

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOFIX MEDICAL INC.,
Petitioner,

v.

SPINE HOLDINGS, LLC,
Patent Owner.

IPR2020-01411
Patent 9,649,203 B2

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

YANG, *Administrative Patent Judge.*

JUDGMENT

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

I. INTRODUCTION

Orthofix Medical Inc. (“Petitioner”) filed a Petition (Paper 2 (“Pet.”)), seeking an *inter partes* review of claims 1–20 of U.S. Patent No. 9,649,203 B2 (Ex. 1001, “the ’203 patent”). We instituted trial to review the challenged claims. Paper 9. Thereafter, Spine Holdings, LLC (“Patent Owner”) filed a Response to the Petition (Paper 11, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 29, “Reply”), and Patent Owner filed a Sur-reply to Petitioner’s Reply (Paper 32, “Sur-reply”).

Patent Owner also filed a Contingent Motion to Amend (Paper 24 (“MTA”)),¹ and Petitioner filed an Opposition to the MTA (Paper 20 (“MTA Opp.” or “MTA Opposition”)). We issued a Preliminary Guidance on the MTA, indicating our initial, preliminary, non-binding views that Petitioner had established a reasonable likelihood that the proposed substitute claims are unpatentable. Paper 26 (“PG”). Thereafter, Patent Owner filed a Reply to Petitioner’s MTA Opposition (Paper 30, “MTA Reply”),² and Petitioner filed a Sur-reply to Patent Owner’s MTA Reply (Paper 35, “MTA Sur-reply”).

An oral hearing for this proceeding was held on December 2, 2021, and the transcript of that hearing is of record. *See* Paper 40 (“Tr.”).

¹ Patent Owner omitted page numbers in its originally filed Contingent Motion to Amend (Paper 19). Paper 22, 3. We expunged Paper 19 and authorized Patent Owner to refile the Motion. *Id.*

² Patent Owner filed Paper 30 as a Revised Contingent Motion to Amend. Paper 30, however, does not include any new proposed substitute claim. Paper 33, 2–3. We, thus, deemed Paper 30 Patent Owner’s Reply to Petitioner’s MTA Opposition. *Id.* at 3.

The Board has jurisdiction under 35 U.S.C. § 6 and issues this Final Written Decision pursuant to 35 U.S.C. § 318 and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–20 of the ’203 patent are unpatentable. We also determine Petitioner has shown by a preponderance of the evidence that Patent Owner’s substitute claims 21–40 are unpatentable and, therefore, we deny Patent Owner’s Contingent Motion to Amend.

A. Related Matters

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

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

B. The ’203 Patent

The ’203 patent relates to spinal fusion, specifically, to spinal implants. Ex. 1001, 1:19–21. The ’203 patent explains that “[i]ntervertebral discs can degenerate or otherwise become damaged over time.” *Id.* at 1:23–24. Before the ’203 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 ’203 patent states that there is a need for “an improved intervertebral implant, as well as related instrumentation, tools, systems and methods.” *Id.* at 1:30–32.

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

According to the ’203 patent,

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

Id. at 1:53–60.

The ’203 patent discloses a method for promoting spinal fusion. *Id.* at 3:22–36. The method comprises providing a spinal implant, positioning the spinal implant between two adjacent vertebral bodies or vertebrae of a patient, and directing at least one graft material into at least one internal chamber through a port of the implant. *Id.* at 3:22–29. The ’203 patent also discloses that excess graft material is configured to exit the at least one

internal chamber through one or more openings of the anterior wall. *Id.* at 3:29–36. According to the ’203 patent, excess graft “can generally fill any gap that exists between the vertebral endplates and the adjacent surfaces of the implant,” resulting in improved spinal fusion. *Id.* at 24:38–53.

C. Illustrative Claims

Claims 1 and 11 of the ’203 patent are independent. Claim 11 is broader than claim 1. Claim 11 is illustrative and, with certain reformatting,³ is reproduced below:

11. [11.0] A method of promoting spinal fusion within a spine of a patient, comprising:

[11.1.1] advancing an implant through an anatomy of a patient,

[11.1.2] the implant comprising at least one internal chamber;

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

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

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

[11.3.3] wherein the graft material is contained within the at least one internal chamber;

³ For ease of reference, Petitioner’s designations to reference the limitations of claim 11 are set forth in brackets. Herein we refer to the limitations of claim 11 using Petitioner’s designations.

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

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

Ex. 1001, 28:42–63.

Claim 1 includes all the limitations of claim 11, and adds that the at least one internal chamber is “defined by peripheral walls of the implant, wherein the implant comprises at least one access port extending through at least one of the peripheral walls of the implant.” *Id.* at 27: 38–41. Claim 1 also recites that “the implant is advanced through an anatomy of a patient using an insertion tool.” *Id.* at 27: 42–43. And the method of claim 1 ends with “withdrawing the insertion tool from the anatomy of the patient, leaving the implant situated between the first and second vertebrae.” *Id.* at 27: 61–63.

D. Instituted Grounds of Unpatentability

We instituted trial to determine whether the challenged claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §⁴	References
1–5, 9–15, 19, 20	103(a)	Alfaro, ⁵ Frey ⁶
6–8, 16–18	103(a)	Alfaro, Frey, Perez-Cruet ⁷

In support of their respective positions regarding the patentability of the original claims, Petitioner relies on the Declarations of Michael Sherman (Exs. 1003, 1024, 1033) and John H. Peloza, M.D. (Ex. 1034); and Patent Owner relies on the Declarations of Baron Lonner, M.D. (Exs. 2010, 2022) and Eric Nauman, Ph.D. (Ex. 2015). Patent Owner also relies on the Declarations of the inventors Jim R. Lynn (Exs. 2006, 2013) and Russell W. Nelson, M.D. (Exs. 2007, 2014), as well as Anna Green (Exs. 2008, 2016), Daniel M. Cislo (Ex. 2009), Dave Matsuura (Ex. 2020), and Belinko Matsuura (Ex. 2021).

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. The parties agree that the challenged claims of the ’203 patent are entitled to the priority of October 4, 2010, the filing date of one of the provisional applications. Sur-reply 9–21; Tr. 26:21–27:5 (Petitioner does not contest that “October 4, 2010 . . . is the appropriate date”). Thus, the pre-AIA version of § 103 applies.

⁵ Alfaro et al., U.S. Patent App. Pub. No. 2010/0262245 A1, published Oct. 14, 2010 (Ex. 1008).

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

⁷ Perez-Cruet et al., U.S. Patent App. Pub. No. 2008/0172128 A1, published July 17, 2008 (Ex. 1004).

II. ANALYSIS

A. *Principles of Law*

To prevail in this *inter partes* review, Petitioner “shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.” 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). 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 skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *KSR*, 550 U.S. at 406.

Obviousness requires more than a mere showing that each limitation in a challenged claim was independently known in the prior art. *KSR*, 550 U.S. at 418. Rather, a patent challenger must articulate a reason why an ordinarily skilled artisan would have combined or modified the prior art references. *Id.* This analysis, however, “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.” *Id.*

We analyze the instituted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art

Petitioner asserts that, at relevant time, a person of ordinary skill in the art (“POSITA”)

would have had a Bachelor of Science degree in the field of Mechanical, Biomechanical or Biomedical engineering as well as at least five years of experience designing and developing spinal implants and related systems, tools and methods. Furthermore, a person with more technical education but less experience could also meet the relevant standard for POSITAs. Alternatively, a POSITA could be a practicing orthopedic or neurosurgeon with experience designing spinal implants.

Pet. 13 (Ex. 1003 ¶¶ 22–25). Patent Owner does not dispute Petitioner’s assertion. *See* Ex. 2022 ¶ 91 (Dr. Lonner providing similar definition of the skill level).

For purposes of this Decision, we adopt Petitioner’s proposed definition of the ordinary skill level, as it is consistent with the disclosures of the ’203 patent and the prior art of record. We also find that the parties’ respective experts, including Mr. Sherman and Dr. Pelosa for Petitioner, and Drs. Lonner and Nauman for Patent Owner, are qualified to offer opinions on the subject matter in this case.

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).

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

D. Prior Art Status of Alfaro

The challenged ’203 patent issued from an application that claims priority to a series of applications, including two provisional applications: (1) Application No. 61/314,509 (“the ’509 provisional”), filed March 16, 2010, and (2) Application No. 61/389,671 (“the ’671 provisional”), filed on October 4, 2010. *See* Ex. 1001, codes 60, 63. 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 9–21; Tr. 24:1–7.

Alfaro is a published U.S. patent application that was filed on February 17, 2010. Ex. 1008, code (22). On its face, Alfaro also claims priority to a provisional application filed on February 18, 2009 (“Alfaro Provisional”). *Id.*, code (60). Petitioner asserts that Alfaro is entitled to the benefit of Alfaro Provisional. Pet. 16 (citing Ex. 1003, App’xs. A, B); *see also* Reply 19–39 (providing a detailed claim chart comparing Alfaro to the Alfaro provisional). Patent Owner does not challenge Petitioner’s showing on this issue. We are satisfied that Petitioner has met its burden in showing the effective date of Alfaro is February 18, 2009. *See Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1380 (Fed. Cir. 2015).

Petitioner bears the burden to show that Alfaro is prior art. *Id.* at 1379. Petitioner argues 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. 15–16.

Patent Owner disputes that Alfaro is prior art under § 102(e) because, according to Patent Owner, evidence shows that the inventors of the '203 patent conceived the claimed subject matter before the effective date of Alfaro, and diligently reduced the invention to practice. PO Resp. 8–30; Sur-Reply 1–8.

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 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. *Id.* at 1363. In this case, Patent Owner must show conception before February 18, 2009, the filing date of Alfaro Provisional, and reasonably continuous diligence in reducing the invention to practice from just before that date to October 4, 2010, the date of Patent Owner's constructive reduction to practice. *See* PO Resp. 29 (“[T]he filing of the ‘671 Application served as constructive reduction to practice.”).

Patent Owner has produced evidence to purportedly antedate Alfaro. It relies on the declarations of both inventors (Exs. 2006, 2007, 2013, 2014), declarations of a former staff member, the patent prosecution attorney, and a collaborator (Exs. 2008, 2009, 2016, 2020, 2021), declarations of two

experts (Exs. 2010, 2015, 2022), as well as other evidence, such as notebook pages, product literature, and email communications (Exs. 2001–2005, 2017, 2018).

Specifically, Patent Owner argues that the testimonies of Mr. Lynn and Dr. Nelson, the inventors of the '203 patent, demonstrated that they conceived the claimed subject matter of the '203 patent no later than April 14, 2008. PO Resp. 8 (citing Ex. 2013 ¶¶ 8, 19; Ex. 2014 ¶¶ 8, 18). Patent Owner relies on Mr. Lynn's notebook pages and the declaration of Ms. Green, a nurse who formerly worked with Dr. Nelson, to corroborate the inventors' testimonies on this issue. *Id.* at 9–17 (citing Ex. 2002, 1–5; Ex. 2016 ¶¶ 9, 12–13).

Petitioner contends that Patent Owner fails to demonstrate conception of the claimed invention before the critical date. Reply 1–10. Specifically, Petitioner asserts that Patent Owner fails to show conception for “directing graft material into the at least one internal chamber of the implant through an access port of the implant to fill the at least one internal chamber of the implant . . . such that the graft material is in flush contact with endplate surfaces of each of the first and second vertebrae,” as recited in independent claims 1 and 11. *Id.* at 3–8. Petitioner also argues that Patent Owner fails to show conception of “using an insertion tool,” as recited in claim 1. *Id.* at 8–10. Patent Owner disagrees. *See* Sur-reply 1–7.

We do not need to reach the parties' dispute 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.

The question of reasonable diligence is one of fact. *Brown v. Barbacid*, 436 F.3d 1376, 1379 (Fed. Cir. 2006). 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).

To antedate Alfaro, Patent Owner must present evidence to show that the inventors were diligent throughout the entire critical period. *See Monsanto*, 261 F.3d at 1369. For our analysis, we divide the critical period into two parts: from February 2009 through January 2010 (Sub-Period 1); and from February 2010 through October 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, we focus our analysis on the inventors' activities during Sub-Period 1.

