

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOFIX MEDICAL INC.,
Petitioner,

v.

SPINE HOLDINGS, LLC,
Patent Owner.

IPR2020-01412
Patent 9,216,096 B2

Before JAMES A. TARTAL, ZHENYU YANG, and
RYAN H. FLAX, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable
Denying Patent Owner's Contingent Motion to Amend
35 U.S.C. § 316(d); 35 U.S.C. § 318(a)

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2020). For the reasons discussed below, we determine Orthofix Medical Inc. (“Petitioner”)¹ has shown by a preponderance of the evidence that claims 1–20 (“the Challenged Claims”) of U.S. Patent No. 9,216,096 B2 (Ex. 1001, “the ’096 patent”) are unpatentable. We also deny the Contingent Motion to Amend of Spine Holdings, LLC (“Patent Owner”).²

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 2 (“Pet.”). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 9 (“Inst. Dec.”). Patent Owner filed a Patent Owner Response. Paper 11 (“Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 28 (“Reply”). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 31 (“Sur-reply”).

Patent Owner also served a Contingent Motion to Amend on Petitioner on May 20, 2021, the day it was due, but did not file the motion until August 5, 2021, as Paper 19. *See* Paper 10 (Scheduling Order), 10. Petitioner filed an opposition to that motion on August 11, 2001. Paper 20 (“MTA Opp.”). We entered an order on August 20, 2021, addressing the late filing of the motion, in which we excused the late filing, but found the

¹ Petitioner identifies only itself as a real party in interest. Pet. 1.

² Patent Owner identifies only itself as a real party in interest. Paper 4, 1.

motion improperly lacked page numbers. Paper 22. Accordingly, we expunged the version of the motion filed as Paper 19 and permitted Patent Owner to refile the motion with page numbers, which was entered on August 23, 2021, as Paper 23 (“MTA”). *See id.* In the MTA, Patent Owner requested preliminary guidance from the Board. MTA 3; *see also* Paper 10, 4–6 (explaining the Board’s Pilot Program Concerning Motion to Amend Practice (citing Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9497 (Mar. 15, 2019) (“MTA Pilot Program Notice”))). The Board subsequently issued Preliminary Guidance on Patent Owner’s Motion to Amend. Paper 25 (“Preliminary Guidance”).

In accordance with the MTA Pilot Program Notice, upon receipt of the Preliminary Guidance, Patent Owner had the option either to file a reply to Petitioner’s opposition to the motion or to file a revised motion to amend proposing revised substitute claims. *See* Paper 10, 5. Patent Owner proceeded to file what it styled “Spine Holdings’ Revised Contingent Motion to Amend” (Paper 29, “MTA Reply”), but did not revise any of its previously proposed substitute claims. In response, we issued an order recognizing Paper 29 as Patent Owner’s Reply to Petitioner’s Opposition to the MTA, not a revised motion. Paper 32, 2–3 (explaining that the MTA Pilot Program Notice states that “[a] revised MTA includes one or more new proposed substitute claims in place of previously presented substitute claims to address issues identified in the preliminary guidance and/or the petitioner’s opposition” (quoting 84 Fed. Reg. at 9499, 9501)). Thereafter,

Petitioner filed a Sur-reply in support of its Opposition to the MTA. Paper 34 (“MTA Sur-reply”).

Following oral argument, we entered a transcript of the hearing in the record. Paper 40 (“Tr.”). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

B. Related Matters

The parties state that the ’096 patent is a subject of *Spine Holdings, LLC v. Orthofix Medical Inc.*, No. 4-20-cv-00077 (E.D. Tex.) (“the district court case”). Pet. 2; Paper 4, 2. Petitioner also states that the ’096 patent is related to U.S. Patent No. 9,649,203 B2 (“the ’203 patent”). Pet. 2. Patent Owner states it owns the ’203 patent, that the ’203 patent is also a subject of the district court case, and that claims of the ’203 patent are challenged by Petitioner in IPR2020-01411. Paper 4, 2.

C. The ’096 Patent

The ’096 patent, titled “Intervertebral Implants and Related Tools,” issued December 22, 2015, from U.S. Application No. 14/694,146 (“the ’146 application”), filed April 23, 2015. Ex. 1001, codes (21), (22), (45), (54). The ’146 application was a continuation of U.S. Application No. 13/725,933, which was a continuation of U.S. Patent Application No. 13/049,693 (“the ’693 application”), filed on March 16, 2011 (Ex. 1007), now U.S. Patent No. 8,343,224. *Id.* at code (63). The ’096 patent also refers back to U.S. Provisional Patent Application No. 61/389,671 (“the ’671 provisional”), filed on October 4, 2010,

and to U.S. Provisional Patent Application No. 61/314,509 (“the ’509 provisional”), filed on March 16, 2010 (Ex. 1006). *Id.* at code (60), 1:6–14.

The ’096 patent “generally relates to spinal fusion, and more specifically, to spinal implants and related systems, tools and methods.” *Id.* at 1:19–21. The ’096 patent states that “[i]ntervertebral discs can degenerate or otherwise become damaged over time.” *Id.* at 1:23–24. Prior to the ’096 patent, it was known that “an intervertebral implant can be positioned within a space previously occupied by a disc” to “help maintain a desired spacing between adjacent vertebrae and/or promote fusion between adjacent vertebrae.” *Id.* at 1:24–28. It was also known that “[t]he use of bone graft and/or other materials within spinal implants can facilitate the fusion of adjacent vertebral bodies.” *Id.* at 1:28–30. The ’096 patent identifies a need for “an improved intervertebral implant, as well as related instrumentation, tools, systems and methods.” *Id.* at 1:30–32.

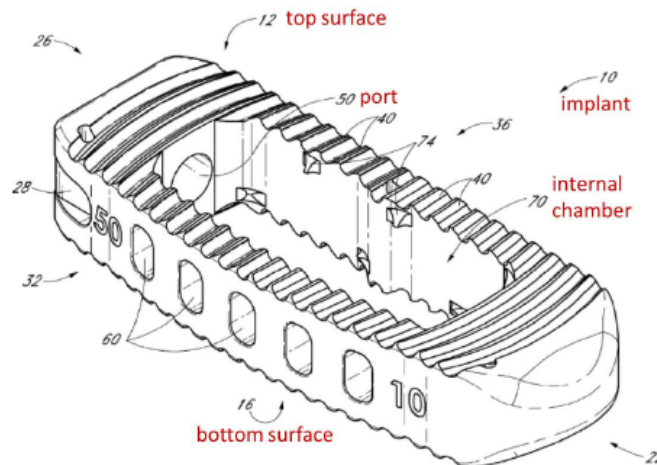
The spinal implant of the ’096 patent comprises at least one internal chamber defined by four walls (an anterior wall, a posterior wall, a first lateral wall, and a second lateral wall) and two surfaces (a top surface and a bottom surface). *Id.* at 1:36–50. The top surface is configured to at least partially engage a lower surface of a first vertebral body and the bottom surface is configured to at least partially engage an upper surface of a second vertebral body. *Id.* at 1:44–50. The two vertebral bodies are adjacent to each other. *Id.* The ’096 patent further states as follows:

The implant further comprises at least one opening extending through the anterior wall, wherein such an opening is in fluid communication with the internal chamber. In some embodiments, the spinal implant additionally comprises at least one access port located in the anterior wall, the first lateral wall

and/or the second lateral wall. In some embodiments, the implant is configured to releasably secure to an insertion tool using the access port.

Id. at 1:52–59.

Figure 1A of the '096 patent, as annotated by Petitioner, is reproduced below.



Pet. 6; Ex. 1001, Fig. 1A. Annotated Figure 1A illustrates a front perspective view of spinal implant 10 according to one embodiment. Ex. 1001, 5:63–64. As depicted in Figure 1A, top surface 12 and bottom surface 16 of implant 10 comprise one or more teeth 40 or protruding members that are sized, shaped, and configured to contact and engage adjacent surfaces of the vertebral endplates once the implant has been positioned within the intervertebral space. *Id.* at 7:26–31. Such teeth or other engagement features 40 can help ensure that implant 10 does not migrate or otherwise undesirably move after implantation. *Id.* at 8:4–6. Implant 10 has left lateral end 26 and right lateral end 22, the exterior of which can be either generally planar (e.g., flat) or rounded, as desired or required. *Id.* at 7:60–61, 9:29–31. As shown in Figure 1A, right lateral

end 22 includes both a vertical taper and a rounded profile when viewed from the top, which can facilitate insertion of implant 10 within the target intervertebral space. *Id.* at 9:5–10. Insertion tool receiving port 50 is positioned along lateral end 26 of implant 10 and is configured to releasably engage a corresponding insertion tool using a threaded connection. *Id.* at 9:34–40, 9:52–54.

Figure 11 of the '096 patent is reproduced below.

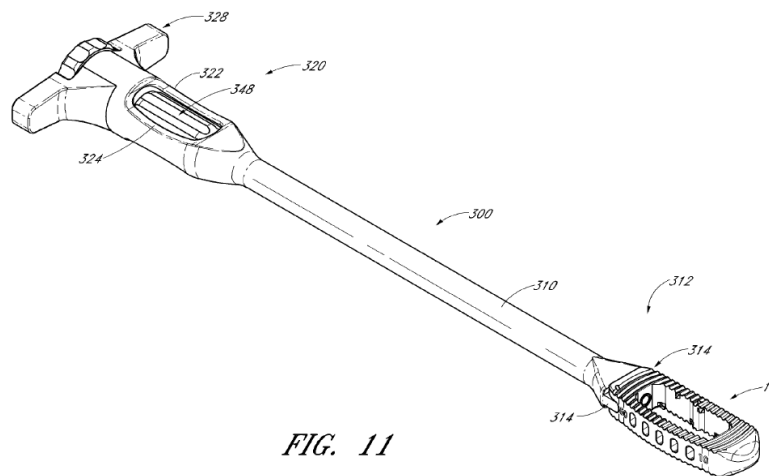


Figure 11 illustrates a perspective view of insertion tool assembly 300 attached to spinal implant 10. *Id.* at 6:28–30; 19:47–50. Proximal portion 320 of insertion tool assembly 300 includes handle 322 and flared end 328. *Id.* at 19:63–65. Insertion tool assembly 300 includes outer elongated member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

thumbwheel 348, which is accessible through window(s) 324 of outer member 310, permitting a surgeon to selectively rotate thumbwheel 348 while grasping insertion tool assembly 300 to engage or release implant 10 from the assembly's distal end. *Id.* 20:19–29. Once implant 10 has been secured to distal end of insertion tool assembly 300, the surgeon can drive implant 10 into the targeted intervertebral space by impacting the proximal end of assembly 300 with a slap hammer assembly, a mallet or other tool or instrument. *Id.* at 20:54–61.

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

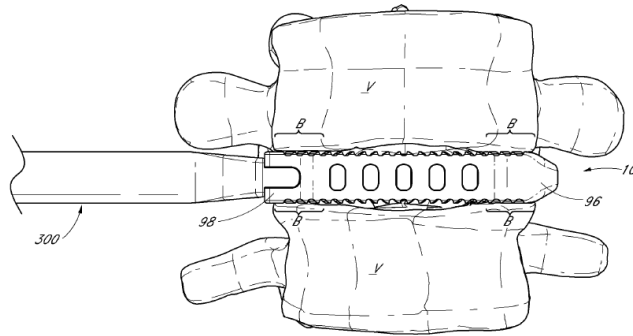


FIG. 7A

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

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

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

D. Illustrative Claim of the '096 Patent

Claims 1 and 16 of the '096 patent are independent and each is directed to a “spinal fusion system.” *Id.* at 27:16–63, 28:48–30:2. Claims 2–15 depend from claim 15 and claims 17–20 depend from claim 16. *Id.* at 27:64–28:47, 30:3–23. Claim 1, reproduced below, is illustrative of the subject matter of the Challenged Claims:

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

(i) an implant comprising:

[1.1.1] a first wall and a second wall, the second wall being generally opposite of the first wall;

[1.1.2] first and second side walls configured to extend between the first wall and the second wall;

[1.1.3] a top surface configured to at least partially engage a lower surface of a first vertebral body;

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;

[1.1.4] at least one internal chamber defined, at least in part, by the first wall, the second wall, the first side wall and the second side wall, wherein the at least one

- internal chamber extends from the top surface to the bottom surface of the implant; and
- [1.1.5] an access port extending through the first wall and being in fluid communication with the at least one internal chamber;
 - [1.1.6] wherein graft material is configured to be passed through the access port so at least a volume of graft material is selectively delivered into the at least one internal chamber;
 - [1.2] (ii) an implant insertion tool sized and configured to position the implant to a target intervertebral space; and
 - [1.3] (iii) a graft material delivery system for delivering a volume of graft material into the at least one internal chamber of the implant, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit;
 - [1.4] wherein, after delivery of the implant within the target intervertebral space, the first and second walls and the first and second sidewalls of the implant are configured to extend between superior and inferior vertebral members adjacent the target intervertebral space; and
 - [1.5.1] wherein the walls and sidewalls of the implant form a continuous peripheral boundary around the at least one chamber upon implantation into the target intervertebral space
 - [1.5.2] such that the at least one chamber contains graft material delivered through the access port, thereby enabling the at least one internal chamber to be filled such that graft material is in flush contact with endplate surfaces of the adjacent superior and inferior vertebral members.

Ex. 1001 at 27:16–63 (bracketed numbering added to match the Petition).

E. References and Testimony

Below we provide a table identifying the references asserted by Petitioner, as well as the exhibits corresponding to the declarations and deposition testimony in the record.³

References and Witness Testimony	Date	Ex. No.
U.S. Pat. App. Pub. No. US 2010/0262245 A1 (“Alfaro”)	Oct. 14, 2010	Ex. 1008
U.S. Patent No. 6,764,491 (“Frey”)	July 20, 2004	Ex. 1005
U.S. Pat. App. Pub. No. US 2008/0172128 A1 (“Perez-Cruet”)	July 17, 2008	Ex. 1004
U.S. Patent No. 6,562,072 B1 (“Fuss”)	May 13, 2003	Ex. 1022
U.S. Patent No. 6,974,480 B2 (“Messerli”)	Dec. 13, 2005	Ex. 1029
Declaration of Michael Sherman Under 37 C.F.R. § 1.68 in Support of Petition for <i>Inter Partes</i> Review	Aug. 27, 2020	Ex. 1003
Declaration of Michael Sherman Under 37 C.F.R. § 1.68 in Support of Petition for <i>Inter Partes</i> Review	Dec. 29, 2020	Ex. 1027
Declaration of Michael Sherman Under 37 C.F.R. § 1.68 in Support of Petitioner Opposition to Motion to Amend	Aug. 11, 2021	Ex. 1028
Declaration of Michael Sherman Under 37 C.F.R. § 1.68 in Support of Petitioner Reply to Patent Owner Response	Sept. 17, 2021	Ex. 1033

³ The table provided identifies only a select number of documents particularly pertinent to this Decision and does not list all references, declarations and deposition testimony introduced in the record. *See, e.g.*, Reply ii–iii (Petitioner’s Updated Exhibit List); Sur-reply iv (Patent Owner’s List of Exhibits). A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding.

References and Witness Testimony	Date	Ex. No.
Declaration of John H. Peloza, M.D., Under 37 C.F.R. § 1.68 in Support of Petitioner Reply to Patent Owner Response	Sept. 17, 2021	Ex. 1034
Declaration of Barron Lonner, M.D. in Support of Patent Owner's Preliminary Response to Petition for <i>Inter Partes</i> Review	Nov. 29, 2020	Ex. 2010
Declaration of Barron Lonner, M.D. in Support of Patent Owner's Response to Petition for <i>Inter Partes</i> Review	May 20, 2021	Ex. 2022
Deposition Transcript of Barron Lonner, M.D.	Sept. 10, 2021	Ex. 1035
Declaration of Jim R. Lynn in Support of Patent Owner's Preliminary Response to Petition for <i>Inter Partes</i> Review	Nov. 24, 2020	Ex. 2006
Declaration of Jim R. Lynn in Support of Patent Owner's Response to Petition for <i>Inter Partes</i> Review	May 19, 2021	Ex. 2013
Declaration of Russell W. Nelson, M.D. in Support of Patent Owner's Preliminary Response to Petition for <i>Inter Partes</i> Review	Nov. 20, 2020	Ex. 2007
Declaration of Russell W. Nelson, M.D. in Support of Patent Owner's Response to Petition for <i>Inter Partes</i> Review	May 19, 2021	Ex. 2014
Declaration of Anna Green in Support of Patent Owner's Preliminary Response to Petition for <i>Inter Partes</i> Review	Nov. 20, 2020	Ex. 2008
Declaration of Anna Green in Support of Patent Owner's [] Response to Petition for <i>Inter Partes</i> Review ⁴	May 20, 2021	Ex. 2016

⁴ Based on the date of Exhibit 2020, we understand it to be in support of the Patent Owner Response, notwithstanding that the title of the document refers to Patent Owner's Preliminary Response.

References and Witness Testimony	Date	Ex. No.
Declaration of Daniel M. Cislo in Support of Patent Owner’s Preliminary Response to Petition for <i>Inter Partes</i> Review	Nov. 13, 2020	Ex. 2009
Declaration of Eric Nauman in Support of Patent Owner’s Response to Petition for <i>Inter Partes</i> Review	May 20, 2021	Ex. 2010
Declaration of Dave Matsuura in Support of Patent Owner’s Response to Petition for <i>Inter Partes</i> Review	May 20, 2021	Ex. 2020
Declaration of Belinko Matsuura in Support of Patent Owner’s Response to Petition for <i>Inter Partes</i> Review	May 20, 2021	Ex. 2021

F. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

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

Pet. 15.

⁵ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102, 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(b)–3(c), 3(n)(1), 125 Stat. 284, 285–87, 293 (2011). There is no dispute that the Challenged Claims have an effective filing date before March 16, 2013, and we apply the pre-AIA versions of these statutes. *See* Sur-reply 9–25; Tr. 23:19–24:7.

III. ANALYSIS OF PATENTABILITY

A. Principles of Law

Petitioner contends under two grounds that claims 1–20 of the '096 patent are unpatentable based on obviousness. *Id.* As set forth in 35 U.S.C. § 103(a),

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); accord *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

B. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Id.* (citation omitted).

Relying on the testimony of its declarant, Mr. Sherman, Petitioner asserts that a person of ordinary skill in the art of the '096 patent, at the time of filing the earliest provisional application,

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

Pet. 11 (Ex. 1003 ¶¶ 22–25). Patent Owner does not dispute Petitioner's proposed level of ordinary skill in the art. *See generally* Resp.; *see also* Ex. 2010 ¶ 83 (Dr. Lonner providing similar definition of the level of ordinary skill). We adopt Petitioner's proposed level of ordinary skill in the art as it is undisputed and consistent with the level of skill reflected in the

prior art and the Specification of the '096 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

As their qualifications are undisputed, we also determine that the parties’ experts are qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 1003 ¶¶ 5–21 (Mr. Sherman’s qualifications); Ex. 1034 ¶¶ 5–12 (Dr. Peloza’s qualifications); Ex. 2019 ¶¶ 6–10 (Dr. Lonner’s qualifications); Ex. 2015 ¶¶ 6, 7 (Dr. Nauman’s qualifications); *see also Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369 (Fed. Cir. 2022) (“To offer expert testimony from the perspective of a skilled artisan in a patent case . . . a witness must at least have ordinary skill in the art”).

C. Claim Construction

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

1. “*graft material delivery system*”

Petitioner contends limitation 1.1.3 (“graft material delivery system”), as well as a substantively similar limitation recited in claim 16, are means-plus-function limitations. Pet. 12. According to Petitioner, the presumption that these limitations are not means-plus-function limitations because they do not use the word “means” is overcome because “graft material delivery system” is not understood in the art as referring to a specific structure and a “conduit,” the only structure recited, is not sufficient for performing the stated function. *Id.* at 12–13 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348–49 (Fed. Cir. 2015) (en banc); Ex. 1003 ¶ 118).

In regard to the corresponding structure, Petitioner directs us to the Specification, which states “In some arrangements, the graft material delivery system comprises a syringe, a sizing tool and a conduit configured to pass through the at least one access port of the spinal implant.” *Id.* at 13 (quoting Ex. 1001, 4:13–22). Petitioner also identifies another structure described in the Specification for performing the function, stating, in reference to Figure 18, that insertion tool 300 may be used to fill the interior chambers of the implant using “a flexible tube, catheter or other conduit of a syringe assembly,” including syringe 650 (having plunger 658, and barrel 652) and tubing 670 (as shown in Figures 13 and 15). *Id.* at 13–14 (citing Ex. 1001, 22:25–32, 22:41–44, 24:42–56; Figs. 13, 15, 18) (emphasis omitted). According to Petitioner, “it suffices here to identify only the structure for performing the claimed function of a syringe attached to a conduit, or a plunger configured to displace graft material within a conduit.” *Id.* at 15 (citing Ex. 1003 ¶¶ 116–125) (emphasis omitted).

In its Response, Patent Owner does not dispute Petitioner’s argument that the “graft material delivery system” limitations of claims 1 and 16 are a means-plus-function limitation or Petitioner’s proposed construction. *See generally* Resp. Moreover, Patent Owner does not present any specific arguments that the “graft material delivery system” limitation of claims 1 and 16 is not taught or suggested by the prior art references. *See id.* at 44–49 (claim 1), 58–63 (claim 16). Thus, the parties have not presented a dispute as to the meaning of the “graft delivery material system” and, for purposes of this Decision, no further express construction is necessary. Only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that “only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs.* in the context of an *inter partes* review).

2. “*continuous peripheral boundary*”

Claims 1 and 16 recite “wherein the walls and sidewalls of the implant form a *continuous peripheral boundary* around the at least one chamber upon implantation.” Ex. 1001, 27:55–57; 28:16–29:1 (emphasis added). Neither party proposes an express construction of “continuous peripheral boundary,” but the parties disagree over what the term encompasses. Pet. 53–55; Reply 38–40; Resp. 44, 58. In our Institution Decision we did not expressly construe “continuous peripheral boundary,” but we did find that Petitioner had shown sufficiently for institution that the limitation was taught by the asserted art “even though the walls and the sidewalls have an

access port or other openings along the outer walls,” because such structure was “consistent with the use of the term “a continuous peripheral boundary” in the ’096 patent,” and that “[r]ead together, limitations [1.5.1] and [1.5.2] require ‘a continuous peripheral boundary around the at least one chamber . . . such that the at least one chamber contains graft material delivered through the access port.’” Inst. Dec. 38. We revisit the issue here and find on the full record no reason to depart from our previous interpretation, as explained below.

Petitioner contends that “‘continuous peripheral boundary’ . . . does not preclude an access port or other openings along the outer wall.” Pet. 53–54 (citing Ex. 1003 ¶¶ 212, 213). In this regard, Petitioner directs us to the Specification of the ’096 patent, which does not use the term “continuous peripheral boundary” outside of the claims, but does state as follows:

According to some embodiments, the spinal implants disclosed herein or equivalents thereof comprise a generally closed structure along their sides. For example, in some arrangements, the only openings along the outer sidewalls (e.g., lateral, posterior, anterior) of an implant are one or more ports 50 (e.g., used to engage the implant with a delivery tool and/or used to pass a graft delivery tube to the interior of the implant) and/or one or more openings that permit excess grafting materials to exit an interior chamber or other cavity of the implant (e.g., openings 60 along the anterior side wall of the implant, as illustrated in FIG. 3A).

Ex. 1001, 10:59–11:2. Petitioner’s interpretation is also consistent with the spacers illustrated in the ’096 patent, which include openings in the outer walls. *See, e.g.*, Ex. 1001, Figs 1A, 1B, 3A, 6A, 6C, 7A, 7B, 11, 12A, 14, 16A, 16B, 16C, 17A, 19, 20.

