

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDACTA USA, INC., PRECISION SPINE, INC., and LIFE SPINE, INC.

Petitioners,

v.

RSB SPINE, LLC,

Patent Owner.

Case No. IPR2020-00265

Patent No. 6,984,234

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 6,984,234
CHALLENGING CLAIMS 35, 37 AND 39**

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PETITIONERS' EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
Ex.1001	U.S. Patent No. 6,984,234 to Bray (“the ’234 patent”)
Ex.1002	U.S. Patent No. 9,713,537 to Bray (“the ’537 patent”)
Ex.1003	Patent Prosecution History of the ’234 patent
Ex.1004	Patent Prosecution History of the ’537 patent
Ex.1005	Declaration of Michael Sherman
Ex.1006	International Publication No. WO 2000/066045A1 (“Michelson ’045”)
Ex.1007	U.S. Patent No. 6,432,106 to Fraser (“Fraser ’106”)
Ex.1008	RESERVED
Ex.1009	December 2, 2019 Proposed Claim Constructions
Ex.1010	U.S. Patent No. 7,112,222 to Fraser (“Fraser ’222”)
Ex.1011	RESERVED
Ex.1012	RESERVED
Ex.1013	U.S. Patent No. 5,800,433 to Benzel (“Benzel”)
Ex.1014	U.S. Patent Pub. No. 2002/0147450 (“LeHuec”)
Ex.1015	Dorland’s Illustrated Medical Dictionary (Anderson, Douglas, ed., The Curtis Center 2003) (“Dorlands Medical Dictionary”)
Ex.1016	U.S. Patent No. 5,609,635 to Michelson (“Michelson ’635”)
Ex.1017	December 12, 2019 Disputed Terms for Constructions
Ex.1018	U.S. Patent No. 6,682,530 to Dixon (“Dixon”)
Ex.1019	U.S. Patent Pub. No. 2008/0058810 to Abdou (“Abdou”)

I. INTRODUCTION

Petitioners request *Inter Partes* Review (“IPR”) of claims 35, 37, and 39 (the “Challenged Claims”) of U.S. Patent No. 6,984,234 (“the ’234 patent”). The Board should institute an IPR and cancel the Challenged Claims.

II. MANDATORY NOTICES

A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Medacta USA, Inc., Precision Spine, Inc., Life Spine, Inc. (“Petitioners”), and Xtant Medical Holdings, Inc. (“Xtant”). Xtant is not a petitioner, but Petitioners list Xtant as a real party-in-interest out of an abundance of caution.¹

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The ’234 patent is related to several pending litigations. RSB Spine, LLC (“Patent Owner”) is asserting the ’234 patent and related U.S. Patent No. 9,713,537 (“the ’537 patent”) against Petitioners and other third parties in the following cases:

- *RSB Spine, LLC. v. Life Spine, Inc.*, 18-cv-1972 (DED);

¹ Petitioners understand that Xtant objects to being identified as a real party-in-interest, and Xtant does not voluntarily agree to be identified as a real party-in-interest. Petitioners understand that Xtant reserves all rights to challenge its identification as a real party-in-interest.

- *RSB Spine, LLC. v. Medacta USA, Inc.*, 18-cv-1973 (DED);
- *RSB Spine, LLC. v. Precision Spine, Inc.*, 18-cv-1974 (DED);
- *RSB Spine, LLC. v. RTI Surgical, Inc.*, No. 18-cv-1975 (DED);
- *RSB Spine, LLC. v. Xtant Medical Holdings, Inc.*, No. 18-cv-1976 (DED); and
- *RSB Spine, LLC. v. DePuy Synthes, Inc.*, 19-cv-1515 (DED).

Petitioners have filed four petitions:

- IPR2020-00274 challenging claims 1-10, 13, 14, 16, 18-20, 22, 24, 25, 28, 29, 31 and 32 of the '234 patent;
- IPR2020-00265 challenging claims 35, 37, and 39 of the '234 patent
- IPR2020-00275 challenging claims 1, 3-6, 10, 13-15, 18-19, 21-22, 24, and 29-30 of the '537 patent; and
- IPR2020-00264 challenging claims 1, 3-6, 10, 12-15, 18, 19, 21, 22, 24, and 29-30 of the '537 patent.

Finally, related U.S. patent application no. 15/723,522 is currently pending.

As of the filing of this petition, no other judicial or administrative matters are known to Petitioners that would affect, or be affected by, a decision in this proceeding.

C. Counsel (37 C.F.R. §42.8(b)(3)) and Service Information (37 C.F.R. §42.8(b)(3)-(4))

Petitioners designate Dion M. Bregman (Reg. No. 45,645) as lead counsel for this matter, and designate Jason C. White (Reg. No. 42,223) as back-up counsel

for this matter.

Postal mailings and hand-deliveries for lead and back-up counsel should be addressed to: Morgan, Lewis & Bockius LLP, 77 W. Wacker Drive, Fifth Floor, Chicago, IL, 60606 (Telephone: 312.324.1000; Fax: 312.324.1001).

Pursuant to 37 C.F.R. §42.8(b)(4), Petitioners consents to e-mail service at: Medacta-IPRs@morganlewis.com.

In compliance with 37 C.F.R. §42.10(b), a Power of Attorney is also filed concurrently herewith.

III. CERTIFICATION AND FEES

Petitioners certify that the '234 patent is available for IPR and that Petitioners are not barred or estopped from requesting this IPR.

Any additional fees for this IPR may be charged to Deposit Account No. 50,0310 (Order No. 002691-8002).

IV. IDENTIFICATION OF CLAIMS AND GROUNDS

The application that issued as the '234 patent was filed on April 21, 2003. Petitioners treat this as the priority date ("Priority Date") for purposes of this proceeding.

Because the filing date of the application that led to the '234 patent is before the effective date of the AIA, March 16, 2013, the pre-AIA statute applies.

The Grounds in this Petition rely on the following prior art references.

Michelson '045 (Ex.1006): This PCT application published on **November 9, 2000** as WO 2000/066045A1 (“Michelson '045”). Michelson '045 is prior art to the '234 patent under pre-AIA §102(b) because it was published before the Priority Date.

Fraser '106 (Ex.1007): U.S. Patent No. 6,432,106 (hereinafter “Fraser '106”) was issued on **August 13, 2002**. Fraser '106 was filed on **November 24, 1999** and is prior art to the '234 patent under pre-AIA §102(a) and (e) because it was issued and was filed before the Priority Date.

Neither **Michelson '045** nor **Fraser '106** were considered by the Examiner during prosecution of the '234 patent.

Petitioners request the Board to find each of the Challenged Claims unpatentable based on the following Grounds:

<u>Ground</u>	<u>Statutory Basis and Art Cited</u>	<u>Claims</u>
1	§103 – Obvious over Michelson '045	35, 37 and 39
2	§103 – Obvious over Fraser '106 in view of Michelson '045	35, 37 and 39

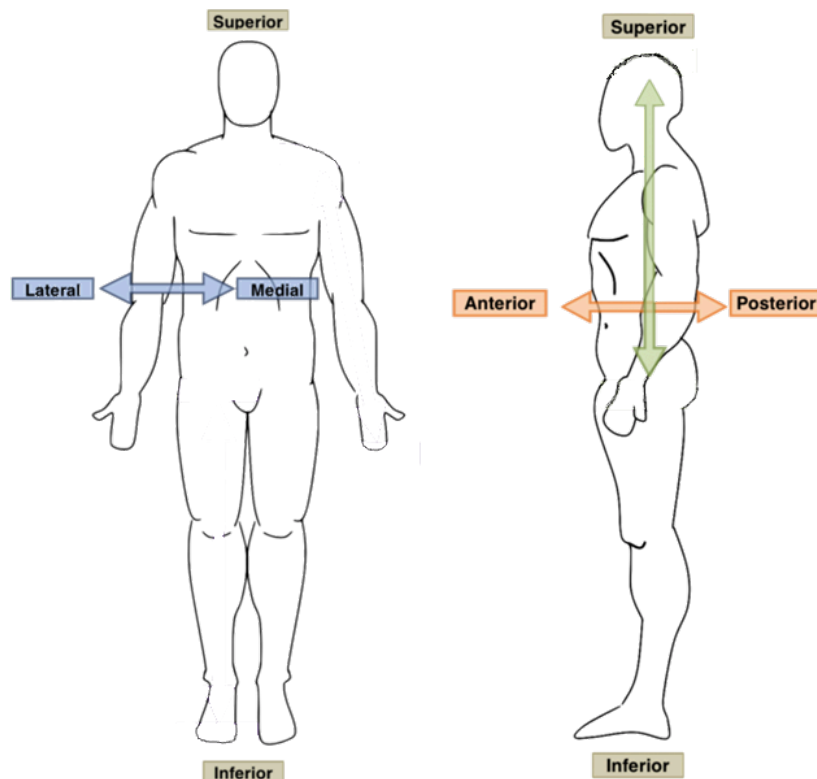
V. BACKGROUND

A. The '234 Patent

The '234 patent “is directed to a bone plate system that is particularly useful for assisting with the surgical arthrodesis (fusion) of two bones together, and more

particularly, to a bone plate that provides and controls limited movement between the bones during fusion.” Ex.1001, 1:6-10. The ’234 patent uses anatomical terms to refer to portions of the implant and/or bones. These terms are described below.

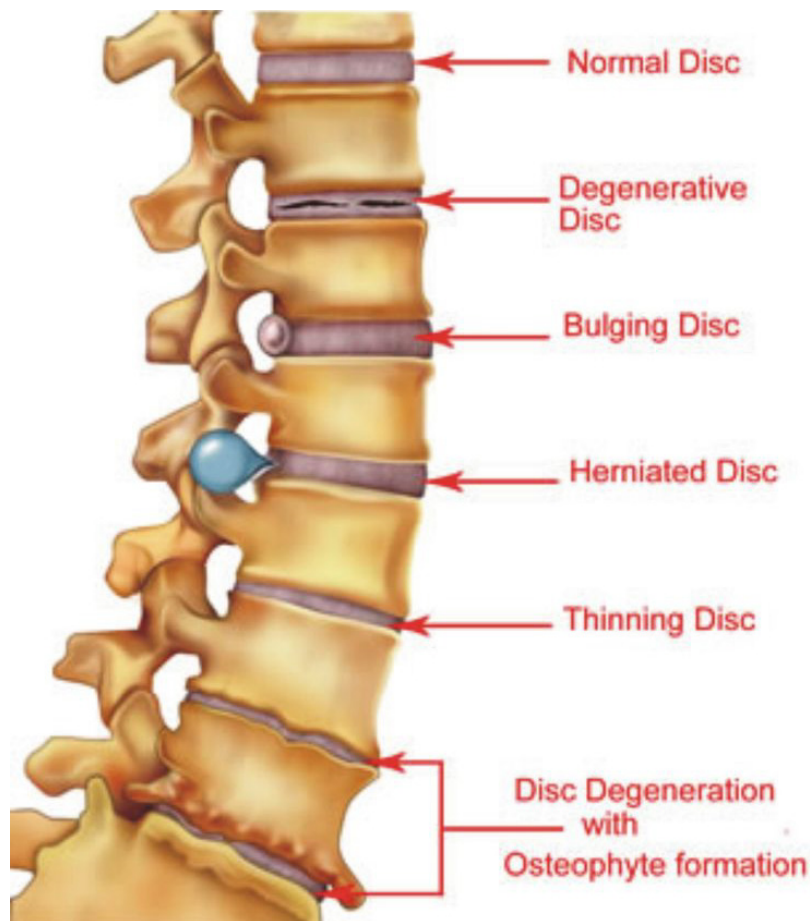
In human anatomy, anterior means “toward the belly surface of the body” and posterior means “towards the back surface of the body.” Ex.1015, 97, 1494. Superior means “situated above, or directed upward” and inferior means “situated below, or directed downward. Ex.1015, 929, 1793. Medial means “pertaining to the middle; closer to the median plane or the midline of a body or structure” and lateral means “denoting a position farther from the median plane or midline of the body or of a structure.” *Id.* at 1001, 1110. *See* depiction below.



Ex.1005, ¶27.

The '234 patent refers to “vertebral bones” found in the human spine.

Ex.1001, 9:32-12:9. The specification explains that “[v]arious types of problems can affect the structure and function of the spinal column [including] ... degenerative conditions of the intervertebral disk or the articulating joints, traumatic disruption of the disk, bone or ligaments supporting the spine, tumor or infection.” Ex.1001, 1:29-33. Depicted below is a spine with a normal disc (at the top) as well as various degenerative spinal conditions:



Ex.1005, ¶28.

To treat these degenerative conditions, the specification discloses that it was

known that “fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone.” Ex.1001, 1:48-51.

In 1988, the Hartshill Horseshoe product was launched, which was the first stand alone, no profile (*i.e.*, fit completely between the vertebral bodies with no supplemental fixation devices) anterior lumbar interbody fusion device. Ex. 1005, ¶32. This horseshoe shaped device included angled screws for securing the device between adjacent vertebral bodies and provided a large interior volume for bone graft material. It also provided ample support around the perimeter of the vertebral body. *Id.*



Figure 1 Hartshill Horseshoe

Despite these disclosures of prior art devices, the '234 patent asserts that its claimed device is inventive for four reasons: (1) it is formed as an interbody plate

that is integral with a spacer, (2) it is fixed to the bones' lip osteophytes with bone screws, (3) it is implanted between the bones so no portion of the device extends beyond the anterior surface of the bones, and (4) it bears weight to hold the bones while sharing weight with bone graft material for fusion. Ex.1001, 1:6-10; 1:56-5; and 2:6-36; *see infra* Section V.B.

Specifically, Figure 1 of the '234 patent, reproduced below, depicts one embodiment of the claimed base plate. Ex.1001, 3:46-48. In this embodiment, the base plate 20 (orange) retains bone graft material 12 (yellow) between first adjacent vertebral body 14 and second adjacent vertebral body 16. Ex.1001, 4:16-22. The base plate 20 (orange) also includes first bone screw 24 (green) and second bone screw 25 (purple), which are used to retain the base plate between the first adjacent vertebral body 14 and the second adjacent vertebral body 16.

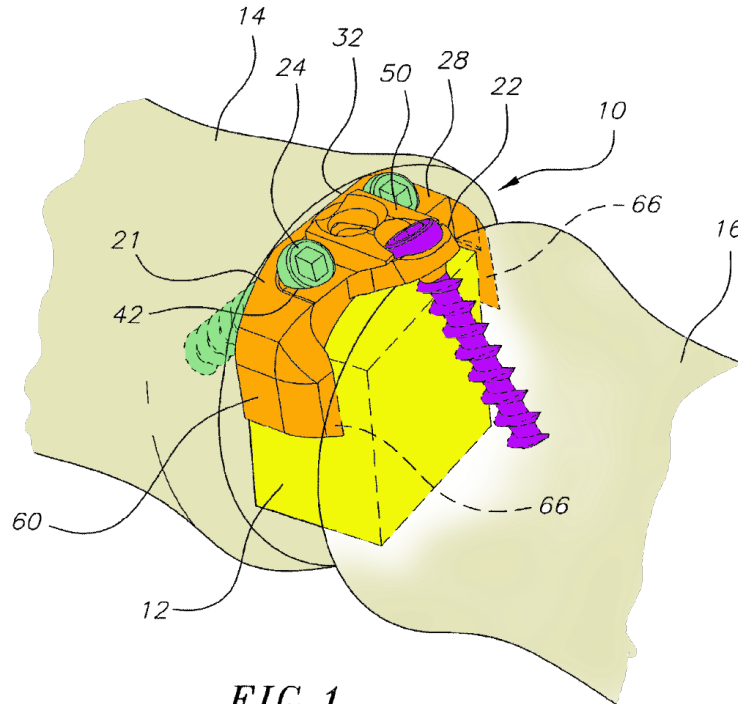


FIG. 1
The '234 Patent, Ex.1001, Fig.1²

This embodiment is also depicted in Figure 3, reproduced below. The base plate 20 (orange) is inter-fit between the first bone 14 and second bone 16, and is adjacent to lateral extents of the bone graft material 12 (yellow). The first bone screw 24 (green) and second bone screw 25 (purple) extend into the vertebral bodies to retain the base plate between the bones.

² Annotations and color added to the drawings throughout unless otherwise noted.

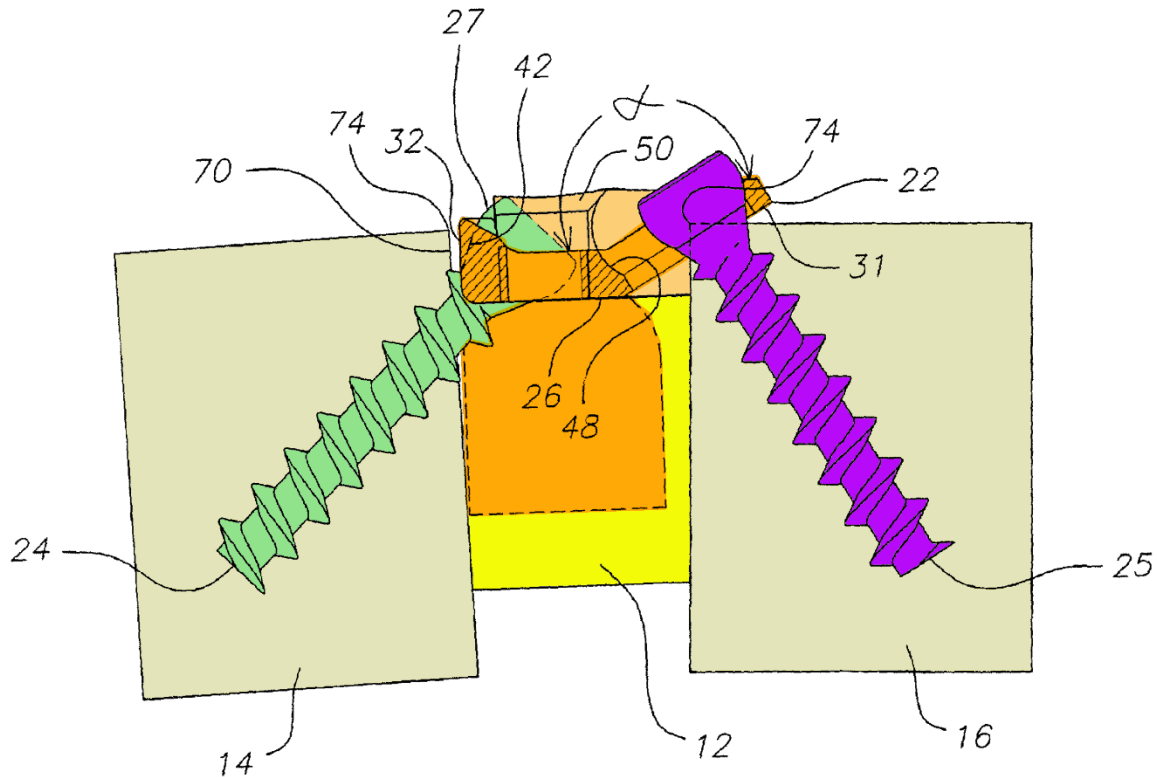
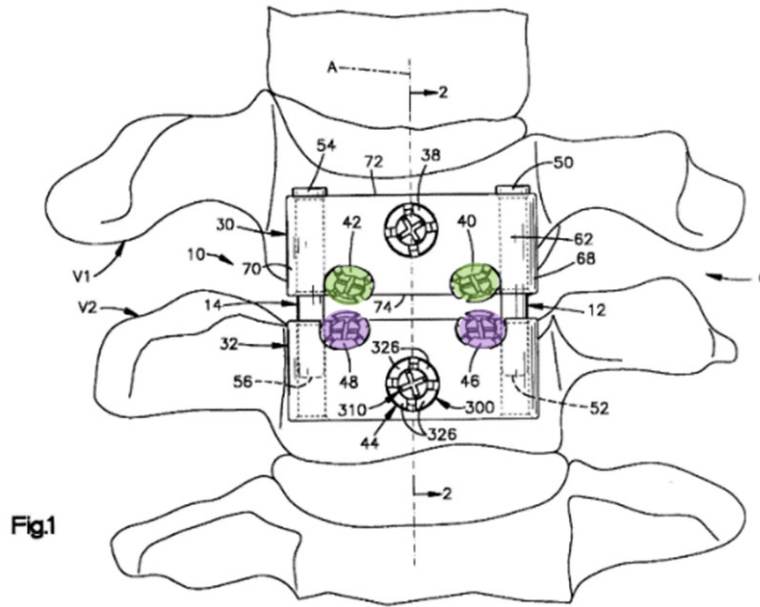


FIG. 3

Ex.1001, Fig.3

B. Prosecution History

U.S. Patent Application No. 10/419,652, which issued as the '234 patent, was filed on April 21, 2003. On May 24, 2005, the Examiner issued a non-final office action rejecting all of the challenged independent claims and several dependent claims as anticipated by U.S. Patent No. 5,800,433 ("Benzel"). A depiction of the Benzel device is below.



