

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner.

Case IPR2025-00225
Patent No. 9,730,805

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. 9,730,805 (EX-1001, "the '805 Patent") filed by Petitioner Globus Medical, Inc. ("Petitioner"). The Petition challenges claims 1-6, 11, 12, and 15-17 (collectively, "the Challenged Claims"), including independent claims 1 and 11. As explained below, none of the Challenged Claims are rendered unpatentable by the cited references, including U.S. Patent No. 8,172,854 ("Blain") (EX-1004), U.S. Patent No. 7,985,255 ("Bray") (EX-1006), and U.S. Patent No. 4,790,303 ("Steffee") (EX-1016).

The Petition fails on two fundamental grounds. First, Petitioner improperly equates Blain's **threaded screw fixation system** with the '805 Patent's **push-in, flanged anchoring mechanism**—two structurally and functionally distinct technologies. Second, Petitioner fails to address the critical limitation requiring that "the delivery mechanism extend outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies"—the very limitation that secured patent allowance during prosecution.

Threaded Screws vs. Push-In Flanged Anchors

Blain discloses a conventional interbody fusion implant where fixation is

achieved by **threaded fasteners** that are **rotated** into bone using a "screw driver" (EX-1004, 8:50-54). Blain's "preventing decoupling" mechanism is an anti-rotation lock—a lobe on the screw head fitting into a recess—designed to stop the screw from backing out once threaded into bone (EX-1002, ¶¶134-137).

The '805 Patent claims a fundamentally different invention. The claimed "independent anchoring members" are not threaded screws requiring rotational insertion, but push-in anchors (e.g., "needles," "pins") that are "tapped, hammered, or simply pushed" into place (EX-1001, 20:49-50). The claimed "preventing decoupling" mechanism is not an anti-rotation lock for threaded fasteners, but **flanges at a proximal end** (Claim 2) that lock to the fusion member by fitting into corresponding recesses (EX-1001, Fig. 16). Petitioner's expert attempts to equate Blain's screw head with the '805 Patent's flanged-base locking mechanism (EX-1002, ¶161), but these serve different purposes: Blain's mechanism prevents a **threaded screw** from **rotating** out; the '805 Patent's mechanism prevents a **push-in anchor** from being **pulled out**.

The Prosecution History Limitation

During prosecution, the limitation requiring that "the delivery mechanism extend outside a patient's body to a medical practitioner" was added and served as the basis upon which the Patent Examiner distinguished the '805 Patent from

Duffield (U.S. Patent No. 9,358,127) and issued a Notice of Allowance (EX-1003). The Examiner allowed the claims after Applicant amended the independent claims to include this specific limitation.

Petitioner minimizes this limitation by characterizing it as "so trivial and un inventive that the Specification of the '805 patent does not discuss it" (EX-1002, ¶76) yet simultaneously argues a POSA would have found it obvious to modify Blain to incorporate this feature (EX-1002, ¶118). This contradiction reveals a fundamental weakness: if the limitation were truly trivial, Petitioner should readily identify explicit prior art disclosure. Instead, Petitioner resorts to unsupported inferences from the mere presence of a handle in Blain's instrument guide. Blain provides no explicit teaching regarding the spatial relationship between the handle and the patient's body during implant positioning.

The "Curved Channel" Failure

For dependent claims requiring "curved channels" (Claims 5, 16), Petitioner presents two contradictory arguments:

Fork 1 (Grounds 1 & 2): Petitioner argues Blain's straight guide channels are "curved" by contorting a litigation-derived position. Petitioner's expert (EX-1002, ¶87) asserts a channel is "curved" if it has a "circular opening" or "concave...

seat." This contradicts the '805 Patent specification, which explicitly distinguishes "curved" channels from "substantially linear" ones (EX-1001, Figs. 46A-46B) and describes curved channels causing anchoring members to follow a "semi-circular path of movement" (EX-1001, 15:25-28). Blain's straight screw guides follow straight paths.

Fork 2 (Ground 3): Petitioner proposes impermissible hindsight by combining Blain (an implant delivery tool with straight guides for threaded screws) with Steffee (a curved fastener for securing bone graft material) (EX-1016). Steffee addresses a completely different problem (bone graft resorption, EX-1016, 1:11-20) with a fundamentally different system (no implant cage, no guide channels, impact-driven insertion via hammer). No POSA would have been motivated to combine these disparate technologies. Petitioner provides no articulated reasoning with rational underpinning—only knowledge gleaned from the '805 Patent itself.

Petitioner's position is particularly disingenuous given that Petitioner argues in the parallel district court litigation that "curved" requires a "curved path" (EX-1022, Globus's District Court Brief)—a position fatal to Petitioner's arguments here but which Petitioner now abandons in favor of its expert's litigation-derived

"applied construction."

Conclusion

The Petition asserts a primary reference (Blain) teaching a fundamentally different class of anchoring system—threaded screws requiring rotational insertion with anti-rotation locking versus push-in flanged anchors with proximal flange locking. Petitioner compounds this error by failing to address the critical "extending outside a patient's body" limitation that secured patent allowance, and attempts to contort "curved" using contradictory arguments, improper litigation-derived constructions, and impermissible hindsight combinations with non-analogous art. The Petition fails to demonstrate that any Challenged Claim is unpatentable.

Accordingly, the Petition should be denied.

II. SUMMARY OF THE '805 patent

A. Specification of the '805 patent

U.S. Patent No. 9,730,805 ("the '805 Patent"), entitled "Intervertebral Fusion Device and Method or Use," issued August 15, 2017, pertains generally to "spinal implants and surgical procedures for spinal fusion and stabilization" (EX1001, 1:20-21) and has an earliest priority date of March 27, 2008.

The '805 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" (EX1001, 1:65-67). 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" (EX1001, 2:1-4).

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 (EX1001, 2:13-18). The core concept involves delivering the fusion member—described as "a shaped block (e.g., a rectangular or oblong block)" (EX1001, 2:19-20)—into the intervertebral space after disc removal. This fusion member is characterized by having "one or more channels (e.g., tubular channels)" (EX1001, 2:20-21).

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" (EX1001, 2:31-34). The specification contemplates various forms for these anchoring members, including "large gauge needles (1-10 mm in outer diameter)" (EX1001, 3:10-11), 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" (EX1001, 3:10-25) 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 withdrawn from the trabecular bone" (EX1001, 3:56-57; 3:59-64).

A significant aspect emphasized in the patent concerns the specific geometry and arrangement of the **channels** within the fusion member. The specification describes embodiments where channels are "curved" (Ex-1001, e.g., 10:5-10, Figs. 4, 16-17, 30-40, 46A-47). The specification explains that for some embodiments, "the flexibility of the needle allows the anchoring member to be advanced through the curved channel of the fusion member" (Ex-1001, 18:35-41). This traversal, in turn, can impart a specific trajectory to the anchoring member's tip. For instance, in one embodiment, "the tip of the anchoring member travels in

a semi-circular path of movement" (Ex-1001, 15:25-28). Other embodiments disclose channels that are "straight uncurled" (Ex-1001, 23:1-3, Figs. 41-42).

The delivery mechanism of some embodiments includes a delivery housing that "houses the anchoring mechanism" and "a retention mechanism that couples the delivery housing to the fusion member" (EX1001, 2:36-38). The delivery housing includes "channels that run the entire length of the delivery housing that guide the anchoring mechanism to the proper channel opening of the fusion member" (EX1001, 2:39-42). In some embodiments, retention rods have "retention teeth that mate with retention grooves on the fusion member" (EX1001, 2:46-48) to form a retention mechanism that allows controllable attachment and detachment.

The anchoring mechanism in some embodiments comprises three pieces: "an anchoring (embedded) member, an intervening member, and a driving (retractable) member" (EX1001, 13:38-40). Other embodiments use a two-piece system with "an anchoring (embedded) member and a driving (retractable) member" (EX1001, 13:42-44). The driving members include "shafts that advance the anchoring members fully into the fusion member or withdraws the anchoring members from the fusion member" and "central lumens that provide a conduit for

delivering polymers to the anchoring members" (EX1001, 14:1-6). Some embodiments provide pivoting mechanisms allowing the anchoring members and intervening members "to pivot with the driving members" (EX1001, 14:50-53).

In summary, the '805 Patent describes an interbody fusion device intended for stabilization, characterized by a fusion block implant containing channels—including embodiments with curved channels—through which flexible anchoring members are passed to secure the implant to adjacent vertebrae, with optional injection of hardening polymers to enhance fixation.

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 terms "housing" and "curved," that contradict the intrinsic

evidence. Patent Owner applies the plain and ordinary meaning to the claim terms, rebutting Petitioner's specific proposals where necessary.:

1. "housing" (Claims 2-4)

- **Petitioner's Proposal (IPR Petition):** "A component that protects, covers, supports, or contains another component".
- **Patent Owner's Position:** Plain and ordinary meaning. No construction necessary.

Petitioner proposes an overly broad construction derived from generic dictionary definitions that improperly encompasses any structural element providing minimal support or containment. This construction would vitiate the distinction between the delivery housing—a specific structural component of the delivery mechanism—and other components such as the fusion member itself, which also "contains" or "supports" anchoring members during use.

