

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner.

IPR2025-00225
Patent 9,730,805 B1

Before JAMES A. TARTAL, ERIC C. JESCHKE, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEYERS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. *Background and Summary*

Globus Medical, Inc. (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–6, 11, 12, and 15–17 (the “challenged claims”) of U.S. Patent 9,730,805 B1 (Ex. 1001, “the ’805 patent”). Paper 1 (“Pet.”). Spinelogik, Inc. (“Patent Owner”) did not elect to file a Preliminary Response.¹ Pursuant to the Memorandum by the Acting Director, dated March 26, 2025, setting forth “Interim Processes for PTAB Workload Management,” Patent Owner filed a Brief in Support of Discretionary Denial (Paper 6), and Petitioner filed a Response opposing Patent Owner’s Request for Discretionary Denial (Paper 7). On June 12, 2025, a decision denying Patent Owner’s Request for Discretionary Denial was issued. Paper 8.

On July 14, 2025, we instituted *inter partes* review. Paper 9 (“Decision on Institution” or “Institution Dec.”). Following institution, Patent Owner filed a Response (Paper 13, “PO Resp.”) and Petitioner filed a Reply (Paper 15, “Pet. Reply”). Patent Owner did not elect to file a Sur-reply.² We held an oral hearing on April 21, 2026, and a transcript of that hearing is included in the record. Paper 20 (“Tr.”).

For the reasons explained in our analysis below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–6, 11, 12, and 15–17 of the ’805 patent are unpatentable.

¹ Patent Owner is not required to file a Preliminary Response. 37 C.F.R. § 42.107(a) (“The patent owner *may* file a preliminary response to the petition.” (emphasis added)).

² Patent Owner is not required to file a Sur-reply. *See* Paper 10, 9 (“Patent Owner *may* file a sur-reply to Petitioner’s reply.” (emphasis added)).

B. Real Parties-in-Interest

Petitioner identifies Globus Medical, Inc. as the real-party-in interest.
Pet. 8.

Patent Owner identifies Spinelogik, Inc. as the real party-in-interest.
Paper 4, 2.

C. Related Matters

The parties identify a number of related proceedings, including *Spinelogik, Inc. v. Globus Med., Inc.*, Case No. 2:23-cv-00529 (EDTX); *Spinelogik, Inc. v. Choice Spine, LLC*, Case No. 2:23-cv-00296 (EDTX); *Spinelogik, Inc. v. Genesys Orthopedics Systems, LLC*, Case No. 2:23-cv-00297 (EDTX); *Spinelogik, Inc. v. Camber Spine Techs, LLC*, Case No. 2:24-cv-00873 (EDTX); and *Globus Med., Inc. v. Spinelogik, Inc.*, Case IPR2025-00226 (PTAB). Pet. 8; Paper 4, 2.

D. Overview of the '805 Patent

The '805 patent is titled "Intervertebral Fusion Device and Method or Use." Ex. 1001, code (54). The '805 patent discloses

an apparatus that (1) delivers a fusion member between two vertebral bodies after at least a portion of the fibrocartilaginous disc between the vertebral bodies has been removed, and (2) affixes the fusion member to the vertebral bodies. In some embodiments, the apparatus includes (1) a fusion member that is delivered and positioned between the vertebral bodies, (2) a delivery mechanism that delivers and positions the fusion member between the vertebral bodies, and (3) an anchoring member that affixes the fusion member to the vertebral bodies.

Id. at 2:8–18. An exemplary embodiment of the '805 patent's intervertebral apparatus is depicted in Figure 1A, reproduced below.

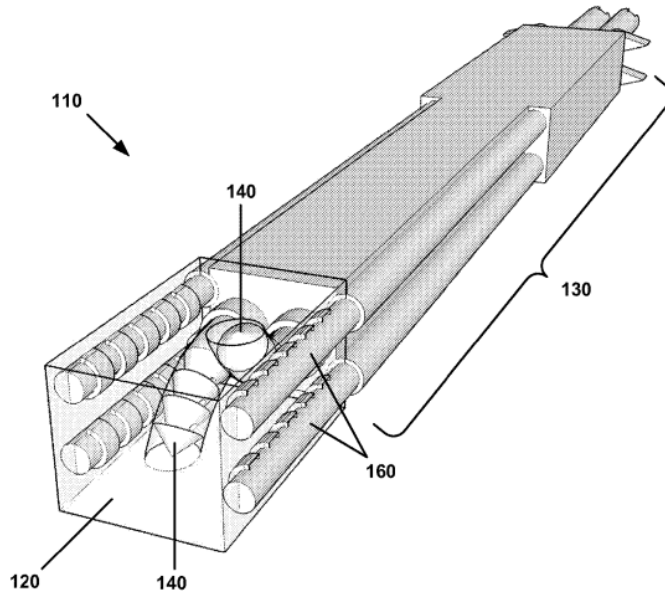


Figure 1A

Figure 1A is a front perspective of the '805 patent's intervertebral apparatus 110, and depicts "delivery mechanism 130 that delivers and positions the fusion member 120 between the vertebral bodies." *Id.* at 4:24–25, 9:30–36.

E. Illustrative Claim

Petitioner challenges claims 1–6, 11, 12, and 15–17 of the '805 patent. Pet. 10. Challenged claims 1 and 11 are independent. Claim 1 is illustrative and is reproduced below.

1. An apparatus comprising:

a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;

a delivery mechanism for delivering the fusion member between the two vertebral bodies, the delivery mechanism extending outside a patient's body to a medical practitioner while

the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,

the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and

a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing through a different channel of the fusion member, (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.

Ex. 1001, 26:11–36.

F. Asserted Grounds and Evidence

Petitioner asserts that claims 1–6, 11, 12, and 15–17 of the ’805 patent are unpatentable on the following grounds (Pet. 11):

Claims Challenged	35 U.S.C. §§³	Basis
1–6, 11, 12, 15–17	102/103	Blain ^{4, 5}
1–6, 11, 12, 15–17	103	Blain, Bray ⁶
5, 16	103	Blain, Bray, Steffee ⁷

Petitioner also relies on the Declaration of Mr. Brad Culbert. Ex. 1002.

³ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103 effective March 16, 2013. Because the ’805 patent’s priority date is before the AIA’s amendments to §§ 102 and 103, this decision refers to the pre-AIA versions of § 103. *See* Pet. 11 (“The earliest possible date of priority of the ’805 Patent is thus March 27, 2008.”).

⁴ US 8,172,854 B2, issued May 8, 2012 (Ex. 1004, “Blain”).

⁵ U.S. Provisional Application No. 60/950,801 (“Blain-Provisional”).

⁶ US 7,985,255 B2, issued July 26, 2011 (Ex. 1006, “Bray”).

⁷ US 4,790,303, issued Dec. 13, 1988 (Ex. 1016, “Steffee”).

II. ANALYSIS

A. Legal Standards

Petitioner bears the burden of persuasion to prove unpatentability of the claims challenged in the Petition, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

1. Anticipation

A prior art reference can only anticipate a claim if it discloses all the claimed limitations “arranged or combined in the same way as in the claim.” *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361 (Fed. Cir. 2012) (quoting *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed. Cir. 2008)). “However, a reference can anticipate a claim even if it ‘d[oes] not expressly spell out’ all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)); see also *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir. 2016) (distinguishing *Net MoneyIN* when the reference in question explicitly contemplated the combination of the disclosed functionalities).

2. Obviousness

A patent claim is unpatentable under 35 U.S.C. § 103 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), if present, any objective evidence of obviousness or non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). There is no objective evidence of obviousness or non-obviousness in the record here.

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party who petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quoting *Intelligent Bio–Sys., Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016)).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (“POSA”) at the time of invention. *Graham*, 383 U.S. at 17. Factors pertinent to determining the level of ordinary skill in the art include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of workers active in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–97 (Fed. Cir. 1983). Not all factors may exist in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, “[t]hese factors are not exhaustive, but . . . merely a guide to determining the level of ordinary skill in the art.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). Further, the prior art itself may reflect an appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Petitioner asserts that one of ordinary skill in the art would have had a bachelor’s or equivalent degree in mechanical engineering or a related discipline (e.g., biomedical engineering, metals and materials engineering), and at least five years of experience with a) designing, developing, evaluating and/or using spine devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants.

Pet. 18–19 (citing Ex. 1002 ¶¶ 77–78). Petitioner also asserts that “[m]ore education can supplement practical experience and vice versa.” *Id.* (citing Ex. 1002 ¶ 78). “Patent Owner does not dispute the proffered definition for a POSA.” PO Resp. 10.

Based on the full record, we determine that Petitioner’s undisputed proposed level of skill is reasonable and consistent with the ’805 patent and the asserted prior art. Thus, for these reasons, we adopt Petitioner’s level of skill in the art.

C. Claim Construction

Under 37 C.F.R. § 42.100(b), we apply the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). That is, “the words of a claim ‘are generally given their ordinary and customary meaning’ . . . that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1312–13.

In our below analysis, we only address the claim construction arguments necessary to resolve the present dispute. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

*1. “housing”*⁸

Claim 2 depends from claim 1 and further requires, in part, “a delivery housing for guiding each independent anchoring member into the fusion member.” Ex. 1001, 26:37–42. Claim 4 depends from claim 2 and further requires “wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.” *Id.* at 26:46–49. Relying on dictionary

⁸ Because construing “housing” was not necessary to reach a decision on institution, we did not explicitly construe this term in our Decision on Institution. Institution Dec. 10–11.

definitions and the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have “understood a *housing* to be a component that protects, covers, supports, or contains another component.” Pet. 19 (citing Ex. 1002 ¶ 81; Ex. 1007, 5; Ex. 1008, 5; Ex. 1009, 5). Petitioner notes that this understanding is consistent with the ’805 patent’s Specification. *Id.* (citing Ex. 1002 ¶ 82). To support its position, Petitioner provides the following side-by-side reproduction of Figure 1A and Figure 6 of the ’805 patent. *Id.* at 20 (citing Ex. 1001, Figs. 1A, 6).

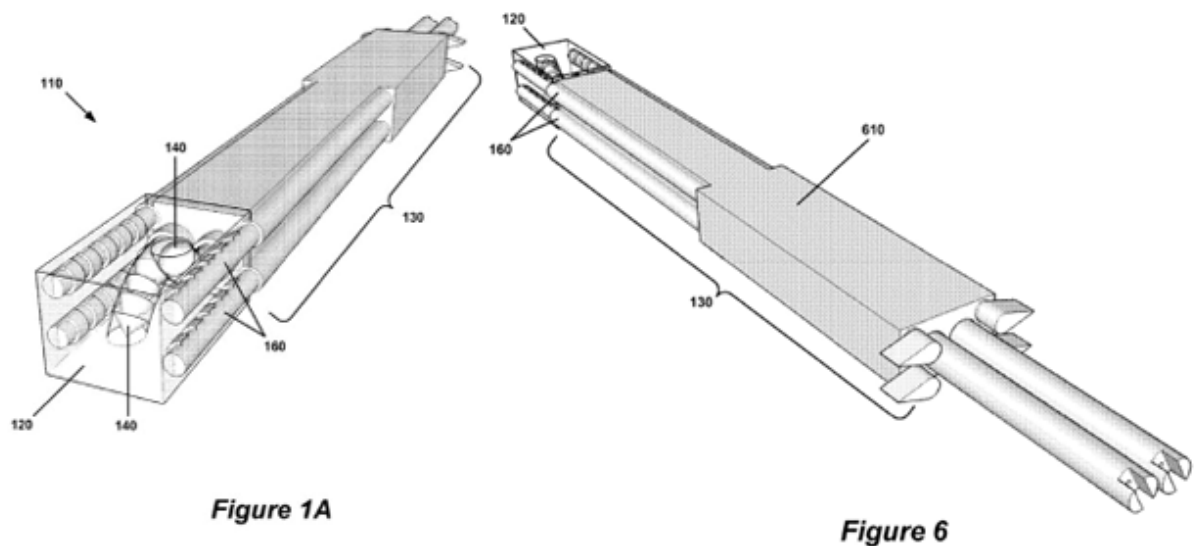


Figure 1A and Figure 6 C each depicts delivery mechanism 130, fusion member 120, and retention rods 160. Ex. 1001, 11:24–32. In addition, Figure 1A identifies anchoring members 140 (*id.* at 9:21–35) and Figure 6 identifies delivery housing 610 (*id.* at 11:27–31). Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have “understood that the delivery housing 610 houses anchoring members/mechanisms 140 because each anchor is supported, contained, and protected within delivery housing as each anchor is guided to the implant,

just as each retention rod 160 is supported, contained, and protected within housing 610.” Pet. 20–21 (footnote omitted) (citing Ex. 1002 ¶ 83; Ex. 1001, 2:37, 7:1–7, 11:27–28, 13:25–27). Petitioner concludes that the ’805 patent “uses the term *housing* in accordance with its customary meaning of a component (e.g., housing 610) that protects, covers, supports, or contains another component (e.g., anchoring members 140, retention rods 160).” *Id.* at 21 (citing Ex. 1002 ¶ 84).

Patent Owner responds arguing that Petitioner improperly relies on a “strained” and “artificially broad” construction of the term “housing,” as it appears in claims 2–4, that contradicts the intrinsic evidence. PO Resp. 10–11. According to Patent Owner, when describing the term “housing,” the ’805 patent’s Specification consistently “refer[s] to a specific component of the delivery mechanism that houses and guides the anchoring mechanism during the delivery process.” *Id.* at 11 (citing Ex. 1001, 2:39–45). Thus, Patent Owner takes the position that the term “housing” needs no formal construction, but instead should be afforded its plain and ordinary meaning. *Id.* at 11–12.

Patent Owner asserts that Petitioner’s proposed construction is improper because it “conflicts with the limitation requiring ‘the delivery mechanism extending outside a patient’s body’—a key feature added during prosecution to distinguish the prior art.” PO Resp. 12. Patent Owner explains that “[i]f ‘housing’ merely means any component providing support, Petitioner could improperly argue that the fusion member itself serves as the ‘delivery housing,’ thereby collapsing the distinction between the fusion member and the delivery mechanism—the same error the Examiner made [during prosecution] with Duffield.” *Id.* Patent Owner concludes that “[t]he plain and ordinary meaning, understood in the context

of the specification, clearly identifies the delivery housing as a component of the delivery mechanism (not the fusion member) that houses and guides anchoring members and retention mechanisms during the surgical procedure.” *Id.* at 12.

