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. 8,795,363 to Bonutti
Appl. No. 13/847,325 filed Mar. 19, 2013
Issued Aug. 5, 2014

IPR Trial No. TBD

PETITION FOR *INTER PARTES*
REVIEW OF U.S. PATENT NO. 8,795,363
PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108

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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. 8,795,363 ("the '363 patent"), attached hereto as Ex. 1001. Petitioners respectfully submit that Independent Claim 1 and Dependent Claims 2, 3, 14, 44, 45, 47, 48 and 50 (the "Challenged Claims") are unpatentable under 35 U.S.C. § 103 in view of the prior art references discussed herein.

The Challenged Claims of the '363 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 '363 patent. As the prior art presented in this Petition demonstrates, spine surgeons had long been using polymeric implants to fuse adjacent vertebral bones in patients suffering from back pain, and had further been securing those implants and vertebral bones with metallic mounting strips and screws. Nor do the various limitations directed at the dimensions of the polymeric body render the Challenged Claims patentably distinct from the prior art. Each and every one of these elements had again long been employed in spinal implants to accommodate the dimensions of the relevant intervertebral space.

Accordingly, Petitioners respectfully request that the Board institute an *inter partes* review of the '363 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"), U.S. Patent No. 8,486,066 ("the '066 patent"), U.S. Patent No. 8,690,944 and the '363 patent. Certain claims of the '363 patent are the subject of this Petition. Petitioners are a party to the Pending Litigation.

The following litigation matter involves the '363 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 '066 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 18, 2015, the Patent Trial and Appeal Board ("the Board") granted institution of IPR2015-01333, which included Challenged Claims 1, 2, 14, 44, and 47 of the '363 patent. The Board instituted these claims over Benezech and Bray, the same prior art combination that forms Ground 1 in this Petition.

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:

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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 ‘363 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 '363 Patent

The '363 patent was filed as Appl. 13/847,325 on March 19, 2013. It is a continuation of Appl. 11/928,400, filed Oct. 30, 2007, now the '944 patent, which is a continuation of Appl. 10/438,705, filed May 15, 2003, now the '066 patent, which is a continuation of Appl. 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 '363 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 '363 patent.

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

Benezech was not disclosed by Applicants nor cited or applied by the Examiner during prosecution of the ‘363 patent.

2. AcroMed, AcroMed Carbon Fiber Interbody Fusion Devices (1998) (“the AcroMed Brochure”) (Ex. 1007)

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. 1017 at ¶¶ 2-5.) The AcroMed Brochure is prior art to the ‘363 patent under 35 U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the effective filing date (June 30, 1998) of the ‘363 patent. The AcroMed Brochure was not disclosed by Applicants nor cited or applied by the Examiner during prosecution of the ‘363 patent.

3. French Patent Application No. FR 2,727,003 to Tisserand (“Tisserand”) (Ex. 1008)[2]

French Patent Application No. FR 2,727,003 to Tisserand (“Tisserand”) (Ex. 1008), entitled “Device for Anterior Stabilization of the Lumbosacral Spine,” published on November 18, 1994. Tisserand is prior art to the ‘363 patent under 35 U.S.C. § 102(b) because it issued more than one year before the effective filing date (June 30, 1998) of the ‘363 patent. Tisserand was not disclosed by Applicants

[2] A certified English translation of Tisserand is attached as Ex. 1009.

nor cited or applied by the Examiner during prosecution of the ‘363 patent.

4. International Application Publication No. WO 97/20526 to Bray (“Bray”) (Ex. 1010)

International Application Publication No. WO 97/20526 to Bray (“Bray”) (Ex. 1010), entitled “Anterior Stabilization Device,” published on June 12, 1997. Bray is prior art to the ‘363 patent under understand that Bray is prior art to the ‘363 patent under 35 U.S.C. § 102(b) because it is a printed publication more than one year before the effective filing date (June 30, 1998) of the ‘363 patent. Bray was not disclosed by Applicants nor cited or applied by the Examiner during prosecution of the ‘363 patent. U.S. Patent No. 5,888,223, which shares a common priority document (i.e., U.S. Provisional Application No. 60/008,365) and includes a specification substantially the same as that of Bray, was disclosed by Applicants during prosecution of the ’363 patent.

Table 1. Grounds for *Inter Partes* Review

Ground	Claim	Statutory Basis and Prior Art
1	1, 2, 3, 14, 44, 45, 47, 48, 50	Obviousness under 35 U.S.C. § 103 over Benezech in view of Bray
2	1, 2, 3, 14, 44, 45, 47, 48, 50	Obviousness under 35 U.S.C. § 103 over Benezech in view of the AcroMed Brochure and/or Tisserand

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

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

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. 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 '363 PATENT

A. Summary of the Patent

The '363 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 ‘363 patent:

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

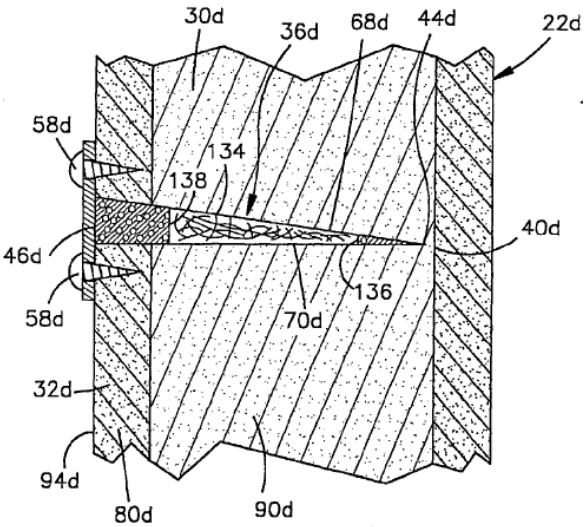

Fig.11

Figure 2: Top view of apparatus assembly in bone

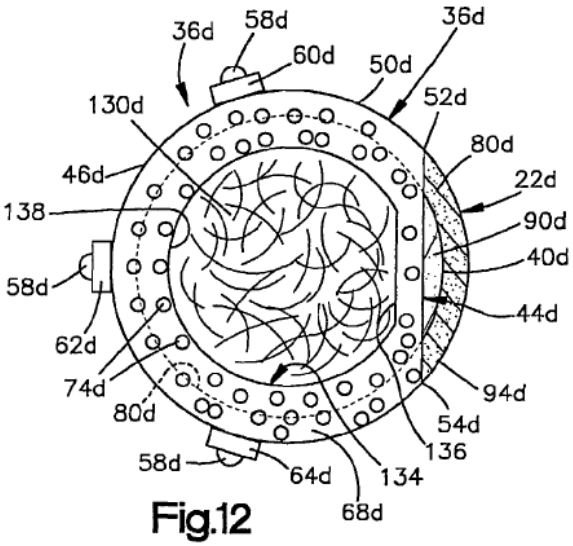

Fig.12

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); 2:6-8.)

The ‘363 patent issued with 85 claims of which independent claim 1 and dependent claims 2, 3, 14, 44, 45, 47, 48 and 50 are the only claims at issue in this Petition.

B. Prosecution History of the ‘363 Patent

The application that issued as the ‘363 patent was originally filed with 44 claims. (Ex. 1011 at 24-28.) On August 30, 2013, the Examiner issued a Restriction Requirement for all claims, requesting that the Applicant elect a single disclosed species. (Ex. 1012 at 1-2.) On September 16, 2013, Applicant responded by electing the species represented by Figures 11 and 12 (reproduced above as Figs. 1 and 2, respectively). (Ex. 1013 at 2.)

On August 30, 2013, the Examiner rejected claims 1, 3-4, 6, 8-13, 15-16, 34-35, 37-38 and 40-45 as obvious over U.S. Patent No. 6,206,922 (“Zdeblick”) in view of U.S. Patent No. 4,599,086 (“Doty”) and rejected claims 17-21, 23-30, 33 and 46 as obvious over U.S. Patent No. 6,482,223 (“Aebi”) in view of Doty. (Ex. 1014 at 3-11.)[3]

On March 20, 2014, Applicant cancelled certain claims, amended certain claims and added 42 new claims. (Ex. 1015 at 2-13.) To overcome the rejection

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[3] Dr. McMillin describes Zdeblick, Doty and Aebi in his declaration. (Ex. 1002 at ¶¶ 46-47, 54.)

over Zdeblick in view of Doty, the Applicant added a limitation to independent claims 1 and 34 (which issued as claims 1 and 32) requiring that the body width is greater than the body length. (Id. at 2, 16.) On June 23, 2014, the Examiner issued a notice of allowance. (Ex. 1016 at 1.) The Examiner did not provide reasons for allowance. (Id.)

C. Level of Ordinary Skill in the Art

A person of ordinary skill in the art with respect to the '363 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 ¶ 59.) 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. (Id.) 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 ¶ 60.)

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. 1005.) 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. 1018 at 18 (identifying "plate" of Benezech as mounting strip) with Ex. 1019 at 7-10 (Patent Owner not disputing teaching of mounting strip).) The Board in its decision to institute *inter partes* review of the IPR2015-01333 did not construe any claim terms (Ex. 1020 at

7) and the Board was persuaded that Benezech disclosed "plate 12" as the mounting strip (id. at 8-12).

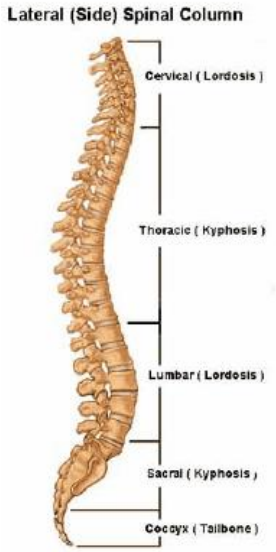
VII. DETAILED EXPLANATION (37 C.F.R. § 42.104(b)(4)-(5))

A. General State of the Art

The '363 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 ¶ 41.) 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. at ¶ 41.) Between 1990 and 1998, over one million spinal fusions were performed in hospitals throughout the U.S. (Id. at ¶ 42.)

