

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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GLOBUS MEDICAL, INC.,  
Petitioner,

v.

SPINELOGIK, INC.,  
Patent Owner.

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Case IPR2025-00226  
Patent No. 8,460,385

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**PATENT OWNER's RESPONSE**

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## I. INTRODUCTION

Patent Owner, Spinelogik, Inc. (“Spinelogik”), submits this Response to the Petition for Inter Partes Review of U.S. Patent No. 8,460,385 (Ex. 1001, “the ’385 patent”) filed by Petitioner Globus Medical, Inc. (“Petitioner”).

The Petition challenges claims 1-5, 7, and 9 of the ’385 patent (collectively, the “Challenged Claims”), including independent claim 1, from which the remaining Challenged Claims depend.

As explained below, the Board should find that none of the Challenged Claims are rendered obvious by the cited references, including U.S. Patent No. 7,942,903 (Ex. 1004, “Moskowitz”), U.S. Patent No. 8,075,593 (Ex. 1006, “Hess”), and U.S. Patent No. 4,790,303 (Ex. 1005, “Steffee”).

The Petition’s arguments are fundamentally flawed and rely on a distorted reading of the claims and the prior art. The lynchpin of the Petition is its attempt to improperly broaden the scope of the claimed “first **curved channel** and a second **curved channel**” to read on simple, *straight* path holes, based on a contrived claim construction argument.

Specifically, Ground 1 fails because its primary reference, Moskowitz, does

not teach "curved channels" as claimed. Moskowitz discloses a "screw box" with "built-in screw and/or drill guides" that follow a *straight* path. The Petition attempts to obscure this fatal deficiency by relying on a contorted claim construction argument, derived not from the patent's intrinsic evidence but from cherry-picked statements allegedly made by Spinelogik in the parallel district court litigation. Petitioner's own expert declaration (Ex. 1002) confirms this tactic, outlining an "applied construction" based on litigation materials (Ex. 1012, 1013) that supposedly deems a channel "curved" merely for having (1) a rounded opening, (2) a tube-like inner wall, or (3) a concave internal seat—features Petitioner argues are present in Moskowitz's straight guides. Petitioner advances this theory even while its expert explicitly acknowledges being *instructed* to use this "applied construction" without opining on its correctness.

This maneuver conveniently ignores that the expert also acknowledges the '385 Patent specification itself repeatedly describes embodiments where "curved" channels follow *a curved path* (e.g., tracing circular, elliptical, or parabolic arcs) and cause an anchoring member to "travel in a semi-circular path of movement"—a structure and function wholly absent from Moskowitz's straight guides. (EX1001, 15:53-58, 23:21-32, 16:63-65). Petitioner cannot rely on a dictionary definition of "channel" as merely a "passage" while simultaneously

manufacturing a complex, litigation-derived definition for "curved" to force the prior art onto the claims.

The Petition's other grounds are equally deficient. Ground 3 is a textbook case of impermissible hindsight, proposing to combine Moskowitz's straight-channel screw box with Steffee's fasteners for *bone graft*. This combination of disparate systems provides no teaching or motivation to arrive at the '385 Patent's specific geometry of *curved channels arranged in parallel cross-sectional planes*. Ground 2 fails at the outset, as it relies on Hess, a non-analogous *interspinous* device whose internal "locking wings" and "guide tracks" bear no structural or functional resemblance to the '385 Patent's claimed fusion member and anchoring system.

In short, the Petition asserts references that are either non-analogous or teach away from the invention. It proposes modifications based on impermissible hindsight, all while attempting to vitiate the '385 Patent's core inventive concept—its specific channel geometry—through a flawed and self-serving claim construction improperly imported from district court litigation.

Accordingly, the Petition should be denied.

## **II. SUMMARY OF THE '385 patent**

### **A. Specification of the '385 patent**

U.S. Patent No. 8,460,385 ("the '385 Patent"), entitled "Fusion Member for Insertion Between Vertebral Bodies," issued June 11, 2013, pertains generally to "spinal implants and surgical procedures for spinal fusion and stabilization" (Ex-1001, 1:29-30) and has an earliest priority date of March 27, 2008.

The '385 Patent purports to address deficiencies in prior art spinal fusion techniques. The specification acknowledges that while surgical fusion is often employed for back and neck pain stemming from conditions such as degenerative disc disease, "failure rates for spinal fusion surgeries remain unacceptably high, greater than 10 percent in most series" (Ex-1001, 2:7-9). While not explicitly detailing all failure modes, the background implies challenges in achieving stable, reliable fusion. Consequently, the patent posits "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" (Ex-1001, 2:10-13).

To meet this stated need, the invention proposes an apparatus comprising generally three main components: (1) a fusion member, (2) a delivery mechanism,

and (3) anchoring members (Ex-1001, 2:18-28). The core concept involves delivering the fusion member—described as "a shaped block (e.g., a rectangular or oblong block)" (Ex-1001, 2:29-30)—into the intervertebral space after disc removal. This fusion member is characterized by having "one or more channels (e.g., tubular channels)" (Ex-1001, 2:30-31).

Subsequently, anchoring members are advanced "through the one or more channels of the fusion member and into the marrow space of one or more of the vertebral bodies, in order to affix the fusion member to the vertebral bodies" (Ex-1001, 2:38-44). The specification contemplates various forms for these anchoring members, including "large gauge needles" (Ex-1001, 7:44-45), and notes they may possess features like "hollow channels and perforated tips in some embodiments" to facilitate injection of "polymethyl methacrylate (PMMA) or other bone cement or hardening polymer material" (Ex-1001, 7:48-54) for enhanced fixation. Surface contours on the anchoring members, such as "angled teeth and backfacing ridges," are also described to "prevent the anchoring members from being easily withdrawn from the bone" (Ex-1001, 8:24-35).

A significant aspect emphasized in the patent, particularly in relation to the claims challenged in the Petition, concerns the specific geometry and arrangement

of the channels within the fusion member. Independent claim 1, for instance, requires "a first curved channel and a second curved channel" (Ex-1001, 26:58-59). Moreover, the claim mandates a specific spatial relationship: "wherein the first curved channel has a first cross-sectional plane along a first path... and the second curved channel has a second cross-sectional plane along a second path..., wherein the first and second cross-sectional planes are parallel to each other" (Ex-1001, 27:4-11). Figure 4 is presented as illustrating channels 410 and 440 where "the cross-sectional planes of the fusion member channels 410 and 440 are parallel to each other but are not parallel to the right and left face of the fusion member 120" (Ex-1001, 10:1-5). Figures 46A and 46B are likewise described as depicting channels 4610 and 4620 that "traverse in parallel cross sectional planes with respect to each other but are non-parallel with respect to the faces of the fusion member" (Ex-1001, 23:66-24:3). Contrastingly, Figure 5B is described such that "the cross-sectional view of the two channels 530... are parallel to the right and left side of the fusion member 120" (Ex-1001, 10:63-11:4).

The function of this curved geometry is linked to the properties of the anchoring member. The specification explains that "the anchoring members comprise a flexible material" in some embodiments, which allows them to "bend to traverse the curved channels of the fusion member. (Ex-1001, 27:57-60). This

traversal, in turn, imparts a specific trajectory to the anchoring member's tip: The movement of the anchoring members through the curved channels and into the vertebral bodies generally causes the tips... to travel in a semi-circular path of movement. (Ex-1001, 15:50-58).

The system further includes a delivery mechanism, which may comprise a delivery housing and retention mechanism elements like "retention rods" (Ex-1001, 11:61-62) that engage "retention grooves" (Ex-1001, 10:20-21) on the fusion member to allow controlled attachment and detachment. Driving members are disclosed to advance the anchoring members, potentially involving intervening members and coupling mechanisms, some permitting pivoting (Ex-1001, 17:1-12; Fig. 14).

In summary, the '385 Patent describes an interbody fusion device intended for stabilization, characterized by a fusion block implant containing channels—specifically including embodiments with curved channels arranged in parallel cross-sectional planes—through which flexible anchoring members are passed to secure the implant to adjacent vertebrae.

**B. Level of Ordinary Skill in the Pertinent Art**

For purposes of this proceeding only, Patent Owner does not dispute the proffered definition for a POSA.

**C. Claim Construction**

Patent claims are construed according to their plain and ordinary meaning as understood by a Person of Ordinary Skill in the Art (POSA) at the time of the invention, viewed in the context of the entire patent, including the specification and prosecution history . As detailed further herein, Petitioner's invalidity arguments improperly rely on strained interpretations and artificially broad constructions, particularly regarding the term "curved channel," that contradict the intrinsic evidence. Patent Owner applies in this response the plain and ordinary meaning to the claim terms, rebutting Petitioner's specific proposals where necessary:

***1. "channel" (Claims 1, 3, 4, 5, 7, 9)***

- **Petitioner's Proposal (IPR Petition):** "a passage through which something moves or is conveyed".
- **Patent Owner's Position:** Plain and ordinary meaning. No construction necessary.

While Petitioner proposes a construction seemingly derived from dictionary definitions , the term "channel" as used in the '385 Patent is readily understood by a POSA in context without needing explicit construction. The specification consistently uses "channel" to refer to a pathway within the fusion member

through which an anchoring member traverses . The specification 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 . Attempting to formally construe such a basic term risks introducing unintended limitations or ambiguity. See, *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (courts need not construe every limitation). Therefore, the plain and ordinary meaning should apply.

## ***2. "curved" (Claim 1 and dependents)***

- **Petitioner's Proposal (IPR Petition):** Petitioner relies on an alleged "applied construction" purportedly derived from Spinelogik's infringement contentions in district court litigation, asserting a channel is "curved" if it has: (1) an opening with curvature; (2) an inner wall with curvature (tube-like); and/or (3) a radial curvature in an inner wall (e.g., a concave seat) . Petitioner also notes an alternative "narrower meaning requiring the channel to follow a curved path".
- **Defendant's Proposal (District Court):** "channel that has a curved path".
- **Patent Owner's Position:** Plain and ordinary meaning. No construction necessary.

