

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner.

IPR2025-00226
Patent 8,460,385 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 1–5, 7, and 9 (the “challenged claims”) of U.S. Patent 8,460,385 B1 (Ex. 1001, “the ’385 patent”). Paper 2 (“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 1–5, 7, and 9 of the ’385 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. 9.

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 IPR2025-00225 (PTAB). Pet. 9; Paper 4, 2.

D. Overview of the '385 Patent

The '385 patent is titled "FUSION MEMBER FOR INSERTION BETWEEN VERTEBRAL BODIES." Ex. 1001, code (54). The '385 patent describes "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." *Id.* at 9:17–21.

Figure 4 of the '385 patent illustrates "the fusion member which includes channels through which anchoring mechanisms can be inserted and advanced." *Id.* at 4:39–41.

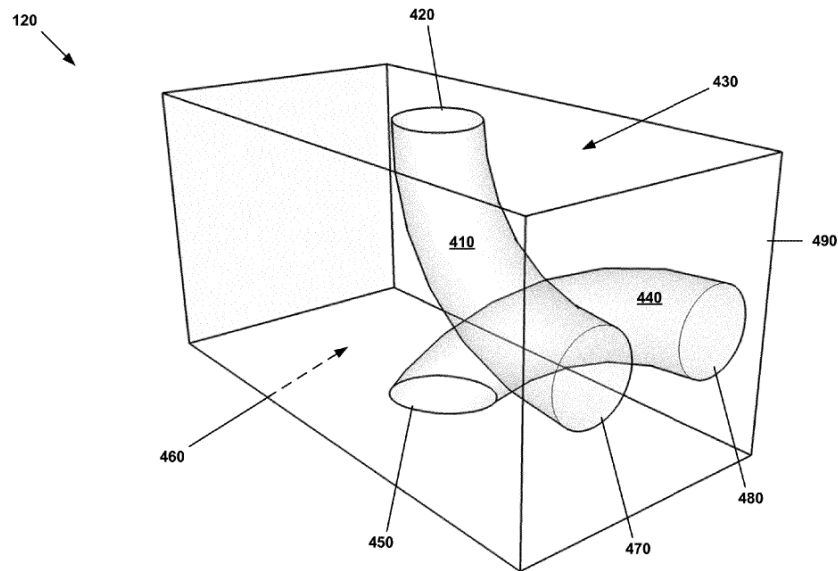


Figure 4

Figure 4 depicts a perspective view of fusion member 120 that includes channels 410 and 440 through which anchoring mechanisms can be inserted and advanced. *Id.* at 9:53–55. Figure 35 of the '385 patent illustrates “anchoring members that have been advanced through the semicircular tubular channels of the fusion member into the marrow space of the vertebral bodies.” *Id.* at 5:47–50.

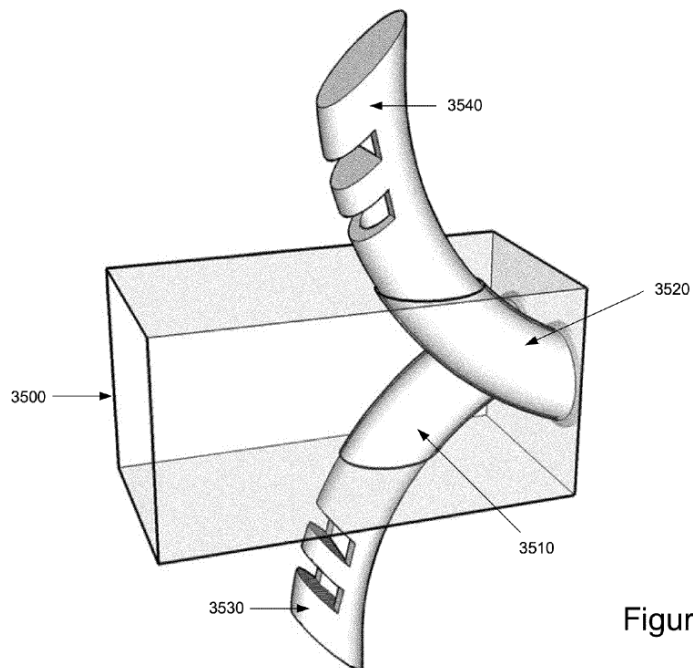


Figure 35

Figure 35 depicts a detailed view of fusion member 3500 that includes two curved anchoring members 3530 and 3540 fully advanced through curved semicircular channels 3510 and 3520 and “into the marrow spaces of the vertebral bodies (not pictured) below and above the fusion member.” *Id.* at 23:21–27.

E. Illustrative Claim

Petitioner challenges claims 1–5, 7, and 9 of the ’385 patent. Pet. 11. Challenged claim 1 is the sole independent claim. Claim 1 is illustrative and is reproduced below.

1. A fusion device comprising:
 - a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel;
 - a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and
 - a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body,wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other.

Ex. 1001, 26:56–27:11.

F. Asserted Grounds and Evidence

Petitioner asserts that claims 1–5, 7, and 9 of the ’385 patent are unpatentable on the following grounds (Pet. 14–15):

Claims Challenged	35 U.S.C. §³	Basis
1–5, 7, 9	103	Moskowitz ⁴
1–5, 7, 9	103	Hess ⁵
1–5, 7, 9	103	Moskowitz, Steffee ⁶

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

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).

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

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 ’385 patent’s priority date is before the AIA’s amendments to § 103, this decision refers to the pre-AIA versions of § 103. See Pet. 15 (“The earliest possible priority date of the ’385 Patent is March 27, 2008.”).

⁴ US 7,942,903 B2, issued May 17, 2011 (Ex. 1004, “Moskowitz”).

⁵ US 8,075,593 B2, issued Dec. 13, 2011 (Ex. 1006, “Hess”).

⁶ US 4,790,303, issued Dec. 13, 1988 (Ex. 1005, “Steffee”).

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. of Calif.*, 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 or metals and materials engineering), and at least five years of experience consisting of (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. 17 (citing Ex. 1002 ¶ 49). Petitioner also asserts that “[m]ore education can supplement practical experience and vice versa.” *Id.* (citing Ex. 1002 ¶ 49). “Patent Owner does not dispute the proffered definition for a POSA.” PO Resp. 9.

Based on the full record, we determine that Petitioner’s undisputed proposed level of skill is reasonable and consistent with the ’385 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. “channel”

Throughout the challenged claims, “channel” appears together with “curved” in the term “curved channel.” For example, claim 1 recites “the fusion member comprising a first curved channel and a second curved channel,” “a first anchoring member configured to insert through the first curved channel,” and “second anchoring member configured to insert through the second curved channel.” Ex. 1001, 26:58–59, 26:60–61, 26:65–66. Prior to institution, Petitioner asserted that one of ordinary skill in the art would “understand the claim term ‘channel’ to refer to a passage through which something moves or is conveyed.” Pet. 18 (citing Ex. 1002 ¶ 54). And, for purposes of our Decision on Institution, we adopted Petitioner’s proposed construction as being “consistent with the intrinsic record.” Institution Dec. 10.

In response, Patent Owner argues that “the term ‘channel’ as used in the ’385 [p]atent is readily understood by a POSA in context without needing explicit construction” and the plain and ordinary meaning should apply. PO Resp. 9–10. According to Patent Owner, the ’385 patent “consistently uses ‘channel’ to refer to a pathway within the fusion member through which an anchoring member traverses” and “explicitly states that channels may have different shapes and sizes and need not have a constant diameter, indicating the patentee did not intend to narrow the term beyond its common understanding.” *Id.*

Petitioner replies noting that Patent Owner’s understanding “is substantively identical to Petitioner’s construction (‘a passage through which something moves or is conveyed’), specifically applied to an anchoring member.” Pet. Reply 6 (Pet. 18; PO Resp. 9–10). Thus, Petitioner concludes that “[t]he parties thus agree with the Board’s construction.” *Id.*

Based on the full record, we agree with Petitioner that the parties’ positions on the meaning of the term “channel” are “substantively identical.” Because we see no difference between the parties’ position on the meaning of “channel,” we continue to adopt Petitioner’s proposed construction as it is consistent with the plain language of the claims and Specification. *See* Pet. 18 (citing Ex. 1001, 9:42–44, 9:53–55, 10:63–66, 11:47–63, 14:25–31, 14:65–67, 16:32–35, 22:51–57, 24:55–67) (The Specification uniformly refers to a “channel” as “a passage through which something (e.g., an anchoring member) traverses.”).

2. “*curved*”

As discussed above, throughout the challenged claims, “curved” appears together with “channel” in the term “curved channel.” Prior to institution, Petitioner asserted that the term “curved” is broad enough to

“receive both linear fastening members and curvilinear fastening members.” Pet. 22–23. According to Petitioner, this construction was based on Patent Owner’s applied interpretation of the term “curved channel” advanced in litigation. Pet. 19–24, 33. In our Decision on Institution, we declined to adopt Petitioner’s proposed construction of what it purported to be Patent Owner’s applied construction in the parallel litigation. *See* Institution Dec. 11–12 (explaining reasons why we did not adopt Petitioner’s proposed construction).

Alternatively, in its Petition, Petitioner suggested that a “curved” channel may have “a narrower meaning requiring the channel to follow a curved path (instead of the straight path identified in the accused products).” Pet. 24. Although our Decision on Institution did not adopt this narrower construction because it was not necessary for purposes of institution, we did find it “be consistent with the ’385 patent’s disclosure.” Institution Dec. 12–13 (citing Ex. 1001, 15:49–53; Ex. 1029, 1).

In 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 refers to a channel following a curved trajectory, distinct from a straight one.” PO Resp. 12.

Petitioner replies noting that the only difference between Patent Owner’s proposed construction and Petitioner’s alternative construction is “the inconsequential substitution of ‘trajectory’ for ‘path.’” Pet. Reply 6–7.