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 ¶ 35.)

Figure 3: 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 ¶ 40.)

In the early 1990s, polymeric materials (biocompatible plastics) were put to use for orthopedic applications such as spinal fusion implants. (Id. at ¶ 49.) 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 ¶¶ 50-51.)

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.

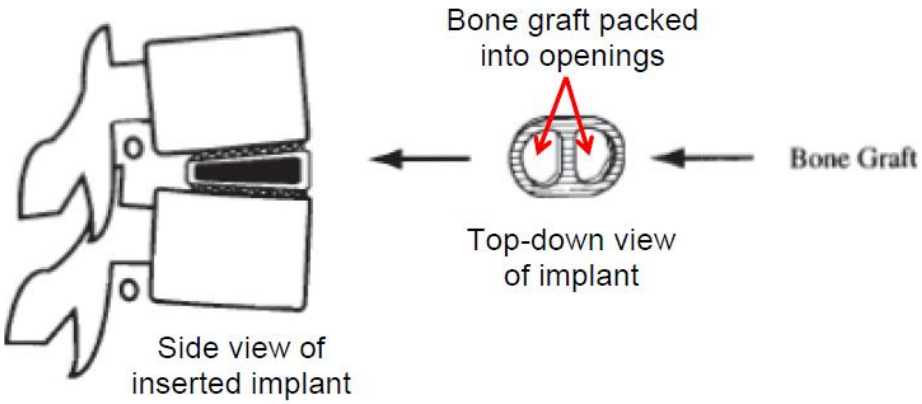
(Id. at ¶ 52.) With the anterior longitudinal ligament and the disc annulus cut, the forces applied on the implanted device by the spine could otherwise move the implant out of place or even eject it from the cavity. (Id.) Even local micromotion at the interface of the implant and the bone should be 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 4: Intervertebral
implant with fixation plate and screws

(Id. at ¶ 53.) Metal was a preferred material for the plate and fixation components due to its high strength and stiffness. (Id. at ¶ 54.)

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 ¶ 45.) 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 5: Wedge-shaped
intervertebral implant with two passages (annotated)



B. Ground 1 – The Challenged Claims are Obvious Over Benezech in View of Bray

1. Challenged Claim 1

The features of the independent Challenged Claim 1 are recited in the headings of sub-paragraphs (a) through (h) below.

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

The preamble of Challenged Claim 1 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.

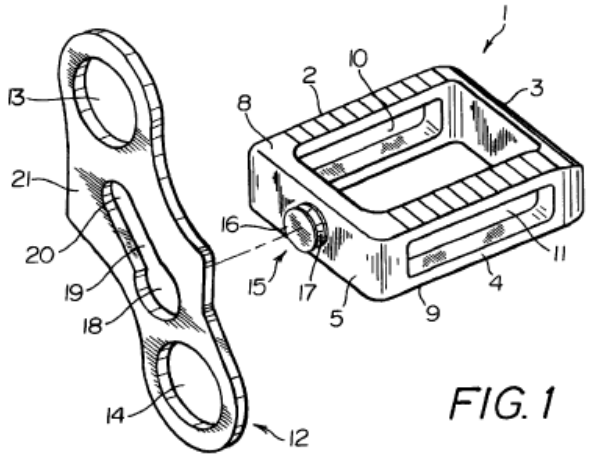
To the extent that the preamble does limit Challenged Claim 1, however, Benezech discloses "an intersomatic vertebrae setting and fusion system . . .

intended to be interposed between two vertebrae." (Ex. 1006 at p. 1, ll. 6-8.) As Dr. McMillin explains, a person of ordinary skill in the art would understand that the spinal implant device of Benezech is implantable 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 implantable device 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.) As illustrated in Figure 6 below (which is Figure 1 of Benezech), the system of Benezech comprises "at least one open internal cage . . . 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.) A person of ordinary skill in the art would understand that the cage is the "body" of the implantable device of Benezech. (Ex. 1002 at ¶ 62.)

Figure 6: Fig. 1 of Benezech



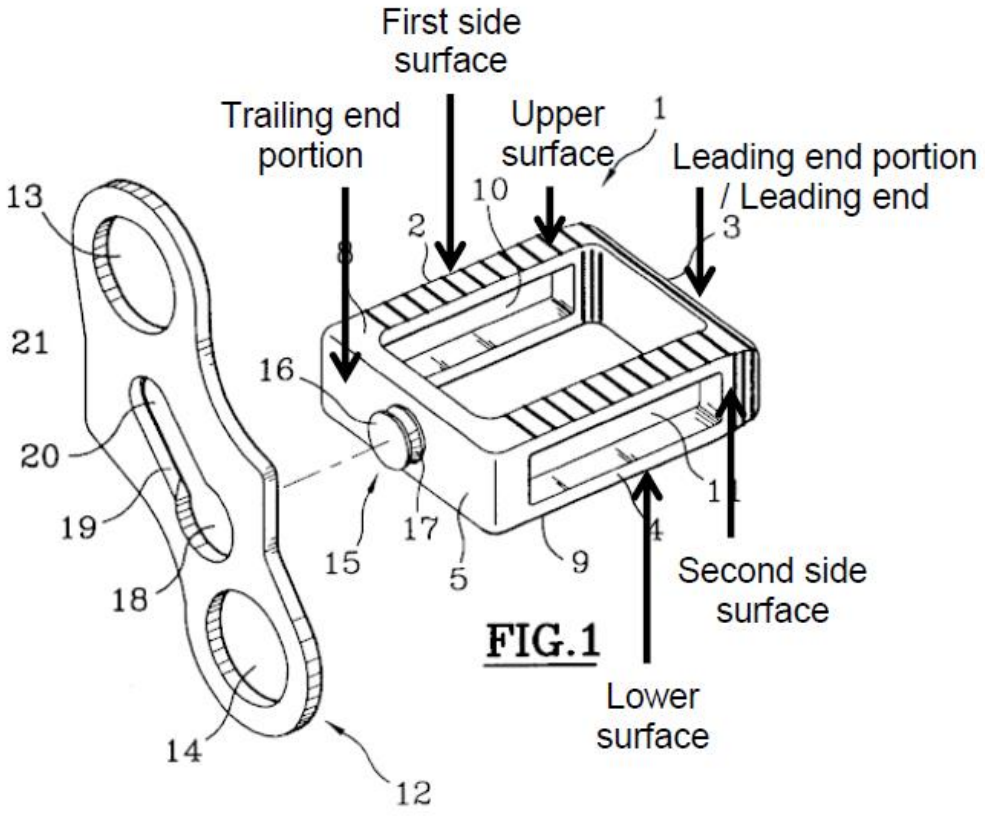
Benezech further discloses that the apparatus assembly is "made of metal or biocompatible plastic material." (Ex. 1006 at p. 2, l. 6.) Biocompatible plastics such as PEEK are polymeric and were known and used for spinal implants as of

1998. Thus, Benezech discloses an implantable device having a body constructed of a polymeric material. (Ex. 1002 at ¶ 63.)

c. "including a trailing end portion, a leading end portion having a leading end, a first side surface, a second side surface, an upper surface and a lower surface,"

As shown in Figure 7 below, Benezech discloses an implantable device with a body that includes a trailing end portion, a leading end portion having a leading end, a first side surface, a second side surface, an upper surface and a lower surface. (Ex. 1002 at ¶ 64.)

Figure 7: Fig. 1 of Benezech (annotations added)

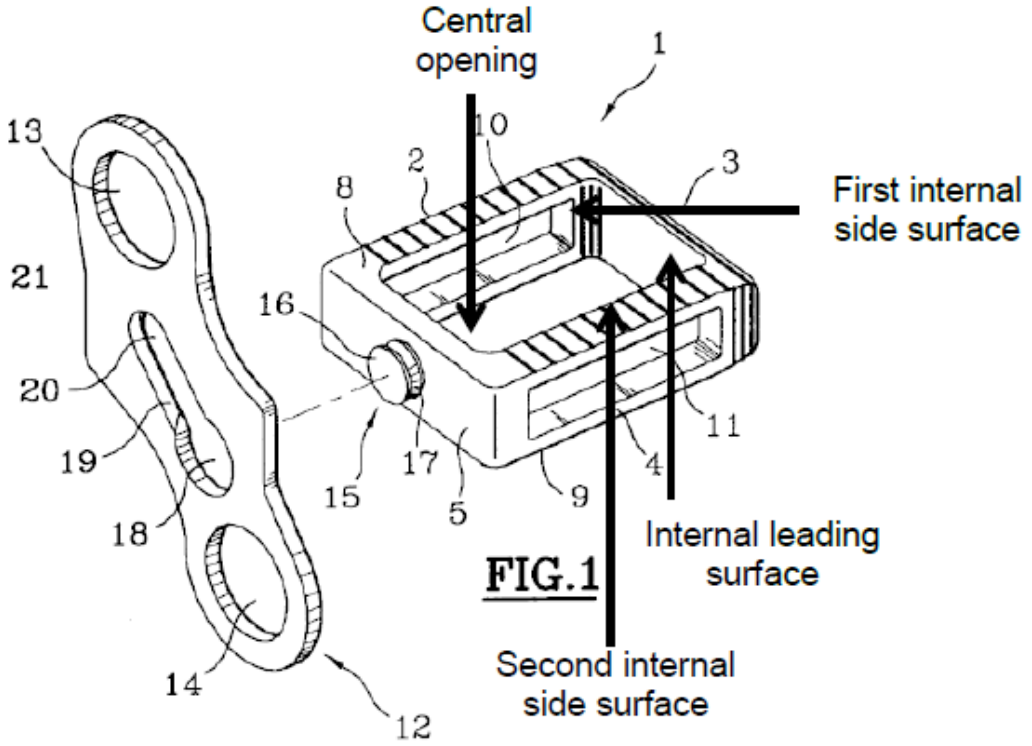


(Id.)

d. "the body further including a central opening extending through the upper surface and the lower surface, the central opening having an internal surface including an internal leading surface, a first internal side surface and a second internal side surface,"

As shown in Figure 8 below, Benezech discloses an implantable device with a body that includes a central opening extending through the upper surface and the lower surface, the central opening having an internal surface including an internal leading surface, a first internal side surface and a second internal side surface. (Ex. 1002 at ¶ 65.)