On August 18, 2005, the Patent Owner argued that Benzel did not disclose the claimed base plate with “a *first end nearer the first bone* and a *second end nearer the second bone*, where in the base plate has a *first screw hole extending through the first end* and a *second screw hole extending through the second end*...”

Ex.1003, 97 (emphasis in original). Instead, the Patent Owner argued:

as illustrated in Fig. 1 of Benzel et al., assuming that the claimed base plate is a combination of the first and second plates 30, 32, the **fasteners 40 and 46 are provided through a middle portion of the plate, not at first and second ends** wherein the first end is nearer a first bone and the second end is nearer a second bone, as required by claim 1.

Ex.1003, 97-98 (emphasis added). Thus, according to the Patent Owner, the first and second ends of the claimed base plate do not include the “middle portion of the plate.”

In this same office action, the Examiner also rejected claims as anticipated by U.S. Patent Pub. No. 2002/0147450 (“LeHuec”). In response, the Applicant argued that LeHuec failed to “disclose a base plate being sized to have an inter-fit between the first and second adjacent bone bodies.” Ex.1003, 99 (emphasis in original). Referring to figure 2 of LeHuec (reproduced below), the Patent Owner argued:

LeHuec et al. discloses a plate provided on a top portion of two adjacent bone bodies. Specifically, the plate of LeHuec et al. is sized such that one end fits on a top surface of a first bone body and an opposing end fits on a top surface of a second, adjoining bone body. Thus, the plate of LeHuec et al. cannot be inter-fit or retained between first and second adjacent bone bodies, as required by claim 35.

Ex.1003, 99 (emphasis added).

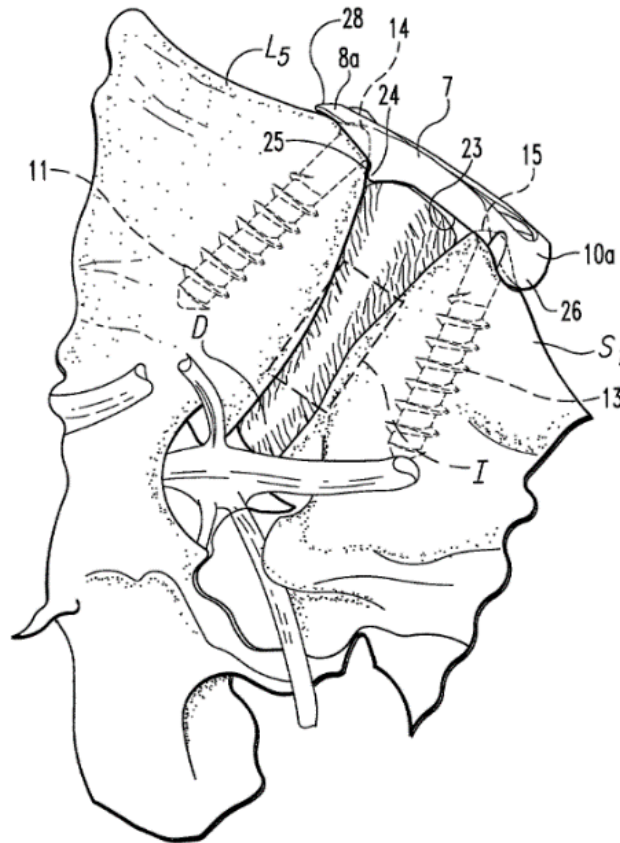


Fig. 2

Ex.1014

Thus, according to the Patent Owner, a base plate is not inter-fit if it has a portion that sits on the top (anterior) surface of the bones. Instead the base plate must be located and retained completely between the vertebrae bones.

In response to these arguments about the location of the first and second end, and the position of the base plate between the bones, the Examiner allowed the claims.

VI. LEVEL OF ORDINARY SKILL

A person having ordinary skill in the art (“POSITA”) at the time of the

alleged invention would have had at least a Bachelor of Science degree in the field of Mechanical, Biomechanical or Biomedical engineering with at least 5 years of experience designing and developing orthopedic implants and/or spinal interbody devices.

VII. CLAIM CONSTRUCTION

In the district court litigation, the parties are engaged in claim construction. On December 12, 2019, Patent Owner, Petitioners, and non-petitioners Xtant and DePuy exchanged their initial list of Proposed Claim Terms for Construction. Exs.1009, 1017. Patent Owner's opening claim construction brief is due on February 12, 2020, the final claim construction brief is due on May 20, 2020, and the *Markman* hearing is scheduled for June 19, 2020.³

Petitioners do not believe that any of these disputed constructions are material to intuition of this petition. However, to ensure that the Board is aware of the parties' current claim construction disputes, the key disputed terms are summarized below.

³ If the district court schedule remains fixed, trial is scheduled for September 27, 2021, which is after the PTAB will render its final written decision in this IPR.

Base Plate	
Petitioners	Patent Owner
“A fixation plate to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material deployed across a bone graft site and is not used with a load-bearing fusion cage. ”	“A fixation plate to stabilize adjacent vertebrae for fusion and distinct from a spacer and bone graft material deployed across a bone graft site.”

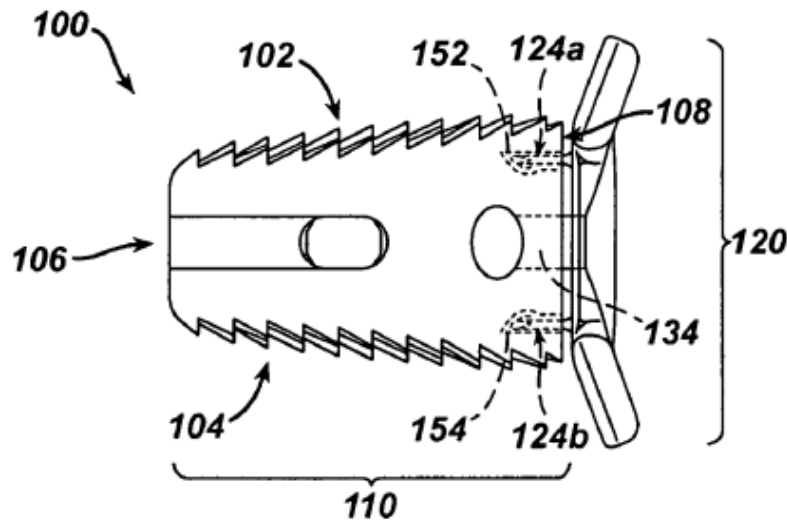
Patent Owner and Petitioners currently agree that a POSITA would understand the term “base plate” to include “a fixation plate to stabilize adjacent vertebrae for fusion” which is “distinct from bone graft material deployed across a bone graft site.” Ex.1005, ¶53.

Patent Owner and Petitioners, however, currently disagree about two aspects of this term. *First*, whether the base plate can be used with a load-bearing fusion cage, and *second* whether the base plate is distinct from such a spacer/cage.

With respect to the first issue, Patent Owner took the position during prosecution that the claims do not cover implants that use load-bearing cages/spacers. In particular, to overcome Fraser ’222, depicted below, Patent Owner distinguished its claims and argued that:

fusion cage 110 is load-bearing between the two vertebral bodies. The plate 120, which is applied after the load-bearing fusion cage 110 is already in place, keeps the load-bearing fusion cage 110 in place. The **plate 120 is applied, again after the load-bearing fusion cage 110 is in place**, to the respective anterior face of each of the two vertebral bodies.

Ex.1004, 222 (emphasis added).

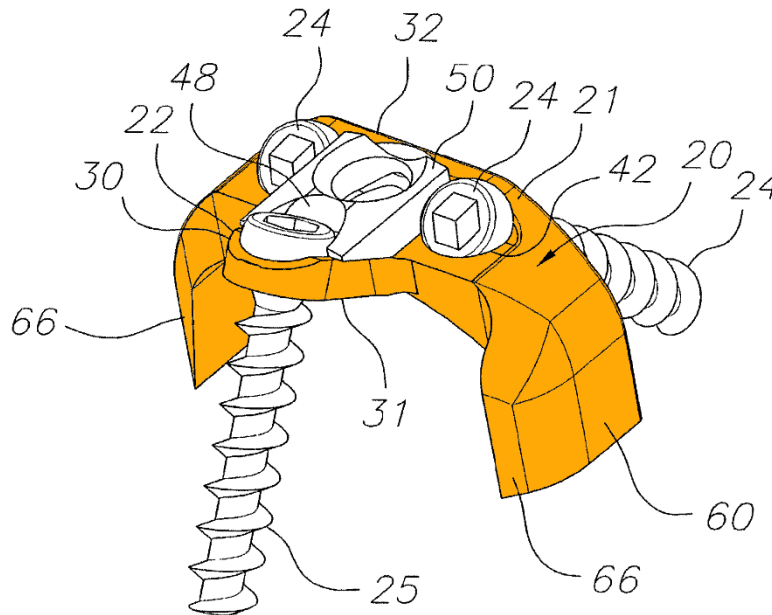


In response, the Examiner issued a notice of allowance over Fraser '222's two-piece plate and fusion cage implant. Ex.1004, 232-33. This **prosecution history disclaimer** is both **clear** and **unambiguous**, and, as such, restricts Patent Owner from now arguing that the claimed base plate can be used with a separate load bearing spacer/cage.

With respect to the second issue, whether the base plate is distinct from a spacer, the intrinsic evidence directly contradicts Patent Owner's proposed construction.⁴ The entire disclosure of the '234 patent is directed to a base plate 20

⁴ It is not clear if Patent Owner's proposed construction requires a "spacer." If so, Patent Owner's construction appears to be limited to a two part system that

(orange) that includes an integrated spacer 60. The '537 patent is also directed to a base plate with an integrated spacer.



The '234 Patent, Ex.1001, Fig.2

Patent Owner's attempt to exclude this embodiment in their proposed construction – in an apparent attempt to avoid the prior art – is improper. The Federal Circuit frequently holds that “a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.” *See, e.g., On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004).

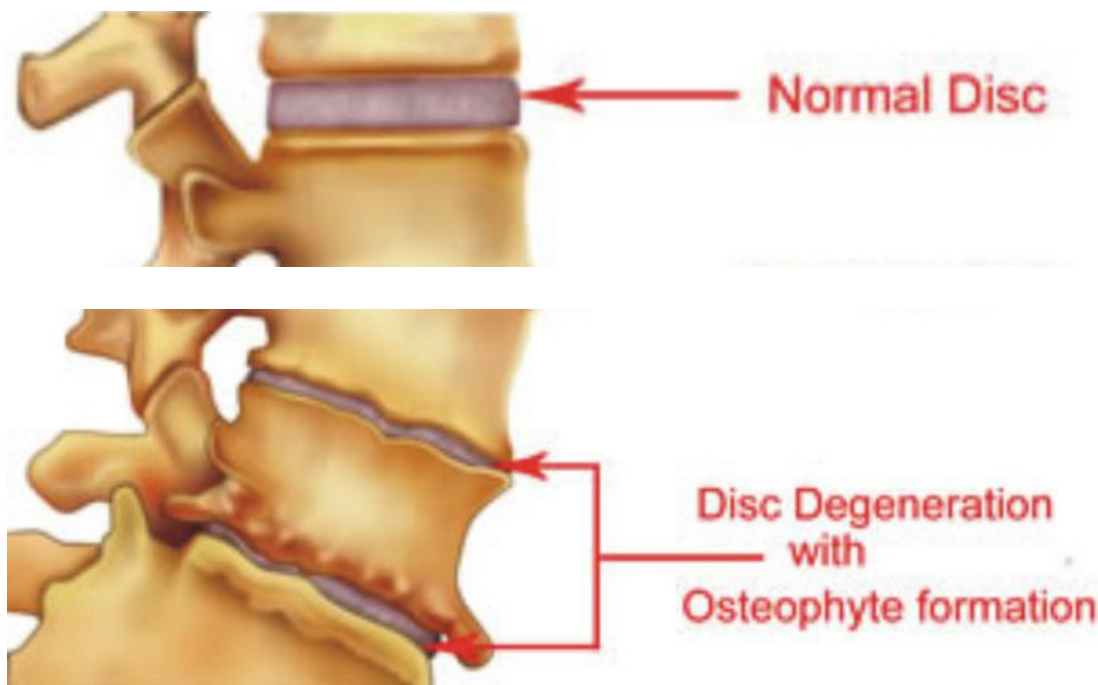
includes (i) a fixation plate and (ii) a separate spacer. Petitioners address this issue in Ground 2 below.

For at least these reasons, Petitioners' proposed construction is correct.

“lip osteophyte” / “lip osteophyte”	
Petitioners	Patent Owner
“growth that projects away from an anterior corner of the bone and is structurally the strongest portion of the vertebral bone.”	“the lip of the vertebral body that is structurally the strongest part of the bone”

Patent Owner and Petitioners currently agree that a POSITA would understand the term “lip osteophyte” is a lip located the corner of the bone and that it is “structurally the strongest portion of the vertebral bone.” Ex.1005, ¶53.

The parties, however, currently disagree about whether a lip osteophyte is a growth that projects away from the bone, as proposed by Petitioners. As discussed in the Background, *see* Section V, a healthy bone does not have any lip osteophytes. However, as depicted below, when a disc degrades a POSITA would understand that lip osteophytes can form on the bones and that they extend away from the bone. Ex.1005, ¶29.



Ex.1005, ¶¶28-29.

For at least these reasons, Petitioners’ proposed construction is correct.

“means for interacting”	
Petitioners	Patent Owner
<p>Function: “Interacting with the first and second bone screws.”</p> <p>Structure: “A portion of the base plate 20 with circular bone screw holes 42 and/or a bone screw slot 48.”</p>	<p>Function: “retaining the base plate between the first and second bone bodies.”</p> <p>Structure: “a portion of the base plate that receives a screw and screw head, plus equivalents thereof.”</p>

This term is governed by 112 ¶ 6. A POSITA would understand that the function is “interacting with the first and second bone screws.” Ex.1001, Abstract, 2:49-56, 4:31-5:9, 6:47-7:5, 7:36-54, 12:21-31; Ex.1005 ¶55. A POSITA would understand that the structures described in the specification for performing this

specified function is the “portion of the base plate 20 with circular bone screw holes 42 and a bone screw slot 48” and equivalents thereof. *Id.*; Ex.1005 ¶56.⁵

“means for permitting movement”	
Petitioners	Patent Owner
Function: “permitting movement of at least one of the first and second bone bodies relative to the base plate” Structure: “the bone screw slot 48.”	Function: “retaining the base plate between the first and second bone bodies.” Structure: “a portion of the base plate that receives a screw and screw head, plus equivalents thereof.”

This term is governed by 35 U.S.C. § 112 ¶ 6. A POSITA would understand that the function is “permitting movement of at least one of the first and second bone bodies relative to the base plate.” Ex.1001, 4:31-5:9, 5:53-6:9, 7:36-54, 12:21-31; Ex.1005 ¶59. This is facilitated by allowing the bone screws to slide vertically along the length of the bone screw slot 48. Ex.1001, 7:39-42. A POSITA would understand that the specification describes that the structure for performing this function is “the bone screw slot 48” and equivalents thereof. *Id.*; Ex.1005 ¶60.

⁵ Petitioners’ construction also aligns with the preferred embodiment, which discloses circular holes 42 and a slot 48. Ex.1001, Fig. 3.

ARGUMENT

The Challenged Claims of the '234 patent are unpatentable in view of the prior art references discussed in each Ground.

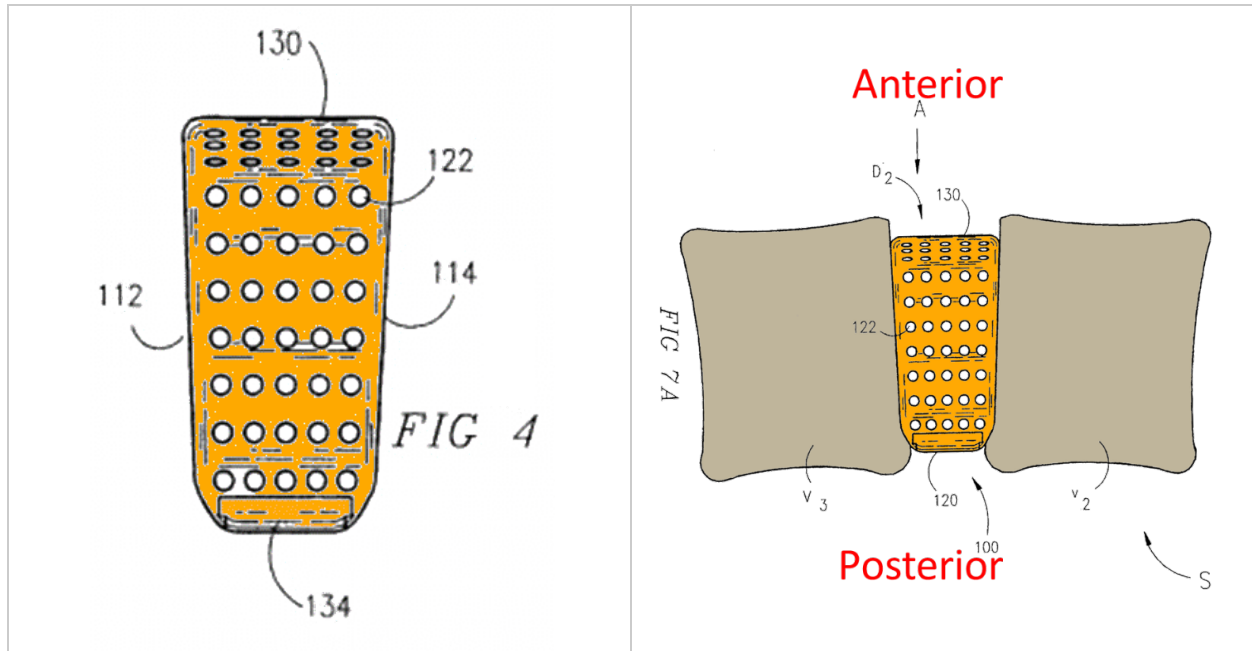
VIII. GROUND #1: MICHELSON '045 RENDERS CLAIMS 35, 37, AND 39 OBVIOUS

Independent claim 35 and dependent claims 37 and 39 of the '234 patent are obvious under 35 U.S.C. §103 by Michelson '045.

Michelson '045 discloses a variety of improved interbody spinal fusion implants. Ex.1006, 2 (“[t]he present invention relates generally to interbody spinal fusion implants.”). Specifically, Michelson '045 discloses that “[i]n order to perform anterior interbody spinal fusion, a significant amount of disc material is removed from the interspace to be fused” and then “the disc space is filled with an implant, which generally includes bone or bone in combination with a reinforcing structure, such as an artificial (other than bone) interbody spinal fusion implant.” *Id.* at 3. Michelson '045 also discloses that “interbody implants [are] adapted for placement within a disc space of the human spine between adjacent vertebral bodies, which implants have surfaces for contacting each of the adjacent vertebral bodies.” Ex.1006, 3. In short, an interbody spinal fusion implant replicates the size, shape, and location of spinal disc material. Ex.1005, ¶¶70-71.

