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

IPR2020-01412
U.S. Patent No. 9,216,096

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

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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. 9,216,096 (the "'096 Patent") relates to spinal implants and related systems and methods. Independent claims 1 and 16 are directed a system having a hollow "implant" with an "access port," an "implant insertion tool," and a "graft material delivery system." Claims 1 and 16 were amended during prosecution to add allegedly novel subject matter to further specify the structure of the spinal implant as it relates to adjacent vertebrae so that the implant "contains graft material delivered through the access port…such that graft material is in flush contact with" adjacent vertebrae. But prior art not previously considered by the Office – namely, Alfaro – discloses the allegedly novel limitations of a system for delivering graft material into a hollow implant after implantation to fill gaps that may exist between the implant and vertebral endplates, 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 ’096 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 ’096 Patent is related to U.S. Patent No. 9,649,203, 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.

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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 '096 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 OVERVIEW OF SPINAL FUSION, THE '096 PATENT, AND THE PROSECUTION HISTORY

A. Overview of Spinal Fusion

Spinal fusion involves joining two or more adjacent vertebrae together and preparing the vertebrae so that they 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 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, ¶ 45.

The disc space between the vertebrae can be approached from different anatomical angles for implant insertion. 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. There is no uniformly "best" approach for all patients and treatment objectives. Rather, surgeons select the best approach based on the circumstances. Ex. 1003, ¶¶ 46-57.

While POSITAs appreciated that surgical techniques could include pre-packing bone graft into the interbody spacer, they also appreciated that certain instrument connections did not permit full packing of the interbody spacer before insertion and that certain situations led to bone graft falling out during insertion. It was well-known to pack additional bone graft into the interior of the interbody spacers after implanting them in the spine. Ex. 1003, ¶¶ 62-67. Building on the experience of packing after implantation, publications referenced by Mr. Sherman show 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*., ¶¶ 68-72.

B. Summary of the '096 Patent

The '096 Patent "generally relates to spinal fusion, and more specifically, to spinal implants and related systems, tools and methods." Ex. 1001, 1:18-21. At least three aspects are described:

1) "Spinal Implant" structure, *see id*., 7:1-17:26;
2) "Implantation into Targeted Intervertebral Space" concerning the instrumentation and process for implanting the implant, *see id*., 17:27-21:4;

and

3) "Filling of the Implant", *see id*., 21:5-26:50.

(1) Spinal Implant

Figure 1A, reproduced below, illustrates an embodiment of an implant. The "implant 10" includes a "top surface 12" and a "bottom surface 16," Ex. 1001, 7:26-37, and 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*., 7:26-31. Teeth may completely or only partially cover either the top or bottom surfaces or both. *Id*., 7:38-45.

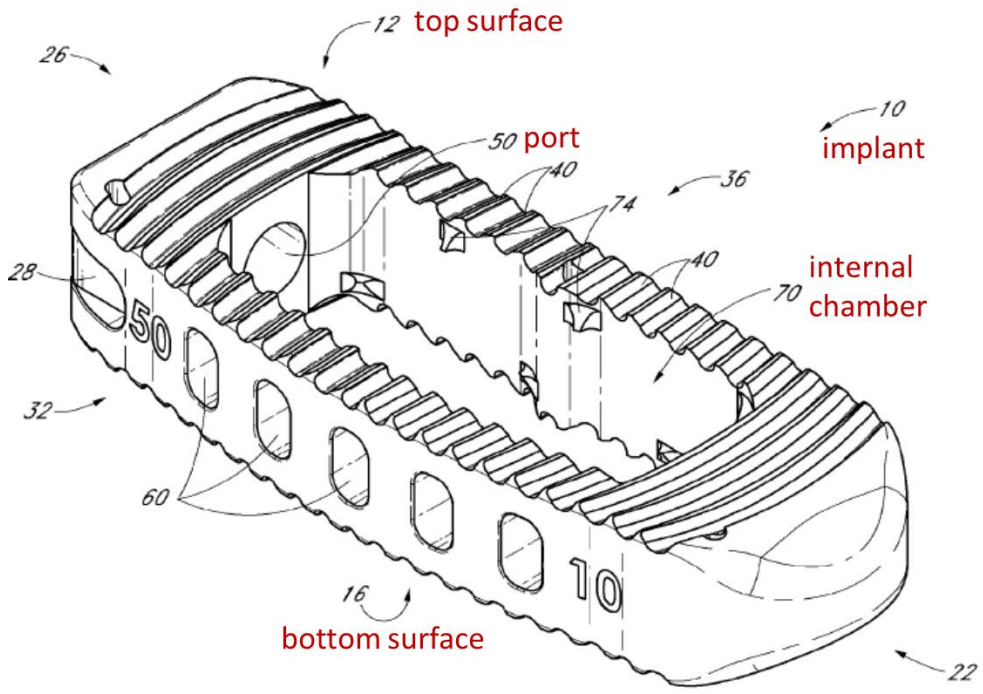


FIG. 1A

Ex. 1001, FIG. 1A[1]; Ex. 1003, ¶ 74

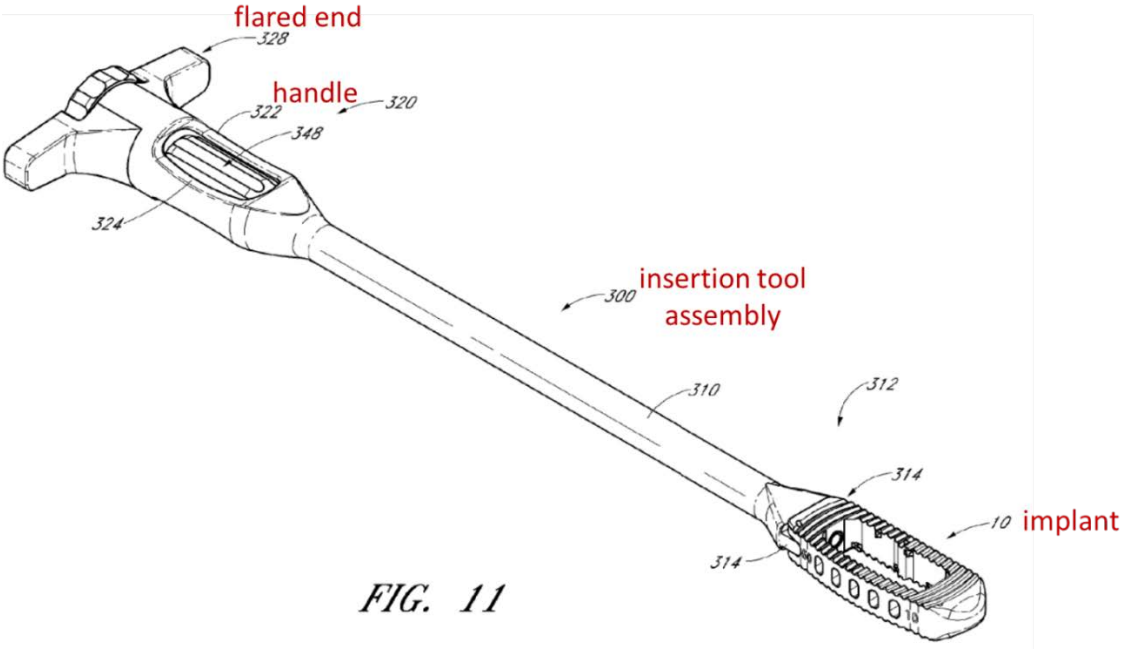
The implant 10 also includes a "port 50 [] configured to releasably engage a corresponding insertion tool." Ex. 1001, 9:52-54; Ex. 1003, ¶¶ 74-76.

(2) Inserting the Implant

Figure 11 illustrates an "insertion tool assembly 300" used by a surgeon to insert the "implant 10" into the target intervertebral space (shown in Figure 7). *See* Ex. 1001, 6:15-17, 15:21-33. In this embodiment, "[t]he proximal portion 320 of

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

the assembly 300 can include a handle 322 and a flared end 328." Ex. 1001, 19-63-65; Ex. 1003, ¶¶ 77-78.



Ex. 1001, Figure 11; Ex. 1003, ¶ 77

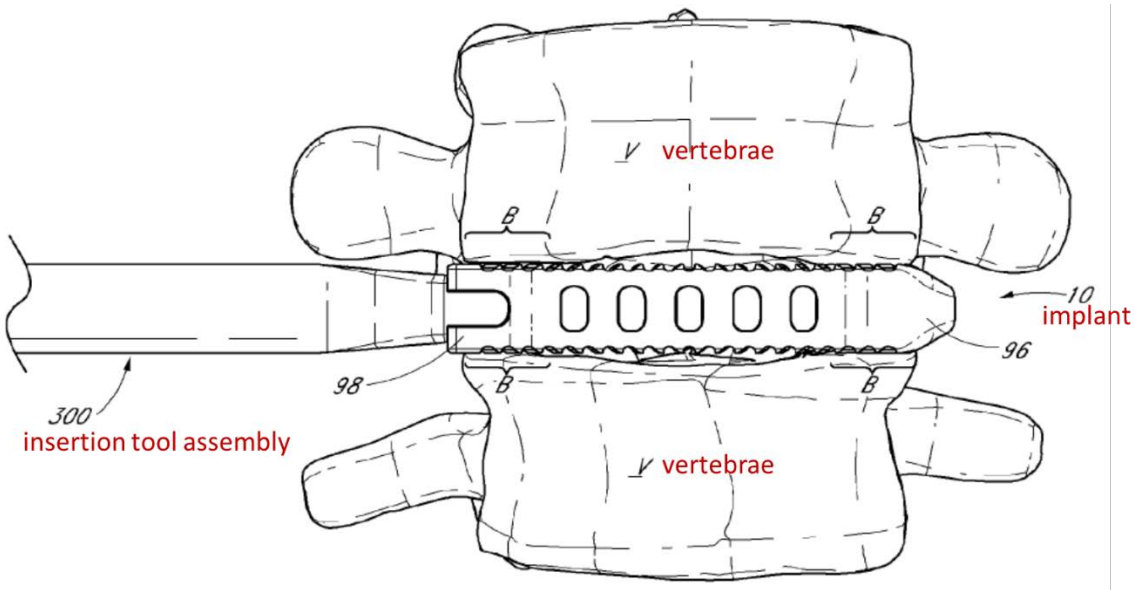


FIG. 7A

Ex. 1001, Figure 7A; Ex. 1003, ¶ 79

(3) Filling the Implant

The implant may be filled (1) during engagement of an "insertion tool assembly" with the implant and after the "insertion tool assembly" has been used to position the implant, Ex. 1001, 24:42-62, or (2) through a bone graft delivery instrument after the "insertion tool assembly…is decoupled from the implant," *id*., 21:41-56. In one embodiment, the insertion tool assembly includes a cannulated rod having an internal passage configured to receive a "fill tube or other conduit" for delivering graft material to the implant after implantation. Ex. 1001, 24:42-62; Ex. 1003, ¶¶ 80-81.

C. Prosecution History of the '096 Patent

In a Pre-Interview Communication, the Examiner rejected claim 2 (which eventually was renumbered as claim 1) on two grounds: (1) based on Perez-Cruet (Ex. 1004); and (2) based on U.S. Patent Publication No. 2008/0125856 (Ex. 1026). Ex. 1002, p. 163.

After an interview, the Examiner indicated that "[f]urther structural recitation of the chamber with respect to the implant walls, accesss [*sic*] port, and recited openings may overcome the art of record." *Id*., p. 278. In a subsequent response, the Applicant amended claim 2 to add two clauses at the end (ultimately issuing in claim 1) related to features determined after implantation, with the amendment indicated as follows:

> (iii) a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit[[.]];
>
> wherein, after delivery of the implant with the target intervertebral space, the first and second walls and the first and second sidewalls of the implant are configured to extend between superior and inferior vertebral members adjacent the target intervertebral space; and
>
> wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the at least one chamber upon implantation into the target intervertebral space such that the at least one chamber contains graft material delivered through the access port, thereby enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.

Ex. 1002, pp. 281-282. The Applicant later filed a Supplemental Amendment to simplify the "implant insertion tool" limitation, *see id*., pp. 300-307, and filed a terminal disclaimer with respect to U.S. Patent No. 8,343,224 (the "'224 Patent"; Ex. 1023), *id*., p. 305. In the next Office communication, a Notice of Allowance issued. *Id*., p. 318.

Alfaro (Ex. 1008), not considered during prosecution, discloses the added limitations. Therefore, the prior art and arguments presented here do not duplicate prosecution. Ex. 1003, ¶¶ 90-92.

Turning to the prosecution history of the '224 Patent, the subject of the terminal disclaimer, the as-filed independent claims of the '224 Patent were rejected as anticipated by Murillo (U.S. 2008/0077247) (Ex. 1025), and many dependent claims were rejected as obvious in view of Murillo and Perez-Cruet (Ex. 1004). Ex. 1024, pp. 122-126. After amending the claims, *id*., pp. 148-151, the claims were later allowed with an amendment including "wherein a length of each of the first and second lateral walls is a minimum of 12% of an overall length of the implant," Ex. 1024, p. 255, a very different limitation than appearing in the '096 Patent claims. Moreover, Murillo only mentions filling a spacer in passing, *see*, *e.g*., Ex. 1025, ¶ [0047] ("…the opening 116 can be configured to allow placement of the bone graft material."), but does not disclose any sort of "*graft*

material delivery system" as recited in claims 1 and 16 of the '096 Patent. Ex. 1003, ¶¶ 93-95.

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 would have had a bachelor's degree in the field of Mechanical, Biomechanical or Biomedical engineering and at least five years of experience in designing and developing spinal implants and related systems, tools and methods. Furthermore, a person with more technical education but less experience could also meet the relevant standard for POSITAs. Alternatively, a POSITA could be a practicing orthopedic surgeon 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 according to 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). For the purposes of this proceeding and the analysis presented herein, only one claim term requires express construction. *Vivid Techs., Inc. v. Am.*

Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). Accordingly, except for the claim term presented below, 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, ¶ 115.

A. *"graft material delivery system"* limitation (claims 1 and 16)

The claim term "*a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit*" appears in claim 1 and also appears in claim 16, except for the underlined portion "*a volume of*," which does not appear in claim 16.

Because this claim term does not use the word "means" or "step," there is a presumption that the term is not a "means-plus-function" claim term. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc). However, the presumption is rebuttable if the term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function. *Id*. at 1349.

The claim term "*graft material delivery system*" is not understood in the art as referring to a specific structure. The only structure recited in the claim term is a "*conduit*," but a "*conduit*" alone is not sufficient for performing the stated function

of "*delivering a volume of graft material into the at least one internal chamber of the implant*." Thus, the claim term is construed as a "means-plus-function" term. Ex. 1003, ¶ 118.

Construing a means-plus-function limitation includes two steps: (1) identifying the claimed function, and (2) identifying the corresponding structure in the specification (including identifying the specific portions of the specification where found) of the patent that performs the function. *Williamson*, 792 F.3d at 1351. The claimed function is identified above as "*delivering a volume of graft material into the at least one internal chamber of the implant*." The corresponding structure in the specification is identified below.

The term "*graft material delivery system*" is used in only one short passage stating: "In some arrangements, the graft material delivery system comprises a syringe, a sizing tool and a conduit configured to pass through the at least one access port of the spinal implant." Ex. 1001, 4:13-22

The '096 Patent also describes another structure for performing the function. Referring to Figure 18, "the insertion tool 300′ can be used to both deliver the implant to its proper intervertebral position and to subsequently **fill the interior chamber(s) of the implant 10** with one or more graft and/or other fill materials" using "a flexible tube, catheter or other conduit of **a syringe assembly**." Ex. 1001, 24:42-56. Such a syringe assembly is illustrated in Figures 13 and 15, below.

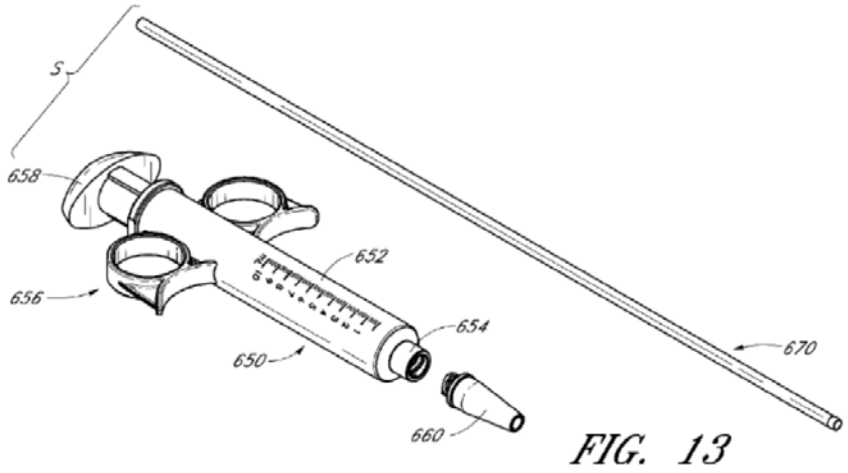


FIG. 13

Ex. 1001, Figure 13 (partial)

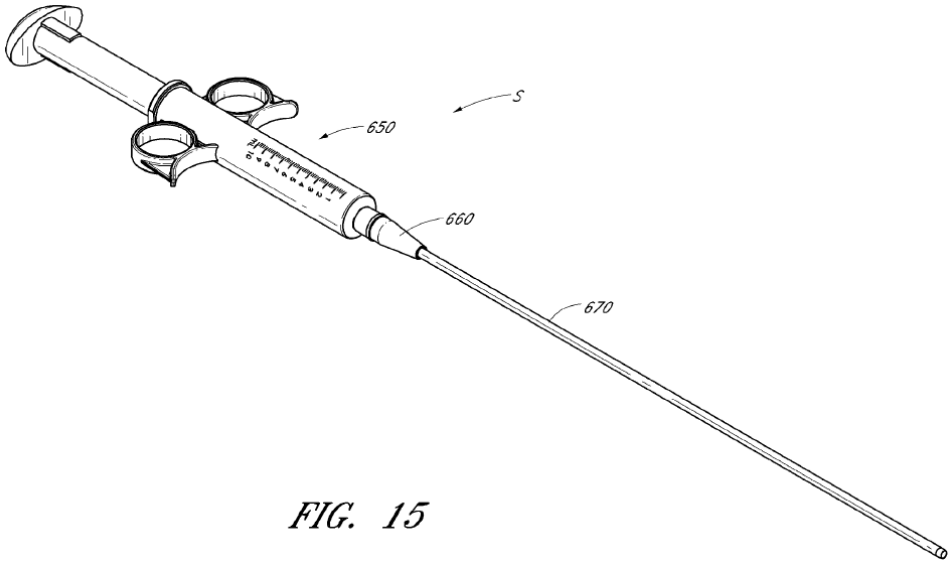


FIG. 15

Ex. 1001, Figure 15

The syringe assembly S includes syringe 650 (having plunger 658, and barrel 652) and tubing 670. *Id*., 22:25-32 and 41-44. The barrel and tubing form a portion of a "*conduit*" for delivery of graft material.

While there may be yet other structures disclosed in the ’096 Patent for performing the claimed function, the claim term is construed only to the extent necessary to resolve the obviousness query. *Vivid Techs., Inc.*, 200 F.3d at 803 (Fed. Cir. 1999). In summary, it suffices here to identify only the structure for performing the claimed function of a syringe attached to a conduit, or a plunger configured to displace graft material within a conduit. Ex. 1003, ¶¶ 116-125.

VII. REQUESTED RELIEF

Petitioner asks that the Board 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 on the following grounds.

Ground	Claims	Basis
Ground 1	1-8 and 10-20	35 U.S.C. § 103 over Alfaro (Ex. 1008) in combination with Frey (Ex. 1005) and Perez-Cruet (Ex. 1004)
Ground 2	9	35 U.S.C. § 103 over Alfaro in combination with Frey, Perez-Cruet, and Fuss (Ex. 1022)

B. Status as Prior Art

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 ’096 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 March 16, 2010 for even the earliest provisional application, U.S. Provisional Application No. 61/314,509 ("'509 Provisional", Ex. 1006).

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, U.S. Patent Publication No. 2008/0172128 ("Perez-Cruet," Ex. 1004) published on July 17, 2008, and U.S. Patent No. 6,562,072 ("Fuss," Ex. 1022) issued on May 13, 2003, making all three references prior art under 35 U.S.C. § 102(b) (pre-AIA).

Additionally, background references Exhibits 1013-1016 and Ex. 1019 are all U.S. patents or 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 '096 Patent is not entitled to the March 16, 2010

filing date of the '509 Provisional. Ex. 1003, ¶¶ 99-114. 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 id*., Appendices A and B.

IX. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-8 and 10-20 are unpatentable as obvious over Alfaro combined with Frey and Perez-Cruet.

1. Summary of Alfaro

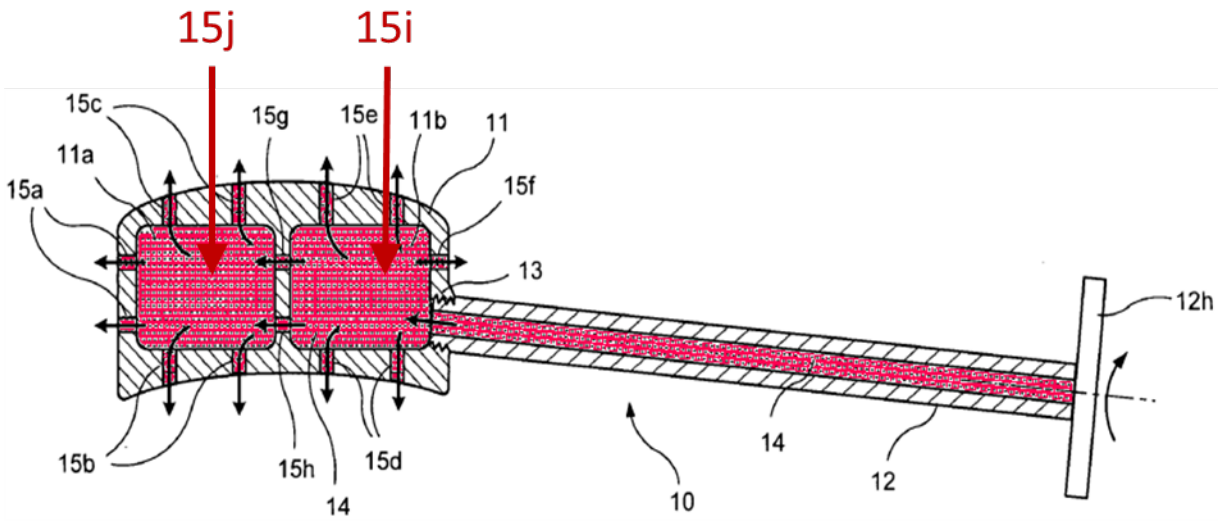
Alfaro describes problems with previous implants/spacers that are pre-loaded with biologic material before insertion into the intervertebral space in that this approach results in "weakened" fusion or "non-fusion." Ex. 1008, ¶ [0009]. To address these problems, Alfaro discloses devices and associated methods in which 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 the [graft material] located in the handle" into the spacer. *Id*., ¶ [0030]; Ex. 1003, ¶¶ 130-131.