The '805 Patent specification uses "housing" consistently to refer to a specific component of the delivery mechanism that houses and guides the anchoring mechanism during the delivery process. The specification states: "the delivery housing channels house and guide the anchoring mechanism to the proper location in the fusion member" (EX-1001, 2:39-45). Figures 1A and 6 illustrate delivery housing 610 as a distinct structural component through which anchoring members 140 and retention rods 160 pass.

Importantly, Petitioner's construction conflicts with the limitation requiring "the delivery mechanism extending outside a patient's body"—a key feature added during prosecution to distinguish the prior art. If "housing" merely means any component providing support, Petitioner could improperly argue that the fusion member itself serves as the "delivery housing," thereby collapsing the distinction between the fusion member and the delivery mechanism—the same error the Examiner made with Duffield.

The plain and ordinary meaning, understood in the context of the specification, clearly identifies the delivery housing as a component of the delivery mechanism (not the fusion member) that houses and guides anchoring members and retention mechanisms during the surgical procedure. No formal construction is necessary.

2. *"each channel of the fusion member is curved" (dependent claims 5 and 16)*

- **Petitioner's Proposal (IPR Petition):** Petitioner relies on an alleged "applied construction" purportedly derived from Spinelogik's infringement contentions, 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) (EX-1002, ¶87).
- **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 district court litigation—a tactic explicitly permitted by *Western Digital 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 Blain'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 (EX-1002, ¶87). Such reliance on extrinsic arguments manufactured for litigation purposes is unnecessary and improper, as the plain meaning is clear from the intrinsic evidence.

The '805 Patent specification provides clear guidance on the meaning of "curved channel." The specification describes channels that "run in parallel planes with respect to each other but are nonparallel to the adjacent faces of the fusion block member" (EX-1001, 5:57-61)." The functional description—causing a semi-circular path of movement—is wholly absent from Blain's straight guides designed for threaded screws inserted via rotation.

The specification explicitly states that anchoring members "can be composed of a material or a combination of materials that provides flexibility" to traverse the curved channels (EX-1001, Figs. 16-18). This design requires channels that follow non-linear trajectories through the fusion member, distinct from straight channels.

Furthermore, Petitioner's proposed alternative construction—"channel that has a curved path"—while more accurate than Petitioner's litigation-derived "applied construction," is precisely the type of redundant paraphrasing discouraged by the Federal Circuit. The term "curved channel" is unambiguous and requires no construction beyond its plain and ordinary meaning, which a POSA understands from the specification to refer to a channel following a curved trajectory through the fusion member, enabling anchoring members to travel along a semi-circular path—distinct from a straight channel designed for threaded screw insertion.

Petitioner's contradictory positions further expose the weakness of its construction. In the parallel district court litigation, Petitioner argues that "curved" requires a "curved path" (EX-1022, Globus's District Court Brief). Yet in this IPR, Petitioner abandons that position in favor of an "applied construction" asserting that Blain's straight guides qualify as "curved" merely because they have circular

openings or tubular inner walls (EX-1002, ¶87). Petitioner cannot have it both ways—the term either requires a curved path (which Blain lacks) or it does not (in which case Petitioner's district court position contradicts its IPR position).

The plain and ordinary meaning should apply without construction.

III. SUMMARY OF THE PRIOR ART

A. U.S. Patent No. 8,172,854 ("Blain") (EX-1004)

Blain is directed to an "attachable instrument guide" specifically designed for use with interbody fusion implants in spinal orthopedic procedures (EX-1004, Title, Abstract). The instrument guide functions as a detachable delivery tool that couples to an interbody fusion implant to facilitate the insertion of bone screws into vertebral bodies (EX-1004, Abstract). Blain's apparatus comprises three primary components: (1) an implant delivery tool (instrument guide 14), (2) an interbody fusion implant (implant 2), and (3) threaded bone fasteners (fasteners 6) (EX-1004, 4:26-36, Figs. 1, 2A-2C). The instrument guide 14 includes a handle 20, a device coupler 16, and guide members/tubes 18 (EX-1004, 4:55-61).

The implant 2 is described as a "flanged interbody fusion implant" designed for insertion between two adjacent vertebral bodies (EX-1004, 4:26-39, Fig. 1). The implant features fastener apertures 4 through which bone screws (fasteners 6)

are inserted to secure the implant to bone (EX-1004, 4:26-39). The instrument guide 14 detachably couples to the implant 2 via the device coupler 16, which engages coupling openings 10, 12 on the implant (EX-1004, 4:44-54, 5:17-22, Figs. 2B-2C). The guide tubes 18 have proximal openings 30 leading to tubular channels that align with the fastener apertures 4 of the implant, allowing fasteners 6 to be driven through the guide tube channels and into the vertebral bodies (EX-1004, 8:5-8, Figs. 2A, 3A, 6A).

The surgical procedure disclosed in Blain involves first attaching the instrument guide 14 to the implant 2 prior to implantation, using the instrument guide as a delivery tool to insert the implant between the vertebral bodies, removing the handle 20 to facilitate access, and then inserting "self-tapping or self-drilling bone fasteners" through the guide tubes 18 using a "screw driver" to fasten the screws to bone (EX-1004, 8:50-54, Figs. 6A-6B, Claim 22). The specification explicitly describes the fasteners as "bone screws" that are "screwed in" and "tightened" to secure the bone plate (EX-1004, 1:37-42, 2:54-60). The guide tubes 18 are described as following straight, linear paths aligned laterally with the implant box to accommodate these rigid, threaded screws (EX-1004, 5:10-17, 8:50-54). Once the fasteners are secured, the handle 20 is reattached to the instrument guide 14, and the instrument guide is detached from the implant by

disengaging the device coupler 16 (EX-1004, Claim 22).

Blain's apparatus differs fundamentally from the apparatus claimed in the '805 Patent in both structure and function. Blain discloses a conventional threaded screw fixation system where rigid bone screws are **rotated** into vertebral bodies through **straight** guide tubes using a screw driver (EX-1004, 8:50-54, 10:60-64). The guide tubes 18 are designed to accommodate straight, threaded fasteners following linear trajectories, not curved channels designed for flexible anchoring members. Blain provides no disclosure of (1) curved channels through which anchoring members traverse to follow a semi-circular path of movement, (2) push-in anchoring members (such as needles or pins) that are "tapped, hammered, or simply pushed" rather than rotated, (3) anchoring members with flanges at a proximal end that lock to the fusion member by fitting into recesses, or (4) anchoring members with hollow central lumens and perforated tips for injecting polymethyl methacrylate (PMMA) or bone cement to enhance fixation (EX-1001, Abstract, Figs. 15-16).

Moreover, Blain's fixation mechanism for "preventing decoupling" operates through an entirely different principle. Blain relies on the threaded engagement between the screw shaft and bone, supplemented by an anti-rotation lock mechanism to prevent the threaded screw from backing out once it has been

screwed into the vertebral body (EX-1004, 5:44-57). This stands in stark contrast to the '805 Patent's claimed system, where "preventing decoupling" is achieved through structural features of the anchoring member itself—specifically, flanges at a proximal end that mechanically lock to the fusion member by fitting into corresponding recesses, preventing the push-in anchor from being pulled out after insertion (EX-1001, Figs. 15-16, Claim 2). Blain's threaded screws requiring rotational insertion with anti-rotation locking and the '805 Patent's push-in flanged anchors with proximal flange locking represent fundamentally different classes of anchoring technology addressing different mechanical challenges through distinct structural solutions.

B. U.S. Patent No. 7,985,255 (Bray) (Ex-1006)

Bray is directed to an interbody implant designed for implantation between two adjacent vertebrae to provide fixation and support (EX-1006, Abstract). The implant comprises a base member 20 having a primary member 100 with two bone screw holes 140 and a secondary member 110 with bone screw hole 180 (EX-1006, 4:37-40, 7:15-18, 7:40-42, Figs. 1, 4, 5). Each screw hole 140 includes a seat 165 configured to receive and retain the head of a bone screw, where the seat has a concave, spherical shape that complements the convex spherical shape of the screw head (EX-1006, 7:30-36). The implant also features a restraining mechanism

comprising restraining plate 60 and restraining plate fixing means 70, designed to securely cover at least a portion of each bone fastener 50 to prevent the fasteners from backing out once they have been screwed through the base member 20 and into the vertebral bodies (EX-1006, 4:49-57, Figs. 1, 9, 10).

Bray further discloses a guide tool 310 used to deliver the base member 20 between the vertebral bodies (EX-1006, 9:61-10:14, Fig. 13). The guide tool 310 includes a handle 320 and a pair of guide tubes 330 through which a surgeon can drill and subsequently insert bone screws 50 to anchor the screws into the bone (EX-1006, Fig. 13). The guide tool functions as a temporary delivery instrument that aligns the guide tubes 330 with the screw holes 140 in the implant, facilitating the insertion of threaded bone screws through the implant and into the adjacent vertebral bodies. Once the screws are secured and the implant is affixed to the vertebrae, the guide tool 310 is removed (EX-1006, 9:61-10:14). The bone screws serve as the primary fixation mechanism, with the restraining plate 60 providing secondary security to prevent screw backout through its locking engagement with the screw heads (EX-1006, 7:30-36, 4:49-57).