Petitioner replies noting that Patent Owner “contends that the ‘delivery housing’ is ‘a component of the delivery mechanism (not the fusion member) that houses and guides anchoring members and **retention mechanisms**.’” Pet. Reply 13 (citing PO Resp. 12, 47). Petitioner points out, however, that “nothing in the claim language requires the ‘retention mechanism’ to be part of the ‘delivery **housing**’—the ‘retention mechanism’ need only be part of the ‘delivery **mechanism**.’” *Id.* Petitioner also points out that Patent Owner improperly attempts to narrow the meaning of “housing” based on its arguments against the prior art. *Id.* (citing PO Resp. 43–45). According to Petitioner, Patent Owner contends that

a “housing” is required to be “a single . . . **unified** housing structure . . . that performs **integrated** functions within a **unified** structural body” and excludes “**separate** structural components that are attached together **to form a modular assembly**,” and must “**permanently**” house “anchoring members” to the exclusion of “**temporary** containment during insertion.”

Id. (citing PO Resp. 43–45).

Based on the full record, we determine that “housing,” as it appears in the context of the term “delivery housing” is a component that is a part of the delivery mechanism (*see* Ex. 1001, 11:27–31) and that simply contains and guides another component during delivery. *See* Ex. 1001, 13:25–27, 21:30–50. Thus, we apply the ordinary meaning of “housing,” as it appears in the context of the term “delivery housing,” and address in the context of

the asserted art, whether Petitioner has shown that the prior art teaches a “delivery housing,” as recited by claims 2 and 4.

2. “*curved*”⁹

Dependent claims 5 and 16 each recite “each channel of the fusion member is curved.” Ex. 1001, 26:50–51, 27:66–67. Prior to institution, Petitioner asserted that a channel is “curved

when it has an: (1) opening with a curvature (e.g., round opening); (2) an inner wall with a curvature (e.g., tubular inner-wall); (3) a radially inward curvature in the inner wall (e.g., a concave surface that forms a spherical anchor head seat); and/or (4) follows a curved path (e.g., an arc-shaped path).”

Pet. 23–24. We did not address Petitioner’s arguments in our Decision on Institution because it was not necessary for purposes of reaching a decision on institution. Institution Dec. 10–11.

In its Response, Patent Owner argues that “[t]he term ‘curved channel’ is unambiguous and requires no construction beyond its plain and ordinary meaning, which a POSA understands from the specification to refer to a channel following a curved trajectory . . . distinct from a straight channel.” PO Resp. 14.

Petitioner replies noting this is “indistinguishable from [Petitioner’s] understanding of plain and ordinary meaning as set forth in the litigation.” Pet. Reply 13 (citing Ex. 1022, 2 (“channel . . . [that] has a curved path”)). Thus, Petitioner concludes that the parties agree on construction of “curved channel.” *Id.* at 13–14.¹⁰

⁹ Although the parties refer to “curved” alone or to a “curved channel,” we understand the parties to be referring to a “channel of the fusion member [that] is curved,” as recited in claims 5 and 16.

¹⁰ At oral argument, the parties confirmed that there was no dispute as to the meaning of “curved channel.” See Tr. 15:12–14 (Petitioner stating that “the

Based on the full record, the parties' agreed-upon construction of the term "curved channel" appears consistent with the plain language of the claims and Specification. Thus, we adopt the parties' agreed-upon construction and construe a channel that is "curved" to mean a channel following a curved trajectory.

D. Anticipation/Oviousness over Blain

Petitioner asserts that claims 1–6, 11, 12, and 15–17 are anticipated by, or would have been obvious over, Blain. Pet. 44–72. Petitioner also relies on the testimony of Mr. Culbert to support its arguments. *Id.* (citing Ex. 1002). For the following reasons, we determine Petitioner has shown by a preponderance of the evidence that claims 1–4, 6, 11, 12, 15, and 17 are anticipated by, or would have been obvious over Blain, but as discussed below, we do not determine whether claims 5 and 16 are unpatentable over Blain.

We address Petitioner's contentions and Patent Owner's arguments below, beginning with a brief overview of Blain.

*1. Overview of Blain (Ex. 1004)*¹¹

Blain relates to "systems and methods for performing spinal fixation, specifically attachable instrument guides used for spinal orthopedic procedures." Ex. 1004, 1:15–17. More particularly, Blain discloses an

instrument guide comprising one or more instrument guide lumens, a handle, and a device coupler is disclosed. The handle is preferably detachable to facilitate access to the instrument guide lumens. The device coupler detachably engages the

parties are essentially in agreement on what that means now"), 40:21–23 (Patent Owner stating that there is no "debate or a disagreement among the parties as to what the construction of curved channel ought to be").

¹¹ Patent Owner does not contest the prior art status of Blain.

implantable device and aligns the instrument guide lumens with the fastener openings on the device.

Id. at 1:52–57. An exemplary embodiment of Blain’s interbody fusion implant 2 is depicted in Figure 1, reproduced below.

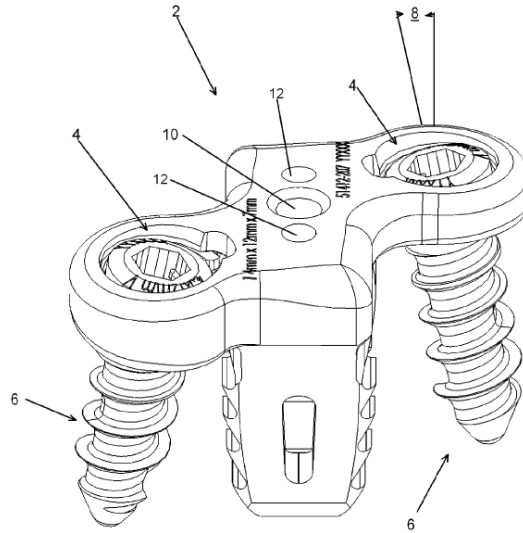


FIG. 1

Figure 1 is a perspective view of a flanged interbody fusion implant 2 including fastener apertures 4, and openings 10, 12 for coupling with instrument guide 14 (not shown). *Id.* at 3:33–34, 4:26–32, 4:39–50.

An exemplary embodiment of Blain’s instrument guide 14 is depicted in Figure 2A, reproduced below.

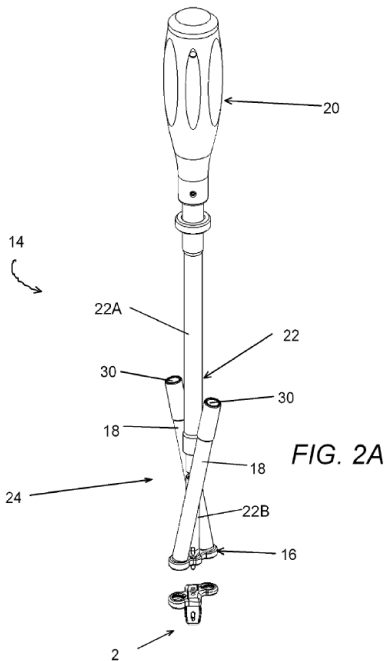


Figure 2A is a perspective side view instrument guide 14 that may be used with the flanged interbody fusion implant 2. Ex. 1004, 3:35–37. Blain discloses that

instrument guide 14 comprises one or more guide members 18 and a device coupler 16 with one or more coupling structures 26, 28 engageable to the implant 2. The instrument guide 14 further comprises a handle 20 and a handle shaft 22 comprising a detachable proximal shaft 22A and a distal shaft 22B attached to the device coupler 16.

Id. at 4:55–61.

2. Analysis of Claim 1

Petitioner asserts that claim 1 is anticipated by, or in the alternative obvious over, Blain. Pet. 44–61 (citing Exs. 1001, 1002, 1004, 1005).¹² Patent Owner responds to Petitioner’s assertions. See PO Resp. 30–85.

¹² Petitioner’s assertions are supported by dual citations to Blain and the Blain-Provisional. Pet. 25 n.8. There is no issue, however

We use Petitioner’s notations to identify the claim elements. *See* Pet. 93 (Petitioner’s challenged claim listing).

a) Claim 1.0 [Preamble]: “An apparatus comprising:”

Petitioner asserts that Blain discloses an interbody fusion implant corresponding to an apparatus. Pet. 44; Ex. 1004, Fig.1. We find that Petitioner’s contention regarding the preamble, which Patent Owner does not dispute, is persuasive.

b) Claim 1.1. “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;”

Petitioner asserts that Blain discloses this limitation. Pet. 44–46 (citing Ex. 1002 ¶¶ 108–111). Petitioner provides the following annotated version of Blain’s Figure 1. *Id.* at 44 (citing Ex. 1004, 4:26–28, Fig. 1; Ex. 1005 ¶ 19, Fig. 1).

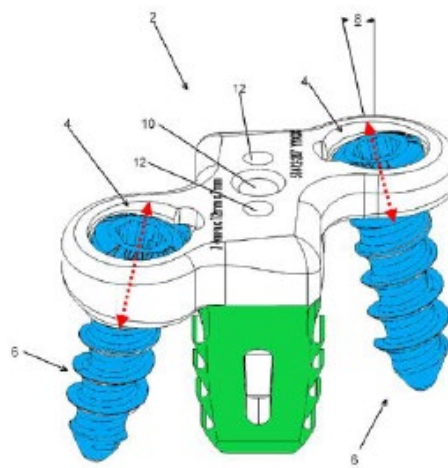


FIG. 1

Figure 1 is a perspective view of a flanged interbody fusion implant annotated to identify the cage portion in green and the fasteners in blue. Pet. 44–45. Petitioner asserts that Blain discloses an “interbody fusion

implant 2” that is “designed to be inserted between two adjacent vertebral bodies to facilitate fusion, providing structural support and stability.” *Id.* (citing Ex. 1002 ¶¶ 108–109). With reference to annotated Figure 1, and relying on the declaration testimony of Mr. Culbert, Petitioner asserts that Blain discloses

the cage portion (green) would be inserted in the disc space between two adjacent vertebral bodies. [Ex. 1002] ¶ 110. One fastener 6 (blue) would be inserted through implant opening 4 and fastened to one vertebral body, and the other fastener 6 (blue) would be inserted into the other opening 4 and fastened to the other vertebral body. *Id.* The fusion would then occur around and through the cage openings. *Id.*

Id. at 45. Also referring to annotated Figure 1, Petitioner asserts that Blain’s interbody implant 2 includes

two channels identified generally by a red-dashed arrow (*a first plurality of channels*). [Ex. 1002 ¶ 111]. Each channel has an opening 4 on the proximal (top) side (*same side*) of the implant and an opening on the distal (bottom) side (not visible). *Id.* (citing Ex. 1004, 4:28–39, Fig. 2B (showing channels without fasteners 6 inserted); Ex. 1005 ¶ [0019]). Each fastener 6 (blue) is inserted through a channel from the proximal side. *Id.* (citing Ex. 1004, 8:5–18; Ex. 1005 ¶ [0035]).

Id. at 46.

In response, Patent Owner argues that “[w]hile Blain does disclose an implant 2 designed for positioning between vertebral bodies with apertures 4, Petitioner’s mapping obscures a critical structural distinction between Blain’s straight-through apertures and the ’805 [p]atent’s internal channel geometry.” PO Resp. 34–35. According to Patent Owner, Blain does not disclose the argued limitation because its “simple fastener apertures 4” are designed to accommodate “threaded bone screws that are ‘screwed in’ via rotational insertion,” “follow straight, linear paths,” and

lack the necessary “internal channel geometry designed to guide flexible anchoring members along curved trajectories to achieve a ‘semi-circular path of movement’ as described in the ’805 [p]atent.” *Id.* (citing Ex. 1004, 1:37–42, 8:50–54, 5:10–17, Fig. 6A).

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member,” as recited by limitation 1.1.

At the outset, we find Patent Owner fails to establish that any of the alleged differences between Blain’s “apertures and the ’805 [p]atent’s internal channel geometry” relate to any particular recitation in argued limitation 1.1. Although we acknowledge that claims 5 and 16 each requires curved trajectories (*see, e.g.*, claim 5 reciting “each channel of the fusion member is curved”), limitation 1.1 does not recite such a feature. As Petitioner correctly notes, “[n]othing in the claim requires a special ‘internal channel geometry,’ ‘shaped block,[’] ‘curved tubular channels,’ non ‘straight-through’ apertures, or ‘flexible’ anchors.” Pet. Reply 14 (footnote omitted). *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (rejecting arguments “not based on limitations appearing in the claims”).

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of limitation 1.1.

c) *Claim 1.2.1. “a delivery mechanism for delivering the fusion member between the two vertebral bodies;”*

Petitioner asserts that Blain discloses this limitation. Pet. 46–51 (citing Ex. 1002 ¶¶ 113–117). Petitioner provides the following annotated version of Blain’s Figure 3A. *Id.* at 46–47 (citing Ex. 1004, Fig. 3A; Ex. 1005, Fig. 3A).

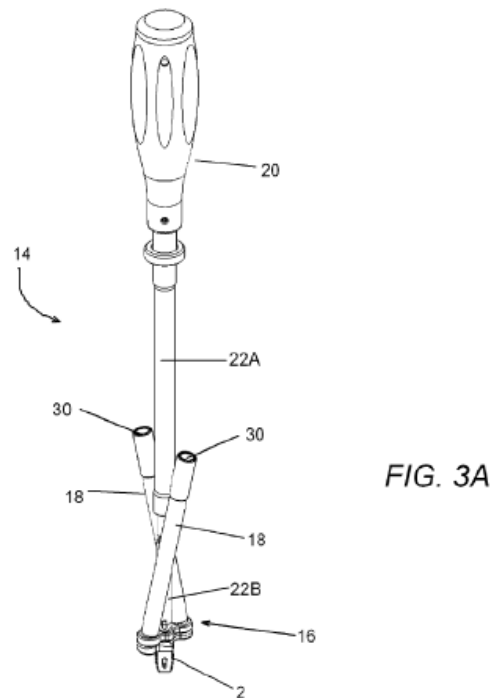


Figure 3A is a perspective side view of Blain’s instrument guide 14. Ex. 1004, 3:41. Petitioner identifies that “instrument guide 14 comprises one or more guide members 18 and a device coupler 16 with one or more coupling structures 26, 28 engageable to the implant 2.” Pet. 47 (citing Ex. 1004, 4:55–58; Ex. 1005 ¶ 20). Petitioner asserts that Blain discloses that instrument guide 14 is attached to implant 2 prior to implantation and “used as a **delivery instrument** used to insert and fix” implant 2 to the spine. *Id.* (citing Ex. 1004, 10:6–13; Ex. 1005 ¶ 45).

Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that “Blain’s delivery mechanism is comprised of very similar structure for delivering the implant 2 as compared to the delivery mechanism disclosed in the ’805 [p]atent.” Pet. 48 (citing Ex. 1002 ¶¶ 115–117). To support its position, Petitioner identifies that several of the features identified in the ’805 patent for “attaching and detaching to the implant” are also disclosed in Blain. *Id.* at 48–51 (citing Ex. 1004, 4:55–61, 5:44–62, 6:25–38, 6:47–67; Ex. 1005 ¶¶ 20, 24, 27, 29; Ex. 1002 ¶¶ 115–117).