For Sub-Period 1, Patent Owner provides no drawings, no notebook pages, or any other evidence to show any activity toward developing the alleged invention during the entire twelve months in Sub-Period 1. Instead, Patent Owner relies on the inventors' testimonies to show reasonably continuous diligence. PO Resp. 24–27 (citing Exs. 2013, 2014). An inventor's testimony regarding reasonable diligence must be corroborated by evidence. *Brown*, 436 F.3d at 1380. As explained below, in this case, the

inventors' testimonies on diligence during Sub-Period 1 are either uncorroborated, or not sufficiently corroborated.

1. Attending Surgeries and Discussions Afterwards

According to Patent Owner, between February 2009 and July 2009, Mr. Lynn attended multiple surgeries performed by Dr. Nelson, with assistance from Ms. Green. PO Resp. 24 (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.

The inventors further testify that “[d]uring, and after, the surgeries, Dr. Nelson, Ms. Green, and Mr. Lynn discussed the flaws with the existing implants and insertion methods and how they could improve their design to address the flaws.” 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. Ms. Green testifies to the same effect. Ex. 2016 ¶¶ 16–34. Neither Ms. Green nor the inventors, however, provide any description of the flaws or improvements discussed.

Patent Owner points to no contemporaneous documents to support the inventors' testimonies, either. 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 in light of any flaws of the prior art or possible design improvements. 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. Peloza, 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, Patent Owner's expert, 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. Absent independent corroborating

evidence showing otherwise, 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.

2. Other Activities

Patent Owner argues that other activities, including searching for a graft material, also demonstrate the inventors' diligence. *See, e.g.*, PO Resp. 24–25.

As a preliminary matter, we note that the challenged claims are method claims reciting “directing graft material into the at least one internal chamber.” Ex. 1001, claims 1, 11. Neither the claims nor the Specification suggests any special property of the graft material. Thus, it is questionable whether searching for a graft material is relevant to our diligence inquiry.

Moreover, the '203 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.” PO 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 2.⁸ *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, 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.

a. 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.” PO Resp. 24 (citing Ex. 2013 ¶¶ 23,⁹ 33,¹⁰ 34; Ex. 2014 ¶ 37; Ex. 2004, 1).

⁸ Patent Owner does not argue that the challenged claims are entitled to the benefit of the '509 provisional filing date. *See* PO Resp. 29 (“[T]he filing of the '671 Application served as constructive reduction to practice.”); *see also* Sur-reply 9–21 (arguing the challenged claims are entitled to the benefit of the '671 provisional filing date on October 4, 2010).

⁹ Paragraph 23 of Mr. Lynn’s declaration relates to alleged conception on April 14, 2008, and not the requisite diligence in February 2009. *See* Ex. 2013 ¶ 23.

¹⁰ There are two paragraphs numbered “33” in Mr. Lynn’s declaration: one spans pages 17 and 18, the other is on page 18 only. The latter relates to Mr. Lynn attending a surgery on February 24, 2009, and thus, does not support Patent Owner’s argument here. *See* Ex. 2013, p. 18.

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 to corroborate 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.

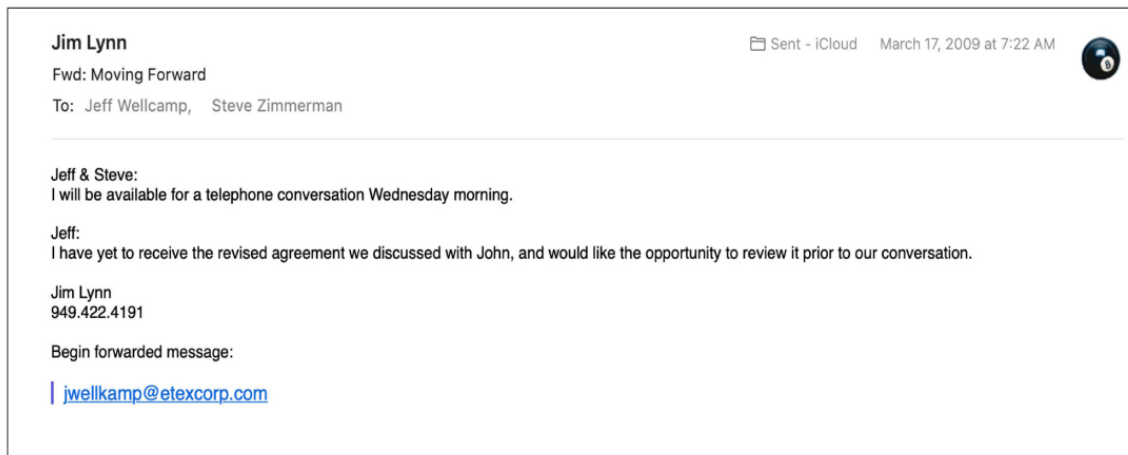
b. March 2009

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." PO 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. *See* Ex. 2003, 2–3. The evidence, however, does not corroborate Mr. Lynn's testimony.

For example, Mr. Lynn testifies that, on March 17, 2009,

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:



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

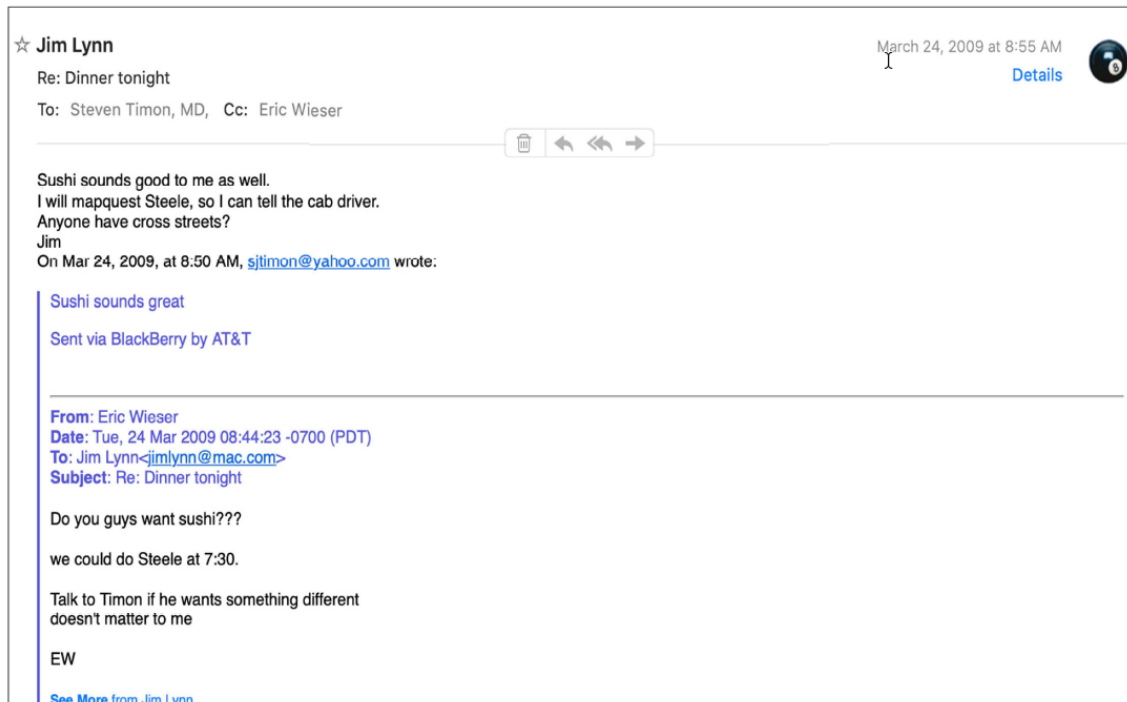
Similarly, the emails cited in paragraph 38 of Mr. Lynn’s declaration does not support his testimony. *See* Ex. 2013 ¶ 38 (citing Ex. 2003, 3).¹¹ Mr. Lynn testifies that the purpose of a March 18, 2009 email from him to two medical doctors “was to set up a future meeting to discuss possible cage designs for our post-fill spinal implant.” 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.¹² *See* Ex. 2003, 3 (emphasis added).

¹¹ Patent Owner also cites paragraph 41 of Dr. Nelson’s declaration. PO 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.

¹² 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.

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 alleged 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:



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.

c. 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. Mr. Lynn also conducted meetings in an effort to arrange for manufacturing of the implant, and a possible sale to their intellectual property in their

implant.” PO Resp. 25 (citing Ex. 2013 ¶¶ 37,¹³ 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

¹³ We have addressed Mr. Lynn’s testimony and evidence relied on in paragraph 37 of his declaration. *See supra* Section II.D.2.b. 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.

material, and OP-1 was one of the candidates that may work in their post-fill spinal implant.

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 find the email communications on April 30, 2009 does not 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.

d. 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.” PO Resp. 25 (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 Vertebron’s assets out of bankruptcy and manufacturing the post-fill spinal implants on our own.” *Id.*

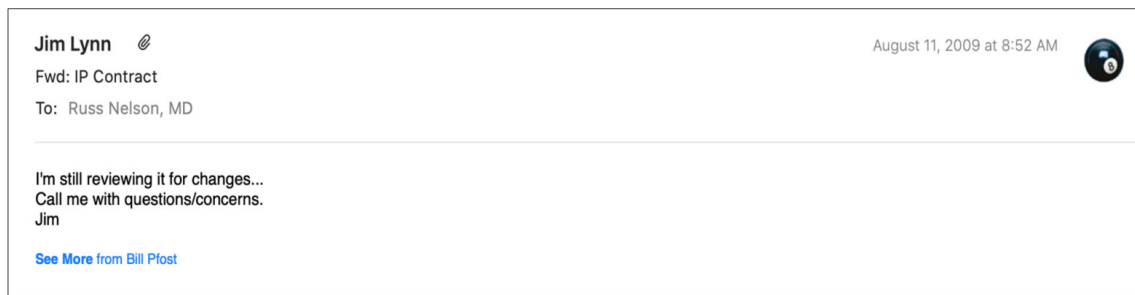
The emails referred to appear to show that Mr. Lynn was concerned about Vertebron’s inventory and the possible termination of an agreement between Vertebron and Invibio. Ex. 2003, 6–7. According to Mr. Lynn, the termination of the agreement “makes *selling* the PEEK interbody cages almost impossible 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.

e. 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. PO Resp. 25 (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." PO Resp. 25 (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". PO

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 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* PO Resp. 26.

f. The Rest of Sub-Period 1¹⁴ (September 2009 to January 2010)

Relying solely on inventors’ testimonies, Patent Owner contends that “[f]ollowing the August 26, 2009 meeting with Lanx, Dr. Nelson and

¹⁴ Patent Owner does not point to any evidence, other than Mr. Lynn’s attendance of surgeries performed by Dr. Nelson (*see* Ex. 2013 ¶¶ 49, 53–56), to support the inventors’ diligence in May and July of 2009.

Mr. Lynn kept working on optimizing the design of the post-fill spinal implant before [they] filed a non-provisional application.” PO Resp. 27 (citing Ex. 2013 ¶ 62; Ex. 2014 ¶ 63). Because we accord little weight to inventors’ uncorroborated testimonies, we are not persuaded by Patent Owner’s otherwise unsupported argument.

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 also points out that, in January 2010, “Mr. Lynn sent Mr. Cislo an invention disclosure for the preparation of the ‘509 Provisional Application.” *Id.* (citing Ex. 2009 ¶¶ 10–17; Ex. 2013 ¶ 64).

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.

3. 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 II.D.1–2.

This is in contrast to Patent Owner’s diligence evidence for Sub-Period 2 from February 2010 to October 2010. For that period, Patent Owner argues that the inventors conducted continuous testing. PO Resp. 28. 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 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. (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 POR 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). Thus, 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).

E. Prior Art Disclosures

1. Alfaro

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

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

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

Id.

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

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

¶ 11. According to Alfaro,

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

Id.

Alfaro teaches the spacer may be any intervertebral spacer, as long as it is attachable and detachable to the handle. *Id.* ¶ 12. The spacer comprises

“voids and spaces which communicate with the chamber of the handle on the one hand and with the intervertebral spaces on the other.” *Id.* “Thus, there is a direct line of flow through the handle into the voids of the spacer and out into the vertebral space.” *Id.*

Alfaro teaches that

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

Id. ¶ 19.

