UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

DEPUY SYNTHES SALES, INC. and

DEPUY SYNTHES PRODUCTS, INC.,

Petitioners

v.

Patent Owner of
U.S. Patent No. 8,486,066 to Bonutti
Appl. No. 10/438,705 filed May 15, 2003
Issued Jul. 16, 2013

---

IPR Trial No. TBD

---

**PETITION FOR *INTER PARTES***
**REVIEW OF U.S. PATENT NO. 8,486,066**
**PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108**

TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Cases** **Page(s)**



**Statutes**



**Other Authorities**

EXHIBIT LIST

| Exhibit No. | Description | Short Reference |
|---|---|---|
| 1001 | U.S. Patent No. 8,486,066 | the ‘066 patent |
| 1002 | Declaration of Dr. McMillin | McMillin Decl. |
| 1003 | Curriculum Vitae of Dr. McMillin | McMillin CV |
| 1004 | List of Prior Art and Materials Considered by Dr. McMillin | McMillin Materials Considered |
| 1005 | French Patent Application No. FR 2,747,034 | Benezech |
| 1006 | Certified translation of French Patent Application No. FR 2,747,034 | Benezech Translation |
| 1007 | French Patent Application No. FR 2,703,580 | Gilles |
| 1008 | Certified translation of French Patent Application No. FR 2,703,580 | Gilles Translation |
| 1009 | ACROMED, ACROMED CARBON FIBER INTERBODY FUSION DEVICES (1998) | AcroMed Brochure |
| 1010 | French Patent No. FR 2,727,003 | Tisserand |
| 1011 | Certified translation of French Patent No. FR 2,727,003 | Tisserand Translation |
| 1012 | U.S. Patent Application No. 10/438,705 | |
| 1013 | Amendment, dated December 13, 2012 | |
| 1014 | Applicant-Initiated Interview Summary | |
| 1015 | Issue Notification, dated June 26, 2013 | |
| 1016 | Declaration of Hassan Serhan | Serhan Decl. |
| 1017 | Petition for *Inter Partes Review* of the ‘066 Patent, IPR2015-01335 | |
| 1018 | Patent Owner’s Response to Petition for *Inter Partes Review* of the ‘066 Patent, IPR2015-01335 | |

FIGURES AND TABLES

| Table No. | Description |
|---|---|
| 1 | Grounds for Inter Partes Review |
| 2 | Challenged Claim 19 is Anticipated by Benezech |
| 3 | Challenged Claim 20 is Anticipated by Benezech |
| 4 | Challenged Claim 22 is Anticipated by Benezech |
| 5 | Challenged Claim 25 is Anticipated by Benezech |
| 6 | Challenged Claim 29 is Anticipated by Benezech |
| 7 | Challenged Claim 19 is Obvious Over Benezech in view of Gilles |
| 8 | Challenged Claim 26 is Obvious Over Benezech in view of Gilles |
| 9 | Challenged Claim 19 is Obvious Over Benezech in view of the AcroMed Brochure |
| 10 | Challenged Claim 26 is Obvious Over Benezech in view of the AcroMed Brochure |
| 11 | Challenged Claim 19 is Obvious Over Benezech in view of Tisserand |
| 12 | Challenged Claim 26 is Obvious Over Benezech in view of Tisserand |

## I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 et seq. and 37 C.F.R. § 42.1 et seq., DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. ("Petitioners"), hereby submit this petition for *inter partes* review ("Petition") of U.S. Patent No. 8,486,066 ("the '066 patent"), attached hereto as Ex. 1001. Petitioners respectfully submit that independent claim 19 and dependent claims 20, 22, 25, 26 and 29 (the "Challenged Claims") are unpatentable under 35 U.S.C. § 103 in view of the prior art discussed herein.

The Challenged Claims of the '066 patent are directed to an implantable device for use in association with bones in a patient comprising a polymeric body and a metallic mounting strip. There was nothing novel about the Challenged Claims as of June 30, 1998, the earliest effective filing date for the '066 patent. The wedge is one of the six simple machines used since the dawn of civilization and, as the prior art presented in this Petition demonstrates, by 1998 polymeric wedge-shaped implants for fusing vertebrae were well-known, as were metallic mounting strips and screws to secure the wedges in place. The only additional elements of the Challenged Claims – the wedge having an opening and top and bottom surfaces that form an acute angle between 1 and 20 degrees – were also standard practice in the spinal implant art as of 1998.

Accordingly, Petitioners respectfully request that the Board institute an *inter*

*partes* review of the ‘066 patent pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.108.

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

### A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Petitioners are the real party-in-interest. The following corporations are related to Petitioners: Johnson & Johnson; Johnson & Johnson International; DePuy Synthes, Inc.; Synthes, Inc.; DePuy Orthopaedics, Inc.; Codman & Shurtleff, Inc.; DePuy Products, Inc.; Synthes USA, LLC; DePuy Spine, LLC.

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

The following litigation matter would affect or be affected by a decision in this proceeding: Bonutti Skeletal Innovations, LLC v. DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc., No. 14-14680-IT (D. Mass.) (“the Pending Litigation”). The litigation involves six patents: U.S. Patent No. 6,099,531 (“the ‘531 patent”), U.S. Patent No. 6,423,063 (“the ‘063 patent”), U.S. Patent No. 7,001,385 (“the ‘385 patent”), the ‘066 patent, U.S. Patent No. 8,690,944 and U.S. Patent No. 8,795,363 (“the ‘363 patent”). Certain claims of the ‘066 patent are the subject of this Petition. Petitioners are a party to the Pending Litigation.

The following litigation matter involves the ‘066 patent and would also affect or be affected by a decision in this proceeding: Bonutti Skeletal Innovations LLC v. Globus Medical Inc., No. 14-6650-WB (E.D. Pa.).

Petitioners are concurrently filing four additional petitions for *inter partes* review that will address (i) certain claims of the '531 patent, (ii) certain claims of the '063 patent, (iii) certain claims of the '385 patent, and (iv) certain claims of the '363 patent. The '066 and '363 patents are related to each other through continuation practice. Petitioners understand that all five patents are owned by Bonutti Skeletal Innovations LLC.

On December 16, 2105, the Patent Trial and Appeal Board ("the Board") granted institution of IPR2015-01335 involving claims 1-3, 8-10, 13, and 16-18 the '066 patent. The Challenged Claims are near-identical to the claims instituted in IPR2015-01335 and this Petition relies on the same main reference (Benezech) the Board considered there.

### C. Lead and Back-up Counsel (37 C.F.R. § 42.8(b)(3))

Petitioners designate the following as lead and back-up counsel, all with Axinn, Veltrop & Harkrider LLP:

| Lead Counsel | Back-up Counsel |
|---|---|
| Jeremy Lowe, Reg. No. 48,085<br>90 State House Square, 9th Floor<br>Hartford, CT 06103<br>Tel: 860-275-8100<br>Fax: 860-275-8101<br>jlowe@axinn.com | Dan Feng Mei, Reg. No. 71,518<br>114 West 47th Street, 22nd Floor<br>New York, NY 10036<br>Tel: 212-728-2200<br>Fax: 212-728-2201<br>dmei@axinn.com |
| Matthew J. Becker, Reg. No. 40,507<br>90 State House Square, 9th Floor<br>Hartford, CT 06103<br>Tel: 860-275-8100 | David K. Ludwig, Reg. No. 69,377<br>90 State House Square, 9th Floor<br>Hartford, CT 06103<br>Tel: 860-275-8100 |

| | |
|---|---|
| Fax: 860-275-8101<br>mbecker@axinn.com | Fax: 860-275-8101<br>dludwig@axinn.com |

A power of attorney is submitted herewith pursuant to 37 C.F.R. § 42.10(b).

### D. Service Information (37 C.F.R. § 42.8(b)(4))

Service of any documents via hand-delivery may be made at the postal mailing addresses of lead and back-up counsel identified above with courtesy copies to the following email addresses: jlowe@axinn.com, mbecker@axinn.com, dmei@axinn.com and dludwig@axinn.com. Petitioners consent to electronic service at these same email addresses.

## III. FEE PAYMENT AUTHORIZATION (37 C.F.R. § 42.103)

In accordance with 37 C.F.R. § 42.103(a), Petitioner authorizes the Patent Office to charge Deposit Account No. 013050 for the fees set forth in 37 C.F.R. § 42.15(a). If payment of additional fees is due during this proceeding, the Patent Office is authorized to charge such fees to Deposit Account No. 013050, and credit any overpayment to the same account.

## IV. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Pursuant to 37 C.F.R. § 42.104(a), Petitioners certify that the ‘385 patent is eligible for *inter partes* review and that Petitioners are not barred or estopped from requesting such review.

## V. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(1)-(2), Petitioners

respectfully request *inter partes* review of the Challenged Claims and request that the Challenged Claims be cancelled.

### A. Effective Filing Date of the '066 Patent

The '066 patent was filed as Appl. No. 10/438,705 on May 15, 2003. It is a continuation of Appl. No. 09/566,070, filed May 5, 2000, now U.S. Patent No. 6,575,982, which in turn is a continuation of Appl. No. 09/109,126, filed June 30, 1998, now U.S. Patent No. 6,086,593. For purposes of the petition only, the earliest effective filing date of the Challenged Claims is June 30, 1998.

### B. Prior Art and Statutory Grounds for the Challenge (37 C.F.R. § 42.104(b))

#### 1. French Patent Application No. FR 2,747,034 to Benezech et al. ("Benezech") (Ex. 1005)[1]

French Patent Application No. FR 2,747,034 to Benezech et al. ("Benezech") (Ex. 1005), entitled "Intersomatic Setting and Fusion System," published October 10, 1997. Benezech is prior art to the '066 patent under 35 U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the earliest effective filing date (June 30, 1998) of the '066 patent. Benezech was neither disclosed by Applicants nor cited or applied by the Examiner during prosecution of the '066 patent.

---

[1] A certified English translation of Benezech is attached as Ex. 1006.

### 2. French Patent Application No. FR 2,703,580 to Gilles ("Gilles") (Ex. 1007)[2]

French Patent Application No. FR 2,703,580 to Gilles ("Gilles") (Ex. 1007), entitled "Cervical Intersomatic Cage," published on October 14, 1994. Gilles is prior art to the '066 patent under U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the earliest effective filing date (June 30, 1998) of the '066 patent. Gilles was neither disclosed by Applicants nor cited or applied by the Examiner during prosecution of the '066 patent.

### 3. AcroMed, AcroMed Carbon Fiber Interbody Fusion Devices (1998) ("the AcroMed Brochure") (Ex. 1009)

ACROMED, ACROMED CARBON FIBER INTERBODY FUSION DEVICES (1998) ("the AcroMed Brochure") (Ex. 1009) was published, made accessible and distributed to the public prior to June 30, 1998, as established by the declaration Hassan A. Serhan. (Ex. 1016 at ¶¶ 2-5.) The AcroMed Brochure is prior art to the '066 patent under 35 U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the earliest effective filing date (June 30, 1998) of the '066 patent. The AcroMed Brochure was neither disclosed by Applicants nor cited or applied by the Examiner during prosecution of the '066 patent.

---

[2] A certified English translation of Gilles is attached as Ex. 1008.

### 4. French Patent Application No. FR 2,727,003 to Tisserand ("Tisserand") (Ex. 1010)[3]

French Patent Application No. FR 2,727,003 to Tisserand ("Tisserand") (Ex. 1010), entitled "Device for Anterior Stabilization of the Lumbosacral Spine," published on November 18, 1994. Tisserand is prior art to the '066 patent under U.S.C. § 102(b) because it issued more than one year before the earliest effective filing date (June 30, 1998) of the '066 patent. Tisserand was neither disclosed by Applicants nor cited or applied by the Examiner during prosecution of the '066 patent.

**Table 1. Grounds for *Inter Partes R*eview**

| Ground | Claim | Statutory Basis and Prior Art |
|---|---|---|
| 1 | 19, 20, 22, 25, 29 | Anticipation under 35 U.S.C. § 102 by Benezech |
| 2 | 19, 20, 22, 25, 26, 29 | Obviousness under 35 U.S.C. § 103 over Benezech in view of Gilles. |
| 3 | 19, 20, 22, 25, 26, 29 | Obviousness under 35 U.S.C. § 103 over Benezech in view of the AcroMed Brochure. |
| 4 | 19, 20, 22, 25, 26, 29 | Obviousness under 35 U.S.C. § 103 over Benezech in view of Tisserand. |

These grounds are described in detail in Section VII below, and are supported by the declaration of Dr. Carl McMillin (Ex. 1002).

Dr. McMillin received a B.A. in Mechanical Engineering in 1969 from the

[3] A certified English translation of Tisserand is attached as Ex. 1011.

