UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Orthofix Medical Inc.
("Orthofix"),

Petitioner

v.

Spine Holdings, LLC ("Spine Holdings")

Patent Owner

IPR2020-01411
U.S. Patent No. 9,649,203

PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

TABLE OF CONTENTS

PETITIONER'S EXHIBIT LIST

Ex. 1001	U.S. Patent No. 9,649,203 to Lynn *et al.* ("the '203 Patent")
Ex. 1002	Prosecution History of the '203 Patent
Ex. 1003	Declaration of Michael Sherman ("Sherman Declaration")
Ex. 1004	U.S. Patent Publication No. 2008/0172128 to M. Perez-Cruet *et al.* ("Perez-Cruet")
Ex. 1005	U.S. Patent No. 6,764,491 to G. Frey *et al.* ("Frey")
Ex. 1006	U.S. Provisional Application No. 61/314,509 ("'509 Provisional")
Ex. 1007	U.S. Provisional Application No. 61/389,671
Ex. 1008	U.S. Patent Publication No. 2010/0262245 to A. Alfaro *et al.* ("Alfaro")
Ex. 1009	K. Phan et al., "Oblique Lumbar Interbody Fusion for Revision of Non-union Following Prior Posterior Surgery: A Case Report," *Orthopaedic Surgery 2015*, Volume 7, Issue 4, pp. 364-367 (Nov. 2015)
Ex. 1010	CV of Michael Sherman
Ex. 1011	U.S. Patent No. 9,168,138 to O'Neil *et al.* ("O'Neil")
Ex. 1012	U.S. Patent No. 2010/0094298
Ex. 1013	U.S. Patent Pub. No. 2008/0071284
Ex. 1014	U.S. Patent Pub. No. 2002/0098222
Ex. 1015	U.S. Patent No. 5,910,315
Ex. 1016	U.S. Patent Pub. No. 2007/0254042
Ex. 1017	R. Haid et al., *Lumbar Interbody Fusion Techniques*, Quality Medical Publishing, Inc. (2003) (selected pages)
Ex. 1018	U.S. Patent Pub. 2009/0198339 to Kleiner et al. ("Kleiner")
Ex. 1019	U.S. Patent No. 6,852,129 to Gerbec *et al.* ("Gerbec")
Ex. 1020	U.S. Provisional Application No. 61/207,912 ("Alfaro Provisional")
Ex. 1021	*Spine Holdings, LLC. v. Orthofix Medical Inc.*, No. 4-20-cv-00077 (E.D. Tex.), Dkt. 8, Order Granting in Part Joint Motion to Stay Pending Inter Partes Review, June 8, 2020
Ex. 1022	U.S. Patent No. 8,308,805 to Lynn *et al.* ("the '805 Patent")
Ex. 1023	Prosecution History of the '805 Patent

Note that the following analysis will cite to the page numbers of the exhibits themselves, as opposed to the page numbers provided within the exhibit (since not

all exhibits have such original page numbers). Also, the following analysis may bold, underline and/or italicize quotations and add color or annotations to the figures from these exhibits for the sake of emphasis, unless otherwise indicated.

I. INTRODUCTION

U.S. Patent No. 9,649,203 (the "'203 Patent") relates to spinal implants and related systems and methods. Independent claims 1 and 11 are directed to positioning a hollow "implant" between vertebrae and, thereafter, "directing graft material" into an "internal chamber" through an "access port" such that "the graft material is in flush contact" with adjacent vertebrae. During prosecution, the Applicant emphasized that the point of novelty is directing graft material into a chamber of the implant through an access port after, rather than before, placement of an implant between the vertebrae. But prior art not previously considered by the Patent Office – namely, Alfaro – discloses this alleged point of novelty, as well as many other features of the claims.

II. MANDATORY NOTICES

A. Real Party-in-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Orthofix Medical Inc. ("Orthofix" or "Petitioner") is a real party-in-interest. No other party has directed, funded, or controlled the filing of this *inter partes* review (IPR), and this IPR was not filed at the behest of any other party.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), to the best knowledge of the Petitioner, the '203 Patent is involved in the following case, whose complaint was filed

January 31, 2020 and which is currently stayed (*see* Ex. 1021):

- *Spine Holdings, LLC. v. Orthofix Medical Inc*., No. 4-20-cv-00077 (E.D. Tex.).

Petitioner is a party to this case.

The '203 Patent is related to U.S. Patent No. 9,216,096, which is the subject of an IPR filed by Petitioner.

C. Lead and Back-up Counsel and Service Information

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following counsel. A power of attorney accompanies this Petition.

Lead Counsel J. Andrew Lowes HAYNES AND BOONE, LLP 2323 Victory Ave. Suite 700 Dallas, TX 75219	Phone: 972-680-7557 Fax: 214-200-0853 andew.lowes.ipr@haynesboone.com USPTO Reg. No. 40,706
Back–up Counsel Clint Wilkins HAYNES AND BOONE, LLP 2323 Victory Ave. Suite 700 Dallas, TX 75219	Phone: 972-739-6927 Fax: 214-200-0853 clint.wilkins.ipr@haynesboone.com USPTO Reg. No. 62,448
John Russell Emerson HAYNES AND BOONE, LLP 2323 Victory Ave. Suite 700 Dallas, TX 75219	Phone: (214)651-5328 Fax: 214-200-0853 RussellEmersonIPR@haynesboone.com USPTO Reg. No. 44,098

Please address all correspondence to lead and back-up counsel. Petitioner consents to electronic service.

III. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ’203 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims identified herein.

IV. TECHNOLOGY BACKGROUND, THE ’203 PATENT, AND THE PROSECUTION HISTORY

A. Overview of Spinal Fusion

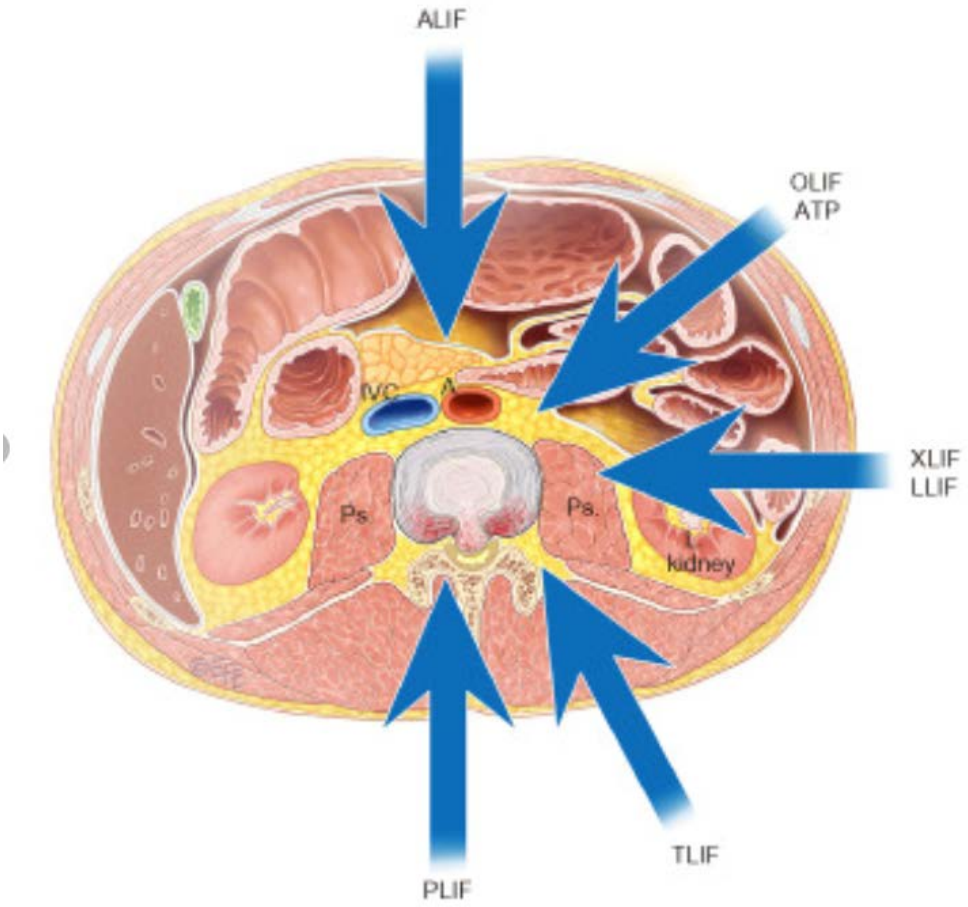
Spinal fusion involves joining two or more adjacent vertebrae together and preparing the vertebrae in a manner that make them initiate a healing process to consolidate the bone into a single mass. The adjacent vertebrae are often distracted (moved apart to increase the spacing) to relieve pressure on exiting nerve roots and a spacer, or implant, is placed in the disc space to maintain the distracted height during bone healing. Moreover, bone graft is typically used in conjunction with the spacer between the vertebrae to facilitate bone growth with the goal being a solid continuous boney structure that can support the spine. Over the course of months, the treated adjacent vertebrae grow together to fuse the adjacent vertebrae and support the spine. Ex. 1003, ¶¶ 42-43.

The disc space between the vertebrae can be approached from different anatomical angles. Before the ’203 Patent (and continuing to the present), manufacturers offered various implants and instruments to accommodate the known approaches, and a surgeon selected the approach based on the

circumstances of the surgery. These different surgical approaches each have a different name depending on the spinal level and approach angle, and often use slightly modified instruments, implants, and surgical techniques – yet, if successful, all result in an interbody fusion. For the lower back, the lumbar surgical approaches include:

- ALIF: Anterior Lumbar Interbody Fusions
- OLIF: Oblique Lumbar Interbody Fusions
- ATP: Anterior To Psoas approach
- XLIF / LLIF: Lateral Lumbar Interbody Fusion
- TLIF: Transforaminal Lumbar Interbody Fusions
- PLIF: Posterior Lumbar Interbody Fusions

The illustration below shows the different angles for these approaches. Ex. 1003, ¶¶ 44-52.



Direction of the oblique lumbar interbody fusion approach (OLIF). ALIF, anterior lumbar interbody fusion; ATP, anterior-to-psoas approach; XLIF, extreme lateral interbody fusion; LLIF, lateral lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion; PLIF, posterior lumbar interbody fusion.

Ex. 1009, Figure 1 (p. 2)

Surgeons select their surgical approach based on several factors. These include:

- The specific patient pathology and severity of disease being treated;
- The presence or absence of a spinal deformity;
- The number of spinal levels being treated;
- The level(s) being treated (cervical, thoracic or lumbar);
- The overall health of the patient; and
- The skill and comfort level of the surgeon with the approach.

Thus, there is no uniformly "best" approach for all patients and treatment

objectives. Rather, surgeons select the best approach based on the circumstances. Ex. 1003, ¶¶ 53-54.

While POSITAs appreciated that surgical techniques can include pre-packing bone graft into the interbody spacer, they also appreciated that certain instrument connections do not permit full packing of the interbody spacer prior to insertion and that certain situations lead to bone graft falling out during insertion. It was well known to pack additional bone graft into the interior of the interbody spacers after implantation in the spine. Ex. 1003, ¶¶ 60-64. Building on the experience of packing after implantation, publications referenced by Mr. Sherman demonstrate that several practitioners were motivated to explore multiple systems and methods to pack or inject graft materials into interbody fusion cages after implanting the cages into the interbody space. *Id*., ¶¶ 65-68.

B. Summary of the ’203 Patent

The ’203 Patent “generally relates to spinal fusion, and, more specifically, to spinal implants and related systems, tools and methods.” Ex. 1001, 1:18-21. The ’203 Patent specification describes at least three aspects of spinal implants and related methods:

(1) the spinal implant structure, *see*, *e.g*., Ex. 1001, 7:6-17:35 (section entitled “Spinal Implant”),

(2) the process of implanting the implant into an intervertebral space, *see*,

e.g., *id.*, 17:36-21:14 (section entitled "Implantation into Targeted Intervertebral Space"), and

(3) filling the implant with graft material after implantation, *see, e.g.*, *id.*, 21:14-27:2 (section entitled "Filling of the Implant").

(1) Spinal Implant

Figure 1A, reproduced below, shows an embodiment of an implant. The "implant 10" includes a "top surface 12" and a "bottom surface 16." *See*, *e.g.*, Ex. 1001, 7:30-41. The implant includes "one or more teeth 40…configured to contact and engage adjacent surfaces of the vertebral endplates once the implant has been positioned within the intervertebral space." *Id.*, 7:30-36. The teeth may partially or completely cover either the top surface, the bottom surface, or both. *Id.*, 7:36-49.

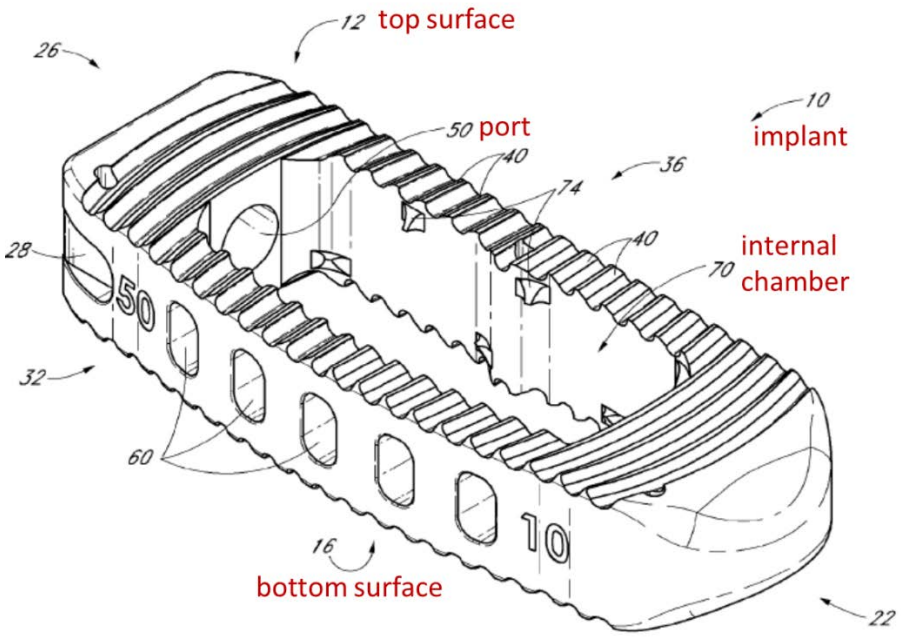


FIG. 1A

Ex. 1001, FIG. 1A[1]; Ex. 1003, ¶ 70

The implant 10 also includes a "port 50." *Id*., 9:59-10:14. In some embodiments, the "port 50 is configured to releasably engage a corresponding insertion tool..." *Id*., 9:60-61. The port 50 may include "a threaded connection" or using "other types of connection features" for engaging with an insertion tool. *Id*., 9:62-10:2; Ex. 1003, ¶¶ 69-72.

(2) Inserting the Implant

Figure 7A, reproduced below, illustrates an anterior side view of implant 10

[1] All shading and color annotations to drawings have been added by Petitioner's expert, unless specified otherwise.

after insertion between adjacent vertebrae V using an insertion tool assembly 300. Ex. 1001, 6:22-24, 15:30-42.

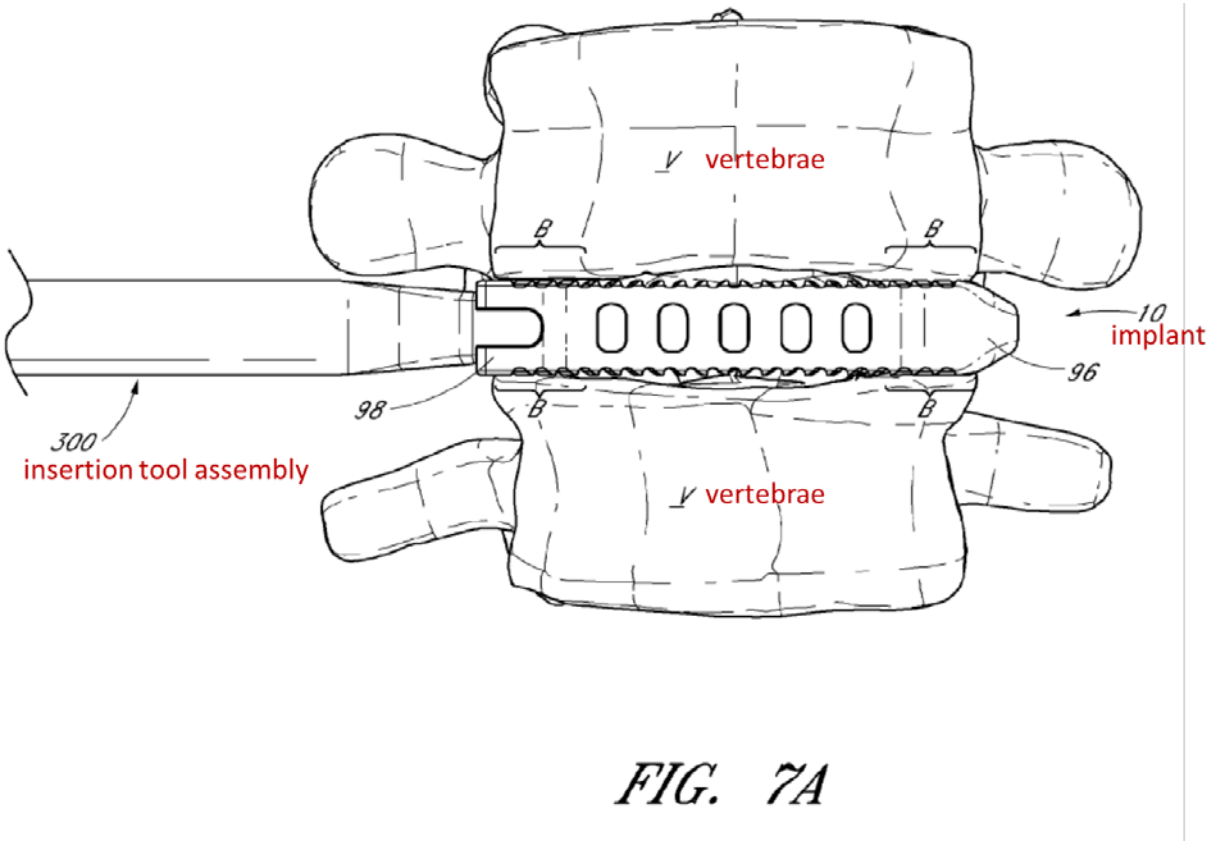


FIG. 7A

Ex. 1001, Figure 7A; Ex. 1003, ¶ 75

While Figure 7A depicts a lateral, or "XLIF," approach to the spine, the '203 Patent does not express a preference for what delivery approach (e.g., direction) a surgeon uses to insert an implant. The '203 Patent mentions in passing a variety of known approaches, saying that "any" approach may be used, *id*., 7:15-19, but only the lateral or XLIF approach is depicted in the figures. Ex. 1003, ¶ 76. As discussed above in Section IV.A ("Overview of Spinal Fusion"), these different

approaches were known before the ’203 Patent, and a POSITA would have known of these different approaches and their trade-offs. Ex. 1003, ¶¶ 73-76.

(3) Filling of the Implant

The ’203 Patent discloses filling the implant with graft material after the implant is inserted between vertebrae. ’203 Patent, 21:15-19. The implant may be filled (1) during engagement of an “insertion tool assembly,” *id.*, 24:59-25:18, or (2) through a bone graft delivery instrument after “insertion tool assembly…is decoupled from the implant,” *id*., 21:52-67. In one embodiment, the ’203 Patent describes an insertion tool assembly having a cannulated rod configured to receive a “fill conduit” for delivering graft material to the implant. *Id.*, 24:59-25:18; Ex. 1003, ¶¶ 77-78.

C. Prosecution History of the ’203 Patent

The Applicant filed the patent application for the ’203 Patent on April 23, 2015, with the title reflecting the focus of filling an implant after implantation: “Methods of Post-Filling an Intervertebral Implant.” Ex. 1002, p. 7. During a preliminary interview the Examiner noted that the new claims recited apparently novel features requiring that “at least one internal chamber of the implant, after implantation, extends from or near an endplate” of the first and second vertebrae; and the search would be directed toward such features. Ex. 1002, p. 175. In the first Office Action, Kleiner (Ex. 1018) was described as disclosing the structural

features and combined with Perez-Cruet's (Ex. 1004) graft delivery system to arguably disclose claim 2 (ultimately issued as claim 1). *Id*., pp. 199-200. Following another interview, the Examiner summarized the interview:

> Applicant's representative, Ted Papagiannis, noted that Kleiner does not explicitly disclose the step of directing graft material into the chamber of the implant after positioning the implant between the first and second vertebrae. Graft material is positioned within Kleiner's implant prior to placement between the adjacent endplates.

Ex. 1002, p. 256. Thus, the Applicant and Examiner apparently agreed that Kleiner discloses directing graft material into an implant before, not after, positioning of the implant between adjacent vertebrae.

In response, the Applicant amended claim 2 to distinguish Kleiner as follows (showing only the amended limitation):

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

Ex. 1002, p. 261. The Applicant generically explained "that the cited references fail to teach or suggest each and every limitation of the claims." *Id*., p. 267. In addition, the Applicant filed a terminal disclaimer with respect to U.S. Patent No. 8,308,805 (the "'805 Patent," Ex. 1022). Ex. 1002, p. 266. The Notice of

Allowance issued next but did not make any substantive remarks. *See id*., pp. 286-299.

As set forth below, Alfaro, which was not considered during prosecution, expressly discloses directing bone graft into an implant "*after positioning the implant between the first and second vertebrae, such that the graft material is in flush contact with endplate surfaces*…" the very feature the Examiner found lacking in the combination of Kleiner and Perez-Cruet during prosecution. Ex. 1003, ¶¶ 86-88.

Turning to the '805 Patent, which was the subject of the terminal disclaimer, the as-filed independent claims of the '805 Patent were rejected as anticipated by Perez-Cruet in an Office Action dated May 2, 2012. Ex. 1023, pp. 110-114. The claims were amended, recognizing that Perez-Cruet does not disclose, inter alia, that graft material is delivered into an internal chamber such that "*graft material contacts, at least partially, an endplate surface of each of the first and second vertebral bodies*." *Id*., p. 139. A Notice of Allowance issued next on August 22, 2012, with agreed Examiner's amendments as to exemplary independent claim 1, including directing graft material into an internal chamber "*to fill the at least one internal chamber of the implant such that the at least one graft material contacts an endplate surface of each of the first and second vertebral bodies*." *Id*., p. 240.

Thus, as compared to prosecution of the ’805 Patent, which relies only on Perez-Cruet, the Examiner in prosecution of the ’203 Patent combined Kleiner with Perez-Cruet. However, as discussed above, Alfaro is different than the combination of Kleiner and Perez-Cruet in ways material to the challenged claims. Ex. 1003, ¶¶ 79-92.

V. LEVEL OF ORDINARY SKILL IN THE ART

The level of ordinary skill in the art may be reflected by the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). To the extent a definition is needed, a person of ordinary skill in the art (“POSITA”) at the time of the earliest provisional application filing (i.e., the filing of Provisional Application No. 61/314,509, which is March 16, 2010) would have had a Bachelor of Science degree in the field of Mechanical, Biomechanical or Biomedical engineering as well as at least five years of experience 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 POSITAs. Alternatively, a POSITA could be a practicing orthopedic or neurosurgeon with experience designing spinal implants. Petitioner’s technical expert, Michael Sherman, whose declaration this Petition cites, was at least a POSITA. Ex. 1003, ¶¶ 22-25.

VI. CLAIM CONSTRUCTION

Claims are construed in an IPR under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). *See* 83 Fed. Reg. 51341 (Oct. 11, 2018). Petitioner believes that, for the purposes of this proceeding, no claim term requires express construction. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Accordingly, this Petition analyzes the claims consistent with ordinary and customary meaning as would be understood by a POSITA in light of the specification. *Phillips*, 415 F.3d at 1314-17; Ex. 1003, ¶ 111.