Thus, Petitioner concludes that the parties agree “on the construction of ‘curved’ channel.” *Id.* at 7.⁷

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. To the extent, Patent Owner’s proposed construction uses “trajectory” while Petitioner’s uses “path,” we agree with Petitioner that the difference is inconsequential, and as such, we adopt the parties agreed-upon construction and construe a channel that is “curved” to mean a channel following a curved trajectory.

D. Obviousness over Moskowitz and the Knowledge of a Person of Ordinary Skill in the Art

Petitioner asserts that claims 1–5, 7, and 9 are unpatentable as obvious over Moskowitz and the knowledge of a person of ordinary skill in the art. Pet. 30–61 (citing Exs. 1001, 1002, 1004). However, as we stated in our Decision on Institution, Petitioner’s arguments regarding the application of Moskowitz and the knowledge of a person of ordinary skill in the art are based on an unreasonable construction of the term “curved channels” that is broad enough to “‘receive both linear fastening members and curvilinear fastening members’” (Pet. 22–23), which we declined to adopt. *See* Institution Dec. 22 (citing Pet. 33) (“Petitioner argues that Moskowitz discloses ‘curved channels’ based on Patent Owner’s ‘applied interpretation of curved channel advanced in litigation.’”).

⁷ 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 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”).

Based on the complete record, as discussed *supra*, Petitioner agrees with Patent Owner that one of ordinary skill in the art “would understand ‘curved channel’ to refer to ‘a channel following a curved trajectory [or path], distinct from a straight one.’” *Supra* § II.C; Pet. Reply 7 (citing PO Resp. 11–12). At the oral hearing, Petitioner acknowledged that it had conceded its ground based only on Moskowitz under the parties’ agreed construction because that ground relied on “straight channels.” Tr. 58:18–30.

Based on Petitioner’s statements at the hearing, we treat Petitioner as no longer maintaining its challenge to claims 1–5, 7, and 9 under Moskowitz and the knowledge of one of ordinary skill in the art. We therefore do not reach the merits of Petitioner’s challenge to claims 1–5, 7, and 9 under Moskowitz. We address Petitioner’s challenges to claims 1–5, 7, and 9 only under obviousness over Hess and obvious over the combination of Moskowitz and Steffee.

E. Obviousness over Hess and the Knowledge of a Person of Ordinary Skill in the Art

Petitioner asserts that claims 1–5, 7, and 9 are unpatentable as obvious over Hess and the knowledge of a person of ordinary skill in the art. Pet. 61–84. Petitioner also relies on the declaration testimony of Mr. Culbert (Ex. 1002) to support its arguments. *Id.* Patent Owner responds to Petitioner’s assertions. *See* PO Resp. 40–55.

We address Petitioner’s contentions and Patent Owner’s arguments below, beginning with a brief overview of Hess. For the following reasons, we determine Petitioner has not shown by a preponderance of the evidence that claims 1–5, 7, and 9 are unpatentable over Hess.

1. Overview of Hess (Ex. 1006)

Hess is directed to “an interspinous implant with deployable wings for treating lumbar spinal stenosis.” Ex. 1006, 1:19–24. Hess discloses that its

device includes a body portion having an interior cavity, a plurality of locking wings adapted and configured to move between a stowed position retracted within the interior cavity of the body portion and a deployed position extended from the interior cavity of the body portion, and means for moving the plurality of locking wings from the stowed position to the deployed position.

Id. at 2:6–13. More particularly, Hess discloses that its interior cavity includes “curved guide tracks 19,” which enable “locking wings 14a–14d” to move from a stowed position to an outward position in order to engage vertebral positions of the spinous process and lock the implant in place. *Id.* at 7:14–32, 10:46–61. Reproduced below, Figures 10A and 10B illustrate Hess’s locking wings in a stowed position and a deployed position, respectively.

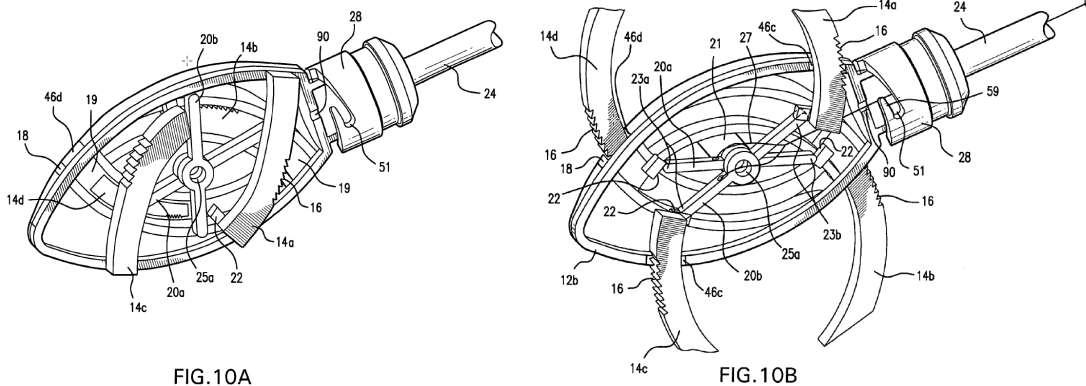


Figure 10A “is a perspective view of the interspinous implant of the subject invention, in cross-section to illustrate the four locking wings and two locking wheels in a stowed position.” *Id.* at 5:53–55. Figure 10B “is a perspective view of the interspinous implant of the subject invention, in

cross-section to illustrate the four locking wings and two locking wheels in a deployed position.” *Id.* at 5:56–58.

2. *Analysis*

Petitioner acknowledges that Hess’s device is “directed to a spinal implant used primarily for interspinous process decompression procedures that can be percutaneously introduced into the interspinous space” (Pet. 61 (quoting Ex. 1006, 2:3–6)), but relying on the declaration testimony of Mr. Culbert, argues that one of ordinary skill in the art would have understood that it would also be “suitable and desirable for use as an intervertebral spinal implant with only minimal modifications” (*id.* at 62 (citing Ex. 1002 ¶ 122)). According to Petitioner one of ordinary skill in the art would have been motivated to modify Hess’s device because it includes “curved anchors, which provide advantages over straight anchors, to better ensure a successful spinal fusion procedure.” *Id.* at 63 (citing Ex. 1002 ¶¶ 123–125). And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art “would have had a reasonable expectation of success in modifying the dimensions of Hess’s device and in using it as an intervertebral implant” because Hess “itself envisioned modifying its shape and dimensions” and “the internal components of Hess’s device do not require its bullet shape.” Ex. 1002 ¶ 128; Ex. 1006, 7:7–13.

In response, Patent Owner argues that Petitioner’s proposed ground of unpatentability based on Hess and the knowledge of one of ordinary skill in the art is deficient because it “relies on improper modification of non-analogous prior art and fundamentally misrepresents how the apparatus disclosed in Hess functions relative to the unique structural and functional requirements imposed by the challenged claims.” PO Resp. 40 (emphasis omitted). Patent Owner contends that Petitioner improperly suggests that

Hess's interspinous implant, which is "intended for interspinous process decompression (IPD) by stabilizing the posterior spinous processes" would be "easily convertible into an interbody fusion device suitable for stabilizing the vertebral bodies." *Id.* at 40–41 (emphasis omitted). According to Patent Owner, "[t]his approach fails because it minimizes the structural differences and conflicting functional objectives inherent in modifying a device intended for the posterior elements of the spine for use in the anterior load-bearing column" (emphasis omitted). *Id.* at 41. Patent Owner also argues that "[w]hile Hess describes its implant as an adjunct to spinal fusion, its primary function is stabilizing the spinous processes using locking wings that deploy laterally via a ratcheting mechanism to fixate bone through expansion" (emphasis omitted). *Id.* (citing Ex. 1006, 2:6–13, 7:33–45).

We are persuaded by Patent Owner that Petitioner has not shown sufficiently that Hess combined with the knowledge of one of ordinary skill in the art teaches or suggests the fusion device recited in claim 1. Petitioner contends that it would have been obvious to one of ordinary skill in the art to have "modif[ied] Hess's device for use as an intervertebral fusion device" (Pet. 61–67), but Hess is directed primarily to a spinal implant "for interspinous process decompression procedures that can be percutaneously introduced into the interspinous space." Ex. 1006, 2:1–6. Hess explains that once its spinal implant is placed between spinous processes,

[t]he locking wings 14a–14d fixate the adjacent spinous processes. While the implant 10 is used primarily as a spacer between spinous processes, the selectively deployable wings 14a–14d enable the implant 10 to be used to distract the spinous process as well. Advantageously, once the wings 14a–14d are deployed to fixate the spinous processes, migration of the implant 10 is prevented.

Id. at 7:38–45. The goal of Hess is to distract and maintain separation between the spinous processes in order to decompress the spinal canal, and thus, “relieve pressure on the spinal cord and nerves by increasing the area of the spinal canal.” Ex. 1006, 1:32–34, 1:50–52, 2:1–6. In contrast, the ’385 patent identifies that “the goal is to achieve solid bony fusion between the involved endplates and eliminate the symptoms caused by motion and associated degenerative and other reactive changes between these unstable vertebral segments.” Ex. 1001, 1:53–57. Thus, Hess’s disclosed implant is designed to distract and stabilize the spinous processes, not to promote solid bony fusion between adjacent vertebral bodies. Consequently, we agree with Patent Owner that “converting Hess for intervertebral fusion would require eliminating its core dynamic stabilization functionality—directly contradicting Hess’s stated design objectives.” PO Resp. 42 (citing Ex. 1006, 2:5–26, 7:43–45).

We also are not persuaded that Petitioner adequately explains why a person of ordinary skill would have modified Hess’s implant in the manner proposed. Petitioner contends that only “minimal modifications” to Hess’s shell dimension and shape would be required for intervertebral use. Pet. 61–67; Ex. 1002 ¶¶ 122–128. However, simply modifying the shape and size of Hess’s shell does not, without more, support a motivation to redesign Hess’s device from a posterior interspinous implant engaging spinous processes to an interbody implant positioned between vertebral bodies and anchored into vertebral bodies. Here, Hess discloses that modifying its dimensions serves to “preserv[e] mobility and alignment.” Ex. 1006, 7:5–7. Conversely, the ’385 patent’s fusion implant serves to limit mobility between vertebrae by achieving “solid bony fusion between the fusion member and the adjacent vertebral bodies.” Ex. 1001, 24:67–25:3.