General Motors Institute of Technology and a Ph.D. from Case Western Reserve University in macromolecular science and operations research in 1974. From 1983 to 1989, Dr. McMillin was an Associate Professor in the Department of Biomedical Engineering and Director of the Cardiovascular Laboratory in the Institute for Biomedical Engineering Research at the University of Akron. From 1989 to 1997, he was Senior Scientist, Director of Polymer Laboratory and Director of R&D at AcroMed Corporation, developing orthopedic implant products, primarily for spinal applications. Since 1999, Dr. McMillan has been a member of the adjunct faculty at Cleveland State University teaching courses including Biomaterials, Artificial Organs and Medical Devices, and Cardiovascular Complications of Diabetes in the doctoral Applied Biomedical Engineering Program. He is the recipient of the 2015 C. William Hall lifetime achievement award from the Society for Biomaterials. As a skilled practitioner in the relevant field since before 1998, Dr. McMillin is qualified to provide an opinion as to what a person of ordinary skill in the art would have understood, known or concluded as of June 30, 1998. Accordingly, he is competent to testify in this proceeding.

## VI. SUMMARY OF THE '066 PATENT

### A. Summary of the Patent

The '066 patent specification describes "a wedge member … used to change a spatial relationship between portions of bone in a patient's body." (Ex. 1001 at

1:20-22.) Figures 1 and 2 below (which are Figures 11 and 12 of the '363 patent), illustrate an embodiment of the '066 patent:

Figure 1: Side cross-section of apparatus assembly in bone

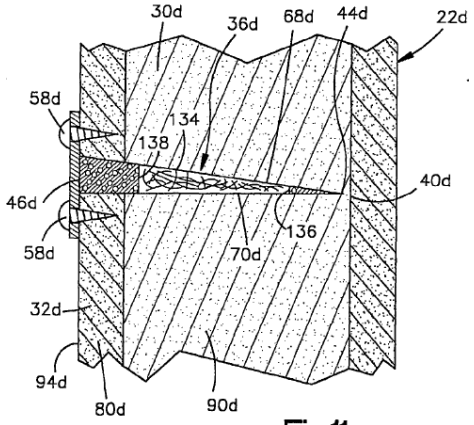


Fig.11

Figure 2: Top view of apparatus assembly in bone

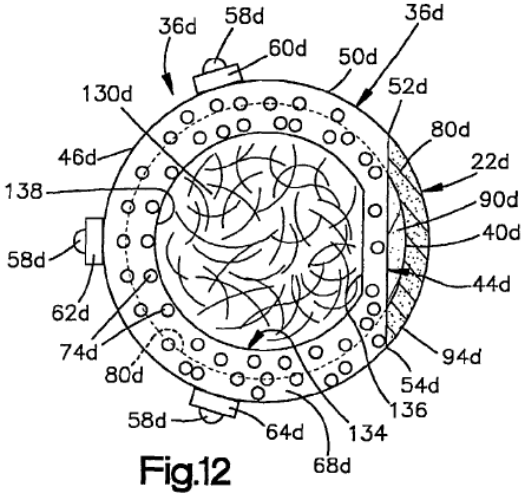


Fig.12

The assembly includes at least two components: a support body and a mounting strip. (Id. at 7:35-48.) The support body is inserted between two bone segments, while the mounting strip abuts the outer side surfaces of the bone segments. (Id.) The mounting strip is affixed to the bone segments with screws, securing the support body in place, as shown in Figure 1. (Id. at Fig. 11 (mounting strip identified as 46d); 4:43-45.) Also depicted in Figures 1 and 2 is a central opening formed in the support body, which can be packed with a bone growth promoting material to allow bone to grow through it. (Id. at Fig. 11 (central opening identified as 134); Fig. 12 (central opening identified as 130d); 2:1-7.)

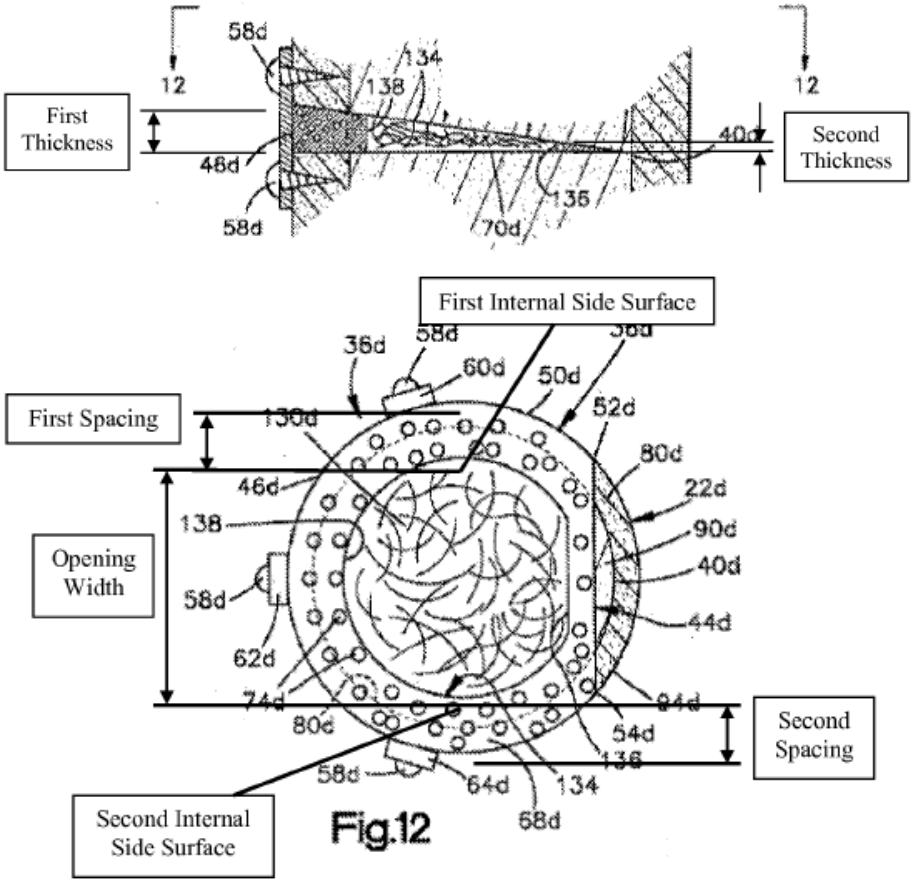
The '066 patent issued with 32 claims of which independent claim 19 and

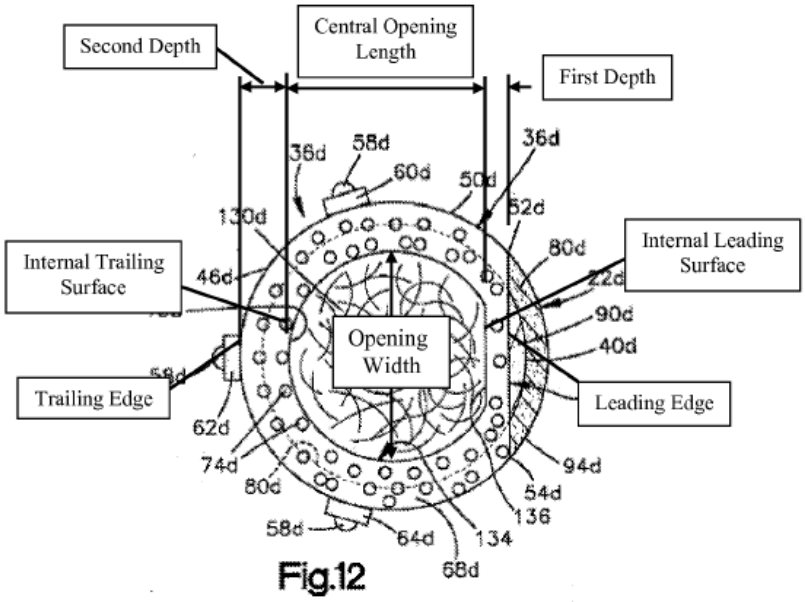
dependent claims 20, 22, 25, 26 and 29 are the only claims at issue in this Petition.

### B. Prosecution History of the '066 Patent

The application that issued as the '066 patent was originally filed with 13 claims. (Ex. 1012 at 42-43.) After a lengthy prosecution lasting over 9 years, Applicant cancelled all pending claims and drafted a new set of claims on December 13, 2012. (Ex. 1013 at 2-6.) The new claims were drawn to apparatus assemblies with specific geometric parameters, which drew support primarily from the application's drawings. (Id. at 2-16.) Applicant provided annotated drawings to clarify the meanings of the new claim terms, as shown in Fig. 3.

Figure 3: Annotated drawings from prosecution history






(Id. at 9, 11.)

On April 25, 2013, Applicant and Examiner had an interview in which Applicant agreed to an Examiner amendment of certain pending claims. (Ex. 1014 at 1.) On July 16, 2013, the application issued as the '066 patent. (Ex. 1015 at 1.)

### C. Level of Ordinary Skill in the Art

A person of ordinary skill in the art with respect to the '066 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience, or a Ph.D. and at least two years of experience. (Ex. 1002 at ¶ 58.) The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a person of ordinary skill could be a Doctor of

Medicine who has completed an accredited residency program in orthopedic surgery followed by at least two years in active practice specializing in orthopedic surgery. (Id. at ¶ 59.)

### D. Claim Construction (37 C.F.R. § 42.104(b)(3))

Petitioners do not concede that the scope of the terms construed or other terms in the claims are reasonably certain to one of ordinary skill in the art. See generally Nautilus, Inc. v. Bioig Instruments, Inc., 134 S.Ct. 2120 (2014). Rather, Petitioners believe that many of the terms are indefinite and reserve all rights to argue indefiniteness in the related litigation.

A patent claim term in *inter partes* review is to be given the "broadest reasonable construction in light of the specification" as commonly understood by those of ordinary skill in the art. 37 C.F.R. § 42.100(b). The terms are given a broad interpretation except where defined otherwise in the specification. In re ICON Health & Fitness, Inc., 496 F.3d 1374, 1379 (Fed. Cir. 2007). Consistent with this standard, and without conceding that these terms should be construed the same way in a district court proceeding, Petitioners provide proposed constructions of certain claim terms below for the purpose of this Petition only.

#### 1. "mounting strip"

The broadest reasonable construction of "mounting strip" includes a "plate" as disclosed in Benezech (Ex. 1006). This is evidenced by the Patent Owner's

Preliminary Response in the related *inter partes review* of the '363 Patent, IPR2015-01333, wherein the Patent Owner did not dispute that Figure 1 of Benezech discloses a mounting strip. (Compare Ex. 1017 at 18 (identifying "plate" of Benezech as mounting strip) with Ex. 1018 at 7-10 (Patent Owner not disputing teaching of mounting strip).)

**2. "edge"**

The broadest reasonable construction of "edge" in Challenged Claim 19 is "external surface." This is consistent with the statement in the specification of the '066 patent that the "wedge member 36d . . . has a thin edge 44d and a thick edge 46d." (Ex. 1001 at 13:64-67.)

Figure 2: Side cross-section of apparatus assembly in bone

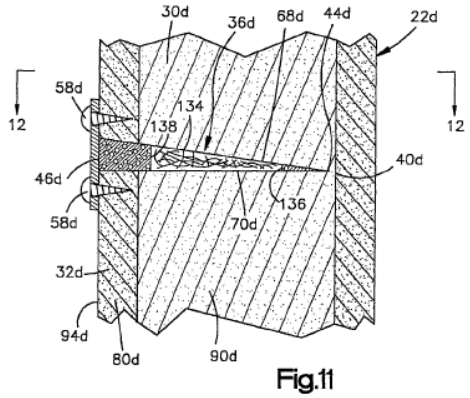


Fig.11

(Id. at Fig. 11.) It is also consistent with the prosecution history of the '066 patent, where the Patent Owner identified the surface of the trailing end of the wedge as an "edge." (See Fig. 3 above, supra at 10-11.)

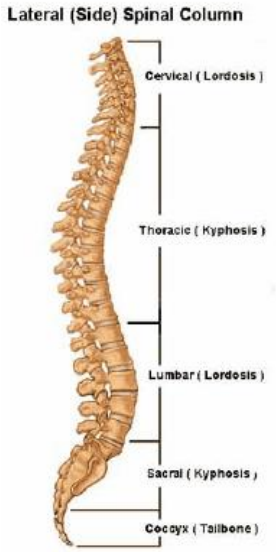
## VII. DETAILED EXPLANATION (37 C.F.R. § 42.104(b)(4)-(5))

### A. General State of the Art

The ‘066 patent is generally directed to an implantable wedge-shaped device with a polymeric body and a metallic mounting strip. (Ex. 1002 at ¶ 15.) As of June 30, 1998, such devices were commonly used to stabilize and fuse vertebrae to relieve pain and correct deformities in patients with various forms of spinal degeneration. (Id. at ¶ 40.) As early as the 1950s, decompression – the removal of the intervertebral disc located between adjacent vertebrae – together with the implantation of a bone graft in the resulting space had been established as a standard method of accomplishing stabilization and fusion. (Id.) Between 1990 and 1998, over one million spinal fusions were performed in hospitals throughout the U.S. (Id. at ¶ 41.)

The normal curvature of the spine consists of lordosis (segments creating a backward-leaning curve) in the cervical region, kyphosis (segments creating a forward-leaning curve) in the thoracic region and lordosis again in the lumbar region and is generated by both wedge-shaped vertebral bodies and wedge-shaped spinal discs. (Id. at ¶ 34.)