Alfaro discloses at least two different spacer shapes: (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 to accommodate alternative insertion techniques. *E.g*., *compare* Figures 8 and 9 (Figure 8 has one screw hole 13 in peripheral walls, and Figure 9 has two

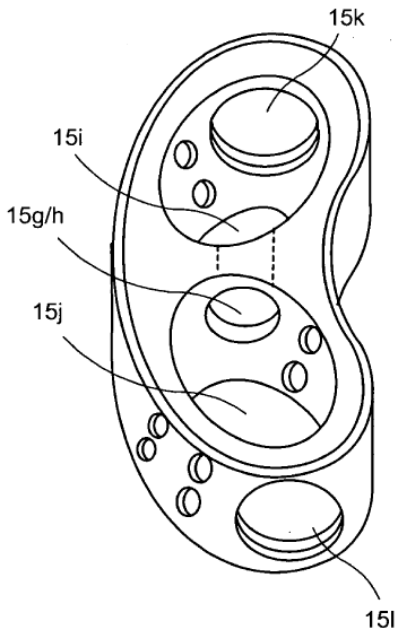
screw holes 15l and 15k). Ex. 1003, ¶ 132-133.

Referring to Figures 1 and 2, a "[h]andle 12 is shown screwed into compartment 11(b) at 13." Ex. 1008, ¶ [0029]. Moreover, "[t]he handle facilitates the introduction of the spacer by the surgeon into the intervertebral space." *Id*., ¶ [0011]. For filling spacers, the handle includes "a direct line of flow [for grafting material] through the handle into the voids of the spacer …" *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 positioned opposite the vertebrae above and below the spacer. Figure 9, also reproduced below, is a perspective view of another embodiment that is filled after implantation.



Ex. 1008, Figure 1; Ex. 1003, ¶ 135



F I G. 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 grooves on surfaces to engage vertebral endplates. *Id*., 20:6-11.

Figures 54 and 55 are reproduced below. Figure 54 is an "end elevational view of an implant," *id*., 5:1-2, illustrating grooves 1014 and "inserter engaging portion 1044" (illustrated as having internal threads), and "FIG. 55 is a top plan view of the implant of FIG. 54," *id*, 5:3, also illustrating the grooves 1014. *See also id*., 20:6-11, and 20:54-58; Ex. 1003, ¶ 136.

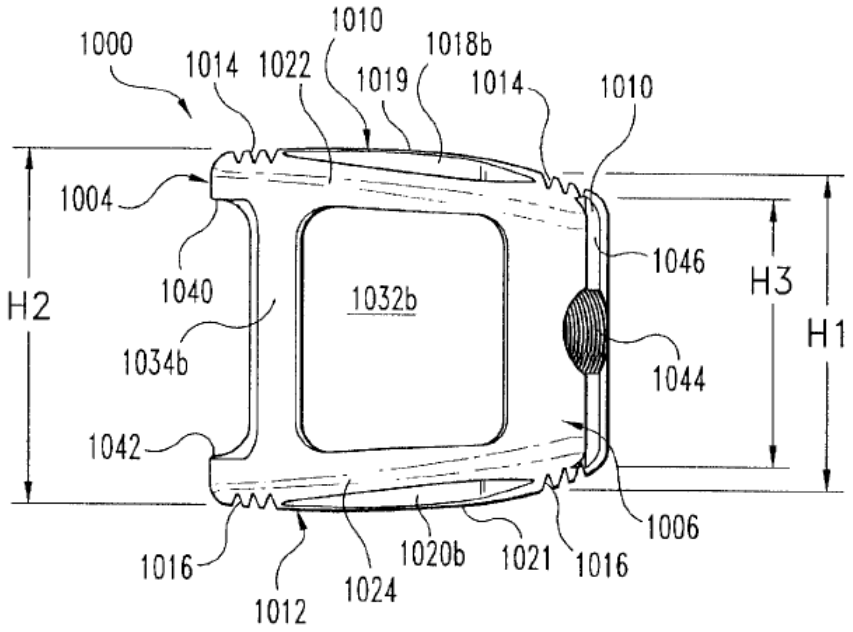


Fig. 54

Ex. 1005, Figure 54 (end view)

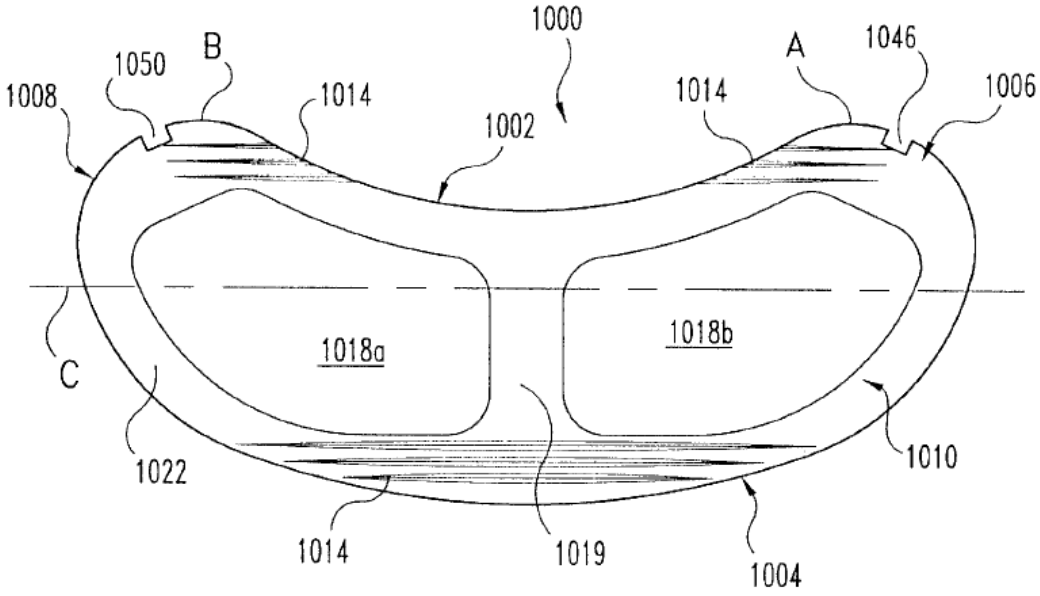


Fig. 55

Ex. 1005, Figure 55 (top view)

3. Reasons to Combine Alfaro and Frey

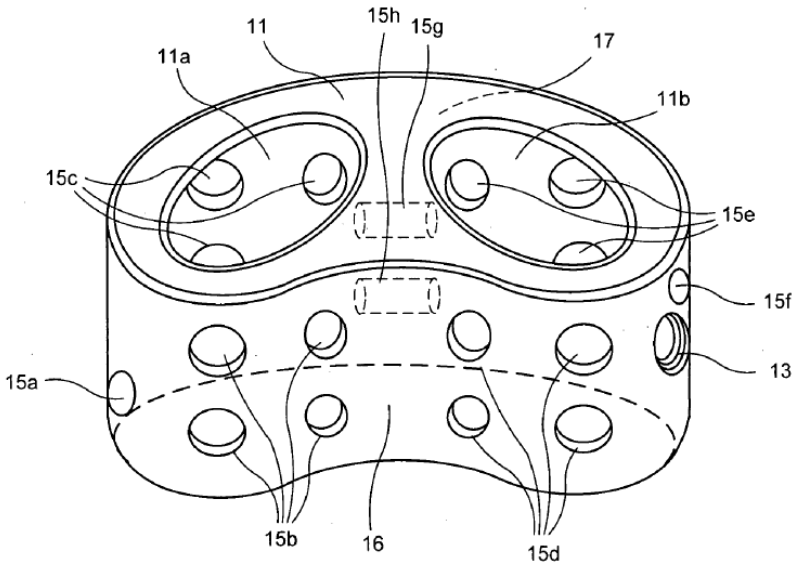
As a threshold matter, Alfaro and Frey are analogous art to the '096 Patent, being directed to the same field of spinal implants for interbody fusion and related systems, tools, and methods. *See, e.g.*, Ex. 1001, 1:18-21 ("1. Field"); Ex. 1008, ¶ [0004]; Ex. 1005, Abstract; Ex. 1003, ¶ 137.

Alfaro discloses that "any spacer" 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." Ex. 1008, ¶ [0012]. 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," Ex. 1008, ¶ [0005], and "[t]he spacer of course, remains in place at the correct site between the vertebrae," *id.*, ¶ [0031].

Frey's implant 1000 includes upper and lower bearing members 1010 and 1012 provided with grooves 1014 and 1016, respectively, for engaging vertebral endplates to "resist posterior and anterior migration of implant 1000 in the disc space." Ex. 1005, 19:50-52 and 20:6-11.

Figure 55 of Frey and Figure 8 of Alfaro, presented below, illustrate similarities between these implants: for example, Alfaro's implant has two chambers 11a and 11b and Frey's implant has two chambers 1018a and 1018b; both implants are similarly shaped; and both implants have screw holes – hole 13

in Figure 8 of Alfaro and "inserter engaging portion 1044" in Figure 54 of Frey – for engaging an insertion device. Ex. 1003, ¶ 138-141.



F I G. 8

Ex. 1008, Figure 8

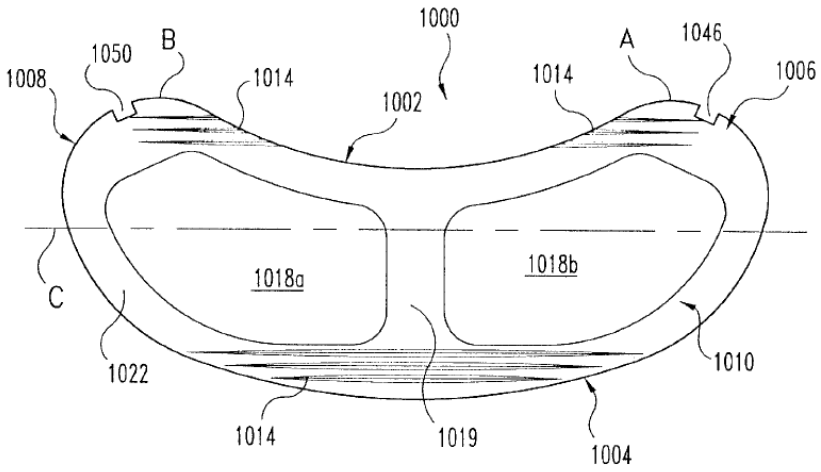


Fig. 55

Ex. 1005, Figure 55

It was desirable that spacers not move after the surgeon inserts the spacer between vertebrae. Ex. 1008, ¶ [0031] ("The spacer of course, remains in place at the correct site between the vertebrae.") For example, movement of the spacer in the intervertebral space adversely affect fusion of the adjacent vertebrae. Ex. 1003, ¶ 142.

Because Frey's grooves 1014, 1016 "resist posterior and anterior migration of implant 1000 in the disc space," Ex. 1005, 20:6-11, a POSITA would have been motivated to include similar grooves on the top and bottom surfaces of Alfaro's implant to resist migration of the implant after implantation. The grooves achieve Frey's stated benefit and promote fusion of adjacent vertebrae because there is less risk of the implant migrating within or out of the space between vertebrae. Ex. 1003, ¶ 143.

Using Frey's grooves on the top and bottom surfaces of Alfaro's implants represents combining prior art elements (Frey's implant groove structure applied to Alfaro's implants) according to known methods to yield the predictable and beneficial result of an implant that resists migration within the intervertebral space and 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, ¶ 144.

Alfaro further teaches that "in use the surgeon implants the spacer into the

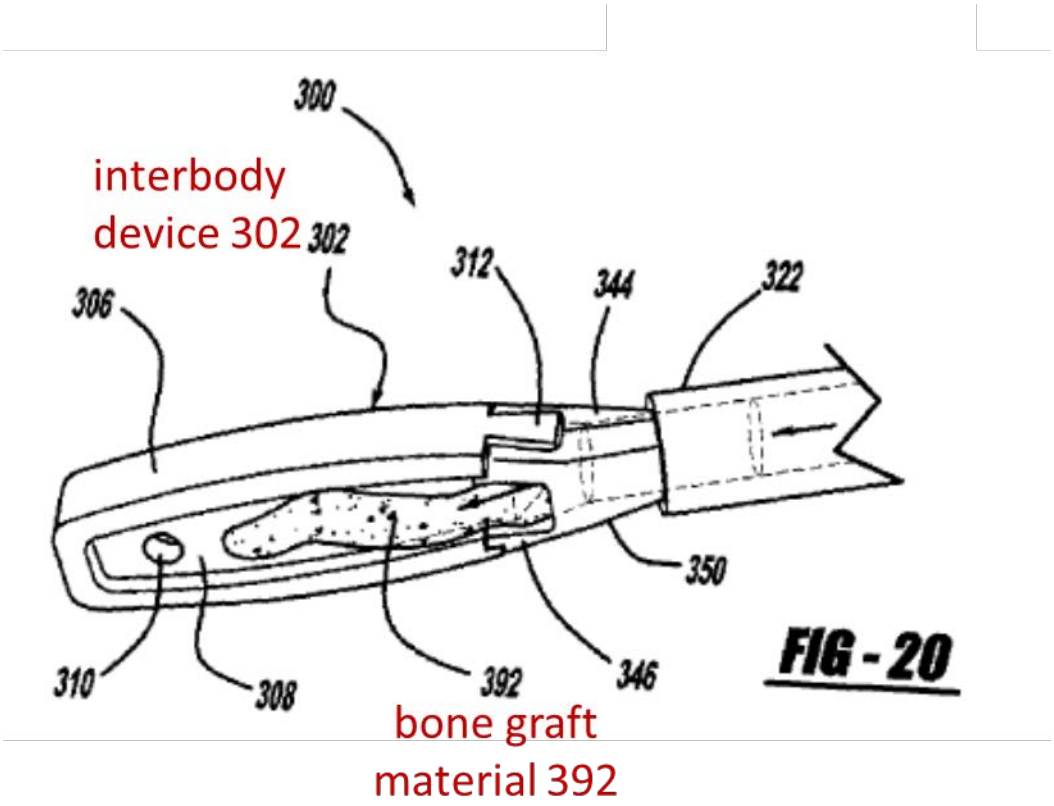
correct location of the patient using the well-known techniques for intervertebral placements and observing all of the normal medical procedures attendant to this procedure." *Id*., ¶ [0030]. As discussed in Section IV.A, surgeons select from among well-known approaches based on the clinical circumstances of each patient. In view of Alfaro's teachings and a POSITA's background knowledge, any of the known approaches was viable. Accommodating these different approaches requires only a simple modification to the location of the screw hole in a lateral wall of the implant. And that modification was well within a POSTIA's skillset. Ex. 1003, ¶ 145.

Frey lists several specific and well-known surgical approaches, including a lateral approach, Ex. 1005, 19:29-33. To the extent a POSITA practicing Alfaro would even need a reference to list the different approaches, a POSITA would have been motivated by the simple desire to implant the spacer to reference Frey's teachings to implant the spacer of Alfaro into an intervertebral disc. Ex. 1003, ¶¶ 146-147.

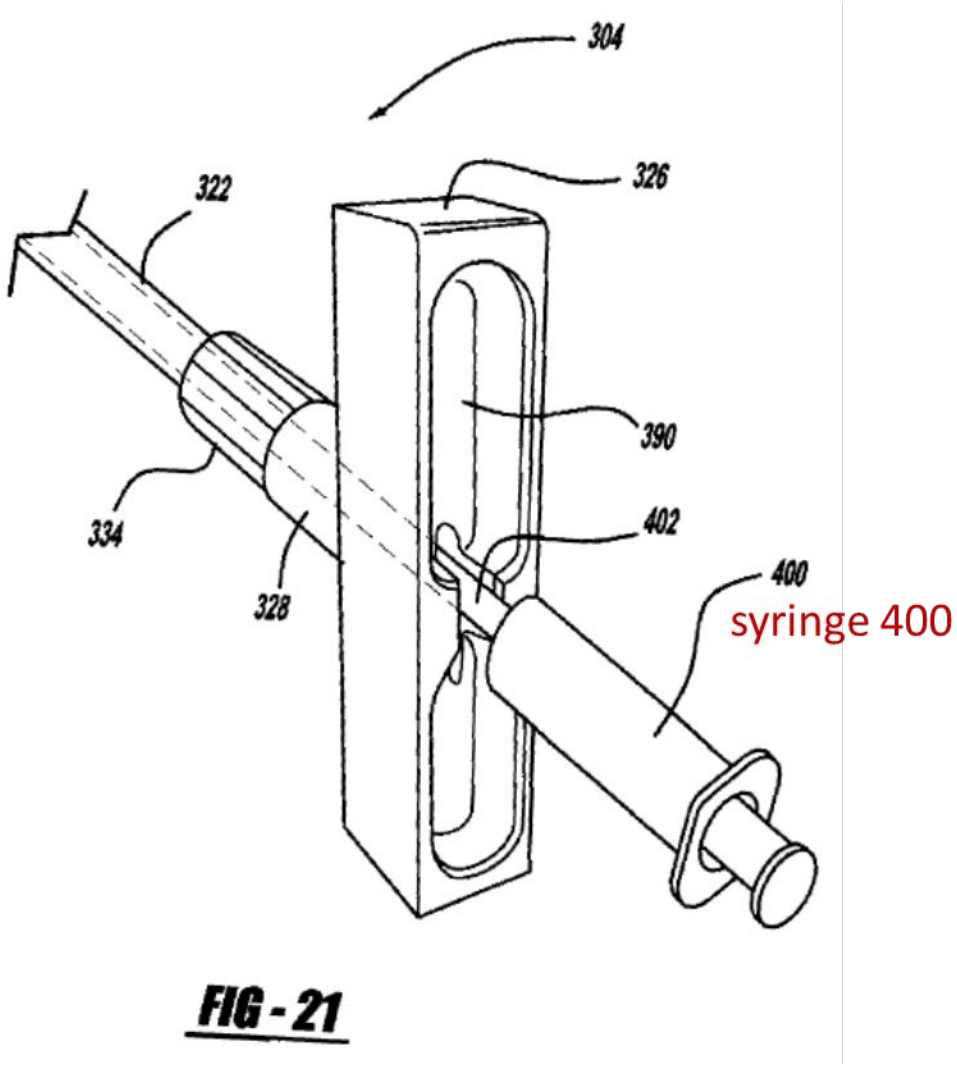
4. Summary of Perez-Cruet

Like Alfaro, Perez-Cruet relates to "[s]pinal fusion" using an interbody spacer, Ex. 1004, ¶¶ [0006] and [0010], and also 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," *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." Ex. 1004, ¶¶ [0034], [0035], [0061], [0062].



Ex. 1004, Figure 20; Ex. 1003, ¶ 149



Ex. 1004, Figure 21; Ex. 1003, ¶ 149

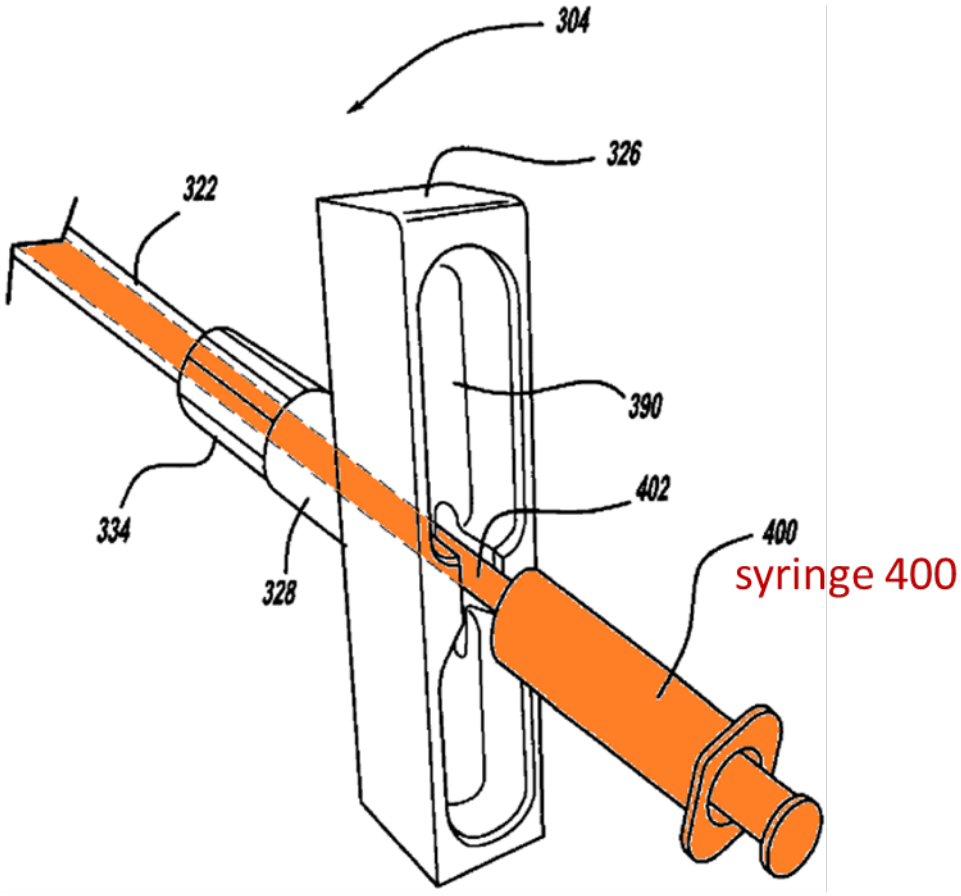
5. Reasons to Combine Alfaro and Perez-Cruet

Perez-Cruet is analogous art to the ’096 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 (“1. Field”); Ex. 1004, ¶¶ [0002] and [0003] (“1. Field of the Invention”); Ex. 1003, ¶ 150.