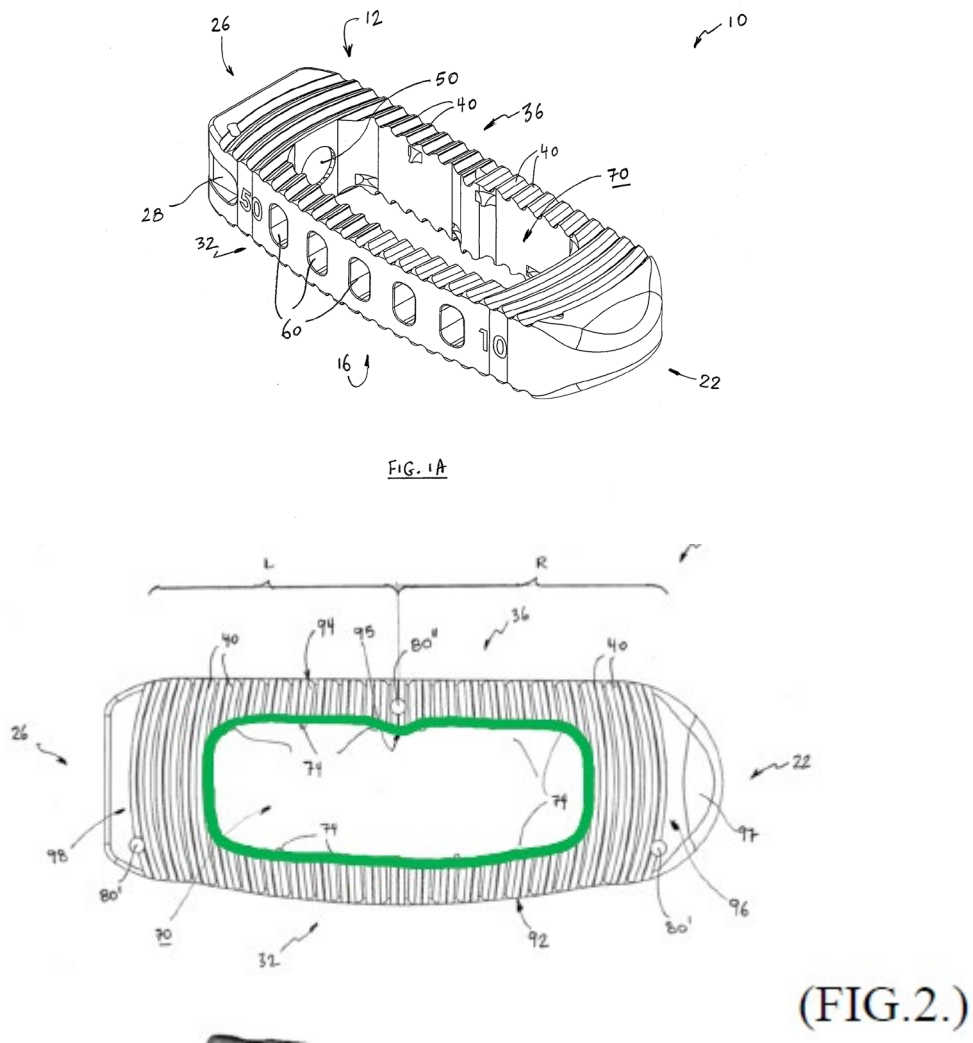
In regard to “continuous peripheral boundary,” Patent Owner argues that it “indicates there are no openings as it is continuous.” Resp. 44 (citing

Ex. 2022 ¶¶ 93–108, 115–134, 203–220).⁶ As purported further support for its interpretation of the claim language, Patent Owner directs us to claim 9, which depends from claim 1, and further recites “[t]he system of claim 1, wherein at least one of the first and second side walls of the implant does not comprise any openings.” Ex. 1001, 28:26–28. Thus, claim 9 further limits claim 1, and requires that among “a first wall,” “a second wall,” and “first and second sidewalls” comprising, in part, the implant, “at least one” of the sidewalls has no openings. Patent Owner references “claim differentiation,” and turns the limitation of claim 9 on its head, arguing that, unlike claim 1, claim 9 “allows for there to be openings on at least one of the side walls.” Resp. 44. We agree with Petitioner that claim 9 narrows claim 1 and “makes it clear that claim 1 is broad enough to encompass implants with openings through sidewalls, including all four implant sidewalls.” Reply 39.

In its Sur-reply, Patent Owner effectively concedes that Petitioner is correct. In support of its contention that “the ’096 [patent] claims find support in the ’671 [provisional],” Patent Owner argues that a “continuous

⁶ As explained below, Patent Owner’s repeated citation to the same broad portions of Dr. Lonner’s declaration fails to identify where Dr. Lonner’s testimony supports any particular argument by Patent Owner. *See infra* Section III.E.2. We have searched Dr. Lonner’s declaration and fail to find any testimony that a “continuous peripheral boundary” precludes any opening, as Patent Owner argues. *See, e.g.*, Ex. 2022 ¶ 125 (stating that the asserted art fails to teach or suggest a “continuous peripheral boundary” because they are “open designs that allow graft material to flow freely from the area that allegedly teaches a chamber”). Petitioner notes that during cross examination Dr. Lonner stated that Figure 19 of the ’096 patent was not an “open cage,” (presumably meaning, not at “open design”), despite having large openings along one side, because it has at least one wall with no holes. Reply 38 (citing Ex. 1035, 120:15–121:3; Ex. 1033 ¶ 70).

peripheral boundary” is disclosed in Figure 2 of the ’671 provisional, which corresponds to a “top view” of the implant shown in Figure 1A of the ’671 provisional. Figure 1A of the ’671 provisional and Figure 2 of the ’671 provisional, as annotated by Patent Owner to show the “continuous peripheral boundary” in green, are reproduced below:



no credible evidence supports Patent Owner’s argument that “continuous peripheral boundary” requires no openings in the walls of an intervertebral insert or spacer. We further find that Petitioner has shown persuasive support in the Specification of the ’096 patent that “continuous peripheral boundary” does not preclude openings in the walls of an intervertebral insert or spacer. *See, e.g.*, Ex. 1001 10:59–11:2, Figs 1A, 1B, 3A, 6A, 6C, 7A, 7B, 11, 12A, 14, 16A, 16B, 16C, 17A, 19, 20.

3. Other Claim Terms

Petitioner does not propose an express construction for any other claim term. Patent Owner does not propose any express construction for any claim term. We find no other claim term requires an express construction for purposes of this Decision.

D. Scope and Content of the Asserted Art

To show the unpatentability of the Challenged Claims, Petitioner relies on Alfaro, Frey, Perez-Cruet, and Fuss. Pet. 15. Each of these references is summarized in relevant part below.

1. Summary of Alfaro

Alfaro, titled “Intervertebral Spacer,” relates to surgical devices for insertion of intervertebral spacer implants and delivery of bone grafting material into intervertebral spaces in surgical procedures. Ex. 1008, code (54), ¶ 4. Alfaro teaches that, to correct various spinal defects, it is often necessary to place exogenous devices between vertebrae in an effort to fuse adjacent vertebrae to each other. *Id.* ¶ 5. One way to achieve this is to introduce and pressure-fit a solid material into the vertebral space between the opposing vertebral bodies. *Id.* Alfaro explains that:

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

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

Alfaro teaches “a delivery system in the form of a unitary device which comprises a spacer disengagingly attached to a hollow handle.” *Id.*

¶ 11. In this regard, Alfaro states as follows:

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

Id. Alfaro teaches that the spacer may be any intervertebral spacer, as long as it is attachable and detachable to the handle. *Id.* ¶ 12. The spacer comprises “voids and spaces which communicate with the chamber of the handle on the one hand and with the intervertebral spaces on the other.” *Id.*

“Thus, there is a direct line of flow through the handle into the voids of the spacer and out into the vertebral space.” *Id.*

Alfaro also teaches as follows:

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

Id. ¶ 19.

Figure 2 of Alfaro is reproduced below:

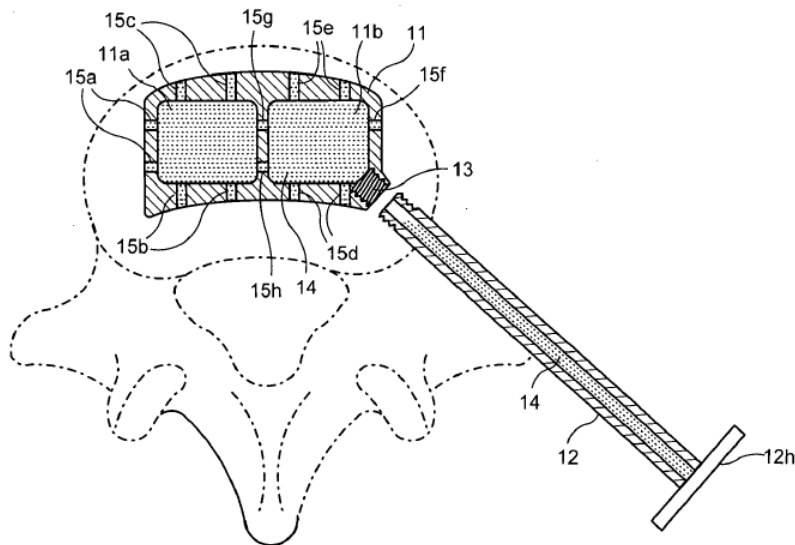


FIG. 2

Figure 2 is a plan view of an embodiment of Alfaro's delivery system containing biologic material and positioned within the anatomy of a patient.

Id. ¶ 24. Spacer 11 comprises compartments 11a and 11b, which are open at

the top and bottom, and adapted to contain demineralized bone matrix (DBM). *Id.* ¶¶ 22, 28; *see also* Ex. 1003 ¶ 131 (Mr. Sherman explaining that DBM is an example grafting material). Handle 12 screws into compartment 11b at 13. *Id.* ¶ 29. Handle 12 is shown to contain DBM 14 in the hollow portion of handle 12 and in compartments 11a and 11b. *Id.* Compartments 11a and 11b are connected by tunneling 15g and 15h to allow biologic material to flow from the compartment of introduction to the other compartment and out into the intervertebral space. *Id.*

2. Summary of Frey

Frey, titled “Devices and Techniques for a Posterior Lateral Disc Space Approach,” relates to methods and instruments for performing disc space preparation and implant insertion from a unilateral approach to the spine through a posterior lateral opening to the disc space. Ex. 1005, codes (54), (57).

Figure 55 of Frey is reproduced below:

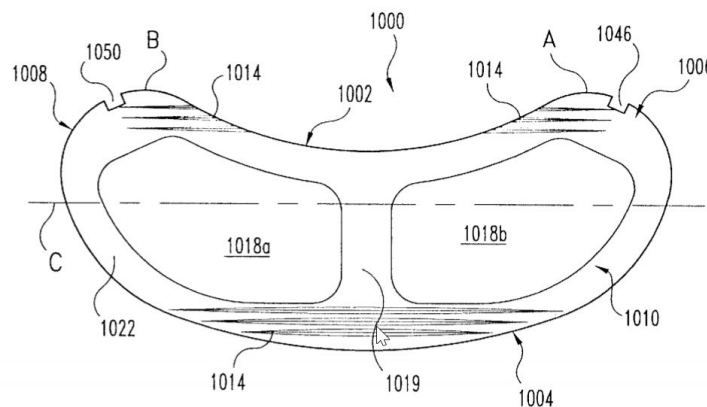


Fig. 55

Figure 55 is a top plan view of an implant according to one aspect of Frey. *Id.* at 5:3. “Implant 1000 is an interbody fusion device or cage that can be packed with bone growth material or other known substance and inserted into disc space D1 to promote bony fusion between vertebrae V1 and V2.”

Id. at 19:18–21. Implant 1000 includes a concave posterior wall 1002, an opposite convex anterior wall 1004, an arcuate leading end wall 1006, and an arcuate trailing end wall 1008. *Id.* at 19:43–46. It further includes an upper bearing member 1010 and a lower bearing member 1012 extending between and connecting walls 1002, 1004, 1006 and 1008. *Id.* at 19:50–52.

Figure 54 of Frey is reproduced below:

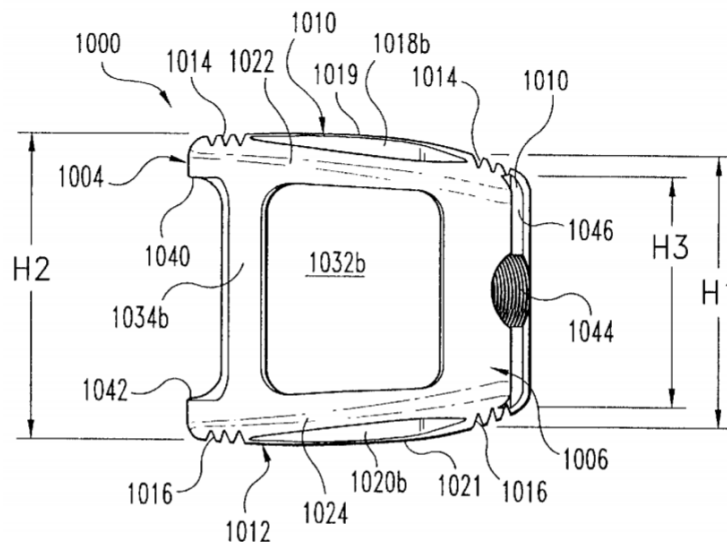


Fig. 54

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

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

Id. at 19:53–60. Frey also teaches that upper bearing member 1010 and lower bearing member 1012 can further be provided with a number of grooves 1014 and 1016, respectively. *Id.* at 20:6–8. “Grooves 1014 and

1016 can engage the vertebral endplates to resist posterior and anterior migration of implant 1000 in the disc space.” *Id.* at 20:8–11.

3. *Summary of Perez-Cruet*

Perez-Cruet, titled “Minimally Invasive Interbody Device Assembly,” relates to a minimally invasive interbody device assembly that includes an interbody device for restoring the disc space height between two adjacent vertebrae during spinal fusion surgery, and an instrument for positioning the device in the disc space and delivering bone graft material to the disc space on both sides of the device. Ex. 1004, code (54), ¶ 3.

Figure 21 of Perez-Cruet is reproduced below:

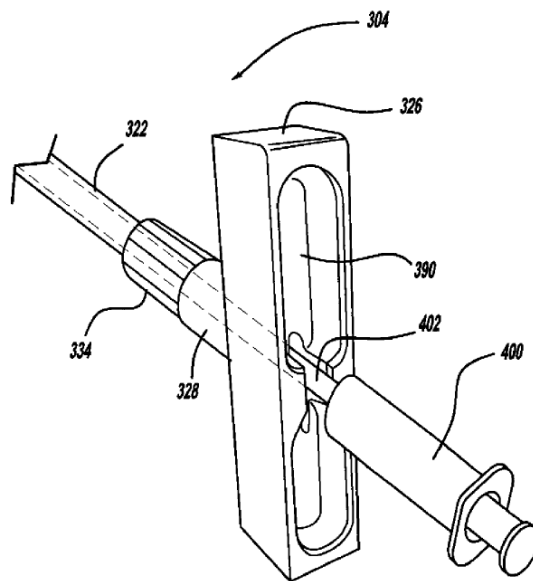


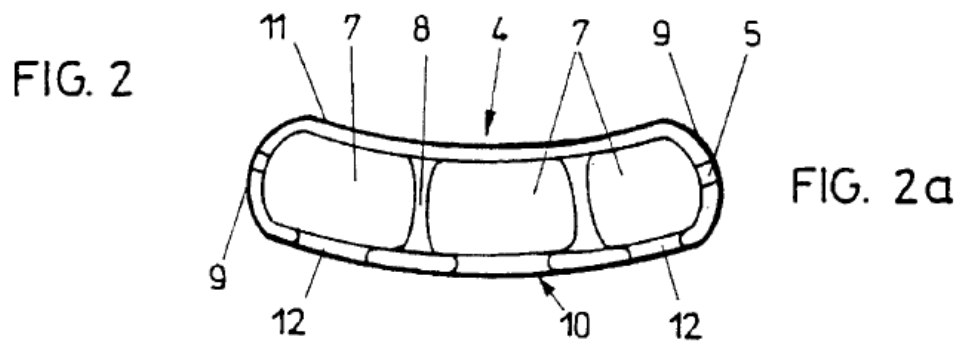
FIG - 21

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

4. Summary of Fuss

Fuss, titled “Implant for Insertion Between Spinal Column Vertebrae,” relates to an implant for insertion between the vertebrae of the spinal column. Ex. 1022, code (54), 1:8–12. Figure 2, which includes Figures 2a–2e, illustrates “schematic top views of differing embodiments of an implant [4].” *Id.* at 6:13–14.

Figure 2a of Fuss is reproduced below.



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

E. Alleged Obviousness over Alfaro, Frey, and Perez-Cruet

Petitioner asserts that claims 1–8 and 10–20 of the '096 patent would have been obvious over the combination of Alfaro, Frey, and Perez-Cruet. Pet. 17–87; Reply 1–8. Patent Owner argues that Alfaro is not prior art to the '096 patent based on alleged prior conception and reduction to practice and that the Challenged Claims would not have been obvious over the asserted art. Resp. 5–68; Sur-reply 1–26. After reviewing the entire record developed at trial, and as explained below, we determine Petitioner has shown, by a preponderance of the evidence, that Alfaro is prior art to the Challenged Claims, that the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests each limitation of claims 1–8 and 10–20, and that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, and Perez-Cruet and would have had a reasonable expectation of success.

1. Whether Alfaro is Prior Art to the Challenged Claims

Petitioner bears the burden to show that Alfaro is prior art. *See Dynamic Drinkware*, 800 F.3d at 1379. With regard to the '096 patent, the parties agree that the earliest priority date for the Challenged Claims is October 4, 2010, the filing date of the '671 provisional. *See* Sur-reply 9–25; Tr. 23:19–24:7. Alfaro, a published U.S. patent application filed on February 17, 2010, references a provisional application filed on February 18, 2009 (the “Alfaro provisional”). Ex. 1008, codes (22), (60). Petitioner has shown, including through a detailed claim chart comparing Alfaro to the Alfaro provisional, that Alfaro is entitled to the benefit of the date of the Alfaro provisional. *See* Pet. 17 (citing Ex. 1003, App’xs. A, B); Reply 19–38. Patent Owner does not dispute the substance of Petitioner’s showing in

this regard and states that although the Board did not determine whether Alfaro was entitled to the benefit of the date of its provisional application in the Institution Decision, it “provides evidence that antedates Alfaro even if it is entitled to the benefit of its provisional application filing date.” Resp 5–6 Thus, Petitioner contends that Alfaro is prior art under 35 U.S.C. § 102(e) because it is entitled to a priority date of February 18, 2009, before October 4, 2010, the priority date of the Challenged Claims. Pet. 15–17; Reply 19 (citing *Dynamic Drinkware*, 800 F.3d at 1380).

Patent Owner disputes the prior art status of Alfaro, arguing as follows:

Alfaro is not prior to the claims of the ‘096 Patent under Section 102(e) because the inventors, Jim Lynn and Dr. Russell Nelson, conceived of the claimed subject matter before the alleged priority date of Alfaro, and Mr. Lynn, Dr. Nelson, and their prosecution counsel (Dan Cislo and Theodore Papagiannis) exercised reasonable diligence to reduce the invention to practice during the legally relevant period (*i.e.*, critical period).

Resp. 5. An inventor may antedate a § 102(e) reference by showing that the invention was conceived before the effective date of the reference, followed by reasonably continuous diligence until the constructive reduction to practice. *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1362 (Fed. Cir. 2001).

The parties dispute whether Patent Owner sufficiently shows conception of the claimed subject matter of the ‘096 patent prior to the effective date of Alfaro, February 18, 2009. *See* Resp. 6–23 (asserting evidence demonstrates a conception date no later than April 14, 2008) (citing, e.g., Ex. 2013, ¶¶ 8, 19; Ex. 2014, ¶¶ 8, 18; Ex. 2016 ¶¶ 9, 12, 13); Reply 1–10. We do not need to reach the dispute of the parties over

conception, because, as explained below, we find Patent Owner has not sufficiently demonstrated that the inventors exercised reasonably continuous diligence in reducing the invention to practice.

Patent Owner must show reasonably continuous diligence in reducing the invention to practice during the critical period from just before the effective date of Alfaro, February 18, 2009, to the date of Patent Owner's constructive reduction to practice, October 4, 2010. *See* Resp. 29 (stating that the filing of the '671 provisional "served as constructive reduction to practice"); *see also Monsanto*, 261 F.3d at 1363 (explaining that time period for which diligence must be shown is from a date just preceding the effective date of the adverse reference, to the constructive reduction to practice). Although Patent Owner relies on the date of constructive reduction to practice, efforts toward actual reduction to practice are relevant to diligence until constructive reduction to practice. *Scott v. Koyama*, 281 F.3d 1243, 1248 (Fed. Cir. 2002).

The question of reasonable diligence is one of fact. *Brown v. Barbacid*, 436 F.3d 1376, 1379 (Fed. Cir. 2006). An inventor's testimony, standing alone, is insufficient to prove diligence, as some form of corroboration is required. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). Patent Owner's evidence includes testimony from Russell W. Nelson, M.D., a co-inventor of the '096 Patent; Jim R. Lynn, a co-inventor of the '096 patent and Dr. Nelson's "spinal implant representative;" Anna Green, a Registered Nurse First Assistant who worked for Dr. Nelson; Daniel M. Cislo, "prosecution counsel" concerning the '096 patent; Dave Matsura, the CEO of Flex Partners, Inc.; and, Belinko Matsura, a partner at

Flex Partners, Inc. Resp. 5–30; Exs. 2006–2009, 2013, 2014, 2016, 2020, 2021.

For purposes of our analysis, and consistent with Petitioner’s arguments, we divide the critical period diligence must be shown into two parts: from February 2009 through January 2010 (“Sub-Period 1”) and from February 2010 through October 4, 2010 (“Sub-Period 2”). Petitioner does not challenge the sufficiency of Patent Owner’s showing of diligence during Sub-Period 2. *See* Reply 12 (acknowledging “the product development activities in Sub-Period 2,” as shown by “declaration evidence supported by corroborating documents,” are “consistent with typical diligence activities”); *see also* Tr. 34:17–25 (stating that for purposes of showing lack of diligence, Petitioner has “focused on that first time period between February 2009 through January 2010”). Thus, our analysis of diligence is focused on the activities of the inventors during Sub-Period 1. Below, we first address evidence of activities related to attendance at surgeries and discussions among Dr. Nelson, Mr. Lynn, and Ms. Green; second, we address evidence of other related activities by Mr. Lynn and Dr. Nelson for each month from February 2009 to January 2010; and third, we apply a rule of reason analysis to the evidence of diligence and conclude the evidence of diligence is insufficient.

a. Attending Surgeries and Discussions Afterwards

Mr. Lynn states that each claimed element of the Challenged Claims was conceived on or before April 14, 2008. Ex. 2013 ¶¶ 23–27. Further, according to Mr. Lynn, “[f]ollowing the April 14, 2008 meeting, [the inventors] began working in earnest on reducing the post-fill spinal implant and insertion method to practice.” *Id.* at ¶ 28. Sub-Period 1 begins in

February 2009, over nine months after the April 14, 2008 conception date. To support a showing of diligence during Sub-Period 1, Patent Owner states that “[b]etween February 2009 and July 2009, Mr. Lynn attended multiple surgeries performed by Dr. Nelson, with assistance from Ms. Green. Resp. 23 (citing Ex. 2013 ¶¶ 32, 33, 36, 37, 39, 41, 43–46, 49–51, 53–56; Ex. 2014 ¶¶ 34–36, 39, 40, 42, 43, 45–48, 50–57). Mr. Lynn’s calendar entries (Ex. 2004) and Ms. Green’s testimony (Ex. 2016 ¶¶ 16–34) support that Mr. Lynn attended surgeries on nineteen dates from February 2009 to July 2009. Ex. 2013 ¶¶ 32, 33, 36, 37, 39, 41, 43–46, 49–51, 53–56. For each and every date, the inventors testify, without further explanation, that “[d]uring and after the surgery, Dr. Nelson, Ms. Green, and I discussed the flaws with the existing implants and insertion methods and how we could improve our design to address the flaws.” *Id.*; Ex. 2014 ¶¶ 34–36, 39, 40, 42, 43, 45–48, 50–57. Ms. Green testifies to the same effect. Ex. 2016 ¶¶ 16–34. Neither the inventors nor Ms. Green, however, provide any description of any flaws or improvements discussed following those nineteen surgery dates spanning six months.

