill implant and insertion method." Ex. 2006 ¶ 7. Mr. Lynn also states that, on February 10, 2008, he began to sketch out designs for the post-fill spinal implant, with notes about some of the objectives, and Exhibit 2002 "is a true and correct copy of the sketches from my February 10, 2008 notebook." Ex. 2006 ¶ 8. Mr. Lynn further states that on April 14, 2008, he attended a meeting with Dr. Nelson and Anna Green, in which they discussed modifications being

considered to the implant design, and that he sketched a drawing of the post-fill spinal implant, and took notes of the discussions about the modifications. Ex. 2006 ¶ 13. Mr. Lynn asserts that a true and correct copy of his sketch from the April 14, 2008 meeting is attached as Exhibit 2002. *Id.*

Patent Owner asserts that its evidence demonstrates conception of the claimed subject matter of the '096 patent no later than April 14, 2008, which is before the February 18, 2009 filing date of the Alfaro provisional. Prelim. Resp. 10 (citing Ex. 2006 ¶¶ 8, 13; Ex. 2007 ¶¶ 8, 14; Ex. 2008 ¶¶ 9, 12–13). Patent Owner argues that Dr. Nelson developed the initial idea for a post-fill spinal implant after he started performing extreme lateral interbody fusion ("XLIF") surgeries in 2007. *Id.* (citing Ex. 2006 ¶¶ 6–7; Ex. 2007 ¶¶ 6–7; Ex. 2008 ¶¶ 6–7). According to Patent Owner, Dr. Nelson noticed that the pre-filled graft material fell out of the spinal implants during insertion between the vertebral bodies, which resulted in gapping between the graft material and the vertebral bodies, which resulted in delayed fusion. *Id.* at 10–11 (citing Ex. 2007 ¶ 6).

Patent Owner also argues that on February 10, 2008, Mr. Lynn sketched out a design of the post-fill spinal implant and recorded ideas for injecting graft material into the spinal implant in a notebook, and discussed these ideas with Dr. Nelson and Ms. Green. *Id.* at 11–12 (citing Ex. 2006 ¶ 8; Ex. 2007 ¶ 8; Ex. 2008 ¶ 9; Ex. 2002, 1–4). Patent Owner asserts that the sketches show that "Dr. Nelson and Mr. Lynn had developed a definitive idea of the configuration of the post-fill spinal implant to facilitate 'controlled graft delivery.'" *Id.* at 13 (citing Ex. 2006 ¶ 10; Ex. 2007 ¶ 9; Ex. 2008 ¶ 9; Ex. 2002, 1–4).

Patent Owner further argues that on April 14, 2008, Dr. Nelson, Mr. Lynn, and Ms. Green held a meeting to discuss proposed modification to the post-fill spinal implant. *Id.* at 14 (citing Ex. 2006 ¶ 13; Ex. 2007 ¶ 12; Ex. 2008 ¶ 12; Ex. 2002, 5). Patent Owner asserts that during this meeting, Mr. Lynn sketched a drawing of their post-fill spinal implant along with the proposed modifications and notes from the meeting. *Id.* (citing Ex. 2006 ¶ 14; Ex. 2007 ¶¶ 13–15; Ex. 2008 ¶¶ 12–13; Ex. 2002, 5). According to Patent Owner, the sketch dated April 14, 2008 shows, among other things, that "Dr. Nelson and Mr. Lynn were considering modifying the nose of the post-fill spinal implant to have a bullet nose for easier insertion into the intervertebral space," and "Dr. Nelson and Mr. Lynn knew what the configuration of the insertion tool would look like." *Id.* at 14–15. Thus, Patent Owner argues that by April 14, 2008, "the inventors possessed a definite and permanent idea for at least all of the elements of claims 1 and 16," as shown in the charts attached at Appendices A and B of Mr. Lynn's and Dr. Nelson's declarations, and that Dr. Lonner "confirms that the charts correctly illustrate all of the claimed elements of claims 1 and 16." *Id.* at 15 (citing Ex. 2006 ¶¶ 60–61; Ex. 2007 ¶¶ 56–57; Ex. 2010 ¶¶ 164–165).

Patent Owner contends that the "critical period for diligence in this matter is from February 17, 2009 to October 10, 2010." Prelim. Resp. 19. Patent Owner argues that the inventors of the '096 patent exercised reasonable diligence to reduce to practice the claimed subject matter of the patent. *Id.* at 19–25. In that regard, Patent Owner asserts, for example, during February 2009 through July 2009, Mr. Lynn attended multiple surgeries that were performed by Dr. Nelson, with assistance from

Ms. Green, and "[d]uring, and after, the surgeries, Dr. Nelson, Ms. Green, and Mr. Lynn discussed the flaws with the existing implants and insertion methods and how they could improve their design to address the flaws." *Id.* at 19–21 (citing Ex. 2006 ¶¶ 19, 21–22, 25–26, 28, 30, 32–35, 38–40, 42–45; Ex. 2007 ¶¶ 23–25, 28–29, 31–32, 34–37, 39, 40–46; Ex. 2008 ¶¶ 16–34; Ex. 2004, 1–6 (2009 calendar)).

Patent Owner also asserts that in August of 2009, "Mr. Lynn retained Dan Cislo to assist in activity related to the preparation and filing" of the '509 provisional. *Id.* at 22 (citing Ex. 2006 ¶ 46; Ex. 2009 ¶ 6). According to Patent Owner, in October 2009, Mr. Cislo performed a patentability search for the post-fill spinal implant and insertion method, and in January 2010, Mr. Lynn sent Mr. Cislo an invention disclosure for preparation of the '509 provisional. *Id.* at 24 (citing Ex. 2009 ¶¶ 9–10; Ex. 2006 ¶ 53). Patent Owner further asserts that between January 13, 2010 and February 23, 2010, Mr. Cislo worked on drafting the '509 provisional, and that on March 16, 2010, "Mr. Lynn instructed Mr. Cislo to file the '509 Provisional Application." *Id.* (citing Ex. 2009 ¶¶ 10–17, 22; Ex. 2006 ¶ 55).

Patent Owner argues that after filing of the '509 provisional, "the inventors kept working on optimizing the design." *Id.* at 24. Patent Owner asserts the inventors (1) "realized that a right angle at the distal tip of the delivery tube was not a necessary element, and that graft material with the right viscosity could flow through the implant without the angled tip," and (2) after continuous testing, "determined that the bridge extending between the two side walls was unnecessary" because the post-fill spinal implant would withstand the compressive forces from the vertebral bodies without the bridge. *Id.* at 24–25 (citing Ex. 2006 ¶ 58; Ex. 2007 ¶ 54).

Patent Owner further asserts that on October 4, 2010, Mr. Lynn instructed Mr. Papagiannis to file the '671 provisional that "served as constructive reduction to practice." *Id.* at 25 (citing Ex. 2006 ¶ 59; Ex. 2007 ¶ 55).

Patent Owner asserts that, accordingly, Alfaro cannot be considered prior art because "[a]pplying the rule of reason analysis, the evidence submitted shows that the inventors diligently worked to reduce the invention to practice during the critical period and established an earlier date of invention than Alfaro." *Id.* at 25–26 (citing *Perfect Surgical Tech., Inc. v. Olympus Am., Inc.,* 841 F.3d 1004, 1009 (Fed. Cir. 2016); *Monsanto Co. v. Mycogen Plant Science,* 261 F.3d 1356 (Fed. Cir. 2001) (finding continuous work despite the lack of daily entries)).

(3) Petitioner's Reply

In its Reply, Petitioner contends that although Patent Owner does not challenge Alfaro having an effective filing date of February 18, 2009, Patent Owner's evidence in support of its attempt to show the claimed subject matter of the '096 patent was conceived before that date, and show diligence in constructively reducing the invention to practice by filing the '671 provisional on October 4, 2010, is unpersuasive. Reply 1. First, Petitioner argues that Patent Owner fails to prove conception of any claim of the '096 patent before Alfaro's effective filing date. *Id.* at 1–5. Petitioner asserts that Patent Owner is required to present evidence of conception for each claim, but Patent Owner "has presented no evidence of conception for any challenged dependent claim[s]." *Id.* at 1–2 (citing *Burroughs Wellcome Co. v. Barr Labs*, 40 F.3d 1223, 1228 (Fed. Cir. 1994); *LG Electronics, Inc. v. ATI Technologies ULC*, IPR2015-00325, Paper 21 at 24 (Patent Owner's

Response)). According to Petitioner, this deficiency is fatal to any attempt to swear behind dependent claims 2–15 and 17–20. *Id.* at 2.