2. Frey

Frey relates to methods and instruments for performing disc space preparation and implant insertion from a unilateral approach to the spine through a posterior lateral opening to the disc space. Ex. 1005, Abstract. Figure 55 of Frey is reproduced below:

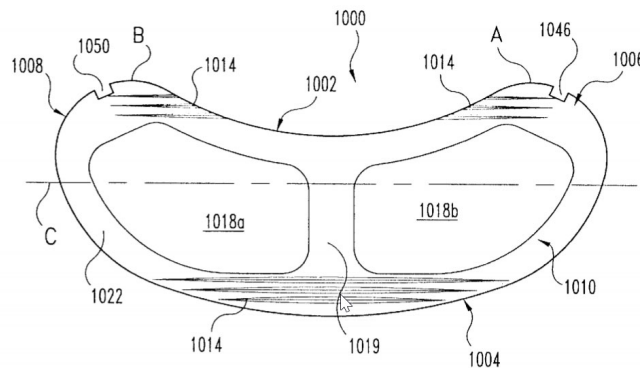


Fig. 55

Figure 55 is a top plan view of an implant according to one aspect of Frey. *Id.* at 5:3. “Implant 1000 is an interbody fusion device or cage that can be packed with bone growth material or other known substance and inserted into disc space D1 to promote bony fusion between vertebrae V1 and V2.” *Id.* at 19:18–21. Implant 1000 includes a concave posterior wall 1002, an opposite convex anterior wall 1004, an arcuate leading end wall 1006, and an arcuate trailing end wall 1008. *Id.* at 19:43–46. It further includes an upper bearing member 1010 and a lower bearing member 1012 extending between and connecting walls 1002, 1004, 1006 and 1008. *Id.* at 19:50–52.

Figure 54 of Frey is reproduced below:

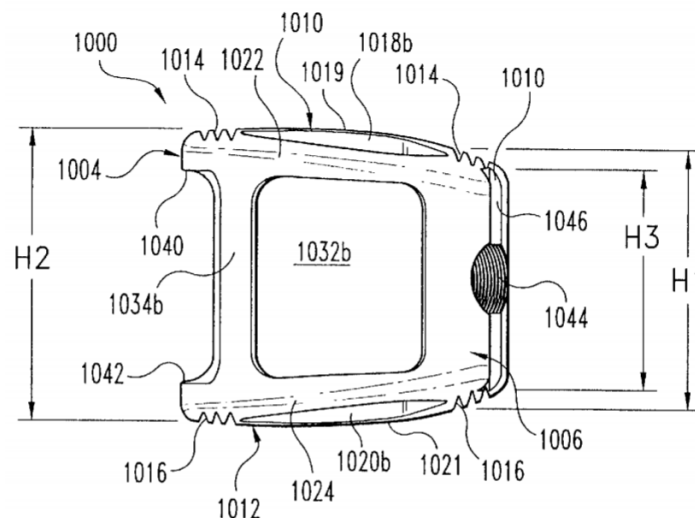


Fig. 54

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

Implant 1000 has a height H1 at the medial portion of posterior wall 1002 and a second height H2 at the medial portion of anterior wall 1004. Upper bearing member 1010 and lower bearing member 1012 have a slight convexity between the anterior and posterior walls 1002, 1004 and height H2 is

preferably greater 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 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. Perez-Cruet

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

F. *Incorporation by Reference*

As a preliminary matter, we note that throughout its Response, Patent Owner has improperly incorporated large portions of the Lonner Declaration by reference. *See* PO Resp. 31–60. For example, for claim 11, Patent Owner cites twenty-one pages, spanning thirty-seven paragraphs, of the Lonner Declaration to support its argument that “Alfaro teaches away from Frey.” *Id.* at 34 (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180). It also relies on the same portions of the Lonner Declaration to support its argument that

“Alfaro and Frey do not teach or suggest an internal chamber extending from a first vertebra to a second vertebra.” *Id.* at 35 (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180). Patent Owner further cites the same twenty-one pages, thirty-seven paragraphs, of the Lonner Declaration to support its argument that “Alfaro and Frey also fail to teach or suggest where the internal chamber retains graft material between first and second vertebral bodies.” *Id.* (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180).

In addition, Patent Owner cites largely overlapping portions of the Lonner Declaration to support its arguments that “[t]he combination of Alfaro and Frey is improper” (PO Resp. 31–32 (citing Ex. 2022 ¶¶ 113–118)), and that Petitioner “improperly relies on hindsight bias” (*id.* at 32–33 (citing Ex. 2022 ¶¶ 93–118)). And, as explained below, Patent Owner relies on substantially the same testimony to support its arguments regarding the patentability of the other challenged claims. *See infra* Sections II.G.2–5, II.H.

Our Rule prohibits incorporating arguments by reference from one document into another. 37 C.F.R. § 42.6(a)(3). In the Response, Patent Owner often does not offer, other than the citation to the pages of the Lonner Declaration, any other explanation or evidence to support its arguments. As a result, we reject Patent Owner’s unsupported, conclusory arguments. Nevertheless, we address Patent Owner’s arguments, emphasizing that Petitioner bears the burden of proving unpatentability of each challenged claim 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*, 800 F.3d at 1378.

G. Obviousness over Alfaro and Frey

Petitioner asserts that claims 1–5, 9–15, 19, and 20 of the ’203 patent would have been obvious over the combination of Alfaro and Frey. Pet. 20–71. After reviewing the entire record developed at trial, and as explained below, we determine Petitioner has shown, by a preponderance of the evidence, that the combination of Alfaro and Frey teaches or suggests each limitation of the challenged claims. *See id.* at 25–71. Petitioner has also shown that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and would have had a reasonable expectation of success when doing so. *See id.* at 20–25. We start our analysis with claim 11, the broadest claim of the ’203 patent.

1. Claim 11

Petitioner provides a detailed analysis, mapping each limitation of claim 11 to the teachings of Alfaro and Frey. Pet. 25–49. Specifically, Petitioner argues that Alfaro teaches preamble [11.0], and limitations [11.1.1], [11.1.2], [11.2], [11.3.1], [11.3.2], [11.3.3], and [11.4.2]. *Id.* at 25–43, 48–49. In addition, Petitioner contends that Alfaro, either alone or combined with Frey, teaches limitation [11.4.1]. *Id.* at 43–47. Petitioner also contends that “there are many reasons a POSITA would have been motivated to incorporate the teachings of Frey in the system of Alfaro.” *Id.* at 25.

Patent Owner alleges multiple faults with Petitioner’s challenge. Patent Owner contends that “[t]he combination of Alfaro and Frey is improper” and is based on improper hindsight bias. PO Resp. 31–33. In fact, Patent Owner continues, “Alfaro teaches away from Frey.” *Id.* at 34.

Regarding the claim limitations, Patent Owner disputes that the prior art teaches limitations [11.4.1] and [11.4.2]. *Id.* at 34–35. We now turn to detailed discussions of the issues raised in the parties’ arguments.

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

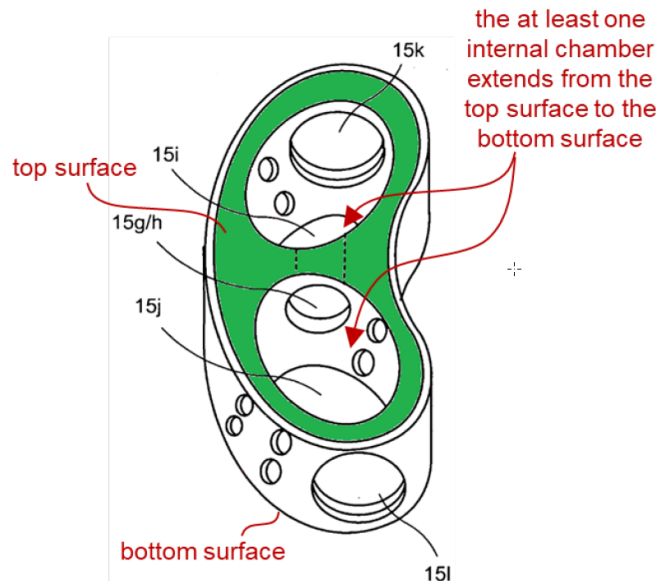


Figure 9 above shows a three-dimension perspective view of the spacer of Alfaro, as colored and annotated by Petitioner. *Id.* at 44; Ex. 1008 ¶ 27. Alfaro teaches that the spacer of Figure 9 comprises two compartments, “open at the top of the spacer and at the bottom at **15(i)** and **15(j)** (in FIG. 9).” Ex. 1008 ¶ 29. The compartments, or chambers, “are adapted to contain DBM [demineralized bone matrix] or any other suitable biologic and communicate with the opposing vertebral surfaces to allow the

biologic to flow into the space.” *Id.* Thus, according to Petitioner, Alfaro teaches preamble [11.0], and limitations [11.1.1], [11.1.2], and [11.2]. Pet. 25–32.

Petitioner also relies on Figure 1 of Alfaro, which is reproduced below.

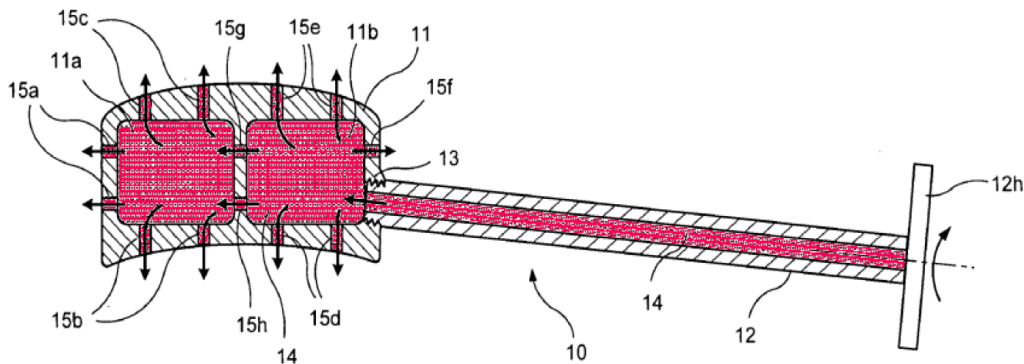


Figure 1 above is a plan view of an embodiment of Alfaro's spacer, with color added by Petitioner. *Id.* at 36; Ex. 1008 ¶ 23. In Figure 1, spacer 11 comprises open compartments 11(a) and 11(b). Ex. 1008 ¶ 29. According to Alfaro,

Handle 12 is shown screwed into compartment 11(b) at 13 and is also shown to contain DBM 14 in the hollow portion of the handle and in compartments 11(a) and 11(b) and in tunnels 15(a), (b), (c), (d), (e) and (f), provided to allow for outflow of DBM or other biologic into the intervertebral space.

Id.

Petitioner argues that screw hole 13 is an example of the claimed “access port.” Pet. 33; *see also id.* (citing Ex. 1008 ¶ 39) (referring to screw holes 15(k) and 15(l) in Figure 9). According to Petitioner, in use, a surgeon would advance the DBM into the compartments of the spacer via a screw hole. *Id.* at 35–36. As a result, Petitioner contends that Alfaro teaches limitations [11.3.1] and [11.3.3]. *Id.* at 32–36, 40–43.

Petitioner asserts that “Alfaro teaches a device and associated process in which gaps between the end plates of the vertebral body and the surfaces of the intervertebral spacer are filled by complete coverage at the surfaces thereof, with a suitable biologic product (e.g., DBM) introduced via the device.” *Id.* at 39–40. Alfaro recognizes

A difficulty with the foregoing procedure when a spacer has been pre-loaded prior to insertion, is that . . . the irregularity of the surfaces of the vertebral end plates will cause . . . gaps between the vertebral end plates, the biologic 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.

Ex. 1008 ¶ 9.

According to Alfaro, it eliminates this disadvantage because “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 its device.

Id. ¶ 10. Alfaro explains

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.

Id. ¶ 19. In view of these and other teachings, Petitioner argues that Alfaro teaches limitation [11.3.2]. Pet. 36–40.