In this regard, Patent Owner points to no contemporaneous documents to support the inventors’ testimonies on these issues. This is especially noteworthy because, according to Patent Owner, “Mr. Lynn, is a fastidious record[-]keeper,” and “[h]ad all of his old calendars, had all of his old emails, had drawings, sketchbooks” that “were dated.” Tr. 38:25–39:2. Yet, Patent Owner has not presented a scintilla of evidence from the relevant six month period to show the discussions after surgeries were substantively directed to diligently reducing the claimed invention to practice (conceived back in April 14, 2008) in light of any flaws of the prior art or possible

design improvement. Thus, we accord little weight to the testimonies of the inventors and Ms. Green of their discussions during and after each surgery between February 2009 and July 2009.

We also discount such testimonies because, as Dr. Pelozza, Petitioner's expert, testifies, in the relevant field, surgeons "routinely interacted with sales representatives from medical device companies providing implants" and "it was not uncommon [for a surgeon] to discuss procedures with sales representatives both before and after a procedure." Ex. 1034 ¶ 28. Indeed, Dr. Lonner confirms that it was "standard" for a sales representative to join in the operating room during a procedure, to discuss patient procedures, and "to review the case and the implants that [the surgeon is] interested in using." Ex. 1035, 85:14–87:11. According to Dr. Lonner, "the sales reps are learning, as well as . . . providing a service. And as part of their providing a service, they want to make sure they have the right inventory for you for the procedure that is at hand." *Id.* at 87:2–7. Dr. Lonner further testifies that, although "not necessarily [a] standard practice," a surgeon also would "potentially" discuss the procedure with the sales representative afterwards. *Id.* at 88:7–12.

During the critical period, Mr. Lynn "was a spinal implant representative for various medical device distribution companies and served, among other physicians, Dr. Russell Nelson." Ex. 2013 ¶ 3; *see also id.* ¶ 7 (Mr. Lynn testifying that he "had been Dr. Nelson's spinal implant representative since around 1994"). Thus, Mr. Lynn attending surgeries performed by Dr. Nelson, as well as discussions among Dr. Nelson, Mr. Lynn, and Ms. Green afterwards, reflect the usual business for a device company representative and a surgeon.

In short, the fact that Mr. Lynn attended surgeries with Dr. Nelson, and had discussion afterwards, is not, itself, evidence of diligence. While Ms. Green supports the inventor's testimony, her testimony is identical to the inventors and provides no additional supporting detail of those conversations, stating only that after each surgery "Mr. Lynn, Dr. Nelson, and I discussed the flaws with the existing implants and how we could improve their design to address the flaws." Ex. 2008, ¶¶ 15–34. Ms. Green refers to herself as an active participant in those discussions—"how we could improve their design"—but provides no testimony of any improvement she proposed or that was discussed after each and every of the nineteen surgery dates identified by Patent Owner. *See id.* We find the identical testimony of Mr. Lynn, Dr. Nelson, and Ms. Green, absent any detail or supporting documentation, to be not credible evidence of diligence during the critical period. Patent Owner has not demonstrated that these activities are related to reducing the allegedly conceived subject matter to practice. In other words, Patent Owner has not shown that these activities demonstrate the requisite diligence to antedate Alfaro.

b. Other Activities

Patent Owner argues that other activities, including searching for a graft material, also demonstrate the inventors' diligence. *See, e.g.,* Resp. 24–25. As a preliminary matter, we note that the Challenged Claims recite "an implant," "an implant insertion tool," and "a graft material delivery system." *See* Ex. 1001, 27:16–63, 28:48–30:2. Neither the claims nor the Specification suggests or requires any special property of the graft material. Thus, we are not persuaded that searching for a graft material is relevant to our diligence inquiry. Moreover, the '096 patent discloses that

“various materials that can be delivered to the internal chamber(s) of an implant include . . . demineralized bone matrix (DBM).” Ex. 1001, 21:20–22. Petitioner points out that Mr. Lynn sold DBM at the relevant time. Pet. 13 (citing Ex. 2003, 1 (Mr. Lynn stating in an email dated February 3, 2009 that “I sell DBM.”)). We agree with Petitioner that this fact “undercuts [Patent Owner’s] arguments that it was necessary to spend years searching for a suitable biologic material when [Mr. Lynn] already had access to DBM.” Reply 13.

Patent Owner also contends that during Sub-Period 1, the inventors engaged in efforts to sell “their intellectual property in their implant.” Resp. 24–25. It is unclear what right Patent Owner is referring to because during that time, the inventors had not filed any patent application. In fact, the first patent application, the ’509 provisional, was not filed until March 2010, in Sub-Period 2.⁷ *See* Ex. 1001, code 60; Ex. 2009 ¶ 22; Ex. 2013 ¶ 66. Moreover, Patent Owner does not point to any binding authority to support, or otherwise persuasively argue, that such a commercial activity should be part of the diligence inquiry.

Despite our doubts of relevance, we discuss below all evidence Patent Owner presents, including what allegedly supports the argument that the inventors spent time and effort searching for a graft material and selling intellectual property rights. We explain our analysis based on the chronological order of the activities.

⁷ Patent Owner does not argue that the Challenged Claims are entitled to the benefit of the ’509 provisional filing date. *See* Resp. 29 (“[T]he filing of the ’671 Application served as constructive reduction to practice”); *see also* Sur-reply 9–25 (arguing the Challenged Claims are entitled to the benefit of the ’671 provisional filing date on October 4, 2010).

i. February 2009

Patent Owner asserts that in February 2009, “Mr. Lynn attended meetings and conferences to find a graft material, arrange for manufacturing of the implant, and a possible sale to their intellectual property in their implant.” Resp. 23–24 (citing Ex. 2013 ¶¶ 33,⁸ 34; Ex. 2014 ¶ 37; Ex. 2004, 1).

Mr. Lynn’s calendar entries show two appointments on February 19, 2009, and an AAOS (American Academy of Orthopedic Surgeons) conference from February 25 to February 27, 2009. Ex. 2004, 1. There is, however, no other evidence supporting the inventors’ testimonies about the purposes of attending the meetings and conferences. Thus, Patent Owner has not shown that the activities relied on here related to the inventors’ diligence in reducing the allegedly conceived subject matter to practice. In other words, the calendars only support Mr. Lynn’s testimony that he attended meetings and conferences.

ii. March 2009

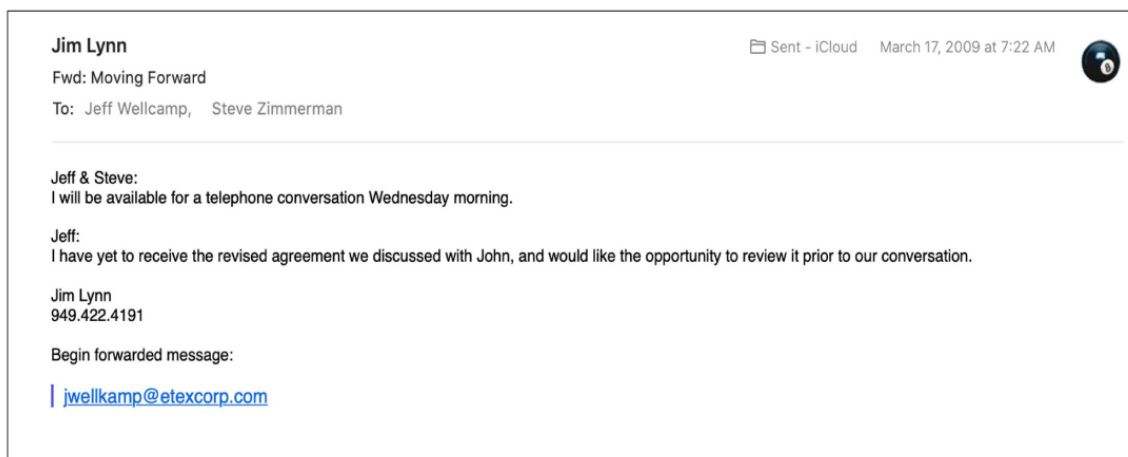
Patent Owner further argues that, in March 2009, “Mr. Lynn corresponded with multiple people in an effort to find a flowable graft material and arrange for manufacturing of the implant, and a possible sale to their intellectual property in their implant.” Resp. 24 (citing Ex. 2013 ¶¶ 37, 38, 40; Ex. 2014 ¶ 41; Ex. 2003, 3–4). As support, Mr. Lynn points to several email communications between him and others. Ex. 2013 ¶ 37

⁸ There are two paragraphs numbered “33” in Mr. Lynn’s declaration: one on page 17, the other on page 18. We understand Patent Owner to intend to refer to paragraph 33 on page 17, as the latter on page 18 relates to Mr. Lynn attending a surgery on February 24, 2009, and thus, does not pertain to Patent Owner’s argument here. *See* Ex. 2013, p. 18.

(referencing Ex. 2003). The evidence, however, does not corroborate Mr. Lynn's testimony. For example, Mr. Lynn testifies regarding March 17, 2009, as follows:

I emailed Jeff Wellcamp, a representative at ETEX. During this time period, I was mostly experimenting with ETEX's flowable biologic material, and I wanted to make sure that ETEX could not claim any rights to our post-fill spinal implant idea. As seen below, the purpose of the email to Mr. Wellcamp was to discuss an agreement regarding our intellectual property rights.

Ex. 2013 ¶ 37. The email message Mr. Lynn cites is reproduced below:



Ex. 2003, 2. The figure above is a reproduction of an email from Mr. Lynn dated March 17, 2009. *Id.* It does not mention, as Mr. Lynn states, biologic material, a post-fill spinal implant, or intellectual property rights.

Similarly, the emails cited in paragraph 38 of Mr. Lynn's declaration does not corroborate his testimony. *See* Ex. 2013 ¶ 38 (citing Ex. 2003, 3).⁹ Mr. Lynn testifies that the purpose of a March 18, 2009, email from him to

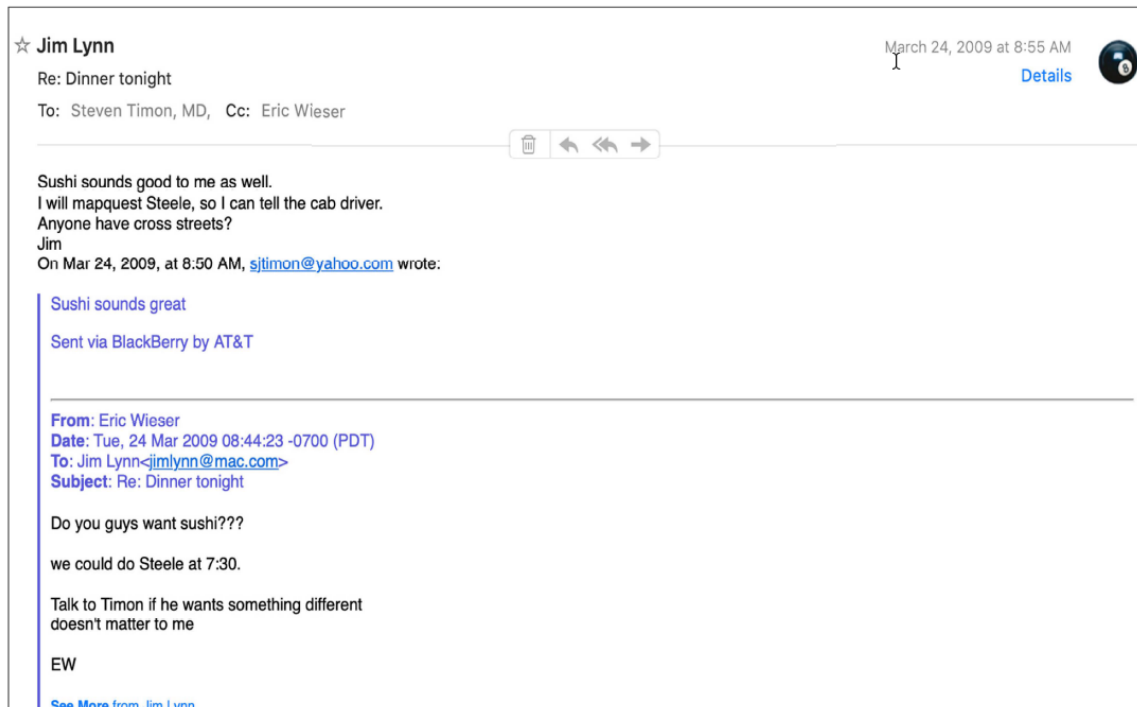
⁹ Patent Owner also cites paragraph 41 of Dr. Nelson's declaration. Resp. 24 (citing Ex. 2014 ¶ 41). All testimony there is essentially the same as that in paragraph 38 of Mr. Lynn's declaration, discussed here. *Compare* Ex. 2013 ¶ 38, *with* Ex. 2014 ¶ 41.

two medical doctors “was to set up a future meeting to discuss possible cage designs for our post-fill spinal implant.” *Id.* The email itself, however, states Mr. Lynn would like to discuss “‘Cabo Spine’ as it relates to *your* TLIF project,” that is, the doctors’ project, and not the inventors’ post-fill spinal implant.¹⁰ *See* Ex. 2003, 3 (emphasis added).

Mr. Lynn further testifies that, on March 18, 2009, he “corresponded with the Cabo Spine Society to update them on the latest events with Vertebron Inc., a spinal implant manufacturer.” Ex. 2013 ¶ 38 (citing Ex. 2003, 4). According to Mr. Lynn, he “proposed that the Cabo Spine Society purchase Vertebron’s assets out of bankruptcy to manufacture the post-fill spinal implant ourselves.” *Id.* That email discusses a petition Mr. Lynn filed “to force Vertebron into involuntary BK,” and the working of a deal so “EVERYONE in Cabo Spine” can “get[] money.” Ex. 2003, 4. Even though one of the purposes of that email was to “[l]et you know what we are planning to do,” there is no mention of manufacturing the post-fill spinal implant. *Id.*

Paragraph 40 of Mr. Lynn’s declaration lends no support to the purported diligence either. Here, Mr. Lynn testifies that, on March 24, 2009, he emailed the same two medical doctors he emailed previously on March 18 to set up a dinner meeting. Ex. 2013 ¶ 40 (citing Ex. 2003, 4). According to Mr. Lynn, “[t]he purpose of the email, as seen below, was to discuss their ideas for the structure of a cage that we could use in our post-fill spinal implant.” *Id.* The email is reproduced below:

¹⁰ Mr. Lynn explains that the “Cabo Spine Society” is a group of people that he “assembled to possibly start a company to manufacture our post-fill spinal implant.” Ex. 2013 ¶ 29.



The figure above is a reproduction of a series of email communications dated March 24, 2009 that Mr. Lynn relies on in paragraph 40 of his declaration. *Id.* It only relates to a dinner arrangement, and does not mention, as Mr. Lynn states, anything about the post-fill spinal implant. The email corroborates Mr. Lynn had plans to have dinner, not what Mr. Lynn asserts was discussed at dinner.

iii. April 2009

Patent Owner next contends that in April 2009, “Mr. Lynn continued to search for a biologic material that would work with their implant,” and “conducted meetings in an effort to arrange for manufacturing of the implant, and a possible sale to their intellectual property in their implant.”

Resp. 24 (citing Ex. 2013 ¶¶ 37,¹¹ 42, 48; Ex. 2014 ¶ 44; Ex. 2003, 3–5).

The evidence Patent Owner relies on, again, does not support this contention.

According to both Mr. Lynn and Dr. Nelson, on April 3, 2009, Dr. Nelson sent an email to Mr. Lynn concerning a bone graft material, OP1. Ex. 2013 ¶ 42; Ex. 2014 ¶ 44. The email they referred to, however, appears to be from Mr. Lynn to Dr. Nelson, not the other way. *See* Ex. 2003, 4. This minor inaccuracy, of course, does not affect our analysis on the merit. We, however, find dubious the testimonies of both Mr. Lynn and Dr. Nelson that (1) “OP1 was a bone graft material the we were considering using with our post-fill spinal implant,” and (2) “[t]he purpose of the email, as seen below, was to help us find a biologic material that would flow in our post-fill spinal implant.” Ex. 2013 ¶ 42; Ex. 2014 ¶ 44.

In the April 3, 2009, email, Mr. Lynn forwarded to Dr. Nelson a newsletter from HealthpointCapital Research Weekly. Ex. 2003, 4. The subject line of the newsletter is “OP-1 Not Approvable; DPAs Expire; OFIX Shareholders Vote Against Ramius.” *Id.* Mr. Lynn, when forwarding the newsletter, merely stated: “Saw this on the wire, yesterday.” *Id.* Without any explanation or other corroborating evidence, this one short sentence does not support the inventors’ testimonies that they were searching for a biologic material, and OP-1 was one of the candidates that may work in their post-fill spinal implant.

¹¹ We have addressed Mr. Lynn’s testimony and evidence relied on in paragraph 37 of his declaration. *See supra*, Section III.E.1.b.ii. We do not repeat the analysis here, other than to note that that paragraph and evidence therein relate to activities in March, and not April, 2009.

Mr. Lynn further testifies that on April 30, 2009, he “emailed Bill Pfof, the Vice President of New Business Development at Lanx. The purpose of the email, as seen below, was to set up a meeting with Lanx to discuss their biologic material.” Ex. 2013 ¶ 48 (citing Ex. 2003, 5). The evidence, however, shows that Mr. Lynn only responded to an email from Bill Pfof. Ex. 2003, 5. Indeed, that chain of email originated from Ms. Elizabeth Perez, “Lanx Biologics VP.” *Id.* After proposing a few dates in May to Mr. Pfof, she wrote: “[t]hank you again for your help!” *Id.* Mr. Pfof forwarded that email to Mr. Lynn, offering to have Ms. Perez “to come out later in May.” *Id.* According to Mr. Pfof, he “want[ed] her to see your tissue facilities” and “to meet with Dr[.] Nelson to discuss specifics of him working on biologics with us in addition to XLIF, etc.” *Id.* Mr. Lynn’s response, in its entirety, reads: “Please let Elizabeth know that we will be in touch with her when it is appropriate.” *Id.*

We do not find the email communications on April 30, 2009, show the inventors’ diligence in reducing the allegedly conceived subject matter to practice. Even if we were to credit Mr. Lynn’s testimony that the purpose of the email “was to set up a meeting with Lanx to discuss their biologic material” (*see* Ex. 2013 ¶ 48), we would agree with Petitioner that “the email appears to be nothing more than a salesperson [Mr. Pfof] doing his job,” that is, attempting to sell more products to Dr. Nelson, a spine surgeon. *See* Reply 15.

iv. May 2009

Patent Owner provides no additional evidence of diligence in May 2009, beyond Mr. Lynn attending surgeries and meeting afterwards, as discussed above. *See* Resp. 24; Ex. 2013 ¶ 49.

v. *June 2009*

Patent Owner argues that, in June of 2009, “Mr. Lynn corresponded with multiple people in an effort to arrange for the manufacture of the implant.” Resp. 24 (citing Ex. 2013 ¶ 52; Ex. 2003, 6–7). Mr. Lynn cites certain email communications dated between June 17 and June 19, 2009. Ex. 2013 ¶ 52 (citing Ex. 2003, 6–7). According to Mr. Lynn, “[t]he purpose of the emails, as seen below, was to begin making a plan for purchasing Vertebtron’s assets out of bankruptcy and manufacturing the post-fill spinal implants on our own.” *Id.*

The emails referred to appear to show that Mr. Lynn was concerned about Vertebtron’s inventory and the possible termination of an agreement between Vertebtron and Invibio. Ex. 2003, 6–7. According to Mr. Lynn, the termination of the agreement “makes *selling* the PEEK interbody cages almost impossible without another agreement (and series of payments).” *Id.* at 6 (emphasis added). Nothing in those emails corroborates Mr. Lynn’s testimony of a plan for manufacturing the post-fill spinal implants.

vi. *July 2009*

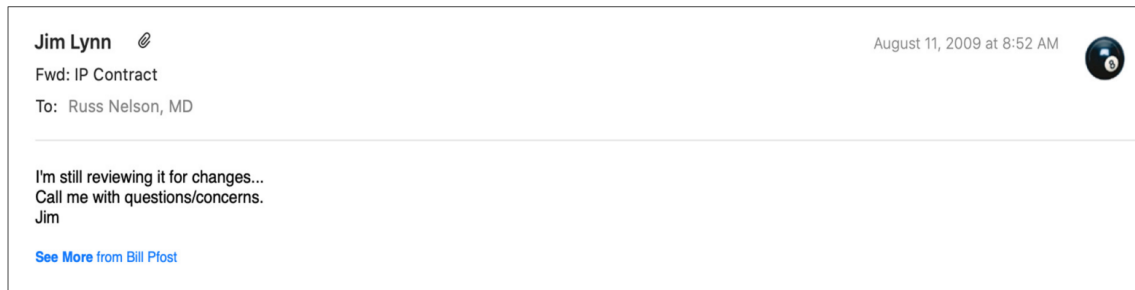
Patent Owner provides no additional evidence of diligence in July 2009, beyond Mr. Lynn attending surgeries and meeting afterwards, as discussed above. *See* Resp. 24; Ex. 2013 ¶¶ 53–56.

vii. *August 2009*

Patent Owner argues that in August 2009, “Mr. Lynn retained Dan Cislo to assist in activity related to the preparation and filing” of the ’509 provisional. Resp. 24 (citing Ex. 2009 ¶ 6; Ex. 2013 ¶ 57). Evidence—or perhaps more accurately, the lack thereof—shows that Mr. Cislo, a patent attorney, did not do anything related to the preparation

and filing of a patent application. In fact, it was not until January 2010 that Mr. Lynn sent an invention disclosure to Mr. Cislo. Ex. 2013 ¶ 64. In view of these facts, merely retaining Mr. Cislo, in and of itself, does not sufficiently demonstrate the inventors' diligence.

Patent Owner asserts that on August 11, 2009, "Mr. Lynn emailed Dr. Nelson about a possible intellectual property agreement with Lanx." Resp. 24 (citing Ex. 2013 ¶ 58; Ex. 2014 ¶ 58; Ex. 2003, 8). Exhibit 2003 is a seven-page document; and thus, the cited eighth page does not exist. Moreover, paragraph 58 of Mr. Lynn's declaration states that the August 11, 2009, email is attached therein. It is not. *See* Ex. 2013 ¶ 58. Paragraph 58 of Dr. Nelson's declaration, however, includes an email communication with that date. *See* Ex. 2014 ¶ 58. That email is reproduced below.



The figure above is a reproduction of an email from Mr. Lynn to Dr. Nelson, dated August 11, 2009. *Id.* According to both Mr. Lynn and Dr. Nelson, "[t]he purpose of the email, as seen below, was to possibly sign an agreement selling our intellectual property rights in the post-fill spinal implant to Lanx." Ex. 2013 ¶ 58; Ex. 2014 ¶ 58. Other than the subject line "IP Contract," the email does not include any substance to sufficiently support the inventors' testimonies.

Patent Owner also argues that on August 26, 2009, Dr. Nelson and Mr. Lynn attended a meeting with Lanx "to discuss a possible acquisition or

licensing of their intellectual property in the post-fill spinal implant.”
Resp. 25 (citing Ex. 2013 ¶ 59; Ex. 2014 ¶ 59). Again, as explained above,
with no patent application on file at the time, it is unclear what intellectual
property Patent Owner is referring to.