We find that Petitioner’s contentions regarding this limitation, which Patent Owner does not dispute, are persuasive.

d) Claim 1.2.2. “the delivery mechanism extending outside a patient’s body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,”

Petitioner acknowledges that Blain does not explicitly disclose that “instrument guide 14 extend[s] outside a patient’s body to a medical practitioner,” but argues that one of ordinary skill in the art “would understand this limitation to be disclosed by Blain.” Pet. 51 (citing Ex. 1002 ¶ 118). Petitioner asserts that Blain’s instrument guide 14 includes

a handheld handle 20 (e.g., like a screwdriver handle), which POSAs readily understood to be designed so that the physician can manipulate the positioning of the implant from outside the patient’s body and rotate the inner shaft 48 to attach to, and detach from, the implant 2 once the implant is inserted.

Id. (citing Ex. 1002 ¶ 119 (citing Ex. 1004, 4:57–62, 7:11–17, 10:6–13)). Petitioner provides several reasons to support this understanding. *Id.* at 51–53 (citing Ex. 1002 ¶ 120; Exs. 1023–1028).

Alternatively, to the extent Blain does not expressly disclose that its instrument guide 14 “extend[s] outside a patient’s body to a medical

practitioner,” Petitioner argues that it would have “been obvious based on common sense and the general knowledge of POSAs to make the length of the shaft of instrument guide 14 sufficiently long so that the physician would not have to stick his or her hand inside the incision location to insert the implant between the vertebrae.” Pet. 53 (citing Ex. 1002 ¶ 123). According to Petitioner, one of ordinary skill in the art would have understood such a configuration to “provid[e] the known benefit of allowing the physician to maneuver and manipulate the delivery tool without having to insert his or her hand into the patient’s body to deliver and position the implant.” *Id.* (citing Ex. 1002 ¶ 124). And, relying on the declaration testimony of Mr. Culbert, Petitioner contends that one of ordinary skill in the art would have “had a reasonable expectation of success in modifying the instrument guide 14 such that its handle 20 and shaft 22 extends outside the patient’s body, as this involved nothing more than lengthening the proximal shaft 22A and/or distal shaft 22B.” *Id.* at 54 (citing Ex. 1002 ¶ 126); *see also* Ex. 1004, 5:4–6; Ex. 1005 ¶ 21 (Blain disclosing that “the relative lengths between the proximal shaft 22A and the distal shaft 22B can vary”).

In response, Patent Owner asserts that “Blain provides no express disclosure of the spatial relationship between the handle and the patient’s body during the critical procedural step when ‘the fusion member is positioned between the two vertebral bodies.’” PO Resp. 37. Instead, Patent Owner argues that “Petitioner relies on unsupported inference, asserting that Blain’s handle 20 ‘would extend outside of the patient’s body when being used to position the implant.’” *Id.* at 36 (citing Ex. 1002 ¶ 118).

And, with respect to obviousness, Patent Owner contends that “Petitioner provides no articulated reasoning with rational underpinning to support the conclusion that a POSA would have understood or been

motivated to configure Blain’s instrument guide such that it extends outside the patient’s body during implant positioning.” PO Resp. 37. In addition, Patent Owner argues that the argued limitation provides “temporal and spatial constraint[s]” that require that “the delivery mechanism must extend outside the patient’s body ‘**while** the delivery mechanism is coupled to the fusion member **and** the fusion member is positioned between the two vertebral bodies.’” *Id.* at 38. According to Patent Owner, however,

Blain’s disclosure that the handle 20 is “detached from the distal shaft 22B” specifically “to insert instruments or fasteners into the guide tubes 18 without potential interference from the protruding handle 20” (EX-1004, 8:46–49) suggests that the handle may be removed precisely to avoid extending outside the patient’s body during fastener insertion—contradicting Petitioner’s theory that the handle necessarily remains attached and extends externally during this critical procedural step.

Id.

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses, and alternatively renders obvious, “the delivery mechanism extending outside a patient’s body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,” as recited by limitation 1.2.2. We begin our analysis addressing the parties’ arguments with respect to anticipation and then obviousness.

Although Petitioner acknowledges that “Blain does not explicitly state that instrument guide 14 *extend[s] outside a patient’s body to a medical practitioner* as claimed” (Pet. 64), we credit Mr. Culbert’s un rebutted declaration testimony that one of ordinary skill in the art “would understand

this limitation to be disclosed by Blain” (*id.* (citing Ex. 1002 ¶ 118)). Here, Mr. Culbert explains that one of ordinary skill in the art “would readily understand that [Blain’s] handle was designed so that the physician can manipulate the positioning of the implant from outside the patient’s body and rotate the inner shaft 48 to attach to, and detach from, the implant 2 once the implant is inserted.” Ex. 1002 ¶ 119 (citing Ex. 1004, 4:57–62, 7:11–17, 10:6–13). Mr. Culbert identifies multiple prior art references demonstrating that spinal delivery tools were “specifically designed” to reach outside a patient’s body because, if they did not extend to reach outside the body, “the physician would be required to insert his or her hand into the patient’s body during deployment of the implant between the vertebral bodies, which would significantly impair the ability of the physician to maneuver and position the implant.” *Id.* ¶ 120 (citing Exs. 1023, 1025, 1026, 1027, 1029). In addition, Mr. Culbert testifies that, based on his surgical experience, he “ha[s] never seen an interbody implant delivery tool that did not exten[d] outside the patient’s body when the implant is between the vertebral bodies.” *Id.* ¶ 121.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of limitation 1.2.2.

We are also persuaded that Petitioner has set forth sufficient articulated reasoning with rational underpinning in support of its assertion that it would have alternatively “been obvious based on common sense and the general knowledge of POSAs to make the length of the shaft of instrument guide 14 sufficiently long so that the physician would not have to stick his or her hand inside the incision location to insert the implant between the vertebrae.” Pet. 53 (citing Ex. 1002 ¶ 123). Contrary to Patent Owner’s argument that “Petitioner provides no articulated reasoning with

rational underpinning to support the conclusion that a POSA would have understood or been motivated to configure Blain's instrument guide such that it extends outside the patient's body during implant positioning" (PO Resp. 37), we find the record adequately demonstrates that at the time of the invention one of ordinary skill in the art would have been motivated to design Blain's instrument guide 14 to extend outside a patient's body, as limitation 1.2.2 requires. *See* Pet. 51–54 (citing Ex. 1002 ¶¶ 123–126; Exs. 1004, 1005, 1014, 1018, 1020, 1023–1028, 1037).

Patent Owner's argument regarding the "temporal and spatial constraints" of the extending outside the body limitation is also unpersuasive as it mischaracterizes the claim language and ignores Blain's explicit disclosure. Claim 1 does not require the delivery mechanism to remain external to the body during fastener insertion. It merely requires it to "extend[] outside a patient's body . . . while the delivery mechanism is coupled to the fusion member and . . . positioned between the two vertebral bodies." In Blain, "instrument guide 14 is attached to the orthopedic device 2 prior to implantation, and the instrument guide 14 is also used as a delivery instrument used to insert and fix the orthopedic device 2 to the spine" (Ex. 1004, 4:55–58, 10:6–10), meaning the handle 20 is necessarily outside the body during this stage.

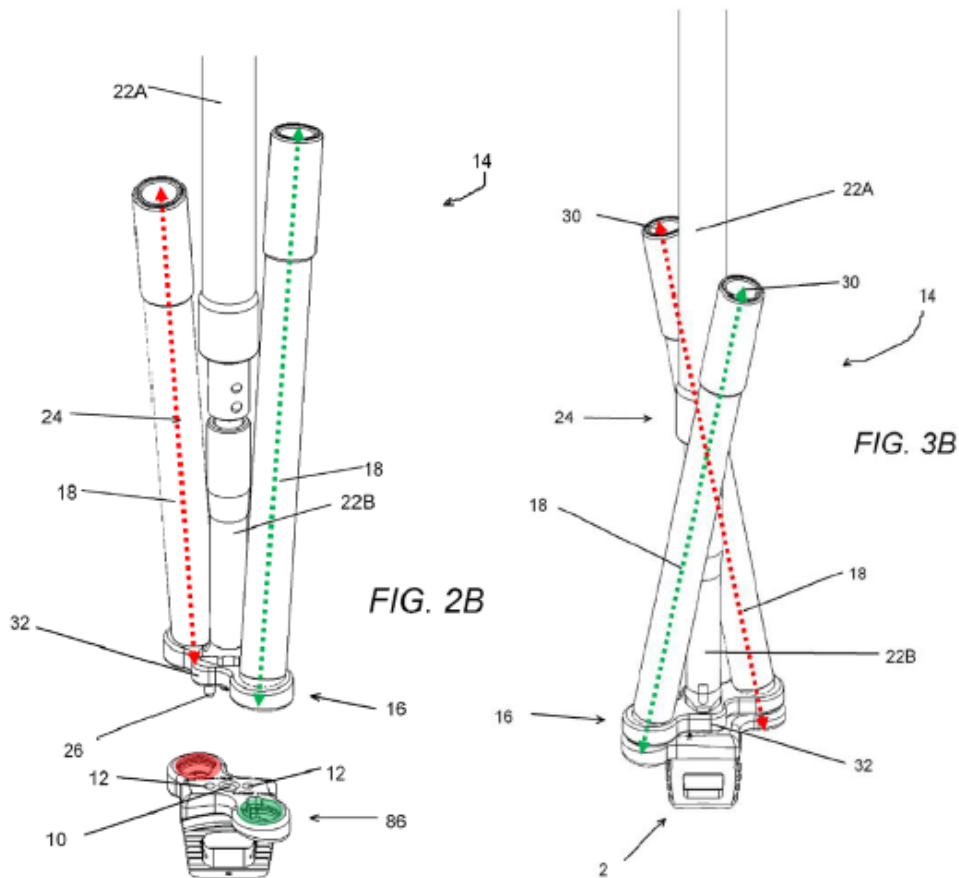
Furthermore, even if the handle is detached to facilitate access during fixation, as Patent Owner suggests (PO Resp. 38), we credit Mr. Culbert's un rebutted declaration testimony, that based on the relative dimensions of instrument guide 14, "during surgery at least the handle 20 and part of proximal shaft 22A of the instrument guide 14 would extend outside of the patient's body through the surgical access channel." Ex. 1002 ¶ 122. In addition, Blain discloses an embodiment where handle 20 may be

permanently attached, which would satisfy the limitation throughout the entire procedure. Pet. Reply 16–17 (citing Ex. 1004, 5:1–3). We also credit Mr. Culbert’s un rebutted declaration testimony that designing Blain’s instrument guide 14 with sufficient length to span from the surgical site to outside the body would allow for a smaller incision on the patient and prevent medical practitioners from obscuring fluoroscopy imaging and unwanted radiation exposure by reaching into the incision. Ex. 1002 ¶¶ 123–24.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain alternatively renders obvious the subject matter of limitation 1.2.2.

- e) *Claim 1.2.3. “the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and”*

Petitioner asserts that Blain discloses this limitation. Pet. 55–57 (citing Ex. 1002 ¶¶ 127–129). Petitioner provides the following annotated version of Blain’s Figures 2B and 3B. *Id.* at 55–56 (citing Ex. 1004, Figs. 2B, 3B; Ex. 1005, Figs. 2B, 3B).



Figures 2B and 3B are detailed bottom perspective views of the flanged interbody fusion implant and the distal end of the instrument guide before (Fig. 2B) and after (Fig. 3B) coupling. Ex. 1004, 3:28–45. With reference to the annotated figures, Petitioner identifies that “one guide tube 18 has a proximal opening 30 of a channel that extends to the opposing end of the guide tube (as indicated by red-dashed arrow) and to a channel opening (not shown) in device coupler 16” and “the other guide tube 18 has a proximal opening 30 of a channel that extends to that guide tube’s opposing end (as indicated by green-dashed arrow).” Pet. 55 (citing Ex. 1004, 8:5–16; Ex. 1005 ¶ 35). Petitioner, thus, contends that “guide instrument channel (red-dashed line) aligns with the implant fastener channel (red circle), and the other guide instrument channel (green-dashed line) aligns with a

different implant fastener channel (green circle).” *Id.* at 56 (citing Ex. 1004, 4:55–58, 5:17–33, 6:1–9; Ex. 1005 ¶¶ 20, 22, 25).

In response, Patent Owner acknowledges that Blain “teach[es] alignment between guide tubes 18 and implant apertures 4” but argues that “Petitioner’s mapping again obscures critical structural and functional distinctions.” PO Resp. 39. According to Patent Owner,

[t]he ’805 [p]atent describes delivery housing channels that “house and guide the anchoring mechanism to the proper location in the fusion member” and that “run the entire length of the delivery housing” (EX1001, 11:42–51). The[S]pecification further explains that these channels accommodate not only anchoring members but also retention mechanisms, stating that “the delivery housing includes channels that guide the retention rods” (EX1001, 2:42–45). Figure 7A illustrates this unified housing structure 610 containing channels for both anchoring members 140 and retention rods 160 (EX1001, Fig. 7A).

Id. Thus, Patent Owner takes the position that the ’805 patent requires a “structurally distinct configuration” from Blain that “lacks the claimed ‘delivery housing’ structure that contains channels for both anchoring members and retention mechanisms within a single unified component, as illustrated in Figure 7A of the ’805 [p]atent.” *Id.* at 39–40 (citing Ex. 1001, Fig. 7A; Ex. 1004, 5:10–17, 5:44–50, 8:5, Fig. 5–8; Ex. 1002 ¶ 144).

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses “the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies,” as recited by limitation 1.2.3.

Despite admitting that Blaine teaches the required alignment between guide tubes 18 and apertures 4, Patent Owner improperly relies on structural and functional distinctions from the Specification that are not recited in argued limitation 1.2.3. Furthermore, we find Patent Owner misrepresents the requirements of limitation 1.2.3, arguing that Blain fails to disclose “the claimed ‘delivery housing’ structure that contains channels for both anchoring members and retention mechanisms within a single unified component.” PO Resp. 40. Although we acknowledge that claims 2 and 4 require a “delivery housing” structure, limitation 1.2.3 does not recite such a feature. *See* Pet. Reply 17 (arguing that only claims 2 and 4 require a delivery housing); *see also In re Self*, 671 at 1348.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of limitation 1.2.3.

- f) *Claim 1.3 “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing through a different channel of the fusion member, (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.”*

Petitioner asserts that Blain discloses this limitation. Pet. 57–61 (citing Ex. 1002 ¶¶ 130–137). Petitioner asserts that, in Blain, “[a]fter the implant 2 is positioned in its desired location and orientation, self-tapping or self-drilling bone fasteners 6 may be inserted into the proximal openings 30 of the guide tubes 18 **and fastened to bone using a screw driver 66.**” *Id.* at 57 (citing Ex. 1004, 8:50–54; Ex. 1005 ¶ 38). In addition, Petitioner asserts that each anchoring member is inserted into a different channel of implant 2, fastened to bone using screw driver 66, and coupled to the vertebral bodies

via threaded engagement to prevent decoupling. Ex. 1002 ¶ 133 (citing Ex. 1004, 8:50–54); Ex. 1005 ¶ 38). And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have understood Blain to disclose an anti-rotation mechanism that would help “prevent the fasteners 6 from ‘backing out’ of the vertebral bodies and/or implant channel due to reverse-rotation.” Pet. 60 (citing Ex. 1002 ¶ 135).