Alfaro suggests using a “syringe-type system for moving [] biologic material

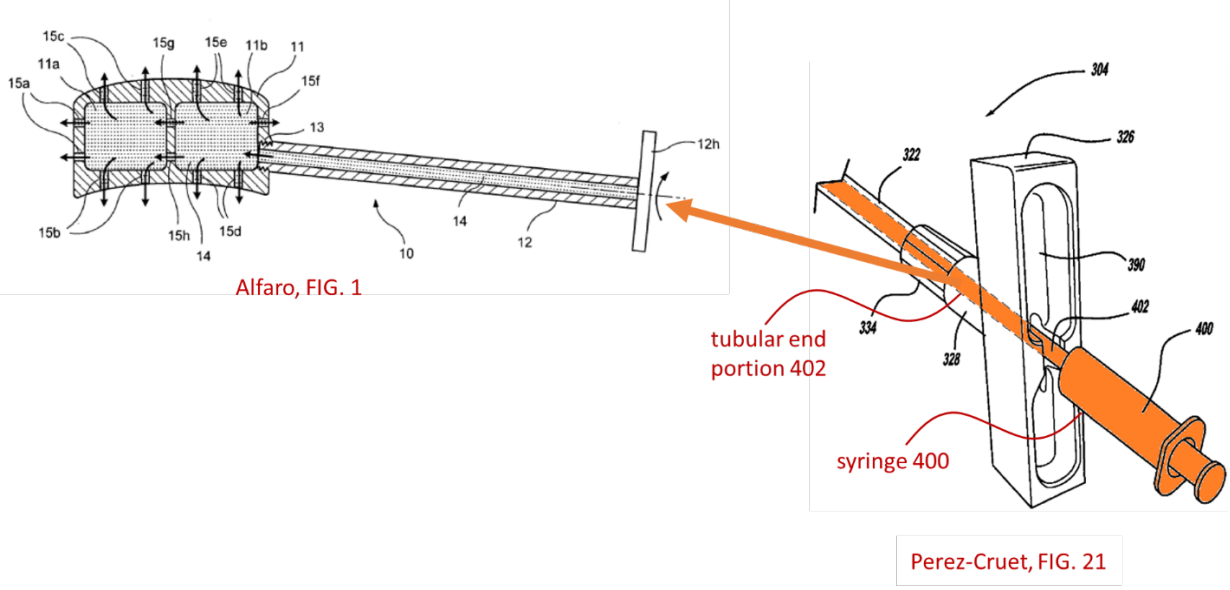
through the handle and into the spacer" and intervertebral space. Ex. 1008, ¶ [0012]; *see also* ¶ [0032]. Alfaro describes different types of handles, with example handles including a "hollow chamber" that can be "engaged and disengaged with the spacer," and prior art "syringes" that "can be adapted" for use with such handles. *Id*., ¶ [0021]; Ex. 1003, ¶ 151.

While Alfaro discloses using syringes to deliver biologic material into 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 to learn how to implement Alfaro's disclosed syringes. 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, ¶ 152.



Ex. 1004, Figure 21; Ex. 1003, ¶ 152

The syringe 400 of Perez-Cruet delivers graft material to an implanted spacer. When used 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 would fit within an exemplary Alfaro handle 12 is illustrated below. Ex. 1003, ¶¶ 153-154.



Sherman, Figure 1; Ex. 1003, ¶ 153

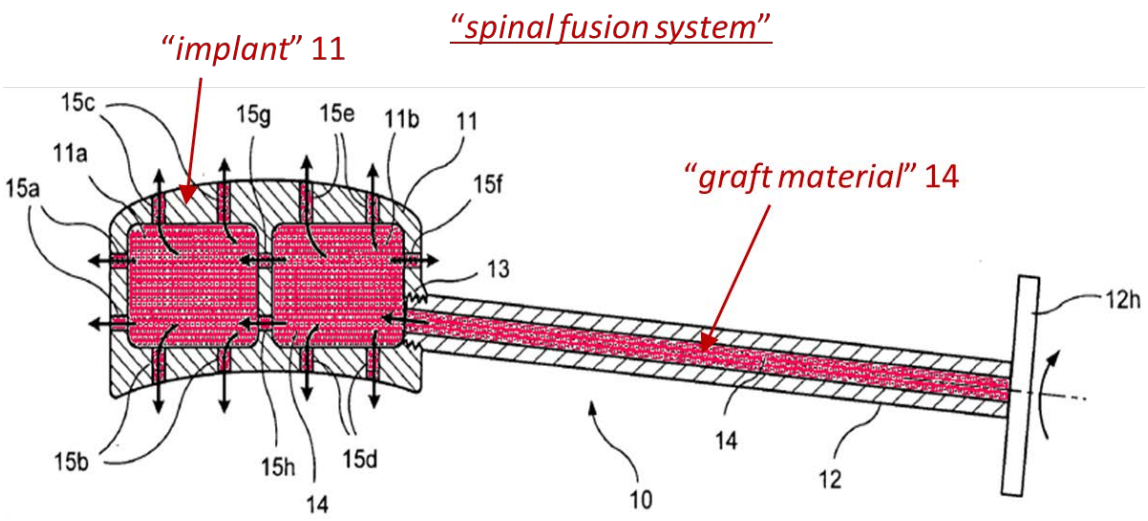
A POSITA would have been motivated to use Perez-Cruet's syringe assembly. For example, it was well known that biologic graft material is commonly provided to a surgeon in the form of a pre-loaded syringe. Ex. 1003, ¶ 155 (citing Ex. 1014). And a syringe was commonly used for reconstituting bone powder and thereafter injecting the reconstituted graft material into a spinal implant. *Id*. (citing Ex. 1015). Alternatively, the pre-loaded syringe may be conveniently manufactured and packaged for transport or delivery to a surgical facility. *Id*. (citing Ex. 1016). As a result, it was obvious to yield predictable and beneficial results and benefits to use the syringe 400 of Perez-Cruet with Alfaro's spacer and handle for convenience, 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. *Id*.

6. Claim 1

a) [1.0] *A spinal fusion system for placing an implant and graft material within a target intervertebral space, the system comprising:*

Alfaro discloses a spacer and a hollow handle that facilitates (1) placing the spacer into the intervertebral space followed by (2) introducing bone graft material into, and around, the spacer. Ex. 1008, ¶ [0011]. An example system is illustrated in Figure 1, reproduced below, including a "spacer 11" attached to a "handle 12" configured for graft material to flow into compartments 11(a) and 11(b) and out into the intervertebral space. *See id.*, ¶ [0029].

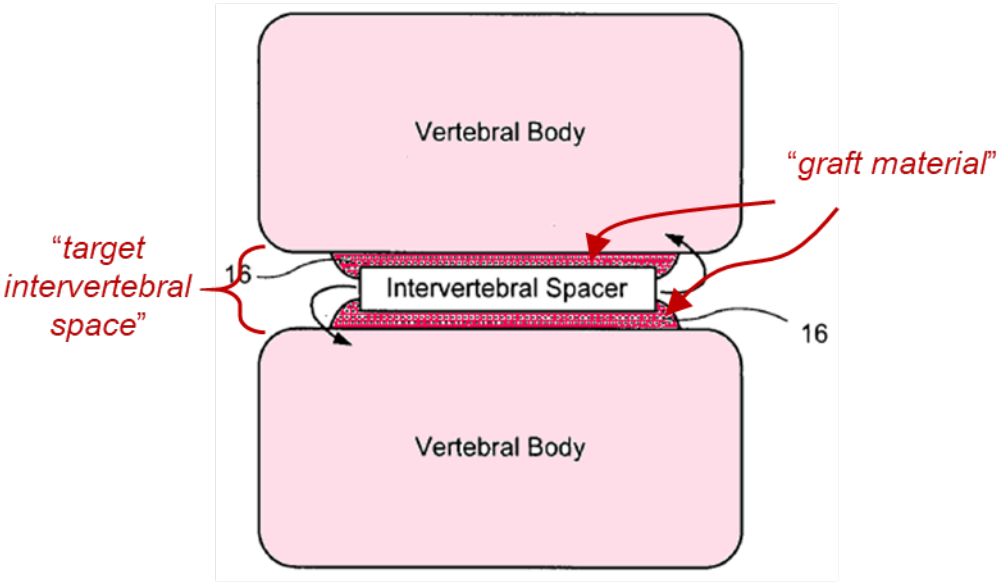


Ex. 1008, Figure 1; Ex. 1003, ¶ 159

Figure 6 is a simplified rendering of an intervertebral spacer positioned between vertebral bodies illustrating graft material flowing out of surfaces of the implant adjacent to vertebral bodies. Alfaro explains that:

> Once the DBM[2] 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.

Ex. 1008, ¶ [0031]. "[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**." *Id*.



Ex. 1008, Figure 6; Ex. 1003, ¶ 160

In summary, Alfaro's discloses a hollow handle that inserts a spacer between adjacent vertebrae and facilitates delivery of graft material to the spacer to effectuate spinal fusion, thereby disclosing [1.0]. Ex. 1003, ¶¶ 157-161.

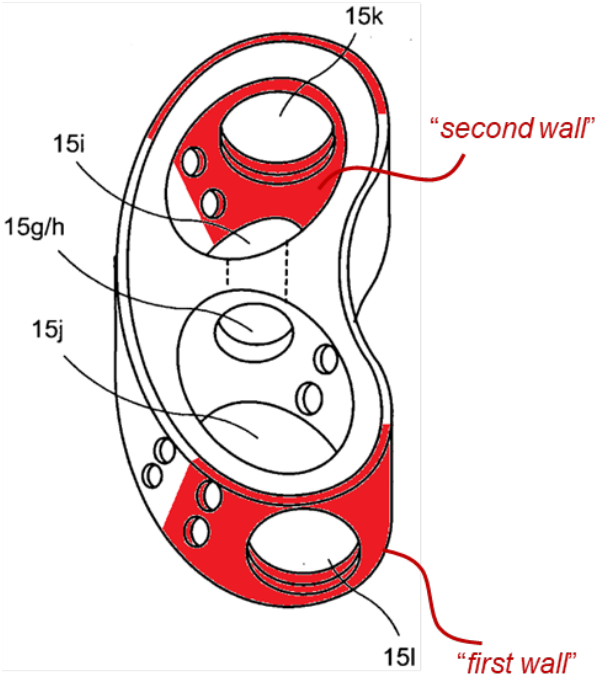
[2] DBM, or demineralized bone matrix, is an example grafting material. Ex. 1003, ¶ 131.

b) [1.1.1] ***an implant comprising: a first wall and a second wall, the second wall being generally opposite of the first wall;***

Alfaro discloses [1.1.1].

Alfaro discloses two embodiments of shapes of a spacer – (1) illustrated in Figures 1 and 2; and (2) illustrated in Figures 8 and 9. Ex. 1008, ¶¶ [0029], [0039]. Both embodiments disclose a "*first wall*" and a "*second wall*" as claimed[3]. Figure 9, reproduced below, is a three-dimensional perspective view of a spacer, having two compartments adapted to contain biologic material. *Id*., ¶ [0039]; Ex. 1003, ¶¶ 163-165.

[3] Alfaro's implants illustrated in the figures have two compartments, similar to Figures 19 and 20 of the '096 Patent.



Ex. 1008, Figure 9; Ex. 1003, ¶ 165

Figure 2, reproduced below, is a "plan view" of the spacer "in place in the anatomy of a patient," and a POSITA would have understood that the spacer has a three-dimensional shape and that what is shown is a cross-section. The spacer 11 is described as having "open compartments 11(a) and 11(b)" that "are adapted to contain DBM or any other suitable biologic." Ex. 1008, ¶ [0029]. Thus, these compartments have a volume and are understood to include walls having "tunnels 15(a), (b), (c), (d), (e) and (f)." *Id*.; Ex. 1003, ¶ 166.

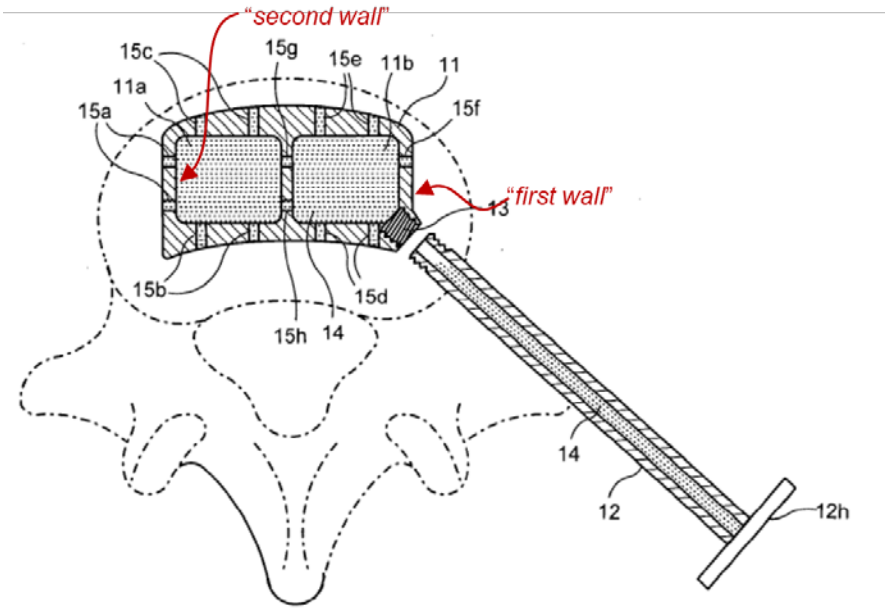


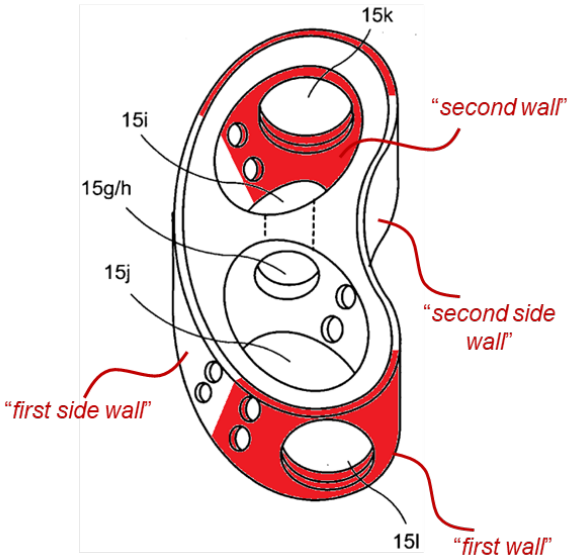
FIG. 2

Ex. 1008, Figure 2; Ex. 1003, ¶ 166

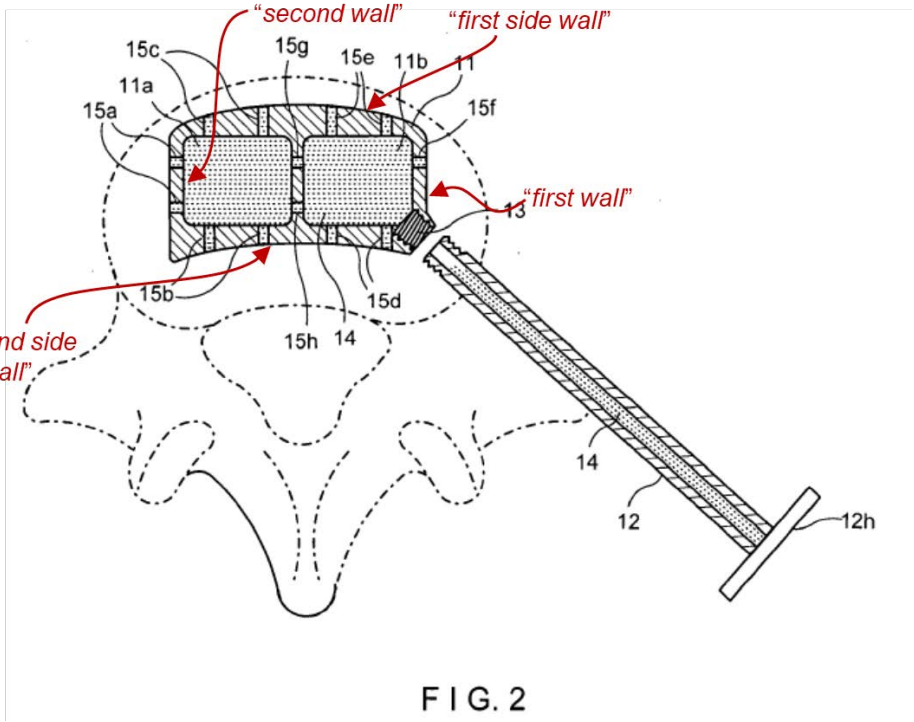
Accordingly, each of the shapes of Alfaro's spacers in Figures 2 and 9 (and associated description) presents an example of [1.1.1]. Ex. 1003, ¶¶ 162-166.

c) [1.1.2] ***[the implant comprising:] first and second side walls configured to extend between the first wall and the second wall;***

Alfaro's Figures 2 and 9, discussed above in [1.1.1], are presented again here. For reasons presented in the analysis of [1.1.1], each of the spacers in Figures 2 and 9 disclose the side walls of [1.1.2]. Ex. 1003, ¶ 168.



Ex. 1008, Figure 9; Ex. 1003, ¶ 168



F I G. 2

Ex. 1008, Figure 2; Ex. 1003, ¶ 168

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

configured to at least partially engage an upper surface of a second vertebral body, the second vertebral body being adjacent to the first vertebral body

Alfaro renders obvious [1.1.3]. Alfaro combined with Frey also renders obvious [1.1.3].

Alfaro generally discloses spacers having various shapes (e.g., "rectangular" or "curvilinear" shapes), one or two compartments, and "top and bottom surface[s]." Ex. 1008, ¶ [0020]. One such spacer that is a "curvilinear" shape 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. *Id*.

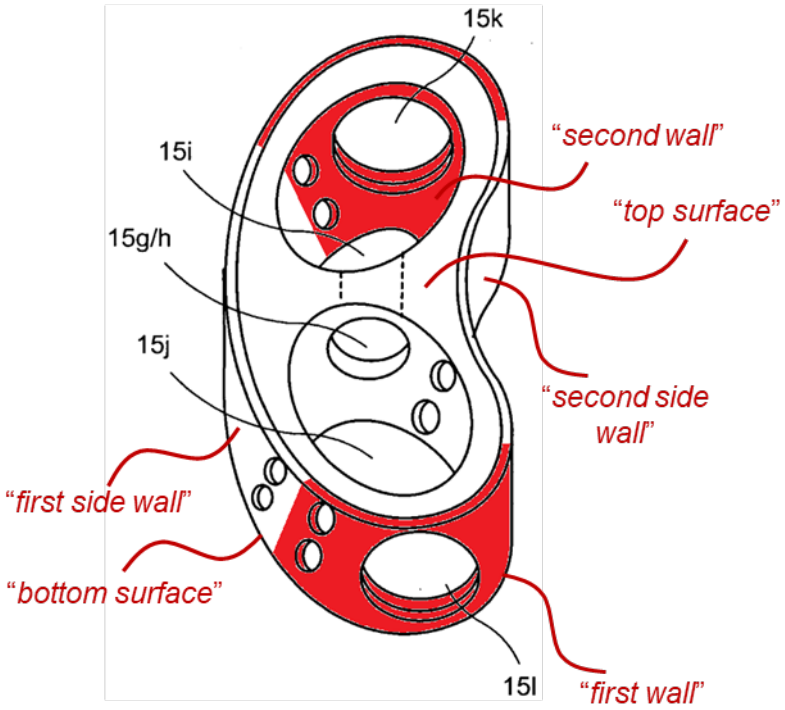
Alfaro further teaches that:

> One particular modality is to introduce a solid material into the vertebral space following a surgical discectomy. The 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., ¶ [0005]; Ex. 1003, ¶ 170-171.

As shown in Figure 9, the "solid material" is illustrated in the form of the intervertebral spacer (i.e., the "*implant*"). *See* Ex. 1008, ¶ [0039]. Due to the "pressure-fit" of Alfaro's spacer into place between the opposing vertebral bodies, Alfaro's top and bottom surfaces are configured to engage endplates of a first and

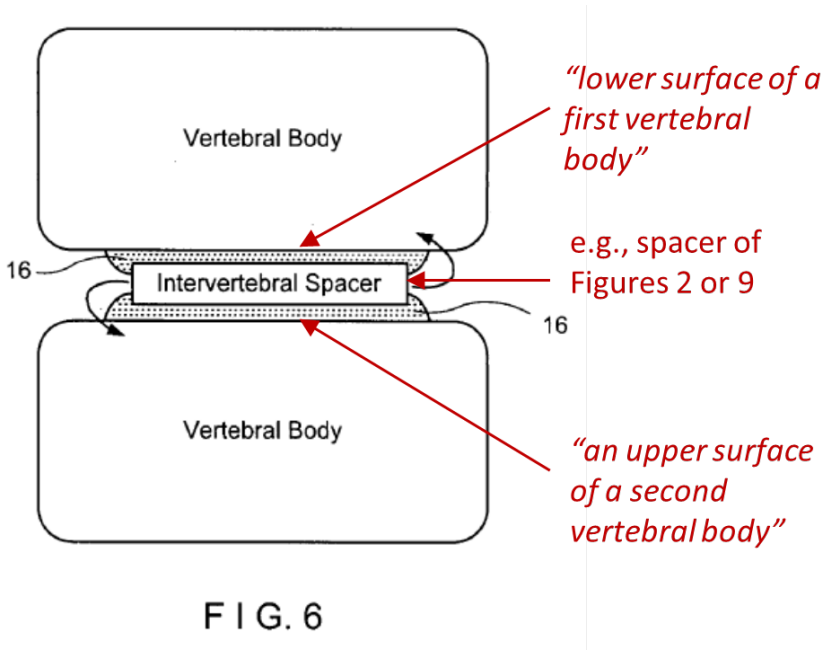
second vertebrae, respectively, thereby disclosing [1.1.3].



Alfaro, Figure 9; Ex. 1003, ¶ 172

The spacer of Figure 2 also has a "*top surface*" and a "*bottom surface*" configured to engage adjacent vertebrae for the same reasons. Ex. 1003, ¶ 172.

Figure 6 illustrates the spacer positioned between vertebrae within the spine of the patient. After the spacer is positioned and DBM is forced into the interior and out through compartments, the spacer "remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031]. Figure 6 is a simplified view – the spacer "remains in place" due to some contact with the vertebrae (the contact is obscured by the DBM in the figure.



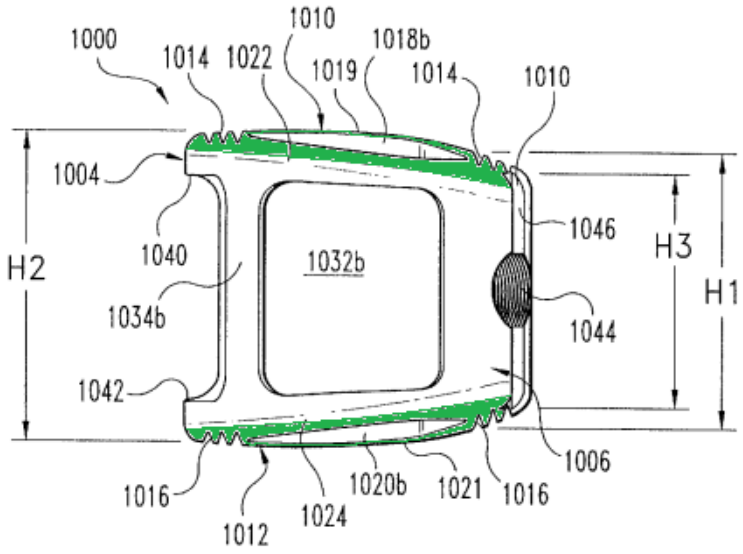
F I G. 6

Alfaro, Figure 6; Ex. 1003, ¶ 173

Thus, Alfaro's disclosure of spacers having top and bottom surfaces that are "pressure-fit into place between the opposing vertebral bodies so as to fix the device in place" discloses [1.1.3]. Ex. 1003, ¶ 174.