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

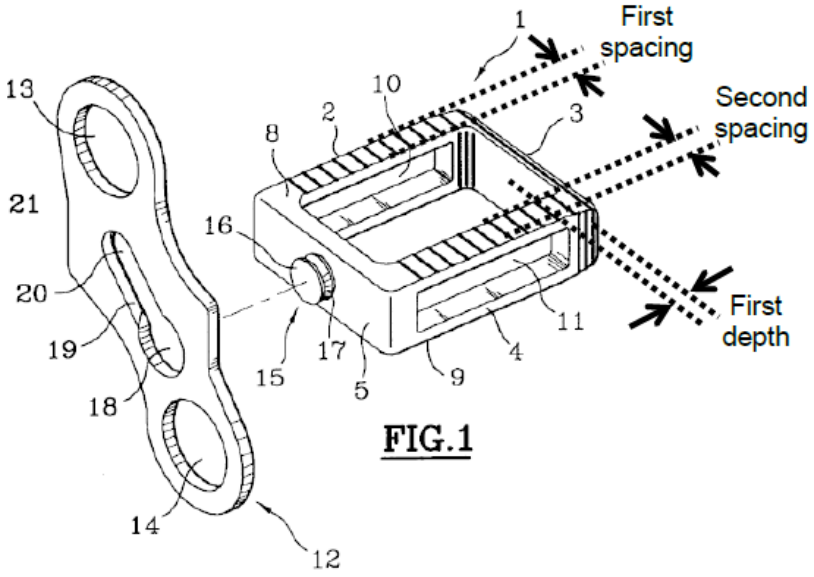


(Id.)

e. "a first depth defined between the leading end and the internal leading surface, a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface, the first spacing being substantially the same as the second spacing and the first depth being less than the first spacing,"

As shown in Figure 9 below, Benezech discloses a device with a body that includes a first depth defined between the leading end and the internal leading surface, a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface the first spacing being substantially the same as the second spacing and, the first depth being less than the first spacing. (Ex. 1002 at ¶ 66.)

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



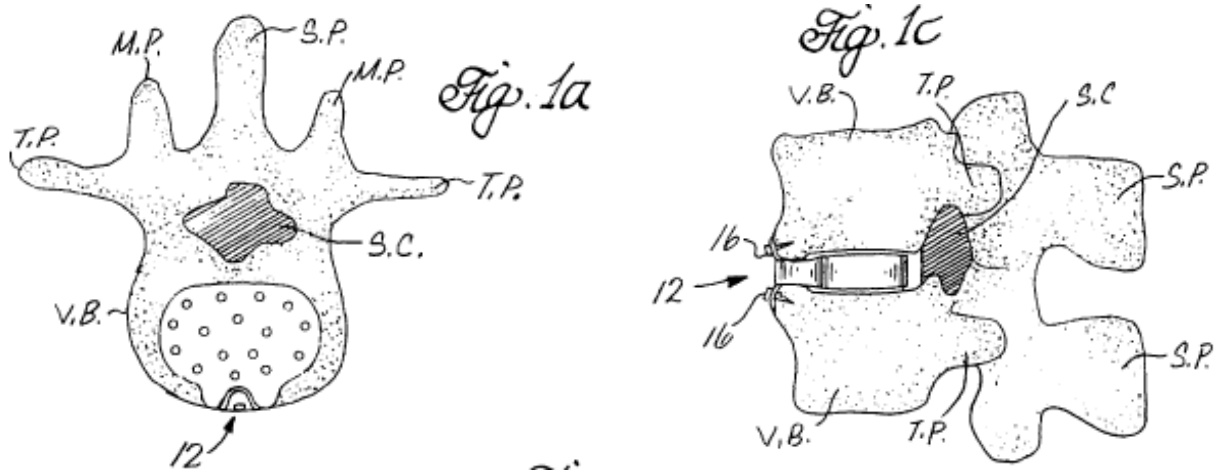
(Id.)

f. "a body width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion, the body width being greater than the body length;"

Benezech does not discloses an implantable device with a body width greater that the body length. As the Board has already found, however, this limitation is disclosed by Bray. (Ex. 1020 at 12.)

Bray discloses "an anterior stabilization device which provides fixation and stabilization at both the anterior margin of the vertebral body and in the anterior column." (Ex. 1010 at p. 3, ll. 7-8.) Bray discloses that "[t]he device is sized according to the particular intervertebral disk which it replaces." (Id. at p. 3, ll. 28-29.) It discloses, for example, an "oval shaped" device designed "utilize the stronger areas of the vertebral body for support." (Id. at p. 5, ll. 34-35.)

Figure 11: Oval shaped device of Bray



Thus, as illustrated in Figure 11 above, Bray discloses an implantable device

having a body width that is greater than the body length. (Ex. 1002 at ¶ 69.)

The Board has already found it reasonably likely that "a person of ordinary skill would have been motivated to make the width of Benezech's device wider than its length to conform to the shape of the vertebrae between which the device would be implanted, as taught by Bray." (Ex. 1020 at 12.) As the Board considered and Dr. McMillin explains, the person of ordinary skill would have known that the width of the vertebral endplate is generally greater than its depth. (Id. at ¶ 70.) The person of ordinary skill would thus have recognized that a device of greater width than length would have an optimized fit, increase the area for bone growth, and, as taught by Bray, ensure proper loading of the implant on the stronger periphery of the endplates to reduce the likelihood of subsidence. (Id.) Furthermore, and again as the Board recognized, Benezech does not teach away from such a modification as the Patent Owner asserted and may assert again. (Ex. 1019 at 11-13.) First, the note 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" could not teach away from modification of *cage 1 according to the example of figure 1*, which is the example discussed in this Petition. (Ex. 1002 at ¶ 70.) Second, in view of the knowledge of one of ordinary skill that the vertebral endplate is generally wider than it is long, there is nothing in Benezech's note about a "perfect adaptation" that teaches away from such a shape.

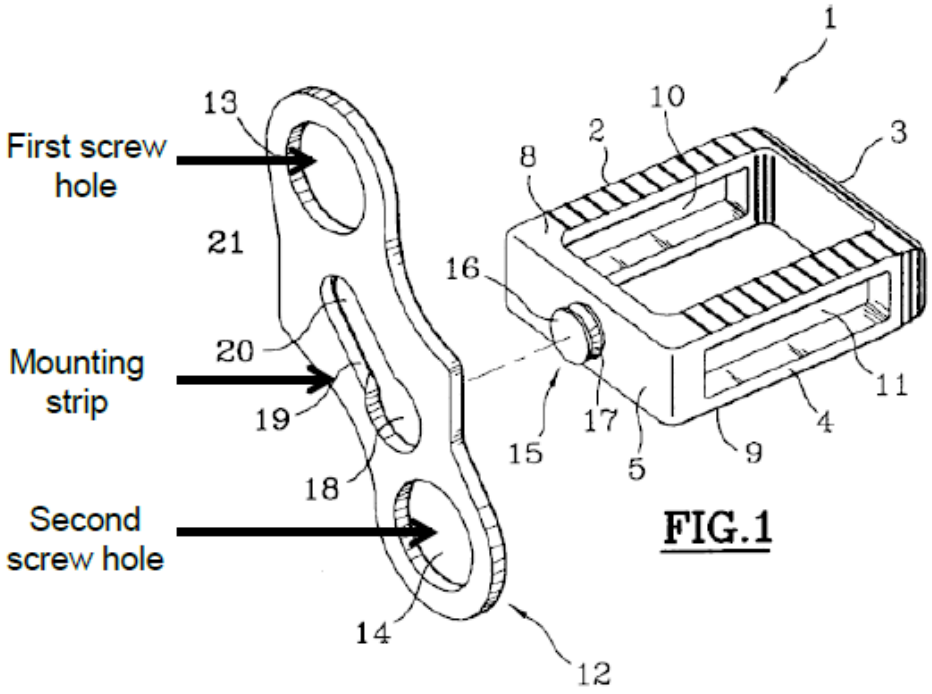
(Id.) Finally, to the extent Patent Owner asserts that Benezech and Bray teaches the use of different size screws, (see Ex. 1019 at 12), this would not have discouraged the person of skill from combining teachings related to the shape of the cages, as opposed to how the cages are secured. (Ex. 1002 at ¶ 70.)

Moreover, Benezech teaches that its device "can have different dimensions in terms of height, width and depth [and] a preferred anatomical shape." (Ex. 1006 at p. 4, ll. 9-12.) Modifying the dimensions of Benezech to have a width greater than its length as taught by Bray would have been routine to the person of ordinary skill in the art and an obvious design choice that would have produced the predictable result of providing an intervertebral fusion system sized according to the particular intervertebral disk which it replaces. (Id. at ¶ 71.) See KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 416 (2007).

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

As seen in Figure 12 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. 27-p. 2, l. 2.)

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



(Ex. 1002 at ¶ 72.) Thus, the implantable device of Benezech includes a mounting strip. (Id. at ¶ 73.) As also seen in Figure 12 above, one of ordinary skill in the art would understand that the mounting strip is connected to the trailing end of the body and has a first and second screw hole. (Ex. 1002.)

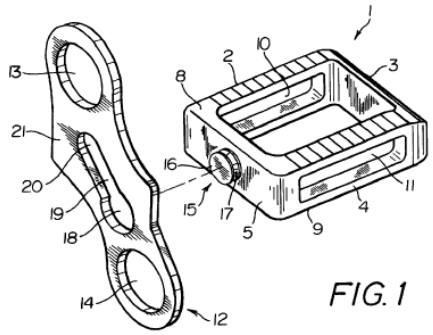
Benezech further discloses that "[t]he setting systems of the invention are produced from titanium alloy or equivalent material, or of a biocompatible plastic material." (Ex. 1006 at p. 6, ll. 8-9.) Thus, Benezech discloses an apparatus assembly having a mounting strip constructed of a metallic material. (Ex. 1002 at ¶ 74.)