Although Hess states that the implant may be used “as an adjunct to spinal fusion procedures” (*id.* at 6:49–52), we do not find that statement, without more, to disclose or suggest reconfiguring Hess’s interspinous implant as an “a fusion member configured to position between first and second vertebral bodies,” as required by limitation [1.1]. At most, Hess’s “adjunct to” statement suggests that the interspinous implant may be used in connection with, or in support of, a fusion procedure. It does not explain how or why Hess’s implant would be redesigned for placement between two adjacent vertebral bodies, nor does it teach that Hess’s locking wings would be reoriented or adapted to anchor into vertebral bodies rather than spinous processes.

On this point, Mr. Culbert states that “[t]he only changes required to modify Hess for use as an intervertebral implant would be to modify the dimensions of Hess’s shell, which was ‘dimensioned and configured for placement between the spinous processes’” (Ex. 1002 ¶ 126 (citing Ex. 1006, 7:3–4)), but Mr. Culbert does not explain how Hess’s locking wings and guide tracks would be reoriented or adapted to function as anchoring members that are inserted into adjacent vertebral bodies rather as opposed to spinous processes. Instead, Mr. Culbert simply states that “Hess’s locking wings *would* engage and at least partially penetrate the superior and inferior adjacent vertebrae” (emphasis added) (Ex. 1002 ¶ 135) without explaining how or why one of ordinary skill in the art would have made the modification with a reasonable expectation of success.

Hess’s disclosure that its shell may have shape variations to match adjacent bone (Ex. 1006, 7:7–13) also does not adequately explain why a person of ordinary skill would have had a reason to redesign Hess’s device for a different intervertebral environment, or why such a redesign would

preserve the claimed arrangement of “curved channels,” i.e., guide tracks, and “anchoring members,” i.e., locking wings. And, to the extent Hess discloses matching the shell to “the profile of the adjacent bone when deployed” (Ex. 1006, 7:11–13), Hess never suggests adapting the shell for placement between two adjacent vertebral bodies or for use as a fusion cage, it discloses that the “shell 12 is dimensioned and configured for placement between the spinous processes of symptomatic disc levels” (*id.* at 7:2–4). Thus, we agree with Patent Owner that the proposed modification “minimizes the structural differences and conflicting functional objectives inherent in modifying a device intended for the posterior elements of the spine for use in the anterior load-bearing column” (emphasis omitted). PO Resp. 41.

For the reasons discussed above, we determine that Petitioner’s reliance on Mr. Culbert’s testimony amounts to more than just providing a motivation to modify Hess. Here, it amounts to relying on expert testimony to supply a missing limitation. As such, Petitioner’s arguments are not persuasive to demonstrate that the prior art teaches the limitations of the claim by a preponderance of the evidence. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, 16 (PTAB Aug. 24, 2022) (precedential) (explaining that relying on expert testimony “is particularly problematic in cases where, like here, expert testimony is offered not simply to provide a motivation to combine prior-art teachings, but rather to supply a limitation missing from the prior art.”).

Accordingly, although Hess discloses a spinal implant with curved guide tracks and deployable locking wings, Petitioner has not shown by a preponderance of the evidence that a person of ordinary skill would have modified Hess’s interspinous implant to arrive at the fusion device of claim

1 with a reasonable expectation of success. We therefore determine that Petitioner has not established that claim 1 is unpatentable as obvious over Hess and the knowledge of one of ordinary skill in the art. Claims 2–5, 7, and 9 rely on the same flawed motivation, and, as such, we determine that Petitioner fails to show by a preponderance of the evidence that claims 2–5, 7, and 9 would have been unpatentable as obvious over Hess and the knowledge of one of ordinary skill in the art.

F. Obviousness over Moskowitz and Steffee

Petitioner asserts that claims 1–5, 7, and 9 are unpatentable as obvious over Moskowitz and Steffee. Pet. 84–96. Petitioner also relies on the declaration testimony of Mr. Brad Culbert (Ex. 1002) to support its arguments. *Id.* Patent Owner responds to Petitioner’s assertions. *See* PO Resp. 55–71.

We address Petitioner’s contentions and Patent Owner’s arguments below, beginning with a brief overview of Moskowitz and Steffee, and the evidence and arguments related to the motivation to combine Moskowitz and Steffee. For the following reasons, we determine Petitioner has shown by a preponderance of the evidence that claims 1–5, 7, and 9 are unpatentable over Moskowitz and Steffee.

1. Overview of Moskowitz (Ex. 1004)

Moskowitz is directed to

a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus.

Ex. 1004, 1:20–27. An exemplary embodiment of Moskowitz’s “screw box” 100 is depicted in Figure 1B, reproduced below.

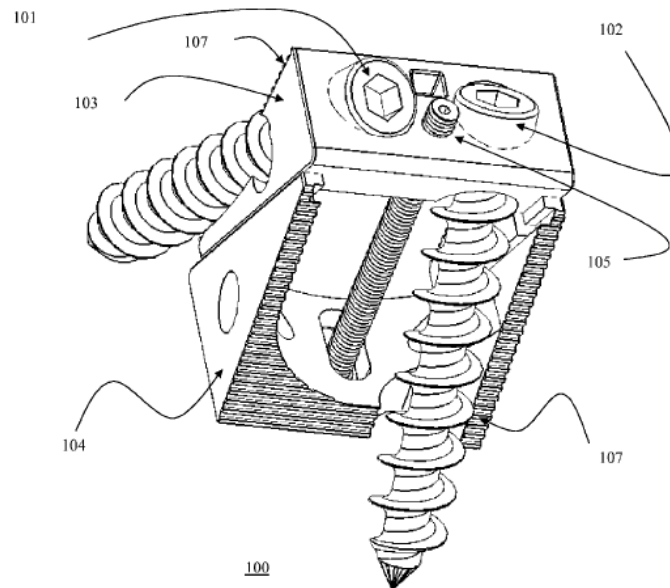


Fig. 1B

Figure 1B illustrates “intervertebral screw box with one lateral oriented BDFT screw and one medially oriented BDFT screw.” *Id.* at 6:22–25. Moskowitz describes that its “screw box” is designed “to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies.” *Id.* at 2:43–45. More particularly, Moskowitz discloses that “[t]he housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively.” *Id.* at 2:45–49.

2. Overview of Steffee (Ex. 1005)

Steffee is directed to “a fastener for securing bone graft between a pair of bone portions.” Ex. 1005, 1:8–9. More particularly, 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.

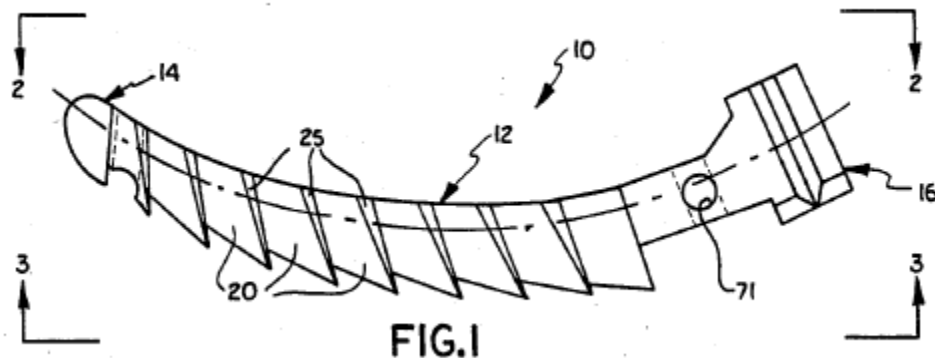


Figure 1 depicts elongated curved fastener 10 including shank portion 12 with “pointed end 14 and at its opposite end has a driving head portion 16” along with a plurality of barbs 20 spaced along the shank portion 12. *Id.* at 2:33–38. According to Steffee, as “fastener 10 is driven into the bone portion, 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.

3. Analysis of Claim 1

Petitioner asserts that claim 1 is unpatentable as obvious over Moskowitz and Steffee. Pet. 84–94 (citing Exs. 1001, 1002, 1004, 1005); *see also* Pet. 30–48 (Petitioner’s contentions regarding Moskowitz). We address Petitioner’s contentions below, beginning with the motivation to combine Moskowitz and Steffee.

We use Petitioner’s notations to identify the claim elements. *See* Pet. 98 (Petitioner’s challenged claim listing).

a) Motivation to Combine

Petitioner asserts that one of ordinary skill in the art would have been “motivated to use Steffee’s curved anchors with Moskowitz’s screw box to minimize potential migration of the screw box after implantation.” Pet. 84 (citing *id.* at 88–90). According to Petitioner, “Steffee taught that forces tending to cause sagittal or lateral movement of the fastener (and thereby migration of the implant) can be minimized or eliminated by using a curved fastener that increases the entry angle of the fastener to near-perpendicular.” *Id.* at 88. Thus, Petitioner asserts that one of ordinary skill in the art would have been “motivated to use Steffee’s curved anchors with Moskowitz’s screw box to lower the forces (acting through Moskowitz’s existing screws) that tended to cause migration of fusion implants.” *Id.* (citing Ex. 1002 ¶ 169).

Petitioner also points out that “Moskowitz’s anchors are threaded screws” (Pet. 89 (citing *id.* at 30–48)), and Petitioner asserts that one of ordinary skill in the art would have

understood that such screws could strip (e.g., due to misalignment or over-torquing), which would reduce the stability of engagement between the fusion member and vertebrae. Ex. 1002 ¶ 170. Because the fasteners in Steffee do not contain threads, and further contained barbs to prevent the fastener from backing out (Ex. 1005, 2:61–68), a POSA would have understood that such fasteners would not be subject to such stripping. Ex. 1002 ¶ 170. Therefore, a POSA would have been motivated to use similar curved fasteners having barbs to eliminate the risk of stripping inherent when using Moskowitz’s screws. *Id.*

Pet. 89. In addition, Petitioner contends that one of ordinary skill in the art would have “had a reasonable expectation of success in making this modification because it would only require the use of known machining

techniques, and because the use of both curved anchors and curved channels had already been shown successful in spinal implants.” *Id.* at 84. Petitioner provides several reasons to support its contention. *See id.* at 90–91.