In addition, Alfaro combined with Frey renders obvious [1.1.3].

Frey teaches an implant 1000 akin to the intervertebral spacer of Alfaro, and further including 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; 20:6-11. Figure 54 illustrates the implant 1000.



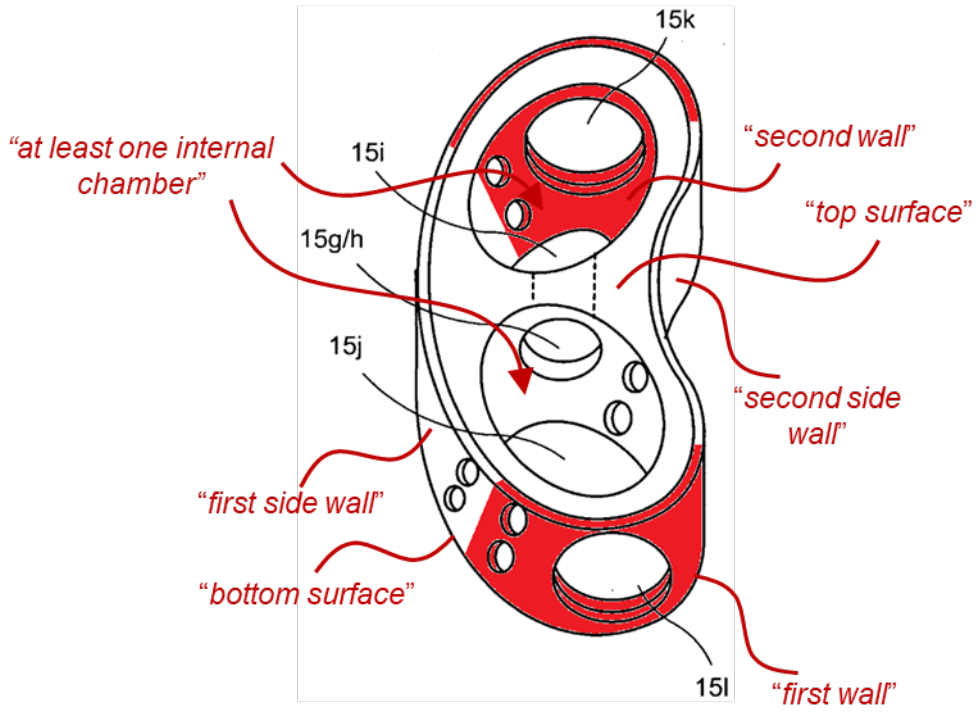
Ex. 1005, Figure 54; Ex. 1003, ¶ 176

It was obvious to modify the top and bottom surfaces of Alfaro's intervertebral spacer to include Frey's grooves 1014 and 1016, respectively, to better resist migration of the intervertebral spacer in the intervertebral space to ensure that Alfaro's implant "remains in place at the correct site between the vertebrae," per Alfaro's teaching. Ex. 1008, ¶ [0031]. The top and bottom surfaces of Alfaro's intervertebral spacer (as modified to include Frey's grooves) more securely engage the endplates of the first and second vertebrae, respectively, thereby rendering obvious [1.1.3]. Ex. 1003, ¶¶ 175-178.

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

Alfaro discloses [1.1.4].

Alfaro discloses spacers in Figures 2 and 9 having "compartments," examples of the claimed "*internal chambers*." Referring to Figures 1 and 2 (and also Figures 8 and 9 because of the same numbering of elements), Alfaro describes "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)." Ex. 1008, ¶ [0029]. Figure 9, reproduced below, shows that the compartments extend from the top surface to the bottom surface. (The compartments shown in the cross-section of Figure 2 extend from the top surface to the bottom surface for the same reasons.) Ex. 1003, ¶ 180.



Ex. 1008, Figure 9; Ex. 1003, ¶ 180

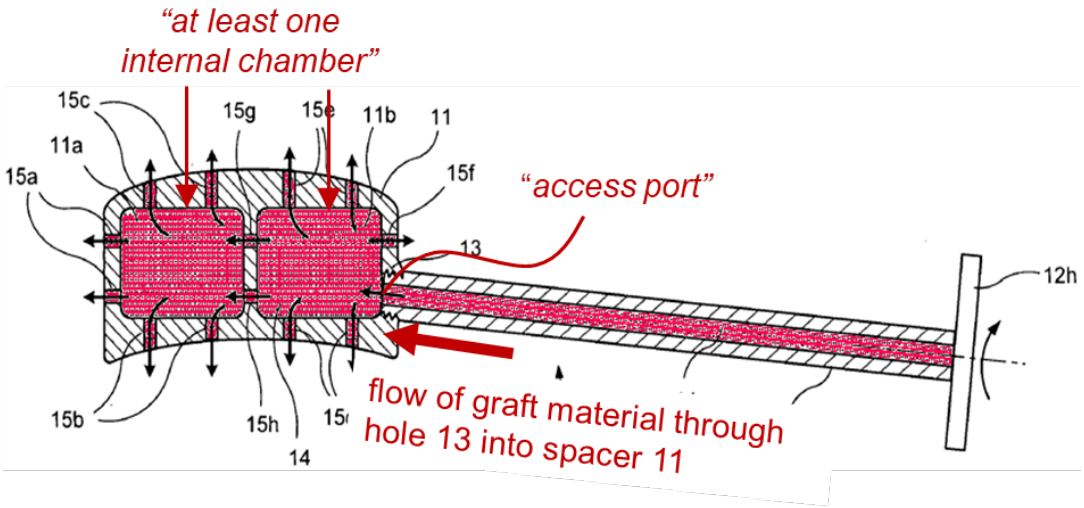
Therefore, Alfaro's spacers with compartments open at the top and bottom

of these spacers (e.g., illustrated in Figures 2 and 9) are examples of [1.1.4]. *Id*.

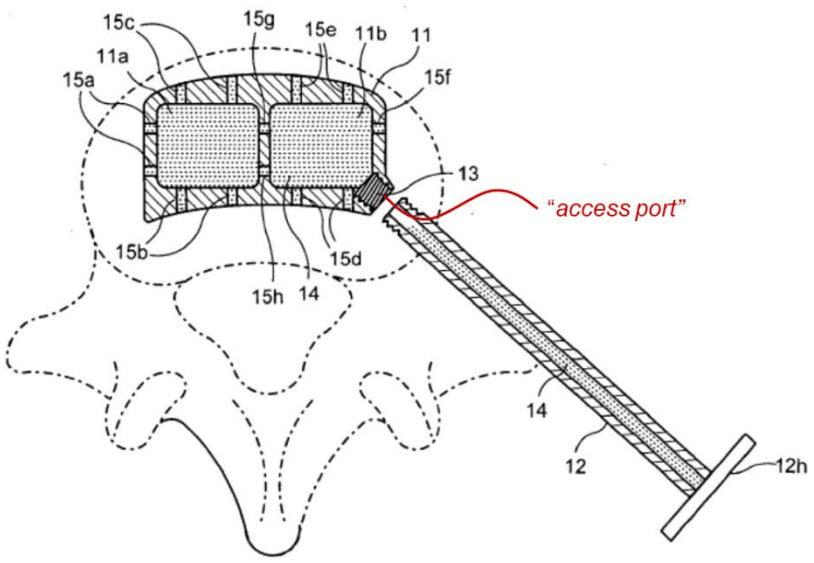
f) [1.1.5] ***[the implant comprising:] an access port extending through the first wall and being in fluid communication with the at least one internal chamber;***

Alfaro discloses [1.1.5].

Alfaro discloses spacers having screw holes to allow for flow of biologic material from a handle into the spacer. *See, e.g.*, Ex. 1008, ¶ [0029] ("Handle 12 is shown screwed into compartment 11(b) at [screw hole] 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.") Screw holes illustrated in Figures 1 and 2 (reproduced below) and Figures 8 and 9 each exemplify an "*access port*."



Ex. 1008, Figure 1; Ex. 1003, ¶ 182



F I G. 2

Ex. 1008, Figure 2; Ex. 1003, ¶ 182

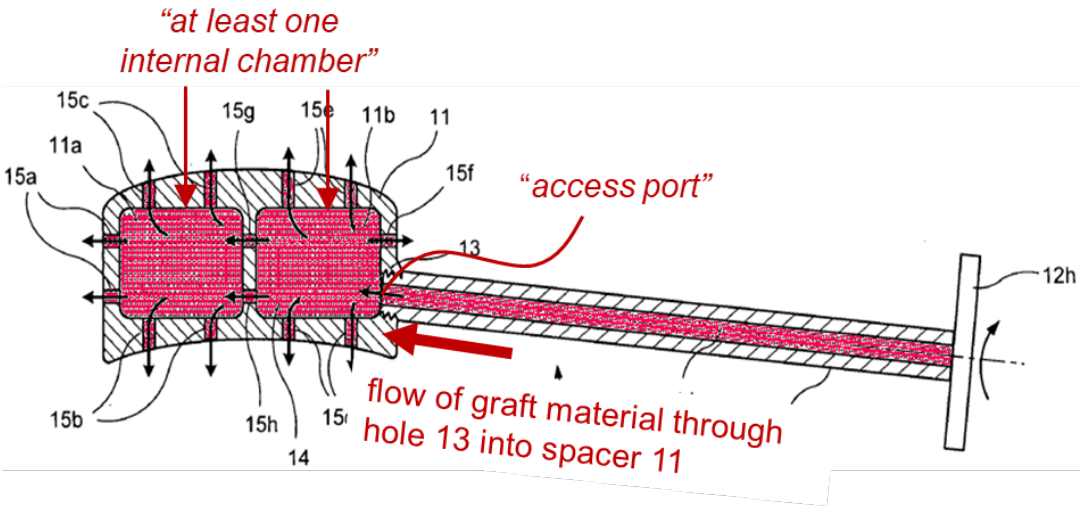
In summary, Alfaro's spacers having a screw hole through which to deliver graft material to implant compartments via a handle discloses [1.1.5]. Ex. 1003, ¶¶ 181-183.

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

Alfaro discloses [1.1.6].

As explained above, Alfaro's spacers include a screw hole, 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*." Alfaro's screw hole in the spacer provides access to compartments 11(a) and 11(b) so that DBM or other

biologic material can be "forced into the interior spacer compartment(s)" as shown in Figure 2 and "into the vertebral spaces" as shown in Figure 6. Ex. 1008, ¶¶ [0030]-[0031].



Ex. 1008, Figure 2; Ex. 1003, ¶ 186

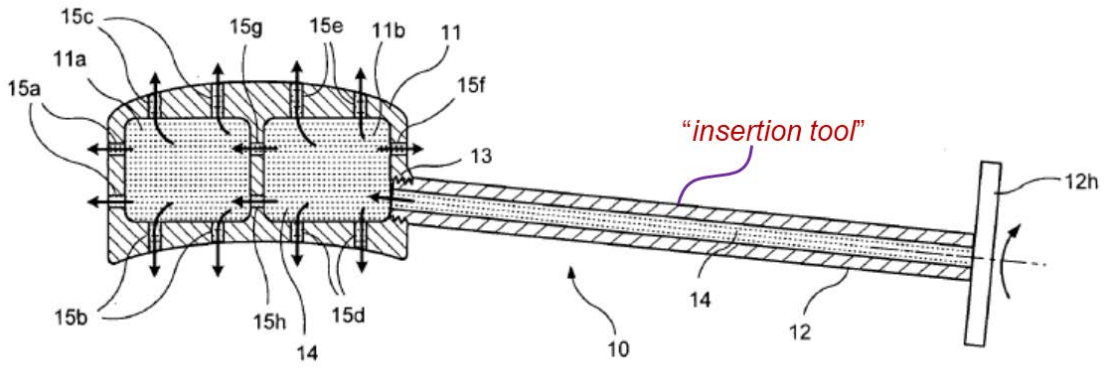
By disclosing DBM flowing through hole 13 and compartments and into the intervertebral spaces shown in Figures 2 and 6, Alfaro discloses that at least one of the compartments 11(a) and 11(b) is filled, thereby disclosing an example of [1.1.6]. Ex. 1003, ¶¶ 184-187.

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

Alfaro discloses [1.2].

Alfaro discloses a handle used as an "*implant insertion tool*": "In practice, the spacer is **inserted surgically into the vertebral space and properly positioned therein using the handle as the inserter**." Ex. 1008, ¶ [0019]; *see also id.*, ¶ [0021] ("The detachable or disengageable **handle acts as an inserter of the**

spacer and comprises a hollow chamber to accommodate the biologic material to be added into the spacer.") Figures 1 and 2, reproduced below, illustrate the handle used as an insertion tool, and Figures 2 and 6 illustrate a spacer 11 in a target intervertebral space after being inserted with a handle 12. Ex. 1003, ¶¶ 189-190*.



Ex. 1008, Figure 1; Ex. 1003, ¶ 190

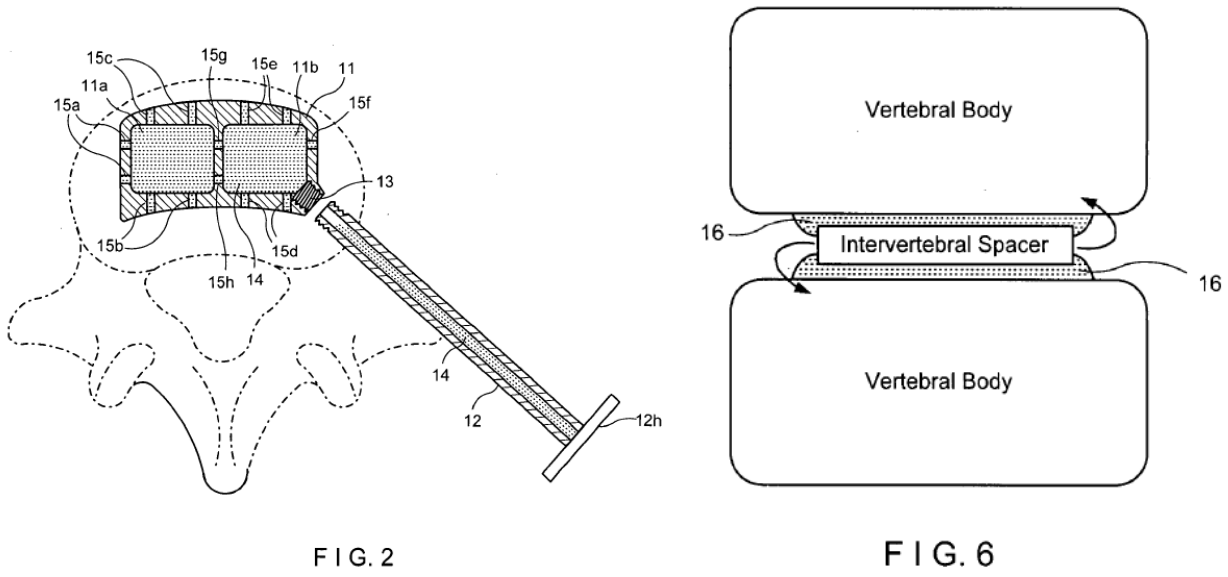


FIG. 2 FIG. 6

Ex. 1008, Figures 2 and 6

Thus, Alfaro discloses a handle coupled to a spacer to insert and position the

spacer surgically into a target space between vertebrae, which is an example of [1.2]. Ex. 1003, ¶¶ 188-192.

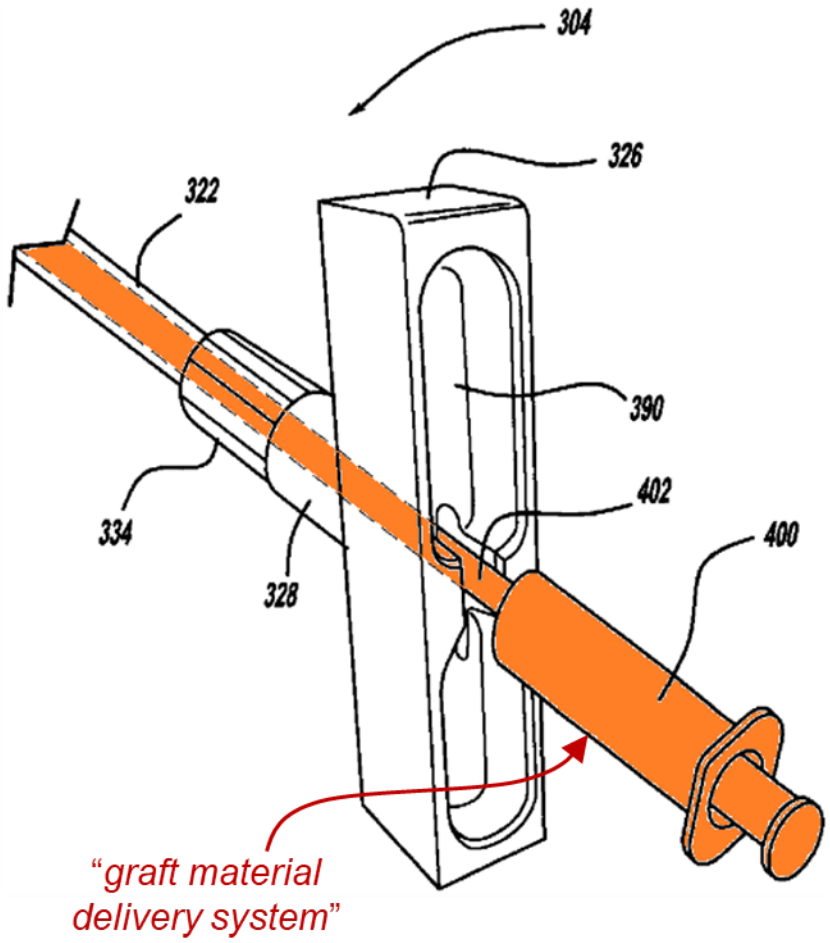
i) **[1.3]** ***(iii) a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit;***

Alfaro combined with Perez-Cruet renders obvious [1.3].

Alfaro suggests using a "syringe-type system" to move graft material through a handle and into the intervertebral space. Ex. 1008, ¶ [0012] ("spacer… needs only to be attachable and detachable to **a handle** capable of containing a … **syringe-type of system** for moving the biologic material through the handle and into the spacer."); *see also id*. ¶ [0032]. Alfaro generally describes different types of handles, including handles with a "hollow chamber" that can be "engaged and disengaged with the spacer." *Id*., ¶ [0021].

Alfaro does not explicitly disclose how its disclosed syringes would connect to Alfaro's hollow handle for delivering biologic material. But Perez-Cruet explicitly discloses such a system. Perez-Cruet illustrates an 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]. The instrument 304 shown in Figure 21, reproduced below, is used "for positioning the interbody device 302, and delivering bone graft

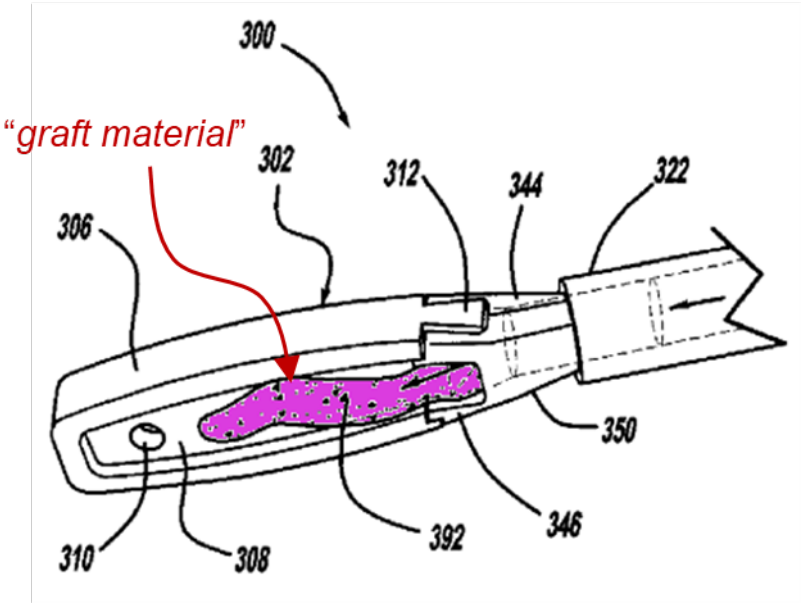
material to the disc space between vertebrae once the interbody device 302 is in the proper position." *Id*., ¶ [0055]; Ex. 1003, ¶¶ 194-196.



Ex. 1004, Figure 21; Ex. 1003, ¶ 195

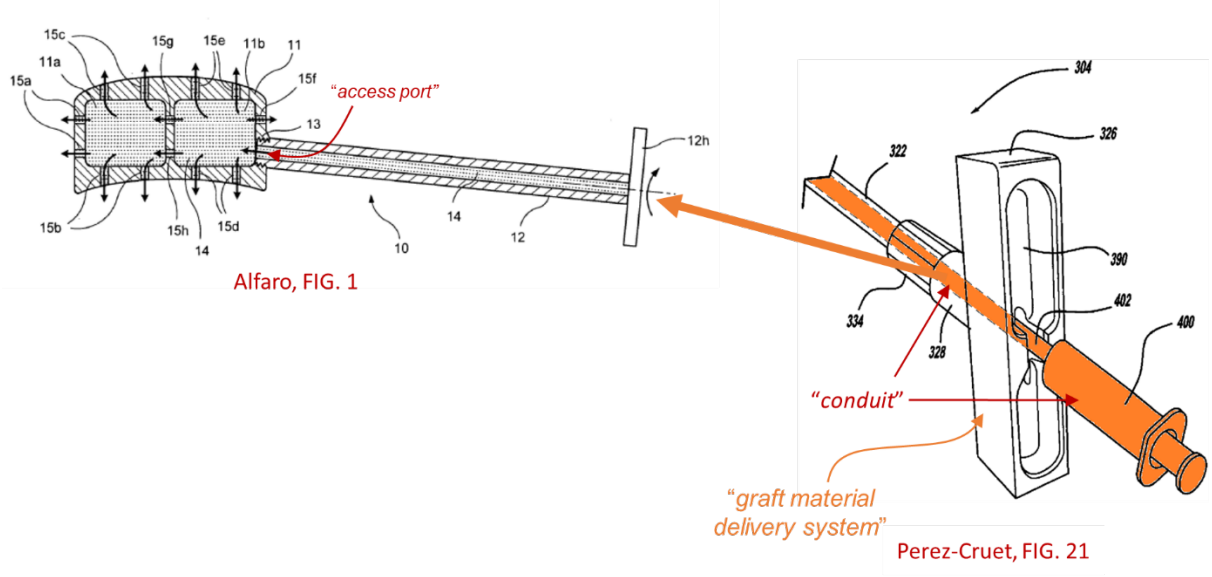
In Figure 20, Perez-Cruet illustrates "bone graft material 392 [being] delivered down the instrument 304 in any suitable manner," such as, for example, "through the instrument 304 using [the] syringe 400 having [the] extended tubular end portion 402." Ex. 1004, ¶ [0062]. When used with Alfaro's handle, Perez-Cruet's syringe "*deliver[s] a volume of 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 handle 12, thereby rendering obvious [1.3]. Ex. 1003, ¶¶ 197-198.