Petitioner's primary argument relies on importing an extrinsic "applied construction" from pending litigation, a tactic explicitly permitted by *W. Digit. Corp. v. SPEX Techs., Inc.* for *Petitioner's convenience* but which does not

bind Patent Owner or reflect the correct meaning based on intrinsic evidence . This extrinsic construction improperly broadens "curved channel" to encompass features Petitioner alleges are present in Moskowitz's *straight* screw guides, such as rounded openings or internal seats . Petitioner's own expert applies this construction only because he was *instructed* to do so, offering no opinion on its correctness.

Such reliance on extrinsic arguments is unnecessary and improper, as the plain meaning is clear from the intrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (prosecution history often lacks clarity and is less useful than the specification). The '385 Patent specification consistently describes "curved channels" in embodiments where the channel follows a non-linear, *curved path*, such as tracing circular, semicircular, elliptical, or parabolic arcs . For instance, it explains that because "the fusion member channel is curved, the path that the anchoring member travels is also curved," causing the anchor tip to travel in a "semi-circular path of movement" . This description informs the POSA's understanding of what "curved channel" plainly means in the context of the patent.

Furthermore, Petitioner's proposed alternative—"channel that has a curved path"—is precisely the type of redundant paraphrasing discouraged by the Federal

Circuit. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (claim construction "is not an obligatory exercise in redundancy"). The 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.

### III. SUMMARY OF THE PRIOR ART

#### A. U.S. Patent No. 7,942,903 (Moskowitz) (Ex-1004)

*Moskowitz* is directed to a "self-drilling bone fusion screw apparatus," specifically an intervertebral device sometimes referred to as a "screw box". The apparatus aims to fuse vertebral bodies together (EX1004, Abstract). One embodiment describes an expandable screw box comprising two sliding bases (103, 104) connected by a height-adjusting screw (105) (EX1004, 7:37-40). Another embodiment describes a non-expandable screw box (200). Both embodiments feature "built-in screw and/or drill guides" allowing insertion of "two self drilling screws" (e.g., 101, 102 or 201, 202) into superior and inferior vertebral bodies (EX1004, 7:62-67). The screws traverse through these guides within the box. Optional holes (108, 208) allow for bone graft packing.

*Moskowitz's* device operates by placing the screw box between vertebrae (EX1004, 2:40-43). Screws are then inserted through the guides in the

box and driven into the adjacent vertebral bodies. The specification describes one screw angled superiorly and the other inferiorly (EX1004, 2:45-51). Figures such as 1C, 1D, and 2C illustrate these guides as channels allowing passage for the screws. The specification notes the screws are "laterally aligned with the box" (EX1004, 5:10-17). A positioning tool (500a) and driver assembly (550), potentially with a flexible shaft (552), are used for placement and insertion (EX1004, 8:63-9:1).

*Moskowitz's* apparatus differs significantly from the apparatus claimed in the '385 Patent. *Moskowitz* discloses a screw box with straight screw/drill guides designed to accommodate straight bone screws. It does not disclose the claimed "first curved channel and a second curved channel" following a curved path through the fusion member, nor does it teach anchoring members configured to traverse such curved paths. Furthermore, while *Moskowitz's* straight guides run in parallel planes, it inherently lacks the claimed structure of curved channels possessing distinct cross-sectional planes along a curved path that are parallel to each other, a key geometric limitation of the '385 Patent claims. *Moskowitz* teaches a fundamentally different anchoring geometry based on straight trajectories.

**B. U.S. Patent No. 8,075,593 (Hess) (Ex-1006)**

*Hess* is directed to a spinal implant "used primarily for interspinous process decompression procedures", although it mentions potential use "as an adjunct to spinal fusion" (EX1006, 2:3-6 and 6:49-52 respectively). The implant (10) comprises a shell or body portion (12) having an interior cavity and typically formed from upper (12a) and lower (12b) shell portions (EX1006, 6:59-65). Housed within the shell are a plurality (typically four) of deployable "locking wings" (14a-14d) which move between a stowed position within the shell and a deployed position extended outward (EX1006, 7:18-22). The shell contains internal "curved guide tracks" (19) that accommodate and guide the wings during deployment (EX1006, 7:29-31). A deployment mechanism, often involving coaxial locking wheels (20a, 20b) actuated by a deployment cable (27), moves the wings from the stowed to the deployed position (EX1006, 3:24-28, and 8:5-19). Ratchet teeth (16) on the wings engage pawl structures (18) near shell openings (46a-46d) to lock the wings in the deployed position (EX1006, 7:33-38; 3:18-23).

*Hess's* device operates by percutaneously introducing the implant (10), typically using a placement tool (24) and potentially guided by a stylet assembly, into the **interspinous space** between the spinous processes of adjacent vertebrae. Once positioned, the deployment cable (27) is actuated (e.g., pulled), causing the

locking wheels (20a, 20b) to rotate (EX1006, 9:48-10:32). This rotation pushes the locking wings (14a-14d) along their respective curved guide tracks (19) within the shell, causing them to extend outward through the shell openings (46a-46d) (EX1006, 8:5-19). In the deployed position, the wings are intended to engage and potentially penetrate the **spinous processes** of the adjacent vertebrae to fixate the implant and prevent migration. The ratchet teeth (16) engage the pawls (18) to maintain the deployed position (EX1006, 2:25-26; 7:18-20; 7:43-45; and 13:30-36).

*Hess's* implant differs fundamentally from the apparatus claimed in the '385 Patent. *Hess* is designed primarily for **interspinous** placement and fixation, engaging the *spinous processes*, not the *vertebral bodies* as required by the '385 patent claims. Its fixation mechanism involves **locking wings** that deploy *from within* the implant shell along internal guide tracks, contrasting sharply with the '385 patent's system of **separate anchoring members** that pass *entirely through* channels within the fusion member to penetrate the vertebral bodies. *Hess does not disclose* a fusion member having "a first **curved channel** and a second **curved channel**" through which separate anchoring members, like those of the '385 patent, traverse to couple the fusion member to the *vertebral bodies*. While *Hess* describes "curved guide tracks" (19) *within* its shell and mentions wings residing in parallel planes, these features relate to the internal deployment path of the wings for

engaging spinous processes and are structurally distinct from the claimed geometry of the '385 patent, which requires specific parallel cross-sectional planes associated with *through-channels* for separate anchors penetrating *vertebral bodies*. *Hess* teaches a different type of implant for a different anatomical location using a fundamentally different fixation structure and mechanism.

In summary, the 385 patent describes an apparatus designed for vertebral body fusion, featuring a block with push/tapped pins inserted through internal curved channels and optionally anchored by injected bone cement. The *Hess* patent describes an apparatus for interspinous stabilization, featuring a shell that deploys ratchet-locked, curved wings using a cable and wheel mechanism to mechanically fix the device posteriorly.

**C. U.S. Patent No. 4,790,303 (Steffee) (Ex-1005)**

*Steffee* is directed to "a fastener for securing bone graft between a pair of bone portions" (EX1005, 1:6-9). The fastener (10) is described as a "curved elongated member" having a shank portion (EX1005, 1:22-28). The core novelty resides in the utilization of an elongate curved member or shank configured for operative deployment such that it extends through the bone graft along the predictable line of resorption (EX1005, 1:29-36). This distinctive, curvilinear geometry ensures that the force applied by the resorbing bone graft acts generally along the longitudinal extent

of the shank, effectively preventing the formation of a damaging moment arm (EX1005, 1:29-36). Structurally, the fastener comprises a shank portion (12) featuring a pointed end (14) and a driving head portion (16), further characterized by a plurality of barbs (20) projecting outwardly therefrom (EX1005, 2:33-38).

The implantation procedure involves driving the fastener, which progresses along a curved path (A) through the bone graft and partially into the adjacent bone portions due to its curved configuration (EX1005, 2:45-48). The driving head (16) features opposite V-shaped grooves (30, 32) adapted to receive gripping jaws (40, 42) of a driving tool (38), which transmits the necessary force, such as striking surface (48) with a hammer, to insert the fastener (EX1005, 3:1-13, 3:18-20). To maximize retention once placed, the barbs (20) have surfaces (25) that are inclined rearwardly, thereby resisting the fastener's withdrawal in a direction opposite to the one in which it was driven (EX1005, 2:61-68, 3:39-44). Furthermore, the stability may be augmented by connecting two fasteners (50, 52) via a wire cable (70) which is threaded through openings (71) located in the driving ends of the fasteners (EX1005, 3:39-44, 4:3-13). This interconnection ensures that if one fastener attempts to move out of the bone, the wire cable forces the other fastener further into the bone portions, thereby creating an extremely reliable attachment (EX1005, 4:14-25).

*Steffee's* disclosure differs significantly from the apparatus claimed in the '385 Patent. *Steffee* teaches a curved fastener designed specifically for securing bone graft material between bones. It does not disclose an intervertebral fusion member (like a block or cage) designed to be placed directly into the disc space and having internal channels through which anchoring members pass. The '385 patent claims a fusion member containing specific "first curved channel and a second curved channel" with a defined parallel relationship between their cross-sectional planes, through which separate anchoring members are inserted to directly affix the fusion member itself to the vertebral bodies. *Steffee* provides no teaching of such an implant structure with internal, precisely oriented curved channels, nor the concept of anchoring the implant through such channels. *Steffee's* fastener is intended to hold graft material in place, relying on the graft for eventual fusion, whereas the '385 patent's anchors directly secure the implant body to the vertebrae via specific channel geometry within that body.