In response, Patent Owner argues that Blain fails to disclose “preventing decoupling of the fusion member from the vertebral body,” as recited by limitation 1.3. PO Resp. 40–43. Patent Owner explains that the ’805 patent achieves fixation and “‘prevent[s] decoupling’ through a specific structural feature: ‘flanges at a proximal end’ of the anchoring member that ‘fit into recesses . . . locking the anchoring members . . . to the fusion member.’” *Id.* at 41 (citing Ex. 1001, Claim 13, Figs. 15–16). According to Patent Owner, “[t]his mechanical interference fit between the proximal flange and the fusion member recess prevents the push-in anchor from being pulled out in the direction opposite to insertion.” *Id.*

Patent Owner asserts that Blain “achieves fixation through an entirely different mechanism: threaded engagement between the screw shaft and bone, supplemented by an anti-rotation locking feature.” PO Resp. 41. Patent Owner argues that Blain’s process “require[es] rotational insertion” (*id.* (citing Ex. 1004, 8:50–54)) whereas “the ’805 [p]atent’s proximal flange mechanism prevents **axial pull-out** of a **push-in anchor** after it has been driven into bone via linear force” (*id.* at 42). More particularly, Patent Owner contends that “the ’805 [p]atent’s anchoring members are explicitly described as being ‘tapped, hammered, or simply pushed’ into place (EX1001, 20:49–53)—a linear force insertion mechanism incompatible with

Blain’s threaded screws requiring rotational insertion.” *Id.* Patent Owner argues further that because Blain’s “threaded screws” “rely[]exclusively on threaded engagement with bone for fixation,” they lack “‘hollow central lumens and perforated tips’ designed for injecting ‘polymethyl methacrylate (PMMA) or other bone cement or hardening polymer material’ through the anchoring member and into the marrow space of vertebral bodies for enhanced fixation.” *Id.* at 42–43 (citing Ex. 1001, 3:10–25, Figs. 15–16; Ex. 1004, 7:49–62).

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies,” as recited by limitation 1.3.

Although Patent Owner argues that the ’805 patent achieves fixation and “prevent[s] decoupling” via “push-in” anchors (such as needles or pins) that are “tapped, hammered, or simply pushed” into place via linear force, we agree with Petitioner that the ’805 patent contradicts Patent Owner’s argument. Pet. Reply 10 (citing Ex. 1001, 23:60–24:4). In this regard, the ’805 patent explicitly states that “anchoring members of some embodiments have threads,” which we understand would allow them to function similarly to Blain’s bone screws. Ex. 1001, 23:60–61. Here, the ’805 patent discloses that “threads allow the anchoring members to be screwed into the desired position within the marrow space of the vertebral bodies.” *Id.* at 23:66–24:2. The ’805 patent even describes that the fusion member channels may include “grooves that compliment the threads” in order to facilitate the advancement of the anchoring members through the channels. *Id.* at 24:2–4.

We also fail to see any requirement in limitation 1.3 that would require “‘flanges at a proximal end’ of the anchoring member that ‘fit into recesses . . . locking the anchoring members . . . to the fusion members,’” as Patent Owner suggests. *Cf.* Ex. 1001, 27:57–59 (unchallenged claim 13 recites “wherein each independent anchoring member comprises flanges at a proximal end of the anchoring members”). Nor do we see any recitation in limitation 1.3 that would require “‘hollow central lumens and perforated tips’ designed for injecting ‘polymethyl methacrylate (PMMA) or other bone cement or hardening polymer material’ through the anchoring member and into the marrow space of vertebral bodies for enhanced fixation.” PO Resp. 42–43. Instead, however, the ’805 patent discloses that “[i]n some embodiments, the anchoring members may be without a central lumen.” Ex. 1001, 25:61–63.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of limitation 1.3.

g) Conclusion for Claim 1

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses each limitation of claim 1 and, accordingly, that claim 1 is anticipated by Blain. We further find that Petitioner also has shown that claim 1 would have been obvious over Blain.

3. *Claim 2 “The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member.”*

Petitioner asserts that Blain discloses this limitation. Pet. 61–64 (citing Ex. 1002 ¶¶ 138–145).

With respect to “a delivery housing,” Petitioner provides the following copies of Blain’s Figure 2C and Figure 4, annotated in yellow, to identify instrument guide 14 with two guide tubes 18 attached to device coupler 16. *Id.* at 61 (citing Ex. 1004, 8:5–20, Figs. 2C, 4; Ex. 1005 ¶¶ 36–37).

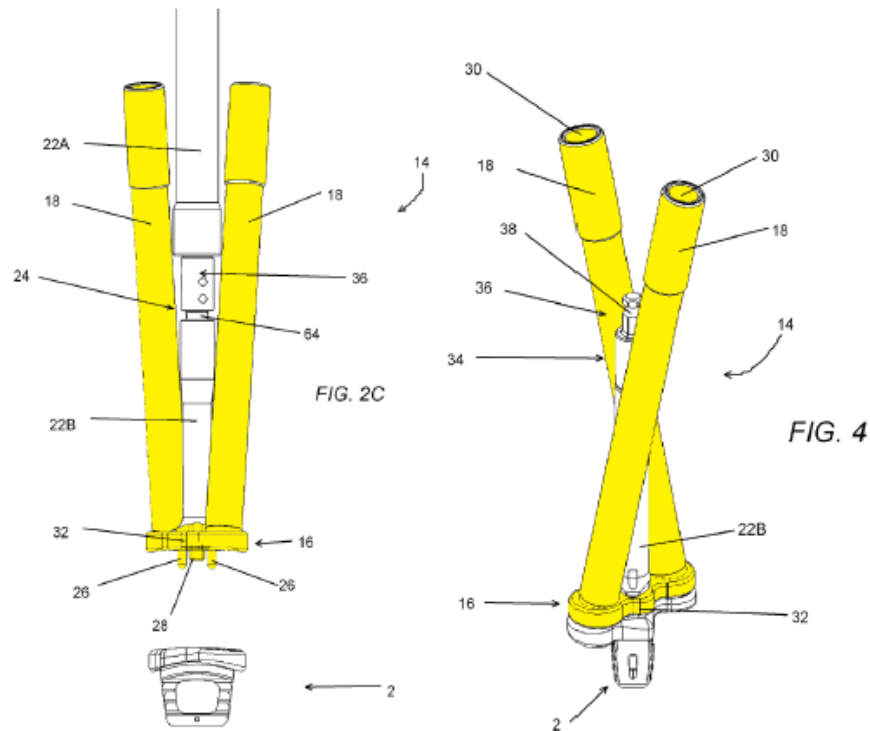


Figure 2C is a detailed bottom perspective view of the flanged interbody fusion implant and the distal end of the instrument guide before coupling. Ex. 1004, 3:35–40. “Figure 4 is a perspective side view of the instrument guide and the flanged interbody fusion implant of FIG. 3B with the handle removed.” *Id.* at 3:46–48. Petitioner first asserts that “[g]uide tubes 18 constitute a *delivery housing* because they are part of the *delivery mechanism* and house fasteners 6 (*anchoring members*) as they pass from the proximal openings 30, through the guide tube channels, to the openings of the device coupler 16.” Pet. 62 (citing Ex. 1002 ¶ 139 (citing Ex. 1004,

5:30–33, 8:5–11, 8:48–54; Ex. 1005 ¶¶ 22, 35, 38)). Petitioner further asserts that

device coupler 16 likewise constitutes a *delivery housing* because it is part of the *delivery mechanism* and houses the fasteners 6 as they pass through the openings in the device coupler 16 on their way to the proximal openings 4 in the fusion implant 2. Ex. 1002 ¶ 140 (citing Ex. 1004, 8:5–11, 8:50–54); Ex. 1005 ¶¶ [0035], [0038]. Both the device coupler 16 and guide tubes 18 are *for guiding each independent anchoring member into the fusion member*, as each provides anchor channels leading to the fastener openings 4 of the implant 2. Ex. 1002 ¶ 141.

Pet. 62.

With respect to “a retention mechanism,” Petitioner provides the following copies of Blain’s Figure 2C and Figure 5, annotated to identify “instrument guide 14 includes inner shaft 42 (green) that resides in outer shaft 46 (pink) and has coupling members 26 (red) and coupling members 28 (at distal end 40 of green shaft 42).” *Id.* at 62–63 (citing Ex. 1004, 6:47–57, Figs. 2C, 5; Ex. 1005 ¶ 29).

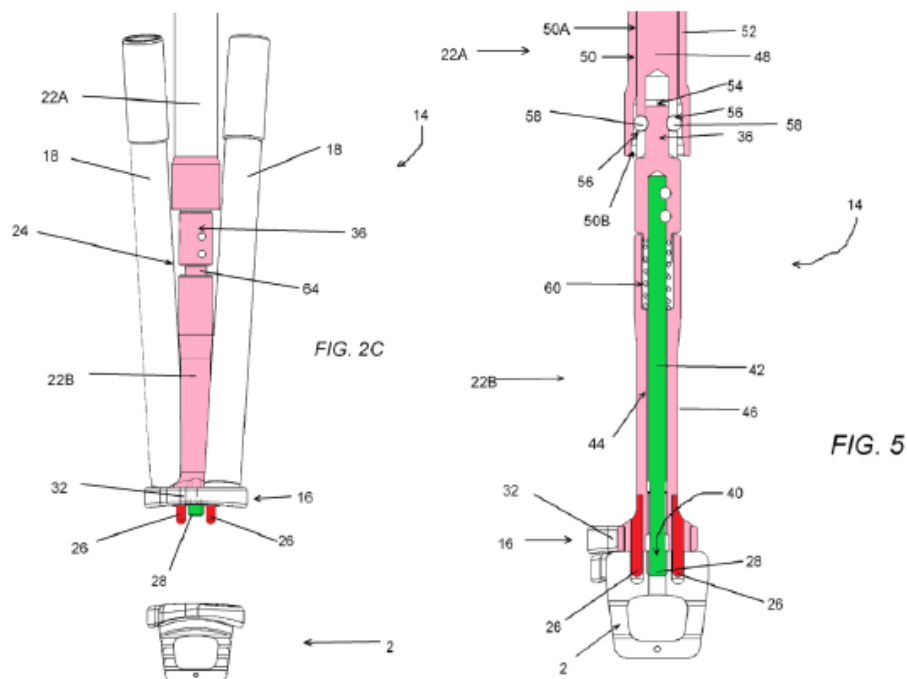


Figure 2C is a detailed bottom perspective view of the flanged interbody fusion implant and the distal end of the instrument guide before coupling. Ex. 1004, 3:35–40. Figure 5 is a “cross-sectional view of the instrument guide and the flanged interbody fusion implant.” *Id.* at 3:49–50. Petitioner asserts that “distal end 40 of the distal inner shaft 42 includes a movable coupling member 28” that “allows the instrument guide to be coupled to the implant 2 in a ‘locking configuration . . . to detachably engage the implant (2).’” Pet. 63 (citing 1004, 5:44–50; Ex. 1005 ¶ 24).

In response, Patent Owner argues that Petitioner “improperly aggregate[s] separate structural components” in Blain to satisfy claim 2’s requirement of “a unified delivery housing.” PO Resp. 43. According to Patent Owner, the ’805 patent describes a single “delivery housing” that “performs integrated functions within a unified structural body” that includes channels that “house and guide the anchoring mechanism” and separately “guide the retention rods.” *Id.* (citing Ex. 1001, 2:42–45). Patent Owner takes the position that “[t]his dual functionality—guiding both anchoring members and retention rods—occurs within a single unified housing structure,” as illustrated by Figure 7A. *Id.* at 43–44 (citing Ex. 1001, Fig. 7A).

Patent Owner argues that “Blain discloses a fundamentally different architecture: **separate structural components** that are attached together to form a modular assembly.” PO Resp. 44. Patent Owner contends that “[t]his modular configuration of separate attached components does not satisfy a claim requiring a single unified ‘delivery housing.’” *Id.* According to Patent Owner, Petitioner “attempts to justify this aggregation by asserting that guide tubes 18 ‘house’ the anchoring members because ‘the guide members 18 support, contain, and protect the fasteners 6 as each fastener is

driven through the guide tubes” (*id.* (citing Ex. 1002 ¶ 139)), but Patent Owner argues that “[t]his argument conflates temporary containment during insertion with structural ‘housing.’ The ’805 [p]atent’s delivery housing contains internal channels that ‘run the entire length of the delivery housing’ to permanently house and guide anchoring members to fusion member channels.” *Id.* at 44–45 (citing Ex. 1001, 2:39–45).

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that “the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member,” as recited by claim 2.

As discussed above in Section II.C.1, a “housing” in the context of a “delivery housing” is a component that contains and guides another component, and as such, we agree with Petitioner that “[n]othing in the ordinary meaning of ‘delivery housing’ requires that it ‘perform[] integrated functions within a *unified structural body*,’ be ‘a *single unified* ‘delivery housing,’ or exclude ‘*separate* components.’” Pet. Reply 19 (citing PO Resp. 43–44, 46; Pet. 12–13).

Consistent with this understanding, Petitioner shows persuasively that Blain’s “instrument guide 14” constitutes a “delivery mechanism” including “guide tubes 18” and “device coupler 16,” which collectively satisfy the “delivery housing” limitation. Pet. 62 (citing Ex. 1002 ¶¶ 139–140; Ex. 1004, 5:30–33, 8:5–11, 8:48–54). These components “house fasteners 6,” i.e., “anchoring members,” by providing channels that contain and guide another component as they pass into the openings of Blain’s

implant. Petitioner also shows persuasively that “inner shaft 42” and “moveable coupling member 28” function together as the claimed “retention mechanism” by creating an interlocking fit that allows “instrument guide 14” to be coupled with “implant 2.” Pet. 62–63 (citing Ex. 1002 ¶¶ 142–144; Ex. 1004, 5:44–50, 6:47–57).

We are not persuaded by Patent Owner’s attempt to distinguish Blain from the subject matter of claim 2 based on its argument that “[t]he ’805 [p]atent’s delivery housing contains internal channels that ‘run the entire length of the delivery housing’ to permanently house and guide anchoring members to fusion member channels.” PO Resp. 44–45 (citing Ex. 1001, 2:39–45). Instead, we determine that Patent Owner’s arguments are directed to unrecited limitations. *See In re Self*, 671 at 1348. As Petitioner correctly notes, the ’805 patent discloses that “the delivery housing may ‘house’ anchoring mechanisms that are only in the housing for deployment (i.e., ‘temporarily’)” and “guide tubes 18/device coupler 16 ‘house’ bone screws that are only in them for deployment.” Pet. Reply 20 (citing Ex. 1001, 2:37, 7:1–7, 11:27–28, 13:25–27).