Bray's implant differs fundamentally from the apparatus claimed in the '805 Patent in structure, fixation mechanism, and functional operation. First, Bray discloses a conventional threaded screw fixation system where bone screws 50

are **rotated** into the vertebral bodies using a screw driver (EX-1006, 4:37-48, 7:15-42). This stands in direct contrast to the '805 Patent's system of **independent anchoring members**—such as needles or pins—that are driven into place by a **linear force** through being "tapped, hammered, or simply pushed" rather than rotated (EX-1001, Abstract). Second, Bray's "preventing decoupling" mechanism operates through the threaded engagement between the screw shaft and bone, with an additional anti-backout restraining plate 60 that mechanically covers the screw heads after insertion (EX-1006, 4:49-57, 7:30-36). The '805 Patent, by contrast, achieves "preventing decoupling" through structural features intrinsic to the anchoring member itself—specifically, **flanges at a proximal end** that mechanically lock to the fusion member by fitting into corresponding recesses, preventing the push-in anchor from being pulled out after insertion (EX-1001, Figs. 15-16, Claim 2).

Third, Bray's guide tool 310 is a simple delivery instrument with straight guide tubes 330 designed to accommodate rigid, threaded screws following linear insertion trajectories (EX-1006, Fig. 13). Bray provides no disclosure of curved channels that enable anchoring members to traverse a semi-circular path of movement, as required by Claims 5 and 16 of the '805 Patent (EX-1001, Abstract). Finally, Bray's screw holes 140 with spherical seats 165 are designed specifically to accommodate the

spherical heads of threaded bone screws, allowing polyaxial screw angulation while maintaining rotational fixation (EX-1006, 7:30-36). This structural feature serves an entirely different function than the '805 Patent's flanged recesses, which lock push-in anchors through interference fit rather than accommodating rotational fasteners.

C. U.S. Patent No. 4,790,303 (Steffee) (Ex-1016)

Steffee is directed to a fastener for securing bone graft between a pair of bone portions (EX-1016, 1:6-9). The fastener 10 is described as a curved elongated member having a shank portion (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 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 (EX-1016, 4:14-25).

Steffee's disclosure differs fundamentally from the apparatus claimed in the '805 Patent in structure, intended use, and functional implementation. First, Steffee teaches a curved fastener itself designed exclusively for securing bone graft material between a pair of bone portions via impact-driven insertion with barbs to prevent backing out (EX-1016, 1:6-9, 2:61-68, 3:1-13). Steffee 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 separate anchoring members pass. The '805 Patent claims a fusion member containing specific curved

channels with a defined spatial relationship through which separate anchoring members are inserted to directly affix the fusion member itself to the vertebral bodies (EX-1001, Abstract, Claims 1, 5, 11, 16). 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.

Second, Steffee's fastener is intended to hold bone graft material in place, relying on the graft for eventual fusion, whereas the '805 Patent's anchors directly secure the implant body to the vertebrae via specific channel geometry within that body (EX-1016, 1:6-9; EX-1001, Abstract). Third, Steffee's curved fastener follows a curved path through bone graft due to the curvature of the fastener itself—the fastener is the curved element (EX-1016, 2:45-48, Fig. 5). The '805 Patent, by contrast, requires curved channels within the fusion member through which separate anchoring members traverse, causing the anchoring members to follow a semi-circular path of movement (EX-1001, Abstract). Fourth, Steffee's fastener is driven by striking it with a hammer via a specialized driving tool 38 with gripping jaws 40, 42 that engage V-shaped grooves 30, 32 on the fastener's driving head (EX-1016, 3:1-13, 3:18-20). The '805 Patent discloses driving members with central lumens that align with hollow channels in the anchoring members to deliver polymethyl methacrylate (PMMA) or bone cement through the anchoring members and into the

marrow space of vertebral bodies for enhanced fixation (EX-1001, Abstract, Figs. 15-16)—a feature entirely absent from Steffee.

Finally, Steffee's retention mechanism relies on rearwardly-inclined barbs 20 and optional wire cable interconnection between multiple fasteners (EX-1016, 2:61-68, 4:3-25), while the '805 Patent achieves "preventing decoupling" through flanges at a proximal end of the anchoring member that lock to the fusion member by fitting into corresponding recesses (EX-1001, Figs. 15-16, Claim 2). Steffee teaches a fundamentally different system—a standalone curved fastener for bone graft fixation—with no delivery mechanism, no internal channels within an implant body, no separate anchoring members driven through such channels, and no PMMA injection capability. Steffee is non-analogous art addressing a different problem (securing bone graft) with a different solution (curved fastener driven directly through graft).

D. General Observations Regarding *Blain, Bray, and Steffee*

None of the prior art references asserted in the Petition—whether considered individually or in the Petitioner's proposed combinations—teach or suggest the core inventive concepts claimed in the '805 Patent. The fundamental deficiency common to all three grounds is the complete absence of any disclosure or suggestion of the critical limitation requiring "**the delivery mechanism extending outside a patient's**

body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies." This limitation, which served as the sole basis upon which the Patent Examiner allowed the challenged claims during prosecution (EX-1003), is not explicitly disclosed in Blain, Bray, or Steffee, nor is it inherent in any of these references.

Moreover, the prior art references fail to disclose the '805 Patent's **push-in flanged anchoring system** designed for linear force insertion ("tapped, hammered, or simply pushed") with **proximal flange locking** to prevent withdrawal (EX-1001, Abstract, Claim 2). Blain (EX-1004) discloses a conventional threaded screw fixation system where rigid bone screws are **rotated** into vertebral bodies through **straight** guide tubes using a "screw driver" (EX-1004, 8:50-54), relying on threaded engagement and an anti-rotation lock mechanism to prevent backing out once screwed into bone (EX-1004, 5:44-57). Bray (EX-1006) similarly discloses threaded bone screws that are **rotated** into vertebrae (EX-1006, 4:37-48, 7:15-42), with an additional anti-backout restraining plate 60 that mechanically covers screw heads after insertion (EX-1006, 4:49-57, 7:30-36). Steffee (EX-1016) discloses curved fasteners 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" (EX-1016, 1:6-9, 2:61-68, 3:1-13), but provides no teaching of an intervertebral fusion member containing internal channels through which separate anchoring members pass.

None of these fixation mechanisms teach or suggest the '805 Patent's structural feature of **flanges at a proximal end** of the anchoring member that lock to the fusion member by fitting into corresponding recesses (EX-1001, Claim 2, Figs. 15-16). The mechanical locking function of proximal flanges—designed to prevent **pull-out** of push-in anchors—is fundamentally distinct from Blain's and Bray's anti-rotation locks designed to prevent **rotation** of threaded screws, and from Steffee's barbs designed to prevent **backing out** of impact-driven fasteners inserted directly through bone graft.

Furthermore, none of the asserted references disclose the '805 Patent's critical **PMMA injection capability** through anchoring members with "hollow central lumens and perforated tips" designed for injecting "polymethyl methacrylate (PMMA) or other bone cement or hardening polymer material" to enhance fixation (EX-1001, Abstract). Blain's threaded screws achieve fixation solely through thread engagement with bone (EX-1004, 7:49-62). Bray's threaded screws rely on thread engagement supplemented by a mechanical restraining plate (EX-1006, 7:30-36). Steffee's fasteners rely exclusively on barbs and optional wire cable interconnection

for retention (EX-1016, 2:61-68, 4:3-25). The complete absence of any teaching regarding hollow anchoring members with perforated tips for polymer delivery underscores the fundamental gap between the prior art and the claimed invention.

Finally, for dependent claims requiring "curved channels" (Claims 5, 16), the asserted prior art is fatally deficient. Blain's guide tubes 18 and fastener apertures 4 are, by simple visual inspection, unequivocally **straight** (EX-1004, Fig. 6A). They are designed to accommodate straight, threaded fasteners following linear trajectories and provide no mechanism for causing anchoring members to follow a "semi-circular path of movement" as required by the '805 Patent (EX-1001, Abstract). Bray's guide tool 310 includes straight guide tubes 330 designed to accommodate rigid, threaded screws following linear insertion trajectories (EX-1006, Fig. 13). Steffee teaches only a **curved fastener itself** designed for securing bone graft—the fastener is the curved element, not a channel within an implant (EX-1016, 2:45-48, Fig. 5). Steffee provides no teaching of curved channels within a fusion member through which separate anchoring members traverse.

In summary, the prior art references asserted in all three grounds teach fundamentally different anchoring systems—**threaded screws requiring rotational insertion** (Blain, Bray) and **curved fasteners for bone graft fixation** (Steffee)—that bear no structural or functional resemblance to the '805

Patent's push-in flanged anchoring system with PMMA injection capability, curved channels enabling semi-circular path movement, and a delivery mechanism extending outside the patient's body during implant positioning.

IV. CLAIMS 1-6, 11, 12, AND 15-17 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	102/103	Blain	1–6, 11, 12, 15–17
2	103	Blain & Bray	1–6, 11, 12, 15–17
3	103	Blain (with or without Bray) - Steffee	5, 16

A. *Legal Standards*

A patent claim is invalid as anticipated under 35 U.S.C. § 102 only if a single prior art reference discloses, either expressly or inherently, each and every limitation of the claimed invention, arranged as in the claim. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). The elements must be "arranged as in the claim" and the reference must enable one skilled in the art to practice the claimed invention. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Inherent anticipation requires that the missing descriptive matter is "necessarily present," not merely "probably or possibly present." *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). A party asserting

inherent anticipation must provide clear and convincing evidence that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *PAR Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014).