VII. REQUESTED RELIEF

Petitioner asks that the Board review the accompanying prior art and analysis, institute a trial for *inter partes* review of claims 1-20 and cancel those claims as unpatentable.

VIII. IDENTIFICATION OF CHALLENGE

A. Challenged Claims and Statutory Grounds

This Petition challenges claims 1-20 of the '203 Patent on the following grounds.

Ground	Claims	Basis
Ground #1	1-5, 9-15, 19, and 20	35 U.S.C. § 103 over Alfaro (Ex. 1008) in combination with Frey (Ex. 1005)
Ground #2	6-8 and 16-18	35 U.S.C. § 103 over Alfaro in combination with Frey and Perez-Cruet (Ex. 1004)

B. Status as Prior Art

The ’203 Patent claims priority to two U.S. provisional applications: U.S. Provisional Application No. 61/314,509 (“’509 Provisional,” Ex. 1006), filed March 16, 2010, and U.S. Provisional Application No. 61/389,671 (Ex. 1007), filed Oct. 4, 2010. Ex. 1001, 1:6-13. However, because 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 ’203 Patent is entitled only to the filing date of its earliest non-provisional application of March 16, 2011. Nevertheless, all references used in Grounds 1 and 2 are prior art relative to the filing date of even the earliest provisional of March 16, 2010.

The application corresponding to U.S. Patent Publication No. 2010/0262245 (“Alfaro”, Ex. 1008) was filed on February 17, 2010. Alfaro is therefore prior art under at least 35 U.S.C. § 102(e) (pre-AIA). U.S. Patent No. 6,764,491 (“Frey,” Ex. 1005) issued on July 20, 2004, and U.S. Patent Publication No. 2008/0172128 (“Perez-Cruet,” Ex. 1004) published on July 17, 2008, making both prior art under 35 U.S.C. § 102(b) (pre-AIA).

Additionally, background references Exhibits 1013-1017 and 1019 are all U.S. patents or U.S. patent publications that published over one year before the filing date of the ’509 Provisional, and Exhibit 1017 is a book published in 2003,

thereby making those documents prior art under 35 U.S.C. § 102(b) (pre-AIA). Background references Exhibits 1011 and 1012 are U.S. patents or patent publications based on applications filed in 2009, thereby making these documents prior art under 35 U.S.C. § 102(e) (pre-AIA).

Should Patent Owner attempt to swear behind Alfaro, Petitioner will respond to Patent Owner's evidence, including with supporting evidence from the Sherman Declaration. For example, the '203 Patent is not entitled to the March 16, 2010 filing date of the '509 Provisional. Ex. 1003, ¶¶ 96-110. Moreover, Alfaro is entitled to the benefit of U.S. Provisional App. No. 61/207,912 (Ex. 1020), which was filed on February 18, 2009. *See* Ex. 1003, Appendices A and B.

IX. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

A. Ground #1: Claims 1-5, 9-15, 19, and 20 are unpatentable as obvious over the combination of Alfaro and Frey.

1. Summary of Alfaro

Alfaro explains that prior-art intervertebral spacers, which are pre-loaded with biologic material before insertion into the intervertebral space, often result in "weakened" fusion or "non-fusion." Ex. 1008, ¶ [0009]. To address these problems, Alfaro discloses devices and associated methods in which a bone-grafting material is delivered into a spacer after the spacer is implanted in an intervertebral space. For example, Alfaro discloses that "in use the surgeon implants the spacer into the correct location of the patient" using an attached

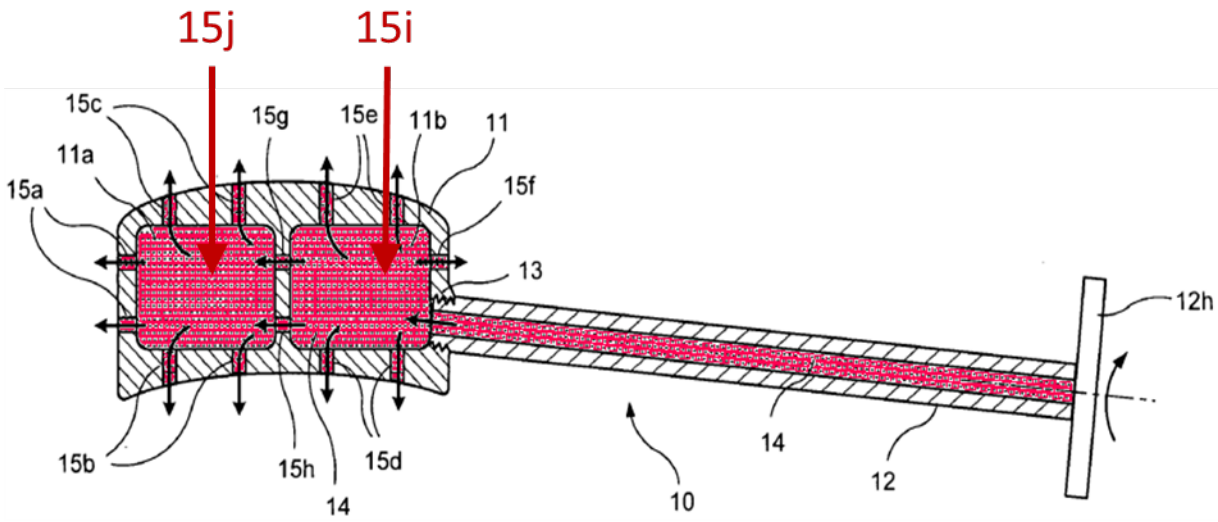
handle, and the surgeon "then advances [graft material] located in the handle" into the spacer. Ex. 1008, ¶ [0030]; Ex. 1003, ¶¶ 117-118.

Alfaro discloses at least two example embodiments for shapes of a spacer: (1) illustrated in Figures 1 and 2, Ex. 1008, ¶ [0029]; and (2) illustrated in Figures 8 and 9, *id*., ¶ [0039]. And each shape illustrates different hole placement(s) in the walls of the spacers. *E.g*., *compare* Figures 1 and 2. Ex. 1003, ¶ 119. These embodiments are merely examples, and "the intervertebral spacer of the device of the invention may be any spacer at all which satisfies the criteria of intervertebral spacers." *Id*., ¶ [0012].

Referring to Figures 1 and 2, "[h]andle 12 is shown screwed into compartment 11(b) at 13." *Id*., ¶ [0029]. Moreover, "[t]he handle facilitates the introduction of the spacer by the surgeon into the intervertebral space." *Id*., ¶ [0011]. With respect to how to fill such spacers with biologic material, the handle includes "a direct line of flow [for grafting material] through the handle into the voids of the spacer and out into the vertebral space." *Id*., ¶ [0012].

Figure 2, reproduced below, is shaded to highlight the location and flow of biologic material through handle 12 into spacer 11 and out through spaces 15a-j, wherein the top and bottom openings of the internal cavities of the spacer, 15i and 15j, are directly opposite the vertebrae above and below the spacer after being

placed in the intervertebral space. Figure 9 is a perspective view of another embodiment. Ex. 1003, ¶¶ 117-122.



Ex. 1008, Figure 2; Ex. 1003, ¶ 122

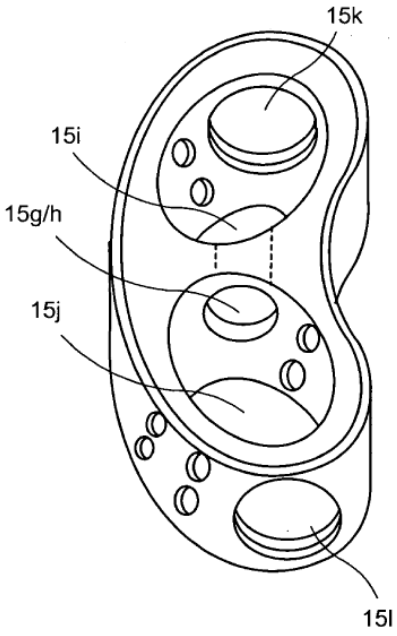


FIG. 9

Ex. 1008, Figure 9

2. Summary of Frey

Frey, like Alfaro, discloses spinal implants. The implants include one or more holes configured for engaging an inserter (e.g., holes that are internally threaded). Ex. 1005, 20:54-62. Frey's implant includes a number of grooves on surfaces to engage vertebral endplates. *Id*., 20:6-11.

Figure 54, reproduced below, is an "end elevational view of an implant" and "FIG. 55 is a top plan view of the implant of FIG. 54," illustrating grooves 1014 and "inserter engaging portion 1044." Ex. 1005, 5:1-3, 20:6-11, and 20:54-58.

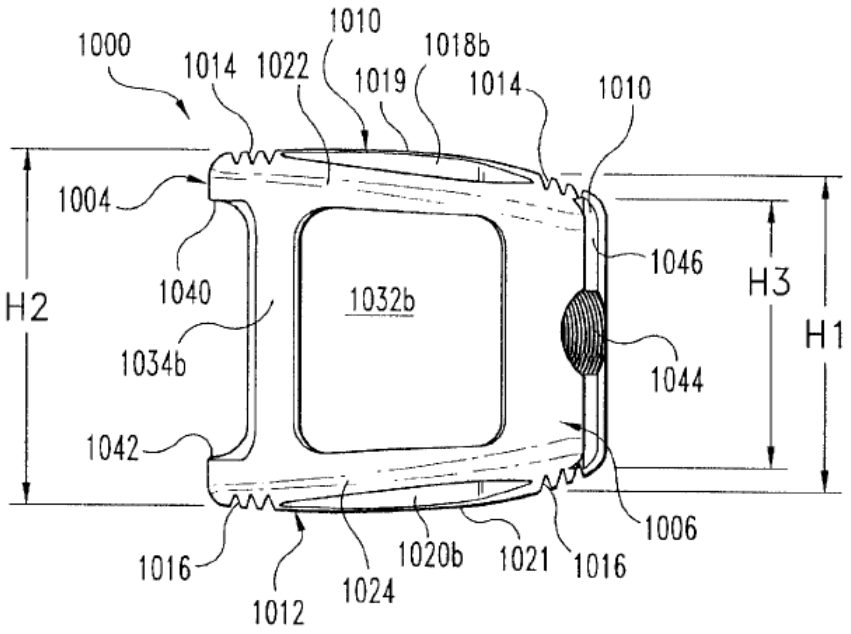


Fig. 54

Frey, Figure 54 (end view)

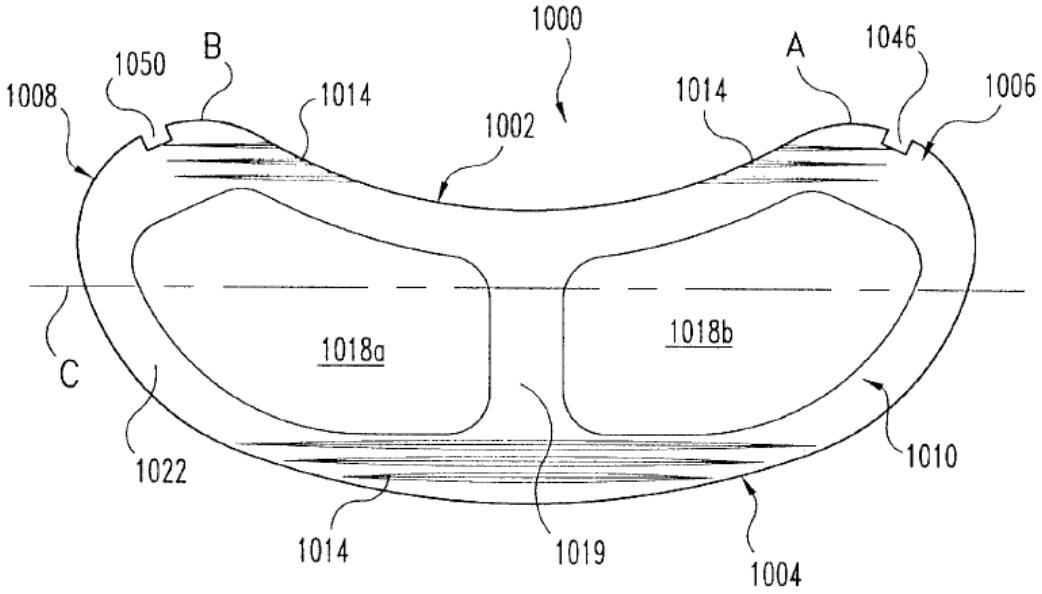


Fig. 55

Ex. 1005, Figure 55 (top view)

3. Reasons to Combine Alfaro and Frey

As a threshold matter, Alfaro and Frey are analogous art to the ’203 Patent, being directed to the same field of spinal implants for interbody fusion and related systems, tools, and methods. *See, e.g.*, Ex. 1001, 1:18-21 (“1. Field”); Ex. 1008, ¶ [0004]; Ex. 1005, Abstract; Ex. 1003, ¶ 124.

Turning to reasons to combine Alfaro and Frey, as explained previously, Alfaro discloses that “any spacer at all” may be used with its disclosure, provided that such a spacer is:

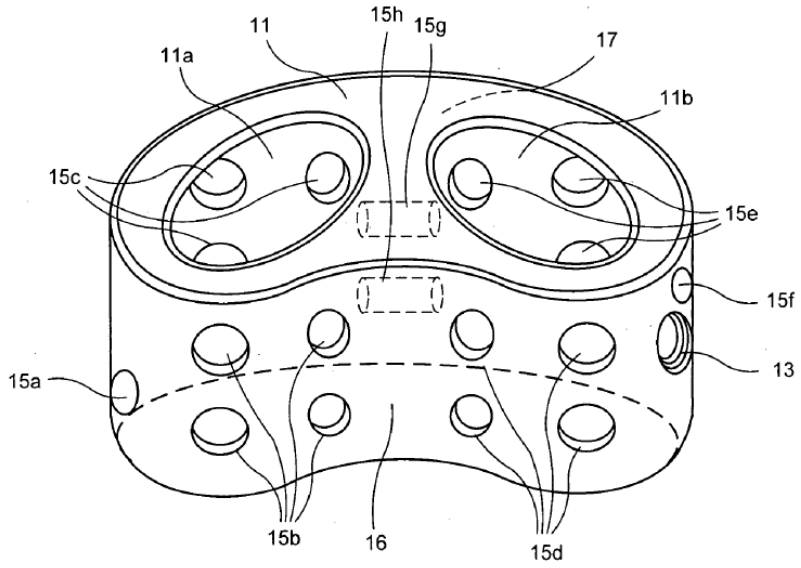
> attachable and detachable to a handle capable of containing a biologic material-advancing means … for moving the biologic material through the handle and into the spacer.

Ex. 1008, ¶ [0012]. Alfaro's spacers, like Frey's spacers, include one or two internal compartments. *Id*., ¶ [0020]. Alfaro further teaches that the implant/spacer is "pressure-fit into place between the opposing vertebral bodies so as to fix the device in place, and in essence, to encourage the two vertebrae to fuse," *id*., ¶ [0005], and "the spacer of course, remains in place at the correct site between the vertebrae," *id*., ¶ [0031].

Frey teaches an implant 1000 akin to the intervertebral spacer of Alfaro. Frey's implant 1000 further includes upper and lower bearing members 1010 and 1012 provided with grooves 1014 and 1016, respectively for engaging vertebral endplates to resist migration of the implant 1000 in the disc space. Ex. 1005, 19:50-52 and 20:6-1 ("Grooves 1014 and 1016 can engage the vertebral endplates to resist posterior and anterior migration of implant 1000 in the disc space.")

Figure 55 of Frey and Figure 8 of Alfaro are presented below to illustrate the similarities between these implant embodiments (e.g., Alfaro's implant has two compartments 11a and 11b and Frey's implant has two compartments 1018a and 1018b; both implants are similarly shaped; and both implants have screw holes –

hole 13 in Figure 8 of Alfaro and "inserter engaging portion 1044" in Figure 54 of Frey – for engaging an insertion device).



F I G. 8

Ex. 1008, Figure 8

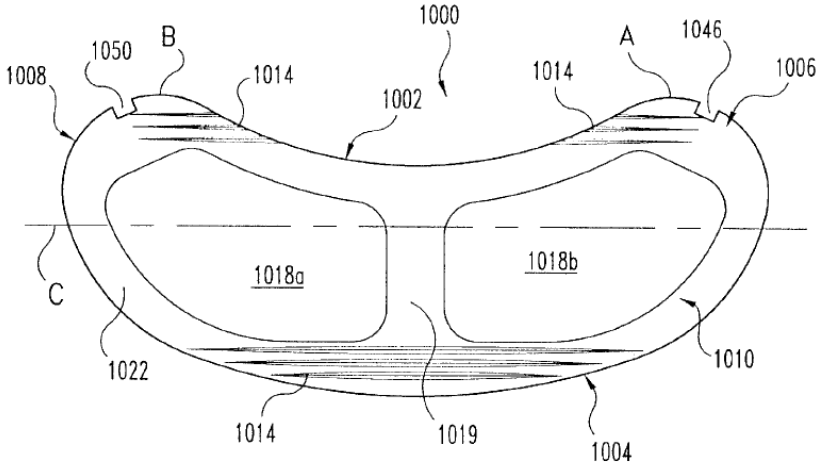


Fig. 55

Ex. 1005, Figure 55

Because a spacer is placed between vertebrae "in an effort to fuse adjacent vertebrae to each other," and **"[i]t 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," Ex. 1008, ¶ [0005], it was well understood that it was desirable that such spacers not move after the surgeon inserts the spacer between vertebrae. As Alfaro recognizes, "[t]he spacer of course, remains in place at the correct site between the vertebrae." *Id*., ¶ [0031]. Movement of the spacer in the intervertebral space would be indicative of a lack of stable fixation and would be detrimental to fusion of the adjacent vertebrae to one another. Ex. 1003, ¶¶ 127-129.

Because Frey's grooves 1014, 1016 provide for "resist[ing] posterior and anterior migration of implant 1000 in the disc space," Ex. 1005, 20:6-11, a POSITA would have been motivated to include such grooves on the top and bottom surfaces of Alfaro's implant to resist migration of the implant after implantation. Such grooves would achieve Frey's stated benefit and also promote fusion of adjacent vertebrae because there is less risk of the implant migrating within or out of the space between vertebrae. Ex. 1003, ¶ 130.

Utilizing Frey's grooves on the top and bottom surfaces of Alfaro's implants represents combining prior art elements (Frey's groove structure on an implant as

applied to Alfaro's implants) according to known methods to yield the predictable result of an implant that is resistant to migration within the intervertebral space. Utilizing Frey's grooves on the surfaces of Alfaro's implant also represents use of a known technique (Frey's grooves on the surface of an implant) to improve similar devices (Alfaro's spacers) in the same way. Ex. 1003, ¶ 131.

Alfaro further teaches that "in use the surgeon implants the spacer into the correct location of the patient using the well-known techniques for intervertebral placements and observing all of the normal medical procedures attendant to this procedure." Ex. 1008, ¶ [0030]. As discussed in Section IV.A herein, different surgical approaches for positioning and inserting an implant into the intervertebral space were well known, including posterior lateral, transforaminal, lateral, anterior, or anterior-lateral approaches. There is no uniformly "best" approach for all patients and treatment objectives. Rather, surgeons select the surgical approach based on the specific clinical circumstances of each patient. In view of Alfaro's teachings and the background knowledge of a POSITA, any of the known approaches was viable. Only a simple modification to the location of the screw hole in a lateral wall of the implant would be required to accommodate these different surgical approaches, a modification well within the skillset of a POSITA. Ex. 1003, ¶ 132.

Frey lists several specific and well-known surgical approaches including:

posterior lateral, *see* Ex. 1005, Title and 1:19-20, transforaminal, *id*., 5:24-25, lateral, anterior or anterior-lateral, *id*., 19:28-32. To the extent a POSITA practicing Alfaro would even need a reference to list the different approaches, a POSITA would have been motivated to reference Frey's teachings in order to implant the spacer of Alfaro into an intervertebral disc. The motivation would have been the simple desire to implant the spacer. Ex. 1003, ¶ 133.

In summary, there are many reasons a POSITA would have been motivated to incorporate the teachings of Frey in the system of Alfaro. Ex. 1003, ¶¶ 124-134.

4. Claim 11[2]

a) [11.0] A method of promoting spinal fusion within a spine of a patient, comprising:

Alfaro discloses claim element [11.0].

Alfaro discloses that "[i]t is often necessary in the correction of various spinal defects, to intervene and place exogenous devices between vertebrae **in an effort to fuse adjacent vertebrae to each other**." Ex. 1008, ¶ [0005]. Alfaro further discloses that "in use the surgeon implants [a] spacer into the correct location of the patient using the well-known techniques for intervertebral

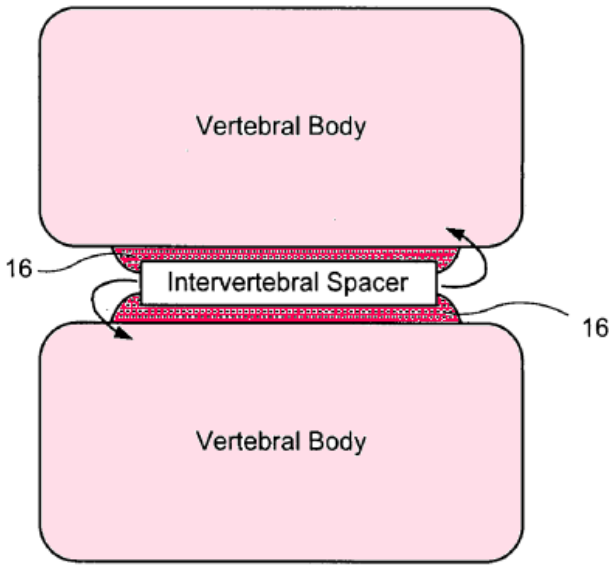
[2] The analysis begins with claim 11, rather than claim 1, because claim 11 is broader than claim 1.

placements and observing all of the normal medical procedures attendant to this procedure." *Id*., ¶ [0030].

Figure 6 illustrates Alfaro's spacer positioned in the correct location of the patient, that is, within the spine of the patient, and graft material flowing out of surfaces of the implant adjacent to vertebral bodies:

> Once the DBM is forced into the interior spacer compartment(s) and tunnels ... with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16, the handle is removed ... and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae.

Id., ¶ [0031].



Ex. 1008, Figure 6; Ex. 1003, ¶ 139

As shown in Figure 6, Alfaro illustrates 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**." Ex. 1008, ¶ [0031].

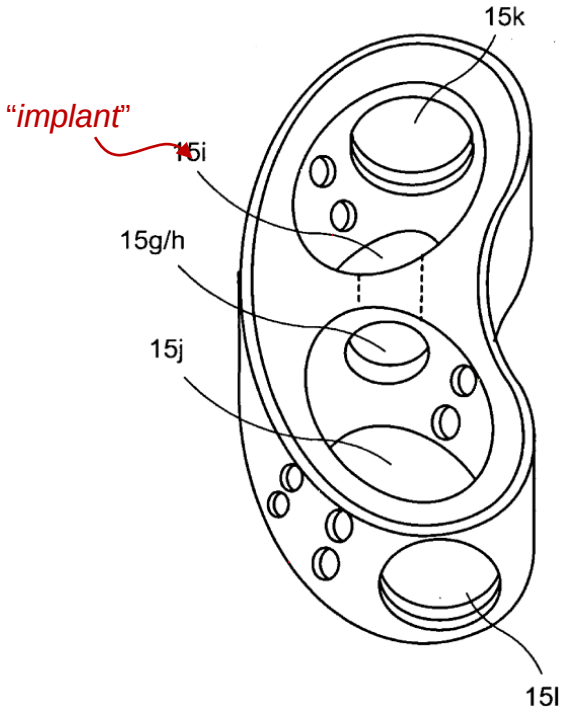
Therefore, Alfaro discloses insertion of a spacer between vertebrae together with grafting material (such as DBM) for fusing the vertebrae, which is an example of [11.0]. Ex. 1003, ¶¶ 135-141.

b) [11.1.1] advancing an implant through an anatomy of a patient

Alfaro discloses [11.1.1].