**D. General Observations Regarding *Moskowitz, Hess, and Steffee***

None of the intervertebral implant or fastener systems disclosed in the asserted prior art references teach or suggest the core inventive concepts claimed in the '385 Patent, specifically failing to describe an intervertebral fusion device comprising a fusion member with both a "first curved channel and a second curved channel,"

through which separate anchoring members affix the fusion member to adjacent vertebral bodies, wherein said curved channels possess distinct "cross-sectional plane[s] along a... path" maintaining a parallel relationship (EX1001, 15:31-58, 23:21-32). Moskowitz (EX1004) is fundamentally different, disclosing a "screw box" utilizing straight cylindrical guides for straight, threaded bone screws designed for rotational insertion via a "screw driver assembly" with "flexible shaft" and "square recess bit" specifically adapted for "turning the screws into the bone" (EX1004, 7:49-62, 8:63-9:1, 10:60-64), lacking any teaching of the claimed curved channels or the specific parallel cross-sectional plane geometry along such paths, and critically lacking any system for polymer injection through central lumens and perforated tips as required by the '385 Patent for achieving "solid mechanical fusion" (EX1001, 3:45-53, 4:5-12, 14:40-42). Hess (EX1006) is even further afield, primarily directed to an interspinous implant engaging spinous processes, not vertebral bodies, and using internal locking wings deploying along internal curved tracks within the shell (EX1006, 5:11-28, 6:38-50), a structure bearing no resemblance to the '385 Patent's fusion member with through-channels for separate anchoring members that traverse curved paths to anchor directly into vertebral bodies. Steffee (EX1005) is similarly deficient, disclosing only a curved fastener itself designed exclusively for "securing bone graft between a pair of bone portions"

via impact-driven insertion with "barbs which prevent the fastener from backing out" (EX1005, 1:6-9, 2:61-68, 3:1-13), and providing no teaching whatsoever of an intervertebral fusion member containing internal channels, let alone the specifically claimed geometry, and critically lacking any central lumen or perforation system for PMMA delivery (EX1005). Thus, none of the references, individually or in Petitioner's hindsight-driven combinations, disclose or suggest the claimed fusion member with its unique arrangement of parallel-plane curved channels designed for guiding flexible anchoring members along precise semi-circular paths for direct fixation via separate anchoring members with specialized PMMA injection capability (EX1001, 15:31-58, 16:63-65, 3:45-53).

#### **IV. CLAIMS 1-5, 7, AND 9 ARE NOT UNPATENTABLE**

Petitioner raised three grounds in its petition, each of which were instituted.

The grounds are as follows:

| Ground | 35 U.S.C. § | References                              | Challenged Claims |
|--------|-------------|-----------------------------------------|-------------------|
| 1      | 103         | Moskowitz & General Knowledge of a POSA | 1-5, 7, and 9     |
| 2      | 103         | Hess & General Knowledge of a POSA      | 1-3, 7, and 9     |
| 3      | 103         | Moskowitz-Steffee                       | 1-5, 7, and 9     |

##### **A. *Legal Standards***

An invention "composed of several elements is not proved obvious merely by

demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

An obviousness determination “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); see *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418.

The Federal Circuit has been clear that motivation to combine references and reasonable expectation of success are separate and distinct elements of the obviousness analysis: “one must have a motivation to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue.” *Intelligent Bio-Sys., Inc., v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir.

2016) (emphasis added); *see also id.*, 1365 (describing the “requirement for a reasonable expectation of success” in the context of obviousness); *Cumberland Pharms. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1221 (Fed. Cir. 2017) (describing motivation to combine and reasonable expectation of success as separate requirements for obviousness analysis).

**B. Petitioner Fails to Properly Establish Obviousness in Ground 1**

Ground 1 of the Petition for Inter Partes Review (IPR2025-00226) asserts that claims 1–5, 7, and 9 of the '385 Patent would have been obvious over the teachings of the *Moskowitz* patent (EX1004) when coupled with the general knowledge possessed by a Person of Ordinary Skill in the Art (POSA) (Pet. at 14, 16). Petitioner attempts to establish a *prima facie* case by characterizing the apparatus disclosed in Moskowitz as meeting or rendering obvious all limitations of the challenged claims. This characterization relies heavily on demonstrating—incorrectly—that inherent structural characteristics of the Moskowitz device satisfy the key requirement of a **"curved channel"** (EX1002, ¶76; Pet. at 31).

Specifically, Petitioner contends Moskowitz's screw box functions as the required **"fusion member"** configured for inter-vertebral positioning (EX1004, 2:40-51; Pet. at 30). This fusion member includes **"built-in screw and/or drill guides"** that serve as the claimed channels, allowing the direct placement of screws

(the "anchoring members") into the adjacent superior and inferior vertebral bodies (EX1004, 2:45-49; Pet. at 31, 43).

Petitioner's rationale necessitates an overly broad interpretation of "curved channel," arguing that Moskowitz's **straight** guides meet this definition merely because they allegedly possess rounded openings, tubular inner walls, and/or an internal curvature serving as a recessed seat for screw heads (EX1002, ¶76; Pet. at 34-35). However, this interpretation improperly conflates geometric features at channel openings with the fundamental requirement that the channel itself follow a curved path through the fusion member. Petitioner asserts that the necessary coupling and affixation of the fusion member to the vertebral bodies are achieved because the screw head engages this internal seat, retaining the screw within the box while the shank penetrates the vertebral body (EX1002, ¶78, ¶92; Pet. at 44). Critically, Moskowitz contains no express disclosure of such an internal seat, and Petitioner's inherency arguments fail because Moskowitz does not necessarily require such a seat—multiple alternative configurations could achieve screw fixation without a seat (EX1004, 7:49-52). Petitioner's reliance on Bray (EX1007) and Fraser (EX1008) to establish the seat feature constitutes an improper obviousness combination lacking proper motivation, analogous art analysis, and reasonable expectation of success (Pet. at 37-42).

Furthermore, Petitioner maintains that the structural arrangement of Moskowitz dictates that the channel paths, which run laterally aligned with the box, inherently possess first and second cross-sectional planes that are parallel to each other, thus satisfying the stringent spatial requirements articulated in independent claim 1 (EX1004, 5:11-18; EX1002, ¶97; Pet. at 48). However, Moskowitz provides no express disclosure regarding the parallel relationship of cross-sectional planes, and Petitioner's arguments for dependent Claims 2-4 are internally inconsistent—asserting the planes are both parallel and not parallel to surfaces depending on which claim limitation is addressed (Pet. at 48-52). The motivation driving a POSA to combine these elements is derived from the acknowledged need in the art to rigidly fixate the interbody device to the vertebrae to prevent migration, thereby supporting a successful fusion outcome (EX1002, ¶83; Pet. at 39).

Petitioner's characterization of Moskowitz, particularly regarding the alleged "curved channels" (EX1002, ¶76; Pet. at 34-35), is fundamentally flawed and ignores critical functional and structural distinctions between the prior art and the claimed invention. The '385 Patent specification consistently describes curved channels as channels that follow curved paths—arcs, circular paths, semicircular paths, elliptical paths, or parabolic paths—through the fusion member (EX1001, 15:31-58, 23:21-32, 23:66-24:16). The specification expressly distinguishes curved

channels from "substantially linear" channels, confirming that "curved" refers to the channel path, not merely geometric features (EX1001, 10:10-13). Moskowitz discloses guides specifically designed for the insertion of relatively rigid, threaded, self-drilling screws that follow straight, linear paths through the triangular sliding bases (EX1004, 2:45-49, 7:49-62, 8:63-91, Figs. 1B-1D). This rigid design stands in direct functional opposition to the preferred embodiments disclosed in the '385 Patent, which emphasize that the anchoring members (pins/needles) are preferably flexible to allow them to bend to traverse through the curved channels (EX1001, 27:57-60).

Petitioner's attempt to satisfy the "curved channel" limitation based on incidental features within Moskowitz's straight guides—such as round openings or a conical seat necessitated by the rigid screw head—constitutes impermissible hindsight reconstruction (EX1002, ¶76, ¶79). Nothing in Moskowitz discloses or suggests channels that follow curved paths, and Petitioner cannot identify any such disclosure (EX1004). However, modifying the rigid guides and corresponding rigid screws of Moskowitz to the true curvilinear path traversed by a flexible anchor, as required for a full obviousness finding against the allowed claims of the '385 Patent, would necessitate a wholesale, non-obvious redesign. A Person of Ordinary Skill in the Art (POSA) would not have possessed a reasonable expectation of success, nor

motivation, to incorporate a flexible anchor system into the Moskowitz device, as such modification undermines the core functionality of the threaded screw fixation described therein (EX1004, 2:36-39).

Moreover, the entire objective of the design in the '385 Patent—allowing the anchoring member to traverse a complex curvilinear direction to achieve precise exit locations and enable PMMA augmentation through flexible needles (EX1001, 15:45-50, 3:45-47, 21:58-65)—is wholly absent from the motivation presented by Moskowitz. The Moskowitz device effectuates fixation by turning or screwing its rigid anchor (EX1004, Abstract, 10:60-64), a method wholly incompatible with the flexible anchors driven along a curve by pushing or impacting as disclosed in the '385 Patent. Additionally, Moskowitz's expandable screw box design with sliding triangular bases (EX1004, 7:38-48) inherently creates looseness between screws and the box, undermining any claimed coupling function—if screws rigidly coupled the box to vertebrae, box expansion would be impossible or would cause screw loosening. Consequently, identifying trivial curvatures within Moskowitz's components, which are integral to its function with rigid screws, fails to establish obviousness. It provides no reason why a POSA would have reasonably expected success in adapting Moskowitz to feature the structurally and functionally distinct curved channels intended for flexible anchors, particularly those designed to

facilitate the novel PMMA augmentation technique described in the '385 Patent. For dependent claims 7 and 9, Moskowitz's generic screwdriver disclosure (EX1004, 8:63-91, Fig. 5H) does not teach specialized driving members with coupling mechanisms, central lumens for polymer delivery, and pivoting mechanisms as described in the '385 Patent (EX1001, 14:20-50, Figs. 19-25), and Moskowitz provides no disclosure of anchoring member bases designed to fit within channel recesses for retention (EX1001, Claim 9, 9:53-67). For these reasons, Ground 1 fails to meet the statutory requirements for obviousness.

### **1. Independent Claim 1**

Petitioner argues that Independent Claim 1 is rendered obvious by *Moskowitz and General Knowledge of a POSA*. Patent Owner disagrees for the reasons below.

#### ***1.1 Claim 1.P "A fusion device comprising:"***

Moskowitz explicitly discloses a "fusion device," specifically characterizing its apparatus as "[a] self-drilling bone fusion screw apparatus" where the screws function "to fuse the vertebral bodies together" (EX1004, Abstract) and asserts the resultant device is a "flexible fusion device" (EX1004, 3:66-67; EX1002, ¶72; Pet. at 30). However, Moskowitz's screw box is fundamentally an expandable construct comprising "two triangular sliding bases" connected by a height-adjusting screw (EX1004, 7:38-48), with primary functionality focused on height adjustment

through sliding mechanisms rather than providing a stable intervertebral spacer with curved channels as claimed in the '385 Patent (EX1001, 2:29-35).