Patent Owner does not challenge Petitioner’s mapping of preamble [11.0], and limitations [11.1.1], [11.1.2], [11.2], [11.3.1], [11.3.2], and [11.3.3] to Alfaro’s teachings. After reviewing the record, we find Petitioner has met its burden in showing that Alfaro teaches these limitations of claim 11, and thus, adopt Petitioner’s mapping of these limitations as our own finding. *See* Pet. 25–43.

Patent Owner, however, disputes that the asserted prior art teaches limitations [11.4.1] and [11.4.2]. PO Resp. 34–35. For ease of reference, we reproduce these limitations again:

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

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

Ex. 1001, 28:58–63 (emphases added).

a. Limitation [11.4.1]: “Near”

Petitioner argues that “Alfaro expressly discloses placing the spacer ‘near’ the adjacent endplates,” as recited in limitation [11.4.1]. Pet. 45. Referring to Figure 9 of Alfaro, Petitioner argues that the curvilinear shaped spacer approximates the shape of a vertebral body, “confirming that the top and bottom surfaces are adjacent to vertebral surfaces.” Pet. 44 (citing Ex. 1003 ¶ 185); *see also* Ex. 1008 ¶ 20 (“[T]he spacer is shaped in a curvilinear fashion to approximate the shape of the vertebral body.”).

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

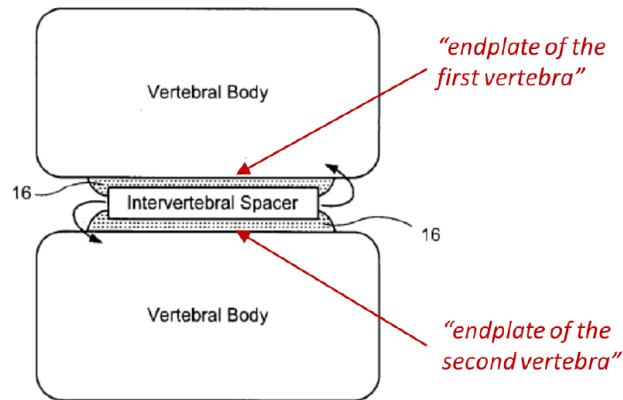


FIG. 6

Figure 6 above shows an elevation view of Alfaro’s approach for delivering a biologic into the intervertebral spaces, as annotated by Petitioner. Pet. 45; Ex. 1008 ¶ 26. Petitioner points out that the spacer is “**pressure-fit into place between the opposing vertebral bodies so as to fix the device in place.**” Pet. 44 (quoting Ex. 1008 ¶ 5, emphasis added by Petitioner). Thus, Petitioner argues that Alfaro teaches at least one internal chamber of an implant near the adjacent endplates of two opposing vertebrae. *Id.* at 45; Reply 39–40.

Patent Owner does not directly address this argument. PO Resp. 35 (only contending “Alfaro and Frey do not teach or suggest an internal chamber extending from a first vertebra to a second vertebra” even though limitation [11.4.1] also recites the internal chamber “near” the adjacent endplates). But, when challenging the combination of Alfaro and Frey as improper, Patent Owner asserts “Alfaro teaches a free-floating cage.” Sur-reply 22; *see also* PO Resp. 31 (“Alfaro is an implant utilized in a post fill configuration with a free floating implant.”). To the extent this argument

is applicable to counter Petitioner's assertion that Alfaro teaches placing the spacer "near" the adjacent endplates, we address it here.

First, 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").

Patent Owner alleges that

At the time of Alfaro, Frey, and the present patent, there were many implants that were put in place without touching the vertebral bodies. Lonner Decl. at ¶¶ 93-118, 176-179. They were inserted for the purpose of providing support when and if the graft material failed or compressed. Lonner Decl. at ¶¶ 93-118, 176-179. Alfaro can be utilized as one of these implants.

PO Resp. 33.

Dr. Lonner's declaration, however, does not support Patent Owner's assertion. In fact, in the fifteen pages of testimony Patent Owner relies on, 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 challenged '203 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.

Moreover, even if Alfaro "can be utilized as one of these [free-floating] implants" (PO Resp. 33), it does not mean Alfaro is used as one. After all, Alfaro states that "the intervertebral spacer of the device of the invention may be any spacer at all which satisfies the criteria of intervertebral spacers." Ex. 1008 ¶ 12. Specifically, Alfaro teaches that the spacer "remains in place at the correct site between the vertebrae." *See id.* ¶ 31. According to Alfaro, "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." *Id.* ¶ 30. And according to Dr. Lonner, "[m]any times," a "spacer would be *forced or driven into position* between a set of vertebral bodies." Ex. 2022 ¶ 81 (emphasis added).

In sum, we are persuaded that Alfaro teaches a pressure-fit system. Thus, we find Alfaro teaches placing the spacer “near” the endplates of the adjacent vertebrae.

Second, Patent Owner contends that, in paragraph 10, Alfaro teaches a complete layer of graft material between the implant and the vertebral bodies, and thus, “there is no contact between the spacer of Alfaro and the vertebral bodies.” Tr. 61:7–25. Similarly, Patent Owner argues that because “Alfaro teaches a free-floating cage,” it “fails to teach engagement between the implant and vertebral bodies.” Sur-reply 22.

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). This directly contradicts Patent Owner’s assertion that Alfaro lacks “interfacing of the implant with the vertebral bodies.” See PO Resp. 32.

In addition, the challenged ’203 patent discloses the same teaching as in Alfaro that Patent Owner relies on. Indeed, Patent Owner argues the device in Alfaro is free-floating because Alfaro teaches “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.” Ex. 1008 ¶ 10; PO Resp. 31; Sur-reply 22 (citing Ex. 1008 ¶ 10); Tr. 61:7–25. But the challenged ’203 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).

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 ’203 patent, we are persuaded, for this reason also, that Alfaro teaches placing the spacer “near” the endplates of the adjacent vertebrae.

Third, the term “near” is not defined in the ’203 patent. During his deposition, Dr. Lonner, Patent Owner’s expert, testified that “within a millimeter or two of one another” would be considered “near” as recited in limitation [11.4.1]. Ex. 1035, 192:20–193:6. This testimony buttresses our conclusion that even if there is a complete layer of graft material in between, Alfaro’s spacer is “near” the endplates of the adjacent vertebrae, as recited in limitation [11.4.1].

b. Limitation [11.4.1]: “From . . . To”

Alternatively, Petitioner argues that the combination of Alfaro and Frey teaches at least one internal chamber of an implant extends from an endplate of the first vertebra to an endplate of the second vertebra, as recited in limitation [11.4.1]. Pet. 45–47. According to Petitioner, Frey teaches an implant similar to the spacer of Alfaro. *Id.* at 45. The implant of Frey has upper and lower bearing members with grooves configured for directly engaging vertebral endplates to resist migration of the implant in the disc space. *Id.* at 45–46 (citing Ex. 1005, 19:50–52, 20:6–11).

Petitioner contends that it would have been obvious to modify the top and bottom surfaces of Alfaro’s spacer to include Frey’s grooves “to better resist migration of the intervertebral spacer in the intervertebral space to ensure that the implant achieves Alfaro’s teaching that the intervertebral spacer ‘remains in place at the correct site between the vertebrae.’” *Id.*

at 46–47 (citing Ex. 1008 ¶ 31). As modified, Petitioner continues, the top and bottom surfaces of Alfaro’s spacer are configured to directly engage the endplates of the first and second vertebrae. *Id.* at 47 (citing Ex. 1003 ¶ 192). As a result, Petitioner concludes that modified Alfaro’s compartments, “which extend from the top surface to the bottom surface of Alfaro’s intervertebral spacer, likewise extend from the endplate of the first vertebra to the endplate of the second vertebra.” *Id.* (citing Ex. 1003 ¶ 193).

Patent Owner disputes Petitioner’s assertion. Patent Owner argues that Petitioner “falsely claims that Alfaro teaches an engagement, or interfacing of the implant and the vertebral bodies.” PO Resp. 33 (citing Ex. 2022 ¶¶ 93–118, 176–179). We disagree with Patent Owner’s characterization of Petitioner’s argument. As discussed above, Petitioner contends that, not Alfaro by itself, but Alfaro as modified by Frey, teaches an engagement of the implant and the vertebrae.¹⁵ Pet. 47; *see also In re Keller*, 642 F.2d 413, 426 (CCPA 1981) (“[O]ne cannot show non-obviousness by attacking references individually where, as here, the [challenges] are based on combinations of references.”).

Regarding the combination of Alfaro and Frey, Patent Owner contends that the two references teach different implant styles for different purposes, and “Frey would defeat the purpose of Alfaro because of its open

¹⁵ We also note Alfaro expressly 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).

change [*sic*] design which would prevent graft material from ever generating a flush contact.” PO Resp. 32 (citing Ex. 2022 ¶¶ 113–118).¹⁶

“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.” *Keller*, 642 F.2d at 425. “Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *Id.*

Here, Petitioner argues Alfaro teaches

a spacer is placed between vertebrae “in an effort to fuse adjacent vertebrae to each other,” and “[i]t is important that the end plates of the superior and inferior vertebrae make good contact to the biologic material since bone does not span a gap or voids without the assistance of a conductive and inductive bridge.”

Pet. 23 (quoting Ex. 1008 ¶ 5). Thus, according to Petitioner, “it was well understood that it was desirable that such spacers not move after the surgeon inserts the spacer between vertebrae.” *Id.*; *see id.* at 46–47 (arguing that Alfaro teaches its spacer must “remain[] in place at the correct site between the vertebrae”) (citing Ex. 1008 ¶ 31).

Petitioner also argues Frey teaches grooves 1014 and 1016 on the upper and lower bearing members engage the vertebral endplates to resist migration of the implant in the disc space. *Id.* at 23, 45–46 (citing Ex. 1005, 19:50–52, 20:6–11). According to Petitioner,

¹⁶ Patent Owner also argues that “the combination would be improper because neither can contain or retain graft material within an internal chamber.” PO Resp. 32. This argument relates to whether the combination teaches limitation [11.4.2], which we discuss below in Section II.G.1.c.

a POSITA would have been motivated to include such grooves on the top and bottom surfaces of Alfaro's implant to resist migration of the implant after implantation. Such grooves would achieve Frey's stated benefit and also promote fusion of adjacent vertebrae because there is less risk of the implant migrating within or out of the space between vertebrae.

Id. at 23 (citing Ex. 1003 ¶ 130).

We are persuaded that 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. *See id.* at 46–47 (citing Ex. 1003 ¶ 192). Patent Owner does not present sufficient evidence or argument to persuade us that Frey's open cage design would have changed this analysis.

Patent Owner also contends that Alfaro teaches away from Frey because Alfaro's implant must include a compartment that is empty of graft material before insertion, whereas Frey teaches an implant with an open cage design. PO Resp. 34 (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180).

A reference teaches away “if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Although Alfaro points out the difficulty with spacers pre-loaded before insertion (Ex. 1008 ¶ 9), it does not address, let alone “criticize, discredit, or otherwise discourage,” having grooves on the spacer's top and bottom surfaces. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Thus, we are not persuaded that Alfaro teaches away from Frey.

In sum, we agree with Petitioner that

It was obvious to modify the top and bottom surfaces of Alfaro's intervertebral spacer press fit into the disc space to include Frey's grooves 1014 and 1016, respectively, to better resist migration of the intervertebral spacer in the intervertebral space to ensure that the implant achieves Alfaro's teaching that the intervertebral spacer "remains in place at the correct site between the vertebrae." Ex. 1008, ¶ [0031]. The top and bottom surfaces of Alfaro's intervertebral spacer (as modified to include Frey's grooves 1014 and 1016, respectively) are configured to directly engage the endplates of the first and second vertebrae, respectively, to resist migration. Ex. 1003, ¶ 192.

Pet. 46–47.

We also agree with Petitioner that

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

Id. at 23–24.