Alfaro "relates to the provision of surgical devices and more particularly to surgical devices for **insertion of intervertebral spacer implants** and delivery of bone grafting material **into intervertebral spaces** in surgical procedures." Ex. 1008, ¶ [0004]. Alfaro further teaches that "in the correction of various spinal defects…[o]ne particular modality is **to introduce a solid material into the vertebral space following a surgical discectomy**." *Id*., ¶ [0005]. More particularly, "[t]he solid material is pressure-fit into place **between the opposing vertebral bodies** so as to fix the device in place, and in essence, to encourage the two vertebrae to fuse." *Id*.

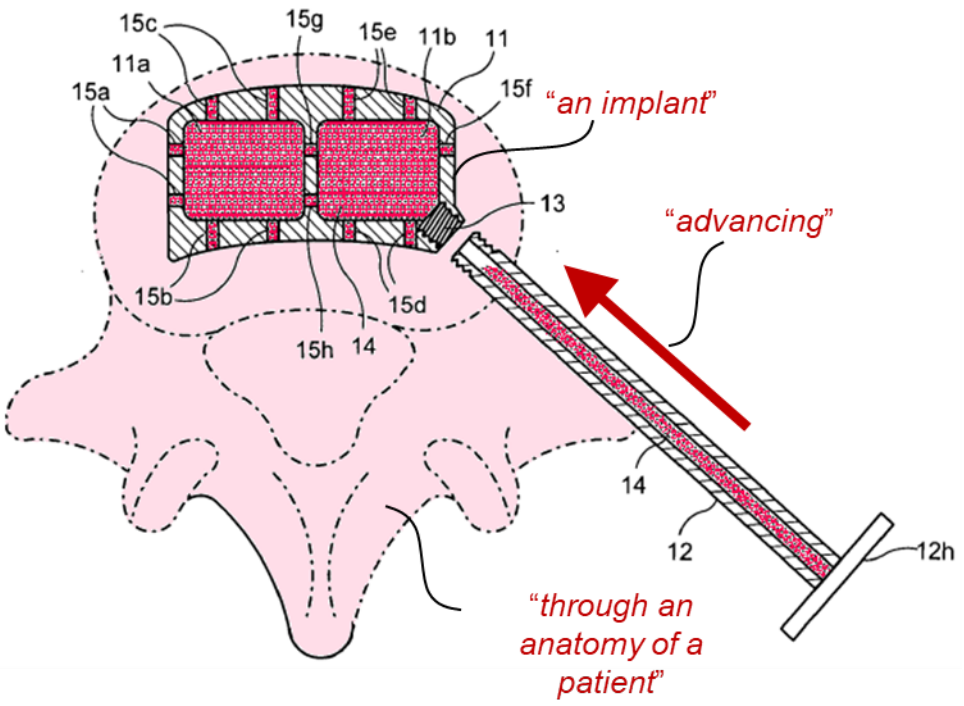
In Figure 9, Alfaro illustrates this "solid material" in the form of an intervertebral spacer (e.g., an "*implant*), according to an embodiment.



Ex. 1008, Figure 9; Ex. 1003, ¶ 146

As shown in Figure 9, the "[s]crew holes 15(k) and 15(l) [are] points of attachment for the holder, offering flexibility as to which side the surgeon prefers to use for delivery of the spacer." Ex. 1008, ¶ [0039].

Alfaro further teaches that "in use **the surgeon implants the spacer into the correct location of the patient** using the well-known techniques for intervertebral placements." *Id*., ¶ [0030]. Figure 2, which is labeled as "a plan view of the delivery device of FIG. 1….in place in the anatomy of a patient," illustrates the intervertebral spacer 11 in a simplified form after being implanted in the anatomy of a patient. *Id*., ¶¶ [0024] and [0029].



Ex. 1008, Figure 2; Ex. 1003, ¶ 150

Therefore, Alfaro discloses and illustrates implanting a spacer between vertebrae in a patient "using the well-known techniques for intervertebral placement," which discloses [11.1.1]. Ex. 1003, ¶¶ 142-151.

c) [11.1.2] the implant comprising at least one internal chamber

Alfaro discloses [11.1.2].

Alfaro discloses different intervertebral spacers having one or two internal compartments or "*chambers*." For example, as shown in the embodiments in Figures 1, 2, 8, and 9 of Alfaro, compartments 11a and 11b are open at the top and bottom of the intervertebral spacer at 15i and 15j. FIGS. 8 and 9 are reproduced

below for reference.

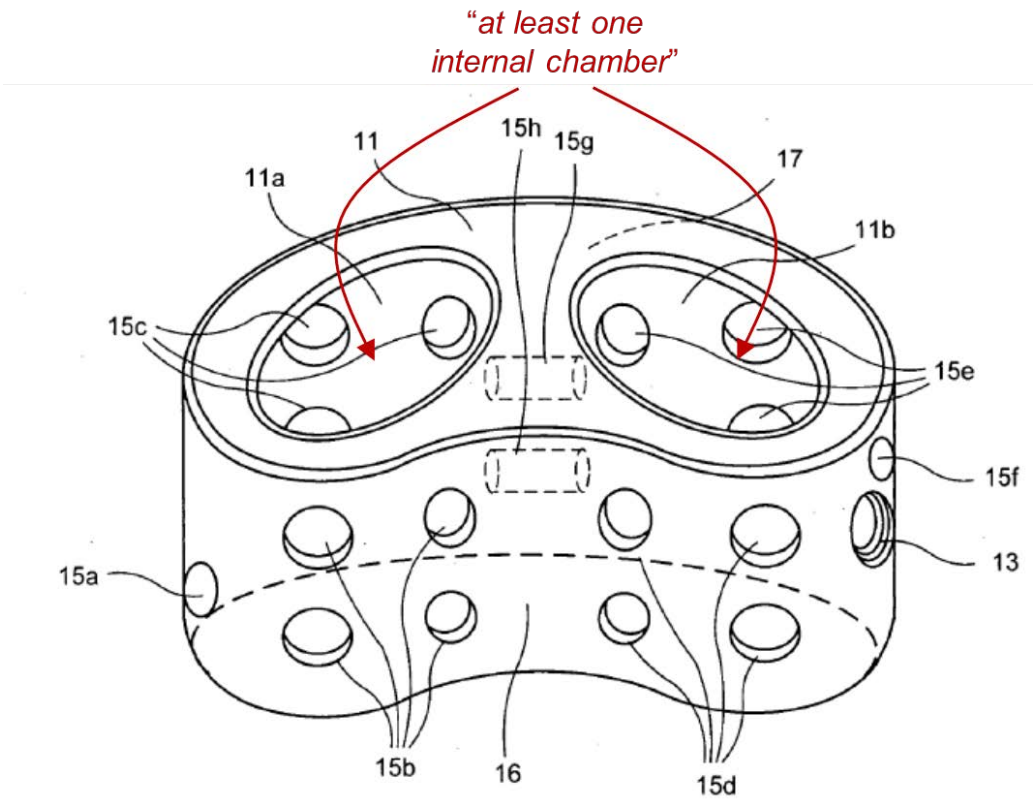
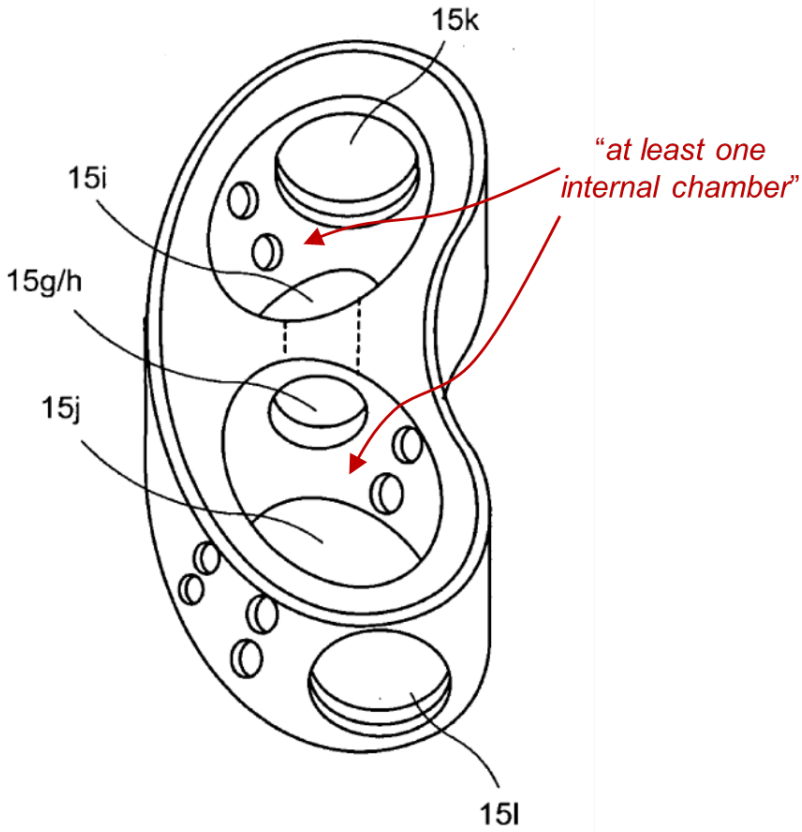


FIG. 8

Ex. 1008, Figure 8; Ex. 1003, ¶ 153



F I G. 9

Ex. 1008, Figure 9; Ex. 1003, ¶ 153

Alfaro also teaches that, "[w]hile two compartments are preferred, it is also contemplated to use only one compartment...." Ex. 1008, ¶ [0020][3].

Therefore, Alfaro discloses and illustrates utilizing implants having one or two compartments, which are examples of [11.1.2]. Ex. 1003, ¶¶ 152-155.

[3] The '203 Patent likewise discloses implants with one or two interior chambers. *See, e.g.*, '203 Patent, 25:47-56 and Figures 19 and 20.

d) **[11.2]** ***positioning the implant between a first vertebra and a second vertebra of a patient, the first and second vertebrae being immediately adjacent to one another***

Alfaro discloses [11.2].

Alfaro teaches that "[i]t is often necessary in the correction of various spinal defects, to intervene and **place exogenous devices between vertebrae** in an effort to fuse **adjacent vertebrae** to each other." Ex. 1008, ¶ [0005]. Furthermore, a "solid material [e.g., "*implant*"] is pressure-fit into place [e.g., "*positioning*"] **between the opposing vertebral bodies** so as to fix the device in place, and in essence, **to encourage the two vertebrae to fuse**." *Id*. Alfaro further teaches that "in use the surgeon implants [a] spacer into the correct location of the patient using the well-known techniques for intervertebral placements." *Id*., ¶ [0030]. In Figure 6, reproduced in [11.0], Alfaro illustrates the spacer positioned in the correct location of the patient, that is, between adjacent vertebral bodies in the spine of a patient.

Therefore, Alfaro discloses positioning an intervertebral spacer between adjacent vertebrae, which is an example of [11.2]. Ex. 1003, ¶¶ 156-160.

e) **[11.3.1]** ***directing graft material into the at least one internal chamber of the implant through an access port of the implant to fill the at least one internal chamber of the implant, after positioning the implant between the first and second vertebrae***

Alfaro discloses [11.3.1].

The intervertebral spacers of Alfaro include a screw hole, *see, e.g.*, Ex. 1008, ¶ [0029], which is an example of "*an access port*," and "compartments 11(a) and 11(b)", which are examples of "*at least one internal chamber of the implant*." For example, such a screw hole is illustrated at location 13 in Figures 1 and 2 of Alfaro. The screw hole is "provided to allow for outflow" of biologic material into compartments 11(a) and 11(b) and into the intervertebral space. *Id*. As another example, in Figure 9, Alfaro illustrates "[s]crew holes 15(k) and 15(l) [as] points of attachment for the holder, offering flexibility as to which side the surgeon prefers to use for delivery of the spacer." Ex. 1008, ¶ [0039].

Examples of an "*access port*" and "*at least one internal chamber*" are illustrated below in Figures 8 and 9.

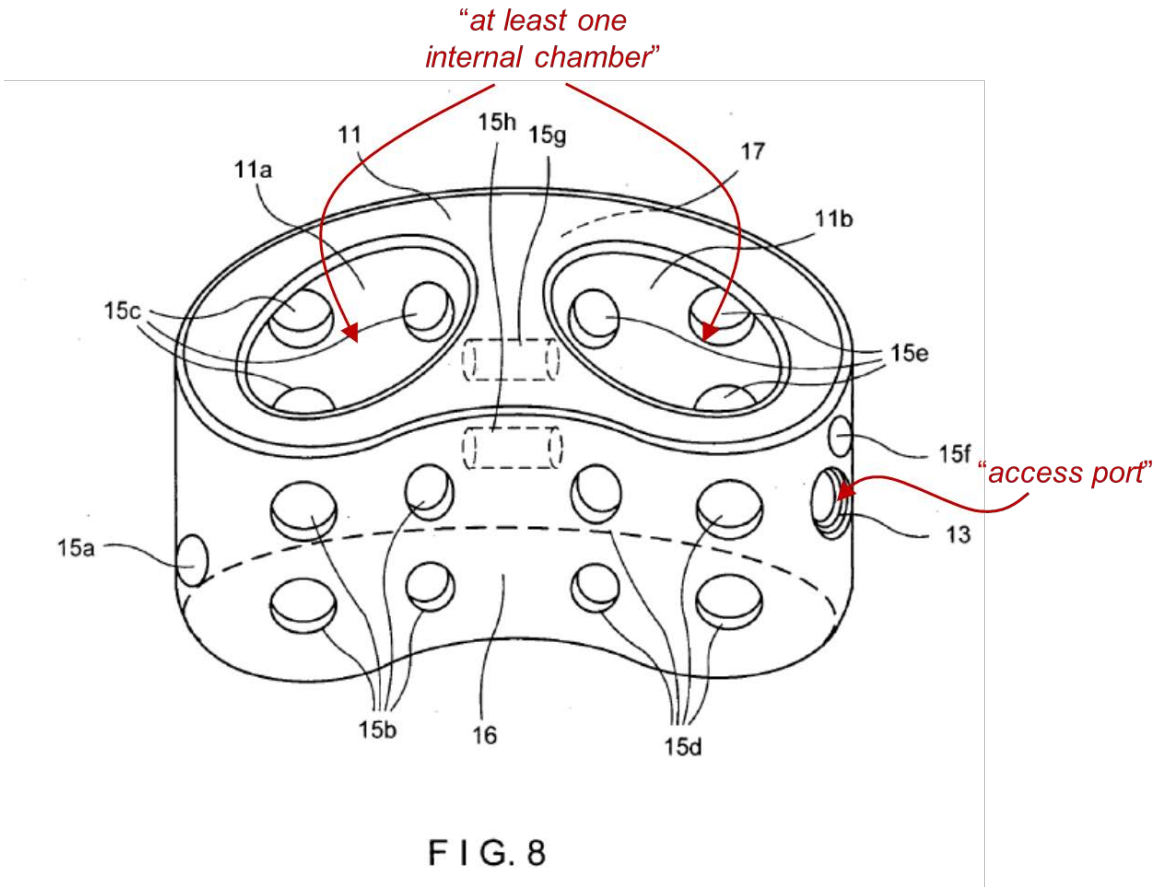


FIG. 8

Ex. 1008, Figure 8; Ex. 1003, ¶ 164

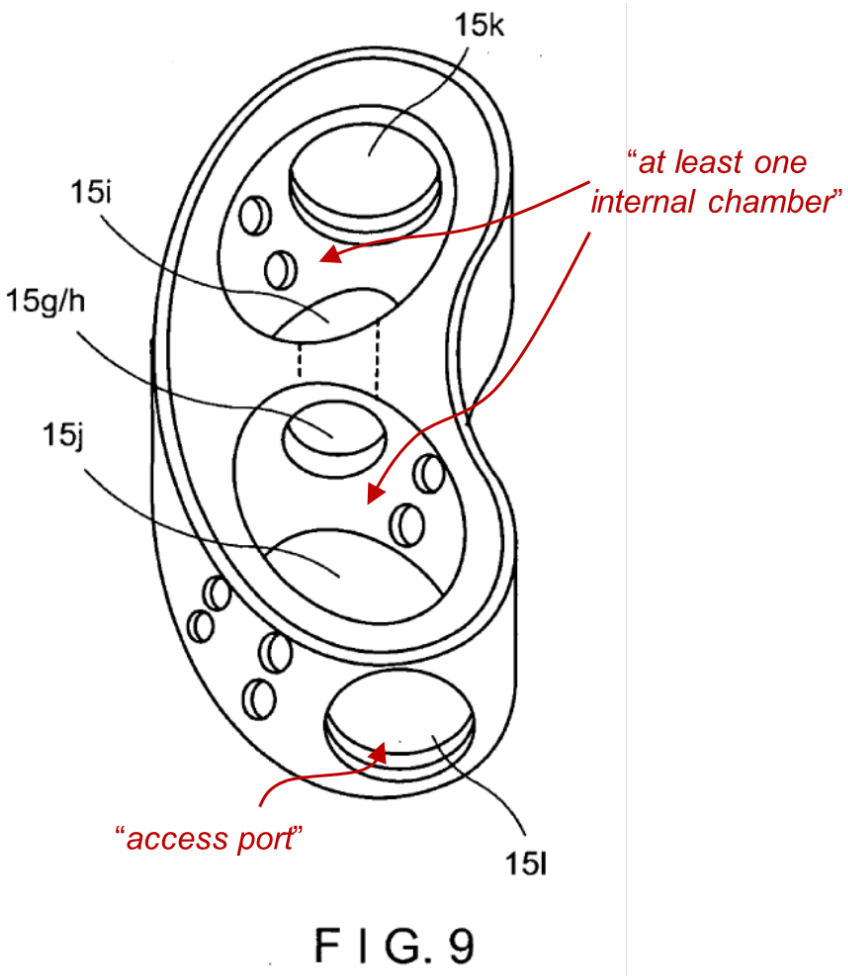
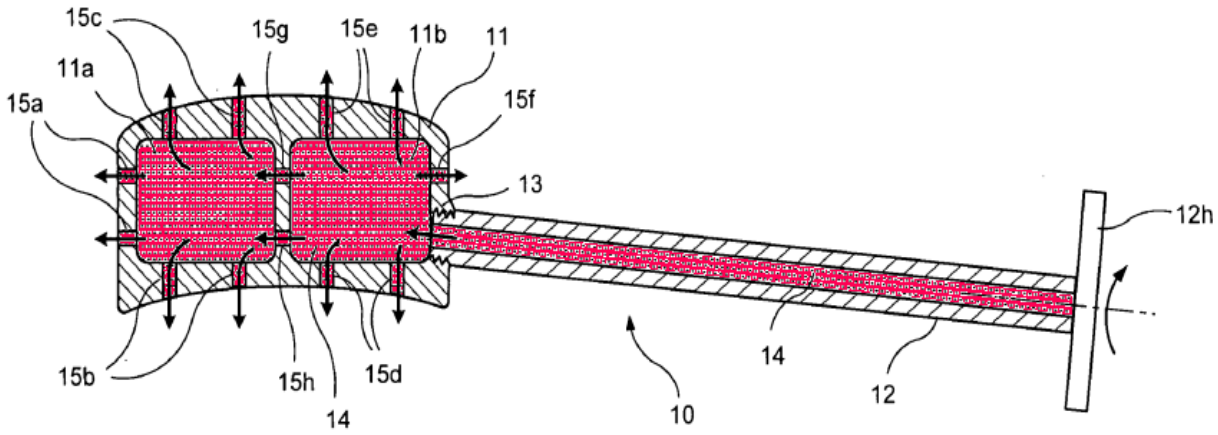


FIG. 9

Ex. 1008, Figure 9; Ex. 1003, ¶ 164

Further, Alfaro's screw hole provides access to "*at least one internal chamber*" to "*fill the at least one internal chamber of the implant, after positioning the implant between the first and second vertebrae*." For example, Alfaro explains the sequence of events as (1) implanting the spacer, followed by (2) forcing DBM into the interior spacer compartment(s) and tunnel(s) via a screw hole. Ex. 1008, ¶¶ [0030]-[0031]. By disclosing demineralized bone matrix (DBM) graft material flowing through compartments and into the vertebral spaces as shown by the

arrows in Figure 1 and DBM placement in Figure 6, Alfaro discloses that at least one of the compartments 11(a) and 11(b) is filled (otherwise, the DBM would not flow out into the intervertebral spaces as shown in Figure 6). Ex. 1003, ¶ 165.



Ex. 1008, Figure 1; Ex. 1003, ¶ 165

In summary, Alfaro discloses that DBM or some other biologic material flows into interior spacer compartments via a screw hole after being inserted between vertebrae and fills those compartments, which is an example of claim element [11.3.1]. Ex. 1003, ¶¶ 161-166.

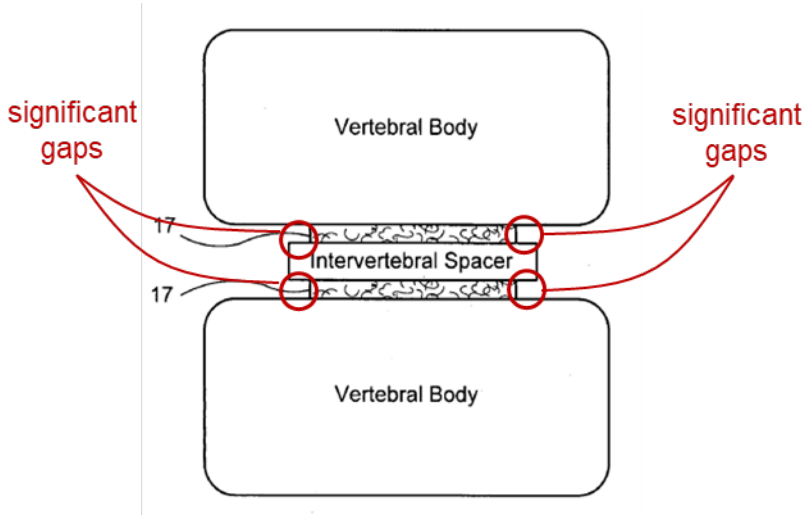
f) **[11.3.2]** ***such that the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae***

Alfaro discloses [11.3.2].

First, with respect to the ’203 Patent disclosure, the ’203 Patent does not use the term “*flush contact*” in the specification nor is it a term of art in the field of spinal fusion. Ex. 1003, ¶ 168. However, the ’203 Patent describes a situation in which any gap that exists between the vertebral endplates and the adjacent surfaces

of the implant is filled. Ex. 1001, 24:38-41 ("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.") Thus, the term "*the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae*" 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. Ex. 1003, ¶ 168.

Turning to Alfaro and applying this understanding, Alfaro discloses that "the current prior art approach as shown in FIG. 7 at 17 ... **may leave significant gaps** between the spacer and the endplates of the inferior and superior vertebral bodies. Because of the nature of osteogenesis, **bone will not grow across the gaps** leaving a significantly weakened placement of the implant." Ex. 1008, ¶ [0031].

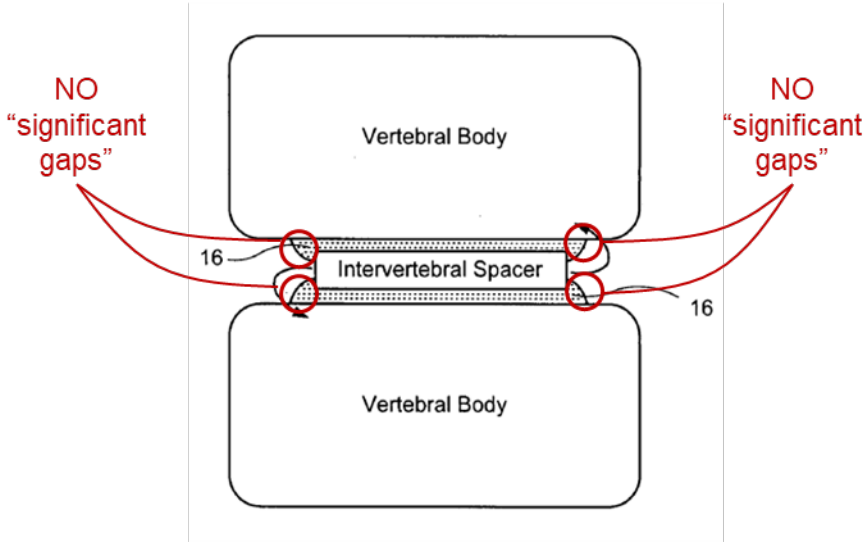


Ex. 1008, Figure 7; Ex. 1003, ¶ 169

To address the gapping problem, Alfaro teaches that "[t]he handle contains

for example, an Archimedes screw to push and deliver demineralized bone matrix (DBM) to the implant site. See FIG. 6 at 16, and FIGS. 1 and 2." Ex. 1008, ¶ [0029]. DBM is a well-known type of graft material. Ex. 1001: 21:19-27. More specifically, "[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels ... with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16, the handle is removed ... and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031][4]; Ex. 1003, ¶ 170.