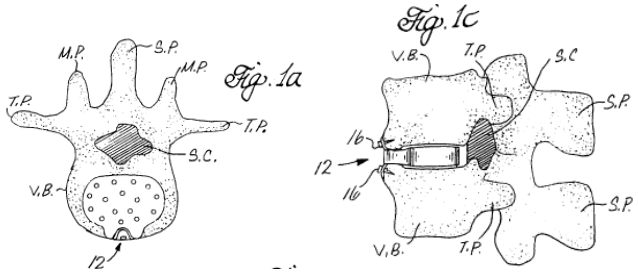
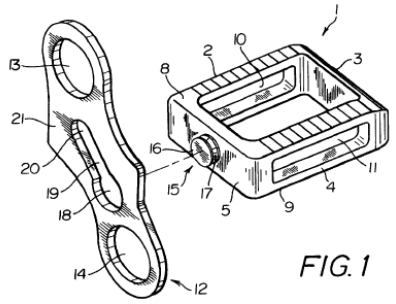
As Dr. McMillin explains, it would have been understood by the person of ordinary skill in the art that Benezech teaches that the body and the mounting strip

of the apparatus assembly can, respectively, be made of a plastic and metallic material. (Ex. 1002 at ¶ 75.) 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. 4,599,086 disclosing a spinal implant 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 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. (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 the claim chart below, Benezech in view of Bray disclose all the elements of Challenged Claim 1 and render the claim invalid as obvious.

Table 2: Challenged Claim 1 is Obvious Over Benezech in View of Bray

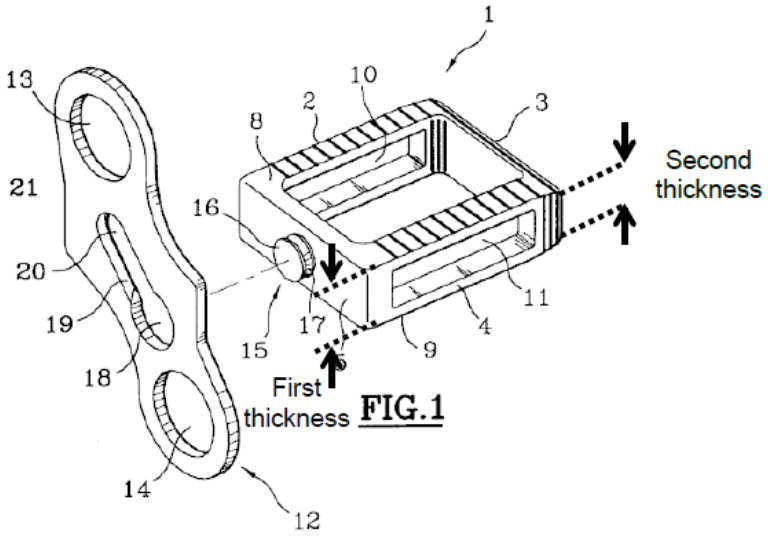
Challenged Claim 1	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
1. An implantable device for use in association with bones in a patient's body,	"[A]n intersomatic vertebrae setting and fusion system . . . intended to be interposed between two vertebrae." (Ex. 1006 at p. 1, ll. 6-8.)
the implantable device 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, a leading end portion having a leading end, a first side surface, a second side surface, an upper surface and a lower surface,	Figure 6: Fig. 1 of Benezech  FIG. 1
the body further including a central opening extending through the upper surface and the lower surface, the central opening having an internal surface including an internal leading surface, a first internal side surface and a second internal side surface,	See Figure 6 above.

a first depth defined between the leading end and the internal leading surface, a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface, the first spacing being substantially the same as the second spacing and, the first depth being less than the first spacing	See Figure 6 above.
a body width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion, the body width being greater than the body length;	Figure 11: Figs. 1a and 1c of Bray 
and a first mounting strip constructed of a metallic material connected to the trailing end portion, a first screw hole and a second screw hole extending through the first mounting strip.	Figure 6: Fig. 1 of Benezech  FIG. 1 "[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.) "The setting systems of the invention are produced from titanium alloy or equivalent material, or of a biocompatible plastic material." (Id. at p. 6, ll. 8-9.)

2. Challenged Claim 2

Challenged Claim 2 depends from claim 1 and further recites "wherein the railing end portion defines a first thickness and the leading end portion defines a second thickness the first thickness being greater than the second thickness."

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

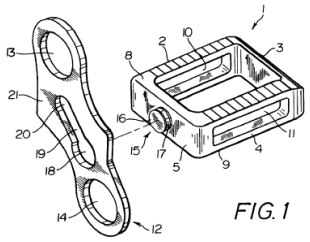


(Ex. 1002 at ¶ 77.) As illustrated in Figure 16 above, Benezech discloses the additional elements of Challenged Claim 2. (Ex. 1002 at ¶ 78.)

Thus, and as further illustrated in the claim chart below, Benezech in view of Bray disclose the additional elements of Challenged Claim 2 and render the claim invalid as obvious.

Table 3: Challenged Claim 2 is Obvious over Benezech in view of Bray

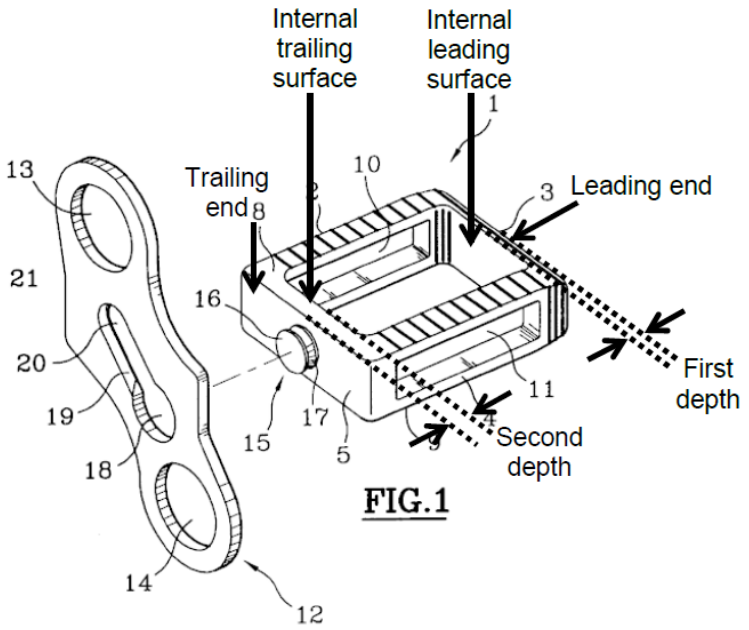
Challenged Claim 2	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.

wherein the trailing end portion defines a first thickness and the leading end portion defines a second thickness, the first thickness being greater than the second thickness.	Figure 6: Fig. 1 of Benezech  FIG. 1

3. Challenged Claim 3

Challenged Claim 3 depends from claim 1 and further recites "wherein the body further includes a second depth defined between an internal trailing surface and the trailing end, the first depth being less than the second depth." As shown in Figure 13 below, this limitation is disclosed in Benezech. (Ex. 1002 at ¶ 79.)

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



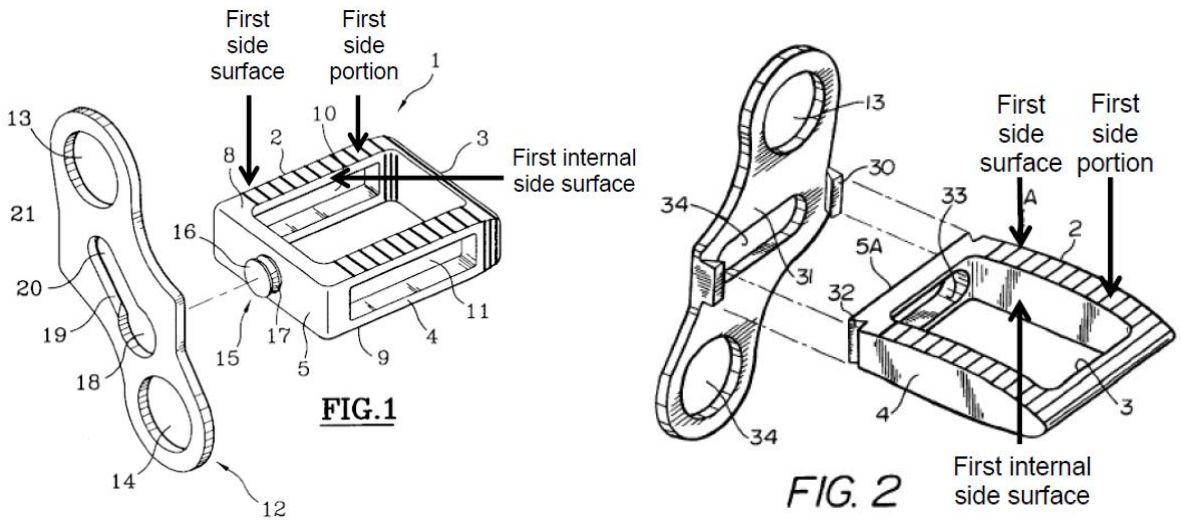
(Id.)

4. Challenged Claim 14

Challenged Claim 14 depends from claim 1 and further recites "wherein the

body includes a first side portion between the first side surface and the first internal side surface, the first side portion constructed of a solid, continuous polymeric material." As illustrated in Figure 14 below, Benezech discloses an embodiment with the additional elements of Challenged Claim 14. (Id. at ¶ 80.)

Figure 14: Embodiments of Benezech (annotation added)



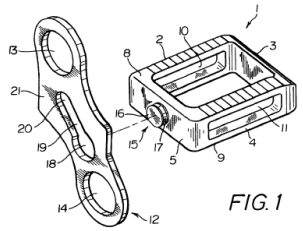
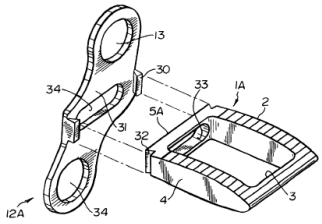
(Id.)