Ex. 1004, Figure 20; Ex. 1003, ¶ 197

An illustration of where Perez-Cruet's syringe 400 and associated extended tubular end portion 402 would fit within an exemplary Alfaro handle 12 is shown below. The syringe 400 and associated extended tubular end portion 402 is an example of the structure corresponding to the function for the claim term of "*a syringe attached to a conduit*," and also "*a plunger configured to displace graft material within a conduit*." *See* Section VI.A (Claim Construction). As shown, Perez-Cruet's instrument 304 includes a reduced-diameter portion of a conduit (the extended tubular end portion 402) extending from an enlarged-diameter portion (the syringe barrel). Ex. 1003, ¶ 199.



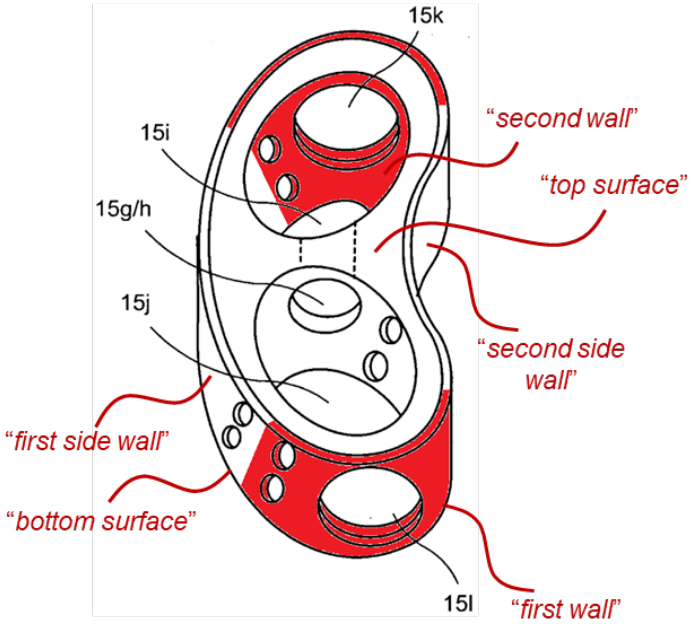
Sherman, Figure 2; Ex. 1003, ¶ 199

For reasons presented in Section IX.A.5, it was obvious to use the syringe 400 of Perez-Cruet with Alfaro's spacer and handle (1) for convenience (since the biologic material already exists in a syringe) and (2) to direct graft material into the compartment 11b of Alfaro's intervertebral spacer (an example of "*delivering a volume* of *graft material into the at least one internal chamber*") by positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's cannulated handle 12, as recited by claim element [1.3]. Ex. 1003, ¶ 200.

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

Alfaro discloses [1.4]. Alfaro combined with Frey also renders obvious [1.4].

Alfaro teaches 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]. Figure 9, for example, illustrates the compartments 11a and 11b extending from a top surface to a bottom surface of the intervertebral spacer.

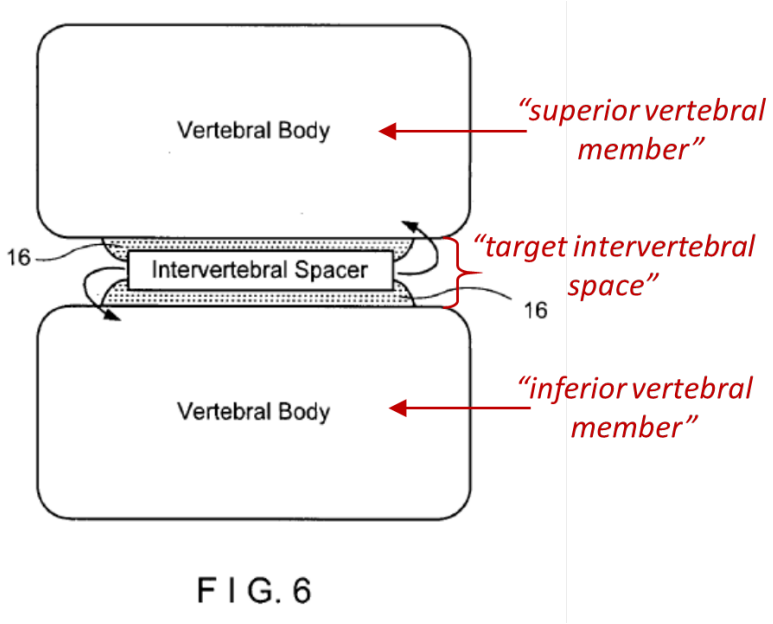


Ex. 1008, Figure 9; Ex. 1003, ¶ 202

Alfaro further teaches that its implants are "**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." Ex. 1008, ¶ [0005]. Figure 9 illustrates this "solid material" in the form of the intervertebral spacer (i.e., the "*implant*"),

according to a "preferred embodiment." *See id.*, ¶ [0039]. Due to the "pressure-fit" of Alfaro's intervertebral spacer into place between the opposing vertebral bodies, the spacer's top and bottom surfaces are configured to engage the endplates of the first and second vertebrae, respectively. Ex. 1003, ¶¶ 203-204.

Alfaro also illustrates the spacer positioned in the correct location of the patient, that is, within the spine of the patient in Figure 6. After the spacer is positioned and DBM is forced into the interior and out through compartments, the spacer "remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031]. Figure 6 is a simplified view – the spacer "remains in place" due to contact with the vertebrae on the top and bottom surfaces.



F I G. 6

Ex. 1008, Figure 6; Ex. 1003, ¶ 205

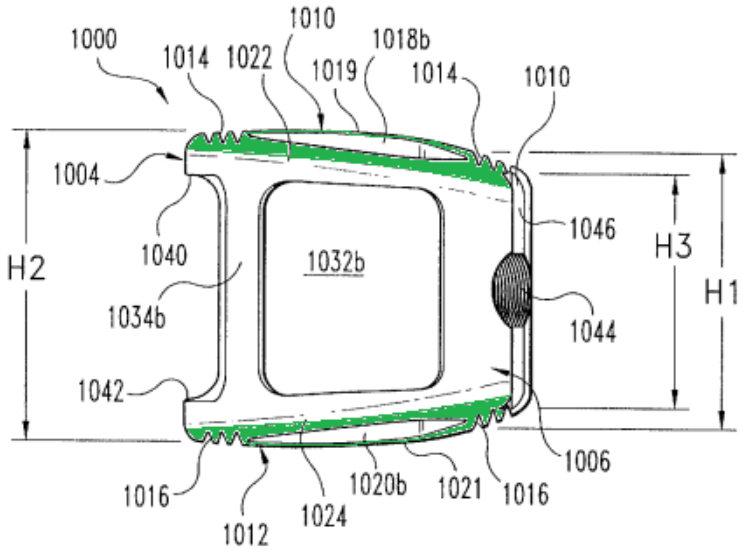
Thus, a POSITA understood that the "*first and second walls and the first*

and second sidewalls" of Alfaro's spacer "*extend between superior and inferior vertebral members adjacent the target intervertebral space*" so that the top and bottom surfaces will contact the vertebrae. Ex. 1003, ¶ 206.

Claim element [1.4] is also obvious over Alfaro combined with Frey.

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, for engaging vertebral endplates to resist migration of the implant 1000 in the disc space. Ex. 1005, 19:50-52; 20:6-11.

Figure 54, below, 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. Figure 56 (a perspective view of the implant 1000) is also presented below.



Ex. 1005, Figure 54; Ex. 1003, ¶ 208

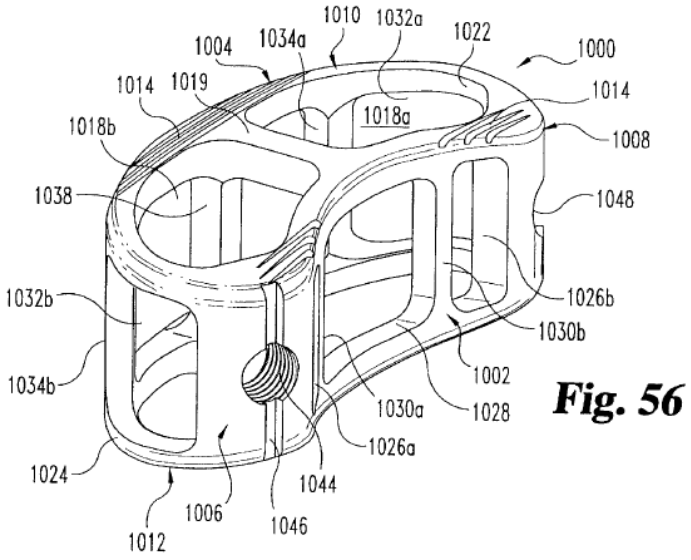


Fig. 56

Ex. 1005, Figure 56

It was obvious to modify the top and bottom surfaces of Alfaro's intervertebral spacer to include Frey's grooves 1014 and 1016, respectively, to prevent the intervertebral spacer from migrating in the intervertebral space to ensure that the spacer achieves Alfaro's teaching that the spacer "remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031]. The top and bottom

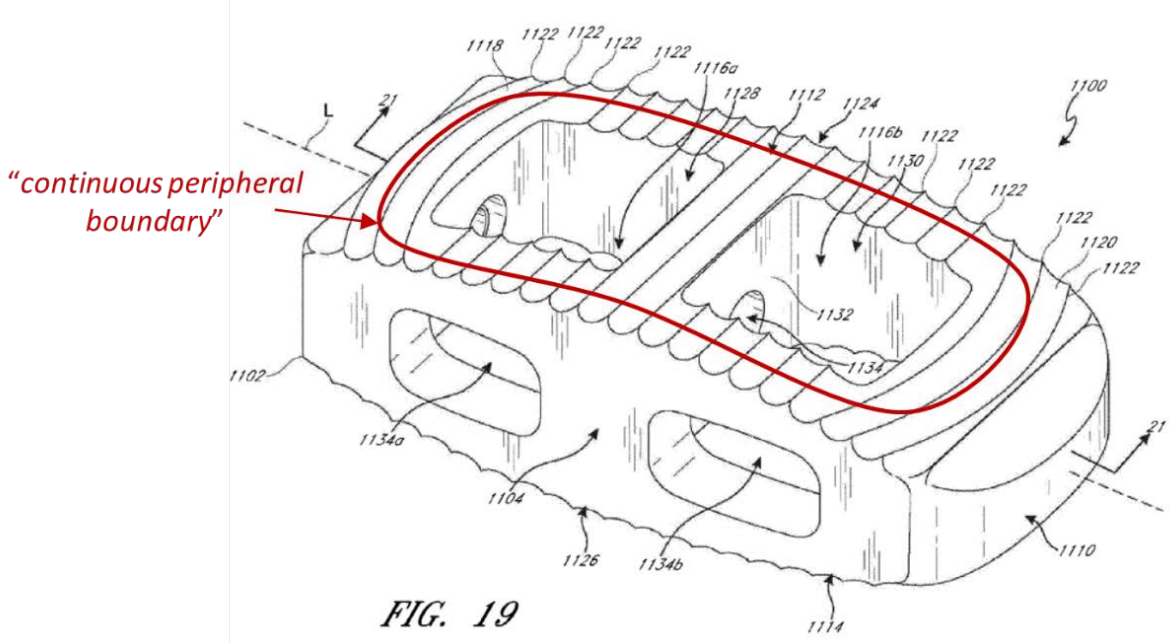
surfaces of Alfaro's intervertebral spacer, as modified to include Frey's grooves 1014 and 1016, respectively, more securely engage the endplates of adjacent vertebrae. Ex. 1003, ¶ 209.

In summary, the top and bottom surfaces of Alfaro's spacers, modified to include Frey's grooves to securely engage adjacent vertebrae, and pressure-fit into place between adjacent vertebrae, renders obvious [1.4]. *Id*., ¶ 210.

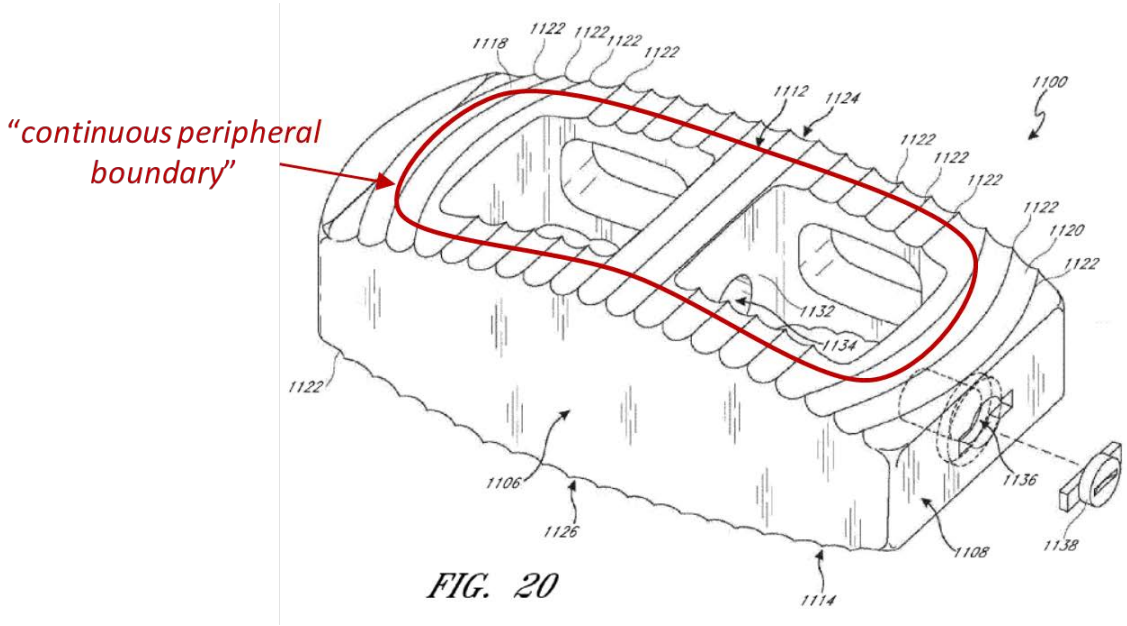
k) [1.5.1] *wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the at least one chamber upon implantation into the target intervertebral space*

Alfaro discloses [1.5.1].

First, the term "*continuous peripheral boundary*" is not used in the '096 Patent specification. Rather, the '096 Patent describes its spacers as having a "generally closed structure" despite having "one or more openings" along "outer sidewalls." Ex. 1001, 10:59-11:2. Figures 19 and 20, reproduced below, illustrate an embodiment in which the implant 1100 comprises a port 1136 and openings 1134a and 1134b extending through the outer walls from the interior chambers 1116a and 1116b. *Id*., 25:38-41 and 26:1-5.



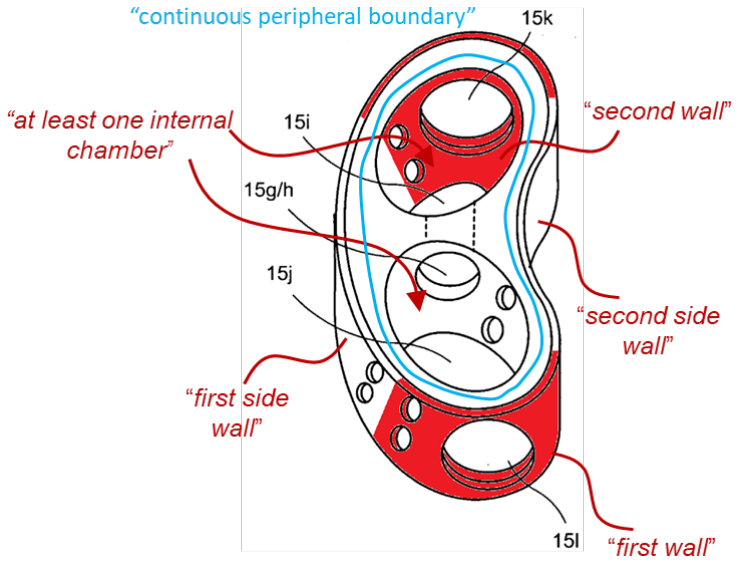
Ex. 1001, Figure 19; Ex. 1003, ¶ 212



Ex. 1001, Figure 20; Ex. 1003, ¶ 212

Thus, the "*continuous peripheral boundary*" of claim element [1.5.1], which is formed by "*the walls and the sidewalls of the implant*," does not preclude an access port or other openings along the outer walls. Ex. 1003, ¶¶ 212-213.

Turning to Alfaro, like Figure 20 of the '096 Patent, the intervertebral spacer in Figure 9 (for example) of Alfaro includes screw holes 15k, 15l and other openings/tunnels in the walls. An outline of a portion of the "*continuous peripheral boundary*" is highlighted.



Ex. 1008, Figure 9; Ex. 1003, ¶ 214

The rectangular spacers 11 in Figures 1 and 2 similarly have such a "*continuous peripheral boundary*" around the compartments.

Thus, each of Alfaro's spacers in Figures 2 and 9 (and associated Figures 1 and 8, respectively) are examples demonstrating claim element [1.5.1]. Ex. 1003, ¶ 215.

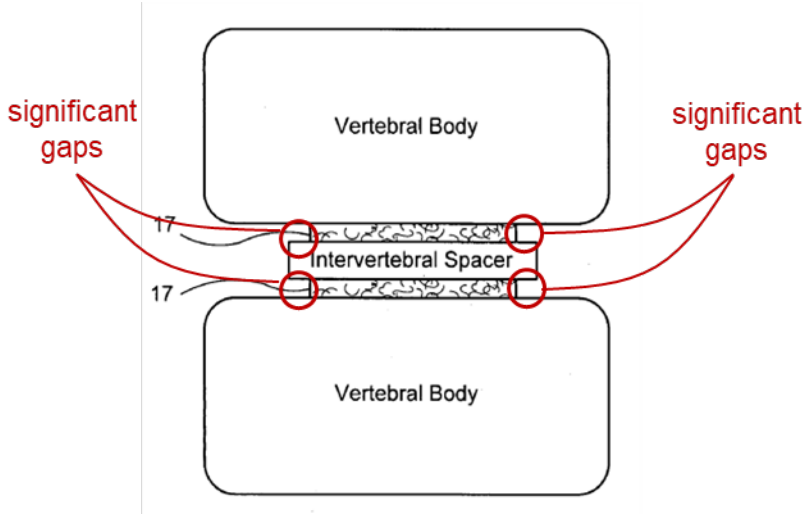
l) [1.5.2] ***such that the at least one chamber contains graft material delivered through the access port, thereby enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.***

Alfaro discloses [1.5.2].

First, the term "*flush contact*" is not used in the '096 Patent specification nor is it a term of art in the field of spinal fusion. Ex. 1003, ¶ 217. But the '096 Patent provides that "excess graft and/or other fill material G can generally fill any gap that exists between the vertebral endplates and the adjacent surfaces of the implant. This can result in improved spinal fusion." Ex. 1001, 24:21-24; *see also* 24:16-20. Thus, the term "*the graft material is in flush contact with adjacent superior and inferior vertebral members*" is understood to include a situation in which gaps that exist between vertebral endplates and adjacent surfaces of the implant are filled with graft material. Ex. 1003, ¶ 217.

Turning to Alfaro and applying this understanding of the claim term, Alfaro teaches 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].

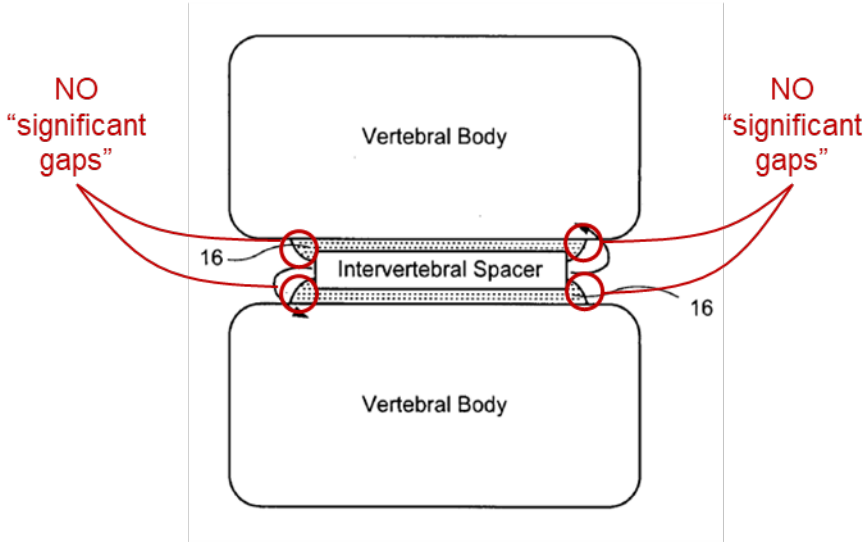


Ex. 1008, Figure 7; Ex. 1003, ¶ 218

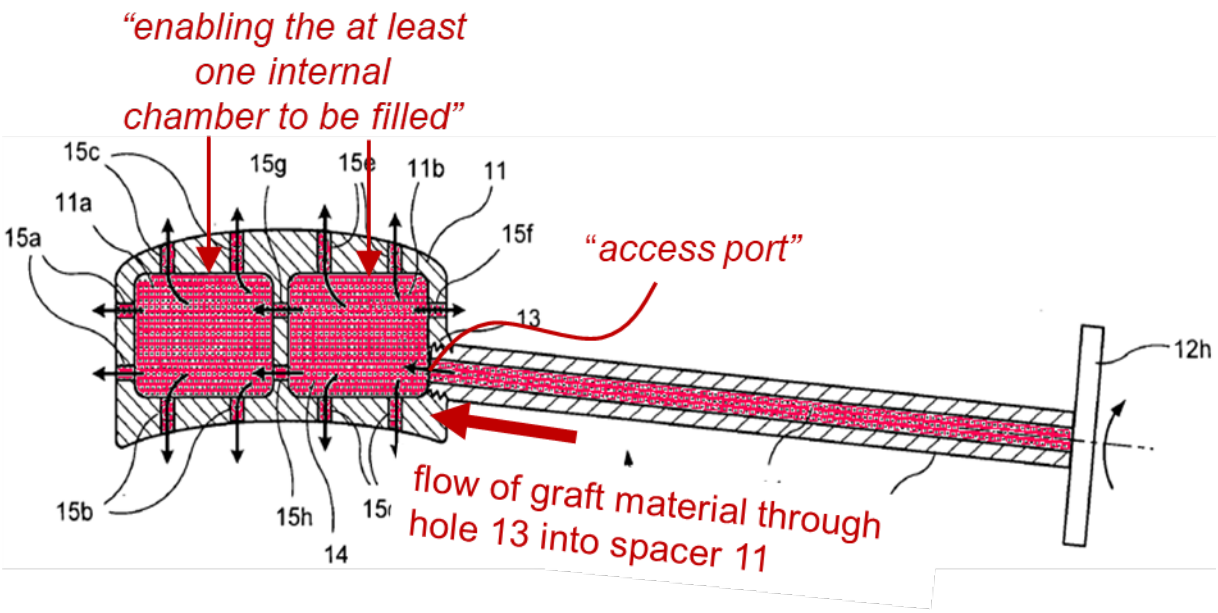
To address the gapping problem, Alfaro provides that, "[i]n the present invention, voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the **virtually complete coverage at the surfaces thereof**, with a suitable biologic product introduced via the unitary device of the invention." *Id*., ¶ [0010]; *see also* ¶ [0019]. Alfaro also provides that "[t]he dimensions of the handle are such that sufficient biologic can be incorporated therein to **fill the compartments and tunnels**, and flow out into the interfaces between the compartments and the vertebrae to provide **substantially complete coverage or coating of the interface surfaces**." *Id*., ¶ [0021].