Figure 4: Curvature of the spine



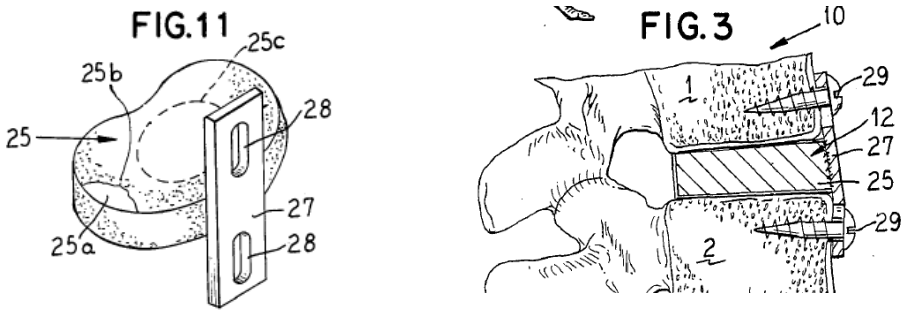

Therefore, as of June 30, 1998, spinal fusion implants were often wedge-shaped in order to restore and maintain lordosis. (Id. at ¶ 39.)

In the early 1990s, polymeric materials (biocompatible plastics) were put to use for orthopedic applications such as spinal fusion implants. (Id. at ¶ 46.) Commonly used polymeric materials at this time included poly(ether ether ketone) (PEEK) and poly(ether ketone ether ketone ketone) (PEKEKK). (Id.) These materials had the advantage of being somewhat compressible, which encourages bone growth and fusion, and radio translucent, which permits post-implantation assessment of fusion using x-rays, computed tomography scans or magnetic resonance imaging. (Id. at ¶¶ 47, 48.)

By 1998 it had long been understood that spinal fusion implants must be fixed in place between vertebrae in order to optimize the environment for fusion.

(Id. at ¶ 49.) With the anterior longitudinal ligament and the disc annulus cut, the forces applied on the implanted device by the spine could otherwise move the implant out of place or even eject it from the cavity. (Id.) Even local micromotion at the interface of the implant and the bone should be minimized for bony fusion to occur. (Id.) Fixing the implant in place also maintains the alignment of the spine around the implant. (Id.) A common fixation method was screwing a metal plate or strip to the vertebrae as shown below:

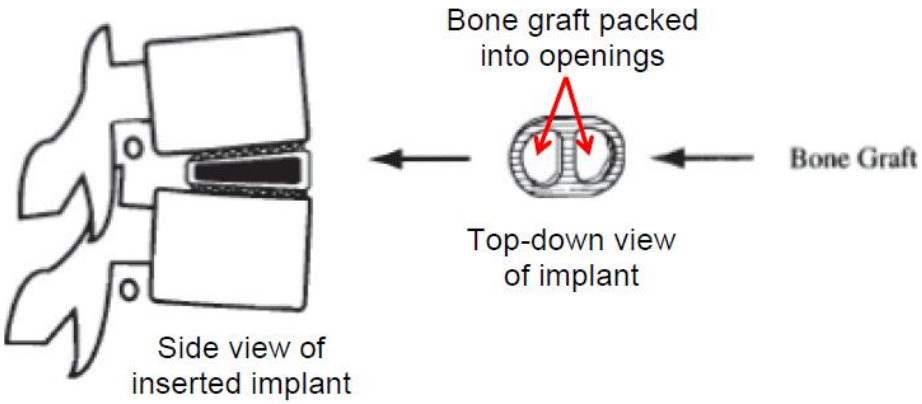
Figure 5: Intervertebral
implant with fixation plate and screws




(Id. at ¶ 51.) Metal was a preferred material for the plate and fixation components due to its high strength and stiffness. (Id. at ¶ 52.)

It was also common by 1998 for spinal implants designed to fuse two vertebrae to contain one or more passages for insertion of bone graft material through which bone growth could occur. (Id. at ¶ 44.) The illustration below shows a wedge-shaped vertical ring implant with two openings for bone graft material that was in use in the early 1990s. (Id.)

Figure 6: Wedge-shaped
intervertebral implant with two passages (annotated)




## B. Ground 1 – Challenged Claims 19, 20, 22, 25 and 29 are Anticipated by Benezech

### 1. Claim 19

The features of the independent Challenged Claim 19 are recited in the headings of sub-paragraphs (a) through (i) below:

#### a. "An implantable device for use in association with bones in a patient's body,"

The preamble of Challenged Claim 19 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999); M.P.E.P. § 2111.02. The preamble is therefore not limiting.

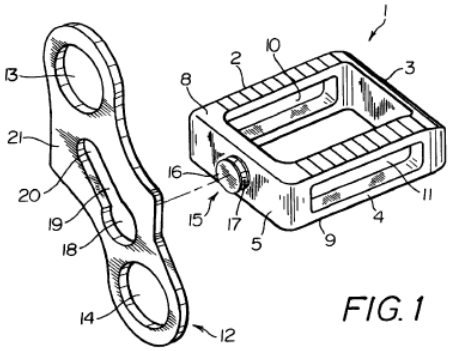
To the extent that the preamble does limit Challenged Claim 19, however, Benezech discloses "an intersomatic vertebrae setting and fusion system . . .

intended to be interposed between two vertebrae." (Ex. 1006 at p. 1, ll. 6-8.) As Dr. McMillin explains, person of ordinary skill in the art would understand that the spinal implant device of Benezech is used between two adjacent vertebra. (Ex. 1002 at ¶ 61.) Benezech thus discloses an implantable device for use in association with bones in a patient's body. (Id.)

**b. "the apparatus assembly comprising: a body constructed of a polymeric material"**

Benezech discloses "an intersomatic vertebrae setting and fusion system . . . intended to be interposed between two vertebrae." (Ex. 1006 at p. 1, ll. 6-8.)

Figure 7: Fig. 1 of Benezech




As illustrated in Figure 7 above (which is Figure 1 of Benezech), the system of Benezech comprises "at least one open internal cage receiving the spongy bone or a bone substitute and . . . means for anchoring to at least two adjacent vertebrae to be secured to each other." (Id. at p. 1, l. 23-p. 2, l. 2.) A person of ordinary skill in the art would thus understand that Benezech discloses an apparatus assembly comprising a body and an external plate adapted for anchoring. (Ex. 1002 at ¶ 62.)

Benezech further discloses that the apparatus assembly is "made of metal or

biocompatible plastic material." (Ex. 1006 at p. 2, l. 6.) As of 1998, biocompatible plastics such as PEEK were known in the art and used for spinal implants. (Ex. 1002 at ¶ 63.) A person of ordinary skill in the art would have known that PEEK is a polymeric material. (Id.) Thus, Benezech discloses an apparatus assembly having a body constructed of a polymeric material. (Id.)

**c. "including a trailing end portion having a trailing edge, a leading end portion having a leading edge,"**

As shown in Figure 8 below, Benezech discloses an apparatus assembly with a body that includes a trailing end portion having a trailing edge and a leading end portion having a leading edge. (Ex. 1002 at ¶ 64.)

Figure 8: Fig. 1 of Benezech (annotations added)

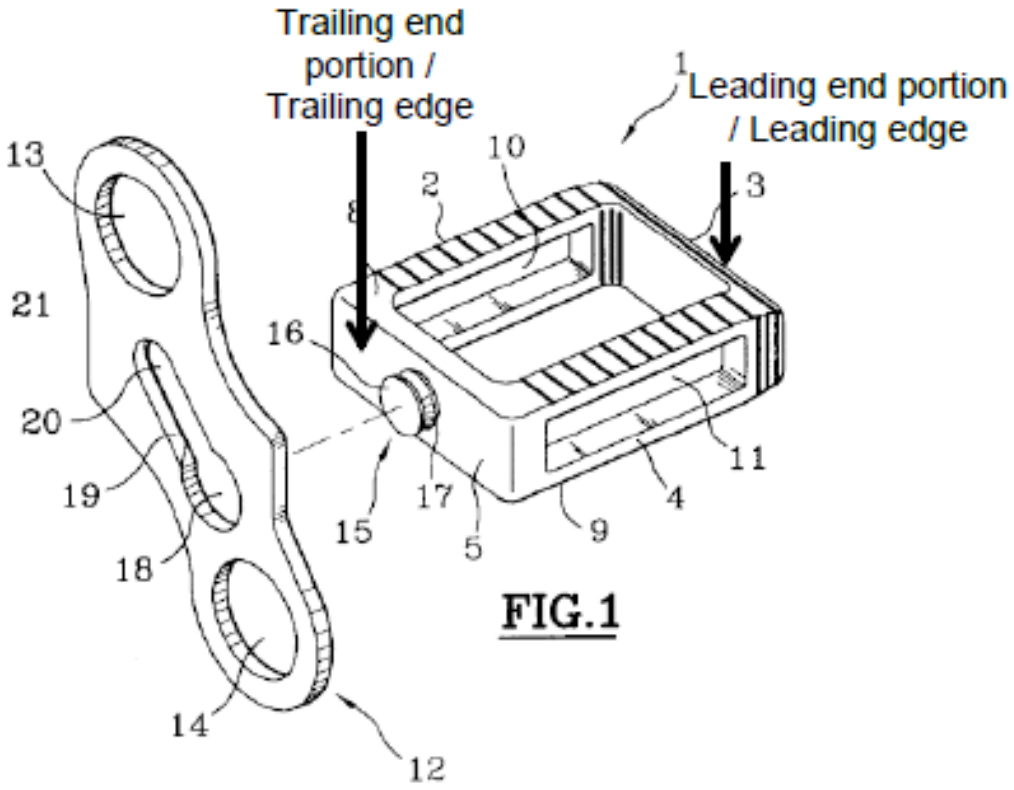
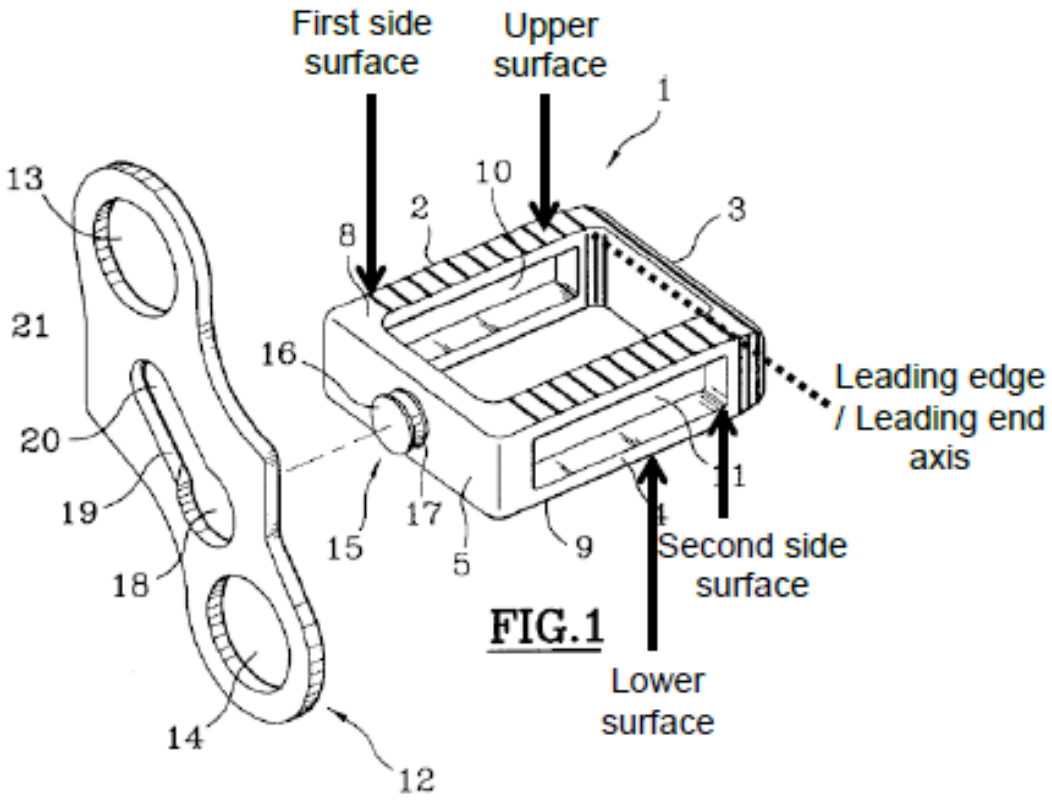



FIG.1

**d. "a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis,"**

As shown in Figure 9 below, Benezech discloses an apparatus assembly with a body that includes a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis. (Ex. 1002 at ¶ 65.)