Petitioner also asserts that Patent Owner's evidence for claims 1 and 16 fails to prove that the inventors possessed all elements of these claims prior to February 18, 2009. *Id.* at 2–5. In that regard, Petitioner argues the evidence is insufficient to show "an implant insertion tool sized and configured to position the implant to a target intervertebral space" because the entirety of Patent Owner's corroborating evidence of conception is the parenthetical "(INSERTER LIKE PILLAR TRIALS)" and an unsupported statement that "[i]t is inherent that the 'inserter' was used to position the implant in the target intervertebral space," "with essentially no disclosure of how such an 'insertor' might be 'configured, sized, designed, or implemented.'" *Id.* at 3 (citing Ex. 1027 ¶¶ 21–22, 24 (Sherman reply declaration); Ex. 2010, 97, 102) (emphasis omitted, alteration in original).

Petitioner also argues Patent Owner is lacking corroborated conception evidence for the following limitations of claims 1 and 16: "a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant; … [and an implant] enabling the at least one internal chamber to be filled such that graft material is in flush contact with the end plate surfaces of the adjacent superior and inferior vertebral members." *Id.* at 4 (italics omitted). Petitioner asserts that, based on the handwritten phrases of "maximum graft fill" and "max contact with endplates," Patent Owner's expert argues that the claimed feature of filling the internal chamber "such that graft material is in flush contact with endplate surface" would be "inherent." *Id.* (citing Ex. 2010, 101–02). Petitioner also asserts that its expert, Mr. Sherman, disagrees

because the referenced disclosure is of a graft delivery system for "controlled graft delivery" with a 90° angled tube shown depositing graft material, and "[t]he cage 'internal chamber' is not 'filled such that graft material is in flush contact' and, even if it were filled by the angled tube, withdrawal of the tube with an angled tip . . . would leave a void after removal." *Id.* at 4–5 (citing Ex. 1027 ¶¶ 10, 12–16, 19) (emphasis omitted). Moreover, Petitioner argues that based on the inventors' testimony it was only after filing the first provisional on March 16, 2010 that "[e]ventually, we realized . . . that graft material with the right viscosity could flow through the implant without the angled distal tip," the evidence of record more strongly suggests it was not until 2010 that the inventors purportedly determined a system with a graft delivery tool and implant combination that would achieve the desired results of an implant "filled such that graft material is in flush contact with the end plate surfaces," as claimed. *Id.* at 5 (citing Ex. 2006 ¶ 58; Ex. 2007 ¶ 54) (emphasis omitted, alteration in original).

Second, Petitioner contends Patent Owner has not demonstrated that the inventors exercised reasonably continuous diligence "throughout the critical period." Reply 5–8 (citing *Perfect Surgical Tech.*, 841 F.3d at 1007, 1009). Petitioner argues, for example, Patent Owner has conjured up a hindsight-driven explanation that "the inventors were searching for a biologic material with a viscosity that could controllably flow through their post-fill spinal implant and Mr. Lynn wanted to find a flowable graft material that would work with the post-fill implant," but "this scheme is not corroborated by any evidence from a non-inventor." *Id.* at 6 (citing Prelim. Resp. 19). Petitioner also argues that Patent Owner "points to no significant

inventive activity during the period from February 2009 to January 2010 related to its theory of searching for a suitable injectable material." *Id.* at 6–8 (citing Ex. 1027 ¶¶ 29–32, 34–35).

Petitioner further argues that, with respect to the April 2010 through October 2010 period, the inventors assert, with no corroboration, that they were involved in "continuous testing," but as with the February 2009–January 2010 period, "there is no evidence of any experimentation with any devices." *Id.* at 8 (citing Prelim. Resp. 25). According to Petitioner, the lack of activity during the period April 2010–October 2010 alone is strong evidence that "the invention was . . . abandoned or unreasonably delayed" and therefore the inventors were not diligent." *Id.* (citing *Perfect Surgical Tech*., 841 F.3d at 1009) (alteration in original).

Thus, Petitioner asserts Alfaro is prior art as to all challenged claims because Patent Owner presents no evidence to swear behind Alfaro for dependent claims 2–15 and 17–20, and Patent Owner's evidence related to claims 1 and 16 is deficient both as to conception and diligence. *Id.*

(4) Patent Owner's Sur-reply

In response, Patent Owner first contends that Petitioner applies an improper standard for antedating a reference by arguing Patent Owner must provide evidence showing that each limitation of every claim antedates the reference. Sur-reply 1. Instead, according to Patent Owner, "the patent owner must only provide evidence of priority with respect to only so much of the claimed invention as the reference is relied upon for disclosing." *Id.* (citing *In re Scheiber,* 587 F.2d 59, 61–62 (CCPA 1978)). Patent Owner argues it has met this standard by providing evidence of priority with what Alfaro has been asserted as disclosing. *Id.* With respect to dependent

claims, Patent Owner argues that "courts have held that any differences between the dependent claims and the conception evidence may be resolved by application of both a POSITA's knowledge and skill and secondary references available at the time of conception." *Id.* (citing *In re Spiller,* 500 F.2d 1170, 1176–77 (CCPA 1974)).[9] Patent Owner also argues that any differences between elements in the dependent claims and the conception evidence can be resolved by Perez-Cruet, Frey, and Fuss ("Secondary References") that Petitioner combines with Alfaro, and predate Alfaro's earliest possible priority date (February 18, 2009) and Patent Owner's "unrebutted constructive reduction to practice date (October 3, 2010),"[10] and the knowledge and skill of a person of ordinary skill in the art. *Id.* at 1–2.

Second, Patent Owner contends that Petitioner applies an improper standard for diligence by asserting Patent Owner is required to provide evidence accounting for "continuous activity" during the critical period because "the law only requires that there be *reasonably continuous activity* during the critical period." *Id.* at 2 (citing *Perfect Surgical Tech.*, 841 F.3d at 1009). Patent argues that, under this legal standard, Patent Owner is not required "to account for every day, week, or even month during the period," and "it is improper to dispute a finding of reasonably continuous activity by focusing on any period of inactivity." *Id.* (citing *Perfect Surgical Tech.*, 841 F.3d at 1009). Patent Owner also argues that "[a]ntedating law also recognizes that the lack of documentary evidence is excusable for events not occurring in the immediate past." *Id.* at 3 (citing *NFC Tech., LLC v. Matal*,

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[9] Person of ordinary skill in the art ("POSITA").
[10] We note that the '671 provisional was filed on October 4, 2010, rather than October 3, 2010.

871 F.3d 1367, 1374 (Fed. Cir. 2017)). According to Patent Owner, it "has produced substantial evidence of the inventors continuously working to reduce their invention to practice, which occurred over ten years ago, with evidentiary gaps excusable under relevant law." *Id.*

Third, Patent Owner argues that Petitioner ignores the significance of its conception evidence in view of the knowledge of a person of ordinary skill in the art. Sur-reply 3–4. With respect to the limitation "an implant insertion tool sized and configured to position the implant to a target intervertebral space," Patent Owner argues that Petitioner's assertion it is not shown in Patent Owner's conception evidence because there is no illustration of an insertion tool, but only a "cryptic" reference to an "inserter like pillar trials," is not persuasive as Petitioner acquired ownership of the Pillar Trial Insertion tool[11] from Blackstone Medical Inc. in 2006, and "it would have been obvious to a POSITA of the insertion tool's configuration and sizing." *Id.* at 4. With respect to the limitation "such that graft material is in flush contact with the endplate surfaces," Patent Owner argues that Petitioner's argument it is not shown in the conception evidence fails for two reasons: (1) a void within the graft material would not otherwise affect flush contact with the endplate surfaces; and (2) the conception evidence unequivocally states that there should be "maximum graft fill" for "contact with [the] concave body" of the vertebral bodies, and a person of ordinary skill "would recognize that the chamber could continue to be filled as the

[11] Patent Owner also asserts that the Pillar Trial Insertion Tool has been publicly available on the internet at the following websites: (1) Layout 1 (mckenzieillustrations.com); and (2) PL-2001.2-Pillar-AL-OpTech-Update-Rev-AA-A4_FNL.pdf (orthofix.com). Sur-reply 3.

angled tip is withdrawn, which would fill the asserted void." *Id.* (alteration in original).