In response, Patent Owner argues that Petitioner’s proposed combination of Moskowitz and Steffee is deficient because it is based on an impermissible hindsight reconstruction of “fundamentally distinct and non-analogous fixation technologies, resulting in a system that fails to meet the essential functional and structural limitations claimed in the ’385 [p]atent.” PO Resp. 55. According to Patent Owner, Petitioner seeks to replace Moskowitz’s threaded screws with Steffee’s curved, barbed fasteners, but the “combination collapses due to the underlying functional incompatibility of the systems.” *Id.* at 56. Patent Owner explains that “Moskowitz achieves fixation via threaded rotation/screwing into the vertebral body using rigid cylindrical guides designed for threaded screw insertion” whereas Steffee “achieves fixation by impact/driving barbed fasteners through bone graft material.” *Id.* (emphasis omitted) (citing Exs. 1004, 1005). Patent Owner contends that one of ordinary skill in the art would have to “choose between these antithetical insertion mechanics” and that adopting Steffee’s impact-driven fasteners would “undermine[] the stable, rigid cylindrical guiding system described by Moskowitz.” *Id.* at 56–57. Patent Owner further argues that Steffee’s curved fasteners are designed for “securing bone graft between vertebral bodies—not for use with intervertebral implants,” and that Petitioner offers “no non-hindsight motivation to redesign Moskowitz’s straight screw guides” into curved channels “capable of navigating a complex curvilinear trajectory.” *Id.* at 57–58.

Patent Owner also argues that the proposed combination still does not disclose “the specialized structural elements central to the ’385 [p]atent’s

novel fixation mechanism: chemical fusion augmented by cement injection.” PO Resp. 58 (emphasis omitted). In this regard, Patent Owner contends that claim 1 requires “anchoring member” having a “central lumen and perforated tips’ specifically for injecting Polymethyl Methacrylate (PMMA) or other hardening polymer into the marrow space to yield ‘[s]olid mechanical fusion’” (*id.* (citing Ex. 1001, 3:34–56, 4:5–12, 14:40–42, 21:57–65)), and argues that “[n]either Moskowitz’s threaded screw nor Steffee’s barbed fastener possesses or suggests this hollow, perforated structure necessary for fluid delivery” (*id.*).

In Patent Owner’s view, “Petitioner attempts to solve the flaw of Moskowitz’s anchor (potential stripping/migration) by substituting the equally deficient fixation method of Steffee (barbed pins without lumens),” but this “modification fails to bridge the critical gap regarding the absence of the specialized PMMA delivery system.” PO Resp. 59 (citing Pet. 88–91). Consequently, Patent Owner contends that one of ordinary skill in the art “would have no motivation or reasonable expectation of success for combining features to create a hollow, flexible needle capable of traversing a curved path for PMMA injection.” *Id.* In addition, Patent Owner contends that because Steffee’s barbed fasteners “cannot be adjusted or repositioned without damaging bone tissue,” their use would defeat “Moskowitz’s fundamental adjustability feature provided by its expandable design.” *Id.*

Patent Owner’s arguments do not undermine Petitioner’s showing because they depend largely on importing unclaimed limitations from the ’385 patent’s Specification into claim 1. Claim 1 does not require a specialized PMMA delivery system, central lumens, perforated tips, flexible needles, and/or any specific “chemical fusion” mechanism. Instead, claim 1 requires a fusion member with first and second curved channels (limitation

1.1) and first and second anchoring members configured to insert through those channels and partially into vertebral bodies while portions remain within fusion member (limitation 1.2). Ex. 1001, 26:56–27:11. To address these limitations, the Petition relies on Moskowitz’s “screw box” as disclosing a fusion member positioned between vertebral bodies (Pet. 30, 92 (citing Ex. 1002 ¶¶ 175–176)) and Steffee’s curved fasteners/anchors (*id.* at 92) with Moskowitz’s existing screw/drill guides being modified “to accommodate the curved anchors” (*id.* at 90 (citing Ex. 1002 ¶ 171)).

As Petitioner correctly points out, Patent Owner’s PMMA and flexible-anchor arguments are not claim limitations, noting that dependent claim 8 separately recites the “anchoring members are made of a flexible material” and dependent claim 10 separately recites that the anchoring members comprise “perforation[s] for delivering a hardening material.” Pet. Reply 8–10 (citing Ex. 1001, 27:57–60, 28:10–13). In addition, the ’385 patent’s Specification confirms that in some embodiments, “the anchoring members may be without a central lumen or perforations along their shaft” and that the “injection of polymer materials may not be needed to anchor the vertebral bodies to the fusion member.” Ex. 1001, 26:32–49. Thus, Patent Owner’s contention that claim 1 requires a “central lumen and perforated tips” for PMMA injection is inconsistent with the language of the claims and Specification. *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (rejecting arguments “not based on limitations appearing in the claims”).

Patent Owner’s “hindsight” and “non-analogous fixation technologies” arguments also fail because we are persuaded that Petitioner has set forth sufficient articulated reasoning with rational underpinning in support of its assertion that one of ordinary skill in the art would have been “motivated to use Steffee’s curved anchors with Moskowitz’s screw box to

minimize potential migration of the screw box after implantation.” Pet. 84–91 (citing Ex. 1002 ¶¶ 159–173). Relying on the unrebutted declaration testimony of Mr. Culbert, Petitioner asserts that those of ordinary skill in the art would have understood “that one reason spinal fusions failed was due to migration of the implant during the initial stabilization period,” and that, “at least one reason such migration occurred was due to forces acting on the implant, including through its anchors or fasteners attached to the vertebrae.” *Id.* at 85–86 (citing Ex. 1002 ¶¶ 164–165).

Petitioner explains that “Steffee solved this problem via curved anchors that traverse the vertebral bodies at a near-perpendicular entry angle.” *Id.* at 86 (citing Ex. 1002 ¶ 166). According to Mr. Culbert’s unrebutted testimony, one of ordinary skill in the art would have “understood that Steffee’s curved fasteners would not be exposed to the same forces (acting through a moment arm) that tended to cause prior art fasteners to lose effectiveness,” and thus, recognized that “the use of curved fastener would inhibit migration of the implant by decreasing the forces applied to the fastener and fusion member (in comparison with a straight anchor entering at a flatter angle).” *Id.* at 87–89 (citing Ex. 1002 ¶¶ 168–169). We agree with Petitioner that this motivation is not hindsight because it comes from the references and known problems in the art, and because Steffee is analogous art. Pet. Reply 11–16. As Petitioner correctly notes,

Steffee is from the same field of endeavor, and a POSA would have understood Steffee to explicitly disclose its use in in [sic] spinal fusion procedures. Petition, 84–85 (citing Ex. 1002 ¶ 163). Steffee is also reasonably pertinent to the problem disclosed in the ’385 [p]atent, because Steffee’s use of curved anchors to prevent migration applies to the problem of failed spinal fusion. *Id.*, 85–88 (citing Ex. 1002 ¶¶ 164–166, 168).

Id. at 13. And, to the extent Patent Owner argues that a person of ordinary skill in the art would not have considered Steffee because Steffee’s “primary function is securing bone graft between vertebral bodies—not for use with intervertebral implants” (PO Resp. 57), we disagree. That argument overlooks Mr. Culbert’s explanation that bone graft was commonly used with intervertebral implants, including in Moskowitz’s own device. Pet. 28–29, 84–89 (citing Ex. 1002 ¶¶ 158, 163, 169; Ex. 1004, 3:39–44). Thus, Steffee’s teachings regarding curved fasteners for securing bone graft and reducing forces that could compromise stable fixation would have been reasonably pertinent to a person of ordinary skill in the art seeking to improve fixation and reduce migration in an intervertebral fusion device.

Equally unpersuasive is Patent Owner’s argument regarding a “functional incompatibility” between Moskowitz’s threaded screws and Steffee’s impact-driven barbed fasteners. Patent Owner’s argument equates to a bodily incorporation argument but the principle for the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference but rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Further, the Supreme Court has emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418. As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 421. “The combination of familiar elements according to

known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416.

Relying on the unrebutted declaration testimony of Mr. Culbert, Petitioner asserts that “modifying Moskowitz’s screw/drill guides to accommodate and complement Steffee’s anchors would have involved the use of machining techniques well known to a POSA.” Pet. 91 (citing Ex. 1002 ¶ 173). Mr. Culbert adds that “the use of curved anchors in spinal implants was already well known.” Ex. 1002 ¶ 173. Also relying on the unrebutted declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art “would have recognized that, because the fasteners require impact for insertion (as opposed to turning as for a screw), that an impact driving tool would be required in place of Moskowitz’s screwdriver,” and notes that “Steffee itself teaches the use of such a tool.” Pet. 90 (citing Ex. 1002 ¶ 172; Ex. 1005, 3:1–13).

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, i.e., replacing Moskowitz’s straight threaded screws with curved fasteners like Steffee’s and modifying Moskowitz’s screw/drill guides to have complementary curved paths. To the extent Patent Owner argues that Petitioner’s rationale “grossly understates the wholesale redesign required” and ignores “critical technical barriers,” including maintaining the structural integrity of Moskowitz’s sliding-base expansion mechanism while creating semicircular channel paths, we agree with Petitioner that Patent Owner’s “wholesale redesign” assertions are unsupported attorney argument and do not rebut Mr. Culbert’s unrebutted declaration testimony. PO Resp. 60; Pet. Reply 17–18, 23–26; Ex. 1002 ¶¶ 172–173, 185. Here, Mr. Culbert explains that a person of

ordinary skill would have had a reasonable expectation of success because modifying the guides would have involved known machining techniques, and curved anchors and curved channels had already been used in spinal implant contexts. Pet. 90–91; Ex. 1002 ¶ 173. Accordingly, we find that the record adequately demonstrates that, at the time of the invention, a person of ordinary skill in the art would have been motivated to modify Moskowitz’s existing screw or drill guides to accommodate Steffee’s curved anchors and would have had a reasonable expectation of success in doing so.