Benezech teaches that the open side portions of the cage depicted in Fig. 1 and the anterior opening depicted in Fig. 2 are all intended to allow the insertion of bone graft material prior to or after installation of the cage between the vertebrae. (Ex. 1002 at ¶ 81; Ex. 1006 at p. 3, ll. 8-11; p. 4, ll. 13-15, 26-29.). Thus, as Dr. McMillin explains, one of skill in the art would understand that the side and anterior openings of the embodiments are interchangeable. (Ex. 1002 at ¶ 81.) The person of ordinary skill would further have recognized that opting for an

anterior opening to allow the insertion of bone graft material after installation of the cage between the vertebrae would permit the side surfaces to be solid, thus increasing the strength of the side walls and improving the containment of the bone graft material. (Id.) Such a modification would therefore have been an obvious design choice resulting in a predictable and easily realizable design. (Id.)

Accordingly, and as further illustrated in the claim chart below, Benezech in view of Bray disclose the additional elements of Challenged Claim 14 and render the claim invalid as obvious.

Table 5: Challenged Claim 14 is Obvious over Benezech in view of Bray

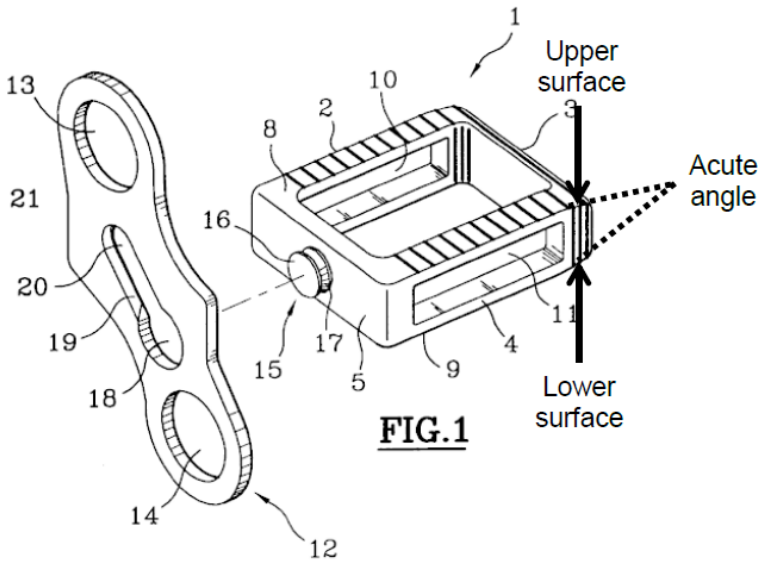
Challenged Claim 14	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.
wherein the body includes a first side portion between the first side surface and the first internal side surface, the first side portion constructed of a solid, continuous polymeric material.	Figure 6: Fig. 1 of Benezech  FIG. 1 Figure 15: Fig. 2 of Benezech  FIG. 2

5. Challenged Claim 44

Challenged Claim 44 depends from claim 1 and further recites "wherein the

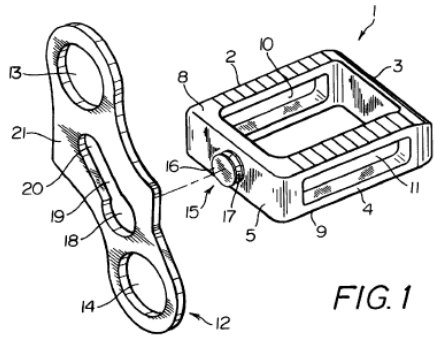
upper and lower surfaces define an acute angle." As illustrated in Figure 21 below, Benezech discloses this element of Challenged Claim 44. (Ex. 1002 at ¶ 83.)

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



(Id.) Thus, and as further illustrated in the claim chart below, Benezech in view of Bray disclose the additional elements of Challenged Claim 44 and render the claim invalid as obvious.

Table 6: Challenged Claim 44 is Obvious over Benezech in view of Bray

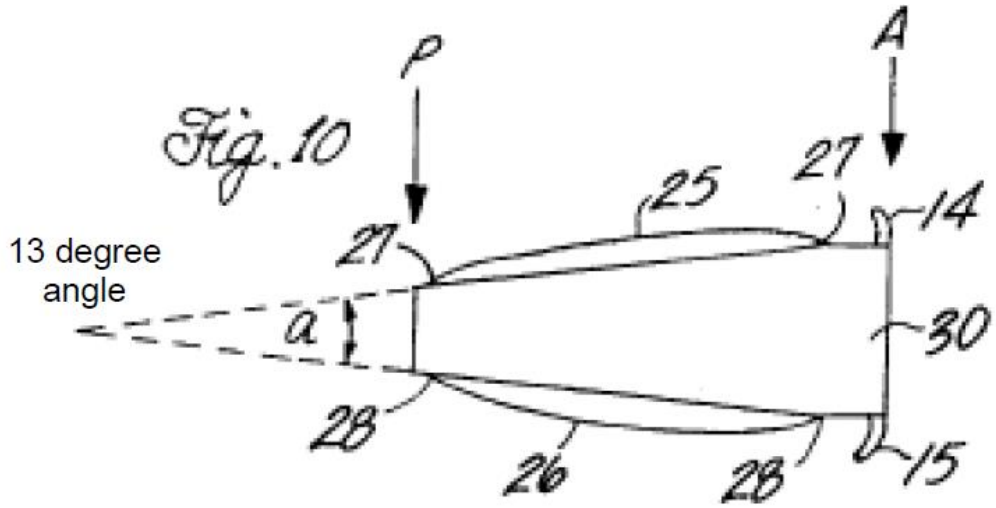
Challenged Claim 44	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.
wherein the upper and lower surfaces define an acute angle.	Figure 6: Fig. 1 of Benezech 

6. Challenged Claim 45

Challenged Claim 45 depends from claim 1 and further recites "wherein the acute angle is between one degree and twenty degrees." While Benezech discloses upper and lower surfaces defining an acute angle, as discussed above, it does not disclose a specific acute angle between one and twenty degrees. Such an angle is disclosed in Bray.

Bray discloses that its device may have upper and lower surfaces defining a "lordotic angle [that] extends from a smaller posterior surface, P, to a larger anterior surface, A. The angle, a, can range from about 1° to about 45°." (Ex. 1010 at p. 8, ll. 31-34.) Bray further discloses a specific example, reproduced in Figure 17 below, where the angle is approximately 13 degrees. (Ex. 1002 at ¶ 86.)

Figure 17: Bray disclosing acute angle of 13 degrees (annotation added)



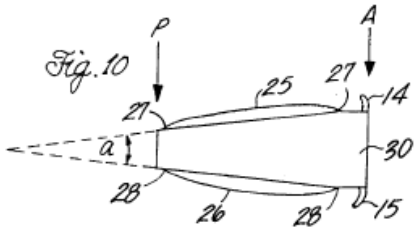
(Id.) Therefore, Bray discloses an acute angle of between one degree and twenty degrees. (Id.)

A person of ordinary skill in the art would understand that the lordotic angle a disclosed in Bray is appropriate to restore and maintain lordosis. (Ex. 1002 at ¶ 87.) Benezech and Bray 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 and maintaining the lordotic angle of the spine. (Id.) The person of ordinary skill in the art would therefore have had incentive to modify the body of Benezech according to the teachings of Bray. (Id.) As discussed above, the Board has already found it reasonably likely that a person of ordinary skill would have been motivated to modify the body of Benezech in view of the teachings of Bray. (Supra at 22-23.)

Modifying the body of Benezech to provide the acute angle disclosed in Bray would have been routine to the person of ordinary skill in the art and produced the predictable result of providing an intervertebral fusion system suitable for restoring and maintaining the lordotic angle of the spine. (Id. at ¶ 87.) 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 Bray disclose the additional elements of Challenged Claim 45 and render the claim invalid as obvious.

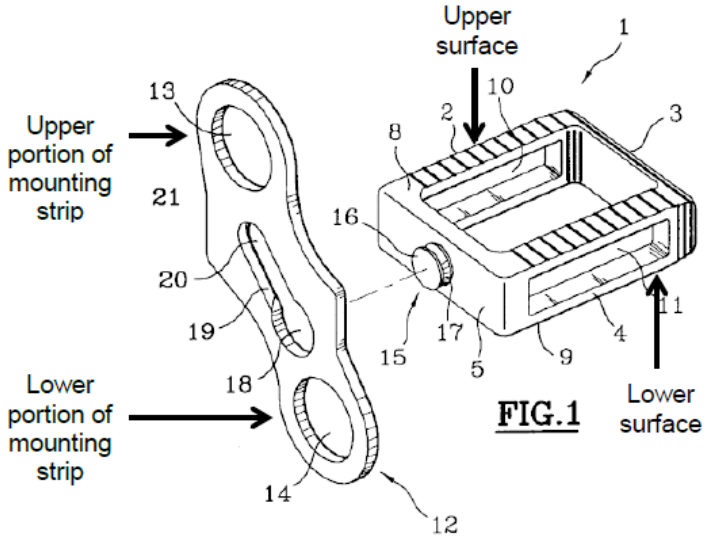
Table 7: Challenged Claim 45 is Obvious over Benezech in view of Bray

Challenged Claim 45	Benezech (Ex. 1006) and Bray (Ex. 1010)
The implantable device of claim 1,	See above regarding claim 1.
wherein the acute angle is between one degree and twenty degrees	Figure 18: Fig. 10 of Bray 

7. Challenged Claim 47

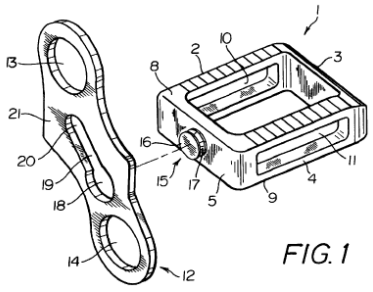
Challenged Claim 47 depends from claim 1 and further recites "wherein the first mounting strip includes an upper portion extending above the upper surface and a lower portion extending below the lower surface in a mounted configuration." As illustrated in Figure 19 below, Benezech discloses a mounting strip that includes an upper portion extending above the upper surface and a lower portion extending below the lower surface in a mounted configuration. (Ex. 1002 at ¶ 90.)