Fourth, Patent Owner contends that Petitioner, in asserting there is insufficient evidence of diligence, "improperly discounts the inventors' testimony that they continuously worked during the April 2010 to October 2010 period." *Id.* Patent Owner argues that Petitioner fails to consider Mr. Cislo's preparation of the '509 provisional as inuring to the benefit of the inventors. *Id.* (citing *Bey v. Kollonitsch*, 806 F.2d 1024, 1027–1028 (Fed. Cir. 1986); *Haskell v. Colebourne*, 671 F.2d 1362, 1368 (CCPA 1982); MPEP § 2138.06 (I) (9th ed. rev. 10.2019 June 2020)). Patent Owner also argues that additional evidence in support of diligence includes the improvements to the implant from the initial conception drawings, as evidenced by the drawings included in the '671 provisional, "namely: (1) removal of the delivery tube; (2) removal of the bracket; and (3) removal of the bridge between the side walls." *Id.* (citing Prelim. Resp. 24–26; *compare* Ex. 2002 *with* Ex. 1001, 10–12). Patent Owner further argues that, "in view of the rule of reason, it is evident that the inventors continued to work on their invention until they filed the '671 [provisional]." *Id.*

For these reasons, Patent Owner asserts it "has presented substantial evidence of conception and diligence for claims 1–20" of the '096 patent to remove Alfaro as a reference. *Id.*

(5) Conclusion on Alfaro as Prior Art on the Current Record

As discussed above, Petitioner has come forward with evidence to support its assertion that Alfaro is in fact prior art because Alfaro is entitled to the benefit of the '912 provisional, which was filed on February 18, 2009. *See* Pet. 16–17. Petitioner has also come forward with evidence and

arguments that Patent Owner's attempt to show conception of the claimed subject matter of the '096 patent before that date, and show diligence in constructively reducing the invention to practice by filing the '671 provisional on October 4, 2010, is unpersuasive because Patent Owner presents no evidence to swear behind Alfaro for dependent claims 2–15 and 17–20, and Patent Owner's evidence related to claims 1 and 16 is deficient both as to conception and diligence. *See* Reply 1–8. As also discussed above, Patent Owner has come forward with evidence and argument that Alfaro is not prior art due to the asserted prior conception, constructive reduction to practice, and diligence on the part of the inventors during the critical period from February 17, 2009 to October 4, 2010. *See* Prelim. Resp. 8–26; Sur-reply 1–5. However, on this record and at this preliminary stage, the evidence and arguments before us are insufficient to show the asserted conception of the invention prior to Alfaro's effective filing date of February 18, 2009, and reasonable diligence in constructively reducing the invention to practice by filing the '671 provisional on October 4, 2010.

Importantly, Patent Owner does not explain in sufficient detail how the proffered testimony and documents disclose every limitation of the challenged claims, as Petitioner asserts Patent Owner is required to do (*see* Reply 1–5), or "so much of the claimed invention as [Alfaro] is relied upon for disclosing," as Patent Owner asserts (*see* Sur-reply 1). In that regard, relying on the testimony of its expert, Mr. Sherman, Petitioner argues that Patent Owner's evidence fails to demonstrate conception of "delivering a volume of graft material into the at least one internal chamber of the implant . . . such that graft material is in flush contact with the endplate surfaces," because the claimed feature is not "inherent" and is inconsistent with

Mr. Lynn's sketch and notes, which are for a graft delivery system for "controlled graft delivery" with a 90º angled tube for depositing graft material. Reply 4–5 (citing Ex. 1027 ¶¶ 10, 12–16, 19; Ex. 2002). Patent Owner does not directly address Petitioner's argument, but instead counters a related, but separate argument that the withdrawal of the angled tube would leave a void. Sur-reply 4. We also note that Petitioner has not had the opportunity to test Patent Owner's evidence through cross-examination of Mr. Lynn, Dr. Nelson, and Ms. Green in this proceeding. We encourage the parties to further develop this issue over the course of the trial.

Thus, for the reasons discussed above, we are persuaded for purposes of this Decision that Alfaro is prior art under § 102(e).

b. Independent claim 1

Petitioner argues that Alfaro teaches all of the limitations of claim 1, except for limitation [1.3], with respect to which Petitioner argues Alfaro combined with Perez-Cruet renders obvious. Pet. 30–59. Petitioner also argues that Alfaro combined with Frey renders obvious limitations [1.1.3] and [1.4]. *Id.* at 35–39, 48–53. Petitioner further argues that a person of ordinary skill in the art would have been motivated to combine Alfaro and Frey (*id.* at 21–24) and Alfaro and Perez-Cruet (*id.* at 26–30).

In its Preliminary Response, Patent Owner contends Petitioner has not met its burden of establishing that claims 1–8 and 10–20 are rendered obvious by Alfaro in view of Frey and Perez-Cruet. Prelim. Resp. 26. With respect to claim 1, although Patent Owner does not refer to specific limitations by number, we understand Patent Owner challenges Petitioner's showing regarding limitations [1.5.1] (reciting, "wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the

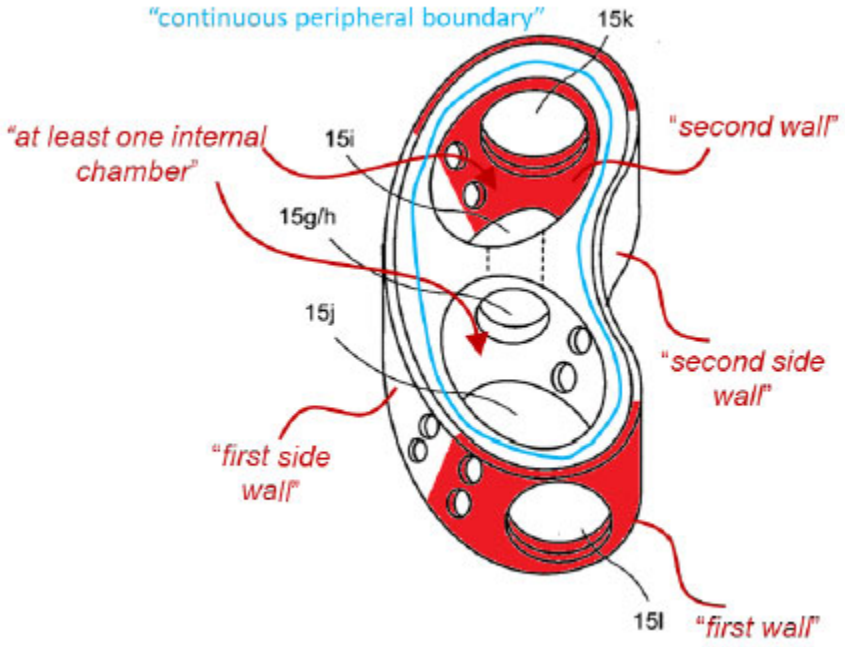
at least one chamber") and [1.5.2] (reciting, "at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent . . . vertebral members"). *Id.* at 27, 38–40. Patent Owner also argues that the combination of references is improper (*id.* at 26–35) and that the references teach away from each other (*id.* at 35–38, 41).

As stated, Patent Owner has not yet challenged Petitioner's showing with respect to the limitations of claim 1 other than limitations [1.5.1] and [1.5.2]. Having reviewed the record, we determine Petitioner has sufficiently shown that the combined teachings of Alfaro, Frey, and Perez-Cruet teach or suggest all of the limitations of claim 1 other than limitations [1.5.1] and [1.5.2]. Based on the current record, and for purposes of this Decision, we agree with Petitioner's analyses of those limitations. *See* Pet. 30–53. We focus our analysis on the two limitations that Patent Owner disputes:

> [1.5.1] wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the at least one chamber upon implantation into the target intervertebral space
>
> [1.5.2] such that the at least one chamber contains graft material delivered through the access port, thereby enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.

Regarding limitation [1.5.1], Petitioner asserts that the term "continuous peripheral boundary" is not used in the '096 Specification, but describes its spacers as having a "generally closed structure" despite having "one or more openings" along "outer sidewalls." Pet. 53 (citing Ex. 1001, 10:59–11:2; Figs. 19–20). Thus, according to Petitioner, the "continuous peripheral boundary" of claim element [1.5.1], which is formed by "the

walls and the sidewalls of the implant," does not preclude an access port or other openings along the outer walls. *Id.* at 54 (citing Ex. 1003 ¶¶ 212–213) (emphasis omitted). Turning to Alfaro, Petitioner argues that like Figure 20 of the '096 patent, the intervertebral spacer in Alfaro's Figure 9, for example, which includes screw holes 15k, 15l and other openings/tunnels in the walls, teaches a "continuous peripheral boundary," a portion of which is highlighted in Petitioner's annotated version of Figure 9, which is reproduced below. *Id.* at 55.



Annotated Figure 9 of Alfaro shows a three dimensional perspective view of an embodiment of Alfaro's spacer, with annotations identifying "at least one internal chamber" (with lead lines to two compartments[12]) "first side wall," "second side wall," "first wall," and "second wall" (all

[12] As Petitioner argues in regard to limitation [1.1.4], Alfaro describes the spacers in Figures 2 and 9 as having "compartments," which are examples of the claimed "internal chambers." *See* Pet. 39–40 (citing Ex. 1008 ¶ 29).

highlighted in red), and an outline of a portion of the "continuous peripheral boundary" (highlighted in blue). Ex. 1008 ¶ 27. Petitioner further asserts that each of Alfaro's spacers shown in Figures 2 and 9 (and associated Figures 1 and 8, respectively) are examples demonstrating limitation [1.5.1]. Pet. 56 (citing Ex. 1003 ¶ 215).