We also are not persuaded by Patent Owner’s assertion that Steffee’s curved fasteners, which Patent Owner contends “cannot be adjusted or repositioned without damaging bone tissue” (PO Resp. 59 (citing Ex. 1005, 2:61–68)), are incompatible with, or would render inoperable, “Moskowitz’s fundamental adjustability feature provided by its expandable design with triangular sliding bases and height-adjusting screw” (*id.* (citing Ex. 1004, 7:38–48)). Instead, we agree with Petitioner that Moskowitz’s expandable design adjusts implant height and depth before anchor insertion. Pet. Reply 24. Here, Moskowitz describes adjusting the screw box using the height/depth adjusting screw, then drilling or starting pilot holes, and then inserting the transvertebral screws through the screw guides. Ex. 1004, 7:41–48, 10:57–64. Therefore, even assuming Steffee’s barbed fasteners could not be repositioned after insertion, such a limitation would not defeat or otherwise render inoperable Moskowitz’s adjustability because the screw box is adjusted before the fasteners are driven into bone. Patent Owner identifies no contrary expert evidence showing that the proposed combination would be inoperable or would undermine the ability to adjust the implant before anchor placement. Pet. Reply 17–18, 24.

b) Claim 1.0 [Preamble]: “A fusion device comprising:”

Petitioner asserts that Moskowitz discloses an intervertebral fusion device. Pet. 91 (citing *id.* at 30 (citing Ex. 1004, Abs., 3:66–67)).

In response, Patent Owner argues that Moskowitz fails to disclose “a fusion device configured with the structural and functional features required by the claimed invention.” PO Resp. 60–61 (citing Ex. 1001, 2:29–48); *see also id.* at 27–28 (arguing that Moskowitz’s screw box fails to disclose “a stable intervertebral spacer with curved channels as claimed in the ’385 [p]atent”).

We have considered Petitioner’s arguments and evidence, and Patent Owner’s counterarguments and find, on the complete trial record, that to the extent the preamble is limiting, Petitioner demonstrates, by a preponderance of the evidence, that the combination of Moskowitz and Steffee renders obvious the subject matter of the preamble.

The preamble of claim 1 recites only “[a] fusion device comprising,” and Petitioner relies on Moskowitz as disclosing a spinal fusion apparatus. Pet. 91; *see also* Pet. 30. In particular, Moskowitz describes “[a] self-drilling bone fusion screw apparatus” in which “[t]he screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together.” Ex. 1004, Abs., 3:66–67. To the extent Patent Owner argues that Moskowitz lacks curved channels, Petitioner does not rely on Moskowitz as disclosing such. Instead, as discussed in greater detail above and below, the Petition suggests modifying Moskowitz’s screw box by replacing Moskowitz’s straight threaded screws with Steffee’s curved fasteners and modifying Moskowitz’s screw/drill guides to have curved paths. Pet. 88–92 (citing Ex. 1002 ¶¶ 169–173, 175–176). Accordingly, Patent Owner’s argument that Moskowitz alone lacks all “structural and functional features” of the claimed

invention does not rebut Petitioner's showing based on the combination of Moskowitz and Steffee.

c) Claim 1.1: "a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel;"

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 92. More particularly, Petitioner asserts that in the proposed combination, "Moskowitz's screw box (as modified) is *a fusion member configured to position between first and second vertebral bodies.*" *Id.* (citing Ex. 1002 ¶ 175; Pet. 30–45). According to Petitioner, it would have been

obvious to use a curved channel, similar to those in Hess, to accommodate the use of a curved anchor, as disclosed in Steffee. A POSA would have found it obvious to modify Moskowitz's screw box to include *a first curved channel and a second curved channel* for use with Steffee's curved anchors as set forth above.

Id. (citing Ex. 1002 ¶ 176; Pet. 84–91).

In response, Patent Owner argues that "[n]othing in Steffee teaches or suggests routing curved fasteners through channels within an intervertebral fusion device," and Petitioner fails "to establish a non-hindsight motivation for a POSA to modify Moskowitz's rigid cylindrical guides into the precise complex, curvilinear path constraints required by the '385 [p]atent merely because a curved anchor exists in the field." PO Resp. 62. According to Patent Owner, "[c]reating semi-circular channel paths through Moskowitz's triangular sliding bases would require wholesale redesign that compromises the structural integrity required for the sliding base expansion mechanism." *Id.* Lastly, Patent Owner argues that even if the proposed combination could produce a "channel capable of passing a curved, non-threaded component,"

the asserted combination would still “lack[] the capacity or functional need to guide a flexible anchor along a precise arcuate path for deep tissue targeting and PMMA delivery, as taught by the ’385 [p]atent.” *Id.* at 63 (citing Ex. 1001, 3:40–53, 15:31–58).

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 Moskowitz and Steffee renders obvious the subject matter of limitation 1.1.

As an initial matter, we note that Petitioner does not rely on Steffee alone to teach routing curved fasteners through channels in an intervertebral fusion device. *See* Pet. Reply 16–17. Instead, Petitioner relies on the combined teachings of Moskowitz and Steffee. Pet. 91. Moskowitz discloses a “screw box” with “built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies” (emphasis omitted). Pet. 30–31 (citing Ex. 1002 ¶¶ 175–176; Ex. 1004, 2:40–51), 92. Steffee teaches curved fasteners/anchors that in the combination would progress along curved paths to “inhibit migration of the implant by decreasing the forces applied to the fastener and fusion member (in comparison with a straight anchor entering at a flatter angle).” Pet. 88–92 (citing Ex. 1002 ¶¶ 159–173, 174–176; Ex. 1005, 1:29–36, 2:45–48). Thus, Patent Owner’s argument that Steffee itself does not disclose channels in an intervertebral implant attacks the references individually rather than addressing what their combined teachings would have suggested to one of ordinary skill in the art at the time of the invention. Pet. Reply 16–17.

Patent Owner's remaining arguments regarding "hindsight" and "wholesale redesign" are not persuasive for the reasons discussed above Section II.D.3.a. We also note that Patent Owner's reliance on "flexible anchor," "deep tissue targeting," and "PMMA delivery" is misplaced for the same reasons discussed above in Section II.D.3.a. Claim 1.1 requires a fusion member comprising "a first curved channel and a second curved channel," it does not require flexible anchoring members, PMMA delivery, or deep-tissue targeting.

d) Claim 1.2: a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body, "

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 92–93. Petitioner asserts that Steffee's curved fastener has a driving head portion 16, similar to the head of Moskowitz's transvertebral screws (*see id.* at 42–45), which remains outside of, and is not driven into, the bone. *Id.* at 92 (citing Ex. 1005, 2:35–37, 2:55–61, 3:1–6, 4:35–42, Fig. 1; Ex. 1004, Fig. 1D). According to Petitioner, in the proposed combination, one of ordinary skill in the art "would have maintained this functionality just as in both Moskowitz and Steffee, such that at least this head portion would remain inside the screw box." *Id.* (citing Ex. 1002 ¶ 178). Petitioner contends that one of ordinary skill in the art "would have recognized that if the fastener heads did not remain in the implant but simply passed through the implant, they would not

affix the implant to the vertebrae.” *Id.* at 93 (citing Ex. 1002 ¶ 178). Petitioner lastly notes that “[a]s both Moskowitz and Steffee disclose the use of two screws or fasteners, Moskowitz-Steffee also possesses *a second anchoring member* configured like the first.” *Id.* (citing Ex. 1002 ¶ 178).

In response, Patent Owner argues that “neither Moskowitz nor Steffee discloses the specialized PMMA augmentation mechanism mandatory for coupling the fusion member as defined in the ’385 [p]atent. PO Resp. 63–64. In addition, Patent Owner contends that because Steffee’s barbed fasteners “cannot be adjusted or repositioned once inserted due to barbs that prevent backing out” (*id.* at 64 (citing Ex. 1005, 2:61–68)), their use would defeat “Moskowitz’s fundamental adjustability feature provided by its expandable design with triangular sliding bases and height-adjusting screw” (*id.* (citing Ex. 1004, 7:38–48)).

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 Moskowitz and Steffee renders obvious the subject matter of limitation 1.2.

At the outset, we find Patent Owner fails to establish that any of the alleged differences between either Moskowitz or Steffee relate to any particular recitation in argued limitation 1.2. Limitation 1.2 requires that each anchoring member passes through its respective curved channel, enters a corresponding vertebral body, and remains partly in the fusion member to couple the fusion member to that vertebral body, but it does not require “specialized PMMA augmentation mechanism mandatory for coupling.” Thus, Patent Owner’s arguments are directed to unrecited limitations. *See Self*, 671 at 1348.

Patent Owner's remaining argument directed to rendering "Moskowitz's fundamental adjustability feature" inoperable is not persuasive for the reasons discussed above Section II.D.3.a.

- e) *Claim 1.3: "wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other."*

Petitioner asserts that the combination of Moskowitz and Steffee discloses this limitation. Pet. 93–94. Petitioner provides the following version of Figure 1C of Moskowitz, annotated in blue, to illustrate first and second cross-sectional planes parallel to each other. *Id.* at 47–48 (citing Ex. 1004, Fig. 1C).