In other words, we are persuaded that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and would have had a reasonable expectation of success when doing so. We are also persuaded that the combination of Alfaro and Frey teaches at least one internal chamber of an implant extends from an endplate of the first vertebra to an endplate of the second vertebra, as recited in limitation [11.4.1].

c. Limitation [11.4.2]

Petitioner argues that Alfaro teaches limitation [11.4.2] “such that the graft material directed into the at least one internal chamber can be substantially retained between the first and second vertebrae.” Pet. 48. Petitioner refers to Alfaro for teaching that “[o]nce the DBM is forced into the interior spacer compartment(s) and tunnels . . . the DBM flow[s] through the compartments and into the vertebral spaces shown in FIG. 6 at 16.” *Id.* (citing Ex. 1008 ¶ 31). According to Petitioner, this teaching, together with Figure 6 of Alfaro, shows that the graft material is substantially retained between the adjacent vertebrae, as claim 11 requires. *Id.* (citing Ex. 1008, FIG. 6).

Patent Owner’s response to this argument, in its entirety, reads:

Alfaro and Frey also fail to teach or suggest where the internal chamber retains graft material between first and second vertebral bodies. Lonner Decl. at ¶¶ 93-107, 113-125, 164-171, 180. Alfaro does not retain the graft material within the internal chamber between the vertebral bodies, and Frey does not teach retaining graft material within an internal chamber. Lonner Decl. at ¶¶ 93-107, 113-125, 164-171, 180.

PO Resp. 35.

As support, Patent Owner cites the exact same twenty-one pages of the Lonner Declaration that it also relies on to argue “Alfaro teaches away from Frey,” and “Alfaro and Frey do not teach or suggest an internal chamber extending from a first vertebra to a second vertebra.” *Id.* at 34–35 (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180). Patent Owner offers no other explanation to support its conclusory argument. We decline to sift

through the cited thirty-seven paragraphs of the expert declaration to look for relevant support when Patent Owner chooses not to do so.

Based on this record, and especially in view of Alfaro’s explicit teaching that the compartments “are adapted to contain DBM or any other suitable biologic” (Ex. 1008 ¶ 39), or are “shown to contain DBM” (*id.* ¶ 29), we are persuaded that Petitioner has met its burden regarding limitation [11.4.2].

d. Summary

In sum, based on this record, Petitioner has met its burden in showing that the combination of Alfaro and Frey teaches each limitation of claim 11 (Pet. 25–49), an ordinarily skilled artisan would have had a reason to combine the teachings (*id.* at 23–25, 46–47), and such combination “represents combining prior art elements . . . according to known methods to yield the predictable result of an implant that is resistant to migration within the intervertebral space” (*id.* at 23–24). In other words, having considered each of the *Graham* factors,¹⁷ we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claim 11 would have been obvious over Alfaro and Frey.

2. Claims 12–15

Each of claims 12–15 depends from claim 11, and further recites a surgical approach, including “lateral” (claim 12), “transforaminal” (claim 13), “anterior” (claim 14), and “posterior” (claim 15). Ex. 1001,

¹⁷ Patent Owner does not argue, or otherwise present evidence to show, objective indicia of nonobviousness.

28:64–29:13. As explained above, Petitioner shows by a preponderance of the evidence that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and that the combination teaches all limitations of claim 11. *See supra* Section II.G.1. We focus our discussion here on the additional limitations of claims 12–15.

Petitioner provides a detailed analysis, mapping the additional limitations of claims 12–15 to the teachings of Alfaro and Frey. Pet. 49–57. Specifically, Petitioner argues that “it was well known to a POSITA that spinal fusions were conducted from various different angles (i.e., using various approaches) to the intervertebral space.” *Id.* at 49. Petitioner refers to Figure 1 of Exhibit 1009, reproduced below, to show the different angles for the different approaches. *Id.* at 5, 50.

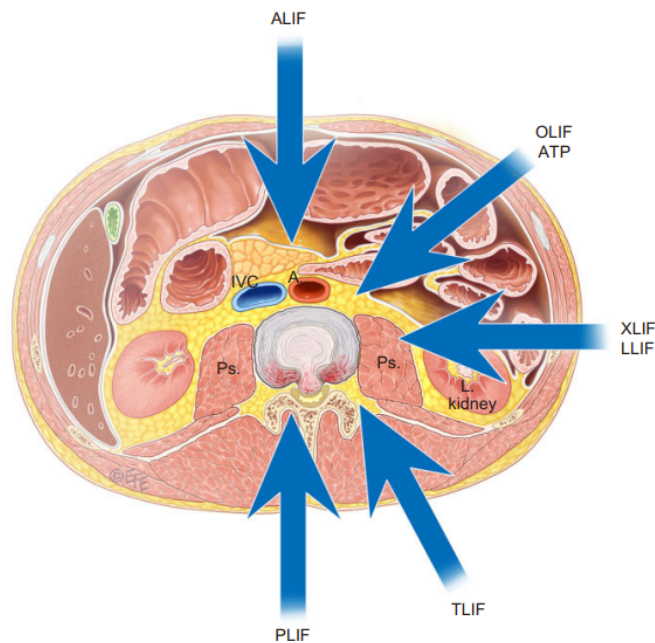


Fig. 1 Direction of the oblique lumbar interbody fusion approach (OLIF). ALIF, anterior lumbar interbody fusion; ATP, anterior-to-psoas approach; XLIF, extreme lateral interbody fusion; LLIF, lateral lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion; PLIF, posterior lumbar interbody fusion.

The figure above shows the angles for anterior (ALIF), lateral (XLIF, and LLIF), transforaminal (TLIF), and posterior (PLIF), lumbar interbody fusion. *Id.* at 5, 50 (citing Ex. 1009, 2).

Petitioner refers to Alfaro's teaching that "in use the surgeon implants the spacer into the correct location of the patient using the well-known techniques for intervertebral placements and observing all of the normal medical procedures." *Id.* at 51 (quoting Ex. 1008 ¶ 30). According to Petitioner, "[t]here is no uniformly 'best' surgical approach for all patients and treatment objectives. Rather, surgeons were known to select the surgical approach based on the circumstances for each patient and POSITA's would modify instrument attachment locations to accommodate desired surgical approaches." *Id.* at 51–52 (citing Ex. 1003 ¶ 204). Petitioner also refers to specific disclosures in Alfaro and Frey for teaching the claimed approaches. *See id.* at 52–57 (for claim 12, citing Ex. 1008 ¶ 39, Figure 1; for claim 13, citing Ex. 1005, 1:63–67, 2:42–46, Figure 53; Ex. 1008, Figure 2; for claim 14, citing Ex. 1005, 19:28–32; for claim 15, citing Ex. 1005, 22:6–12).

To counter Petitioner's arguments that claims 12–15 are unpatentable, Patent Owner relies on nearly twenty-two pages of Lonner Declaration, twenty-one pages of which are the same that Petitioner relies on to support its arguments regarding claim 11. *See* PO Resp. 35–36 (citing Ex. 2022 ¶¶ 93–107, 113–127, 164–171, 180).

As explained above, we reject Patent Owner's improper attempts to incorporate large portions of the Lonner Declaration by reference. *See supra* Section II.F. Nevertheless, we address those arguments below.

First, Patent Owner argues that “Frey teaches away from an anterior approach technique stating it requires additional time, effort, and risk.” *Id.* at 35 (citing Ex. 2022 ¶¶ 93–107, 113–127, 164–171, 180). Patent Owner does not refer to Frey for the alleged statements. And even if Frey does state so, such statements do not amount to “criticize, discredit, or otherwise discourage” anterior approach. *See Fulton*, 391 F.3d at 1201.

Second, Patent Owner contends that “Frey does not specifically discuss a purely lateral approach or a transforaminal approach.” PO Resp. 36. Petitioner, however, relies on Alfaro, and not Frey, for teaching a lateral approach. *See* Pet. 54 (citing Ex. 1008 ¶ 39, Figure 1). And Frey specifically teaches instruments and methods “for disc space preparation and implant insertion from a transforaminal approach to the spine.” *See* Ex. 1005, 22:3–6; *see also id.* at 1:18–20 (stating its invention “relates to implants, methods and instruments for use in a posterior lateral approach to the disc space, such as a transforaminal approach”).

Third, Patent Owner concedes that Frey teaches a posterior approach but contends that Petitioner has failed in its challenge of claim 11, which claim 15 depends from. PO Resp. 36. As explained above, we are persuaded that Petitioner has met its burden in showing that claim 11 would have been obvious over Alfaro and Frey. *See supra* Section II.G.1.

In sum, we conclude Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 12–15 would have been obvious over Alfaro and Frey.

3. Claim 19

Claim 19 depends from claim 11, and further recites “wherein graft material is directed into the at least one internal chamber of the implant so that at least a volume of excess graft material exits the at least one internal chamber of the implant through at least one opening along a peripheral wall of the implant.” As explained above, Petitioner shows by a preponderance of the evidence that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and that the combination teaches all limitations of claim 11. *See supra* Section II.G.1. We focus our discussion here on the additional limitation of claim 19. Petitioner relies on Alfaro for teachings this additional limitation. Pet. 58 (citing Ex. 1008 ¶¶ 20, 29, Figure 1).

Patent Owner argues that “Frey would cause Alfaro to be unsuitable for the purpose of allowing at least a volume of excess graft material to exit through a peripheral wall of the implant from at least one internal chamber,” because Frey does not have an internal chamber or any peripheral walls. PO Resp. 37 (citing Ex. 2022 ¶¶ 93–107, 113–125, 128–132, 164–171, 180).

Petitioner relies on Alfaro for teaching both the internal chamber and the peripheral wall. Pet. 58. Patent Owner’s attack of Frey does not undermine Petitioner’s obviousness challenge based on the combination of Alfaro and Frey. *See Keller*, 642 F.2d at 426.

We adopt Petitioner’s mapping of the additional limitation of claim 19 as our own finding (Pet. 58), and conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claim 19 would have been obvious over Alfaro and Frey.

4. Claim 20

Claim 20 depends from claim 11, and further requires “at least a volume of the graft material delivered into the at least one internal chamber exists through an interface between an endplate surface of the first or second vertebra and an upper or lower surface of the implant.” As explained above, Petitioner shows by a preponderance of the evidence that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and that the combination teaches all limitations of claim 11. *See supra* Section II.G.1. We focus our discussion here on the additional limitation of claim 20. Petitioner relies on Alfaro for teachings this additional limitation. Pet. 59–60 (citing Ex. 1008 ¶ 31, Figure 6).

Patent Owner rehashes the same argument that Alfaro teaches a free-floating device that does “not have an interface between an [*sic*] surface of the implant and the vertebral bodies.” PO Resp. 37 (citing Ex. 2022 ¶¶ 93–107, 113–125, 128–132, 164–171, 180). For the same reason explained above, we reject Patent Owner’s argument. *See supra* Section II.G.1.a.

We adopt Petitioner’s mapping of the additional limitation of claim 20 as our own finding (Pet. 59–60), and conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claim 20 would have been obvious over Alfaro and Frey.

5. Claims 1–5, 9, and 10

Claims 1–5, 9, and 10 parallel claims 11–15, 19, and 20, respectively. Independent claim 1 includes all the limitations of claim 11, and adds that the at least one internal chamber is “defined by peripheral walls of the

implant, wherein the implant comprises at least one access port extending through at least one of the peripheral walls of the implant.” *Id.* at 27: 38–41. Claim 1 also recites that “the implant is advanced through an anatomy of a patient using an insertion tool.” *Id.* at 27: 42–43. And the method of claim 1 ends with “withdrawing the insertion tool from the anatomy of the patient, leaving the implant situated between the first and second vertebrae.” *Id.* at 27: 61–63. Each of claims 2–5, 9, and 10 depends from claim 1, and further recites the additional limitations recited in claims 12–15, 19, and 20, respectively. We focus our analysis on claim 1.

Petitioner provides a detailed analysis, mapping the limitations of claims 1 to the teachings of Alfaro and Frey. Pet. 60–69. Patent Owner does not challenge Petitioner’s mapping of the additional limitations of claim 1. Instead, Patent Owner makes the same arguments here as in addressing claim 11. *Compare* PO Resp. 39 (citing Ex. 2022 ¶¶ 93–107, 113–118, 133–138, 164–171, 180), *with id.* at 34–35 (citing Ex. 2022 ¶¶ 93–107, 113–125, 164–171, 180). For the same reason as explained above, we reject Patent Owner’s arguments. *See supra* Section II.G.1. We adopt Petitioner’s accounting of each limitation of claim 1 as our own finding (Pet. 60–69), and conclude that the combination of Alfaro and Frey teaches each limitation of claim 1.