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of claim 2, rendering dependent claim 2 anticipated by, and obvious over, Blain.

4. *Claim 3 “The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member.”*

Petitioner asserts that Blain discloses this limitation. Pet. 64 (citing Ex. 1002 ¶ 146). With reference to annotated Figure 5 (*see supra* § II.D.), Petitioner asserts that Blain discloses “the *retention mechanism* includes a

retention rod in the form of inner shaft 42 (green), which has a distal end 40 with coupling member 28 that couples to the coupling opening 10 of fusion implant 2.” *Id.* (citing Ex. 1002 ¶ 146). Petitioner further asserts that Blain’s “*retention mechanism* comprises coupling members 26, which are also rods used to couple the instrument guide 14 to the implant 2 via coupling openings 12 in the implant.” *Id.* (citing Ex. 1004, 6:1–8).

In response, Patent Owner argues that Blain’s “inner shaft 42” is a “complex internal component concealed within distal outer shaft 46 that does not engage the side of the fusion member” (PO Resp. 48 (citing Ex. 1004, Figs, 2C, 5)) whereas “[t]he ’805 [p]atent’s ‘retention rod’ is a specific, simple structure exemplified by retention rods 160, which are guided by dedicated channels 710 in the delivery housing and feature retention teeth 910 that directly engage retention grooves 150 on the lateral surfaces of the fusion member.” *Id.* (citing Ex. 1001, Figs. 5A, 7A, 10A–10C). Patent Owner concludes that one of ordinary skill in the art “would not have understood Blain’s complex, internal, central-axis driveshaft to be the same as the ’805 [p]atent’s simple, externally-engaging retention rod. Blain’s retention mechanism and the claimed ‘retention rod’ are structurally and functionally distinct.” *Id.*

Although Patent Owner argues that the ’805 patent’s “retention rod” requires a simple, external structure with “retention teeth 910 that directly engage retention grooves 150 on the lateral surfaces of the fusion member” (PO Resp. 48), we find no such requirement in the claim. Limitations not appearing in the claims cannot be relied upon for patentability. *See In re Self*, 671 at 1348. Nor do we see anything in the ’805 patent that requires the rod to engage the implant externally or possess specific teeth structures. Here, claim 3 broadly recites “the retention mechanism comprises at least

one retention rod for coupling with the fusion member.” And, absent any argument based on features appearing in the claim, Petitioner shows persuasively that “Blain’s inner shaft 42 (including its coupling member 28 (green)) and coupling members 26 (red) are ‘rods’ that ‘retain’—qualifying each as a ‘retention rod.’” Pet. Reply 21.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of claim 3, rendering dependent claim 3 anticipated by, and obvious over, Blain.

5. *Claim 4 “The apparatus of claim 2, wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.”*

Petitioner asserts that Blain discloses this limitation. Pet. 64–65 (citing Ex. 1002 ¶ 147). More particularly, Petitioner asserts that “coupling the instrument guide 14 (including the device coupler 16 and guide tubes 18) to the implant 2, causes each channel (red-dashed channel and green dashed-channel) of the instrument guide 14 to be aligned with a different channel (red circle and green circle, respectively) of the implant 2.” *Id.* at 65 (citing Ex. 1002 ¶ 147; Ex. 1004, 5:30–33).

In response, Patent Owner argues that Blain fails to disclose the claimed “align[ment]” because “Blain’s ‘guide tubes 18’ (Petitioner’s ‘second plurality of channels’) and its ‘device coupler 16’ are part of a *single, rigid assembly*,” and as such, “[t]he alignment between these components *is fixed and pre-exists* any ‘coupling’ event.” PO Resp. 49 (citing Ex. 1004, Fig. 2A). According to Patent Owner, “[t]he ‘coupling’ event in Blain is the *separate* act of locking the tool’s internal ‘inner shaft 42’ to the implant’s central opening 10” (*id.* (citing Ex. 1004, Fig. 5))

whereas “[i]n the ’805 patent, the ‘delivery housing’ (610) is a single component that itself is coupled to the fusion member (e.g., via retention rods 160)” (*id.* (citing Ex. 1001, Fig. 6)). Thus, according to Patent Owner, “[t]his *act of coupling the housing* is what ‘causes’ the internal anchor channels (720) to simultaneously align with the fusion member channels.” *Id.* at 49–50.

Petitioner replies that Patent Owner’s argument is “irrelevant” because

the claim merely requires that “the coupling of the ***delivery housing*** [guide tubes 18/device coupler 16] to the ***fusion member*** [implant 2] causes each channel of the fusion member [red/green circles] to be aligned with a different channel of the delivery mechanism [red/green dashed-lines].” This “coupling” clearly occurs when the ***coupling*** members 26 and 28 of the guide tubes 18/device coupler 16 (*delivery housing*) couple with the corresponding recesses of the implant 2 (*fusion member*).

Pet. Reply 23. Petitioner contends that Patent Owner’s argument that “‘coupling’ only occurs upon the ‘separate act of locking the tool’s internal ‘inner shaft 42’ to the implant central opening 10’” is inconsistent with the ’805 patent and the plain and ordinary meaning of “coupling” (*id.* (citing PO Resp. 49)), which Petitioner asserts “is to ‘come together; unite’” (*id.* at 24 (citing Ex. 1043, 4; Ex. 1044, 3; Ex. 1045, 3)). Petitioner adds that

[t]his indisputably occurs when coupling members/structures 26, 28 of Blain’s coupling device 16 engage/join/mate with the openings of the fusion member, aligning the anchor member channels of the delivery mechanism and fusion member. Indeed, the [S]pecification of the ’805 [p]atent teaches degrees of coupling—“coupling” generally, “fully” coupled, and “fixedly” coupled. Ex. 1001, 2:35–39, 4:5–6, 12:7–15. Although “fixedly” coupling may require fully “locking” two components together, “coupling” does not.

Id. at 24.

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that “the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism,” as recited by claim 4.

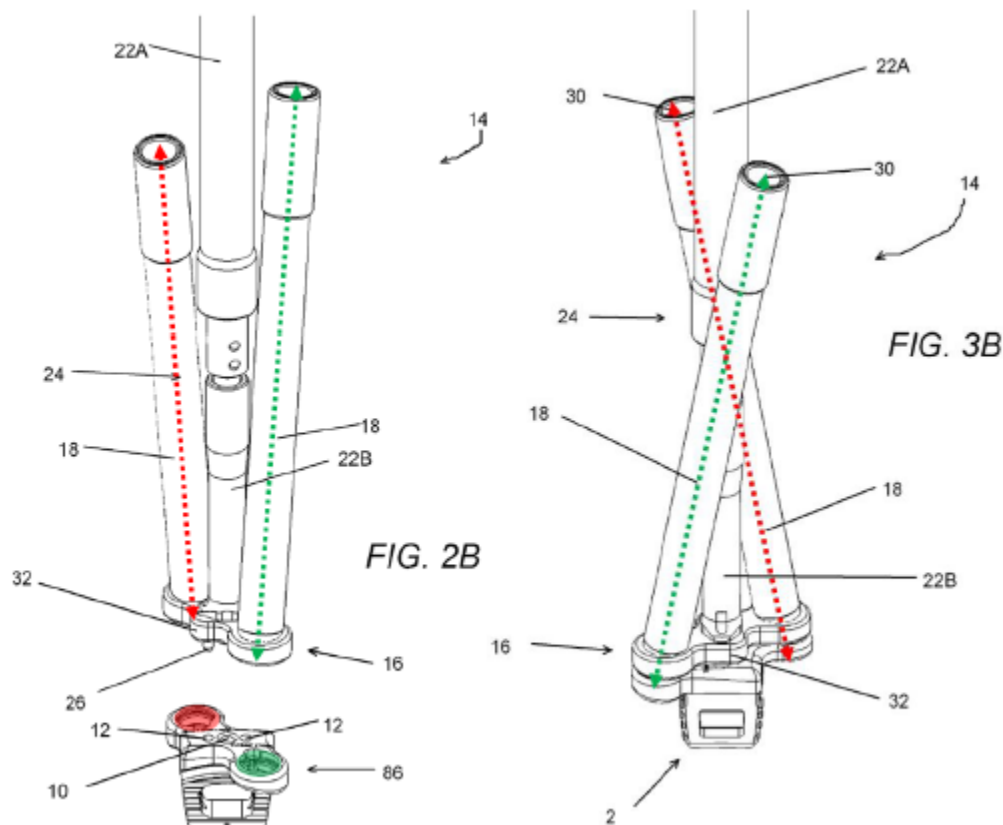
Petitioner shows persuasively that the physical interaction between Blain’s delivery tool 14 and implant 2 satisfies the functional limitation of causing alignment, as required by claim 4. Although Patent Owner argues that alignment is a preexisting condition due to the “*single, rigid assembly*” of Blain’s “guide tubes 18” and “device coupler 16,” we find alignment between two separate components, i.e., instrument guide 14 and fusion member 2, is functionally established only upon the act of joining them. In this regard, Blain discloses that “instrument guide 14 comprises one or more guide members 18 and a device coupler 16 with one or more coupling structures 26, 28 engageable to the implant 2.” Ex. 1004, 4:55–59. Thus, we agree with Petitioner that “coupling members/structures 26, 28 of Blain’s coupling device 16 engage/join/mate with the openings of the fusion member, aligning the anchor member channels of the delivery mechanism and fusion member.” Pet. Reply 24. This understanding is consistent with the ’805 patent’s disclosure that “[t]he delivery mechanism includes (1) a delivery housing 610 that houses the anchoring mechanism and retention rods 160, and (2) four retention rods 160 that couple the delivery housing 610 with the fusion member 120.” Ex. 1001, 11:27–31.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain

discloses the subject matter of claim 4, rendering dependent claim 4 anticipated by, and obvious over, Blain.

6. *Claim 6 “The apparatus of claim 1, wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.”*

Petitioner asserts that Blain discloses this limitation. Pet. 66–67 (citing Ex. 1002 ¶ 151). Petitioner provides the following annotated versions of Blain’s Figures 2B and 3B. *Id.* at 66 (citing Ex. 1004, Figs. 2B, 3B).



Figures 2B and 3B are detailed bottom perspective views of the flanged interbody fusion implant and the distal end of the instrument guide before (Fig. 2B) and after (Fig. 3B) coupling. Ex. 1004, 3:28–45. With reference

to Figures 2B and 3B above, Petitioner asserts that “each fastener 6 traverses through a different channel of the implant (e.g., red circle or green circle) through a corresponding channel of a guide rod 18 (e.g., as indicated by red-dashed or green-dashed line) of the instrument guide 14.” Pet. 66 (citing Ex. 1002 ¶ 151; Ex. 1004, 4:55–58, 5:17–33, 6:1–9, 8:50–54).

In response, Patent Owner argues that “Blain teaches the generic concept of passing a *screw* through a *straight, separate guide tube*. It does not teach the claimed invention: passing a *flexible, barbed pin* through a *curved channel* within an *integrated housing*.” PO Resp. 53.

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that “wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism,” as recited by claim 6.

As Petitioner correctly notes, “[t]here is no basis for requiring this channel to be part of a ‘a single, integrated structure containing channels for both the anchors (720) and retention rods (710).’” Pet. Reply 25 (citing PO Resp. 52). Nor is there any “basis for requiring this channel to be ‘curved’” or for requiring “‘anchoring members’ to exclude rotatable, threaded anchors.” *Id.* (citing PO Resp. 53). Thus, Patent Owner’s arguments unpersuasive because they are not commensurate in scope with limitations recited by dependent claim 6. Limitations that do not appear in the claims cannot be relied upon for patentability. *See In re Self*, 671 F.2d at 1348.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain

discloses the subject matter of claim 6, rendering dependent claim 6 anticipated by, and obvious over, Blain.

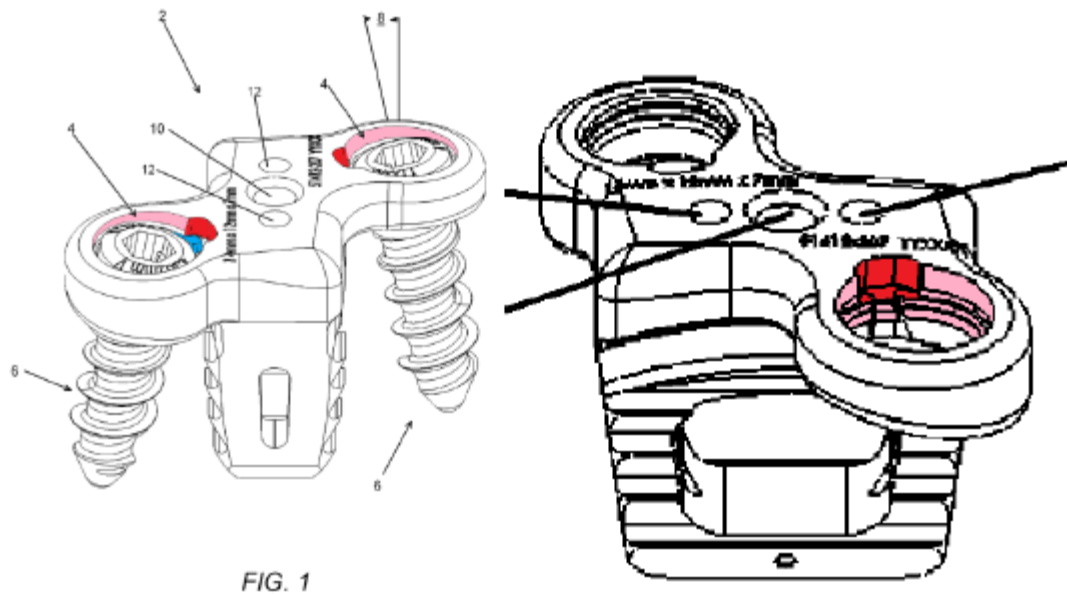
7. Independent Claim 11

Claim 11 is the other challenged independent claim of the '805 patent. Petitioner asserts that claim 11 is anticipated by, or in the alternative obvious over Blain, for the same reasons discussed above with respect to claim 1. Pet. 67–68 (citing *id.* at 44–61). Patent Owner also relies on its argument made with respect Claim 11. PO Resp. 53–55.

After our review of Petitioner's assertions and the supporting evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses each limitation of claim 11 and, accordingly, that claim 11 is anticipated by Blain, as well as that claim 11 would have been obvious over Blain, for the same reasons discussed above with respect to claim 1. *See* § II.B.2.