In the Preliminary Response, Patent Owner argues "a continuous peripheral boundary around the at least one chamber" is not taught by Alfaro and Frey which teach openings along a wall and an open cage, respectively. Prelim. Resp. 38 (citing Ex. 2010 ¶¶ 97–101; Ex. 1008, Fig. 6, ¶ 10; Ex. 1005, 19:16–21). According to Patent Owner, "[t]he open designs of Alfaro and Frey allow graft material to flow freely from the area that allegedly teaches a chamber in each of them." *Id.* at 38–39 (citing Ex. 2010 ¶¶ 97–101).

Based on Petitioner's evidence and arguments as summarized above, and for purposes of this Decision, we agree with Petitioner that Alfaro teaches the walls and sidewalls of Alraro's spacer form "a continuous peripheral boundary" around the at least one chamber upon implantation, even though the walls and the sidewalls have an access port or other openings along the outer walls, that is consistent with the use of the term "a continuous peripheral boundary" in the '096 patent. Read together, limitations [1.5.1] and [1.5.2] require "a continuous peripheral boundary around the at least one chamber . . . such that the at least one chamber contains graft material delivered through the access port." In that regard, we note that Alfaro expressly teaches that the spacer's compartments (in

Figures 1 and 9) "are adapted to contain DBM[13] or any other suitable biologic," or are "shown to contain DBM." Ex. 1008 ¶ 29. In addition, Dr. Lonner's testimony that Alfaro and Frey teach "open designs that allow graft material to flow freely from the area that allegedly teaches a chamber in each of them" is not persuasive because it is conclusory and unsupported by Dr. Lonner's citations to Alfaro and Frey. *See* Ex. 2010 ¶ 97. Thus, we are persuaded Petitioner has sufficiently shown that Alfaro teaches limitation [1.5.1].

Regarding limitation [1.5.2], Petitioner asserts that the term "flush contact" is not used in the '096 patent Specification, nor is it a term of art in the spinal fusion field, but the '096 patent states that "excess graft and/or other fill material G can generally fill any gap that exists between the vertebral endplates and the adjacent surfaces of the implant. This can result in improved spinal fusion." Pet. 56 (citing Ex. 1001, 24:16–20, 24:21–24; Ex. 1003 ¶ 217). Thus, according to Petitioner, "the term 'the graft material is in flush contact with [endplate surfaces of the] adjacent superior and inferior vertebral members' is understood to include a situation in which gaps that exist between vertebral endplates and adjacent surfaces of the implant are filled with graft material." *Id.* (citing Ex. 1003 ¶ 217) (emphasis omitted).

Turning again to Alfaro, Petitioner argues Alfaro teaches that the current prior art approach as shown in Figure 7 "may leave significant gaps between the spacer and the endplates of the inferior and superior vertebral bodies." *Id.* at 56–57 (citing Ex. 1008 ¶ 31; Fig. 7). Petitioner also argues

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[13] According to Mr. Sherman, "DBM is demineralized bone matrix and an example grafting material." Ex. 1003 ¶ 131.

that, to address the gapping problem, Alfaro describes that, "[i]n the present invention, voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product introduced via the unitary device of the invention." *Id.* at 57 (citing Ex. 1008 ¶¶ 10, 19) (emphasis omitted, alteration in original). Petitioner notes that Alfaro also provides that "[t]he dimensions of the handle are such that sufficient biologic can be incorporated therein to fill the compartments and tunnels, and flow out into the interfaces between the compartments and the vertebrae to provide substantially complete coverage or coating of the interface surfaces." *Id.* (citing Ex. 1008 ¶ 21) (emphasis omitted, alteration in original). Petitioner further notes Alfaro describes that "[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels as shown in FIG. 2 . . . with the DBM flowing through the compartments and into the vertebral spaces shown in Fig. 6 . . . , the handle is removed," and that "by forcing the DBM into the implant in this manner, less gapping of DBM between the intervertebral spacer and the endplates of the vertebrae occurs leading to substantially increased fusion rates." *Id.* at 57–58 (citing Ex. 1008 ¶ 31; Fig. 6) (emphasis omitted, alteration in original). Thus, Petitioner argues, "Alfaro teaches a device and associated process in which spacer compartments are filled and gaps between the end plates of the vertebral bodies and the spacer surfaces are also filled by complete coverage at their surfaces, with a suitable biologic product introduced via a hollow handle connected to the spacer via a screw hole ('access port'), thereby disclosing [1.5.2]." *Id.* at 59 (citing Ex. 1003 ¶¶ 220–222) (emphasis omitted).

Patent Owner argues that neither Alfaro nor Frey teach or suggest "flush contact of a graft material with the endplate surfaces of each of the first and second vertebrae and that graft material being contained within the at least one internal chamber." Prelim. Resp. 40 (citing Ex. 2010 ¶¶ 97–101; Ex. 1008, Fig. 6, ¶ 10; Ex. 1005, 19:16–21). Patent Owner also argues Alfaro illustrates and teaches "that the graft material exits the implant creating a barrier between the vertebral bodies and the implant, as well as extruding from the sidewalls of Alfaro." *Id.* (citing Ex. 2010 ¶¶ 97–101; Ex. 1008, Fig. 6, ¶ 10).

Based on Petitioner's evidence and arguments as discussed above, and for purposes of this Decision, we agree with Petitioner that Alfaro's disclosures, including that "voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product" and that "excess material floods the space . . . between the surfaces and the vertebrae giving a complete coverage or permeation of the interfaces," teach or suggest that graft material is in "flush contact" with the endplate surfaces of the adjacent superior and inferior vertebral members, as the term is used in the '096 patent. *See* Ex. 1008 ¶¶ 10, 19, 21.
Dr. Lonner's testimony concerning Alfaro is unpersuasive. *See* Ex. 2010 ¶ 100. Although Dr. Lonner cites Figure 6 and paragraph 10 of Alfaro as supporting his testimony that Alfaro does not teach "flush contact with the vertebral bodies and the graft material being contained within the . . . internal chamber," but teach that "graft material flows out and away from the implant," Dr. Lonner provides no analysis or explanation of why Figure 6 and paragraph 10 allegedly support his testimony. In addition, as

discussed above, Alfaro expressly teaches that the spacer's compartments (in Figures 1 and 9) "are adapted to contain DBM or any other suitable biologic," or are "shown to contain DBM." Ex. 1008 ¶ 29. Thus, we are persuaded Petitioner has sufficiently shown that Alfaro teaches limitation [1.5.2].

(1) Motivation to combine

Regarding the combination of Alfaro and Frey, Petitioner argues that Figure 55 of Frey and Figure 8 of Alfaro illustrate similarities between these implants, including "Alfaro's implant has two chambers 11a and 11b and Frey's implant has two chambers 1018a and 1018b; both implants are similarly shaped; and both implants have screw holes . . . for engaging an insertion device." Pet. 21–22 (citing Ex. 1003 ¶¶ 138–141; Ex. 1008, Fig. 8; Ex. 1005, Fig. 55). Petitioner also argues that Frey's implant 1000 includes upper and lower bearing members provided with grooves 1014 and 1016 for engaging vertebral endplates to "resist posterior and anterior migration of implant 1000 in the disc space." *Id.* at 21 (citing Ex. 1005, 19:50–52, 20:6–11). Petitioner further argues that in view of Alfaro's teaching that the spacer "remains in place at the correct site between the vertebrae," a person of ordinary skill would have been motivated to include grooves similar to Frey's grooves 1014 and 1016 on the top and bottom surfaces of Alfaro's implant to resist migration of the implant after implantation. *Id.* at 23 (citing Ex. 1008 ¶ 31; Ex. 1003 ¶¶ 142–143). Moreover, Petitioner argues that "Frey lists several specific and well-known surgical approaches, including a lateral approach" (*id.* at 24 (citing Ex. 1005, 19:29–33)), and to the extent a skilled artisan practicing Alfaro would have even needed a reference to list the different approaches, the skilled artisan "would have been motivated by

the simple desire to implant the spacer to reference Frey's teachings to implant the spacer of Alfaro into an intervertebral disc" (*id.* (citing Ex. 1003 ¶¶ 146–147)).

Patent Owner argues that the combination of Alfaro and Frey is improper "in light of the intended purposes of the two devices." Prelim. Resp. 26–27 (citing Ex. 2010 ¶ 93). In particular, Patent Owner argues that because the two references teach different types of implants for "much different purposes," a doctor or designer would not have been motivated to combine the references. *Id.* at 30–31 (citing Ex. 2010¶¶ 166–169).[14] Based on the current record, we are not persuaded by Patent Owner's 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; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller***,** 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."). Here, Petitioner argues that: (1) Alfaro teaches its spacer must "remain[] in place at the correct site between the vertebrae"

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[14] Patent Owner also argues that the combination of Alfaro and Frey would be improper because they do not teach or suggest various features of the claims, including retaining graft material within an internal chamber and "flush contact of the graft material with the endplate surfaces of each of the first and second vertebrae." Prelim. Resp. 27–29, 34–35 (citing Ex. 2010¶¶ 93, 166–169, 174–175). It appears these arguments concern whether the combination teaches certain limitations, rather than whether a person of ordinary skill would have been motivated to combine the references.