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



(Id.) Thus, and as further illustrated in the claim chart below, Benezech in view of Bray disclose the additional elements of Challenged Claim 47 and render the claim invalid as obvious.

Table 8: Challenged Claim 47 is Obvious over Benezech in view of Bray

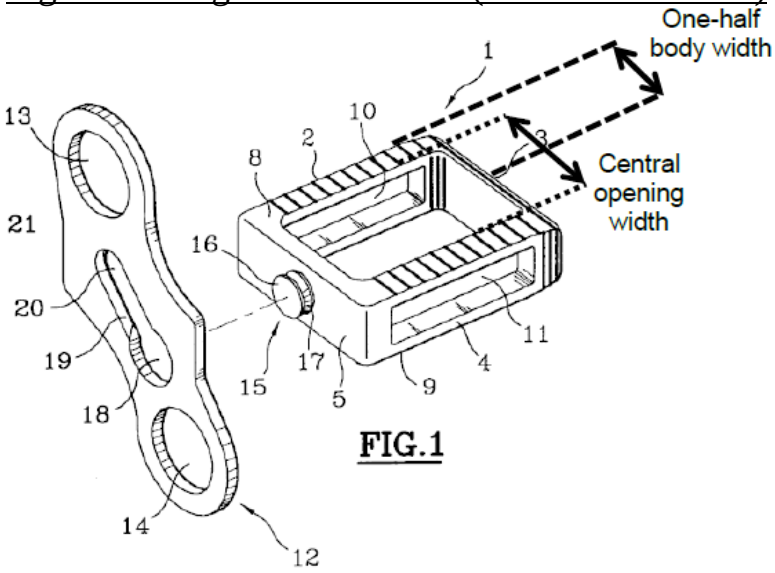
Challenged Claim 47	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.
wherein the first mounting strip includes an upper portion extending above the upper surface and a lower portion extending below the lower surface in a mounted configuration.	Figure 6: Fig. 1 of Benezech  FIG. 1

8. Challenged Claim 48

Challenged Claim 48 depends from claim 1 and further recites "wherein the

central opening defines a central opening width defined between the first internal side surface and the second internal side surface, the central opening width being greater than the one-half the body width." As seen in Figure 20 below, Benezech discloses a central opening defining a central opening width defined between the first internal side surface and the second internal side surface, the central opening width being greater than one-half the body width. (Ex. 1002 at ¶ 92.)

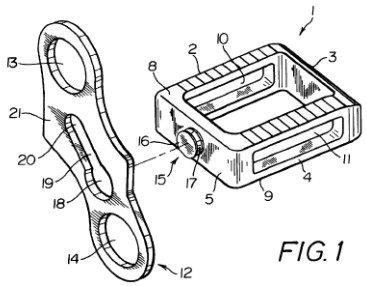
Figure 20: Fig. 1 of Benezech (annotations added)



(Id.) Thus, and as further illustrated in the claim chart below, Benezech in view of Bray disclose the additional elements of Challenged Claim 48 and render the claim invalid as obvious.

Table 9: Challenged Claim 48 is Obvious over Benezech in view of Bray

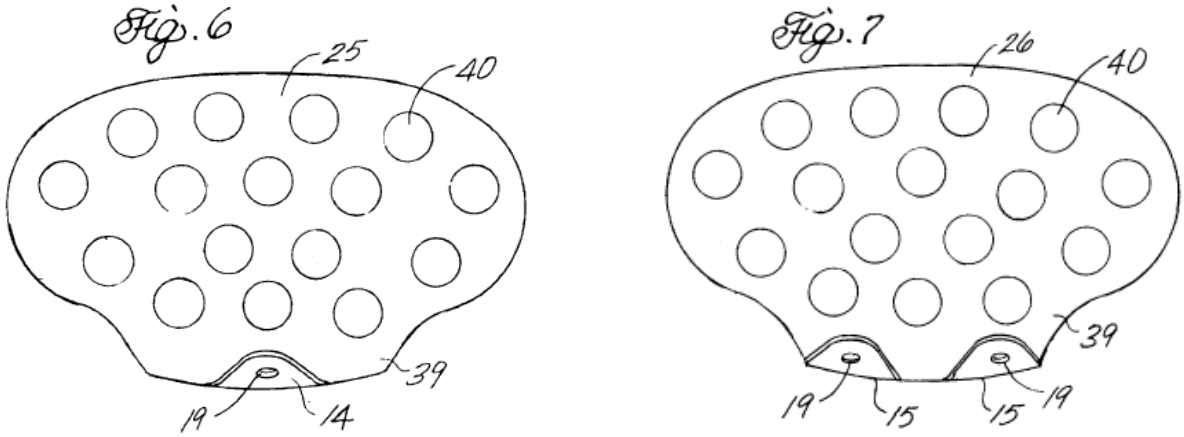
Challenged Claim 48	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.

wherein the central opening defines a central opening width defined between the first internal side surface and the second internal side surface, the central opening width being greater than the one-half the body width.	Figure 6: Fig. 1 of Benezech  FIG. 1

9. Challenged Claim 50

Challenged Claim 50 depends from claim 1 and further recites "wherein the body further includes a second opening extending through the upper surface and the lower surface configured to allow bone growth through the body, the second opening being generally straight." As illustrated in Figure 21 below, Bray discloses a plurality of openings. (Ex. 1002 at ¶ 94.)

Figure 21: Plurality of Openings of Bray



(Id.) Figures 6 and 7 show "a plurality of holes 40" through the surfaces of the superior wall 25 and inferior wall 26. (Id. at ¶ 95; Ex. 1010 at p. 6, l. 38 – p. 7, l. 20.) A person of ordinary skill in the art would understand that the superior and

inferior wall are the upper and lower surfaces of the body. (Ex. 1002 at ¶ 95.) Bray further discloses that the plurality of holes are created by "drilling" through the surfaces. (Ex. 1010 at p. 7, ll. 3-4.) Thus, a person of ordinary skill would understand that the holes, or openings, are generally straight. (Ex. 1002 at ¶ 95.) The person of ordinary skill would understand that from a manufacturing standpoint it is easier to make openings that are straight than curved or bent, and further that there would be no design reason to provide openings that are not straight. (Id.) Bray further discloses that the holes "allow for bone to grow . . . [in order] to fuse the two vertebrae together." (Ex. 1010 at p. 7, l. 1.) Thus, Bray discloses a second opening extending through the upper surface and the lower surface configured to allow bone growth through the body, the second opening being generally straight. (Ex. 1002 at ¶ 95.)

A person of ordinary skill in the art would understand that the upper and lower surfaces with a plurality of openings as disclosed in Bray provide advantageous containment of the bone graft material in the center of the cage while still providing the required contact between the graft material and the vertebral endplates for bone growth and fusion to occur. (Id. at ¶ 96.) Benezech and Bray both disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) The person of ordinary skill in the art would therefore have had incentive to modify the body of Benezech according to the

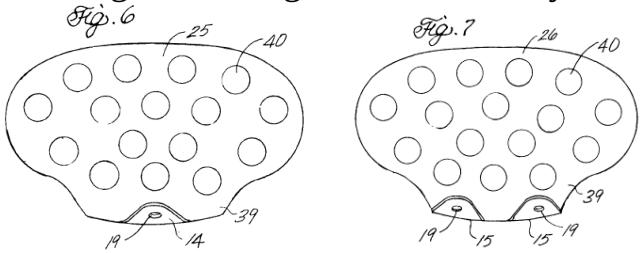
teachings of Bray. (Id.) As discussed above, the Board has already found it reasonably likely that a person of ordinary skill would have been motivated to modify the body of Benezech in view of the teachings of Bray. (Supra at 22-23.)

Modifying the body of Benezech to provide the upper and lower surfaces with a plurality of openings disclosed in Bray would have been routine to the person of ordinary skill in the art and produced the predictable result of providing an intervertebral fusion system suitable for restoring and maintaining the lordotic angle of the spine. (Id. at ¶ 96.) 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 Bray disclose the additional elements of Challenged Claim 50 and render the claim invalid as obvious.

Table 10: Challenged Claim 50 is Obvious over Benezech in view of Bray

Challenged Claim 50	**Benezech (Ex. 1006) and Bray (Ex. 1010)**
The implantable device of claim 1,	See above regarding claim 1.

wherein the body further includes a second opening extending through the upper surface and the lower surface configured to allow bone growth through the body, the second opening being generally straight.	"The superior wall is preferably porous, i.e., comprises pores or holes, to allow for bone to grow through the pores or holes to fuse the two vertebrae together. As illustrated, the superior surface could be made porous by drilling a plurality of holes 40 through the surface." (Ex. 1010 at p. 6, l. 37 – p. 7, l. 2.) "The inferior wall is a mirror image of the superior wall and is preferably also made porous. In the preferred embodiment, holes 40 are drilled through the surface." (Id. at p. 7, ll. 10-11.) Figure 21: Figs. 6 and 7 of Bray 

C. Ground 2 – The Challenged Claims are Obvious over Benezech in view of the AcroMed Brochure and/or Tisserand

1. Challenged Claim 1

The features of the independent Challenged Claim 1 are recited in the headings of sub-paragraphs (a) through (h) below.