8. *Claim 12 “The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member.”*

Petitioner asserts that Blain discloses this limitation. Pet. 68–70 (citing Ex. 1002 ¶¶ 158–160). Petitioner provides the following annotated copies of Blain's Figures 1 and 2B. *Id.* at 69 (citing Ex. 1004, Figs. 1, 2B).



Figures 1 and 2B are a perspective views of Blain's interbody fusion implant 2. Ex. 1001, 3:33–34, 3:37–40. With reference to annotated Figures 1 and 2B, Petitioner asserts that

Blain's fasteners 6 threadingly engage the threading (pink) of the implant channels. Additionally, the proximal openings include recesses (red) that lobes (blue) of the fastener heads seat into once fully threaded into the openings, locking the fasteners to the implant, thereby preventing their counterclockwise rotation to back out of the penetrated bone or implant.

Pet. 68–69. And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have “understood that the threaded engagement of the fasteners 6 to the implant openings 4 and the anti-rotation mechanism “lock” each fastener to the implant once the fasteners are fully advanced through the implant channels, which helps further prevent decoupling of the implant from the vertebral body.” *Id.* at 69 (citing Ex. 1002 ¶ 158).

In response, Patent Owner argues that Petitioner improperly “equate[s] Blain’s conventional anti-rotation feature for a *threaded screw*

with the '805 patent's specific *flange-based locking system* for a *push-in anchoring member*." PO Resp. 55; *see also id.* at 56 ("Blain's anti-rotation stop for a *screw* is not the claimed flange-and-cavity lock for a *decouplable, push-in pin*.").

We have considered Petitioner's arguments and evidence, and Patent Owner's counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that "wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member," as recited by claim 12.

At the outset, we find Patent Owner fails to establish that any of the alleged differences between Blain's "anti-rotation mechanism" and "the '805 patent's specific *flange-based locking system* for a *push-in anchoring member*" relate to any particular recitation in claim 12. And, to the extent Patent Owner attempts to limit "locking" to a specific flange-based locking system for non-threaded push-in pins, we find Patent Owner's argument to be contradicted by the '805 patent's Specification.

In this regard, the '805 patent explicitly teaches that "anchoring members of some embodiments have threads" and the "[t]he threads allow the anchoring members to be screwed into the desired position." Ex. 1001, 23:60–24:4. In addition, we credit the unrebutted declaration testimony of Mr. Culbert who opines that the '805 patent "characterizes fitting a head of an anchoring member into a recess of an anchor channel of the fusion implant after the anchors have been coupled to the vertebrae as 'locking' the anchoring member and fusion implant together." Pet. 70 (citing Ex. 1002 ¶¶ 159–160). We find Mr. Culbert's opinion to be credible and supported by

the '805 patent's disclosure. Ex. 1001, 15:63–16:2, *see also id.* Figs. 48C, 48D (illustrat[ing] alternative anchoring member tips).

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of claim 12, rendering dependent claim 12 anticipated by, and obvious over, Blain.

9. *Claim 15 “The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism.”*

Petitioner asserts that Blain discloses this limitation. Pet. 70–72 (citing Ex. 1002 ¶¶ 162–163). More particularly, Petitioner asserts that “Blain teaches that bone fasteners are ‘fastened to bone using a screw driver 66.’” *Id.* at 71 (emphasis omitted) (citing Ex. 1004, 8:50–54; Ex. 1005 ¶ 38). And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have

understood that the screw driver drives each fastener 6 through a guide tube 18 and, when it screws each fastener 6 into the vertebral bodies, each fastener 6 is driven further through its guide tube 18 and through the opening of coupling device 16 of the instrument guide 14 as the fastener penetrates further and further into the vertebral body.

Id. at 71–72 (citing Ex. 1002 ¶ 163).

In response, Patent Owner argues that Petitioner improperly “equates Blain’s ‘screw driver 66’ with the claimed ‘driving member.’” PO Resp. 56. According to Patent Owner, one of ordinary skill in the art “would not find these components to be the same” because “[t]he ‘driving member’ of the ‘805 patent . . . is a specialized component designed to apply *linear, axial* force (i.e., ‘tapping, hammering, or simply pushing’) to an ‘independent anchoring member’ (e.g., a nonthreaded pin 1410, 1910) and is specifically

configured to decouple from that anchor.” *Id.* (citing Ex. 1001, 13:55–14:13, 17:34–44). In contrast, “Blain’s ‘screw driver 66’ is a conventional tool designed to apply *rotational torque* to a *threaded fastener* (6).”

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that “a driving member configured to drive each independent anchoring member through the delivery mechanism,” as recited by claim 15.

Patent Owner argues that the ‘805 patent is limited to a “driving member” that is a specialized tool that applies only linear force, but neither claim 15 nor the ‘805 patent’s Specification is so limiting. Initially, we note that claim 15 simply recites the functional requirement “configured to drive” without specifying the type of force (linear vs. rotational) that needs to be applied to “each independent anchoring member.” Ex. 1001, 27:63–65. And, while Patent Owner argues that the ‘805 patent requires a “nonthreaded pin” distinct from Blain’s threaded screw (PO Resp. 56), the ‘805 patent explicitly teaches that “anchoring members of some embodiments have threads” and the “[t]he threads allow the anchoring members to be screwed into the desired position.” Ex. 1001, 23:60–24:4. Because the ‘805 patent encompasses threaded fasteners that are *screwed* into position, we find the ‘805 patent implicitly contemplates rotational tools, like Blain’s screwdriver 66, that constitute a “driving member” configured to “drive” an anchor.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of claim 15, rendering dependent claim 15 anticipated by, and obvious over, Blain.

10. Claim 17 “*The fusion device of claim 11, wherein each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism in order to couple the fusion member to the penetrated vertebral body.*”

Claim 17 is substantially similar to claim 6. Petitioner asserts that Blain discloses the subject matter of claim 17 for the same reasons as claim 6. Pet. 72 (citing *id.* at 66–67). Petitioner adds that “Blain teaches that ‘fasteners 6 may be inserted into the proximal opens 30 of the guide tubes 18 and fastened to bone using a screw driver 66’” and that “[e]ach fastener 6 is thus inserted into a respective guide tube 18 of the instrument guide 14 in order to couple the fusion implant 2 to the penetrated vertebral body.” *Id.* at 72 (citing Ex. 1002 ¶¶ 165–166; Ex. 1004, 8:50–54; Ex. 1005 ¶ 38). Patent Owner makes the same arguments in regard to claim 17 as Patent Owner raised in regard to claim 6. *See* PO Resp. 58 (“[T]his claim is a near-verbatim repeat of Claim 6, and Petitioner’s argument . . . is the same flawed tautology.”).

After our review of Petitioner’s assertions and the supporting evidence, we determine that Petitioner has shown by a preponderance of the evidence that Blain discloses the subject matter of claim 17, rendering dependent claim 17 anticipated by, and obvious over, Blain. *See* § II.D.6.

11. *Conclusion for claims 2–4, 6, 11, 12, 15, and 17*

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that Blain anticipates and renders obvious the subject matter of claims 2–4, 6, 11, 12, 15, and 17.

12. Claims 5 and 16 “wherein each channel of the fusion member is curved.”

Petitioner originally challenged claims 5 and 16 based anticipation by and obviousness over Blain. Pet. 65–66, 72. At the oral hearing, Petitioner acknowledged that “under the agreed construction of curved channel,” Blain does not anticipate or render obvious claims 5 and 16. Tr. 16:15–16; *see also id.* at 15:17–19 (Petitioner stating that “we can see that under Grounds 1 and 2, curved channel would not be met by the prior art as we’ve applied it”).

Based on Petitioner’s statements at the hearing, we do not reach the merits of Petitioner’s contentions because Petitioner no longer maintains its challenges to claims 5 and 16 as anticipated by or obvious over Blain, alone. We address below Petitioner’s challenge to claims 5 and 16 only under alleged obviousness based on the combination of Blain, Bray, and Steffee. *See infra* Section II.F.

13. Conclusion for Anticipation By and Obviousness Over Blain

Consequently, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–4, 6, 11, 12, 15, and 17 are unpatentable over Blain, but as discussed above, we do not determine whether claims 5 and 16 are unpatentable over Blain.

E. Obviousness over Blain and Bray

Petitioner asserts that claims 1–6, 11, 12, and 15–17 are unpatentable as obvious over Blain and Bray. Pet. 72–84. Petitioner also relies on the testimony of Mr. Culbert to support its arguments. *Id.* (citing Ex. 1002). Patent Owner responds to Petitioner’s assertions. *See* PO Resp. 59–64. For the following reasons, we determine Petitioner has shown by a preponderance of the evidence that claims 1–4, 6, 11, 12, 15, and 17 are

unpatentable over Blain and Bray, but as discussed below, we do not determine whether claims 5 and 16 are unpatentable over the combination of Blain and Bray.

We address Petitioner’s contentions and Patent Owner’s arguments below, beginning with a brief overview of Bray.

*1. Overview of Bray (Ex. 1006)*¹³

Bray is directed to “[a]n interbody device for the fixation and support of adjacent bone bodies” and “includes a body for implantation at a location between the two vertebrae and one or more protrusions extending from the body.” Ex. 1006, Abstract. An exemplary embodiment of Bray’s interbody fusion implant 10 is depicted in Figure 1, reproduced below.

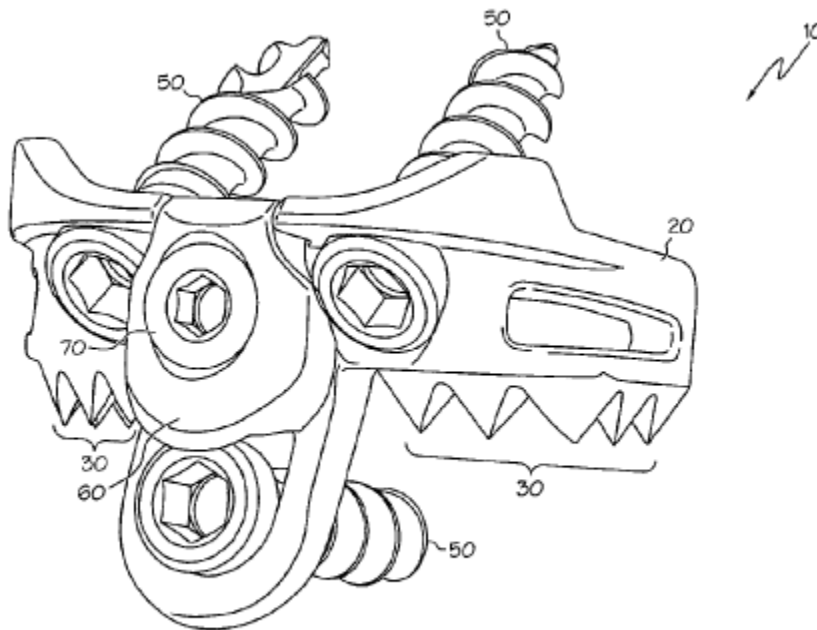


FIG. 1

Figure 1 is a perspective view of interbody device 10 including base member 20 with bone fasteners 50 coupled to base member 20. *Id.* at 4:38–40,

¹³ Patent Owner does not contest the prior art status of Bray.

4:49–51. An exemplary embodiment of Bray’s base member 20 is depicted in Figure 4, reproduced below.

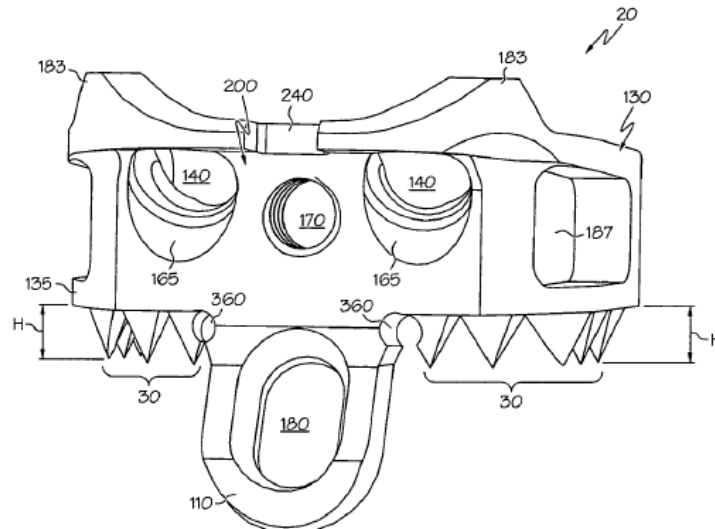


Figure 4 is a perspective view of base member 20 including two bone screw holes 140 with seats 165 and secondary member 110 with bone screw hole 180. *Id.* at 7:15–18, 7:30–36. Bray also discloses that

interbody device 10 also includes a restraining means for restricting movement of one or more bone fasteners 50 coupled to the base member 20. The restraining means can be any means for securely covering at least a part of each of the bone fasteners 50 so that the bone fasteners 50 cannot back out from the bone bodies once screwed in through the base member 20 of the device 10.

Id. at 4:49–55. Bray discloses that in one embodiment, “the bone screw restraining means comprises a restraining plate 60 and a restraining plate fixing means 70.” *Id.* at 4:55–57.

2. Analysis of Claims 1 and 11

Petitioner maintains that Blain teaches or suggests all the elements of independent claims 1 and 11 for the reasons identified with respect to

anticipation and obviousness over Blain, alone. Pet. 73. Petitioner further asserts that to the extent “Blain does not *disclose preventing decoupling of the fusion member from the penetrated vertebral body* as recited in claim elements 1.3 and 11.3, it would have been obvious to modify Blain in view of Bray.” *Id.* at 73–77 (citing Ex. 1002 ¶¶ 170–178). More particularly, Petitioner asserts that “Bray teaches the use of a restraining plate 60 to ‘lock’ its anchors 50 to the implant, thereby helping to prevent decoupling of the fusion member from the penetrated vertebral body.” Pet. 74 (citing Ex. 1002 ¶¶ 170–171; Ex. 1006, 4:49–57, 9:2–6).

Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that

[i]t would have been obvious to use Bray’s restraining plate as a simple, yet improved, alternative to the anti-rotation-mechanism of Blain. [Ex. 1002] ¶ 172. POSAs recognized that overlay-type “locking” mechanisms were well-known and effective, which is why they were commonly used in prior art implants. *Id.* (citing Ex. 1030, 4:43-53; Ex. 1017, 4:62-5:13). A POSA would have understood that the restraining plate would prevent the fasteners 6 backing out from Blain’s implant under any scenario, whereas the anti-rotation mechanism only prevents backing out due to reverse rotation. Ex. 1002 ¶ 172.

Pet. 74. According to Petitioner, one of ordinary skill in the art would have understood that “incorporating the restraining plate of Bray into Blain involved nothing more than applying a known technique (preventing an anchor from backing out of an implant using a restraining plate) to improve a similar device (e.g., Blain’s implant) in an entirely predictable way.” *Id.* at 76 (citing Ex. 1002 ¶ 176). Petitioner also explains why one of ordinary skill in the art would have had a reasonable expectation of success in making this modification. *Id.* (citing Ex. 1002 ¶ 177).