(Pet. 23 (citing Ex. 1008 ¶ 31)); (2) Frey teaches grooves on the upper and lower bearing members engage the vertebral endplates to "resist posterior and anterior migration of the implant . . . in the disc space" (*id.* at 21 (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 Alfaro's spacer to include Frey's grooves to better resist migration of the spacer (*id.* at 23 (citing Ex. 1003 ¶¶ 143–144)). Patent Owner does not present sufficient evidence or argument to persuade us that Frey's open cage design would have changed this analysis.

Regarding the combination of Alfaro and Perez-Cruet, Petitioner argues Alfaro suggests using a '"syringe-type system for moving [] biologic material through the handle and into the spacer' and intervertebral space." Pet. 26–27 (citing Ex. 1008 ¶¶ 12, 32) (alteration in original). Petitioner also argues that given the broad disclosure of Alfaro, a person of ordinary skill in the art would have been motivated to look to Perez-Cruet, which provides an illustrated example of a syringe-type system, as suggested by Alfaro, namely, syringe 400 having extended tubular end portion 402 for delivering bone graft material through the instrument 304, as shown in Figure 21. *Id.* at 27–29 (citing Ex. 1004 Fig. 21, ¶ 62; Ex. 1003 ¶ 152). Petitioner further argues that a person of ordinary skill in the art would have been motivated to use Perez-Cruet's syringe assembly because, for example, "it was well known that biologic graft material is commonly provided to a surgeon in the form of a pre-loaded syringe." *Id.* at 29 (citing Ex. 1003 ¶ 155 (citing Ex. 1014) (Wironen 2002 bone paste patent)).

In response, Patent Owner argues that Perez-Cruet cannot be combined with Alfaro and Frey because it is "an entirely different type of

implant" and "does not have an internal chamber that allows for endplate-to-endplate fusion through the implant." Prelim. Resp. 27–28 (citing Ex. 1004 Figs. 4, 5, 20; Ex. 2010 ¶¶ 94–96). Patent Owner also argues that the implant device of Perez-Cruet requires the modification of its orientation after the initial insertion, "the rotation from a horizontal orientation to a vertical orientation . . . to allow the implant device to become a weight or load bearing spacer rather than a fusion assisting implant." *Id.* at 31 (citing Ex. 2010 ¶¶ 170–171). In addition, Patent Owner asserts that "a plate within the center of Perez-Cruet prevents graft material from freely moving between the two sides of Perez-Cruet, and would defeat the purpose of fusion if utilized in a horizontal orientation." *Id.* (citing Ex. 2010 ¶¶ 170–171). Patent Owner further argues that "because Perez-Cruet is a spacer device, it is not intended to support or assist in the fusion of two vertebral bodies, and in particular the fusion of two vertebral bodies through the implant." *Id.* at 32 (citing Ex. 2010 ¶¶ 170–171).

For purposes of this Decision, we agree with Petitioner. Based on Petitioner's evidence and arguments discussed above, Petitioner has shown that (1) Alfaro suggests a syringe-type system for moving biologic material through the handle and into the spacer and intervertebral space and (2) Perez-Cruet specifically discloses such a syringe-type system, which a skilled artisan would have been motivated to look to. Patent Owner's arguments concerning the differences in Perez-Cruet's implant are not persuasive on the current record because Petitioner proposes combining Alfaro with Perez-Cruet based on Perez-Cruet's disclosure of its syringe system for teaching "a graft material delivery system," recited in limitation [1.3] (Pet. 45–48), and relies on Alfaro, and Alfaro combined with Frey, as

teaching the claimed "implant" *(id.* at 30–39). *See In re Merck & Co. Inc.,* 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references."). In addition, we are not persuaded by Patent Owner's argument concerning Perez-Cruet's implant because, as explained above, the obviousness analysis does not require bodily incorporation. *See In re Keller,* 642 F. 2d at 425.

Thus, on the current record, we determine Petitioner's arguments, as discussed above, provide sufficient reasoning with rational underpinning for combining the teachings of Alfaro and Frey, and Alfaro and Perez-Cruet, with a reasonable expectation of success. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418–19 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")).

(2) Do the references "teach away"

Patent Owner also argues that the references teach away from each other and, therefore, are improperly combined by Petitioner. Prelim. Resp. 35–38, 41. In particular, Patent Owner contends that Alfaro teaches away from Frey because, although Alfaro states that graft material can be delivered to other types of implants, there are certain requirements laid out, which Frey does not meet, because Frey "is an open cage with no defined chamber, tunnels, leaders, or holes that would allow for receiving bone grafting material." Prelim. Resp. 35–36 (citing Ex. 1008 ¶ 12; Ex. 2010 ¶ 176).

Based on the current record, we are not persuaded by Patent Owner's argument. A reference that "merely expresses a general preference for an

alternative invention but does not criticize, discredit, or otherwise discourage investigation into" the claimed invention does not teach away. *Meiressone v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (quoting *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013)). 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.

Similarly, Patent Owner argues that Perez-Cruet cannot be combined with Alfaro and Frey because Perez-Cruet's implant requires a different orientation, does not allow for an internal chamber that extends from or near a first vertebral body, to or near a second vertebral body, to allow for fusion through the implant, and has a central plate blocking the flow of graft material between what might be argued is a chamber. *Id.* at 36–37 (citing Ex. 2010 ¶¶ 177–179). Based on the current record, we are not persuaded by this argument either because Perez-Cruet does not "criticize, discredit, or otherwise discourage" an implant having an internal chamber into which graft material is delivered.

(3) Summary

For the reasons discussed above, Petitioner has sufficiently shown for purposes of this Decision that the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests the subject matter of claim 1 and has provided sufficient reasoning with rational underpinning for combining these references in the manner claimed with a reasonable expectation of success. Accordingly, we determine the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claim 1 is

unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, and Perez-Cruet.

b. Claims 2–8 and 10–20

Petitioner contends that the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests the limitations of claims 2–8 and 10–20 of the '096 patent. Pet. 59–90. Patent Owner presents arguments with respect to each of these claims and contends they are patentable over the cited references. Prelim. Resp. 41–52. We have reviewed and considered all of the evidence and arguments presented by Petitioner and Patent Owner. On the current record and for purposes of this Decision, we determine Petitioner sufficiently shows that the combined teachings of Alfaro, Frey, and Perez-Cruet teach or suggest the subject matter of claims 2–8 and 10–20 and provides sufficient reasoning with rational underpinning for combining the teachings as claimed.

Claim 2 depends from claim 1 and further recites "wherein the conduit is configured to pass through the access port of the implant to position the conduit within the at least one internal chamber of the implant. Ex. 1001, 24:64–67. For purposes of this Decision, Petitioner sufficiently shows that Alfaro combined with Perez-Cruet teaches or suggests passing the extended tubular end portion 402 (conduit) of Perez-Cruet's syringe 400 through Alfaro's handle 12, through Alfaro's screw hole 15l, and into compartment 11b of Alfaro's intervertebral spacer, which renders clam 2 obvious. Pet. 59–61 (citing Ex. 1004 Fig. 11, ¶ 53; Ex. 1003 ¶¶ 226–227). On the current record, Patent Owner's argument that there is no teaching of "a conduit being passed through the access port of an implant," which is based on the testimony of Dr. Lonner, is not persuasive because

Dr. Lonner's testimony is conclusory and unsupported with any explanation or technical reasoning of why Perez-Cruet fails to teach or suggest this feature of claim 2. *See* Prelim. Resp. 41; Ex. 2010 ¶ 103. And, Patent Owner's argument that the combination of references fails to teach positioning the conduit within the chamber to allow the graft material to have "flush contact" with two vertebral bodies is unavailing for the reasons discussed *supra* regarding limitation [1.5.2]. *See supra* Section II.C.4.b.

With respect to claim 3, Petitioner sufficiently shows that Alfaro combined with Perez-Cruet renders obvious claim 3, which depends from claim 1 and further recites "wherein the graft material delivery system additionally comprises a fill tool assembly, the fill tool assembly being configured to selectively engage at least a portion of the implant, wherein the fill tool assembly comprises a cannulated shaft." Ex. 1001, 28:1–5. In that regard, Petitioner shows that, since Alfaro suggests using any disengageable means to connect handle 12 with the intervertebral spacer 11 (Ex. 1008 ¶ 21), it was obvious to implement handle 12 of Alfaro with Perez-Cruet's instrument 304, including cylindrical body portion 322 and elongated cylindrical grasping portion 340, and to compatibly modify the intervertebral spacer of Alfaro such that the fingers 346 of Perez-Cruet's grasping portion 340 can secure instrument 304 to Alfaro's intervertebral spacer 11. Pet. 62–67 (citing Ex. 1004 Figs. 13–16, ¶¶ 56–57; Ex. 1008 ¶ 21; Ex. 1003 ¶¶ 231–239).