Patent Owner also repeats its argument that, because Alfaro teaches a free-floating device with “its implant surfaces completely covered,” it is improper to combine Alfaro and Frey. PO Resp. 39–40 (citing Ex. 2022 ¶¶ 93–107, 113–118, 133–138, 164–171, 180). For the same reason

explained above, we reject Patent Owner’s argument. *See supra* Section II.G.1.b.

Patent Owner further contends that Alfaro teaches away from Frey because “Alfaro teaches that previous implants have a problem of the pre-filled graft material falling out of the implant during its insertion.” PO Resp. 38 (citing Ex. 2022 ¶¶ 93–107, 113–118, 133–138, 164–171, 180). Thus, according to Patent Owner, Frey “would not be an implant that would be considered combinable with the implant of Alfaro.” *Id.* As explained above (*see supra* Section II.G.1.b), Alfaro does not “criticize, discredit, or otherwise discourage” Frey’s teaching of having grooves on the spacer’s top and bottom surfaces. *See Fulton*, 391 F.3d at 1201. Thus, we are not persuaded that Alfaro teaches away from Frey.

In sum, based on this record, Petitioner has met its burden in showing that the combination of Alfaro and Frey teaches each limitation of claim 1 (Pet. 60–69). And as explained above (*see supra* Section II.G.1.b), an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and would have had a reasonable expectation of success when doing so. In other words, having considered each of the *Graham* factors, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claim 1 would have been obvious over Alfaro and Frey.

In addition, for the same reason as explained in our analysis of claims 12–15, 19, and 20 (*see supra* Sections II.G.2–4), we conclude that Petitioner has demonstrated by a preponderance of the evidence that the

subject matter of claims 2–5, 9, and 10 would have been obvious over Alfaro and Frey.

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

Petitioner asserts that claims 6–8 and 16–18 of the '203 patent would have been obvious over the combination of Alfaro, Frey, and Perez-Cruet. Pet. 71–91. After reviewing the entire record developed at trial, and as explained below, we determine Petitioner has shown, by a preponderance of the evidence, that the combination of the asserted references teaches or suggests each limitation of the challenged claims. *See id.* at 78–91. Petitioner has also shown that an ordinarily skilled artisan would have had a reason to combine the teachings of the asserted references, and would have had a reasonable expectation of success when doing so. *See id.* at 73–78.

1. Claim 16

Claim 16 of the '203 patent depends from claim 11 and further recites wherein directing the graft material into the at least one internal chamber comprises using a graft material delivery system, the graft material delivery system comprising a conduit, wherein a volume of graft material is configured to be delivered to the at least one internal chamber of the implant via the conduit.

Ex. 1001, 29:13–18. As explained above, Petitioner shows by a preponderance of the evidence that an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Frey, and that the combination teaches all limitations of claim 11. *See supra* Section II.G.1. We focus our discussion here on the additional limitation of claim 16 and on reasons supporting the combination of Alfaro and Perez-Cruet with respect to this limitation.

Petitioner argues that Alfaro teaches a “syringe-type of system” for moving graft material through the handle and into the spacer. Pet. 80 (citing Ex. 1008 ¶ 12); *see also* Ex. 1008 ¶ 32 (teaching syringes as means for delivering graft material). Petitioner acknowledges that “Alfaro does not explicitly disclose the implementation details of its disclosed syringes and how they would interface with Alfaro’s hollow handle” for delivering graft material. Pet. 80. According to Petitioner, an ordinarily skilled artisan “would have been motivated to look to other references for implementation details regarding the implementation of its disclosed syringes.” *Id.* at 74–75.

Petitioner asserts that “Perez-Cruet provides an illustrated example of a syringe-type system, as suggested by Alfaro, namely, a syringe 400 having an extended tubular end portion 402 for delivering bone graft material through the instrument 304.” *Id.* at 75 (citing Ex. 1004 ¶ 62, Figure 21). “When utilized with Alfaro’s handle,” Petitioner continues, “Perez-Cruet’s syringe directs graft material into an internal compartment of a spacer . . . by positioning the extended tubular end portion 402 of Perez-Cruet’s syringe 400 through Alfaro’s handle 12.” *Id.* at 76 (citing Ex. 1003 ¶ 266), *see also id.* at 82–83 (citing Ex. 1003 ¶ 279–281) (the same); *id.* at 85 (“[T]he syringe 400 of Perez-Cruet, including the extended tubular end portion 402, is an example of ‘a conduit’ as claimed.” (citing Ex. 1003 ¶ 288)). Thus, Petitioner concludes that the combination of Alfaro and Perez-Cruet teaches the additional limitation of claim 16. *Id.* at 84.

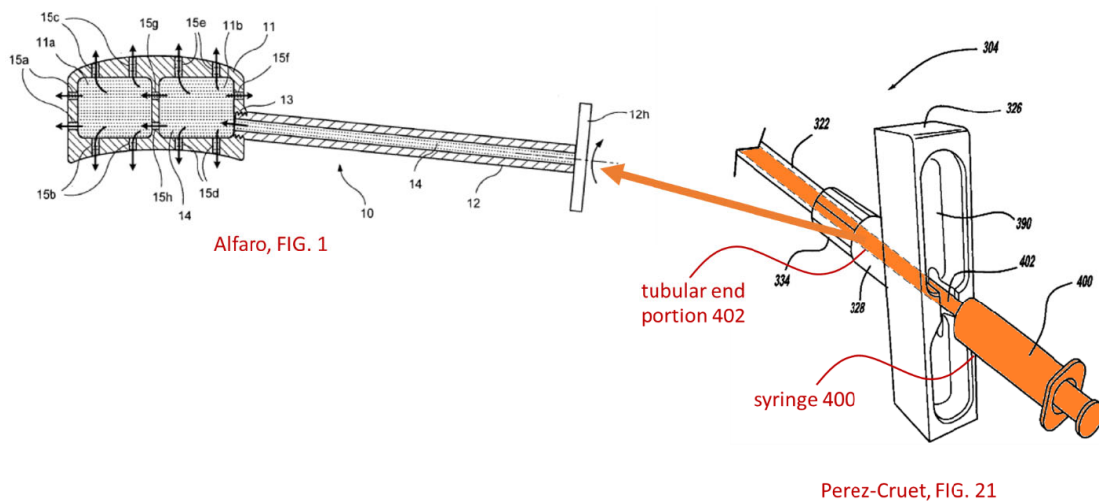
Patent Owner does not dispute this assertion. After reviewing the record, we find Petitioner has met its burden in showing that the asserted prior art teaches each limitation of claim 16.

Patent Owner, however, contends that the combination of Alfaro, Frey, and Perez-Cruet is improper. PO Resp. 44–45 (citing Ex. 2022 ¶¶ 93–125, 133–138, 146–149, 164–183). According to Patent Owner, “Perez-Cruet has no internal chamber and cannot deliver a volume of graft material via a graft delivery system and a conduit to the internal chamber.” *Id.* at 45. Patent Owner also asserts that “the plate of Perez-Cruet prevents solid fusion between the two sides of the implant, and regardless of the graft delivery system, delivery to the at least one internal chamber is not possible.” *Id.*

As explained above (*see supra* Section II.G.1.b), we are not persuaded by this line of arguments because for a proper obviousness analysis, one cannot attack references individually where the challenge is based on combinations of references. *See Keller*, 642 F.2d at 426. Here, Petitioner relies on Alfaro, and not Perez-Cruet, for teaching an internal chamber. Pet. 29–31 (citing Ex. 1008 ¶ 20, Figures 8, 9); *see also id.* at 76, 82 (discussing directing graft material into the compartment 11b of Alfaro’s intervertebral spacer).

In addition, Patent Owner argues that Perez-Cruet is “a vertically aligned cage,” and thus, “does not allow for fusion in the same manner or methods of Alfaro or Frey.” PO Resp. 44. Further, Patent Owner argues that “the insertion techniques taught for Perez-Cruet are different from those of Alfaro and Frey,” and thus, “a combination of Alfaro or Frey with Perez-Cruet would render Alfaro and Frey unsuitable for their intended purposes.” *Id.*

Again, obviousness does not require bodily incorporation. *See Keller*, 642 F.2d at 425. Here, Petitioner relies on Perez-Cruet for teaching a specific syringe as an example of Alfaro’s general disclosure of a “syringe-type of system” for delivering graft material. *See* Pet. 74–76 (citing Ex. 1004 ¶ 62, Figure 21; Ex. 1008 ¶¶ 12, 21, 32). In particular, Petitioner presents an example, reproduced below, showing how the syringe of Perez-Cruet would be integrated with Alfaro’s spacer. *Id.* at 76 (citing Ex. 1003 ¶ 266).



Sherman, Figure 1

Shown above is Figure 1 of the Sherman Declaration. Ex. 1003 ¶ 266. It combines Figure 1 of Alfaro and Figure 21 of Perez-Cruet, with coloring and annotations added by Mr. Sherman. *Id.* According to Mr. Sherman, this figure illustrates “where Perez-Cruet’s syringe 400 and associated extended tubular end portion 402 would fit within an exemplary Alfaro handle 12.” *Id.*

Mr. Sherman explains that

The syringe 400 of Perez-Cruet is a syringe used to deliver graft material to one or more compartments of an implanted spacer. When utilized with Alfaro's handle, Perez-Cruet's syringe directs graft material into an internal compartment of a spacer, e.g., the compartment 11b of Alfaro's intervertebral spacer, by positioning the extended tubular end portion 402 of Perez-Cruet's syringe 400 through Alfaro's handle 12.

Id.

We find Mr. Sherman's testimony on this point credible and persuasive. We further agree with Petitioner that the differences among the Alfaro, Frey, and Perez-Cruet implants "do not relate to how or why Perez-Cruet's graft material delivery system would work with Alfaro's implant." Reply 48 (citing Ex. 1033 ¶ 78).

In sum, based on this record, we are persuaded by, and thus, adopt, Petitioner's analyses that the combination of Alfaro, Frey, and Perez-Cruet teaches each limitation of claim 16, and that an ordinarily skilled artisan would have had a reason to combine the teachings. *See* Pet. 73–84. Thus, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claim 16 would have been obvious over Alfaro, Frey, and Perez-Cruet.

2. Claims 17 and 18

Claim 17 depends from claim 16 and further recites additional limitation [17.1]: "wherein directing the graft material into the at least one internal chamber comprises passing the conduit through the access port of the implant to position the conduit within the at least one internal chamber of the implant." Ex. 1001, 29:19–30:3.

Claim 18 depends from claim 16 and further recites additional limitation [18.1]: “wherein the graft delivery system further comprises a plunger assembly configured to be positioned and moved within the conduit, the method further comprising actuating the plunger assembly to move a volume of graft material through the conduit and into the at least one internal chamber of the implant.” *Id.* at 30:4–9.

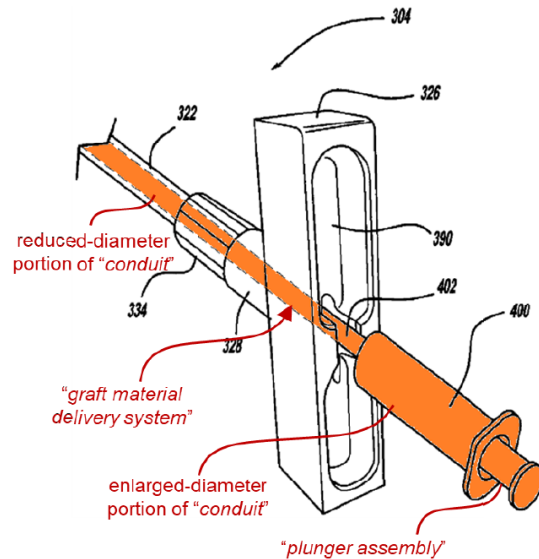
As explained above, Petitioner shows by a preponderance of the evidence that an ordinarily skilled artisan would have had a reason to combine the teachings of the asserted references, and that the combination teaches all limitations of claim 16. *See supra* Section II.H.1. We focus our discussion here on the additional limitations of claim 17 and 18.