[4] Figures 6 and 7 are understood as simplified views of a spacer between vertebrae to emphasize that graft material fills gaps between surfaces of the spacer and adjacent vertebral bodies and do not suggest that there is no contact between a spacer and vertebrae, for the spacer "remains in place" due to some contact with vertebrae. Ex. 1003, ¶ 170, n. 7.



Ex. 1008, Figure 6; Ex. 1003, ¶ 170

"[B]y 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." Ex. 1008, ¶ [0031]. Further, Alfaro provides 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." *Id.*, ¶ [0010]. Further still, Alfaro provides that "[t]he 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**." *Id.*, ¶ [0019].

In summary, Alfaro teaches a device and associated process in which gaps between the end plates of the vertebral body and the surfaces of the intervertebral

spacer are filled by complete coverage at the surfaces thereof, with a suitable biologic product (e.g., DBM) introduced via the device, thereby disclosing claim element [11.3.2]. Ex. 1003, ¶¶ 167-173.

g)* [11.3.3] *wherein the graft material is contained within the at least one internal chamber

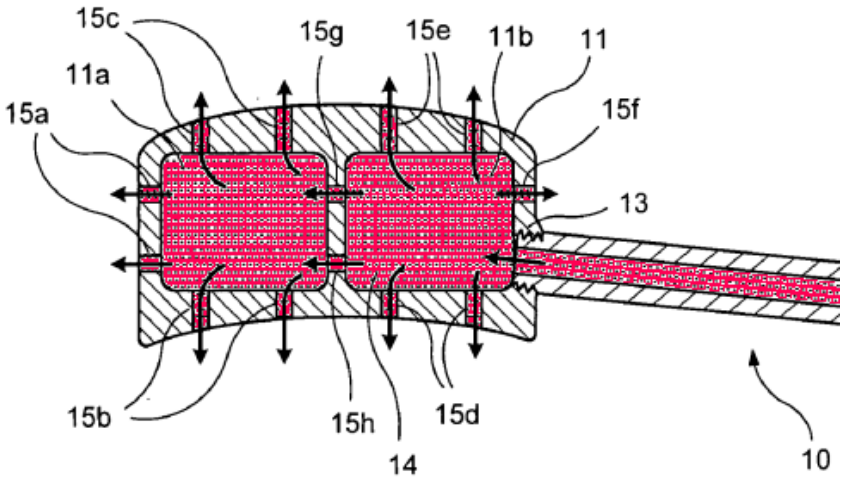
Alfaro discloses [11.3.3].

First, an analysis of the claim term in light of the '203 Patent disclosure yields the following insights. The '203 Patent provides that

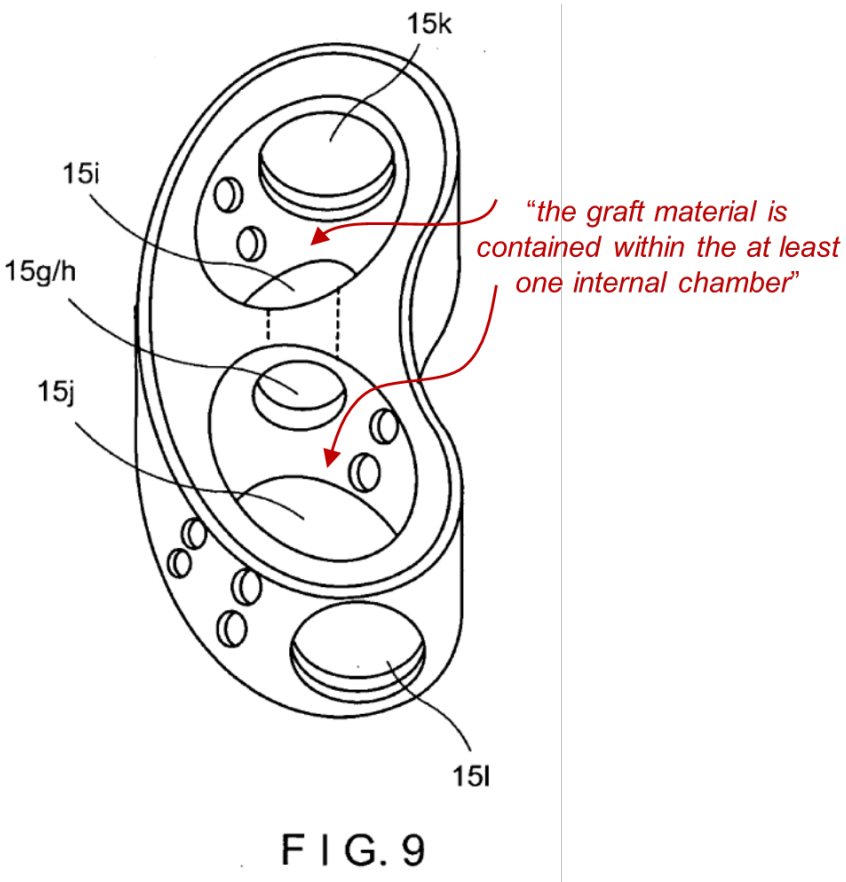
> the spinal implants disclosed herein or equivalents thereof comprise **a generally closed structure** along their sides. For example, in some arrangements, the only openings along the outer sidewalls are … **one or more openings that permit excess grafting materials to exit an interior chamber** or other cavity of the implant (e.g., **openings 60 along the anterior side wall of the implant**, as illustrated in FIG. 3A).

Ex. 1001, 11:1-11. For example, in Figure 20, the '203 Patent illustrates an embodiment in which the implant 1100 comprises a port 1136 and openings 1134a and 1134b. *See id*., 25:54-59 and 26:23-31. In other words, the '203 Patent contemplates that the interior chambers 1116a and 1116b can "contain" graft material delivered through the port 1136 despite the presence of the openings 1134a and 1134b. Ex. 1003, ¶¶ 175-176. Thus, openings in implant side walls can be present while "*the graft material is contained within the at least one internal chamber*," as recited in claim element [11.3.3]. *Id*., ¶ 177.

Turning to Alfaro, similar to the openings 1134a and 1134b formed in the '203 Patent's implant 1100, the intervertebral spacer of Alfaro includes tunnels formed therethrough. Despite the existence of these tunnels, the compartments 11a and 11b, which are "open at the top of the spacer and at the bottom at 15(i) and 15(j) (in FIG. 9)," "are adapted **to contain DBM or any other suitable biologic** and communicate with the opposing vertebral surfaces to allow the biologic to flow into the space." Ex. 1008, ¶ [0029]; *see also* ¶ [0039]. Furthermore, in Figure 1, compartments 11(a) and 11(b) and tunnels 15(a)-15(f) are "**shown to contain DBM 14**." *Id.*, ¶ [0029].



Ex. 1008, Figure 1 (partial); Ex. 1003, ¶ 179



F I G. 9

Ex. 1008, Figure 9; Ex. 1003, ¶ 178

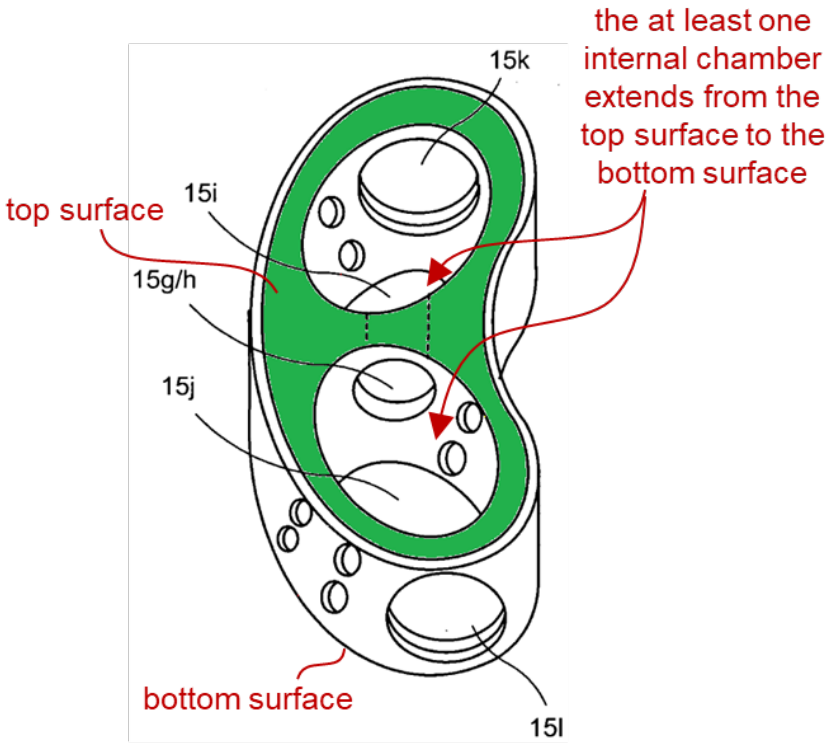
In summary, (1) Alfaro discloses compartments that "contain" graft material; (2) openings in the peripheral walls of the implant can be present while "*the graft material is contained within the at least one internal chamber*," and, in this regard, Alfaro's intervertebral spacer includes tunnels equivalent to the openings 1134a and 1134b formed in the '203 Patent's implant 1100; and (3) an interface between the implant and the first or second vertebrae can be present while "*the graft material is contained within the at least one internal chamber*," and, in this regard, the device of Alfaro permits graft material to flow out into the

interfaces between the compartments and the vertebrae in a manner equivalent to that described in the ’203 Patent. In view of (1)-(3), Alfaro discloses [11.3.3]. Ex. 1003, ¶¶ 178-183.

h) **[11.4.1]** ***wherein the at least one internal chamber of the implant, after implantation, extends from or near an endplate of the first vertebra to or near an endplate of the second vertebra***

Alfaro discloses [11.4.1]. Alfaro combined with Frey also renders obvious [11.4.1].

Alfaro discloses that “[t]he device comprises spacer 11 which comprises **open compartments 11(a) and 11(b)**, open at the top of the spacer and at the bottom at 15(i) and 15(j) (in FIG. 9) which are adapted to contain DBM or any other suitable biologic and communicate with the **opposing vertebral surfaces** to allow the biologic to flow into the space.” Ex. 1008, ¶ [0029]. In Figure 9, Alfaro illustrates the compartments 11a and 11b extending from a top surface to a bottom surface of the intervertebral spacer.

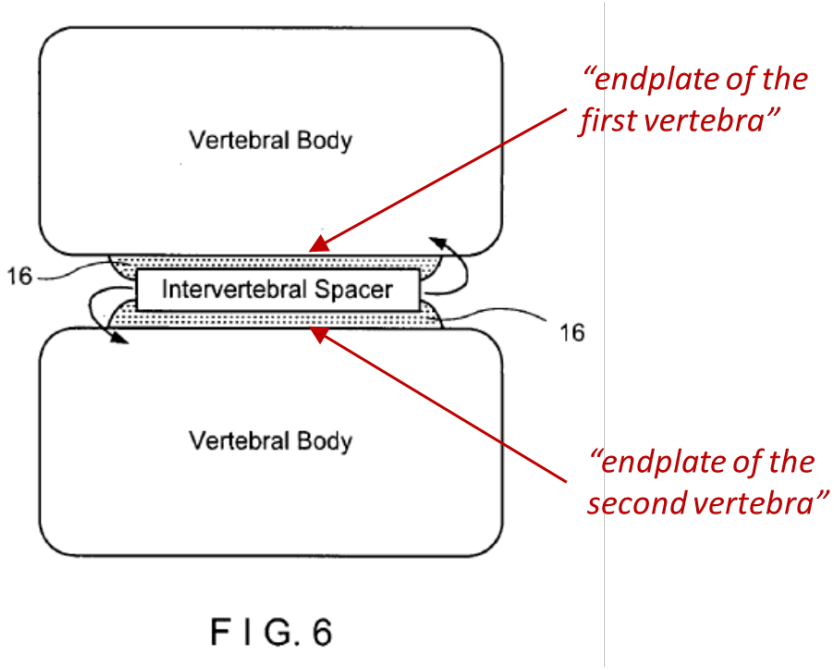


Ex. 1008, Figure 9; Ex. 1003, ¶ 185

Alfaro discloses spacers with general shapes and one or two compartments. Alfaro, ¶ [0020] (describing "rectangular," "kidney," and "curvilinear" and shapes). One such spacer that is "curvilinear" is shown in Figures 8 and 9, with a shape that approximates the shape of a vertebral body, confirming that the top and bottom surfaces are adjacent to vertebral surfaces. Ex. 1003, ¶ 185.

Alfaro further teaches that "[t]he solid material is **pressure-fit into place <u>between the opposing vertebral bodies</u> so as to fix the device in place**, and in essence, to encourage the two vertebrae to fuse." Ex. 1008, ¶ [0005]. As shown in Figure 9, Alfaro illustrates this "solid material" in the form of the intervertebral spacer (i.e., the "*implant*"). *See id.*, ¶ [0039]. The side view of Figure 6

demonstrates that at least one internal chamber of an implant "*extends from or near an endplate of the first vertebra to or near an endplate of the second vertebra*."



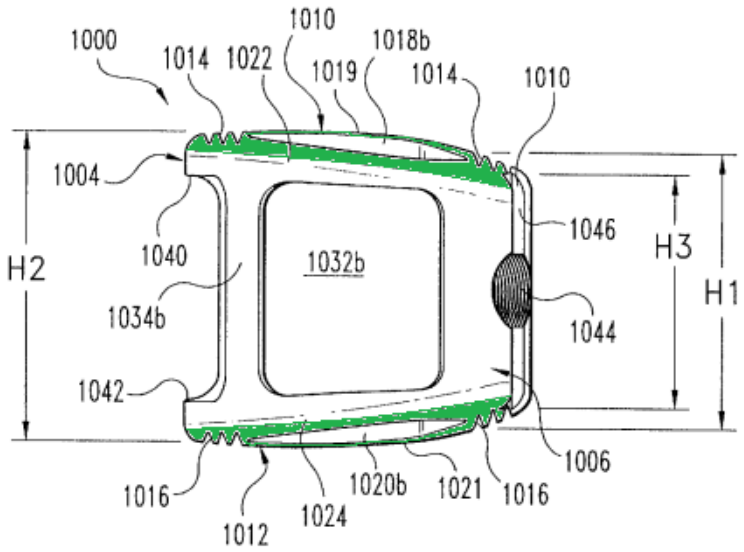
F I G. 6

Ex. 1008, Figure 6; Ex. 1003, ¶ 189

The term "*near*" is not defined in the specification of the '203 patent. *Id*., ¶ 190. It is respectfully submitted that Alfaro expressly discloses placing the spacer "*near*" the adjacent endplates. *Id*. Still further, to the extent "*to*" and "*from*" the adjacent vertebrae is not expressly disclosed in Alfaro, claim element [11.4.1] is obvious over Alfaro in view of Frey, as explained below.

Frey teaches an implant 1000 akin to the intervertebral spacer of Alfaro, which implant 1000 includes upper and lower bearing members 1010 and 1012 provided with grooves 1014 and 1016, respectively, configured for directly

engaging vertebral endplates to resist migration of the implant 1000 in the disc space. Ex. 1005, 19:50-52, 20:6-11. In Figure 54, Frey illustrates an end view of the implant 1000 including the upper and lower bearing members 1010 and 1012 provided with the grooves 1014 and 1016, respectively. The heights of the anterior and posterior walls are different in order to correspond to the anatomy of the spine. *Id*., 19:58-60 ("[H]eight 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."); Ex. 1003, ¶ 191.



Frey, Figure 54; Ex. 1003, ¶ 191

It was obvious to modify the top and bottom surfaces of Alfaro's intervertebral spacer press fit into the disc space to include Frey's grooves 1014 and 1016, respectively, to better resist migration of the intervertebral spacer in the intervertebral space to ensure that the implant achieves Alfaro's teaching that the

intervertebral spacer "remains in place at the correct site between the vertebrae.[5]" Ex. 1008, ¶ [0031]. The top and bottom surfaces of Alfaro's intervertebral spacer (as modified to include Frey's grooves 1014 and 1016, respectively) are configured to directly engage the endplates of the first and second vertebrae, respectively, to resist migration. Ex. 1003, ¶ 192.

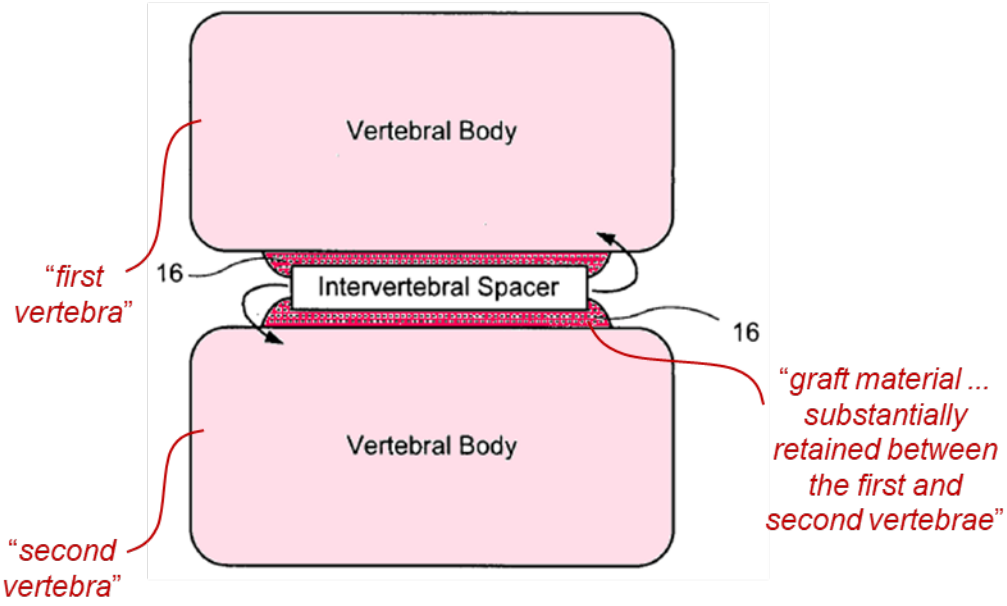
Moreover, as a result of such engagement between the top and bottom surfaces of Alfaro's spacer (as modified to include Frey's grooves 1014 and 1016, respectively) and the endplates of the first and second vertebrae, respectively, Alfaro's compartments 11a and 11b, which extend from the top surface to the bottom surface of Alfaro's intervertebral spacer, likewise extend from the endplate of the first vertebra to the endplate of the second vertebra, as required by claim element [11.4.1]. Ex. 1003, ¶ 193. Therefore, in addition to "*near*" being disclosed by Alfaro, Alfaro combined with Frey renders obvious the "*to*" and "*from*" limitations, thereby rendering obvious [11.4.1]. Ex. 1003, ¶¶ 184-194.

[5] It was also obvious to modify the heights of the sidewalls of Alfaro's spacer as needed (e.g., illustrated in FIG. 54; *see* Frey, 19:58-60) relative to the disc space size to more closely correspond to the anatomy of the vertebral endplates. Ex. 1003, ¶ 192.

i) **[11.4.2]** ***such that the graft material directed into the at least one internal chamber can be substantially retained between the first and second vertebrae***

Alfaro discloses [11.4.2].

Alfaro teaches "[o]nce the DBM is forced into the interior spacer compartment(s) [e.g., "*the at least one internal chamber*"] and tunnels ... with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16, the handle is removed ... and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031].



Ex. 1008, Figure 6; Ex. 1003, ¶ 196

As shown in Figure 6, the bone graft material is substantially retained between the adjacent vertebrae, as recited by claim element [11.4.2]. Ex. 1003, ¶ 197.

This is further confirmed by Alfaro's disclosure 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." Ex. 1008, ¶ [0010]; Ex. 1003, ¶ 198.

Therefore, Alfaro's disclosure of forcing DBM into interior spacer compartments of an implant and into vertebral spaces, as shown in Figure 6 for example, while the implant remains in place between adjacent vertebral endplates discloses an example of claim element [11.4.2]. Ex. 1003, ¶¶ 195-199.

5. Claims 12-15

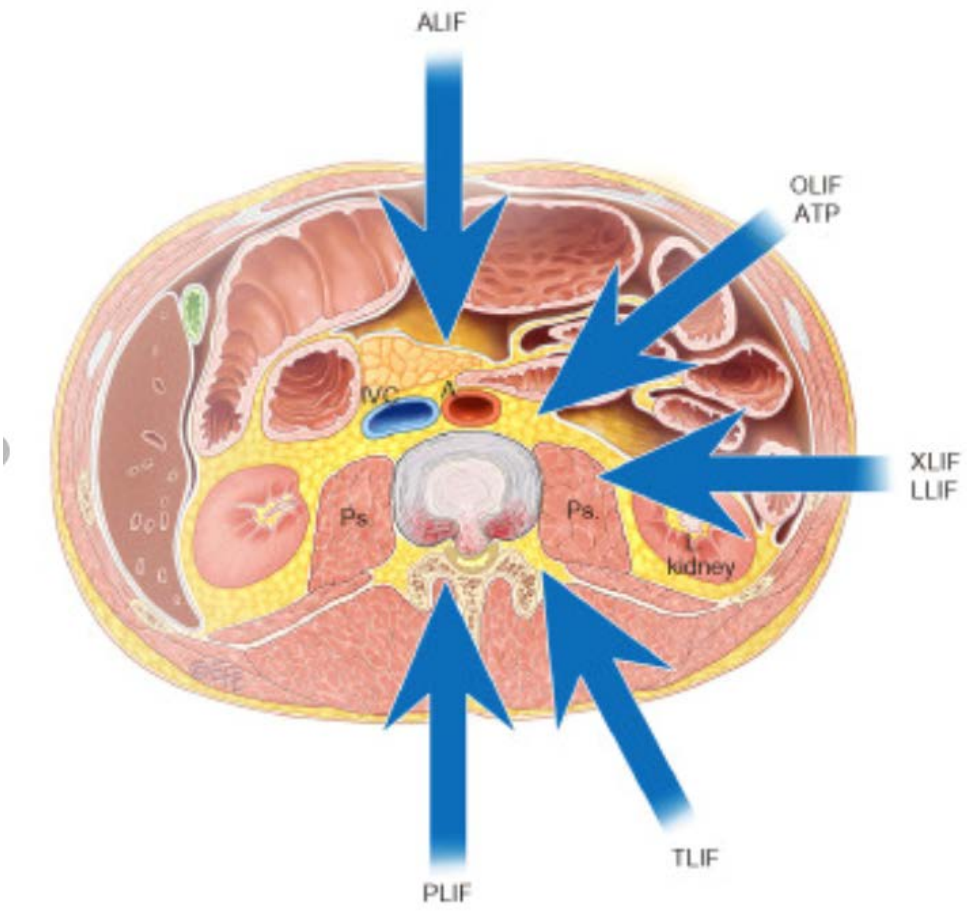
Claims 12-15 are considered together because they differ only in the named surgical approach, with claim 12 reciting a "*lateral*" approach, claim 13 reciting a "*transforaminal*" approach, claim 14 reciting an "*anterior*" approach, and claim 15 reciting a "*posterior*" approach. The following analysis is common to claims 12-15.