For the reasons discussed *supra* regarding claim 1, we do not agree with Patent Owner's argument that claim 3 is patentable for the same reasons as claim 1. Prelim. Resp. 41–42; *see supra* Section II.C.4.b. We also do not agree with Patent Owner's arguments that there is no teaching of

"a fill tool assembly with a can[n]ulated shaft" and "Petitioner has improperly relied on Perez-Cruet to teach or suggest a fill tool assembly." *Id.* at 42 (citing Ex. 2010 ¶ 104). Contrary to Patent Owner's arguments, as discussed above, Petitioner relies on the combination of Alfaro's handle 12 and Perez-Cruet's instrument 304, including cylindrical body portion 322 and elongated cylindrical grasping portion 340 (having a cannulated shaft), with Alfaro's spacer 11 modified such that the fingers 346 of Perez-Cruet's grasping portion 340 can secure instrument 304 to Alfaro's spacer. And, for the reasons discussed above regarding claim 2, we do not agree with Patent Owner's argument that Perez-Cruet "show[s] the implant insertion tool engaging with the fill tool assembly not the implant." *Id.* (citing Ex. 2010 ¶ 104; Ex. 1004 Figs. 14, 15); *see* Pet. 61 (citing Ex. 1003 ¶ 227) ("obvious to pass the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's handle 12, through Alfaro's screw hole 15l, and into the compartment 11b of Alfaro's intervertebral spacer").

Claim 4 depends from claim 3 and further recites "wherein the fill tool assembly is configured to ensure that a distal end of the conduit routed through the cannulated shaft of the fill tool assembly is properly positioned within the at least one internal chamber of the implant." Ex. 1001, 28:6–10. For purposes of this Decision, Petitioner has sufficiently shown that Alfaro combined with Perez-Cruet renders claims 4 obvious based on Petitioner's evidence and arguments discussed regarding claim 3 and limitation [1.3]. Pet. 68–70 (citing Ex. 1003 ¶¶ 242, 244–245; Ex. 1004 Fig. 11). Patent Owner's argument that "[n]one of Alfaro, Perez-Cruet, nor Frey teach or suggest a conduit routed through a cannulated shaft of the fill tool assembly" is not persuasive for the reasons discussed above regarding claim 3. Prelim.

Resp. 42 (citing Ex. 2010 ¶¶ 105–108). In addition, Patent Owner's arguments that the cage of Perez-Cruet "does not allow for fusion of two vertebral bodies" and does not teach "at least one chamber to contain graft material, or at least one chamber that extends from a top surface of the implant to a bottom surface" are unavailing because Petitioner's proposed combination does not rely on Perez-Cruet as teaching these features. *Id.* at 42–43 (citing Ex. 2010 ¶¶ 105–108; Ex. 1004, code (57), Figs. 4, 5, 20).

Claim 5 depends from claim 3 and further recites "wherein graft material is configured to be delivered through the fill tool assembly, either directly through the cannulated shaft or via the conduit, wherein the conduit is removably positioned through the cannulated shaft." Ex. 1001, 28:11–15. Petitioner sufficiently shows that Alfaro combined with Perez-Cruet renders claim 5 obvious because, as discussed regarding claims 3 and 4,

> when Alfaro's handle is implemented as Perez-Cruet's instrument 304 and the intervertebral spacer of Alfaro is compatibly modified, "graft material is configured to be delivered through the fill tool assembly [e.g., Perez-Cruet's guiding portion 340] . . . via the conduit [e.g., Perez-Cruet's extended tubular end portion 402] . . . removably positioned through the cannulated shaft [e.g., of the guiding portion 340)]."

Pet. 70–71 (citing Ex. 1003 ¶¶ 251–252) (emphasis omitted). We do not agree with Patent Owner's argument that the references do not teach a "cannulated shaft" of the fill tool assembly or "conduit" that allows for delivery of graft material because, as discussed above, Petitioner has shown that Perez-Cruet's fill tool assembly comprises guiding portion 340, which has a cannulated shaft, and extended tubular end portion 402, which is the conduit.

Claim 6 depends from claim 5 and further recites "wherein the fill tool assembly comprises at least one alignment feature configured to engage at least a portion of the implant, wherein at least one alignment feature provides assurance that the fill tool assembly is properly positioned relative to the implant." Ex. 1001, 28:17–21. Petitioner argues that Alfaro combined with Perez-Cruet renders claim 6 obvious because fingers 346 (around end portion 312) that connect Perez-Cruet's guiding portion 340 to Alfaro's spacer provide an example of "at least one alignment feature configured to engage at least a portion of the implant," wherein the alignment feature provides assurance that the fill tool assembly (e.g., Perez-Cruet's grasping portion 340) is properly positioned relative to the implant. Pet. 71–72 (citing Ex. 1004, Fig. 16, ¶ 58; Ex. 1003 ¶¶ 255–257). Patent Owner argues that claim 6 is patentable because Perez-Cruet "only teaches engagement of an insertion tool with an implant," but this engagement "does not allow for proper positioned of the tool or assembly in relation to the implant as it is part of the engagement of the implant with other devices not alignment." Prelim. Resp. 44 (citing Ex. 2010 ¶¶ 113–115; Ex. 1004, Figs. 14, 15). On the current record and for purposes of this Decision, we agree with Petitioner and determine Petitioner has sufficiently shown through its evidence and arguments summarized above that Alfaro combined with Perez-Cruet teaches, and renders obvious, claim 6.

Claim 7 depends from claim 6 and further recites "wherein the last one alignment feature comprises at least one of a tab and a wing." Ex. 1001, 28:22–23. Petitioner argues that "[i]n addition to being examples of 'alignment features,' the fingers 346 of Perez-Cruet are examples of tabs or wings (e.g., similar to what the '096 Patent labels as 'tabs or wings 622'

at 22:12 and illustrated in Figure 13)." Pet. 72–73 (citing Ex. 1003 ¶ 259). Patent Owner argues that, "[m]uch like claim 6, a tab and wing are not taught by the combination of references and in particular Perez-Cruet." Prelim. Resp. 44–45 (citing Ex. 2010 ¶¶ 116–118). On the current record and for purposes of this Decision, we agree with Petitioner and determine Petitioner has sufficiently shown through its evidence and argument discussed above that Perez-Cruet teaches or suggests claim 7.

Claim 8 depends from claim 1 and further recites "wherein the implant insertion tool is configured to releasably secure to the access port." Ex. 1001, 28:24–25. Petitioner argues that "Alfaro's disclosure of a handle screwed into an access port, which can also be unscrewed and detached, is an example of claim element [8.1]." Pet. 73–74 (citing Ex. 1003 ¶ 262–263; Ex. 1008, Fig. 2, ¶¶ 21, 29, 31). Patent Owner's arguments are unavailing because they do not concern the limitations of claim 8, but instead assert the references do not teach "endplate-to-endplate fusion through an internal chamber of an implant" and "graft material provided through an access port to an internal chamber would be allowed to generate flush contact and generate fusion through the implant," which features are not recited in claim 8. Prelim. Resp. 45 (citing Ex. 2010 ¶¶ 116–125). Thus, on the current record and for purposes of this Decision, we determine Petitioner has sufficiently shown through its evidence and argument discussed above that Alfaro teaches or suggests claim 8.

Claim 10 depends from claim 1 and further recites "wherein the implant comprises at least one of polyether etherketone (PEEK), a metal and an alloy." Ex. 1001, 28:29–31. Petitioner argues that Alfaro teaches claim 10 because Alfaro discloses that "[t]he spacer may be constructed of

biologically acceptable material such as titanium, stainless steel, allograft bone, PEEK, or the like." Pet. 74 (citing Ex. 1003 ¶ 22; Ex. 1003 ¶ 265) (emphasis omitted). Patent Owner argues that only Alfaro teaches any reference to a PEEK material, but none of Alfaro, Perez-Cruet, or Frey teaches or suggests a combination of PEEK with a metal and an alloy. Prelim. Resp. 45 (citing Ex. 2010 ¶ 126; Ex. 1008 ¶ 22). Based on the record and for purposes of this Decision, Petitioner has sufficiently shown through its evidence and argument that Alfaro teaches claim 10. Patent Owner's argument that none of the references teach an implant comprising a "combination" of PEEK, metal, and an alloy is unavailing because it is not commensurate with the scope of claim 10, which requires only that the implant comprises "at least one of" PEEK, a metal, and an alloy.