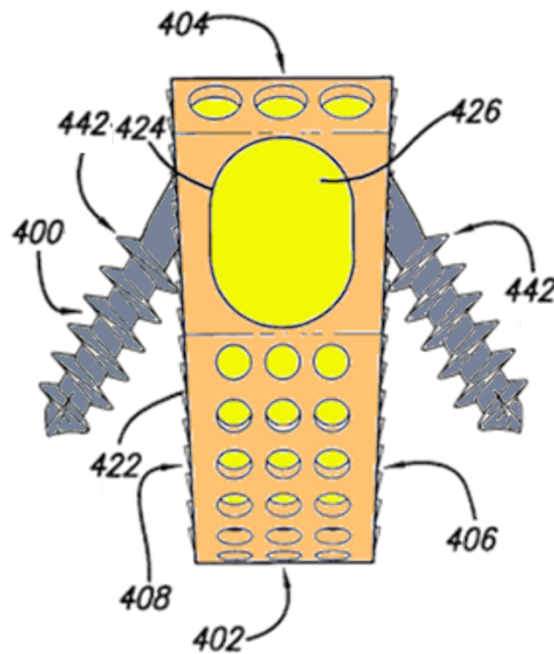
Furthermore, Michelson '045 depicts several interbody spinal fusion implants and where they are placed in the spine. For example, Michelson '045

incorporates by reference the “lordotic interbody spinal fusion implants such as disclosed in U.S. Patent No. 5,609,635 to Michelson.” *Id.* Below is an example of this interbody implant and its location in the spine:



Michelson '635, Ex.1016, Figs. 4 and 7A

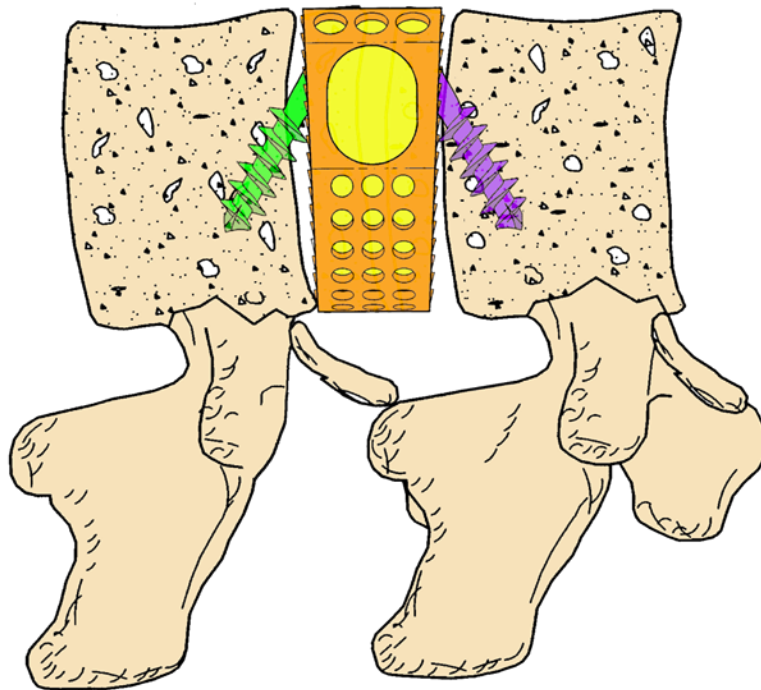
This ground relies on Michelson '045's fourth embodiment, namely implant 400, which is the interbody implant below:



Michelson '045, Ex.1006, Fig.24

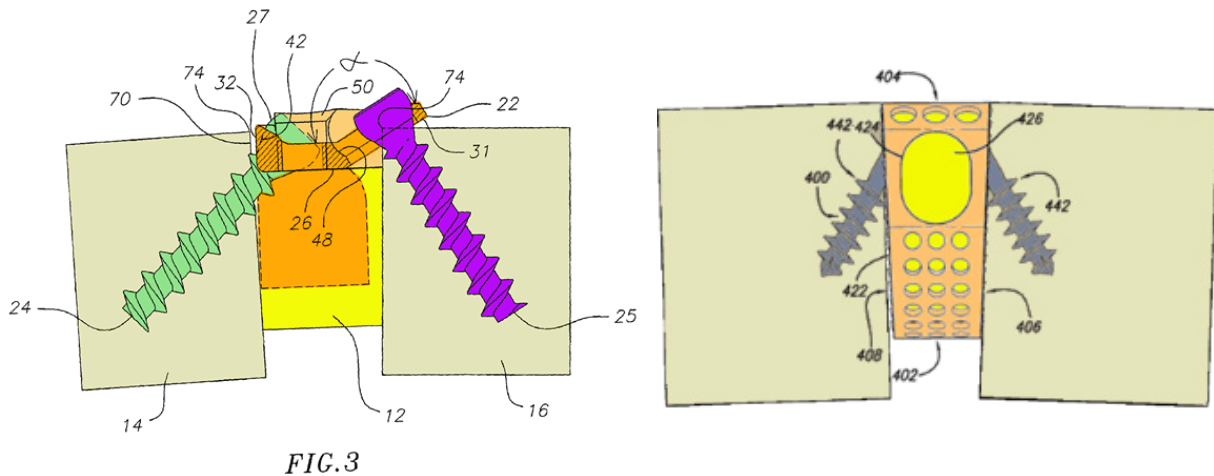
Just like all interbody implants, Michelson '045 discloses that implant 400 “functionally substitutes for the anterior longitudinal ligament at the level to be fused, **without protruding from the spine.**” *Id.*

Mr. Sherman depicts implant 400 between two bones in the image below:



Michelson '045, Ex.1006, Fig.24 (depicted between two bones)

Additionally, following the style used in the '234 patent, he also depicts implant 400 between two boxes representing vertebral bones, and orients the anterior surfaces of implant 400 and the bones as the top of the image. The implant disclosed in the '234 patent and the Michelson '045 implant 400 are depicted below:



'234 patent, Ex.1001, Fig.3

**Michelson '045, Ex.1006, Fig.24
(depicted between bones)**

Although this is only one example of how implant 400 would be placed between two bones (*e.g.*, it could be placed in a more/less anterior position depending on the shape and condition of the bones, and the screws could be inserted at different angles) it is generally representative of how implant 400 would be placed in the spine. Ex.1005, ¶¶72-75.

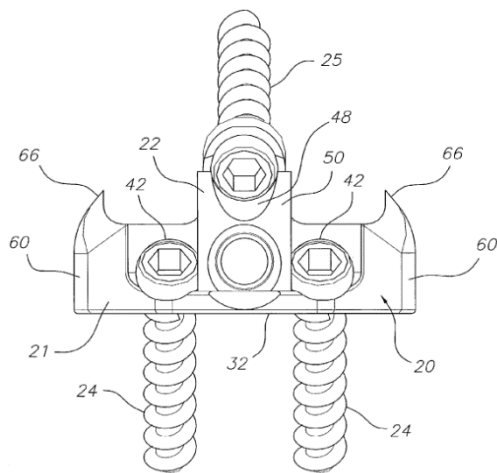
A. Claim 35

1. Element 35[Preamble – A bone stabilization plate system including

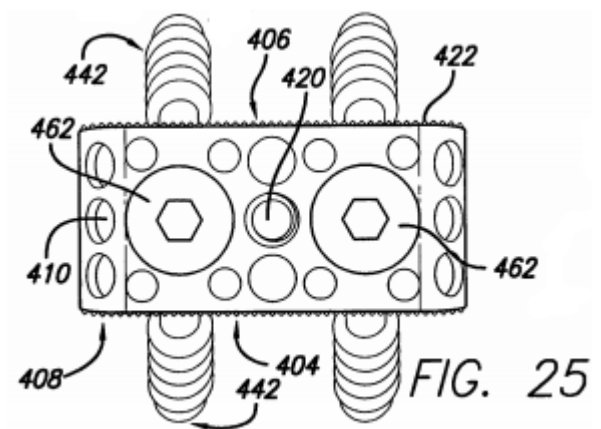
The preamble is not a limitation of the claim, as it does not breath life or meaning into the claim. *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012) (“as a general rule preamble language is not treated as limiting.”). Nonetheless, as shown below, Michelson '045 discloses the preamble.

In particular, Michelson '045 teaches “[t]he present invention relates generally to **interbody spinal fusion implants.**” Ex.1006, 2. Michelson '045

explains that “[i]mplants, artificial or natural, are placed at least in part within a disc space and in contact with each of the vertebral bodies adjacent that disc space for spacing apart and aligning those vertebral bodies and for allowing for the growth of bone in continuity from vertebral body to adjacent vertebral body through said implant.” *Id.*, 17-18; *see* Ex.1005, ¶¶76-80. The Michelson implant is depicted below.



'234 patent, Ex.1001, Fig.4



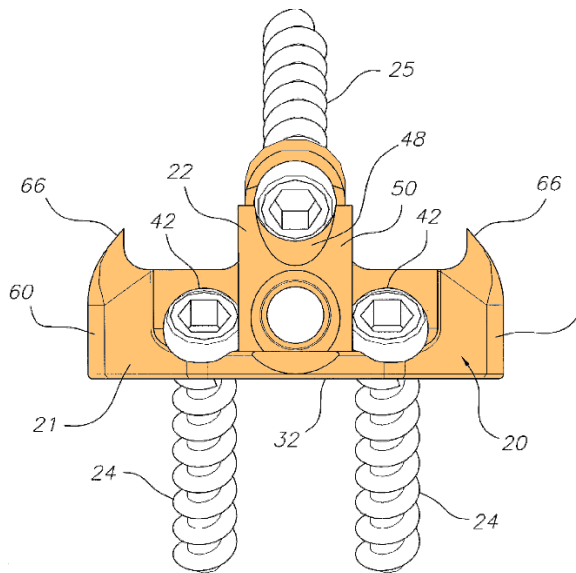
Michelson '045, Ex.1006, Fig.25

As such, Michelson '045 discloses “[a] bone stabilization plate system.”

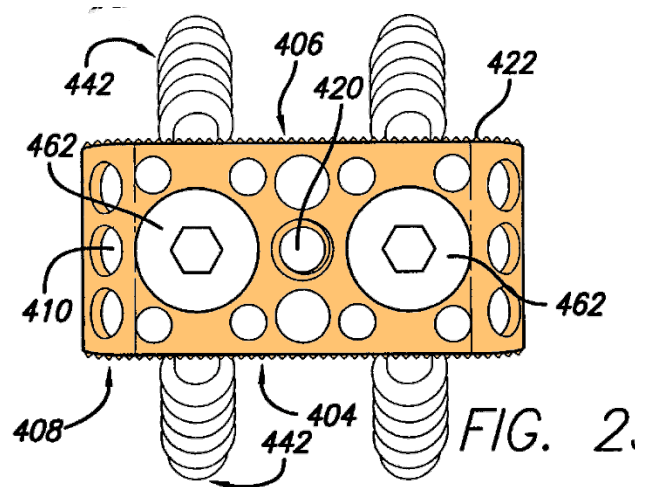
2. Element 35[a] – a base plate

With respect to the base plate, as discussed in Section VII, the term “base plate” means “a fixation plate to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material deployed across a bone graft site and is not used with a load-bearing fusion cage.” As shown in the side-by-side comparison

figures, below, like the '234 patent, Michelson '045 discloses a fixation plate 404 to stabilize adjacent vertebrae for fusion.



'234 patent, Ex.1001, Fig.4



Michelson '045, Ex.1006, Fig.25

Michelson '045 further teaches that this implant is distinct from bone graft material and that it includes openings for insertion of separate bone graft material. Specifically, Michelson '045 discloses that “[t]o the extent that such implants are hollow and have openings through the surfaces, **those openings and those hollows can preferably be filled with fusion promoting substances, including substances that are osteogenic, osteo-inductive, or osteo-conductive**, whether naturally occurring, or artificially produced.” Ex.1006, 9; *see* Ex.1005, ¶¶83-84. (describing bone graft material as a substance added during surgery that is osteogenic, osteo-inductive, and/or osteo-conductive).

Michelson '045 also explains that its implant is integrated with a load-bearing fusion cage (*i.e.*, single-piece device), and is not used with a separate load-bearing fusion cage (*i.e.*, two-piece device). Ex.1006, 16-17. Further, as shown in the comparison, above, like the '234 patent, the Michelson '045 implant is a single-piece device and does not use a separate load-bearing fusion cage.

Therefore, Michelson '045 discloses a base plate.

3. Element 35[b] – for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies

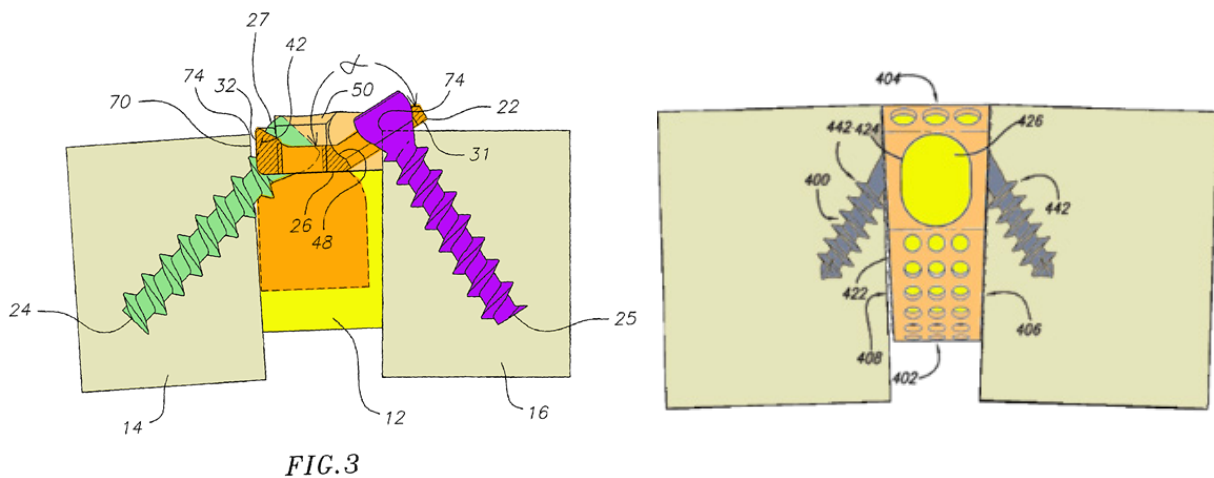
The '234 patent admits that this limitation was known in the prior art—explaining “[t]he spinal column comprises a series of vertebrae stacked on top of each other”—which in any event is disclosed by Michelson '045. Ex.1001, 1:16-17.

First, the '234 patent specification explains it was known to fuse the adjacent vertebrae together, Ex.1001, 44-47, and that “fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone.” Ex.1001, 48-51.

Second, Michelson '045 discloses an “invention relate[d] generally to **interbody spinal fusion implants.**” Ex.1006, 2. Michelson '045 discloses that “[t]o the extent that such implants are hollow and have openings through the

surfaces, those openings and those hollows can preferably be filled with fusion promoting substances, including substances that are osteogenic, osteo-inductive, or osteo-conductive, whether naturally occurring, or artificially produced.” Ex.1006, 9; *see* Ex.1005, ¶¶87-89.

Further, implant 400 is depicted below between the bones, and like the 234 implant, it has a base plate (orange) retaining the bone graft material (yellow).



'234 patent, Ex.1001, Fig.3

**Michelson '045, Ex.1006, Fig.24
(depicted between bones)**

As such, the '234 patent admits that the limitation “first and second longitudinally-aligned, adjacent bone bodies” was known in the prior art, and Michelson '045 discloses this limitation as well.

4. Element 35[c] – and for permitting force transmission between the first and second bone bodies through the bone graft material

Michelson '045 discloses this limitation because it discloses inserting the base plate in between two bones and allowing those bones to contact the base plate

and the bone graft material that occupies the cavities in the base plate, and it discloses using bone screws to keep the base plate in contact with the bones.

With respect to the contact between the base plate and the bones, Michelson '045 teaches that “each implant, when inserted, will have an **upper implant surface for engaging the upper of the adjacent vertebral bodies and an opposed lower implant surface for engaging the adjacent lower vertebral body**. It is desirable that each of **these opposed surfaces has at least one opening**, and possibly a plurality of openings, sufficient in size, and in continuity with each other, **to allow for the growth of bone from vertebral body to adjacent vertebral body through said implant.**” Ex.1006, 9; *see* Ex.1005, ¶93. Michelson '045 further teaches “[i]mplant 400 has opposed **upper and lower vertebral body engaging surfaces 406 and 408**, respectively, which preferably have surface irregularities serving to both increase the surface area of the implant and **the ability of the implant to engage the adjacent vertebral bodies, thereby enhancing their stability.**” Ex.1006, 16; *see* Ex.1005, ¶93.

With respect to the bone graft material, as previously described, Michelson '045 teaches “[t]o the extent that such implants are hollow and have openings through the surfaces, **those openings and those hollows can preferably be filled with fusion promoting substances.**” Ex.1006, 9; *see* Ex.1005, ¶94.

Next, Michelson '045 discloses that that “[b]one screws 442 further serve to pull the vertebral bodies to upper and lower implant surfaces 406 and 408 so as to increase the compressive load thereon.” Ex.1006, 18; *see* Ex.1005, ¶95.

A POSITA would understand that when the implant 400 engages the surfaces of the vertebrae, the implants transmit force between the vertebrae through the bone graft material filled within the implant hollow openings. Ex.1005, ¶96. A POSITA would further understand that when the bone screws engage each of the vertebral bodies, those screws would “pull the vertebral bodies to upper and lower implant surfaces 406 and 408 so as to increase the compressive load thereon . . .” including the compressive load on the bone graft material. Ex.1005, ¶¶96-98. As such, a POSITA would understand that Michelson '045 discloses implants that permit force transmission between the first and second bone bodies through the bone graft material. *Id.*

Therefore, Michelson '045 discloses this limitation.

5. Element 35[d] – the base plate being sized to have an inter-fit

Michelson '045 discloses this limitation and each of the following features.

- a. the base plate being sized to have an inter-fit between the first and second adjacent bone bodies*

As discussed above in Section VII, incorporated here, the term “sized to have an inter-fit between” (the first and second adjacent bone bodies)” means

“sized to fit completely in between the first and second adjacent bone bodies to allow partial sharing of the weight of the bone bodies across the bone graft site.”

Michelson '045 teaches this features because it discloses that the **“trailing end 402 of implant 400** could be generally convex and, still further, **could be curved so as to generally conform to the contour of the anterior vertebral body in order to sit in close approximation thereto, without the need to be significantly recessed.”** Ex.1006, 16; *see* Ex.1005, ¶101. This allows the implant to fit completely in between the first and second adjacent bone bodies without extending beyond the perimeter of the bones or covering the anterior surfaces of the bones. Like the implant in the '234 patent, the Michelson '045 implant 400 is depicted below inter-fit between the bones.

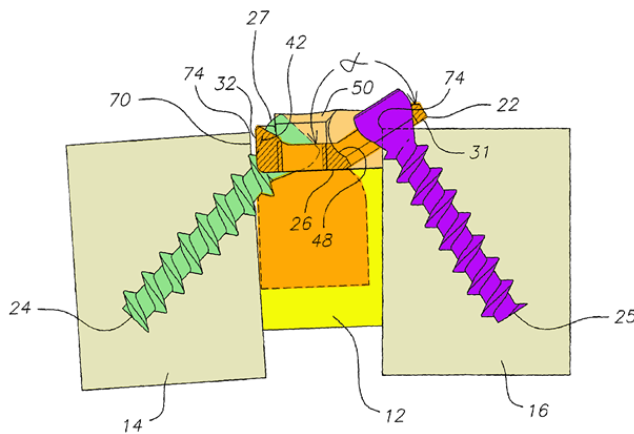
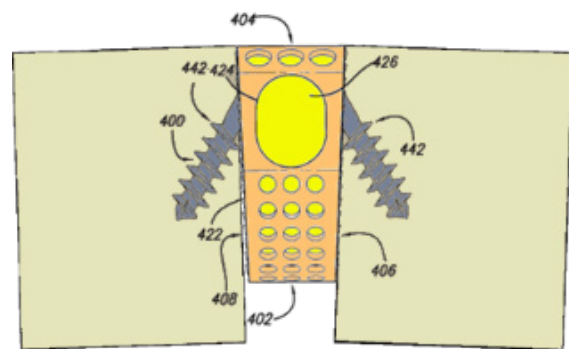


FIG. 3

'234 patent, Ex.1001, Fig.3

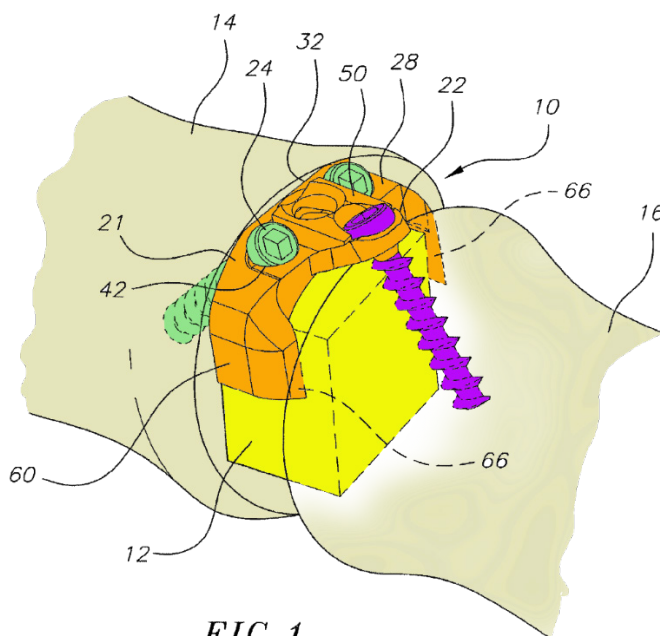


Michelson '045, Ex.1006, Fig.24
(depicted between bones)

Therefore, Michelson '045 discloses “the base plate being sized to have an inter-fit between the first and second adjacent bone bodies.”

b. the base plate...being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material

Regarding the second feature, the base plate being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material, Michelson '045 teaches that bone graft can be filled with fusion promoting substances. Michelson '045 teaches “[t]o the extent that such implants are hollow and have openings through the surfaces, **those openings and those hollows can preferably be filled with fusion promoting substances, including substances that are osteogenic, osteo-inductive, or osteo-conductive,** whether naturally occurring, or artificially produced.” Ex.1006, 9; *see* Ex.1005, ¶¶96-97, 103-105 (describing bone graft material as matter that is added during surgery to promote bone growth via osteogenic, osteo-inductive, or osteo-conductive processes). Like the implant in the '234 patent, the Michelson '045 implant 400 is depicted below adjacent to lateral extents of the bone graft material.



'234 patent, Ex.1001, Fig.1

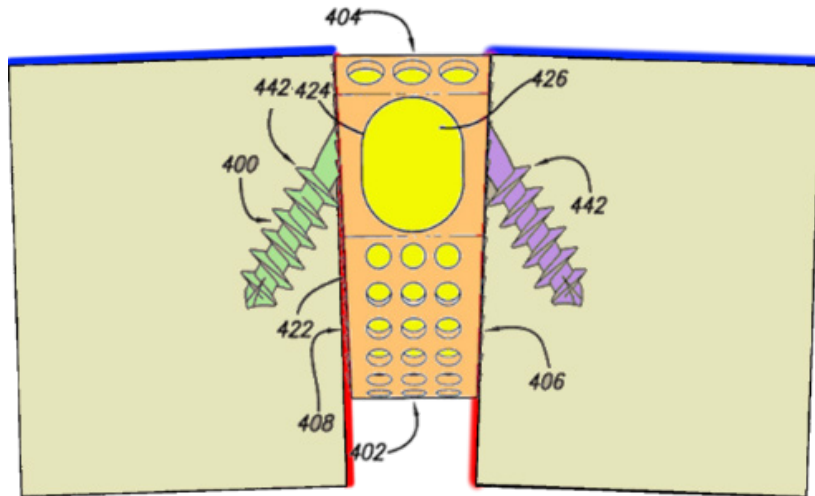
FIG. 21

A POSITA would understand that when the implant 400 engages the surfaces of the vertebrae, the first and second bone bodies would be in direct contact with the bone graft material. Ex.1005, ¶104. A POSITA would further understand that when the bone screws engage each of the vertebral bodies, those screws would “**pull the vertebral bodies** to upper and lower implant surfaces 406 and 408 so as **to increase the compressive load thereon . . .**” including the compressive load on the bone graft material. As such, a POSITA would understand that Michelson ’045 discloses that the first and second bone bodies engage the bone graft material. *Id.*

Therefore, Michelson '045 discloses “the base plate...being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material.”

6. Element 35[e] – and at least first and second bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies

Michelson '045 teaches that its implants “**are adapted to receive through their trailing ends at least a pair of appropriately sized opposed bone screws that can be directed at an appropriate angle**, at least one each, **into each of the adjacent vertebral bodies adjacent the disc space to be fused.**” Ex.1006, 9; *see* Ex.1005, ¶106. In particular, Michelson '045 teaches “[b]one screws 442 further serve to pull the vertebral bodies to upper and lower implant surfaces 406 and 408 so as to increase the compressive load thereon and mitigate against a loss of that compressive load or a **distraction anteriorly** which might otherwise occur if a patient were to bend back and forth or otherwise extend.” Ex.1006, 18; *see* Ex.1005, ¶107. These bone screws (green and purple) are depicted in Fig.24, below.



Michelson '045, Ex.1006, Fig.24 (depicted between bones)

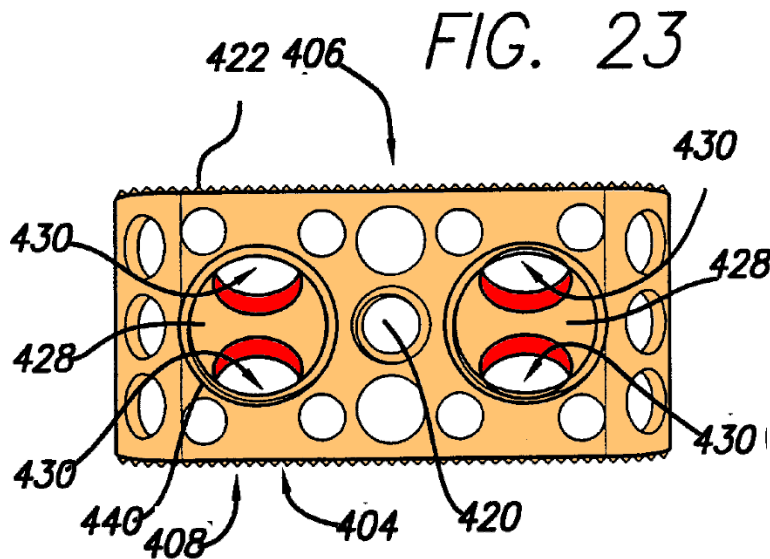
As such, Michelson '045 discloses “at least first [green] and second [purple] bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies.”

7. Element 35[f] – and the base plate having means for interacting with the first and second bone screws

As discussed above in Section VII, incorporated here, the claimed function is “interacting with the first and second bone screws,” and the corresponding structure is “a portion of the base plate 20 with circular bone screw holes 42 and/or a bone screw slot 48” and equivalents thereof.

Michelson '045 teaches that “holes 430 [are] adapted to receive a bone screw 442.” Ex.1006, 17; *see* Ex.1005, ¶110. In addition, Michelson '045 teaches that circular “[h]oles 430...are angled apart so as to assure that a pair of bone screws 442 inserted therethrough will be directed one each into each of the

vertebral bodies adjacent the disc space containing implant 400.” Ex.1006, 19; *see* Ex.1005, ¶110. These circular bone screw holes (red) are depicted in Fig.23, below.⁶



Michelson '045, Ex.1006, Figs. 23

As described in the following Section 8, and incorporated here, a POSITA, reading Michelson '045 alone, would have known to modify these circular holes 430 into slots.

Therefore, Michelson '045 discloses a “base plate having means for interacting [circular holes 430 or slots] with the first and second bone screws

⁶ Even under Patent Owner’s proposed construction, Michelson '045 explicitly discloses “a portion of the base plate [circular holes 430] that receives a screw [442] and screw head [452].” Ex.1005, ¶109-111.

[screws 442]. Or, applying the claim construction, Michelson '045 discloses a portion of the base plate with circular bone screw holes (*e.g.*, circular holes 43)) and/or a bone screw slot (*see* section below, incorporated here) and equivalents thereof for interacting with the first and second bone screws. Accordingly, Michelson '045 discloses this limitation.

8. Element 35[g] – the means for interacting including means for permitting movement of at least one of the first and second bone bodies relative to the base plate.

As discussed above in Section VII, incorporated here, the claimed function is “permitting movement of at least one of the first and second bone bodies relative to the base plate,” and the corresponding structure for performing the function is “the **bone screw slot 430**” and equivalents thereof. *See* Ex.1001, 4:31-5:9, 5:53-6:9, 7:36-54, 12:21-31. As described below, a POSITA would have known to modify holes 430, depicted in figures 23 and 27 of the Michelson '045 implant 400, into slots based on additional teachings about implant 400 in Michelson '045.

With respect to implant 400, Michelson '045 discloses a “**structure . . . to allow for but [*i.e.*, only] one degree of freedom of the locked screws for the settling or the coming closer together of the adjacent vertebrae.**” Ex.1006, 19; *see* Ex.1005, ¶113. A POSITA would understand that one degree of freedom to allow for settling of the vertically stacked vertebrae refers to translation or movement along a single vertical axis. Ex.1005, ¶113. In case there is any doubt,

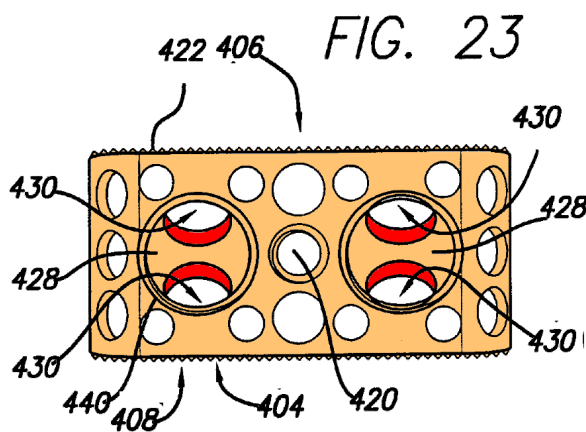
“one degree of freedom” does not mean rotating the bones through one degree. *Id.* A POSITA would also understand that movement with only one degree of freedom must also promote fusion of the bones. In particular, translation of the screw in the superior/inferior direction (*i.e.*, up and down the spine) would permit a **“settling or the coming closer together of the adjacent [vertically stacked] vertebrae.”**

Ex.1006, 18. Ex.1005, ¶114.

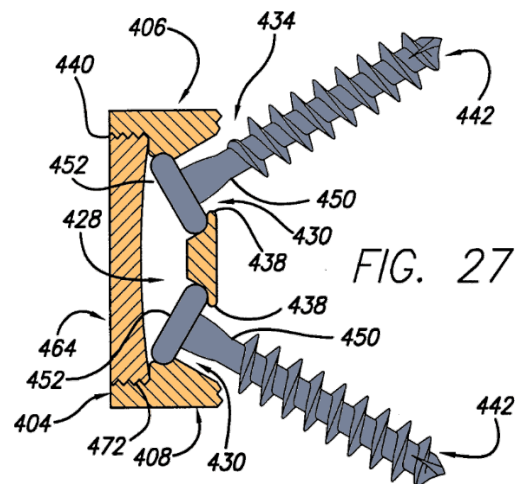
To achieve these teachings about implant 400 in Michelson '045 – permitting one degree of freedom and promoting settling of the bones – a POSITA would understand that the explicit or inherently disclosed structure is a vertical slot in the base plate that corresponds to the shank of the bone screw.

Ex.1005, ¶114.

Michelson '045 shows circular holes 430 in figures 23 and 27 that are larger than the shaft of the screws to allow for movement in multiple degrees of freedom:



Michelson '045, Ex.1006, Fig.23



Michelson '045, Ex.1006, Fig.27

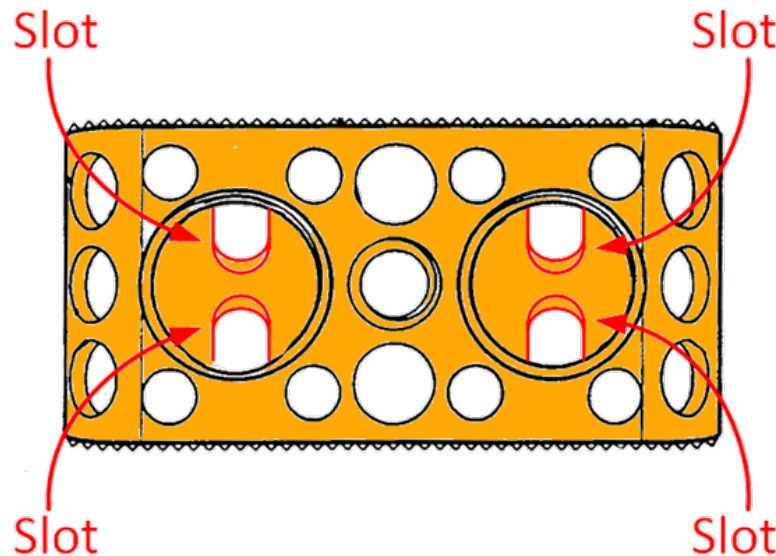
These large circular holes that allow movement in multiple degrees of freedom are not vertical slots that allow movement in only one degree of freedom, as described in Michelson '045. In other words, Michelson '045 discloses that implant 400 in figures 23 and 27 is designed to allow the screw to move with more than one degree of freedom (*i.e.*, move in more than one direction) after implantation. Specifically, screw 442 has **“a smooth shaft portion 450 of a lesser cross sectional dimension than hole 430 which**, in combination with the available space within common hole 428 between screw head 452 and lock 462, **allows for bone screw 442 to** operate as a lag screw, but, nevertheless, **be capable of some variability in its positioning and ability to move closer to implant 400 in the event of subsequent settling of the vertebral bodies towards implant 400.”** Ex.1006, 18; *see* Ex.1005, ¶118.

Therefore, a POSITA reading the remainder of Michelson '045 would be motivated to modify the base plate and holes 430 depicted in implant 400, at figures 23 and 27, to create a vertical slot, *i.e.*, a **“structure . . . to allow for but one degree of freedom** of the locked screws **for the settling or the coming closer together of the adjacent vertebrae.”** Ex.1006, 18; *see* Ex.1005, ¶117.

Modifying the circular holes 430 into a slot is elementary. For example, a POSITA would simply narrow the width of holes 430, or increase the height of hole 430, to form a slot that only allows movement in the superior/inferior

direction (*i.e.*, up/down the spine). Ex.1005, ¶119. Alternatively, a POSITA would simply replace the circular holes 430 with vertical slots. Movement in the superior/inferior direction is movement in a single degree of freedom that allows the bone to settle, as disclosed by Michelson '045. Ex.1005, ¶119; Ex.1006, 18.

As depicted below, a POSITA would understand that narrowing the circular holes 430 would result in creating a set of bone screw slots, as shown in red below. Ex.1005, ¶119.



Michelson '045, Ex.1006, Fig.23 (holes 430 modified into slots)

A POSITA would be motivated to modify (or replace) circular holes 430 with vertical slots because a vertical slot would prevent movement of the bone laterally (*i.e.*, side-to-side) while still permitting movement in the superior/inferior direction (*i.e.*, up/down the spine) to allow the bones to settle. Ex.1005, ¶115.

With respect to the top bone, a POSITA would also understand that inferior

movement along a slot would promote fusion, ensuring contact between the bone graft material and the endplates of the adjacent vertebral bodies. In contrast, lateral movement – which is possible in hole 430 – could hinder fusion of the bone by introducing shear between the bone graft material and the bone, which could cause wear and potentially maligned fusion. Ex.1005, ¶115. In short, a slot permits superior/inferior movement, which promotes fusion, while lateral movement hinders fusion, thereby providing the one degree of freedom taught by Michelson '045 for implant 400. Ex.1005, ¶120.

For at least these reasons, a POSITA would have modified the implant 400 of figures 23 and 27 of Michelson '045 to include “**a bone screw slot**” that performs the function of “permitting movement of at least one of the first and second bone bodies relative to the base plate.”⁷

As described above, Michelson '045 discloses each and every limitation recited by independent claim 35 of the '234 patent and this claim is unpatentable.

B. Claim 37 – Lateral tabs

Claim 37 depends from independent claim 35. All the limitations of claim

⁷ Under Patent Owner’s construction, Michelson '045 discloses “a portion of the base plate [circular holes 430] that receives a screw [442] and screw head [452], plus equivalents thereof.” Ex.1005, ¶¶112-121.

35, discussed above and incorporated here, are disclosed by Michelson '045.

1. Element 37[a] – the base plate includes two lateral tabs for location between the first and second adjacent bone bodies

Regarding the first feature, as shown in annotated figure 21, below,

Michelson '045 discloses two lateral tabs in figure 21 (a top cross-sectional (view):

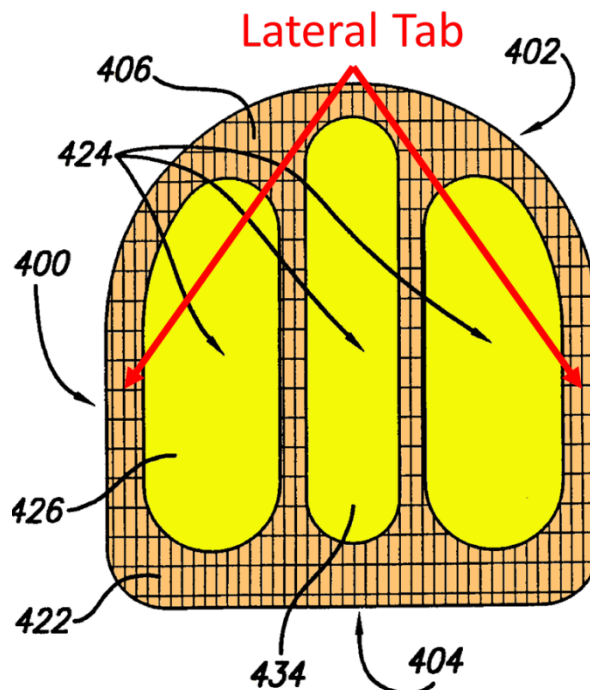
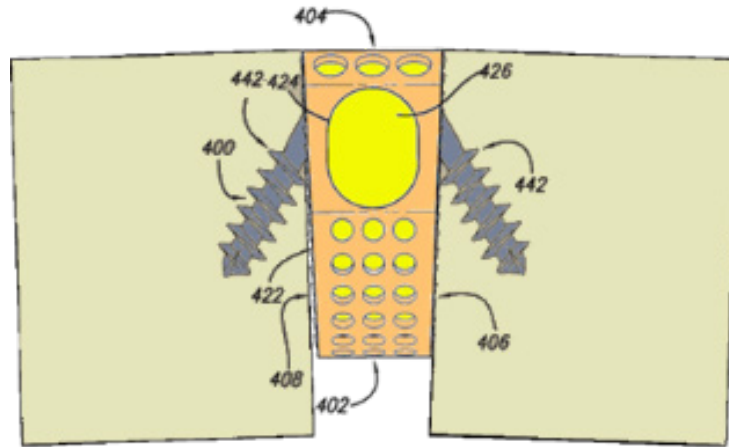


FIG. 21

Michelson '045, Ex.1006, Fig.21

Furthermore, Michelson '045 teaches these two lateral tabs are located between the first and second bones. This can be seen, for example, in the figure below showing the implant 400 (figure 24) in between the two vertebrae bones.

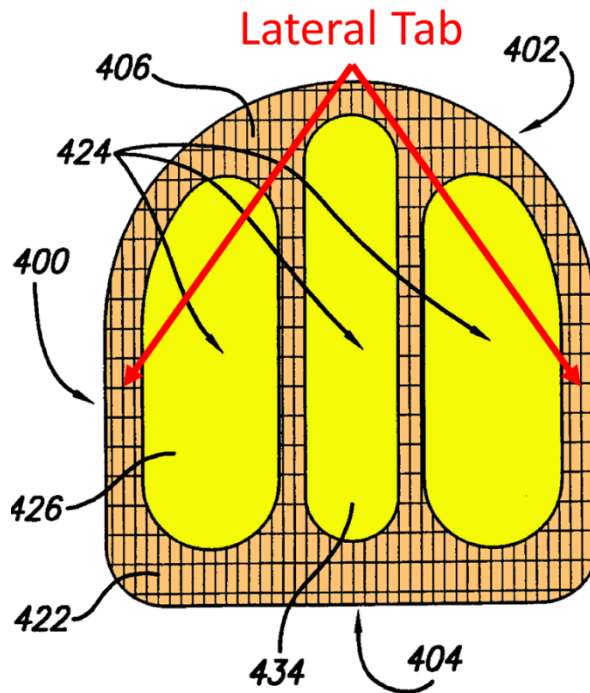


Michelson '045, Ex.1006, Fig.24 (depicted between bones)

Therefore, Michelson '045 discloses “the base plate includes two lateral tabs for location between the first and second adjacent bone bodies.”

2. **Element 37[b] – the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space of the base plate for location of the bone graft material therein**

Michelson '045 teaches “[t]o the extent that such implants are hollow and have openings through the surfaces, **those openings and those hollows can preferably be filled with fusion promoting substances, including substances that are osteogenic, osteo-inductive, or osteo-conductive**, whether naturally occurring, or artificially produced.” Ex.1006, 9; *see* Ex.1005, ¶127. Furthermore, as shown in annotated figure 21, below, Michelson '045 discloses the ends of the tabs provide for an open space in the base plate that can be filled with bone graft material (yellow).



Michelson '045, Ex.1006, Fig.21

Therefore, Michelson '045 discloses “the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space of the base plate for location of the bone graft material therein.”

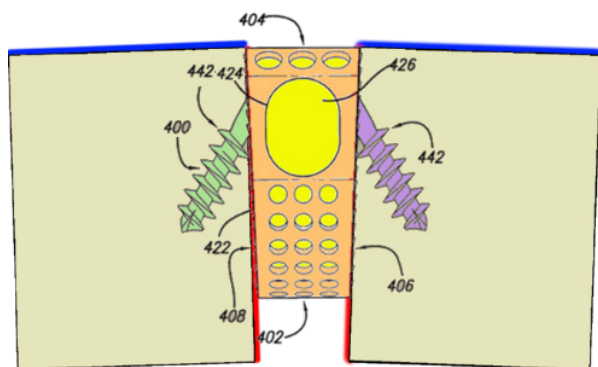
Therefore, as described above, Michelson '045 discloses this claim limitation “the base plate includes two lateral tabs for location between the first and second adjacent bone bodies, the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space [windows or slots 424 and central hollow chamber 426] of the base plate for location of the bone graft material therein.”

C. **Claim 39**

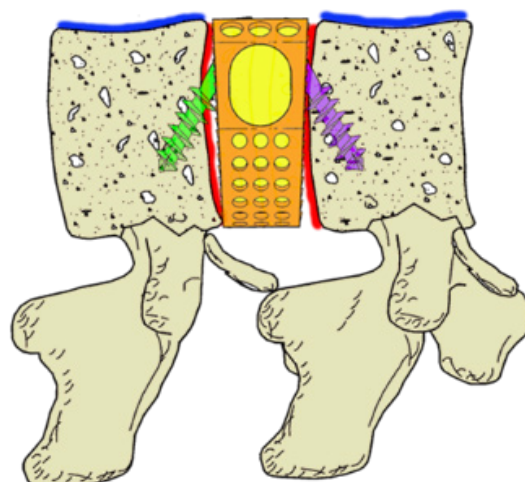
Claim 39 depends from independent claim 35. All the limitations of claim 35, discussed above and incorporated here, are disclosed by Michelson '045.

1. **Element 39[a] – wherein each of the bone bodies has an outwardly-facing surface and each of the bone bodies has a side surface facing toward the side surface of the other bone body**

Michelson '045 discloses this limitation, as do all normal human vertebral bones. In particular, Michelson '045 teaches “each implant, when inserted, will have an upper implant surface for engaging **the upper of the adjacent vertebral bodies** and an opposed lower implant surface for engaging **the adjacent lower vertebral body**. Ex.1006, 9; *see* Ex.1005, ¶¶132-133. For example, with reference to the two figures below, Michelson '045 discloses two adjacent vertebral bodies having outwardly facing surfaces (identified in blue) and each vertebral body having a side surface (identified in red) facing toward the side surface of the other vertebral body.



**Michelson '045, Ex.1006, Fig.24
(depicted between two bones)**



**Michelson '045, Ex.1006, Fig.24
(depicted between two bones)**

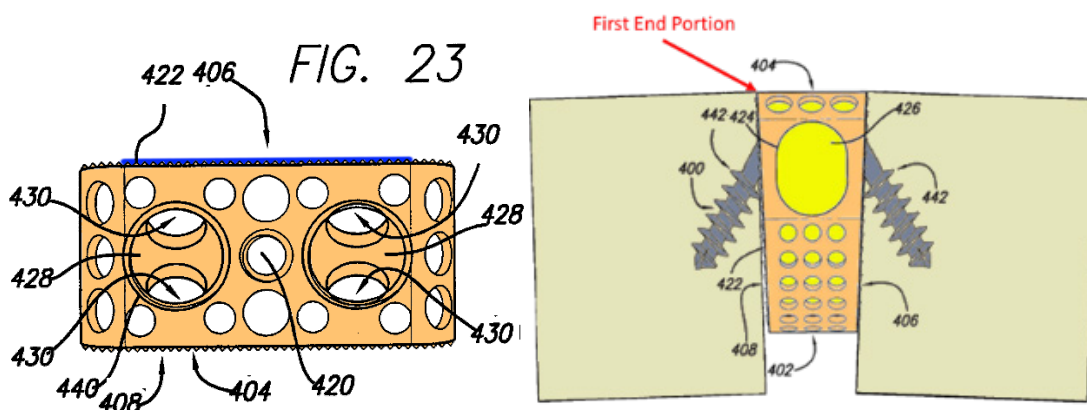
Therefore, Michelson '045 discloses “wherein each of the bone bodies [vertebrae] has an outwardly-facing surface [blue] and each of the bone bodies has a side surface [red] facing toward the side surface of the other bone body.”

2. **Element 39[b] – the base plate having a first end portion adjacent to the first bone body, the first end portion having an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body**

Michelson '045 discloses this limitation and all three of these features.

- a. *the base plate having a first end portion adjacent to the first bone body*

Regarding the first feature, as shown in figures 23 and 24, below, Michelson '045 depicts a base plate with a first end portion that is next to the first bone.



Michelson '045, Ex.1006, Figs.23, 24

Therefore, Michelson '045 discloses “the base plate having a first end portion [blue edge of upper implant surface 406] adjacent to the first bone body.”

- b. the first end portion having an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body*

Michelson '045 is directed to “an implant that is resistant to dislodgment and functionally substitutes for the anterior longitudinal ligament at the level to be fused, **without protruding from the spine.**” *Id.* Michelson '045 discloses that the “trailing end 402 of implant 400 could be generally convex and, still further, could be curved so as to generally conform to the contour of the anterior vertebral body in order to sit in close approximation thereto, without the need to be significantly recessed.” Ex.1006, 16. A POSITA would understand that Michelson '045 teaches that the implant, while not significantly recessed, is still recessed relative to the outwardly-facing surface of the first bone body. Ex.1005, ¶140. Further,

Michelson '045 warns against affixing any spinal implant hardware anteriorly to the vertebral bodies. Ex.1006, 4, Ex.1005, ¶139. As shown by the side-by-side figures, below, like the '234 patent, the Michelson '045 implant 400 is positioned at a position recessed, and almost flush, relative to the bones. A POSITA would understand that the Michelson '045 implant 400 should be recessed, or almost flush, with the bones to ensure that nothing protrudes from the spine and that the exact depth of the implant will be determined by the condition of the patient's spine. Ex.1005, ¶¶139-142.

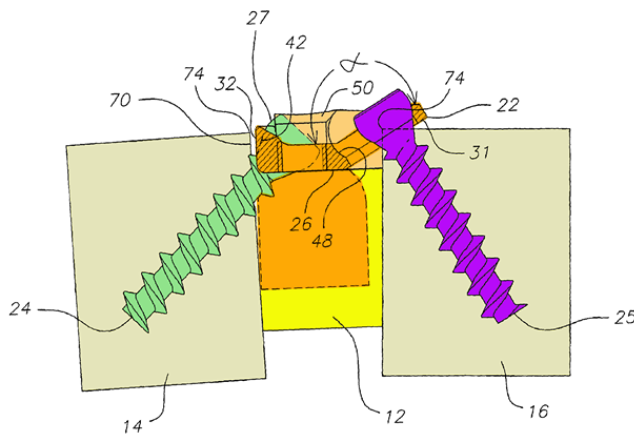
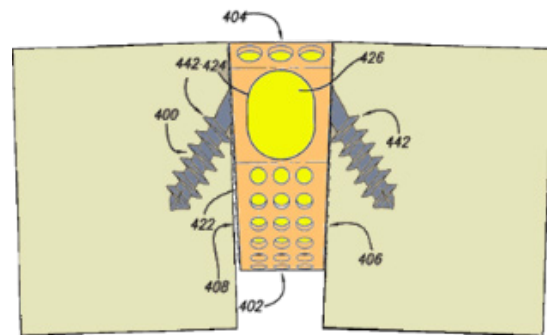


FIG. 3

'234 patent, Ex.1001, Fig.3



Michelson '045, Ex.1006, Fig.24

For these reasons, Michelson '045 discloses “the base plate having a first end portion [blue edge of upper implant surface 406] adjacent to the first bone body, the first end portion having an outwardly-facing surface [upper edge of

trailing end 404] for location at a position recessed relative to the outwardly-facing surface of the first bone body.”

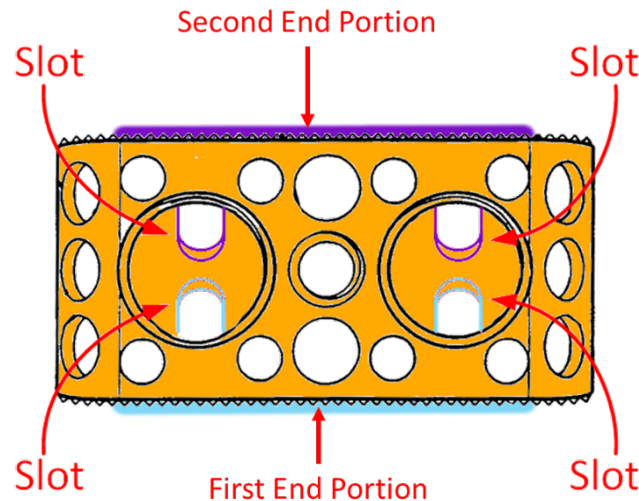
3. Element 39[c] – the first end portion having a first screw hole that opens toward the side surface of the first bone body, the base plate having a second end portion that has a second screw hole that opens toward the second bone body

a. the first end portion having a first screw hole...the base plate having a second end portion that has a second screw hole

Michelson '045 discloses a base plate having a first end and a second end, and each end has a screw hole. Specifically, Michelson '045 discloses that “[i]mplant 400 has **opposed upper and lower vertebral body engaging surfaces 406 and 408, respectively.**” Ex.1006, 16; *see* Ex.1005, ¶145. These features are also depicted in modified figure 23 below, specifically a base plate with a first end (blue) nearer the first bone and a second end (purple) nearer the second bone. Ex.1005. ¶145. Michelson '045 also discloses a first screw hole extending through the first end (blue) and a second screw hole extending through the second end (purple) in this same figure. *Id.*

As discussed above with respect to claim 35, *see* Section A.8, a POSITA would have been motivated to modify (or replace) circular holes 430 with vertical slots. The term “hole,” as used in this claim, is directed to any aperture, which can

have any geometric shape including a circular hole or slot.⁸ As such, the one or more slots of modified Figure 23 of Michelson '045 (as discussed above with respect to claim 35, and incorporated here) disclose the broader term “holes” of claim 39.



⁸ The term “hole” in this claim must mean an “aperture” generally, and not a “circular hole” in particular. The preferred embodiment discloses two circular holes 42 on one side of the implant and a slot 48 on the other side of the implant. Ex.1001, Fig. 3. Therefore, for the claim to cover the preferred embodiment of the patent, the “holes” in this claim must mean an aperture that includes both circular holes and slots. Seldom, if ever, does a construction exclude the preferred embodiment. *Globetrotter Software v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1381 (Fed. Cir. 2004).

Michelson '045, Ex.1006, Fig.23

Therefore, Michelson '045 discloses “the first end portion [blue edge of surface 404] having a first screw hole [blue slots]...the base plate having a second end portion [purple edge of surface 406] that has a second screw hole [purple slots].”⁹

- b. a first screw hole that opens toward the side surface of the first bone body...a second screw hole that opens toward the second bone body*

With respect to the second feature, screw holes that extend though the base plate and open toward the side surfaces of the bones, Michelson '045 discloses that “[t]he implants of the present invention differ from all prior art implants in that **they are adapted to receive through their trailing ends at least a pair of appropriately sized opposed bone screws that can be directed at an appropriate angle, at least one each, into each of the adjacent vertebral bodies adjacent the disc space** to be fused.” Ex.1006, 9; *see* Ex.1005, ¶147.

⁹ Under Patent Owner’s construction for the term “means for interacting with the first and second bone screws,” Michelson '045 discloses this claim limitation, *i.e.*, circular holes 430 in the first and second ends of the base plate, as depicted in figure 23. Ex.1005, ¶145.

Michelson '045 also teaches that **“trailing end 404 of implant 400 has, in addition to the plurality of bone holes 410, two specialized common holes 428, each containing two further holes 430. Each of holes 430 is adapted to receive a bone screw 442 through trailing end 404 of implant 400 at an angle such that the bone screw would be directed first through trailing end 404, then through either one of upper or lower vertebral bone engaging surfaces 406 and 408 of implant 400, and finally into the vertebral body itself at an angle preferably between 25° and 75°.”** Ex.1006, 17; *see* Ex.1005, ¶148.

As shown by the side-by-side figures, below, like the '234 patent, Michelson '045 discloses screw holes, which are modified into slots as described above, that extend through the base plate and open toward the side surfaces of the bones.

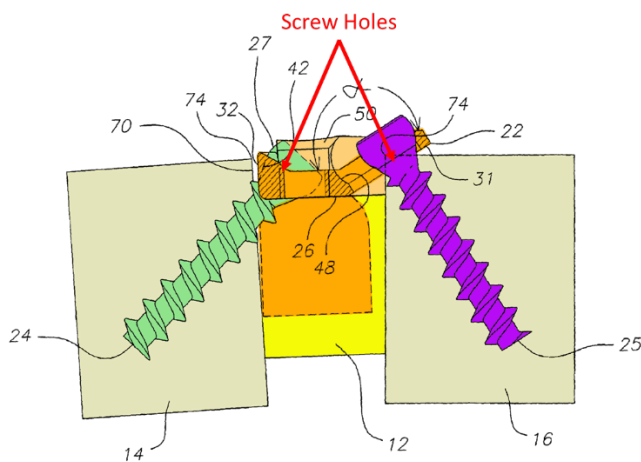
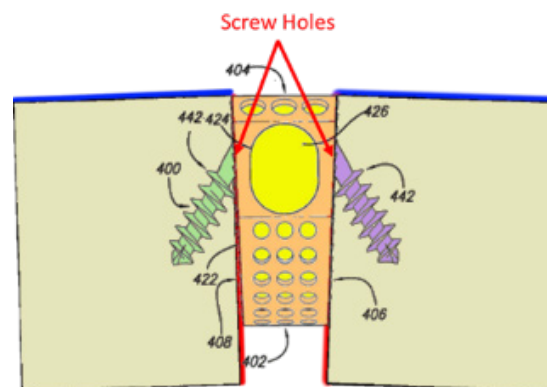


FIG. 3

'234 patent, Ex.1001, Fig.3



Michelson '045, Ex.1006, Fig.24

For the reasons above, Michelson '045 discloses “the first end portion having a first screw hole that opens toward the side surface of the first bone body,

the base plate having a second end portion that has a second screw hole that opens toward the second bone body.”

4. **Element 39[d] – the first and second bone screws extending through the first and second holes into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.**

- a. *the first and second bone screws extending through the first and second holes into the first and second bone bodies, respectively*

Michelson '045 teaches that bone screws 442 are used to secure the implant to the first and second bone bodies. Specifically, Michelson '045 teaches “[e]ach of holes 430 is adapted to receive a bone screw 442 through trailing end 404 of implant 400 at an angle such that the bone screw would be directed first through trailing end 404, then through either one of upper or lower vertebral bone engaging surfaces 406 and 408 of implant 400, and finally **into the vertebral body itself at an angle preferably between 25° and 75°.**” Ex.1006, 17; *see* Ex.1005, ¶152.

These screws are depicted below in the '537 patent and in Michelson '045.

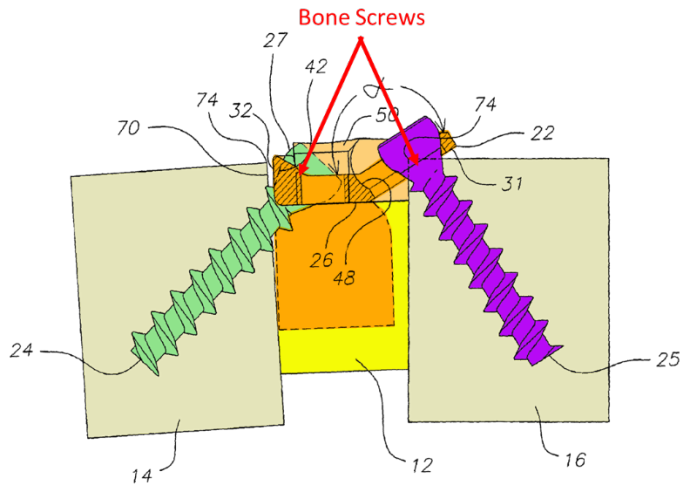
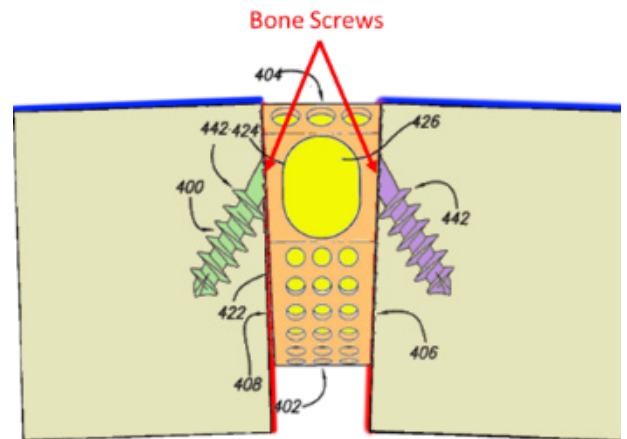


FIG. 3

'234 patent, Ex.1001, Fig.3



Michelson '045, Ex.1006, Fig.24

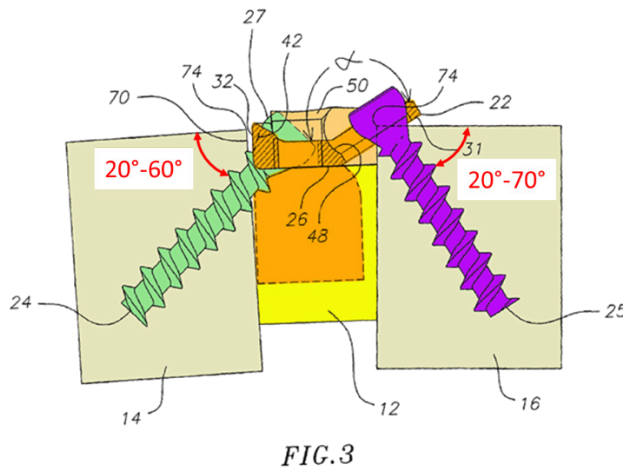
Therefore, Michelson '045 discloses “the first and second bone screws [bone screws 442] extending through the first and second holes [holes 430, as modified into slots] into the first and second bone bodies, respectively.”

b. each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies

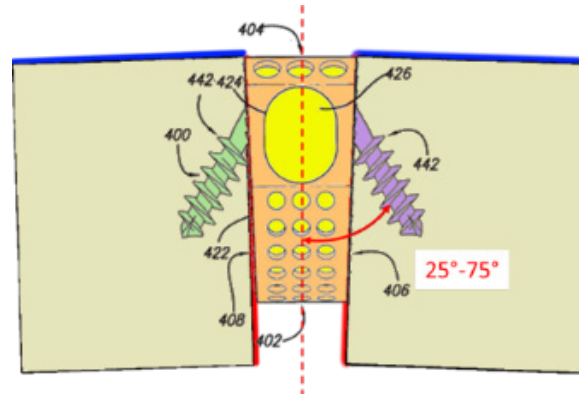
As to the second feature, Michelson '045 discloses that “**screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant.” Ex.1006, 32, 101; *see* Ex.1005, ¶154. This is the equivalent of 15° and 65° from the top surface of the bone, which is non-orthogonal to the longitudinal alignment of the first and second bone bodies. Ex.1005, ¶154.

Furthermore, as shown by the side-by-side figures, below, like the '234 patent, Michelson '045 discloses a first (green) and second (purple) bone screws

extending through the first and second holes into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.



'234 patent, Ex.1001, Fig.3



**Michelson '045, Ex.1006,
Figs. 24 and 46E**

For these reasons, Michelson '045 discloses “the first and second bone screws [bone screws 442] extending through the first and second holes [holes 430] into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.”

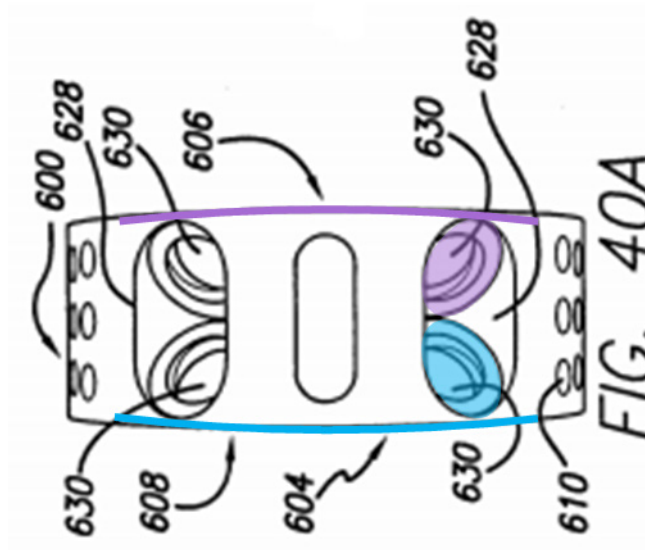
D. Claim 39 (embodiment 400 in view of embodiment 600')

Claim 39 is obvious in view of Michelson '045 (embodiment 400) for the reasons provided in Section VIII.D, and incorporated here.

To the extent that the Board determines that the first/second end limitation requires at least a portion of the bone screw holes in the first/second end to

intersect with the corner of the top surface and the side surface of the base plate, it would have been obvious to a POSITA to adjust the location of the bone screw holes in Michelson '045 (embodiment 400) to the superior and inferior corners of the base plate, as depicted in Michelson '045 (embodiment 600). Ex.1005, ¶158.

In fact, Michelson '045 discloses this design in implant 600'. Specifically, Michelson '045 discloses that “[t]railing end 604' has **bone screw receiving holes 630a-630d** for receiving bone screws 642 therein. Bone screw receiving holes 630a' and 630d' are **oriented toward lower surface 608'** for engaging a vertebral body above implant 600'. Opposed bone screw receiving **openings 630b' and 630c' are oriented toward upper surface 606'** for engaging a vertebral body below implant 600'.” Ex.1006, 22-23. As depicted in figure 40A, below, Michelson '045 depicts these bone screws (as modified into slots) located at the first and second ends (*i.e.*, at the corner of the base plate).



Michelson '045, Ex.1006, Fig.40A

A POSITA would have been motivated to combine the disclosures of implant 400 and implant 600, both from Michelson '045, for several reasons. First, Michelson '045 implants 400 and 600 are analogous art to the '234 patent. Just like the '234 patent, implants 400 and 600 are directed to a spinal implant device for fixation and support of vertebrae. *See* Ex.1006, 17-18 (describing insertion of implant 400); *id.* at 2 (describing insertion of implant 600). Therefore, implants 400 and 600 of Michelson '045 are in the same field of endeavor as the '234 patent.

Second, Michelson '045 provides an express motivation to combine the teachings of implant 400 with other embodiments in the reference, including implant 600. Ex.1006, 18 (teaching the screw and lock arrangement used with implant 400 and shown in figure 27 can be used “with any of the other

embodiments of the present invention as may be appropriate.”)

Finally, a POSITA would recognize advantages to locating the bone screw holes at the superior and inferior edges of the top surface of the baseplate, as depicted in embodiment 600. Ex.1005, ¶163. Locating the screw holes closer to the centerline of the top surface limits the range of screw angles available to a surgeon. *Id.* Thus, a POSITA would also recognize that a design with screw holes closer to the superior and inferior edges would give the surgeon significant advantages during surgery, especially in complicated cases where there is significant degradation of the bone. *Id.* Furthermore, a POSITA would understand that locating the screw holes at the first and second ends (including at the corner between the top and side surfaces) would provide a wider footprint (*i.e.*, range of options) for screw insertion. *Id.* Screw holes located at the first and second ends also allow the bone screws to enter into the bones as close to the anterior portion of the bone as possible. *Id.*

With respect to embodiments 400 and 600, a POSITA would have recognized that this combination merely involves the simple substitution of one known element (*i.e.*, screw hole locations of implant 400) for another (*i.e.*, the screw hole locations of implant 600). As such, these physical modifications to the location of the bone screw holes would be well within a POSITA’s skill (and a POSITA would have more than a reasonable expectation of success) as they would

only require moving the screw holes to the edges of the implant and slightly adjusting their trajectories, all of which is explicitly disclosed by Michelson '045. Ex.1005, ¶164.

Therefore, Michelson '045 renders claim 39 obvious.

**IX. GROUND #2: FRASER '106 IN VIEW OF MICHELSON '045
RENDERS CLAIMS 35, 37, AND 39 OBVIOUS**

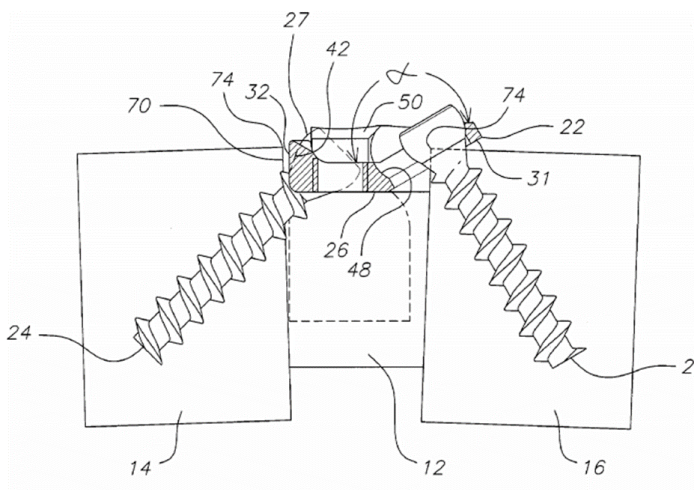
For the reasons stated below, claims 35, 37 and 39 of the '234 patent are rendered obvious under 35 U.S.C. §103 by Fraser '106 in view of Michelson '045.

A. Claim 35

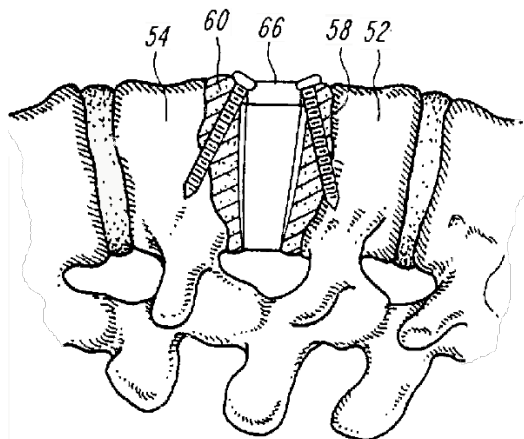
1. Element 35[Preamble] – A bone stabilization plate system including

The preamble is not a limitation of the claim, as it does not breath life or meaning into the claim. *Aspex Eyewear*, 672 F.3d 1335, 1347 (Fed. Cir. 2012). Nonetheless, as shown below, Fraser '106 discloses the preamble.

As shown in the side-by-side comparison figures, below, Fraser '106 discloses the bone stabilization plate system recited by the '234 patent. In particular, Fraser '106 teaches that the “spinal fixation assembly includes a fusion cage to which a plate is mated.” Ex.1007, Abstract. Fraser '106 explains that “[t]he plate is configured to receive, retain and orient bone screws, thereby holding the fusion cage and adjacent vertebral bodies in a **stable relationship to promote fusion.**” Ex.1007, 1:36-42.



'234 patent, Ex.1001, Fig.3



Fraser '106, Ex.1007, Fig.8

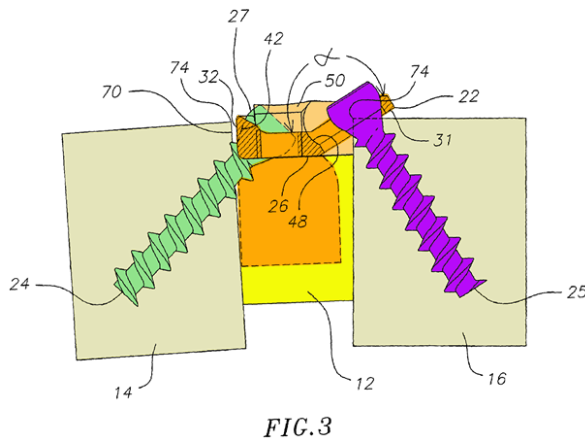
As such, Fraser '106 discloses this limitation.

2. Element 35[a] – a base plate

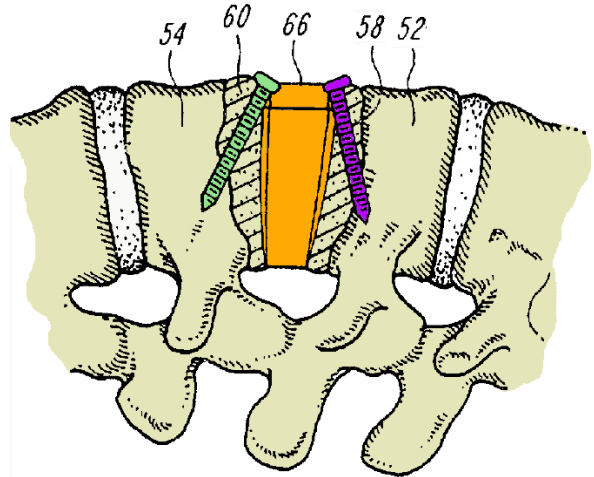
a. *Petitioner's proposed construction*

As discussed in Section VII, the term “base plate” means “a fixation plate to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material deployed across a bone graft site and is not used with a load-bearing fusion cage.” Fraser '106 discloses a base plate that meets this definition.

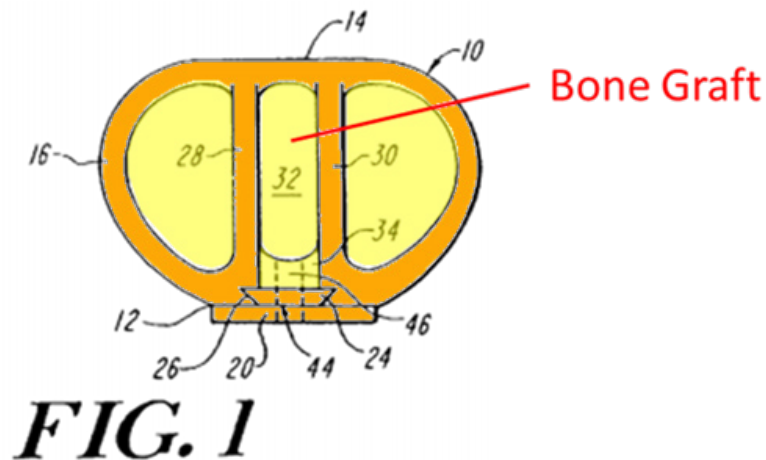
As shown below, like the '234 patent, Fraser '106 discloses a fixation plate 66 to stabilize adjacent vertebrae for fusion. Fraser '106 explains that “[t]he plate is configured to receive, retain and orient bone screws, thereby holding the fusion cage and adjacent vertebral bodies in a stable relationship to promote fusion.” Ex.1007, 1:36-42; *see* Ex.1005, ¶171 (describing how the plate stabilizes the bones for fusion).



'234 patent, Ex.1001, Fig.3



Fraser '106 also discloses that the base plate is distinct from bone graft material.



Fraser '106, Ex.1007, Fig.1

Specifically, Fraser '106 teaches that “[p]rior to inserting a fusion cage between vertebral bodies, the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone,

or demineralized bone matrix (DBM) to promote fusion.” Ex.1007, 4:38-43; *see* Ex.1005, ¶173.

Further, Fraser ’106 discloses an implant with a base plate and an integrated load-bearing fusion cage (orange, above), *i.e.*, is not used with a separate load-bearing fusion cage or spacer. In particular, Fraser ’106 states that in one embodiment **“the plate 20 can be bonded firmly to the body 10 so that the plate and body cannot move with respect to each other.”** Ex.1007, 2:34-35, 43-45; *see* Ex.1005, ¶174.

Therefore, Fraser ’106 discloses the claimed base plate, *i.e.*, a fixation plate (orange above) to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material (yellow above) deployed across a bone graft site and is not used with a separate load-bearing fusion cage.

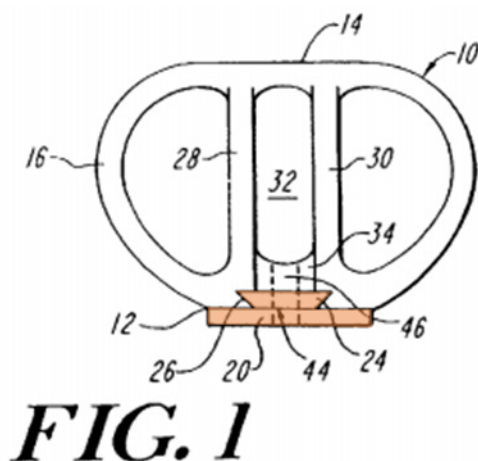
b. Base plate distinct from a separate spacer (i.e., two-piece implant)

Patent Owner’s preliminary construction in district court states that the base plate is distinct from both bone graft material and a spacer. The parties agree that the base plate is separate from the bone graft material, however, it is unclear from Patent Owner’s proposed construction whether the claims also require a separate spacer. Therefore, for the sake of completeness in this petition, and to the extent that the Patent Owner argues and the Board agrees that the claims require both a

base plate and a separate spacer (i.e., a two-piece implant), this ground also explains how Fraser '106 discloses a two-piece implant.

Fraser '106 discloses a two-piece embodiment where the plate 20 and body 10 are not bonded. In particular, Fraser '106 teaches that “[a]though the plate 20 can be bonded firmly to the body 10 so that the plate and body cannot move with respect to each other, **they can also be mated to allow movement with respect to each other.**”¹⁰ Ex.1007, 2:43-46. In particular, Fraser '106 teaches “**the plate 20 includes a tenon 24 that is disposed within a mortise 26 defined by the body 10**, wherein the tenon can slide in a superior/inferior direction within the mortise.” Ex.1007, 2:46-50. The base plate in the alternative embodiment of Fraser '106 is shown below.

¹⁰ Fraser '106 discloses an embodiment where plate 20 is fixedly bonded to body 10. The remaining disclosures with respect to body 10 are identical whether the plate 20 is fixedly bonded or mated to allow for movement.



Fraser '106, Ex.1007, Fig.1

This base plate is also used for fixation to stabilize adjacent vertebrae for fusion, Ex.1007, 1:40-42 and 2: 43-45; *see* Ex.1005, ¶177-178, and it is distinct from bone graft material deployed across a bone graft site. Ex.1007, 4:37-42; *see* Ex.1005, ¶178.

Therefore, Fraser '106 discloses the claimed base plate through both the one-piece embodiment and through the two-piece embodiment.

3. Element 35[b] – for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies

a. Petitioner's proposed construction

The '234 patent admits that this limitation was known in the prior art—explaining “[t]he spinal column comprises a series of vertebrae stacked on top of each other”—which in any event is disclosed by Fraser '106. Ex.1001, 1:16-17.

First, the '234 patent specification explains it was known to fuse the adjacent vertebrae together, Ex.1001, 44-47, and that “fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone.” Ex.1001, 48-51.

Second, Fraser '106 discloses that “the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion.” Ex.1007, 4:37-42; *see* Ex.1005, ¶182. Fraser '106 further teaches that its “plate is configured to receive, retain and orient bone screws, thereby **holding the fusion cage and adjacent vertebral bodies in a stable relationship to promote fusion.**” Ex.1007, 1:40-42; *see* Ex.1005, ¶182. Figure 1, below, shows the area where bone graft material (yellow) can be retained within the body 10 of Fraser '106:

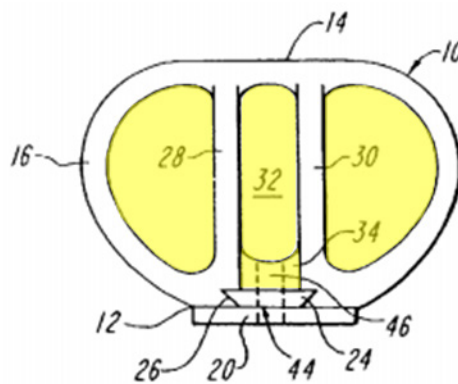


FIG. 1

Fraser '106, Ex.1007, Fig.1

Therefore, Fraser '106 discloses retaining bone graft within the implant, which is implanted between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other. As shown by the side-by-side figures, below, like the 234 patent, Fraser '106 discloses retaining bone graft material between adjacent vertebral bone bodies:

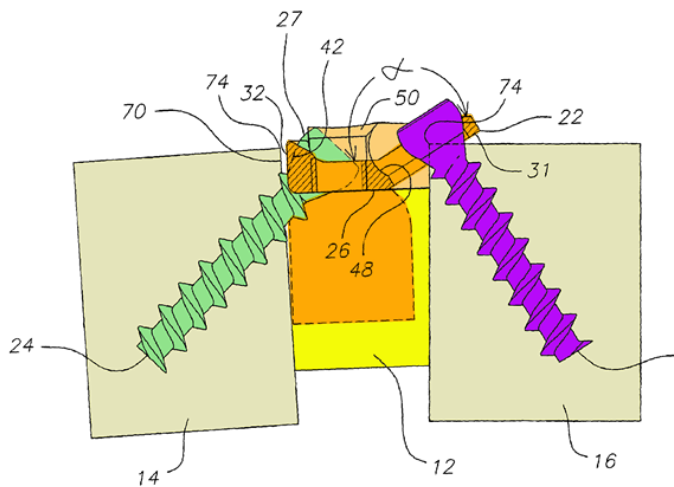
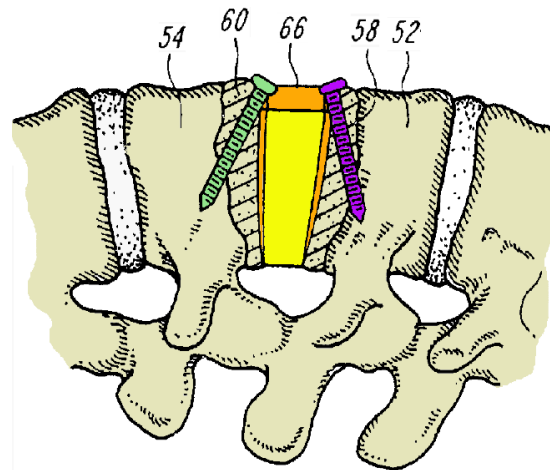


FIG. 3

'234 patent, Ex.1001, Fig.3



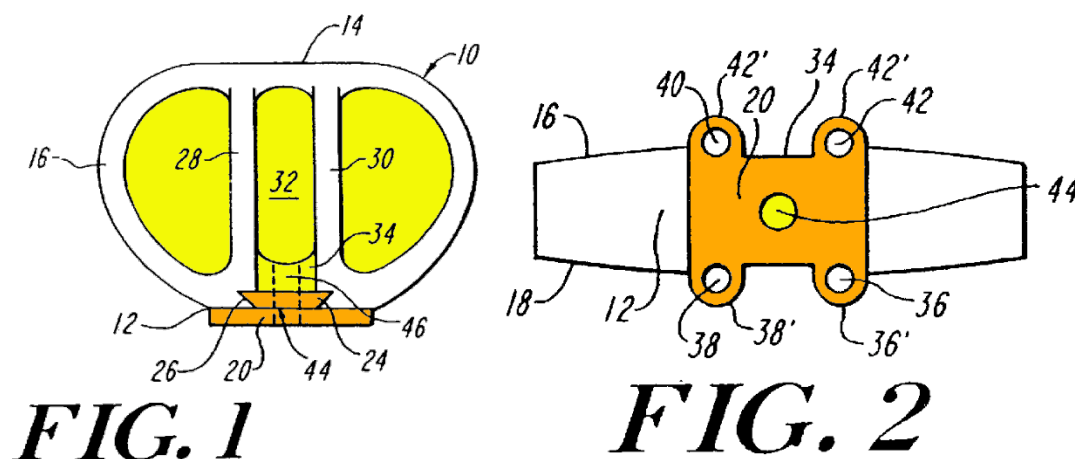
Fraser '106, Ex.1007, Fig.8

b. *Base plate distinct from a separate spacer (i.e., two-piece implant)*

Fraser '106 also discloses a two-piece embodiment (a base plate distinct from a spacer) where the plate 20 and body 10 are not bonded.

In this embodiment, Fraser '106 discloses that the base plate retains bone graft material as required by the claim. Specifically, Fraser '106 teaches “the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to

promote fusion.” Ex.1007, 4:37-42; *see* Ex.1005, ¶185. This area includes the tool “guide path,” which “is between the transverse elements in the space numbered 32” and “can further include a notch or depression 34.” Figures 1 and 2, below, shows the area where bone graft material (yellow) can be retained within the body 10 of Fraser ’106, including within notch or depression 34:



Fraser ’106, Ex.1007, Figs. 1 and 2

Therefore, Fraser ’106 discloses “for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies.”

4. Element 35[c] – and for permitting force transmission between the first and second bone bodies through the bone graft material

Fraser ’106 discloses this limitation because the cavity between the bones is occupied by the implant, which then engages with each bone. Specifically, Fraser ’106 teaches that “[t]he profile and slightly bowed or convex superior and inferior surfaces of **the fusion cage body** closely approximate the shape of a natural disk

and **provide an excellent, stable, load-bearing surface.**” Ex.1007, 4:48-54; *see* Ex.1005, ¶187. Fraser ’106 further discloses that “the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion.” Ex.1007, 4:37-42; *see* Ex.1005, ¶188.

A POSITA would understand that after the Fraser ’106 implant is filled with bone graft material and subsequently inserted between the surfaces of the vertebrae, the vertebrae would be in direct contact with the bone graft material. Ex.1005, ¶¶188-189. A POSITA would further understand that when the bone screws engage each of the vertebral bodies, those screws would place a compressive load on the bone graft material and promote fusion between the bones. *Id.* These compressive loads would be further enhanced when individual that receives the implant is upright and active. As such, a POSITA would understand that Fraser ’106 discloses that the base plate shares weight with bone graft material for fusion. *Id.*

As such, Fraser ’106 discloses “permitting force transmission between the first and second bone bodies through the bone graft material.”

5. Element 35[d] – the base plate being sized to have an inter-fit between the first and second adjacent bone bodies and adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material

Fraser '106 discloses this limitation and both of these features.

a. the base plate being sized to have an inter-fit between the first and second adjacent bone bodies

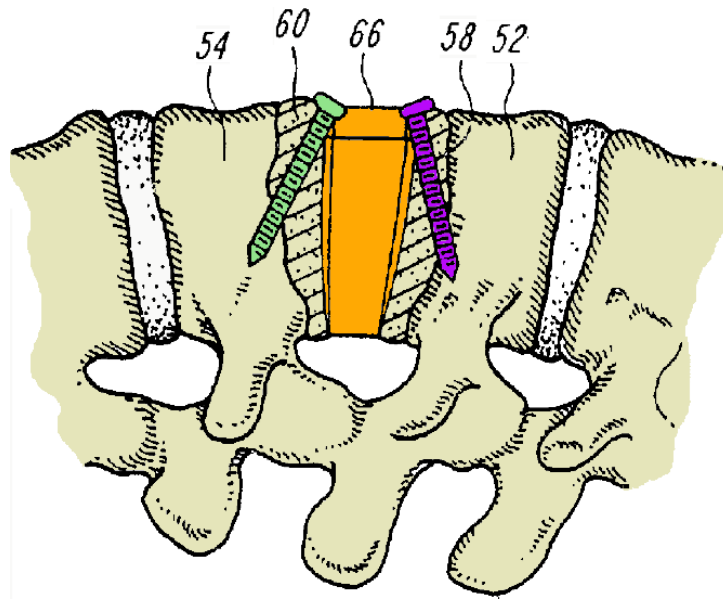
With respect to the first feature, as discussed above in Section VII, incorporated here, the term “sized to have an inter-fit between” (the first and second adjacent bone bodies)” means “sized to fit completely in between the first and second adjacent bone bodies to allow partial sharing of the weight of the bone bodies across the bone graft site.”

With respect to the disclosures in Fraser '106, “[t]he cage includes **a body 10 that approximates the shape and size of the annulus portion of a disk** which normally separates two vertebral bodies.” Ex.1007, 2:21-23; *see* Ex.1005, ¶194.

The specification also discloses that “[t]he **profile and slightly bowed or convex superior and inferior surfaces of the fusion cage body closely approximate the shape of a natural disk** and provide an excellent, stable, load-bearing surface.”

Ex.1007, 4:48-52; *see* Ex.1005, ¶194. Thus, Fraser '106 discloses that the shape of the implant is designed to fit in the cavity between the bones that was previously occupied by the disk. As shown in Figure 8, this allows the implant to fit completely in between the first and second adjacent bone bodies without extending

beyond the perimeter of the bones or covering any portion of the anterior surface of the bones.



Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses “the base plate being sized to have an inter-fit between the first and second adjacent bone bodies.”

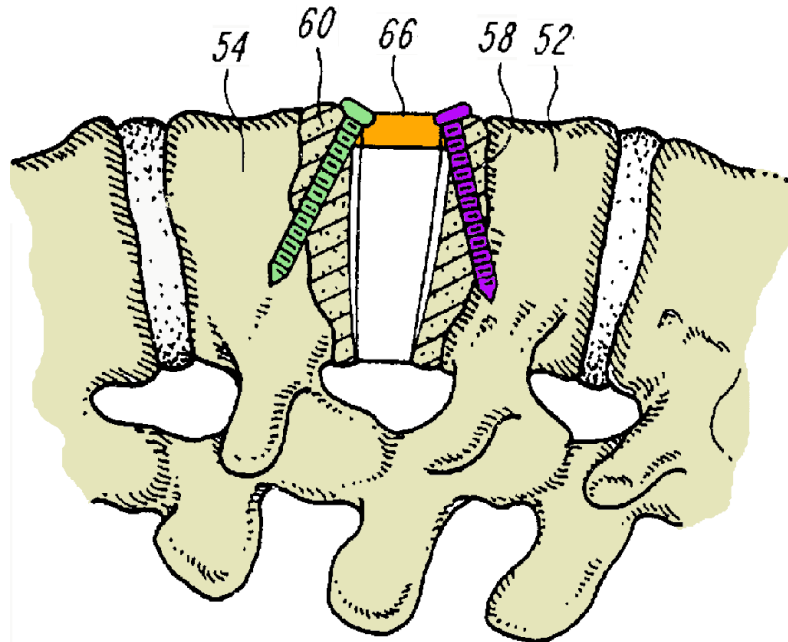
- b. the base plate...being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material*

Regarding the second feature, the base plate being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material, Fraser '106 teaches that bone graft can be filled with fusion promoting substances. Specifically, Fraser '106 discloses that “the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote

fusion.” Ex.1007, 4:37-42; *see* Ex.1005, ¶197. A POSITA would understand that when the Fraser ’106 implant engages the surfaces of the vertebrae, the first and second bone bodies would be in direct contact with the bone graft material. Ex.1005, ¶197. As such, a POSITA would understand that Fraser ’106 discloses that the first and second bone bodies engage the bone graft material. *Id.*

- (1) Base plate distinct from a separate spacer (*i.e.*, two-piece implant)

With respect to Fraser ’106 two-piece embodiment, Fraser ’106 also discloses this limitation. As shown in Figure 8, below, the Fraser ’106 two-piece embodiment discloses the base plate (orange) being sized to have an inter-fit between the first and second adjacent bone bodies.



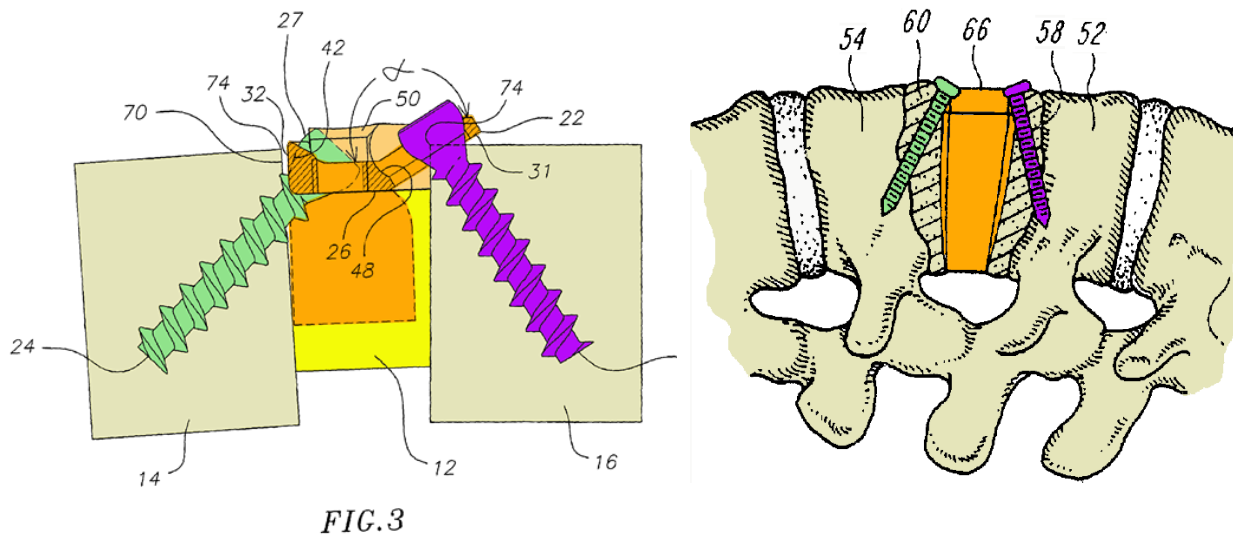
Fraser ’106, Ex.1007, Fig.8

For the same reasons discussed above with respect to the single-piece embodiment, Fraser '106 teaches the remaining claim elements with respect to the two-piece embodiment.

Therefore, Fraser '106 discloses “the base plate...being adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material.”

6. Element 35[e] – and at least first and second bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies

As shown by the side-by-side figures, below, Fraser '106 discloses first (green) and second (purple) bone screws for extending into the first and second bone bodies, respectively, to retain the base plate (orange) between the first and second bone bodies in the same way that the '234 patent depicts this element.



'234 patent, Ex.1001, Fig.3

Fraser '106, Ex.1007, Fig.8

Fraser '106 further teaches that “the plate is configured to receive, retain and orient **bone screws, thereby holding the fusion cage and adjacent vertebral bodies in a stable relationship to promote fusion.**” Ex.1007, 1:40-43; *see* Ex.1005, ¶202.

As such, Fraser '106 discloses “at least first [green] and second [purple] bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies.”

7. Element 35[f] – the base plate having means for interacting with the first and second bone screws

Fraser '106 discloses this limitation. As discussed above in Section VII, incorporated here, the claimed function is “interacting with the first and second bone screws,” and the corresponding structure is “a portion of the base plate 20 with circular bone screw holes 42 and a bone screw slot 48” and equivalents thereof.

Fraser '106 discloses **bone screw holes 36, 38, 40 and, 42**, Ex.1007, 3:7-12; *see* Ex.1005, ¶205, that meet the function of interacting with the bone screws as depicted below.

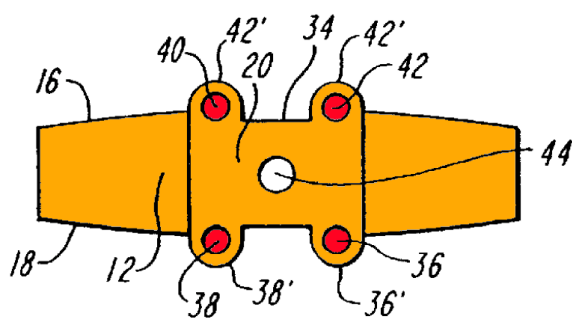
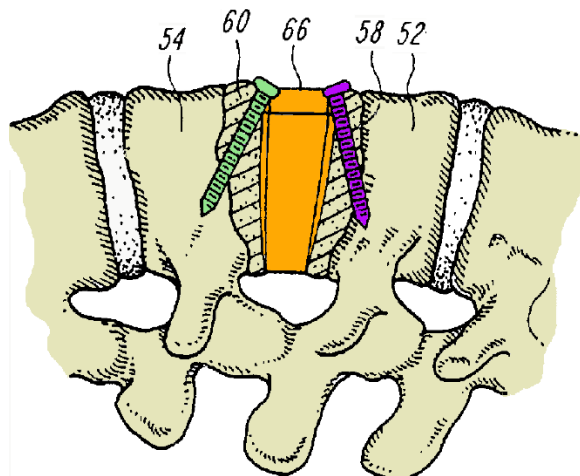


FIG. 2

Fraser '106, Ex.1007, Fig.2



Fraser '106, Ex.1007, Fig.8

Fraser does not explicitly disclose a slot because holes 36, 38, 40, and 42 are not slots. As discussed below in more detail, however, a POSITA would be motivated to use a slot.

Therefore, Fraser '106 discloses a “base plate having means for interacting [holes 36, 38, 40 and 42] with the first and second bone screws [46 and 48].

8. Element 35[g] – the means for interacting including means for permitting movement of at least one of the first and second bone bodies relative to the base plate.

As discussed above in Section VII, incorporated here, the function is “permitting movement of at least one of the first and second bone bodies relative to the base plate,” and the structure is “the bone screw slot 430” and equivalents thereof. See Ex.1001, 4:31-5:9, 5:53-6:9, 7:36-54, 12:21-31. Fraser '106 in view of Michelson '045 meets this limitation.

Fraser 106 discloses an implant with bone screws and “a plurality of fins extending outward from the fusion cage on one of the superior face and the inferior

face.” Ex.1007, cl. 18. These fins allow the bones to settle after implantation as the spine compresses. *Id.* at 3:47-52. However, in Fraser ’106, when the bones settle the disclosed locking screws, *see* figures 1-3, don’t allow relative motion between the screws and the base plate because the bones and screws cannot move relative to each other. To address this issue, a POSITA would have known to modify (or replace) the locking screw holes disclosed in figure 2 with another known structure that allows bones to settle in the inferior direction (*i.e.*, in the downward vertical direction of the spine). Ex.1005, ¶208. One such structure that permits this movement is a vertical slot. A POSITA could modify the holes in Fraser ’106 by expanding the height of the holes to create slots, as depicted below. Ex.1005, ¶208.

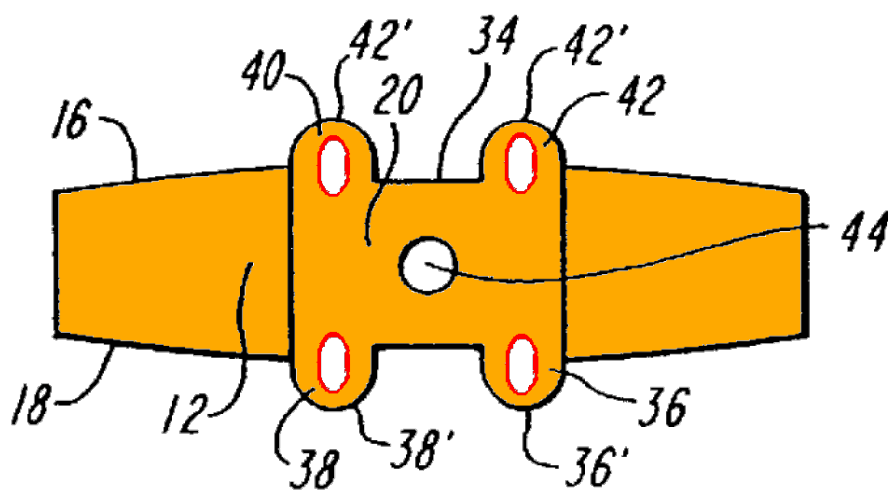


FIG. 2

Fraser '106, Ex.1007, Fig.2 (modified with slots)

A POSITA would be motivated to modify or replace holes with slots for the same reasons as discussed above in Section VIII.A.8. Specifically, a POSITA would be motivated to modify (or replace) the bone screw holes in Fraser '106 with a bone screw slot because a slot prevents movement of the bone laterally (*i.e.*, side-to-side), and permits movement in the superior/inferior direction (*i.e.*, up/down the spine). Ex.1005, ¶115. With respect to the top bone, a POSITA would also understand that inferior movement along a slot would promote fusion, ensuring contact between the bone graft material and the endplates of the adjacent vertebral bodies. In contrast, lateral movement could hinder fusion of the bone by introducing shear between the bone graft material and the bone, which would cause wear and potentially improper fusion.

As described above, Fraser '106 in view of Michelson '045 renders obvious each and every limitation recited by independent claim 35 of the '234 patent and this claim is unpatentable.

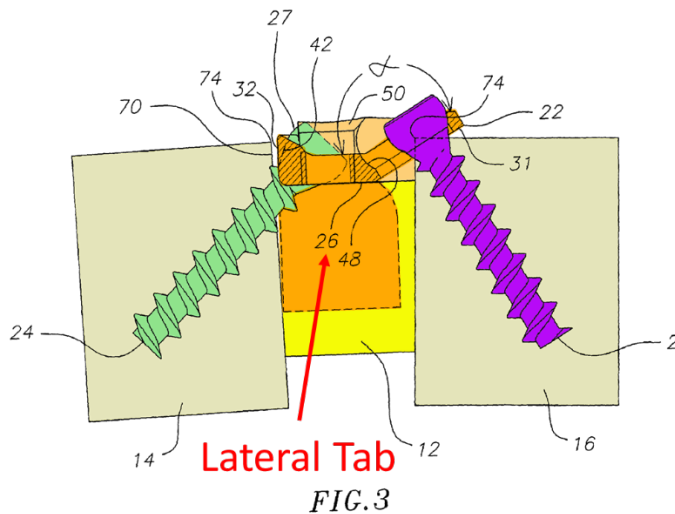
B. Claim 37 – Lateral tabs

Claim 37 depends from independent claim 35. All the limitations of claim 35, discussed above and incorporated here, are disclosed by Fraser '106.

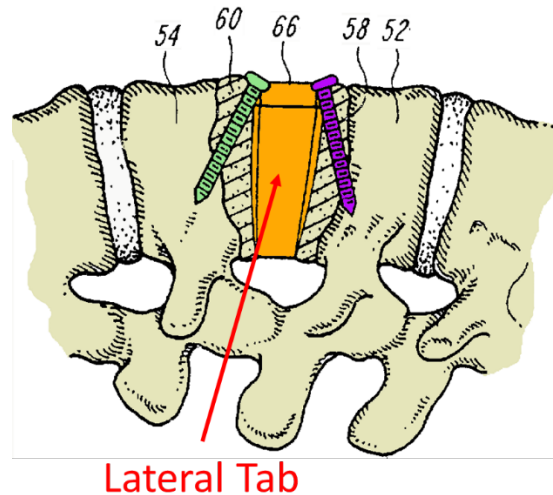
Fraser '106 discloses this claim and both of these features. Ex.1005, ¶¶212-213.

1. Element 37[a] – the base plate includes two lateral tabs for location between the first and second adjacent bone bodies

With respect to the two lateral tabs, as shown by the side-by-side figures, below, like the '234 patent, Fraser '106 discloses the base plate includes two lateral tabs configured for location between the first and second adjacent bone bodies.

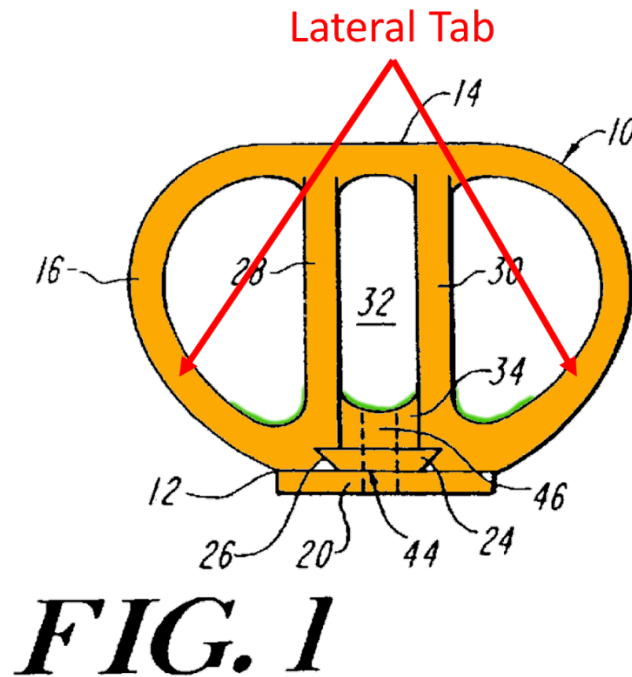


'234 patent, Ex.1001, Fig.3



Fraser '106, Ex.1007, Fig.8

Furthermore, as shown in figure 1, Fraser '106 discloses two lateral tabs that extend from opposite ends of the bottom surface (green) of the base plate.



Fraser '106, Ex.1007, Fig.1

Therefore, Fraser '106 discloses “the base plate includes two lateral tabs for location between the first and second adjacent bone bodies.”

2. **Element 37[b] – the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space of the base plate for location of the bone graft material therein**

Fraser '106 teaches that “the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion.” Ex.1007, 4:37-42; *see* Ex.1005, ¶217. Figure 1, above, shows the area where bone graft material (yellow) can be retained within the body 10 of Fraser '106 between the lateral tabs.

Therefore, Fraser '106 discloses “the lateral tabs are spaced apart from each

other such that ends of the lateral tabs provide for an open space of the base plate for location of the bone graft material therein.”

Therefore, as described above, Fraser ’106 discloses this claim limitation “the base plate includes two lateral tabs for location between the first and second adjacent bone bodies, the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space [windows or slots 424 and central hollow chamber 426] of the base plate for location of the bone graft material therein.”

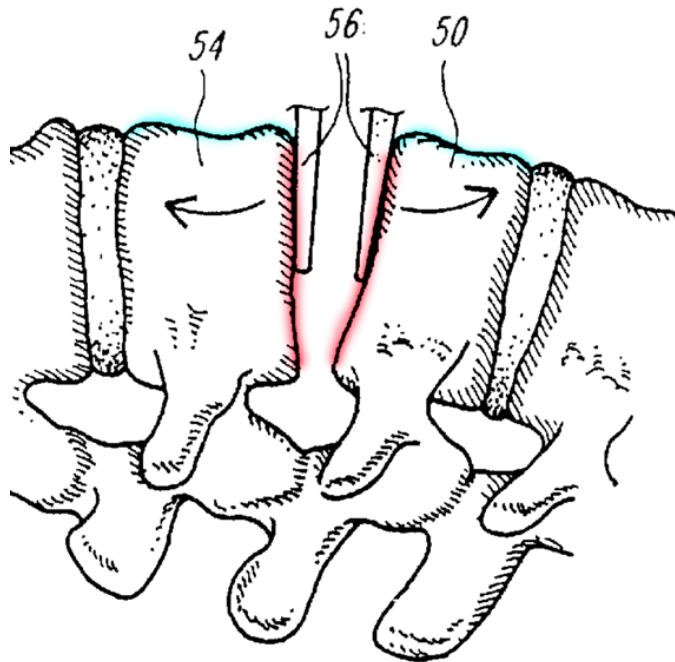
C. Claim 39

Claim 39 depends from independent claim 35. All the limitations of claim 35, discussed above and incorporated here, are disclosed by Fraser ’106.

1. Element 39[a] – wherein each of the bone bodies has an outwardly-facing surface and each of the bone bodies has a side surface facing toward the side surface of the other bone body

As an initial matter, this limitation merely describes the natural configuration of a vertebral bone. The ’234 patent specification explains that “[t]he spinal column comprises **a series of vertebrae stacked on top of each other**” and that “[e]ach vertebra has a cylindrical shaped vertebral body in the anterior portion of the spine with an arch of bone to the posterior which covers the neural structures.” Ex.1001, 1: 16-17, 22-24. As such, this limitation is known in the art.

Additionally, Fraser '106 discloses this limitation, as do all human vertebral bones. Specifically, Fraser '106 is directed toward “medical devices, and more particularly to an implantable structure for promoting fusion of **adjacent vertebral bodies.**” Ex.1007, 1:14-16; *see* Ex.1005, ¶222. With reference to figure 7, Fraser '106 discloses two adjacent vertebral bodies having top surfaces (identified in blue) and each vertebral body having a side surface (identified in red) facing toward the side surface of the other vertebral body.



Fraser '106, Ex.1007, Fig.7

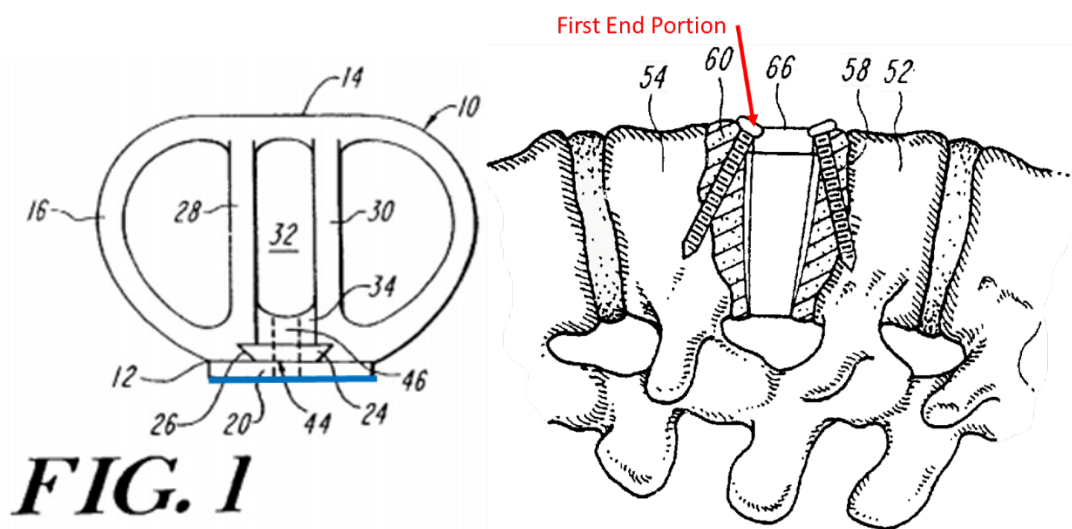
Therefore, Fraser '106 discloses “wherein each of the bone bodies [50 and 54] has an outwardly-facing surface [blue] and each of the bone bodies has a side surface [red] facing toward the side surface of the other bone body.”

2. **Element 39[b] – the base plate having a first end portion adjacent to the first bone body, the first end portion having an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body**

Fraser '106 discloses this limitation and all three of these features.

- a. *the base plate having a first end portion adjacent to the first bone body the first end portion having an outwardly-facing surface*

As shown in figures 1 and 8, below, Fraser '106 discloses that the base plate has a first end portion adjacent to the first bone body, and that this first end portion has an outwardly-facing surface.



Fraser '106, Ex.1007, Figs. 1 and 8

Therefore, Fraser '106 discloses “the base plate having a first end portion [blue edge] adjacent to the first bone body [52], the first end portion having an outwardly-facing surface.”

- b. for location at a position recessed relative to the outwardly-facing surface of the first bone body*

Regarding the last feature, the first end recessed relative to the outwardly-facing surface of the first bone, Fraser '106 teaches that “[t]he cage includes a **body 10 that approximates the shape and size of the annulus portion of a disk** which normally separates two vertebral bodies.” Ex.1007, 2:21-23; *see* Ex.1005, ¶¶227-229. The specification also discloses that “[t]he **profile and slightly bowed or convex superior and inferior surfaces of the fusion cage body closely approximate the shape of a natural disk** and provide an excellent, stable, load-bearing surface.” Ex.1007, 4:48-52; *see* Ex.1005, ¶¶227-229. Furthermore, Fraser '106 fits between and attaches to the superior and inferior surfaces of the bones. Fraser '106 explicitly teaches that it is important for the implant to sit flush with, or recessed from, the anterior surface of the vertebrae. Ex.1007, 4:16-19 (“[i]t is important to note that screw heads 62 and 64 are **flush or sub-flush with the anterior face surface 66 of the fusion cage, thus minimizing the likelihood that major blood vessels running along the spine will be injured.**”); *see* Ex.1005, ¶¶227-229. Thus, Fraser '106 discloses that the shape of the implant is designed to fit in the cavity between the bones that was previously occupied by the disk. A POSITA would understand that the implant of Fraser '106, being designed to fit in the cavity between the bones, would be recessed relative to the outwardly-facing surface of the first bone. Ex.1005, ¶¶227-229.

Therefore, Fraser '106 discloses “an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body.”

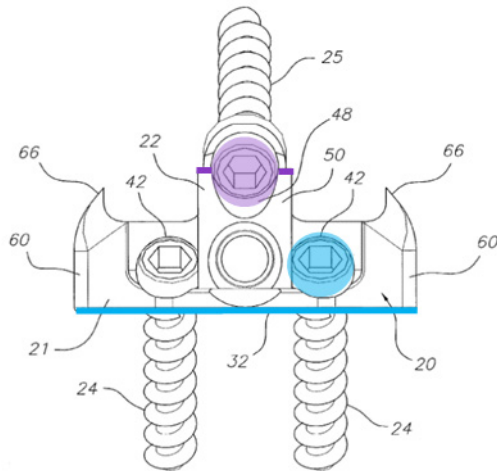
For these reasons, Fraser '106 discloses “the base plate having a first end portion [blue edge] adjacent to the first bone body, the first end portion having an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body.”

3. Element 39[c] – the first end portion having a first screw hole that opens toward the side surface of the first bone body, the base plate having a second end portion that has a second screw hole that opens toward the second bone body

Fraser '106 discloses this limitation and both of these features.

- a. the first end portion having a first screw hole...the base plate having a second end portion that has a second screw hole*

As shown in the side-by-side comparison figures, below, like the '234 patent, Fraser '106 discloses its base plate has first (blue) and second (purple) bone screw holes (modified into slots as described in claim 35 above) at the first (blue) and second ends (purple). This term is directed to a hole, which refers to a broad category of apertures, including a slot. As such, the slots of claim 35 meet the hole limitation of this claim.



'234 patent, Ex.1001, Fig.4

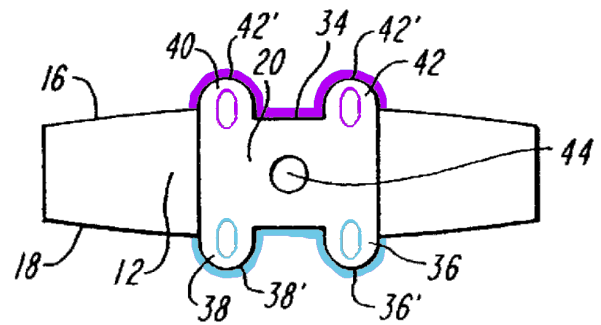


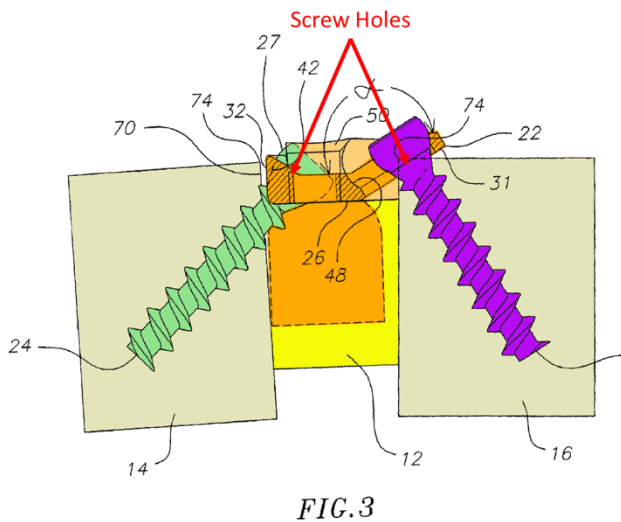
FIG. 2

Fraser '106, Ex.1007, Fig.2

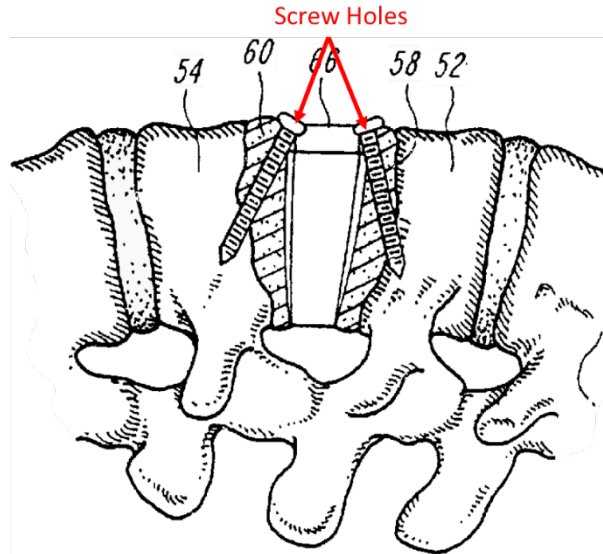
Therefore, Fraser '106 discloses “the first end portion [blue edge] having a first screw hole [36 and 38 highlighted blue]...the base plate having a second end portion [purple edge] that has a second screw hole [40 and 42 highlighted purple].”

- b. a first screw hole that opens toward the side surface of the first bone body...a second screw hole that opens toward the second bone body*

With respect to the second feature, as shown in the side-by-side figures, below, like the '234 patent, Fraser '106 depicts the first and second screw holes (as slots) open towards the side surfaces of the first and second bone bodies, respectively.



'234 patent, Ex.1001, Fig.3



Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses “a first screw hole that opens toward the side surface of the first bone body...a second screw hole that opens toward the second bone body.”

4. **Element 39[d] – the first and second bone screws extending through the first and second holes into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.**

As shown by the side-by-side figures, below, like the '234 patent, Fraser '106 discloses the first (green) and second (purple) bone screws extending through the first and second holes (as slots) into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.

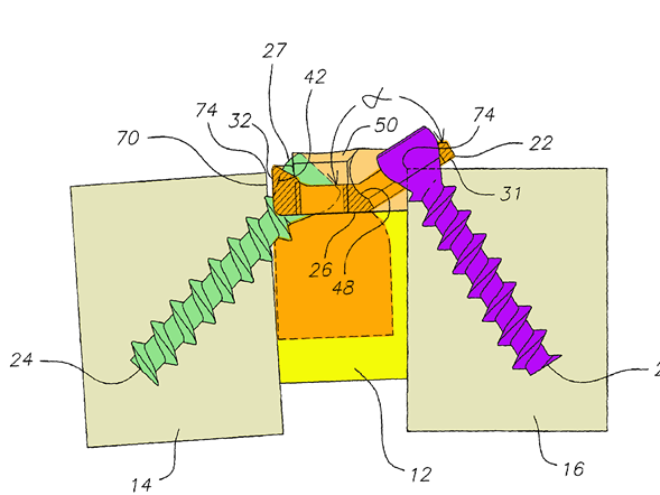
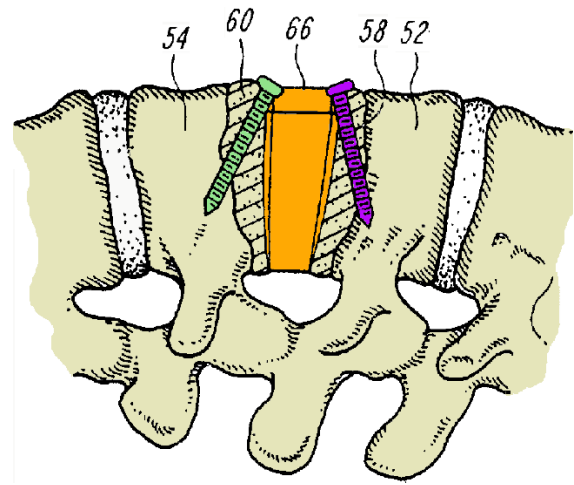


FIG. 3

'234 patent, Ex.1001, Fig.3



Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses this claim limitation.

As described above, Fraser '106 in view of Michelson '045 renders obvious each and every limitation recited by independent claim 39 of the '234 patent and this claim is unpatentable.

A. Reasons and Motivations to Combine Fraser '106 in view of Michelson '045

As Mr. Sherman explains in his declaration, a POSITA would have been motivated to combine Fraser '106 and Michelson '045 for several reasons. *See* Ex.1005, ¶¶233-244.

- 1. A POSITA would have considered both Fraser '106 and Michelson '045 because they are analogous art**

Fraser '106 and Michelson '045 are both analogous art to the alleged

invention claimed in the '234 patent because they are in the same field of endeavor. *In re Bigio*, 381 F.3d at 1325. The '234 patent defines its “Technical Field” as “implant devices for the fixation and support of bone bodies” Ex.1001, 1:32-33. Just like the '234 patent, Fraser '106 and Michelson '045 are directed to a spinal implant device for fixation and support of vertebrae. Ex.1007, Abstract (“A spinal fixation assembly”), 1:36-38; Ex.1006, Abstract (“an interbody spinal fusing implant (100)...to permit for the growth of bone from vertebral body to adjacent vertebral body through the implant.”), 2. Fraser '106 and Michelson '045 are also in the same field of endeavor as (and thus analogous to) the alleged invention claimed in the '234 patent because they each disclose ways to prevent the bone screws from backing out. *Compare* Ex.1001 *with* Ex.1006-7; Ex.1005, ¶¶234-239.

Fraser '106 and Michelson '045 are also analogous to alleged invention claimed in the '234 patent because they are reasonably pertinent to the technical problem allegedly addressed by the claimed invention. *In re Bigio*, 381 F.3d at 1325. According to the '234 patent, the problem is providing an implant that supports adjacent vertebrae for fusion without damaging the spinal cord or adjacent tissue. Ex.1001. Fraser '106 discloses an implant that sits “flush or sub-flush...thus minimizing the likelihood that major blood vessels running along the spine will be injured.” Ex.1007, 2:21-23, 4:16-19. Michelson '045 discloses that nothing should sit on the anterior surface of the vertebrae because that could cause

ruptured blood vessels or death. Ex.1006, 4 and 16; Ex.1005, ¶¶234-239.

2. The combination of Fraser '106 and Michelson '045 merely involves the simple substitution of one known element for another

A POSITA would have combined Fraser '106 and Michelson '045 because the combination merely involves the simple substitution of one known element (*i.e.*, the Fraser '106 locking screw) for another (*i.e.*, the Michelson '045 toggle screw with locking plate). Fraser '106 teaches that exposed screws can cause significant harm to a patient. *See also* Ex.1004, 4:16-19; Ex.1005, ¶240. A POSITA would have recognized that the Michelson '045 toggle screw with locking plate was a known anti-back out device that could be substituted for the locking screws disclosed in Fraser '106. Ex.1005, ¶240.

3. A POSITA would have wanted to modify Fraser '106 with the teachings of Michelson '045

A POSITA would have considered the Fraser '106 implant and been motivated to the useful features that existed in other prior art implants, like the anti-back out mechanism disclosed in Michelson '045. Ex.1005, ¶¶241-244. Michelson '045 discloses using a screw anti-back out system with standard bone screws to compensate for settling of the bones after implantation. A POSITA would have recognized that using toggle screws to permit the bones to settle was advantageous, so long as there was an anti-back out mechanism. Ex.1005, ¶¶241-244. A POSITA would have recognized that the anti-back out plates are easy to

use and implement in a variety of implant designs. *Id.* Further, Fraser '106 does not disclose any structure that would preclude or interfere with an anti-back out plate. *Id.* The result of this simple modification to Fraser '106 would have yielded predictable and successful result—namely, a spinal implant with an anti-back out plate that can securely hold bone screws in place but still enable the bone to settle subsequent to implantation. *Id.*

Therefore, Fraser '106 in view of Michelson '045 renders at least claims 35, 37 and 39 of the '234 patent obvious.

X. CONCLUSION

Trial should be instituted and the Challenged Claims should be cancelled as unpatentable.

Dated: December 13, 2019

Respectfully Submitted,

/ Dion M Bregman /
Dion M. Bregman, Reg. No. 45,645

U.S. PATENT NO. 6,984,234 – Listing of Challenged Claims

No.	Claim Elements
35[Preamble]	A bone stabilization plate system including
35[a]	a base plate
35[b]	for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies
35[c]	and for permitting force transmission between the first and second bone bodies through the bone graft material
35[d]	the base plate being sized to have an inter-fit between the first and second adjacent bone bodies and adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material
35[e]	and at least first and second bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies
35[f]	the base plate having means for interacting with the first and second bone screws
35[g]	the means for interacting including means for permitting movement of at least one of the first and second bone bodies relative to the base plate.
37[Preamble]	The bone stabilization plate system according to claim 35,
37[a]	wherein the base plate includes two lateral tabs for location between the first and second adjacent bone bodies
37[b]	the lateral tabs are spaced apart from each other such that ends of the lateral tabs provide for an open space of the base plate for location of the bone graft material therein
39[Preamble]	The bone stabilization plate system according to claim 35,

No.	Claim Elements
39[a]	wherein each of the bone bodies has an outwardly-facing surface and each of the bone bodies has a side surface facing toward the side surface of the other bone body
39[b]	the base plate having a first end portion adjacent to the first bone body, the first end portion having an outwardly-facing surface for location at a position recessed relative to the outwardly-facing surface of the first bone body
39[c]	the first end portion having a first screw hole that opens toward the side surface of the first bone body, the base plate having a second end portion that has a second screw hole that opens toward the second bone body
39[d]	the first and second bone screws extending through the first and second holes into the first and second bone bodies, respectively, each at an angle that is non-orthogonal to the longitudinal alignment of the first and second bone bodies.

CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 13,990 words, as counted by Microsoft Word, and is therefore in compliance with the 14,000-word limit established by 37 C.F.R.

42.24(a)(1)(i). Accordingly, pursuant to 37 C.F.R. 42.24(d), lead counsel for the Petitioners hereby certifies that this Petition complies with the type-volume limits established for a petition requesting PGR.

Dated: December 13, 2019

Respectfully Submitted,

/ Dion M. Bregman /
Dion M. Bregman, Reg. No. 45,645

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. 42.6(4) and 42.105, lead counsel for Petitioners hereby certifies that on December 13, 2019, copies of this Petition, Power of Attorney, Petitioners' Ranking and Explanation for Two Petitions Challenging U.S. Patent No. 6,984,234, and all supporting exhibits were sent via Federal Express to the correspondence address of record for the '234 patent:

Ronald M. Kachmarik
COOPER LEGAL GROUP LLC
6505 Rockside Road, Suite 330
Independence, OH 44131

A courtesy copy of this Petition and supporting exhibits was also served via email on Patent Owner's counsel of record in the district court litigation:

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Petition for IPR of U.S. Patent No. 6,984,234
Case No. IPR2020-00265

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