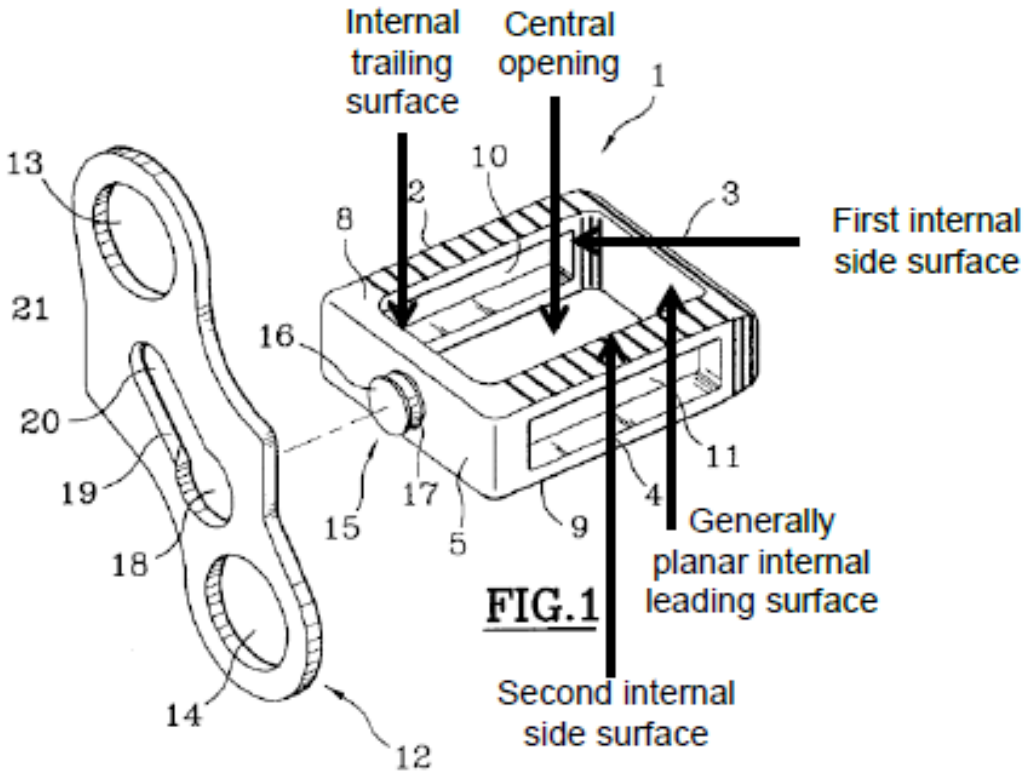
Figure 9: Fig. 1 of Benezech (annotations added)



**e. "the body further including a central opening formed in the body and extending through the upper surface and the lower surface, the central opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface,"**

As shown in Figure 10 below, Benezech discloses an apparatus assembly with a body that includes a central opening formed in the body and extending through the upper surface and the lower surface, the central opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface. (Ex. 1002 at ¶ 66.)

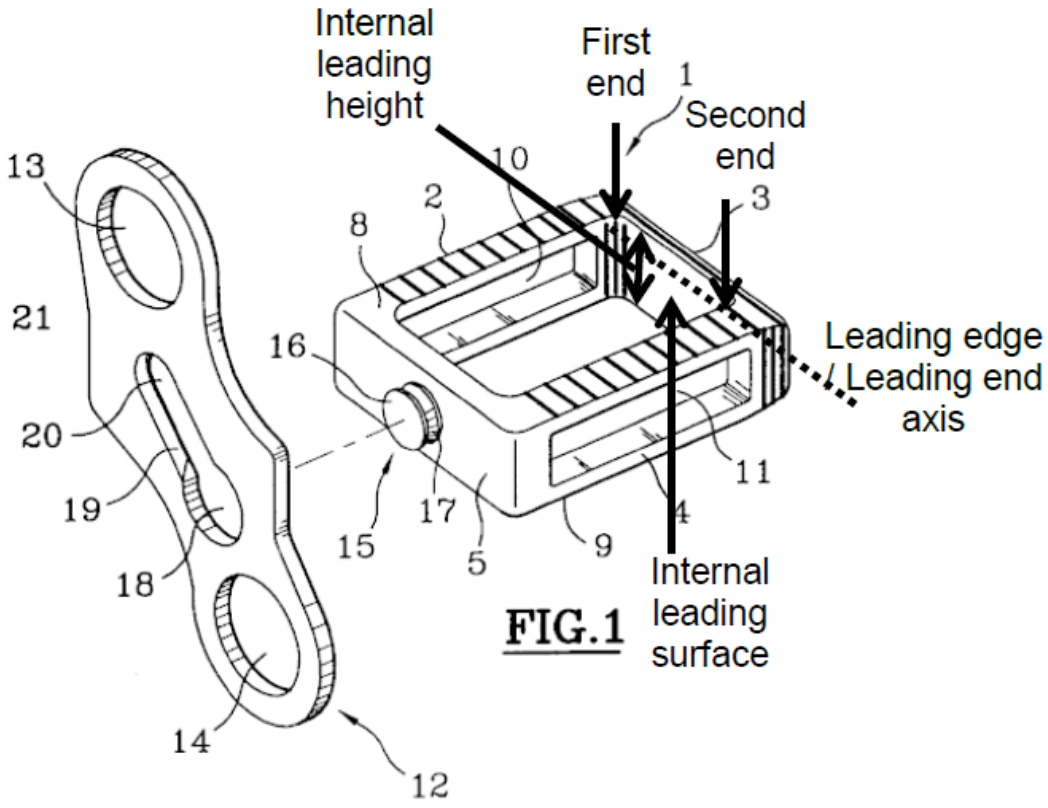
Figure 10: Fig. 1 of Benezech (annotations added)



**f. "the internal leading surface including a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end,"**

As shown in Figure 11 below, Benezech discloses an apparatus assembly with a body that includes an internal leading surface that includes a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end. (Ex. 1002 at ¶ 67.)

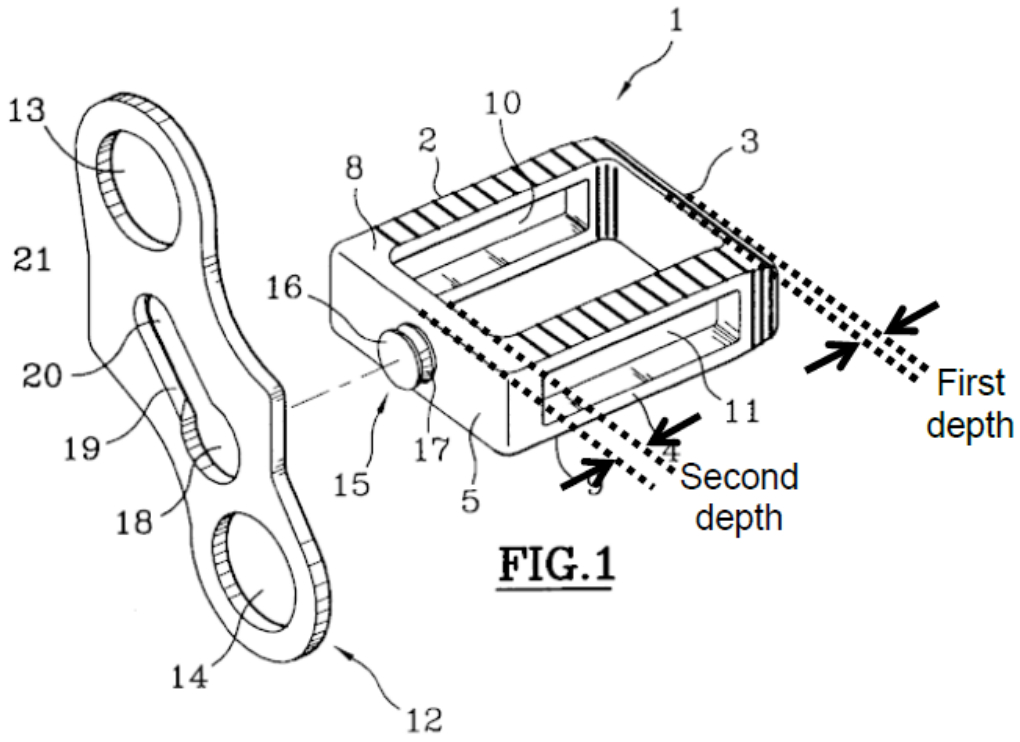
Figure 11: Fig. 1 of Benezech (annotations added)



**g. "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth,"**

As shown in Figure 12 below, Benezech discloses an apparatus assembly with a body that includes a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth. (Ex. 1002 at ¶ 68.)

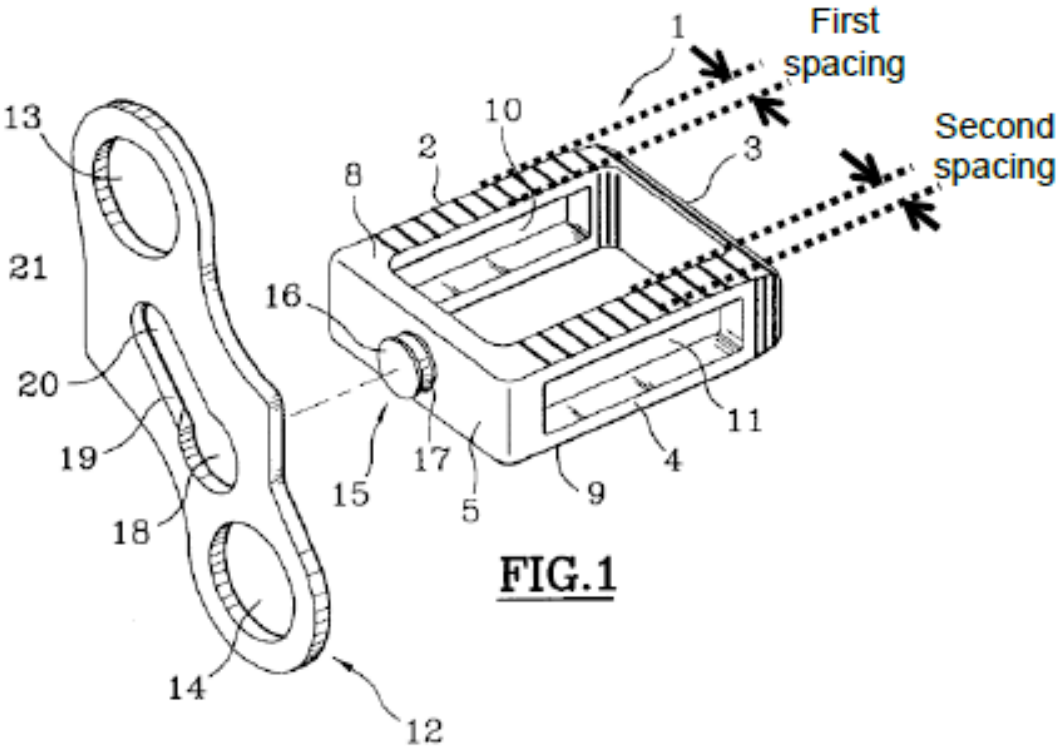
Figure 12: Fig. 1 of Benezech (annotations added)



**h. "wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing, the first spacing being substantially the same as the second spacing;"**

As shown in Figure 13 below, Benezech discloses an apparatus assembly with a body wherein a first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing, the first spacing being substantially the same as the second spacing. (Ex. 1002 at ¶ 69.)

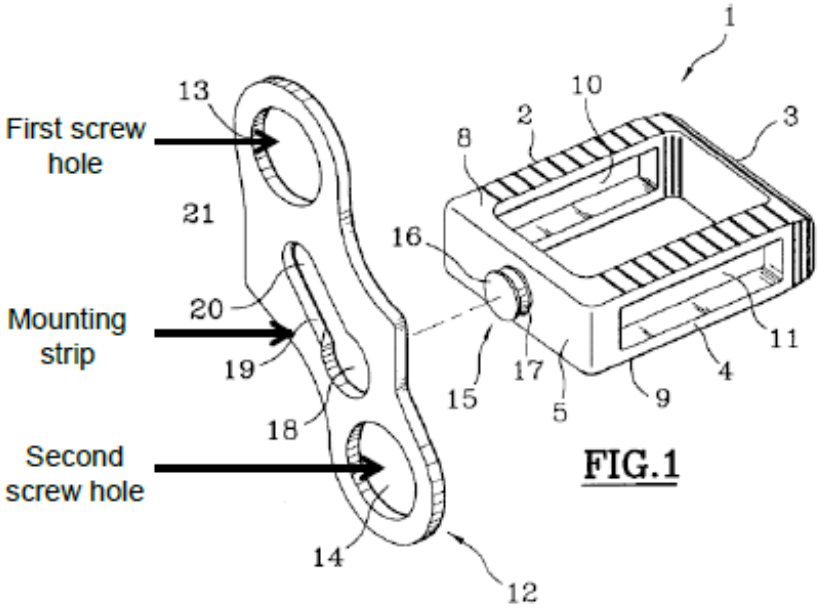
Figure 13: Fig. 1 of Benezech (annotations added)



**i. "and a first mounting strip connected to the trailing end portion, the first mounting strip constructed of a metallic material, a first screw hole and a second screw hole extending through the first mounting strip."**

As illustrated in Figure 14 below, the apparatus assembly disclosed in Benezech includes "an external element forming a flange (plate) . . . having at each of its means for anchoring to at least two adjacent vertebrae to be secured to each other." (Ex. 1006 at p. 1, l. 23 - p. 2, l. 2.)

Figure 14: Fig. 1 of Benezech (annotations added)




(Ex. 1002 at ¶ 70.) Thus, the apparatus assembly of Benezech includes a mounting strip. (Id.) As also seen in Figure 14, the mounting strip is connected to the trailing end of the body and has a first and second screw hole.