Regarding claim 11, which depends from claim 1, Petitioner sufficiently shows, for purposes of this Decision, that Figure 9 of Alfaro illustrates "a spacer shape with a planar top surface," which teaches or suggests "wherein at least one of the top and bottom surfaces of the implant is generally planar," as recited in claim 11. Pet. 74–75 (citing Ex. 1008 Fig. 9, ¶ 20; Ex. 1003 ¶¶ 268–269). Patent Owner's argument that, for at least the same reasons regarding claim 1, claim 11 is not taught by Alfaro, Frey, or Perez-Cruet is unavailing for the reasons discussed *supra* regarding claim 1. Prelim. Resp. 46; *see* Section II.C.4.b. Patent Owner's argument that the cited references do not teach an implant being "planar" is also unavailing because it is based on Dr. Lonner's testimony that the references do not teach an implant being "planar, curved, or having walls of different heights," which is conclusory and unsupported with a citation to any evidence or an explanation of why the references allegedly fail to teach the

"generally planar" limitation of claim 11. *Id.* (citing Ex. 2010 ¶¶ 127–133).

Claim 12 depends from claim 1 and further recites "wherein at least one of the top and bottom surfaces of the implant is generally curved." Ex. 1001, 28:34–35. For purposes of this Decision, Petitioner sufficiently shows that Alfaro combined with Frey renders claim 12 obvious because modifying the "top surface" of Alfaro's spacer to be "generally curved," as taught by Frey, would better correspond to the anatomy of the vertebral endplates. Pet. 75–77 (citing Ex. 1008 ¶ 31; Ex. 1005 19:53–55, 19:55–60; Ex. 1003 ¶¶ 271–274). Patent Owner makes the same arguments with respect to claim 12 as for claim 11. Prelim. Resp. 46. For the same reasons discussed above regarding claim 11, these arguments are unavailing to show the references allegedly fail to teach the "generally curved" limitation of claim 12.

Claim 13 depends from claim 1 and further recites "wherein the implant comprises a lordotic implant, such that a height of the first wall is different than a height of the second wall." Ex. 1001, 28:36–38. For purposes of this Decision, Petitioner sufficiently shows that Alfaro combined with Frey renders claim 13 obvious because (1) Alfaro's spacer can be used in a variety of surgical approaches for inserting the spacer (with the screw hole moved as necessary), (2) Frey teaches implant 1000 with different heights of "leading" and "trailing" end walls "to establish lordosis when implant 1000 is inserted in the disc space," and (3) a person of ordinary skill in the art would have been motivated to modify Alfaro's spacer to have Frey's "different heights to maintain proper spinal lordosis (thereby more closely matching the spinal anatomy)," as explained in Frey. Pet. 77–80 (citing Ex. 1008, Fig. 9 Ex. 1003 ¶¶ 277–282; Ex. 1005, Fig. 54,

19:60–65, 19:67–20:5). Patent Owner makes the same arguments with respect to claim 13 as for claim 11. Prelim. Resp. 46. For the same reasons discussed above regarding claim 11, these arguments are unavailing to show the references allegedly fail to teach the limitations of claim 13.

Claim 14 depends from claim 1 and further recites "wherein the implant comprises a lateral implant, a TLIF implant, an ALIF implant or a PLIF implant." Ex. 1001 28:39–41. Petitioner argues that Alfaro discloses claim 14 because Figure 1 of Alfaro "illustrates an embodiment in which the threaded hole 13 is formed in the intervertebral spacer 11 to facilitate a lateral approach." Pet. 80 (citing Ex. 1003 ¶¶ 286–287). Petitioner also argues that Alfaro combined with Frey renders claim 14 obvious because Frey teaches that aspects of the invention may be used for "a variety of surgical applications including . . . a lateral approach," and a person of ordinary skill would have understood from Frey that Alfaro's implant would be inserted into the disc space using the "lateral approach" taught by Frey. *Id.* at 80–81 (citing Ex. 1003 ¶¶ 287–288; Ex. 1005, 22:6–12). Patent Owner argues (1) that Alfaro does not teach any particular method or approach for use of the implant and (2) Frey only teaches "posterior or posterior lateral (transforaminal) approaches" and "teaches away from an anterior or direct lateral approach." Prelim. Resp. 46 (citing Ex. 1003 ¶¶ 127–135; Ex. 1005 1:14-20, 1:36–55). On the current record and for purposes of this Decision, we agree with Petitioner because Dr. Lonner does not address Figure 1 of Alfaro and ignores Frey's teaching that aspects of the described inventions may be used for "spinal surgery . . . from a lateral approach." *See* Ex. 1005 22:6–12. Thus, for purposes of this Decision, Petitioner sufficiently shows based on its evidence and arguments that

Alfaro discloses claim 14 and Alfaro combined with Frey renders claim 14 obvious.

Claim 15 depends from claim 1 and further recites "wherein the fill tube assembly[15] further comprises a plunger assembly configured to be positioned within the conduit, wherein the plunger assembly is selectively actuated in order to provide the necessary driving force to move a volume of graft material through the conduit and into the at least one internal chamber of the implant." Ex. 1001, 28:42–47. Petitioner argues that Alfaro combined with Perez-Cruet teaches or suggests claim 15 because syringe 400 (of Perez-Cruet's graft material delivery system shown in Figure 21) "includes a barrel (an example enlarged-diameter portion of the "*conduit*") with a plunger inside to move graft material down the barrel and reduced-diameter portion (the extended tubular end portion)." Pet. 81–82 (citing Ex. 1003 ¶¶ 290–292; Ex. 1004, Fig. 1). Relying on Dr. Lonner's testimony, Patent Owner argues that there is no teaching or suggestion in the references of "the positioning and movement of a plunger within a conduit." Prelim. Resp. 46–47 (citing Ex. 2010 ¶¶ 136–139). We do not agree with Patent Owner's argument because Dr. Lonner's testimony is conclusory and unsupported by the citation of any evidence or an explanation or technical reasoning of why Perez-Cruet's syringe 400 fails to teach or suggest "the positioning and movement of a plunger within a conduit." Thus, on this record and for purposes of this Decision, Petitioner sufficiently shows based

[15] Petitioner argues there is no antecedent basis for the term "the fill tube assembly," so the term "the fill tube assembly" must be a typo and was instead meant to be "the graft material delivery system," referring back to claim 1. Pet. 81–82.

on its evidence and argument summarized above that Alfaro combined with Perez-Cruet teaches or suggests claim 15.

Independent claim 16, like claim 1, is directed to "a spinal fusion system." Ex. 1001, 28:48–30:2. Petitioner has designated the limitations of claim 16 as [16.0], [16.1.1]–[16.1.7], and [16.2]–[16.5]. Pet. 83–86. As Petitioner argues, claim 16 recites the same or substantially the same limitations as claim 1 with only minor differences. *Id.* For example, limitation [16.1.2] recites "side walls," whereas limitation [1.1.2] recites "first and second" side walls. *Compare* Ex. 1001, 28:54–55 (claim 16), *with id.* at 27:22–23 (claim 1). And, limitation [16.3] recites delivering "graft material," whereas limitation [1.3] recites delivering "a volume of" graft material. *Compare* Ex. 1001, 29:11–12 (claim 16), *with id.* at 27:39–40 (claim 1). Thus, Petitioner argues that based on its analysis of the limitations of claim 1, the corresponding limitations of claim 16 are disclosed or rendered obvious by the corresponding references. Pet. 83–86.

Similar to its arguments regarding limitations [1.5.1] and [1.5.2], Patent Owner argues that Alfredo and Frey do not teach or suggest "a continuous peripheral boundary around the at least one chamber," and "flush contact of a graft material with the endplate surfaces of each of the first and second vertebrae and that graft material being contained with the at least one internal chamber." Prelim Resp. 47–49 (citing Ex. 2010 ¶¶ 140–144; Ex. 1008, Fig. 6, ¶ 10; Ex. 1005, 19:16–21). For the reasons discussed above regarding limitations [1.5.1] and [1.5.2], and for purposes of this Decision, we do not agree with Patent Owner's arguments. *See supra* Section II.C.4.b.

Patent Owner also argues that Frey teaches away from Alfaro because Frey teaches that each implant should be packed with graft material prior to insertion within a vertebral space. *Id.* at 50 (citing Ex. 2010 ¶¶ 140–144; Ex. 1005, 19:16–21). We are not persuaded by this argument because although Frey expresses a general preference for pre-loaded implants, Frey does not "criticize, discredit, or otherwise discourage" an implant having an internal chamber into which graft material is delivered after it is inserted in an intervertebral space. *See Meiressone,* 849 F.3d at 1382.

At this stage of the proceeding and based on Petitioner's arguments and evidence regarding claim 1, we determine Petitioner has sufficiently shown that the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests the subject matter of claim 16.