Nevertheless, according to Patent Owner,

During the August 26, 2009 meeting, Dr. Nelson and Mr. Lynn discussed their current configuration of the post-fill spinal implant. Additionally, Dr. Nelson noted their experiences designing their post-fill spinal implant. (Ex. 2013, ¶ 60; Ex. 2014, ¶ 60; Ex. 2005, pp. 7.) Dr. Nelson and Mr. Lynn discussed the issues resulting from the existing technology. *Id.* The inventors explained how their post-fill design obviated these flaws and produced superior fusion results.

Id. at 26.

Other than the inventors’ testimonies stating the same, Patent Owner relies on Exhibit 2005, which includes (1) a confidentiality agreement from the August 26, 2009, meeting with Lanx (Ex. 2005, 1–5; Ex. 2013 ¶ 59; Ex. 2014 ¶ 59); (2) Dr. Nelson’s boarding pass (Ex. 2005, 6; Ex. 2014 ¶ 60); (3) alleged notes taken by Dr. Nelson during the meeting (Ex. 2005, 7; Ex. 2014 ¶ 60); and (4) three drawings of an implant (Ex. 2005, 8–10). The evidence Patent Owner relies on does not sufficiently support its assertion.

First, the confidentiality agreement defines Lanx and the inventors “individually as a ‘party’ and collectively as the ‘parties.’” Ex. 2005, 1. It states “the party receiving Proprietary Information shall be referred to as the ‘Receiving Party or Recipient’ and the party disclosing Proprietary Information shall be referred to as the ‘Disclosing Party.’” *Id.* It does not state Dr. Nelson and Mr. Lynn are the “Disclosing Party.” Indeed, according to the confidentiality agreement, “the parties recognize that there

is a need to *disclose to one another* certain of their *respective* Proprietary Information.” *Id.* (emphases added).

Second, assuming the undated page 7 of Exhibit 2005 is notes Dr. Nelson took during that meeting, it is unclear whether they relate to the subject matter allegedly conceived by the inventors, or Lanx’s proprietary information. *See* Ex. 2005, 7. For one, Patent Owner has not explained sufficiently why Dr. Nelson would take notes of their own experiences and ideas. *See* Ex. 2014 ¶ 60 (Dr. Nelson testifying that “I took notes concerning our experiences designing our post-fill spinal implant”). More importantly, according to the confidential agreement, both parties disclosed proprietary information during that meeting, and Patent Owner has not shown sufficiently the notes relate to the inventors’ post-fill spinal implant.

Third, the three drawings of an implant on pages 8 to 10 of Exhibit 2005 are undated. *See* Ex. 2005, 8–10. Other than the “confidential” stamp, there is no other marking on those pages that indicates who created the drawings. Again, given both parties (Lanx and the inventors) disclosed proprietary information during that meeting, the drawings do not support Patent Owner’s argument that they relate to the inventors’ post-fill design. *See* Resp. 26.

viii. September 2009

Relying solely on inventors’ testimonies, Patent Owner contends that “[f]ollowing the August 26, 2009 meeting, Dr. Nelson and Mr. Lynn kept working on optimizing the design of the post-fill spinal implant before [they] filed a non-provisional application.” Resp. 26 (citing Ex. 2013 ¶ 62; Ex. 2014 ¶ 63). Patent Owner provides no additional evidence of diligence in September. *See id.* Because we accord little weight to inventors’

uncorroborated testimonies, we are not persuaded by Patent Owner's otherwise unsupported argument.

ix. October 2009

Patent Owner argues that in October 2009, "Mr. Cislo performed a patentability search for [the inventors'] post-fill spinal implant and insertion method." *Id.* (citing Ex. 2009 ¶ 9). Patent Owner has not produced evidence about the parameters of the patentability search Mr. Cislo performed in October 2009. *See* Ex. 2009 ¶ 9 (Mr. Cislo merely stating the patentability search is "work related to the '509 Provisional Application"). Again, as explained above, Patent Owner does not argue that the challenged claims are entitled to the benefit of the '509 provisional filing date. *See supra*, Section II.D.2 n.9. Even so, we accept that the patentability search and the invention disclosure related to the '509 provisional evince the inventors' diligence in the reduction to practice.

x. November 2009

Patent Owner provides no additional evidence of diligence in November 2009. *See* Resp. 26–27.

xi. December 2009

Patent Owner provides no additional evidence of diligence in December 2009. *See id.*

xii. January 2010

Patent Owner states that in January 2010, "Mr. Lynn sent Mr. Cislo an invention disclosure for the preparation of the '509 Provisional Application," and that, then, for over a month, from January 13, 2010 to February 23, 2010, "Mr. Cislo worked on drafting the '509 Application." *Id.* at 27 (citing Ex. 2009 ¶¶ 10–17; Ex. 2013 ¶ 64).

c. Rule of Reason Analysis

For purposes of antedating potential prior art, Patent Owner only needs to show reasonably, and not perfectly, continuous diligence. *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1009 (Fed. Cir. 2016); *see also Monsanto*, 261 F.3d at 1369 (“[T]here need not necessarily be evidence of activity on every single day if a satisfactory explanation is evidenced.”). We consider evidence of diligence as a whole by application of a rule of reason. *Brown*, 436 F.3d at 1379.

In this case, Patent Owner relies on inventors’ testimonies to show diligence. Those testimonies, except the ones related to the patentability search in October 2009 and the invention disclosure in January 2010, are either uncorroborated or insufficiently corroborated. *See supra*, Sections III.E.1.a–b. This is in contrast to Patent Owner’s diligence evidence for Sub-Period 2, from February 2010 to October 2010. For Sub-Period 2, Patent Owner argues that the inventors conducted continuous testing. Resp. 27–29. As support, Patent Owner relies not only on the inventors’ testimonies, but also independent evidence from Flex Partners, Inc., the company hired to perform the testing, including the declarations of Dave Matsuura and Belinko Matsuura. *Id.* (citing Ex. 2013 ¶¶ 69–75; Ex. 2014 ¶ 65; Exs. 2018, 2020, 2021). Patent Owner argues, Petitioner does not dispute, and we agree, that the evidence for Sub-Period 2 shows:

an explanation of the work that was being performed each month during this period, evidence of prototypes of the implant at various stages of the development; detail of the extensive consideration to make sure that the graft material would flow in the implant; and extensive research for the graft delivery system because the existing systems at the time of development could not safely deliver graft material into the implant.

Id. at 28 (citing Ex. 2018, 31–36, 38; Ex. 2020, 14); *see also* Reply 12 (“With respect to the time period Feb. 2010 to Oct. 2010 (Sub-Period 2), the [Patent Owner Response] relies upon new declaration evidence supported by corroborating documents that Flex Partners was conducting product testing and design modifications consistent with typical diligence activities.”).

We are cognizant that diligence only needs to be reasonably continuous, and that, under a rule of reason, “corroboration of every factual issue contested by the parties is not a requirement of law.” *Brown*, 436 F.3d at 1380. But for Sub-Period 1, there is no competent evidence to demonstrate diligence for ten months (from February to September, and from November to December 2009). The lack of corroborating evidence is highlighted by thin evidence Patent Owner does bring forth as purported corroboration, including, for example, an email disclosing no more than a discussion of what to have for dinner. *See* Ex. 2013 ¶ 40 (citing Ex. 2003, 4). Thus, we have considered all of the corroborating evidence Patent Owner has provided, and we find Patent Owner has not shown sufficiently that the inventors exercised reasonably continuous diligence during Sub-Period 1 spanning February 2009 to January 2010. In sum, Patent Owner has not sufficiently demonstrated that the inventors exercised reasonably continuous diligence throughout the entire critical period (from February 2009 to October 2010). As a result, Patent Owner fails to antedate Alfaro as prior art under § 102(e).

2. *Undeveloped Arguments and Improper Incorporation by Reference*

As a preliminary issue, Patent Owner raises various arguments, frequently untethered to any specific claim limitation, often confusing whether an element is taught with the sufficiency of the reasons supporting

the combination, and typically without adequate explanation, merely citing without any specificity large portions of Dr. Lonner's Declaration as purported support. Resp. 30–69. For example, Patent Owner makes the following arguments: “the combination of Alfaro and Frey is improper in light of the intended purposes of the two devices,” citing Dr. Lonner's declaration (Ex. 2022, ¶¶ 93–108, 115–120, 203–220); “the combination of Alfaro and Frey do not teach or suggest substantially retaining graft material between the first and second vertebrae” and “do not teach or suggest the retainment of graft material within an internal chamber in manner that allows endplate-to-endplate connection,” citing Dr. Lonner's declaration (Ex. 2022, ¶¶ 93–108, 115–120, 203–220); “Alfaro does not teach the retainment of graft material to allow flush contact, and Frey does not teach that graft material would extend outside the implant,” citing Dr. Lonner's declaration (Ex. 2022, ¶¶ 93–108, 115–120, 203–220); and “Perez-Cruet cannot be combined with Alfaro and Frey because it is an entirely different type of implant,” citing Dr. Lonner's declaration (Ex. 2022, ¶¶ 93–108, 115–124, 203–220). Resp. 30–33.

The overlapping portions of Dr. Lonner's declaration cited by Patent Owner with respect to these examples (Ex. 2022, ¶¶ 93–108, 115–120, 203–220) spans forty paragraphs and twenty-six pages. *See* Ex. 2022. Patent Owner, however, may not incorporate arguments by reference from one document into another. 37 C.F.R. § 42.6(a)(3). We have considered all of the arguments raised by Patent Owner in its Response, and find that, to the extent Patent Owner presents undeveloped arguments citing large portions of testimony without any specificity or correlation to the issue raised, those

arguments are not persuasive. We further address Patent Owner's arguments in detail below.

3. *Differences Between the Subject Matter of Independent Claim 1 and Alfaro, Frey, and Perez-Cruet*

Petitioner shows how the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests each limitation of claim 1 because its contentions are supported by the cited evidence of record, as discussed below. *See* Pet. 30–59, Reply 38–43. Patent Owner's arguments to the contrary are not persuasive because they are not supported by the cited evidence of record. *See, e.g.,* Resp. 30–41, 44–49; Sur-reply 25–26.

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

To the extent the preamble of claim 1 is limiting, Petitioner shows that Alfaro teaches an intervertebral spacer 11, for placement in a target intervertebral space, and handle 12 for introducing graft material into spacer compartments 11(a) and 11(b) of spacer 11, corresponding to the recited “spinal fusion system” because its contentions are supported by the cited evidence of record. Pet. 30–31 (citing Ex. 1008 ¶ 11, 29, 31, Figs. 1, 6; Ex. 1003 ¶ 157–161).

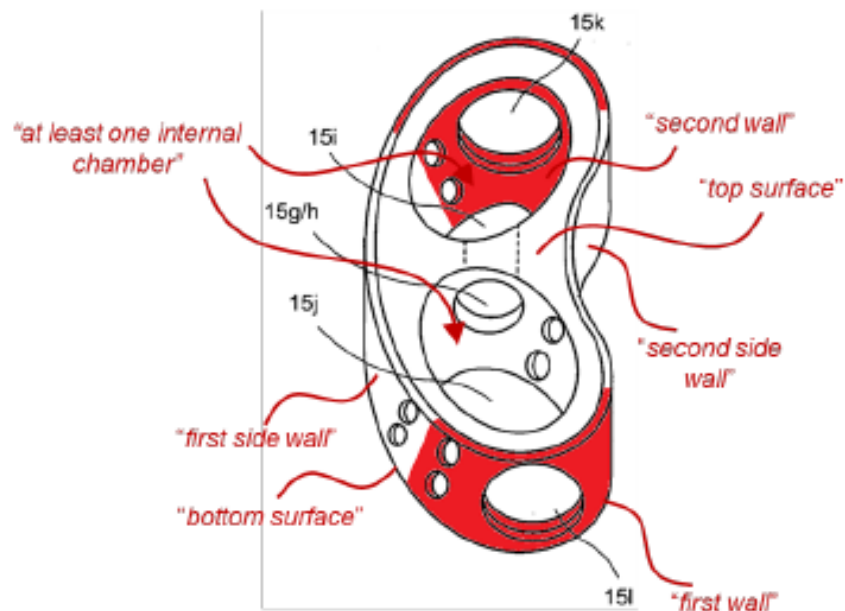
an implant comprising:

[1.1.1] a first wall and a second wall, the second wall being generally opposite of the first wall;

[1.1.2] first and second side walls configured to extend between the first wall and the second wall;

Petitioner shows, and Patent Owner does not dispute, that Alfaro teaches two embodiments of spacers, one illustrated in Figures 1 and 2, and the second in Figures 8 and 9, where both embodiments include a “first

wall,” a “second wall,” and “first and second sidewalls,” as claimed. Pet. 32–33 (citing Ex. 1003 ¶ 162–66, 168; Ex. 1008 ¶¶ 29, 39, Figs. 1, 2, 8, 9). Reproduced below is an annotated version of Figure 9 of Alfaro illustrating a spacer with walls and surfaces labeled, corresponding to the recited elements of claim 1.



Pet. 40; Ex. 1003 ¶ 183. The annotated version of Figure 9 above shows a spacer with walls and sidewalls, as recited in claim 1.

- [1.1.3] a top surface configured to at least partially engage a lower surface of a first vertebral body;*
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;

Petitioner shows that both embodiments of the spacers of Alfaro include a top surface and a bottom surface configured to engage a first vertebral body and a second vertebral body, respectively, as claimed,

because its contentions are supported by the cited evidence of record. Pet. 35–38 (citing Ex. 1003 ¶¶ 170–73; Ex. 1008 5, 20, 31, 39, Figs. 2, 6, 8, 9). Top and bottom surfaces are identified in the annotated version of Figure 9 of Alfaro above.

As further support, Petitioner directs us to the background discussion of Alfaro, which states that in correcting spinal defects it is “often necessary” to “place exogenous devices between vertebrae” in an effort to fuse the vertebrae.” Pet. 36; Ex. 1005 ¶ 5. Alfaro expressly states as follows:

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. Petitioner explains, and we agree, that the “solid material,” also referred to as “the device,” is the intervertebral spacer, and that it is “pressure-fit” between opposing vertebral bodies such that the top and bottom surfaces are configured to engage vertebrae, as claimed. *Id.* at 36–37 (citing Ex. 1003 ¶ 172; Ex. 1008 ¶ 39). We recognize that in the context of the quote above Alfaro is discussing the background of the invention, however, the improvement Alfaro is directed to does not address the “pressure-fit” approach, and instead focuses on how, in the prior art, the spacer was “pre-loaded” with graft material. Ex. 1008 ¶¶ 5–8. Alfaro expressly states as follows:

A difficulty with the foregoing procedure when a spacer has been pre-loaded prior to insertion, is that as the surgeon is driving the intervertebral spacer into the intervertebral space, the biologic material that had been packed into the spacer will often fall out and/or settle. In addition, the irregularity of the surfaces

of the vertebral end plates will cause gaps between the vertebral end plates, the bio logic material and the intervertebral spacer. This prevents a complete and total fusion of the disparate materials thereby providing a potentially weakened fusion or non-fusion.

Id. ¶ 9.

Alfaro proceeds to explain as follows:

In the present invention, voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product introduced via the unitary device of the invention.

Id. at ¶ 10. As Mr. Sherman explains, Alfaro’s spacer is “pressure-fit into place” and the “spacer ‘remains in place’ due to some contact within the vertebrae.” Ex. 1003 ¶¶ 173, 174. To the extent “configured . . . to engage” requires further disclosure than the pressure-fit top and bottom surfaces of Alfaro, Petitioner also shows that “Frey teaches an implant 1000 akin to the intervertebral spacer of Alfaro” with “upper and lower bearing embers 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” because its contentions are supported by the cited evidence of record. Pet. 38 (citing Ex. 1005, 19:50–52, 20:6–11). In this regard, Mr. Sherman explains that “[t]he 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 the first and second vertebrae, respectively.” Ex. 1003 ¶ 177.

Patent Owner argues that “Alfaro teaches that the implant has a layer of graft material between it and the vertebral bodies, in a manner that covers the surfaces of the implant completely,” and that “[b]ecause of this lack of

engaging or interfacing of the implant with the vertebral bodies, it goes against the very teaches [sic] of spinal implants and the fusion process.” Resp. 31–32 (citing Ex. 1008, ¶¶ 0011, 0022; Ex. 2022 ¶¶ 93–108, 115–120, 203–220); *see also id.* at 40 (arguing that “Alfaro does not teach or suggest engagement of the implant with the vertebral bodies,” because “Figure 6 of Alfaro demonstrates that the implant is supported by the graft material between the implant and the vertebral bodies” (citing Ex. 2020 ¶¶ 93–108, 115–124, 203–216)); *id.* at 31 (arguing that “Alfaro is an implant utilized in a post fill configuration with a free floating implant as shown in the figures of Alfaro” (citing Ex. 2020 ¶¶ 93–108, 115–120, 203–220)).

Patent Owner’s argument and Dr Lonner’s testimony both rely heavily on Figure 6 of Alfaro. Reproduced below are Figures 6 and 7 of Alfaro.

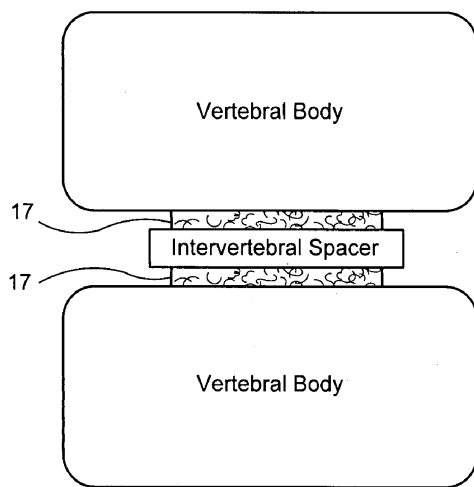


FIG. 7

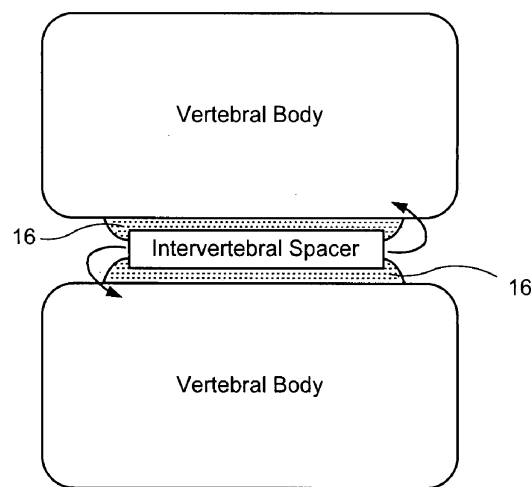


FIG. 6

Alfaro states that Figures 6 and 7 “show in an elevation view, a prior art approach (FIG. 7) for delivering a biologic into the intervertebral spaces and the approach of the present invention (FIG. 6) of forcing DBM into the

implant in situ as shown by the arrows.” Ex. 1008 ¶ 26. More specifically, Figures 6 and 7 show identical rectangular shapes labeled “Vertebral Body” above and below substantially, more narrow identical rectangular shapes labeled “Intervertebral Spacer.” Figure 7 shows DBM as element 17 represented by a shaded rectangular shape between a top and bottom “Vertebral Body” and the “Intervertebral Spacer,” extending less than the full width of the rectangle labeled “Intervertebral Spacer.” *Id.* at ¶ 17. Similarly, Figure 6 shows DBM as element 16 represented by a generally rectangular shape between a top and bottom “Vertebral Body” and the “Intervertebral Spacer,” but with DBM shape having rounded ends that extend beyond the “Intervertebral Spacer.” *Id.* at ¶ 29.

According to Patent Owner, Figure 6 is not a schematic diagram, but “is, in fact, [Alfaro’s] invention because it’s backed up by text that says complete coverage by the graft material on the top, bottom, and other surfaces,” and “this complete coverage, that means it’s not touching the vertebrae.” Tr. 68:9–25. We disagree. Presumably, Patent Owner is referring to Alfaro’s statement that “voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product introduced via the unitary device of the invention. Ex. 1008 ¶ 10; *see also* Sur-reply 25 (arguing the device in Alfaro is free-floating because Alfaro teaches “complete coverage of the surfaces of the implant” (citing Ex. 1008 ¶ 10)). But the ’096 patent discloses the same: “[a]ccording to some embodiments, 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.” Ex. 1001, 24:38–41 (emphasis added).

Moreover, Alfaro teaches “even distribution of the biologic outflow within the space and around the top and bottom surface *interfaces of the spacers and vertebrae*.” Ex. 1008 ¶ 20 (emphasis added). Because the “virtually complete coverage” of graft material in Alfaro is the same as “fill[ing] any gap” between the spacer and the endplates in the ’096 patent, we are persuaded, for this reason also, that Alfaro teaches top and bottom surfaces “to at least partially engage” the vertebrae above and below the implant, as required by limitation 1.1.3.

Moreover, in regard to Figures 6 and 7, Alfaro explains as follows:

Once 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 as by unscrewing it or pulling it away from its pressure fit or snap-on fit, and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae. It can be seen that by forcing the DBM into the implant in this manner, less gapping of DBM between the intervertebral spacer and the endplates of the vertebrae occurs leading to substantially increased fusion rates. This is to be compared to the situation existing using the current prior art approach as shown in FIG. 7 at 17 which 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. The prior art approach involves placing the spacer and then attempting to introduce biologic material from a remote discharge device such as a syringe or delivery gun.

Id. at ¶ 31. We agree with Mr. Sherman that Figure 6 is “a simplified rendition of the Alfaro spacer intended for comparison to prior art Figure 7,” and neither the prior art spacer nor the spacer of Alfaro are “free-floating,”

but rather “Alfaro’s explicit teachings confirms that both Figures 6 and 7 are stylized drawings,” whereby spacer remains in place “due to being in contact with, and specifically ‘pressure-fit’ between [] adjacent vertebrae. Ex. 1033 ¶ 62 (citing Ex. 1008 ¶¶ 5, 26, 31; Ex. 2022 ¶ 119)

During oral argument, Patent Owner challenged Petitioner’s reliance on paragraph 5 of Alfaro for teaching a pressure-fit system. Tr. 60:21–61:6. According to Patent Owner, Alfaro later “points out the deficiencies and the problems of that pressure-fit system.” *Id.* We disagree with Patent Owner’s interpretation of Alfaro.

The inventors of Alfaro state that “[a]s far as we know, implant inserters have not heretofore been used to deliver the biologic material to the spacer.” Ex. 1008 ¶ 8. Alfaro describes the device of its invention as “a delivery system in the form of a unitary device” that, “via the material-advancing means,” pushes biological material “through the chamber into the voids of the spacer and out into the intervertebral space,” after “the spacer is inserted surgically into the vertebral space and properly positioned.” *Id.* ¶¶ 11, 19. Thus, Alfaro teaches a device that eliminates the disadvantages of, not the pressure-fit system, but the pre-loaded spacers. *See id.* ¶ 9 (discussing the difficulty with the prior-art procedures “when a spacer has been pre-loaded prior to insertion”).

In this regard, we further find that Dr. Lonner does not point to a single prior-art implant that was “put in place without touching the vertebral bodies.” Ex. 2022 ¶¶ 93–118, 176–179. Indeed, the term “free-floating” does not appear in the ’096 patent or any of the prior art references. Tr. 63:14–64:4. Instead, it is a term coined by Dr. Lonner for this proceeding. *Id.* Yet, Dr. Lonner testified during his deposition that even

though he has performed hundreds of surgeries involving placing a spacer into the intervertebral space, he “never” used a spacer that floated between the vertebral without touching the endplates. Ex. 1035, 66:17–25. To the contrary, Dr. Lonner testified that “it was normal and correct to have the spacer between the vertebrae contact the endplates.” *Id.* at 71:2–6.