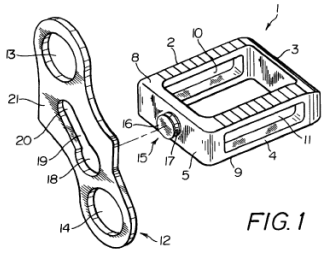
Benezech further discloses that "[t]he setting systems of the invention are produced from titanium alloy or equivalent material, or of a biocompatible plastic

material." (Ex. 1006 at p. 6, ll. 8-9.) Thus, Benezech discloses an apparatus assembly having a mounting strip constructed of a metallic material. (Id. at ¶ 71.)

As Dr. McMillin explains, it would have been understood by the person of ordinary skill in the art that Benezech teaches that the body and the mounting strip of the apparatus assembly can, respectively, be made of a plastic and metallic material. (Ex. 1002 at ¶ 72.) Dr. McMillin explains that the use of such a combination was well-known in the art at the time, citing by way of example U.S. Patent No. 4,743,256 disclosing a spinal implant disclosed having a body made of a bio-compatible plastic and retaining plate made of a biocompatible metal. (Id.) The person of ordinary skill would also have known that the body of a spinal implant is beneficially constructed of a polymeric material such as a biocompatible plastic because the compression permitted by such materials encourages bone growth and hence fusion to occur. (Id.) Furthermore, a biocompatible plastic can be radio translucent and thus offers the additional benefit of permitting assessment of the fusion or tumor recurrence by x-ray, MRI and other forms of scans. (Id.) The mounting strip, on the other hand, could beneficially be metallic in order to minimize any movement of the body after implantation and handle higher loads. (Id.) For these reasons as well, the person of ordinary skill in the art would have understood that Benezech discloses a body made of polymeric material and a mounting strip made of metallic material. (Id.)

In sum, and as further illustrated in Table 2 below, Benezech discloses all of the elements of Challenged Claim 19 and renders the claim invalid as anticipated.

**Table 2: Challenged Claim 19 is Anticipated by Benezech**

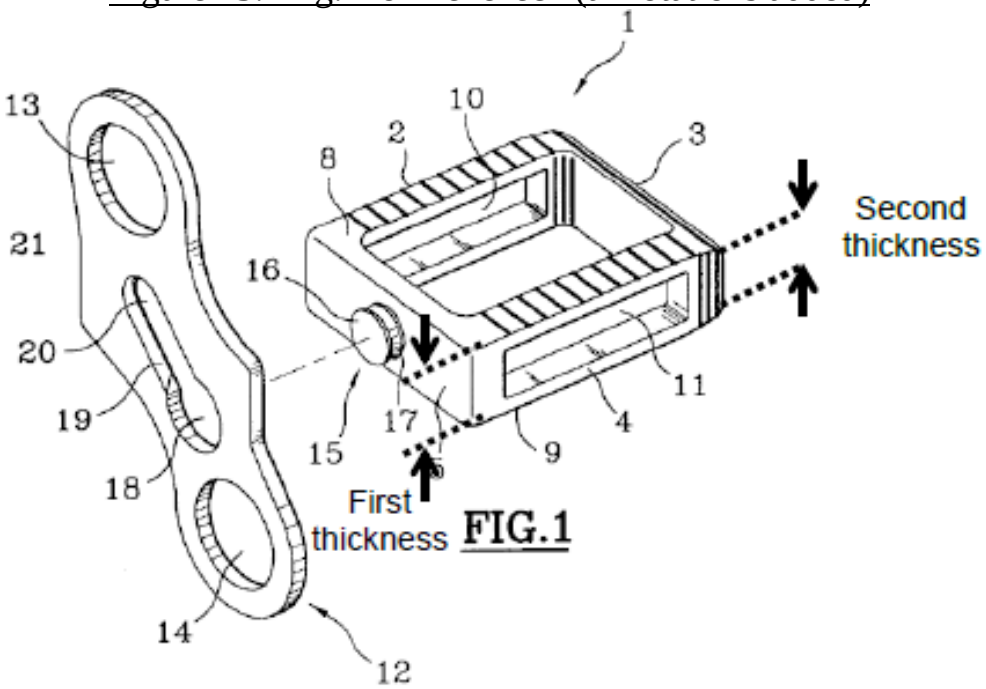
| Challenged Claim 19 | Benezech (Ex. 1006) |
|---|---|
| An apparatus assembly for use in association with bones in a patient's body, | Not material to patentability. "[A]n intersomatic vertebrae setting and fusion system . . . intended to be interposed between two vertebrae." (Ex. 1006 at p.1, ll. 6-8.) |
| the apparatus assembly comprising: a body constructed of a polymeric material | "[T]he system . . . includ[es] at least one open internal cage receiving the spongy bone or a bone substitute and intended to be interposed between two vertebrae during . . . and having at each of its ends means for anchoring to at least two adjacent vertebrae to be secured to each other." (Id. at p. 1, l. 23-p. 2, l. 2.) "Said cage is rigid, made of metal or biocompatible plastic material." (Id. at p. 2, l. 6.) |
| including a trailing end portion having a trailing edge, a leading end portion having a leading edge, | Figure 7: Fig. 1 of Benezech  FIG. 1 |
| a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis, | See Figure 7 above. |
| the body further including a central opening formed in the body and extending through the upper surface and the lower surface, the central | See Figure 7 above. |

| Challenged Claim 19 | Benezech (Ex. 1006) |
|---|---|
| opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface, | |
| the internal leading surface including a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end, | See Figure 7 above. |
| a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth, | See Figure 7 above. |
| wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing, the first spacing being substantially the same as the second spacing; and | See Figure 7 above. |
| a first mounting strip connected to the trailing end portion, the first mounting strip constructed of a metallic material, a first screw hole and a second screw hole extending through the first mounting strip. | "[T]he system includ[es] an external element forming a flange (plate) . . . having at each of its means for anchoring to at least two adjacent vertebrae to be secured to each other." (Id. at p. 1, l. 23-p. 2, l.2.) "Said cage is rigid, made of metal or biocompatible plastic material." (Id. at p. 2, l. 6.) |

### 2. Challenged Claim 20

Challenged Claim 20 depends from claim 19 and further recites "wherein the trailing end portion has a first thickness and the leading end portion has a second thickness, the first thickness being greater than the second thickness." As illustrated in Figure 15 below, Benezech discloses the additional elements of Challenged Claim 20:

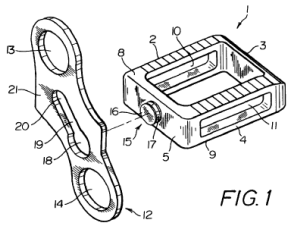
Figure 15: Fig. 1 of Benezech (annotations added)




(Ex. 1002 at ¶ 74.) Thus, and as further illustrated in Table 3 below, Benezech discloses the additional elements of Challenged Claim 20 and renders the claim invalid as anticipated.

**Table 3: Challenged Claim 20 is Anticipated by Benezech**

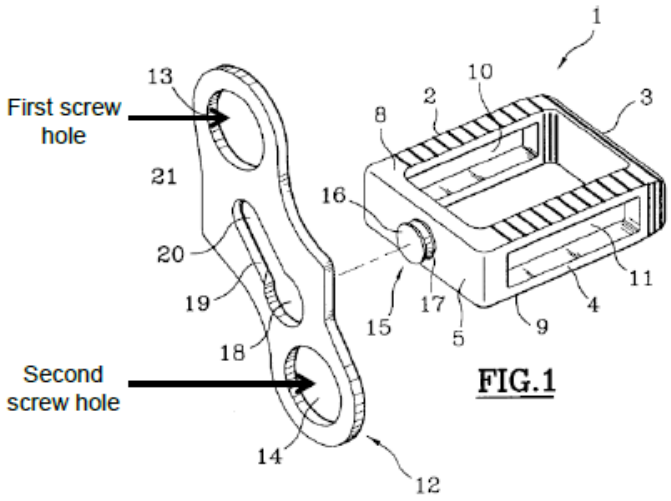
| Challenged Claim 20 | Benezech (Ex. 1006) |
|---|---|
| The apparatus assembly of claim 19, | See Table 2 above. |

| | |
|---|---|
| wherein the trailing end portion has a first thickness and the leading end portion has a second thickness, the first thickness being greater than the second thickness. | Figure 7: Fig. 1 of Benezech<br>  <br>FIG. 1 |

### 3. Challenged Claim 22

Challenged Claim 22 depends from claim 19 and further recites "a first screw configured for mounting in the first screw hole; and a second screw configured for mounting in the second screw hole." As shown in Figure 16 below, Benezech discloses an apparatus assembly having a first and second screw hole. (Ex. 1002 at ¶ 76.)

Figure 16: Fig. 1 of Benezech (annotations added)

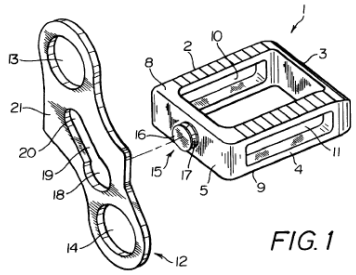



Benezech further discloses that "the means of anchoring the plate 12, 12A onto the vertebrae, after securing the cage 1, 1A, is achieved by means of pedicle screws (not shown) passing through corresponding holes 13, 14 made in the ends

of said flange 12, 12A." (Ex. 1006 at p. 5, ll. 13-16.) Benezech also teaches that plates of the apparatus assembly "are shown with one attachment per screw per vertebrae." (Id. at p. 5, l. 27.) Benezech therefore discloses a first and second screw configured for mounting in first and second screw holes. (Ex. 1002 at ¶ 77.)

Thus, and as further illustrated in Table 4 below, Benezech discloses the additional elements of Challenged Claim 22 and renders the claim invalid as anticipated.

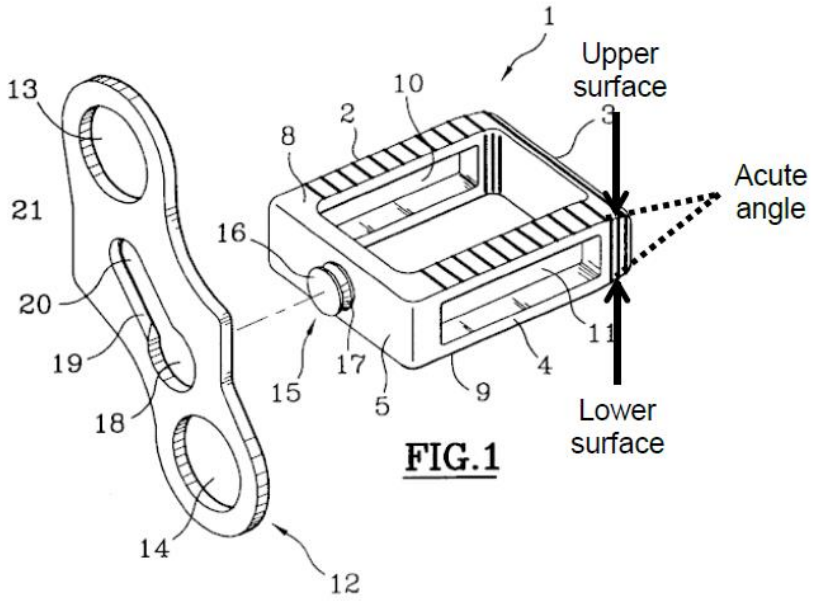
**Table 4: Challenged Claim 22 is Anticipated by Benezech**

| Challenged Claim 22 | Benezech (Ex. 1006) |
|---|---|
| The apparatus assembly of claim 19, | See Table 2 above. |
| further comprising: a first screw configured for mounting in the first screw hole; and a second screw configured for mounting in the second screw hole. | Figure 7: Fig. 1 of Benezech<br>  <br>FIG. 1<br>"[T]he means of anchoring the plate 12, 12A onto the vertebrae, after securing the cage 1, 1A, is achieved by means of pedicle screws (not shown) passing through corresponding holes 13, 14 made in the ends of said flange 12, 12A." (Ex. 1006 at p. 5, ll. 13-16.) "The plates of the apparatus assembly "are shown with one attachment per screw per vertebrae." (Id. at p. 5, l. 27.) |

### 4. Challenged Claim 25

Challenged Claim 25 depends from claim 19 and further recites "wherein the upper and lower surfaces define an acute angle." As illustrated in Figure 17 below, Benezech discloses the additional element of Challenged Claim 25. (Ex. 1002 at ¶ 79.)

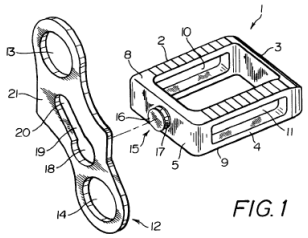
Figure 17: Fig. 1 of Benezech (annotations added)




Thus, and as further illustrated in Table 5 below, Benezech discloses the additional elements of Challenged Claim 25 and renders the claim invalid as anticipated.