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 asserts that claims 1-6, 11, 12, and 15-17 of the '805 Patent are anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 over Blain (EX-1004) in view of the general knowledge possessed by a Person of Ordinary Skill in the Art (POSA) (Pet. at 10-11, 44-72). Petitioner's Ground 1 fails under both legal standards.

As an anticipation ground, Blain fails to disclose, either expressly or inherently, each and every limitation of the challenged claims. Most critically, Blain provides no express or inherent disclosure of the limitation requiring "**the delivery**

mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies" (Claims 1, 11)—the very limitation that served as the sole basis upon which the Patent Examiner allowed the challenged claims during prosecution (EX-1003). Petitioner's expert acknowledges that Blain does not explicitly state this limitation but argues it would have been "obvious" to a POSA (EX-1002, ¶118). This concession is fatal to the anticipation ground: anticipation requires that a single prior art reference disclose, either expressly or inherently, each and every element as set forth in the claim. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). An obviousness analysis cannot salvage a failed anticipation argument.

As an obviousness ground, Petitioner attempts to establish a *prima facie* case by characterizing Blain's instrument guide system as meeting or rendering obvious all limitations of the challenged claims (Pet. at 44-72; EX-1002, ¶¶90-123). This characterization is fundamentally flawed for multiple independent reasons. First, Petitioner fails to provide any articulated reasoning with rational underpinning to support the proposition that the "extending outside a patient's body" limitation would have been obvious (EX-1002, ¶118). Petitioner's expert merely asserts that Blain's handle 20 "would extend outside of the patient's body when being used to position

the implant" without identifying any express teaching in Blain or articulating why a POSA would have understood this spatial relationship to be necessary or even likely (EX-1002, ¶118). This fails to meet the requirement that an obviousness determination must be supported by "articulated reasoning with some rational underpinning." *KSR*, 550 U.S. at 418.

Second, Petitioner's obviousness analysis improperly relies on an overly broad, litigation-derived "applied construction" of "curved channel" that contradicts the intrinsic evidence (EX-1002, ¶87; Pet. at 21-24, 65-66). Petitioner argues that Blain's **straight** guide tubes 18 satisfy the "curved channel" limitation of Claims 5 and 16 merely because they allegedly possess rounded openings, tubular inner walls, and/or an internal curvature serving as a recessed seat for screw heads (EX-1002, ¶87). 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. As explained in Section II.C above, the '805 Patent specification consistently describes "curved channels" as channels that enable anchoring members to "travel in a semi-circular path of movement" (EX-1001, 15:25-28)—a functional characteristic wholly absent from Blain's straight guides designed for threaded screws inserted via rotation (EX-1004, 8:50-54, Fig. 6A).

Third, Petitioner's characterization of Blain's threaded screw fixation system

as teaching the claimed "independent anchoring members" that are "for preventing decoupling of the fusion member from the first vertebral body" (Claims 1, 11) ignores the fundamental structural and functional distinctions between threaded screw systems and push-in flanged anchor systems. Blain discloses bone screws that achieve fixation through **threaded engagement** with bone and prevent backing out through an **anti-rotation lock mechanism** (EX-1004, 5:44-57, 8:50-54). The '805 Patent claims anchoring members with "**flanges at a proximal end**" that lock to the fusion member by fitting into corresponding recesses (Claim 13, Figs. 15-16)—a mechanically distinct locking function designed to prevent **pull-out** of push-in anchors rather than **rotation** of threaded screws. Petitioner's expert attempts to equate Blain's screw head with the claimed flanged-base locking mechanism (EX-1002, ¶161), but these serve fundamentally different purposes in mechanically distinct anchoring systems.

Finally, Petitioner provides no articulated motivation to combine Blain's threaded screw system with the general knowledge allegedly possessed by a POSA to arrive at the claimed push-in flanged anchor system with PMMA injection capability through curved channels (Pet. at 43-72). The motivation Petitioner identifies—"rigidly fixate the interbody device to the vertebrae to prevent migration" (EX-1002, ¶83)—is adequately addressed by Blain's existing threaded screw system.

Petitioner provides no rational underpinning explaining why a POSA would have been motivated to abandon Blain's proven threaded screw fixation in favor of the fundamentally different push-in flanged anchor system claimed in the '805 Patent, nor why a POSA would have had a reasonable expectation of success in making such a wholesale redesign. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (requiring both motivation to combine and reasonable expectation of success).

As detailed below, Ground 1 fails for each challenged claim.

1. Independent Claim 1

Petitioner asserts that Blain anticipates or renders obvious every limitation of Claim 1 (Pet. at 44-61; EX-1002, ¶¶90-123). This assertion fails under both anticipation and obviousness standards for multiple independent reasons.

1.1 Claim 1.P "An apparatus comprising:"

Blain does not disclose the preamble, as will be explained below.

1.2 Claim 1.1 "a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member"

Petitioner maps this limitation to Blain's "flanged interbody fusion implant 2" having "fastener apertures 4" (Pet. at 44-46; EX-1002, ¶¶91-94; EX-1004, Fig. 1, 4:28-37). While Blain does disclose an implant 2 designed for positioning between

vertebral bodies with apertures 4, Petitioner's mapping obscures a critical structural distinction between Blain's straight-through apertures and the '805 Patent's internal channel geometry.

The '805 Patent specification describes the fusion member as "a shaped block" having "one or more channels (e.g., tubular channels)" that extend through the fusion member along specific trajectories (EX1001, 2:19-25). Importantly, the specification explains that "in some embodiments, the fusion member includes curved tubular channels" and that these channels "run in parallel planes with respect to each other but are nonparallel to the adjacent faces of the fusion block member" (EX1001, 5:57-61, Fig. 46A, 46B, and 47). This internal channel architecture—particularly when combined with the "curved channel" limitation of dependent Claim 5—creates a specific geometric configuration enabling the '805 Patent's unique anchoring trajectory.

Blain, by contrast, discloses simple fastener apertures 4 designed solely to accommodate threaded bone screws that are "screwed in" via rotational insertion (EX-1004, 1:37-42, 8:50-54). Blain's apertures follow straight, linear paths aligned laterally with the implant to facilitate screw insertion via screwdriver rotation (EX-1004, 5:10-17, Fig. 6A). Blain provides no teaching of internal channel geometry designed to guide flexible anchoring members along curved trajectories to achieve

a "semi-circular path of movement" as described in the '805 Patent (EX1001, 15:25-28).

1.3 Claim 1.2.1 "a delivery mechanism for delivering the fusion member between the two vertebral bodies, the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,"

This limitation is the linchpin of Claim 1 and represents the sole basis upon which the Patent Examiner allowed the challenged claims during prosecution after amending the claims to overcome Duffield (EX-1003). Petitioner's attempt to satisfy this limitation using Blain's instrument guide 14 fails for lack of express or inherent disclosure.

Petitioner maps the "delivery mechanism" to Blain's "instrument guide 14," comprising handle 20, guide members 18, and device coupler 16 (Pet. at 46-51; EX-1002, ¶¶95-100; EX-1004, 4:55-61). Petitioner's expert acknowledges that Blain does not explicitly state that the instrument guide extends outside a patient's body during implant positioning (EX-1002, ¶118). Instead, Petitioner relies on unsupported inference, asserting that Blain's handle 20 "would extend outside of the patient's body when being used to position the implant" (EX-1002, ¶118).

This inference is insufficient to establish either anticipation or obviousness. For anticipation, a prior art reference must disclose, either expressly or inherently, each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Inherent anticipation requires that the missing limitation 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). Blain provides no express disclosure of the spatial relationship between the handle and the patient's body during the critical procedural step when "the fusion member is positioned between the two vertebral bodies." Petitioner's bald assertion that the handle "would" extend outside the body constitutes speculation, not inherent disclosure.

For obviousness, Petitioner provides no articulated reasoning with rational underpinning to support the conclusion that a POSA would have understood or been motivated to configure Blain's instrument guide such that it extends outside the patient's body during implant positioning. *KSR*, 550 U.S. at 418. The '805 Patent specification itself never explicitly discloses that its delivery mechanism extends outside a patient's body (EX1001, generally)—a fact Petitioner's expert characterizes as evidence that the limitation is "so trivial and uninventive that the Specification of the '805 patent does not discuss it" (EX-1002, ¶76). Yet if the limitation is truly

trivial, Petitioner should have no difficulty identifying explicit prior art disclosure. The absence of such disclosure, combined with the Examiner's determination that this limitation distinguishes Duffield, demonstrates that the limitation is neither anticipated nor obvious from Blain.