[1.1.4] 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

As illustrated in the annotated version of Figure 9 of Alfaro (reproduced above in regard to limitation 1.1.2), Petitioner shows that Alfaro teaches “open compartments 11(a) and 11(b), open at the top of the spacer and at the bottom at 15(i) and 15(j),” corresponding to the recited “at least one internal chamber” because its contentions are supported by the cited evidence of record. Pet. 40–41 (citing Ex. 1003 ¶ 180; Ex. 1008 ¶ 29); *see also* Ex. 1008, Fig. 2 (showing in cross section an internal chamber of a spacer extending from the top surface to the bottom surface).

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

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

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

Petitioner shows that Alfaro teaches a spacer with screw holes through which graft material is delivered to the internal chamber of the implant, as

claimed because its contentions are supported by the cited evidence of record. Pet. 41–42 (citing Ex. 1003 ¶ 181–83; Ex. 1008 ¶ 29, Figs. 1, 2, 8, 9). In this regard, Petitioner provides an annotated version of Figure 1 of Alfaro, reproduced below.

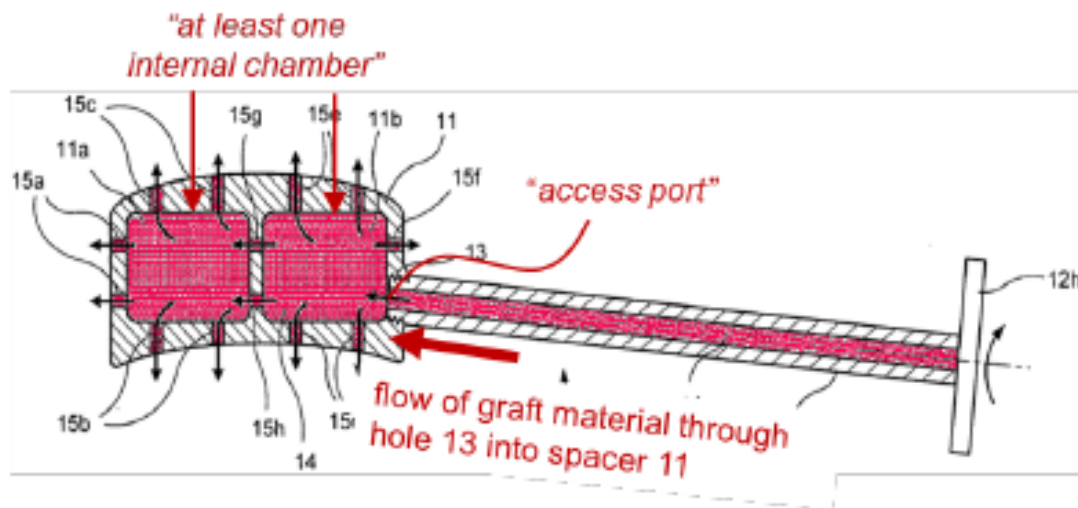


Figure 1 of Alfaro, annotated by Petitioner, shows screw hole 13, corresponding to the recited “access port.” Pet. 41 (citing Ex. 1003 ¶ 182; Ex. 1008, Fig. 1). Alfaro explains in this regard that “[h]andle 12 is shown screwed into compartment 11(b) at [screw hole] 13 and is also shown to contain DBM 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.” Ex. 1008, ¶ 29. Accordingly, graft material passes through screw hole 13, the “the access port,” and is delivered to the internal chamber of the implant, as recited. Pet. 42–43 (citing Ex. 1003 ¶¶ 184–187; Ex. 1008, ¶ 30, 31, Figs. 2, 6). Petitioner also shows that Alfaro teaches the spacer is inserted using a handle, corresponding to the recited “implantation tool.” *Id.* at 43–45 (citing Ex. 1003 ¶¶ 188–192; Ex. 1008 ¶¶ 19, 21, Figs. 1, 2, 6). Alfaro expressly explains that “[t]he detachable or disengageable

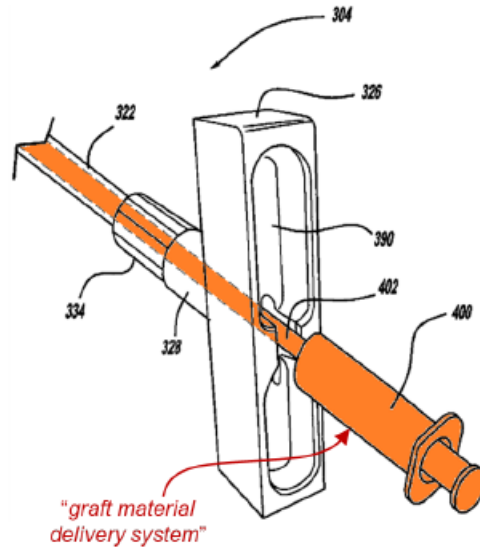
handle acts as an inserter of the spacer and comprises a hollow chamber to accommodate the biologic material to be added into the spacer.” Ex. 1008 ¶ 21.

[1.3] 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;

Petitioner, relying on Alfaro in combination with Perez-Cruet, shows how the asserted art teaches or suggests the recited “graft material delivery system” because its contentions are supported by the cited evidence of record. Pet. 45–48 (citing, e.g., Ex. 1003 ¶¶ 194–200; Ex. 1004 ¶ 55, 62, Figs. 20, 21). Alfaro states that the spacer “needs only to be attachable and detachable to a handle capable of containing a biologic material-advancing means such as an Archimedes screw, a plunger or syringe-type of system for moving the biologic material through the handle and into the spacer.” Ex. 1008 ¶ 12. According to Petitioner, Alfaro “does not explicitly disclose how its disclosed syringes would connect to Alfaro’s hollow handle for delivering biologic material.” Pet. 45; *see also* Ex. 1003 ¶¶ 194–95 (explaining that “Alfaro is very general in terms of the type of handle,” providing examples that include “a ‘hollow chamber’ and that can be ‘engaged and disengaged with the spacer,’ as well as “the use of a syringe,” but “does not provide details regarding it syringe”).

Petitioner relies on Perez-Cruet as teaching “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.” Pet. 45 (quoting Ex. 1004, ¶ 62). In this regard, Petitioner provides an annotated version of Figure 21 of Perez-Cruet, reproduced below.



Pet. 46. With respect to Figure 21, Perez-Cruet states that “the bone graft material is delivered through the instrument 304 using a syringe 400 having an extended tubular end portion 402.” Ex. 1004 ¶ 62. We also find persuasive Mr. Sherman’s explanation of how the combination of Alfaro and Perez-Cruet teaches or suggests the recited “graft material delivery system” of claim 1 as follows:

The syringe 400 of Perez-Cruet is a syringe used to deliver graft material to one or more compartments of an implanted spacer. When utilized with Alfaro’s handle, Perez-Cruet’s syringe “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 claim element [1.3].

Ex. 1003 ¶ 198.

[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;

Petitioner shows that the spacer of Alfaro is implanted in the intervertebral space and that the walls and sidewalls of the spacer are configured to extend between the adjacent vertebral members because its contentions are supported by the cited evidence of record. Pet. 49–51 (citing Ex. 1003 202–204, 206; Ex. 1008 ¶¶ 5, 29, 31, 39 Figs. 6, 9). Alfaro expressly states as follows:

Once 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 as by unscrewing it or pulling it away from its pressure fit or snap-on fit, and the procedure, for purposes of this invention, is terminated. The spacer of course, remains in place at the correct site between the vertebrae.

Ex. 1008 ¶ 31; *see also id.* at ¶¶ 5, 30 (describing in the background that a spacer is “pressure-fit into place between the opposing vertebral bodies so as to fix the device in place,” and further stating with regard to the spacer of Alfaro 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”). Mr. Sherman further explains that “it would have been obvious to modify the heights of the sidewalls of Alfaro’s spacer as needed . . . relative to the disc space size to more closely correspond to the

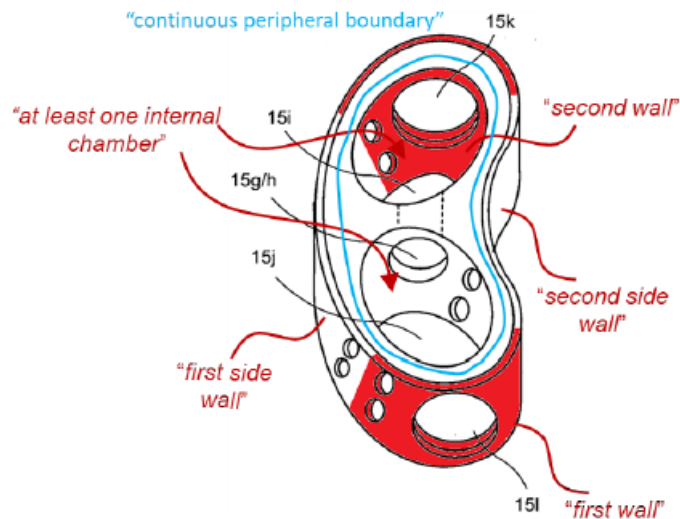
anatomy of the vertebral endplates.” Ex. 1003 ¶ 177 (citing Ex. 1005, 19:58–60, Fig. 54).

Although we find no lack of disclosure of limitation 1.4 in Alfaro, alone, Petitioner further shows that Alfaro in combination with Frey also teaches or suggests limitation [1.4]. Pet. 51–53. In particular, as with limitation [1.1.3], Petitioner relies on Frey’s disclosure of grooves 1014 and 1016 on upper and lower bearing members 1010 and 1012, respectively, as applied to the top and bottom surfaces of Alfaro’s spacer “to prevent the intervertebral spacer from migrating in the intervertebral space.” *Id.* at 52 (citing Ex. 1008 ¶ 31). Thus, Petitioner shows that “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” teaches limitation [1.4] because its contentions are supported by the cited evidence of record. *Id.* at 53 (citing Ex. 1003 ¶¶ 209, 210).

[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

Petitioner relies on Alfaro as teaching limitation 1.5.1, including “a continuous peripheral boundary.” Petitioner argues that like Figure 20 of the ’096 patent, the intervertebral spacer in Alfaro’s Figure 9, for example, which includes screw holes 15k, 15l and other openings/tunnels in the walls, teaches a “continuous peripheral boundary,” a portion of which is highlighted in Petitioner’s annotated version of Figure 9. Pet. 55.

Petitioner's annotated version of Figure 9 is reproduced below:



Pet. 55; Ex. 1003 ¶ 214. Annotated Figure 9 of Alfaro shows a three-dimensional perspective view of an embodiment of Alfaro's spacer, with annotations identifying "at least one internal chamber" (with lead lines to two compartments¹²) "first side wall," "second side wall," "first wall," and "second wall" (all highlighted in red), and an outline of a portion of the "continuous peripheral boundary" (highlighted in blue). Ex. 1008 ¶ 27. Petitioner further shows that each of Alfaro's spacers shown in Figures 2 and 9 (and associated Figures 1 and 8, respectively) are examples demonstrating limitation [1.5.1]. Pet. 56 (citing Ex. 1003 ¶ 215). Moreover, Alfaro expressly teaches that the spacer's compartments (in Figures 1 and 9) "are adapted to contain DBM or any other suitable biologic," or are "shown to contain DBM." Ex. 1008 ¶ 29. Thus, for these

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

reasons Petitioner shows the walls and sidewalls of Alfaro's insert teach limitation 1.5.1.

Patent Owner argues that "a continuous peripheral boundary around the at least one chamber is not taught by Alfaro and Frey which teach openings along a wall and an open cage respectively." Resp. 44 (citing Ex. 1005, 19:16–21; Ex. 1008, Fig. 6, ¶ 10; Ex. 2010 ¶¶ 93–108, 115–134, 203–220). Petitioner does not rely on Frey for limitation 1.5.1. Moreover, as explained above, Petitioner has shown that "a continuous peripheral boundary" does not preclude an intervertebral spacer with walls that have openings. *See supra* Section III.C.2.

[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.

Petitioner shows that Alfaro teaches the elements of limitation [1.5.2], including a chamber that contains graft material delivered through the access port, thereby "enabling" the chamber "to be filled such that graft material is in "flush contact" with the endplates of the adjacent vertebral members because its contentions are supported by the cited evidence of record. Pet. 56–59 (citing Ex. 1003 ¶¶ 220–222; Ex. 1008 ¶¶ 10, 19, 21, 31). Petitioner explains that the term "flush contact" is not used in the '096 patent Specification outside of the claims, nor is it a term of art in the spinal fusion field. *Id.* at 56 (citing Ex. 1003 ¶ 217). The '096 patent does state 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," which "can result in improved spinal fusion." Pet. 56 (quoting

Ex. 1001, 24:16–20, 24:21–24); Ex. 1003 ¶ 217. Thus, we agree with Petitioner that “the term ‘the graft material is in flush contact with [endplate surfaces of the] adjacent superior and inferior vertebral members’ is understood to include a situation in which gaps that exist between vertebral endplates and adjacent surfaces of the implant are filled with graft material.” *Id.* (citing Ex. 1003 ¶ 217) (emphasis omitted).

Turning again to Alfaro, Petitioner shows Alfaro teaches previous approaches in the prior art “may leave significant gaps between the spacer and the endplates of the inferior and superior vertebral bodies.” *Id.* at 56–57 (citing Ex. 1008 ¶ 31; Fig. 7). Petitioner also shows that, to address the gapping problem, Alfaro describes that, “[i]n the present invention, voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product introduced via the unitary device of the invention.” *Id.* at 57 (citing Ex. 1008 ¶¶ 10, 19) (emphasis omitted, alteration in original). Petitioner also shows that Alfaro teaches a handle for insertion of the spacer sized “such that sufficient biologic can be incorporated therein to fill the compartments and tunnels, and flow out into the interfaces between the compartments and the vertebrae to provide substantially complete coverage or coating of the interface surfaces.” *Id.* (citing Ex. 1008 ¶ 21) (emphasis omitted, alteration in original).

Alfaro expressly describes that “[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels as shown in FIG. 2 . . . with the DBM flowing through the compartments and into the vertebral spaces shown in Fig. 6 . . . , the handle is removed,” and that “by forcing the DBM into the implant in this manner, less gapping of DBM between the

intervertebral spacer and the endplates of the vertebrae occurs leading to substantially increased fusion rates.” *Id.* at 57–58 (citing Ex. 1008 ¶ 31; Fig. 6) (emphasis omitted, alteration in original). Thus, Petitioner shows that “Alfaro teaches a device and associated process in which spacer compartments are filled and gaps between the end plates of the vertebral bodies and the spacer surfaces are also filled by complete coverage at their surfaces, with a suitable biologic product introduced via a hollow handle connected to the spacer via a screw hole (‘access port’), thereby disclosing [1.5.2].” *Id.* at 59 (citing Ex. 1003 ¶¶ 220–222) (emphasis omitted).

Patent Owner’s arguments to the contrary are refuted by the express disclosures of Alfaro above. In this regard we also credit the testimony of Mr. Sherman (Ex. 1003 ¶¶ 217– 222; Ex. 1033 ¶¶ 68–70) over that of Dr. Lonner (Ex. 2022 ¶¶ 125–130), because Mr. Sherman’s testimony is supported by the express disclosure of Alfaro and Dr. Lonner’s testimony is unsupported and contrary to the express teachings of Alfaro.

Patent Owner argues that “none of the references, and Perez-Cruet, teach or suggest at least one chamber to contain graft material, or at least one chamber that extends from or near a first vertebrae, to or near a second vertebrae in a manner that allows for the graft material to be substantially retained between the vertebral bodies through the chamber of the cage. Resp. 33 (citing Ex. 1004, Figs. 4, 5, and 20; Ex. 2022 ¶¶ 93–108, 115–124, 203–220). Relatedly, Patent Owner states that “the internal chamber would need to be filled in order to obtain maximum contact (i.e., flush contact) with vertebral endplates.” Resp. 21 (citing Ex. 2015 ¶ 34 (discussing a different issue)). Thus, Patent Owner argues that Alfaro does not teach an

internal chamber that retains graft material, and, therefore, the internal chamber of Alfaro cannot be filled such that the graft material is in flush contact with the adjacent vertebral endplates. Specifically, Patent Owner argues as follows:

While Alfaro does teach the ability to post-fill an implant, it does not teach the containment and/or retainment of graft material within the internal chamber of the implant as is shown in figure 6 of Alfaro that illustrate the lack of retainment. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216.

Resp. 40; *see also id.* at 31 (arguing that the combination of Alfaro and Frey does not teach or suggest “substantially retaining graft material” or “retainment of graft material within an internal chamber in [a] manner that allows endplate-to-endplate connection”) (citing Ex. 2022 ¶¶ 93–108, 115–120, 203–220; Ex. 1005, Fig. 56; Ex. 1008, Figs. 6, 7); *id.* at 32 (arguing that “Alfaro and Frey do not teach flush contact”) (citing Ex. 2020 ¶¶ 93–108, 115–120, 203–220); *id.* at 45 (arguing that “the open designs of Alfaro and Frey allow graft material to flow freely from the area that allegedly teaches a chamber in each of them” and that “Alfaro teaches placement of graft material without the implant engaging the vertebra because of layer of graft material between the implant and vertebrae”) (citing Ex. 2020 ¶¶ 93–108, 115–134, 203–220; Ex. 1008 ¶ 10, Fig. 6); *id.* at 47 (arguing that Alfaro and Frey do not teach “flush contact” or “graft material being contained within the at least one internal chamber”) (citing Ex. 1005, 19:16–21; Ex. 1008 ¶ 10, Fig. 6; Ex. 2020 ¶¶ 93–108, 115–134, 203–220).¹³ According to Patent

¹³ Patent Owner argues that “the cage of Frey” is an “open design” that cannot retain graft material and that “Perez-Cruet cannot contain or retain graft material.” Resp. 45–46, 48–49. Petitioner does not rely on Frey or Perez-Cruet with regard to limitation 1.5.2.

Owner “Alfaro, illustrates and teaches that the graft material exits the implant creating a barrier between the vertebral bodies and the implant, as well as extruding from the sidewalls of Alfaro. Resp. 47–48 (citing Ex. 1008 ¶ 10, Fig. 6; Ex. 2022 ¶¶ 93–108, 115–134, 203–220.

Dr. Lonner’s testimony that Alfaro and Frey teach “open designs that allow graft material to flow freely from the area that allegedly teaches a chamber in each of them” is not persuasive because it is conclusory and unsupported by Dr. Lonner’s citations to Alfaro and Frey. *See* Ex. 2022 ¶¶ 125–130. Although Dr. Lonner cites Figure 6 and paragraph 10 of Alfaro as supporting his testimony that Alfaro does not teach “flush contact with the vertebral bodies and the graft material being contained within the . . . internal chamber,” but teach that “graft material flows out and away from the implant,” Dr. Lonner provides no persuasive analysis or explanation of why Figure 6 and paragraph 10 allegedly support his testimony. In addition, as discussed above, Alfaro expressly teaches that the spacer’s compartments (in Figures 1 and 9) “are adapted to contain DBM or any other suitable biologic,” or are “shown to contain DBM.” Ex. 1008 ¶ 29. Based on Petitioner’s evidence and arguments as discussed above, we agree with Petitioner that Alfaro’s disclosures, including that “voids and gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by the virtually complete coverage at the surfaces thereof, with a suitable biologic product” and that “excess material floods the space . . . between the surfaces and the vertebrae giving a complete coverage or permeation of the interfaces,” teach or suggest that graft material is in “flush contact” with the endplate surfaces of the adjacent superior and inferior vertebral members, as the term is used in the ’096 patent. *See*

Ex. 1008 ¶¶ 10, 19, 21. Thus, we are persuaded Petitioner shows that Alfaro teaches limitation [1.5.2].

4. *Differences Between the Subject Matter of Independent Claim 16 and Alfaro, Frey, and Perez-Cruet*

Independent claim 16, like claim 1, is directed to “a spinal fusion system.” Ex. 1001, 28:48–30:2. Petitioner has designated the limitations of claim 16 as [16.0], [16.1.1]–[16.1.7], and [16.2]–[16.5]. Pet. 83–86. As Petitioner shows, claim 16 recites the same or substantially the same limitations as claim 1 with only minor differences. *Id.* For example, limitation [16.1.2] recites “side walls,” whereas limitation [1.1.2] recites “first and second” side walls. *Compare* Ex. 1001, 28:54–55 (claim 16), *with id.* at 27:22–23 (claim 1). And, limitation [16.3] recites delivering “graft material,” whereas limitation [1.3] recites delivering “a volume of” graft material. *Compare* Ex. 1001, 29:11–12 (claim 16), *with id.* at 27:39–40 (claim 1). Petitioner shows how the combination of Alfaro, Frey, and Perez-Cruet teaches or suggests each limitation of claim 16 for substantially the same reasons Petitioner shows for claim 1. Pet. 83–86.

Patent Owner disputes Petitioner’s contentions with respect to claim 16 for the same reasons Patent Owner raised with regard to claim 1, which we address above in regard to claim and reject as to claim 16 for the same reasons. After reviewing the record, we find Petitioner shows each limitation of claim 16 was taught by the asserted references and we adopt Petitioner’s mapping of the limitations of claim 16 (Pet. 83–86) as our own finding because its contentions are supported by the cited evidence of record.

5. *Differences Between the Subject Matter of Dependent Claim 2 and Alfaro, Frey, and Perez-Cruet*

Claim 2 depends from claim 1 and further recites “wherein the conduit is configured to pass through the access port of the implant to position the conduit within the at least one internal chamber of the implant.” Ex. 1001, 24:64–67. As with limitation 1.3, Petitioner shows the combination of Alfaro and Perez-Cruet teaches “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.” Pet. 59–60 (citing Ex. 1003 ¶ 225, Ex. 1004, Fig. 21; Ex. 1008 Fig. 1). Petitioner further shows that Perez-Cruet expressly teaches positioning the conduit within the internal chamber of the implant. Pet. 60–61; Ex. 1003 ¶ 226–27; Ex. 1004, Fig. 11 (showing delivery conduit 208 extended beyond the distal end of insertion instrument 210 and into the interior space of the implant).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 49–51. Patent Owner’s argument that there is no teaching of “a conduit being passed through the access port of an implant,” which is purportedly based on the testimony of Dr. Lonner, is not persuasive because Dr. Lonner’s testimony is conclusory and unsupported with any explanation or technical reasoning of why Perez-Cruet fails to teach or suggest this feature of claim 2. We credit the testimony of Mr. Sherman (Ex. 1003 ¶¶ 223–227) over Dr. Lonner’s testimony because Mr. Sherman’s testimony is consistent with and supported by the express disclosures of Alfaro and Perez-Cruet. Patent Owner’s additional arguments largely mirror arguments made with respect to claim 1 and are unpersuasive for the same reasons as provided above. After reviewing the record, we find

Petitioner shows each limitation of claim 2 was taught by the asserted references and we adopt Petitioner's mapping of the limitations of claim 2 (Pet. 59–61) as our own finding because its contentions are supported by the cited evidence of record.

6. *Differences Between the Subject Matter of Dependent Claim 3 and Claim 17 and Alfaro, Frey, and Perez-Cruet*

Claim 3, which depends from claim 1, and claim 17, which depends from claim 16, each recite the additional limitation of: “wherein the graft material delivery system additionally comprises a fill tool assembly, the fill tool assembly being configured to selectively engage at least a portion of the implant, wherein the fill tool assembly comprises a cannulated shaft.”