**Table 5: Challenged Claim 25 is Anticipated by Benezech**

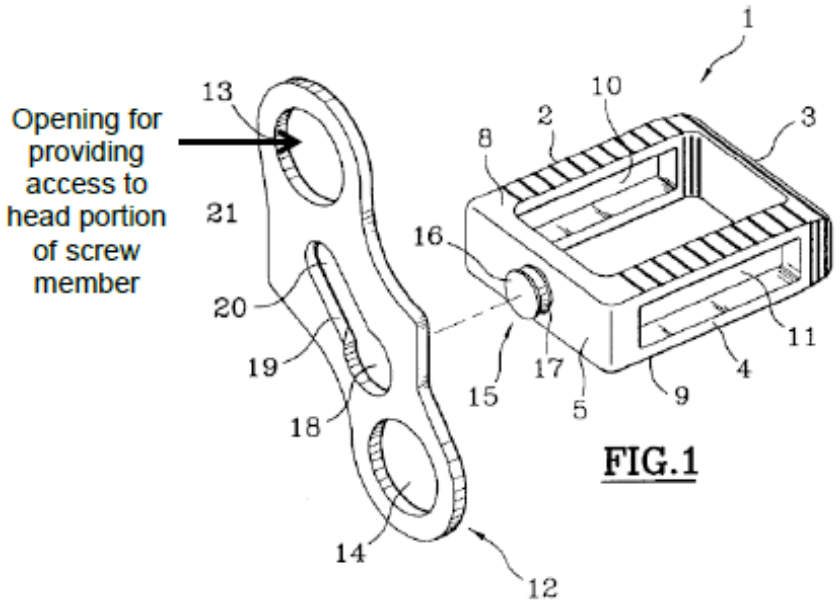
| Challenged Claim 25 | Benezech (Ex. 1006) |
|---|---|
| The apparatus assembly of claim 19, | See Table 2 above. |
| wherein the upper and lower surfaces define an acute angle. | Figure 7: Fig. 1 of Benezech |

| | |
|---|---|
| |  FIG. 1 |

### 5. Challenged Claim 29

Challenged Claim 29 depends from claim 19 and further recites "wherein the mounting strip includes an opening formed therein, the opening configured in the mounted configuration to provide access to a head end portion of a screw member." As shown in Figure 18 below, Benezech discloses an apparatus assembly having a mounting strip with an opening. (Ex. 1002 at ¶ 82.)

Figure 18: Fig. 1 of Benezech (annotations added)

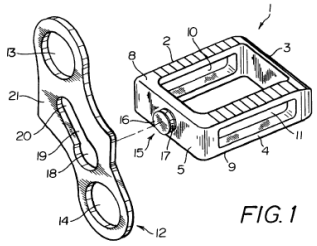



Benezech further discloses that "the means of anchoring the plate 12, 12A onto the vertebrae, after securing the cage 1, 1A, is achieved by means of pedicle

screws (not shown) passing through corresponding holes 13, 14 made in the ends of said flange 12, 12A." (Ex. 1006 at p. 5, ll. 13-16.) Benezech also teaches that plates of the apparatus assembly "are shown with one attachment per screw per vertebrae." (Id. at p. 5, l. 27.) Benezech therefore discloses a mounting strip with an opening configured in the mounted configuration to provide access to a head end portion of a screw member. (Ex. 1002 at ¶ 83.)

Thus, and as further illustrated in Table 7 below, Benezech discloses the additional elements of Challenged Claim 29 and renders the claim invalid as anticipated.

**Table 6: Challenged Claim 29 are Anticipated by Benezech**

| Challenged Claim 29 | Benezech (Ex. 1006) |
|---|---|
| The apparatus assembly of claim 19, | See Table 2 above. |
| wherein the mounting strip includes an opening formed therein, the opening configured in the mounted configuration to provide access to a head end portion of a screw member. | Figure 7: Fig. 1 of Benezech<br>  <br>FIG. 1<br>"[T]he means of anchoring the plate 12, 12A onto the vertebrae, after securing the cage 1, 1A, is achieved by means of pedicle screws (not shown) passing through corresponding holes 13, 14 made in the ends of said flange 12, 12A." (Ex. 1006 at p. 5, ll.13-16.) "The plates are shown with one attachment per screw per vertebrae." (Id. at p. 5, l. 27.) |

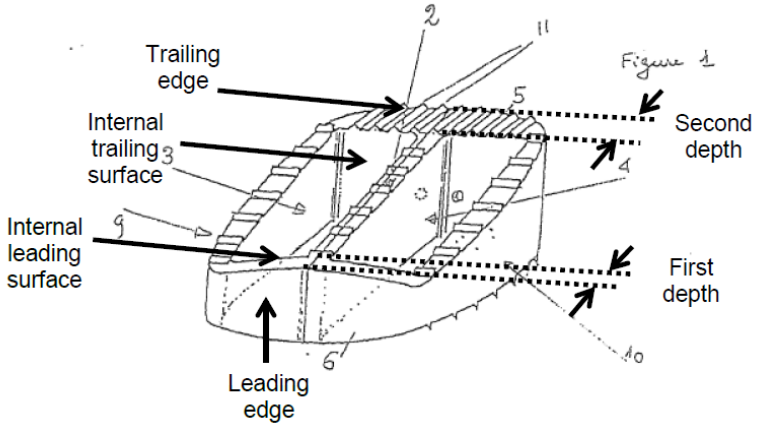
### C. Ground 2 – The Challenged Claims are Obvious over Benezech in View of Gilles

#### 1. Challenged Claim 19

The Petitioners submit that each and every limitation of Challenged Claim 19 is disclosed in Benezech. (Supra at 17-28.) The Petitioners anticipate, however, that the Patent Owner may assert that Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth." If so, and to the extent the Board agrees, this limitation is disclosed in Gilles and, as Dr. McMillin explains, it would have been obvious to one of skill in the art to modify the body of Benezech in view of Gilles to have a first depth less than a second depth.

Gilles discloses a "[c]ervical intersomatic cage" for "fusion of vertebrae during discectomy. . . ." (Ex. 1008, cover page.) Like Benezech, Gilles discloses an implantable device for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id. at 1:7-8; 2:25; Ex. 1002 at ¶ 86.) The cage of Gilles is shaped as a wedge with a first depth (the wall on the posterior or leading side) less than the second depth (the wall on the anterior or trailing side):

Figure 19: Fig. 1 of Gilles (annotations added)




(Ex. 1002 at ¶ 86.)

Gilles teaches that "[t]he height of the posterior face (6) is sufficient to enable the preservation of a normal cervical height. The height of the anterior face (5) is slightly greater to make it possible to obtain the appropriate degree of lordosis." (Ex. 1008 at 2:25-27.) A person of ordinary skill in the art would know that the posterior face is the leading edge, i.e., the edge that is inserted first between the vertebrae of the patient, and that the anterior face is the trailing edge. (Ex. 1002 at ¶ 87.) Thus, and as illustrated in Figure 19 above, the wedge-shaped cage of Gilles has a first depth being less than the second depth. (Id.)

The person of ordinary skill in the art would have had several incentives to modify the second depth of Benezech as taught by Gilles. (Id. at ¶ 88.) First, Benezech and Gilles both disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Furthermore, as Dr. McMillin explains, a person of ordinary skill would have known that the

vertebral end plate upon which any intervertebral implant would sit – including the body of the system disclosed in Benezech – consists of a relatively soft core made of cancellous bone surrounded by a harder shell consisting of cortical bone. (Id.) He would further understand that any intervertebral implant that – like Benezech and Gilles – is designed for anterior implantation (through the front of the patient's body) and will rest largely on the anterior side of the vertebral endplate after implantation. (Id.) Therefore, he would understand that a cage having a larger second depth, i.e., a larger anterior wall, would provide more surface area to contact the hard cortical bone of the anterior sides of the two adjacent vertebrae. (Id.) By distributing more of the compression force onto the harder cortical bone, having a larger anterior wall would reduce the likelihood of the cage subsiding (sinking) into the endplate over time. (Id.)

Moreover, one of ordinary skill in the art would have known that with anterior spine surgery the spine and intervertebral disc space are deep in a patient's torso. (Id. at ¶ 89.) Typically, therefore, the surgeon must attach the implant to an inserter tool. (Id.) The inserter tool is by necessity attached to the anterior or trailing surface of the implant. (Id.) And as Dr. McMillin explains, a person of ordinary skill would have known that a thicker anterior wall provides for better attachment to the inserter tool and minimizes the risk of the implant breaking during the implantation procedure. (Id.)

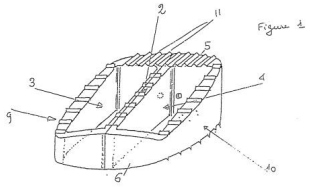
Thus, the person of ordinary skill in the art would have had incentives to modify or substitute the second depth of Benezech according to Gilles, and doing so would have been routine to the person of ordinary skill in the art and yielded a predictable result. (Id.) Such a modification or substitution was therefore obvious. See KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 416 (2007).

Petitioners anticipate that the Patent Owner may argue that it would not have been obvious to modify the cage in Benezech because of the statement in Benezech that "the shape and particular profile of the cage 1A according to the example of figure 2 allow for a perfect adaptation to the intervertebral space." As Dr. McMillin explains, however, Benezech's general reference to "the intervertebral space" would not have suggested to the person of ordinary skill that the specific profile of figure 2 would be ideal for *every* intervertebral space of every patient. (Ex. 1002 at ¶80.) On the contrary, the person of ordinary skill would know that every patient presents a different spinal anatomy and that the intervertebral spaces have significant variations depending upon the patient's condition and the specific area of the spine requiring intervention. (Id.) Thus, Benezech itself teaches that the cage "can have different dimensions in terms of height, width and depth [and] can also have . . . a preferred anatomical shape." (Ex. 1006 at 4:9-12.)

In sum, and as further illustrated in Table 7 below, Benezech in view of

Gilles disclose all the elements of Challenged Claim 19 and render the claim invalid as obvious.

**Table 7: Challenged Claim 19 is Obvious Over Benezech in view of Gilles**

| Challenged Claim 19 | Benezech (Ex. 1006) and Gilles (Ex. 1008) |
|---|---|
| An apparatus assembly for use in association with bones in a patient's body, | See Table 2 above. |
| the apparatus assembly comprising: a body constructed of a polymeric material | See Table 2 above. |
| including a trailing end portion having a trailing edge, a leading end portion having a leading edge, | See Table 2 above. |
| a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis, | See Table 2 above. |
| the body further including a central opening formed in the body and extending through the upper surface and the lower surface, the central opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface, | See Table 2 above. |
| the internal leading surface including a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end, | See Table 2 above. |
| a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth, | Figure 20: Fig. 1 of Gilles  |
| wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side | See Table 2 above. |

| Challenged Claim 19 | Benezech (Ex. 1006) and Gilles (Ex. 1008) |
|---|---|
| surface at a second spacing, the first spacing being substantially the same as the second spacing; and | |
| a first mounting strip connected to the trailing end portion, the first mounting strip constructed of a metallic material, a first screw hole and a second screw hole extending through the first mounting strip. | See Table 2 above. |

### 2. Challenged Claims 20, 22, 25 and 29

As discussed above, Challenged Claims 20, 22, 25 and 29 all depend from claim 19 and recite additional limitations that are disclosed in Benezech. (Supra at 28-34.) And as also discussed above, to the extent Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth," Challenged Claim 19 is obvious over Benezech in view of Gilles. (Supra at 34-39.) Therefore, Challenged Claims 20, 22, 25 and 29 are also obvious over Benezech in view of Gilles.

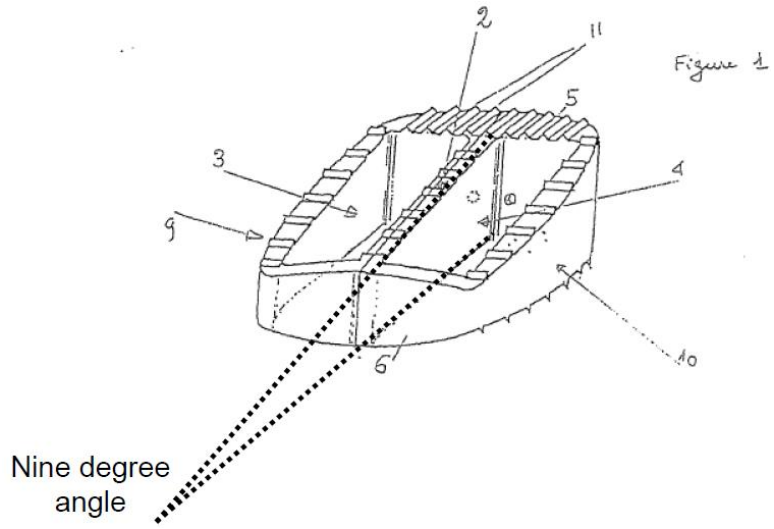
### 3. Challenged Claim 26

Challenged Claim 26 depend from claim 19 and further recites "wherein the acute angle is between one degree and twenty degrees."

As discussed above, Gilles discloses a cervical intersomatic cage for fusion of vertebrae during discectomy." (Supra at 35.) As the title suggests, the cage of Gilles is intended for fusion of vertebrae located in the cervical region of the spine.