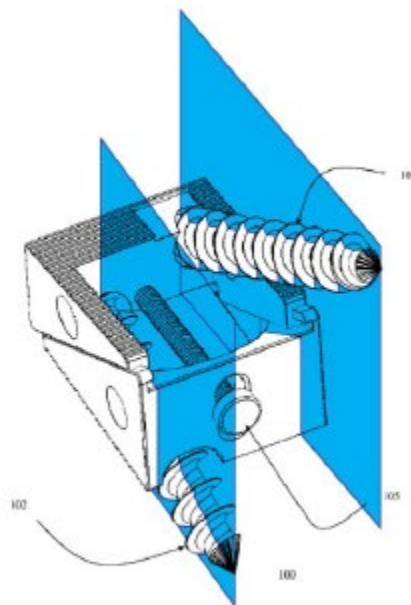


Fig. 1C

Figure 1C depicts Moskowitz's screw box with one lateral oriented screw and one medially oriented screw, and is annotated by Petitioner to

illustrate Moskowitz's channels having parallel cross-sectional planes. *Id.* According to Petitioner, one of ordinary skill in the art would have understood Moskowitz's "channels to have these cross-sectional planes not only based on Moskowitz's figures, but from its description explaining that the body of each screw member is 'laterally aligned with the box,' indicating that the channels along which the screws run are parallel to the box's sides." *Id.* at 48 (citing Ex. 1004, 5:11–18; Ex. 1002 ¶ 97). Petitioner adds that "Steffee also teaches that its anchors are inserted parallel to one another" (*id.* at 93–94 (citing Ex. 1005, Fig. 4)), and relying on the declaration testimony of Mr. Culbert, concludes that one of ordinary skill in the art "would have maintained the same cross-sectional planes in Moskowitz-Steffee as disclosed in Moskowitz itself, which are parallel" (*id.* at 93 (citing Ex. 1002 ¶ 179)).

In response, Patent Owner acknowledges that "Moskowitz discloses parallel channel orientations" (PO Resp. 64 (Ex. 1004, 5:11–18; Pet. at 93–94)), but argues that "this parallelism in Moskowitz results from the symmetry of accommodating rigid, linear-rotation screws within a box" (emphasis omitted) (*id.* at 64–65 (citing Ex. 1004, 7:49–62)). According to Patent Owner, "Petitioner provides no evidence that parallel cross-sectional planes would be maintained after wholesale redesign of Moskowitz's straight screw guides into semi-circular curved channels." *Id.* at 65 (citing Pet. 93–94).

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 Moskowitz and Steffee renders obvious the subject matter of limitation 1.3.

We are not persuaded by Patent Owner's argument. Patent Owner acknowledges that Moskowitz discloses parallel channel orientations. PO Resp. 64. Patent Owner's contention that such parallelism results from the use of rigid, linear screws does not adequately address why one of ordinary skill would not have maintained the parallel spatial relationship disclosed in Moskowitz when modifying the channels to accommodate the curved anchors as taught by Steffee. On this record, we credit the unrebutted declaration testimony of Mr. Culbert that the proposed modification would have been within the ordinary skill in the art and would have preserved the claimed parallel cross-sectional planes. Ex. 1002 ¶ 179.

f) Conclusion for Claim 1

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Moskowitz and Steffee renders obvious all of the limitations of claim 1.

4. *Claim 2 "The fusion device of claim 1, wherein the first and second cross-sectional planes are parallel to at least one surface of the fusion member."*

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 94 (citing Ex. 1002 ¶ 180), 48–49 (citing Ex. 1004, Fig. 1C; Ex. 1002 ¶ 98). Petitioner provides the following version of Figure 1C of Moskowitz, annotated in yellow, to illustrate first and second cross-sectional planes that are parallel to at least one surface of the fusion member. *Id.* at 48–49 (citing Ex. 1004, Fig. 1C).

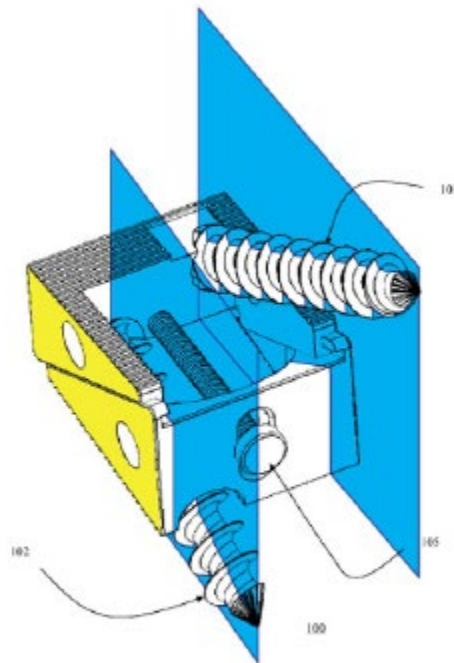


Fig. 1C

Figure 1C depicts Moskowitz's screw box with one lateral oriented screw and one medially oriented screw, and is annotated by Petitioner to illustrate "Moskowitz's *first and second cross-sectional planes are parallel to at least one surface of the fusion member.*" *Id.* at 48.

In response, Patent Owner argues that the proposed combination is deficient because "creating curved channels would fundamentally alter Moskowitz's geometry, and Petitioner provides no evidence that surface relationships would be maintained." PO Resp. 66 (citing Pet. at 94).

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 Moskowitz and Steffee renders obvious the subject matter of claim 2.⁸

Patent Owner contends that modifying Moskowitz to include curved channels would “fundamentally alter Moskowitz’s geometry” and that Petitioner provides no evidence that the claimed surface relationships would be maintained. PO Resp. 66. However, we agree with Petitioner “[t]he only proposed modification to the channel geometries is adding internal curvature, and there is no reason—certainly, no reason explained by [Patent Owner]—why merely changing internal curvature would somehow displace the terminal points of Moskowitz’s channels on the fusion member’s surfaces (and thus their plane orientation).” Pet. Reply 28 (citing Pet. 94; Ex. 1002 ¶¶ 180–182). Patent Owner does not identify persuasive evidence that curving the channels would necessarily change how the channels interface with the screw box surfaces in a manner inconsistent with claim 2.

5. *Claim 3 “The fusion device of claim 1, wherein neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.”*

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 94 (citing Ex. 1002 ¶ 181), 49–50 (citing Ex. 1004, Fig. 1C; Ex. 1002 ¶ 100). Petitioner provides the following version of Figure 1C of Moskowitz, annotated in yellow, to illustrate at least

⁸ Patent Owner’s arguments against Moskowitz regarding claim 2 are based on Moskowitz’s lack of “curved channels” and on unclaimed limitations (*see, e.g.*, PO Resp. 32 (“Moskowitz lacks the fundamental structural and functional characteristics of the elements defined in Claim 1 (functional curved channels, push-in PMMA anchors)”), and as such, not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

one surface of the fusion member is not parallel to the channels' planes. *Id.* at 49–50 (citing Ex. 1004, Fig. 1C).

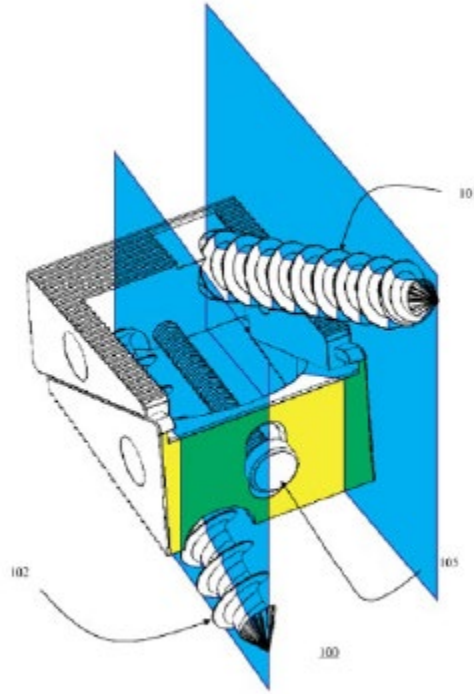


Fig. 1C

Figure 1C depicts Moskowitz's screw box with one lateral oriented screw and one medially oriented screw, and is annotated by Petitioner to illustrate that "neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member." *Id.* at 49 (emphasis omitted).

Other than asserting that "Petitioner makes the same unsupported assertion for Claim 3," Patent Owner does not provide specific argument with regard to claim 3. PO Resp. 66. Instead, Patent Owner relies on the arguments presented for claim 2 above.

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

the combination of Moskowitz and Steffee renders obvious the subject matter of claim 3.⁹

6. *Claim 4 “The fusion device of claim 1, wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member, wherein the first cross-sectional plane is not parallel to either of the two surfaces to which the first curved channel opens and the second cross-sectional plane is not parallel to either of the two surfaces to which the second curved channel opens.”*

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 94 (citing Ex. 1002 ¶ 182), 50–52 (citing Ex. 1004, Figs. 1B, 1C; Ex. 1002 ¶¶ 101–103). Petitioner provides the following side-by-side versions of annotated Figures 1B and 1C of Moskowitz.

⁹ Patent Owner’s arguments against Moskowitz regarding claim 3 are based on Moskowitz’s lack of “curved channels” and on unclaimed limitations (*see, e.g.*, PO Resp. 33 (“this argument fails because it relies on the same flawed antecedent basis as Claim 2 (lack of a functionally defined curved channel and the proper anchoring member)”), and as such, not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

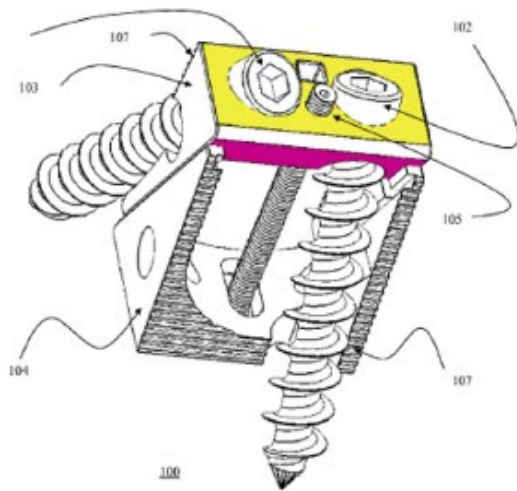


Fig. 1B

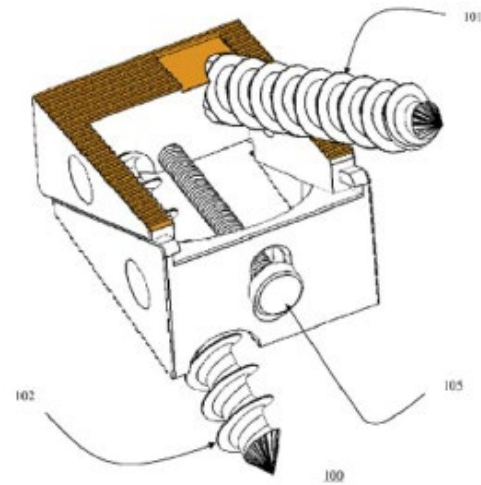


Fig. 1C

Figure 1B depicts a superior perspective of Moskowitz's screw box and Figure 1C depicts an inferior perspective. Ex. 1004, 6:22–26. With reference to the annotated Figures, Petitioner asserts that

the first curved channel (right) opens to at least two surfaces: the proximal surface (yellow) and a second top surface (pink). The second curved channel (Fig. 1B, left) also opens to the proximal surface (yellow). As shown in Fig. 1C, this channel (now on the right) also opens to an additional, bottom surface (orange). Thus, both curved channels open to at least two surfaces of the fusion member—a first (yellow) surface for both channels, and different second surfaces (pink or orange).