Ex. 1001, 28:1–5, 30:8–12. Petitioner shows that Alfaro teaches using any disengageable means to connect handle 12 with the intervertebral spacer 11. Pet. 61–63 (citing Ex. 1003 ¶ 231; Ex. 1008 ¶ 21). Petitioner relies on the combination of Alfaro's handle 12 and Perez-Cruet's instrument 304, including cylindrical body portion 322 and elongated cylindrical grasping portion 340 (having a cannulated shaft), with Alfaro's spacer 11 modified such that the fingers 346 of Perez-Cruet's grasping portion 340 can secure instrument 304 to Alfaro's spacer. *Id.* at 63–67 (citing Ex. 1003 ¶ 232–39; Ex. 1004 ¶¶ 56, 57, 62, Figs. 13, 14, 15, 16, 19, 21; Ex. 1008 ¶ 21).

We have considered each of Patent Owner's arguments to the contrary and find they have no merit. Resp. 51. Patent Owner's assertion that Figures 14 and 15 of Perez-Cruet “show the implant insertion tool engaging with the fill tool assembly not the implant” fails to address the combination of features Petitioner relies upon from both Alfaro and Perez-Cruet. We credit the testimony of Mr. Sherman (Ex. 1003 ¶¶ 228–239) over Dr. Lonner's testimony because Mr. Sherman's testimony is consistent with

and supported by the express disclosures of Alfaro and Perez-Cruet. Patent Owner's additional arguments largely mirror arguments made with respect to claims 1 and 2 and are unpersuasive for the same reasons as provided above. After reviewing the record, we find Petitioner shows each limitation of claim 3 and claim 17 was taught by the asserted references and we adopt Petitioner's mapping of the limitations of claim 3 and claim 17 (Pet. 61–67, 86) as our own finding.

7. *Differences Between the Subject Matter of Dependent Claim 4 and Claim 18 and Alfaro, Frey, and Perez-Cruet*

Claim 4, which depends from claims 1 and 3, and claim 18, which depends from claims 16 and 17, each recite the additional limitation of: “wherein the fill tool assembly is configured to ensure that a distal end of the conduit routed through the cannulated shaft of the fill tool assembly is properly positioned within the at least one internal chamber of the implant.” Ex. 1001, 28:6–10; 30:8–12. Petitioner shows that “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 151, and into the compartment 11b of Alfaro’s intervertebral spacer.” Pet. 69. Petitioner further shows that “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.” *Id.* at 68–70 (citing Ex. 1003 ¶¶ 242, 244, 245; Ex. 1004, Fig. 11).

We have considered each of Patent Owner’s arguments to the contrary and find they are not persuasive. Resp. 51–52. Patent Owner’s argument that “[n]one of Alfaro, Perez-Cruet, nor Frey teach or suggest a conduit routed through a cannulated shaft of the fill tool assembly” is not persuasive for the reasons discussed above regarding claims 1 and 3. Resp. 51–52 (citing Ex. 2022 ¶¶ 93–108, 115–134, 143–147, 203–220). In addition, Patent Owner’s arguments that the cage of Perez-Cruet “does not allow for fusion between two vertebral bodies” and does not teach “a chamber for receiving graft material” are unavailing because Petitioner’s proposed combination does not rely on Perez-Cruet as teaching these features. After reviewing the record, we find Petitioner shows each limitation of claim 4 and claim 18 was taught by the asserted references and we adopt Petitioner’s mapping of the limitations of claim 4 and claim 18 (Pet. 68–70, 86–87) as our own finding.

8. *Differences Between the Subject Matter of Dependent Claim 5 and Claim 19 and Alfaro, Frey, and Perez-Cruet*

Claim 5, which depends from claims 1 and 3, and claim 19, which depends from claims 16 and 17, each recite the additional limitation of: “wherein graft material is configured to be delivered through the fill tool assembly, either directly through the cannulated shaft or via the conduit, wherein the conduit is removably positioned through the cannulated shaft.” Ex. 1001, 28:11–15; 30:13–17. Petitioner shows that Alfaro combined with Perez-Cruet teaches the additional limitations because, as discussed regarding claims 3 and 4, Petitioner shows as follows:

when Alfaro’s handle is implemented as Perez-Cruet’s instrument 304 and the intervertebral spacer of Alfaro is compatibly modified, “graft material is configured to be delivered through the fill tool assembly [e.g., Perez-Cruet’s

guiding portion 340] . . . via the conduit [e.g., Perez-Cruet’s extended tubular end portion 402] . . . removably positioned through the cannulated shaft [e.g., of the guiding portion 340)].”

Pet. 70–71 (citing Ex. 1003 ¶¶ 251–252) (emphasis omitted).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 53. We do not agree with Patent Owner’s argument that the references do not teach a “conduit routed through a cannulated shaft of the fill tool assembly” because, as discussed above, Petitioner shows that Perez-Cruet’s fill tool assembly comprises guiding portion 340, which has a cannulated shaft, and extended tubular end portion 402, which is the conduit. After reviewing the record, we find Petitioner shows each limitation of claim 5 and claim 19 was taught by the asserted references and we adopt Petitioner’s mapping of the limitations of claim 5 and claim 19 (Pet. 70–71, 86–87) as our own finding.

9. *Differences Between the Subject Matter of Dependent Claim 6 and Alfaro, Frey, and Perez-Cruet*

Claim 6 depends from claim 5 and further recites “wherein the fill tool assembly comprises at least one alignment feature configured to engage at least a portion of the implant, wherein at least one alignment feature provides assurance that the fill tool assembly is properly positioned relative to the implant.” Ex. 1001, 28:17–21. Petitioner shows that Alfaro combined with Perez-Cruet teaches the additional limitations of claim 6 because fingers 346 (around end portion 312) that connect Perez-Cruet’s guiding portion 340 to Alfaro’s spacer provide an example of “at least one alignment feature configured to engage at least a portion of the implant,” wherein the alignment feature provides assurance that the fill tool assembly (e.g., Perez-

Cruet's grasping portion 340) is properly positioned relative to the implant. Pet. 71–72 (citing Ex. 1004, Fig. 16, ¶ 58; Ex. 1003 ¶¶ 255–257).

We have considered each of Patent Owner's arguments to the contrary and find they have no merit. Resp. 53–54. Patent Owner argues that Perez-Cruet “only teaches engagement of an insertion tool with an implant,” but this engagement “does not allow for proper positioned of the tool or assembly in relation to the implant as it is part of the engagement of the implant with other devices not alignment.” Resp. 54 (citing Ex. 1004, Figs. 14, 15; Ex. 2022 ¶¶ 93–108, 115–134, 143, 148–154, 203–220). We credit the testimony of Mr. Sherman (Ex. 1003 ¶¶ 255–257) over Dr. Lonner's testimony because Mr. Sherman's testimony is consistent with and supported by the express disclosures of Alfaro and Perez-Cruet. After reviewing the record, we find Petitioner shows each limitation of claim 6 was taught by the asserted references and we adopt Petitioner's mapping of the limitations of claim 6 (Pet. 71–72) as our own finding.

10. Differences Between the Subject Matter of Dependent Claim 7 and Alfaro, Frey, and Perez-Cruet

Claim 7 depends from claim 6 and further recites “wherein the last one alignment feature comprises at least one of a tab and a wing.” Ex. 1001, 28:22–23. Petitioner shows that “[i]n addition to being examples of ‘alignment features,’ the fingers 346 of Perez-Cruet are examples of tabs or wings (e.g., similar to what the '096 Patent labels as ‘tabs or wings 622’ at 22:12 and illustrated in Figure 13).” Pet. 72–73 (citing Ex. 1003 ¶ 259). We find Petitioner's identification of finger 346 of Perez-Cruet corresponds to the recited “tab” or “wing,” and Patent Owner offers no persuasive argument to the contrary.

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 54–55. Patent Owner argues that, “[m]uch like claim 6, a tab and wing are not taught by the combination of references and in particular Perez-Cruet.” Resp. 54–55 (citing Ex. 2022 ¶¶ 93–108, 115–134, 143, 148–157, 203–220). Patent Owner also argues Petitioner may not rely on the same elements of Perez–Cruet “to teach both claim 6 and claim 7” under “the all-claims limitation rule.” *Id.* (citing Ex. 2022 ¶¶ 93–108, 115–134, 143, 148–157, 203–220). Patent Owner provides no other explanation in support of its argument, which we find conclusory, inadequately developed, and unexplained. As support, Patent Owner, again, cites to the same large portions of Dr. Lonner’s Declaration and nothing else. After reviewing the record, we find Petitioner shows each limitation of claim 7 was taught by the asserted references and we adopt Petitioner’s mapping of the limitations of claim 7 (Pet. 72–73) as our own finding.

11. Differences Between the Subject Matter of Dependent Claim 8 and Alfaro, Frey, and Perez-Cruet

Claim 8 depends from claim 1 and further recites “wherein the implant insertion tool is configured to releasably secure to the access port.” Ex. 1001, 28:24–25. Petitioner shows that “Alfaro’s disclosure of a handle screwed into an access port, which can also be unscrewed and detached, is an example of claim element [8.1].” Pet. 73–74 (citing Ex. 1003 ¶ 262–263; Ex. 1008, Fig. 2, ¶¶ 21, 29, 31).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 55. Patent Owner’s arguments are unavailing because they do not concern the limitations of claim 8, but instead assert the references do not teach “endplate-to-endplate fusion

through an internal chamber of an implant” and “graft material provided through an access port to an internal chamber would be allowed to generate flush contact and generate fusion through the implant,” which features are not recited in claim 8. *Id.* (citing Ex. 2022 ¶¶ 93–108, 1115–134, 158–164, 203–220). After reviewing the record, we find Petitioner shows each limitation of claim 8 was taught by the asserted references and we adopt Petitioner’s mapping of the limitations of claim 8 (Pet. 73–74) as our own finding.

12. Differences Between the Subject Matter of Dependent Claim 10 and Alfaro, Frey, and Perez-Cruet

Claim 10 depends from claim 1 and further recites “wherein the implant comprises at least one of polyether etherketone (PEEK), a metal and an alloy.” Ex. 1001, 28:29–31. Petitioner shows that Alfaro teaches claim 10 because Alfaro discloses that “[t]he spacer may be constructed of biologically acceptable material such as titanium, stainless steel, allograft bone, PEEK, or the like.” Pet. 74 (citing Ex. 1003 ¶ 22; Ex. 1003 ¶ 265) (emphasis omitted).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 55–56. Patent Owner argues that only Alfaro teaches any reference to a PEEK material, but none of Alfaro, Perez-Cruet, or Frey teaches or suggests a combination of PEEK with a metal and an alloy. *Id.* (citing Ex. 1008 ¶ 22; Ex. 2022 ¶ 93–108, 115–134, 165, 203–220). Patent Owner’s argument is unavailing because it is not commensurate with the scope of claim 10, which requires only that the implant comprises “at least one of” PEEK, a metal, and an alloy.

13. Differences Between the Subject Matter of Dependent Claim 11 and Alfaro, Frey, and Perez-Cruet

Claim 11 depends from claim 1 and further recites “wherein at least one of the top and bottom surfaces is generally planar.” Petitioner shows that the top surface of the spacer of Alfaro is planar. Pet. 74–75 (citing Ex. 1003 ¶ 269; Ex. 1008, Fig. 9).

Patent Owner’s argument that, for at least the same reasons regarding claim 1, claim 11 is not taught by Alfaro, Frey, or Perez-Cruet is unavailing for the reasons discussed above regarding claim 1. Resp. 56. Patent Owner’s argument that the cited references do not teach an implant being “planar” is also unavailing. *Id.* (citing Ex. 2022 ¶¶ 93–108, 115–134, 166–172, 203–220). Presumably, Patent Owner is relying on Dr. Lonner’s testimony that “the cited references do not teach . . . an implant being planar.” Ex. 2022 ¶ 172. Dr. Lonner’s statement is conclusory, unsupported by any citation to any evidence, not credible, and inconsistent with the claim language at issue, which recites “generally planar.” We credit the testimony of Mr. Sherman over Dr. Lonner as it is consistent with and supported by Alfaro. *See* Ex. 1003 ¶¶ 268, 269.

14. Differences Between the Subject Matter of Dependent Claim 12 and Alfaro, Frey, and Perez-Cruet

Claim 12 depends from claim 1 and further recites “wherein at least one of the top and bottom surfaces of the implant is generally curved.” Ex. 1001, 28:34–35. Petitioner shows that Frey teaches an implant with a top and a bottom surface that are “generally curved.” Pet. 75–77 (citing Ex. 1003 ¶ 271–274; Ex. 1005, 19:53–60, Fig. 54).

Patent Owner’s argument that, for at least the same reasons regarding claim 1, claim 12 is not taught by Alfaro, Frey, or Perez-Cruet is unavailing

for the reasons discussed above regarding claim 1. Resp. 56. Patent Owner's argument that the cited references do not teach an implant being "curved" is also unavailing. *Id.* (citing Ex. 2022 ¶¶ 93–108, 115–134, 166–172, 203–220). Presumably, Patent Owner is relying on Dr. Lonner's testimony that "the cited references do not teach . . . an implant being . . . curved." Ex. 2022 ¶ 172. Dr. Lonner's statement is conclusory, unsupported by any citation to any evidence, not credible, and inconsistent with the claim language at issue, which recites "generally curved." We credit the testimony of Mr. Sherman over Dr. Lonner as it is consistent with and supported by Frey. *See* Ex. 1003 ¶¶ 272–74.

15. Differences Between the Subject Matter of Dependent Claim 13 and Alfaro, Frey, and Perez-Cruet

Claim 13 depends from claim 1 and further recites "wherein the implant comprises a lordotic implant, such that a height of the first wall is different than a height of the second wall." Ex. 1001, 28:36–38. Petitioner shows that Frey teaches implant 1000 with different heights of "leading" and "trailing" end walls "to establish lordosis when implant 1000 is inserted in the disc space." Pet. 77–80 (citing Ex. 1008, Fig. 9 Ex. 1003 ¶¶ 277–282; Ex. 1005, Fig. 54, 19:60–65, 19:67–20:5).

Patent Owner's argument that, for at least the same reasons regarding claim 1, claim 11 is not taught by Alfaro, Frey, or Perez-Cruet is unavailing for the reasons discussed above regarding claim 1. Resp. 56. Patent Owner's argument that the cited references do not teach an implant "having walls of different heights" is also unavailing. *Id.* (citing Ex. 2022 ¶¶ 93–108, 115–134, 166–172, 203–220). Presumably, Patent Owner is relying on Dr. Lonner's testimony that "the cited references do not teach . . . an implant . . . having walls of different heights." Ex. 2022 ¶ 172.

Dr. Lonner’s statement is conclusory, unsupported by any citation to any evidence, and not credible. We credit the testimony of Mr. Sherman over Dr. Lonner as it is consistent with and supported by Frey. *See* Ex. 1003 ¶¶ 277–81.

16. Differences Between the Subject Matter of Dependent Claim 14 and Alfaro, Frey, and Perez-Cruet

Claim 14 depends from claim 1 and further recites “wherein the implant comprises a lateral implant, a TLIF implant, an ALIF implant or a PLIF implant.” Ex. 1001 28:39–41. Petitioner shows that Alfaro discloses claim 14 because Figure 1 of Alfaro “illustrates an embodiment in which the threaded hole 13 is formed in the intervertebral spacer 11 to facilitate a lateral approach.” Pet. 80 (citing Ex. 1003 ¶¶ 286–287). Petitioner also shows that Frey teaches that aspects of the invention may be used for “a variety of surgical applications including . . . a lateral approach,” and a person of ordinary skill would have understood from Frey that Alfaro’s implant would be inserted into the disc space using the “lateral approach” taught by Frey. *Id.* at 80–81 (citing Ex. 1003 ¶¶ 287–288; Ex. 1005, 22:6–12).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 56–57. According to Patent Owner, “[t]he cited references do not teach or suggest particular approaches for the surgeries that utilize the implants” and “[w]hile Frey teaches posterior or posterior lateral (transforaminal) approaches, it teaches away from an anterior or direct lateral approach.” Resp. 56–57 (citing Ex. 1005, 1:14–20, 1:36–55; Ex. 2022 ¶¶ 93–108, 115–134, 173, 174, 203–220). Patent Owner’s argument is not persuasive because it is unresponsive to what Petitioner’s relies on to show how the limitation is taught by the prior art,

conclusory, and unsupported. We credit the testimony of Mr. Sherman over Dr. Lonner as it is consistent with and supported by Alfaro and Frey. *See* Ex. 1003 ¶¶ 284–288.

17. Differences Between the Subject Matter of Dependent Claim 15 and Claim 20 and Alfaro, Frey, and Perez-Cruet

Claim 15, which depends from claim 1, and claim 20, which depends from claim 16, each recite the additional limitation of: “wherein the fill tube assembly¹⁴ further comprises a plunger assembly configured to be positioned within the conduit, wherein the plunger assembly is selectively actuated in order to provide the necessary driving force to move a volume of graft material through the conduit and into the at least one internal chamber of the implant.” Ex. 1001, 28:42–47; 30:18–23.

Petitioner shows that Alfaro combined with Perez-Cruet teaches claim 15 because syringe 400 (of Perez-Cruet’s graft material delivery system shown in Figure 21) includes a barrel in an “enlarged-diameter portion of the ‘conduit’ with a plunger inside to move graft material down the barrel and [a] reduced-diameter portion (the extended tubular end portion).” Pet. 81–82 (citing Ex. 1003 ¶¶ 290–292; Ex. 1004, Fig. 1).

We have considered each of Patent Owner’s arguments to the contrary and find they have no merit. Resp. 57. Patent Owner argues the asserted art fails to teach a plunger in a conduit, and that Perez-Cruet shows only a plunger “within a syringe that is coupled to a conduit.” *Id.* (citing Ex. 2022

¹⁴ Petitioner argues there is no antecedent basis for the term “the fill tube assembly,” so the term “the fill tube assembly” must be a typo and was instead meant to be “the graft material delivery system,” referring back to claim 1. Pet. 81–82. Patent Owner does not dispute Petitioner’s understanding. *See* Resp. 57.

¶¶ 93–108, 115–134, 175–178, 203–220). Patent Owner’s argument is not persuasive because it is conclusory and unsupported by the citation of any evidence or an explanation or technical reasoning of why Perez-Cruet’s syringe 400 fails to teach or suggest “the positioning and movement of a plunger within a conduit.” We credit the testimony of Mr. Sherman over Dr. Lonner as it is consistent with and supported by Alfaro and Perez-Cruet. *See* Ex. 1003 ¶¶ 290–291.

18. Reasons Supporting the Combination of Alfaro, Frey, and Perez-Cruet

Petitioner argues that a person of ordinary skill in the art would have been motivated to combine Alfaro and Frey (Pet. 21–24) and Alfaro and Perez-Cruet (*id.* at 26–30).

a. Alfaro and Frey

Petitioner explains that, as a threshold matter, Alfaro and Frey are analogous art to the ’096 patent as they are directed to the same field of spinal implants for interbody fusion. *Id.* at 21 (citing Ex. 1001, 1:18–21; Ex. 1003 ¶ 137; Ex. 1005, Abstract; Ex. 1008 ¶ 4). Petitioner shows that Alfaro expressly states “any spacer” that is “attachable and detachable to a handle capable of containing a biologic material-advancing means” may be used in combination with its teachings, and that the spacers of Alfaro and Frey are both pressure-fit spacers, structurally similar, and detachable to a handle. *Id.* at 21–22 (citing Ex. 1003 ¶¶ 138–141; Ex. 1008 ¶¶ 5, 12, 31, Fig. 8; Ex. 1005, 19:50–52, 20:6–11, Fig. 55). In light of the need to keep the spacer at the correct site between vertebrae (*see* Ex. 1003 ¶ 142; Ex. 1008 ¶ 31), Petitioner reasons that a person of ordinary skill in the art would have been motivated to include grooves 1014 and 1016 of Frey for engaging vertebral endplates on the top and bottom surfaces of Alfaro’s implant to

obtain Frey’s stated benefit of resisting migration of the implant and to promote fusions of adjacent vertebrae. Pet. 21–23, 39 (citing Ex 1003 ¶ 143, 175–178; Ex. 1005, 19:50–52; 20:6–11). We agree with Petitioner that “[u]sing Frey’s grooves on the top and bottom surfaces of Alfaro’s implants represents combining prior art elements . . . 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.” Pet. 23 (citing Ex. 1003 ¶ 144).

b. Alfaro and Perez-Cruet

Petitioner explains that, as a threshold matter, Perez-Cruet is also analogous art to the ’096 patent as they are directed to the same field of spinal implants for interbody fusion. Pet. 26 (citing Ex. 1001, 1:18–21; Ex. 1003 ¶ 150; Ex. 1004 ¶¶ 2, 3). Patent Owner states that Perez-Cruet “is not an analogous device to Alfaro and Frey,” purportedly because it lacks a “chamber that extends between the first and second vertebral bodies.” Resp. 49, 64; *see also* Ex. 2022 ¶ 138 (Dr. Lonner stating the same). To the extent Patent Owner intends to argue that Perez-Cruet is not analogous art, Patent Owner’s argument is undeveloped, unsupported and has no merit. A reference is considered analogous prior art: (1) if the reference is from the same field of endeavor as the claimed subject matter, or (2) if the reference “is reasonably pertinent to the particular problem with which the inventor is involved,” even though the reference is not within the field of the inventor’s endeavor. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Perez-Cruet is analogous art to the ’096 patent because Perez-Cruet is directed to an intervertebral insert and device for positioning the

insert, the identical field to which the '096 patent is directed. *See, e.g.*, Ex. 1001, code (57); Ex. 1004, code (57).

Petitioner shows that Alfaro expressly teaches the use of “a ‘syringe-type system for moving [] biologic material through the handle and into the spacer’ and intervertebral space.” *Id.* at 26–27 (quoting Ex. 1008 ¶ 12). Petitioner further shows that Alfaro describes handles with a “hollow chamber” that can be “engaged and disengaged with the spacer,” as well as “syringes” that “can be adapted” for use with such handles. *Id.* (citing Ex. 1003 ¶ 151; Ex. 1008 ¶ 21). Petitioner also shows that “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.” *Id.* at 27–28 (citing Ex. 1003 ¶ 152; Ex. 1004 ¶ 62; Fig. 21).

Petitioner reasons, and we agree, that a person of ordinary skill in the art would have been motivated to use the syringe 400 of Perez-Cruet with Alfaro, because Alfaro suggests using a “syringe-type system,” it was well known that biologic graft material is commonly provided to a surgeon in the form of a pre-loaded syringe, the pre-loaded syringe may be conveniently manufactured and packaged for transport or delivery to a surgical facility, and, in the alternative, a syringe was commonly used for reconstituting bone powder and thereafter injecting the reconstituted graft material into a spinal implant. *Id.* at 29–30 (citing Ex. 1003 ¶ 155 (citing Exs. 1014, 1015, 1016)). We find persuasive Petitioner’s reasoning that a person of ordinary skill would have had reason the “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 . . . by positioning the extended tubular end portion 402 of Perez-Cruet’s syringe 400 through Alfaro’s cannulated handle 12. Pet. 29–30, 48 (citing, e.g., Ex. 1003, ¶¶ 155, 200).