Moreover, the claimed limitation requires a specific functional state: the delivery mechanism must extend outside the patient's body "**while** the delivery mechanism is coupled to the fusion member **and** the fusion member is positioned between the two vertebral bodies" (emphasis added). This temporal and spatial constraint requires simultaneous satisfaction of three conditions: (1) delivery mechanism extends outside body, (2) delivery mechanism coupled to fusion member, and (3) fusion member positioned between vertebral bodies. Blain's disclosure that the handle 20 is "detached from the distal shaft 22B" specifically "to insert instruments or fasteners into the guide tubes 18 without potential interference from the protruding handle 20" (EX-1004, 8:46-49) suggests that the handle may be removed precisely to avoid extending outside the patient's body during fastener insertion—contradicting Petitioner's theory that the handle necessarily remains attached and extends externally during this critical procedural step.

1.4 Claim 1.2.2 "the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels ... fusion member between the two vertebral bodies; and"

Petitioner maps this limitation to Blain's guide tubes 18 having "tubular channels" that align with fastener apertures 4 when the instrument guide 14 is coupled to implant 2 (Pet. at 51-54; EX-1002, ¶¶101-107; EX-1004, 5:10-22, Abstract). While Blain does teach alignment between guide tubes 18 and implant apertures 4, Petitioner's mapping again obscures critical structural and functional distinctions.

The '805 Patent describes delivery housing channels that "house and guide the anchoring mechanism to the proper location in the fusion member" and that "run the entire length of the delivery housing" (EX1001, 11:42-51). The specification further explains that these channels accommodate not only anchoring members but also retention mechanisms, stating that "the delivery housing includes channels that guide the retention rods" (EX1001, 2:42-45). Figure 7A illustrates this unified housing structure 610 containing channels for both anchoring members 140 and retention rods 160 (EX1001, Fig. 7A).

Blain, by contrast, discloses a structurally distinct configuration. Blain's guide tubes 18 are separate tubular structures designed solely to guide bone screws (EX-1004, 5:10-17, 8:5-8). The retention mechanism—comprising inner shaft 42 and

movable coupling member 28—is housed within a completely separate structural element, the "distal outer shaft 46" (EX-1004, 5:44-50, Fig. 5; EX-1002, ¶144). This separation means that Blain lacks the claimed "delivery housing" structure that contains channels for both anchoring members and retention mechanisms within a single unified component, as illustrated in Figure 7A of the '805 Patent (EX1001, Fig. 7A).

1.5 Claim 1.3 " a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing ... (iv) preventing decoupling of the fusion member from the penetrated vertebral body."

This limitation requires anchoring members that perform four distinct functions, the fourth of which—"preventing decoupling of the fusion member from the vertebral body"—lies at the heart of Patent Owner's push-in flanged anchor system versus Petitioner's threaded screw system.

Petitioner maps the "plurality of independent anchoring members" to Blain's "bone fasteners 6" (Pet. at 57-61; EX-1002, ¶¶108-123; EX-1004, 4:28-37, 8:50-54). While Blain's bone fasteners do traverse through implant apertures and penetrate vertebral bodies, Petitioner's assertion that they satisfy the "preventing decoupling" function through the same structural mechanism as the '805 Patent is technically inaccurate and legally insufficient.

The '805 Patent achieves "preventing decoupling" through a specific structural feature: "flanges at a proximal end" of the anchoring member that "fit into recesses... locking the anchoring members... to the fusion member" (EX1001, Claim 13, Figs. 15-16). The specification explains that "flanged bases 1645-1650 fit into recesses... 1685-1690... locking the anchoring members 1410-1420 to the fusion member 120 once the anchoring members are fully advanced through the fusion member's channels" (EX1001, 15:39-16:8). This mechanical interference fit between the proximal flange and the fusion member recess prevents the push-in anchor from being pulled out in the direction opposite to insertion.

Blain, by contrast, achieves fixation through an entirely different mechanism: threaded engagement between the screw shaft and bone, supplemented by an anti-rotation locking feature. Blain states that "fasteners 6 may be inserted into the proximal opens 30 of the guide tubes 18 and fastened to bone using a screw driver 66" (EX-1004, 8:50-54)—a process requiring rotational insertion. The specification further describes that "the proximal openings include recesses (red) that lobes (blue) of the fastener heads seat into once fully threaded into the openings, locking the fasteners to the implant, thereby preventing their counter-clockwise rotation to back out" (EX-1004, 5:44-57; Pet. at 69, annotated Fig. 2B).

Petitioner's expert attempts to equate Blain's anti-rotation lock mechanism with the '805 Patent's proximal flange locking by asserting that both involve a head fitting into a recess (EX-1002, ¶161). This superficial comparison ignores the fundamental mechanical distinction: Blain's anti-rotation mechanism prevents **rotational movement** (backing out via counter-clockwise rotation) of a **threaded fastener** after it has been screwed into bone, while the '805 Patent's proximal flange mechanism prevents **axial pull-out** of a **push-in anchor** after it has been driven into bone via linear force. These are mechanically distinct locking functions serving different purposes in fundamentally different anchoring systems.

Moreover, the '805 Patent's anchoring members are explicitly described as being "tapped, hammered, or simply pushed" into place (EX1001, 20:49-53)—a linear force insertion mechanism incompatible with Blain's threaded screws requiring rotational insertion. The '805 Patent further describes anchoring members having "hollow central lumens and perforated tips" designed for injecting "polymethyl methacrylate (PMMA) or other bone cement or hardening polymer material" through the anchoring member and into the marrow space of vertebral bodies for enhanced fixation (EX1001, 3:10-25, Figs. 15-16). Blain provides no disclosure of this PMMA injection capability through hollow anchoring members,

instead relying exclusively on threaded engagement with bone for fixation (EX-1004, 7:49-62).

2. Claim 2

"The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member"

Petitioner asserts that Blain's instrument guide 14 comprises both (1) a "delivery housing" mapped to "guide tubes 18 attached to device coupler 16," and (2) a "retention mechanism" mapped to "inner shaft 42 and movable coupling member 28" (Pet. at 61-64; EX-1002, ¶¶138-145). These mappings improperly aggregate separate structural components to satisfy a single claimed unified housing structure, revealing fundamental misunderstandings of both Blain's architecture and the claimed invention.

Firstly, the '805 Patent describes "a delivery housing" (singular) that performs integrated functions within a unified structural body. The specification states "the delivery housing channels house and guide the anchoring mechanism to the proper location in the fusion member" and separately that "the delivery housing includes channels that guide the retention rods" (EX1001, 2:42-45). This dual functionality—guiding both anchoring members and retention rods—occurs within a single unified

housing structure. Figure 7A illustrates delivery housing 610 containing channels for **both** anchoring members 140 **and** retention rods 160 within the same structural component (EX1001, Fig. 7A).

Blain discloses a fundamentally different architecture: **separate structural components** that are attached together to form a modular assembly. Petitioner maps the "delivery housing" to "guide tubes 18 (yellow) attached to device coupler 16 (yellow)" (Pet. at 61-62; EX-1002, ¶¶138-140, annotated Figs. 2C, 4). Petitioner's expert admits these components are "**attached to**" each other (EX-1002, ¶138)—language that necessarily means they are **separate components** that have been joined together, not a single unified housing. Blain describes guide tubes 18 as discrete tubular structures designed solely to guide bone screws, which mate with or attach to device coupler 16 (EX-1004, 5:10-17, 8:5-20). This modular configuration of separate attached components does not satisfy a claim requiring a single unified "delivery housing."

Petitioner's expert attempts to justify this aggregation by asserting that guide tubes 18 "house" the anchoring members because "the guide members 18 support, contain, and protect the fasteners 6 as each fastener is driven through the guide tubes" (EX-1002, ¶139). This argument conflates temporary containment during insertion with structural "housing." The '805 Patent's delivery housing contains

internal channels that "run the entire length of the delivery housing" to permanently house and guide anchoring members to fusion member channels (EX1001, 2:39-45). Blain's guide tubes 18 are **external tubular attachments** through which screws pass during insertion—they provide temporary guiding, not structural housing within an integrated delivery housing containing both anchoring channels and retention mechanisms.

Secondly, claim 2 requires "a retention mechanism for fixedly coupling **the delivery housing** to the fusion member"—meaning the retention mechanism must couple the **housing itself** (which contains channels for guiding anchoring members) to the fusion member. This structural relationship is critical: the unified housing that guides the anchoring members must be coupled to the fusion member by the retention mechanism.

Petitioner maps the retention mechanism to Blain's "inner shaft 42" and "movable coupling member 28" (Pet. at 62-64; EX-1002, ¶¶141-145). Critically, Petitioner's expert admits that this retention mechanism "is disposed within device coupler 16" and "the inner shaft 42 is within the distal shaft 22B portion of the handle shaft 22" (EX-1002, ¶¶141-144, annotated Fig. 5). This admission is fatal to Petitioner's mapping because it confirms that Blain's retention mechanism resides within **device coupler 16 and distal shaft 22B—not** within the guide tubes 18 that

Petitioner identifies as the "delivery housing" for guiding anchoring members (compare EX-1002, ¶¶138-140 with ¶¶141-145).

This structural separation is dispositive. Blain's anchoring member guiding function (performed by guide tubes 18) and retention mechanism function (performed by inner shaft 42/coupling member 28 within device coupler 16/distal shaft 22B) are housed in **separate structural elements** that have been attached together to form a modular assembly. The '805 Patent, by contrast, requires a single unified "delivery housing" containing channels for **both** the anchoring members **and** the retention mechanism within the same housing structure (EX1001, 11:37-52, Fig. 7A).