More specifically, "[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." Ex. 1008, ¶ [0031]. "[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." *Id*.



Ex. 1008, Figure 6; Ex. 1003, ¶ 219



Ex. 1008, Figure 2; Ex. 1003, ¶ 219

In summary, Alfaro teaches a device and associated process in which spacer compartments are filled and gaps between the end plates of the vertebral bodies and the spacer surfaces are also filled by complete coverage at their surfaces, with a suitable biologic product introduced via a hollow handle connected to the spacer via a screw hole ("*access port*"), thereby disclosing [1.5.2]. Ex. 1003, ¶¶ 220-222.

7. Claim 2

a) [2.0] *The system of claim 1,*

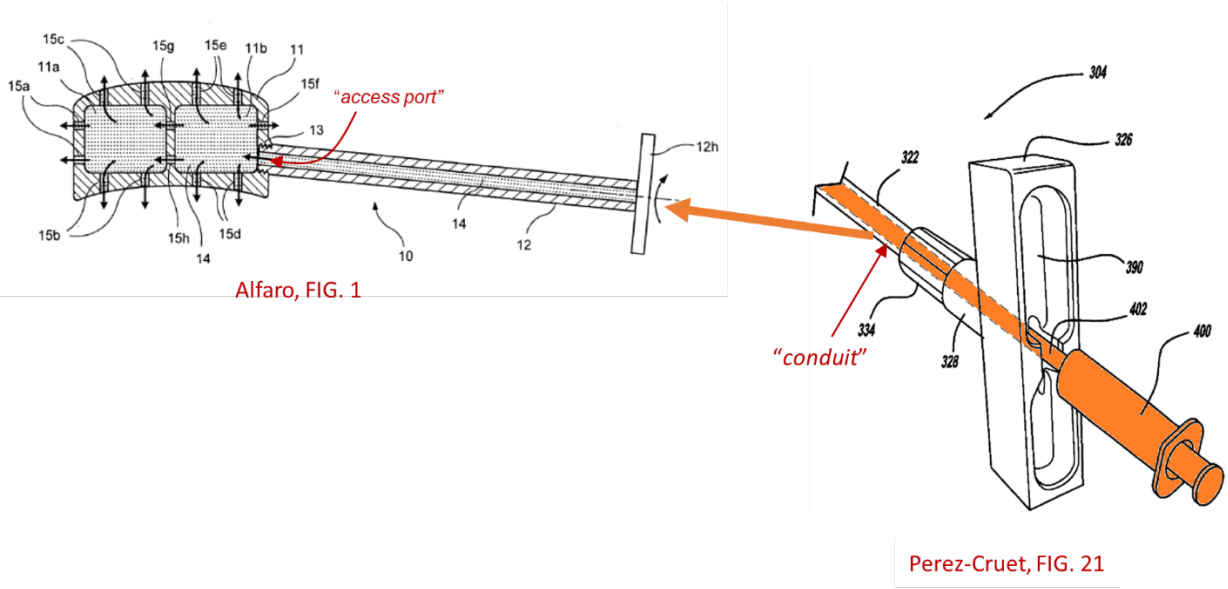
See analysis of claim 1.

b) [2.1] *wherein the conduit is configured to pass through the access port of the implant to position the conduit within the at least one internal chamber of the implant.*

Alfaro combined with Perez-Cruet renders obvious [2.1].

As discussed above with claim element [1.3], Alfaro combined with Perez-

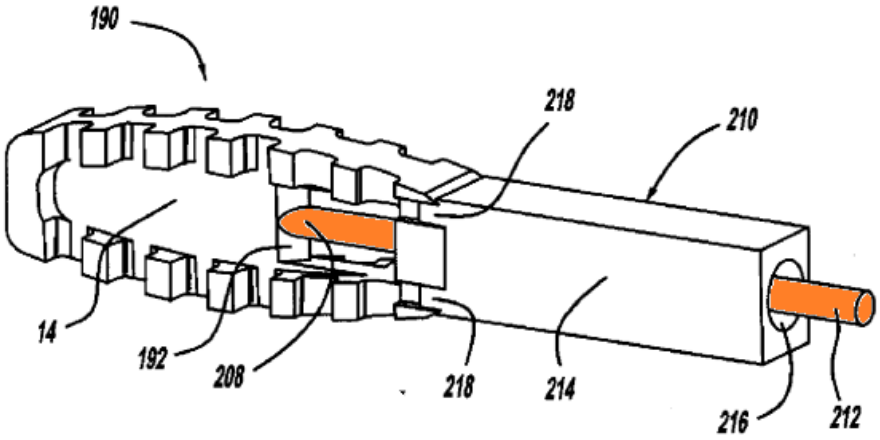
Cruet discloses positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's cannulated handle 12 to direct graft material into the compartments 11a and 11b of Alfaro's intervertebral spacer. The combination is illustrated below.



Sherman, Figure 3; Ex. 1003, ¶ 225

In Figure 11, Perez-Cruet discloses that the delivery conduit 208 is extended beyond the distal end of the insertion instrument 210 and into the interior space of the implant. Perez-Cruet teaches an "interbody device 190 in combination with … 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 192 so that bone graft material forced through the tube 212 is dispersed on both sides of the center plate 14 as discussed above." *Id*. There are only two options for how far to extend the tubular end through the instrument: 1) positioning the tubular

end within the instrument with graft flowing through instrument; or 2) positioning the tubular end beyond the instrument into the implant (as in Figure 11 of Perez-Cruet). Given these two limited options, it would be obvious to try either one to fill the implant. Ex. 1003, ¶ 226.



Ex. 1004, Figure 11 (shaded); Ex. 1003, ¶ 226

Since Perez-Cruet teaches an embodiment in which a fill tube is extended through a bore of an insertion tool so that the end of the fill tube can deliver graft material to the interbody device, 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, which renders obvious claim element [2.1]. Ex. 1003, ¶ 227.

8. Claim 3

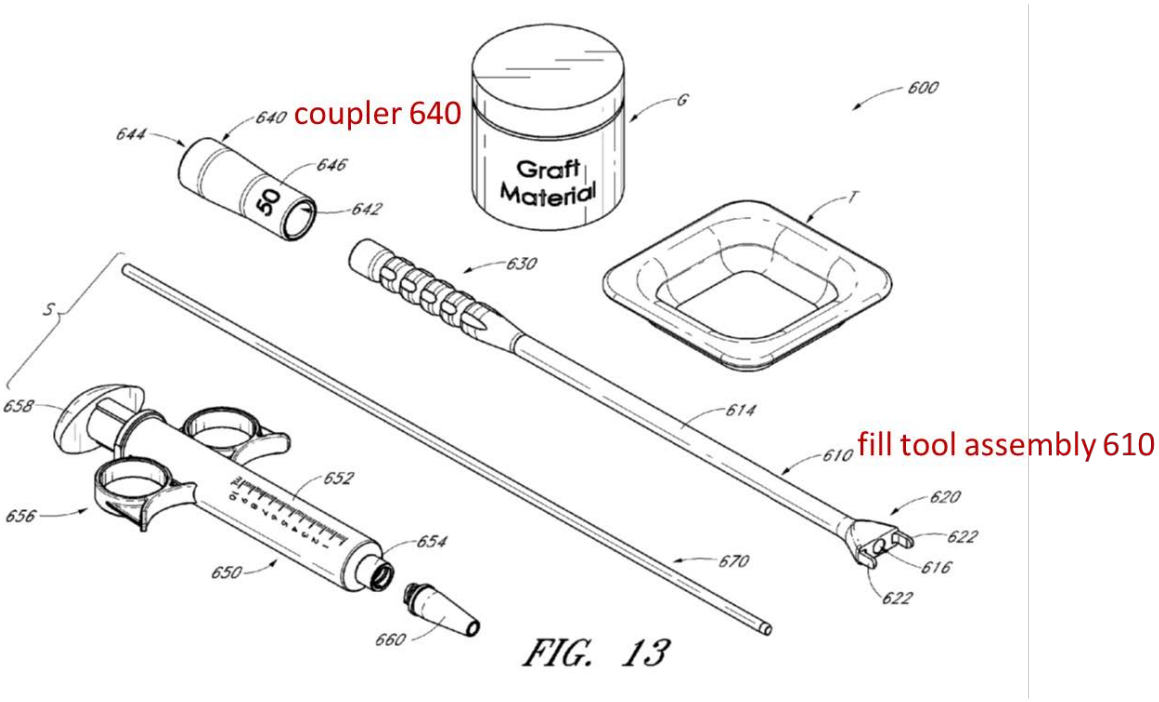
a) [3.0] *The system of claim 1,*

See analysis of claim 1.

b) [3.1] ***wherein the graft material delivery system additionally comprises a fill tool assembly, the fill tool assembly being configured to selectively engage at least a portion of the implant, wherein the fill tool assembly comprises a cannulated shaft.***

Alfaro combined with Perez-Cruet renders obvious [3.1].

First, Figure 13 of the '096 Patent (below) discloses a fill tool assembly 610 and an optional coupler 640 that may be added to the fill tool assembly. In this embodiment, the fill tool assembly 610 guides the graft delivery conduit 670 to the implant. *See also* Figures 16A-16C.



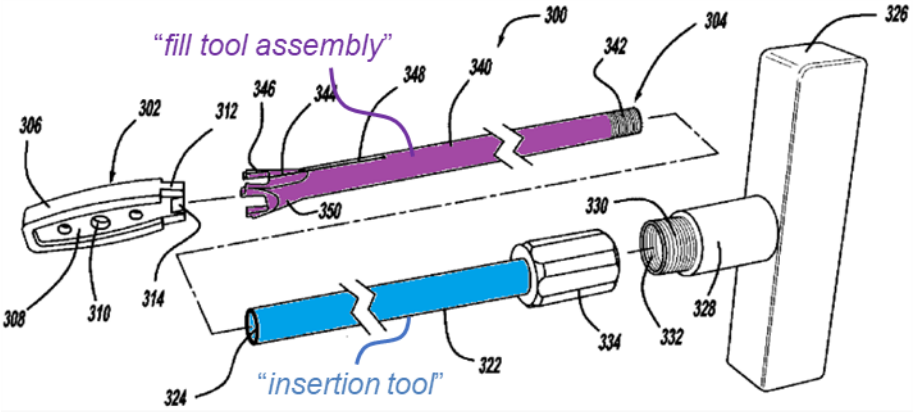
Ex. 1001, Figure 13; Ex. 1003, ¶ 230

Turning to Alfaro, although Alfaro's figures illustrate a handle having a threaded end, Alfaro discloses that "a pressure fit, a clip-on, a snap-on, or bayonet mount mechanisms are likewise suitable. Any disengageable means is suitable."

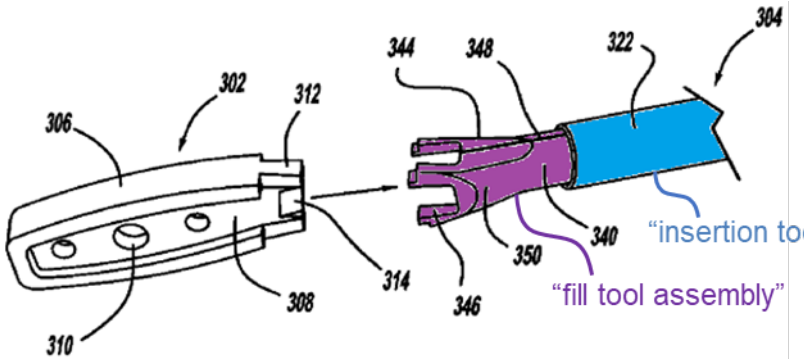
Ex. 1008, ¶ [0021]. Thus, Alfaro discloses that a clip-on or snap-on device is "suitable" and "there are many handles or holders in the prior art which may be used in combination with the spacer," *id*., providing the explicit motivation to use such prior art devices that "pressure fit," "snap-on," or "clip-on" to a spacer. Perez-Cruet presents one such prior art assembly. Ex. 1003, ¶ 231.

In Figures 13, 14, and 15, Perez-Cruet illustrates an example of the disengageable means suggested by Alfaro, namely, an instrument 304 including a cylindrical body portion 322 and an elongated cylindrical grasping portion 340 having fingers 346 for engaging an interbody device 302 and a handle 326. Grasping refers to engagement of the implant by fingers 346. However, as is evident from Figures 19 and 21, the elongated non-finger section of instrument 340 functions to guide bone graft or a conduit for delivering bone graft to the internal chamber of the implant. Therefore, instrument 340 will be referred to hereafter as either a "grasping portion 340" or a "guiding portion 340" depending on the function being referenced. The handle attaches to the guiding portion 340 via external threads 342 and internal threads 332 and to the body portion 322 via connection portion 334 and outer threaded portion 330. *See* Ex. 1004, ¶¶ [0056] and [0057]. In use, the instrument assembly is engaged with the implant and used to insert the implant into position in the spine. With reference to the system of Figure 21, a conduit portion 402 is guided by the guiding portion 340 to the

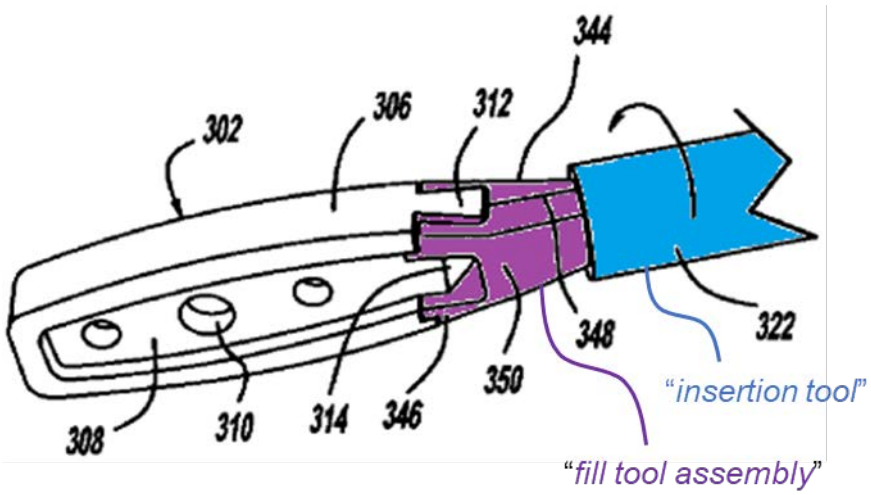
implant, similar to how the tubing 670 is guided by the fill tool assembly 610 in the '096 Patent. Ex. 1003, ¶ 232.



Ex. 1004, Figure 14; Ex. 1003, ¶ 232 (exploded view)



Ex. 1004, Figure 15; Ex. 1003, ¶ 232 (open position)



Ex. 1004, Figure 16; Ex. 1003, ¶ 233 (engaged position, arrow indicates direction of implant manipulation)

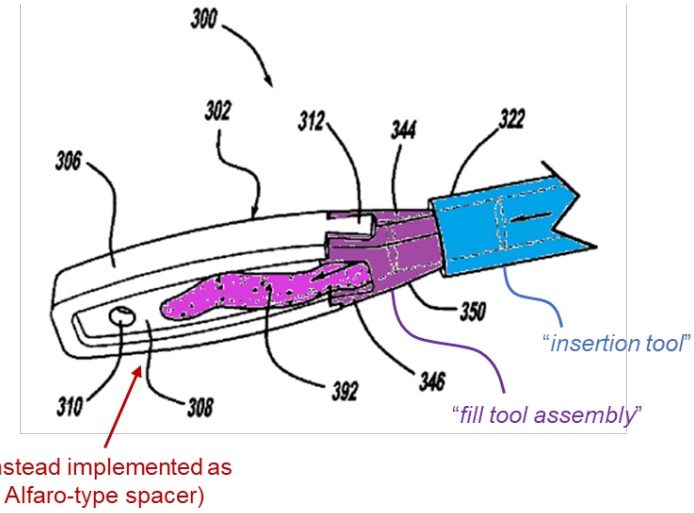
Since Alfaro suggests using any disengageable means to connect the handle 12 with the intervertebral spacer 11, it was obvious to implement the handle 12 of Alfaro with Perez-Cruet's instrument 304 and to compatibly modify the intervertebral spacer of Alfaro such that the fingers 346 of Perez-Cruet's grasping portion 340 can secure the instrument 304 to Alfaro's intervertebral spacer 11. Ex. 1003, ¶ 234.

Such a modification would be obvious to a POSITA. For example, Alfaro explains that any "detachable" and "hollow" handle "may be used provided it can be engaged and disengaged with the spacer… There are many handles or holders in the prior art which may be used in combination with the spacer." Ex. 1008, ¶ [0021]. Such a combination might involve placing four receiving recesses or notches around the port of the Alfaro implant 11 to receive four "fingers 346"

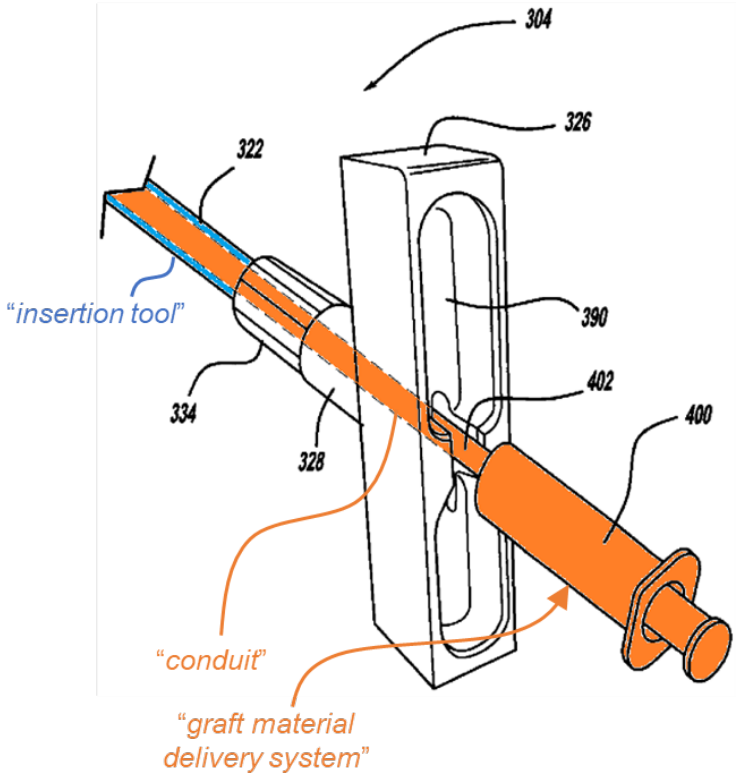
projections from a Perez-Cruet style fill tool assembly 344. Ex. 1003, ¶ 235.

A POSITA would appreciate that such an obvious modification to the coupling between implant and instruments inhibits accidental loosening of the implant connection during filling, allows easier removal without torquing the implant or any need to have a counter torque instrument, and removes concerns regarding cross threading the inserter during surgery. *Id*., ¶ 236.

Returning to the teachings of Perez-Cruet, Figures 20 and 21, reproduced below, illustrate "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." Ex. 1004, ¶ [0062].



Ex. 1004, Figure 20; Ex. 1003, ¶ 237



Ex. 1004, Figure 21; Ex. 1003, ¶ 237

When Alfaro's handle is implemented as Perez-Cruet's instrument 304, the intervertebral spacer of Alfaro is compatibly modified, and the fingers 346 of Perez-Cruet's grasping portion 340 secure the instrument 304 to Alfaro's intervertebral spacer 11, to thereby guide the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Perez-Cruet's instrument 304 to deliver grafting materials to Alfaro's intervertebral spacer 11, thereby rendering obvious [3.1]. Ex. 1003, ¶¶ 238-239.

9. Claim 4

a) [4.0] ***The system of claim 3,***

See analysis of claim 3.

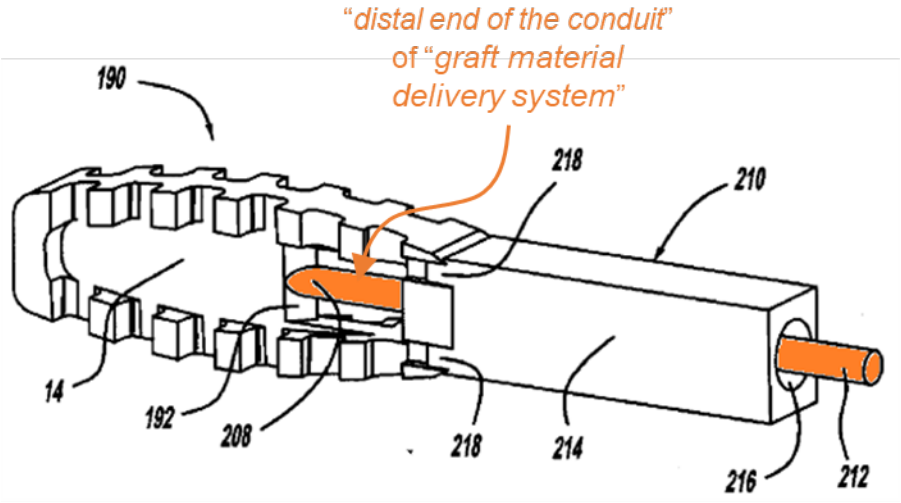
b) [4.1] ***wherein the fill tool assembly is configured to ensure that a distal end of the conduit routed through the cannulated shaft of the fill tool assembly is properly positioned within the at least one internal chamber of the implant.***

Alfaro combined with Perez-Cruet renders obvious claim element [4.1].

As discussed above with claim element [3.1], it was obvious to implement Alfaro's handle using Perez-Cruet's instrument 304 and to compatibly modify the intervertebral spacer of Alfaro such that the fingers 346 of Perez-Cruet's guiding portion 340 can secure the instrument 304 to Alfaro's intervertebral spacer 11. Moreover, when Alfaro's handle is implemented using Perez-Cruet's instrument 304, the intervertebral spacer of Alfaro is compatibly modified, and the fingers 346 of Perez-Cruet's guiding portion 340 secure the instrument 304 to Alfaro's intervertebral spacer 11, the extended tubular end portion 402 of Perez-Cruet's syringe 400 is extendable through Perez-Cruet's instrument 304 to deliver grafting materials to Alfaro's intervertebral spacer 11. Ex. 1003, ¶ 242.