***1.2 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 relies on an overbroad, non-functional interpretation of "curved" to assert that Moskowitz's channels meet this limitation (EX1002, ¶76; Pet. at 33). Petitioner argues the cylindrical guides for threaded screws constitute a "curved channel" merely because they possess rounded openings, tubular internal walls, or contain an implicit internal seat for the screw head (EX1002, ¶76). This interpretation fails because it ignores the functional constraints placed on the term "curved channel" by the '385 Patent specification:

- The claimed channels define a path requiring non-linear traversal (EX1001, 15:53-58), often spanning semi-circular arcs (EX1001, 23:21-32) that enable the tip of the anchoring member to travel in a semi-circular path of movement (EX1001, 15:53-58).
- The design demands that the anchor either possesses or relies on flexibility to "bend to traverse through the first and second curved channels" (EX1001, 16:56-65).
- The specification explicitly distinguishes curved channels from "substantially linear" channels, confirming that "curved" refers to the channel

path through the fusion member, not merely to geometric features (EX1001, 10:10-13).

Moskowitz's channels, in contrast, are fundamentally straight cylindrical guides designed exclusively to accommodate threaded bone screws that are explicitly described as being "screwed into" the vertebral bodies (EX1004, 7:49-52; EX1004, 10:62-64). The function is rotational and largely linear access (EX1002, ¶76). Moskowitz describes that "the body of each screw member is laterally aligned with the box" (EX1004, 5:11-18), confirming straight linear trajectories through the screw box. Petitioner does not—and cannot—identify any disclosure in Moskowitz of channels that trace arcs or curved paths through the screw box. Petitioner fails to demonstrate that Moskowitz's rigid guides either perform the necessary non-linear guidance function or necessitate the intrinsic flexibility inherent in the claimed structure (EX1001, 16:56-65). The asserted reliance on superficial geometry (rounded openings) is wholly inadequate to establish obviousness of the structural and functional design recited in the claim (EX1002, ¶76).

Furthermore, Moskowitz does not disclose an internal seat as Petitioner alleges (Pet. at 34-42). Moskowitz contains no express disclosure of an internal seat, and Petitioner's inherency arguments fail under established law requiring that missing matter be "necessarily present, not merely probably or possibly

present." *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Moskowitz's screws function by threading into bone, not by mechanical retention via a seat—Moskowitz states that screws "penetrate" and "traverse" the bases (EX1004, 7:49-52), suggesting passage through rather than retention within.

***1.3 Claim 1.2 "a first anchoring member configured to insert through the first curved channel ..., in order to couple the fusion member with the second vertebral body,"***

Petitioner improperly equates Moskowitz's threaded bone screws (101, 102) with the specific anchoring members required by the claim (EX1002, ¶90; Pet. at 42). The mechanism of fixation taught by the '385 Patent is functionally incompatible with that disclosed in Moskowitz:

- **Insertion Mechanism:** The '385 Patent anchoring members (e.g., large gauge needles 1-10 mm in outer diameter) are inserted by being pushed (EX1001, 3:34-40) via force exerted by "tapping, hammering, or simply pushing at its proximal end" (EX1001, 21:57-61). The system is expressly designed to avoid rotation (EX1001, 22:1-2).
- **Fixation/Retention:** The '385 Patent mandates anchors possess a central lumen and perforated tips (EX1001, 3:45-53) for the purpose of injecting polymethyl methacrylate (PMMA) or other hardening polymer (EX1001, 3:40-45). This injection, combined with anti-withdrawal contours (angled teeth/backfacing ridges), yields "solid mechanical fusion" (EX1001, 4:5-12).

Moskowitz's screws rely solely on engagement of their threads with bone tissue (EX1004, 7:49-62; EX1004, 10:62-64) and are inserted by rotation/screwing (EX1002, ¶90). Furthermore, Moskowitz's expandable screw box design with "two triangular sliding bases" adjusted by a height-adjusting screw (EX1004, 7:38-48) inherently creates looseness between screws and the box. If the screws rigidly coupled the box to the vertebrae as claimed, box expansion would be impossible or would cause screw loosening or bone damage. Petitioner fails to address or account for the complete absence in Moskowitz of the PMMA delivery structure or the push-in insertion method essential to the claimed anchoring member design (EX1002, ¶¶90, 93).

***1.4 Claim 1.3 "wherein the first curved channel has a first cross-sectional plane along a first path ...., wherein the first and second cross-sectional planes are parallel to each other."***

Petitioner asserts parallelism based on Moskowitz's figures and the general description that screws are "laterally aligned with the box" (EX1004, 5:11-18; EX1002, ¶97; Pet. at 48). However, Moskowitz provides no express disclosure that the screw channels traverse parallel cross-sectional planes. Moreover, Moskowitz describes screws "driven in two opposing directions into superior and inferior vertebral bodies" (EX1004, 2:45-49), suggesting diverging rather than parallel trajectories to accommodate anatomical constraints. This overlooks the contextual

relevance of this limitation in the '385 Patent, where parallelism is required to manage the complex, non-linear path of curved channels and ensure that the flexible anchoring members do not hinder one another during their arcuate traversal (EX1001, 15:53-58; EX1001, 23:66-24:16). Since Moskowitz employs rigid screws in simple cylindrical guides designed for linear insertion, the underlying technical problem solved by ensuring parallel planes in the '385 Patent (managing complex, space-constrained curvilinear movement) is entirely absent in Moskowitz.

## 2. 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 relies on figures suggesting that the channel planes in Moskowitz may be parallel to certain faces of the screw box (EX1002, ¶98; Pet. at 48). This dependent claim fails because the anchor system disclosed in Moskowitz lacks the fundamental structural and functional characteristics of the elements defined in Claim 1 (functional curved channels, push-in PMMA anchors). Moreover, Moskowitz provides no express disclosure that the cross-sectional planes are parallel to any surface of the screw box. Petitioner's assertion relies solely on annotated Expert's personal opinion from Figure 1C, not actual disclosure from Moskowitz (Pet. at 48). The putative parallelism cited by Petitioner arises incidentally from the

rectilinear geometry of a screw guide passing through a box and is not derived from the inventive complexity introduced by the required "curved channel" and flexible anchoring member system of the '385 Patent.

**3. 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 correctly observes that Moskowitz's channels traverse obliquely through the device such that the planes are necessarily non-parallel to some outer surfaces (EX1002, ¶100; Pet. at 49). However, 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). Critically, Petitioner's arguments for Claims 2 and 3 are internally inconsistent—Petitioner asserts that the cross-sectional planes ARE parallel to at least one surface for Claim 2 (Pet. at 48), yet also asserts the planes are NOT parallel to at least one surface for Claim 3 (Pet. at 49). This contradiction reveals the speculative nature of Petitioner's geometric analysis. The existence of an oblique channel for a rigid screw does not render obvious the specific combination of a fusion member accommodating a flexible anchor navigating a constrained curvilinear path, as mandated by the '385 Patent.

**4. Claim 4:**

***4.1 The fusion device of claim 1, “wherein the first curved channel opens to ... of the fusion member”***

Petitioner asserts that Moskowitz discloses openings on the proximal face (entry) and the superior/inferior faces (exit) (EX1002, ¶¶101-102; Pet. at 50). While Moskowitz's channels may open to multiple surfaces, this does not cure the fundamental deficiency: Moskowitz lacks curved channels as required by base Claim 1. Because Moskowitz fails to disclose curved channels that follow curved paths through the fusion member, it cannot satisfy any dependent claim limitations.

***4.2 “wherein the first cross-sectional plane is not parallel to ... second curved channel opens.”***

Petitioner argues that the cross-sectional planes in Moskowitz are inherently non-parallel (e.g., perpendicular) to the surfaces through which the channels open (EX1002, ¶103; Pet. at 51). However, this assertion directly contradicts Petitioner's argument for Claim 2, where Petitioner stated the planes ARE parallel to at least one surface (Pet. at 48). Petitioner cannot have it both ways—the cross-sectional planes cannot be simultaneously parallel and perpendicular to the fusion member surfaces. These contradictions demonstrate that Petitioner is manipulating Moskowitz's geometry post hoc to fit different claim limitations, rather than providing clear and consistent disclosure. This structural arrangement in the '385 Patent is designed to

facilitate the complex trajectory of the curved channel needed for the flexible anchor to enter from one face and target an exit location on a non-parallel face (EX1001, 15:53-58). Moskowitz's structure merely permits the simple insertion of a rotating screw at an angle suitable for threaded fixation, lacking the requisite analogous complexity or functional innovation required by the independent claim.

**5. Claim 5:**

***5.1 The fusion device of claim 1, "wherein the first and second curved channels open to a first surface of the fusion member ... curved channel traverses to a third surface of the fusion member;"***

Petitioner argues Moskowitz discloses this by showing channels entering the proximal face (first surface) and traversing oppositely to the superior and inferior faces (second and third surfaces) (EX1002, ¶104; Pet. at 52). However, Moskowitz's straight channels do not "traverse" in the manner contemplated by the '385 Patent. The specification describes traversal as the curved path the channel follows through the fusion member—enabling anchoring members to "exit the second surface of the fusion member at a first desired location" through curved routing (EX1001, Fig. 16). Moskowitz's straight channels provide no mechanism for achieving precise exit location targeting through channel curvature.

***5.2 "wherein the traversal of the first and second curved channels through the fusion member allows ...hindering the first anchoring member's insertion through the fusion member."***

Petitioner asserts the "without hindering" limitation is met because Moskowitz's channels are parallel (EX1002, ¶107; Pet. at 54). This argument is predicated on the flawed reading of the antecedent basis (Claim 1) and ignores the fundamental difference in device mechanics. The non-hindrance feature in the '385 Patent is specifically relevant due to the spatial constraints imposed by routing flexible anchors along adjacent, defined curvilinear paths (EX1001, 14:47-15:24). The '385 Patent achieves "desired location" targeting through curved channel paths that guide flexible anchoring members to precise exit points (EX1001, 15:53-58, 23:21-32). Moskowitz's straight channels provide no such functionality—the straight trajectory offers no mechanism for adjusting exit locations through channel geometry. Because Moskowitz employs rigid screws in simple cylindrical tracks, the inherent geometric constraints addressed by the non-hindrance element in the '385 Patent are absent, rendering the proposed modification based on generalized parallelism non-obvious.