As discussed in Section IV.A herein, it was well known to a POSITA that spinal fusions were conducted from various different angles (i.e., using various approaches) to the intervertebral space. These different surgical approaches each have a different name, and often use slightly modified instruments, implants, and surgical techniques yet, if successful, all result in an interbody fusion. These

lumbar surgical approaches include:

- XLIF / LLIF: Lateral Lumbar Interbody Fusion
- TLIF: Transforaminal Lumbar Interbody Fusions
- ALIF: Anterior Lumbar Interbody Fusions
- PLIF: Posterior Lumbar Interbody Fusions

The illustration below shows the different angles for these approaches. See Section IV.A and Ex. 1003, ¶¶ 49-52 and 201-202 for more detail on the various approaches.



Direction of the oblique lumbar interbody fusion approach (OLIF). ALIF, anterior lumbar interbody fusion; ATP, anterior-to-psoas approach; XLIF, extreme lateral interbody fusion; LLIF, lateral lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion; PLIF, posterior lumbar interbody fusion.

Ex. 1009, Figure 1 (p. 2) (color in original)

The explanation of the various approaches is presented as background because none of the approaches is explained in the ’203 Patent. Rather, the ’203 Patent mentions the various approaches only in passing without expressing the meaning of various acronyms, without explaining how the different approaches would be performed, and without explaining any modifications to the implant desirable to utilize such approach. *See* Ex. 1001, 7:15-19 (mentioning the use of “XLIF,” “TLIF,” “ALIF,” “PLIF,” and “any other approach or technique”). The ’203 Patent depicts only the lateral, or XLIF, approach in the figures (e.g., Figures 7A and 14) . Ex. 1003, ¶ 203. Thus, the ’203 Patent assumes the various acronyms and associated surgical techniques were known to a POSITA. Ex. 1003, ¶ 203.

The XLIF/LLIF approach is an example of the “*lateral*” approach of claim element [12.1], the TLIF approach is an example of the “*transforaminal*” approach of claim element [13.1], the ALIF approach is an example of the “*anterior*” approach of claim element [14.1], and the PLIF is an example of the “*posterior*” approach of claim element [15.1]. Each of these approaches was a known technique for carrying out Alfaro’s general teaching that “in use the surgeon implants the spacer into the correct location of the patient using the well-known techniques for intervertebral placements and observing all of the normal medical procedures attendant to this procedure.” Ex. 1008, ¶ [0030]. There is no uniformly “best” surgical approach for all patients and treatment objectives. Rather, surgeons

were known to select the surgical approach based on the circumstances for each patient and POSITA's would modify instrument attachment locations to accommodate desired surgical approaches. Ex. 1003, ¶ 204.

Furthermore, although Alfaro illustrates an embodiment of the interbody fusion device 11 after its insertion into the intervertebral space using the handle 12 from a posterolateral approach (Figure 2) and from a lateral approach (Figure 1), Alfaro teaches flexibility in placement of the screw hole on the spacer for using the spacer. *See, e.g.*, Ex. 1008, ¶ [0029] ("If desired, an additional screw hole can be placed at the side opposite 13 (see FIG. 1 and FIG. 9 at 15(k) and 15(l)) to provide flexibility for using the spacer and an additional tunnel outlet for biologic material.") In view of the foregoing, it is apparent that Alfaro's intervertebral spacer 11 is insertable into the intervertebral space using a variety of different approaches, and the spacer would be modified as needed by modifying the location of the screw hole to accommodate various surgical approaches. Accordingly, Alfaro in view of the background of a POSITA renders obvious claim elements [12.1], [13.1], [14.1], and [15.1]. Ex. 1003, ¶ 205.

However, to the extent Alfaro does not explicitly disclose an approach of one of these claim elements, the surgical approach with related implant modification would have been obvious further in view of Frey.

As noted, Alfaro does not define a specific surgical approach to the

intervertebral disc space but indicates the use of well-known (surgical) techniques. Frey lists several specific and well-known surgical approaches including: posterior **lateral** [claim element 12.1], *see* Ex. 1005, title and 1:17-20 ("the present invention relates to implants, methods and instruments for use in a posterior **lateral** approach", **transforaminal** [element 13.1], *id*., 5:24-25 ("a posterior lateral approach to the disc space, such as provided with a **transforaminal** approach…"), lateral, **anterior** [element 14.1] or anterior-lateral, *id*., 19:28-32, and "… including but not limited to spinal surgery from a unilateral **posterior** approach [element 15.1], a **lateral** approach, an oblique approach, and through laparoscopic or endoscopic instruments from any of a variety of angles or approaches to the spine," *id*. 22:5-13. To the extent a POSITA would even need a reference to list the different approaches, a POSITA practicing Alfaro would have been motivated to reference Frey's teachings in order to modify Alfaro's implant spacer as needed to engage an insertion instrument for insertion into an intervertebral disc space. The motivation would have been the simple desire to accommodate well-known techniques to implant the spacer. Ex. 1003, ¶ 207.

Beyond the analysis above, which renders claim elements [12.1]-[15.1] obvious, there is even more specific explicit disclosure of claim elements [12.1] and [13.1], as presented below. Ex. 1003, ¶¶ 200-208.

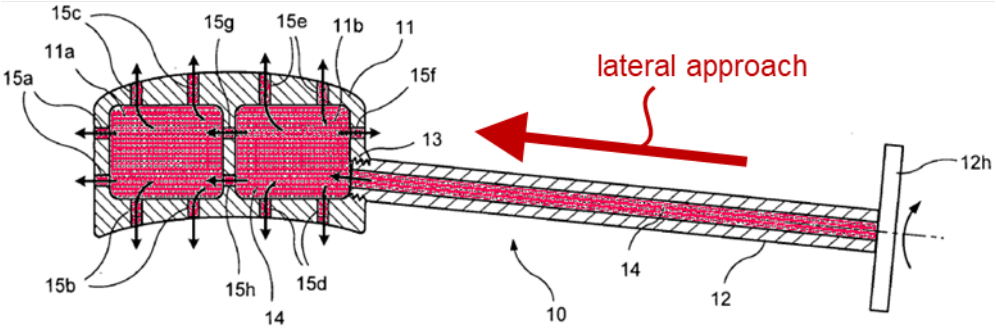
a) [12.0], [13.0], [14.0], [15.0] *The method of claim 11*

See analysis of claim 11.

b) [12.1] *wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a lateral approach.*

Beyond the analysis presented above, additional evidence supports that Alfaro discloses [12.1].

In Figure 9, Alfaro illustrates that "[s]crew holes 15(k) and 15(l) show points of attachment for the holder, **offering flexibility as to which side the surgeon prefers to use for delivery of the spacer**." Alfaro, ¶ [0039].



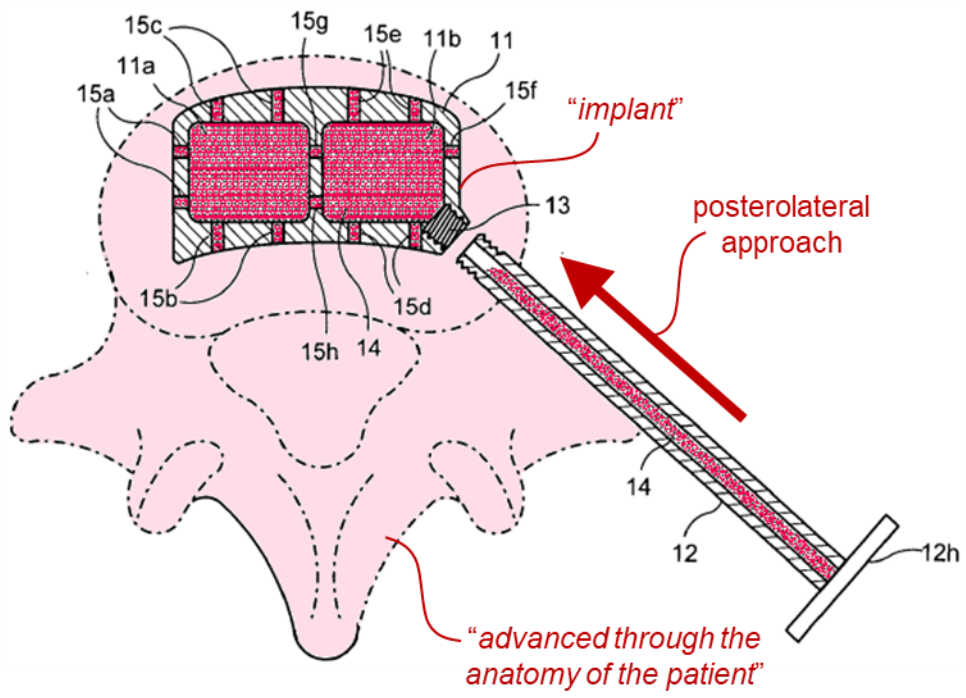
Ex. 1008, Figure 1; Ex. 1003, ¶ 212

Furthermore, as shown in FIG. 1 of Alfaro, when threadably engaged with the alternatively located threaded hole 13, the handle 12 is oriented relative to the intervertebral spacer 11 to facilitate positioning of the intervertebral spacer 11 "*between the first and second vertebrae using a lateral approach*," as required by claim element [12.1]. Therefore, Alfaro explicitly discloses (and illustrates) [12.1]. Ex. 1003, ¶¶ 210-213.

c) [13.1] *wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a transforaminal approach*

Beyond the analysis presented above, additional evidence supports that Alfaro discloses [13.1], and Alfaro combined with Frey also renders obvious [13.1].

In Figure 2 Alfaro illustrates an interbody fusion device 11 after its insertion into the intervertebral space, from a posterolateral approach using the handle 12. A transforaminal approach is one example of a posterior lateral approach. *See* Frey, 1:63-67 and 2:42-46; Ex. 1003, ¶ 215.

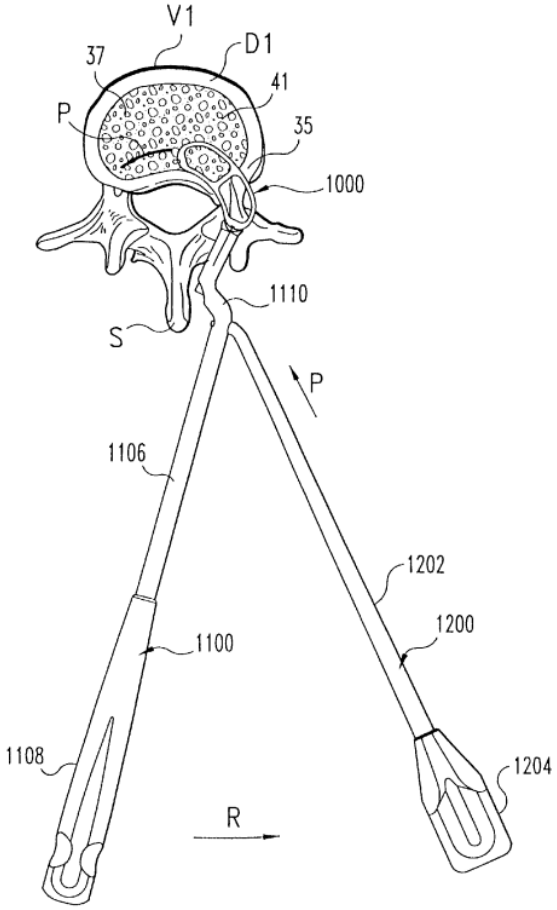


Ex. 1008, Figure 2; Ex. 1003, ¶ 215

The posterolateral approach shown in FIG. 2 of Alfaro is one example of the

"*tranforaminal approach*" described in the '203 Patent (compare spinal anatomy in Alfaro, Figure 2 to Ex. 1009, Figure 1, TLIF) and recited by claim element [15.1].

Turning to Frey, Figure 53 also illustrates the implant 1000 being inserted via a transforaminal approach.



Frey, Figure 53

Thus, to the extent that Alfaro does not expressly disclose a transforaminal approach, Frey expressly discloses implantation of an implant 1000 akin to Alfaro's intervertebral spacer 11 via a "*transforaminal approach*." A POSITA would have modified the location of Alfaro's screw hole 15k and/or 15l to permit

insertion of the intervertebral spacer 11 using the well-known transforaminal approach taught by Frey in order to better accommodate the required angle of the surgical approach, as explained in Section IV.A, thereby rendering obvious [13.1]. Ex. 1003, ¶¶ 214-219.

d) [14.1] *wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using an anterior approach.*

See analysis above for claim elements [12.1]-[15.1], explaining that Frey discloses implantation from an anterior approach. Ex. 1005, 19:28-32; Ex. 1003, ¶ 220.

e) [15.1] *wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a posterior approach.*

See analysis above for claim elements [12.1]-[15.1], explaining that Frey discloses implantation from a "unilateral **posterior** approach." Ex. 1005, 22:6-12; Ex. 1003, ¶ 221.

6. Claim 19

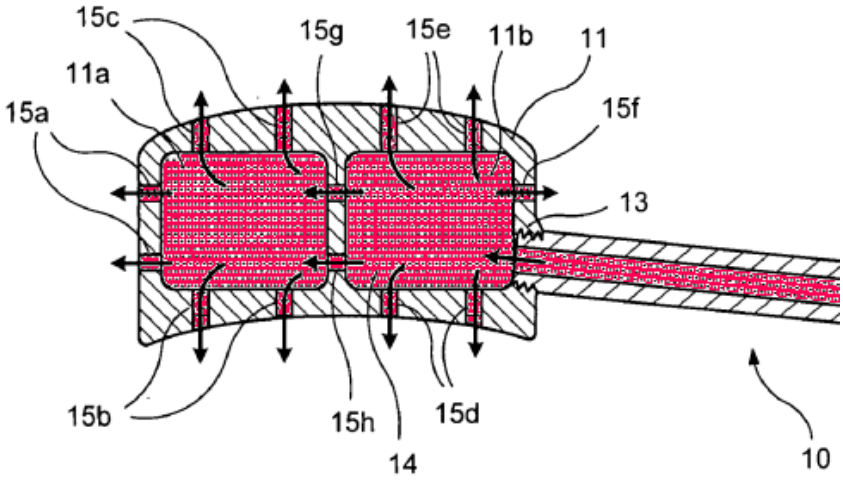
a) [19.0] *The method of claim 11*

See analysis of claim 11.

b) *[19.1] wherein graft material is directed into the at least one internal chamber of the implant so that at least a volume of excess graft material exits the at least one internal chamber of the implant through at least one opening along a peripheral wall of the implant*

Alfaro discloses [19.1].

As illustrated in Figure 1, Alfaro illustrates the handle 12 "screwed into compartment 11(b) at 13 and is also shown to contain DBM 14 in the hollow portion of the handle and in compartments 11(a) and 11(b) and **in tunnels 15(a), (b), (c), (d), (e) and (f), provided to allow for outflow of DBM or other biologic into the intervertebral space**." Ex. 1008, ¶ [0029]; *see also* ¶ [0020].



Ex. 1008, Figure 1 (partial); Ex. 1003, ¶ 224

Alfaro's disclosure and illustration of biologic material flowing into compartments 11(a) and 11(b) and tunnels 15(a)-15(f), each of which is an "*opening along a peripheral wall of the implant*," is an example disclosure of [19.1]. Ex. 1003, ¶¶ 223-225.

7. Claim 20

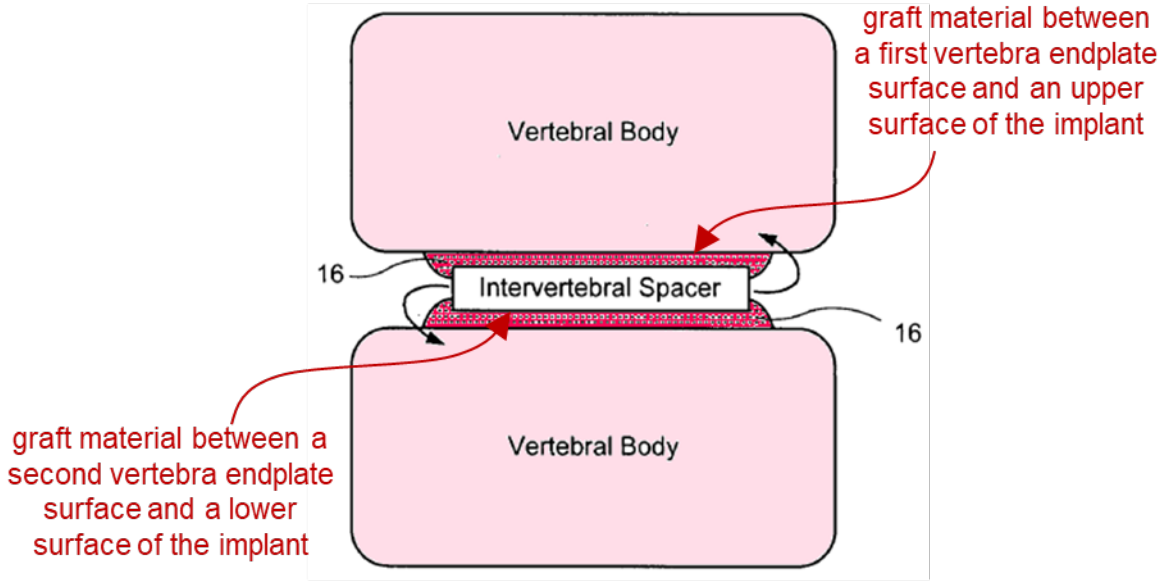
a) [20.0] *The method of claim 11*

See analysis of claim 11.

b) [20.1] *wherein graft material is directed into the at least one internal chamber of the implant so that at least a volume of the graft material delivered into the at least one internal chamber exists through an interface between an endplate surface of the first or second vertebra and an upper or lower surface of the implant*

Alfaro discloses [20.1].

Figure 6 of Alfaro, reproduced below, illustrates that "[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels as shown in FIG. 2 at 11(a) and 11(b) and 15(a), (b), (c), (d), (e) and (f) respectively, **with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16**, the handle is removed ... and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031].



Ex. 1008, Figure 6; Ex. 1003, ¶ 228

Thus, Alfaro's disclosure of DBM ("*graft material*") flowing through compartments of the spacer ("*at least one internal chamber*") and into vertebral spaces shown in FIG. 6 above discloses claim element [20.1]. Ex. 1003, ¶¶ 227-229.

8. Claim 1

a) [1.0] *A method of promoting spinal fusion within a spine of a patient, comprising:*

Claim element [1.0] is identical to [11.0]. Therefore, Alfaro discloses [1.0] for the same reasons as disclosing [11.0].

b) [1.1.1] *advancing an implant through an anatomy of a patient,*

Claim element [1.1.1] is identical to [11.1.1]. Therefore, Alfaro discloses

[1.1.1] for the same reasons as disclosing [11.1.1].

c) [1.1.2] *the implant comprising at least one internal chamber defined by peripheral walls of the implant,*

Claim element [1.1.2] is the same as [11.1.2], except that [1.1.2] adds the language "*defined by peripheral walls of the implant*". Thus, see the analysis of [11.1.2], which demonstrates that Alfaro discloses "*the implant comprising at least one internal chamber*." Alfaro further discloses [1.1.2].

The '203 patent discloses spacers with a single internal chamber (FIG. 1A) and a pair of internal chambers (FIG. 19). Alfaro also teaches different intervertebral spacers having one or two compartments or "*chambers*," and just like the '203 patent embodiments, these compartments are defined by the peripheral walls of the spacer. Alfaro, ¶ [0020]. For example, as shown in the embodiments in Figures 1, 2, 8, and 9 of Alfaro, the compartments 11a and 11b are open at the top and bottom of the intervertebral spacer at 15i and 15j and these compartments are defined by peripheral walls. FIGS. 8 and 9 are reproduced below for reference.

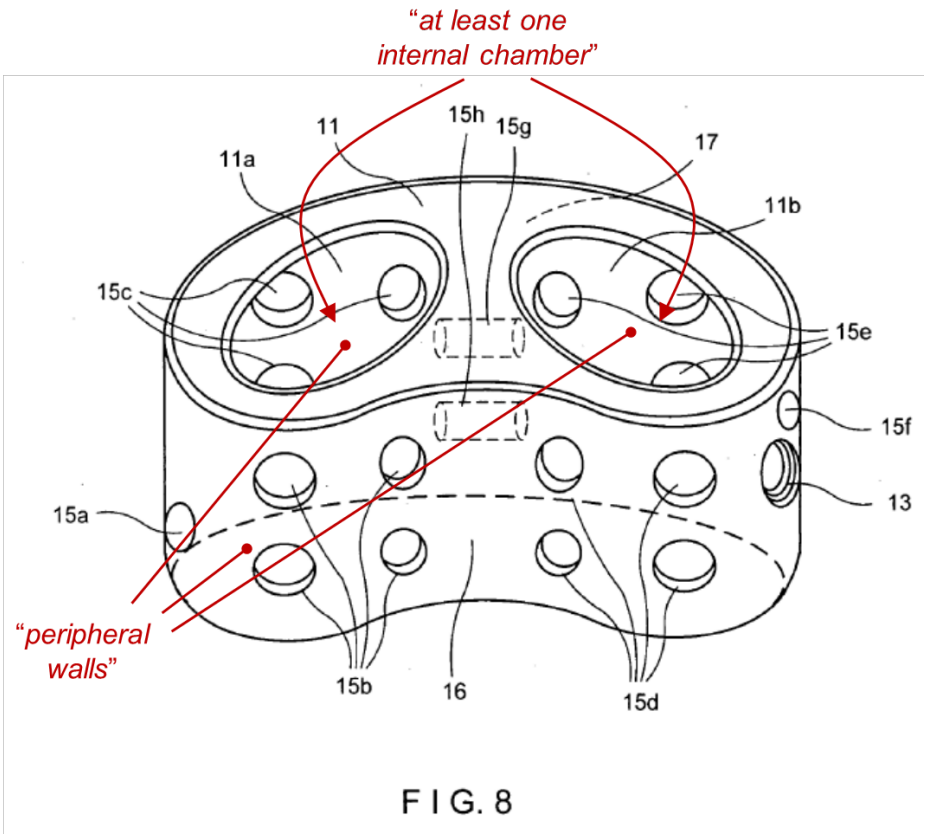


FIG. 8

Ex. 1008, Figure 8; Ex. 1003, ¶ 233

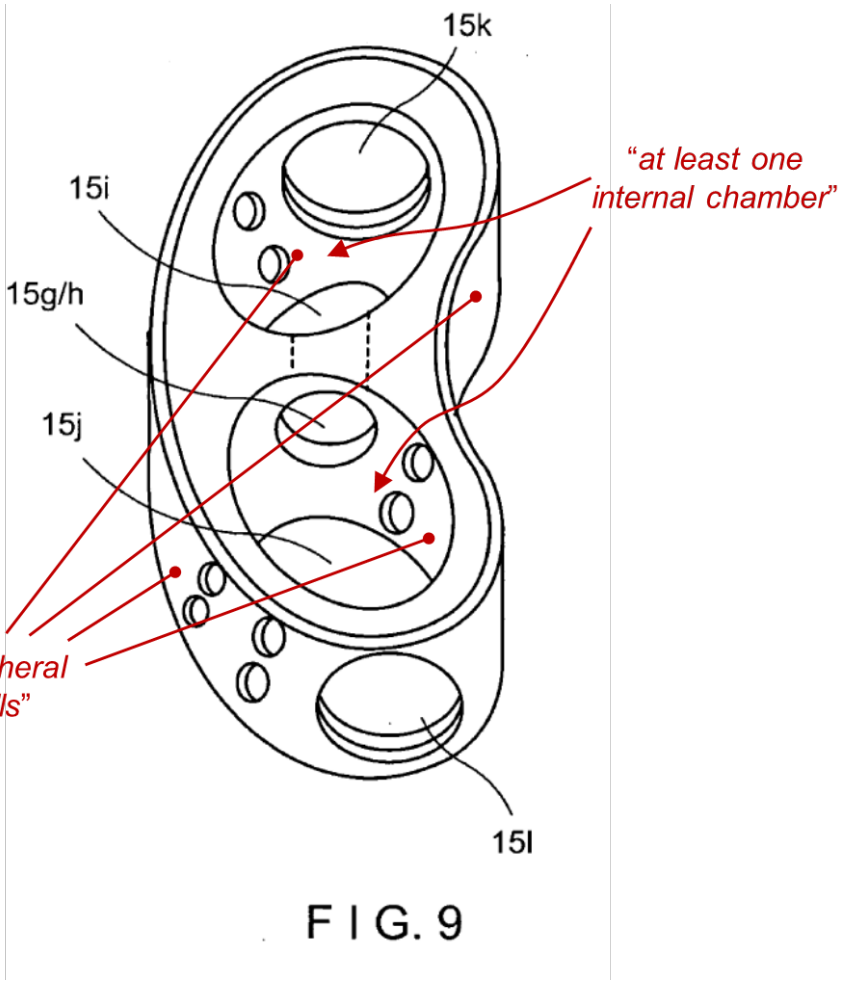


FIG. 9

Ex. 1008, Figure 9; Ex. 1003, ¶ 233

Therefore, Alfaro's disclosure and illustration of an implant having one or more internal compartments defined by peripheral walls discloses claim element [1.1.2]. Ex. 1003, ¶¶ 232-235.

d) [1.1.3] *wherein the implant comprises at least one access port extending through at least one of the peripheral walls of the implant*

Alfaro discloses [1.1.3].