Additionally, as discussed above with claim element [1.3], a POSITA would have passed the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's screw hole 15l and into the compartment 11b of Alfaro's intervertebral spacer to implement a syringe-type system with Alfaro's handle.

Figure 11 of Perez-Cruet illustrates an embodiment in which a fill tube 212 extends through a cylindrical bore 216 so that an end 208 of the fill tube 212 is positioned within an interbody device 190.



Ex. 1004, Figure 11; Ex. 1003, ¶ 244

Thus, when Alfaro's handle is implemented as Perez-Cruet's instrument 304, the intervertebral spacer of Alfaro is compatibly modified, the fingers 346 of Perez-Cruet's guiding portion 340 secure the instrument 304 to Alfaro's intervertebral spacer 11, and the extended tubular end portion 402 of Perez-Cruet's syringe 400 is passed through Perez-Cruet's instrument 304, through Alfaro's screw hole 15l, and into the compartment 11b of Alfaro's intervertebral spacer. In these instances, Perez-Cruet's guiding portion 340 (part of the "*fill tool assembly*") ensures that the extended tubular end portion 402 of Perez-Cruet's syringe 400 is properly positioned within the compartment 11b of Alfaro's intervertebral spacer,

thereby rendering obvious [4.1]. Ex. 1003, ¶ 245.

10. Claim 5

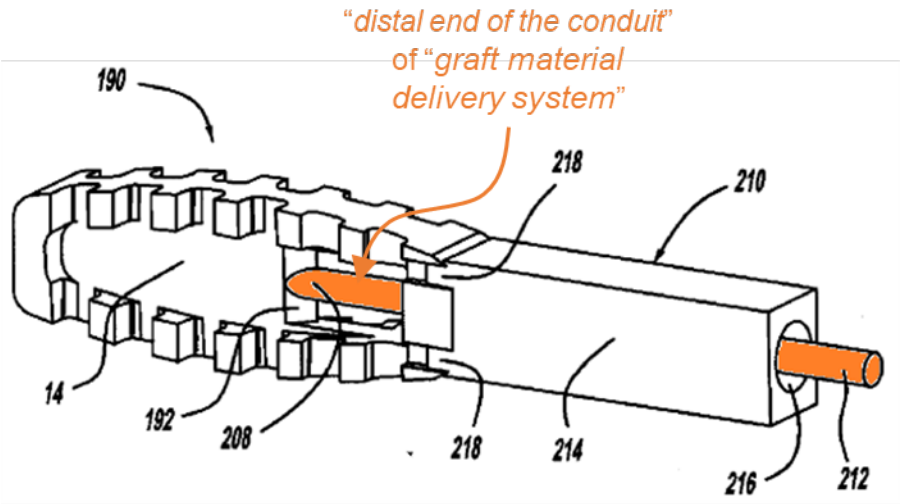
a) [5.0] ***The system of claim 3,***

See analysis of claim 3.

b) [5.1] ***wherein graft material is configured to be delivered through the fill tool assembly, either directly through the cannulated shaft or via the conduit, wherein the conduit is removably positioned through the cannulated shaft.***

Alfaro combined with Perez-Cruet renders obvious [5.1].

As explained in the analysis of [4.1], Figure 11 of Perez-Cruet illustrates an embodiment in which a fill tube 212 extends through a cylindrical bore 216 so that an end 208 of the fill tube 212 is positioned within an interbody device 190:



Ex. 1004, Figure 11; Ex. 1003, ¶ 250

Thus, as explained in [4.1], when Alfaro's handle is implemented as Perez-Cruet's instrument 304 and the intervertebral spacer of Alfaro is compatibly modified,

"*graft material is configured to be delivered through the fill tool assembly* [e.g., Perez-Cruet's guiding portion 340] ... *via the conduit* [e.g., Perez-Cruet's extended tubular end portion 402] ... *removably positioned through the cannulated shaft* [e.g., of the guiding portion 340)]," thereby rendering obvious claim element [5.1]. Ex. 1003, ¶¶ 251-252.

11. Claim 6

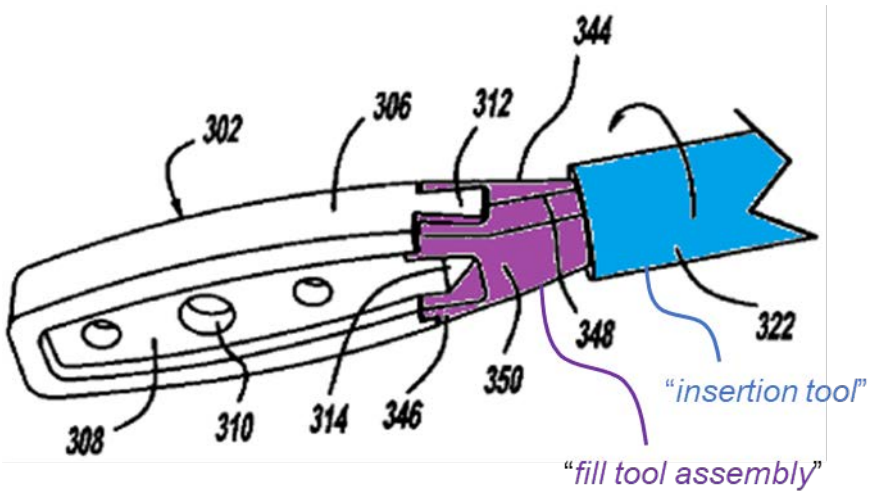
a) [6.0] *The system of claim 5,*

See analysis of claim 5.

b) [6.1] *wherein the fill tool assembly comprises at least one alignment feature configured to engage at least a portion of the implant, wherein at least one alignment feature provides assurance that the fill tool assembly is properly positioned relative to the implant.*

Alfaro combined with Perez-Cruet renders obvious claim element [6.1].

In Figure 16, Perez-Cruet further illustrates that "[t]he tapered portion 350 causes the slot 348 to close, which pinches the fingers 346 around the end portion 312 **rigidly securing the interbody device 302 to the instrument 304**." Ex. 1004, ¶ [0058].



Ex. 1004, Figure 16; Ex. 1003, ¶ 256

The fingers 346 connecting Perez-Cruet's guiding portion 340 to Alfaro's intervertebral spacer is an example of "*at least one alignment feature configured to engage at least a portion of the implant* [e.g., Alfaro's intervertebral spacer)], *wherein at least one alignment feature provides assurance that the fill tool assembly* [e.g., Perez-Cruet's grasping portion 340] *is properly positioned relative to the implant*," thereby rendering obvious [6.1]. Ex. 1003, ¶¶ 255-257.

12. Claim 7

a) [7.0] *The system of claim 6,*

See analysis of claim 6.

b) [7.1] *wherein the last one alignment feature comprises at least one of a tab and a wing.*

In addition to being examples of "*alignment features*," the fingers 346 of Perez-Cruet are examples of tabs or wings (e.g., similar to what the '096 Patent labels as "tabs or wings 622" at 22:12 and illustrated in Figure 13). Ex. 1003,

¶ 259.

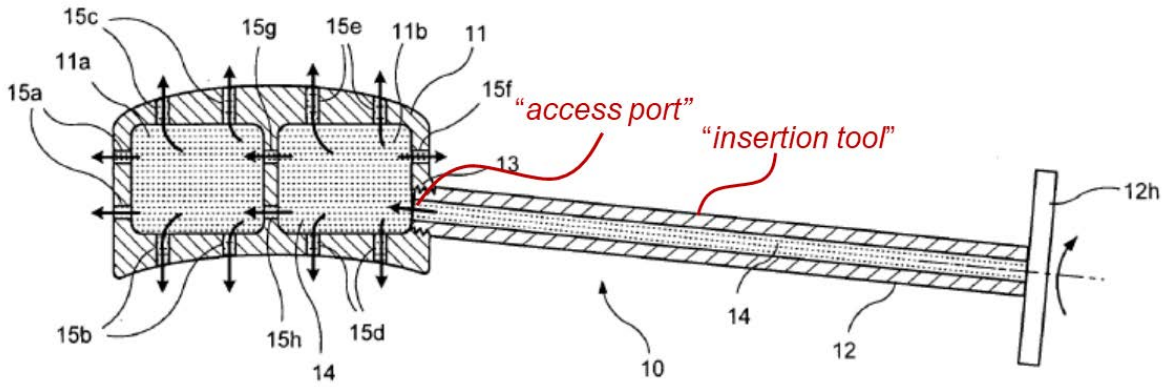
13. Claim 8

a) [8.0] *The system of claim 1,*

See analysis of claim 1.

b) [8.1] *wherein the implant insertion tool is configured to releasably secure to the access port.*

Alfaro discloses that "[t]he **detachable or disengageable** handle acts as an inserter of the spacer and comprises a hollow chamber to accommodate the biologic material to be added into the spacer," Ex. 1008, ¶ [0021], and continues "[h]andle 12 is shown *screwed into* compartment 11(b) at [*access port*] 13," *id*., ¶ [0029], and "the handle is removed as by unscrewing it [at *access port*] or pulling it away from its pressure fit or snap-on fit," *id*., ¶ [0031]. *See also id*., Figure 2. Figure 1 Alfaro is reproduced below to illustrate the handle used as an insertion tool.



Ex. 1008, Figure 1; Ex. 1003, ¶ 262

Thus, Alfaro's disclosure of a handle screwed into an access port, which can also be unscrewed and detached, is an example of claim element [8.1]. Ex. 1003, ¶ 263.

14. Claim 10

a) [10.0] *The system of claim 1,*

See analysis of claim 1.

b) [10.1] *wherein the implant comprises at least one of polyether etherketone (PEEK), a metal and an alloy.*

Alfaro teaches that "[t]he spacer may be constructed of biologically acceptable material such as titanium, stainless steel, allograft bone, **PEEK**, or the like," Alfaro, ¶ [0022], thus disclosing [10.1]. Ex. 1003, ¶ 265.

15. Claim 11

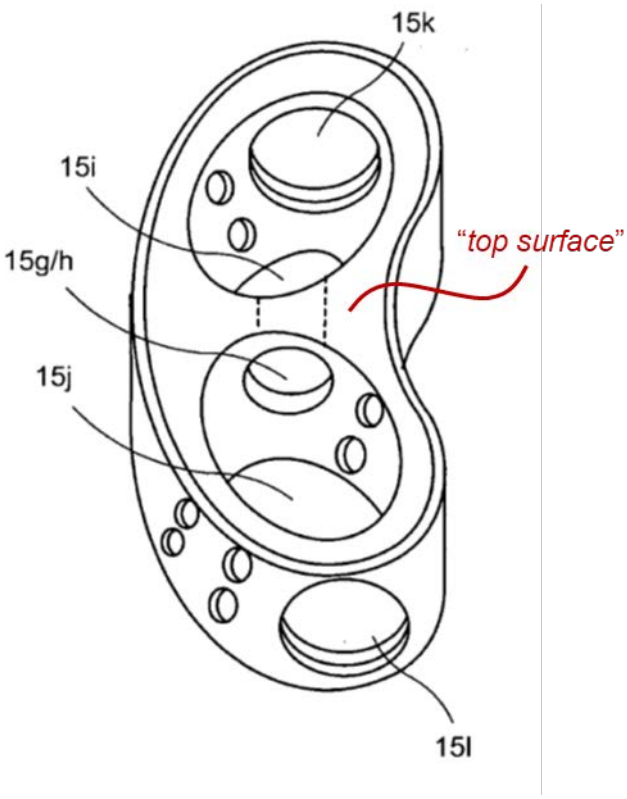
a) [11.0] *The system of claim 1,*

See analysis of claim 1.

b) [11.1] *wherein at least one of the top and bottom surfaces of the implant is generally planar.*

Alfaro discloses that applicable spacers come in a variety of shapes. Ex. 1008, ¶ [0020] (e.g., "rectangular," "kidney shape," "oblong or round"). Thus, based on Alfaro's generic description, a POSITA would have understood that an implant can have a planar top and/or bottom surface, rendering obvious [11.1]. Ex. 1003, ¶ 268.

Moreover, a spacer shape with a planar top surface is illustrated in Figure 9.



Ex. 1008, Figure 9; Ex. 1003, ¶ 269

As shown in Figure 9, the "*top surface*" of the intervertebral spacer is "*generally planar*," thus disclosing [11.1]. Ex. 1003, ¶ 269.

16. Claim 12

a) [12.0] *The system of claim 1,*

See analysis of claim 1.

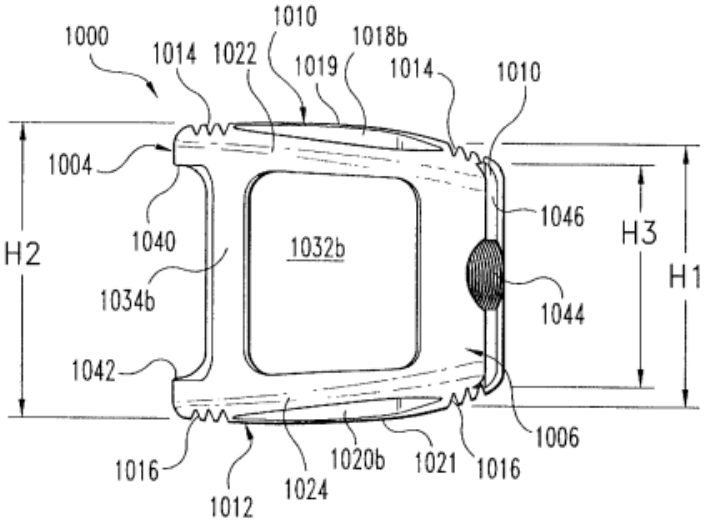
b) [12.1] *wherein at least one of the top and bottom surfaces of the implant is generally curved.*

Alfaro combined with Frey renders obvious claim element [12.1].

As discussed in the analysis of claim element [1.1.3]: (1) due to the "pressure-fit" of Alfaro's intervertebral spacer into place between the opposing

vertebral bodies, Alfaro's top and bottom surfaces are configured to engage endplates of adjacent first and second vertebrae; and (2) it was obvious to modify the top and bottom surfaces of Alfaro's intervertebral spacer 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 spacer achieves Alfaro's teaching that the spacer "remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031].

Frey teaches that "[i]mplant 1000 has a height H1 at the medial portion of posterior wall 1002 and a second height H2 at the medial portion of anterior wall 1004." Ex. 1005, 19:53-55.



Ex. 1005, Figure 54

As a result, "[u]pper bearing member 1010 and lower bearing member 1012 have **a slight convexity between the anterior and posterior walls 1002, 1004**

and height H2 is preferably greater then H1 in order to correspond to the anatomy of the vertebral endplates at the posterior portion of disc space D1." Ex. 1005, 19:55-60. Thus, it was further obvious to modify the "top surface" of Alfaro's intervertebral spacer to be "generally curved," as taught by Frey, to better correspond to the anatomy of the vertebral endplates, thereby rendering obvious claim element [12.1]. Ex. 1003, ¶¶ 271-274.

17. Claim 13

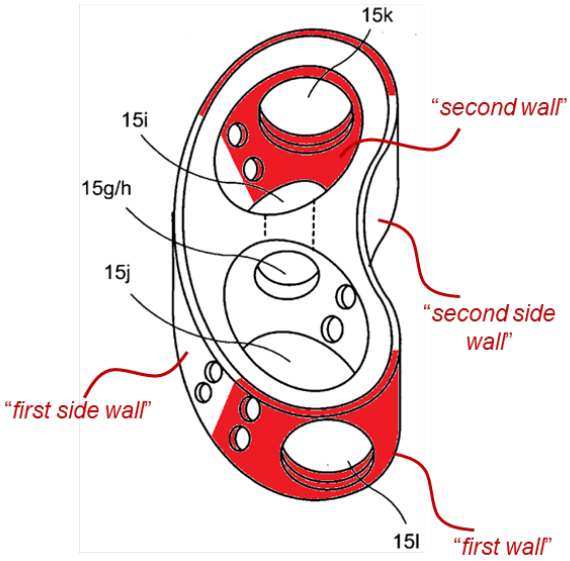
a) [13.0] *The system of claim 1,*

See analysis of claim 1.

b) [13.1] *wherein the implant comprises a lordotic implant, such that a height of the first wall is different than a height of the second wall.*

Alfaro combined with Frey renders obvious [13.1].

As discussed in connection with [1.1.1], Alfaro teaches an intervertebral spacer comprising the "*first wall*" and the "*second wall*." In the analysis of claim element [1.1.1], although the screw holes are located in what is illustrated in Alfaro's Figure 9 as the "*first wall*" and the "*second wall*," it was understood, based on Alfaro's teachings, that a screw hole could be placed at different points around the periphery of Alfaro's spacer, depending on the surgeon's preferred angle of approach to the spine for inserting the spacer in the specific circumstance. Thus, it was also known to place a screw hole in what is labeled as a "*side wall*" in Figure 9 below:



Ex. 1008, Figure 9; Ex. 1003, ¶ 277

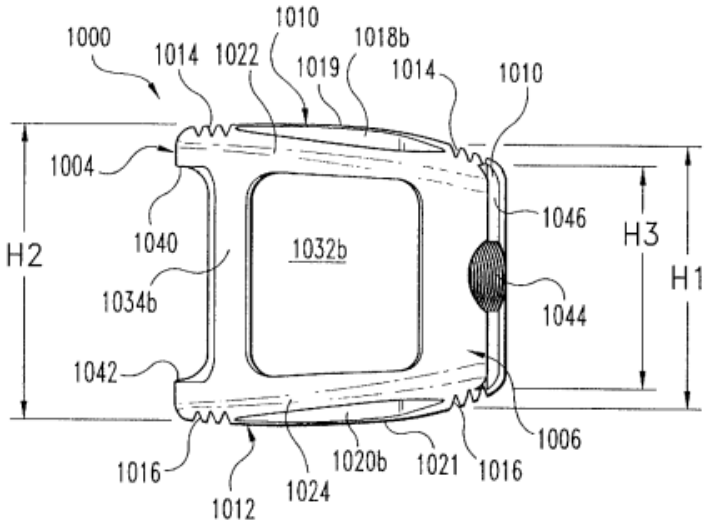
In fact, what is labeled as the "*first wall*" and "*second wall*" could be instead labeled as "*first side wall*" and "*second side wall*," respectively, in the figure above. Ex. 1003, ¶ 277.

The '096 Patent does not express a preference for what delivery approach (e.g., direction) a surgeon uses to insert an implant, mentioning a variety of known approaches in passing, saying that "any" approach may be used. Ex. 1001, 7:11-15. The '096 Patent assumes that a POSITA has pre-existing knowledge of these different approaches. As discussed in Section IV.A ("Overview of Spinal Fusion"), various approaches were known before the '096 Patent, and a POSITA would have known of these different approaches and the various trade-offs among them.

Therefore, Alfaro's intervertebral spacer 11 is insertable into the intervertebral space using a variety of different approaches, and a POSITA can and

would modify the spacer as needed by locating the screw hole to accommodate various approaches, as explained further in Section IX.A.3 (Reasons to Combine Alfaro and Frey).

With this as background, Frey teaches an implant 1000 akin to Alfaro's intervertebral spacer but with differing heights of "leading" and "trailing" end walls. Ex. 1005, 19:60-65. As shown in Figure 54, "the difference in heights between the upper and lower bearing members at the anterior and posterior walls can be provided so as to **establish lordosis** when implant 1000 is inserted in the disc space. Implant 1000 thus has application in restoring and **maintaining spinal lordosis** from a posterolateral approach." *Id*., 19:67-20:5.



Ex. 1005, Figure 54

As discussed in Section IX.A.3 (Reasons to Combine Alfaro and Frey), Alfaro's spacer would have been modified to include Frey's grooves and likewise been modified to have the different heights to maintain proper spinal lordosis

(thereby more closely matching the spinal anatomy), as explained in Frey. Accordingly, Alfaro's spacer with the different walls relabeled to switch the "*wall*" and "*side wall*" labels, with the screw hole moved to accommodate a different approach (such that the "*access port extend[s] through the first wall*" as recited in [1.1.5]), and with a shape that maintains lordosis to more closely match the spinal anatomy with the height of the "*first wall*" different than the "*second wall*," as taught by Frey, renders obvious [13.1]. Ex. 1003, ¶¶ 278-282.

18. Claim 14

a) [14.0] *The system of claim 1,*

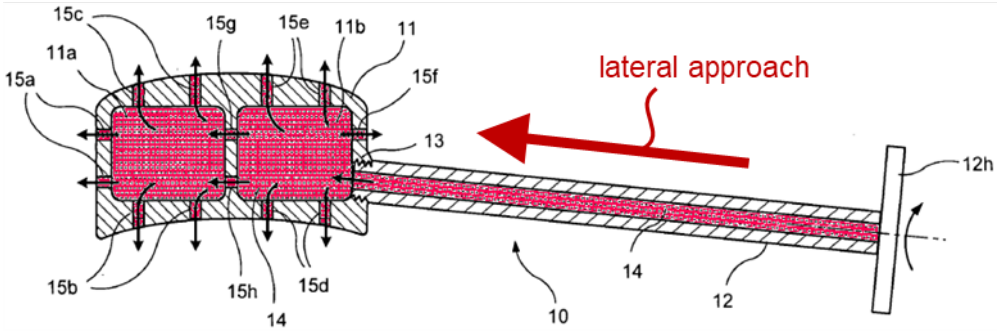
See analysis of claim 1.

b) [14.1] *wherein the implant comprises a lateral implant, a TLIF implant, an ALIF implant or a PLIF implant.*

Alfaro discloses [14.1]. Alfaro combined with Frey also renders obvious [14.1].

The '096 Patent mentions a variety of known surgical approaches in passing, stating that "any" approach may be used. Ex. 1001, 7:11-15. The "*implant*" referred to in claim element [14.1] is understood as one that is compatible with one of the recited approaches. Ex. 1003, ¶ 285.

Turning to Alfaro, Figure 1 illustrates an embodiment in which the threaded hole 13 is formed in the intervertebral spacer 11 to facilitate a lateral approach, thereby disclosing [14.1]. Ex. 1003, ¶¶ 286-287.



Ex. 1008, Figure 1; Ex. 1003, ¶ 287

Frey teaches that "there are aspects of the inventions described herein that may be used or modified for use for a variety of surgical applications including … **a lateral approach**." Frey, 22:6-12. Thus, a POSITA would have understood from Frey that such implants, including the intervertebral spacer 11 taught by Alfaro, would be inserted into the disc space using a variety of approaches, such as the lateral approach explicitly taught by Frey, thereby rendering obvious [14.1]. Ex. 1003, ¶¶ 287-288.