Moreover, because the retention mechanism in Blain resides within device coupler 16 (separate from guide tubes 18), Blain's retention mechanism couples the **entire instrument guide assembly**(including handle 20, shaft 22, device coupler 16, and guide tubes 18) to the implant 2 (EX-1004, 5:17-22, 5:44-50). It does not couple a unified "delivery housing" (containing channels for both functions) to the fusion member as required by the claim. Petitioner's attempt to aggregate guide tubes 18 + device coupler 16 into a collective "housing" merely confirms that Blain discloses multiple separate components, not the claimed unified housing structure.

Accordingly, Blain fails to anticipate or render obvious Claim 2.

3. Claim 3

"The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member"

Petitioner's anticipation argument fails because Blain does not disclose the limitations of Claim 2, from which Claim 3 depends. As established in the response to Claim 2 above, Blain fails to disclose the claimed "delivery housing." The '805 Patent requires a single, integrated delivery housing (e.g., 610) containing channels for **both** the anchoring members and the retention mechanism (e.g., retention rods in channels 710) (EX1001, Figs. 6, 7A). Blain teaches no such integrated structure. Instead, Blain discloses a bifurcated system where anchoring members (fasteners 6) are guided by separate guide tubes 18, while the retention mechanism (inner shaft 42) is housed in a completely separate component, the distal outer shaft 46 (EX-1004, Fig. 5). Because Petitioner cannot identify the antecedent "delivery housing" of Claim 2, its challenge to dependent Claim 3 fails.

Even if Petitioner could overcome this fatal flaw—which it cannot—its Claim 3 argument fails independently. Petitioner improperly equates Blain's complex

internal driveshaft assembly (inner shaft 42) with the claimed "retention rod" (Pet. at 64; EX-1002, ¶146; EX-1004, Fig. 5). This mapping is technically unsound.

The '805 Patent's "retention rod" is a specific, simple structure exemplified by retention rods 160, which are guided by dedicated channels 710 in the delivery housing and feature retention teeth 910 that directly engage retention grooves 150 on the **lateral surfaces** of the fusion member (EX1001, Figs. 5A, 7A, 10A-10C). This is a direct, external, multi-point locking system.

Blain's inner shaft 42 is fundamentally different—a complex internal component concealed within distal outer shaft 46 that does not engage the side of the fusion member (EX-1004, Fig. 5). Instead, it terminates in movable coupling member 28 that engages a single, central coupling opening 10 on the **proximal face** of the implant (EX-1004, Figs. 2C, 5).

A POSA would not have understood Blain's complex, internal, central-axis driveshaft to be the same as the '805 Patent's simple, externally-engaging retention rod. Blain's retention mechanism and the claimed "retention rod" are structurally and functionally distinct.

Accordingly, Blain fails to anticipate or render obvious Claim 3.

4. Claim 4:

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

Petitioner's argument for Claim 4 fails for the same antecedent reason as Claim 3: Blain (Ex. 1004) does not disclose the "delivery housing" recited in Claim 2. (Sec. II.C.1, *supra*).

Even setting aside this fatal flaw, Petitioner's argument is technically incorrect. Petitioner alleges that Blain's "aligned coupling ... matches the guide lumens 18 ... with the fastener apertures 4." (Ex. 1002, ¶ 147). This misrepresents how Blain's tool functions. Blain's "guide tubes 18" (Petitioner's "second plurality of channels") and its "device coupler 16" are part of a *single, rigid assembly*. (Ex. 1004, Fig. 2A). The alignment between these components is *fixed and pre-exists* any "coupling" event.

The "coupling" event in Blain is the *separate* act of locking the tool's *internal* "inner shaft 42" to the implant's central opening 10. (Ex. 1004, Fig. 5). This act *secures* the already-aligned tool; it does not *cause* the alignment.

The '805 patent claims a different structure and function. In the '805 patent, the "delivery housing" (610) is a single component that *itself* is coupled to the fusion member (e.g., via retention rods 160). (Ex. 1001, Fig. 6). This *act of coupling the*

housing is what "causes" the internal anchor channels (720) to simultaneously align with the fusion member channels. Blain's bifurcated system—where alignment is manual and precedes a separate, internal locking step—does not teach the claimed invention where the coupling of the housing *itself causes* the alignment.

5. Claim 5:

"The apparatus of claim 1, wherein each channel of the fusion member is curved."

Petitioner's challenge to Claim 5 is a textbook example of litigation-driven sophistry. It relies entirely on the "applied construction" that Petitioner's expert, Dr. Culbert, was "instructed" to use—namely, that the plain word "curved" can mean any channel with a "round opening" or a "concave ... seat." (Ex. 1002, ¶ 87-88, 148-150). This construction is demonstrably false and is contradicted by the '805 patent and by Petitioner's own arguments in federal court.

First, the '805 patent's specification explicitly distinguishes between "curved channels" (e.g., Fig. 30, 46A) and an alternate embodiment with "straight uncurled channels" (Ex. 1001, 23:1-2, Figs. 41-42). Blain's fastener apertures 4 (Ex. 1004) are, by any objective measure, straight, just like the "straight uncurled channels" embodiment the patentee expressly distinguished. Petitioner's construction, which would find Blain's straight channels to be "curved" simply because they have a

"round opening" (Ex. 1002, ¶ 149), would render the patient's own distinction between "curved" and "straight" meaningless.

Second, Petitioner's "applied construction" is a sham. In the parallel district court litigation, Petitioner argues for the exact opposite construction, asserting that this precise term must be construed as "channel that has a curved path" (50 Globus Claim Construction Brief.pdf, p. 10). Petitioner is thus arguing from both sides of its mouth: a narrow "curved path" construction to avoid infringement in district court, and a limitless "round opening" construction to argue invalidity before this Board.

Petitioner's "applied construction" is baseless. Under the correct, plain and ordinary meaning—which requires a "curved path" as confirmed by the specification and Petitioner's own court briefing—Blain's straight channels (Ex. 1004, Fig. 6A) do not anticipate. Claim 5 is not unpatentable.

6. Claim 6:

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

Petitioner's challenge to Claim 6 fails, as it depends on the flawed and unsupported mappings for independent Claim 1. As established *supra*, Blain (Ex.

1004) does not disclose the "delivery mechanism," "first plurality of channels," or "independent anchoring members" as claimed.

Even if Petitioner could establish its basis in Claim 1, its argument for Claim 6 is a tautology that improperly equates Blain's conventional, straight-screw system with the distinct structure of the '805 patent. Petitioner merely asserts that Blain's fastener (6) passes through its guide tube (18) and into its implant aperture (4) (Ex. 1002, ¶ 151), a generic action true of virtually *any* guided surgical tool. This superficial similarity does not establish anticipation.

Petitioner's mapping conveniently ignores that the components in Blain are structurally and functionally different from those claimed:

- **"channel of the delivery mechanism":** Petitioner maps this to Blain's "guide tubes 18." (Ex. 1002, ¶ 151). As established for Claim 2, these tubes are separate components from the housing for the retention mechanism (the "distal outer shaft 46"). They are *not* the claimed "delivery housing" (610), which is a *single, integrated* structure containing channels for *both* the anchors (720) and retention rods (710). (Ex. 1001, Fig. 7A).
- **"channel of the fusion member":** Petitioner maps this to Blain's "fastener apertures 4." (Ex. 1002, ¶ 110). As established for Claim 5, these are *straight*,

uncurled channels for screws, not the "curved channels" taught by the '805 patent.

- **"anchoring member":** Petitioner maps this to Blain's "bone fasteners 6." (Ex. 1002, ¶ 130). These are *threaded screws* inserted by *rotation* with a "screw driver" (66). (Ex. 1004, 8:50-54). They are not the '805 patent's "independent anchoring members" (e.g., 1410), which are barbed, flexible pins inserted by linear force and decoupled from a "driving member."

At best, Blain teaches the generic concept of passing a *screw* through a *straight, separate guide tube*. It does not teach the claimed invention: passing a *flexible, barbed pin* through a *curved channel* within an *integrated housing*. Petitioner has failed to show Blain teaches the claimed structure, and its challenge to Claim 6 must be rejected.

7. Claim 11:

7.1 Claim 11.PA fusion device comprising:"

Blain does not disclose the preamble as shown below.

7.2 Claim 11.1 "a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;"

See claim element 1.1 above

7.3.1 Claim 11.2.1 "a delivery mechanism for delivering the fusion member between the two vertebral bodies, the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies"

See claim element 1.2.1 above.

7.3.2 Claim 11.2.2 "the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and"

See claim element 1.2.2 above

7.3.3 Claim 11.3 "a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) coupling the fusion member to the vertebral body, and (ii) preventing decoupling of the fusion member from the vertebral body."

See claim element 1.3 above

8. Claim 12

"The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member"

Petitioner's challenge to Claim 12 fails for the same antecedent reasons fatal to its challenge to Claim 1 and 11: Blain (Ex. 1004) does not disclose the claimed

"delivery mechanism" or "independent anchoring members" as recited in independent Claim 11.