Pet. 50–51 (citing Ex. 1002 ¶¶ 101–102).

Petitioner also provides the following side-by-side versions of annotated Figures 1B and 1C of Moskowitz.

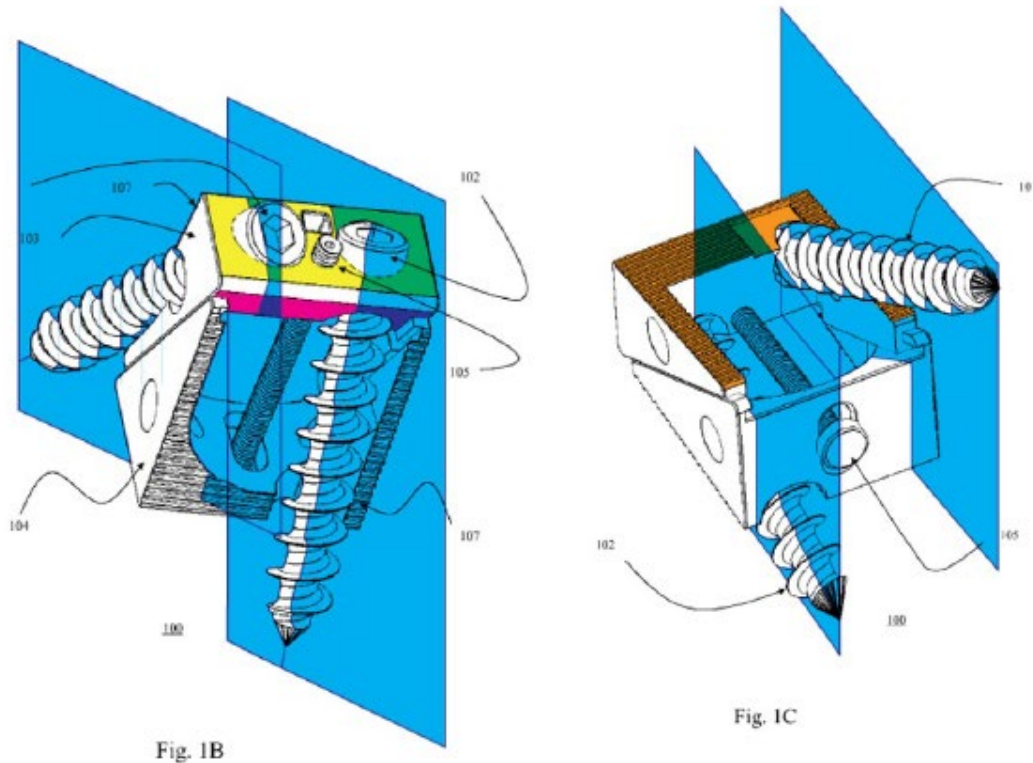


Figure 1B depicts a superior perspective of Moskowitz screw box and Figure 1C depicts an inferior perspective. Ex. 1004, 6:22–26. With reference to the second set of annotated Figures, Petitioner asserts that “neither of the first or second cross-sectional planes are parallel to any of the surfaces to which any of the curved channels open. Ex. 1002 ¶ 103. Rather, “the cross-sectional planes are perpendicular to each of the surfaces to which the channels open.” Pet. 51–52 (citing Ex. 1002 ¶ 103). Petitioner adds that “[t]he channels in the proposed combination would open to the same surfaces of the fusion member as in Moskowitz, with only the internal curvature of the channels being changed.” *Id.* at 94.

In response, Patent Owner contends that Petitioner’s “assertion ignores that creating curved channels would fundamentally change how channels interface with the screw box surfaces, and Petitioner provides no

evidence supporting this conclusory statement” (emphasis omitted). PO Resp. 66 (citing Pet. 94).

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 Moskowitz and Steffee renders obvious the subject matter of claim 4.¹⁰

Contrary to Patent Owner’s argument, Petitioner’s asserted combination does not require redesigning Moskowitz’s screw box surfaces. Instead, the Petition suggests modifying the path of Moskowitz’s internal channels to accommodate Steffee’s curved anchors while maintaining Moskowitz’s channel arrangement. Pet. 84–94. Thus, we agree with Petitioner “[t]he only proposed modification to the channel geometries is adding internal curvature, and there is no reason—certainly, no reason explained by [Patent Owner]—why merely changing internal curvature would somehow displace the terminal points of Moskowitz’s channels on the fusion member’s surfaces (and thus their plane orientation).” Pet. Reply 28 (citing Pet. 94; Ex. 1002 ¶¶ 180–182). Patent Owner does not identify persuasive evidence that curving the channels would necessarily change how the channels interface with the screw box surfaces in a manner inconsistent with claim 4.

¹⁰ Patent Owner’s arguments against Moskowitz regarding claim 4 are based on Moskowitz’s lack of “curved channels” (*see, e.g.*, PO Resp. 34 (“Because Moskowitz fails to disclose curved channels that follow curved paths through the fusion member, it cannot satisfy any dependent claim limitations”), and as such, are not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

7. *Claim 5 “The fusion device of claim 1, wherein the first and second curved channels open to a first surface of the fusion member but the first curved channel traverses to a second surface of the fusion member and the second curved channel traverses to a third surface of the fusion member; wherein the traversal of the first and second curved channels through the fusion member allows (i) the first anchoring member to enter the first surface of the fusion member but exit the second surface of the fusion member at a first desired location on the second surface of the fusion member and (ii) the second anchoring member to enter the first surface of the fusion member but exit the third surface of the fusion member at a second desired location on the second surface without hindering the first anchoring member's insertion through the fusion member.”*

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 95 (citing Ex. 1002 ¶ 183), 52–55 (citing Ex. 1002 ¶¶ 104–107). Petitioner asserts that

[a]s shown for claim 4, the first and second curved channel each open to a first surface—the proximal (yellow) surface through which the screws enter the box. The first curved channel opens to a second surface—the top (pink) surface, while the second curved channel opens to a third surface—the bottom (orange) surface.

Id. at 52 (citing Ex. 1002 ¶ 104). Petitioner explains that “the first curved channel opens to the top of the screw box, and its screw engages the superior vertebral body, while the second curved channel opens to the bottom, and its screw engages the inferior vertebral body.” *Id.* at 53 (citing Ex. 1002 ¶ 104). Petitioner contends that this is the same arrangement depicted in the Figure 16 of the ’385 patent. *Id.*

Petitioner further asserts that

[a]s shown for Claim 4, the first and second anchoring members each enter their respective channels at the proximal opening of the respective channel into the screw box. Each anchoring member also exits their respective surfaces, at a

desired location of the designers of the Moskowitz device. Ex. 1002 ¶ 106. Because the channels are parallel, so are the screws contained in the channels, and they enter and exit the surfaces of the screw box without hindering one another. Ex. 1002 ¶ 107.

Pet. 54–55.

In response, Patent Owner argues that Petitioner’s “assertion fails because Steffee’s straight-through bone graft fasteners do not traverse along curved paths to achieve precise exit locations as required by the ’385 [p]atent” (emphasis omitted). PO Resp. 67 (citing Ex. 1001, 9:42–55, 15:53–58).

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 Moskowitz and Steffee renders obvious the subject matter of claim 5.¹¹

Patent Owner’s argument is unpersuasive because it attacks Steffee individually rather than the proposed combination of Moskowitz and Steffee. Petitioner does not contend that Steffee alone discloses the claimed curved channels through a fusion member. Instead, Petitioner relies on Moskowitz for the fusion member and channels and on Steffee for curved anchors, with Moskowitz’s channels modified to follow curved paths that would accommodate Steffee’s curved anchors. Patent Owner does not identify persuasive evidence that such a modification would preclude the

¹¹ Patent Owner’s arguments against Moskowitz regarding claim 5 are based on Moskowitz’s lack of “curved channels” (*see, e.g.*, PO Resp. 35 (“Moskowitz’s straight channels do not ‘traverse’ in the manner contemplated by the ’385 [p]atent”), and as such, are not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

channels from traversing the fusion member as claimed, nor does Patent Owner show that claim 5 requires “precise exit locations” beyond what is claimed.

8. *Claim 7 “The fusion device of claim 1, wherein each anchoring member is configured to couple to a driving member, wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”*

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 95–96 (citing Ex. 1002 ¶ 185), 55–58 (citing Ex. 1002 ¶¶ 110–112; Ex. 1004, 8:63–9:1, 9:4–8, 10:60–64, 11:8–10). Relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would understand that Moskowitz’s

positioning tool 500a and driver assembly 550 comprise a driving member. Ex. 1002 ¶ 110. The positioning tool is coupled with the screws to position them in place, and the driver assembly is coupled with the screws when it engages to turn them to screw into the vertebral bodies. *Id.* Thus, each anchoring member is configured to couple to a driving member.