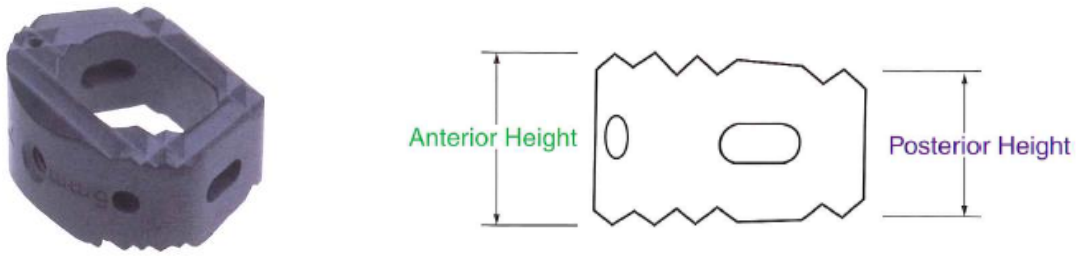
As demonstrated above, every element of the Challenged Claim 1 is disclosed by Benezech except for the limitation that the implantable device comprise a body with "a body width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion, the body width being greater than the body

length." (Supra at 16-27.) This limitation is disclosed in both the AcroMed Brochure and in Tisserand.

a. The AcroMed Brochure

The AcroMed Brochure discloses several interbody fusion implants for anterior column support and restoration of the physiological alignment of the spine. (Ex. 1007 at 2.) Among other implantable devices, the AcroMed Brochure discloses the Cervical I/F Cage, which has "a shape to match the medial-lateral and anterior-posterior dimensions for anterior cervical fusion." (Id. at 5.)

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

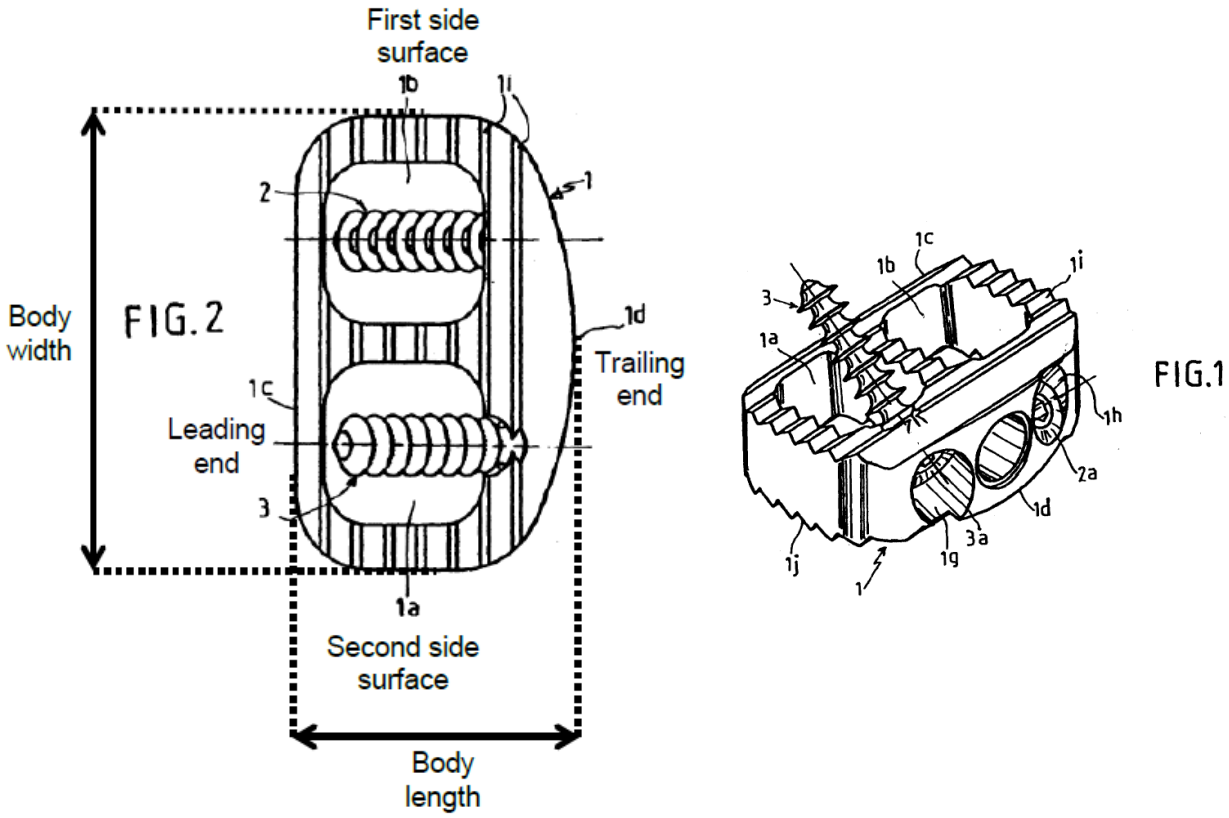


The AcroMed Brochure also discloses that the Cervical I/F Cage has an "AP length" of 13 mm and a "lateral width" of 16 mm for the standard size, and 15 mm and 19 mm for the large size. (Id. at 5.) As Dr. McMillin explains, a person of ordinary skill in the art would know that "AP" stands for Anterior-Posterior, and that the posterior is the leading edge, i.e., the edge that is inserted first between the vertebrae of the patient, while the anterior is the trailing edge. (Ex. 1002 at ¶ 100.) Thus, the Cervical I/F Cage has a body width greater than the body length. (Id.)

b. 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. 1009 at p. 1, ll. 5-6, p. 1, l. 22 – p. 2, l. 3.)

Figure 23: Figs. 1 and 2 of Tisserand (annotations added)



(Ex. 1002 at ¶ 101.) 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.) As Dr. McMillin explains, a person of ordinary skill in the art would have known 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 ¶ 102.) Thus, as illustrated in Figure 23 above, the body of the device disclosed in Tisserand has a width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion a body width that is greater than the body length. (Id.)

c. Modifying Benezech in View of the AcroMed Brochure and/or Tisserand Was Obvious

As already discussed, the Board has found it reasonably likely that "a person of ordinary skill would have been motivated to make the width of Benezech's device wider than its length to conform to the shape of the vertebrae between which the device would be implanted, as taught by Bray." (Ex. 1020 at 12.) As Dr. McMillin explains, the person of ordinary skill would have been motivated to modify Benezech in the same way in view of the AcroMed Brochure and/or Tisserand. (Ex. 1002 at ¶ 103.) And for the same reasons as discussed above, Benezech does not teach away from such a modification. (Supra at 22-23.)

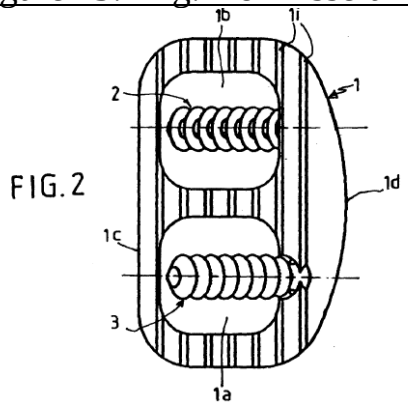
Benezech teaches that its device "can have different dimensions in terms of height, width[,] depth [and] a preferred anatomical shape." (Ex. 1006 at p. 4, ll. 9-12.) Modifying the dimensions of the body of Benezech to have a width greater than its length as taught by the AcroMed Brochure and/or Tisserand would have been routine to the person of ordinary skill in the art and an obvious design choice

that would have produced the predictable result of providing an intervertebral fusion system sized according to the particular intervertebral disk which it replaces. (Ex. 1002 at ¶ 104.) See KSR, 550 U.S. at 416.

In sum, and as further illustrated in the claim chart below, Benezech in view of the AcroMed Brochure and/or Tisserand disclose all the elements of Challenged Claim 1 and render the claim invalid as obvious.

Table 11: Challenged Claim 1 is Obvious Over Benezech in View of AcroMed Brochure and/or Tisserand

Challenged Claim 1	Benezech (Ex. 1006), the AcroMed Brochure (Ex. 1007), Tisserand (Ex. 1009)
An implantable device for use in association with bones in a patient's body,	See Table 2 above.
the implantable device comprising: a body constructed of a polymeric material	See Table 2 above.
including a trailing end portion, a leading end portion having a leading end, a first side surface, a second side surface, an upper surface and a lower surface,	See Table 2 above.
the body further including a central opening extending through the upper surface and the lower surface, the central opening having an internal surface including an internal leading surface, a first internal side surface and a second internal side surface,	See Table 2 above.

a first depth defined between the leading end and the internal leading surface, a first spacing defined between the first side surface and the first internal side surface and a second spacing defined between the second side surface and the second internal side surface, the first spacing being substantially the same as the second spacing and, the first depth being less than the first spacing	See Table 2 above.
a body width defined between the first side surface and the second side surface and a body length defined between the leading end and a trailing end of the trailing end portion, the body width being greater than the body length;	Figure 24: Dimensions of Cervical I/F Cage AP LENGTH: 13 LATERAL WIDTH: 16 Figure 25: Fig. 2 of Tisserand  FIG. 2
and a first mounting strip constructed of a metallic material connected to the trailing end portion, a first screw hole and a second screw hole extending through the first mounting strip.	See Table 2 above.

2. Challenged Claims 2, 14, 44, 47 and 48

As discussed above, Challenged Claims 2, 14, 44, 47 and 48 all depend from claim 1 and recite additional limitations that are disclosed in Benezech. (Supra at 28-32, 35-38.) As also discussed above, claim 1 is obvious over Benezech in view

of the AcroMed Brochure and/or Tisserand. Therefore, Challenged Claims 2, 14, 44, 47 and 48 are also obvious over Benezech in view of the AcroMed Brochure and/or Tisserand.