Even if Petitioner could establish a proper antecedent basis—which it cannot—its mapping for Claim 12 is technically deficient. Petitioner attempts to equate Blain's conventional anti-rotation feature for a *threaded screw* with the '805 patent's specific *flange-based locking system* for a *push-in anchoring member*.

Petitioner alleges Blain's head-lobe-and-recess feature (Ex. 1002, ¶ 158, annotating Fig. 1) constitutes the claimed "locking." This is incorrect. Blain's feature is designed for a single purpose: to prevent a *threaded fastener* (6) from *unscrewing* (i.e., counter-rotating) after it has been fully torqued into place.

The '805 patent claims a different structure for a different function. The "locking" described in the '805 patent involves a "flanged base" (e.g., 1710) on the proximal end of the *non-threaded, push-in* anchoring member, which mechanically seats and locks into a complementary "flange cavity" (1720) in the fusion member. (Ex. 1001, 16:2-25, Figs. 16-17). This structure is designed to *axially retain* the push-in anchor against pull-out forces and, critically, to *prevent its rotation during decoupling* of the driving member (Ex. 1001, 17:21-25). This decoupling-related function is wholly absent from, and unnecessary in, Blain's simple "screw driver" (66) system.

Blain's anti-rotation stop for a *screw* is not the claimed flange-and-cavity lock for a *decouplable, push-in pin*. Petitioner has failed to show that Blain discloses this limitation.

9. Claim 15

"The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism"

Petitioner's challenge to Claim 15 fails because its antecedent basis, Claim 11, is not anticipated by Blain (Ex. 1004).

Furthermore, Petitioner's mapping for this claim is technically flawed. Petitioner equates Blain's "screw driver 66" with the claimed "driving member." (Ex. 1002, ¶ 162). A POSA would not find these components to be the same, as they are structurally and functionally distinct.

- The "driving member" of the '805 patent (e.g., 1430, 1900) is a specialized component designed to apply *linear, axial force* (i.e., "tapping, hammering, or simply pushing") to an "independent anchoring member" (e.g., a non-threaded pin 1410, 1910) and is specifically configured to *decouple* from that anchor. (Ex. 1001, 13:55-14:13, 17:34-44).

- Blain's "screw driver 66" is a conventional tool designed to apply *rotational torque* to a *threaded fastener* (6) that is *not* designed to be decoupled from its head. (Ex. 1004, 8:50-54).

Blain's tool *rotates a screw*; the claimed invention *drives a pin*. These are fundamentally different mechanisms of action. Because Blain's "bone fastener 6" is not the claimed "independent anchoring member," Blain's "screw driver 66" is necessarily not the claimed "driving member." Petitioner has failed to show Blain anticipates this limitation.

10. Claim 16:

“The fusion device of claim 11, wherein each channel of the fusion member is curved”

.Petitioner's argument for Claim 16, like its argument for identical Claim 5 fails. *See* claim 5 above.

11. Claim 17:

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

Petitioner's challenge to Claim 17 fails, as it is dependent on the un-taught limitations of Claim 11.

Moreover, this claim is a near-verbatim repeat of Claim 6, and Petitioner's argument (Ex. 1002, ¶ 165-166) is the same flawed tautology. Petitioner's assertion that Blain's *screw* (6) passes through a *guide tube* (18) and into an *aperture* (4) does not establish anticipation because, as repeatedly demonstrated, Blain's components are not the claimed components.

Blain teaches a *threaded screw* (6) inserted by *rotation* (via "screw driver 66") through a *straight, separate guide tube* (18) that is part of a bifurcated tool.

The '805 patent claims a *flexible, non-threaded, barbed pin* (e.g., 1410) inserted by *linear force* (via "driving member" 1430) through a *corresponding channel* (720) in a *single, integrated delivery housing* (610) and into a *curved channel* in the fusion member.

Blain's system is structurally and functionally different. Petitioner has failed to show Blain teaches the claimed limitations.

* * *

For all the foregoing reasons, Petitioner cannot legally sustain its burden to prove anticipation or show obviousness in Ground 1 over *Blain* alone or with *General Knowledge of POSA*.

C. Petitioner Fails to Properly Establish Obviousness in Ground 2

Petitioner's Ground 2, which proposes combining U.S. Patent No. 8,172,854 ("Blain," Ex. 1004) with U.S. Patent No. 7,985,255 ("Bray," Ex. 1006), is a quintessential example of impermissible hindsight. This Ground fails for at least three independent reasons: (1) the combination is improper as it merely picks and chooses components from two distinct, complete, and competing prior art systems; (2) the combination fails to teach the limitations of the independent claims for the same reasons Blain alone failed in Ground 1; and (3) the combination is technically flawed and does not teach the specific limitations of the dependent claims.

Ground 2 is essentially identical to Ground 1 with the addition of Bray as a purported secondary reference. As explained in the response to Ground 1 above, Blain fails to anticipate or render obvious the challenged claims for multiple independent reasons, including: (1) failure to disclose the critical "extending outside a patient's body" limitation, (2) failure to disclose a unified delivery housing containing channels for both anchoring members and retention mechanisms, (3) mischaracterization of threaded screws with anti-rotation locking as satisfying push-in anchors with proximal flange locking, and (4) failure to disclose curved channels enabling semi-circular path movement. These deficiencies are not remedied by adding Bray to the combination.

Petitioner's sole reason for adding Bray to Ground 2 is to allegedly provide additional support for the "housing" limitation (Pet. at 72-77; EX-1002, ¶¶186-203). Specifically, Petitioner argues that Bray's restraining plate 60 with restraining plate fixing means 70 provides an additional example of a "housing" or "cover" structure (Pet. at 73-74; EX-1002, ¶¶190-193; EX-1006, 4:49-57, Figs. 1, 9, 10). This argument fails for multiple reasons which are discussed below.

1. Independent Claims 1 and 11

As discussed *supra*, Petitioner provides no articulated reasoning explaining why a POSA would have been motivated to combine Blain and Bray, and even if combined, the resulting combination fails to cure the fundamental deficiencies identified in Ground 1.

Petitioner's Ground 2 argument for independent Claims 1 and 11 is substantively identical to Ground 1, with the sole addition that "it would have been obvious to modify Blain in view of Bray" to allegedly provide an anti-backout mechanism (Pet. at 73-77; EX-1002, ¶¶167-187). This proposed modification fails for multiple independent reasons.

a. Blain Already Contains Anti-Backout Mechanism. Petitioner's expert admits that Blain already discloses an anti-backout mechanism where "lobes (blue) of the fastener heads seat into [recesses] once fully threaded into the openings,

locking the fasteners to the implant, thereby preventing their counter-clockwise rotation to back out" (EX-1002, ¶158; Pet. at 69, annotated Fig. 2B). Given that Blain already prevents screws from backing out via anti-rotation locking, Petitioner provides no articulated reasoning explaining why a POSA would have been motivated to add Bray's **additional** restraining plate 60 to achieve the same anti-backout function. This constitutes impermissible hindsight. *KSR*, 550 U.S. at 418.

b. Bray's Restraining Plate Does Not Remedy Ground 1 Deficiencies. Even assuming *arguendo* that a POSA would have been motivated to combine Blain and Bray—which Petitioner fails to establish—the resulting combination still fails to satisfy the challenged claims for all the reasons explained in Ground 1. Bray's restraining plate 60 is a **post-implantation cover** that is secured over bone screw heads **after** the screws have been fully inserted and the implant affixed to the vertebrae (EX-1006, 4:49-57, 9:61-10:14). It is not part of a delivery mechanism and provides no teaching regarding: (1) a unified delivery housing containing channels for both anchoring members and retention mechanisms (Blain's separate guide tubes 18 and device coupler 16 structure remains unchanged), (2) push-in anchoring members with proximal flange locking (both Blain and Bray use threaded screws with anti-rotation mechanisms), (3) curved channels for semi-circular path movement (both references have straight guides/apertures for threaded

screws), or (4) a delivery mechanism extending outside the patient's body during implant positioning.

c. Lack of Motivation to Combine. Petitioner provides no articulated reasoning explaining why a POSA would have been motivated to combine Blain's **pre-implantation** instrument guide (used during initial implant delivery and screw insertion) with Bray's **post-implantation** restraining plate (secured after screw insertion is complete). These references address different procedural stages and serve different functions. Petitioner's assertion that both references relate to spinal implants with bone screws constitutes the type of "obvious to try" reasoning explicitly rejected by the Supreme Court. *KSR*, 550 U.S. at 421.

For the same reasons explained in the response to Claim 1 in Ground 1 above, Blain in view of Bray fails to render obvious Claims 1 and 11.

2. Claims 5 and 16 (Curved Channels)

Petitioner asserts that Claims 5 and 16 would have been obvious over Blain in view of Bray based on the same flawed "curved channel" construction applied in Ground 1 (Pet. at 77-81; EX-1002, ¶¶188-197). Bray provides no teaching regarding curved channels. Bray discloses bone screws 50 that pass through **straight** apertures in implant 10 (EX-1006, Figs. 1, 9, 10). Adding Bray's post-implantation restraining

plate to Blain does nothing to transform Blain's straight guide tubes into curved channels enabling semi-circular path movement.