The intervertebral spacers of Alfaro include a screw hole, which is an

example of "*an access port*." Such a screw hole 13 is illustrated in Figures 1 and 2. Ex. 1008, ¶ [0029]. The screw hole at 13 extends through a peripheral wall of the implant to provide access to internal compartments 11(a) and 11(b) so that biologic material can flow into the implant via the screw hole. *Id*., ¶¶ [0029]-[0030].

As another example, in Figure 9, Alfaro illustrates "[s]crew holes 15(k) and 15(l) [as] points of attachment for the holder." *Id*., ¶ [0039]. Figures 8 and 9, below, illustrate [1.1.3]. Ex. 1003, ¶ 239.

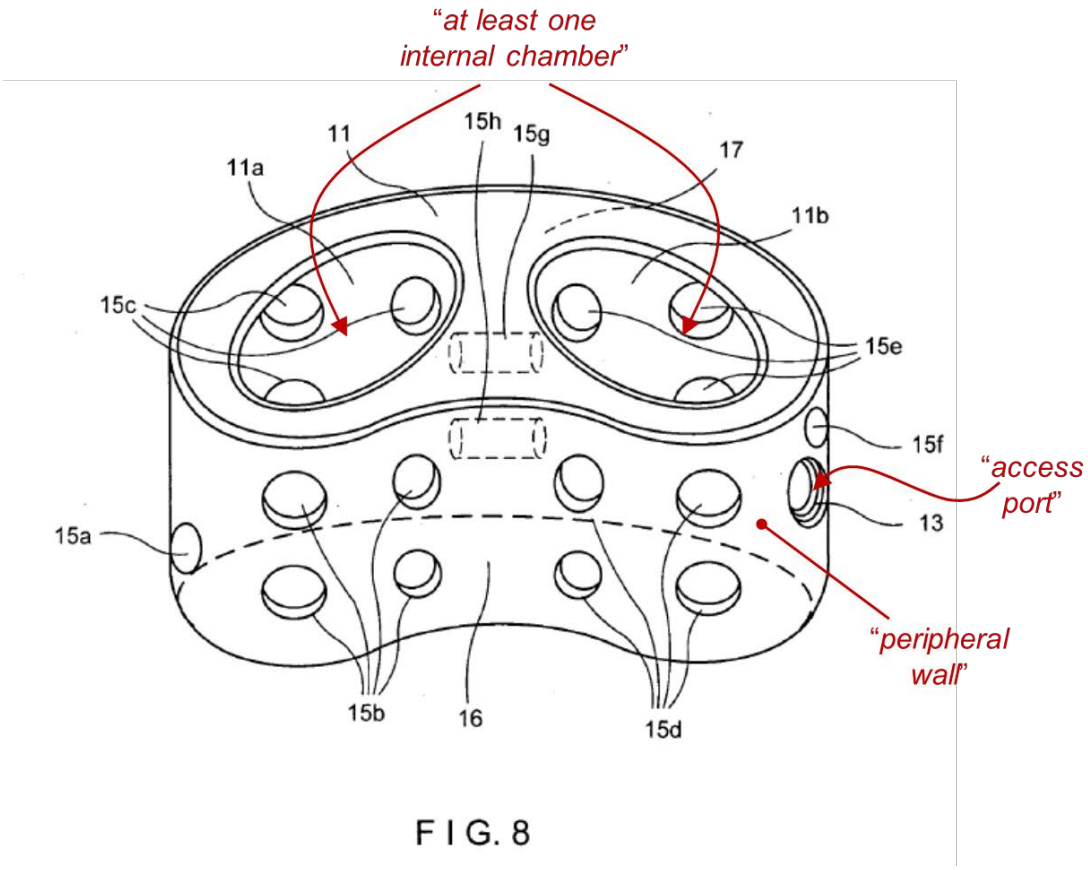


FIG. 8

Ex. 1008, Figure 8; Ex. 1003, ¶ 239

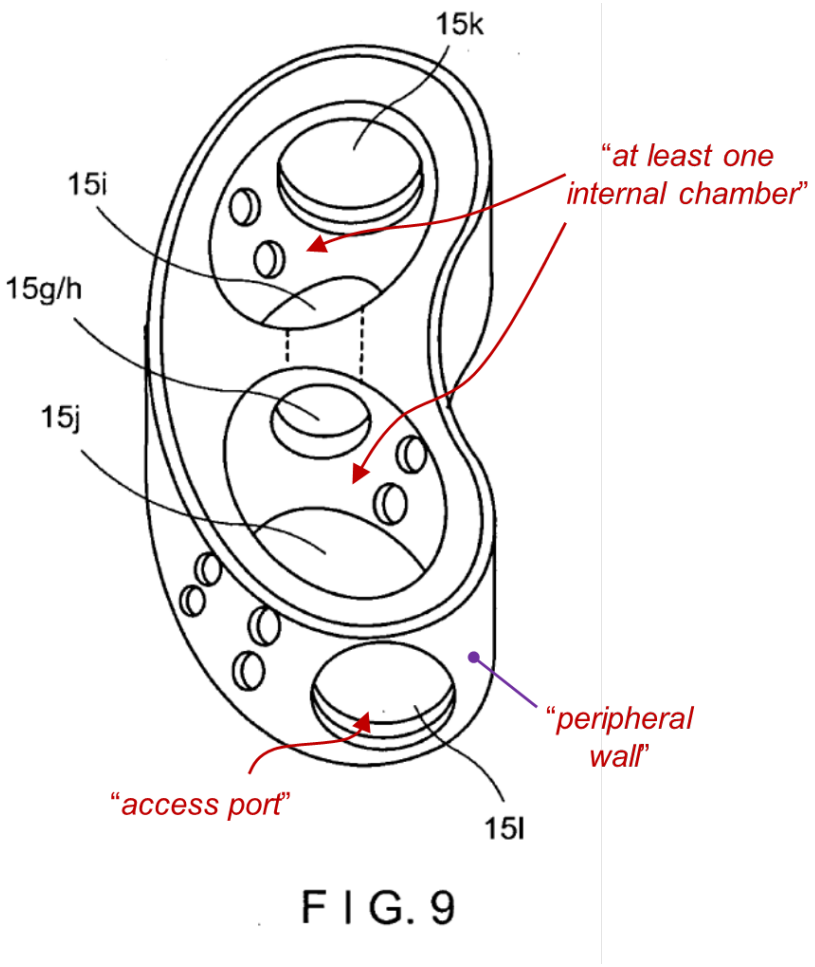


FIG. 9

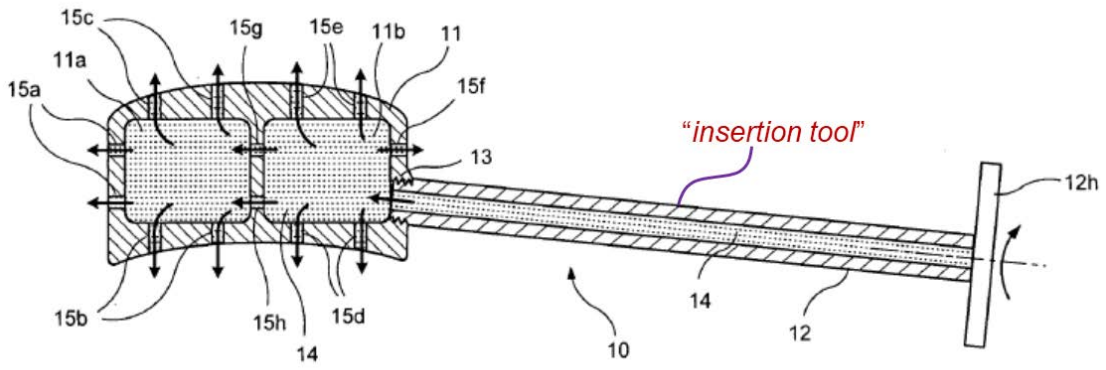
Ex. 1008, Figure 9; Ex. 1003, ¶ 239

Alfaro's disclosure of a screw hole in a wall of a spacer to allow DBM or other biologic material to flow into the spacer through a handle attached at screw hole discloses [1.1.3]. Ex. 1003, ¶¶ 236-240.

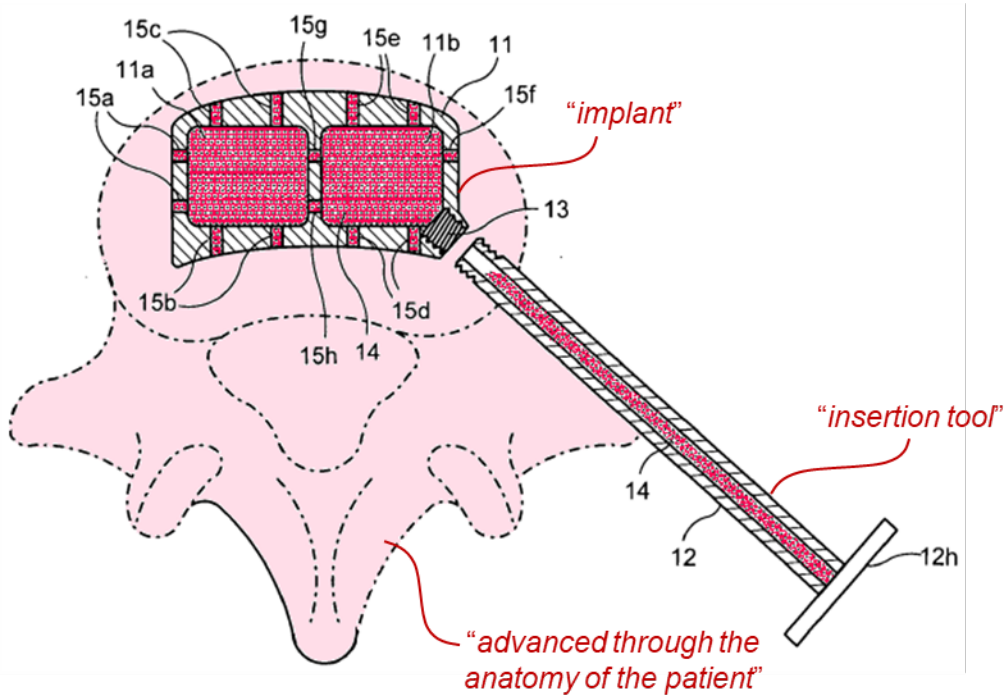
e) [1.2] *wherein the implant is advanced through an anatomy of a patient using an insertion tool*

Alfaro's "spacer is inserted surgically into the vertebral space and properly positioned therein **using the handle as the inserter**." Ex. 1008, ¶ [0019]. Figures 1 and 2 are reproduced below to illustrate the handle used as an insertion tool, and

Figures 2 and 6 illustrate the spacer in a patient anatomy after being inserted. Ex. 1003, ¶ 242.



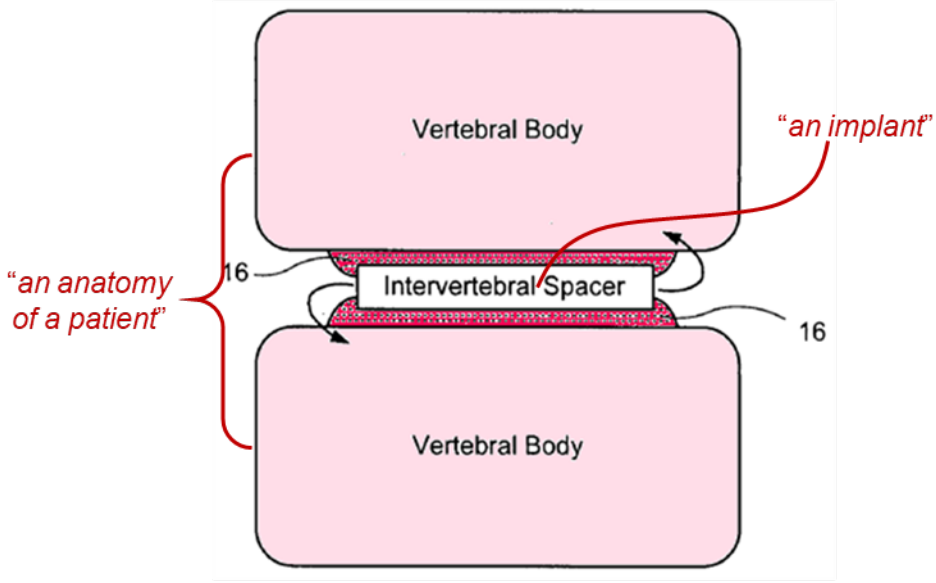
Ex. 1008, Figure 1; Ex. 1003, ¶ 242



Ex. 1008, Figure 2; Ex. 1003, ¶ 242

Thereafter, "[o]nce the DBM is forced into the interior spacer

compartment(s) and tunnels ... with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16, the handle is removed ... and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae." *Id*., ¶ [0031].



Ex. 1008, Figure 6; Ex. 1003, ¶ 243

Alfaro's disclosure of a handle attached to a spacer to surgically insert the spacer into the vertebral space and properly position the spacer therein discloses [1.2]. Ex. 1003, ¶¶ 241-244.

f) [1.3] *positioning the implant between a first vertebra and a second vertebra of a patient, the first and second vertebrae being immediately adjacent to one another*

Claim element [1.3] is identical to claim element [11.2]. Therefore, Alfaro discloses [1.3] for the same reasons as disclosing [11.2].

g) [1.4.1] ***directing graft material into the at least one internal chamber of the implant through the at least one access port to fill the at least one internal chamber of the implant, after positioning the implant between the first and second vertebrae***

Claim element [1.4.1] is substantially the same as [11.3.1]. Therefore, Alfaro discloses [1.4.1] for the same reasons as disclosing [11.3.1]. Ex. 1003, ¶ 246.

h) [1.4.2] ***such that the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae; and***

Claim element [1.4.2] is identical to claim element [11.3.2]. Therefore, Alfaro discloses [1.4.2] for the same reasons as disclosing [11.3.2].

i) [1.4.3] ***wherein the graft material is contained within the at least one internal chamber***

Claim element [1.4.3] is identical to claim element [11.3.3]. Therefore, Alfaro discloses [1.4.3] for the same reasons as disclosing claim element [11.3.3].

j) [1.5.1] ***wherein the at least one internal chamber of the implant, after implantation, extends from or near an endplate of the first vertebra to or near an endplate of the second vertebra*** **[1.5.2]** ***such that the graft material directed into the at least one internal chamber can be substantially retained between the first and second vertebrae***

Claim elements [1.5.1] and [1.5.2] are identical to claim elements [11.4.1] and [11.4.2], respectively. Therefore, Alfaro discloses [1.5.1] and [1.5.2] for the same reasons as disclosing [11.4.1] and [11.4.2], respectively, and Alfaro combined with Frey also renders obvious [1.5.1] for the same reasons as rendering

obvious claim element [11.4.1].

k) [1.6] *withdrawing the insertion tool from the anatomy of the patient, leaving the implant situated between the first and second vertebrae.*

Alfaro teaches that, "[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels ... with the DBM flowing through the compartments and into the vertebral spaces shown in FIG. 6 at 16, **the handle ["*insertion tool*"] is removed** ["*withdrawn*"]... and the procedure, for purposes of this invention, is terminated. **The spacer of course, remains in place at the correct site between the vertebrae**." Ex. 1008, ¶ [0031]. Therefore, Alfaro discloses claim element [1.6]. Ex. 1003, ¶ 252.

9. Claims 2-5

a) [2.0], [3.0], [4.0], [5.0] *The method of claim 1*

See analysis of claim 1.

b) [2.1] ***wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a lateral approach.***

c) [3.1] ***wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a transforaminal approach.***

d) [4.1] ***wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using an anterior approach.***

e) [5.1] ***wherein the implant is advanced through the anatomy of a patient and positioned between the first and second vertebrae using a posterior approach.***

Claim elements [2.1]-[5.1] are identical to elements [12.1]-[15.1], respectively. Therefore, Alfaro renders obvious [2.1]-[5.1] for the same reasons as rendering obvious [12.1]-[15.1], respectively, and Alfaro combined with Frey renders obvious [2.1]-[5.1] for the same reasons as rendering obvious [12.1]-[15.1], respectively. Ex. 1003, ¶ 254.

10. Claim 9

a) [9.0] ***The method of claim 1***

See analysis of claim 1.

b) [9.1] ***wherein graft material is directed into the at least one internal chamber of the implant so that at least a volume of excess graft material exits the at least one internal chamber of the implant through at least one opening along a peripheral wall of the implant.***

Claim element [9.1] is identical to claim element [19.1]. Therefore, Alfaro discloses [9.1] for the same reasons as disclosing [19.1].

11. Claim 10

a) [10.0] *The method of claim 1*

See analysis of claim 1.

b) [10.1] *wherein graft material is directed into the at least one internal chamber of the implant so that at least a volume of the graft material delivered into the at least one internal chamber exists through an interface between an endplate surface of the first or second vertebra and an upper or lower surface of the implant.*

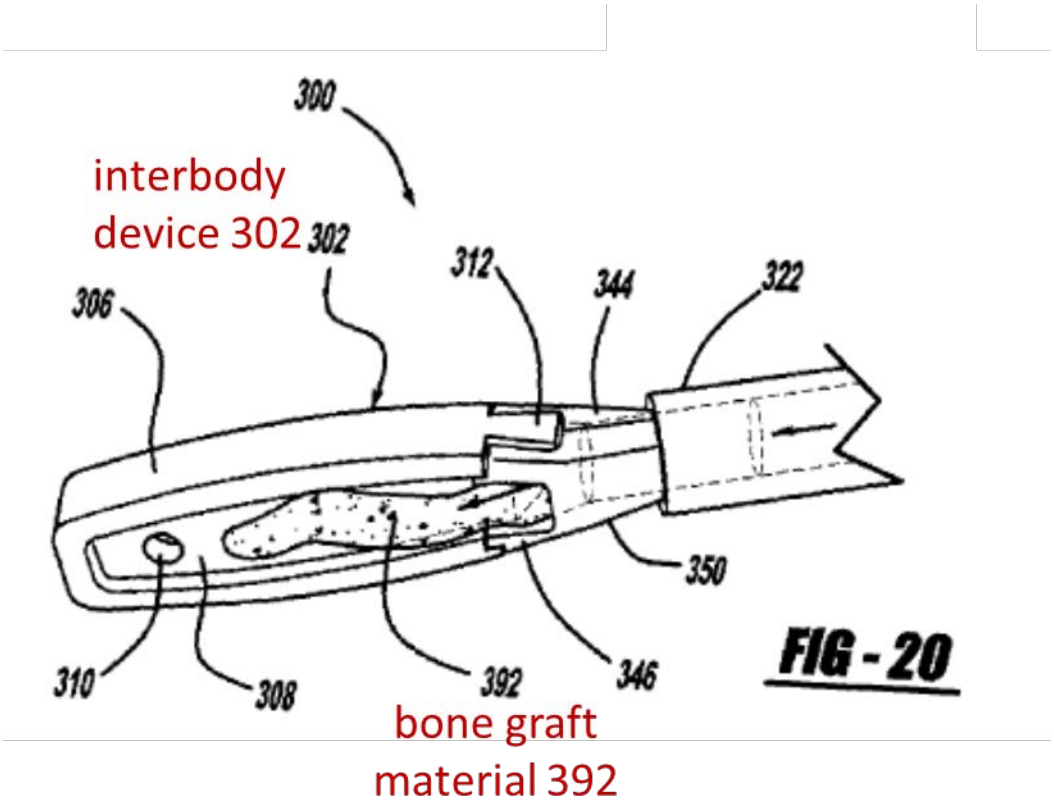
Claim element [10.1] is identical to claim element [20.1]. Therefore, Alfaro discloses [10.1] for the same reasons as disclosing [20.1].

B. Ground #2: Claims 6-8 and 16-18 are unpatentable as obvious over the combination of Alfaro, Frey, and Perez-Cruet.

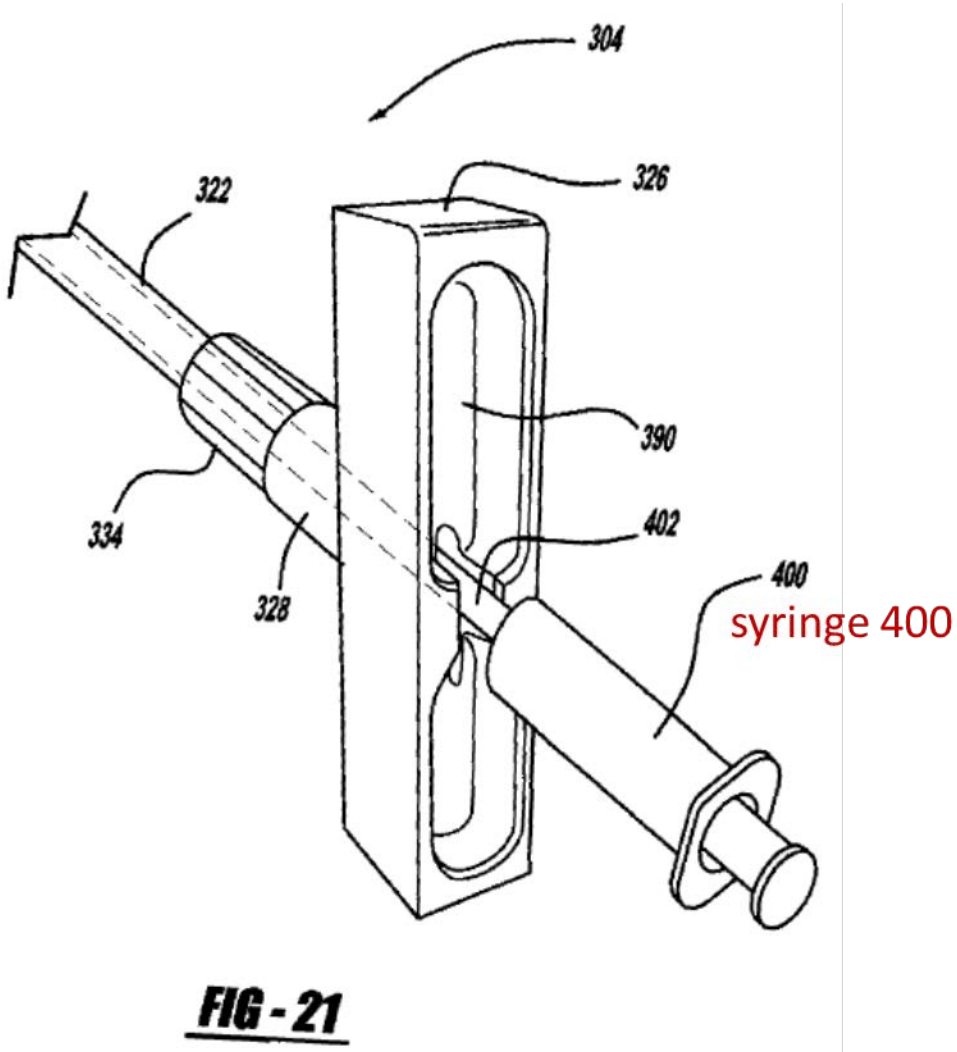
1. Summary of Perez-Cruet

Similar to Alfaro, Perez-Cruet relates to "[s]pinal fusion" using an interbody device (e.g., a "cage"). *See* Ex. 1004, ¶¶ [0006] and [0010]. Perez-Cruet additionally presents "an instrument detachably coupled to the interbody device for positioning the device in the disc space and delivering bone graft material to the disc space that is distributed on both sides of the interbody device." *Id*., ¶ [0011].

Figure 20, reproduced below, illustrates an "interbody device" 302 with graft material 392 delivered therein, and Figure 21, reproduced below, illustrates an assembly "employing a syringe [400] for delivering bone graft material down the instrument." *Id*., ¶¶ [0034], [0035], [0061], [0062].



Ex. 1004, Figure 20; Ex. 1003, ¶ 262



Ex. 1004, Figure 21; Ex. 1003, ¶ 262

2. Reasons to Combine Alfaro and Perez-Cruet

Perez-Cruet is analogous art to the ’203 Patent, as these documents are both directed to the same field of spinal implants for interbody fusion and related systems, tools, and methods. *See*, *e.g.*, Ex. 1001, 1:18-21 (“Field”); Ex. 1004, [0002] and [0003] (“1. Field of the Invention”). As explained herein, Perez-Cruet is also reasonably pertinent to the problems addressed by the ’203 Patent of

developing "an improved intervertebral implant, as well as related instrumentation, tools, systems and methods." *See* Ex. 1001, 1:30-32; Ex. 1003, ¶ 263.

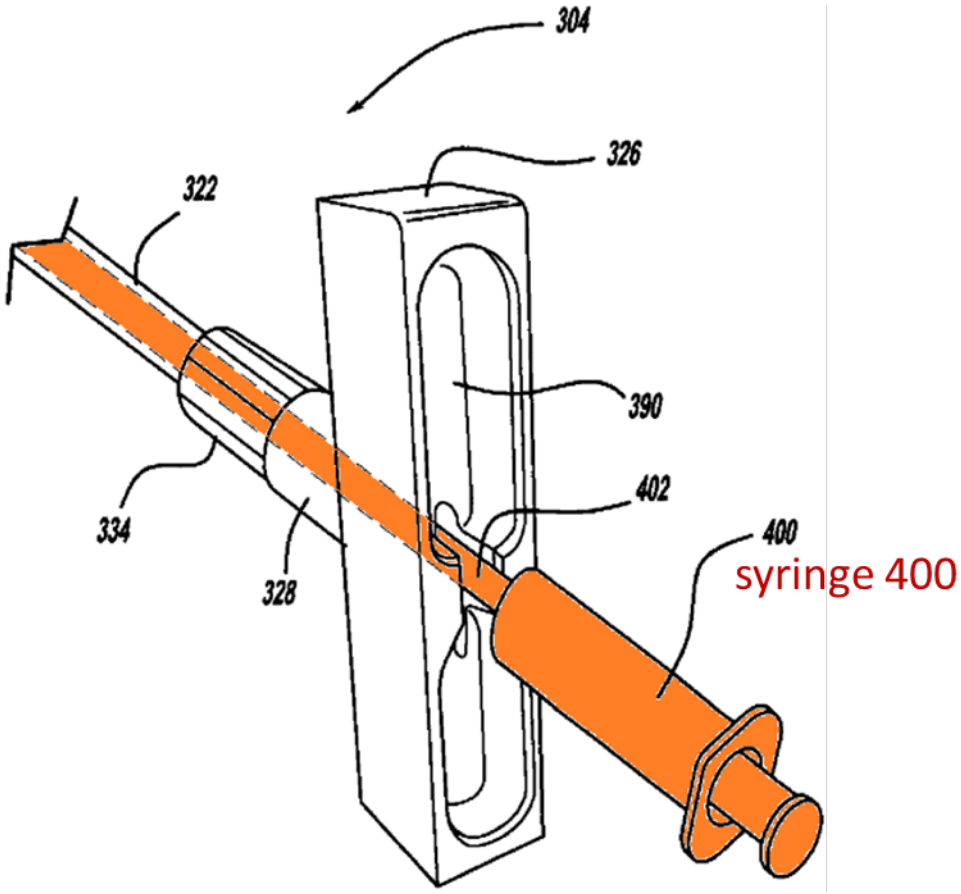
Turning to reasons to combine, Alfaro's disclosure is very general in terms of the type of spacer, associated handle, and associated mechanism for delivering biologic material, which may include a "syringe-type of system":

> In a simple form, the intervertebral spacer of the device of the invention may be **any spacer at all** which satisfies the criteria of intervertebral spacers. It needs only to be attachable and detachable to a handle capable of containing a biologic material-advancing means **such as** an Archimedes screw, a plunger or **syringe-type of system** for moving the biologic material through the handle and into the spacer.

Ex. 1008, ¶ [0012]; *see also* ¶ [0021] (describing prior art "syringes" that "can be adapted to be disengagingly attachable" to a spacer) and ¶ [0032]. Alfaro is also very general in terms of the type of handle, with example handles including a "hollow chamber" and that can be "engaged and disengaged with the spacer." *Id*., ¶ [0021].

While Alfaro discloses the use of syringes for delivering biologic material to the spacer, Alfaro does not disclose the implementation details of its disclosed syringes and how they would connect to Alfaro's hollow handle for delivering biologic material. Thus, given the broad disclosure of Alfaro, a POSITA would have been motivated to look to other references for implementation details

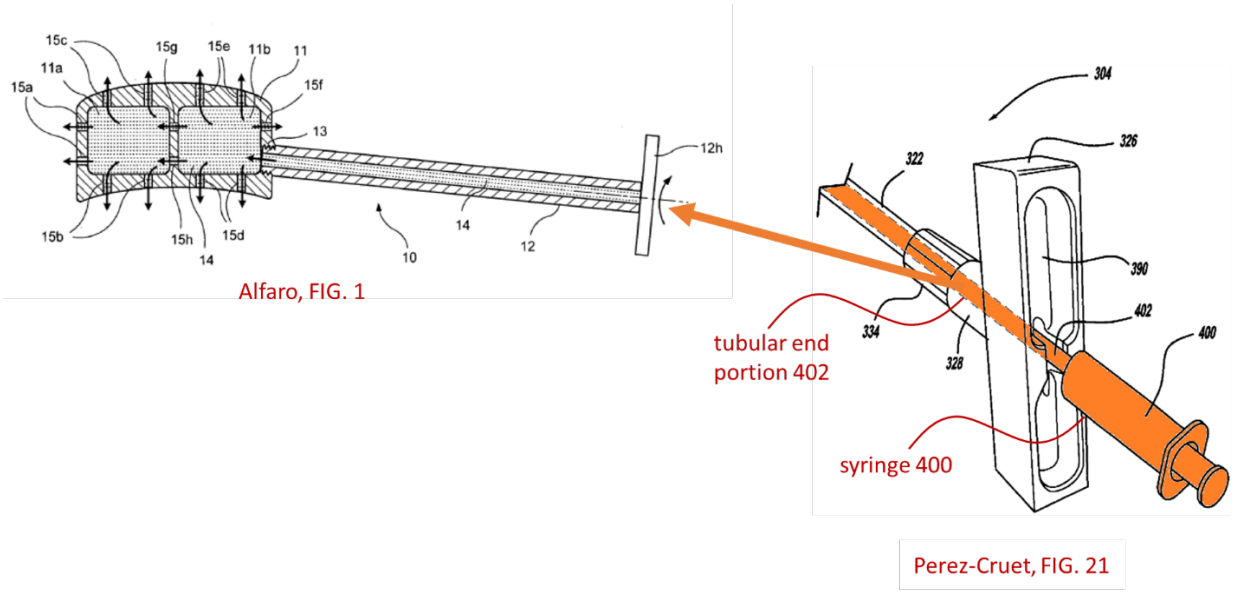
regarding the implementation of its disclosed syringes and how they would connect to Alfaro's handle with "hollow chamber" for delivering biologic material. Perez-Cruet explicitly discloses an example of such a syringe in the same context as Alfaro. Specifically, Perez-Cruet provides an illustrated example of a syringe-type system, as suggested by Alfaro, namely, a syringe 400 having an extended tubular end portion 402 for delivering bone graft material through the instrument 304, as shown in Figure 21, reproduced below. Ex. 1004, ¶ [0062]; Ex. 1003, ¶ 265.



Ex. 1004, Figure 21; Ex. 1003, ¶ 265

The syringe 400 of Perez-Cruet is a syringe used to deliver graft material to

one or more compartments of an implanted spacer. When utilized with Alfaro's handle, Perez-Cruet's syringe directs graft material into an internal compartment of a spacer, e.g., the compartment 11b of Alfaro's intervertebral spacer, by positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's handle 12. An illustration of where Perez-Cruet's syringe 400 and associated extended tubular end portion 402 (without delivery instrument 304) would fit within an exemplary Alfaro handle 12 is illustrated below. Ex. 1003, ¶ 266.



Sherman, Figure 1; Ex. 1003, ¶ 266

Obviousness does not require physical combination or bodily incorporation but rather what the combined teachings of the references would have suggested to a POSITA at the time of the alleged invention. *In re Keller*, 642 F. 2d 413, 425 (C.C.P.A. 1981). Nevertheless, the annotated figure above is but one simple

example of how a syringe 400 and associated extended tubular portion 402 would be integrated with Alfaro's hollow handle 12. Thus, Perez-Cruet provides implementation detail for Alfaro's disclosed use of a syringe to deliver graft material. Ex. 1003, ¶ 267.

There are additional reasons to combine Alfaro and Perez-Cruet. It was well known to a POSITA that biologic material is commonly provided to a surgeon in the form of a pre-loaded syringe. Moreover, a syringe was commonly used for reconstituting bone powder and thereafter injecting the reconstituted graft material into a spinal implant. Alternatively, a syringe pre-loaded with biologic material may be conveniently manufactured and packaged for transport or delivery to a surgical facility. Ex. 1003, ¶ 268 (citing Exs. 1014-1016).

Because Alfaro suggests using a syringe-type system to move graft material through the handle and into the intervertebral spacer, and because a syringe-type system was commonly utilized to provide bone graft material to a surgeon (e.g., in the form of a pre-loaded syringe conveniently delivered to the surgical facility) or reconstitute graft material, it would have been obvious to replace the Archimedes screw or the screw and floating piston shown in Figures 4D and 5D, respectively, of Alfaro with the syringe 400 of Perez-Cruet for convenience, because the biologic material is pre-loaded in a syringe, and to direct graft material into the compartment 11b of Alfaro's intervertebral spacer by positioning the extended

tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's cannulated handle 12. Ex. 1003, ¶ 268.

Therefore, there are many reasons why Alfaro would have been combined with Perez-Cruet, and it was abundantly clear how the teachings would have been combined. Ex. 1003, ¶¶ 263-269.

3. Claim 16

a) [16.0] *The method of claim 11*

See analysis of claim 11.

b) [16.1] *wherein directing the graft material into the at least one internal chamber comprises using a graft material delivery system, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via a conduit.*

Alfaro combined with Perez-Cruet renders obvious [16.1].

First, an analysis of the '203 Patent disclosure is presented. In an embodiment, the '203 Patent provides that "[i]n some arrangements, the graft material delivery system comprises a syringe ... and a conduit configured to pass through the at least one access port of the spinal implant." Ex. 1001, 4:24-27. Figures 13 and 15 illustrate the syringe assembly S including a syringe 650 and a conduit 670. *Id*., 22:37-23:11. The syringe 650 "can include a barrel portion 652" and "a plunger 658 that can be selectively advanced within the barrel 652." *Id*., 22:39-44. The barrel 652 and conduit 670 are each examples of the claimed

"*conduit*." This syringe assembly is an example of a "*graft material delivery system*." Ex. 1003, ¶¶ 272-273.

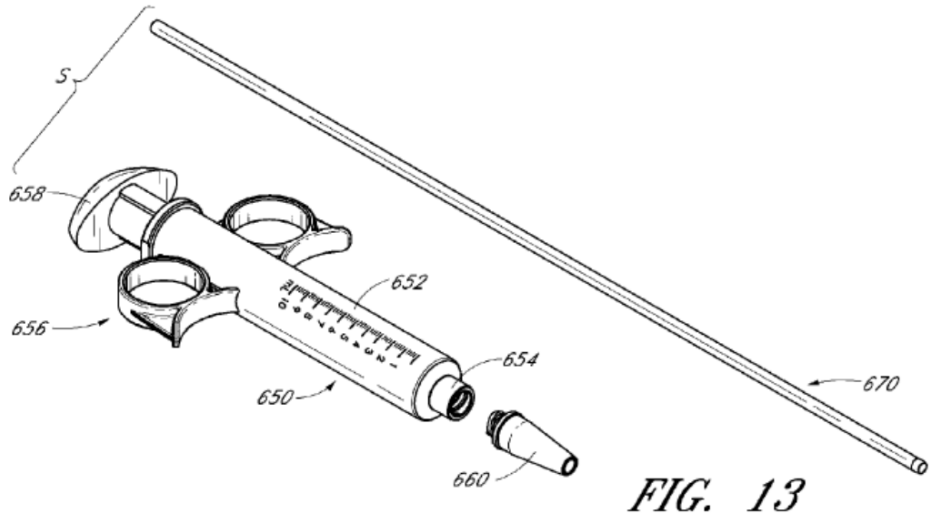


FIG. 13

Ex. 1001, Figure 13 (partial)

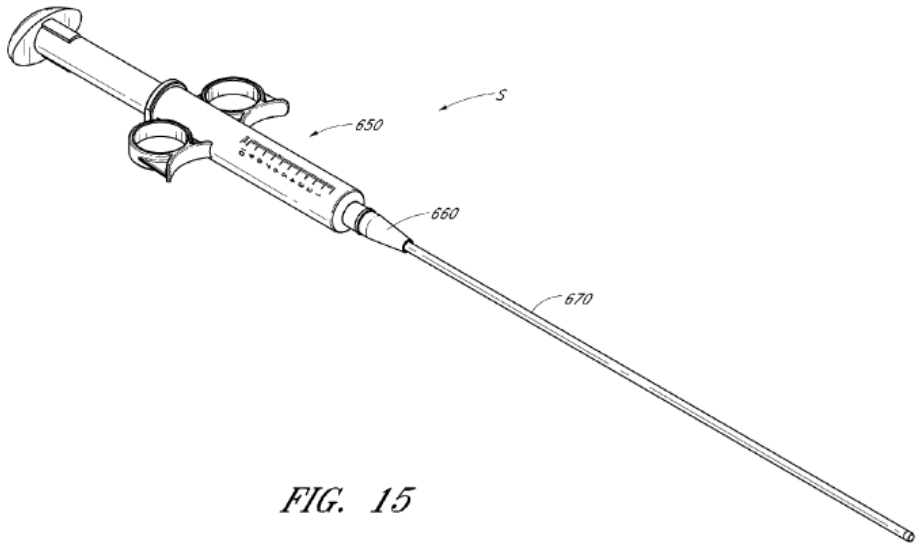
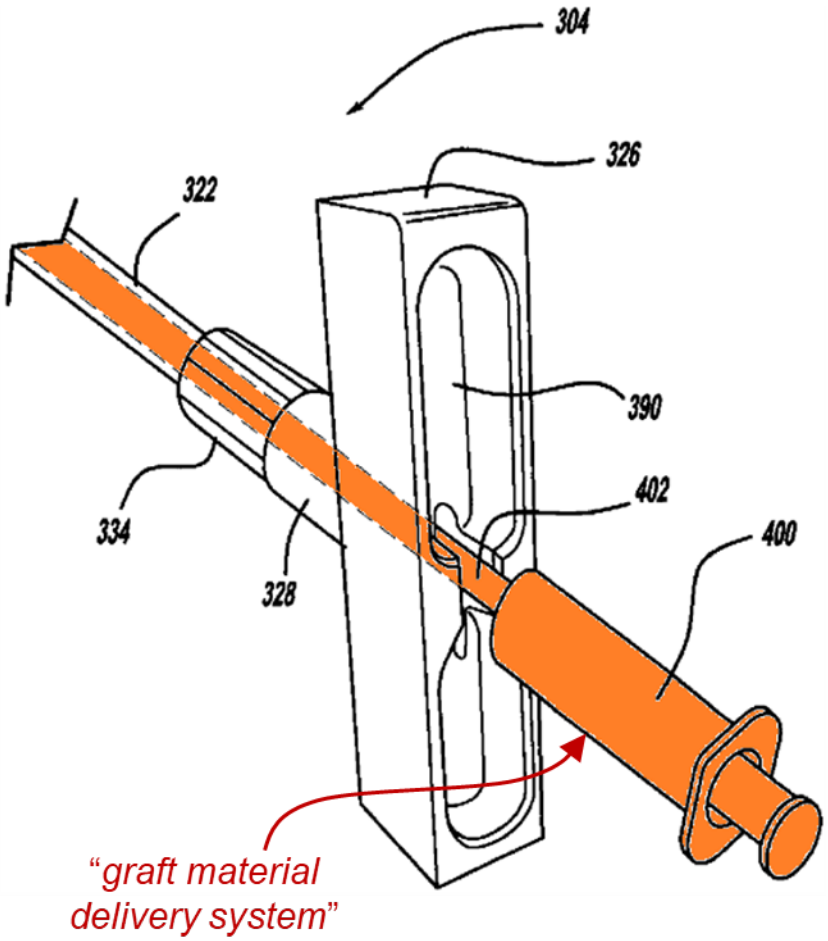


FIG. 15

Ex. 1001, Figure 15

Turning to the prior art, Alfaro discloses using a "syringe-type of system" to move graft material through a handle and into the intervertebral space. *See* Ex. 1008, ¶¶ [0012] and [0032]. Alfaro explains that "**any other [delivery mechanism] present in the art**" may be used to deliver graft material into the spacer. *Id.*, ¶ [0030].

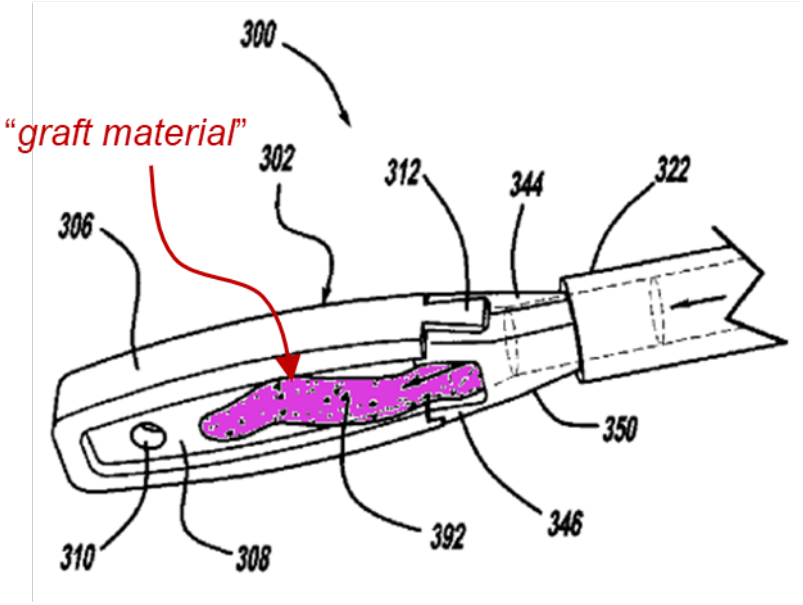
Alfaro does not explicitly disclose the implementation details of its disclosed syringes and how they would interface with Alfaro's hollow handle for delivering biologic material. Perez-Cruet discloses one such prior art syringe system. Perez-Cruet provides an illustrated example of a syringe-type system, as suggested by Alfaro, namely, a syringe 400 having an extended tubular end portion 402 for delivering bone graft material through the instrument 304. Ex. 1004, ¶ [0062]; Ex. 1003, ¶ 276.



Ex. 1004, Figure 21; Ex. 1003, ¶ 276

The instrument 304 shown in Figure 21 of Perez-Cruet is used "for positioning the interbody device 302 and delivering bone graft material to the disc space between vertebrae once the interbody device 302 is in the proper position." Ex. 1004, ¶ [0055].

In Figure 20, Perez-Cruet illustrates "bone graft material 392 [being] delivered down the instrument 304 in any suitable manner," such as, for example, "through the instrument 304 using [the] syringe 400 having [the] extended tubular end portion 402." *Id.*, ¶ [0062].

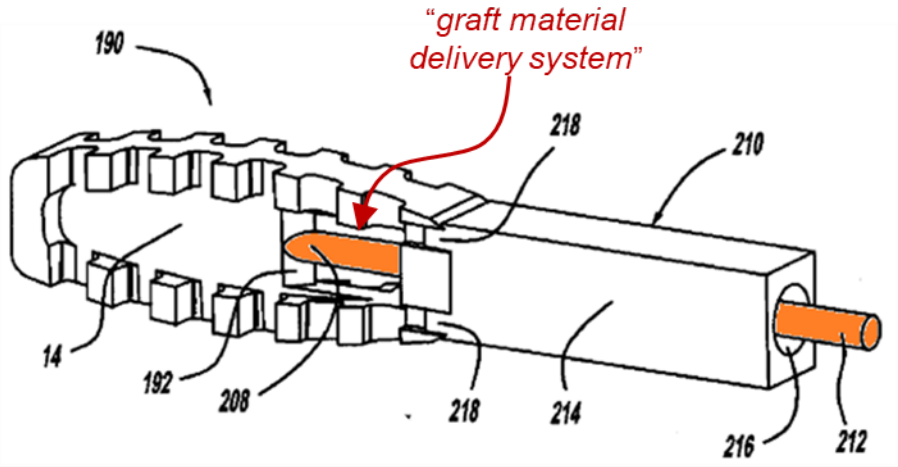


Ex. 1004, Figure 20; Ex. 1003, ¶ 278

Alfaro discloses the concept of a spacer and simple ways to connect a spacer to a handle having a cannulated portion (e.g., via a screw hole in the side of the spacer) that provides access to the compartments of a spacer. A POSITA would have been motivated to determine how to utilize a syringe-type system, as suggested by Alfaro, with Alfaro's handle and spacer. *See* Section IX.B.2 ("Reasons to Combine Alfaro and Perez-Cruet"). The syringe 400 of Perez-Cruet is a syringe used to deliver graft material to one or more compartments of an implanted spacer through an insertion handle. When utilized with Alfaro's handle, Perez-Cruet's syringe directs "*the graft material into the at least one internal chamber*," e.g., the compartment 11b of Alfaro's intervertebral spacer, as required by [16.1], by positioning the extended tubular end portion 402 of Perez-Cruet's

syringe 400 through Alfaro's handle 12. Ex. 1003, ¶¶ 279-281.

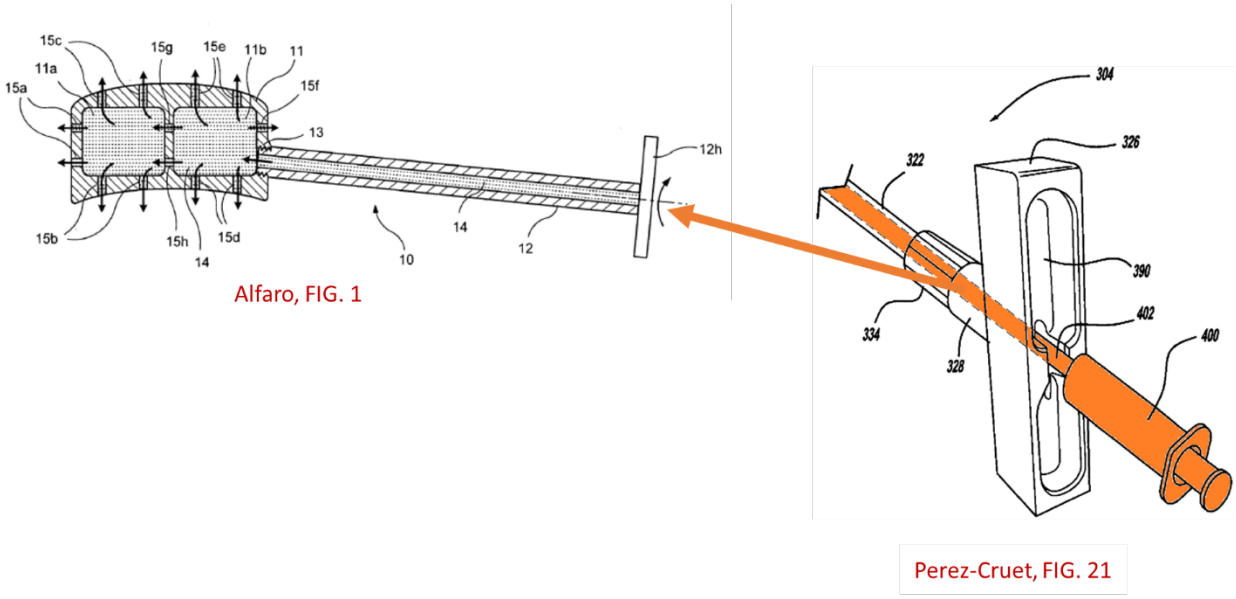
In addition, in the embodiment of Figure 11, reproduced below, Perez-Cruet illustrates an "interbody device 190 in combination with a rotating tool 210 and a fill tube 212." Ex. 1004, ¶ [0053]. As shown in Figure 11, "[t]he fill tube 212 extends through the bore 216 and is coupled to or positioned relative to the ridge 190 so that bone graft material forced through the tube 212 is dispersed on both sides of the center plate 14 as discussed above." *Id*., ¶ [0053].



Ex. 1004, Figure 11; Ex. 1003, ¶ 283

Thus, Perez-Cruet discloses a fill tube that is extended through a bore of an insertion tool so that the end of the fill tube is positioned within an internal chamber of an interbody device. In light of the teachings of Alfaro that disclose the use of a syringe to deliver biologic material and that disclose a handle with a conduit for delivering biologic material to an implanted spacer, it would have been

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, as further discussed below in connection with claim element [17.1], rendering obvious claim element [16.1]. An example combination of Alfaro and Perez-Cruet's teachings is illustrated below. Ex. 1003, ¶¶ 271-284.



Sherman, Figure 1; Ex. 1003, ¶ 284

4. Claim 17

a) [17.0] *The method of claim 16*

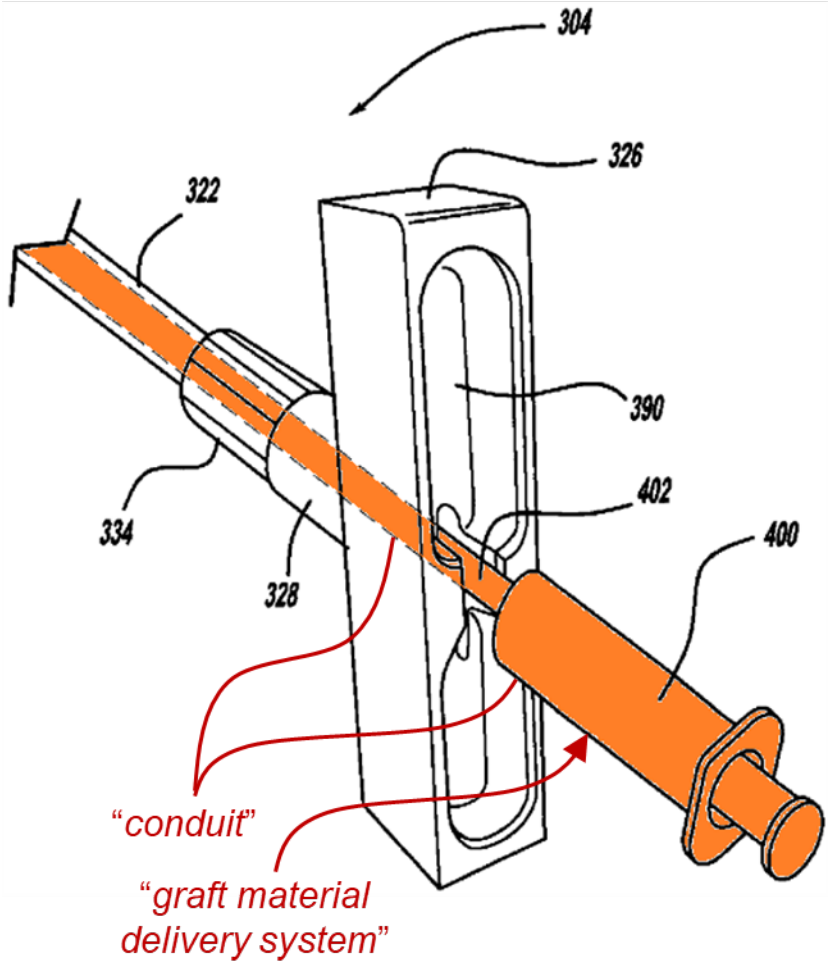
See analysis of claim 16.

b) [17.1] ***wherein directing the graft material into the at least one internal chamber comprises passing the conduit through the access port of the implant to position the conduit within the at least one internal chamber of the implant.***

Alfaro combined with Perez-Cruet renders obvious [17.1].

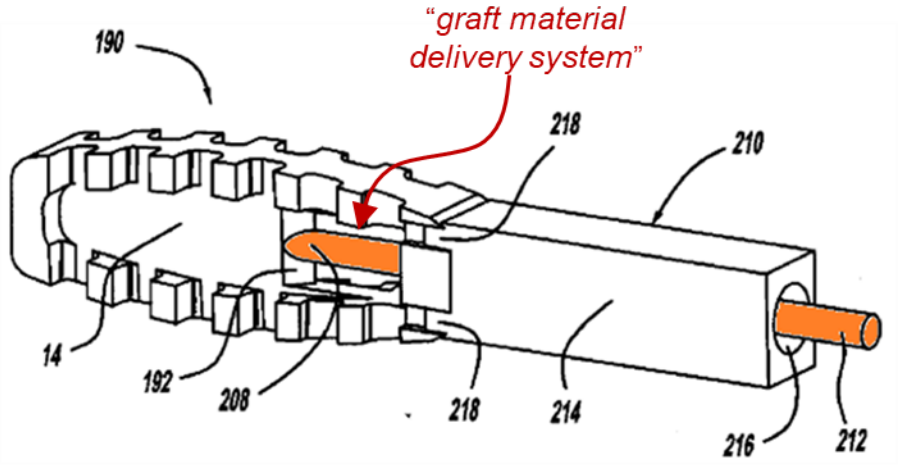
As discussed above in the analysis of [16.1], it was obvious to implement Alfaro's disclosed syringe for delivering biologic material to a spacer using the syringe 400 of Perez-Cruet and to direct "*the graft material into the at least one internal chamber*," e.g., the compartment 11b of Alfaro's intervertebral spacer, by positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's hollow handle 12.

In Figure 21, reproduced below, Perez-Cruet illustrates the syringe 400 having the extended tubular end portion 402 for delivering bone graft material through the instrument 304. Ex. 1004, ¶ [0062]. As discussed above in the analysis of [16.1], the syringe 400 of Perez-Cruet, including the extended tubular end portion 402, is an example of "*a conduit*" as claimed. Ex. 1003, ¶ 288.



Ex. 1004, Figure 21; Ex. 1003, ¶ 288

Furthermore, in an embodiment, Perez-Cruet teaches an "interbody device 190 in combination with a rotating tool 210 and a fill tube 212." Ex. 1004, ¶ [0053]. As shown in Figure 11, reproduced below, "[t]he fill tube 212 extends through the bore 216 and is coupled to or positioned relative to the ridge 190 so that bone graft material forced through the tube 212 is dispersed on both sides of the center plate 14 as discussed above." Ex. 1004, ¶ [0053].



Ex. 1004, Figure 11; Ex. 1003, ¶ 289

Thus, in view of Alfaro's disclosure of using a hollow handle as an insertion tool, the hollow handle having a conduit in fluid communication with chambers of an intervertebral spacer to deliver biologic material to the intervertebral spacer, further in view of Alfaro's teachings of using a syringe to deliver the biologic material, and further in view of Perez-Cruet's disclosure of a syringe coupled to the interior of an intervertebral spacer via a hollow handle, it was 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, thereby rendering obvious claim element [17.1]. Ex. 1003, ¶¶ 286-290.

5. Claim 18

a) [18.0] *The method of claim 16*

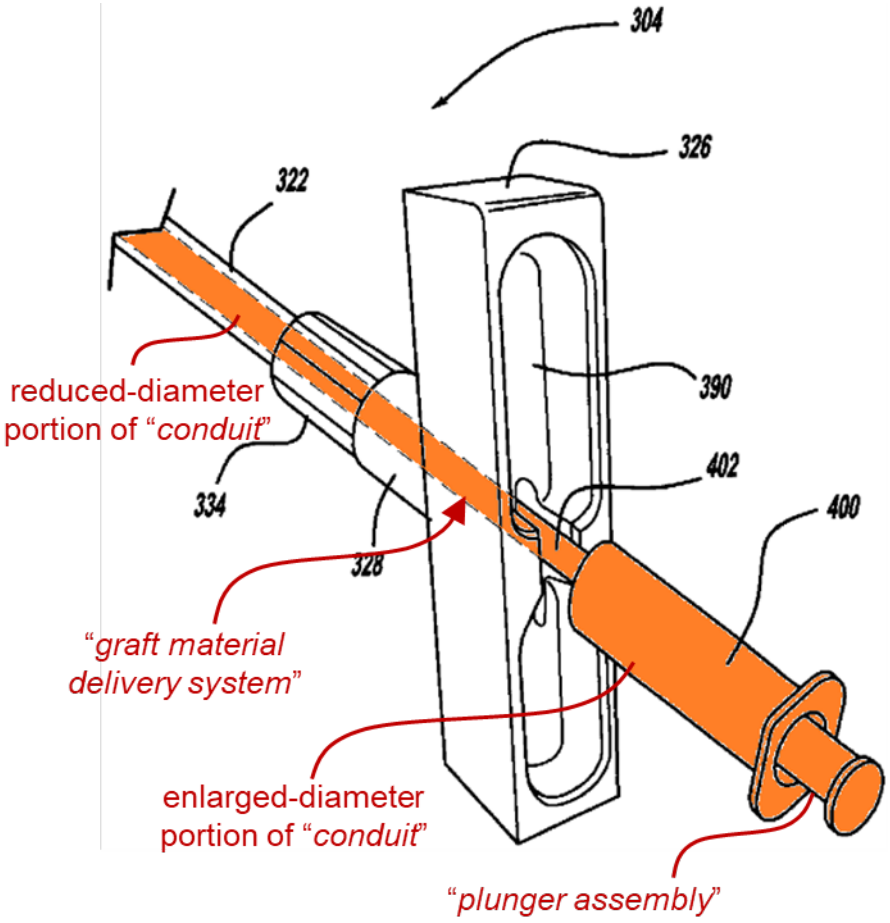
See analysis of claim 16.

b) [18.1] ***wherein the graft delivery system further comprises a plunger assembly configured to be positioned and moved within the conduit, the method further comprising actuating the plunger assembly to move a volume of graft material through the conduit and into the at least one internal chamber of the implant.***

Alfaro combined with Perez-Cruet renders obvious [18.1].

As discussed above in the analysis of claim element [16.1], the '203 patent discloses an embodiment of a graft delivery device formed of the larger diameter syringe barrel and interconnected narrow diameter extension forming a conduit for delivery of the bone graft. And no distinction is made in the claim language regarding the relative diameters of different sections of a conduit.

Alfaro suggests using a syringe to move graft material through a hollow handle and into an intervertebral spacer, and Perez-Cruet discloses the structural details of such a syringe. For example, in Figure 21, reproduced below, Perez-Cruet illustrates the syringe 400 (having a barrel as a first "*conduit*" portion as claimed) including a reduced-diameter portion (the extended tubular end portion 402) extending from an enlarged-diameter portion (the syringe barrel) through a hollow handle 326. Ex. 1003, ¶¶ 293-294.



Ex. 1004, Figure 21; Ex. 1003, ¶ 294

As shown in Figure 21, the enlarged-diameter portion accommodates "*a plunger assembly configured to be positioned and moved within the conduit*," e.g., within the syringe barrel, "*the method further comprising actuating the plunger assembly to move a volume of graft material through the conduit*," e.g., delivering bone graft material using the syringe 400, including the enlarged-diameter syringe barrel and the reduced-diameter extended tubular end portion 402, Ex. 1004, ¶ 62 "*and into the at least one internal chamber of the implant*," e.g., the compartment

11b of Alfaro's intervertebral spacer 11, thus rendering obvious claim element [18.1]. Ex. 1003, ¶ 295.

6. Claim 6

a) [6.0] ***The method of claim 1***

See analysis of claim 1.

b) [6.1] ***wherein directing the graft material into the at least one internal chamber comprises using a graft material delivery system, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit.***

Claim element [6.1] is identical to claim element [16.1]. Thus, Alfaro combined with Perez-Cruet renders obvious [6.1] for the same reasons as presented in the analysis of [16.1].

7. Claim 7

a) [7.0] ***The method of claim 6***

See analysis of claim 6.

b) [7.1] ***wherein directing the graft material into the at least one internal chamber comprises passing the conduit through the at least one access port of the implant to position the conduit within the at least one internal chamber of the implant.***

Claim element [7.1] is identical to claim element [17.1]. Thus, Alfaro combined with Perez-Cruet renders obvious [7.1] for the same reasons as presented in the analysis of [17.1].

8. Claim 8

a) [8.0] *The method of claim 6*

See analysis of claim 6.

b) [8.1] *wherein the graft delivery system further comprises a plunger assembly configured to be positioned and moved within the conduit, the method further comprising actuating the plunger assembly 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.*

Claim element [8.1] is the same as claim element [18.1], except that [8.1] adds the underlined claim language above. For reasons presented in the analysis of claim element [18.1], Alfaro combined with Perez-Cruet renders obvious claim element [8.1]. The verbiage added to [8.1] does not add anything substantively to [18.1] because the reason a plunger is moved in a syringe is to "*provide the necessary driving force*" to move a volume of graft material into the implant. Ex. 1003, ¶¶ 301-305.

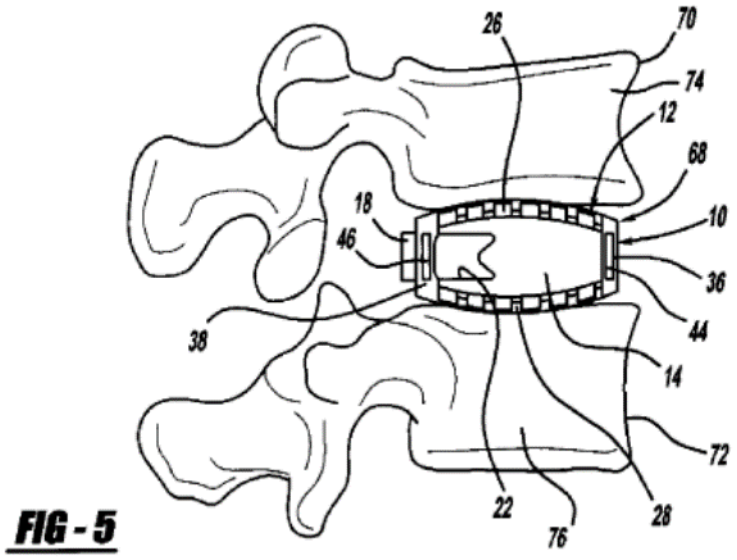
X. THERE IS NO BASIS FOR DISCRETIONARY DENIAL

No other IPR has ever been filed against the '203 Patent, the only litigation ever involving the '203 Patent is currently stayed (*see* Ex. 1021), and the primary reference used herein – Alfaro – was not considered during prosecution (e.g., as explained in Section IV.C, "Prosecution History of the '203 Patent").

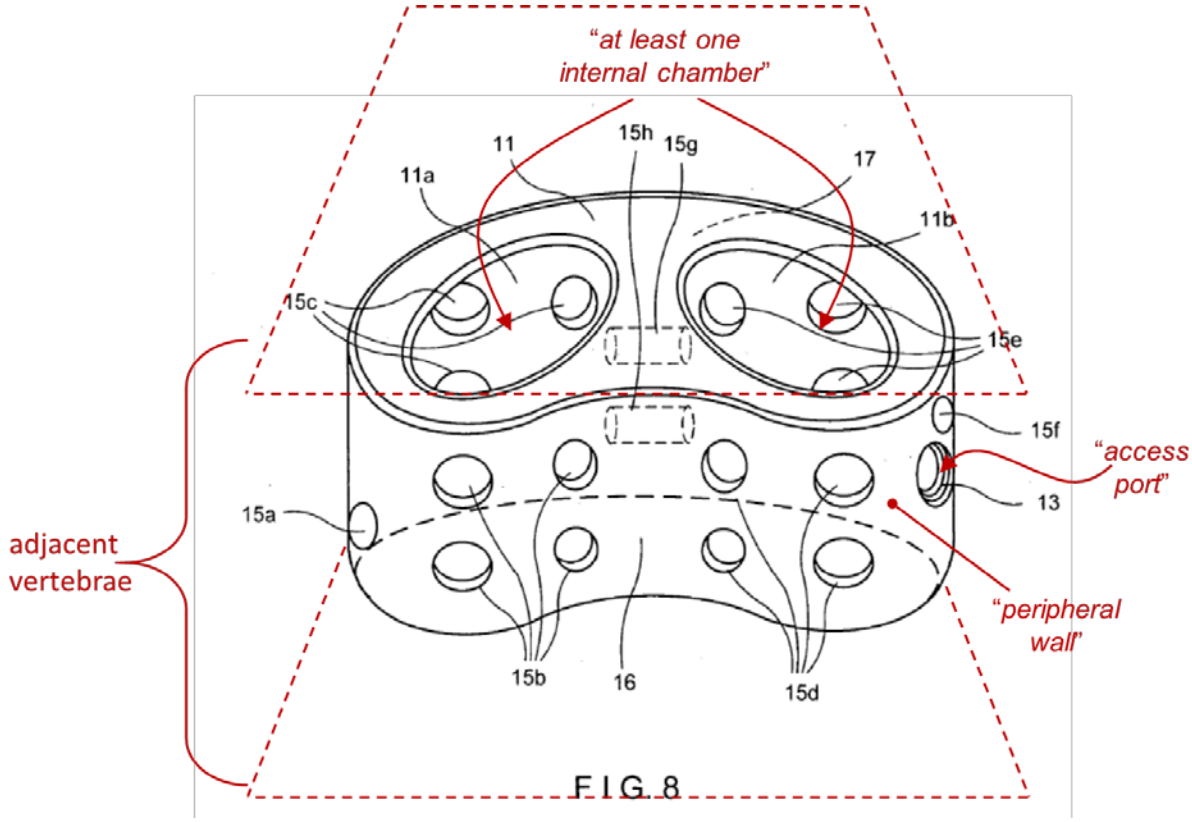
Further with respect to determining whether to exercise discretion under

§ 325(d), "the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (designated: March 24, 2020). Neither condition in the first part of the framework is satisfied in this case.

In the first Office Action, Kleiner (Ex. 1018) was described as disclosing the structural features and combined with Perez-Cruet's (Ex. 1004) graft delivery system to arguably disclose then-pending claim 2 (ultimately issued as claim 1). Ex. 1002, pp. 199-200. The Examiner and Applicant subsequently agreed that "[g]raft material is positioned within Kleiner's implant prior to placement between the adjacent endplates." *Id.*, p. 256 (emphasis added). Furthermore, Perez-Cruet's implant is oriented differently than Alfaro's implant in the intervertebral space – rotated 90 degrees as compared to Alfaro's implant such that adjacent vertebrae rest on peripheral walls of Perez-Cruet's implant, whereas top and bottom surfaces of Alfaro's implant face adjacent vertebrae. *See* Ex. 1004, ¶ [0043] and Figure 5 (below); Ex. 1008, Figure 8 (below); Ex. 1003, ¶ 88.



Ex. 1004, Figure 5



Ex. 1008, Figure 8; Ex. 1003, ¶ 88

As a result, the Applicant amended the independent claims to clarify that graft material is directed into an internal chamber of the implant "*after positioning*" the implant between vertebrae, "*such that the graft material is in flush contact with endplate surfaces*" of adjacent vertebrae. Ex. 1002, pp. 261, 263. As set forth in the analysis of claim elements [11.3.1]-[11.3.3], Alfaro discloses the very feature the Examiner found lacking in the combination of Kleiner and Perez-Cruet during prosecution. Thus, this Petition does not present the same or substantially the same prior art or arguments presented during prosecution of the '203 Patent. Ex. 1003, ¶¶ 87-88.

During prosecution of the '203 Patent, the Applicant also filed a terminal disclaimer with respect to U.S. Patent No. 8,308,805 (the "'805 Patent," Ex. 1022). Ex. 1002, p. 266. Turning to prosecution of the '805 Patent, the as-filed independent claims of the '805 Patent were initially rejected as anticipated by Perez-Cruet. Ex. 1023, pp. 110-114. The independent claims were amended to overcome Perez-Cruet, including directing graft material into an internal chamber "*to fill the at least one internal chamber of the implant such that the at least one graft material contacts an endplate surface of each of the first and second vertebral bodies*." *Id*., p. 240.

Thus, as compared to prosecution of the '805 Patent, which relies only on Perez-Cruet, the Examiner combined Kleiner with Perez-Cruet during prosecution

of the ’203 Patent. However, as discussed above, Alfaro, which was not considered during prosecution of either of the ’805 or ’203 Patents, is different than the combination of Kleiner and Perez-Cruet in ways material to the challenged claims. Accordingly, part (1) of *Advanced Bionic*’s framework is not satisfied because neither the same or substantially the same art nor the same or substantially the same arguments are presented herein as compared to prosecution, so there is no basis for discretionary denial under 35 U.S.C. § 325(d). Ex. 1003, ¶¶ 89-92.

XI. CONCLUSION

For the reasons presented above, institution of *inter partes* review of claims 1-20 of the ’203 Patent is requested.

Dated: August 25, 2020

Respectfully submitted,

By: /J. Andrew Lowes/
J. Andrew Lowes
Registration No.: 40,706
Customer No. 27683
Attorney Docket No. 48017.244
Lead Counsel for Petitioner Orthofix

XII. CERTICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Petitioner Orthofix, declares that the argument section of this Petition (Sections I, III–XI) has a total of 13,844 words according to the word count tool in Microsoft Word™.

/J. Andrew Lowes/
J. Andrew Lowes
Registration No.: 40,706
Lead Counsel for Petitioner Orthofix

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: Lynn *et al.*	§	Petition for *Inter Partes* Review
	§	
U.S. Patent No. 9,649,203	§	Attorney Docket No.: 48017.244
	§	
Issued: May 16, 2017	§	Customer No.: 27683
	§	
Title: METHODS OF POST-FILLING AN INTERVERTEBRAL IMPLANT	§	Real Party-in-Interest: Orthofix Medical Inc.

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.205, that service was made on the Patent Owner as detailed below.

Date of service	August 25, 2020
Manner of service	FEDERAL EXPRESS
Documents served	Petition for *Inter Partes* Review Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104; Petitioner's Exhibit List; Certificate of Word Count; Exhibits: Ex. 1001 through Ex. 1023
Persons served	Knobbe Martens Olson & Bear LLP 2040 Main Street, Fourteenth Floor Irvine, CA 92614

/J. Andrew Lowes/
J. Andrew Lowes
Registration No.: 40,706
Lead Counsel for Petitioner Orthofix