Regarding claim 17, which depends from claim 16, Petitioner argues it is identical to "claim element [3.1]," and "according to the analysis of [3.1], Alfaro combined with Perez-Cruet renders obvious [17.1]." Pet. 86. For purposes of this Decision, Petitioner has sufficiently shown that Alfaro combined with Perez-Cruet renders claim 17 obvious based on Petitioner's evidence and arguments discussed regarding limitation [3.1]. *Id.* at 62–67 (citing Ex. 1004, Figs. 13–16, ¶¶ 56–57; Ex. 1008 ¶ 21; Ex. 1003 ¶¶ 231–239). Patent Owner argues that claim 17 is patentable for the same reasons as claim 16. Prelim. Resp. 50 (citing Ex. 2010 ¶ 145). For the reasons discussed above regarding claim 16, we do not agree with Patent Owner's argument that claim 17 is patentable for the same reasons as claim 16.

Claims 18 and 19 depend from claim 17 and further recite limitations identified by Petitioner as claim elements [18.1] and [19.1], which are reproduced below:

> [18.1] wherein the fill tool assembly is configured to ensure that a distal end of the conduit routed through the cannulated shaft of the fill tool assembly is properly positioned within the at least one internal chamber of the implant.
>
> [19.1] wherein graft material is configured to be delivered through the fill tool assembly, either directly through the cannulated shaft or via the conduit, wherein the conduit is removably positioned through the cannulated shaft.

Pet. 87; *see also* Ex. 1001, 30:8–12 (claim 18), 30:13–17 (claim 19).

Petitioner argues that claim elements [18.1] and [19.1] are identical to claim elements [4.1] and [5.1], respectively, and "according to the analysis of [4.1] and [5.1], Alfaro combined with Perez-Cruet renders obvious [18.1] and [19.1], respectively." On this record and for purposes of this Decision, Petitioner has sufficiently shown that Alfaro combined with Perez-Cruet renders claims 18 and 19 obvious based on Petitioner's evidence and arguments discussed *supra* regarding claims 4 and 5, respectively. Pet. 68–70 (claim 4), 70–71 (claim 5). Patent Owner argues that claims 18 and 19 are patentable based on the same arguments presented with respect to claims 4 and 5. Prelim. Resp. 50–52. For the reasons discussed above with respect to these arguments regarding claims 4 and 5, we do not agree with Patent Owner's arguments regarding claims 18 and 19.

Claim 20 depends from claim 16 and is otherwise identical to claim 15. *Compare* Ex. 1001 30:18–23 (claim 20), *with id.* at 28:42–47 (claim 15). Petitioner argues that according to its analysis of claim 15, Alfaro combined with Perez-Cruet renders obvious claim 20. Pet. 87. On this record and for purposes of this Decision, Petitioner has sufficiently shown that Alfaro combined with Perez-Cruet renders claim 20 obvious based on Petitioner's evidence and arguments discussed regarding claim 15.

See id. at 81–82. Patent Owner argues that claim 20 is patentable based on the same arguments presented with respect to claim 15. Prelim. Resp. 52. For the reasons discussed above with respect to these arguments regarding claim 15, we do not agree with Patent Owner's arguments regarding claim 20.

Thus, for the reasons discussed above, we determine for purposes of this Decision that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 2–8 and 10–20 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, and Perez-Cruet.

D. Ground 2: Asserted Obviousness over Alfaro, Frey, Perez-Cruet, and Fuss

Claim 9 depends from claim 1 and further recites "wherein at least one of the first and second side walls of the implant does not comprise any openings." Ex. 1001, 28:26–28. Petitioner contends that claim 9 of the '096 patent is unpatentable under 35 U.S.C. § 103 as obvious over the combination of Alfaro, Frey, Perez-Cruet, and Fuss. Pet. 88–90. In particular, relying in part on the testimony of Mr. Sherman, Petitioner argues that Alfaro combined with Fuss renders claim 9 obvious and provides reasoning for combining the teachings of Alfaro and Fuss. *Id.* Relying on the testimony of Dr. Lonner, Patent Owner contends claim 9 is patentable because Fuss does not teach "a continuous peripheral wall defining an internal chamber" and Fuss cannot be combined with Alfaro, Frey, and Perez-Cruet. Prelim. Resp. 52–54 (citing Ex. 1022 Fig. 2a; Ex. 2010¶¶ 157–160).

1. Overview of Fuss

Fuss is U.S. Patent No. 6,562,072 B1 titled "Implant for Insertion Between Spinal Column Vertebrae." Ex. 1022, code (54). Fuss relates to an implant for insertion between the vertebrae of the spinal column. *Id.* at 1:8–12. Figure 2, which includes Figures 2a–2e, illustrates "schematic top views of differing embodiments of an implant [4]." *Id.* at 6:13–14. Figure 2a of Fuss is reproduced below.

FIG. 2

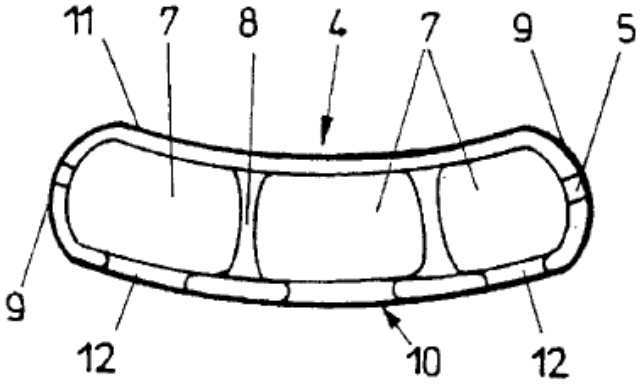

FIG. 2a

Id. at Fig. 2a. As shown in Figure 2a, implant 4 has opening 5 in the outwardly facing outer surface thereof for the application or fixing of an instrument during the process of inserting the implant. *Id.* at 6:30–34. Implant 4 comprises three substantially vertically extending continuous recesses or break-throughs 7, which are filled with bone mass prior to installation of implant 4. *Id.* at 6:55–62. Implant 4 has convexly curved boundary face 10, with openings 12, and boundary face 11, which does not incorporate any openings to avoid bone material issuing out at such points. *Id.* at 7:1–17. Claim 1 of Fuss is directed to an "implant" in which the "second boundary face" is "free of break-throughs" (openings). *Id.* at 10:11–12.

2. Analysis

Petitioner asserts that, like Alfaro's implants, which include one or two open compartments to be filled with grafting material to facilitate fusion with adjacent vertebrae, Fuss's "implant 4 comprises three substantially vertically extending continuous recesses or break-throughs 7" configured to contain graft material. Pet. 88 (citing Ex. 1022, 6:56–62). Petitioner argues that Fuss's implant 4 includes openings on side 10, but not on side 11, "which yields benefits: 'the boundary face 11 of the implant 4 facing the spinous process does not incorporate openings or breakthroughs so as to avoid bone material issuing out at such points or to prevent any possible intrusion thereof into the vicinity of the adjoining vertebral canal.'" *Id.* at 88–89 (citing Ex. 1022, 7:7–16) (emphasis omitted). Petitioner also argues that

> [a]lthough Alfaro's embodiments illustrate openings/tunnels 15(a)–15(f) around the periphery of the implant, for the reasons given in Fuss, a POSITA would have considered it beneficial not to include any openings along the "second side wall" indicated below [of Alfaro], which corresponds to "boundary face 11" of Fuss's implant. The same reasoning likewise applies to the spacer 11 presented in Figure 9 of Alfaro.

Id. at 89–90 (citing Ex. 1003 ¶¶ 317, 320; Ex. 1008, Figs. 2, 9; Ex. 1022, Fig. 2a).

At this stage of the proceeding and based on Petitioner's evidence and arguments summarized above, we determine Petitioner has sufficiently shown that the combination of Alfaro and Fuss teaches or suggests the subject matter of claim 9 and has provided sufficient reasoning with rational underpinning for combining these references in the manner claimed with a reasonable expectation of success. Patent Owner's arguments that the

references cannot be combined because the implants are different are unpersuasive for the reasons discussed above. *See* Prelim. Resp. 52–53. We also do not agree with Patent Owner's argument, based on Dr. Lonner's testimony, that "Fuss does not teach a continuous peripheral wall defining an internal chamber" because (1) it is contrary to Fuss's disclosure of boundary face 11, which does not incorporate any openings (*see* Ex. 1022, Fig. 2a; 7:7–17), and (2) the cited portions of Dr. Lonner's testimony do not even mention this feature of claim 9, much less provide evidence or technical reasoning in support of the argument (*see* Prelim. Resp. 53–54 (citing Ex. 2010 ¶¶ 157–161)).

Accordingly, we determine the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claim 9 is unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, Perez-Cruet, and Fuss.

III. CONCLUSION

For the above reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one claim of the '096 patent is unpatentable on the grounds asserted in the Petition.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to all of the grounds identified 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, which commences on the entry date of this decision.

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