Id. at 56–57 (emphasis omitted). Also, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art would understand that Moskowitz’s “positioning tool and driver assembly are configured to decouple from the screws once the screws are satisfactorily engaged with the superior and inferior vertebral bodies.” *Id.* at 57 (citing Ex. 1002 ¶ 112).

With respect to Steffee, Petitioner asserts that “head 16 of Steffee’s curved fasteners each include grooves ‘adapted to receive gripping jaws . . . of a driving tool’ which ‘holds and drives the fastener 10 into the bone portions . . . and bone graft.’” Pet. 95 (citing Ex. 1005, 3:2–6).

Petitioner explains that one of ordinary skill in the art “would have modified Moskowitz’s positioning tools to accommodate a gripping and driving design such as that disclosed in Steffee to use Steffee’s curved fasteners.” *Id.* (citing Ex. 1002 ¶ 185). And, relying on the declaration testimony of Mr. Culbert, Petitioner asserts that one of ordinary skill in the art “would have reasonably expected that a driving tool similar to that disclosed in Steffee would have been readily adapted for use with Moskowitz’s screw box in the proposed combination.” *Id.* at 96 (citing Ex. 1002 ¶ 185).

In response, Patent Owner argues that neither Moskowitz nor Steffee teaches a “driving member” that provides

(1) **axial pushing or impacting force for the non-threaded anchor** insertion via “tapping, hammering, or simply pushing at its proximal end” (EX1001, 3:34–40, 21:57–61), and (2) a central lumen to serve as a “conduit for delivering polymers to the anchoring member” including PMMA injection through the anchoring member into vertebral bodies (EX1001, 3:45–53, 14:20–50, 14:40–42).

PO Resp. 68. Additionally, Patent Owner argues that “Steffee’s driving tool is designed to remain coupled to the fastener only during insertion, and the specification states the tool ‘holds and drives the fastener’ but does not describe a decoupling mechanism after PMMA injection as required by the ’385 [p]atent (EX1005, 3:1–13).” *Id.* at 69.

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 Moskowitz and Steffee renders obvious the subject matter of claim 7.¹²

Patent Owner’s argument is unpersuasive because claim 7 does not require the driving member to include a central lumen, deliver PMMA, inject polymer through the anchoring member, or decouple after PMMA injection. Nor does claim 7 specify any particular manner in which the driving member must “drive” the anchoring member. Thus, Patent Owner’s argument relies on embodiments disclosed in the Specification, rather than the claim language itself. *See Self*, 671 F.2d at 1348.

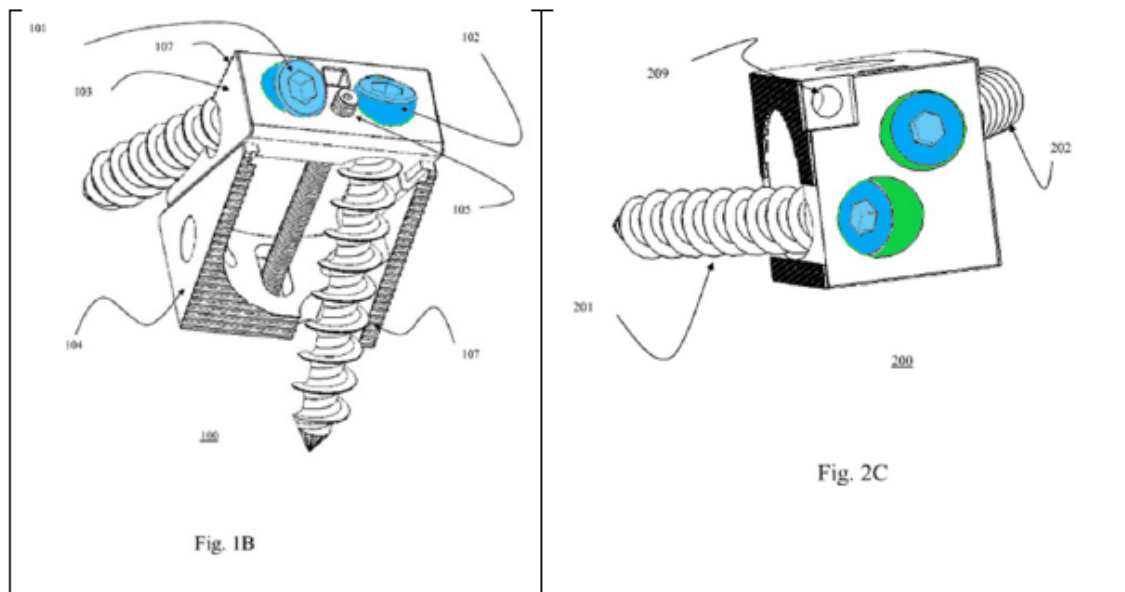
Here, Petitioner relies on Steffee’s tool that “holds and drives the fastener” as the claimed driving member. Pet. 95 (citing Ex. 1005, 3:1–13). Thus, Steffee teaches a driving member that drives the fastener during insertion, which is sufficient for the claimed limitation. Petitioner also notes that one of ordinary skill in the art would have understood that, like the driving member disclosed in Moskowitz, the driving member disclosed in Steffee would also “be removed after implantation.” Pet. 96 (citing Ex. 1002 ¶ 185), 57–58 (citing Ex. 1002 ¶ 112). And, contrary to Patent Owner’s argument, the absence of PMMA-delivery functionality or post-injection decoupling does not demonstrate that the asserted combination is deficient because neither feature is recited in claim 7.

9. *Claim 9 “The fusion device of claim 1, wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess, wherein each anchoring*

¹² Patent Owner’s arguments against Moskowitz regarding claim 7 are based on unclaimed limitations (*see, e.g.*, PO Resp. 37 (“Moskowitz’s driver assembly . . . lacks the required functionality for polymethyl methacrylate (PMMA) injection or push-in impact delivery”), and as such, are not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.”

Petitioner asserts that the combination of Moskowitz and Steffee renders obvious this limitation. Pet. 96 (citing Ex. 1002 ¶ 186), 58–61 (citing Ex. 1002 ¶¶ 115–117). Petitioner provides the following side-by-side versions of annotated Figures 1B and 2C of Moskowitz. Figures 1B and 2C are annotated in blue, to illustrate “that each transvertebral screw has a base or head.” Pet. 59–60 (citing Ex. 1002 ¶ 117). Figure 2C, is also annotated in green, to illustrate that “[t]he base or head fits within the cylindrical recess . . . inside the proximal surface of the screw box.” *Id.* (citing Ex. 1002 ¶ 117).



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

Moskowitz, “each channel also contained a seat inside the channel, or that the inclusion of such a seat was obvious” and “[t]he portion of each channel between the proximal opening and the seat comprises the *recess* for each *opening*.” Pet. 58 (citing Ex. 1002 ¶ 115), 42–46. Mr. Culbert explains that “[t]he insertion of each screw into the vertebral bodies, while partially remaining in the screw guide, with the screw head engaging the seat in each channel in the base, would be understood as comprises a coupling between the screw box and each vertebral body.” Ex. 1002 ¶ 93; *see also* Pet. 60 (citing Ex. 1002 ¶ 117). And, in the combination, Petitioner asserts that “head portion 16 of Steffee’s fasteners would fit in the channels’ recesses, as in Moskowitz itself.” Pet. 96 (citing Ex. 1002 ¶ 186).

In response, Patent Owner argues that “[t]he conventional seating of a rotating threaded screw (Moskowitz) or the reliance on barbed retention (Steffee) provides no structural suggestion or motivation for creating the highly specialized locking architecture demanded by Claim 9 for anchoring a non-threaded, PMMA-delivered system.” PO Resp. 71 (citing Ex. 1001, 16:63–17:27, 17:23–27).

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 Moskowitz and Steffee renders obvious the subject matter of claim 9.¹³

¹³ Patent Owner’s arguments against Moskowitz regarding claim 9 are based on unclaimed limitations (*see, e.g.*, PO Resp. 39 (“Moskowitz provides no disclosure of screw heads with specialized bases designed to fit within channel recesses for retention purposes”), and as such, are not persuasive against the combination of Moskowitz and Steffee for the reasons already discussed.

Patent Owner's argument is unpersuasive because it is not commensurate in scope with claim 9. Patent Owner argues that Moskowitz's threaded screw seating and Steffee's barbed retention do not suggest the "highly specialized locking architecture" allegedly required for a "non-threaded, PMMA-delivered system." PO Resp. 71. However, as Petitioner explains, "[t]here is no need for the combination to create a 'highly specialized locking architecture' for anchoring a 'PMMA-delivered system' because those are not claim limitations." Pet. Reply 30. Instead, Petitioner's asserted combination need only teach or suggest the limitations actually recited in claim 9. Accordingly, Patent Owner's argument does not undermine Petitioner's showing for claim 9.

10. Conclusion based on the combination of Moskowitz and Steffee

Consequently, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–5, 7, and 9 are unpatentable over the combination of Moskowitz and Steffee.

III. CONCLUSION¹⁴

After considering the evidence and arguments presented in the Petition, the Patent Owner's Response, and the Petitioner's Reply, we determine that a preponderance of the evidence establishes, as shown in the following table:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5, 7, 9	103	Moskowitz		1–5, 7, 9 ¹⁵
1–5, 7, 9	103	Hess		1–5, 7, 9
1–5, 7, 9	103	Moskowitz, Steffee	1–5, 7, 9	
Overall Outcome			1–5, 7, 9	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 7, and 9 of the '385 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.

¹⁴ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

¹⁵ We treat Petitioner as no longer maintaining its challenge to claims 1–5, 7, and 9 under obviousness over Moskowitz.

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FOR PETITIONER:

James Hall
Stephen Zinda
CABELLO HALL ZINDA, PLLC
james@chzfir.com
stephen@chzfir.com

FOR PATENT OWNER:

Michael Fuller
GARTEISER HONEA PLLC
sfuller@ghiplaw.com

Rene Vazquez
SINERGIA TECH. LAW GROUP, PLLC
rvazquez@sinergialaw.com