With regard to claim 3 and the recited “fill tool assembly,” Petitioner explains that a person of ordinary skill in the art would have been motivated “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,” because it would have “inhibit[ed] accidental loosening of the implant connection during filling, allow[ed] easier removal without torquing the implant or any need to have a counter torque instrument, and remove[d] concerns regarding cross threading the inserter during surgery.” Pet. 65–66 (citing Ex. 1003 ¶¶ 233, 234, 236; Ex. 1004, Fig. 16; Ex. 1008 ¶ 21). We find Petitioner’s reasoning persuasive because it is because supported by the cited evidence of record.

c. Patent Owner’s Arguments Disputing Petitioner’s Rationale Are Not Persuasive

First, Patent Owner argues that “[t]he combination of Alfaro and Frey is improper in light of the intended purposes of the two devices.” Resp. 30–31 (citing Ex. 2022 ¶¶ 93–108, 115–120, 203–220); *see also id.* at 33–36 (arguing the same). According to Patent Owner, the spacer of Frey would have been packed with graft material before insertion. *Id.* Patent Owner’s argument is misplaced as the features of Frey Patent Owner focuses on are not tied to the teachings of Frey Petitioner relies upon, such as grooves on the top and bottom surfaces of Frey’s implant. *See* Pet. 21–23. “The test for obviousness is not whether the features of a secondary reference may be

bodily incorporated into the structure of the primary reference.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). “Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *Id.*

Here, Petitioner argues that: (1) Alfaro teaches its spacer must “remain[] in place at the correct site between the vertebrae” (Pet. 23 (citing Ex. 1008 ¶ 31)); (2) Frey teaches grooves on the upper and lower bearing members engage the vertebral endplates to “resist posterior and anterior migration of the implant . . . in the disc space” (*id.* at 21 (citing Ex. 1005, 19:50–52, 20:6–11)); and (3) the combination of Alfaro and Frey would have suggested to an ordinarily skilled artisan to modify the top and bottom surfaces of Alfaro’s spacer to include Frey’s grooves to better resist migration of the spacer (*id.* at 23 (citing Ex. 1003 ¶¶ 143–144)). Patent Owner does not present sufficient evidence or argument to persuade us that Frey’s open cage design would have changed this analysis.

For the same reason, Patent Owner’s argument that “Perez-Cruet cannot be combined with Alfaro and Frey because it is an entirely different type of implant,” is not persuasive. Resp. 32–33; *see also id.* at 36–39 (arguing the same). Patent Owner’s argument is misplaced as the features of Perez-Cruet Patent Owner focuses on are not tied to the teachings of Perez-Cruet Petitioner relies upon, such as a graft material delivery system. *See* Pet. 45–46. Regarding the combination of Alfaro and Perez-Cruet, Petitioner argues Alfaro suggests using a “‘syringe-type system for moving [] biologic material through the handle and into the spacer’ and intervertebral space.” Pet. 26–27 (citing Ex. 1008 ¶¶ 12, 32) (alteration in original). Petitioner also argues that given the broad disclosure of Alfaro, a

person of ordinary skill in the art would have been motivated to look to Perez-Cruet, which provides an illustrated example of a syringe-type system, as suggested by Alfaro, namely, syringe 400 having extended tubular end portion 402 for delivering bone graft material through the instrument 304, as shown in Figure 21. *Id.* at 27–29 (citing Ex. 1004 Fig. 21, ¶ 62; Ex. 1003 ¶ 152). Petitioner further argues that a person of ordinary skill in the art would have been motivated to use Perez-Cruet’s syringe assembly because, for example, “it was well known that biologic graft material is commonly provided to a surgeon in the form of a pre-loaded syringe.” *Id.* at 29 (citing Ex. 1003 ¶ 155 (citing Ex. 1014) (Wironen 2002 bone paste patent)).

Second, Patent Owner argues as follows:

While Orthofix relies on Frey and/or Perez-Cruet to teach the engagement and positioning of the implant with respect to the vertebral bodies, this reliance is misplaced, as Frey and Perez-Cruet do not support fusion through the implant, and in particular Perez-Cruet, while engaging with the vertebral bodies, does not allow for fusion through the implant as due to the vertical orientation. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216. First, Alfaro is designed to excrete graft material from multiple openings, filling the area surrounding the implant with graft material, and resulting in the positioning of graft material in such a way that the graft material becomes the load bearing material, as seen in figure 6 of Alfaro. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216. Both Frey and Perez-Cruet teach the implant being the load bearing surface not the graft material, but neither Frey or Perez-Cruet teach or suggest fusion through the implant. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216. Second, because of the load bearing characteristics of Perez-Cruet and Frey, if the teachings of Alfaro are combined with each of the secondary references the implant could possibly move or shift during fusion risking further injury to the patient as the implants do not allow for fusion through the implant. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216. Accordingly, a combination of Alfaro, Perez-

Cruet, and Frey is misplaced. Lonner Decl. at ¶¶ 93–108, 115–124, 203–216.

Resp. 40–41. Patent Owner does not persuasively explain how its assertion that “Frey and Perez-Cruet do not support fusion through the implant” has any bearing on the reasons Petitioner identifies for the asserted combination. Patent Owner’s argument also suggests it is based on Patent Owner’s argument that Alfaro teaches a “free floating” spacer, which we rejected for the reasons provided above. Finally, Patent Owner suggests bodily incorporating all of the teachings of Alfaro, Frey, and Perez-Cruet presents issues, but neglects to address the teachings of each reference upon which Petitioner relies. As noted above, “whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference” is not the test for obviousness. *Keller*, 642 F.2d at 425; *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”).

Third, Patent Owner argues that “Alfaro and Frey teach away from one another” because, although Alfaro states that graft material can be delivered to other types of implants, there are certain requirements laid out, which Frey does not meet, because Frey “is an open cage with no defined chamber, tunnels, leaders, or holes that would allow for receiving bone grafting material.” Resp. 41–42, 48 (citing Ex. 1008 ¶ 12; Ex. 2022 ¶¶ 93–108, 115–124, 203–217). Patent Owner also argues that Perez-Cruet teaches away from Alfaro and Frey because it requires “a different orientation of the implant” and lacks “an internal chamber . . . for fusion through the implant.” Resp. 42–44, 48–49. According to Patent Owner, “a doctor would not consider using the implant of Perez-Cruet in place of an Alfaro or Frey

implant,” and “the vertical orientation [of Perez-Cruets implant] defeats the intended purpose” of Alfaro and Frey. *Id.* at 43. Petitioner, however, does not propose using the implant of Perez-Cruet in place of an Alfaro or Frey implant. We have considered all of the issues raised by Patent Owner, and none support a teaching away argument.

A reference that “merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into” the claimed invention does not teach away. *Meiresone v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (quoting *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013)). For example, although Alfaro points out the difficulty with spacers pre-loaded before insertion (Ex. 1008 ¶ 9), it does not address, let alone “criticize, discredit, or otherwise discourage,” having grooves on the spacer’s top and bottom surfaces, which is the teaching of Frey Petitioner relies upon, or using a graft material delivery system, which is the teaching of Perez-Cruet that Petitioner relies on. Thus, we are not persuaded that Alfaro teaches away from Frey, or that Perez-Cruet teaches away from Alfaro or Frey.

On the full record, we determine Petitioner shows, as discussed above, sufficient reasoning with rational underpinning for combining the teachings of Alfaro and Frey, and Alfaro and Perez-Cruet, with a reasonable expectation of success. *See KSR*, 550 U.S. at 418–19 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)).

*19. Collective Consideration of the Graham Factors*¹⁵

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Alfaro, Frey, and Perez-Cruet teaches each limitation of claims 1–8 and 10–20 and has also shown that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, and Perez-Cruet, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that claims 1–8 and 10–20 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, and Perez-Cruet.

F. Alleged Obviousness over Alfaro, Frey, Perez-Cruet, and Fuss

Petitioner contends that claim 9 of the '096 patent is unpatentable under 35 U.S.C. § 103 as obvious over the combination of Alfaro, Frey, Perez-Cruet, and Fuss. Pet. 88–90 (citing, e.g., Ex. 1003 ¶¶ 317, 320; Ex. 1008, Figs. 2, 9; Ex. 1022, Fig. 2a). Patent Owner disputes Petitioner's contentions. Resp. 68–69; Sur-reply 25–26.

Claim 9 depends from claim 1 and further recites “wherein at least one of the first and second side walls of the implant does not comprise any openings.” Ex. 1001, 28:26–28. We focus our discussion on the additional limitations of claim 9 and adopt our analysis above with regard to the limitations of claim 1, from which claim 9 depends.

¹⁵ With respect to the Challenged Claims, the parties did not introduce evidence of secondary considerations of nonobviousness.

Petitioner shows that implant 4 of Fuss 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.’” Pet. 88–90 (citing Ex. 1022, 6:56–62, 7:7–16) (emphasis omitted). Petitioner further reasons a person of ordinary skill in the art would have had reason to modify Alfaro’s implant, which included “openings/tunnels 15(a)–15(f) around the periphery of the implant” in light of Fuss “not to include any openings along the ‘second side wall’ of Alfaro, “which corresponds to ‘boundary face 11’ of Fuss’s implant.” *Id.* (citing Ex. 1003 ¶ 316–21); *see also id.* (explaining that the “same reasoning likewise applies to the spacer 11 presented in Figure 9 of Alfaro”).

In addition to raising arguments that mirror arguments Patent Owner raised with regard to claim 1 (and, specifically, reasons the combination of Perez-Cruet with Alfaro and Frey “is improper”), which we find unpersuasive for the same reasons addressed above, Patent Owner further argues that “Alfaro and Frey cannot be combined with Fuss, because the implants are different.” Resp. 68 (citing Ex. 2022 ¶¶ 93–108, 115–134, 196–202, 203–220). Patent Owner states as follows:

Fuss does not teach or suggest an internal chamber that extends from a first vertebra to a second vertebra. Lonner Decl. at ¶¶ 93–108, 115–134, 196–202, 203–220. Because of this, Fuss cannot teach the retainment of graft material within the implant and generating flush contact with the vertebral bodies. Lonner Decl. at ¶¶ 93–108, 115–134, 196–202, 203–220. Thus, the combination of Alfaro, Frey, Perez-Cruet, and Fuss is improper.

Id. at 69. Patent Owner’s arguments are unpersuasive because Petitioner does not rely on Fuss to show “retainment of graft material.” Patent Owner also argues that “Fuss does not teach an implant that can be post filed [sic] as it has no openings for receiving a graft delivery tool or assembly.” *Id.* at 69 (citing Ex. 1022, Fig. 2a; Ex. 2022 ¶¶ 93–108, 115–134, 196–220). Patent Owner’s arguments are unpersuasive because Petitioner does not rely on Fuss to show “an implant that can be post filed.” Lastly, Patent Owner argues that “Fuss does not teach a continuous peripheral boundary defining an internal chamber and having at least one sidewall without openings.” *Id.* (citing Ex. 2022 ¶¶ 93–108, 115–134, 196–220). Patent Owner’s arguments are unpersuasive because Petitioner does not rely on Fuss to show “a continuous peripheral boundary defining an internal chamber.”

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Alfaro, Frey, Perez-Cruet, and Fuss teaches each limitation of claim 9 and has also shown that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, Perez-Cruet, and Fuss, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that claim 9 is unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, Perez-Cruet, and Fuss.

IV. ANALYSIS OF PATENT OWNER’S CONTINGENT MOTION TO AMEND

Because we conclude that Petitioner shows, by a preponderance of the evidence, that each of claims 1–20 is unpatentable, we next consider Patent Owner’s Contingent Motion to Amend.¹⁶ See MTA 1. Patent Owner proposes substitute claims 21–40 as replacements to claims 1–20. MTA 3. For the reasons below, we find Petitioner shows by a preponderance of the evidence that proposed substitute claims 21–40 are unpatentable under 35 U.S.C. § 103(a) and, therefore, we deny Patent Owner’s Contingent Motion to Amend.

A. Principles of Law Concerning a Motion to Amend

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). “Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.” See *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). The Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board, effective prior to Patent Owner filing its Motion to Amend, “assigns the burden of persuasion to the patent owner to show, by a preponderance of the evidence, that [the] motion to amend complies with” those statutory and

¹⁶ The MTA includes an “Appendix A” with page numbering that is consecutive across both the motion and the appendix, that is, Appendix A spans pages 28 to 35. When referring to material in Appendix A, we cite to “MTA” and the corresponding page number.

regulatory requirements. 85 Fed. Reg. 82923, 82924 (Dec. 21, 2020). Accordingly, Patent Owner must provide a claim listing reproducing each proposed substitute claim, and must make an initial showing to demonstrate the following: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial; and (3) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

It is Petitioner’s burden to show, by a preponderance of the evidence, that any proposed substitute claim is unpatentable. 85 Fed. Reg. 82924. Thus, the Board also must assess the patentability of proposed substitute claims “without placing the burden of persuasion on the patent owner.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see Lectrosonics*, Paper 15 at 3–4 (discussing *Aqua Products* and the burden of persuasion). After *Aqua Products*, the U.S. Court of Appeals for the Federal Circuit further clarified the burden of persuasion in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017), amended by *Bosch Automotive Service Solutions, LLC v. Iancu*, No. 2015-1928 (Fed. Cir. Mar. 15, 2018). According to *Aqua Products*, *Bosch*, and *Lectrosonics*, a patent owner does not bear the burden of persuasion to show that the proposed substitute claims are patentable. Rather, ordinarily “the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the evidence.” *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *Lectrosonics*, Paper 15 at 3–4. To determine whether a petitioner has proven the substitute claims are unpatentable, the Board focuses on “arguments and theories raised by the petitioner in its

petition or opposition to the motion to amend.” *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020).

B. Proposed Substitute Claims

Patent Owner proposes amended independent claim 21 as a substitute for independent claim 1 and proposes amended independent claim 36 as a substitute for independent claim 16. *Id.* at 4. Patent Owner asserts that proposed substitute claims 21 and 36 amend claims 1 and 16 only by adding two narrowing features: (i) “the second wall configured to prevent passage of graft material through the second wall” (the “prevent passage” limitation); and (ii) “wherein the second wall of the implant comprises a tapered end opposite the at least one internal chamber, and the tapered end allows for easier delivery of the implant” (the “tapered end” limitation).¹⁷ MTA Reply 1–2, 28–30, 32–34. Patent Owner additionally proposes dependent claims 22–35 as respective substitutes for dependent claims 2–15 and proposes dependent claims 37–40 as respective substitutes for dependent claims 17–20. *Id.* at 30–32, 34, 35. Each of the proposed substitute dependent claims is identical to one of the original dependent claims, but updated to depend from the appropriate proposed substitute independent claim. *Id.*

Proposed substitute claim 21 is representative of the proposed substitute claims and is reproduced below, using underscoring to indicate text added to claim 1. *Id.* at 3, 28–30.

¹⁷ We note that the “prevent passage” limitation of substitute claim 21 states “the second wall configured,” whereas substitute claim 36 states “the second wall is configured.” We find no substantive significance to this difference and note the “prevent passage” limitation and the “tapered end” limitation are otherwise identical in substitute claims 21 and 36.

21. A spinal fusion system for placing an implant and graft material within a target intervertebral space, the system comprising:

(i) an implant comprising:

a first wall and a second wall, the second wall being generally opposite of the first wall and the second wall configured to prevent passage of graft material through the second wall;

first and second side walls configured to extend between the first wall and the second wall;

a top surface configured to at least partially engage a lower surface of a first vertebral body;

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;

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

an access port extending through the first wall and being in fluid communication with the at least one internal chamber;

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

(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 the second wall of the implant comprises a tapered end opposite the at least one internal chamber, and the tapered end allows for easier delivery of the implant;

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

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.

Id. at 28–30.

C. Whether the Amendment Proposes a Reasonable Number of Substitute Claims and Responds to a Ground of Unpatentability Involved in the Trial

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). Patent Owner proposes no more than one substitute claim for each challenged claim. MTA 3. “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see* 37 C.F.R. § 42.221(a)(3). Petitioner does not argue otherwise. *See generally* MTA Opp. Therefore, we determine that Patent Owner proposes a reasonable number of substitute claims.

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i). Patent Owner asserts that none of the references cited by Petitioner teaches or suggests the limitations added by the amendments to claims 1 and 16, and that the amended claims are patentable over the prior art of record. MTA 4. Petitioner does not dispute that Patent Owner’s amendment responds to a ground of unpatentability in this trial. *See generally* MTA Opp. We determine that the amended language in the proposed substitute claims seeks to overcome the asserted art and is,

therefore, responsive to a ground of unpatentability involved in this trial.

D. Whether the Amendment Seeks to Enlarge the Scope of the Claims or Seeks to Introduce New Subject Matter

An amendment may not enlarge the scope of the claims of the patent or introduce new matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). Patent Owner shows that proposed substitute claims 21 and 36 “retain all features” of claims 1 and 16, respectively, “add only narrowing features,” and, as a result, “do not enlarge the scope” of claims 1 and 16 “in any way.” MTA 4. Petitioner does not contest Patent Owner’s arguments on this point. *See generally* MTA Opp. We agree with Patent Owner that proposed substitute claims 21–40 include narrowing limitations as compared to each corresponding original claim. *See* MTA 5–35.

Patent Owner also is required to show written description support in “the original disclosure of the patent for each claim that is . . . amended,” and in “an earlier-filed disclosure for each claim for which the benefit of the filing date of the earlier filed disclosure is sought.” 37 C.F.R. § 42.121(b). New subject matter is any addition to the claims that lacks sufficient support in the subject patent’s original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . , the new claim[] must find support in the original specification.”).

In the MTA, Patent Owner identifies written description support only for proposed substitute claims 21 and 36 and only in the ’509 provisional and the ’671 provisional, not in the ’146 application (the original disclosure of the ’096 patent). *See* MTA 5–24 (citing Ex. 1006; Ex. 1007); Opp. 1–2 (arguing that Patent Owner fails to meet its burden of identifying written

description support in the original disclosure and provisional applications for the proposed substitute claims).

In our Preliminary Guidance, we stated that “there appears to be adequate written description support for the proposed amendments in one or more of the ’509 provisional, the ’671 provisional, and the original disclosure of the ’096 patent.” Paper 25, 6. We discussed the support for the proposed amendments and explained to Patent Owner as follows:

Patent Owner is required to show written description support in “the original disclosure of the patent for each claim that is . . . amended,” and in “an earlier-filed disclosure for each claim for which the benefit of the filing date of the earlier filed disclosure is sought.” See 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2). Patent Owner’s Motion, however, identifies written description support for proposed substitute claims 21 and 36 and cites only the ’509 and ’671 provisionals, without providing any corresponding citations from the original disclosure of the ’096 patent. *See* Mot. 5–24; Opp. 1–2 (arguing that Patent Owner fails to meet its burden of identifying written description support in the original disclosure and provisional applications for the proposed substitute claims). Patent Owner should show support for each proposed substitute claim (including dependent claims 22–35 and 37–40) in each of the required disclosures (including the original disclosure of the ’096 patent) through a reply to this guidance or through the filing of a revised motion to amend.

Paper 25, 6 n.5.

In reply, Patent Owner provides claim charts for each proposed substitute claim showing “where support for each amended claim element appears in the originally filed disclosure issued as the ’096 [p]atent.” MTA Reply 2–17 (citing Ex. 1002). In its Sur-reply, Petitioner does not dispute the sufficiency of Patent Owner’s identification of written description support in the ’146 application for the proposed substitute

claims.¹⁸ *See generally* MTA Sur-reply. We find Patent Owner’s identification of support in the ’146 application shows sufficient written description support for each of the proposed amended claims. MTA Reply 2–17 (citing Ex. 1002).

E. Obviousness Over Alfaro, Frey, Perez-Cruet, and Messerli

Patent Owner states that its “amendments clarify the structure of the spinal implants” of independent claims 1 and 16, and that “none of the references cited by Petitioner teach or suggest the limitations added by these amendments.” MTA 4. Petitioner contends substitute independent claim 21 (and substitute claims 22–28 and 30–35, which depend therefrom) and substitute independent claim 36 (and substitute claims 37–40, which depend therefrom) would have been obvious over Alfaro, Frey, Perez-Cruet, and Messerli.¹⁹ MTA Opp. 4; MTA Sur-reply 2–10. Petitioner states that it “relies upon its Petition to demonstrate that the non-amended limitations of claims 1 and 16 are obvious over the combination of Alfaro, Frey, and Perez-Cruet,” and focuses its analysis on “the portions of substitute claims 21 and 36 that are added by amendment to claims 1 and 16.” MTA Opp. 4. In particular, Petitioner asserts the “prevent passage” limitation and

¹⁸ In this regard, we note Petitioner argued in its opposition that Patent Owner failed to show written description support in the ’509 provisional for certain limitations of substitute claims 21 and 36 that are also limitations in claims 1 and 16. MTA Opp. 2–4. Petitioner does not argue a lack of written description support in the ’146 application for these limitations. *See generally* MTA Sur-reply.

¹⁹ We exclude substitute claim 29 from our discussion of this ground of unpatentability because claim 29 includes the same limitation as original claim 9, which we found unpatentable over the combination of Alfaro, Frey, Perez-Cruet, and Fuss. *See supra* Section II.F.

the “tapered end” limitation of substitute claims 21 and 36 (the only limitations added to claims 1 and 16) would have been obvious over Alfaro and Messerli.²⁰ *Id.* Patent Owner disputes Petitioner’s contentions, primarily with regard to whether a person of ordinary skill in the art “would have been motivated to combine the asserted references to achieve the proposed claimed subject matter” and “would have had a reasonable expectation of success from doing so.” MTA Reply 17–24. Below we summarize Messerli in relevant part, analyze whether the asserted combination teaches the additional limitations of the substitute claims, evaluate whether Petitioner has shown a sufficient reason for the asserted combination. We conclude Petitioner shows by a preponderance of the evidence that substitute claims 21–28 and 30–40 would have been obvious over the asserted prior art.

1. Summary of Messerli

Messerli is directed to an intervertebral implant and instrumentation for use in a transforaminal posterior lumbar interbody fusion procedure. Ex. 1029, 1:17–19. Messerli states the transforaminal posterior lumbar interbody fusion implant (“T-PLIF implant”) is designed for use as an intervertebral spacer in spinal fusion surgery where an affected disk is removed from between two adjacent vertebrae and replaced with an implant

²⁰ Petitioner also argues that the “prevent passage” limitation is indefinite because “unless the ‘*second wall*’ of an implant has no holes or openings at all . . . the determination of whether a given implant structure is within the claim scope or not is also a function of the graft material particles sizes in the claimed ‘*graft material*.’” MTA Opp. 24–25. Because we find the substitute claims would have been obvious over the asserted prior art, we do not reach the issue of indefiniteness raised by Petitioner.

that provides segmental stability and allows for bone to grow between the two vertebrae to bridge the gap created by disk removal. *Id.* at 5:66–6:5.

Messerli discloses multiple embodiments of spinal implants that narrow or taper at an end of the implant to facilitate insertion between adjacent vertebrae. For example, in one embodiment, illustrated in Figures 2A–2D, the implant “tapers gradually along the longitudinal axis 36 of implant 22 so that it is thinnest at the narrow ends 25 of implant 22 . . . facilitating insertion of implant 22 into the affected disc space.” Ex. 1029, 6:42–49. Another embodiment of an implant is illustrated in Figures 16A–16E. *Id.* at 7:57–59.

Figure 16D of Messerli is reproduced below.

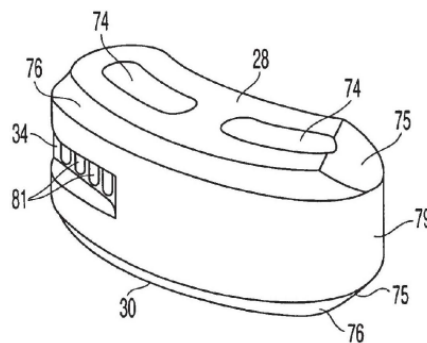


Fig. 16D

Figure 16D is a perspective view of the implant. *Id.* at 6:38–39. Superior and inferior surfaces 28, 30 are arcuate shaped, and the implant has a thickness, which is preferably greatest at a center portion and gradually tapers becoming thinnest at its narrow ends. *Id.* at 7:65–8:2. Messerli discloses the implant has chamfer 75 on both its superior and inferior surfaces that form “a wedge-like shape at insertion end 79 to facilitate implant insertion through the transforaminal window.” *Id.* 8:22–27. The implant includes “a pair of vertical through-channels 74 . . . which may be

packed with bone graft and other bone growth inducing material prior to and/or after implantation to aid in spinal fusion.” *Id.* at 8:17–22.