(Ex. 1008 at 1:7-8; 2:25; Ex. 1002 at ¶ 94.) Figure 21 below shows that the cage of Gilles is wedge-shaped with a nine degree angle:

Figure 21: Interbody cage of Gilles (annotated)




(Ex. 1002 at ¶ 94.) As shown, the person of ordinary skill in the art would be able to determine that the angle of the cage disclosed in Gilles is approximately nine degrees by using a simple protractor. (Id. at ¶ 95.) The person of ordinary skill would appreciate, therefore, that the interbody cage disclosed in Gilles exhibits an acute angle between 1 and 20 degrees. (Id.)

Gilles further teaches that "[t]he height of the posterior face (6) is sufficient to enable the preservation of a normal cervical height. The height of the anterior face (5) is slightly greater to make it possible to obtain the appropriate degree of lordosis." (Ex. 1008 at p. 2, ll. 25-27.) Thus, a person of ordinary skill in the art would understand that the top and bottom surfaces of the cage of Gilles form an angle that is appropriate to restore lordosis in the cervical area of the spine.

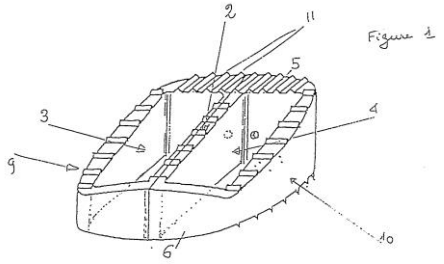
(Ex. 1002 at ¶ 96.)

The person of ordinary skill in the art would have had incentive to modify the body of Benezech as taught by Gilles. (Id. at ¶ 97.) Benezech and Gilles both disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Benezech is not, however, especially adapted to restoring the lordotic angle of a specific area of the spine. (Id.) Therefore, in order to provide a spinal fusion implant adapted to restoring lordosis in the cervical area of the spine, one of ordinary skill in the art would have had incentive to modify the cage of Benezech according to Gilles. Modifying the cage of Benezech to provide the acute angle disclosed in Gilles would have been routine to the person of ordinary skill in the art and produced the predictable result of providing an intervertebral fusion system adapted for regions of the cervical area of the spine with lordosis. (Id. at ¶ 108.) Such a modification was therefore obvious. See KSR, 550 U.S. at 416.

Thus, and as further illustrated in Table 8 below, Benezech in view of Gilles disclose all the elements of Challenged Claim 26.

**Table 8: Challenged Claim 26 is Obvious Over Benezech in view of Gilles**

| **Challenged Claim 26** | **Benezech (Ex. 1006) and Gilles (Ex. 1008)** |
|---|---|
| The apparatus assembly of claim 25, | See above regarding claim 25. |

| | |
|---|---|
| wherein the acute angle is between one degree and twenty degrees. | Figure 20: Fig. 1 of Gilles<br>  <br>"The height of the posterior face (6) is sufficient to enable the preservation of a normal cervical height. The height of the anterior face (5) is slightly greater to make it possible to obtain the appropriate degree of lordosis." (Ex. 1008 at p.2, ll.25-27.) |

### D. Ground 3 – The Challenged Claims are Obvious over Benezech in view of the AcroMed Brochure

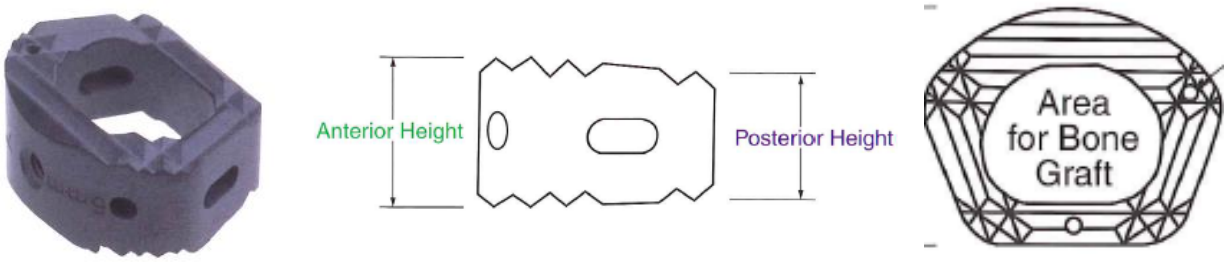
#### 1. Challenged Claim 19

The Petitioners submit that each and every limitation of Challenged Claim 19 is disclosed in Benezech. (Supra at 17-28.) The Petitioners anticipate, however, that the Patent Owner may assert that Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth." If so, and to the extent the Board agrees, this limitation is disclosed in the AcroMed Brochure.

The AcroMed Brochure discloses several interbody fusion implants for restoration of the physiological alignment of the spine. (Ex. 1009 at 2.) Among other implantable devices, the AcroMed Brochure discloses the Cervical I/F Cage,

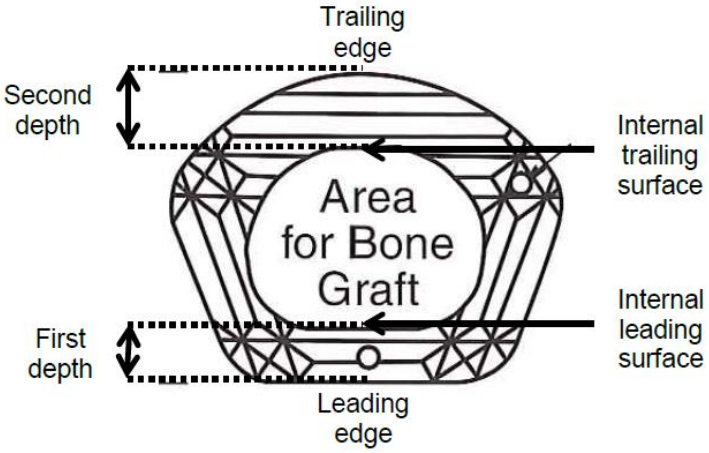
which it discloses has "a trapezoidal shape to match the . . . dimensions appropriate for anterior cervical fusion." (Id. at 5.) Figure 22 below reproduces figures of the Cervical I/F Cage provided in the AcroMed Brochure:

Figure 22: Representations of the Cervical I/F Cage in the AcroMed Brochure




A person of ordinary skill in the art would know that the posterior end is the leading edge, i.e., the edge that is inserted first between the vertebrae, and that the anterior is the trailing edge. (Ex. 1002 at ¶ 102.) Thus, as seen in Figure 23 below, the Cervical I/F Cage has a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth. (Id.)

Figure 23: Cervical I/F Cage of the AcroMed Brochure (annotations added)



(Id.) The person of ordinary skill in the art would have had several incentives to modify the second depth of Benezech as taught by the Cervical I/F Cage. (Id. at ¶ 103.) First, both the device of Benezech and the Cervical I/F Cage are orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Furthermore, as Dr. McMillin explains, a person of ordinary skill would have known that the vertebral end plate upon which any intervertebral implant would sit – including the body of the system disclosed in Benezech – consists of a relatively soft core made of cancellous bone surrounded by a harder shell consisting of cortical bone. (Id.) A person of ordinary skill would further understand that any intervertebral implant that – like Benezech and the Cervical I/F Cage – is designed for anterior implantation (through the front of the patient's body) and will rest largely on the anterior side of the vertebral endplate after implantation. (Id.) Therefore, she would understand that a cage having a larger second depth, i.e., a larger anterior wall, would provide more surface area to contact the hard cortical bone of the anterior sides of the two adjacent vertebrae. (Id.) By distributing more of the compression force onto the harder cortical bone, having a larger anterior wall would reduce the likelihood of the cage subsiding (sinking) into the endplate over time. (Id.)

Moreover, one of ordinary skill in the art would have known that with anterior spine surgery the spine and intervertebral disc space are deep in a patient's

torso. (Id. at ¶ 104.) Typically, therefore, the surgeon must attach the implant to an inserter tool. (Id.) The inserter tool is by necessity attached to the anterior or trailing surface of the implant. (Id.) Significant forces can be used to push the implant into the disc space and then to adjust the position of the implant in the disc space. (Id.) And as Dr. McMillin explains, a person of ordinary skill would have known that a thicker anterior wall would provide for better attachment to the inserter tool and minimize the risk of the implant breaking during the implantation procedure. (Id.)

Thus, the person of ordinary skill in the art would have had incentives to modify or substitute the second depth of Benezech according to the Cervical I/F Cage, and doing so would have been routine to the person of ordinary skill in the art and yielded a predictable result. (Id.) Such a modification or substitution was therefore obvious. See KSR, 550 U.S. at 416.

In sum, and as further illustrated in Table 9 below, Benezech in view of the Cervical I/F Cage in the AcroMed Brochure disclose all the elements of Challenged Claim 19 and render the claim invalid as obvious.

**Table 9: Challenged Claim 19 is Obvious Over Benezech in view of the AcroMed Brochure**

| Challenged Claim 19 | Benezech (Ex. 1006) and the AcroMed Brochure (Ex. 1009) |
|---|---|
| An apparatus assembly for use in association | See Table 2 above. |

| Challenged Claim 19 | Benezech (Ex. 1006) and the AcroMed Brochure (Ex. 1009) |
|---|---|
| with bones in a patient's body, | |
| the apparatus assembly comprising: a body constructed of a polymeric material | See Table 2 above. |
| including a trailing end portion having a trailing edge, a leading end portion having a leading edge, | See Table 2 above.<br>See Table 2 above. |
| a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis, | See Table 2 above. |
| the body further including a central opening formed in the body and extending through the upper surface and the lower surface, the central opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface, | See Table 2 above. |
| the internal leading surface including a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end, | See Table 2 above. |
| a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth, | Figure 24: Cervical I/F Cage<br>  |

| Challenged Claim 19 | Benezech (Ex. 1006) and the AcroMed Brochure (Ex. 1009) |
|---|---|
| wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing, the first spacing being substantially the same as the second spacing; and | See Table 2 above. |
| a first mounting strip connected to the trailing end portion, the first mounting strip constructed of a metallic material, a first screw hole and a second screw hole extending through the first mounting strip. | See Table 2 above. |

### 2. Challenged Claims 20, 22, 25 and 29

As discussed above, Challenged Claims 20, 22, 25 and 29 all depend from claim 19 and recite additional limitations that are disclosed in Benezech. (Supra at 28-34.) And as also discussed above, to the extent Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth," Challenged Claim 19 is obvious over Benezech in view of the AcroMed Brochure. (Supra at 43-47.) Therefore, Challenged Claims 20, 22, 25 and 29 are also obvious over Benezech in view of the AcroMed Brochure.

### 3. Challenged Claim 26

Challenged Claim 26 depends from claim 19 and further recites "wherein the

acute angle is between one degree and twenty degrees." The AcroMed Brochure discloses that the Cervical I/F Cage is "seven degrees from anterior to posterior, consistent with the physiological sagittal plane alignment of the cervical spine." (Ex. 1009 at 5.) Thus, a person of ordinary skill in the art would understand that the top and bottom surfaces of the cage of Gilles form an angle that is appropriate to restore lordosis in the cervical area of the spine. (Ex. 1002 at ¶ 107.)

The person of ordinary skill in the art would have had incentive to modify the body of Benezech as disclosed by the Cervical I/F Cage. (Id. at ¶ 108.) The device of Benezech and the Cervical I/F Cage are both orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Benezech is not, however, especially adapted to restoring the lordotic angle of a specific area of the spine. (Id.) Therefore, in order to provide a spinal fusion implant adapted to restoring lordosis in the cervical area of the spine, one of ordinary skill in the art would have had incentive to modify the cage of Benezech according to the Cervical I/F Cage. (Id.) Modifying the cage of Benezech to provide the acute angle disclosed by the Cervical I/F Cage would have been routine to the person of ordinary skill in the art and produced the predictable result of providing an intervertebral fusion system adapted for regions of the cervical area of the spine with lordosis. (Id.) Such a modification was therefore obvious. See KSR, 550 U.S. at 416.

Thus, and as further illustrated in Table 10 below, Benezech in view of the AcroMed Brochure disclose all the elements of Challenged Claim 26 and render the claim invalid as obvious.

**Table 10: Challenged Claim 26 is Obvious Over Benezech in view of the AcroMed Brochure**

| **Challenged Claim 26** | **Benezech (Ex. 1006) and the AcroMed Brochure (Ex. 1009)** |
|---|---|
| The apparatus assembly of claim 25, | See Table 10 above. |
| wherein the acute angle is between one degree and twenty degrees. | "[T]he [Cervical I/F Cage] features a wedge of seven degrees from anterior to posterior, consistent with the physiological sagittal plane alignment of the cervical spine." (Ex. 1009 at 5.) |

### E. Ground 4 – The Challenged Claims are Obvious over Benezech in view of Tisserand

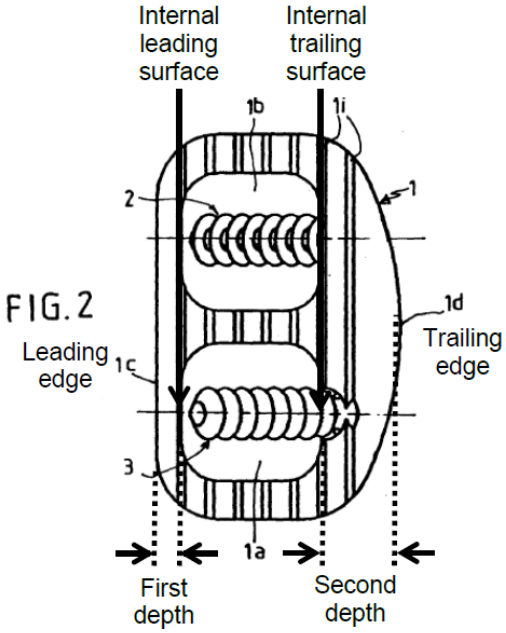
#### 1. Challenged Claim 19

The Petitioners submit that each and every limitation of Challenged Claim 19 is disclosed in Benezech. (Supra at 17-28.) The Petitioners anticipate, however, that the Patent Owner may assert that Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth." If so, and to the extent the Board agrees, this limitation is disclosed in Tisserand.