For claim 17, Petitioner refers to Figures 11 and 21 of Perez-Cruet. Pet. 85–87 (citing Ex. 1004 ¶¶ 53, 62, Figures 11, 21). According to Petitioner,

[I]n view of Alfaro’s disclosure of using a hollow handle as an insertion tool, the hollow handle having a conduit in fluid communication with chambers of an intervertebral spacer to deliver biologic material to the intervertebral spacer, further in view of Alfaro’s teachings of using a syringe to deliver the biologic material, and further in view of Perez-Cruet’s disclosure of a syringe coupled to the interior of an intervertebral spacer via a hollow handle, it was obvious to pass the extended tubular end portion 402 of Perez-Cruet’s syringe 400 through Alfaro’s handle 12, through Alfaro’s screw hole 151, and into the compartment 11b of Alfaro’s intervertebral spacer, thereby rendering obvious claim element [17.1].

Id. at 87 (citing Ex. 1003 ¶¶ 286–290).

For claim 18, Petitioner again refers to Figure 21 of Perez-Cruet, reproduced below.



Shown above is Figure 21 Perez-Cruet, as annotated and colored by Petitioner. Pet. 89. According to Petitioner,

As shown in Figure 21, the enlarged-diameter portion accommodates “a plunger assembly configured to be positioned and moved within the conduit,” e.g., within the syringe barrel, “the method further comprising actuating the plunger assembly to move a volume of graft material through the conduit,” e.g., delivering bone graft material using the syringe 400, including the enlarged-diameter syringe barrel and the reduced-diameter extended tubular end portion 402, Ex. 1004, ¶ 62[,] “and into the at least one internal chamber of the implant,” e.g., the compartment 11b of Alfaro’s intervertebral spacer 11, thus rendering obvious claim element [18.1].

Id. at 89–90 (citing Ex. 1003 ¶ 295).

Patent Owner largely repeats arguments similar to those presented above. *See* PO Resp. 45–47 (citing Ex. 2022 ¶¶ 93–125, 133–138, 146–156, 164–183). For example, Patent Owner contends that “Perez-Cruet, Alfaro, and Frey do not teach [or suggest] a conduit positioned through an access port within the internal chamber.” *Id.* at 45. Patent Owner also asserts that “the combination is improper because Perez-Cruet teaches a plate within an

internal area of the implant that would prevent passage of a conduit within the internal area of Perez-Cruet.” *Id.*; *see also id.* at 46 (the same).

We repeat that for a proper obviousness analysis, one cannot attack references individually where the challenge is based on combinations of references. *See Keller*, 642 F.2d at 426. We also repeat that obviousness does not require bodily incorporation. *Id.* at 425.

Here, Petitioner relies on the *combination* of Alfaro and Perez-Cruet for teaching “passing the conduit through the access port of the implant,” as recited in claim 17. Pet. 87 (arguing that it would have been obvious to “pass the extended tubular end portion 402 of Perez-Cruet’s syringe 400 through Alfaro’s handle 12, through Alfaro’s screw hole 151, and into the compartment 11b of Alfaro’s intervertebral spacer”). It matters not that each reference, individually, does not teach the additional limitation recited in claim 17. Nor does it matter that Perez-Cruet’s plate would “prevent passage of a conduit within the *internal area of Perez-Cruet*.” *See* PO Resp. 45 (emphasis added).

In sum, based on this record, we are persuaded by, and thus, adopt, Petitioner’s analyses that the combination of Alfaro, Frey, and Perez-Cruet teaches each limitation of claims 17 and 18, and that an ordinarily skilled artisan would have had a reason to combine the teachings. *See* Pet. 73–78, 84–90. Thus, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 17 and 18 would have been obvious over Alfaro, Frey, and Perez-Cruet.

3. Claims 6–8

Claim 6 depends from claim 1, and further recites the same additional limitation as claim 16. Each of claims 7 and 8 depends from claim 6, and further recites the same additional limitations as claims 17 and 18, respectively. For claims 6–8, the parties present the same arguments as those for claims 16–18. *See* Pet. 90–91; PO Resp. 47–49. For the same reasons explained above (*see supra* Sections II.H.1–2), we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 6–8 would have been obvious over Alfaro, Frey, and Perez-Cruet.

I. Summary

After reviewing the entire record and weighing evidence offered by both parties, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 of the '203 patent would have been obvious over the asserted prior art.

III. CONTINGENT MOTION TO AMEND

Having determined that Petitioner has shown by a preponderance of the evidence that original claims 1–20 of the '203 patent are unpatentable, we proceed to address Patent Owner's Contingent Motion to Amend. Patent Owner proposes substitute claims 21–40 to replace original 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). Ordinarily, the petitioner “bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable.” 37 C.F.R. § 42.121(d)(2); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15, 3–4 (PTAB Feb. 25, 2019) (precedential); *Bosch Auto. Serv. Sols. LLC v. Iancu*, 878 F.3d 1027, 1040 (Fed. Cir. 2017).

But before considering the patentability of the substitute claims, we first must determine whether the MTA meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. Patent Owner bears the burden of persuasion to show that: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial; (3) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; and (4) the original disclosure sets forth written description support for each proposed claim. *Id.*; 35 U.S.C. § 316(d); 37 C.F.R. § 42.121(d)(1).

B. Proposed Substitute Claims

Patent Owner proposes substitute claims 21 and 31 to replace original independent claims 1 and 11, respectively. MTA 4; *see also id.* at Appendix A (illustrating amendments to proposed claim language).

Proposed substitute claim 21, which would replace claim 1, recites (with underlining representing text added to claim 1):

21. A method of promoting spinal fusion within a spine of a patient, comprising:

advancing an implant through an anatomy of a patient, the implant comprising at least one internal chamber defined by peripheral walls of the implant, wherein the implant comprises at least one access port extending through at least one of the peripheral walls of the implant wherein the at least one peripheral wall opposite the at least one access port is configured to prevent passage of graft material;

wherein the implant is advanced through an anatomy of a patient using an insertion tool, and the implant comprises a tapered end opposite the at least one access port and on a side of the at least one peripheral wall opposite the at least one internal chamber, and the tapered end eases advancement of the implant through the anatomy of the patient;¹⁸

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

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

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

¹⁸ Petitioner refers to this additional limitation as the “tapered end limitation.” MTA Opp. 21. For consistency and ease of reference, we do the same.

withdrawing the insertion tool from the anatomy of the patient, leaving the implant situated between the first and second vertebrae.

Id. at Appendix A.

Proposed substitute claim 31, which would replace claim 11, recites (with underlining representing text added to claim 11):

31. A method of promoting spinal fusion within a spine of a patient, comprising:

advancing an implant through an anatomy of a patient, the implant comprising at least one internal chamber and a tapered end along an outer portion of the implant to ease advancement of the implant through the anatomy of the patient;

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

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

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

Id.

Patent Owner additionally proposes dependent claims 22–30 as respective substitutes for dependent claims 2–10 and proposes dependent claims 32–40 as respective substitutes for dependent claims 12–20. *Id.* Each proposed substitute dependent claim is identical to one of the original dependent claims, but updated to depend from the appropriate proposed substitute independent claim. *Id.*

C. Statutory and Regulatory Requirements

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.”). “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). Patent Owner proposes no more than one substitute claim for each challenged claim. MTA 3; *see id.* at Appendix A. Petitioner does not argue otherwise. 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 11, 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. We

determine that the amended language in the proposed substitute claims is responsive to a ground of unpatentability involved in this trial.

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 argues that proposed substitute claims 21 and 31 “retain all features” of claims 1 and 11, respectively, “add only narrowing features,” and, as a result, “do not enlarge the scope” of claims 1 and 11 “in any way.” MTA 4. Petitioner does not contest Patent Owner’s arguments on this point. We determine that each proposed substitute claim includes narrowing limitations and does not enlarge the scope of the corresponding original claim. *See* MTA, Appendix A.

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 31 and only in the ’509 and the ’671 provisionals, without providing any corresponding citations from the original disclosure of the ’203 patent. *See* MTA 4–19 (citing Exs. 1006, 1007); MTA 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 “Patent Owner should show support for each proposed substitute claim (including dependent claims 22–30 and 32–40) in each of the required disclosures (including the original disclosure of the ’203 patent) through a reply to this guidance or through the filing of a revised motion to amend.” PG 6 n.5.

In the MTA 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 ’203 Patent.” MTA Reply 2–16 (citing Ex. 1002). Petitioner does not dispute, and we are satisfied with, the sufficiency of Patent Owner’s identification of written description support in original disclosure of the ’203 patent for the proposed substitute claims.¹⁹

D. Obviousness Over Alfaro, Frey, and Messerli

Patent Owner argues that its “amendments clarify the structure of the spinal implants” of independent claims 1 and 11, and that “none of the references cited by Petitioner teach or suggest the limitations added by these amendments.” MTA 4.

¹⁹ Petitioner argues that there is no written description support in the ’509 provisional for certain limitations of proposed substitute claims 21 and 31 that are also limitations in original claims 1 and 11. MTA Opp. 2–3. Petitioner does not argue lack of written description support in the original disclosure of the ’203 patent for these limitations.

Petitioner contends proposed substitute independent claims 21 and 31 would have been obvious over Alfaro, Frey, and Messerli. MTA Opp. 3–4; MTA Sur-reply 2–11. In support of its patentability challenge of the proposed substitute claims, Petitioner relies on the Declaration of Michael Sherman (Ex. 1028). Petitioner states that it “relies upon its Petition to demonstrate that the non-amended limitations of claims 1 and 11 are obvious over the combination of Alfaro and Frey” and focuses its analysis on “the portions of substitute claims 21 and 31 that are added by amendment to claims 1 and 11.” MTA Opp. 3–4. In particular, Petitioner asserts the newly added limitations of proposed substitute claims 21 and 31 would have been obvious over Alfaro and Messerli.²⁰ *Id.*

Patent Owner argues Petitioner has not shown that an ordinarily skilled artisan “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 16.

Below, we summarize Messerli in relevant part, analyze whether the asserted combination teaches the additional limitations of the proposed substitute claims, and evaluate whether Petitioner has shown a sufficient reason for the asserted combination. We conclude Petitioner shows by a preponderance of the evidence that proposed substitute claims 21 (and

²⁰ Petitioner also argues that proposed substitute claims 21 and 31 are indefinite. MTA Opp. 24–25. Because we find these claims would have been obvious over the asserted prior art, we do not reach the issue of indefiniteness raised by Petitioner.

proposed substitute claims 22–25, 29 and 30, which depend therefrom) and 31 (and proposed substitute claims 32–35, 39 and 40, which depend therefrom), would have been obvious over the asserted prior art.²¹

1. Disclosure 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 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.” *Id.* at 6:42–49. Another embodiment of an implant is illustrated in

²¹ Proposed substitute claims 26–28 and 36–38 include the same limitations as those in original claims 6–8 and 16–18, respectively. *See* MTA, Appendix A. As explained above, we conclude claims 6–8 and 16–18 would have been obvious over Alfaro, Frey, and Perez-Cruet. *See supra* Section II.L. Thus, we discuss the patentability of proposed substitute claims 26–28 and 36–38 separately. *See infra* Section III.E.

Figures 16A–16E. *Id.* at 7:57–59. Figure 16D of Messerli is reproduced below.

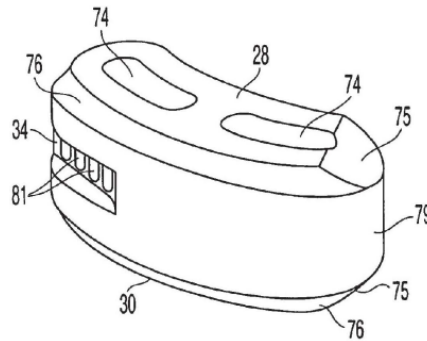


Fig. 16D

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. Additional Limitations of Proposed Substitute Claims 21 and 31

As explained above, Petitioner has shown by a preponderance of the evidence that the combination Alfaro and Frey teaches each limitation of claims 1 and 11. *See supra* Sections II.G.1, II.G.5. For the same reasons provided there, we find the combination of Alfaro and Frey teaches the limitations of proposed substitute claims 21 and 31 that are identical to those

of claims 1 and 11, respectively. We focus our discussion here on the additional limitations of proposed substitute claims 21 and 31.

Petitioner argues Messerli teaches an implant, with a shape similar to Alfaro's implant, "in which the leading tapered end is closed (*i.e.* no openings)." MTA Opp. 18 (citing Ex. 1028 ¶ 63; Ex. 1029, Fig 16D). According to Petitioner, "[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." *Id.* at 19 (citing Ex. 1028 ¶ 63). Patent Owner does not dispute, and we agree with Petitioner, that the combination of Alfaro and Messerli teaches or suggests the limitation "wherein the at least one peripheral wall opposite the at least one access port is configured to prevent passage of graft material," as recited in proposed substitute claim 21. *See id.* at 18–19.

Petitioner also asserts that the combination of Alfaro and Messerli teaches the tapered end limitation. *Id.* at 21–23. Petitioner refers to Messerli for teaching the use of "tapered" implants that are thinnest at the "narrow ends" to provide a "proper anatomical fit" while "facilitating insertion" of implants "into the affected disc space." MTA Opp. 7, 21 (citing Ex. 1029, 6:42–49). Messerli also teaches, Petitioner continues, that the "insertion end" has "chamfer 75" forming "a wedge-like shape at insertion end 79 to facilitate implant insertion." *Id.* at 21–22 (citing Ex. 1029, 8:24–26). Petitioner relies on Figures 16A–16E of Messerli for teaching an example implant that demonstrates a tapered implant "having both tapering along an axis toward 'narrow ends' (including at an insertion end) . . . and an

insertion end that has a chamfer.” *Id.* at 22 (citing Ex. 1029, 7:65–8:2, 8:23–24, Figs. 16A, 16D, 16E). According to Petitioner, both the “narrow end” and the chamfer demonstrate a “tapered end” as claimed. *Id.* (citing Ex. 1028 ¶¶ 70–72). Patent Owner does not dispute, and we agree with Petitioner, that the combination of Alfaro and Messerli teaches or suggests the tapered end limitation recited in proposed substitute claim 21. *See id.* at 21–23.

The additional limitations of proposed substitute claim 31 are substantially the same as those of proposed substitute claim 21, and the parties advances substantially the same arguments addressing them. *See* MTA Opp. 23–24; MTA Reply 22–23. For the same reasons explained above, we find the combination of Alfaro and Messerli teaches or suggests the additional limitations of proposed substitute claim 31.

3. Reason to Combine and Reasonable Expectation of Success

As explained above, Petitioner has shown, by a preponderance of the evidence, sufficient reason supporting the combination of Alfaro and Frey with respect to claims 1 and 11. *See supra* Section II.G.1.b. We adopt that analysis for the identical limitations of proposed substitute claims 21 and 31. We focus our discussion here on reasons supporting the combination of Alfaro and Messerli with respect to the additional limitations of proposed substitute claims 21 and 31.

Petitioner argues there are several reasons to combine Alfaro and Messerli. Opp. 6–12, 19–24. For example, Petitioner points out that Alfaro teaches “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.” *Id.* at 7 (citing Ex. 1008 ¶¶ 12, 20). According to Petitioner, this disclosure, along with Alfaro’s teachings to use “well-known techniques” for intervertebral placements, would have motivated an ordinarily skilled artisan to review the prior art, such as Messerli, for existing intervertebral spacers. *Id.* (citing Ex. 1028 ¶¶ 26–30). Petitioner asserts Messerli is compatible with Alfaro because it describes implants that are similar in structure. *Id.* at 10–11 (citing Ex. 1008 ¶ 12; Ex. 1028 ¶¶ 40–41; Ex. 1029, 2:5–8, 3:56–58, 4:30–32, 6:32–41, 8:17–22, 10:58–63, Figs. 16C–16D).

Petitioner asserts 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.’” *Id.* at 8 (citing Ex. 1008 ¶ 5). According to Petitioner, “Alfaro applies to any of these types of implants because Alfaro’s 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 (citing Ex. 1008 ¶¶ 12, 20; Ex. 1028 ¶¶ 31–33), 22–23 (citing Ex. 1008 ¶ 12; Ex. 1028 ¶¶ 73–74).

Petitioner argues that “[a]pplying Messerli’s teachings of tapering of implants and chamfering the leading surface to Alfaro’s implants” would “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.

In addition, according to Petitioner, “[i]t was well known that implants positioned by impaction often include tapered leading ends to accomplish a wedge-effect self-distraction.” *Id.* (citing Ex. 1028 ¶¶ 35–37, which in turn, cite Exs. 1030–1032), 11–12 (citing Ex. 1028 ¶ 42), 18 (citing Ex. 1028 ¶ 63), 23–24 (citing Ex. 1028 ¶¶ 75–80). Petitioner contends that “[a]s there are no distraction instruments disclosed in Alfaro, it would have been obvious to a POSITA 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.* at 10.

Petitioner argues that

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).

Id. at 9 (citing Ex. 1028 ¶ 38; Ex. 1029, Fig. 16D).

Petitioner further asserts that “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.* (citing Ex. 1028 ¶ 38).

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). MTA Reply 17, 22. Patent Owner emphasizes that Alfaro teaches “[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**.” *Id.* at 17 (quoting 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.” *Id.*; *see also id.* at 21 (arguing Alfaro teaches away because it requires the implant to have a plurality of leader lines).

Patent Owner does not cite to any prior-art teaching or expert testimony to support its attorney argument that, in Alfaro, the leading lines in the leading wall are critical to the even distribution of graft material. More importantly, Petitioner argues that, to promote and increase spinal fusion, Alfaro’s implants deliver 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. MTA Sur-reply 4–5 (citing Ex. 1003 ¶¶ 117, 118, 122; Ex. 1034 ¶¶ 31–33). We agree with Petitioner that the combination of Alfaro and Messerli is consistent with this principle 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.* at 5 (citing Ex. 1034 ¶¶ 31–33).

In addition, Petitioner acknowledges “[a] POSITA 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 10 (citing Ex. 1003 ¶ 76; Ex. 1028 ¶ 39). We agree with Petitioner that, even if there are drawbacks to removing openings in the leading wall of Alfaro, “a POSITA would have recognized the advantages provided by removal of the openings.” *Id.*; *see also Fulton*, 391 F.3d at 1200 (“[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.”).

Patent Owner also 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 18. We agree with Patent Owner that “compatibility by itself” may be an insufficient rationale to combine references. *See id.* at 19. We, however, disagree with Patent Owner over its characterization of Petitioner’s arguments. Instead, as explained above, Petitioner has presented numerous benefits yielded by the combination. *See, e.g., MTA Opp.* 9, 18–19 (discussing the benefit of a tapered end to provide proper anatomical fit and to facilitate insertion into the intervertebral space and self-extraction therefrom) (citing Ex. 1028 ¶¶ 35–38, 62–63). We are persuaded that Petitioner’s compatibility argument only “further demonstrate[s] that the combination yields obvious and predictable results.” MTA Sur-reply 6.

Patent Owner further argues that Messerli’s implant is incompatible with Alfaro’s implant because Alfaro identifies Messerli’s packing techniques as a “disadvantage” and therefore, “Alfaro would discourage a

POSITA from using Messerli's implant according to Alfaro's teachings." MTA Reply 19 (citing Ex. 1008 ¶¶ 9, 29, Figs. 1, 2, 8, 9). The portions of Alfaro that Patent Owner relies on discuss a difficulty with a spacer that "has been pre-loaded prior to insertion." *See* Ex. 1008 ¶ 9. As Petitioner correctly points out, Messerli instead teaches packing the compartments with bone graft material "after implantation." *See* MTA Sur-reply 7 (citing Ex. 1029, 3:56–58, 4:30–32, 8:17–22, 10:58–63; Ex. 1028 ¶ 22). Thus, we disagree with Patent Owner that Alfaro would have discouraged the use of Messerli's implant according to Alfaro's teachings.

Patent Owner asserts that an ordinarily skilled artisan would not have combined Alfaro and Messerli because they "teach diametrically opposed implants." MTA Reply 21. According to Patent Owner, Alfaro's implants are free floating, whereas Messerli's is designed to be "pressure-fit" between vertebrae. *Id.* (citing Ex. 2022 ¶ 117). As explained above, we are not persuaded that Alfaro's implants are free floating. *See supra* Section II.G.1.b. Thus, we reject Patent Owner's challenge to the reason to combine on this basis.

In sum, Petitioner has identified numerous benefits for combining the teachings of Alfaro and Messerli, supported by the teachings of the asserted prior art references and knowledge within the level of ordinary skill at the time the claimed invention. *See* MTA Opp. 6–12. Thus, we are persuaded that an ordinarily skilled artisan would have been motivated to combine the teachings of Alfaro and Messerli with regard to the additional limitations of proposed substitute claims 21 and 31.

We also agree with Petitioner that

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

Id. at 11–12 (citing Ex. 1028 ¶ 42). In other words, we find an ordinarily skilled artisan would have had a reasonable expectation of success when combining the prior-art teachings to arrive at the claimed subject matter.

4. Summary

Based on this record, Petitioner has met its burden in showing that the combination of Alfaro, Frey, and Messerli teaches each limitation of proposed substitute claims 21 and 31, an ordinarily skilled artisan would have had a reason to combine the teachings of the asserted references, and such combination represents combining prior art elements according to known methods to yield the predictable results. Having considered each of the Graham factors,²² we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of proposed substitute claims 21 and 31 would have been obvious over Alfaro, Frey, and Messerli.²³

²² Patent Owner does not argue, or otherwise present evidence to show, objective indicia of nonobviousness of the proposed substitute claims.

²³ Petitioner also asserts that proposed substitute claims 21 and 31 would have been obvious over Alfaro, Frey, Messerli, and Fuss. MTA Opp. 12–15,

In addition, for the same reasons explained in our analysis of claims 2–5, 9, 10, 12–15, 19, and 20, we find that the asserted prior art references also teach each limitation of proposed substitute claims 22–25, 29, 30, 32–35, 39, and 40. *See supra* Sections II.G.2–5. Thus, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of proposed substitute claims 22–25, 29, 30, 32–35, 39, and 40 would have been obvious over Alfaro, Frey, and Messerli.

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

In the MTA, Patent Owner proposes replacing original claims 6–8 and 16–18 with substitute claims 26–28 and 36–38, respectively. MTA, Appendix A. Each of proposed substitute claims 26–28 and 36–38 is identical to the original claim it replaces, but updated to depend from the appropriate proposed substitute independent claim. *Id.*

As explained above, we find an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, and Perez-Cruet, and the combination teaches each limitation of claims 6–8 and 16–18. *See supra* Sections II.H. We also find an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro and Messerli, and the combination teaches each limitation of proposed substitute claims 21 and 31. *See supra* Section III.D.3. For those same reasons, we find an ordinarily skilled artisan would have had a reason to combine the teachings of Alfaro, Frey, Perez-Cruet, and Messerli, and the combination teaches each limitation of

19–21. We do not need to reach that argument because Petitioner has shown that the subject matter of proposed substitute claims 21 and 31 would have been obvious over Alfaro, Frey, and Messerli.

proposed substitute claims 26–28 and 36–38. In other words, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the subject matter of proposed substitute claims 26–28 and 36–38 would have been obvious over Alfaro, Frey, Perez-Cruet, and Messerli.

IV. CONCLUSION²⁴

After reviewing the entire record and weighing evidence offered by both parties, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 of the '203 patent would have been obvious over the asserted prior art.

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–5, 9–15, 19, 20	103	Alfaro, Frey	1–5, 9–15, 19, 20	
6–8, 16–18	103	Alfaro, Frey, Perez-Cruet	6–8, 16–18	
Overall Outcome			1–20	

²⁴ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

We also determine that Petitioner has demonstrated by a preponderance of the evidence that the proposed substitute claims are unpatentable under 35 U.S.C. § 103 as obvious over the combined teachings of the cited references. Accordingly, we deny Patent Owner's Contingent Motion to Amend.

Motion to Amend Outcome	Claims
Original Claims Cancelled 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	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 are unpatentable;

FURTHER ORDERED that Patent Owner's Contingent Motion to Amend 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.

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