In response, Patent Owner argues that “Petitioner provides no articulated reasoning explaining why a POSA would have been motivated to combine Blain and Bray” in order to “provide an anti-backout mechanism.” PO Resp. 60. According to Patent Owner, Petitioner acknowledges that “Blain already discloses an anti-backout mechanism” (*id.* at 60–61 (citing Ex. 1002 ¶ 158; Pet. 69)) and Bray’s restraining plate is merely “a **post-implantation cover** that is secured over bone screw heads after the screws have been fully inserted and the implant affixed to the vertebrae” (*id.* at 61 (citing Ex. 1006, 4:49–57, 9:61–10:14)). Petitioner further argues that Bray’s restraining plate “is not part of a delivery mechanism” and fails to teach “a unified delivery housing,” “push-in anchoring members,” “curved channels,” and/or “a delivery mechanism extending outside the patient’s body during implant positioning.” *Id.* at 61–62.

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that the combination of Blain and Bray renders obvious claims 1 and 11.

At the outset, we find that Patent Owner mischaracterizes Petitioner’s motivation to combine. Petitioner does not propose adding Bray to address the “housing” limitation, but instead explained that one of ordinary skill in the art “would have been motivated to use the restraining plate as an improved **alternative** (i.e., substitute) to the anti-rotation mechanism of Blain.” Pet. Reply 27 (citing Pet. 74–77). We credit the unrebutted declaration testimony of Mr. Culbert on this point. For example, Mr. Culbert opines that one of ordinary skill in the art would have “understood that using Bray’s restraining plate eliminates the need for the anti-rotation mechanism—namely the lobes on the anchor heads, the

recesses in the anchor channels, and the threading in the anchor channels.” Pet. 75 (citing Ex. 1002 ¶ 173). In addition, Mr. Culbert testifies that using Bray’s restraining plate as an alternative would “reduce the complexity of machining the implant while providing a more reliable and robust anti-backout mechanism” and make removal simpler “if the anchors need to be unthreaded.” *Id.* (citing Ex. 1002 ¶¶ 173–174).

We also are not persuaded by Patent Owner’s attempt to distinguish between Blain as a “**pre-implantation** instrument guide (used during initial implant delivery and screw insertion)” and Bray as a “**post-implantation** restraining plate (secured after screw insertion is complete).” PO Resp. 62. Like the bone fasteners in Blain that couple the implant to bone (*see* Ex. 1004, 8:50–54), Bray discloses that its restraining plate secures the fasteners to the bone once the device is screwed into place (Ex. 1006, 4:49–57). *See* § II.D. Thus, we agree with Petitioner that “Blain’s anti-rotation mechanism and Bray’s restraining plate are both part of their respective *fusion members* and act to lock [the] structure in place after implant fixation.” Pet. Reply 27–28.

Equally unpersuasive are Patent Owner’s assertions regarding “a unified delivery housing,” “push-in anchoring members,” “curved channels,” and/or “a delivery mechanism extending outside the patient’s body during implant positioning.” PO Resp. 61–62. As discussed above, neither claim 1 nor claim 11 requires “a unified delivery housing,” “push-in anchoring members,” or “curved channels.” Thus, Patent Owner cannot rely on these features to distinguish claims 1 and 11 over the asserted combination. And with respect to Patent Owner’s argument regarding “a delivery mechanism extending outside the patient’s body during implant positioning,” Petitioner relies on Blain, not Bray to address this limitation as

discussed above with respect to obviousness and anticipation by Blain, alone. *See* § II.D. *supra*.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Blain and Bray renders obvious the subject matter of claims 1 and 11.

3. *Claims 5 and 16*

Petitioner originally challenged claims 5 and 16 as obvious over Blain and Bray. Pet. 77–83. At the oral hearing, Petitioner acknowledged that “under the agreed construction of curved channel,” Blain and Bray do not render obvious claims 5 and 16. Tr. 16:15–16; *see also id.* 15:17–19 (Petitioner stating that “we can see that under Grounds 1 and 2, curved channel would not be met by the prior art as we’ve applied it”).

Based on Petitioner’s statements at the hearing, we do not reach the merits of Petitioner’s contentions because Petitioner no longer maintains its challenges to claims 5 and 16 as obvious over Blain and Bray. We address below Petitioner’s challenge to claims 5 and 16 only under alleged obviousness based on the combination of Blain, Bray, and Steffee. *See infra* Section II.F.

4. *Claim 12*

Petitioner maintains that Blain teaches or suggests all the elements of claim 12. Pet. 83; *see* § II.D.8. Petitioner further asserts that to the extent “Blain does not teach the limitations of claim 12, they would have been obvious based on the combination of Blain and Bray.” Pet. 83. More particularly, Petitioner asserts that

it would have been obvious to modify Blain to include the restraining plate of Bray as an alternative to Blain’s anti-rotation

mechanism. Because the restraining plate prevents the fasteners 6 of Blain from backing out of (or separating from) the fusion implant 2, the restraining plate *locks* each fastener 6 to the fusion implant 2.

Id. (citing Ex. 1002 ¶ 191). Petitioner adds that

Bray specifically teaches that the restraining plate 60 is fixed into place after the bone screws 50 have been “inserted into the bone screw holes 140 and the bone screw slot 180” and threaded to the vertebral bodies. Ex. 1006, 10:35–50. Thus, *the locking occurs once the anchoring member is fully advanced through the channel of the fusion member.*

Id. (citing Ex. 1002 ¶ 191).

In response, Patent Owner argues that the combination of Blain and Bray fails to teach or suggest the subject matter of claim 12 because “Bray’s restraining plate serves the same anti-rotation function as Blain’s lobe-and-recess mechanism—preventing threaded screws from rotating counter-clockwise and backing out.” PO Resp. 63. According to Patent Owner, “[n]either reference discloses the claimed locking mechanism where ‘flanges at a proximal end fit into recesses . . . locking the anchoring members to the fusion member once the anchoring members are fully advanced through the fusion member’s channels’ to prevent axial pull-out of push-in anchors.” *Id.*

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that Petitioner demonstrates, by a preponderance of the evidence, that Blain discloses that “wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member,” as recited by claim 12.

Patent Owner’s arguments are unavailing for the reasons expressed above for claim 12 with respect to anticipation and obviousness over Blain,

alone, as discussed above. *See* § II.D.8. Additionally, we also agree with Petitioner that Patent Owner’s argument is “premised on misrepresenting that Bray’s restraining plate is ‘in addition to’ (rather than ‘an alternative to’) Blain’s anti-rotation mechanism and improperly reading limitations into the claim, such as ‘flanged’ anchors.” Pet. Reply 28.

Therefore, after reviewing the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Blain and Bray renders obvious the subject matter of claim 12.

5. Claims 2–4, 15, and 17

Petitioner asserts that the additional limitations of claims 2–4, 15, and 17 are disclosed by Blain for the same reasons discussed above with regard to unpatentability over Blain, alone. Pet. 84 (citing *id.* at 61–72).

Patent Owner does not specifically contest Petitioner’s showing for claims 2–4, 15, and 17 under obviousness over Blain and Bray other than to assert that Blain and Bray fail to render obvious these claims for the same reasons explained based on Blain alone. PO Resp. 64. We found those arguments unpersuasive as to unpatentability based on Blain alone and find them equally unpersuasive as to obviousness over Blain and Bray for the same reasons. *See* § II.D.

6. Conclusion for Obviousness Over Blain and Bray

Consequently, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–4, 6, 11, 12, 15, and 17 are unpatentable over the combination of Blain and Bray, but, as discussed above, we do not determine whether claims 5 and 16 are unpatentable over the combination of Blain and Bray.

*F. Obviousness over Blain (with or without Bray) and Steffee*¹⁴

Petitioner asserts that claims 5 and 16 are unpatentable as obvious over Blain (with or without Bray) and Steffee. Pet. 84–91. Petitioner also relies on the testimony of Mr. Culbert to support its arguments. *Id.* (citing Ex. 1002). Patent Owner responds to Petitioner’s assertions. *See* PO Resp. 64–70. For the following reasons, we determine Petitioner has shown by a preponderance of the evidence that claims 5 and 16 would have been obvious over Blain (with or without Bray) and Steffee.

We address Petitioner’s contentions and Patent Owner’s arguments below, beginning with a brief overview of Steffee.

1. Overview of Steffee (Ex. 1016)

Steffee is directed to “a fastener for securing bone graft between a pair of bone portions.” Ex. 1016, 1:8–9. Steffee identifies that

It is known that bone graft contracts as it resorbs. This characteristic of bone graft has resulted in difficulties in securing bone graft between spaced apart bone portions which are to be connected by the bone graft. Typically, staples are used to secure bone graft between bone portions. As the bone graft resorbs, it applies a force to a leg of the staple. The force acts through a moment arm and causes the leg to pivot relative to a portion of the staple base. This causes the staple to loose [sic] its effectiveness.

Id. at 1:11–20. To address these drawbacks, Steffee discloses a fastener comprising “a curved elongated member having a shank for extending into the bone graft and the pair of bone portions to secure the bone graft and pair of bone portions together.” *Id.* at 1:24–28. An exemplary embodiment of Steffee’s fastener is depicted in Figure 1, reproduced below.

¹⁴ Patent Owner does not contest the prior art status of Steffee.

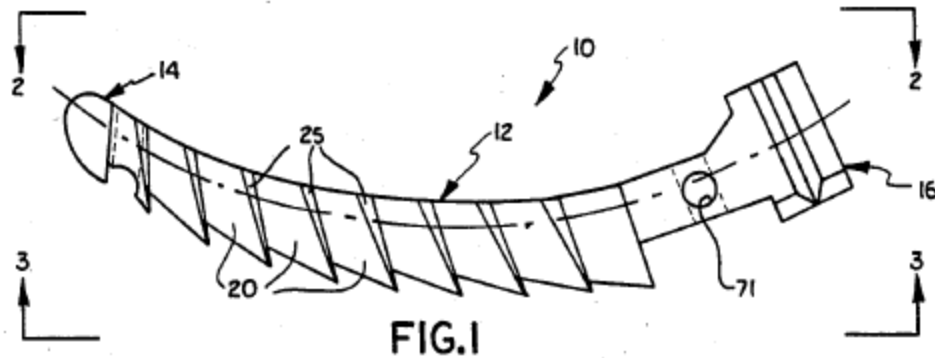


Figure 1 depicts elongated curved fastener 10 including shank portion 12 with “pointed end 14 and at its opposite end has a driving head portion 16” along with a plurality of barbs 20 spaced along the shank portion 12. *Id.* at 2:33–38. According to Steffee, as “fastener 10 is driven into the bone portion, due to its curved configuration, it progresses along a curved path A through the bone graft 24 and into bone portion 26.” *Id.* at 2:45–48. More particularly, Steffee discloses that its

shank extends through the bone graft in a direction along a line extending through the bone graft and bone portions and along which the bone graft resorbs. Thus, the force applied to the shank by the bone graft as it resorbs acts generally along the longitudinal extent of the shank. Thus, the force does not act through a moment arm nor does it have a detrimental effect on the fastener.

Id. at 1:29–36.

2. *Petitioner’s Assertions for Claims 5 and 16*

Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that “[i]t was understood that one reason fusion implants fail was due to migration of the implant,” and that one of ordinary skill in the art “understood that one reason migration occurred was due to forces acting on the implant, including through its anchors or fasteners.” Pet. 84–85 (citing

Ex. 1002 ¶¶ 194–195; Ex. 1016, 1:11–20). And to counteract “anchor migration,” Steffee used a rigid curved anchor “because these anchors are not as susceptible to the same forces that affect straight anchors and cause sagittal and lateral movement.” *Id.* at 85 (citing Ex. 1002 ¶¶ 196–198). And, based on Steffee’s teachings, Petitioner concludes that one of ordinary skill in the art “would have found it obvious to modify Blain to incorporate Steffee’s rigid curved anchors in order to prevent migration, which can cause an implant and its anchors to backout of the vertebral bodies.” *Id.* (citing Ex. 1002 ¶ 199).

Petitioner acknowledges that Steffee concerns “bone graft between vertebral bodies,” but, relying on Mr. Culbert’s declaration testimony, Petitioner asserts that “migration was a well-known and understood problem with interbody implants with anchors as well,” and one of ordinary skill in the art “would have readily recognized that, just as the curved anchor of Steffee inhibits migration that causes staples to come out, a curved anchor would provide the same benefit of inhibiting migration that causes straight implant anchors (like Bray’s) to come out or loosen.” Pet. 86 (citing Ex. 1002 ¶¶ 201–202 (citing Ex. 1034, 13:17–30; Ex. 1030, 1:31–39; Ex. 1032, 4:61–64; Ex. 1033, 23:48–50)). Also, relying on Mr. Culbert’s declaration testimony, Petitioner asserts that one of ordinary skill in the art would have “recognized that having two curved fasteners that curve in non-identical directions (as taught by Steffee) would further resist migration” and recognized that curved barbed anchors are less prone stripping over thread screws. *Id.* at 87 (citing Ex. 1002 ¶ 203).

Petitioner notes that Steffee identifies that “its curved fastener is ‘simple yet extremely effective’ for interbody fusion” (Pet. 87 (citing Ex. 1016, 2:29–33)), and as such, one of ordinary skill in the art would have

“recognized that the use of curved anchors was suitable for use with an implant device such as that shown in Blain” given that “the use of curved anchors with spinal implants was not novel” and “the same or similar forces are present during interbody fusion regardless of whether an implant is used” *id.* (citing Ex. 1002 ¶¶ 204, 206; Ex. 1035, 2:57–61; Ex. 1019, 7:14–25). Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have “understood that the shape of the implant channels should match the shape of the anchor shaft to facilitate guiding the anchors into the vertebral bodies, as the curved anchors are rigid and cannot deform to conform to anchor channels that follow a straight path.” *Id.* (citing Ex. 1002 ¶ 205).

Relying further on Mr. Culbert’s declaration testimony, Petitioner asserts that one of ordinary skill in the art would have

understood that modifying Blain to incorporate a curved anchor would have required simply replacing the anchoring screws 6 of Blain with curved barbed anchors similar to those of Steffee and modifying the fastener channels (of implant 2) and guide tube 18 channels (of guide instrument 14) to have shapes complementary to the curved anchors, such that the fastener channels are curved.