19. Claim 15

a) [15.0] *The system of claim 1,*

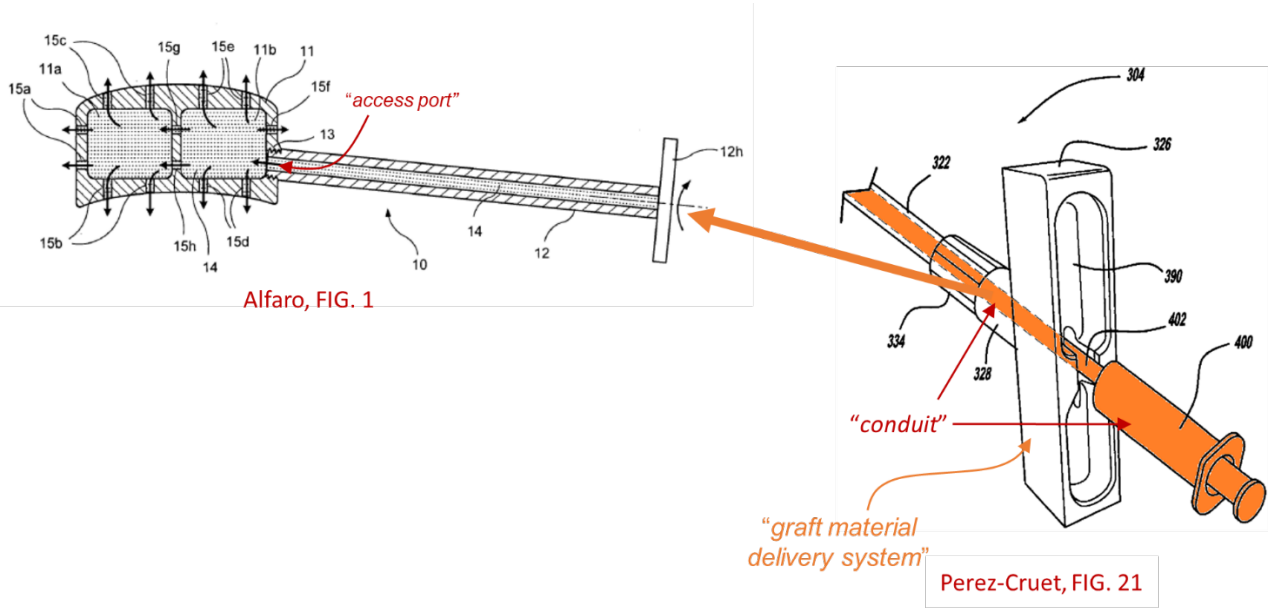
See analysis of claim 1.

b) [15.1] *wherein the fill tube assembly further comprises a plunger assembly configured to be positioned within the conduit, wherein the plunger assembly is selectively actuated in order to provide the necessary driving force to move a volume of graft material through the conduit and into the at least one internal chamber of the implant.*

First, there is no antecedent basis for the term "*the fill tube assembly*," so the

term "*the fill tube assembly*" must be a typo and was instead meant to be "*the graft material delivery system*," referring back to claim 1. Ex. 1003, ¶ 290.

As explained in connection with [1.3], Alfaro combined with Perez-Cruet discloses the following:



Sherman, Figure 4; Ex. 1003, ¶ 291

The syringe 400 includes a barrel (an example enlarged-diameter portion of the "*conduit*") with a plunger inside to move graft material down the barrel and reduced-diameter portion (the extended tubular end portion), thereby disclosing [15.1]. Ex. 1003, ¶¶ 290-292.

20. Claim 16

a) **[16.0]** ***A spinal fusion system for placing an implant and graft material within a target intervertebral space, the system comprising:***

b) **[16.1.1]** ***(i) an implant comprising: a first wall and a second wall, the second wall being generally opposite of the first wall;***

Claim elements [16.0] and [16.1.1] are identical to claim elements [1.0] and [1.1.1], respectively. Therefore, according to the analysis of [1.0] and [1.1.1], Alfaro discloses [16.0] and [16.1.1], respectively.

c) **[16.1.2]** ***[the implant comprising:] side walls configured to extend between the first wall and the second wall;***

Claim element [16.1.2] is substantially the same as claim element [1.1.2] ([1.1.2] merely adds "*first and second*" side walls). Therefore, according to the analysis of [1.1.2], Alfaro discloses [16.1.2].

d) **[16.1.3]** ***[the implant comprising:] a top surface configured to at least partially engage a lower surface of a first vertebral body; [and] a bottom surface configured to at least partially engage an upper surface of a second vertebral body, the second vertebral body being adjacent to the first vertebral body;***

Claim element [16.1.3] is identical to claim element [1.1.3]. Therefore, according to the analysis of [1.1.3], Alfaro combined with Frey renders obvious [16.1.3].

e) [16.1.4] ***[the implant comprising:] at least one internal chamber defined, at least in part, by the first wall, the second wall and the side walls, wherein the at least one internal chamber extends from the top surface to the bottom surface of the implant,***

Claim element [16.1.4] is substantially the same as [1.1.4] ([1.1.4] includes the added specificity of the "*first*" and "*second*" side walls). Therefore, according to the analysis of [1.1.4], Alfaro discloses [16.1.4]. Ex. 1003, ¶ 297.

f) [16.1.5] ***wherein the first and second walls and side walls form a continuous peripheral boundary around the at least one chamber upon implantation into a target intervertebral space; and***

Claim element [16.1.5] is substantially the same as [1.5.1] (element [16.1.5] merely adds "*first and second*" in front of "*walls*" and removes "*of the implant*" after "*sidewalls*"). Therefore, according to the analysis of [1.5.1], Alfaro discloses claim element [16.1.5]. Ex. 1003, ¶ 298.

g) [16.1.6] ***[the implant comprising] an access port extending through the first wall and being in fluid communication with the at least one internal chamber;***

Claim element [16.1.6] is identical to claim element [1.1.5]. Therefore, according to the analysis of [1.1.5], Alfaro discloses [16.1.6].

h) [16.1.7] ***wherein graft material is configured to be passed through the access port for delivery into the at least one internal chamber;***

Claim element [16.1.7] is broader than (although very similar to) claim element [1.1.6]. Therefore, according to the analysis of [1.1.6], Alfaro discloses

[16.1.7]. Ex. 1003, ¶ 300.

i) [16.2] ***(ii) an implant insertion tool sized and configured to position the implant to a target intervertebral space; and***

Claim element [16.2] is identical to claim element [1.2]. Therefore, according to the analysis of [1.2], Alfaro discloses [16.2].

j) [16.3] ***(iii) a graft material delivery system for delivering graft material into the at least one internal chamber of the implant, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit;***

Claim element [16.3] is nearly identical to, and substantially the same as, claim element [1.3] (which recites "*a volume of*" graft material). Accordingly, claim element [1.3] is slightly narrower than claim element [16.3]. Therefore, according to the analysis of [1.3], Alfaro combined with Perez-Cruet renders obvious [16.3]. Ex. 1003, ¶ 302.

k) [16.4] ***wherein, after delivery of the implant within the target intervertebral space, the first and second walls and the first and second sidewalls of the implant are configured to extend between superior and inferior vertebral members adjacent the target intervertebral space; and***

Claim element [16.4] is identical to claim element [1.4]. Therefore, according to the analysis of [1.4], Alfaro discloses [16.4].

l) **[16.5]** ***wherein the at least one internal chamber is configured to contain graft material enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.***

As shown in a comparison of claim elements in Ex. 1003, ¶ 304, claim element [1.5.2] and claim element [16.5] are substantively similar, with claim element [1.5.2] being slightly narrower. Therefore, according to the analysis of [1.5.2], Alfaro discloses [16.5].

21. Claim 17

a) **[17.0]** ***The system of claim 16,***

See analysis of claim 16.

b) **[17.1]** ***wherein the graft material delivery system additionally comprises a fill tool assembly, the fill tool assembly being configured to selectively engage at least a portion of the implant, wherein the fill tool assembly comprises a cannulated shaft.***

Claim element [17.1] is identical to claim element [3.1]. Therefore, according to the analysis of [3.1], Alfaro combined with Perez-Cruet renders obvious [17.1].

22. Claims 18-19

a) **[18.0]/[19.0]** ***The system of claim 17,***

See analysis of claim 17.

b) [18.1] ***wherein the fill tool assembly is configured to ensure that a distal end of the conduit routed through the cannulated shaft of the fill tool assembly is properly positioned within the at least one internal chamber of the implant.***

c) [19.1] ***wherein graft material is configured to be delivered through the fill tool assembly, either directly through the cannulated shaft or via the conduit, wherein the conduit is removably positioned through the cannulated shaft.***

Claim elements [18.1] and [19.1] are identical to claim elements [4.1] and [5.1], respectively. Therefore, according to the analysis of [4.1] and [5.1], Alfaro combined with Perez-Cruet renders obvious [18.1] and [19.1], respectively.

23. Claim 20

a) [20.0] ***The method of claim 16,***

See analysis of claim 16.

b) [20.1] ***wherein the fill tube assembly further comprises a plunger assembly configured to be positioned within the conduit, wherein the plunger assembly is selectively actuated in order to provide the necessary driving force to move a volume of graft material through the conduit and into the at least one internal chamber of the implant.***

Claim element [20.1] is identical to claim element [15.1]. Therefore, according to the analysis of [15.1], Alfaro combined with Perez-Cruet renders obvious [20.1].

B. Ground 2: Claim 9 is unpatentable as obvious over the combination of Alfaro, Frey, Perez-Cruet, and Fuss.

1. Claim 9

a) [9.0] *The system of claim 1,*

See analysis of claim 1.

b) [9.1] *wherein at least one of the first and second side walls of the implant does not comprise any openings.*

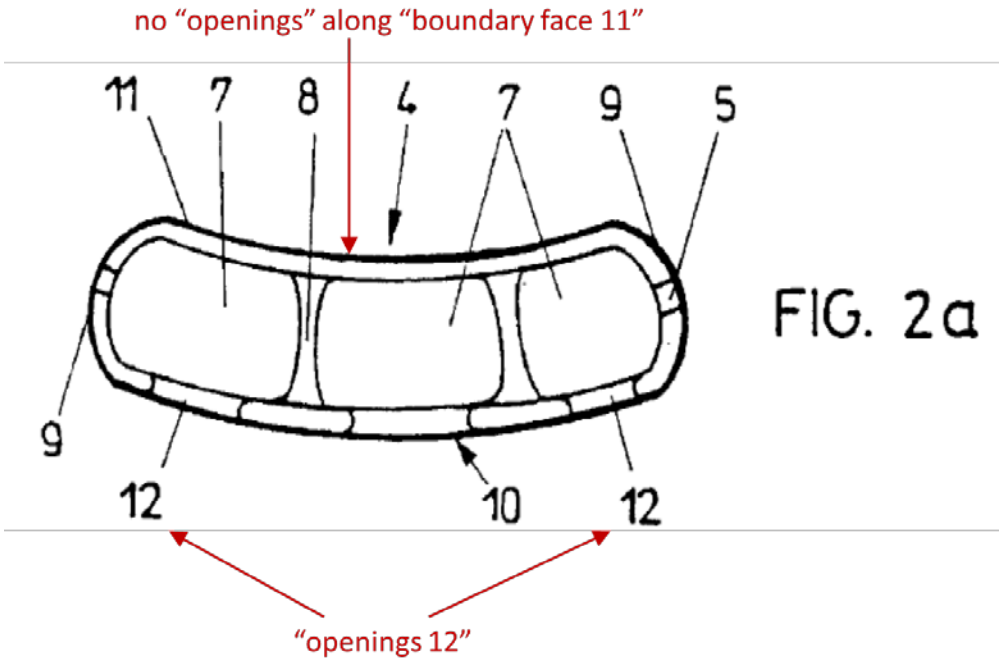
Alfaro combined with Fuss renders obvious claim element [9.1].

Fuss relates to spinal implants. Ex. 1022, 1:8-12. Figure 1 illustrates two adjacent vertebrae "between which an implant [4] … has been inserted," and Figures 2a-2e illustrate "schematic top views of differing embodiments of an implant [4]." *Id*., 6:10-14.

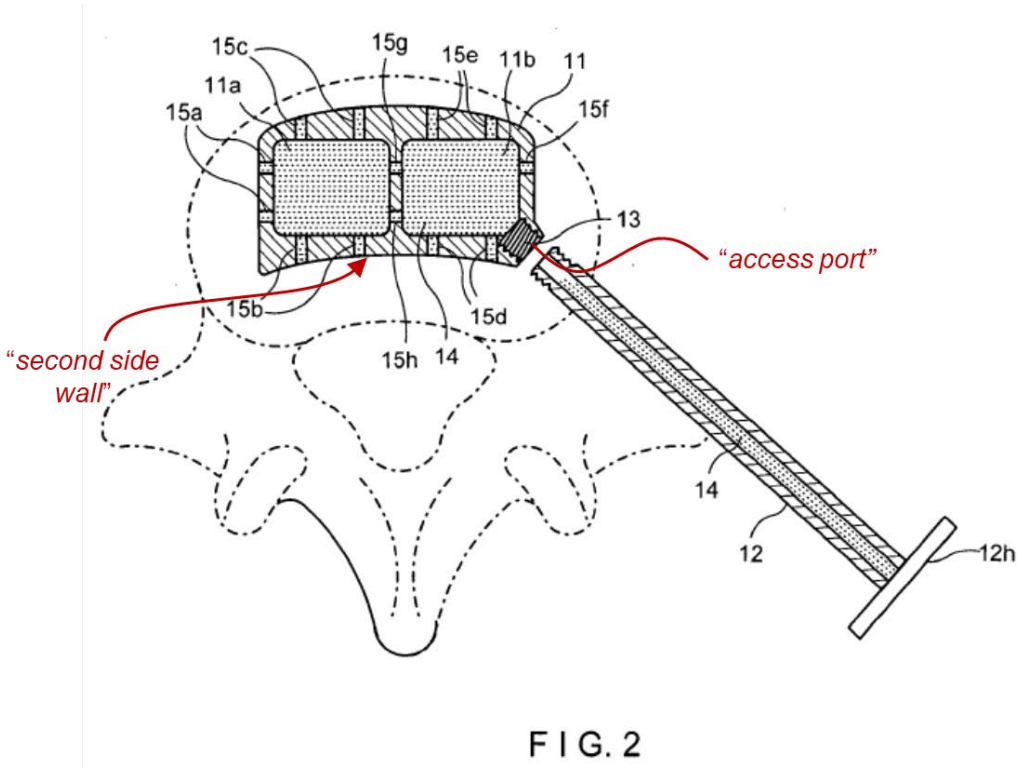
The implant 4 in Figure 2 includes an "opening 5 in the outwardly facing outer surface…serving for the application or fixing of an instrument during the process of inserting the implant 4." *Id*., 6:30-35. Further, like Alfaro's implants, which include one or two open compartments to be filled with grafting material to facilitate fusion with adjacent vertebrae, Fuss's "implant 4 comprises three substantially vertically extending continuous recesses or break-throughs 7" configured to contain graft material. *Id*., 6:56-62. Moreover, Fuss's implant 4 includes openings on side 10 but not on side 11, which yields benefits: "**the boundary face 11 of the implant 4 facing the spinous process does not incorporate openings or breakthroughs** so as to avoid bone material issuing out

at such points or **to prevent any possible intrusion thereof into the vicinity of the adjoining vertebral canal**." *Id*., 7:7-16. Claim 1 of Fuss is similarly directed to an "implant" in which one of two boundary faces is free of openings (or "breakthroughs"). *Id*., 10:6-12.

Although Alfaro's embodiments illustrate openings/tunnels 15(a)-15(f) around the periphery of the implant, for the reasons given in Fuss, a POSITA would have considered it beneficial not to include any openings along the "*second side wall*" indicated below, which corresponds to "boundary face 11" of Fuss's implant. The same reasoning likewise applies to the spacer 11 presented in Figure 9 of Alfaro. Ex. 1003, ¶ 320.



Ex. 1022, Figure 2a; Ex. 1003, ¶ 317



F I G. 2

Ex. 1008, Figure 2; Ex. 1003, ¶ 320

Therefore, Fuss's teachings would have motivated a POSITA to implement Alfaro's implant without any openings along one of the side walls (e.g., along the "*second side wall*" in Figure 2 above), thereby rendering obvious [9.1]. Ex. 1003, ¶¶ 316-321.

X. THERE IS NO BASIS FOR DISCRETIONARY DENIAL

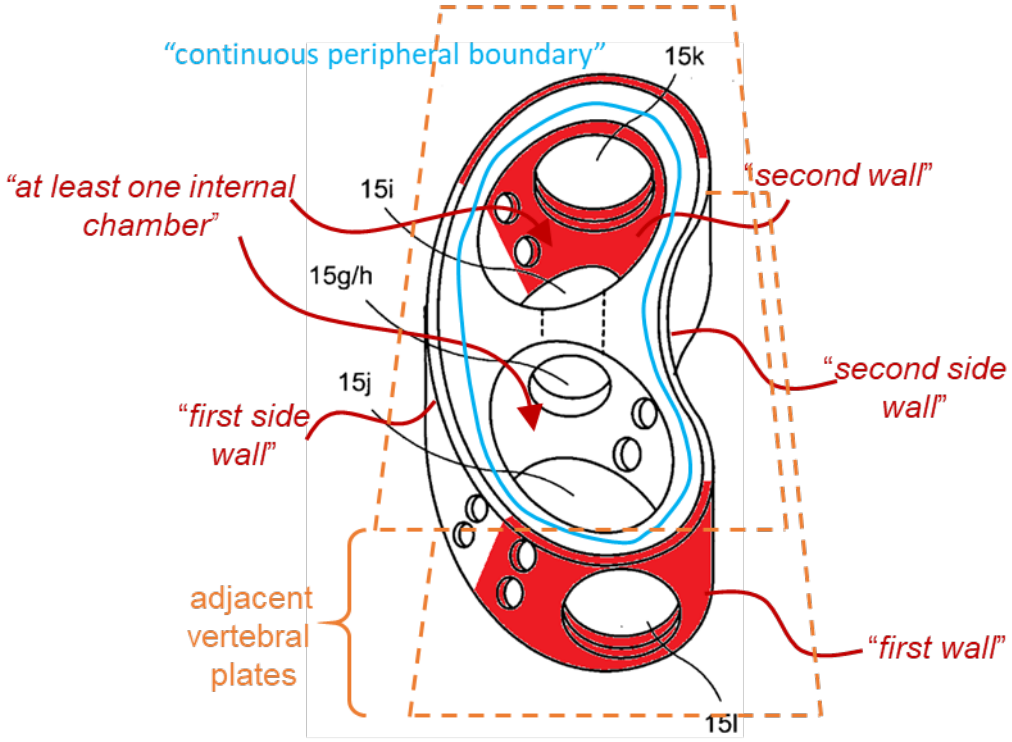
No other IPR has ever been filed against the '096 Patent, the only litigation ever involving the '096 Patent is currently stayed (*see* Ex. 1021), and the primary reference presented here – Alfaro – was not considered during prosecution.

When 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, p. 8 (Feb. 13, 2020) (designated: March 24, 2020). Neither condition in the first part of the framework is satisfied in this case.

During prosecution of the '096 Patent, the Applicant amended the independent claims to add two clauses, including claim elements [1.5.1] and [1.5.2], to overcome rejections based on Perez-Cruet and Ex. 1026. Ex. 1002, p. 163. Perez-Cruet does not disclose these limitations because Perez-Cruet's implant is oriented differently than Alfaro's implant in the intervertebral space. Perez-Cruet's implant is rotated 90 degrees as compared to Alfaro's implant. Thus, adjacent vertebrae rest on peripheral walls of Perez-Cruet's implant, whereas top and bottom surfaces of Alfaro's implant face adjacent vertebrae, as illustrated in Figure 9 of Alfaro, annotated by Petitioner's expert below. *See* Ex. 1004, ¶ [0043] and Figure 5; Ex. 1003, ¶¶ 92-93. Similarly, the Examiner correctly applied the teachings of Ex. 1026 (also by the same lead inventor, Perez-Cruet) for similar reasons. *See* Ex. 1026, ¶ [0040] ("[T]he interbody device 126 is **rotated** when it is

inserted into the disc space so that it is turned from a flat configuration to an upright configuration to provide a force to separate the discs.") As set forth in the analysis of claim elements [1.5.1] and [1.5.2], Alfaro discloses the very feature the Examiner found lacking in Perez-Cruet (and Ex. 1026) during prosecution. Thus, this Petition does not present the same or substantially the same prior art or arguments presented during prosecution of the '096 Patent. Ex. 1003, ¶¶ 90-91.



Alfaro, Figure 9; Ex. 1003, ¶ 92

During prosecution of the '096 Patent, the Applicant also filed a terminal disclaimer with respect to U.S. Patent No. 8,343,224 (the "'224 Patent," Ex. 1023). Ex. 1002, p. 305. During prosecution of the '224 Patent, the as-filed independent claims were initially rejected as anticipated by Murillo (U.S. Patent Pub.

2008/0077247) (Ex. 1025), and many dependent claims were rejected as obvious in view of Murillo and Perez-Cruet (Ex. 1004). Ex. 1024, pp. 122-126. After amending the claims, Ex. 1024, pp. 148-151, the claims were subsequently allowed with an examiner's amendment, including "wherein a length of each of the first and second lateral walls is a minimum of 12% of the overall length of the implant." Ex. 1024, p. 255. Thus, the independent claims were allowed with very different limitations than in the '096 Patent. Moreover, Murillo mentions filling a spacer only in passing, *see, e.g.*, Ex. 1025, ¶ [0047] ("…the opening 116 can be configured to allow placement of the bone graft material."), but does not disclose any sort of "*graft material delivery system*" as recited in claims 1 and 16 of the '096 Patent or "*enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members,*" as recited in claims 1 and 16. Ex. 1003, ¶ 94.

Therefore, Alfaro, which was not considered during prosecution of either of the '224 or '096 Patents, is different than the art considered during prosecution – Perez-Cruet, Ex. 1026, and Murillo – 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 here as compared to prosecution. So there is no basis for discretionary denial under 35 U.S.C. § 325(d). Ex. 1003, ¶ 95.

XI. CONCLUSION

For the reasons presented above, institution of *inter partes* review of claims 1-20 of the ’096 Patent is requested.

Dated: August 28, 2020

Respectfully submitted,

By: /J. Andrew Lowes/
J. Andrew Lowes
Registration No.: 40,706
Customer No. 27683
Attorney Docket No. 48017.245
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 13,738 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. 9,216,096	§	Attorney Docket No.: 48017.245
	§	
Issued: Dec. 22, 2015	§	Customer No.: 27683
	§	
Title: INTERVERTEBRAL IMPLANTS AND RELATED TOOLS	§	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 28, 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. 1017 & Ex. 1019 through Ex. 1026
Persons served	Knobbe Martens Olson & Bear LLP 2040 Main Street, Fourteenth Floor Irvine, CA 92614

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