For the same reasons explained in the response to Claim 5 in Ground 1 above, Blain in view of Bray fails to render obvious Claims 5 and 16.

3. Claim 12 (Locking Mechanism)

Petitioner asserts that Claim 12 would have been obvious over Blain in view of Bray based on Bray's restraining plate 60 providing an additional anti-backout mechanism (Pet. at 83; EX-1002, ¶¶198-200). This argument fails because Bray's restraining plate serves the same anti-rotation function as Blain's lobe-and-recess mechanism—preventing threaded screws from rotating counter-clockwise and backing out. Neither reference discloses the claimed locking mechanism where "flanges at a proximal end fit into recesses... locking the anchoring members to the fusion member once the anchoring members are fully advanced through the fusion member's channels" to prevent axial pull-out of push-in anchors.

For the same reasons explained in the response to Claim 12 in Ground 1 above, Blain in view of Bray fails to render obvious Claim 12

4. Other Challenged Claims

Petitioner provides no substantive Ground 2 analysis for Claims 2-4, 6, 15, and 17, instead relying entirely on the Ground 1 analysis with a perfunctory

statement that Bray does not change the analysis (Pet. at 84; EX-1002, ¶¶201-203). For the same reasons explained in the responses to these claims in Ground 1 above, Blain in view of Bray fails to render obvious Claims 2-4, 6, 15, and 17.

Accordingly, all challenged claims remain patentable over Ground 2

* * *

For all the foregoing reasons, Petitioner cannot legally sustain its burden to show obviousness in Ground 2 over *Blain* and *Bray*.

D. Petitioner Fails to Properly Establish Obviousness in Ground 3

Petitioner's Ground 3 is impermissible hindsight, failing to establish that a POSA would have been motivated to combine Blain (EX-1004) with Steffee (EX-1016) to render Claims 5 and 16 obvious (Pet. at 84-91; EX-1002, ¶¶204-246). Claims 5 and 16 recite "wherein each channel of the fusion member is curved" (EX1001, Claims 5, 16). This proposed combination is non-analogous, structurally mischaracterized, technically infeasible, and fatally inconsistent with Ground 2.

Steffee is Non-Analogous Art. The '805 Patent and Blain concern interbody fusion implants inserted into the disc space and anchored via fasteners passing **through** the implant (EX1001, Claims 1, 11; EX-1004, 4:26-39). Steffee is directed to a completely different problem: "securing bone graft between a pair of bone portions" using a fastener designed to prevent stress concentration from bone

graft resorption (EX-1016, 1:6-9, 1:29-36, Fig. 5). Steffee's curved fastener is driven **directly through bone graft material** to hold graft in place, not to anchor a rigid implant (EX-1016, 2:45-48).

Steffee fails both prongs of the non-analogous art test. First, Steffee is not from the same field of endeavor—interbody fusion devices versus bone graft fixation systems. Second, Steffee is not reasonably pertinent to the problem faced by the inventor. The '805 Patent addresses securing an implant via anchoring members driven through precisely engineered channels in a rigid implant structure. Steffee addresses preventing bone graft resorption-induced stress concentration using curved fastener geometry. A POSA seeking to improve interbody fusion fixation would not have looked to Steffee's bone graft fastener. *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011).

Core Structural Mischaracterization. Even assuming *arguendo* Steffee is analogous art—which it is not—Petitioner fundamentally mischaracterizes both Steffee and the claimed invention. Steffee teaches a curved **fastener** where the curvature resides **in the fastener itself**—the fastener follows a curved path through bone graft (EX-1016, 2:45-48, Fig. 5). There is no implant with internal channels, no fusion member with engineered channel geometry, and no separate anchoring members traversing through channels.

The '805 Patent requires "a fusion member... wherein the fusion member has a first plurality of channels" and separately "a plurality of independent anchoring members... traversing through a different channel of the fusion member" (EX1001, Claims 1, 11). Claims 5 and 16 add "wherein each channel of the fusion member is curved." The **channel** must be curved, not the fastener. The specification describes "curved tubular channels" that "run in parallel planes... but are nonparallel to the adjacent faces of the fusion block member" (EX1001, 5:57-61). Figures 46A-46B illustrate curved channels 4610, 4620 following non-linear trajectories **through** the fusion member, causing anchoring members to achieve "semi-circular path of movement" (EX1001, Figs. 46A-46B, 15:25-28).

Steffee's standalone curved fastener driven directly through bone graft provides no teaching of an intervertebral fusion member containing precisely engineered curved **channels** through which separate anchoring members traverse. This reflects fundamentally different structural configurations: the '805 Patent's curved channels within rigid implant structure enable controlled anchoring trajectories through engineered channel geometry; Steffee's curved fastener addresses stress concentration in bone graft through fastener shape.

Technical Infeasibility. The proposed combination is technically impossible as presented. Petitioner argues a POSA would replace Blain's straight fasteners with

Steffee's curved fasteners to "minimize post-surgery migration" and "prevent backing out" (Pet. at 89-91; EX-1002, ¶¶196, 201). But Blain already prevents backing out via anti-rotation locking where "lobes of the fastener heads seat into [recesses], locking the fasteners to the implant, thereby preventing their counter-clockwise rotation to back out" (EX-1004, 5:44-57). Petitioner provides no reasoning why a POSA would abandon Blain's proven threaded screw system with integrated anti-backout mechanism in favor of Steffee's permanent, impact-driven barbed fastener designed for bone graft fixation. *KSR*, 550 U.S. at 418.

Moreover, Dr. Culbert's assertion that a POSA would simply drive Steffee's curved fastener through Blain's delivery tool ignores mechanical reality (EX-1002, ¶205). Blain's delivery tool has rigid, straight guide tubes 18 (EX-1004, Fig. 2A). A POSA would know that attempting to hammer a rigid, **curved** fastener (Steffee's fastener 10, Fig. 1) through a rigid, **straight** tube (Blain's guide tubes 18) would fail—the fastener would jam where its curvature exceeded the straight tube bore.

To achieve the combination, the POSA would have to completely redesign Blain's external tool to have curved guide tubes matching Steffee's fastener curvature. Petitioner provides no motivation for this substantial secondary modification. Blain's single reference to a "non-linear guide member" as a theoretical alternative (EX-1004, 8:14-16) does not suggest combining it with an impact-driven,

barbed fastener from a non-analogous bone-graft system. This cursory mention does not constitute motivation to combine incompatible systems from different fields addressing different problems.

Fatal Inconsistency with Ground 2. Ground 3 is fatally inconsistent with Ground 2, proving Petitioner's "curved channel" theories are post-hoc rationalizations. In Ground 2, Petitioner argues a POSA would find Blain's straight channels "curved" by adding Bray's concave seat—the channel remains on a straight path but has a circular opening and concave surface (Pet. at 77-81). Here, Petitioner argues a POSA would make channels "curved" by re-engineering them to have a curved **path** geometry to accommodate Steffee's curved fastener trajectory (Pet. at 98-103).

These are completely different, mutually exclusive modifications. Ground 2 requires no path modification—just adding a concave surface to a straight channel. Ground 3 requires fundamental re-engineering of the channel path from straight to curved. A POSA cannot simultaneously: (a) leave the channel path straight while adding only a concave seat, and (b) redesign the entire channel path to be curved. This "pick-and-choose" approach proves these arguments are not based on what a POSA would have actually done, but on whatever combination Petitioner needs to construct a hindsight-based obviousness argument. *In re Beattie*, 974 F.2d 1309,

1312 (Fed. Cir. 1992).

No Reasonable Expectation of Success. Even if motivated—which Petitioner fails to establish—Petitioner provides no basis for reasonable expectation of success. The modification requires: (1) abandoning Blain's threaded screw system, (2) replacing straight guide tubes with curved guide tubes, (3) redesigning implant channels for curved fastener trajectories, and (4) ensuring curved geometry achieves stable fixation. Petitioner offers no analysis of these challenges, no explanation for determining appropriate curvature, no teaching regarding how curved channels would interface with Blain's implant structure, and no basis for concluding the combination would successfully achieve interbody fusion device fixation. *Intelligent Bio-Sys.*, 821 F.3d at 1367.

Additionally, the Blain+Steffee combination inherits all fatal Ground 1 deficiencies: no disclosure of "extending outside a patient's body" limitation, no unified delivery housing, threaded screws rather than push-in anchors with proximal flange locking, and no PMMA injection capability. Adding Steffee provides no teaching to cure any of these deficiencies.

For all these reasons—non-analogous art, structural mischaracterization, technical infeasibility, lack of motivation, no reasonable expectation of success, fatal Ground 2 inconsistency, and uncured Ground 1 deficiencies—Petitioner's Ground 3

is a quintessential "obvious to try" argument proposing combination of incompatible parts from non-analogous systems, which would not have worked as proposed and would not have resulted in the claimed invention.

Accordingly, Claims 5 and 16 remain patentable over Ground 3.

* * *

For all the foregoing reasons, Petitioner cannot legally sustain its burden to show obviousness in Ground 3 over *Blain (with or without Bray)* 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 /s/

CERTIFICATE OF COMPLIANCE

Patent Owner certifies that Patent Owner's Preliminary Response contains 13,685 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^h 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
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Dated: October 28, 2025

Respectfully submitted,

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