Pet. 88 (citing Ex. 1002 ¶ 206). Petitioner notes that Blain discloses that its guide tubes 18 may be “linear or non-linear” (*id.* (citing Ex. 1004, 8:8–16; Ex. 1005 ¶ 35)) and one of ordinary skill in the art would have appreciated that “that curved channels would have been necessary to ensure that the rigid anchors did not become stuck or trapped when attempting to drive them through the screw/drill guides during surgery” (*id.* (citing Ex. 1002 ¶ 206)). Mr. Culbert adds that through the use of “basic machining principles,” one of ordinary skill in the art would have had a reasonable expectation of success in making these proposed modifications, which would only entail

modifying Blain's anchors to be curved and barbed and also modifying the contours of the guide tubes and fusion member channels to fit the concave surface of Steffee's fasteners along the curved path taken by the fastener. *Id.* at 91 (citing Ex. 1002 ¶210). And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would have "understood and found it obvious that, once these minor modifications are made, an impact driving tool (e.g., surgical hammer) would be used to drive the barbed anchors into their respective vertebral bodies as taught by Steffee." *Id.* (citing Ex. 1002 ¶ 209 (citing Ex. 1016, 3:4–13)). Petitioner adds that Blain discloses that "other [driving] tools are known in the art and may be used with the non-linear guide members." *Id.* (citing Ex. 1004, 8:14–16).

3. Patent Owner's Arguments

Patent Owner contends that Petitioner's ground of unpatentability based on Blain (with or without Bray) and Steffee is deficient. PO Resp. 64–70. More particularly, Patent Owner argues that Petitioner fails to establish obviousness because the asserted combination is based on "impermissible hindsight," non-analogous art, and "fail[s] to establish that a POSA would have been motivated to combine" the asserted references. *Id.* We address Patent Owner's arguments in greater detail below.

4. Analysis of Claims 5 and 16

Patent Owner argues that Steffee is non-analogous art because it is directed to "securing bone graft between a pair of bone portions' using a fastener designed to prevent stress concentration from bone graft resorption.'" PO Resp. 64–65 (citing Ex. 1016, 1:6–9, 1:29–36, Fig. 5). Patent Owner adds that "Steffee's curved fastener is driven **directly through bone graft material** to hold graft in place, not to anchor a rigid

implant” like the ’805 patent is directed to. *Id.* at 65 (citing Ex. 1016, 2:45–48). Thus, Patent Owner argues that one of ordinary skill in the art “seeking to improve interbody fusion fixation would not have looked to Steffee’s bone graft fastener.” *Id.* (citing *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011)).

Petitioner responds arguing that Steffee is analogous art because it “is directed toward interbody fusion using anchors to fix graft between vertebrae, and the ’805 [p]atent is directed toward interbody fusion using anchors to fix an implant between vertebrae.” Pet. Reply 29. Petitioner adds that Steffee is also reasonably pertinent to “the problems confronted by the ’805 inventor, e.g., improving the reliability and success rate of interbody fusion.” *Id.* at 30 (citing Pet. 84–85; Ex. 1002 ¶¶ 193–198).

Based on the full record, we agree with Petitioner that Steffee is directed to analogous art. The scope of analogous prior art is defined as: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

The ’805 patent states that it “pertains to spinal implants and surgical procedures for spinal fusion and stabilization.” Ex. 1001, 1:20–21. The ’805 patent identifies “a need in the art for an improved method to effect a more rapid, reliable fusion between unstable vertebral segments and avoid the considerable medical and economic impact of failed spinal fusions.” *Id.* at 2:1–4. As Petitioner points out, “Steffee is directed toward interbody fusion using anchors to fix graft between vertebrae.” Pet. Reply 29; Ex. 1016, 1:10–19. Although Steffee does not disclose an interbody fusion

implant, it is similarly directed to a “fastener for securing bone graft in position between a pair of bone portions to be interconnected by the bone graft.” Ex. 1016, 2:29–32.

The analogous art inquiry does not require that the reference disclose the same type of implant or identical structural environment. Instead, a reference may be analogous if it is reasonably pertinent to the problem faced by the inventor. Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that it was known in the art “that one reason fusion implants fail was due to migration of the implant” and “one reason migration occurred was due to forces acting on the implant, including through its anchors or fasteners.” Pet. 84–85 (citing Ex. 1002 ¶¶ 194–195; Ex. 1016, 1:11–20; Ex. 1033, 23:48–50; Ex. 1032, 4:61–64; Ex. 1034, 13:15–30; Ex. 1030, 1:31–39). Given that Steffee’s teaches curved fasteners to improve fixation stability in a fusion environment, we find it is reasonably pertinent to the problem of improving spinal fusion reliability and reducing migration. We are persuaded that a person of ordinary skill seeking to improve spinal fusion reliability and anchoring stability would have considered Steffee reasonably pertinent. We thus find that regardless whether Steffee is from the same field of endeavor as the ’805 patent it is reasonably pertinent to the particular problem faced by the inventor of the ’805 patent. *See Bigio*, 381 F.3d at 1325.

Patent Owner asserts that the addition of Steffee still fails to cure the deficiencies identified in Blain and Bray. PO Resp. 65–69. More particularly, Patent Owner argues that

Steffee teaches a curved **fastener** where the curvature resides **in the fastener itself**—the fastener follows a curved path through bone graft (EX-1016, 2:45–48, Fig. 5). There is no implant with internal channels, no fusion member with engineered channel

geometry, and no separate anchoring members traversing through channels.

Id. at 65. Thus, “Steffee’s standalone curved fastener driven directly through bone graft provides no teaching of an intervertebral fusion member containing precisely engineered curved channels through which separate anchoring members traverse.” *Id.* at 66.

We are not persuaded by Patent Owner’s argument that Steffee lacks an implant with internal curved channels. As Petitioner correctly notes, it does not rely on Steffee for such a disclosure. Pet. Reply 34. Rather, Petitioner relies on Blain for the interbody fusion implant and fastener channels, and on Steffee for the teaching of curved fasteners and their fixation benefits in a fusion context. *See* Pet. 84–91. And, in doing so, the asserted combination modifies Blain’s implant channels to accommodate Steffee’s curved fasteners.

On this point, Mr. Culbert explains that one of ordinary skill in the art using Steffee’s rigid curved fasteners with Blain’s implant would have recognized that “the shape of the implant channels should match the shape of the anchor shaft to facilitate guiding the anchors into the vertebral bodies” because Steffee’s “curved anchors are rigid and cannot deform to conform to anchor channels that follow a straight path.” Ex. 1002 ¶ 205. We find Mr. Culbert’s opinion to be credible and supported by Blain’s disclosure that guide members “may be linear or non-linear” and that non-linear guide members may facilitate access to difficult anatomical sites. Ex. 1004, 8:8–16. Therefore, Patent Owner’s argument is unpersuasive because it attacks Steffee in isolation and does not address the combined teachings.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to “replace Blain’s straight fasteners with Steffee’s

curved fasteners to ‘minimize post-surgery migration’ and ‘prevent backing out’” (PO Resp. 66–67 (citing Pet. 89–91; Ex. 1002 ¶¶ 169, 201)) because “Blain already prevents backing out via anti-rotation locking” (*id.* at 67 (citing Ex. 1004, 5:44–57)).

We are not persuaded by Patent Owner’s argument that Blain’s anti-rotation mechanism eliminates any motivation to use Steffee’s curved fasteners. At as initial matter, we note that the Petition identifies that Blain’s anti-rotation feature “helps prevent the fasteners 6 from ‘backing out’ of the vertebral bodies and/or implant channel due to reverse-rotation.” Pet. 60 (citing Ex. 1002 ¶ 135). In contrast, Petitioner relies on Steffee’s curved anchors to “minimize the lateral forces acting on the anchor and the implant, thereby minimizing lateral movement (or migration) of the implant.” *Id.* at 87 (citing Ex. 1002 ¶ 202). In its Reply, Petitioner explains that

Steffee’s curved anchors helps prevent them from pulling ***out of the bone***. Pet., 86–88. The curved anchors thus provide improved attachment ***to the bone***, rather than simply locking the fusion member and anchors together while leaving the anchors (and thus implant as a whole) more susceptible to loosening from the bone via migration. *Id.*

Pet. Reply 32. Therefore, even if Blain’s anti-rotation feature reduces one mode of fastener backing out, it does not negate the motivation to use Steffee’s curved anchors to improve resistance to migration, loosening, or pullout forces.

We also credit the unrebutted declaration testimony of Mr. Culbert who explains “a non-linear anchor would minimize the lateral forces acting on the anchor and the implant, thereby minimizing lateral movement (or migration) of the implant” (Pet. 86–87 (citing Ex. 1002 ¶ 202)), and as such, provide a predictable improvement in fixation stability. *See* Ex. 1002

¶¶ 201–205. Thus, we determine that Blain’s anti-rotation mechanism does not eliminate or otherwise undercut the motivation to incorporate Steffee’s curved fasteners. Rather, Steffee provides a known alternative fixation approach with predictable benefits in resisting migration and improving fixation stability. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (obviousness does not require incorporating all teachings of one reference into another).

In addition, Patent Owner argues that Petitioner provides “no motivation” to support its contention that one of ordinary skill in the art would have “redesign[ed] Blain’s external tool to have curved guide tubes matching Steffee’s fastener curvature.” PO Resp. 67. According to Patent Owner, “Blain’s single reference to a ‘non-linear guide member’” (*id.* (citing Ex. 1004, 8:14–16)) is insufficient “motivation to combine incompatible systems from different fields addressing different problems” (*id.* at 68).

We are not persuaded by Patent Owner’s argument that Petitioner provides “no motivation” to modify Blain’s guide tubes. To begin, we note that Patent Owner mischaracterizes Petitioner’s rationale. Petitioner does not rely solely on Blain’s statement that guide members may be non-linear. Rather, Petitioner relies on Steffee’s teaching of curved fasteners and their fixation benefits (Pet. 84–91), Blain’s express disclosure that guide members “may be linear or non-linear” (Ex. 1004, 8:8–16) and Mr. Culbert’s un rebutted declaration testimony that one of ordinary skill in the art would have understood that a rigid curved fastener requires a corresponding curved guide path to avoid interference or jamming (Ex. 1002 ¶¶ 205–210). Petitioner’s reasoning supplies a rational underpinning for the proposed modification.

We also reject Patent Owner’s characterization of Blain and Steffee as incompatible systems from different fields. Both references address spinal fusion fixation, and as discussed above, Steffee is reasonably pertinent to improving spinal fusion reliability and reducing migration. Patent Owner offers only attorney argument and no expert testimony rebutting Petitioner’s evidence that the proposed modification would have been within ordinary mechanical skill and would have predictably accommodated Steffee’s curved fasteners. On this record, we credit the unrebutted declaration testimony of Mr. Culbert. Ex. 1002 ¶¶ 192–210. Accordingly, we find that Petitioner has articulated sufficient motivation, with rational underpinning, for modifying Blain’s guide tubes and implant channels to be curved when incorporating Steffee’s curved fasteners.

Patent Owner argues last that Petitioner has failed to demonstrate a reasonable expectation of success because the proposed combination would require one of ordinary skill in the art to undertake extensive modifications, including “(1) abandoning Blain’s threaded screw system, (2) replacing straight guide tubes with curved guide tubes, (3) redesigning implant channels for curved fastener trajectories, and (4) ensuring curved geometry achieves stable fixation.” PO Resp. 69. We disagree.

As an initial matter, Patent Owner overstates the scope and complexity of the proposed modification. Patent Owner alleges that “Petitioner offers no analysis of these challenges” (PO Resp. 69), however, we find Petitioner adequately explains that

modifying Blain to incorporate a curved anchor would have required simply replacing the anchoring screws 6 of Blain with curved barbed anchors similar to those of Steffee and modifying the fastener channels (of implant 2) and guide tube 18 channels (of guide instrument 14) to have shapes

complementary to the curved anchors, such that the fastener channels are curved.

Pet. 88 (citing Ex. 1002 ¶ 206). Relying on the un rebutted declaration testimony of Mr. Culbert, Petitioner asserts that “the use of curved anchors with spinal implants was not novel” (*id.* at 87 (citing Ex. 1002 ¶ 206 (citing Ex. 1035, 2:57–61; Ex. 1019, 7:14–25))) and the proposed modifications “would require only the use of basic machining principles well known to a POSA” (*id.* at 91 (citing Ex. 1002 ¶ 210)).

“The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (“[F]ailure to consider the appropriate scope of the . . . patent’s claimed invention in evaluating the reasonable expectation of success . . . constitutes a legal error that [is] review[ed] without deference.”) (citation omitted) (alteration in original). The expectation of success need only be reasonable rather than absolute. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (“[C]ase law is clear that obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.”).

Here, Blain teaches that its guide members “may be linear or non-linear,” that non-linear guide members may facilitate access to difficult anatomical sites, and that “[n]on-linear or flexible drills, screw drivers and other tools are known in the art and may be used with the non-linear guide members.” Ex. 1004, 8:8–16. Thus, Blain confirms that non-linear guide structures and tools for use with such structures were known in the art.

Steffee demonstrates that curved fasteners themselves were known and operable in spinal fusion-related applications. Ex. 1016, 1:29–36, 2:45–48. And, as Petitioner points out, Steffee teaches that its curved anchors are “simple yet extremely effective” for interbody fusion. Pet. Reply 32 (citing Ex. 1016, 2:29–33). Thus, Steffee supports the conclusion that one of ordinary skill in the art would have reasonably expected curved fasteners to provide stable fixation when incorporated into a fusion system.

Based on the full record, Petitioner demonstrates by a preponderance of the evidence that Blain (with or without Bray) and Steffee teach or suggest all the limitations of claims 5 and 16, and that an ordinarily skilled artisan would have had a reason to implement these teachings to arrive at the subject matter of these claims with a reasonable expectation of success. Patent Owner does not present evidence on objective indicia of nonobviousness. Thus, for the reasons discussed above, we determine Petitioner demonstrates by a preponderance of the evidence that claims 5 and 16 would have been obvious over Blain (with or without Bray) and Steffee. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. Nothing in the record suggests that Petitioner’s proposed combination of known prior art elements according to their known functions would involve more than routine engineering efforts.

III. CONCLUSION¹⁵

After considering the evidence and arguments presented in the Petition, the Patent Owner’s Response, and the Petitioner’s Reply, we

¹⁵ 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*

determine that a preponderance of the evidence establishes that claims 1–6, 11, 12, 15–17 of the '805 patent are unpatentable, as shown in the following table:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–6, 11, 12, 15–17	102/103	Blain	1–4, 6, 11, 12, 15, 17	5, 16 ¹⁶
1–6, 11, 12, 15–17	103	Blain, Bray	1–4, 6, 11, 12, 15, 17	5, 16 ¹⁷
5, 16	103	Blain, Bray, Steffee	5, 16	
Overall Outcome			1–6, 11, 12, 15–17	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6, 11, 12, 15–17 of the '805 patent have been shown by a preponderance of the evidence to be unpatentable; and

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

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).

¹⁶ We treat Petitioner as no longer maintaining its challenges to claims 5 and 16 under anticipation and obviousness over Blain.

¹⁷ We treat Petitioner as no longer maintaining its challenges to claims 5 and 16 under obviousness over Blain and Bray.

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