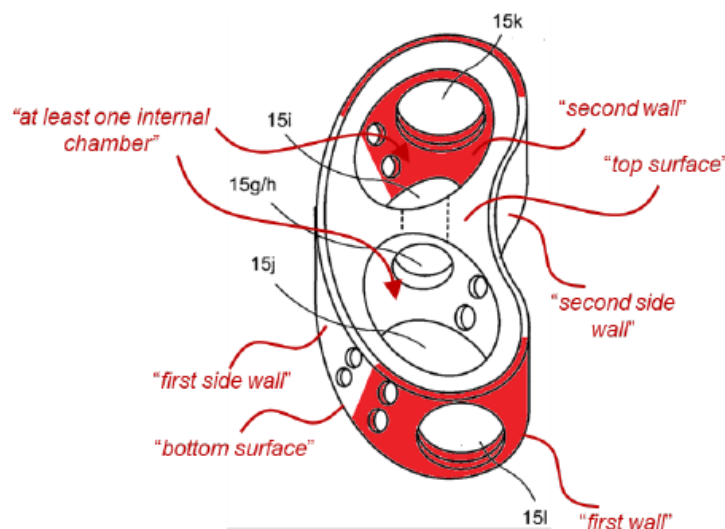
2. *Differences Between the Subject Matter of Substitute Claims 21 and 36 and Alfaro, Frey, Perez-Cruet, and Messerli*

Petitioner shows by a preponderance of the evidence that the limitations of substitute claims 21 and 36 identical to the limitations of claims 1 and 16 are taught or suggested by Alfaro, Frey, and Perez-Cruet for the same reason provided above. *See supra* Section II.E.3–4. We focus our discussion here on the additional limitations of substitute claims 21 and 36.

a first wall and a second wall, the second wall being generally opposite of the first wall and the second wall configured to prevent passage of graft material through the second wall [the “prevent passage” limitation]

Petitioner shows that Alfaro teaches “a first wall and a second wall, the second wall being generally opposite of the first wall.” Pet. 32–33 (citing Ex. 1008, Fig. 9); Ex. 1028 ¶¶ 59–60.

An annotated version of Figure 9, as submitted by Petitioner, is reproduced below.



MTA Opp. 18 (citing Pet. 40; Ex. 1008, Fig. 9; Ex. 1028 ¶ 60). Figure 9 of

Alfaro depicts an intervertebral spacer according to a preferred embodiment. Ex. 1008 ¶ 39. Petitioner includes annotations in Figure 9 identifying structure corresponding to a “first wall” being generally opposite to a “second wall,” and a “first side wall” being generally opposite to a “second side wall,” as recited. *See id.* at ¶ 39. Figure 9 also shows screw holes 15(l) and 15(k) in a first wall and a second wall, respectively. *Id.* Screw holes (15)(l) and 15(k) “show points of attachment for the holder, offering flexibility as to which side the surgeon prefers to use for delivery of the spacer.” *Id.* According to Petitioner “Alfaro explicitly teaches that only one screw hole may be used and that a second screw hole is optional.” MTA Opp. 19 (citing Ex. 1008 ¶ 29; Ex. 1028 ¶ 62). Although not explicitly stated by Petitioner, presumably Petitioner’s contention is that if there is only one screw hole in a first wall, the absence of any second screw hole in the second wall teaches or suggests a “second wall configured to prevent passage of graft material through the second wall.” *See id.* Even if screw hole 15(k) is eliminated from the spacer shown in Figure 9, Petitioner’s annotated red coloring of a “second wall” in Figure 9 still includes two smaller holes adjacent screw hole 15(k) that would appear not to prevent passage of graft material. Mr. Sherman’s testimony similarly fails to explain how Alfaro, alone, discloses the “prevent passage” limitation. *See* Ex. 1028 ¶¶ 58–62. Thus, Petitioner has not shown how Alfaro, alone, teaches or suggests the “prevent passage” limitation.

Petitioner, however, also relies on Messerli and shows that, in Figure 16D, Messerli illustrates an implant with a shape similar to Alfaro’s implant “in which the leading tapered end is closed (*i.e.* no openings).” MTA Opp. 20 (citing Ex. 1028 ¶ 64; Ex. 1029, Fig 16D). Mr. Sherman

explains that “[a]s a consequence of the leading end of the implant being solid (with no holes), graft material is prevented from flowing out of the leading end of the implant when packed with bone graft material after implantation.” Ex. 1028 ¶ 64. Based on the evidence cited by Petitioner, we find, and Patent Owner does not dispute, that the combination of Alfaro and Messerli teaches or suggests the “prevents passage” limitation. *See generally* MTA Reply.

wherein the second wall of the implant comprises a tapered end opposite the at least one internal chamber, and the tapered end allows for easier delivery of the implant [the “tapered end” limitation]

Petitioner shows that Messerli teaches the use of “tapered” implants that are tapered from the mid-section along longitudinal axis 36 of implant 22 and thinnest at the “narrow ends” to provide a “proper anatomical fit” while “facilitating insertion” of implants “into the affected disc space.” MTA Opp. 22–23 (citing Ex. 1029, 6:42–49). Petitioner further explains that Messerli also teaches that the “insertion end” has “chamfer 75” forming “a wedge-like shape at insertion end 79 to facilitate implant insertion.” *Id.* (citing Ex. 1029, 8:22–27). Petitioner further shows that Messerli discloses an example implant in Figures 16A–16E that demonstrates a tapered implant “having both tapering along an axis toward ‘narrow ends’ (including at an insertion end) (*id.* (citing Ex. 1029, 7:65–8:2, Fig. 16A)) and an insertion end that has a chamfer” (*id.* (citing Ex. 1029, 8:23–24, Figs. 16D, 16E)), both of which demonstrate a “tapered end” as claimed. *Id.* at 23 (citing Ex. 1028 ¶¶ 71–73). Thus, as explained by Petitioner, Messerli discloses that implant 22 tapers gradually along longitudinal axis 36 “so that it is thinnest at the narrow ends 25” and that

implant 22 has chamfer 75 on both its superior and inferior surfaces 28, 30 forming “a wedge-like shape at insertion end 79.” Ex. 1029, 6:42–49; 8:22–27. Based on the evidence cited by Petitioner, we find, and Patent Owner does not dispute, that the combination of Alfaro and Messerli teaches or suggests the “tapered end” limitation. *See generally* MTA Reply.

3. *Reasons Supporting the Combination of Alfaro, Frey, Perez-Cruet, and Messerli*

As explained above, Petitioner has shown by a preponderance of the evidence sufficient reason supporting the combination of Alfaro, Frey, and Perez-Cruet with respect to claims 1 and 16, and we adopt that analysis here for the identical limitations of substitute claims 21 and 36. *See supra* Sections II.E.3, II.E.4, II.E.18. We focus our discussion here on reasons supporting the combination of Alfaro and Messerli with respect to the additional limitations of substitute claims 21 and 36.

Petitioner shows there are several reasons to combine Alfaro and Messerli. Opp. 7–12, 19–20, 23–24. Initially, Petitioner explains that, as a threshold matter, Alfaro and Messerli are analogous art to the ’096 patent as they are directed to the same field of spinal implants for interbody fusion. *Id.* at 7 (citing Ex. 1001, 1:19–21; Ex. 1008 ¶ 4; Ex. 1029, Abstract, 1:15–20, 8:17–22; Ex. 1028 ¶ 25).

Petitioner states Alfaro discloses that “any spacer at all” may be used with its disclosure, provided that such a spacer is “attachable and detachable to a handle capable of containing a biologic material-advancing means,” and that this disclosure, along with Alfaro’s teaching that “well-known techniques for intervertebral placements” are used, would have motivated a person of ordinary skill to review the prior art for existing intervertebral

spacers, such as Messerli. *Id.* at 7–8 (citing Ex. 1008 ¶¶ 12, 20; Ex. 1028 ¶¶ 26–33).

With regard to the “tapered end” limitation in particular, Petitioner explains that “[a]pplying Messerli’s teachings of tapering of implants and chamfering the leading surface to Alfaro’s implants amounts to combining prior art elements according to known methods to yield the obvious, beneficial, and predictable result of an implant with tapered ends to provide a proper anatomical fit and facilitate insertion into the intervertebral space, while retaining the ability to be filled with bone graft material after implantation. *Id.* at 9. Petitioner supports its rationale by showing that “[i]t was and is well known that implants positioned by impaction often include tapered leading ends to accomplish a wedge-effect self-distraction (creating space for the implants by moving obstructions, such as vertebra, apart from each other and out of the way of the implant) of the intervertebral space.” *Id.* (citing Ex. 1028 ¶¶ 35–37), 12 (citing Ex. 1028 ¶ 42), 19 (citing Ex. 1028 ¶ 63), 24 (citing Ex. 1028 ¶¶ 76–77). Further, in this regard, Petitioner explains that “[t]he teachings of Messerli regarding tapered ends of the implant facilitating insertion apply . . . to any implant involving a posterior approach and, more generally, any device being pressure-fit into a tight space (e.g., ‘pressure-fit into place between the opposing vertebral bodies’[]),” and that “Alfaro applies to any of these types of implants because [its] teachings apply to ‘any spacer at all’ that is ‘attachable and detachable to a handle capable of containing a biologic material-advancing means.’” *Id.* at 8–10 (citing Ex. 1008 ¶¶ 5, 12, 20; Ex. 1028 ¶¶ 31–37); *see also id.* at 23–24 (citing Ex. 1008 ¶ 12; Ex. 1028 ¶¶ 74–75).

With regard to the “prevent passage” limitation, Petitioner shows as follows:

Due to the forces exerted on the leading tapered end, the need to resist these forces during impaction, and the desire to minimize friction of the wedging implant making it as efficient as possible, the leading end of an implant is often solid with no openings in the leading end which is opposite the insertion tool attachment opening (the trailing end). Ex. 1028 (citing Ex. 1029). *Id.* at 10 (citing Ex. 1028 (citing Ex. 1029)). Petitioner further explains that “[a]s there are no distraction instruments disclosed in Alfaro, it would have been obvious to a [person of ordinary skill] to include a closed tapered leading end as disclosed in Messerli to permit self-distraction of the disc space as the implant is impacted into position.” *Id.* Petitioner also asserts “[t]his is consistent with Alfaro’s teaching of ‘using well known techniques for intervertebral placement,’” and “implants with smooth leading ends (tapered, rounded corners and no openings) are beneficial to facilitate insertion by inhibiting soft tissue adjacent the vertebra from being inadvertently snagged as the implant is being inserted.” *Id.* at 10 (citing Ex. 1008 ¶ 30; Ex. 1028 ¶ 38).

Petitioner acknowledges a person of ordinary skill in the art “would have understood the tradeoffs involved with the leading end not including holes versus the leading end including holes, depending on the surgical approach, shape of the implant, and placement of the implant in the intervertebral space.” *Id.* at 11 (citing Ex. 1003 ¶ 76, Ex. 1028 ¶ 39). Petitioner explains how Messerli and Alfaro describe implants that are similar in structure and compatible and, thus, combinable. *Id.* at 11–12 (citing Ex. 1008 ¶ 12; Ex. 1028 ¶¶ 40–41; Ex. 1029, Figs. 16C–16D, 2:5–8, 3:56–58, 4:30–32, 6:32–41, 8:17–22, 10:58–63). Petitioner also shows that

the combination of Messerli's "implants with tapered narrow ends (including at an insertion end) and/or a chamfered insertion end to facilitate insertion and provide proper anatomical fit" with Alfaro's "use of a handle that facilitates insertion of an implant and filling of the implant with bone graft material after implantation" is a combination of "prior art elements according to known methods to yield predictable results."

Id. at 12 (citing Ex. 1028 ¶ 42).

For the reasons above, as supported by the evidence cited, Petitioner shows persuasively through articulated reasoning with rational underpinning that a person of ordinary skill would have been motivated to combine the teachings of Alfaro and Messerli with regard to the additional limitations of substitute claims 21 and 36 with a reasonable expectation of success. We have considered each of Patent Owner's arguments to the contrary, and find them unpersuasive and insufficiently supported, for the reasons provided below. *See* MTA Reply 17–24.

First, Patent Owner argues that modifying Alfaro with Messerli's tapered end wall would have rendered Alfaro's implant unsatisfactory for its intended purpose by obviating an explicit benefit (i.e., even graft distribution around the implant). *Id.* at 18, 23. As support, Patent Owner relies on Alfaro's disclosure that "[a] plurality of leader lines is provided, preferably spaced around the compartments, so as to promote even distribution of the biologic outflow within the space and around the top and bottom surface interfaces of the spacers and vertebrae and the sidewalls thereof." Ex. 1008 ¶ 20. Patent Owner argues that "by removing the leading lines from Alfaro's leading wall, the modified Alfaro implant will not promote even distribution of graft material around the implant, which is critical for Alfaro

to achieve increased fusion rates.” MTA Reply 19. Patent Owner’s argument is unsupported attorney argument and contrary to the express disclosure of Alfaro it purports to rely on, which makes clear that the leader lines are only “preferably” spaced around the compartments, and does not suggest that leader lines spaced around the compartment must necessarily include leader lines in the leading wall.

Petitioner further shows that removal of the openings from the leading tapered wall of the combined Alfaro-Messerli implant would not make the resulting implant “unsatisfactory for its intended purpose.” MTA Sur-reply 3. Petitioner explains that Alfaro’s implants are used to promote and increase spinal fusion by delivering bone graft material into an implant “after the spacer is inserted in an intervertebral space” using the known technique of “post packing” with bone graft after implantation so there are no empty spaces in the cage. *Id.* at 4 (citing Ex. 1003 ¶¶ 130–131, 135 (citing Ex. 1008 ¶¶ 9, 12, 30); Ex. 1034 ¶¶ 31–33). Petitioner’s asserted combination of Alfaro and Messerli is consistent with Alfaro because by delivering bone graft material after implant insertion, “problems related to biologic material settling or falling out during placement of the implant are avoided.” *Id.* (citing Ex. 1003 ¶¶ 130–131). Moreover, we agree with Petitioner that even if there would have been drawbacks to removing openings in the leading wall of Alfaro, a person of ordinary skill in the art “would have recognized the advantages provided by removal of the openings, thereby rendering the challenged claim obvious. *Id.* (citing *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (“a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination

claimed by the patent applicant is the preferred, or most desirable, combination”).

Next, Patent Owner argues that Petitioner’s “principal rationale” for combining Alfaro’s implant with Messerli’s teachings is that Messerli’s implants are “fully compatible” with Alfaro. MTA Reply 20. Patent Owner further argues that “[c]ompatibility by itself is an insufficient rationale to combine references,” and that “[i]nstead, Petitioner must articulate a reasoning that would have given a [person of ordinary skill] a reasonable expectation of success.” *Id.* (emphasis omitted).

Although we agree generally with Patent Owner that “compatibility by itself” may be an insufficient rationale to combine references in certain instances, we agree with Petitioner that Patent Owner “ignores most of Petitioner’s arguments in alleging that Petitioner’s “principal rationale” for combining Alfaro and Messerli is compatibility of the references.” MTA Sur-reply 5. Petitioner shows that it “specified several ways that Messerli’s implants are compatible with Alfaro’s implants in order to further demonstrate that the combination yields obvious and predictable results.” *Id.* (citing MTA Opp. 11–12 (explaining similarities in vertical compartments implants, packing the implants with biologic material after implantation, and Messerli’s implants attachable/detachable to handles such as Alfaro’s)). Petitioner also shows that it presented numerous benefits yielded by the combination. *Id.*; *see also* MTA Opp. 9–10 (discussing the benefit of a tapered end to proper anatomical fit and to facilitate insertion into the intervertebral space) (citing Ex. 1008 ¶ 30; Ex. 1028 ¶ 38).

Patent Owner further argues that Messerli’s implant is incompatible with Alfaro’s implant because Messerli is not configured to receive graft

material through an instrument like Alfaro's injection handle, but instead Messerli teaches that the vertical components 74 are "packed with bone graft" through channels 78, 80. MTA Reply 20 (citing Ex. 1029, 8:18–20, 9:13–14, 9:32–34). Patent Owner also argues that Alfaro identifies Messerli's packing techniques as a "disadvantage" and, therefore, Alfaro would have discouraged a person of ordinary skill from using Messerli's implant according to Alfaro's teachings. *Id.* We are not persuaded by Patent Owner's argument because, as Petitioner shows, both Messerli and Alfaro describe packing the compartments with bone graft material "after implantation," and we are not persuaded that Messerli's implant is "incompatible" with Alfaro's merely because it does not use an injection handle to perform the packing. *See* MTA Sur-reply 6. We also agree with Petitioner's argument that Patent Owner appears to attack Messerli, as not having identical teachings to Alfaro, but that is not required to show obviousness. MTA Sur-reply 6–7 (citing *Keller*, 642 F.2d at 425) ("[T]he test [for obviousness] is what the combined teachings of the references would have suggested to those of ordinary skill in the art.").

Patent Owner further argues Petitioner has not provided any rationale for why a person of ordinary skill in the art "would have modified Alfaro's implant with only the smooth tapered edge of Messerli," and asserts that Petitioner's rationale for combining is improperly driven by hindsight bias. MTA Reply Opp. 21. We are not persuaded by these arguments either as there is no legal basis to suggest that in relying on a combination of known elements in the art to show obviousness, the asserted combination must include every feature of every reference. As Petitioner explains, and we agree, Petitioner has provided an "extensive and reasoned discussion"

regarding how and why a person of ordinary skill would have modified Alfaro's implant with the teachings of Messerli. MTA Sur-reply 6 (citing MTA Opp. 7–12; Ex. 1028 ¶ 38). Patent Owner's "hindsight bias" argument also is not persuasive because Petitioner relies on the teachings of the prior art references and "takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from . . . [the '096 patent's] disclosure." *See In re McLaughlin*, 443 F.2d 1392, 1313–14 (CCPA 1971).

Relatedly, Patent Owner argues Messerli does not disclose that the 16D embodiment "could be modified to have peripheral channels and a solid, tapered end wall" and, therefore, "the Alfaro-Messerli combination would lead a POSITA to modify Alfaro's implant not to include any peripheral openings" and such a modification "does not render the proposed claimed subject matter obvious." MTA Reply 22. Patent Owner asserts that, even assuming the 16D embodiment could be so modified, Alfaro teaches away from combining because it requires the implant to have a plurality of leader lines. *Id.* (citing Ex. 1008 ¶ 20). We are not persuaded by Patent Owner's argument because, as discussed above, Alfaro does not require the implant to have openings through the leading wall. *See* MTA Sur-reply 3–4 (citing Ex. 1003 ¶¶ 130–133, 135; Ex. 1034 ¶¶ 31–33). And, contrary to Patent Owner's argument, Alfaro does not teach away from a solid tapered leading wall because, as Petitioner asserts, Alfaro does not "criticize, discredit, or otherwise discourage" a tapered leading wall with no openings. *Id.* at 7 (citing *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1320 (Fed. Cir. 2015)).

Lastly, Patent Owner argues that Dr. Lonner has established that Alfaro's implants are designed to be free floating, whereas Petitioner acknowledges that the implant of Messerli is designed to be "pressure-fit" between vertebrae. MTA Reply 22 (citing MTA Opp. 8, 23; Ex. 2022 ¶ 119). Patent Owner then asserts that because "Alfaro and Messerli teach diametrically opposed implants," a person of ordinary skill in the art would not have been motivated to combine these references. *Id.* Patent Owner's argument is not persuasive because we agree with Petitioner that Alfaro's implants are not designed to be "free floating" and that Alfaro "does not intend to deviate from well-known spacer structures or normal surgical techniques that beneficially use contact between a spacer and adjacent vertebrae." MTA Sur-reply 7–8 (citing Pet. Reply 40–43); *see also supra* Section II.E.3. (rejecting Petitioner's argument that Alfaro's implant is "free floating").

4. *Collective Consideration of the Graham Factors*²¹

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Alfaro, Frey, Perez-Cruet, and Messerli teaches each limitation of substitute claims 21–28 and 30–40 and has also shown that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, Perez-Cruet, and Messerli, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner

²¹ With respect to the proposed substitute claims, the parties did not introduce evidence of secondary considerations of nonobviousness.

has not shown by a preponderance of the evidence that substitute claims 21–28 and 30–40 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, Perez-Cruet, and Messerli.

F. Obviousness Over Alfaro, Frey, Perez-Cruet, Fuss, and Messerli

Petitioner contends that substitute claims 21–40 would have been obvious over the combination of Alfaro, Frey, Perez-Cruet, Fuss, and Messerli. MTA Opp. 4. Having found that Petitioner has shown that substitute claims 21–28 and 30–40 would have been obvious over the combination of Alfaro, Frey, Perez-Cruet, and Messerli, we limit our consideration here to substitute claim 29. Petitioner contends that Fuss teaches openings on one side of an implant, but not the other. MTA Opp. 13–14 (citing Ex. 1022, 7:7–16, 10:6–12, Fig 2a; Ex. 1028 ¶ 44). Petitioner also address reasons in support of the combination of Alfaro and Fuss, in view of Messerli. *Id.* at 14–17.

Substitute claim 29 depends from substitute claim 21 and includes additional limitations identical to original claim 9. *See* MTA 31; Ex. 1001, 28:26–28. As explained above, Petitioner has shown that claim 9 would have been obvious over the combination of Alfaro, Frey, Perez-Cruet, and Fuss. *See supra* Section II.F. Petitioner has also shown that claim 21 would have been obvious over the combination of Alfaro, Frey, Perez-Cruet, and Messerli. *See supra* Section III.E. Patent Owner does not separately address substitute claim 29 or the addition of Fuss to the combination of Alfaro, Frey, Perez-Cruet, and Messerli. Patent Owner states that “Petitioner’s alternative ground that Alfaro combined with Fuss (in view of Messerli) fails for at least the same reasons as above because Petitioner fails to cure the deficiencies identified in Messerli with Fuss.” MTA Reply 22. We rejected

Patent Owner's arguments directed to the combination of Alfaro and Messerli for the reasons provided above. Accordingly, we need not reach Petitioner's arguments that the additional limitations of substitute claim 21, from which substitute claim 29 depends, also would have been obvious with the further addition of Fuss.

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has demonstrated by a preponderance of the evidence that proposed substitute dependent claim 29 is unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of Alfaro, Frey, Perez-Cruet, Fuss, and Messerli.

V. CONCLUSION

For the above reasons, we conclude Petitioner has met its burden of showing, by a preponderance of evidence, that claims 1–20 of the '096 patent are unpatentable. We also deny Patent Owner's Contingent Motion to Amend because Petitioner has shown by a preponderance of the evidence that proposed substitute claims 21–40 are unpatentable under 35 U.S.C. § 103(a) as obvious over the combined teachings of the cited references.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, based on a preponderance of the evidence, claims 1–20 of U.S. Patent No. 9,216,096 B2 have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner’s Contingent Motion to Amend that includes proposed substitute claims 21–40 is denied; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–8, 10–20	103(a)	Alfaro, Frey, Perez-Cruet	1–8, 10–20	
9	103(a)	Alfaro, Frey, Perez-Cruet, Fuss	9	
Overall Outcome			1–20	

The table below summarizes our conclusions as to Patent Owner’s Contingent Motion to Amend.

Motion to Amend Outcome	Claims
Original Claims Canceled by Amendment	
Substitute Claims Proposed in the Amendment	21–40
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	21–40
Substitute Claims: Not Reached	

IPR2020-01412
Patent 9,216,096 B2

For PETITIONER:

J. Andrew Lowes
Clint Wilkins
John Russell Emerson
HAYNES AND BOONE, LLP
andrew.lowes.ipr@haynesboone.com
clint.wilkins.ipr@haynesboone.com
russellemersonipr@haynesboone.com

For PATENT OWNER:

David W. Carstens
J. Andrew Reed
J. Miguel Hernandez
Brian A. Carpenter
CARSTENS & CAHOON, LLP
carstens@cclaw.com
jareed@cclaw.com
hernandez@cclaw.com
carpenter@cclaw.com