6. **Claim 7:**

***7.1 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 Moskowitz's positioning tool (500a) and screw driver assembly (550) constitute the driving member and that decoupling is inherent, as all surgical tools are removed (EX1004, 8:63-9:1; EX1002, ¶¶110, 112; Pet. at 55). This interpretation fails because it overlooks the functional demands imposed by the '385 Patent's novel anchoring system:

- The driving member of the '385 Patent must be configured not only to impart axial impact/pushing force for insertion of the non-threaded anchor (EX1001, 3:34-40), but also must provide a central lumen allowing the post-insertion delivery of polymers including PMMA injection through the anchoring member into the vertebral bodies (EX1001, 3:54-4:12; EX1001, 14:40-42). The specification describes specialized driving members with coupling mechanisms, central lumens for polymer delivery, and pivoting mechanisms (EX1001, 14:20-50, Figs. 19-25).

Moskowitz's driver assembly (550) utilizes a flexible shaft (552) and square recess bit (553) specifically adapted for rotational force (screwing) (EX1004, 8:63-9:1) and lacks the required functionality for polymethyl methacrylate (PMMA) injection or push-in impact delivery. Moskowitz's generic screwdriver disclosure

does not teach specialized driving members configured to couple, deliver impact force without rotation, inject polymers through central lumens, or pivot as described in the '385 Patent. Therefore, Moskowitz does not disclose an analogous "driving member" required to achieve the claimed function. Petitioner's assertion that decoupling is "inherent" because surgical tools are removed (Pet. at 57) is mere a personal opinion unsupported by evidence from Moskowitz.

**7. Claim 9:**

***9.1 The fusion device of claim 1, "wherein each channel of the fusion member has an opening on a surface of the fusion member and ... into the vertebral body."***

Petitioner argues that the cylindrical space surrounding the screw head in Moskowitz constitutes the necessary "recess" and that the screw head functions as the "base" maintained within this recess (EX1002, ¶¶115, 117; Pet. at 59). This construction fails to appreciate the structural necessity behind this limitation in the '385 Patent:

- The '385 Patent explicitly defines a specialized structure involving a flanged base (1645-1650) fitting into a channel recess of increased diameter (flange cavity) (1685-1690) (EX1001, 16:26-16:32). This mechanism is crucial for mechanically locking the non-threaded push-in anchor in place and often

includes features (like a protruding tooth) to prevent rotation during decoupling (EX1001, 16:40-55).

Moskowitz uses conventional threaded screws whose retention mechanism relies fundamentally on thread engagement with bone (EX1004, 7:49-62). Moskowitz provides no disclosure of screw heads with specialized bases designed to fit within channel recesses for retention purposes. As established for Claim 1.1, Moskowitz does not disclose an internal seat, and Petitioner's inherency arguments fail. Petitioner's proposed mapping conflates the generic space associated with a conventional screw head with the specialized structural architecture required to retain and prevent rotation of the novel, non-threaded push-in anchor central to the '385 Patent design. Petitioner's annotated Figure 1D (Pet. at 59) shows only a conventional screw head, not a specialized base with flanges configured to fit within a recess as claimed (EX1001, Claim 9, Fig. 16).

Furthermore, Petitioner's reliance on *Bray and Fraser* to establish the recess feature (Pet. at 37-42) constitutes an improper combination without proper obviousness analysis. Petitioner provides no motivation to combine, no analysis of whether they are analogous art, and no evidence of reasonable expectation of success—all requirements for an obviousness showing under *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

\* \* \*

For all the foregoing reasons, Petitioner cannot legally sustain its burden to show obviousness in Ground 1 over *Moskowitz* and *General Knowledge of POSA*.

**C. Petitioner Fails to Properly Establish Obviousness in Ground 2**

Petitioner fails to demonstrate by a preponderance of the evidence that any of the challenged claims are unpatentable under Ground 2, which relies on U.S. Patent No. 8,075,593 ("Hess" (EX1006)) combined with the knowledge of a Person of Ordinary Skill in the Art (POSA) (Pet. at 61). Petitioner's analysis 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 of the U.S. Patent No. 8,460,385 ("the '385 Patent"). The proposed combination fails because the core inventive elements of the '385 Patent—particularly the mechanisms enabling **non-linear flexible anchor insertion** through curved channels and **cement-augmented fixation** via PMMA injection—are wholly absent and non-obvious in Hess.

**1. Hess Is Not Analogous Art and Requires Non-Obvious Redesign**

Petitioner attempts to render Hess obvious by arguing that its fundamental design, intended for **interspinous process decompression (IPD)** by stabilizing the posterior spinous processes, is easily convertible into an interbody fusion device

suitable for stabilizing the vertebral bodies (EX1002, ¶122; Pet. at 61-62). This 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.

Hess explicitly teaches dynamic stabilization without fusion (EX1006, 2:5-26, Abstract). While 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 (EX1006, 2:6-13, 7:33-45, 7:43-45). The '385 Patent, by contrast, describes fusion members configured as "shaped blocks (e.g., rectangular or oblong blocks)" placed "between endplates of adjacent vertebrae following a partial or complete discectomy" to restore disc height and facilitate rigid fusion through PMMA-augmented anchors (EX1001, 2:29-35, 2:40-48, 4:5-12).

The modification proposed by Petitioner—changing Hess's "bullet" shape to a rectangular "box cage" (EX1002, ¶126; Pet. at 65)—is a **non-analogous leap** that ignores the specialized mechanical function of the internal components and the fundamentally different biomechanical loading conditions in the intervertebral disc space. A POSA lacked motivation and a reasonable expectation of success to perform the necessary wholesale internal redesign to convert a posterior ratcheting

expansion fixation device with laterally deploying rigid wings into an anterior load-bearing device using superiorly and inferiorly directed flexible, push-in, PMMA-augmented anchors (Pet. at 62-67). Moreover, converting Hess for intervertebral fusion would require eliminating its core dynamic stabilization functionality—directly contradicting Hess's stated design objectives (EX1006, 2:5-26, 7:43-45).

## **2. Hess Fails to Disclose a Functionally Equivalent "Curved Channel"**

Independent Claim 1 requires a **"first curved channel"** designed to facilitate movement along a constrained curvilinear path (EX1001, 15:53-58). Petitioner relies on the explicit textual disclosure in Hess that the device includes **"two curved guide tracks (19)"** (EX1006, 7:26-29; Pet. at 67). However, even accepting this literal reading, the function of Hess's guide track is fundamentally incompatible with the inventive utility of the curved channel in the '385 Patent:

- **Hess's Function:** Hess's guide tracks constrain the movement of rigid, deployable locking wings which are moved incrementally by coaxial locking wheels and a deployment cable (a ratcheting mechanism) (EX1006, 3:24-28, 7:26-45, 8:5-19). The channel guides the lateral expansion/deployment of a rigid wing structure from stowed to deployed positions within the interspinous implant (EX1002, ¶130).
- **The '385 Patent Function:** The claimed curved channel facilitates the specialized function of guiding an anchoring member that must **"bend to traverse through the [curved] channel"** (EX1001, 16:63-

65), allowing the anchor (a flexible needle/pin with 1-10 mm outer diameter and central lumen) to be inserted along a **"semi-circular path of movement"** using impact or pushing force without rotation (EX1001, 15:53-58, 21:57-61, 3:34-40). The curved channels enable precise targeting of exit locations on vertebral body surfaces and accommodate the anatomical constraints of intervertebral placement (EX1001, 9:42-55, 15:53-58, 23:21-32).

The essential requirement of the '385 Patent—that the channel constrain a non-linear path enabling the use of a flexible, push-in anchor with central lumen for PMMA injection—is entirely absent from Hess. A POSA designing a device using Hess's ratcheting wing mechanism would have no reason to convert the guide tracks to accommodate an entirely different physical modality of anchoring (flexible, pushed-in fixation with cement augmentation) because doing so would eliminate Hess's deployment mechanism and core functionality.

### **3. Hess Fails to Disclose the Specific Anchoring Member**

Claim 1 further requires "a first anchoring member configured to insert through the first curved channel..." in order to couple the fusion member (EX1001, Claim 1). Petitioner equates Hess's ratcheting locking wings (14a-14d) with the claimed anchoring member (EX1002, ¶132; Pet. at 69). This equivalence fails due to critical functional and structural differences:

- **Hess's Anchors:** Hess's members are specialized rigid locking wings secured by ratchet teeth engaging a pawl structure (EX1006, 3:18-23, 7:33-45). They rely on mechanical expansion and lateral constraint against the spinous processes for fixation (EX1006, 7:43-45, 13:30-36). **The wings deploy via cables and locking wheels in a ratcheting motion—fundamentally incompatible with the push-in insertion method** (EX1006, 8:5-23).
- **The '385 Patent Anchors:** The claimed anchoring members are structured specifically as **large gauge needles (1-10 mm in diameter) with central lumens and perforated tips** intended to be pushed or hammered into place without rotation, relying on **PMMA injection through the central lumen** and specialized anti-withdrawal contours (angled teeth/ridges) for **"solid mechanical fusion"** (EX1001, 3:34-56, 3:45-53, 4:5-12, 21:57-65). The specification emphasizes that the anchoring members are preferably flexible to **"bend to traverse through the first and second curved channels"** (EX1001, 16:63-65, 27:57-60).

Petitioner entirely omits discussion of the absolute requirement in the '385 Patent for the anchoring member to be configured for PMMA injection (i.e., having a hollow channel and perforated tip) and reliance on non-threaded, push-in retention (EX1001, 3:45-53, 7:57-58). The operational mechanics and the fundamental means of fixation (ratchet/expansion vs. cement/impact) are antithetical, precluding a finding of obviousness. Nothing in Hess discloses or

suggests anchoring members with central lumens for polymer delivery—the critical functional element that distinguishes the '385 Patent's invention (EX1006).

#### **4. Dependent Claims Fail Due to Mismatched Design Philosophies**

The fundamental operational mismatch renders dependent claims unpatentable over Hess for the same reasons.

For these reasons, Ground 2 fails to meet the statutory requirements for obviousness.