Tisserand discloses an implantable fusion device for use in the lumbosacral

spine, i.e., for fusing lumbar vertebrae or the lumbosacral hinge, "by the anterior approach." (See Ex. 1002 at ¶ 112; Ex. 1011 at p. 1, ll. 5-6, p. 1, l. 22 – p. 2, l. 3.)

Figure 25: Fig. 2 of Tisserand (annotations added)




(Ex. 1002 at ¶ 112; Ex. 1011 at Fig. 2.)

Tisserand teaches that to "enabl[e] fasteners to be implanted in the cortical-cancellous bone of the vertebral bodies, the holes consist of internal recesses formed from the anterior face of the element." (Id. at p. 2, ll. 5-8.) A person of ordinary skill in the art would know that the anterior face is the trailing edge, i.e., the edge that is trailing as the implant is inserted into the patient's spine, and that the posterior face is the leading edge. (Ex. 1002 at ¶ 112.) Thus, and as illustrated in Figure 25 above, the cage of Tisserand has a first depth being less than the second depth. (Id.)

The person of ordinary skill in the art would have had several incentives to modify the second depth of Benezech as taught by Tisserand. (Id. at ¶ 113.) First, both Benezech and Tisserand disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Furthermore, as Dr. McMillin explains, a person of ordinary skill would have known that the vertebral end plate upon which any intervertebral implant would sit – including the body of the system disclosed in Benezech – consists of a relatively soft core made of cancellous bone surrounded by a harder shell consisting of cortical bone. (Id.) She would further understand that any intervertebral implant that – like Benezech and Tisserand – is designed for anterior implantation (through the front of the patient's body) will rest largely on the anterior side of the vertebral endplate after implantation. (Id.) Therefore, she would understand that a cage having a larger second depth, i.e., a larger anterior wall, would provide more surface area to contact the hard cortical bone of the anterior sides of the two adjacent vertebrae. (Id.) By distributing more of the compression force onto the harder cortical bone, having a larger anterior wall would reduce the likelihood of the cage subsiding (sinking) into the endplate over time. (Id.)

Moreover, one of ordinary skill in the art would have known that with anterior spine surgery the spine and intervertebral disc space are deep in a patient's torso. (Id. at ¶ 114.) Typically, therefore, the surgeon must attach the implant to

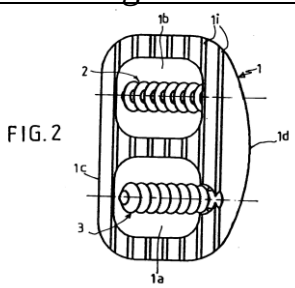
an inserter tool. (Id.) The inserter tool is by necessity attached to the anterior or trailing surface of the implant. (Id.) As Dr. McMillin explains, a person of ordinary skill would have known that a thicker anterior wall provide for better attachment to the inserter tool and minimizes the risk of the implant breaking during the insertion and adjustment of the implant during the surgery. (Id.)

Thus, the person of ordinary skill in the art would have had incentives to modify or substitute the second depth of Benezech according to Tisserand, and doing so would have been routine to the person of ordinary skill in the art and yielded a predictable result. (Id.) Such a modification or substitution was therefore obvious. See KSR, 550 U.S. at 416.

Thus, and as further illustrated in the claim chart below, Benezech in view of Tisserand disclose all the elements of Challenged Claim 19 and render the claim invalid as obvious.

**Table 11: Challenged Claim 19 is Obvious Over Benezech in view of Tisserand**

| **Challenged Claim 19** | **Benezech (Ex. 1006) and Tisserand (Ex. 1011)** |
|---|---|
| An apparatus assembly for use in association with bones in a patient's body, | See Table 2 above. |
| the apparatus assembly comprising: a body constructed of a polymeric material | See Table 2 above. |
| including a trailing end portion having a trailing edge, a leading end portion having a leading edge, | See Table 2 above. |

| | |
|---|---|
| a first side surface, a second side surface, an upper surface and a lower surface, the leading edge defining a leading end axis, | See Table 2 above. |
| the body further including a central opening formed in the body and extending through the upper surface and the lower surface, the central opening having an internal surface including a generally planar, internal leading surface, a first internal side surface, a second internal side surface and an internal trailing surface, | See Table 2 above. |
| the internal leading surface including a substantially linear portion extending substantially parallel to the leading end axis between a first end and a second end, the internal leading surface defining an internal leading height that is substantially constant between the first end and the second end, | See Table 2 above. |
| a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth, | Figure 26: Fig. 2 of Tisserand   |
| wherein the first internal side surface is spaced from the first side surface at a first spacing and the second internal side surface is spaced from the second side surface at a second spacing, the first spacing being substantially the same as the second spacing; and | See Table 2 above. |
| a first mounting strip connected to the trailing end portion, the first mounting strip constructed of a metallic material, a first screw hole and a second screw hole extending through the first mounting strip. | See Table 2 above. |

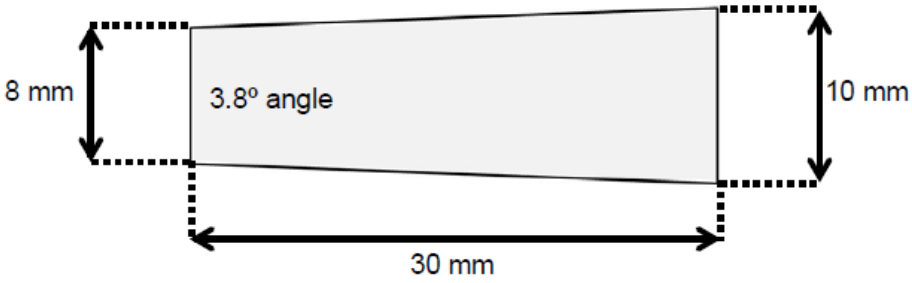
### 2. Challenged Claims 20, 22, 25 and 29

As discussed above, Challenged Claims 20, 22, 25 and 29 all depend from claim 19 and recite additional limitations that are disclosed in Benezech. (Supra at 28-34.) And as also discussed above, to the extent Benezech does not disclose "a first depth defined between the leading edge and the internal leading surface, a second depth defined between the internal trailing surface and the trailing edge, the first depth being less than the second depth," Challenged Claim 19 is obvious over Benezech in view of Tisserand. Therefore, Challenged Claims 20, 22, 25 and 29 are also obvious over Benezech in view of Tisserand.

### 3. Challenged Claim 26

Challenged Claim 26 depend from claim 19 and further recites "wherein the acute angle is between one degree and twenty degrees." Tisserand discloses a small, a medium and a large size of its implantable devices. (Ex. 1011 at p. 4, ll. 18-25.) The small size has a length of about 30 mm. (Id. at p. 4, ll. 20-21.) Tisserand further teaches that for an implant intended for the lumbosacral level L5-S1, the small size has an anterior height of 10 mm and a posterior height of 8 mm. (Id. at p. 5, ll. 3-7.) As Dr. McMillin explains, a person of ordinary skill in the art would appreciate that the above dimensions provide a device with the following side profile:

Figure 27: Illustration depicting teaching of Tisserand




(Ex. 1002 at ¶ 118.) A person of ordinary skill would further understand that the implant with these dimensions discloses an acute angle of approximately 4 degrees. (Id.) Tisserand therefore discloses an acute angle between one degree and twenty degrees. (Id.)

The person of ordinary skill in the art would have had incentive to modify the body of Benezech as taught by Tisserand. (Id. at ¶ 120.) Benezech and Tisserand both disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Benezech is not, however, especially adapted to restoring the lordotic angle of a specific area of the spine. (Id.) Therefore, in order to provide a spinal fusion implant adapted to restoring lordosis in the lumbar area of the spine, one of ordinary skill in the art would have had incentive to modify the cage of Benezech according to Tisserand. (Id.) Modifying the cage of Benezech to provide the acute angle disclosed in Tisserand would have been routine to the person of ordinary skill in the art and produced the predictable result of providing an intervertebral fusion system adapted for lumbar

areas of the spine with lordosis. (Id.) Such a modification was therefore obvious. See KSR, 550 U.S. at 416.

Thus, and as further illustrated in the claim chart below, Benezech in view of Tisserand disclose all the elements of Challenged Claim 26 and render the claim invalid as obvious.

**Table 12: Challenged Claim 26 is Obvious Over Benezech in view of Tisserand**

| **Challenged Claim 26** | **Benezech (Ex. 1006) and Tisserand (Ex. 1011)** |
|---|---|
| The apparatus assembly of claim 25, | See Table 12 above. |
| wherein the acute angle is between one degree and twenty degrees. | "It should be noted that the element (1) is produced in essentially three sizes, namely: - a small size with a width of around 20 mm and a length of around 30 mm . . . ." (Ex. 1008 at p. 4, ll.18-21.) "Three types of implants are available for the L5-S1 level, the anterior heights of which are respectively 10 mm, 12 mm and 14 mm, while the posterior heights are 8 mm, 10 mm and 12 mm." (Id. at p. 5, ll. 3-5.) |

### F. Any Secondary Considerations of Nonobviousness Fail to Overcome the Strong *Prima Facie* Showing of Obviousness

Petitioners are not aware of any evidence of secondary considerations of nonobviousness such as unexpected results, commercial success, long-felt but unsolved needs or failure of others to achieve the claimed apparatus. Even if the Patent Owner could somehow present a secondary consideration of nonobviousness, however, it could not rescue the Challenged Claim in view of the

strength of the *prima facie* obviousness case demonstrated by the prior art discussed in this petition. See, e.g., Q.I. Press Controls, B.V. v. Lee, 752 F.3d 1371, 1380 (Fed. Cir. 2014) (finding relevant secondary considerations not outweighing the *prima facie* case of obviousness); Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1344 (Fed. Cir. 2013) ("[W]here a claimed invention represents no more than the predictable use of prior art elements according to established functions, as here, evidence of secondary indicia are frequently deemed inadequate to establish non-obviousness.")

## VIII. CONCLUSION

Petitioners submit that issues have been presented that demonstrate a reasonable likelihood that claims 19, 20, 22, 25, 26 and 29 of the '066 patent are unpatentable as obvious. Petitioners therefore request that the Board grant *inter partes* review to cancel these claims.

Respectfully submitted,

AXINN, VELTROP & HARKRIDER, LLP

Dated: December 29, 2015 By: /Jeremy Lowe/

Jeremy Lowe, Registration No. 48,085
Matthew J. Becker, Registration No. 40,507
David K. Ludwig, Reg. No. 69,377
Axinn, Veltrop & Harkrider, LLP
90 State House Square
Hartford, CT 06103
Tel: (860) 275-8100

Dan Feng Mei, Registration No. 71,518
Axinn, Veltrop & Harkrider, LLP
114 West 47 Street
New York, NY 10036
Tel: (212) 728-2210

Customer No. 067272

Attorneys for Petitioners
DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc.

## CERTIFICATE OF SERVICE

I hereby certify that a true and correct coy of **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT No. 8,486,066 PURSUANT TO 35 U.S.C. § 312 and 37 C.F.R § 42.108** was served on December 29, 2015 via *FedEx Priority Overnight* service to the corresponding address for the subject patent pursuant to 37 C.F.R § 42.105:

Peter M. Bonutti
1303 W. Evergreen Plz
Effingham, IL 62401

Sandy Blackmon
1557 Lake O'Pines Street, NE
Hartville, OH 44632

Jennifer Graff
Kristy Kappelman
2400 Dallas Parkway
Suite 200
Plano, TX 75093

In addition, a courtesy copy of the above was sent to opposing counsel in the litigation at issue via email/*[FedEx Priority Overnight]* addressed as follow:

Kevin Gannon (BBO# 640931)
kgannon@hayesmessina.com
Hayes Messina Gilman & Hayes, LLC
200 State Street
6th Floor
Boston, MA 02109
(617) 345-6900

John M. Desmarais
jdesmarais@desmaraisllp.com
Laurie Stempler
lstempler@desmaraisllp.com
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Telephone: (212)-351-3400
Facsimile: (212)-351-3401

Dated: December 29, 2015

By: /Jeremy Lowe/

Jeremy Lowe
Registration No. 48,085
jlowe@axinn.com
Axinn, Veltrop & Harkrider, LLP
90 State House Square
Hartford, CT 06103
Tel: (860) 275-8100

Customer No. 067272

Attorney for Petitioners
DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc.