

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GLOBUS MEDICAL, INC.  
Petitioner,

v.

SPINELOGIK, INC.,  
Patent Owner

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

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**PETITION FOR INTER PARTES REVIEW**

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## **EXHIBIT LIST**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                     |
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| 1001               | U.S. Patent No. 8,460,385 to Wensel (“the ’385 Patent”)                                                                                                                                                                                                                                                                |
| 1002               | Expert Declaration of Brad Culbert                                                                                                                                                                                                                                                                                     |
| 1003               | File History, U.S. Patent Application 12/705,972 (’385 Patent).                                                                                                                                                                                                                                                        |
| 1004               | U.S. Patent No. 7,942,903 (“Moskowitz”)                                                                                                                                                                                                                                                                                |
| 1005               | U.S. Patent No. 4,790,303 (“Steffee”)                                                                                                                                                                                                                                                                                  |
| 1006               | U.S. Patent No. 8,075,593 to Hess (“Hess”)                                                                                                                                                                                                                                                                             |
| 1007               | U.S. Patent Application Publication US 2006/0030851 (“Bray”)                                                                                                                                                                                                                                                           |
| 1008               | U.S. Patent Application Publication US 2005/0085913 (“Fraser”)                                                                                                                                                                                                                                                         |
| 1009               | Excerpts from Webster’s New World College Dictionary (4th Ed., 1999)                                                                                                                                                                                                                                                   |
| 1010               | Excerpts from The Oxford American Desk Dictionary (1998)                                                                                                                                                                                                                                                               |
| 1011               | Excerpts from The American Heritage Dictionary (2nd College Ed., 1982)                                                                                                                                                                                                                                                 |
| 1012               | Infringement Contentions Claim Chart of ’385 Patent                                                                                                                                                                                                                                                                    |
| 1013               | YouTube Video File cited in Patent Owner’s Infringement Contents available at: <a href="https://www.globusmedical.com/products/hedron-ia/">https://www.globusmedical.com/products/hedron-ia/</a> downloaded from <a href="https://www.youtube.com/watch?v=mfkNhww75N0">https://www.youtube.com/watch?v=mfkNhww75N0</a> |
| 1014               | USPTO Discretionary Denial Guidance                                                                                                                                                                                                                                                                                    |
| 1015               | U.S. Patent No. 9,980,824                                                                                                                                                                                                                                                                                              |
| 1016               | Lumbar Interbody Fusion Techniques <i>Cages, Dowels, and Grafts</i> , ed. Haid, Jr. et al., Quality Medical Publishing, Inc., St. Louis, Missouri 2003.                                                                                                                                                                |

| Exhibit No. | Description                                                                                                                                                        |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1017        | Advances in Spinal Fusion – Molecular Science, Biomechanics, and Clinical Management, ed. Lewandrowski et al., Marcel Dekker, Inc., New York, New York 2004.       |
| 1018        | U.S. Patent 8,100,955                                                                                                                                              |
| 1019        | U.S. Patent No. 7,662,186                                                                                                                                          |
| 1020        | U.S. Patent No. 7,041,135                                                                                                                                          |
| 1021        | U.S. Patent Application Publication No. US 2009/0112261                                                                                                            |
| 1022        | U.S. Patent No. 6,447,546                                                                                                                                          |
| 1023        | U.S. Patent 8,172,854                                                                                                                                              |
| 1024        | U.S. Patent 8,273,127                                                                                                                                              |
| 1025        | Machinery Handbook, 28th Ed. (excerpts)                                                                                                                            |
| 1026        | A Method to Machine a Curved Tunnel with EDM, International Journal of Electrical Machining, No. 7, 2002, Goto et al.                                              |
| 1027        | Curriculum Vitae of Brad Culbert                                                                                                                                   |
| 1028        | Plaintiff’s Disclosure of Proposed Constructions, <i>Spinelogik Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-00529-JRG (E.D. Tex. Oct. 30, 2024)                 |
| 1029        | Defendant Globus Medical, Inc.’s Preliminary Claim Constructions, <i>Spinelogik Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-00529-JRG (E.D. Tex. Oct. 30, 2024) |

## **CONVENTIONS OF THE PETITION**

1. All emphasis is added unless otherwise noted.
2. “POSA” refers to a person of ordinary skill in the art at the time of the claimed invention.
3. Claim terms have been italicized in Sections III and VIII.-X.
4. Even when not explicitly referenced, the analysis of all dependent claims incorporates the analysis of the independent claim from which they depend by reference.

## **MANDATORY NOTICES (37 C.F.R. § 42.8)**

### **42.8(b)(1)-RPI**

The real party in interest is Globus Medical, Inc. (“Globus”).

### **42.8(b)(2)–Related Matters**

- *Spinelogik, Inc. v. Globus Medical, Inc.*, No. 2:23-cv-00529 (E.D. Tex.) filed Nov. 17, 2023. Service occurred on Nov. 21, 2023.
- *Spinelogik, Inc. v. Choice Spine, LLC*, No. 2:23-cv-00296 (E.D. Tex.) filed June 22, 2023.
- *Spinelogik, Inc. v. Genesys Orthopedics Sys., LLC*, No. 2:23-cv-00297 (E.D. Tex.) filed June 22, 2023
- *Spinelogik, Inc. v. Camber Spine Techs., LLC*, 2:24-cv-00873 (E.D. Tex.) filed October 29, 2024
- *Globus Medical, Inc. v. Spinelogik, Inc.*, IPR2025-00225 (PTAB) filed November 21, 2024.

**42.8(b)(3)-Counsel**

|                        |                                                                              |
|------------------------|------------------------------------------------------------------------------|
| <u>Lead Counsel</u>    | James H. Hall<br>Reg. No. 66,317<br>James@CHZFirm.com<br>(832) 631-9993      |
| <u>Back-up Counsel</u> | Stephen D. Zinda<br>Reg. No. 67,272<br>Stephen@CHZFirm.com<br>(832) 631-9990 |

Globus has filed a Power of Attorney concurrently with this petition.

**42.8(b)(4)-Service**

Service via mail or hand-delivery may be made on Globus at: Cabello Hall Zinda, PLLC 801 Travis Suite 1610, Houston, Texas 77002. The fax number for Globus's counsel is (832) 631-9991. Globus consents to electronic service by email when sent to all of the following email addresses: james@chzfirm.com; stephen@chzfirm.com; and paralegal@chzfirm.com.

Proof of service of this petition and exhibits is provided in the appended certificate of service.

## **I. INTRODUCTION**

Globus Medical, Inc. (“Petitioner” or “Globus”) requests *inter partes* review of claims 1–5, 7, and 9 of U.S. Patent No. 8,460,385 (“the ’385 Patent”), which, according to PTO records, is assigned to Spinelogik, Inc. (“Patent Owner” or “Spinelogik”). The challenged claims are unpatentable and should be cancelled as shown herein.

## **II. STANDING**

Globus certifies that the ’385 Patent is available for IPR and Globus is not barred or estopped from requesting IPR of any of the challenged claims.

## **III. BACKGROUND**

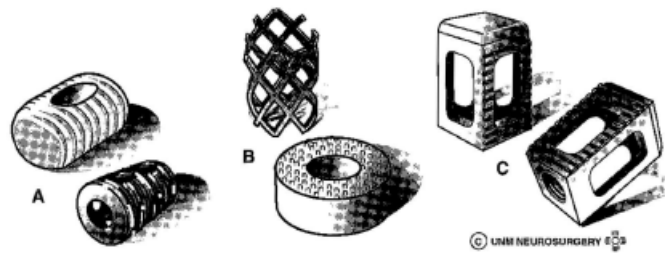
### **A. Technological Background**

The fusion of adjacent bone structure is commonly performed to provide for long-term replacement to compensate for degenerative and or deteriorated disorders in bone. In many cases, low back pain can be avoided by preventing relative motion between spinal vertebrae. By fusing the contiguous vertebrae in the lumbar region, lower back pain can be abated. Ex. 1002 ¶ 63.

Surgical techniques were known for use in spinal stabilization. Surgical techniques sought to rigidly join the vertebrae that are separated by a degenerated disc. Ideally, the surgery effectively replaced the vertebra-disc-vertebra combination with a single rigid vertebra. Various surgical techniques have been developed to approximate this ideal. *Id.* ¶ 64.

Many of the techniques begin by partially removing the degenerative disc material. Where the techniques differ is in their strategy for replacing the disc material. Some procedures fill the void left between the contiguous vertebra with bone graft materials. Other techniques rely on the use of an implant acting alone or along with bone graft. *Id.* ¶ 65.

Various types and styles of interbody vertebral implants have been developed. One category included “cages” shaped alternatively as horizontal cylinders, vertical rings, or open boxes (“box cages”) comprised of various materials such as bone, metals, and polymers:



■ ■ ■ ■ FIGURE 3-2. Current cage designs basically follow the pattern of threaded horizontal cylinders (A), vertical rings (B), or open boxes (C). A variety of materials including bone, metals, and polymers are used in the manufacture of these devices. (Reproduced with permission from the Division of Neurosurgery, University of New Mexico, Albuquerque, New Mexico.)

Ex. 1002 ¶ 66 (citing Ex. 1016 at 8, Ex. 1017 at 9). Eventual fusion of the opposing bone segments results from bone growth into and through the implant. *Id.*

In some cases, the above procedures have failed due to shifting of the implant between the adjacent vertebrae during the initial stabilization period (before fusion takes place). This is known as “migration”: sagittal (forward/backward) and/or lateral (side-to-side) movement of the implant in the intervertebral space between

the vertebral body endplates. *Id.* ¶ 67. This movement of the implant can lead to discomfort and serious consequences for the patient due to the proximity of nerves and blood vessels in the implanted area, and thus is recognized as detrimental to the success of intervertebral fusion procedures. *Id.* Accordingly, various solutions have been advance to prevent or minimize this movement. *Id.* (citing Ex. 1018, 1019, 1020, 1022, 1024).

### **B. The '385 Patent**

The '385 Patent describes an intervertebral fusion member as a shaped rectangular or oblong block having one or more channels, for placement between adjacent vertebrae. Ex. 1001, 2:29-45. One or more anchoring members are pushed through the channels and into the vertebrae, to affix the fusion member to the vertebrae. *Id.* Figure 4 is a transparent perspective of the fusion member and channels for its anchoring members, which run in planes that are parallel to one another. *Id.*, 4:39-41, 10:1-14. Figure 35 shows the anchoring members advanced into the vertebrae (not shown) inside the channels, which “traverse cross-sectional planes parallel to one another as well as to the lateral fusion member surfaces.” *Id.*, 5:47-50; 23:21-32.

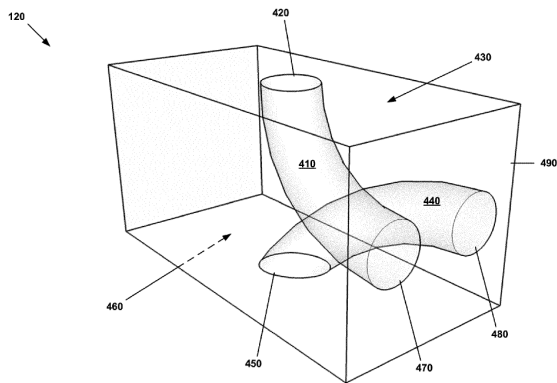


Figure 4

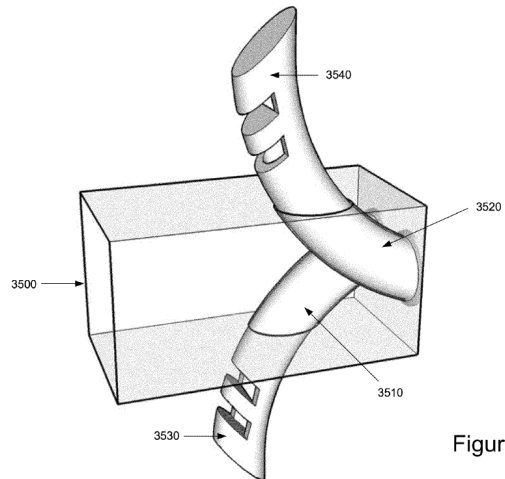


Figure 35

During prosecution, after a restriction requirement, the applicant elected species pertaining to Figures 35-36. Ex. 1003, 237-239, 250-252. The examiner issued a non-final rejection. *Id.*, 271-279. None of the references asserted here were before the examiner. *See id.*; Ex. 1001 (“References Cited”). The applicant then amended the claims to require, among other changes, that the channels be curved. *Id.*, 309-316. The examiner then allowed the amended claims. *Id.*, 334.

#### IV. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))

##### A. Statement of Requested Relief

Globus requests institution and cancellation of the identified claims in view of Grounds 1-3 below. All statutory references are to pre-AIA statutes. All required fees or credits should be deducted or credited to Deposit Account 603139, referencing attorney docket number 231-112.

| Ground | Claims    | Basis (§ 103)                           |
|--------|-----------|-----------------------------------------|
| 1      | 1-5, 7, 9 | Moskowitz & General Knowledge of a POSA |

| Ground | Claims    | Basis (§ 103)                      |
|--------|-----------|------------------------------------|
| 2      | 1-3, 7, 9 | Hess & General Knowledge of a POSA |
| 3      | 1-5, 7, 9 | Moskowitz-Steffee                  |

The earliest possible priority date of the '385 Patent is March 27, 2008 (“Critical Date”). Globus does not believe that the '385 Patent is entitled to this priority date, and challenges this priority date to the extent that Spinelogik asserts it. But even if the '385 Patent is entitled to this priority date, Globus asserts prior art pre-dating it. Each reference pre-dates the Critical Date and qualifies as prior art as shown below.

| Reference | Filing Date<br>(non-provisional) | Publication Date | Prior Art Under   |
|-----------|----------------------------------|------------------|-------------------|
| Moskowitz | 08/21/2007                       | 02/07/2008       | §§ 102(a), 102(e) |
| Hess      | 01/30/2008                       | 02/26/2009       | §§ 102(a), 102(e) |
| Steffee   | 01/11/1987                       | 12/31/1988       | § 102(b)          |

Globus reserves the right to rebut any effort by Patent Owner to antedate Moskowitz or Hess based on alleged conception, diligence and reduction to practice, including by demonstrating that each reference is entitled to priority to its earlier

applications.<sup>1</sup>

### **B. Unpatentability**

Claims 1–5, 7, and 9 are unpatentable as detailed in Sections VIII.-X.

### **C. Supporting Evidence**

The relevance of Globus’ evidence, including identification of specific evidence that support this challenge, is found in Sections III. and V.-X. This Petition is supported by the declaration of Brad Culbert (Ex. 1002), who has the qualifications necessary to opine on the knowledge of a POSA, explaining what the art would have conveyed to a POSA as of the Critical Date. Ex. 1002 ¶¶ 48-51. All elements of the challenged claims are taught in the prior art as explained herein. For each ground under 35 U.S.C. § 103(a), the motivation to combine and the basis for a reasonable expectation of success are established. Accordingly, this Petition demonstrates a reasonable likelihood of prevailing with respect to at least one of the claims challenged in the petition.

---

<sup>1</sup> Moskowitz claims priority as a CIP to application 11/536,815 filed on Sep. 29, 2006, which claims priority as a CIP to application 11/208,644 filed on Aug. 23, 2005, and to provisional application 60/670,231 filed on Apr. 12, 2005. Ex. 1004, 1. Hess claims priority to four provisional applications, dated from May 1, 2007 through October 29, 2007. Ex. 1006, 1.

## **V. LEVEL OF ORDINARY SKILL**

A POSA would have had a bachelor's or equivalent degree in mechanical engineering or a related discipline (e.g., biomedical or metals and materials engineering), and at least five years of experience consisting of (a) designing, developing, evaluating and/or using spine devices, (b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and (c) biomechanical and functional loading of orthopedic implants. Ex. 1002 ¶ 49. More education can supplement practical experience and vice versa. *Id.* For example, a POSA could have an advanced degree in the technical disciplines noted above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above. *Id.*

## **VI. CLAIM CONSTRUCTION (37 CFR § 42.104(B)(3))**

Patent claims are construed in accordance with their ordinary and customary meanings as understood by a POSA. 37 C.F.R. § 42.100(b). Globus addresses the meaning of certain claim terms that may be relevant to the application of the prior art. Globus reserves the right to respond to any construction issues raised by

Spinelogik.<sup>2</sup>

**1. *channel* (all challenged claims)**

A POSA would understand the claim term “channel” to refer to a passage through which something moves or is conveyed. Ex. 1002 ¶ 54 (citing Ex. 1009, Ex. 1010, Ex. 1011). This is consistent with the usage of “channel” throughout the specification, which uniformly refers to a passage through which something (e.g., an anchoring member) traverses. Ex. 1001, 9:42-44, 9:53-55, 10:63-66, 11:47-63, 14:25-31, 14:65-67, 16:32-35, 22:51-57, 24:55-67. The specification places no limits on the term, such as requiring particular dimensions (e.g., length, diameter) but states that “[o]ther embodiments have channels of different shapes and sizes.” *Id.*, 13:51-52. Indeed, the specification explains how, in some embodiments, “a circular channel with a constant diameter throughout its **entire length** can guide the anchoring mechanism,” showing that the applicant knew how to impart additional requirements to the ordinary meaning of “channel” when desired. *Id.*, 13:48-51; *see*

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<sup>2</sup> During parallel litigation, Spinelogik did not agree to any of Globus’s proposed constructions, and asserted that plain and ordinary meaning should apply to all terms. *See* Ex. 1028, Ex. 1029. Neither party identified any terms as subject to 35 U.S.C. § 112. *See id.* Globus does not identify any issues related to compliance with 35 U.S.C. § 12 here.

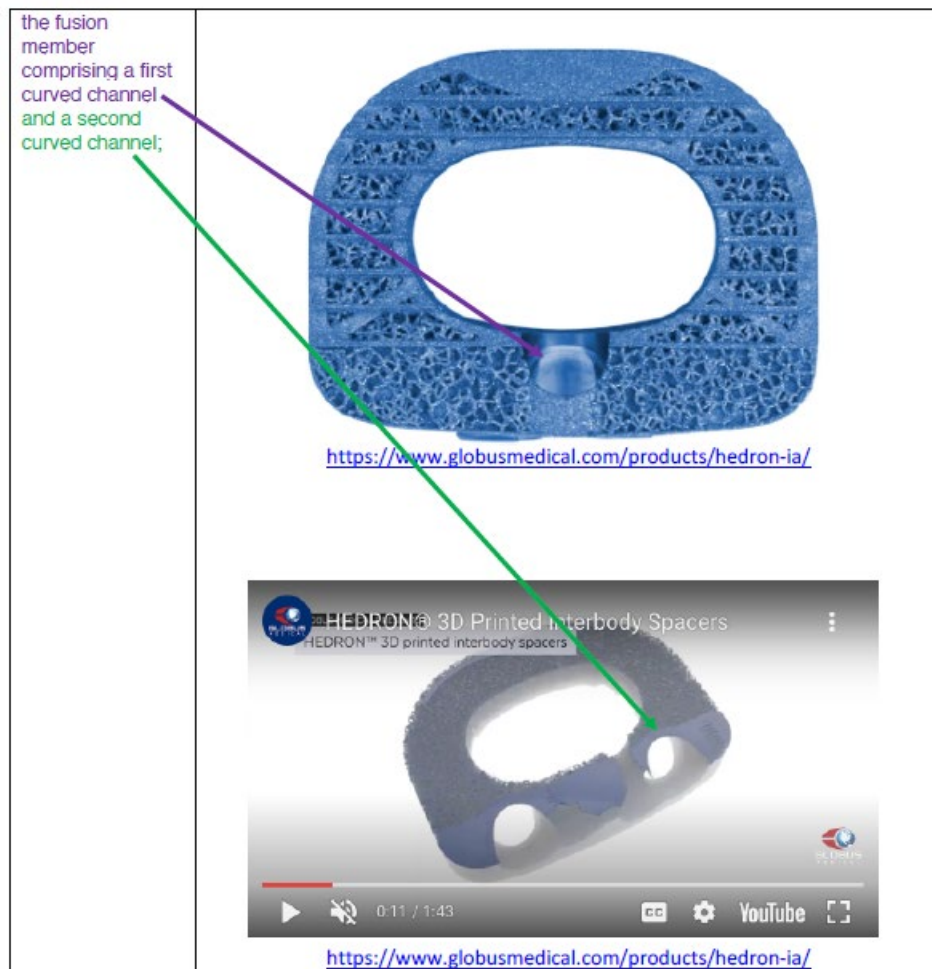
*also id.*, 10:10-13 (“Even though the fusion member channels shown in these figures are curved and tubular, one of ordinary skill in the art will know that the channels may be other shapes or configurations ....”); Ex. 1002 ¶ 55.

## **2. *curved* (claim 1 and dependents)**

Petitioner applies the claim construction for “curved” (modifying “channel”) applied by Spinelogik in its infringement contentions in pending litigation. Petitioner expresses no subjective agreement or disagreement with that construction here. *See W. Digit. Corp. v. SPEX Techs., Inc.*, IPR2018-00084, Paper 14 at 11 (PTAB April 25, 2018) (explaining that “37 C.F.R. § 104(b)(3) does not require Petitioner to express its subjective agreement regarding correctness of its proffered claim constructions or to take ownership of those constructions” and further that a “[p]etitioner complies with our rules by identifying claim constructions it proposes as the basis for requesting review of the challenged claims,” even where that construction is based on constructions proposed by a patent owner); *see also Donnelly Distrib. LLC v. Russo Trading Co.*, IPR2019-00761, Paper 8 at 17-18 (PTAB Sept. 6, 2019) (agreeing that petitioner had shown the prior art met challenged claim limitations in view of patent owner’s infringement contentions).

Spinelogik alleges that the anchor openings of Petitioner’s accused implants constitute “curved channels” as recited in claim 1. A representative example from Spinelogik’s infringement contentions is shown below, citing publicly available

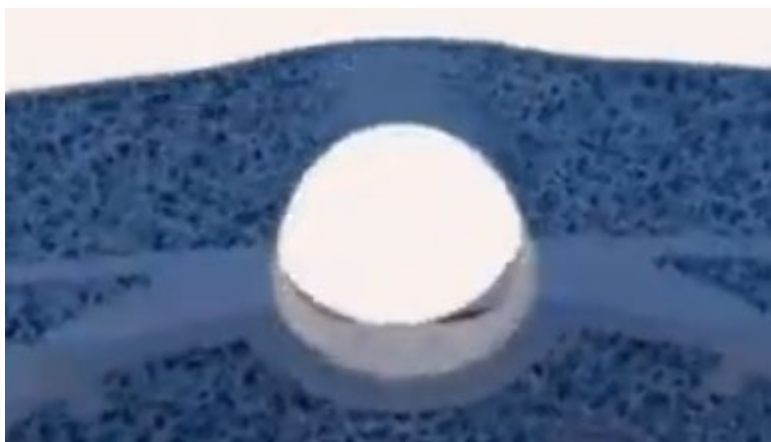
materials including an embedded video:



Ex. 1012, 34.

The cited video (Ex. 1013) discloses that the accused product contains an aperture for its anchors comprising a tubular channel having straight sides extending from one surface to another, as shown in the screen shots (and magnifications of same) below:





Ex. 1013 (frames from video at 0:23).

The contentions also cite a discussion in Petitioner's patent, U.S. Patent No.

9,980,824 (Ex. 1015), stating that the channels (bores 26) “may be substantially linear” which “allows bores 26 to receive both linear fastening members and curvilinear fastening members.” Ex. 1012, 5. Figure 4 depicting the bores is reproduced below. Ex. 1015, Fig. 4.

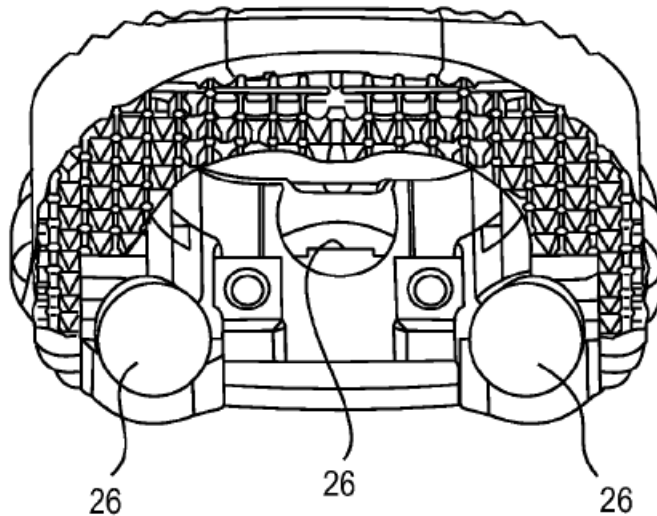


**FIG. 4**

These materials demonstrate that the path followed by the identified channels is straight, but is “curved” because it has some curvature in the sidewalls and other aspects. Ex. 1002 ¶¶ 57-60. Spinelogik thus applies *curved* to accused channels regardless of whether the channel follows a curved path like channels in the preferred embodiments that are referred to as “curved” in the specification. Ex. 1002 ¶¶ 56, 60-61; *see also, e.g.*, Ex. 1001, 15:31-58 (referencing Fig. 14 and explaining that “[a]s the fusion member channel is curved, the path that the anchoring member

travels is also curved. In other words, the anchoring member traverses in a second direction that is curved throughout its advancement through the fusion member channel. Accordingly, from the initial configuration of the anchoring mechanism to its final configuration, the tip of the anchoring member travels in a semi-circular path of movement”; *id.*, 23:21-32 (“In FIGS. 35-37, an embodiment of the fusion member 3500 includes two curved semicircular channels 3510 and 3520.”); *id.*, 24:4-9 (“FIG. 46B illustrates that each of the channels 4610 and 4620 trace circular arcs that are a portion of two conceptual circles which traverse planes that are parallel to each other and non-parallel to all faces of the fusion member. These channels are traversed by curved anchoring members (not pictured)”); *see also id.*, Fig. 46A (components 4610 and 4620), Fig. 4 (components 410 and 440), Fig. 30 (components 3020, 3030 3040, 3050).

Using Spinelogik’s applied construction, a channel is “curved” when it has: (1) an opening with a curvature (e.g., rounded openings); (2) an inner wall with a curvature (e.g., tube-like wall); and/or (3) a radial curvature in an inner wall (e.g., a concave surface that forms a seat to engage the head of an anchor). Ex. 1002 ¶ 61.

Petitioner demonstrates that the claims are unpatentable over all asserted grounds using Spinelogik’s broad applied construction. But even if a “curved” channel has a narrower meaning requiring the channel to follow a curved path (instead of the straight path identified in the accused products), Petitioner

demonstrates that the challenged claims are also unpatentable over at least Grounds 2 and 3.

## **VII. BRIEF DESCRIPTION OF THE ASSERTED REFERENCES**

### **A. Moskowitz**

Moskowitz teaches an intervertebral device for use in spinal fusion. Ex. 1004, Abstract, 1:20-26. As pictured in Figure 1A below, one embodiment is an expandable “screw box” consisting of two triangular sliding bases (103, 104), penetrated by two threaded bone screws (101, 102) at holes allowing traversal of the screws through internal drill or screw guides. *Id.*, Abstract, 7:37-41, 7:49-53, 7:65-8:9. The screws traverse through the screw box for screwing into separate vertebral bodies to effect vertebral fusion. *Id.*, 8:17-19, 10:62-63. The height of the screw box is adjustable by turning a height-adjusting screw connecting the two triangular bases. *Id.*, 7:38-48. Both bases (103, 104) have holes (108) which can optionally be filled with bone graft. *Id.*, 7:57-62.

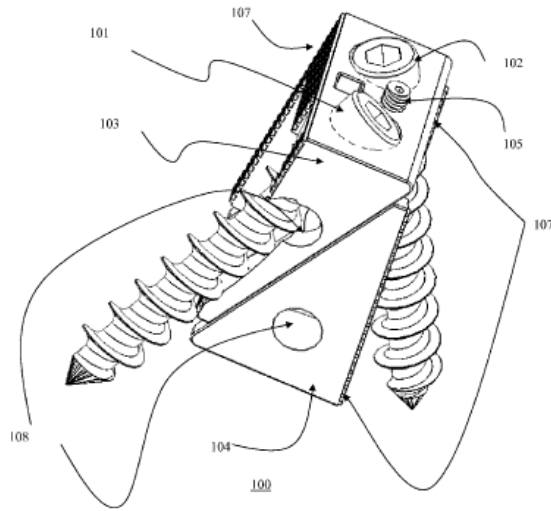


Fig. 1A

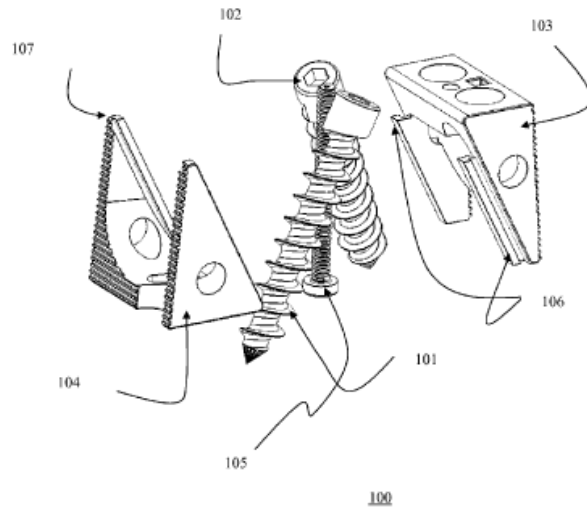


Fig. 1D

## B. Hess

Hess teaches an implant (10) having an upper shell (12a) and lower shell (12b). Ex. 1006, Abstract, 6:59-61.

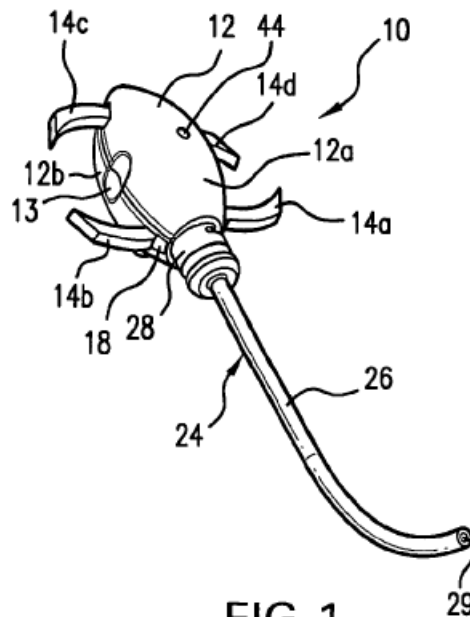


FIG. 1

The implant's interior cavity contains curved guide tracks (19) for four locking wings (14a-14d) that move from a stowed to deployed position. *Id.*, 7:18-22, 7:26-31, 8:5-19. When deployed, the wings extend out of their respective openings (46a-46d) and fixate into the surrounding bone, locking the implant into place. *Id.*, 7:38-45, 7:56-58. The implant is depicted with wings in the stowed (Fig. 10A) and deployed (Fig. 10B) positions. *Id.*, 5:53-58.

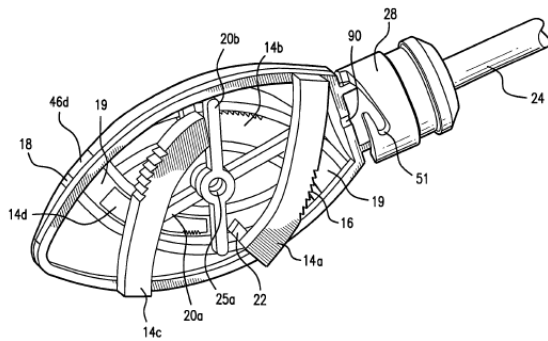


FIG. 10A

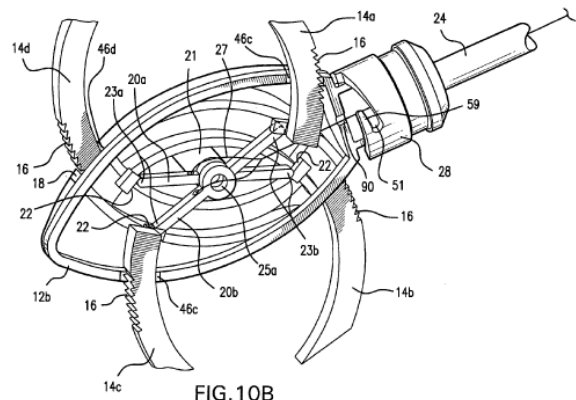


FIG. 10B

### C. Steffee

Steffee teaches a curved, elongated fastener for use in securing bone graft between bone portions. Ex. 1005, Abstract.

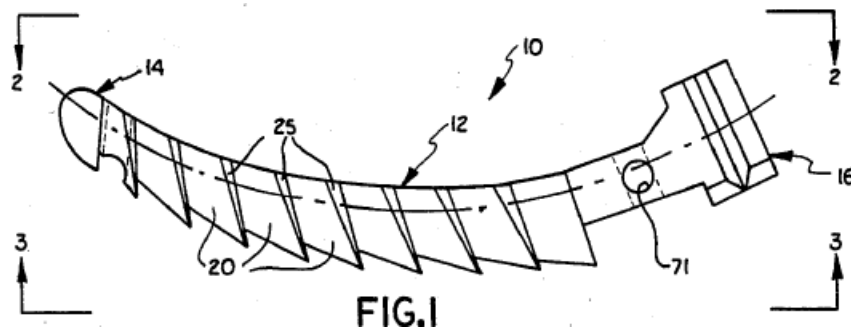
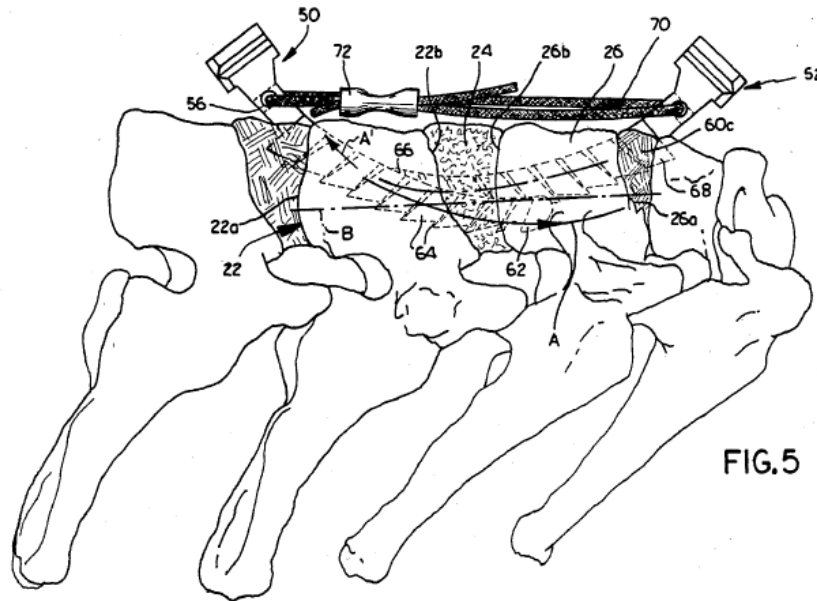


FIG. I

Each fastener has a shank portion (12) with a driving head (16), pointed end (14),

and barbs (20) which prevent the fastener from backing out. *Id.*, 2:33-38, 2:61-68. Figure 5 shows two fasteners (50, 52) securing bone graft (24) to adjacent vertebrae (22, 26). *Id.*, 3:16-19; Ex. 1002 ¶ 155. Steffee explains that “[a]s the fastener 10 is driven into the bone portion [22], due to its curved configuration, it progresses along a curved path A through the bone graft 24 and into bone portion 26.” *Id.* at 2:45-48



In another embodiment (Fig. 6, below), each fastener (90, 92) is driven into the side of a corresponding vertebral body (100, 102) and curves into bone graft between those bodies and into the opposing body. Ex. 1005, 4:23-34.

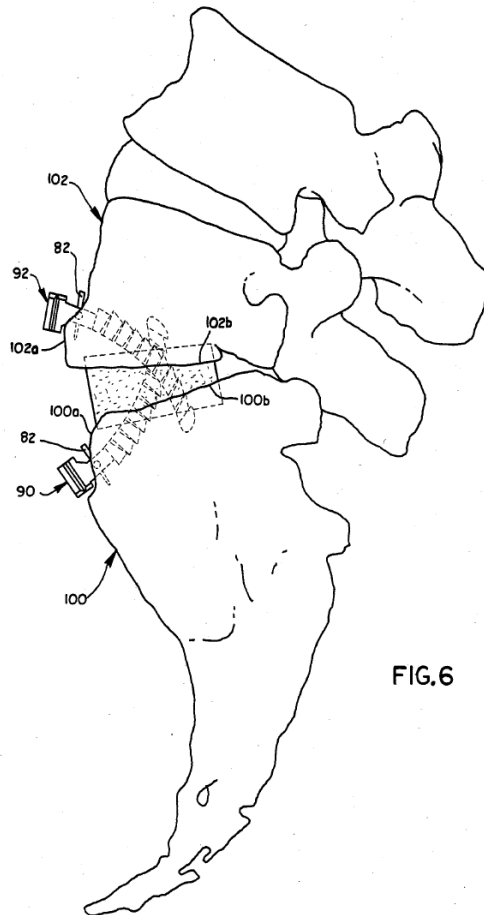


FIG. 6

Thus, a POSA would understand that Steffee discloses interbody fusion using bone graft held by curved fasteners. Ex. 1002 ¶ 158. Although Steffee does not discuss the use of intervertebral implants, bone graft was commonly packed in and around such implants to facilitate vertebral fusion. Ex. 1004, 3:39-44; Ex. 1007 [0038]; Ex. 1023, 1:31-34).

## **VIII. GROUND 1 – MOSKOWITZ AND GENERAL KNOWLEDGE OF A POSA**

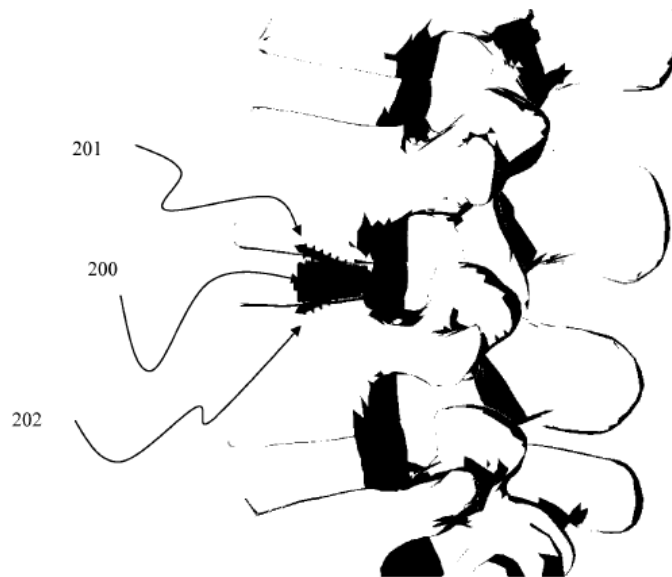
### **A. Claim 1**

#### **Claim 1.0 “A fusion device comprising:”**

Moskowitz discloses *a fusion device*: “[a] self-drilling bone fusion screw apparatus” where “[t]he screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together.” Ex. 1004, Abstract. “This device therefore is a flexible fusion device.” *Id.*, 3:66-67.

#### **Claim 1.1 “a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel”**

Moskowitz’s fusion device is a “screw box” (*fusion member*) “placed inter-vertebrally,” that is, “between vertebral bodies.” *Id.*, 2:40-51. *Position[ing] between first and second vertebral bodies* is shown, for example, in Fig. 6B, which “illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws.” Ex. 1004, 9:15-17.



The screw box includes *a first curved channel and a second curved channel* for screws to be driven into the vertebral bodies above and below the implant: “[t]he housing screw box incorporates **built-in screw and/or drill guides** which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies.” *Id.*, 2:45-49. In the figures below, the channels have been annotated in green. Embodiment IA is shown in a superior perspective (Fig. 1B) and in exploded view (Fig. 1D):

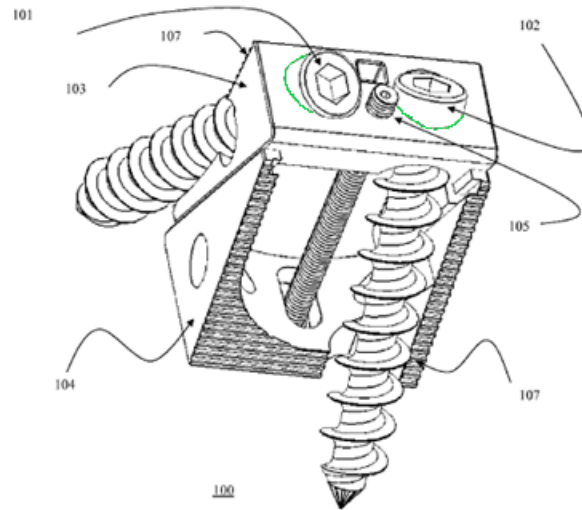


Fig. 1B

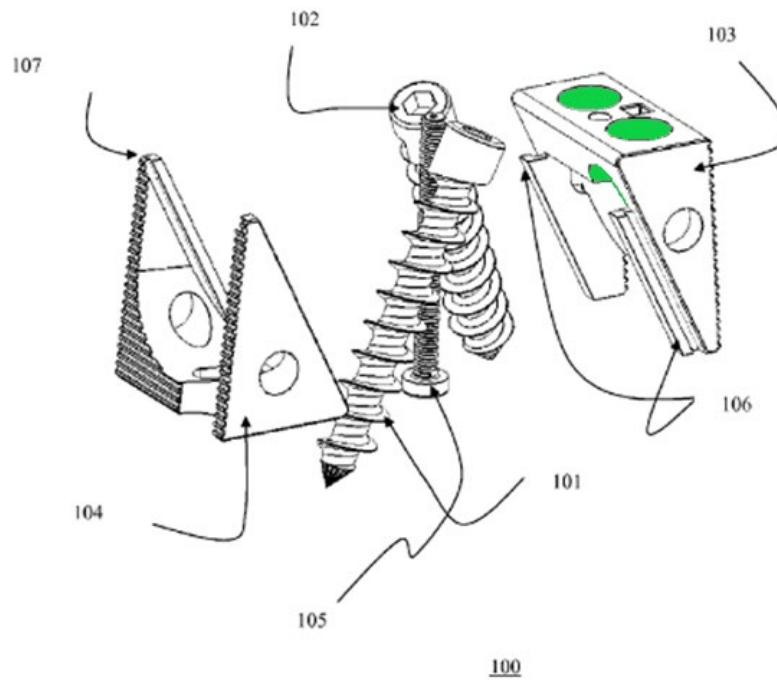


Fig. 1D

Embodiment II is shown in a superior perspective (Fig. 2C):

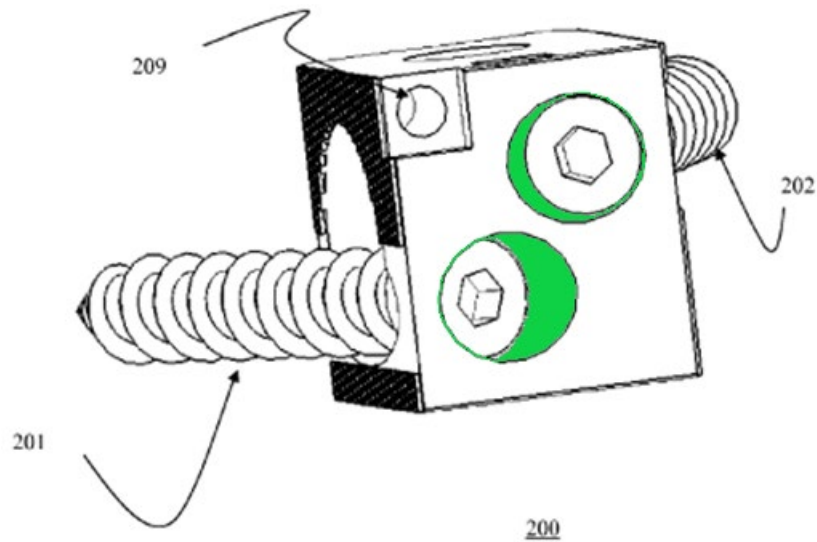


Fig. 2C

Under Spinelogik’s applied interpretation of *curved channel* advanced in litigation (*see* Section VI.2.), both channels are “curved” in at least three ways.

First, as shown in Figures 1C and 1D (annotated below), *each channel* (green) has a rounded proximal opening on the side where the screws are inserted, and a rounded distal opening that the screw protrudes from:

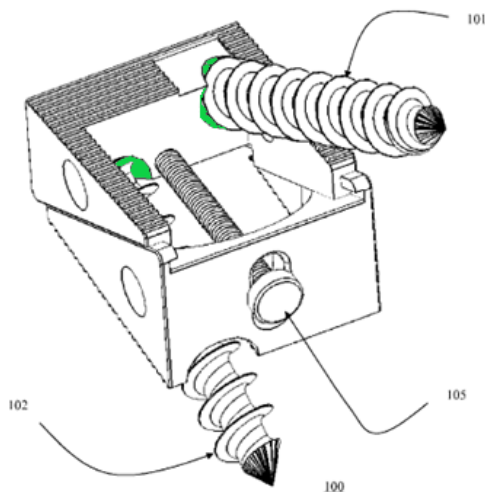


Fig. 1C

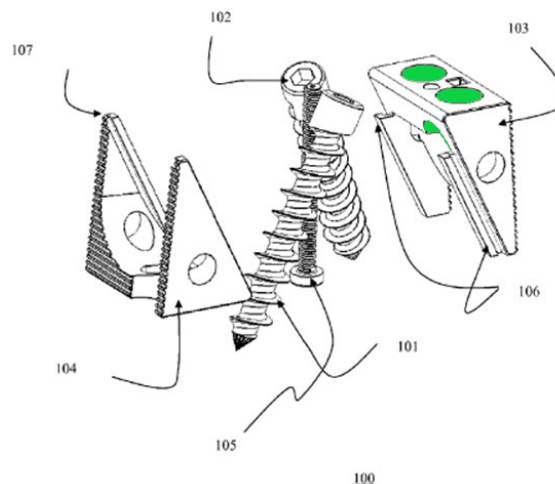


Fig. 1D

Because the channel openings are round, each *channel* is “curved” using Spinelogik’s applied construction. Ex. 1002 ¶ 76.

Second, as also shown in the annotated figures each *channel* has a tubular inner wall extending from one opening to the other opening. Because the inner wall is tubular, each *channel* is “curved” under Spinelogik’s applied construction. A POSA would understand the channels to necessarily have a tubular inner wall because they circumscribe the inserted screws along the length of the passage through the wall of the triangular sliding base. Ex. 1002 ¶ 76; Ex. 1004, 7:49-52 (“Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100 .... in opposing directions ....”).

Third, each channel is “curved” because the channels necessarily contain an internal curvature (which may be the same as or separate from the beginning of the screw threading) which serves as a recessed seat to engage the bearing surface on

the underside of each screw's head. Ex. 1002 ¶ 76. The internal design of the channel is not shown in the foregoing figures. This seat may be seen in Figure 4C, a portion of which is annotated below:

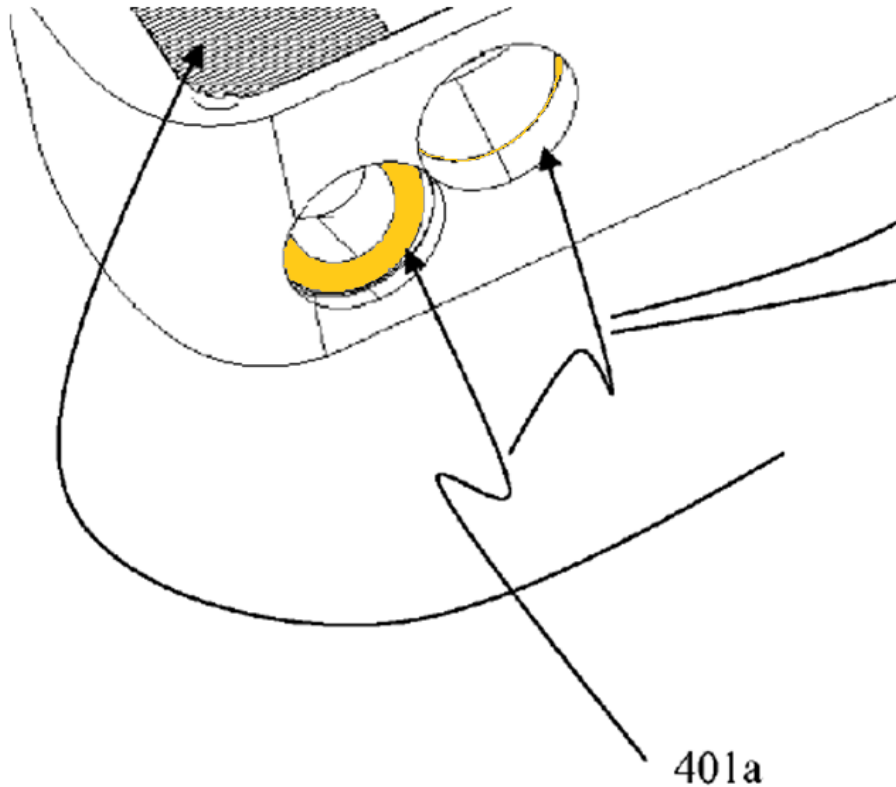
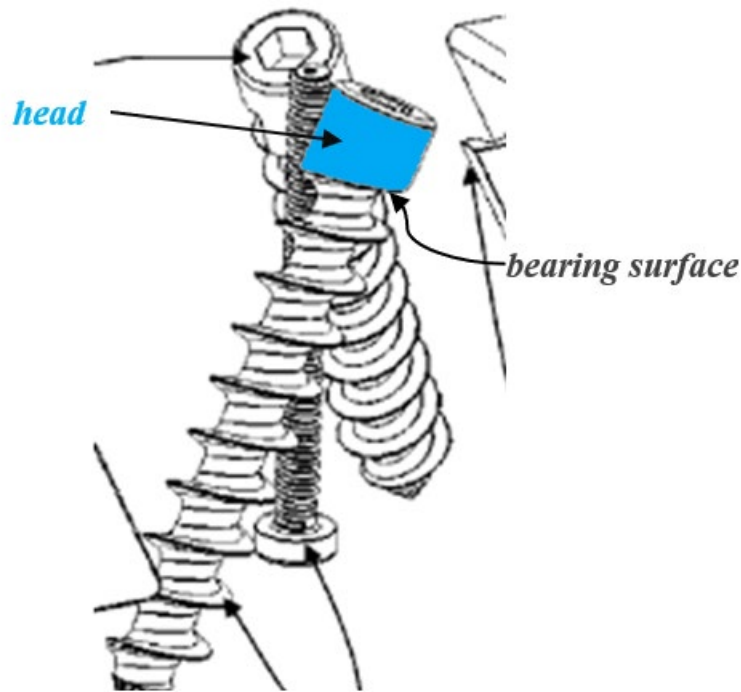


Figure 4C relates to an embodiment using a circumferential cage around two of the screw boxes. Ex. 1004, 6:41-43. The cage itself contains perforations 401a for the placement of the screws. *Id.*, 8:37-38. The figure discloses or suggests the internal seat (orange) of the channels, inside the circumferential cage. Ex. 1002 ¶ 77.

Even if Figure 4C did not disclose or suggest the internal seat in each channel, such a seat would also be understood to be necessarily present or at least obvious, because it is required to retain the screws within each channel via engagement with the bearing surface on the underside of each screw's head, which are shown in Figure

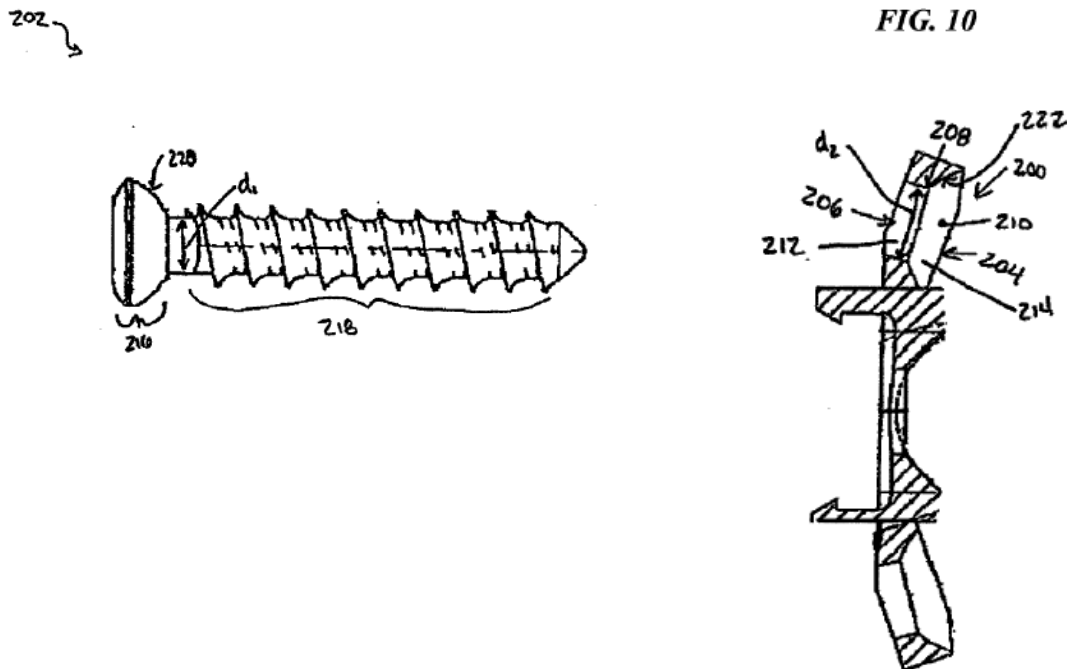
1D below. Ex. 1002 ¶ 78. Each screw has a pronounced cylindrical head having an underside at an angle (which may be the same as that of the screw's threads). *Id.* ¶ 79. A POSA would understand that this underside comprises the bearing surface of the head which will engage an internal seat (which could be the beginning of the threading inside the channel designed to engage the screw threads). *Id.* This engagement between implant and bearing surface is necessary because this engagement affixes the screw to the base. *Id.* Without it, the screw would not engage with the base but simply pass through it. *Id.* The screw would therefore be unable to serve its purpose of affixing the device to the vertebral bodies, but would instead only affix the screw to the bone. *Id.* This would defeat the purpose of the screws, and there would be no need for the pronounced screw head without such seat. *Id.* The seat also serves as a stop so that, during surgery, the physician will know when the screw is fully advanced. *Id.* The angled seat which engages the screw head itself comprises a curvature within the channel, and therefore serves as another reason that the channels are "curved." *Id.*



To the extent Spinelogik argues that Moskowitz itself does not necessarily contain or itself render obvious a channel having such a seat, the inclusion of such a seat was obvious based on the general knowledge of a POSA. *Koninklijke Phillips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020).

As discussed above, a POSA understood that, to create the engagement between the base and the screw necessary to affix the base to the vertebral bodies, the base must contain a surface such as a seat to engage the bearing surface of the screw heads. Ex. 1002 ¶ 80. Such a design is disclosed in multiple prior art implants, in addition to being a well-known design by which screws (and other fasteners) affix objects together. *Id.* ¶¶ 80-81 (explaining the traditional design of screws having a “raised countersunk head”).

As mentioned, the design was present in multiple prior art implants. For example, Fraser teaches the use of an “inner lumen 210” (channel) having “a shape and size adapted to receive the head 216 of a bone screw 202” as shown in Figs. 9 and 10 below. Ex. 1008 [0061], Figs. 9, 10; Ex. 1002 ¶ 81.



Fraser’s screw “includes a head 216 and a threaded shank 218. The head 216 of the bone screw 202 includes a substantially convex, slightly rounded outer surface 220. The first portion 214 of the inner lumen 210 of the aperture 200 has a concave sidewall 222, e.g., a generally spherical recess, to allow the rounded head 216 of the bone screw 202 to seat therein.” Ex. 1008 [0061]. A POSA would understand that the concave sidewall (the seat) both prevents the screw from advancing through the implant and allows the angle of the screw to be slightly adjusted. Ex. 1002 ¶ 81.

Another example of this design is disclosed in Bray. In Bray, each bone screw extends through holes 140 (channels), which “are sufficiently large to allow a portion of a respective bone screw to pass therethrough but not large enough to allow a retaining portion of the bone screw through, such as the head of the bone screw.” Ex. 1007 [0047], Figs. 3, 4. Each of the “bone screw holes 140 has a seat 165 on which the retaining portion of a respective bone screw rests. Each seat 165 has a generally concave spherical shape and the surface of the retaining portion of the bone fastener in contact with the seat 165 has a complementary convex spherical configuration.” *Id.*

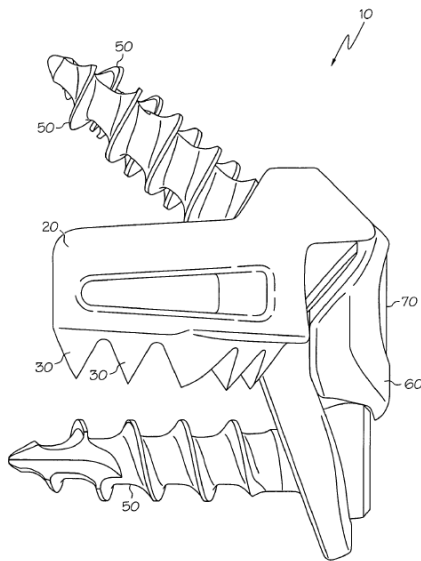


FIG. 3

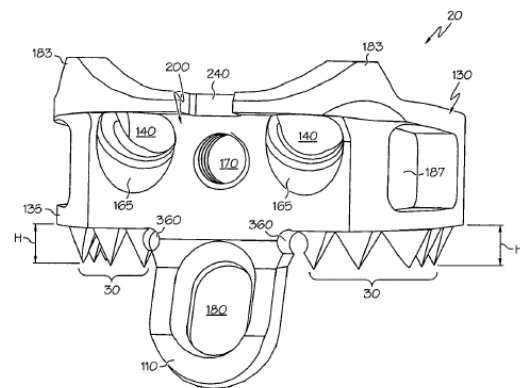


FIG. 4

A POSA would have been motivated to include such a seat within his general knowledge (as represented in Bray and/or Fraser) to enable the screw to affix the base to the vertebral bodies. Ex. 1002 ¶ 83. A POSA was also motivated to include such a seat for the same reasons explained in Bray—to include a channel that allows

“a portion of a respective bone screw to pass therethrough but not large enough to allow a retaining portion of the bone screw through, such as the head of the bone screw.” *Id.*; Ex. 1007 [0047]. Such a design engages the bearing surface of the bone screw with the base member such that tightening the screw into the vertebral body affixes the implant itself, and not merely the screw, to the bone. Ex. 1002 ¶ 83. Such a design was desirable because it would firmly attach Moskowitz’s screw box to the superior and inferior vertebral bodies. *Id.* Such firm attachment was required to keep the screw box in place after implantation (thus preventing migration), which would increase the chance that the fusion procedure will succeed. *Id.* ¶ 83.

A POSA was also motivated to add concave seats having a radially inward curvature, such as those in Bray and Fraser, because they would allow the screws to pivot on their seats, enabling the screw angle to be adjusted to the desired angle for insertion. Ex. 1002 ¶ 84 (citing Ex. 1007 [0047] and Ex. 1008 [0014]). Using such a seat would also optionally allow for use of a screw having a convex head (to match the concave seat) for a closer fit to the seat, although this modification would simply be a design choice and would not have been necessary. *Id.* Such a modification provides the additional benefit of allowing the screw angle to be adjusted by pivoting (as expressly discussed by Fraser) so that the anchor can be adjusted to the desired angle for insertion. *Id.* Additionally, the use of an anchor with a spherical versus planar head was merely an obvious, alternative design choice, as was designing the

seat to have a complementary shape to provide for close conformity to the screw head. Ex. 1002 ¶ 85. A POSA would have recognized no appreciable difference in using a spherical anchor head rather than a planar head, aside from the benefits previously discussed. *Id.*

A POSA had a reasonable expectation of success in using a seat such as that in Bray and Fraser because such designs were standard screw seat designs for engaging with screw heads to allow the screw to affix the seat-containing component to whatever material the screw was designed to penetrate. Ex. 1002 ¶ 86. A POSA also had a reasonable expectation of success including such a seat because such designs had been successfully implemented in similar spinal fusion implants as shown by Bray and Fraser. *Id.* ¶ 87. As in Moskowitz, the prior art implants have bone screw holes configured such that the bone screws extend through the hole at an angle. *Id.* The bone screw holes in Bray extend through posterior corners of the device in exactly the same way as in Moskowitz, as shown in posterior views from Moskowitz (Fig. 1C) and Bray (Fig. 5) below. *Id.*

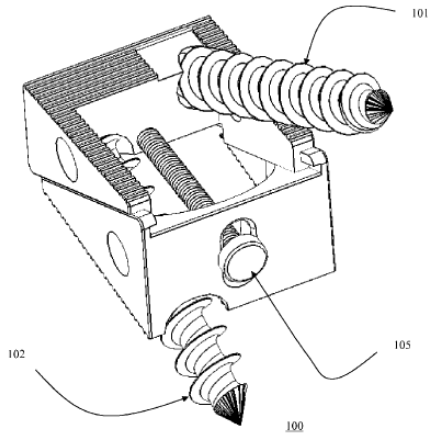


Fig. 1C

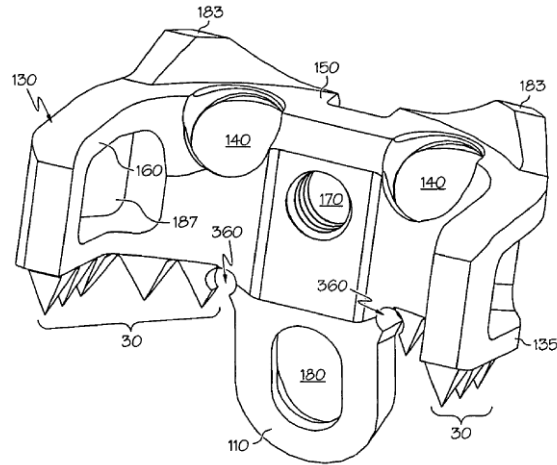


FIG. 5

While it is not necessary that the channels contain a seat that has a concave shape to satisfy Spinelogik’s applied construction of *curved channel*, such a concave shape also qualifies to render the channel “curved.” Ex. 1002 ¶¶ 88-89.

Ground 1 thus discloses and/or renders obvious “*the fusion member comprising a first curved channel and a second curved channel.*”

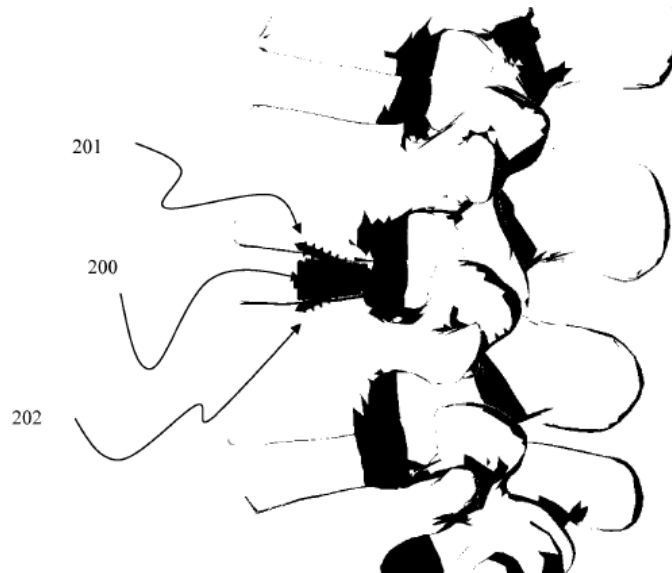
**Claim 1.2 “a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring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

Moskowitz’s screws comprise its *anchoring members*, which insert into the screw guides through the rounded openings in the box (the first and second *curved*

*channels*). Moskowitz's screw box "incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly." Ex. 1004, 2:43-51. As illustrated in Figures 1-6, "[t]ransvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally." *Id.*, 7:49-62. During surgery, "a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505." *Id.*, 10:54-64. Thus, one of Moskowitz's screws is inserted *partially into the first vertebral body* (either the superior or inferior vertebral body). Ex. 1002 ¶ 90.

Further, *a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body.* Moskowitz' apparatus is described as "a box, a first screw member having a tapered end and a threaded body **disposed at least partially within the box** and laterally aligned with the box, a second screw member having a tapered end and a threaded body **disposed at least partially within the box** and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box." Ex. 1004, 5:11-18. Further, "Figures 6A and B illustrate the process of insertion and final placement of

the construct into the lumbar spine.” *Id.*, 11:8-9. Fig. 6B provides a “three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.” *Id.*, 9:15-18. As can be seen from Fig. 6B, each anchoring member/screw remains partially within the screw box, while also inserted into a vertebral body. Ex. 1002 ¶¶ 91-92 Further, a POSA would have understood that each screw will remain partially within the screw box to provide necessary engagement between the screw and base, as discussed for claim element 1.1 above. *Id.* ¶ 92.



The screws also *couple the fusion member with the first vertebral body*. Moskowitz explains that “[i]n all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudal [sic] directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed

into the inferior vertebral body.” Ex. 1004, 3:11-16. The insertion of each screw into the vertebral bodies, while partially remaining in the screw guide, with the screw head engaging the seat in each channel in the base, comprises a coupling between the screw box and each vertebral body. Ex. 1002 ¶ 93.

In addition, Moskowitz explains that “[t]he screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together.” Ex. 1004 Abstract. “The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the ... screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.” *Id.*, 2:36-39. The intervertebral bone agents, placed in perforations in the screw box to promote bone growth throughout, as well as the superior and inferior oriented screws, fuses the superior and inferior vertebral bodies. *Id.*, 3:39-44, 8:17-18. This bone growth would not be in the optimal location for a successful outcome if the screws did not firmly couple the screw box with the vertebral bodies, because the screw box might otherwise migrate after initial placement. Ex. 1002 ¶ 94.

Moskowitz’s embodiments contain at least two screws in a screw box, as plainly shown in Figs. 1A-2C and 4A-4C, and thus contain both *a first* and *second anchoring member*. Accordingly, Moskowitz discloses both *a first and second anchoring member* configured as required by the claim.

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

Moskowitz’s curved channels each have a *cross-sectional plane along the channel’s path that is traversed by the curved channel through the fusion member.*

As shown in the ’385 Patent, the referenced cross-sectional planes are planes parallel to the channel’s path (the same path taken by the anchor inside the channel) which bisect the channel. This is shown with regard to Fig. 5B, reproduced below. The patent explains that “the cross-sectional view of the two channels 530 that go through the fusion member 120 are parallel to the right and left side of the fusion member 120.” Ex. 1001, 10:63-11:4.

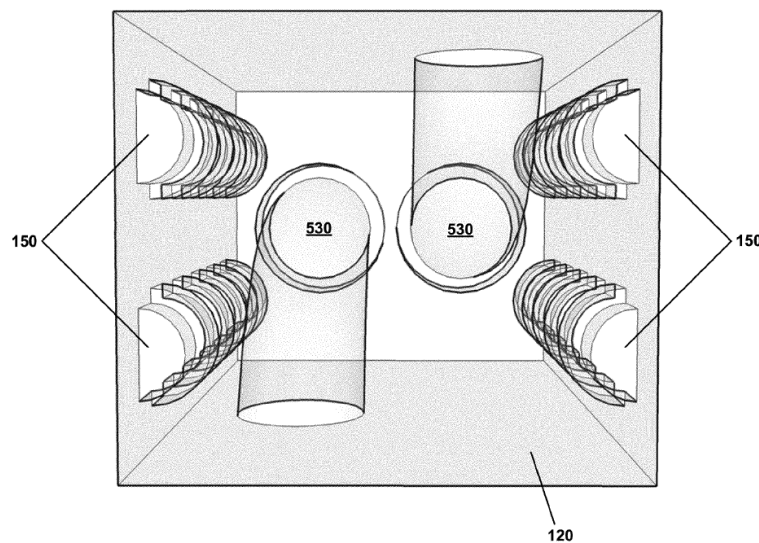
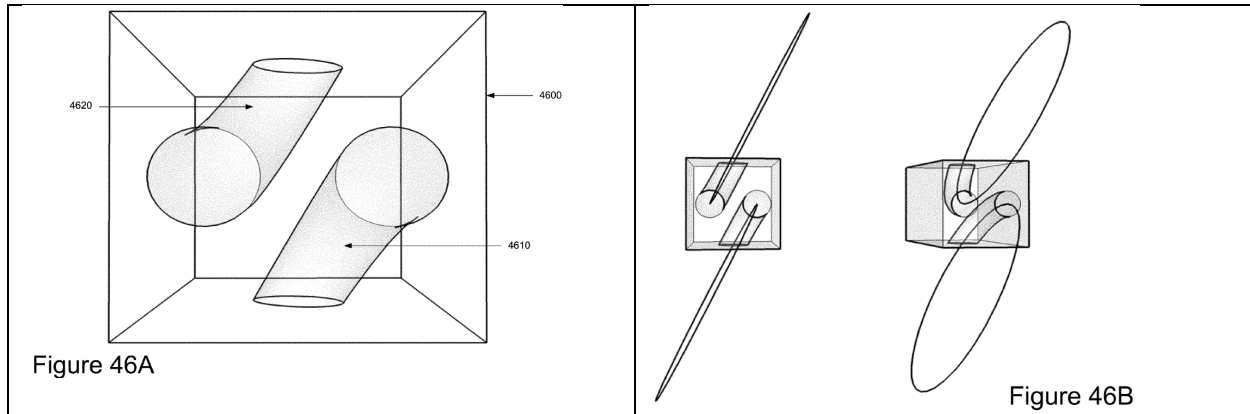


**Figure 5B**

The location of the cross sectional planes is also explained with reference to

Figs. 46A and 46B, which show a fusion member having “channels that run in parallel planes with respect to each other but are nonparallel to the adjacent faces of the fusion block member.” *Id.*, 5:65-6:3. These figures are reproduced below:



See also *id.*, 23:66-24:16 (“Channels 4610 and 4620 **traverse in parallel cross-sectional planes** with respect to each other but are non-parallel with respect to the faces of the fusion member. FIG. 46B illustrates that each of the channels 4610 and 4620 trace circular arcs that are a portion of two conceptual circles **which traverse planes that are parallel to each other** and non-parallel to all faces of the fusion member.”).

Each of Moskowitz’s curved channels have a cross-sectional plane along the channel’s path, that is traversed by the channel through the fusion member. This is best seen in Figure 1C, annotated below to include the cross-sectional planes (blue), but a POSA would understand each of Moskowitz’s figures to show these same planes. Ex. 1002 ¶ 97.

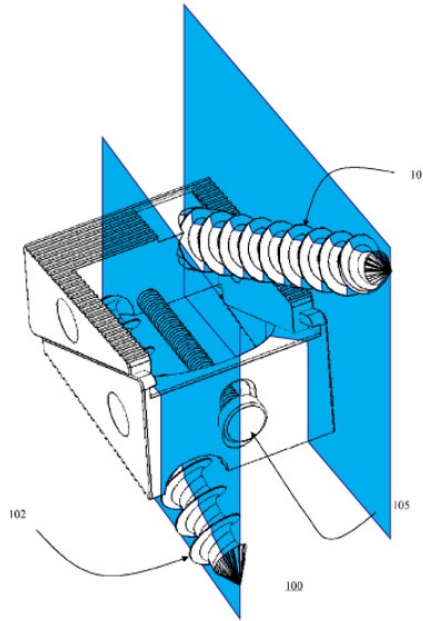


Fig. 1C

As can be seen, both the *first and second cross-sectional planes are parallel to each other. Id.* A POSA would understand the channels to have these cross-sectional planes not only based on Moskowitz’s figures, but from its description explaining that the body of each screw member is “laterally aligned with the box,” indicating that the channels along which the screws run are parallel to the box’s sides. Ex. 1004, 5:11-18; Ex. 1002 ¶ 97.

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

Moskowitz’s *first and second cross-sectional planes are parallel to at least one surface of the fusion member*. That surface is shown in yellow in annotated Fig. 1C below. Ex. 1002 ¶ 98.

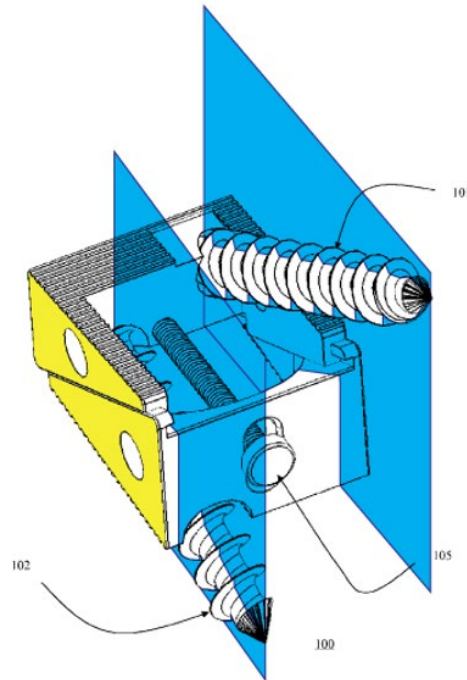


Fig. 1C

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

Claim 3 does not require that the cross-sectional planes be non-parallel with **all** surfaces of the fusion member, but only with *at least one surface*. As shown below, at least one surface (yellow) of the fusion member is not parallel to the channels’ planes. Thus, *neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member*. Ex. 1002 ¶ 100.

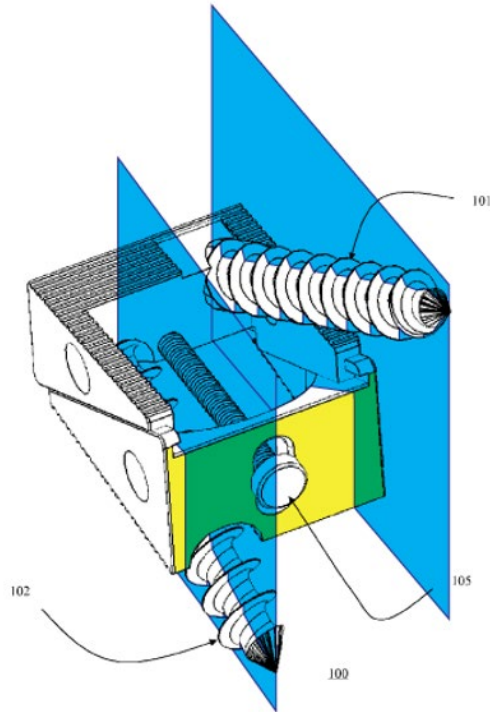


Fig. 1C

**D. Claim 4: “The fusion device of claim 1,”**

**Claim 4.1 “wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member,”**

Figure 1B illustrates a superior perspective of Moskowitz embodiment IA, while Figure 1C provides an inferior perspective. Ex. 1004, 6:22-26. As shown in annotated 1B below, the first curved channel (right) opens to at least two surfaces: the proximal surface (yellow) and a second top surface (pink). The second curved channel (Fig. 1B, left) also opens to the proximal surface (yellow). As shown in Fig. 1C, this channel (now on the right) also opens to an additional, bottom surface (orange). Thus, both curved channels open to at least two surfaces of the fusion

member—a first (yellow) surface for both channels, and different second surfaces (pink or orange). Ex. 1002 ¶¶ 101-102. Thus, Moskowitz discloses that its *first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member*.

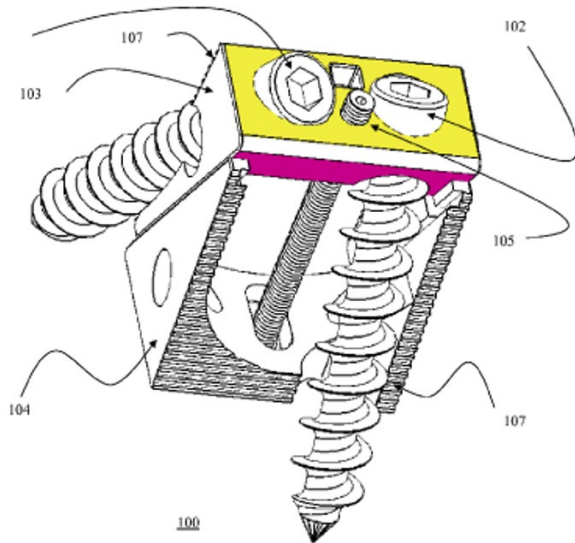


Fig. 1B

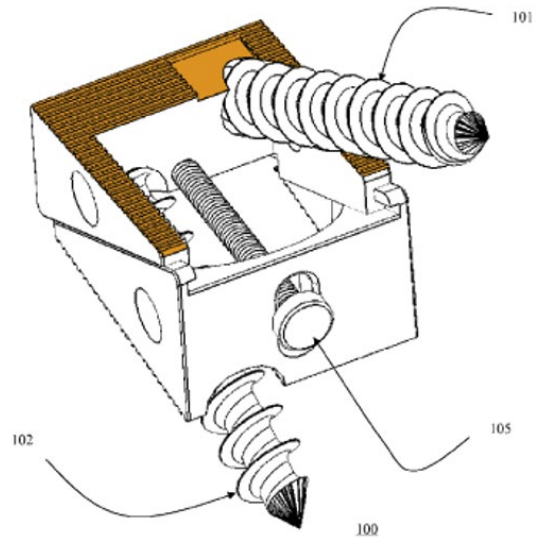


Fig. 1C

**Claim 4.2** “wherein the first cross-sectional plane is not parallel to either of the two surfaces to which the first curved channel opens and the second cross-sectional plane is not parallel to either of the two surfaces to which the second curved channel opens.”

As shown in the annotated figures below, neither of the first or second cross-sectional planes are parallel to any of the surfaces to which any of the curved channels open. Ex. 1002 ¶ 103. Rather, the cross-sectional planes are perpendicular

to each of the surfaces to which the channels open. *Id.* Moskowitz thus discloses all elements of Claim 4.

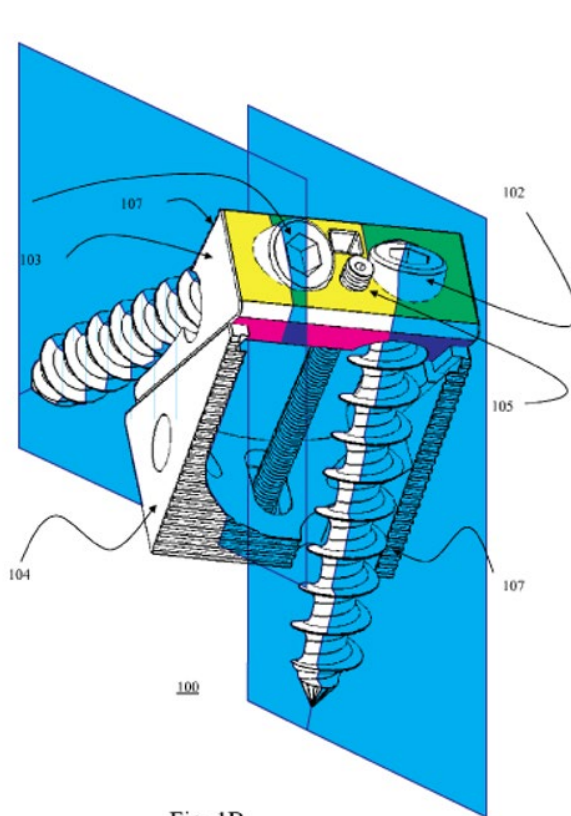


Fig. 1B

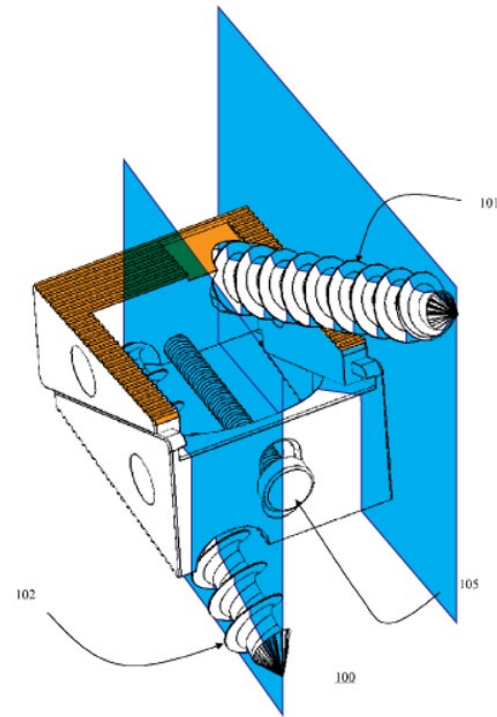


Fig. 1C

**E. Claim 5: “The fusion device of claim 1,”**

**5.1 “wherein the first and second curved channels open to a first surface of the fusion member but the first curved channel traverses to a second surface of the fusion member and the second curved channel traverses to a third surface of the fusion member;”**

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

1002 ¶ 104. That is, the first curved channel opens to the top of the screw box, and its screw engages the superior vertebral body, while the second curved channel opens to the bottom, and its screw engages the inferior vertebral body. *Id.* This is precisely the same arrangement described in the '385 Patent as shown in, for example, Fig. 16. *Id.* Thus, Moskowitz discloses this limitation.

**5.2“wherein the traversal of the first and second curved channels through the fusion member allows (i) the first anchoring member to enter the first surface of the fusion member but exit the second surface of the fusion member at a first desired location on the second surface of the fusion member and (ii) the second anchoring member to enter the first surface of the fusion member but exit the third surface of the fusion member at a second desired location on the second surface<sup>3</sup> without hindering the first anchoring member's insertion through the fusion member.”**

As shown for Claim 4, the first and second anchoring members each enter their respective channels at the proximal opening of the respective channel into the screw box. Each anchoring member also exits their respective surfaces, at a desired location of the designers of the Moskowitz device. Ex. 1002 ¶ 106. Because the channels are parallel, so are the screws contained in the channels, and they enter and

---

<sup>3</sup> Globus notes that the claim requires the second anchoring member to “exit the **third** surface ... at a second desired location on the **second** surface.” This appears to be a logical impossibility and Globus has found no disclosure in the '385 Patent referencing such a configuration. Globus has accordingly mapped the asserted prior art to this claim as if it required the second anchoring member to “exit the **third** surface of the fusion member at a second desired location on the **third** surface ....” In doing so, Globus does not intend to make any admissions regarding the proper scope of this claim and reserves all rights with respect to claim construction, non-infringement, and invalidity.

exit the surfaces of the screw box without hindering one another. Ex. 1002 ¶ 107. Accordingly, Moskowitz discloses all elements of Claim 5.

**F. Claim 7**

**7.1 “wherein each anchoring member is configured to couple to a driving member,”**

Moskowitz teaches that a positioning tool 500a and driver assembly 550 are used for “impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone.” Ex. 1004, 8:63-9:1. These components are shown in Fig. 5H reproduced below.

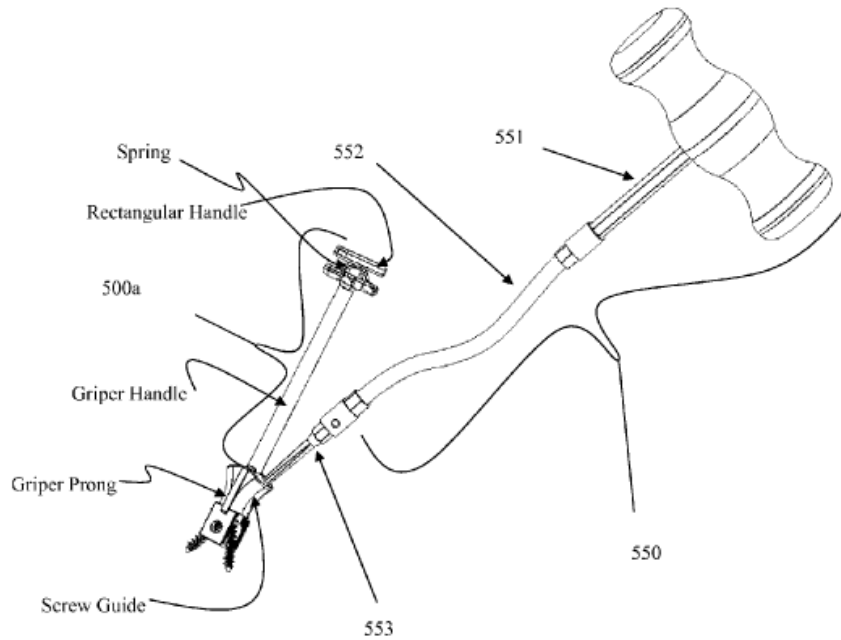


FIG. 5H

Moskowitz explains that the positioning tool 500a has a handle which “serves to position the screw box within the intervertebral space, and screws 201, 202 within the screw box.” *Id.*, 9:4-8. Once the screw box is placed in position, “a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.” *Id.*, 10:60-64.

A POSA would understand from this description that the positioning tool 500a and driver assembly 550 comprise a driving member. Ex. 1002 ¶ 110. The

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

**7.2“wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”**

As discussed for element 7.1, the purpose of the driver assembly is to screw the transvertebral screws into the vertebral bodies. The driving member is thus *configured to drive the anchoring member into the corresponding vertebral body.* Ex. 1002 ¶ 111.

A POSA would also understand that the positioning tool and driver assembly are configured to decouple from the screws once the screws are satisfactorily engaged with the superior and inferior vertebral bodies. Ex. 1002 ¶ 112. This is apparent from the description, as well as from Figs. 6A and 6B which illustrate “the process of insertion and final placement of the construct into the lumbar spine.” Ex. 1004, 11:8-10. Neither figure shows the driver assembly engaged with the screw box, showing that the assembly is ultimately decoupled with the anchoring member, as would be expected pursuant to the standard procedure for deploying such implants uses similar driving and placement assemblies, which (after placement and insertion is complete) are removed before the surgery is completed, as these devices are for

use during surgery but are not designed to remain within the human body. Ex. 1002 ¶ 112. Thus, a POSA would have understood that Moskowitz’s placement tool and driver assembly are necessarily decoupled from the transvertebral screws. *Id.* Accordingly, Moskowitz discloses the elements of Claim 7.

**G. Claim 9: “The fusion device of claim 1,”**

**9.1 “wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess,”**

The ’385 Patent describes certain embodiments (e.g., Fig. 16) having a recess to accommodate a flange at the base of each anchoring member. Ex. 1001, 9:53-67, 21:17-27. The specification describes certain recesses as “a recess of increased diameter.” *Id.* But the claim does not contain a similar limitation, indicating that the claimed recess need not have an diameter larger than the rest of the channel. Ex. 1002 ¶ 114.

As discussed for element 1.2, each channel has a proximal opening on the surface of the screw box. As explained for that element, a POSA understood that each channel also contained a seat inside the channel, or that the inclusion of such a seat was obvious. *See* Claim 1.2 above. The portion of each channel between the proximal opening and the seat comprises the *recess* for each *opening*. Ex. 1002 ¶ 115.

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

Moskowitz’s Fig. 1D, annotated below, shows that each transvertebral screw has a base or head (blue).

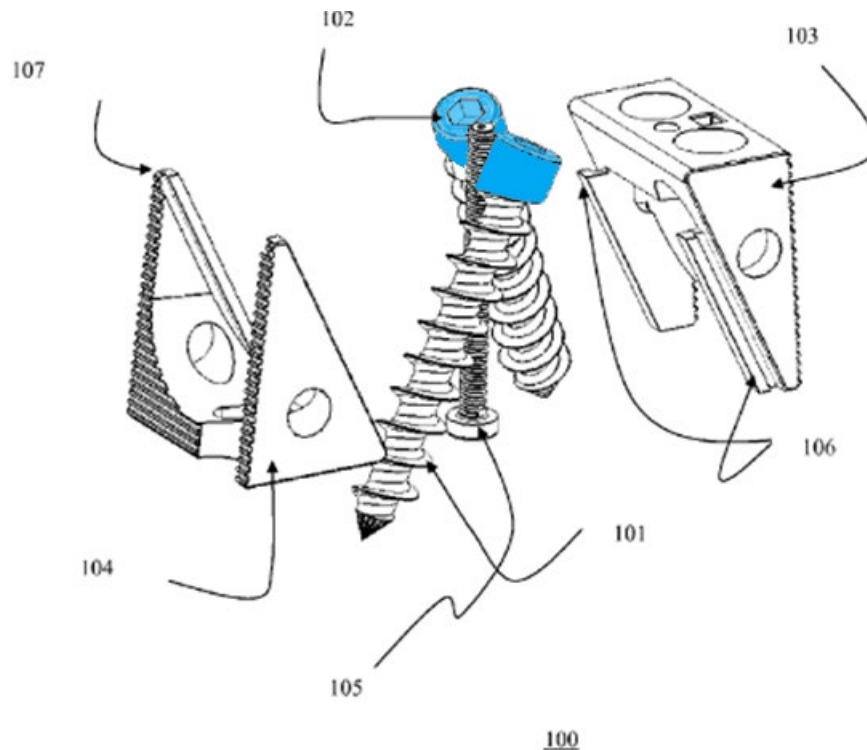
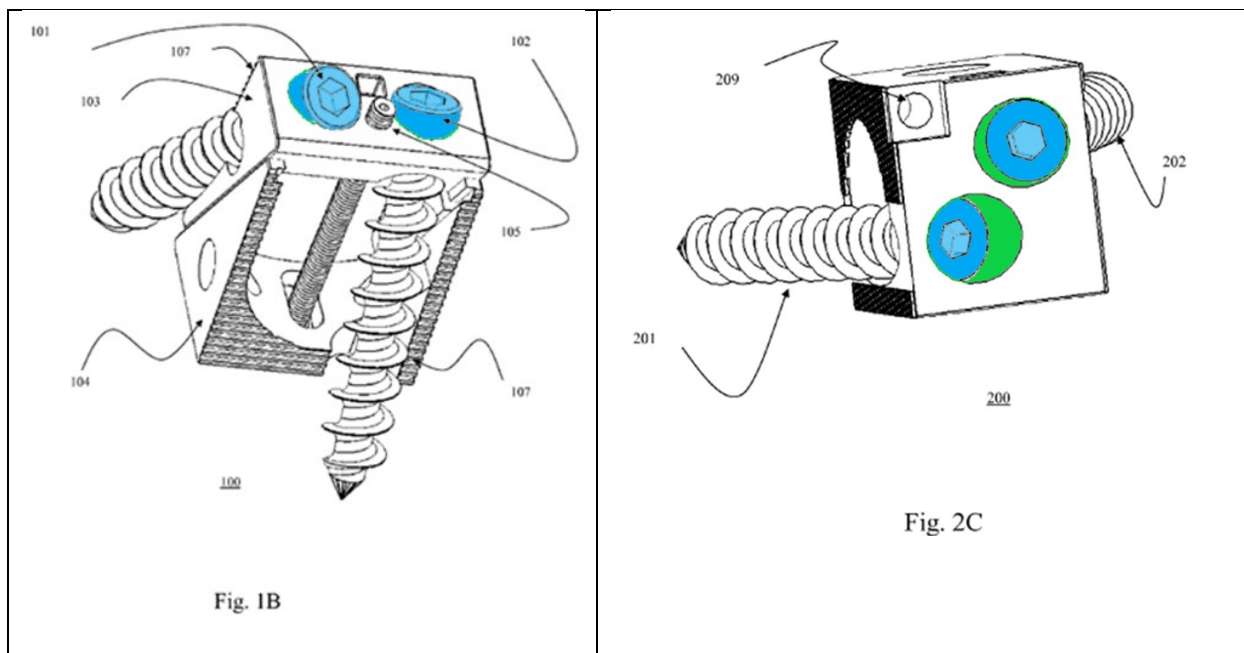


Fig. 1D

The base or head fits within the cylindrical recess (green in annotated Figs. 1B and 2C below) inside the proximal surface of the screw box. Ex. 1002 ¶ 117.



As discussed for element 1.2, a POSA would understand that the channel includes a seat which is engaged by the base or head of the screw, which retains the screw in the screw box as it is being turned and advanced into the vertebral body. *Id.*; see Claim 1.2 above. The base/head of the screw is retained within the recess (the portion of the channel between the proximal surface and the seat). Ex. 1002 ¶ 117. Fig. 6B shows that the screw is maintained at least partially within the screw box while the screw is inserted into the vertebral body. *Id.*

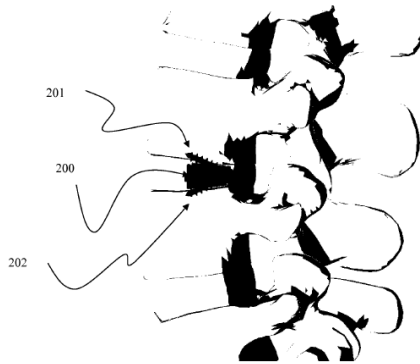


Fig. 6B

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

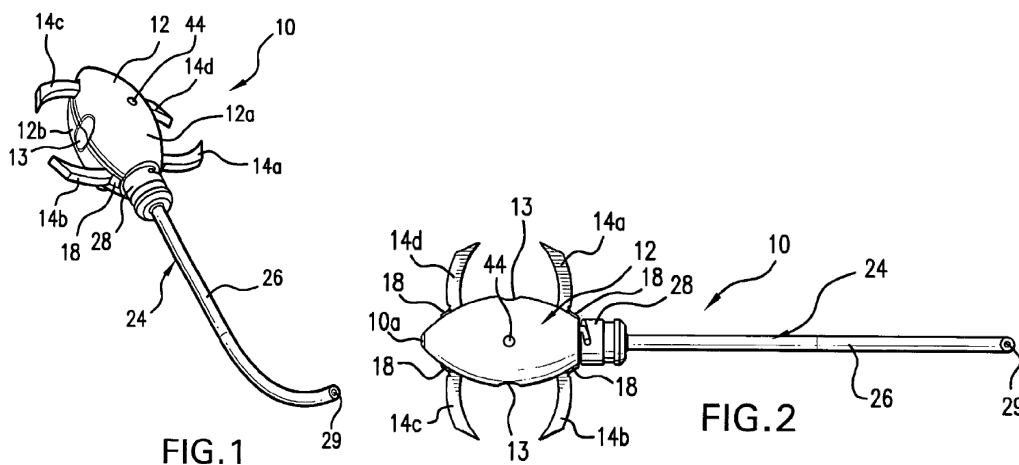
## **IX. GROUND 2 – HESS AND GENERAL KNOWLEDGE OF A POSA**

### **A. Claim 1**

#### **Claim 1.0**

Hess explains that its “[i]mplant ... is particularly well adapted for use in performing minimally invasive surgical procedures for treating spinal stenosis, including, for example, interspinous process decompression (IPD).” Ex. 1006, 6:45-48. Hess’s device is thus “directed to a spinal implant used primarily for interspinous process decompression procedures that can be percutaneously introduced into the interspinous space.” Ex. 1006, 2:3-6. Figures 1 and 2 of Hess depict an interspinous

implant 10 that “can be used ... as an adjunct to spinal fusion procedures.” Ex. 1006, 6:43-52; *id.*, Abstract (“A spinal implant for treating lumbar spinal stenosis or as an adjunct to spinal fusion.”).



Hess’s implant 10, shown in Figures 1 and 2 reproduced above, possesses “locking wings” (14a-14d above) which are “adapted and configured to engage adjacent vertebral portions of the spinous process.” *Id.*, 7:18-20.

A POSA would have understood that Hess, although primarily directed at an interspinous implant, was also suitable and desirable for use as an intervertebral spinal implant with only minimal modifications. Ex. 1002 ¶ 122. A POSA would have understood that Hess was designed to stabilize two parts of the spine—the spinous processes of adjacent vertebrae. *Id.* Hess was designed to be inserted through an access channel with its anchors extending into a plane perpendicular to the implant’s length. Ex. 1006, 9:48-10:32. An intervertebral fusion implant is similarly

inserted through an access channel and designed to stabilize the vertebral bodies until they fuse. Ex. 1002 ¶ 122. Moreover, Hess—like intervertebral implants—was designed for permanent implantation. *Id.*; Ex. 1006, 13:30-45.

A POSA was also motivated to use Hess due to its curved anchors, which provide advantages over straight anchors, to better ensure a successful spinal fusion procedure. Ex. 1002 ¶¶ 123-125. It was well understood that loosening or migration of an intervertebral implant in the initial post-surgery stabilization period must be limited or (if possible) prevented, so that the implant remains in a fixed position to stabilize the vertebrae and to support fusion between the vertebrae. Ex. 1002 ¶ 123; *see also* Ex. 1018, 23:48-50 (reducing migration via “teeth” on the implant surfaces); Ex. 1019, 4:61-64 (inhibiting migration using “roughened surface topography” on the implant surfaces, for “gripping adjacent bone”); Ex. 1020, 13:15-30 (discussing various implant bone screw designs to prevent screw migration, which a POSA would understand to cause migration of the implant); Ex. 1024, 1:31-39 (“One problem with prior art spinal fusion techniques relates to device migration. For example, prior to complete bone fusion, a fusion device may migrate from the desired position.”); *id.*, 4:26-28 (using a retention device to prevent “anterior and lateral migration”).

A POSA understood that, to prevent loosening and/or migration of the interbody implant, the anchor members used to secure the implant device to the

vertebrae should ideally be as perpendicular to the interbody device as possible when inserted into the vertebral body. *Id.* ¶ 124. Anchors inserted at other angles allow a larger moment arm to act on the anchors, applying greater lateral force to the anchor and implant and urging it to move laterally. *Id.* (citing Ex. 1005). When anchors are inserted perpendicular to the vertebral body, the moment arm acting on the anchors is as small as possible, meaning that the applied forces must act along the longitudinal axis of the anchor (straight up or down). *Id.* Such forces do not tend to cause lateral or sagittal movement of the implant. *Id.* Thus, anchors inserted perpendicular to the vertebral body require the greatest force (relative to other insertion angles) to pull the anchor from the bone post-surgery while the vertebrae fuse. *Id.*

That said, a truly perpendicular approach is not practically feasible because there is insufficient space between the vertebrae and through the implant to drive an anchor during surgery. *Id.* ¶ 125. The access channels for anchoring members are linear to the implant (generally, from front to back). Therefore, the anchors must be inserted in this direction. *Id.* Using a curved anchor—one that curves upwards or downwards—allows anchors inserted in the linear direction to penetrate the adjacent vertebrae as close to perpendicular to the implant as possible. *Id.* Thus, a POSA was motivated to use curved anchors such as those in Hess to minimize migration of the implant. *Id.*

The only changes required would be to modify the dimensions of Hess's shell, which was "dimensioned and configured for placement between the spinous processes," (Ex. 1006, 7:3-4), for use instead as an intervertebral implant. Ex. 1002 ¶ 126. Hess itself explains that the "bullet" shape shown in its figures could easily be modified for "many other variations" for the purpose of "match[ing] the profile of the adjacent bone when deployed." Ex. 1006, 7:7-13. Thus, this modification entailed merely modifying the external dimensions such that the implant formed, for example, a rectangular box (having optional external ridges) to interface with the superior and inferior vertebrae. Ex. 1002 ¶ 126. Such a "box cage" design was common for intervertebral implants before the time of the invention. *Id.* This change would enable the implant to serve as a stable interbody platform to support the vertebrae during the fusion process. *Id.* If necessary, the implant's design could be modified to increase strength as well. *Id.* Such a modification would entail simply modifying (thickening) the wall thickness of the implant shell or using stronger materials. *Id.* A POSA would understand that the implant shell must be able to withstand the expected forces for an intervertebral implant, and would make such modifications as needed. *Id.* Such a change was well within the skill of a POSA and could reasonably be expected to be successful based on prior art designs such as in Moskowitz, Bray, and Fraser. *Id.*

A POSA would also have optionally created perforations in the implant device to allow for the interpenetration of artificial bone graft material, to promote fusion (bone growth) between the two vertebrae in and not merely around the implant. Ex. 1002 ¶ 127. The use of such perforations for enabling fusion using such bone graft material was also within the general knowledge of a POSA when constructing intervertebral fusion devices. *Id.* (citing Ex. 1007, Ex. 1023). This modification is optional, as not all such fusion devices possessed such perforations to allow graft material to penetrate the device's internal cavities. *Id.*

A POSA would have had a reasonable expectation of success in modifying the dimensions of Hess's device and in using it as an intervertebral implant. Ex. 1002 ¶ 128. This is because, first, Hess itself envisioned modifying its shape and dimensions as explained above. That is, Hess's particular shape was merely a design choice. *Id.* Second, because the internal components of Hess's device do not require its bullet shape (as noted by Hess itself), but could be easily contained in a rectangular box suitable for use as an intervertebral implant. *Id.* The changes to the internal components required would have been recognized as simple, straightforward mechanical changes well within the skills of a POSA. *Id.*

Thus, a POSA understood that Hess, with minimal modifications, was suitable and desirable for use as an intervertebral fusion device to stabilize the vertebrae for

fusion. Accordingly, a POSA would have considered it obvious to modify Hess's device for use as an intervertebral fusion device. Ex. 1002 ¶ 128.

### **Claim 1.1**

As discussed above, it was obvious to modify Hess's device to function as an intervertebral fusion apparatus *configured to position between adjacent first and second vertebral bodies*.

Hess's implant possesses four internal curved guide tracks (each a *channel*) for each of its four locking wings:

During deployment of the implant 10, the locking wings 14a-14d are stowed within the shell 12 of the implant 10, as best seen in FIGS. 10A and 11, forming a streamlined structure. As best seen in FIGS. 4, 5A, 5B, 6A, 6B, 10A and 10B, **two curved guide tracks 19** formed within the shell portions 12a, 12b accommodate the wings 14a-14d in the stowed position.

Ex. 1006, 7:26-29. Figure 10A and 10B are annotated below to show the location of the curved guide tracks corresponding to wings 14b and 14d in green:

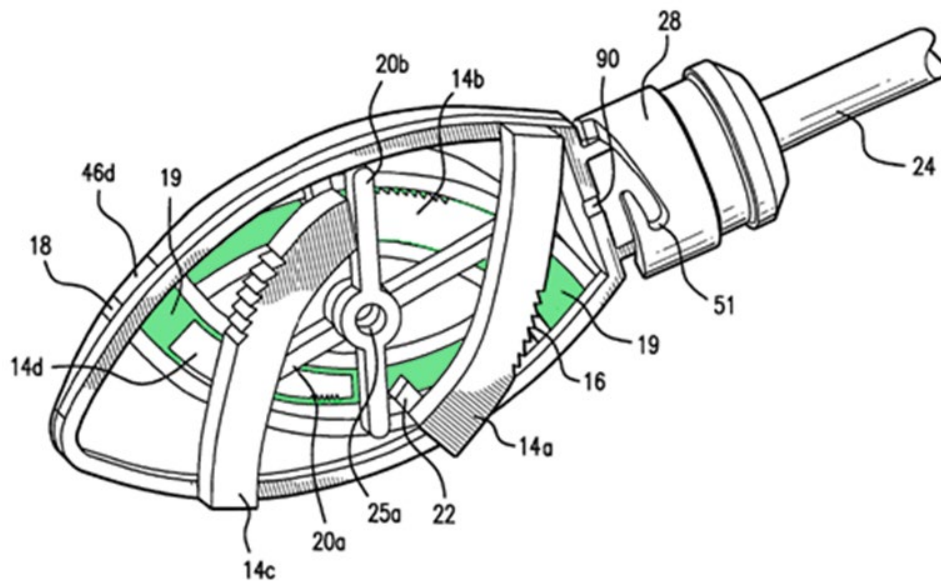


FIG. 10A

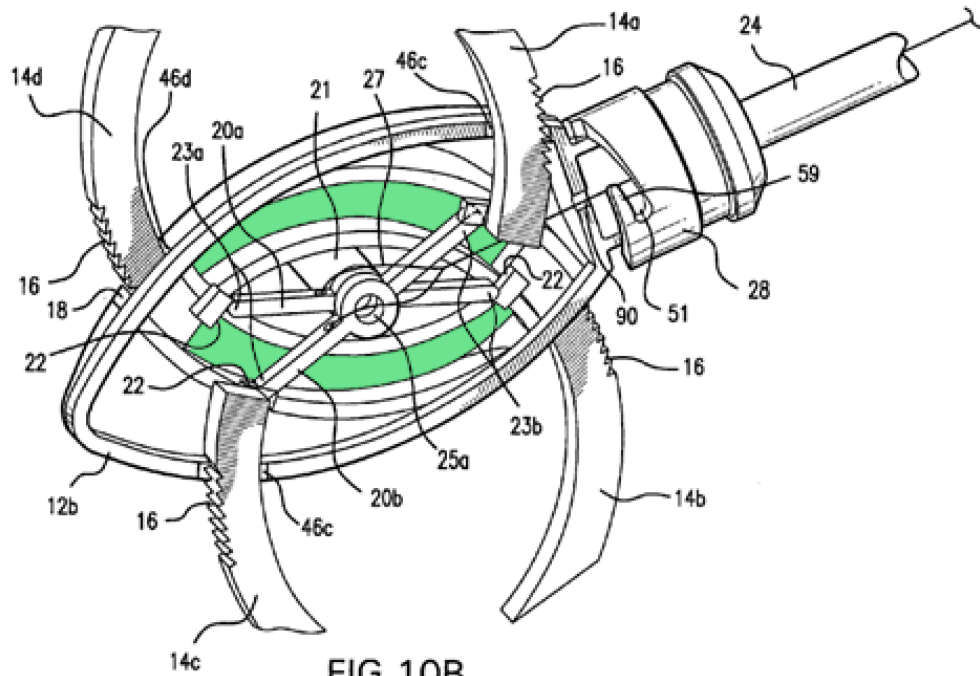


FIG. 10B

*Id.* Figs. 10A, 10B; *see also* Figs. 5A, 5B, 6A, 6B; Ex. 1002 ¶ 130. Guide tracks

corresponding to locking wings 14a and 14c are not shown but are identical. Ex. 1002 ¶ 131. The *first curved channel* corresponds to the guide track for wing 14a or 14d. If the *first curved channel* is that for wing 14a, the *second curved channel* would be the guide track for wing 14b. If the *first curved channel* is that for wing 14d, the *second curved channel* would be the guide track for wing 14c. *Id.*

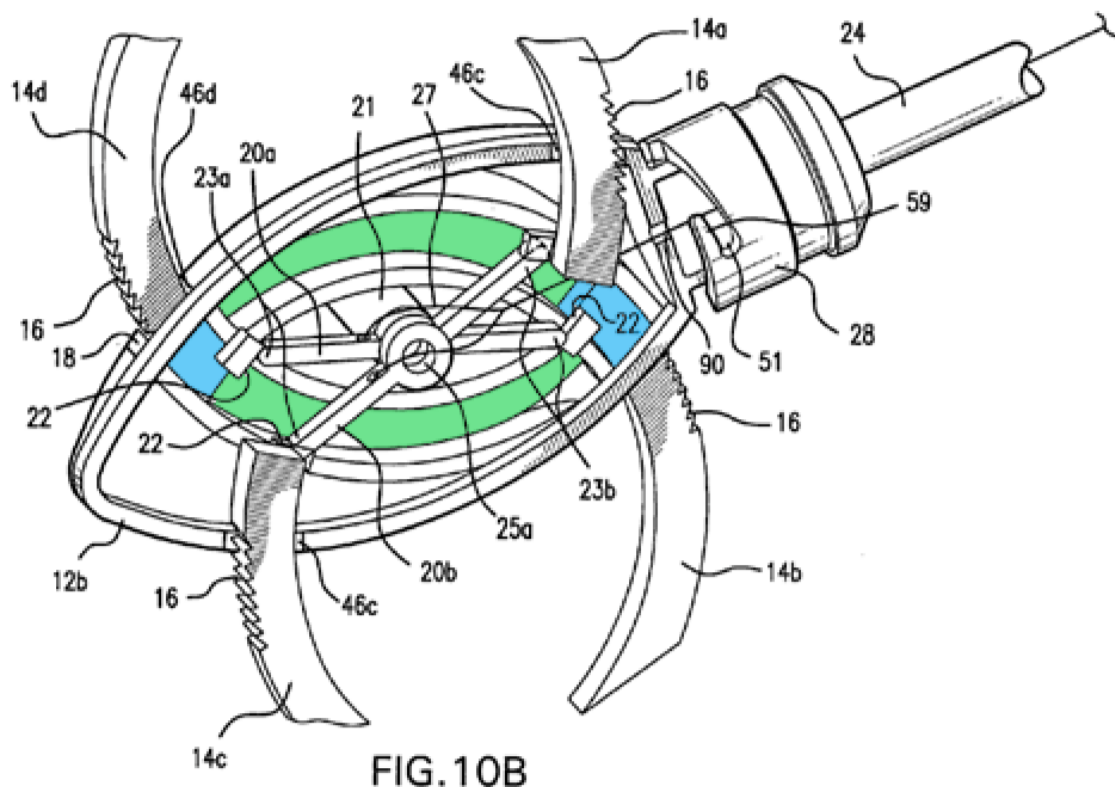
### **Claim 1.2**

Hess's device, in its most basic configuration, "includes a body portion having an interior cavity, a plurality of locking wings adapted and configured to move between a stowed position retracted within the interior cavity of the body portion and a deployed position extended from the interior cavity of the body portion, and means for moving the plurality of locking wings from the stowed position to the deployed position." Ex. 1006, 2:6-13. The locking wings are deployed "to engage the spinous processes of adjacent vertebrae." *Id.*, 2:25-26. In the modified device, the locking wings would engage the vertebral bodies. Ex. 1002 ¶ 132.

The main shell of the device "houses four deployable ratcheting locking wings 14a-14d adapted and configured to engage adjacent vertebral portions of the spinous process. The shell 12 has four openings 46a-46d that allow the locking wings 14a-14d to extend outward from the shell 12." *Id.*, 7:21-22. "Advantageously, once the wings 14a-14d are deployed to fixate the spinous processes, migration of the implant 10 is prevented." *Id.*, 7:43-45. Further, the tips of the locking wings "can be sharp to

create penetration of the spinous processes” “so that the edge that forms a point on opposing claws so that the opposing wings could penetrate deeper or through the spinous process bones.” *Id.*, 13:30-36.

As shown in annotated Figure 10B below, at least a portion (blue) of the locking wings also remains within the shell in the deployed position.



*Id.*, 5:56-58, Fig. 10B; Ex. 1002 ¶ 134.

As modified, a POSA understood that Hess’s locking wings would engage and at least partially penetrate the superior and inferior adjacent vertebrae instead of the spinous processes. Ex. 1002 ¶ 135. This would effectively couple the shell with the vertebral bodies. *Id.*

Thus, Hess as modified discloses *a first anchoring member* (e.g., either locking wing 14a or 14d) *configured to insert through the first curved channel* (the guide track 19 corresponding to the selected locking wing 14a or 14d) *and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body.* Ex. 1002 ¶ 136.

One of the other locking wings comprise the second anchoring member. Thus, if the first anchoring member is locking wing 14a or 14d, the second locking wing would be 14b or 14c, respectively. *Id.* ¶ 137. Therefore, locking wing 14b or 14c is the *second anchoring member configured to insert through the second curved channel* [the guide track corresponding to the chosen locking wing] *and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body.* *Id.*

### **Claim 1.3**

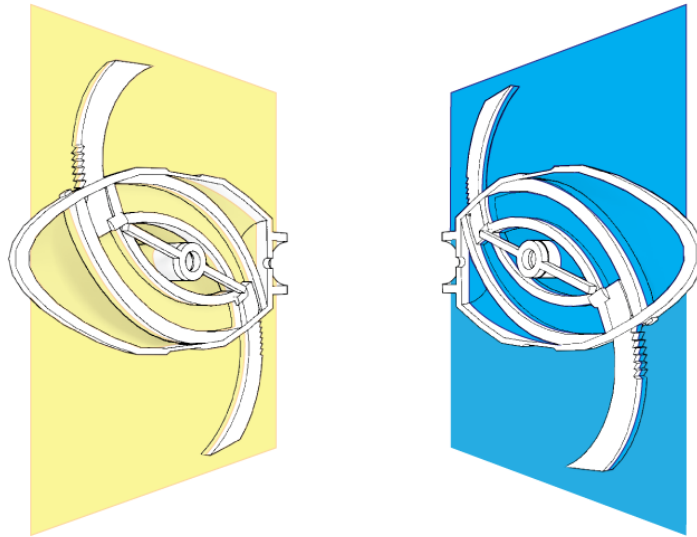
A first pair of Hess's anchors (locking wings), which travel through the curved guide tracks, are explicitly disclosed as each "located on first parallel, spaced apart geometric planes that extend on a first side of a centerline of the shell," while the other pair "are located on second parallel, spaced apart geometric planes that extend on a second side of the centerline of the shell." Ex. 1006, 3:31-35. Thus, as explained

with reference to Figure 3, “in a deployed position, locking wing 14*b* resides in a deployment plane that is parallel to the deployment plane of locking wing 14*c*. Similarly, locking wing 14*a* resides in a plane that is parallel to the deployment plane of locking wing 14*d*. It follows that, locking wings 14*a* and 14*c* reside in a common deployment plane, and locking wings 14*b* and 14*d* reside in a common deployment plane.” *Id.*, 7:46-58.

Because each of the wings travels through a guide track, a POSA understood that each pair of guide tracks would likewise reside in parallel deployment planes. Ex. 1002 ¶ 139. Thus, for example, the guide track for either locking wing 14*a* or 14*d* has a *first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member*, while the guide track for either locking wing 14*b* or 14*c* has a *second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member*, and the *first and second cross-sectional planes are parallel to each other*. That is, the guide track for first anchoring member 14*a* is parallel to the guide track for second anchoring member 14*b*. If the first anchoring member is 14*d*, its guide track is parallel to the guide track for second anchoring member 14*c*. *Id.*

Even without this explicit description, it is apparent from Hess’s figures that the guide tracks each have cross-sectional planes traversed by each channel through the shell, and that the cross-sectional planes are parallel to each other. This can be



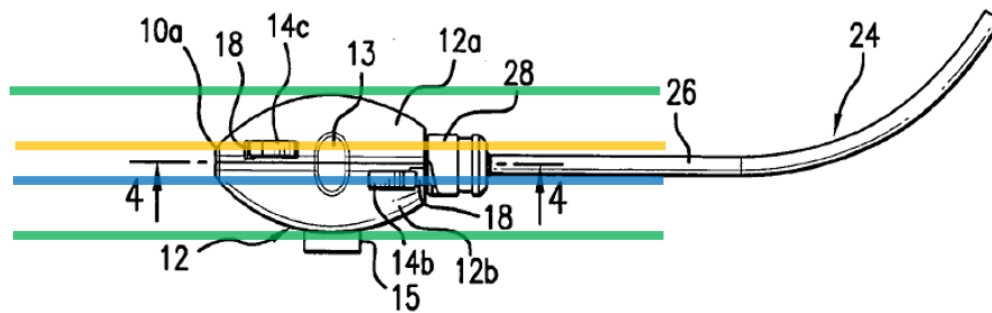


## **B. Claim 2**

The planes of Hess's guide tracks are parallel to at least one surface of its shell, specifically the top and bottom of its shell when viewed from the side.<sup>4</sup> Ex. 1002 ¶ 142. This is shown in annotated Figure 3 below, where the plane of those surfaces is noted in green. *Id.*

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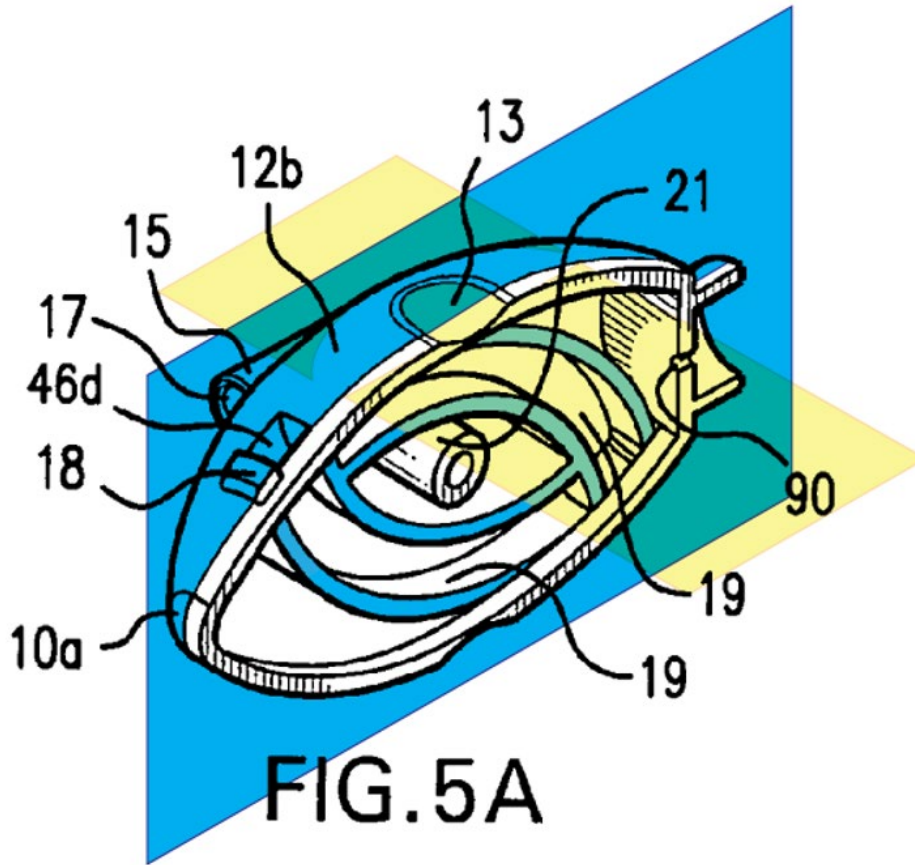
<sup>4</sup> As deployed, these surfaces are actually the sides of the shell. Ex. 1002 ¶ 142 n.1.



Further, as modified, Hess's shape would be a rectangular shape suitable for use as an intervertebral fusion apparatus. Ex. 1002 ¶ 143. Thus, the planes of each of the guide tracks would be parallel with the straight sides (the top and bottom in Figure 3) of the implant. *Id.* Thus, Ground 2 discloses that *the first and second cross-sectional planes are parallel to at least one surface of the fusion member.*

### C. Claim 3

Hess's shell has opposing depressions 13 on the top or bottom of the implant to match the profile of the adjacent bone when deployed. Ex. 1006, 7:11-13. As shown in annotated Figure 5A below, the surface containing these depressions is perpendicular to the plane of the curved guide tracks. Ex. 1002 ¶ 144.



As modified, Hess's shell would be a rectangular box suitable for use as an intervertebral fusion implant. Ex. 1002 ¶ 145. Thus, the guide tracks would be perpendicular to the corresponding surfaces (the top and bottom of the implant when positioned as it would be placed between vertebrae) in the modified implant as well. *Id.* Thus, *neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.*

#### **D. Claim 7**

##### **Claim 7.1**

Hess's *anchoring members* (locking wings) are deployed when a "locking

wheel” causes them to move. The locking wheels themselves are actuated by a deployment cable, controlled by the surgeon:

A pair of coaxial locking wheels rotatably mount in the shell to selectively exert a force against each locking wing to move the locking wings from the stowed to the deployed position and a deployment cable couples to the wheels to actuate rotation of the wheels.

Ex. 1006, 3:24-28. With reference to Figs. 10a and 10b partially annotated below, Hess explains that during surgery, the implant (10) is held in position by the surgeon using placement tools (not shown—see Fig. 20) and one or more deployment cables (27) (orange) are pulled to actuate the locking wings (14a-14d). *Id.*, 11:55-12:4. A distal end of the cable(s) is attached to an opening (41) in the coaxial locking wheels (20a, 20b) (pink) so that as the cable is pulled, the locking wheels rotate about the central hub (21). *Id.* Fig. 10A details the position before deployment, while 10B illustrates after deployment. *Id.*, 5:53-58, 10:53-58. The ends (23a, 23b) of the locking wheels push against surfaces (22) of the locking wings, causing them to slide outward in their guide tracks (19). Upon deployment, the locking wings engage the adjacent bone. *Id.*, 8:5-19, 11:55-12:4. After deployment, the cable maybe be disengaged or cut. *Id.*, 8:18-19.

Pre-  
Deployment

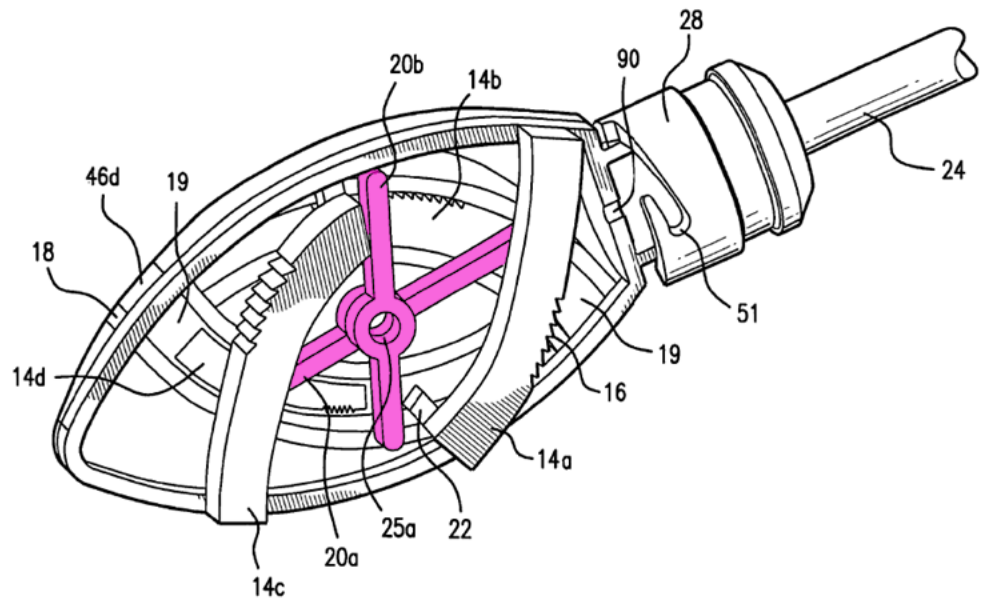


FIG. 10A

Post-  
Deployment

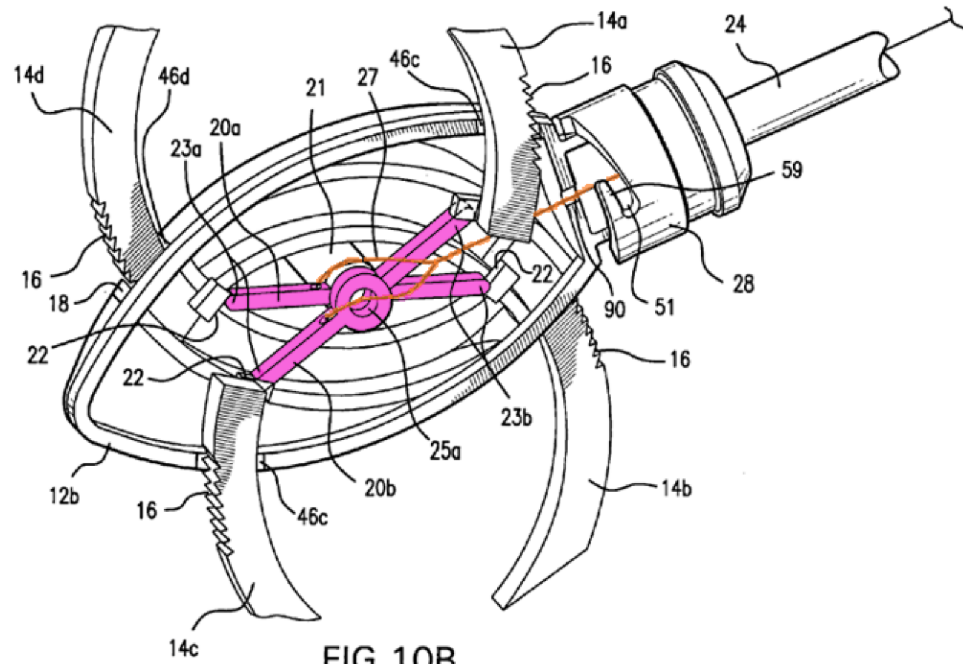


FIG. 10B

Hess's deployment cable(s) 27 actuates rotation of the locking wheels, which in turn move the locking wings through their guide tracks and cause them to deploy and engage the adjacent bone (as modified, the vertebral bodies). Ex. 1002 ¶ 147. Thus, the cables are a *driving member*, configured to couple to the locking wings (*anchors*) via the locking wheels. *Id.* Hess thus teaches that *each anchoring member is configured to couple to a driving member*.

### **Claim 7.2**

As detailed for Claim 7.1 above, the *driving member* (cable 27) is configured to drive the *anchoring members* (locking wings) from their stowed to deployed position, at which point they are driven into the superior and inferior vertebral bodies. *See* Claim 7.1 above; Ex. 1006, 13:30-36 (explaining that the locking wing tips penetrate the spinous process bones). After deployment, the cable may be decoupled from the anchoring member—either by disengaging or cutting. Ex. 1006, 8:18-19, 8:50-56. In either case, the cable is either completely or partially decoupled from the locking wings. The operation of the cable would not change in the modified version of Hess, except that (as explained for Claim 1) the locking wings will engage the vertebral bodies and not the spinous processes. Ex. 1002 ¶ 148. Thus, Hess teaches a *driving member configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member*.

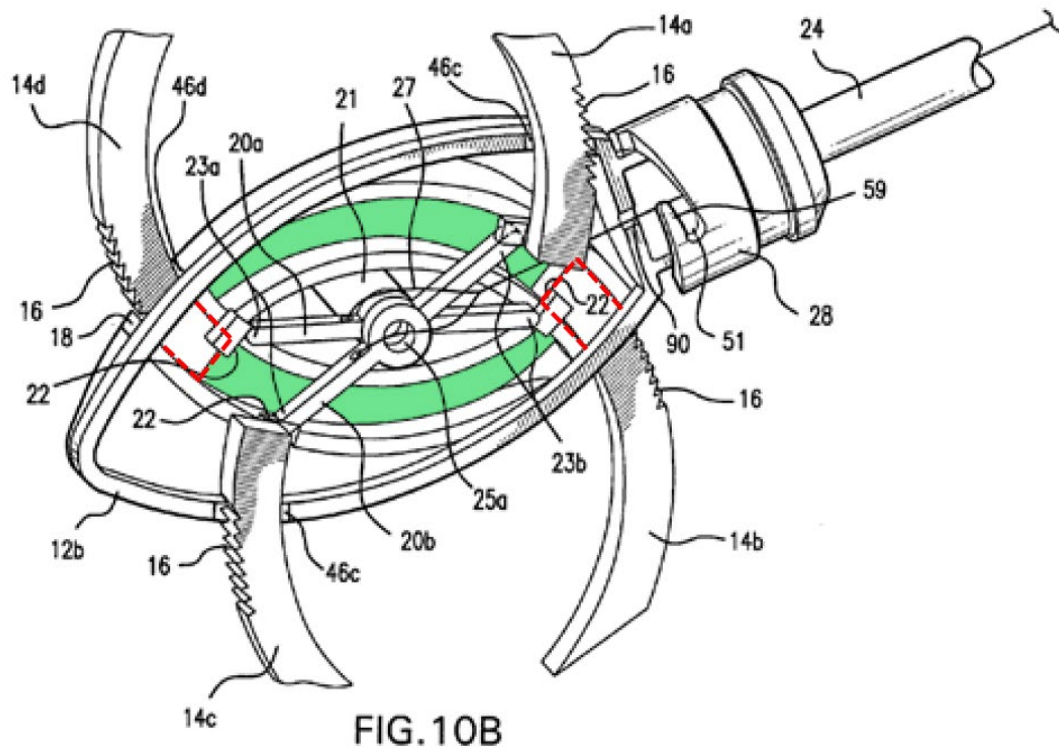
## E. Claim 9

### Claim 9.1

Hess's device includes openings in the shell for its guide tracks for deployment of the locking wings. Hess explains that the shell has "upper and lower shell portions **defining four interior grooves that terminate in openings in the shell.**" Ex. 1006, 3:13-18. As shown in Fig. 10B below, each opening possesses a *recess* (red dashes) into the fusion member along the length of the channel. Ex. 1002 ¶ 150. Hess thus discloses that *each channel possesses an opening on a surface of the fusion member* at openings 46a-46d in the shell and *the opening has a recess.*

Hess also discloses an additional recess. Each opening possesses a "pawl structure" formed adjacent each opening. Ex. 1006, 3:13-18. A POSA understood that a "pawl" generally refers to a curved bar or lever that engages the teeth of a ratchet. Ex. 1002 ¶ 141. The pawl structure engages ratchet teeth on the locking wings to lock them in position. *Id.*, 3:18-23; *see also id.*, 7:33-38. The pawl structure (18) is described in Hess as extending from the interior surface of each channel and adjacent the recess formed by the openings (46a-46d) of each channel in the shell, as shown in Figures 5B and 10B below. A POSA would have understood that, in addition to the recess in each channel, that each pawl structure (which is a protrusion from the wall of the opening into the channel to engage the ratchet teeth on the wing) effectively forms a recess on at least one side of the pawl's protrusion. Ex. 1002

¶ 151. The recess is relative to the protrusion formed by the pawl structure. *Id.* Thus, this is an additional *recess* (in addition to the *recess* formed by the end of each channel next to the opening) present in Hess. *Id.*



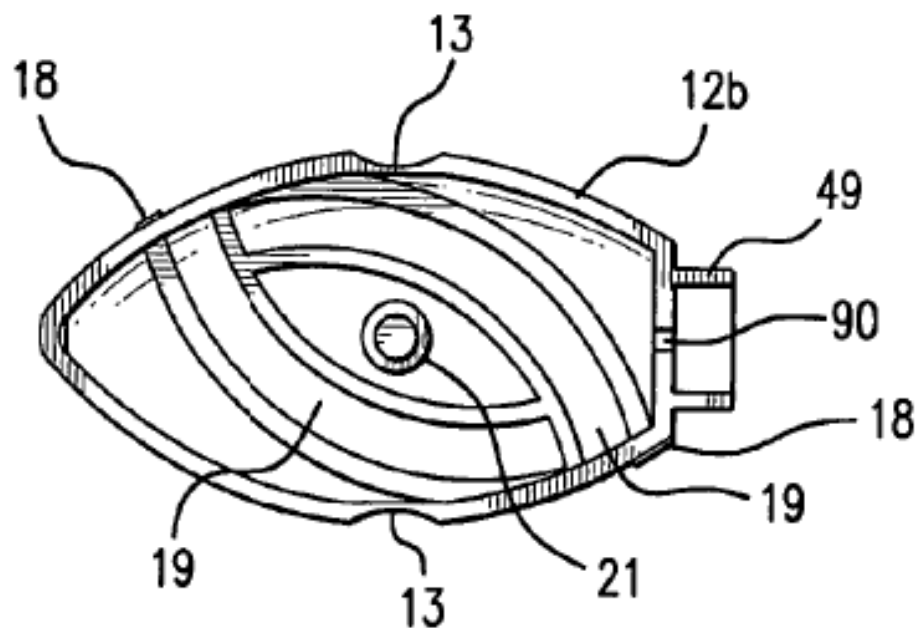
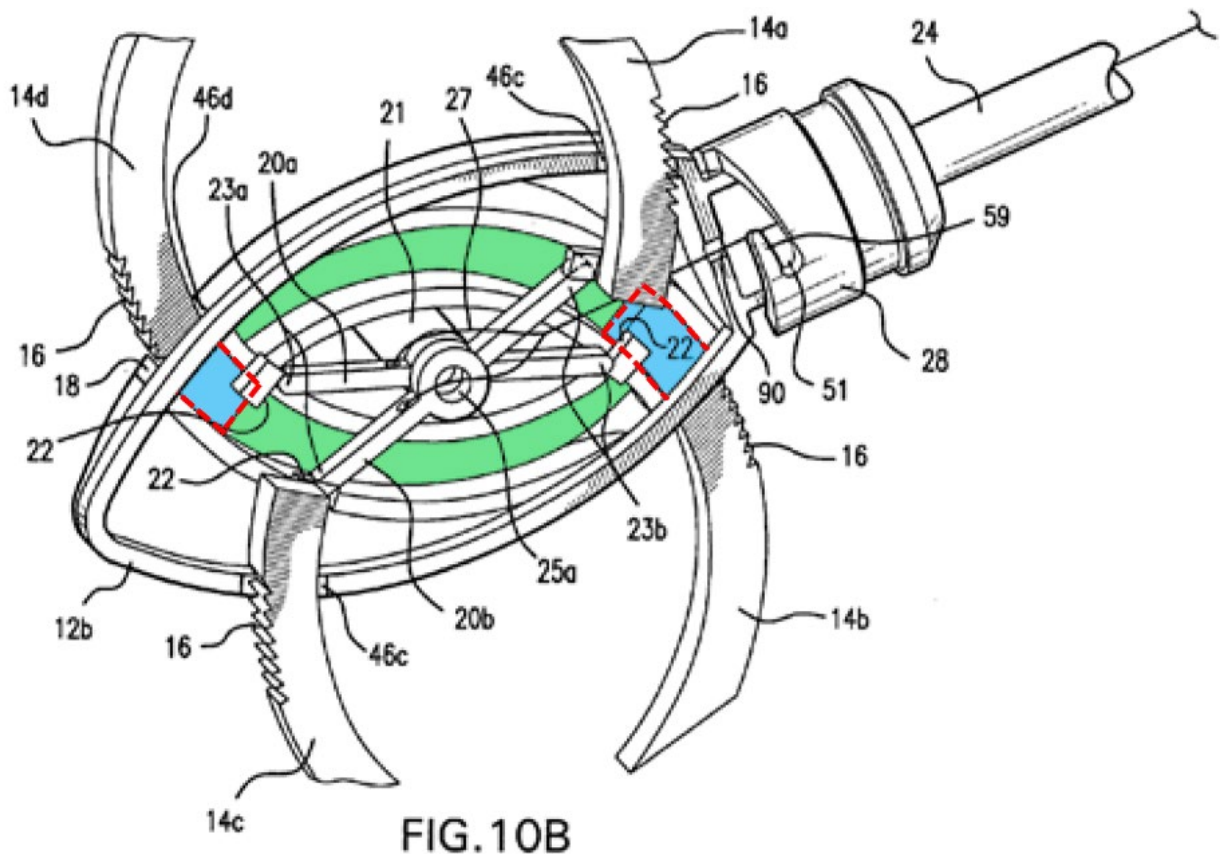


**FIG. 5B**

**Claim 9.2**

Hess's locking wings (*anchoring members*) each have a base portion that remains inside the shell, within the internal recess below the opening for each of the guide tracks (*channels*). Annotated Fig. 10B below highlights the base portion of the locking wings in blue and the channels in green. As can be seen, at least a portion of each locking wing remains inside the shell, occupying a portion of the channel (the *recess*, red-dashed lines) while the tips of the locking wings penetrate the vertebral bodies. Ex. 1002 ¶ 152.



Thus, each anchoring member *has a base that fits within the recess of the channel associated with the anchoring member that maintain(s) the anchoring member at least partially in the fusion member, while the anchoring member is inserted into the vertebral body.* This operation would not change in the modified version of Hess for use as an intervertebral fusion device. Ex. 1002 ¶ 153.

Further, at least one groove in the ratchet teeth on each locking wing is engaged by the pawl structure, meaning that the adjacent teeth would fit into the relative recess formed on each side of the tooth. *Id.* This also meets the limitation, as each locking wing (*anchoring member*) has a base (portion having ratchet teeth)

*that fits within the pawl's recess (which is in the channel), with the engagement between pawl, recess, and ratchet teeth maintain[ing] the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body. Id.*

## **X. GROUND 3 – MOSKOWITZ IN VIEW OF STEFFEE**

### **A. It was obvious to combine Moskowitz with Steffee.**

A POSA would have considered it obvious to combine Moskowitz with Steffee. Ex. 1002 ¶¶ 159-173. As discussed in detail below, a POSA was motivated to use Steffee's curved anchors with Moskowitz's screw box to minimize potential migration of the screw box after implantation. Section X.A.2. This modification would entail modifying the screw box to include channels having a curved path, to accommodate the curved anchors. *Id.* A POSA had a reasonable expectation of success in making this modification because it would only require the use of known machining techniques, and because the use of both curved anchors and curved channels had already been shown successful in spinal implants. Section X.A.3. This combination would possess all elements of the challenged claims. *See* Sections X.B.-X.H.

#### **1. Steffee is Analogous to the Claimed Invention.**

Steffee is from the same field of endeavor as the '385 Patent, which includes "surgical procedures for spinal fusion and stabilization." Ex. 1001, 1:29-30. Steffee

relates to “a fastener for securing bone graft between a pair of bone portions.” Ex. 1005, 1:6-9. A POSA would have understood Steffee to relate to such procedures because bone graft material was commonly used in spinal fusion procedures. Ex. 1002 ¶ 163; *see* Section VII.C. Although Steffee does not reference spinal fusion in its text, a POSA would have understood Steffee to explicitly disclose using its invention in a spinal fusion procedure based on at least its Figures 5 and 6, which depict the use of Steffee’s fasteners with bone graft material placed between two vertebral bodies. Ex. 1002 ¶ 163; Ex. 1005, 3:14-38 (referencing “fibrocartilaginous disk 60b”), 4:23-34, Figs. 5-6. Such bone graft material was used without implants (Ex. 1001, 1:58-61, Ex. 1018, 1:35-38), and together with implants (Ex. 1004, 3:39-44; Ex. 1019, 2:65-3:3); Ex. 1002, ¶ 163. Thus, Steffee is from the same field of endeavor as the ’385 Patent.

Steffee is also reasonably pertinent to the problem facing the inventor of the ’385 Patent—improving the reliability of fusion “between unstable vertebral segments” to “avoid the considerable medical and economic impact of failed spinal fusions.” Ex. 1001, 2:10-13. A POSA understood that one reason spinal fusions failed was due to migration of the implant during the initial stabilization period. Ex. 1002 ¶ 164.

A POSA also understood that at least one reason such migration occurred was due to forces acting on the implant, including through its anchors or fasteners

attached to the vertebrae. Steffee explains that it was known that bone graft contracts as it resorbs (that is, as the bone graft material breaks down and forms the substrate for new bone growth). Ex. 1005, 1:11; Ex. 1002 ¶ 165. This “has resulted in difficulties in securing bone graft between spaced apart bone portions which are to be connected by the bone graft.” *Id.*, 1:12-14. Further, as the bone graft resorbs, it applies a force to the straight legs of the prior art staples (referenced in Steffee) that were used to secure bone graft between bone portions. *Id.*, 1:16-17. “The force acts through a moment arm and causes the leg to pivot relative to a portion of the staple base,” causing the staple to [lose] its effectiveness.” *Id.*, 1:17-20.

Steffee solved this problem via curved anchors that traverse the vertebral bodies at a near-perpendicular entry angle. For example, in Fig. 6 (below), anchor 92 enters the bone graft, as well as vertebral body 100, at an angle nearly perpendicular to the vertebrae surface (100b). Ex. 1002 ¶ 166.

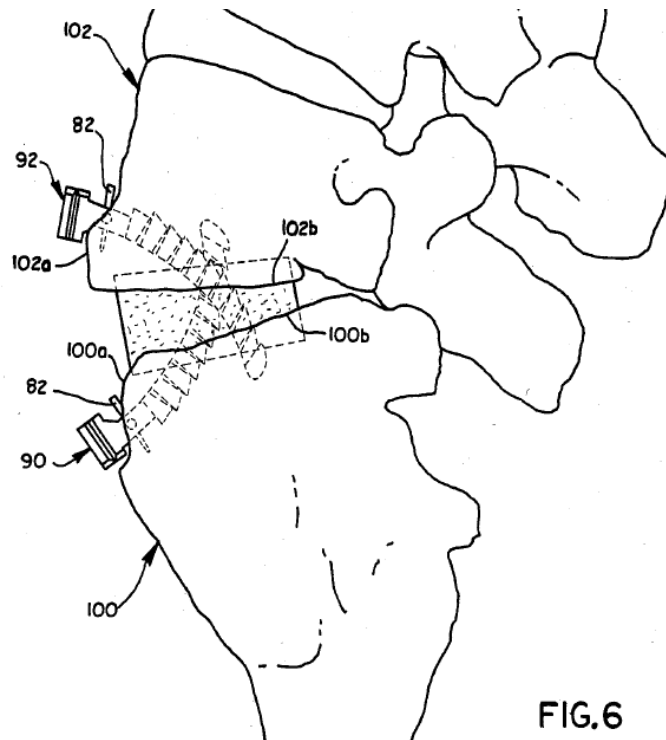


FIG. 6

Steffee explains that its curved fastener:

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

*Id.*, 1:29-36.

Thus, a POSA understood that Steffee's curved fasteners would not be exposed to the same forces (acting through a moment arm) that tended to cause prior art fasteners to lose effectiveness. Ex. 1002 ¶ 168. A POSA understood that this

meant the forces acting on the anchor that tend to cause sagittal and lateral movement, and thus migration of the implant, would be lower than they would be for straight fasteners inserted at a flatter angle. *Id.* Accordingly, a POSA would have considered Steffee as reasonably pertinent to the problem facing the inventor—increasing the reliability and success rate of spinal fusion procedures—because it related to minimizing the forces causing migration of spinal fusion implants. *Id.*

**2. A POSA was motivated to combine Moskowitz and Steffee.**

A POSA was motivated to use Steffee's curved anchors with Moskowitz's screw box to lower the forces (acting through Moskowitz's existing screws) that tended to cause migration of fusion implants. Ex. 1002 ¶ 169. As discussed above, it was desirable to avoid migration of the implant, thereby increasing the chances of a successful spinal fusion. A POSA understood that this migration was caused by forces acting on the implant to move in the space between the vertebrae, including forces acting on the screws inserted into the vertebral bodies and surrounded by bone graft material, which would thereby act on the fusion member engaged with each screw. *Id.* ¶ 169. As discussed, Steffee taught that forces tending to cause sagittal or lateral movement of the fastener (and thereby migration of the implant) can be minimized or eliminated by using a curved fastener that increases the entry angle of the fastener to near-perpendicular. Section X.A.1. Because this decreases or eliminates the moment arm acting on the fastener as explained in Steffee, a POSA

understood that the use of curved fastener would inhibit migration of the implant by decreasing the forces applied to the fastener and fusion member (in comparison with a straight anchor entering at a flatter angle). Ex. 1002 ¶ 169. The curved anchor would cause the force applied to the anchor by the bone graft as it resorbs to act “generally along the longitudinal extent” of the anchor member, and therefore not “through a moment arm” so as to avoid having “a detrimental effect on the fastener.” *Id.*; Ex. 1005, 1:31-36. Thus, a POSA was motivated to use Steffee’s curved anchors with Moskowitz’s screw box to allow a more perpendicular insertion of the anchor into a vertebral body. Ex. 1002 ¶ 169.

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

Using the curved anchors with the screw box would have entailed modifying Moskowitz's existing screw or drill guides to accommodate the curved anchors. Ex. 1002 ¶ 171. This would have entailed adding at least some curvature to the channels, complementing the curvature of the anchors. *Id.* This would ensure that the anchors did not become stuck or trapped when attempting to drive them through the screw/drill guides during surgery. *Id.* This is because, when inserting a curved object into a straight tube or channel, the object will become stuck and unable to pass through if the channel has sufficient length. *Id.* To ensure this would not occur during surgery, a POSA would have modified Moskowitz's existing screw/drill guides to have a curved path complementary to the curvature of Steffee's anchors. *Id.*

### **3. A POSA had a reasonable expectation of success.**

Making the contemplated modifications to Moskowitz's screw box would have generally required replacing Moskowitz's transvertebral screws with curved fasteners like those in Steffee and modifying Moskowitz's screw/drill guides to have a size and curvature complementary to Steffee's anchors. Ex. 1002 ¶ 172. A POSA also would have recognized that, because the fasteners require impact for insertion (as opposed to turning as for a screw), that an impact driving tool would be required in place of Moskowitz's screwdriver. *Id.* Steffee itself teaches the use of such a tool. Ex. 1005, 3:1-13 (referencing driving tool 38 in Fig. 7).

A POSA had a reasonable expectation of success in modifying Moskowitz's

implant to utilize Steffee's anchors. Ex. 1002 ¶ 173. First, modifying Moskowitz's screw/drill guides to accommodate and complement Steffee's anchors would have involved the use of machining techniques well known to a POSA. *Id.* Second, the use of curved anchors in spinal implants was already well known. *Id.* As discussed above, Hess taught the use of such curved anchors (passing through curved channels) for an interspinous implant. *See* Section IX.A. Curved anchors had also been successfully applied in other intervertebral implants. *See* Ex. 1022, 4:15-29 (referencing tangs 220), Figs. 1, 9. Finally, the use of tools for impacting intervertebral implants and their anchors was well known. *See* Ex. 1004, 9:3-11 (explaining that positioning tool 500a can be used to impact the screw box itself by "tapping the handle with a mallet"); *see also* Ex. 1021 [0142]; Ex. 1023, 8:14-16; Ex. 1002 ¶ 173. Therefore, a POSA had a reasonable expectation of success in combining Moskowitz and Steffee. *Id.*

Other relevant aspects of the asserted combination are discussed with respect to the individual claim elements below.

## **B. Claim 1**

### **Claim 1.0**

Moskowitz discloses an intervertebral *fusion device*. *See* Section VIII.A., Claim 1.0.

### **Claim 1.1**

In Moskowitz-Steffee, Moskowitz's screw box (as modified) is a *fusion member configured to position between first and second vertebral bodies*. See Section VIII.A., Claim 1.1; Ex. 1002 ¶ 175.

It was obvious to use a curved channel, similar to those in Hess, to accommodate the use of a curved anchor, as disclosed in Steffee. A POSA would have found it obvious to modify Moskowitz's screw box to include *a first curved channel and a second curved channel* for use with Steffee's curved anchors as set forth above. Ex. 1002 ¶ 176; *see* Section X.A.

### **Claim 1.2**

The shank of Steffee's curved fastener has a driving head portion 16, similar to the head of Moskowitz's transvertebral screws, which comprises the widest part of the fastener. Ex. 1005, 2:35-37; 2:55-61, Fig. 1; Ex. 1004, Fig. 1D. The head portion couples with a driving tool for driving the fastener into the bone. Ex. 1005, 3:1-6, 4:35-42. Steffee's head portion remains outside of and is not driven into the bone. *See* Ex. 1005, Figs. 4-6. In Moskowitz-Steffee, a POSA would have maintained this functionality just as in both Moskowitz and Steffee, such that at least this head portion would remain inside the screw box. Ex. 1002 ¶ 178. This is because a POSA understood that the bearing surface of the head portion must be securely engaged with the implant after implantation; otherwise, the implant will not be

secured to the vertebral bodies but will tend to move to the extent any “play” between the fastener head and implant exists. *Id.* This would not be desirable for the reasons previously discussed. *Id.*; see Sections III.A., X.A. Further, a POSA would have recognized that if the fastener heads did not remain in the implant but simply passed through the implant, they would not affix the implant to the vertebrae. Ex. 1002 ¶ 178; see also Section VIII.A Claim 1.1. By ensuring that the head portion contacts a seat inside the implant, *a portion* (the head) of the *anchoring member* (fastener) will necessarily *remain within the fusion member* (screw box) *in order to couple the screw box with each vertebral body*. Ex. 1002 ¶ 178.<sup>5</sup>

As both Moskowitz and Steffee disclose the use of two screws or fasteners, Moskowitz-Stepfee also possesses a *second anchoring member* configured like the first. Ex. 1002 ¶ 178.

### **Claim 1.3**

A POSA would have maintained the same cross-sectional planes in Moskowitz-Stepfee as disclosed in Moskowitz itself, which are parallel. Ex. 1002 ¶ 179; see Section VIII.A., Claim 1.3. Steffee also teaches that its anchors are inserted

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<sup>5</sup> To the extent that Spinelogik argues that Moskowitz does not itself disclose the use of a seat, it would have been obvious for the reasons discussed for Ground 1. Section VIII.A. Claim 1.1; Ex. 1002 ¶ 178 n.2.

parallel to one another. Ex. 1005, Fig. 4. Accordingly, Moskowitz-Steffee discloses that the cross-sectional planes traversed by the first and second curved channels are parallel. Ex 1002 ¶ 179.

**C. Claim 2**

As the relative alignment of the channels and fasteners in Moskowitz-Steffee is the same as Moskowitz itself, the combination discloses that the *first and second cross-sectional planes are parallel to at least one surface of the fusion member* for the same reasons discussed for Ground 1. Ex. 1002 ¶ 180; Section VIII.B.

**D. Claim 3**

As the relative alignment of the channels and fasteners in Moskowitz-Steffee is the same as Moskowitz itself, the combination discloses that *neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member* for the same reasons discussed for Ground 1. Ex. 1002 ¶ 181; Section VIII.C.

**E. Claim 4**

The channels in the proposed combination would open to the same surfaces of the fusion member as in Moskowitz, with only the internal curvature of the channels being changed; accordingly, Moskowitz-Steffee discloses these elements for the same reasons explained for Ground 1. Ex. 1002 ¶ 182; Section VIII.D.

## **F. Claim 5**

The channels in the proposed combination would open to the same surfaces of the fusion member as in Moskowitz; accordingly, Moskowitz-Steffee discloses these elements for the same reasons explained for Ground 1. Ex. 1002 ¶ 183; Section VIII.E. Because both fasteners remain in their respective channels in the combination, a POSA would have understood that the second anchor would exit its respective surface without hindering the first anchor's insertion through the fusion member. Ex. 1002 ¶ 183.

## **G. Claim 7**

Unlike Moskowitz's screws which are inserted by turning via a positioning tool containing a screw driver (*see* Section VIII.F), Steffee's fasteners are inserted with a driving tool. The head 16 of Steffee's curved fasteners each include grooves "adapted to receive gripping jaws ... of a driving tool" which "holds and drives the fastener 10 into the bone portions ... and bone graft." Ex. 1005, 3:2-6.

While the two anchors are inserted differently, a POSA would have modified Moskowitz's positioning tools to accommodate a gripping and driving design such as that disclosed in Steffee to use Steffee's curved fasteners. Ex. 1002 ¶ 185. Such tools were well known as discussed above, and a POSA would therefore have expected them to be easily adapted for use with Moskowitz's apparatus. *Id.* As these devices are quite simple mechanically, and serve the basic function of holding the

implant in place while driving the anchoring members, a POSA would have reasonably expected that a driving tool similar to that disclosed in Steffee would have been readily adapted for use with Moskowitz's screw box in the proposed combination, especially because there were no reasons to expect any issues in making such a modification. *Id.* Accordingly, Moskowitz-Steffee discloses that each *anchoring member (fastener) is configured to couple to a driving member, wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body.* Further, as in Moskowitz, a POSA would have understood the driving member would be removed after implantation. Ex. 1002 ¶ 185. Thus, the combination discloses that the driving member *decouples from the anchoring member.* *Id.*

#### **H. Claim 9**

Each channel in Moskowitz-Steffee has an opening on the surface of the fusion member having a recess, and the head portion 16 of Steffee's fasteners would fit in the channels' recesses, as in Moskowitz itself. Ex. 1002 ¶ 186; *see* element 1.2 above; *see also* Section VIII.G. Thus, Moskowitz-Steffee discloses all limitations of Claim 9.

#### **XI. THE CO-PENDING LITIGATION PROVIDES NO BASIS FOR DISCRETIONARY DENIAL.**

Petitioner stipulates that, if the PTAB institutes trial, Petitioner will not pursue in *Spinelogik, Inc. v. Globus Medical, Inc.*, No. 2-23-cv-00529, any grounds that

were raised or reasonably could have been raised in this IPR. When such a stipulation is presented, the PTAB will not discretionarily deny institution in view of parallel district court litigation. Ex. 1014, 3, 7-8.

## **XII. CONCLUSION AND FEES**

The challenged claims are unpatentable. Globus respectfully requests that trial be instituted and that claims 1–5, 7, and 9 of the '385 Patent be cancelled.

Dated: November 21, 2024

Respectfully submitted,

/James H. Hall/  
James H. Hall  
Registration No. 66,317

## **APPENDIX: CHALLENGED CLAIM LISTING**

| Claim Element | Limitation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.0           | A fusion device comprising:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.1           | a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel;                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.2           | a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body, |
| 1.3           | wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other.                                                                                                                                                           |
| 2             | The fusion device of claim 1, wherein the first and second cross-sectional planes are parallel to at least one surface of the fusion member.                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3             | The fusion device of claim 1, wherein neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.1           | The fusion device of claim 1, wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member,                                                                                                                                                                                                                                                                                                                                                                  |
| 4.1           | wherein the first cross-sectional plane is not parallel to either of the two surfaces to which the first curved channel opens and the                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| Claim Element | Limitation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               | second cross-sectional plane is not parallel to either of the two surfaces to which the second curved channel opens.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 5.1           | The fusion device of claim 1, wherein the first and second curved channels open to a first surface of the fusion member but the first curved channel traverses to a second surface of the fusion member and the second curved channel traverses to a third surface of the fusion member;                                                                                                                                                                                                                                                                                                |
| 5.2           | wherein the traversal of the first and second curved channels through the fusion member allows<br>(i) the first anchoring member to enter the first surface of the fusion member but exit the second surface of the fusion member at a first desired location on the second surface of the fusion member and<br>(ii) the second anchoring member to enter the first surface of the fusion member but exit the third surface of the fusion member at a second desired location on the second surface without hindering the first anchoring member's insertion through the fusion member. |
| 7.1           | The fusion device of claim 1, wherein each anchoring member is configured to couple to a driving member,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 7.2           | wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 9.1           | The fusion device of claim 1, wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess,                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 9.2           | wherein each anchoring member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.                                                                                                                                                                                                                                                                                                              |

## **CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS**

Pursuant to 37 C.F.R. § 42.24 *et seq.*, the undersigned certifies that this document complies with the type-volume limitations. This document, excluding those portions identified under § 42.24 (a)(1) (table of contents, table of authorities, mandatory notices under § 42.8, certificates of service and compliance with word count, appendix of exhibits, and claim listing) contains 13,931 words as calculated by the word processing program used in creating it.

/James H. Hall/  
James H. Hall

## **CERTIFICATE OF SERVICE**

I hereby certify that on this 21st day of November 2024, a copy of this Petition for Inter Partes Review and Exhibits 1001–1029 were served pursuant to Priority Mail Express (Next Day) on the following correspondence address of record with the United States Patent and Trademark for Patent Owner Spinelogik Inc.’s attorney/agent of record for the challenged patent:

Attention: Mani Adeli  
Attention: Nathaniel Ross  
ADELI LLP  
P.O. Box 516  
Pacific Palisades, CA 90272

Service of the above materials is also made pursuant to Federal Express to the same attorney/agent of record at the current “Contact” address listed on their firm website (<https://adelillp.com/contact/>):

Attention: Mani Adeli  
Attention: Nathaniel Ross  
ADELI LLP  
10880 Wilshire Boulevard, Suite 1101  
Los Angeles, CA 90024

Service of the above materials is also made via email to Patent Owner Spinelogik Inc.’s Counsel of Record in Parallel Litigation:

Christopher Honea  
Garteiser Honea  
119 West Ferguson  
Tyler, TX 75702  
[chonea@ghiplaw.com](mailto:chonea@ghiplaw.com)

/James H. Hall/  
James H. Hall