UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

RSB SPINE, LLC,

Patent Owner.

Case No. IPR2020-00274

Patent No. 6,984,234

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,984,234 CHALLENGING CLAIMS 1-10, 13-14, 16, 18-20, 22, 24-25, 28-29, AND 31-32

TABLE OF CONTENTS

PETITIONERS' EXHIBIT LIST

Exhibit	Description
Ex.1001	U.S. Patent No. 6,984,234 to Bray ("the '234 patent")
Ex.1002	Reserved
Ex.1003	Patent Prosecution History of the '234 patent
Ex.1004	Reserved
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	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	Reserved
Ex.1015	*Dorland's Illustrated Medical Dictionary* (Anderson, Douglas, ed., The Curtis Center 2003) ("Dorlands Medical Dictionary")
Ex.1016	Reserved

Ex. 1017	Reserved
Ex. 1018	Reserved
Ex. 1019	Reserved

I. INTRODUCTION

Petitioners request *Inter Partes* Review ("IPR") of claims 1-10, 13-14, 16, 18-20, 22, 24-25, 28-29, 31, and 32 (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, LLC ("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, LLC*, 18-cv-1972 (D. Del.);
- *RSB Spine, LLC. v. Medacta USA, Inc.*, 18-cv-1973 (D. Del.);

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

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, 29, and 30 of the '537 patent; and
- IPR2020-00264 challenging claims 1, 3-6, 10, 12-15, 18, 19, 21, 22, 24, 29, and 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))

Lead Counsel for Petitioners	**Back-up Counsel for Petitioners**
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Please address all correspondence to lead and back-up counsel as shown above. Petitioner consents to electronic service by e-mail to all of the e-mail addresses provided. For 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.

Pursuant to 37 C.F.R. §42.103, Petitioners authorize the USPTO to charge/refund Deposit Account No. 19-0741 for the required fees as well as for any fee deficiencies and credit overpayments.

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 only, and reserve the right to challenge this date in the pending district court litigations.

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:

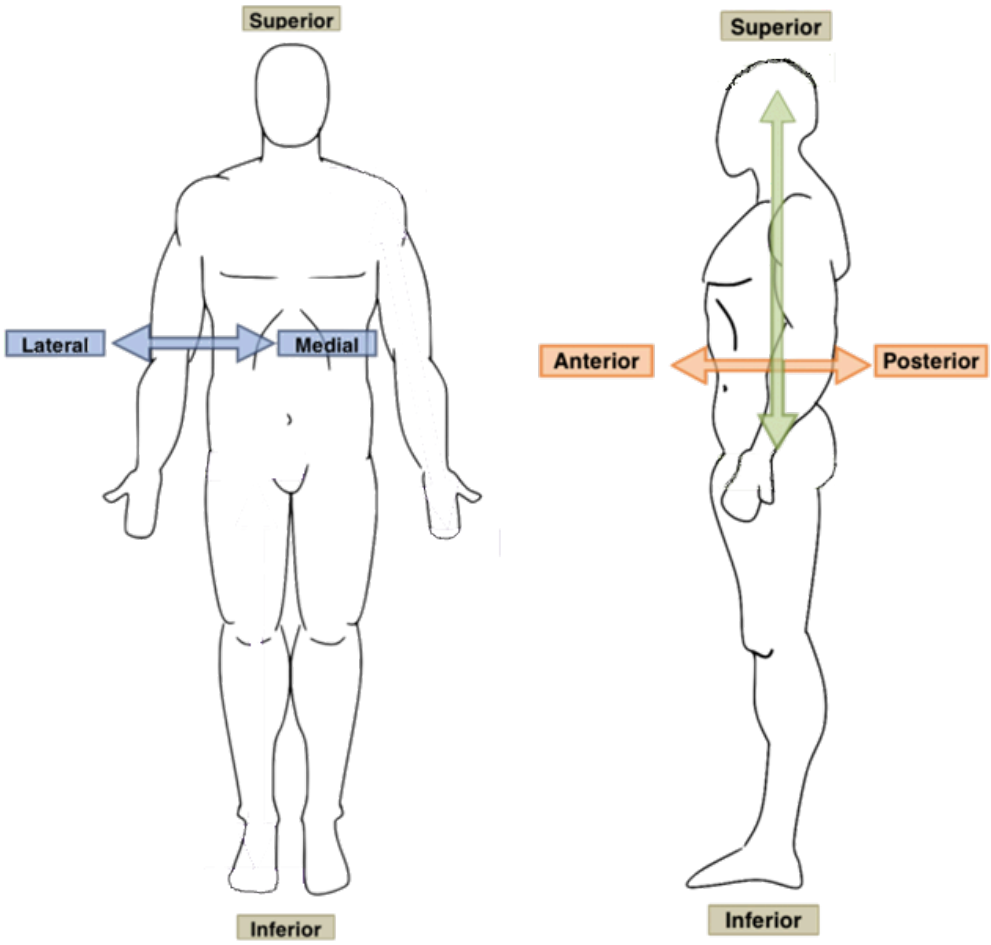
Ground	Statutory Basis and Art Cited	Claims
1	§103 – Obvious over Michelson '045	1-10, 13-14, 16, 18-20, 22, 24-25, 28-29, 31 and 32
2	§103 – Obvious over Michelson '045 in view of Fraser '106	2-8 and 16

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 at 1:6-10.

In human anatomy, anterior means “toward the belly surface of the body” and posterior means “towards the back surface of the body.” Ex.1015 at 97, 1494. Superior means “situated above, or directed upward” and inferior means “situated below, or directed downward. Ex.1015 at 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.

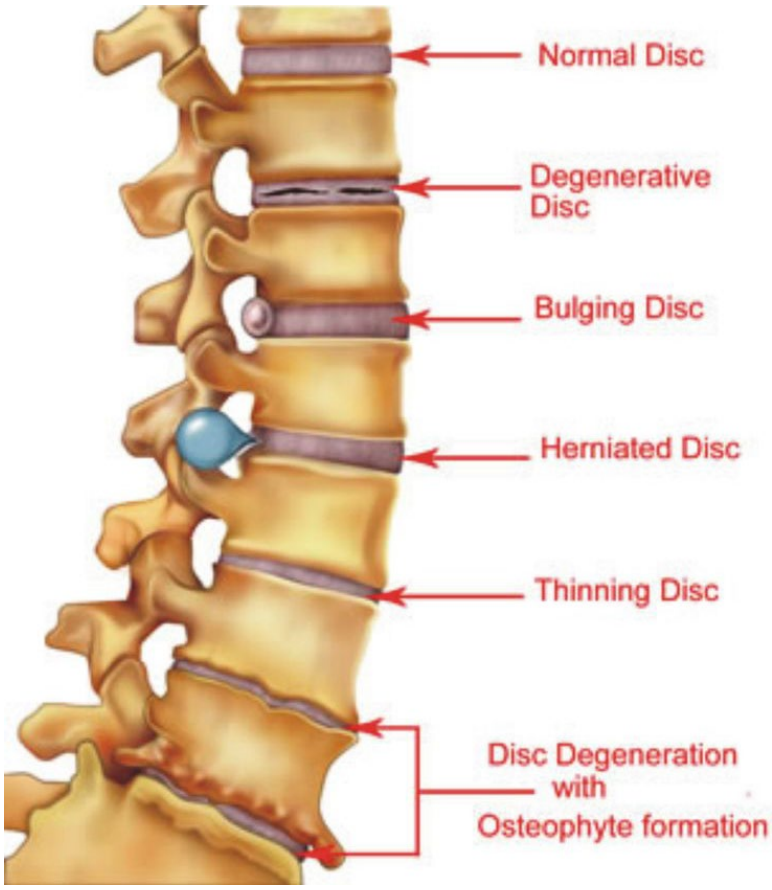


Ex.1005 at ¶25.

The '234 patent refers to "vertebral bones" found in the human spine. Ex.1001, 9:32-12:9. The '234 patent explains that "[t]he spinal column comprises a series of vertebrae stacked on top of each other" and that "[b]etween each vertebral body is an intervertebral disk, a cartilaginous cushion to help absorb impact and dampen compressive forces on the spine." Ex.1001 at 1:16-17, 22-24. 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 at 1:29-33.

Depicted below is a spine with a normal disc (at the top) as well as various degenerative spinal conditions:



Ex.1005 at ¶27.

To treat these degenerative conditions, the specification discloses that it was known to fuse the adjacent vertebrae together by "removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral

bodies together." Ex.1001 at 1:44-47. In addition, 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 at 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 an interbody plate that is integral with a spacer, (2) it is fixed to the lip osteophytes with bone screws, and (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 at 1:6-10; 1:56-5; and 2:6-36.

Specifically, Figure 1 of the ’234 patent, reproduced below, depicts one embodiment of the claimed base plate. Ex.1001 at 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 at 5:35-41. The base plate 20 (orange) also includes first bone screw 24 (green) and second bone screw 25 (purple) to retain the base plate between first adjacent vertebral body 14 and second adjacent vertebral body 16.

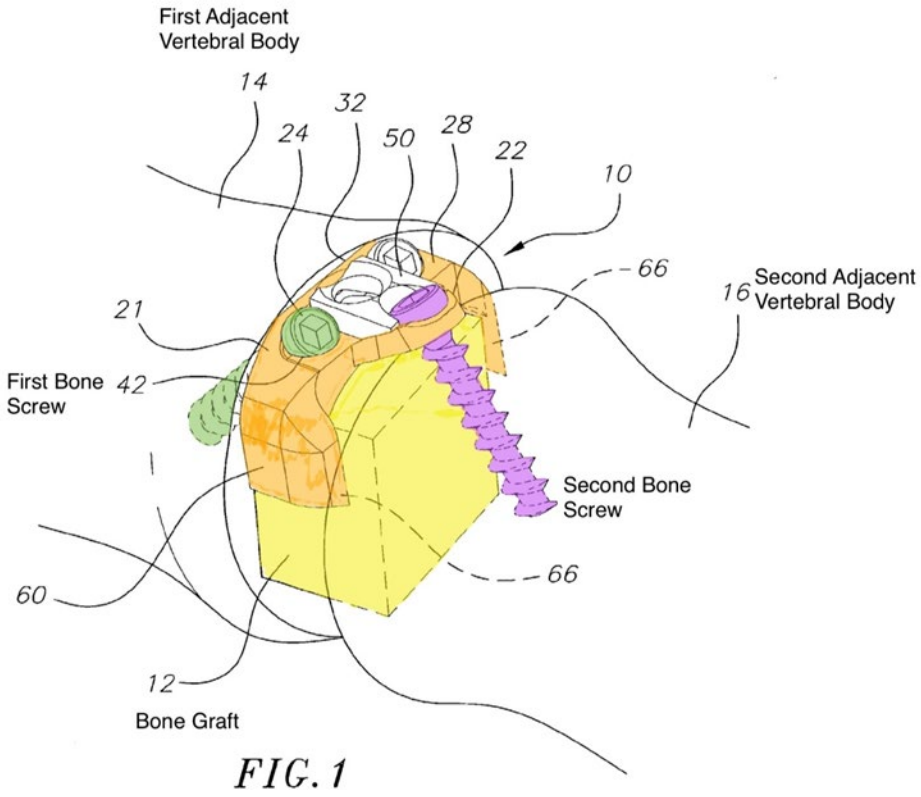
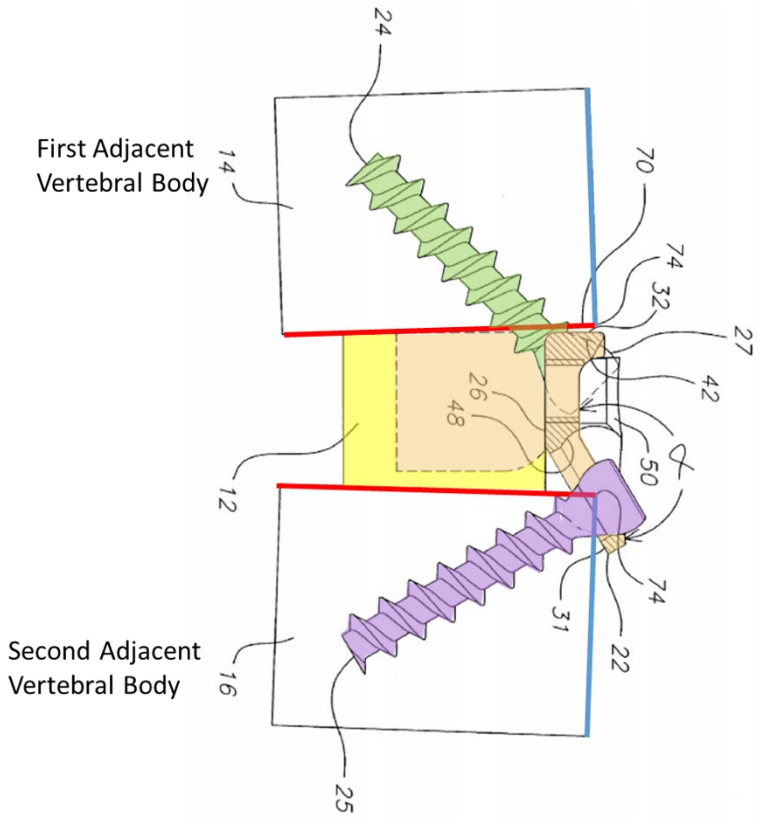


FIG. 1

The '234 Patent, Ex.1001, Fig. 1 (colorized, annotated)[2]

This embodiment is also depicted in Figure 3, reproduced below, and displays the outwardly-facing top surfaces (blue) and side surfaces (red) of each bone 14, 16. 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 first and second vertebral bodies, respectively, to retain the base plate between the bones.

[2] Annotations and color added throughout.



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") (Ex. 1013). A depiction of the Benzel device is below.

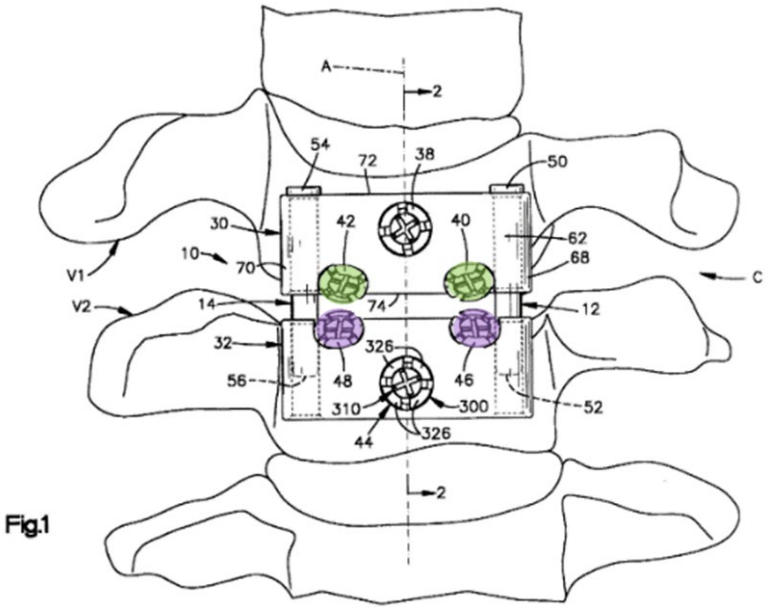


Fig.1

On August 18, 2005, the applicant argued that Benzel did not disclose the claimed base plate with "a *first* <u>*end*</u> *nearer the first bone* and a *second* <u>*end*</u> *nearer the second bone*, where in the base plate has a *first screw hole extending through the first* <u>*end*</u> and a *second screw hole extending through the second* <u>*end*</u> . . ." Ex.1003 at 97 (emphasis in original). Instead, the applicant 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 ***<u>fasteners 40 and 46 are provided through a middle portion of the plate, not at first and second ends</u>*** 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 at 97-98 (emphasis added).

Thus, according to the applicant, 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 at 99 (emphasis in original). Referring to figure 2 of LeHuec (reproduced below), the applicant 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 at 99 (emphasis added).

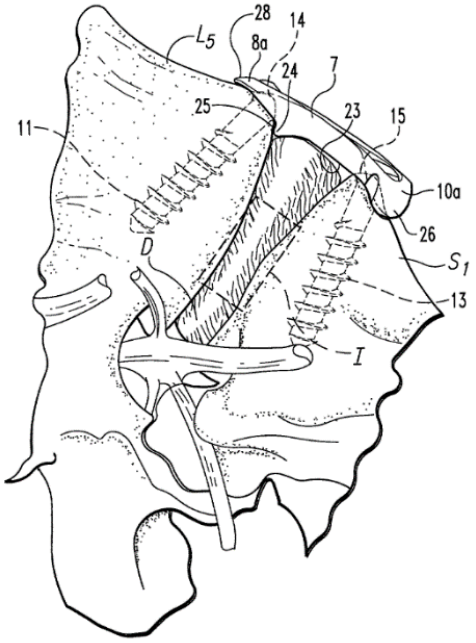


Fig. 2

Thus, according to the applicant, a base plate is not inter-fit if it has any portion that sits on the top (anterior) surfaces of the bones, and instead the base plate must be retained between the 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 5-10 years of experience designing and developing orthopedic implants and/or spinal

interbody devices. Ex.1005 at ¶22.

VII. CLAIM CONSTRUCTION

In the district court litigation, the parties are engaged in claim construction. On December 2, 2019, Patent Owner, Petitioners, and non-petitioners Xtant and DePuy exchanged their initial list of Proposed Claim Terms for Construction. Ex. 1009. 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. The parties are continuing to negotiate the scope of these proposed constructions. As such, the proposed constructions that the parties may rely on in district court are not finalized.

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.

A. "base plate"

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."

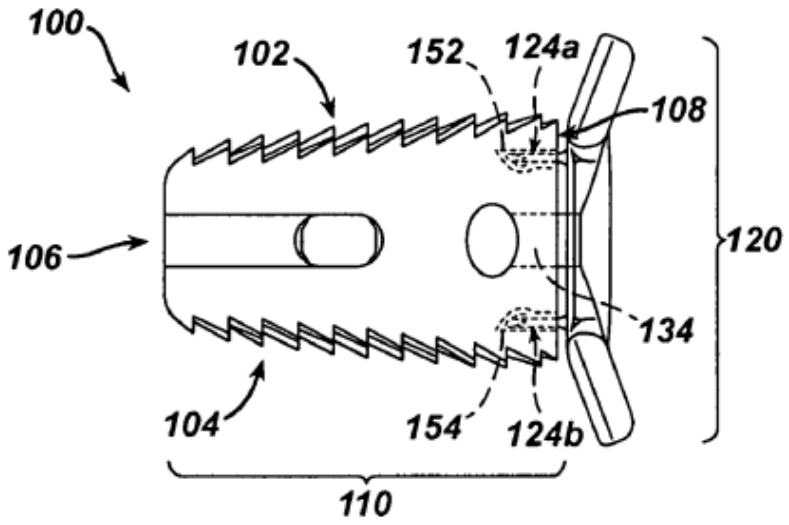
Patent Owner and Petitioners currently agree that a POSITA would understand the term "base plate" to include "a fixation plate to stabilize adjacent vertebrae for fusion" which is "distinct from bone graft material deployed across a bone graft site." Ex.1009.

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 a spacer.

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

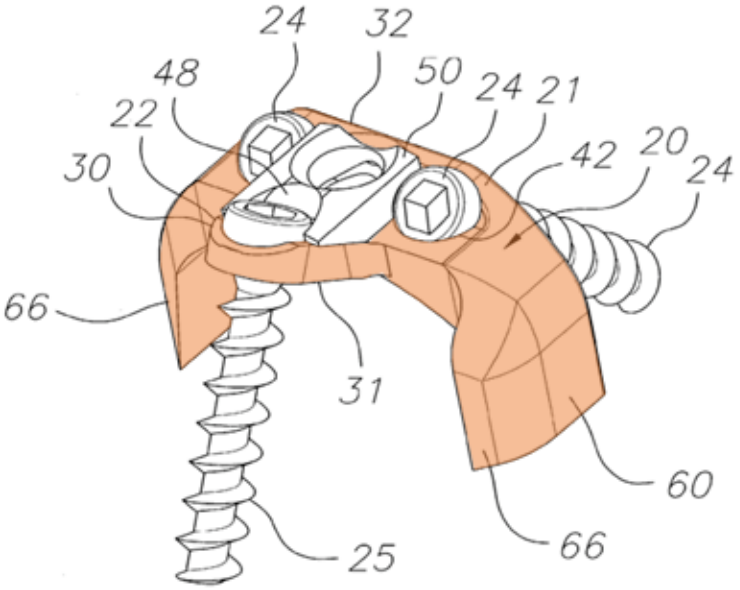
> **fusion cage 110 is load-bearing** between the two vertebral bodies. The plate 120, which is applied after the load-bearing fusion cage 110 is already in place, keeps the load-bearing fusion cage 110 in place. The **plate 120 is applied, again after the load-bearing fusion cage 110 is in place**,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

Ex. 1010 at 222 (emphasis added).



In response, the Examiner issued a notice of allowance over Fraser '222's two-piece plate and fusion cage implant. Ex.1010 at 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. The entire disclosure of the '234 patent is directed to a base plate 20 (orange) that includes an integrated spacer 60.



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

Patent Owner's attempt to exclude a spacer in their proposed construction is wrong. 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).

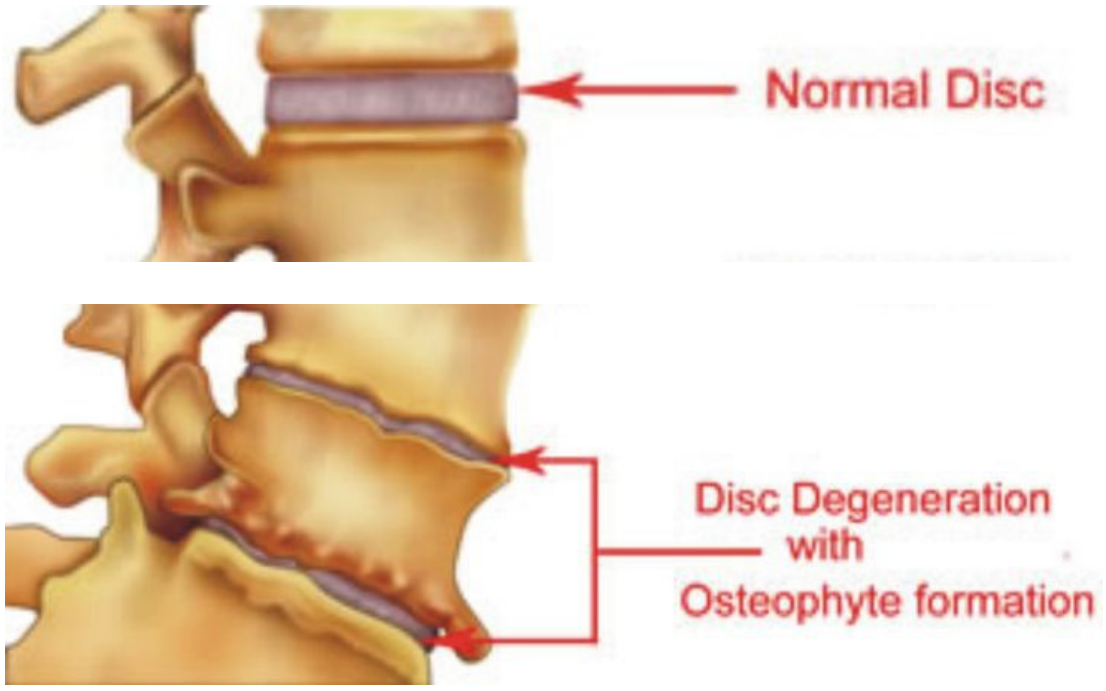
For at least these reasons, Petitioners' proposed construction is correct.

B. "lip osteophyte" / "lip osteophite"

"lip osteophyte" / "lip osteophite"	
Petitioners	**Patent Owner**
"bony out**growth** at the 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.1009.

The parties, however, currently disagree about whether a lip osteophyte is a growth at the anterior corner the bone, as proposed by Petitioners. As discussed above, in Section V, a healthy bone does not have any lip osteophytes. However, 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 at ¶27.



Ex.1005 at ¶27.

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

C. "bone screw retaining means" (Claim 22)

"bone screw retaining means"	
Petitioners	**Patent Owner**
§112, ¶ 6 limitation **Function**: "securedly covering at least a part of the [first, second, and/or third] bone screws to prevent the bone screws from backing out." **Structure**: "A single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws."	§112, ¶ 6 **Function:** "securedly covering at least a part of the [first, second, and/or third] bon screws to prevent the bone screws from backing out." **Structure:** "A single retaining plate, multiple retaining plates that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws, plus equivalents thereof."

Patent Owner and Petitioners currently agree that this term is governed by 112 ¶ 6. Ex. 1009. The parties also agree that the function requires the prevention of bone screws from packing out.

The parties currently disagree about whether the structure includes "a retaining plate and a set screw." The parties also disagree about whether the structure includes "equivalents." The '234 patent discloses a retaining plate and a set screw as a bone screw retaining means. Ex.1001 at 5:35-41; 6:10-3.

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

ARGUMENT

The Challenged Claims of the ’234 patent are unpatentable in view of the prior art references discussed herein. Each ground and the supporting reasons for the unpatentability of each Challenged Claim are discussed below.

VIII. GROUND #1: MICHELSON ’045 RENDERS INDEPENDENT CLAIMS 1, AND 22 AND DEPENDENT CLAIMS 2-10, 13-14, 16, 18-20, 24-25, 28-29, 31, AND 32 OBVIOUS

For the reasons stated below, at least independent claims 1, and 22, and dependent claims 2-10, 13-14, 16, 18-20, 24-25, 28-29, 31, and 32 of the ’234 patent are rendered obvious under 35 U.S.C. §103 by Michelson ’045.

A. Claim 1

1. A method for joining first and second bones having top surfaces and side surfaces generally facing each other, the method comprising:

The preamble is not a limitation of the claim because 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 this limitation. Ex.1005 at ¶57.

With respect to the ’234 patent, the specification explains that “[t]he spinal column comprises a series of vertebrae stacked on top of each other” and that “[b]etween each vertebral body is an intervertebral disk, a cartilaginous cushion to

help absorb impact and dampen compressive forces on the spine." Ex.1001 at 16-17, 22-24. The specification then admits that it was known to fuse the adjacent vertebrae together, Ex.1001 at 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 at 48-51.

Michelson '045 also discloses an "invention relate[d] generally to **interbody spinal fusion implants**." Ex.1006 at 2. For example, with reference to figure 24 (below), Michelson '045 discloses first and second bone bodies having top surfaces (blue) and side surfaces (red) facing each other. These bones are then fused together with the implant depicted in figure 24 (also below).

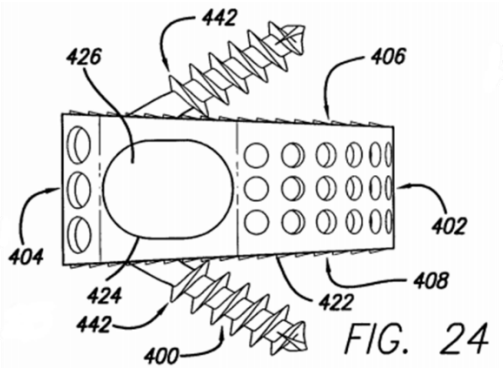
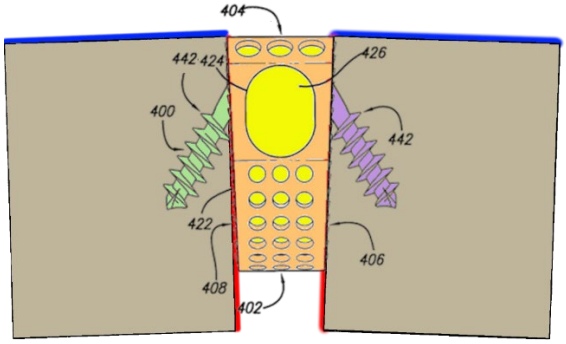


FIG. 24



Michelson '045, Ex.1006, Fig. 24

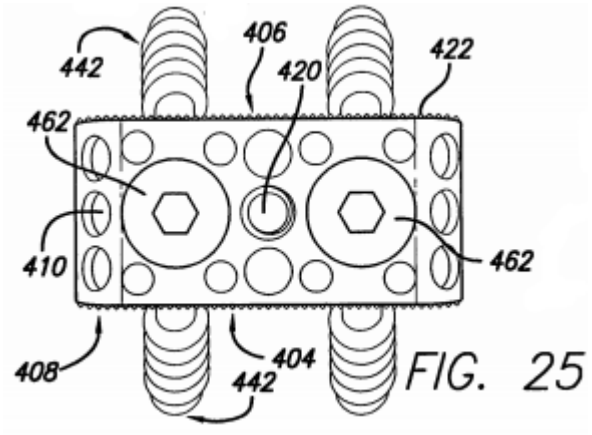
As such, the '234 patent admits that the limitation "[a] method for joining first and second bones having top surfaces and side surfaces generally facing each other" was known in the prior art, and Michelson '045 explicitly discloses this same limitation.

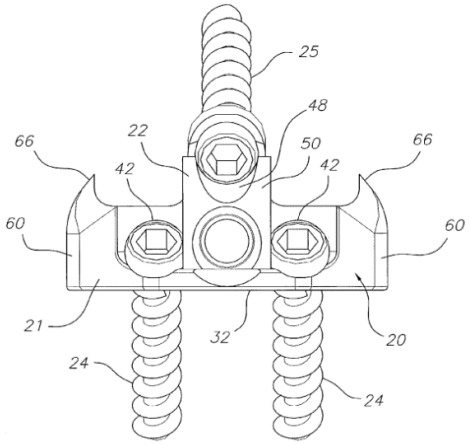
2. inserting between the side surfaces of the bones a base plate having a first end nearer the first bone and a second end nearer the second bone, wherein the base plate has a first screw hole extending through the first end and a second screw hole extending through the second end;

This limitation includes four features: (1) a base plate, (2) inserting the base plate between the bones, (3) a base plate with first and second ends near each bone, and (4) screw holes that extend though the base plate. Michelson '045 discloses this limitation and each of these four features. Ex.1005 at ¶62.

With respect to the base plate, as discussed in Section VII.A, 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.





Michelson '045, Ex.1006, Fig. 25 **'234 patent, Ex.1001, Fig. 4**

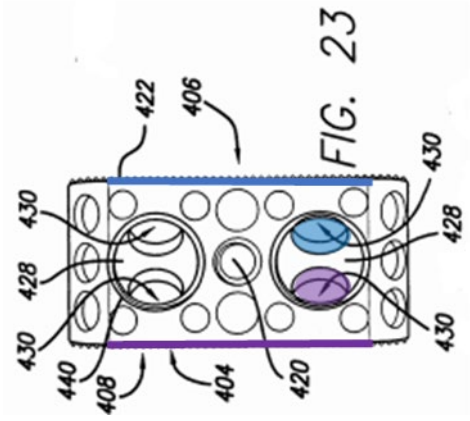
Michelson '045 further teaches that this implant is distinct from bone graft material and that it includes openings for insertion of separate bone graft material. Ex.1006 at 9; *see* Ex.1005 at ¶64.

Michelson '045 also explains that its implant is ***integrated*** with a load-bearing fusion cage— not used with a separate load-bearing fusion cage. As shown in the comparison above, like the '537 patent, the Michelson '045 implant is a single component and does not use a separate load-bearing fusion cage.

Therefore, Michelson '045 discloses the claimed base plate, as it is properly construed.

With respect to the second feature, inserting the base plate between the bones, Michelson '045 discloses a base plate that is placed between the bones, as opposed to other prior art implants that are attached to the anterior surface of the bones. Ex.1006 at 9; *see* Ex.1005 at ¶¶66. The cavity in-between the bones where the Michelson '045 device is implanted is depicted in figs. 24 and 25 above.

With respect to the third feature, a base plate with first and second ends near each bone, Michelson '045 describes that its base plate has upper and lower ends that conform to the respective bones and contact those bones. Ex.1005 at ¶67. A depiction of the Michelson '045 base plate with a first end (blue) nearer the first bone and a second end (purple) nearer the second bone is in figure 23 below. Figure 23 also depicts a first screw hole extending through the first end (blue) and a second screw hole extending through the second end (purple).



Michelson '045, Ex.1006, Fig. 23

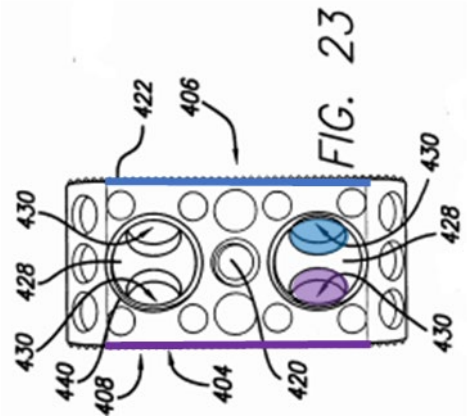
With respect to the fourth feature, screws that extend though the base plate and into each bone, Michelson '045 teaches that the base plate has several screw holes that allow a surgeon to insert bone screws to secure the base plate to each bone. Ex.1006 at 9, 17; *see* Ex.1005 at ¶68.

Therefore, as described above, Michelson '045 discloses this limitation.

3. introducing a first bone screw through the first screw hole and into the first bone, wherein the first bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 60°;

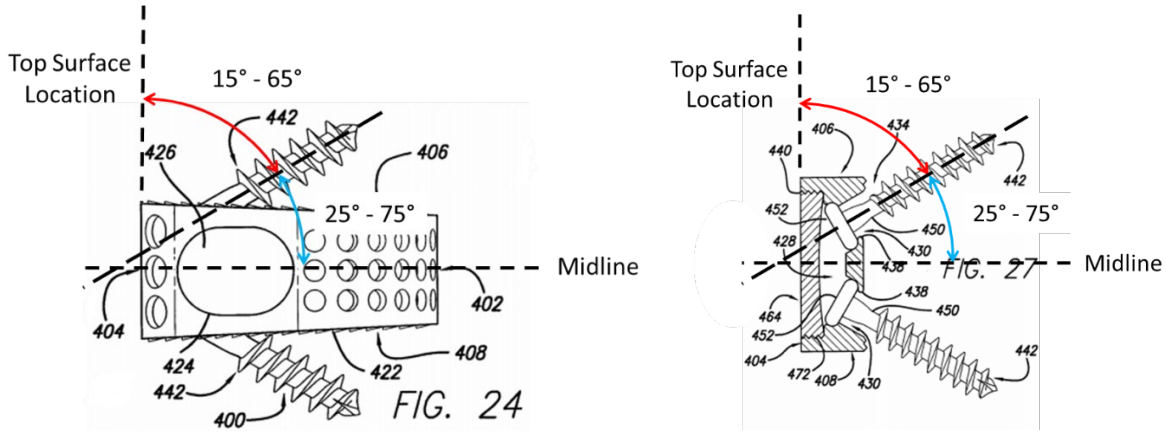
This limitation includes two features: (1) a first screw inserted through a screw hole and into the bone, and (2) that the angle of the screw ranges from about 20° to about 60°. Michelson '045 discloses this limitation and both of these features. Ex.1005 at ¶71.

With respect to the first feature, introducing a first bone screw through a first screw hole and into the first bone, 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 at 17. The first bone screw hole is depicted below as hole 430 (blue).



Michelson '045, Ex.1006, Fig. 23

With respect to the second feature, that the angle of the screw ranges from about 20° to about 60°, Michelson '045 discloses that "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101. This is the equivalent of the range 15° to 65° from the top surface of the bone. Ex.1005 at ¶¶73-74. This range is further depicted in figures 24 and 27 below.



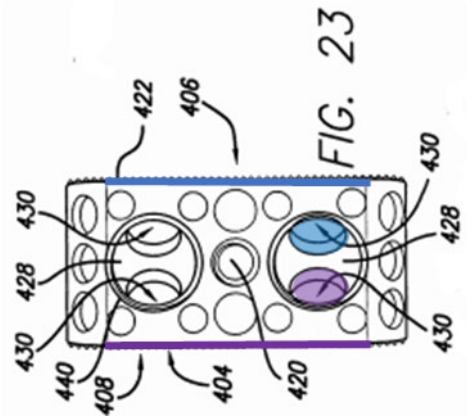
Michelson '045, Ex.1006, Figs. 24 and 27

Therefore, as described above, Michelson '045 discloses this limitation.

4. introducing a second bone screw through the second screw hole and into the second bone, wherein the second bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 70°, and;

This limitation includes two features: (1) a second screw inserted through a screw hole into the bone, and (2) that the angle of the screw ranges from about 20° to about 70°. Michelson '045 discloses this limitation and both of these features. Ex.1005 at ¶76.

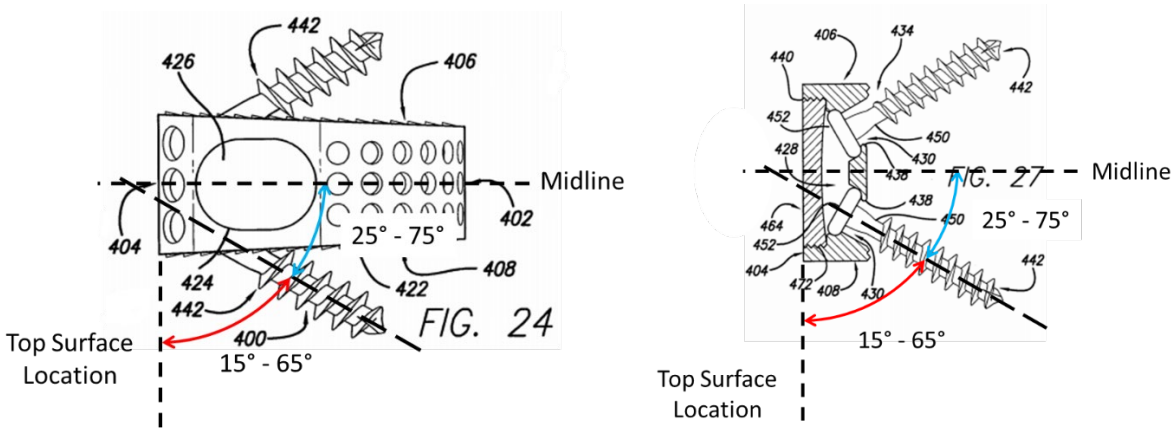
With respect to introducing a second bone screw through a second screw hole and into the first bone, Michelson '045 teaches this limitation. Ex.1006 at 7; Ex.1005 at ¶77. The second bone screw hole is depicted below as hole 430 (purple).



Michelson '045, Ex.1006, Fig. 23

With respect to the second feature, introducing the second bone screw at an angle relative to the top surface of the bone ranging from about 20° to about 70°,

Michelson '045 discloses this range. Ex.1006 at 32, 101; *see* Ex.1005 at ¶78. This range is further depicted in figures 24 and 27 below.

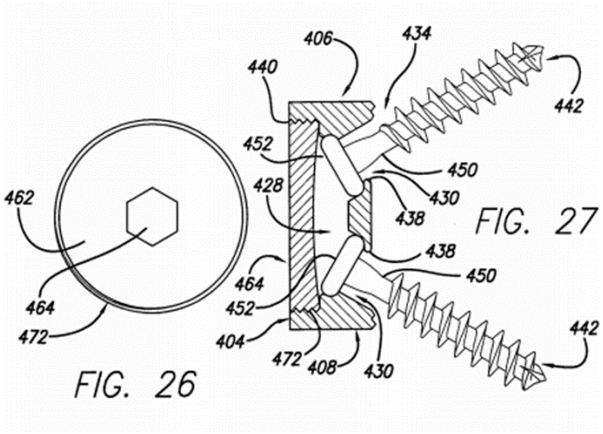


Michelson '045, Ex.1006, Figs. 24 and 27

Therefore, as described above, Michelson '045 discloses this limitation.

5. covering at least a part of the first bone screw and at least a part of the second bone screw to prevent the first and second bone screws from backing out of the first and second bones, respectively.

Michelson '045 discloses this limitation. Ex.1006 at 18; *see* Ex.1005 at ¶¶80-81. As depicted in figures 26 and 27 below, Michelson '045 discloses that the base plate includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out.



Michelson '045, Ex.1006, Figs. 26 and 27

Therefore, as described above, Michelson '045 discloses this limitation.

With respect to independent claim 1 of the '234 patent, Michelson '045 discloses each and every limitation.

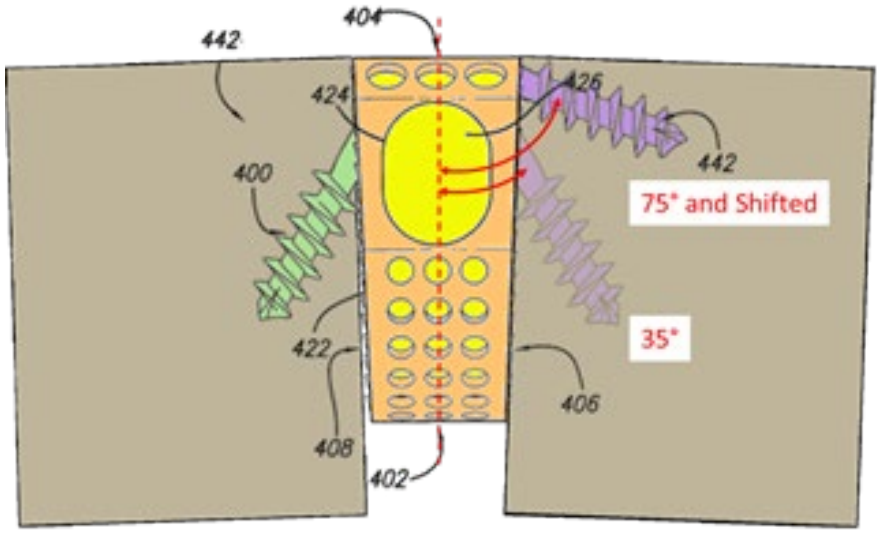
B. Claim 2

Claim 2 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Ex.1005 at ¶¶84-85.

Claim 2 further recites the limitation "wherein the first bone screw is introduced into the first bone at a corner of the bone formed between the top surface and side surface of the first bone." Michelson '045 discloses this limitation because the bone screws can be inserted through the corner and at low angle relative to the top surface of the bone. Ex.1005 at ¶86; Ex.1006 at 17, 32, 101.

Furthermore, if the first bone screw of the Michelson '045 device is

introduced through the first screw hole at a 75° angle relative to the midline of the base plate, then the screw will be introduced into the first bone at a corner of the bone formed between the top surface and side surface of the first bone. Ex.1005 at ¶87. Below in an overlay of implant 400 (figure 24) on top of a side view of the spine. In this annotated figure, the screw is inserted at 75° from the midline of the base plate, which results in the bone screw being introduced at a corner of the bone formed between the top surface and side surface of the first bone. Ex.1005 at ¶88.



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

It would have been obvious to a POSITA to shift the position of the screw as shown in Figure 38 below, in order to accommodate the 75° angle. Ex.1005 at ¶89.

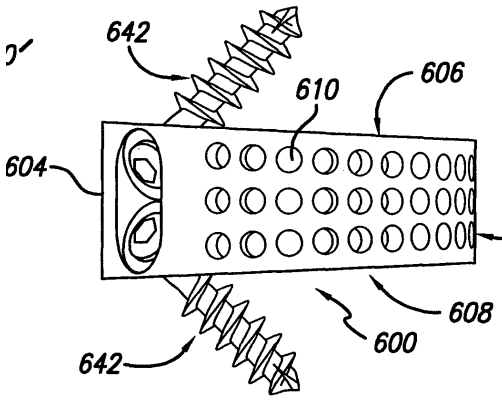


FIG. 38

Michelson '045, Ex.1006, Fig.38

Therefore, Michelson '045 discloses this limitation.

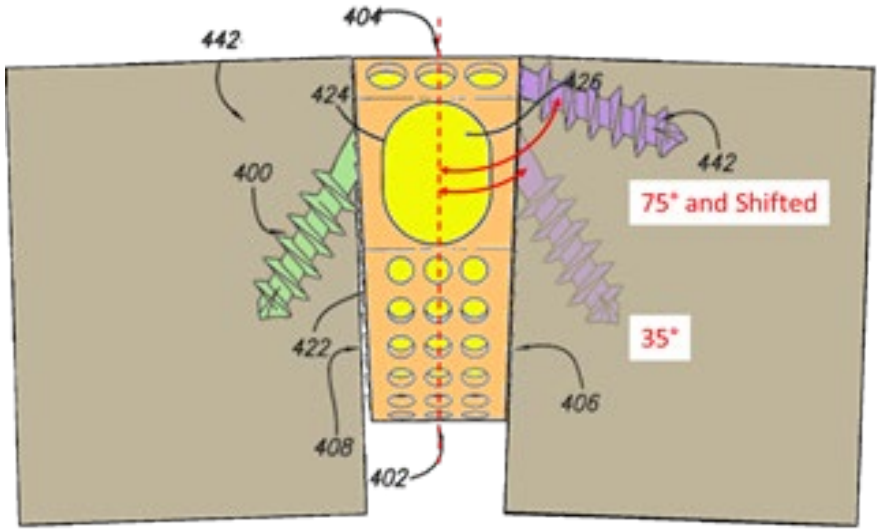
C. Claims 3 and 4

Claim 3 depends from claim 2, which depends from independent claim 1. Claim 4 also depends from independent claim 1. All the limitations of claims 1 and 2, discussed above and incorporated here, are disclosed by Michelson '045.

Claims 3 and 4 further recite the limitation "wherein the second bone screw is introduced into the second bone at a corner of the bone formed between the top surface and side surface of the second bone." Michelson '045 discloses these claim limitations. Ex.1005 at ¶97; Ex.1006 at 32, 101.

As such, if the second bone screw of the Michelson '045 device is introduced through the second screw hole at a 75° angle relative to the midline of the base plate, then the screw will be introduced into the second bone at a corner of

the bone formed between the top surface and side surface of the first bone. Ex.1005 at ¶¶94-96. As shown below in an overlay of implant 400 (figure 24) on top of a side view of the disk space in a spine, at 75° from the midline of the base plate, the first bone screw is introduced at a corner of the bone formed between the top surface and side surface of the first bone:



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

Therefore, Michelson '045 discloses this limitation.

D. Claim 6

Claim 6 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 6 further recites the limitation "wherein the first and second bones are first and second vertebral bodies, respectively, and wherein the first bone screw is introduced into the lip osteophite of the first vertebral body and the second bone

screw is introduced into the lip osteophite of the second vertebral body."

This limitation includes two features: (1) the bones are vertebral bodies and (2) the first and second bone screws are introduced into the lip osteophites of the first and second vertebral bodies. Michelson '045 discloses both of these features. Ex.1005 at ¶100.

With respect to the vertebral bodies, Michelson '045 teaches the first and second bones are first and second vertebral bodies, respectively. Ex.1005 at ¶101.

With respect to the lip osteophyte feature, as discussed above in Section VII.B, incorporated here, "lip osteophites" means "bony outgrowth at the anterior corner of the bone and is structurally the strongest portion of the vertebral bone."

As explained in Sections VIII.A.3 and VIII.A.4 above, Michelson '045 teaches "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101; *see* Ex.1005 at ¶¶101-103. This is the equivalent of 15° and 65° from the top surface of the bone. Ex.1005 at ¶¶101-103.

Michelson '045 discloses its implants are designed to fit between the first and second vertebral bodies, with its bone screws introduced into the lip osteophytes of each vertebral body. Michelson '045 provides an example of this with reference to implants 800 and 900 in figure 53:

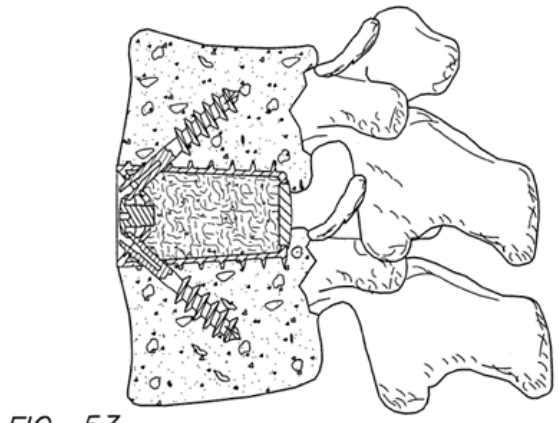
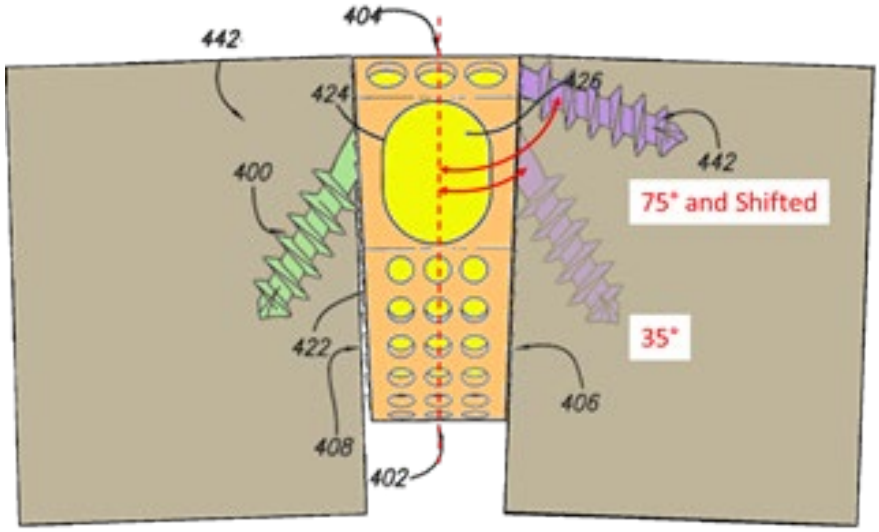


FIG. 53

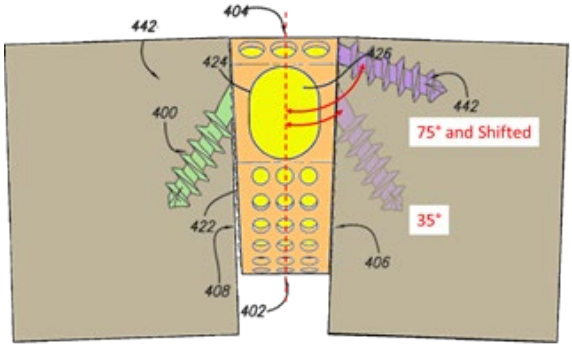
Michelson '045, Ex.1006, Fig. 53

If the first and second bone screws of the Michelson '045 implant 400 were introduced through the first and second screw holes at 20° and 15° angles relative to the top surface of the bones, respectively, as required by claim 1, the first bone screw would be introduced into the lip osteophite of the first vertebral body and the second bone screw would be introduced into the lip osteophite of the second vertebral body. Ex.1005 at ¶¶103-107. Further, as shown below in an overlay of implant 400 (figure 24) on top of a side view of the disk space in a spine, at 15° from the top surfaces of the bone, the first bone screw would be introduced into the lip osteophite of the first vertebral body and the second bone screw would be introduced into the lip osteophite of the second vertebral body:

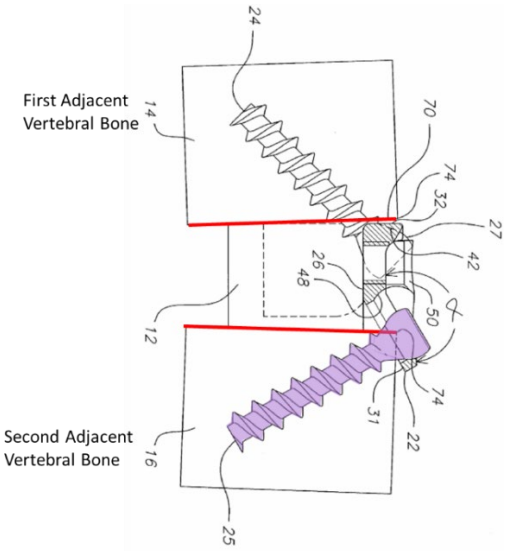


Michelson ’045, Ex.1006, Fig.24 (depicted between bones)

Finally, as shown by the side-by-side figures below, like the ’234 patent, Michelson ’045 discloses screws that are introduced into the lip osteophyte of the bones.



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



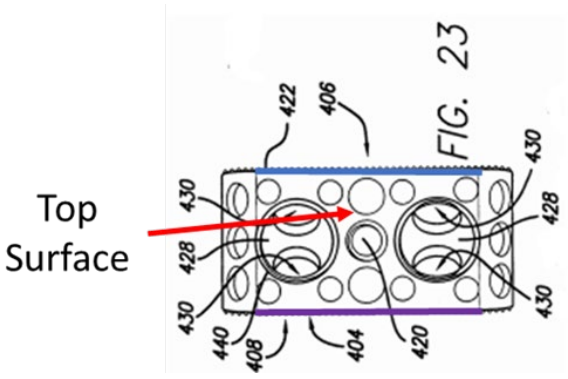
’234 patent, Ex. 1001, Fig. 3

Therefore, as described above, Michelson '045 discloses this limitation.

E. Claim 5, 7 and 8

Claim 5 depends from claim 4 and independent claim 1. Claim 7 depends from claim 6 and independent claim 1. Claim 8 depends from independent claim 1. All the limitations of claims 1, 4 and 6, discussed above are incorporated here, and are disclosed by Michelson '045. Claims 5 and 8 further recite the limitation "wherein the base plate has a top surface that sits at or below the top surfaces of the first and second bones." Claim 7 is nearly identical to claims 5 and 8 and further recites the limitation "wherein the base plate has a top surface that sits at or below the top surfaces of the first and second vertebral bodies."

Michelson '045 discloses these claim limitations. Ex.1005 at ¶108. Specifically, Michelson '045 discloses a base plate having a top surface, a first end (blue) and a second end (purple) as depicted in figure 23 below.



Michelson '045, Ex.1006, Fig. 23

Further, Michelson '045 teaches against affixing any spinal implant hardware anteriorly to the vertebral bodies adjacent the disc space to be fused. In particular, Michelson '045 teaches "[t]hose skilled in the art have shown great reluctance to utilize such hardware because of **the potential for the hardware to impinge on vital body structures**, such as the aorta, vena cava, or great iliac vessels" and because such placement "could cause sudden death." Ex.1006 at 4; *see* Ex.1005 at ¶¶110.

Therefore, 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*. For example, Michelson '045 teaches "**trailing end 402 of implant 400** . . . **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 at 16; *see* Ex.1005 at ¶111.

Therefore, Michelson '045 discloses these limitations.

F. Claim 9

Claim 9 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 9 further recites the limitation "wherein the first bone screw is introduced at an angle relative to the top surface of the bone ranging from about 40° to about 50°."

Michelson '045 discloses this limitation. Ex.1005 at ¶113.

As explained in Sections VIII.A.3 and VIII.A.4 above, Michelson '045 teaches "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101; *see* Ex.1005 at 114. This is the equivalent of 15° and 65° from the top surface of the bone. *Id.* at ¶114.

Therefore, Michelson '045 discloses this limitation.

G. Claim 10

Claim 10 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 10 further recites the limitation "wherein the second bone screw is introduced at an angle relative to the top surface of the bone ranging from about 45° to about 65°." Michelson '045 discloses this claim. Ex.1005 at ¶116.

As explained in Sections VIII.A.3 and VIII.A.4 above, Michelson '045 teaches "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101; *see* Ex.1005 at ¶117. This is the equivalent of 15° and 65° from the top surface of the bone. *Id.* at ¶117.

Therefore, Michelson '045 discloses this limitation.

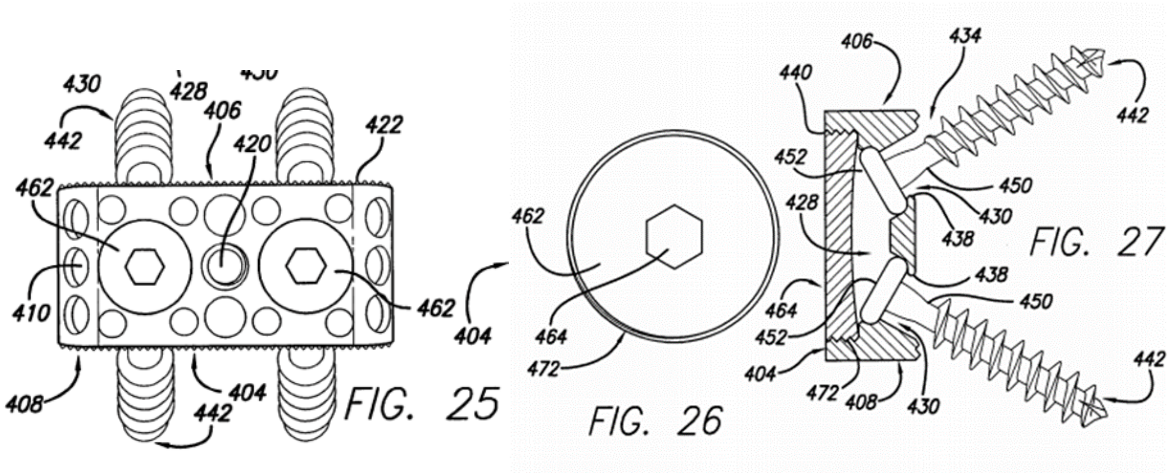
H. Claim 13

Claim 13 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 13

further recites the limitation "wherein the first and second bone screws are covered by a single retaining plate." Michelson '045 discloses this claim. Ex.1005 at ¶119.

Michelson '045 teaches "trailing end 404 of **implant 400 is adapted** to receive a total of four bone screws 442 deployed in upwardly and downwardly projecting opposed pairs, and **further to receive into common holes 440 threaded lock members 462, preventing screws 442 from backing out**." Ex.1006 at 18; *see* Ex.1005 at ¶120.

As shown in figures 25, 26 and 27 below, Michelson '045 teaches the base plate includes a single lock 462 that covers the first and second bone screws to prevent them from backing out.



Michelson '045, Ex.1006, Figs. 25, 26 and 27

Therefore, Michelson '045 discloses this limitation.

I. Claim 14

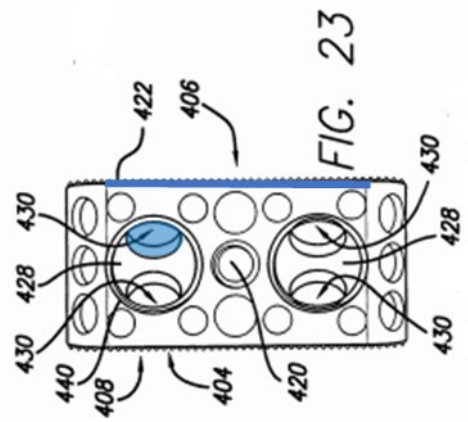
Claim 14 depends from independent claim 1. All the limitations of claim 1,

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

1. wherein the base plate has a third screw hole extending through the first end, the method further comprising:

Michelson '045 teaches "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 [for a total of four bone screw holes]**." Ex.1006 at 17; *see* Ex.1005 at ¶124.

As shown in figure 23 below, Michelson '045 teaches the base plate includes base plate has a third screw hole (blue) extending through the first end (blue).



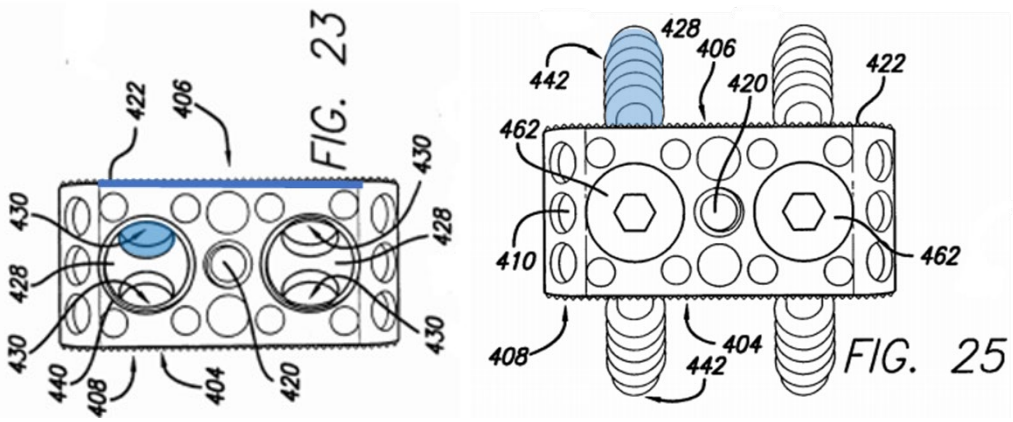
Michelson '045, Ex.1006, Fig. 23

Therefore, Michelson '045 discloses this limitation.

2. introducing a third bone screw through the third screw hole and into the first bone, wherein the third bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 60°, and

This limitation includes two features: (1) a third screw inserted through screw hole into the bone and (2) the angle of the third screw ranging from about 20° to about 60°. Michelson '045 discloses both of these features.

With respect to introducing a third bone screw through the first screw hole and into the first bone, Michelson '045 teaches this feature as depicted in figures 23 and 25 with respect to implant 400.



Michelson '045, Ex.1006, Figs. 23 and 25

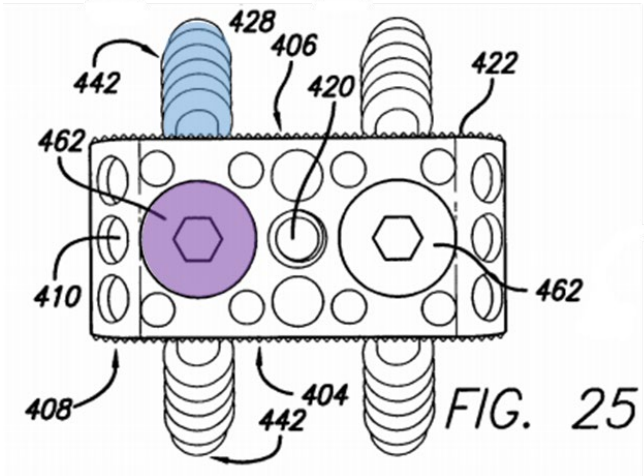
With respect to the second feature, introducing the third bone screw at an angle relative to the top surface of the bone ranging from about 20° to about 60°, as explained in Sections VIII.A.3 and VIII.A.4 above, Michelson '045 teaches "said **screw holes are angled between 25 and 75 degrees from the mid-**

longitudinal axis of said implant." Ex.1006 at 32, 101; *see* Ex.1005 at ¶125. This is the equivalent of 15° and 65° from the top surface of the bone. Ex.1005 at ¶125.

Therefore, as described above, Michelson '045 discloses this limitation.

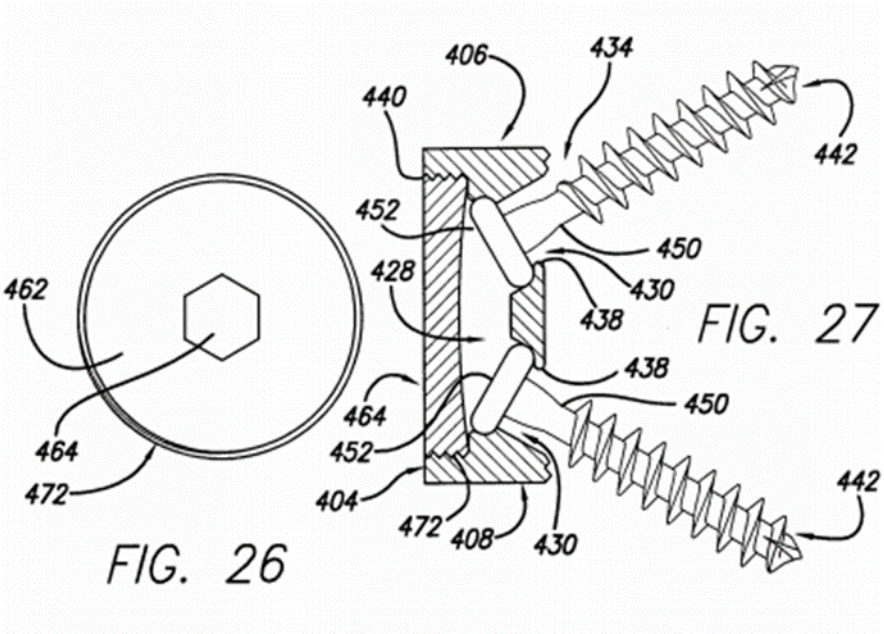
3. covering at least a part of the third bone screw to prevent the third bone screw from backing out of the first bone.

Michelson '045 teaches that "trailing end 404 of **implant 400 is adapted** to receive a total of four bone screws 442 deployed in upwardly and downwardly projecting opposed pairs, and **further to receive into common holes 440 threaded lock members 462, preventing screws 442 from backing out**." Ex.1006 at 18. In particular, Michelson '045 teaches "**lock 462 takes the form of a disc with a threaded side wall 472**, capable of threadably engaging threads 472 within common hole 428." *Id*. The lock disc (purple) is depicted in figure 25 below, as covering the third screw (blue).



Michelson '045, Ex.1006, Fig. 25

Further, as shown in figures 26 and 27 below, Michelson '045 teaches that the base plate includes a lock 462 that covers part of the third bone screw to prevent it from backing out.



Michelson '045, Ex.1006, Figs. 26 and 27

Therefore, Michelson '045 discloses this limitation. Ex.1005 at ¶¶132-136.

In summary and as described above, Michelson '045 discloses each and every limitation recited by claim 14 of the '234 patent.

J. Claim 16

Claim 16 depends from claim 14, which depends from independent claim 1. All the limitations of claims 1 and 14, discussed above and incorporated here, are disclosed by Michelson '045. Claim 16 further recites the limitation "wherein the first and second bones are first and second vertebral bodies, respectively, and

wherein the first and third bone screws are introduced into the lip osteophite of the first vertebral body, and the second bone screw is introduced into the lip osteophite of the second vertebral body."

This claim includes two features: (1) the bones are vertebral bodies and (2) the first and second bone screws are introduced into the lip osteophites of the first and second vertebral bodies. Michelson '045 discloses this claim and both of these features. Ex.1005 at ¶137.

With respect to the vertebral bodies, as discussed above in Section VIII.A.1, Michelson '045 teaches the first and second bones are first and second vertebral bodies, respectively.

With respect to the lip osteophite feature, as explained in Sections VIII.A.3 and VIII.A.4 above, Michelson '045 teaches that each of "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101. This is the equivalent of 15° and 65° from the top surface of the bone. Ex.1005 at ¶138.

As discussed in Section VIII.D, when the screws are angled at least at 15° from the top surface of the bone, Michelson '045 teaches the first bone screw is introduced into the lip osteophite of the first vertebral body and the second bone screw is introduced into the lip osteophite of the second vertebral body.

For the same reasons explained in Section VIII.D with respect to the first bone screw, Michelson '045 further teaches a third bone screw is introduced into the lip osteophite of the first vertebral body.

Therefore, Michelson '045 discloses this claim.

K. Claim 19

Claim 19 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 19 further recites the limitation "wherein the first and second bones are first and second vertebral bodies, the method further comprising introducing a bone graft between the side surfaces of the first and second vertebral bodies prior to insertion of the base plate."

This limitation includes two features: (1) the bones are vertebral bodies and (2) introducing a bone graft between the side surfaces of the first and second vertebral bodies prior to insertion of the base plate. Michelson '045 discloses this claim and both of these features. Ex.1005 at ¶145.

With respect to the vertebral bodies, as discussed above in Section VIII.D, Michelson '045 teaches the first and second bones are first and second vertebral bodies, respectively.

With respect to the bone graft feature, the '234 patent admits it was known to fuse the adjacent vertebrae together by "removing the intervertebral disk and

replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together." Ex.1001 at 1:44-47; Ex.1005 at ¶148.

Michelson '045 teaches that its 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 at 19; *see* Ex.1005 at ¶¶149-151.

Because the implant of Michelson '045 is filled with bone graft material, a POSITA would understand that when the implant is being inserted between the vertebral bones, the bone graft is necessarily introduced between the side surfaces of the first and second vertebral bodies prior to insertion of the base plate. Ex.1005 at ¶152. In particular, the bone graft is introduced between the side surfaces of the first and second vertebral bodies before the implant is fully inserted between the vertebral bones. *Id.* at ¶152.

Therefore, Michelson '045 discloses these limitations.

L. Claim 20

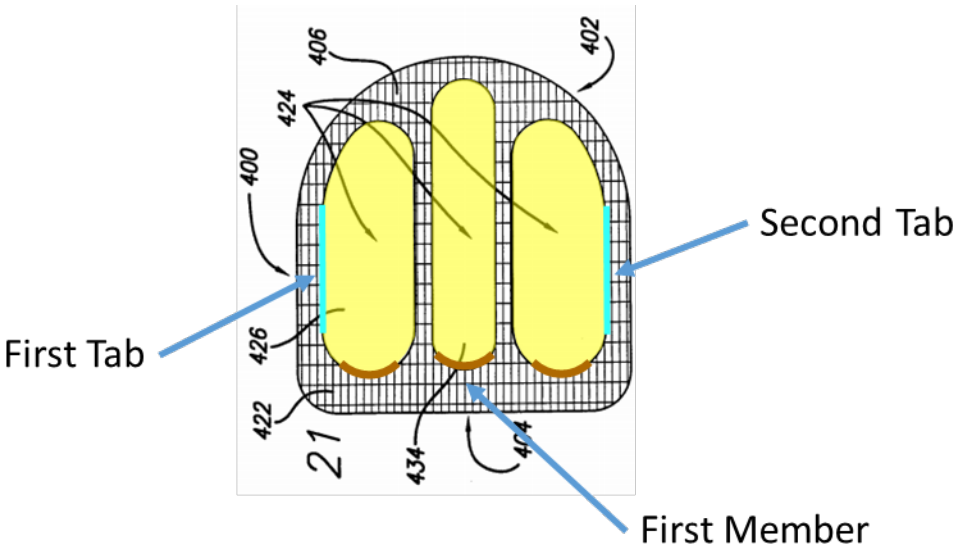
Claim 20 depends from claim 19, which depends from independent claim 1. All the limitations of claims 1 and 19, discussed above, are disclosed by Michelson '045. Claim 20 further recites the limitation "wherein the base plate includes a

first member that sits on a top surface of the bone graft and first and second tabs extending from the first member along first and second side surfaces of the bone graft in a direction generally transverse to the first and second vertebral bodies."

This claim includes three features: (1) a first member that sits on a top surface of the bone graft; (2) first and second tabs extending from the first member along first and second side surfaces of the bone graft; (3) the tabs extending in a direction generally transverse to the first and second vertebral bodies. Michelson '045 discloses this claim and each of these features. Ex.1005 at ¶¶154-155.

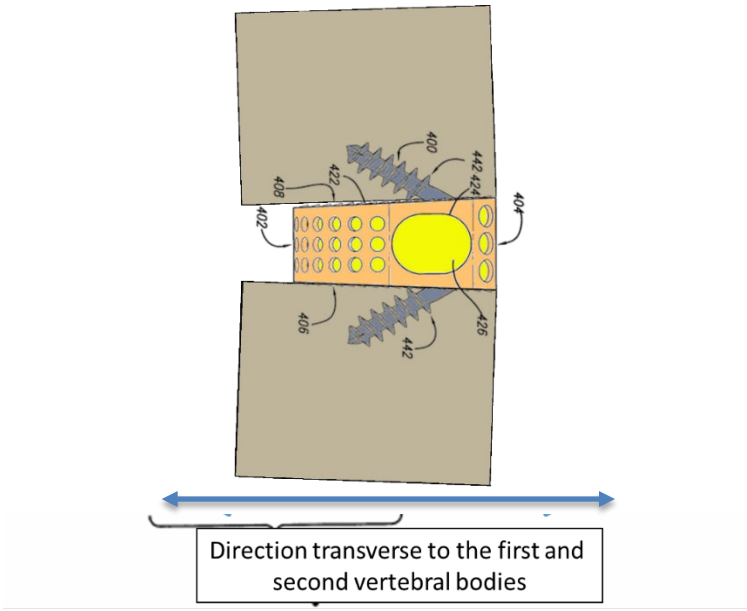
With respect to the first member, Michelson '045 teaches "[i]mplant 400 has a convex leading end 402 and an opposite **trailing end 404, here shown as having a generally straight mid-portion with radiused junctions to the side walls of implant 400**." Ex.1006 at 16; *see* Ex.1005 at ¶156.

Regarding the first and second tabs, as shown in annotated figure 21 below, Michelson '045 discloses a first member that sits on a top surface (brown) of the bone graft (yellow) and first and second tabs extending from the first member along first and second side surfaces (teal) of the bone graft:



Michelson '045, Ex.1006, Fig. 21

Finally, Michelson '045 discloses the tabs extend in a direction generally transverse to the first and second vertebral bodies as shown below in an overlay of implant 400 (figure 24) on top of a side view of the disk space in a spine:



Michelson '045, Ex.1006, Fig. 24

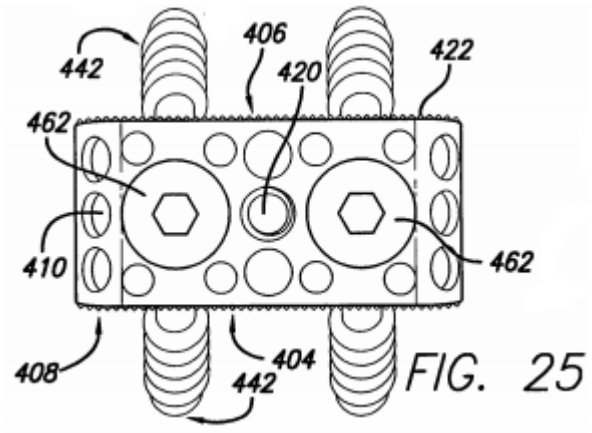
Therefore, as described above, Michelson '045 discloses these limitations.

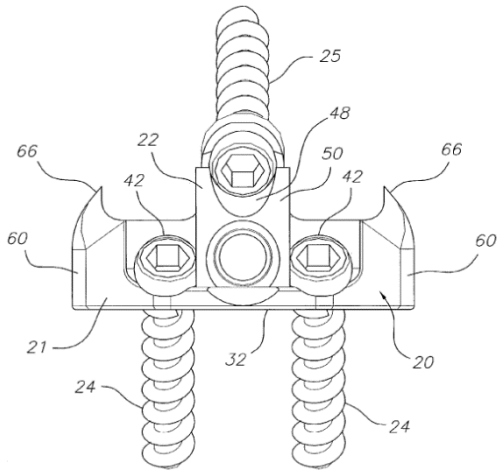
M. Claim 22

1. A bone stabilization plate system comprising:

To the extent the preamble is a limitation of the claim, Michelson '045 discloses this limitation. Ex.1005 at ¶160.

As shown in the side-by-side comparison figures below, Michelson '045 discloses the bone stabilization plate system recited by the '234 patent. In particular, Michelson '045 teaches "[t]he present invention relates generally to **interbody spinal fusion implants**." Ex.1006 at 2; *see* Ex.1005 at ¶¶162-163.





Michelson '045, Ex.1006, Fig. 25 **'234 patent, Ex.1001, Fig. 4**

As such, Michelson '045 discloses this limitation.

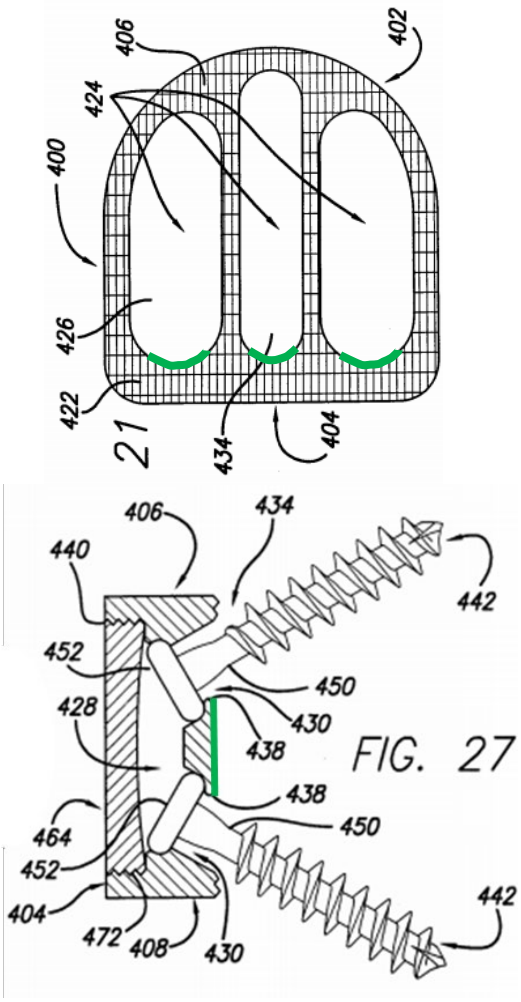
2. a base plate having bottom surface and first and second ends, the first end comprising a first bone screw region having a first bone screw hole extending therethrough at an angle relative to the bottom surface of the base plate ranging from about 20° to about 60°

This limitation include four features: (1) a base plate, (2) the base plate having a bottom surface and first and second ends, (3) the first end comprising a first bone screw region having a first bone screw hole, and (4) the bone screw hole extending at an angle relative to the bottom surface of the base plate ranging from about 20° to about 60°. Michelson '045 discloses each of these four features. Ex.1005 at ¶¶166-167.

With respect to the base plate, as discussed in Section VIII.A.2, Michelson '045 discloses a base plate.

With respect to the second feature, a base plate having a bottom surface and first and second ends, Michelson '045 describes that its base plate has upper and lower ends that conform to the respective bones. Ex.1006 at 16; *see* Ex.1005 at ¶169.

The Michelson '045 base plate having a bottom surface (green) and first (blue) and second ends (purple) are identified in figures 21 and 27 below.

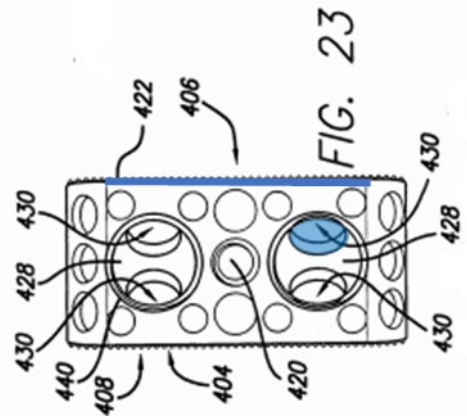


Michelson ’045, Ex.1006, Figs. 21 and 27

Regarding the third feature, the first end comprising a first bone screw region having a first bone screw hole, Michelson ’045 teaches “**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 at 17.

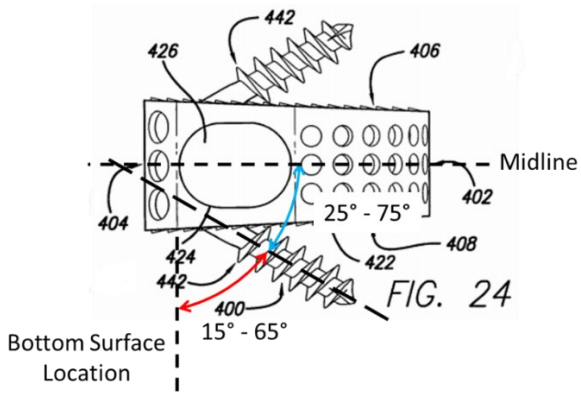
The base plate having the first end comprising a first bone screw region having a first bone screw hole (blue) is identified in figure 23 below.



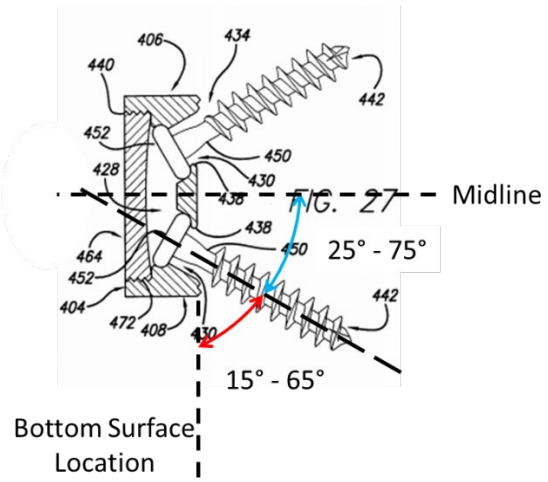
Michelson '045, Ex.1006, Fig. 23

Finally, with respect to the fourth feature, Michelson '045 teaches bone screw holes extending at between a 15° and 65° angle relative to the bottom surface. Ex.1006 at 17, 32, 101; *see* Ex.1005 at ¶172.

As shown in figures 24 and 27 below, Michelson '045 teaches the base plate includes a first bone screw hole extending at between a 15° and 65° angle relative to the bottom surface.



Michelson '045, Ex.1006, Fig. 24



Michelson '045, Ex.1006, Fig. 27

Therefore, as described above, Michelson '045 discloses these limitations.

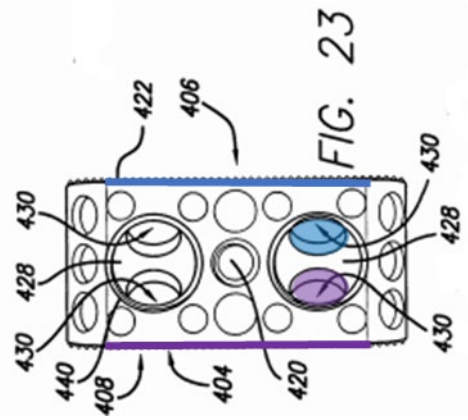
3. the second end comprising a second bone screw region having a second bone screw hole extending therethrough at an angle relative to the bottom surface of the base plate ranging from about 20° to about 70°;

This limitation includes two features: (1) a second end comprising a second bone screw region having a second bone screw hole and (2) the screw hole extending at an angle relative to the bottom surface of the base plate ranging from about 20° to about 70°. Michelson '045 discloses both of these features. Ex.1005 at ¶¶175-76.

With respect to the first feature, 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 at 17.

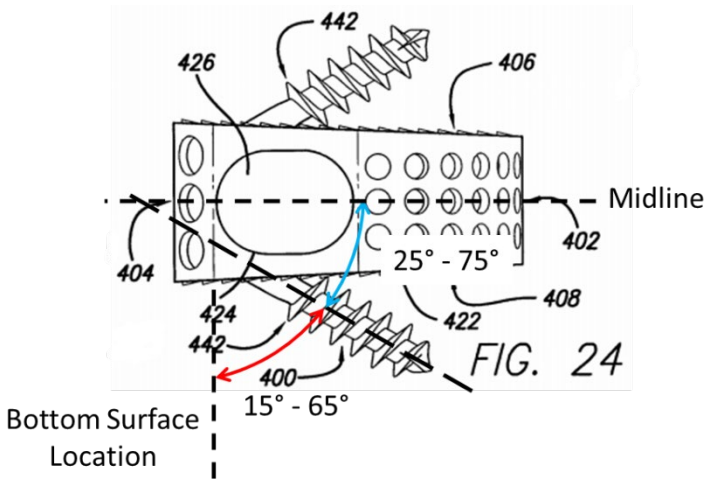
The base plate having the second end comprising a second bone screw region having a second bone screw hole (purple) is identified in figure 23 below.

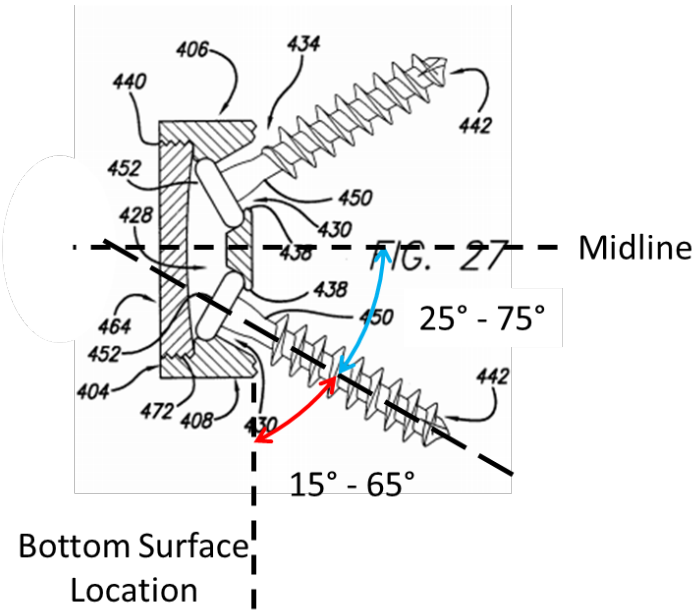


Michelson '045, Ex.1006, Fig. 23

With respect to the second feature, Michelson '045 teaches bone screw holes extending at between a 15° and 65° angles relative to the bottom surface. Ex.1006 at 17, 32, and 101; Ex.1005 at ¶179.

As shown in figures 24 and 27 below, Michelson '045 teaches the base plate includes a second bone screw hole extending at between a 15° and 65° angle relative to the bottom surface.





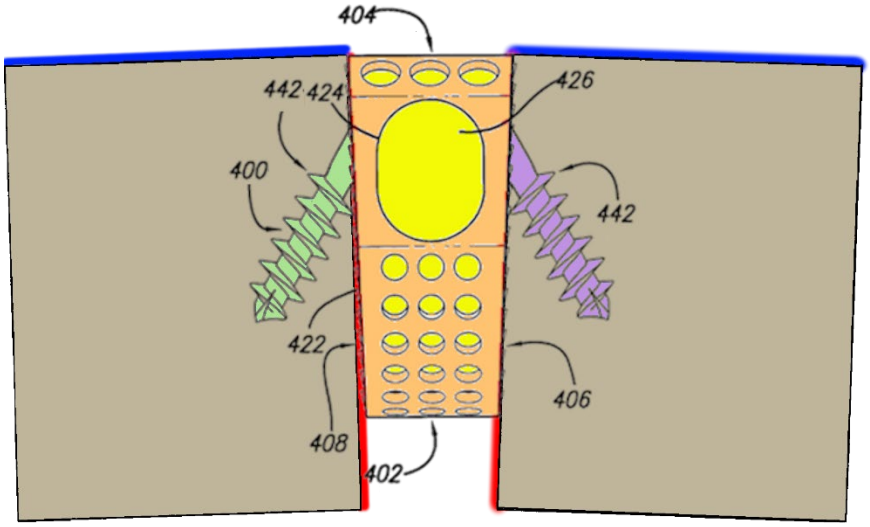
Michelson '045, Ex.1006, Figs. 24 and 27

Therefore, as described above, Michelson '045 discloses these limitations.

4. a first bone screw capable of securing the base plate to a first bone by insertion through the first bone screw hole; a second bone screw capable of securing the base plate to a second bone by insertion through the second bone screw hole; and

Michelson '045 discloses this limitation. Ex.1006 at 9, 17; *see* Ex.1005 at ¶182.

As shown below in an overlay of implant 400 (figure 24) on top of a side view of the disk space in a spine below, Michelson '045 discloses first (green) and second (purple) bone screws inserted through the first and second bone screw holes, respectively to secure the base plate (orange) to the first and second bones.



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

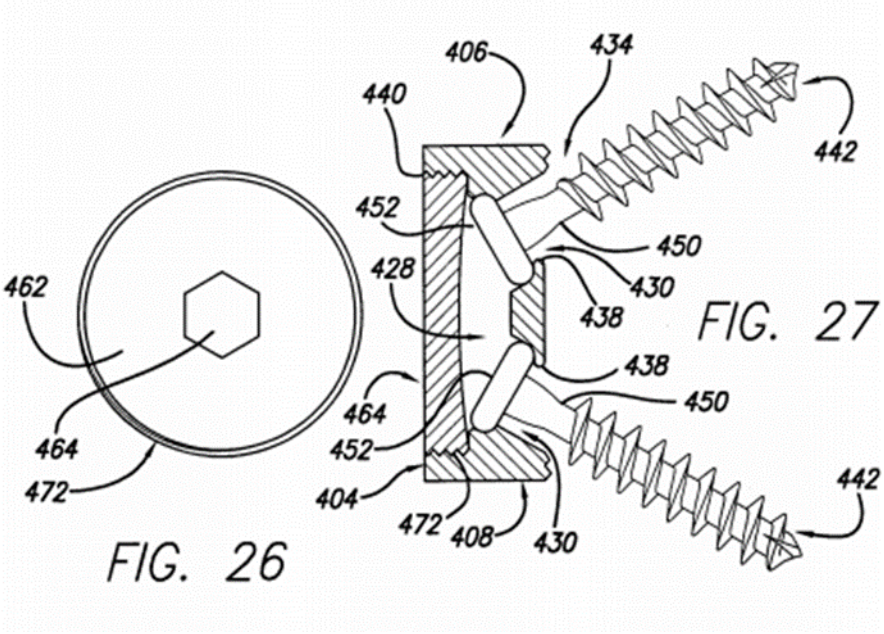
Therefore, Michelson '045 discloses this limitation.

5. a bone screw retaining means for securedly covering at least a part of the first and second bone screws to prevent the bone screws from backing out from the first and second bones.

With respect to the bone screw retaining means, as discussed in Section VII.C, the term "bone screw retaining means," is governed by 112 ¶ 6. The structure of this term, to the extent it is defined, is "(1) a retaining plate and a set screw;" or "(2) one or more screws with heads that overlap at least a portion of one or more bone screws to thereby prevent the bone screws from backing out."

Michelson '045 teaches "trailing end 404 of **implant 400 is adapted** to receive a total of four bone screws 442 deployed in upwardly and downwardly projecting opposed pairs, and **further to receive into common holes 440 threaded lock members 462, preventing screws 442 from backing out**." Ex.1006 at 18; *see* Ex.1005 at ¶189.

As shown in figures 26 and 27 below, Michelson '045 teaches the base plate includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out.



Michelson ’045, Ex.1006, Figs. 26 and 27

Therefore, Michelson ’045 discloses this limitation.

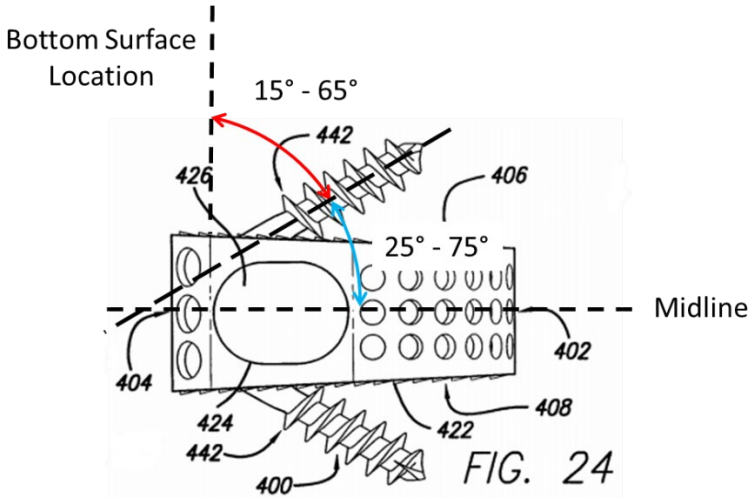
In summary, Michelson ’045 discloses each and every element recited by claim 22 of the ’234 patent.

N. Claim 24

Claim 24 depends from independent claim 22. All the limitations of claim 22, discussed above and incorporated here, are disclosed by Michelson ’045. Claim 24 further recites the limitation “wherein the first bone screw hole extends through the base plate at an angle relative to the bottom surface of the base plate ranging from about 40° to about 50°.” Michelson ’045 discloses this claim. Ex.1005 at ¶192.

As explained in Sections VIII.M.2 and VIII.M.3 above, Michelson ’045

teaches "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101; *see* Ex.1005 at ¶193. This is the equivalent of 15° and 65° from the bottom surface of the bone as shown below in figure 24. Ex.1005 at ¶193.



Michelson '045, Ex.1006, Fig. 24

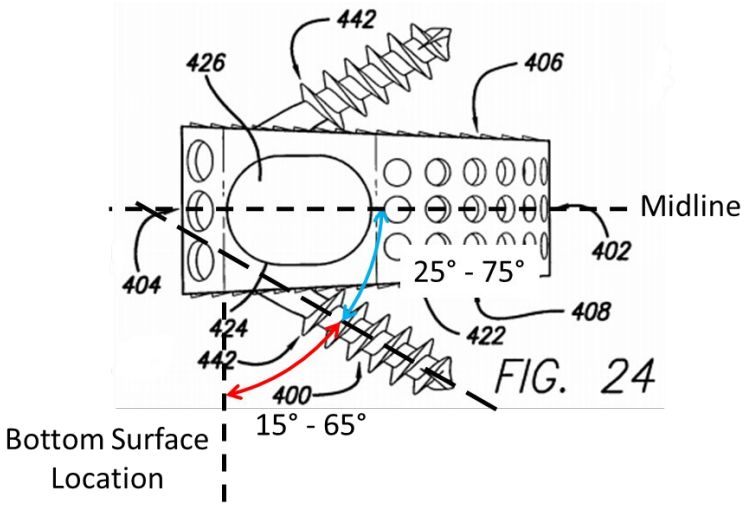
Therefore, Michelson '045 teaches this claim.

O. Claim 25

Claim 25 depends from independent claim 22. All the limitations of claim 22, discussed above and incorporated here, are disclosed by Michelson '045. Claim 25 further recites the limitation "wherein the second bone screw hole extends through the base plate at an angle relative to the bottom surface of the base plate ranging from about 45° to about 65°." Michelson '045 discloses this claim. Ex.1005 at ¶195.

As explained in Sections VIII.M.2 and VIII.M.3 above, Michelson '045

teaches "said **screw holes are angled between 25 and 75 degrees from the mid-longitudinal axis** of said implant." Ex.1006 at 32, 101. This is the equivalent of 15° and 65° from the bottom surface of the bone as shown below in figure 24. Ex.1005 at ¶196.



Michelson '045, Ex.1006, Figs. 24

Therefore, Michelson '045 discloses this claim limitation.

P. Claim 28

Claim 28 depends from independent claim 22. All the limitations of claim 22, discussed above and incorporated here, are disclosed by Michelson '045. Claim 28 further recites the limitation "wherein the first and second bone screws are covered by a single retaining plate." Michelson '045 discloses this claim. Ex.1005 at ¶198.

As explained in Section VIII.H above, Michelson '045 teaches the first and

second bone screws are covered by a single retaining plate.

Therefore, Michelson '045 discloses this claim limitation.

Q. Claim 29

Claim 29 depends from independent claim 22. All the limitations of claim 22, discussed above and incorporated here, are disclosed by Michelson '045. Claim 29 further recites the limitation "wherein the base plate has a third screw hole extending through the first end of the base plate at an angle relative to the bottom surface of the base plate ranging from about 20° to about 60°, and where the system further comprises a third bone screw capable of securing the base plate to the first bone by insertion through the third bone screw hole."

This claim includes three features: (1) a third screw hole extending through the first end of the base plate; (2) the third screw hole extending at an angle relative to the bottom surface of the base plate ranging from about 20° to about 60°; and (3) a third bone screw capable of securing the base plate to the first bone by insertion through the third bone screw hole. Michelson '045 discloses this claim and each of these three features. Ex.1005 at ¶201.

Regarding the first feature, as explained in Section VIII.I.1, Michelson '045 teaches a third screw hole extending through the first end of the base plate.

Regarding the second feature, the third screw hole extending at an angle relative to the bottom surface of the base plate ranging from about 20° to about

60°, Michelson '045 teaches this feature for the same reasons explained in Section VIII.I.2.

Finally, with respect to the third feature, as explained in Section VIII.I.2, Michelson '045 teaches a third bone screw capable of securing the base plate to the first bone by insertion through the third bone screw hole.

Therefore, Michelson '045 discloses this claim.

R. Claims 18 and 31

Claim 18 depends from independent claim 1 and dependent claim 14. All the limitations of claim 1 and claim 14, discussed above and incorporated here, are disclosed by Michelson '045. Claim 31 depends from independent claim 22 and dependent claim 29. All the limitations of claim 22 and claim 29, discussed above, are disclosed by Michelson '045. Claims 18 and 31 further recite the limitation "wherein the first, second and third bone screws are covered by a single retaining plate." Ex.1001 at 10:20-22; 11:29-31.

As discussed above, in Section VIII.H, Michelson '045 discloses a retaining plate. Michelson '045 teaches that the retaining plate can be used to cover more than two bone screws. For example, Michelson '045 discloses an embodiment with four openings for bone screws. Ex.1006 at 15. Michelson '045 further discloses that a "lock 362 is inserted into the threaded aperture 320 by means of a driver placed into hex well 364 and then tightened down to the back of implant

300." Ex.1006 at 15. As shown in Figure 18 below the lock covers up to four bone screw holes.

Michelson '045, Ex.1006, Figs. 18

A POSITA would have been motivated to alter the 400 embodiment of Michelson '045, shown in Figure 24, to use the single lock shown in Figure 18 because this would result in fewer surgical steps compared to using multiple locks.

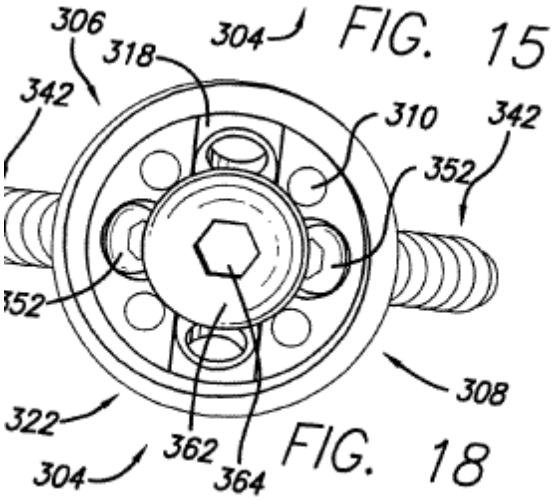


FIG. 15

FIG. 18

Ex. 1005 at ¶¶206-208.

Therefore, Michelson '045 discloses this limitation.

S. <u>Claim 32</u>

Claim 32 depends from independent claim 22. All the limitations of claim 22, discussed above and incorporated here, are disclosed by Michelson '045. Claim 32 further recites the limitation "wherein the base plate includes a first member that sits on a top surface of a bone graft and first and second tabs extending from the first member along first and second side surfaces of the bone

graft in a direction generally transverse to first and second vertebral bodies." Michelson '045 discloses this claim. Ex.1005 at ¶209.

The features of this claim are identical to those found in claim 20, discussed in Section VIII.L above. For the same reasons explained in Section VIII.L above, Michelson '045 teaches the base plate includes a first member that sits on a top surface of a bone graft and first and second tabs extending from the first member along first and second side surfaces of the bone graft in a direction generally transverse to first and second vertebral bodies.

Therefore, Michelson '045 discloses this claim.

T. Claims 1 and 22 – First/Second Ends

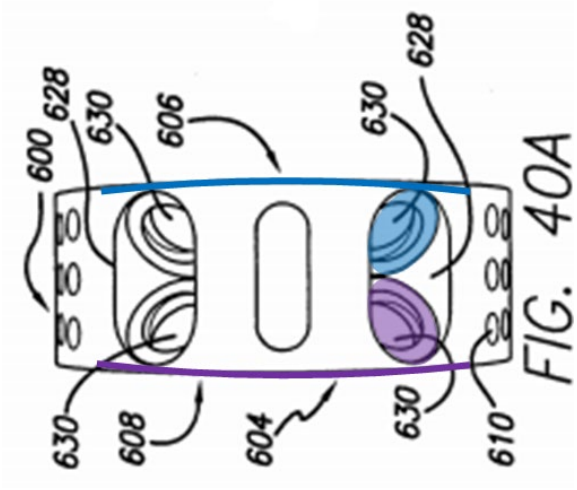
Claims 1 and 22 do not require the claimed first and second ends be limited to the upper and lower corners of the base plate. In the event that the Board determines that the claimed first end and second end only comprises the corner of the base plate, it would have been obvious to a POSITA to adjust the location of the Michelson '045 bone screws found in implant 400 to the upper and lower edges of the base plate. Ex.1005 at ¶214.

Michelson '045 discloses the remainder of the claim limitations of claims 1 and 22, as set forth in Ground 1, and are incorporated here. As mentioned above, Michelson '045 discloses screw holes at the first and second ends of the top surface of the baseplate. A POSITA would, however, recognize there are

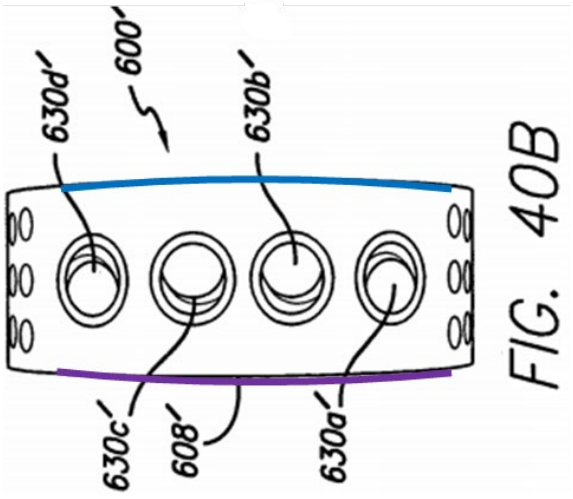
significant advantages to locating the bone screw holes at the upper and lower edges of the top surface of the baseplate. Ex.1005 at ¶216.

In fact, Michelson '045 teaches that this design could be easily implemented, for example, as disclosed by implant 600. Michelson '045 teaches "Trailing 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 at 22-23.

As shown in figures 40A and 40B below, Michelson '045 teaches two alternative embodiments, one with the bone screws located at the first and second ends and another with the bone screws all in the middle.



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



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

These physical modifications 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. Ex.1005 at ¶¶218-219.

Therefore, Michelson '045 renders claims 1 and 22 obvious.

IX. GROUND #2: MICHELSON '045 IN VIEW OF FRASER '106 RENDERS CLAIMS 2-8 AND 16 UNPATENTABLE AS OBVIOUS

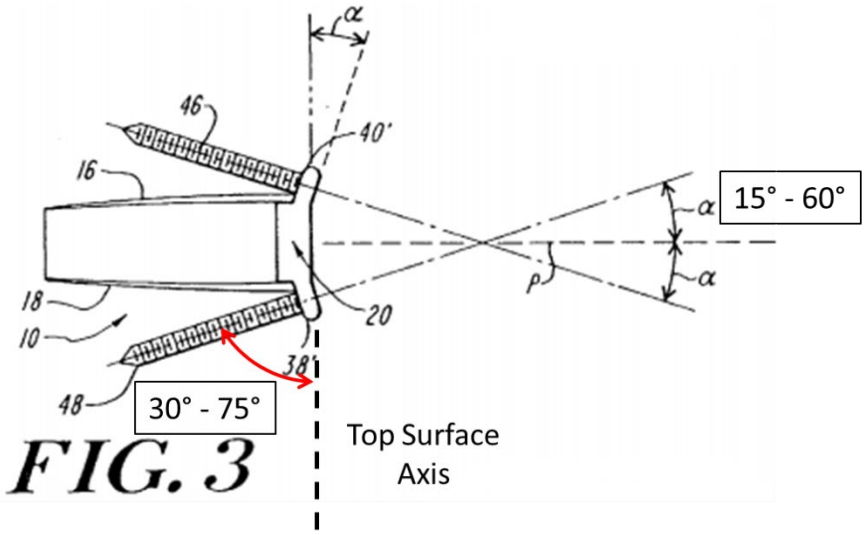
For the reasons stated below, at least claims 2-8 and 16 of the '234 patent are rendered obvious under 35 U.S.C. §103 by Michelson '045 in view of Fraser '106.

A. Claim 2

Claim 2 depends from independent claim 1. As discussed above in Ground 1, incorporated here, Michelson '045 discloses claim 1's limitations. Claim 2 further recites the limitation "wherein the first bone screw is introduced into the first bone at a corner of the bone formed between the top surface and side surface of the first bone." Michelson '045 in view of Fraser '106 discloses this claim. Ex.1005 at ¶221.

Fraser '106 discloses a first bone screw is introduced into the first bone at a corner of the bone formed between the top surface and side surface of the first bone. In particular, Fraser '106 teaches "**bone screws 46 and 48**, each having a

head and a shank are shown disposed through the holes in tabs 40′ and 38′, respectively, such that **the head of each screw engages the respective tab to inhibit passage of the head through the aperture in the tab**." Ex.1006 at 3:13-17; *see* Ex.1005 at ¶222. With respect to the top surface of the base plate, the disclosed angle ranges from 30° to 75°.



Fraser '106, Ex.1007, Fig. 3

As shown by the side-by-side figures below, when angled at 30° with respect to the top surface, Fraser '106 discloses the first bone screw (green) is introduced into the first bone at a corner of the bone formed between the top surface (blue) and side surface (red) of the first bone.

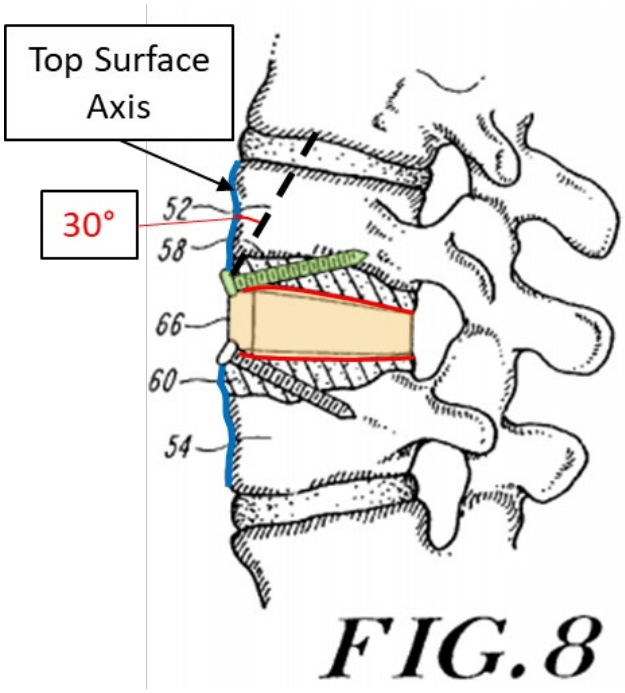
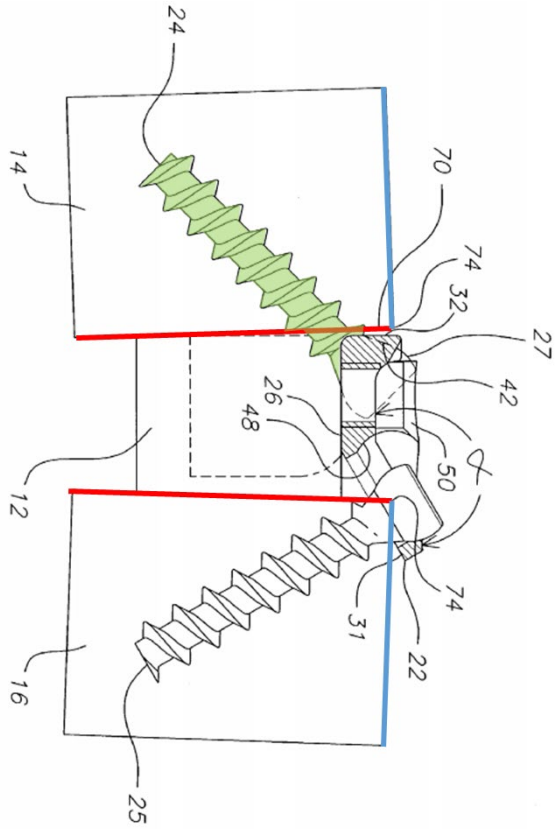


FIG. 8



Fraser '106, Ex.1007, Fig. 8 **'234 patent, Ex.1001, Fig. 3**

Therefore, Michelson '045 in view of Fraser '106 discloses this limitation.

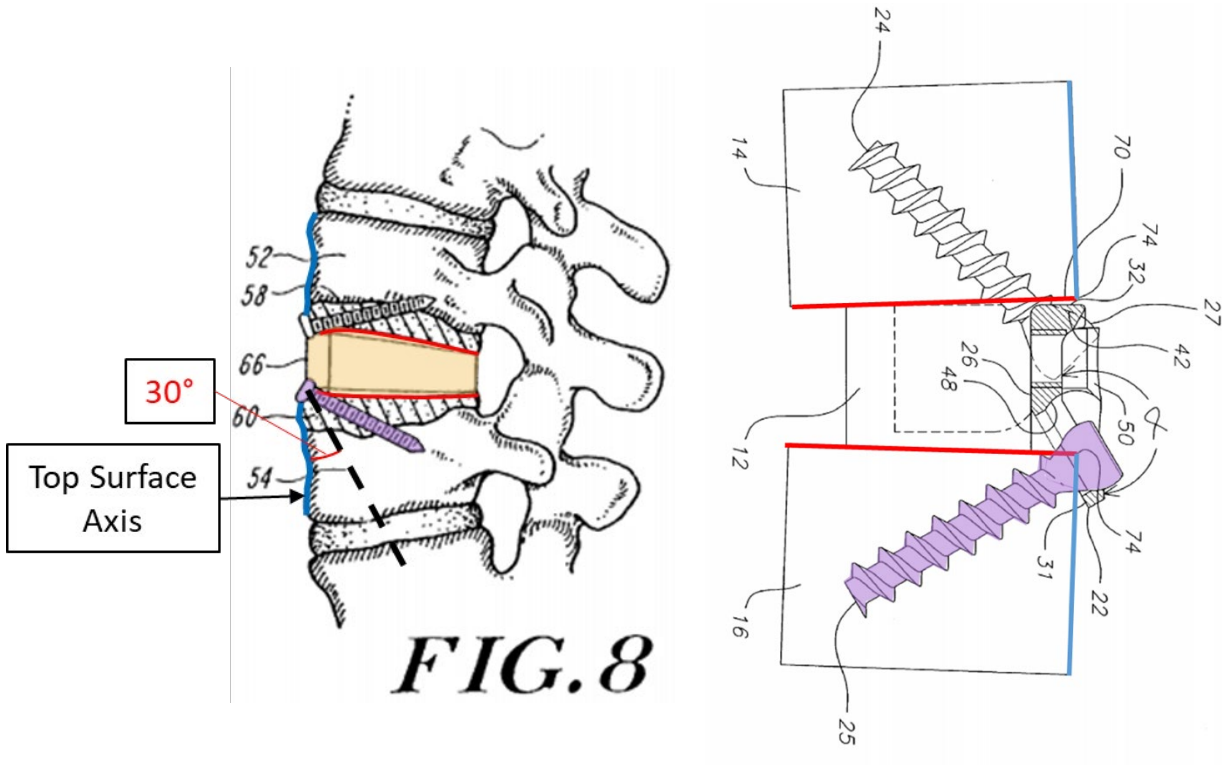
B. <u>Claims 3 and 4</u>

Claim 3 depends from claim 2, which depends from independent claim 1. Claim 4 also depends from independent claim 1. As discussed above in Ground 1, incorporated here, Michelson '045 discloses claim 1's limitations. As discussed above in this Ground 3, Michelson '045 in view of Fraser '106 discloses claim 2's limitations. Claims 3 and 4 are identical and further recite "wherein the second bone screw is introduced into the second bone at a corner of the bone formed

between the top surface and side surface of the second bone." Michelson '045 in view of Fraser '106 discloses these claim limitations. Ex.1005 at ¶225.

As explained in Section IIX.A above, Fraser '106 teaches its bone screws enter the vertebral bone at an angle ranging from 30° to 75° with respect to the top surface of the base plate. Ex.1005 at ¶226.

As shown by the side-by-side figures below, when angled at 30° with respect to the top surface, Fraser '106 discloses the second bone screw (purple) is introduced into the second bone at a corner of the bone formed between the top surface (blue) and side surface (red) of the first bone.



Fraser '106, Ex.1007, Fig. 8 **'234 patent, Ex.1001, Fig. 3**

Therefore, Michelson '045 in view of Fraser '106 discloses this limitation.

C. Claim 6

Claim 6 depends from independent claim 1. As discussed above in Ground 1, incorporated here, Michelson '045 discloses claim 1's limitations. Claim 6 further recites the limitation "wherein the first and second bones are first and second vertebral bodies, respectively, and wherein the first bone screw is introduced into the lip osteophite of the first vertebral body and the second bone screw is introduced into the lip osteophite of the second vertebral body."

This limitation includes two features: (1) the bones are vertebral bodies and (2) the first and second bone screws are introduced into the lip osteophites of the first and second vertebral bodies. To the extent Michelson '045 alone does not teach this claim, Michelson '045 in view of Fraser '106 discloses this claim and both of these features. Ex.1005 at ¶229.

With respect to the vertebral bodies, as discussed above in Section VIII.A.1, Michelson '045 teaches the first and second bones are first and second vertebral bodies, respectively.

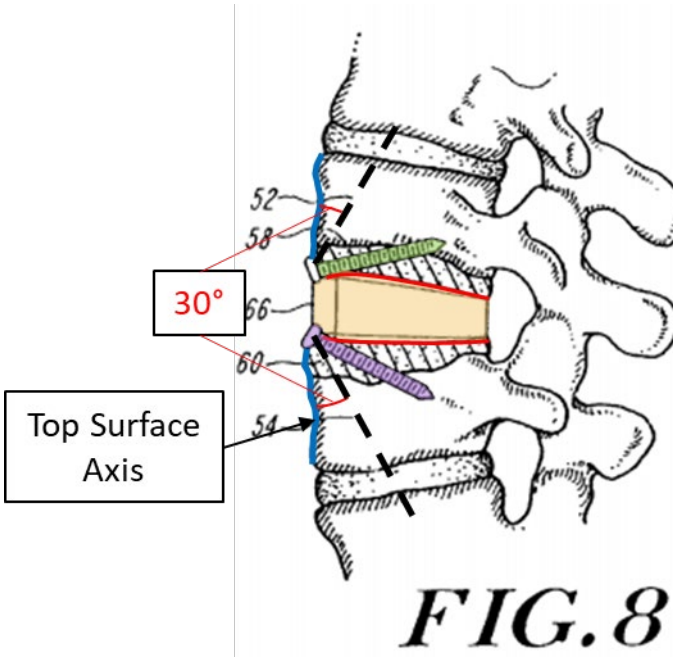
With respect to the lip osteophyte feature, as discussed above in Section VII.B, incorporated here, "lip osteophytes" means "bony outgrowth at the anterior corner of the bone and is structurally the strongest portion of the vertebral bone."

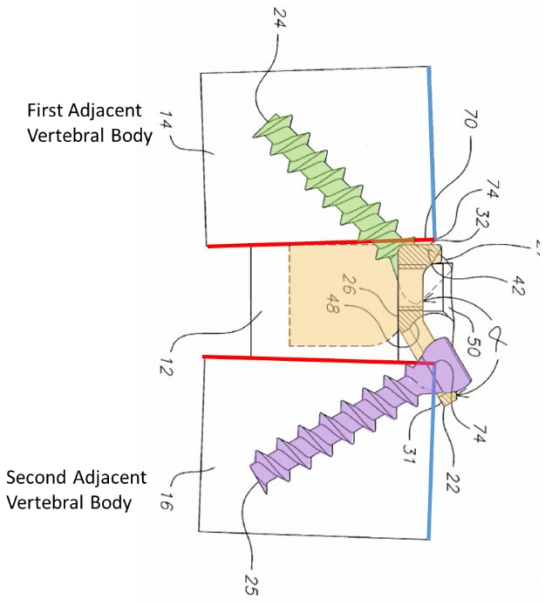
As explained in Section IIX.A above, Fraser '106 teaches its bone screws

enter the vertebral bone at an angle ranging from 30° to 75° with respect to the top surface of the base plate. Ex.1005 at ¶232.

If the first and second bone screws of the Fraser '106 device were introduced through the first and second screw holes at 30° angles relative to the top surface of the bones, respectively, the first bone screw would be introduced into the lip osteophite of the first vertebral body and the second bone screw is introduced into the lip osteophite of the second vertebral body. Ex.1005 at ¶234.

As shown by the side-by-side figures below, like the '234 patent, Michelson '045 discloses "wherein the first and second bones are first and second vertebral bodies, respectively, and wherein the first bone screw (green) is introduced into the lip osteophite of the first vertebral body and the second bone screw (purple) is introduced into the lip osteophite of the second vertebral body."





Fraser '106, Ex.1007, Fig. 8 **'234 patent, Ex.1001, Fig. 3**

Therefore, Michelson '045 in view of Fraser '106 discloses this claim.

D. Claim 5, 7 and 8

Claim 5 depends from claim 4 and independent claim 1. Claim 7 depends from claim 6 and independent claim 1. Claim 8 depends from independent claim 1. As discussed above in Ground 1, incorporated here, Michelson '045 discloses claim 1's limitations. As discussed above in this Ground 3, Michelson '045 in view of Fraser '106 discloses all of the limitations of claims 4 and 6. Claims 5 and 8 are identical and further recite "wherein the base plate has a top surface that sits at or below the top surfaces of the first and second bones." Claim 7 is nearly identical to claims 5 and 8 and further recites the limitation "wherein the base plate has a top surface that sits at or below the top surfaces of the first and second vertebral

bodies." Michelson '045 discloses these claim limitations. Ex.1005 at ¶236.

As shown by the side-by-side figures below, like the '234 patent, Fraser '106 discloses a base plate (orange) that has a top surface (yellow) that sits at or below the top surfaces (blue) of the first and second bones/vertebral bodies (*see also* Ex.1005 at ¶237):

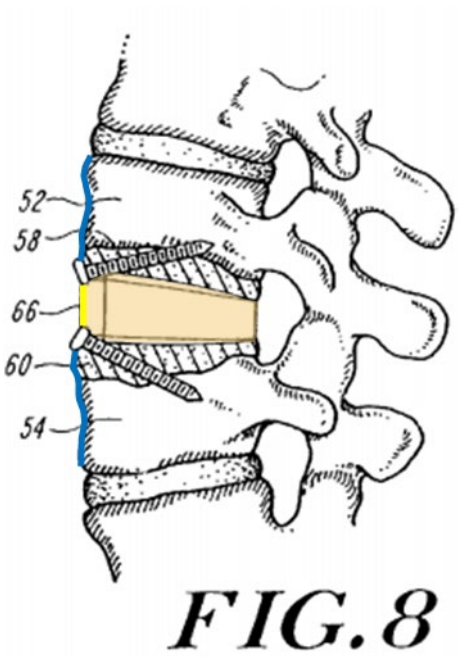
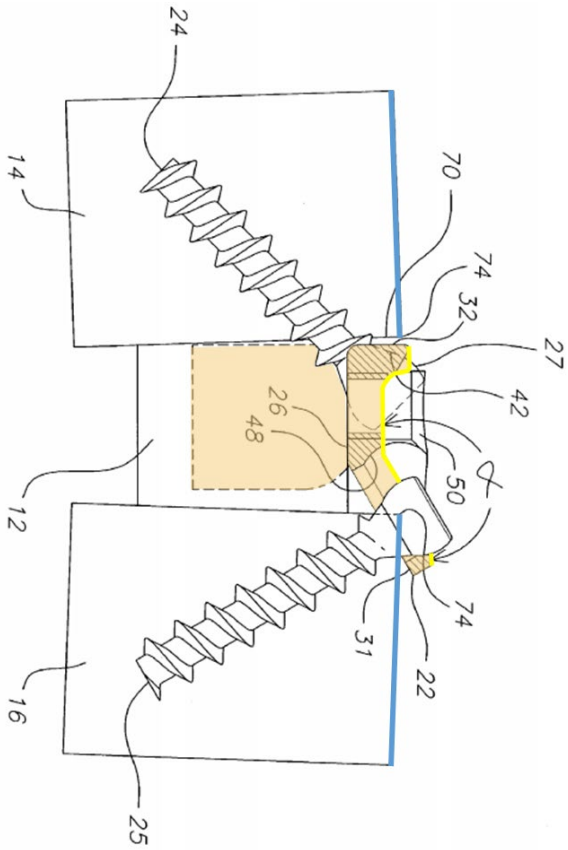


FIG. 8



Fraser '106, Ex.1007, Fig. 8 **'234 patent, Ex.1001, Fig. 3**

Michelson '045 in view of Fraser '106 discloses "wherein the base plate has a top surface that sits at or below the top surfaces of the first and second bones" and "wherein the base plate has a top surface that sits at or below the top surfaces

of the first and second vertebral bodies."

E. Claim 16

Claim 16 depends from claim 14, which depends from independent claim 1. As discussed above in Ground 1, incorporated here, Michelson '045 discloses all the limitations of claim's 1 and 14. Claim 16 further recites the limitation "wherein the first and second bones are first and second vertebral bodies, respectively, and wherein the first and third bone screws are introduced into the lip osteophite of the first vertebral body, and the second bone screw is introduced into the lip osteophite of the second vertebral body."

This claim includes two features: (1) the bones are vertebral bodies and (2) the first and second bone screws are introduced into the lip osteophites of the first and second vertebral bodies. To the extent Michelson '045 alone does not teach this claim, Michelson '045 in view of Fraser '106 discloses this claim and both features. Ex.1005 at ¶240.

With respect to the vertebral bodies, as discussed above in Section VIII.A.1, Michelson '045 teaches the first and second bones are first and second vertebral bodies, respectively.

With respect to the lip osteophyte feature, as explained in Section IIX.A above, Fraser '106 teaches its bone screws enter the vertebral bone at an angle ranging from 30° to 75° with respect to the top surface of the base plate. Ex.1005

at ¶¶243-244.

As discussed in Section IIX.D, when the screws are angled at least at 30° from the top surface of the bone, Michelson '045 in view of Fraser '106 teaches the first bone screw is introduced into the lip osteophite of the first vertebral body and the second bone screw is introduced into the lip osteophite of the second vertebral body.

For the same reasons explained in Section IIX.D with respect to the first bone screw, Michelson '045 in view of Fraser '106 further teaches a third bone screws is introduced into the lip osteophite of the first vertebral body.

Therefore, Michelson '045 teaches this claim.

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

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 at ¶246.

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

Fraser '106 and Michelson '045 are both analogous art to the alleged invention claimed in the '234 patent. Here, the '234 patent defines its "Technical Field" as "implant devices for the fixation and support of bone bodies." Ex.1001 at 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. *See* Fraser '106, Ex.1007, Abstract ("A spinal fixation assembly"), 1:36-38; Michelson '045, 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."). 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 at ¶251.

Fraser '106 is analogous to the '234 patent. Fraser '106 is directed to a spinal implant device for fixation and support of vertebrae. *See* Fraser '106, Ex.1006 at Abstract ("A spinal fixation assembly"), 1:36-38; Ex.1005 at ¶251. Therefore, Fraser '106 is squarely in the same field of endeavor as the '234 patent. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (explaining prior art is analogous where "the art is from the same field of endeavor, regardless of the problem addressed").

Because Fraser '106 discloses an intervertebral implant that uses bone screws to secure the implant and stabilize vertebrae to be fused, Fraser '106 is analogous and in the same field of endeavor as the '234 patent and Michaelson '045. Therefore, Fraser '106 and Michelson '045 are analogous art and would have been considered by a POSITA attempting to solve the problem identified in

the ’234 patent. Ex.1005 at ¶¶246-251.

In addition, Fraser ’106 and Michelson ’045 are analogous art to the ’234 patent because they are reasonably pertinent to the technical problem allegedly addressed by the claimed invention. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (explaining that prior art—even if not within the field of endeavor—is still analogous if it “is reasonably pertinent to the particular problem with which the inventor is involved”). According to the ’234 patent, the problem to be solved is providing an implant that supports adjacent vertebrae for fusion without damaging the spinal cord or adjacent tissue. *See* Ex.1001; Ex.1005 at ¶247.

Here, Fraser ’106 and Michelson ’045 address this very problem by disclosing spinal implants that sit flush and recessed with the perimeter of the vertebrae. Ex.1005 at ¶248. Specifically, Fraser ’106 teaches its implant approximates the shape of the annulus portion of the vertebrae and its screws sit flush or sub-flush to avoid harming major blood vessels. Ex.1006 at 2:21-23; 4:16-19; Ex.1005 at ¶249. Similarly, Michelson ’045 teaches its implants match the shape of the vertebrae and no metal or screws sit on the anterior surface of the vertebrae to avoid ruptured blood vessels and even cause death. Ex.1006 at 4, 16; Ex.1005 at ¶250.

In sum, Fraser ’106 and Michelson ’045 are not only in the same field of endeavor as the ’234 patent, but also specifically address the very problem the ’234

patent purports to solve. Ex.1005 at ¶¶246-251. Therefore, Fraser '106 and Michelson '045 are analogous art and would have been considered by a POSITA attempting to solve the problem identified in the '234 patent.

2. There is an express motivation to combine Michelson '045 and Fraser '106

Michelson '045 provides an express motivation for the combination with Fraser '106 because Michelson '045 teaches its improved spinal implant designs may be used in other spinal implant devices. *See* Ex.1006 at 5; Ex.1005 at ¶252; *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (finding a reference that suggested use of shapes other than those expressly described provided a motivation for a POSITA to combine its teaching with other references disclosing other shapes); *In re Gartside*, 203 F.3d 1305, 1321 (Fed. Cir. 2000) (finding patents' disclosure of "low residence times" to prevent undesired effects provided a motivation for a POSITA to look to another patent describing "low residence time" reactions including "the precise residence time in the disputed claims").

A POSITA would have been motivated to look to the teachings of other references, such as Fraser '106, to find other applications for the Michelson '045 designs. Ex.1005 at ¶¶252-253. A POSITA would have combined Michelson '045 with Fraser '106 because Fraser '106 teaches using bone screws located at the upper and lower edges of the top surface of the implant in an interbody spinal

implant just like the one disclosed in Michelson '045. Ex.1005 at ¶254.

Fraser '106 also provides a motivation to combine with Michelson '045. Fraser '106 expressly teaches that exposed screws can cause significant harm to a patient and discloses an anti-back out mechanism. *See* Ex.1006 at 4:16-19. Because Fraser '106 teaches use of anti-back out screws, a POSITA would have been motivated to look to the teachings of other spinal implant references that prevent screw back out, such as Michelson '045. A POSITA would have combined Fraser '106 with Michelson '045 because Michelson '045 discloses a spinal implant that utilizes a screw anti-back out system that can be used with standard bone screws to compensate for subsequent settling of the bones after implantation. Ex.1006 at 27; Ex.1005 at ¶255.

A POSITA would have combined Michelson '045 with Fraser '106 because Fraser '106 teaches using an interbody spinal implant just liked the one disclosed in Michelson '045 that can be used with an anti-back out screw mechanism. Ex.1005 at ¶256.

3. The combination of Fraser '106 and Michelson '045 would have yielded an improved spinal implant

A POSITA would have also combined Fraser '106 and Michelson '045 because he or she would have recognized that Fraser '106's teachings could be applied to improve Michelson '045's spinal implant. Ex.1005 at ¶256.

In particular, a POSITA would have recognize there are significant advantages to locating the bone screw holes at the upper and lower edges of the top surface of the baseplate. Ex.1005 at ¶258. In particular, locating the screw holes closer to the centerline of the top surface of the baseplate would limit the range of screw angles available to a surgeon and the location of the screw insertion of the vertebrae. *Id*. A POSITA would recognize that a design that provides a surgeon with additional screw insertion options would provide significant advantages during surgeries, especially in complicated cases where there is significant degradation of the bone. *Id*.

Therefore, a POSITA would have been motivated to apply the teachings of Fraser '106 to locate the bone screw holes at the edges of the top surface of the base plate to allow for improve screw insertion angles, such as the ones taught in Michelson '045. *Id.* The addition of this relocated screw holes would have been a straightforward task that would have simply involved modifying the drilled screw hole of the Michelson '045 device. *Id.* Michelson '045 does not disclose any structures that would preclude or interfere with such a modification. *Id.* The results of this simple modification to Michelson '045 would have yielded predictable and successful results—namely, a spinal implant with an improved range of screw insertion angles to securely hold implant in place. *Id.*

Therefore, Fraser '106 in view of Michelson '045 renders at least claims 2-8, and 16 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,

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CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 12,587 words, as counted by Microsoft Word 2016, 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 IPR.

Dated: December 13, 2019

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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 and all supporting exhibits were sent via Federal Express to the correspondence address of record for the '234 patent:

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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:

Dated: December 13, 2019

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