##### **1. Independent Claim 1**

Petitioner argues that Independent Claim 1 is rendered obvious by *Hess and General Knowledge of a POSA*. Patent Owner disagrees for the reasons below.

##### ***1.1 Claim 1.P "A fusion device comprising:"***

Petitioner asserts that Hess discloses a fusion device (Pet. at 61). Spinelogik disagrees as explained below.

##### ***1.2 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 relies on the literal recitation in Hess of "**two curved guide tracks (19)**" to satisfy the requirement for a "curved channel" (EX1006, 7:26-29; Pet. at 67). This argument fails because the channels in Hess are structurally and functionally incompatible with the channels required by the '385 Patent.

The '385 Patent describes curved channels that guide flexible anchoring members (preferably large gauge needles with central lumens) along curved paths through the fusion member to achieve precise insertion angles and exit locations in vertebral bodies (EX1001, 3:34-53, 15:31-58, 16:63-65). The specification explains that "as the fusion member channel is curved, the path that the anchoring member travels is also curved" and that "the anchoring member traverses in a second direction that is curved throughout its advancement through the fusion member channel," such that **"the tip of the anchoring member travels in a semi-circular path of movement"** (EX1001, 15:31-58, 15:53-58, 23:21-32). Critically, the anchoring members are **"preferably flexible to 'bend to traverse through the first and second curved channels'"** (EX1001, 16:63-65, 27:57-60).

Hess's guide tracks, by contrast, are designed to accommodate the deployment motion of **rigid ratcheting locking wings** (14a-14d) that are incrementally moved from stowed to deployed positions by **coaxial locking wheels** actuated by a **deployment cable** (EX1006, 3:24-28, 7:18-31, 7:26-45, 8:5-19). The curvature in Hess's guide tracks serves to **facilitate the deployment mechanism**—allowing the wings to rotate laterally outward from the bullet-shaped interspinous implant body to engage spinous processes, not to guide flexible anchors along curved trajectories

for direct superior/inferior insertion into vertebral body endplates (EX1006, 7:26-29, 8:5-19).

A POSA would recognize that a guide track designed exclusively for incremental, mechanical deployment of rigid wings cannot fulfill the requirement of routing a flexible anchor along a curved trajectory induced by axial pushing/impacting force (EX1001, 21:57-61). Hess's rigid locking wings cannot "bend to traverse through curved channels" as required by the '385 Patent's anchoring members (EX1001, 16:63-65). The ratcheting mechanism requires rigid structural integrity to engage the pawl teeth and maintain locked positions (EX1006, 7:18-38, 7:33-45).

Moreover, Hess does not disclose or suggest PMMA injection through central lumens—a critical functional element that distinguishes the claimed invention. The '385 Patent's anchoring members include **central lumens and perforated tips specifically designed for post-insertion PMMA or polymer injection** to achieve "**solid mechanical fusion**" (EX1001, 3:45-53, 4:5-12, 14:40-42, 21:58-65). Hess's rigid locking wings possess no such lumens and achieve fixation solely through mechanical expansion and lateral constraint against spinous processes via ratchet teeth engagement (EX1006, 7:43-45, 13:30-36). Therefore, the channels disclosed

by Hess are functionally dissimilar to the inventive curved channels claimed in the '385 Patent, failing to establish obviousness.

***1.3 Claim 1.2 "a first anchoring member configured to insert through the first curved channel ..., in order to couple the fusion member with the second vertebral body,"***

Petitioner improperly equates Hess's rigidly secured **ratcheting locking wings** (14a-14d) with the specialized anchoring members claimed in the '385 Patent (EX1002, ¶132; Pet. at 69). This conflation overlooks the critical functional and structural elements necessary for the '385 Patent's fixation mechanism.

**The '385 Patent's anchoring members are inserted by being pushed or hammered** without rotation: "tapping, hammering, or simply pushing at its proximal end" (EX1001, 21:57-61, 3:34-40). The system includes a tooth that prevents the anchoring member from rotating when the driving member is uncoupled (EX1001, 17:23-27). The claimed device utilizes anchoring members that are large gauge needles (1-10 mm in outer diameter) that rely primarily on **PMMA injection through a central lumen and perforated tips** augmented by backfacing ridges for retention, yielding "**Solid mechanical fusion**" (EX1001, 3:35-53, 4:5-12).

**Hess's locking wings are deployed via cables and locking wheels in a ratcheting motion** (EX1006, 8:5-23, 3:24-28, 8:50-56). The wings are specialized expansion mechanisms that achieve fixation solely through mechanical constraint

and the engagement of **ratchet teeth (16) with a pawl structure (18)** (EX1006, 7:33-45). They are deployed by cable tension and incremental ratcheting, not axial impact/pushing (EX1006, 3:24-28).

Hess entirely lacks any disclosure of an anchoring member configured with a central lumen for PMMA delivery or the required push-in insertion modality (EX1002, ¶132). Hess's wings achieve fixation through "**mechanical expansion and lateral constraint against bone**" (EX1006, 7:43-45, 13:30-36)—a fixation mechanism wholly incompatible with the '385 Patent's PMMA-augmented flexible needle system. This demonstrates a fundamental structural incompatibility between the respective anchoring systems.

***1.4 Claim 1.3 "wherein the first curved channel has a first cross-sectional plane along a first path ...., wherein the first and second cross-sectional planes are parallel to each other."***

Petitioner correctly cites Hess describing that its locking wings reside in parallel deployment planes (EX1006, 3:31-35, 7:46-58; Pet. at 71). However, this parallelism is incidental to the deployment mechanism for the rigid wings within the rigid shell and fails to disclose the technical significance necessary to meet the claim.

The parallel relationship in the '385 Patent addresses the spatial constraint required to accommodate the simultaneous, non-interfering movement of **adjacent flexible anchors** following complex curvilinear trajectories (EX1001, 15:53-58,

23:66-24:16). The parallelism ensures that flexible anchoring members traversing curved paths do not hinder one another during arcuate traversal through the fusion member (EX1001, 23:66-24:16).

The parallelism in Hess merely reflects the symmetric design of the two pairs of rigid locking wings deployed laterally to engage spinous processes (EX1006, 7:46-58). This geometric relationship in Hess's interspinous design serves a different technical purpose—ensuring symmetrical lateral wing deployment from the bullet-shaped implant—and does not translate to the spatial requirements of an intervertebral fusion device with superiorly and inferiorly directed flexible anchoring members. A geometric similarity arising from an entirely different mechanical objective cannot render obvious the constraints demanded by the core inventive feature—**the curved channel and flexible anchor system**.

## 2. 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."*

Claim 2, requiring that the parallel cross-sectional planes be parallel to at least one surface of the fusion member, fails for lack of adequate antecedent basis in Hess (Claim 1 deficiencies). While Petitioner notes that the planes of Hess's guide tracks are parallel to the sides of its bullet-shaped shell (EX1002, ¶142; Pet. at 74), this

geometry arises solely from the rigid shell architecture designed for interspinous stabilization, having no functional relationship to the unique problems solved by the parallel curved paths of the '385 Patent. The alleged parallelism in Hess is incidental to its interspinous design and provides no teaching or suggestion for the spatial relationships required in an intervertebral fusion device configured as shaped rectangular or oblong blocks placed between vertebral body endplates (EX1001, 2:29-35).

### 3. 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."*

**Claim 3**, requiring that neither cross-sectional plane be parallel to at least one surface of the fusion member, fails for the same deficiencies in antecedent basis (Claim 1). Although Petitioner points out surfaces (e.g., the superior/inferior **depressions 13** of the shell shown in Figure 5A) that would necessarily be non-parallel to the guide tracks (EX1006, Fig. 5A; EX1002, ¶144; Pet. at 76), this is an obvious characteristic of the geometry of the non-rectangular shell itself and does not represent an intended design constraint relevant to the functionally distinct internal anchoring architecture defined by the challenged claims. Hess's shell depressions are designed to "**match the profile of the adjacent**

**bone when deployed"** in the interspinous space (EX1006, 7:11-13)—an anatomical interface requirement specific to interspinous placement that has no relevance to intervertebral fusion member surface geometry.

**4. Claim 7:**

*7.1 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 identifies Hess's **deployment cable (27)** as the claimed driving member, arguing it drives the locking wings (anchoring members) and decouples when cut/released (EX1006, 3:24-28, 8:18-19; Pet. at 76, 79). This analysis fails to meet the functional requirements of the '385 Patent.

The '385 Patent requires the driving member **to apply axial impact or pushing force** for insertion of the non-threaded anchor (EX1001, 3:34-40, 21:57-61), and **must further comprise a central lumen to provide a conduit for delivering polymers** including PMMA injection through the anchoring member into vertebral bodies (EX1001, 3:45-53, 14:20-50, 14:40-42). The driving member includes specialized coupling mechanisms and pivoting mechanisms (EX1001, 14:20-50, Figs. 19-25).

Hess's deployment cable (27) applies rotational force to wheels (20a, 20b) to actuate incremental expansion and locking of the rigid wings through ratcheting motion (EX1006, 3:24-28, 8:5-19). It serves absolutely no role in axial driving or specialized material conveyance. The cable serves only to rotate locking wheels for incremental ratcheting deployment—it does not deliver impact force, does not contain lumens for polymer delivery, and does not enable PMMA injection.

The methods of coupling, driving, and fixation **are fundamentally distinct**. Hess's system relies on tension and rotation for expansion/fixation, while the '385 Patent relies on axial force and chemical augmentation for fixation. Hess's cable decoupling (cutting/releasing) is functionally unrelated to the decoupling mechanism in the '385 Patent designed to leave the PMMA delivery anchor fixedly locked via specialized flanged bases after cement injection (EX1001, 9:53-67, 17:23-27, 21:17-27). Without addressing the critical structural requirement of the central lumen for PMMA injection, Petitioner fails to establish that Hess possesses an analogous driving member, rendering Claim 7 non-obvious.

**5. Claim 9:**

***9.1 The fusion device of claim 1, "wherein each channel of the fusion member has an opening ...member is inserted into the vertebral body."***

Petitioner attempts to meet the recess and base limitation by pointing to the opening recess created by the guide track termination (EX1006, 3:13-18; Pet. at 80) and asserting that the **pawl structure (18)** engaging the **ratchet teeth (16)** forms an additional retention mechanism (EX1002, ¶151; Pet. at 81). This interpretation completely ignores the necessary functional context of the '385 Patent.

The '385 Patent describes specialized recesses of increased diameter (flange cavities) that accommodate flanged bases on anchoring members (EX1001, 16:63-17:27, 9:53-67). The structural necessity of the recess in the '385 Patent is to accommodate a dedicated **flanged base** (e.g., **flange cavity 1685-1690**) that mechanically locks **the non-threaded push-in anchor** in place, typically employing a tooth feature to resist rotation during the decoupling of the driver shaft (EX1001, 16:63-17:2, 17:23-27). This mechanism ensures the anchor remains seated prior to the chemical augmentation of fixation (PMMA hardening).

**Hess's pawl/ratchet (18/16) system** serves the entirely different function of enabling incremental expansion locking of the rigid wing as it is deployed through cable-actuated ratcheting motion (EX1006, 7:33-45), not seating or preventing the

withdrawal of a push-in device. The pawl **protrudes into the guide track** to engage ratchet teeth on the locking wings for incremental locking during deployment (EX1006, 7:33-45). **This ratcheting engagement mechanism bears no relation to the flange-and-cavity retention system** described in the '385 Patent for maintaining non-threaded anchoring members partially within the fusion member during insertion. Thus, the physical retention mechanism necessary to render Claim 9 obvious is wholly absent from Hess, demonstrating that the challenged claims are not unpatentable over Hess.

\* \* \*

For all the foregoing reasons, Petitioner cannot legally sustain its burden to show obviousness in Ground 2 over *Hess* and *General Knowledge of POSA*.

**D. Petitioner Fails to Properly Establish Obviousness in Ground 3**

Petitioner fails to demonstrate by a preponderance of the evidence that any of the challenged claims (1–5, 7, and 9) of the U.S. Patent No. 8,460,385 ("the '385 Patent") are unpatentable under Ground 3, which relies on the combination of Moskowitz (EX1004) and Steffee (EX1005) (Pet. at 84-96). Petitioner's attempt to combine these references represents an impermissible combination 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 Patent.

While Petitioner correctly identifies the general need to minimize implant migration, this superficial motivation is insufficient to justify the wholesale, non-obvious redesign required to transition from Moskowitz's threaded screw-based system to the unique flexible anchor, curved channel, and PMMA-augmented fixation architecture of the '385 Patent.

### **The Combination Requires Incompatible Structural and Functional Modifications**

Petitioner's obviousness rationale requires replacing the threaded screws utilized by Moskowitz with the curved, barbed fasteners disclosed in Steffee, necessitating the simultaneous modification of Moskowitz's internal screw guides into true curved channels (Pet. at 88-92). This combination collapses due to the underlying functional incompatibility of the systems.

**Non-Analogous Fixation Mechanisms:** Moskowitz achieves fixation via threaded rotation/screwing into the vertebral body using rigid cylindrical guides designed for threaded screw insertion (EX1004, 7:49-62, 8:63-9:1, 10:60-64). Moskowitz's screws are inserted by rotation via a "screw driver assembly" with "flexible shaft" and "square recess bit" specifically adapted for "turning the screws into the bone" (EX1004, 8:63-9:1). Steffee, conversely, achieves fixation by **impact/driving** barbed fasteners through bone graft material (EX1005, Abstract, 2:45-48, 2:61-68, 3:1-6). Steffee explains: "The fasteners are driven into the

bone portions via a driving tool" with "gripping jaws" that hold and drive the fastener (EX1005, 3:1-6, 4:35-42). The fasteners include "barbs which prevent the fastener from backing out" once inserted (EX1005, 2:61-68). A Person of Ordinary Skill in the Art (POSA) attempting this combination must choose between these antithetical insertion mechanics. Selecting Steffee's impact insertion undermines the stable, rigid cylindrical guiding system described by Moskowitz, particularly the embodiments utilizing sliding bases for expansion (EX1004, 7:38-48).

**Curved Channel Mismatch:** While Steffee introduces a curved anchor, its primary function is securing bone graft between vertebral bodies—not for use with intervertebral implants (EX1005, Abstract, 2:33-38, 3:16-19). Steffee explicitly states: "bone graft is secured between bone portions" via curved fasteners that pass through the graft material (EX1005, 2:33-38). The "curved channel" recited in the '385 Patent specifies a channel following a complex path (e.g., semi-circular arcs) that necessitates the anchor to **"bend to traverse through the first and second curved channels"** such that "the tip of the anchoring member travels in a semi-circular path of movement" (EX1001, 15:31-58, 15:53-58, 16:63-65, 27:57-60). Moskowitz's channels are straight cylindrical guides designed for rigid threaded screws (EX1004, 7:49-62), intrinsically incompatible with this requirement. Petitioner offers no non-hindsight motivation to redesign Moskowitz's straight

guides from supporting rigid, twisting elements to supporting flexible, impacted elements capable of navigating a complex curvilinear trajectory (Pet. at 88-92).

### **The Combination Fails to Disclose the Inventive Fixation System**

The fundamental flaw in Ground 3 is that neither Moskowitz nor Steffee discloses the specialized structural elements central to the '385 Patent's novel fixation mechanism: **chemical fusion augmented by cement injection**.

**Missing PMMA Lumen Structure (Claim 1.2):** Independent claim 1 requires an anchoring member configured not merely for blunt insertion but for performing the function of coupling the fusion member to the vertebral body. The specification teaches that this function is uniquely achieved by using anchors (e.g., large gauge needles) having a **"central lumen and perforated tips"** specifically for injecting **Polymethyl Methacrylate (PMMA) or other hardening polymer** into the marrow space to yield "Solid mechanical fusion" (EX1001, 3:34-56, 3:45-53, 4:5-12, 14:40-42, 21:57-65). Neither Moskowitz's threaded screw nor Steffee's barbed fastener possesses or suggests this hollow, perforated structure necessary for fluid delivery, precluding them from meeting the functional definition of the anchoring member disclosed by the '385 Patent. Steffee's fasteners are rigid structures with "barbs which prevent the fastener from backing out" that rely solely on mechanical barb engagement—not PMMA augmentation (EX1005, 2:61-68).

**Insufficient Motivation/Expectation of Success:** 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) (Pet. at 88-91). This modification fails to bridge the critical gap regarding the absence of the specialized PMMA delivery system. A POSA 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, starting from the disparate technologies of a threaded cage system (Moskowitz) and an impact-driven bone graft fastener (Steffee). Moreover, Moskowitz already addresses migration prevention through its bi-directional screw fixation system (EX1004, 2:36-39, 7:49-62), and Petitioner provides no evidence that Moskowitz's screw fixation was inadequate.

Additionally, Steffee's curved fasteners, once driven into position via barbs, cannot be adjusted or repositioned without damaging bone tissue (EX1005, 2:61-68). This incompatibility defeats Moskowitz's fundamental adjustability feature provided by its expandable design with triangular sliding bases and height-adjusting screw (EX1004, 7:38-48).

### **Dependent Claims Rely on Mismatched Operational Mechanics**

The combination fails to render dependent claims obvious because combining

Moskowitz and Steffee produces hybrid structural elements functionally unrelated to the claimed device (Pet. at 91-96). Petitioner's assertion that creating curved channels in Moskowitz's triangular sliding bases requires only "machining techniques well known to a POSA" (Pet. at 91) grossly understates the wholesale redesign required and ignores critical technical barriers, including maintaining structural integrity of the sliding base expansion mechanism while creating semi-circular channel paths (Claims 2-5). Moreover, Steffee's driving tool with simple "gripping jaws" designed for impact-driven insertion (EX1005, 3:1-6, 4:35-42) lacks the central lumen for PMMA delivery required by Claim 7 (EX1001, 3:45-53, 14:20-50, 14:40-42), and Steffee's "driving head" with "grooves adapted to receive gripping jaws" (EX1005, 2:33-37) fails to disclose the specialized flanged base designed to fit within flange cavities to prevent rotation during decoupling as required by Claim 9 (EX1001, 16:63-17:27, 17:23-27, 9:53-67). For these reasons, Ground 3 fails to meet the statutory requirements for obviousness.

**1. Independent Claim 1**

***1.1 Claim 1.P "A fusion device comprising:"***

Petitioner asserts that "Moskowitz discloses an intervertebral fusion device" (Pet. at 91). While Moskowitz describes a screw box for intervertebral placement, the proposed Moskowitz-Steffee combination fails to disclose a fusion device

configured with the structural and functional features required by the claimed invention (EX1001, 2:29-48), as explained below.

***1.2 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"***

While Petitioner attempts to introduce the requisite curvature by substituting Moskowitz's screws with Steffee's curved fasteners (EX1005, 2:45-48; Pet. at 92), the combination fails to disclose a functional curved channel meeting the design constraints of the '385 Patent.

Moskowitz's channels are inherently straight cylindrical guides designed exclusively to accommodate rigid threaded screws during rotational insertion via a "screw driver assembly" with "flexible shaft" and "square recess bit" specifically adapted for "turning the screws into the bone" (EX1004, 7:49-62, 8:63-9:1, 10:60-64). The required "curved channel" of the '385 Patent is functionally defined by a path following non-linear arcs such that "the tip of the anchoring member travels in a semi-circular path of movement" (EX1001, 15:53-58, 23:21-32). The specification explains that "as the fusion member channel is curved, the path that the anchoring member travels is also curved" and that anchoring members are "preferably flexible to 'bend to traverse through the first and second curved channels'" (EX1001, 15:31-58, 16:63-65, 27:57-60).

Steffee's curved fasteners, by contrast, are designed exclusively for securing bone graft between bone portions—not for use with intervertebral implants (EX1005, Abstract, 1:6-9, 2:33-38, 3:16-19). Steffee states: "bone graft is secured between bone portions" via curved fasteners that pass directly through the graft material (EX1005, 2:33-38). Nothing in Steffee teaches or suggests routing curved fasteners through channels within an intervertebral fusion device (EX1005). Steffee's curvature serves to accommodate bone graft resorption forces and minimize moment arm effects (EX1005, 1:29-36, 2:45-48)—a technical problem wholly unrelated to guiding flexible anchors through curved channels in an intervertebral implant.

Petitioner has failed 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 Patent merely because a curved anchor exists in the field (Pet. at 88-92). Creating 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 (EX1004, 7:38-48). Petitioner's assertion that such modifications "would have involved the use of machining techniques well known to a POSA" (Pet. at 91) grossly understates the redesign required and provides no evidence of reasonable

expectation of success.

The combination produces a channel capable of passing a curved, non-threaded component, but critically lacks 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 Patent (EX1001, 3:40-53, 15:31-58).

***1.3 Claim 1.2 "a first anchoring member configured to insert through the first curved channel ..., in order to couple the fusion member with the second vertebral body,"***

Petitioner asserts that Steffee's barbed fastener comprises the necessary anchoring member (EX1005, Abstract; Pet. at 92-93). This element suffers a fatal structural deficiency: neither Moskowitz nor Steffee discloses the specialized PMMA augmentation mechanism mandatory for coupling the fusion member as defined in the '385 Patent.

The '385 Patent explicitly defines its anchoring member (e.g., a large gauge needle 1–10 mm in outer diameter) as possessing a central lumen and perforated tips designed specifically for injecting polymethyl methacrylate (PMMA) or other polymer into the marrow space for "Solid mechanical fusion" (EX1001, 3:34-56, 3:45-53, 4:5-12, 14:40-42, 21:57-65). The anchoring members are inserted by "tapping, hammering, or simply pushing at its proximal end" without rotation (EX1001, 21:57-61, 3:34-40).

Steffee discloses a solid barbed shank with "barbs which prevent the fastener from backing out" designed for axial impact insertion via a "driving tool" with "gripping jaws" (EX1005, 2:33-38, 2:61-68, 3:1-13, 4:35-42). It contains neither a central lumen nor perforations for chemical augmentation of the bone-implant interface (EX1005). Steffee's fasteners achieve fixation solely through mechanical barb engagement with bone tissue (EX1005, 2:61-68)—a fundamentally different fixation mechanism from the '385 Patent's PMMA-augmented system.

Moreover, Steffee's barbed fasteners cannot be adjusted or repositioned once inserted due to barbs that prevent backing out (EX1005, 2:61-68). This incompatibility defeats Moskowitz's fundamental adjustability feature provided by its expandable design with triangular sliding bases and height-adjusting screw (EX1004, 7:38-48). The combination thus fails to teach or render obvious the essential structural requirement—the polymer delivery capability—that differentiates the novel anchoring member of the '385 Patent from traditional mechanical fasteners.

***1.4 Claim 1.3 "wherein the first curved channel has a first cross-sectional plane along a first path ...., wherein the first and second cross-sectional planes are parallel to each other."***

Petitioner correctly notes that Moskowitz discloses parallel channel orientations (EX1004, 5:11-18; Pet. at 93-94). However, **this parallelism in**

**Moskowitz results from the symmetry of accommodating rigid, linear-rotation screws within a box** (EX1004, 7:49-62). This incidental geometrical similarity fails to render obvious the technical necessity of maintaining parallel planes in the '385 Patent, where parallelism is an architectural constraint imposed by managing the adjacent, complex, non-linear traversal paths of flexible anchoring members to ensure they do not hinder one another during arcuate traversal through the fusion member (EX1001, 15:53-58, 23:66-24:16).

Creating curved channels in Moskowitz's triangular sliding bases would fundamentally alter the device's geometry (EX1004, 7:38-48), and 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 (Pet. at 93-94). The structural modifications required to create complex curved channel geometries would necessarily change the spatial relationships between channels, and Petitioner provides no analysis demonstrating that parallelism would be preserved.

## **2. 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 discloses that the first and second

cross-sectional planes are parallel to at least one surface of the fusion member for the same reasons discussed for Ground 1" (Pet. at 94); (EX1002, ¶180). This assertion fails because creating curved channels would fundamentally alter Moskowitz's geometry, and Petitioner provides no evidence that surface relationships would be maintained (Pet. at 94).

**3. 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 makes the same unsupported assertion for Claim 3 (Pet. at 94); (EX1002, ¶181). The same deficiencies apply.

**4. Claim 4:**

***4.1 The fusion device of claim 1, wherein the first curved channel opens to ...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 channels in the proposed combination would open to the same surfaces of the fusion member as in Moskowitz" (Pet. at 94); (EX1002, ¶182). **This 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 (Pet. at 94).

**5. Claim 5:**

***5.1 The fusion device of claim 1, "wherein the first and second curved channels open to a first surface of the fusion member ...second desired location on the second surface without hindering the first anchoring member's"***

Petitioner asserts that the combination would satisfy these limitations "for the same reasons explained for Ground 1" (Pet. at 95); (EX1002, ¶183). **This 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 Patent (EX1001, 9:42-55, 15:53-58).**

**6. Claim 7:**

***7.1 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 argues that "a POSA would have modified Moskowitz's positioning tools to accommodate a gripping and driving design such as that disclosed in Steffee" (Pet. at 95-96); (EX1002, ¶185). Petitioner's argument that a customized driving tool combining Moskowitz's screwdriver (EX1004, 8:63-9:1) and Steffee's mallet-driven impact surface (EX1005, 3:1-13) would be obvious is inherently flawed because the resulting tool still fails to teach the critical functional capacity required by the '385 Patent.

The driving member in the '385 Patent must provide dual functionality: (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). The specification explains that driving members include "a shaft that advances the anchoring member" and "**a central lumen** that provides a conduit for delivering polymers to the anchoring member" such that "the central lumen in the driving member aligns with the hollow channel... in its corresponding anchoring member" (EX1001, 3:54-4:12).

Moskowitz's screwdriver assembly comprises a "flexible shaft" and "square recess bit" specifically adapted for rotational insertion via "turning the screws into the bone" (EX1004, 8:63-9:1)—not axial impact delivery. Steffee's driving tool comprises simple "gripping jaws" (40, 42) that hold and drive the fastener via mallet impact to a surface (48) (EX1005, 3:1-13, 4:35-42). Neither component reference teaches a driver possessing this dual push/lumen capability required for PMMA injection (EX1001, 14:40-42). Steffee's **simple gripping-jaw driver possesses no central lumen for polymer delivery** (EX1005, 3:1-6), and Petitioner provides no explanation for how this critical structural requirement could be

incorporated into the proposed combination (Pet. at 95-96).

Moreover, 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 Patent (EX1005, 3:1-13). The '385 Patent describes specialized decoupling designed to leave the PMMA delivery anchor fixedly locked via flanged bases after cement injection (EX1001, 9:53-67, 17:23-27, 21:17-27). Therefore, the combination cannot disclose the specialized driving member required by Claim 7.

**7. Claim 9:**

***9.1 The fusion device of claim 1, "wherein each channel of the fusion member has an opening on a surface of the fusion member ... is inserted into the vertebral body."***

Petitioner asserts that "the head portion of Steffee's fasteners would fit in the channel's recesses, as in Moskowitz itself" (Pet. at 96); (EX1002, ¶186). Petitioner's assertion that Steffee's fastener head portion (16) fitting into Moskowitz's cylindrical channel recess meets this claim limitation ignores the specialized function of the '385 Patent's design (Pet. at 96).

The recess and base in the '385 Patent define a **dedicated structural lock** for maintaining retention of the **non-threaded push-in anchor** prior to permanent PMMA augmentation. The specification describes **specialized recesses of**

**increased diameter (flange cavities) that accommodate flanged bases** on anchoring members (EX1001, 16:63-17:27, 9:53-67). The specification explains: "each anchoring member has a base (1645-1650) that fits within the recess of the channel (flange cavity) (1685-1690)" to "mechanically lock the non-threaded push-in anchor in place" (EX1001, 16:63-17:27). This system often uses a flanged base fitting into a recessed cavity that may include a tooth feature to prevent rotation when the driver is decoupled (EX1001, 17:23-27, 9:53-67). The specification states: "In some embodiments, the flange cavity may have at least one tooth (not pictured) protruding toward the center of the cavity opening that locks the anchoring member to the fusion member when the anchoring member is fully advanced through the fusion member's channels. In addition, this tooth prevents the anchoring member from rotating when the driving member is uncoupled from the anchoring member" (EX1001, 17:23-27).

Moskowitz's alleged channel seat (if present) serves merely to engage the bearing surface of threaded screws during rotational insertion (EX1004, 7:49-62)—not to prevent rotation of non-threaded push-in anchors during decoupling. Steffee's fastener head portion (16) comprises simple "grooves adapted to receive gripping jaws" (EX1005, 2:33-37)—not a specialized flanged base designed to fit within recesses of increased diameter with anti-rotation features. Steffee's fasteners rely on

barbed retention via "barbs which prevent the fastener from backing out" (EX1005, 2:61-68)—a fundamentally different retention mechanism from the '385 Patent's flange-and-cavity system designed for non-threaded anchors with PMMA delivery capability.

The 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 (EX1001, 16:63-17:27, 17:23-27). Petitioner's conclusory assertion fails to establish that the proposed combination renders obvious the claimed recess-and-base retention mechanism (Pet. at 96).

\* \* \*

For all the foregoing reasons, Petitioner cannot legally sustain its burden to show obviousness in Ground 3 over *Moskowitz* in view of *Steffee*.

## **V. CONCLUSION**

For at least the reasons recited above, Patent Owner requests that the PTAB find the challenged claims *not* unpatentable.

Dated: October 28, 2025

Respectfully submitted,  
**For Spinelogik, Inc.**

By: /René A. Vazquez/  
René A. Vazquez (Lead Counsel)  
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## **CERTIFICATE OF COMPLIANCE**

Patent Owner certifies that Patent Owner's Preliminary Response contains 13,958 words exclusive of a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing, according to Microsoft Word.

Dated: October 28, 2025

Respectfully submitted,

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**§ 42.6(e)—CERTIFICATION OF SERVICE**

In accordance with § 42.6(e)(1), the undersigned certifies that on the 28<sup>h</sup> day of October 2025, the above PATENT OWNER RESPONSE was served, via electronic mail upon the following counsel for Patent Owner,

- Stephen D. Zinda [Stephen@CHZfirm.com](mailto:Stephen@CHZfirm.com)
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Dated: October 28, 2025

Respectfully submitted,

/s/ M. Scott Fuller

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