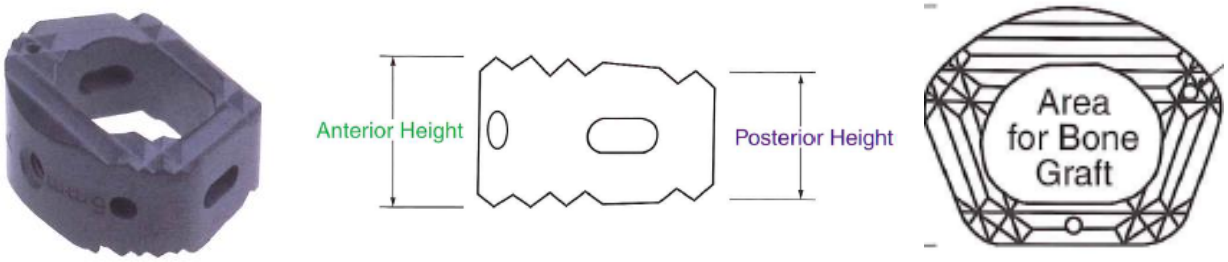
3. Challenged Claim 3

Challenged Claim 3 depends from claim 1 and further recites "wherein the body further includes a second depth defined between an internal trailing surface and the trailing end, the first depth being less than the second depth." As discussed above (supra at 29), Benezech teaches this limitation. To the extent the Board finds that Benezech does not teach this limitation, however, it is disclosed in the AcroMed Brochure and/or Tisserand.

a. The AcroMed Brochure

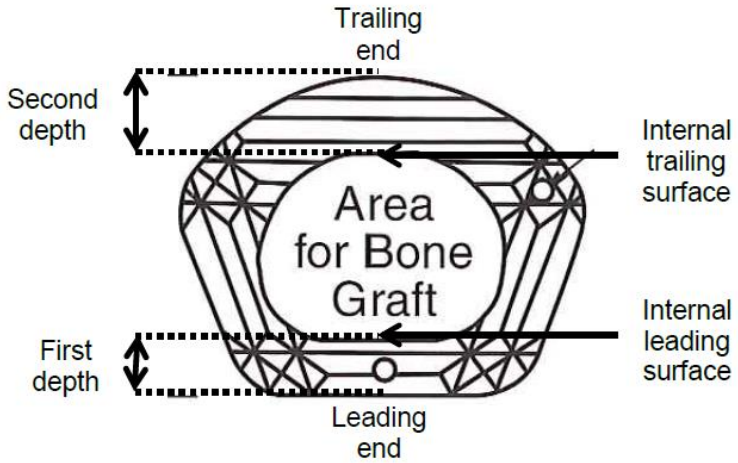
The AcroMed Brochure discloses several interbody fusion implants for anterior column support and restoration of the physiological alignment of the spine. (Ex. 1007 at 2.) Among other implantable devices, the AcroMed Brochure discloses the Cervical I/F Cage, which it discloses has a "shape to match the . . . 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



As Dr. McMillin explains, a person of ordinary skill in the art would know that the posterior is the leading end, i.e., the end that is inserted first between the vertebrae of the patient, and that the anterior is the trailing end. (Ex. 1002 at ¶ 109.) Thus, as seen in Figure 18 below, the Cervical I/F Cage has a first depth defined between the leading end and the internal leading surface, a second depth defined between the internal trailing surface and the trailing end, the first depth being less than the second depth. (Id.)

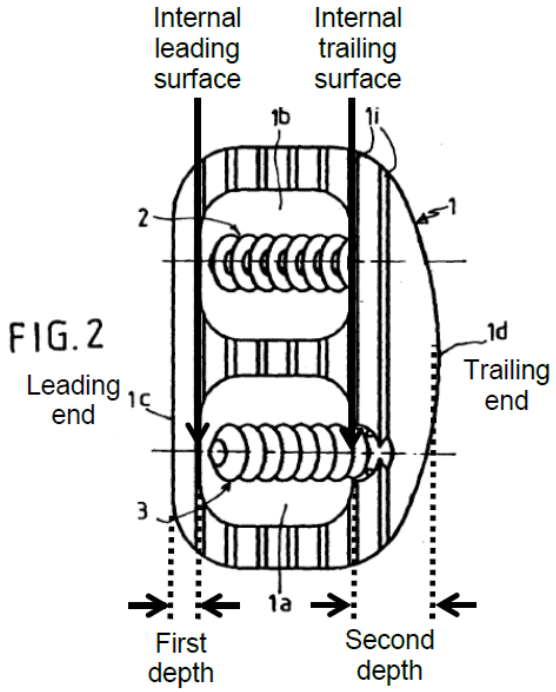
Figure 26: Cervical I/F Cage (annotations added)



b. Tisserand

The cage of Tisserand also has a first depth being less than the second depth, as illustrated in Figure 27 below. (Id. at ¶ 110.)

Figure 27: Fig. 2 of Tisserand (annotations added)



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." (Ex. 1009 at p. 2, ll. 5-8.) As discussed above, Dr. McMillin explains that the person of ordinary skill would know that the anterior face is the trailing end, i.e., the end that is trailing as the implant is inserted into the patient's spine, and that the posterior face is the leading end. (Ex. 1002 at ¶ 111.)

c. Modifying Benezech in View of the AcroMed Brochure and/or Tisserand Was Obvious

The person of ordinary skill in the art would have had several incentives to modify the second depth of Benezech as taught by the AcroMed Brochure and/or Tisserand. (Id. at ¶ 112.) First, Benezech, the AcroMed Brochure and Tisserand all 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 the devices of Benezech, the AcroMed Brochure and Tisserand – 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.)

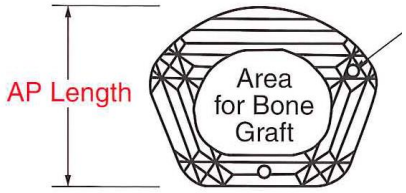
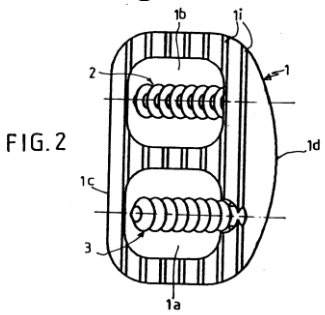
Moreover, one of ordinary skill in the art would have known that with

anterior spine surgery the spine and intervertebral disc space are deep in a patient's torso. (Id. at ¶ 113.) 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 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 the AcroMed Brochure and/or Tisserand. As discussed above, the Board has already found it reasonably likely that a person of ordinary skill would have been motivated to modify the body of Benezech in view of prior art teachings. (Supra at 22-23.) Doing so would have been routine to the person of ordinary skill in the art and yielded a predictable result. (Ex. 1002 at ¶ 113.) 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 AcroMed Brochure and/or Tisserand disclose the additional elements of Challenged Claim 3 and render the claim invalid as obvious.

Table 12: Challenged Claim 3 is Obvious over Benezech in view of AcroMed Brochure and/or Tisserand

Challenged Claim 3	Benezech (Ex. 1006), the AcroMed Brochure (Ex. 1007), or Tisserand (Ex. 1009)
The implantable device of claim 1,	See above regarding claim 1.
wherein the body further includes a second depth defined between an internal trailing surface and the trailing end, the first depth being less than the second depth.	Figure 28: Cervical I/F Cage  Figure 25: Fig. 2 of Tisserand 

4. Challenged Claim 45

Challenged Claim 45 depends from claim 1 and further recites "wherein the acute angle is between one degree and twenty degrees." This limitation is disclosed in both the AcroMed Brochure and Tisserand.

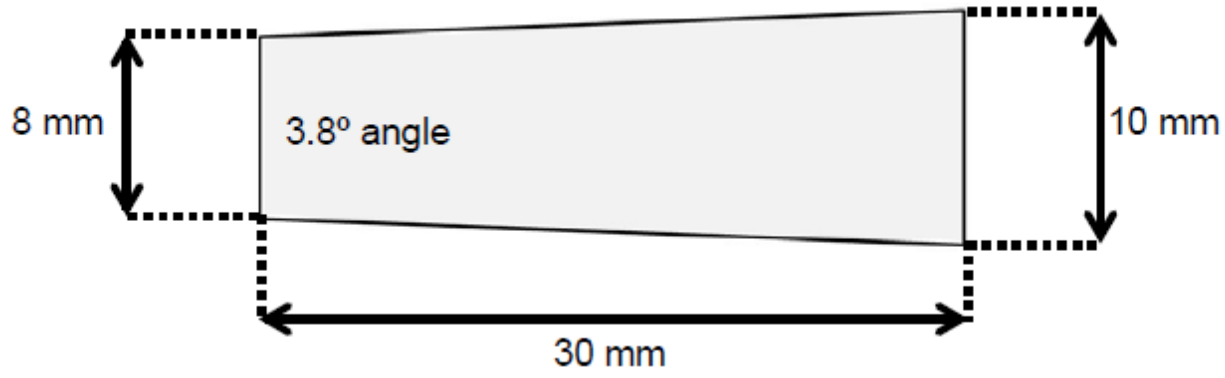
a. The AcroMed Brochure

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. 1007 at 5.)

b. Tisserand

Tisserand discloses a small, a medium and a large size of its implantable devices. (Ex. 1009 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 29: Illustration depicting teaching of Tisserand



(Ex. 1002 at ¶ 117.) 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.)

c. Modifying Benezech in View of the AcroMed Brochure and/or Tisserand Was Obvious

A person of ordinary skill in the art would understand that the angles

disclosed in the AcroMed Brochure and Tisserand are appropriate to restore and maintain lordosis in portions of the spine. (Ex. 1002 at ¶ 118.) Benezech, the AcroMed Brochure and Tisserand all disclose orthopedic devices for use in spinal fusion procedures intended for fusion of adjacent vertebrae. (Id.) Benezech is not, however, especially adapted to restoring and maintaining the lordotic angle of the spine. (Id.) The person of ordinary skill in the art would therefore have had incentive to modify the body of Benezech according to the AcroMed Brochure and/or Tisserand. (Id.) As discussed above, the Board has already found it reasonably likely that a person of ordinary skill would have been motivated to modify the body of Benezech in view of other prior art teachings. (Supra at 22-23.)

Modifying the body of Benezech to provide the acute angle disclosed in the AcroMed Brochure and/or 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 suitable for restoring and maintaining the lordotic angle of the spine. (Id. at ¶ 118.) 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 the AcroMed Brochure and/or Tisserand disclose the additional elements of Challenged Claim 45 and render the claim invalid as obvious.

Table 13: Challenged Claim 45 is Obvious over Benezech in view of AcroMed Brochure or Tisserand

Challenged Claim 45	Benezech (Ex. 1006),the AcroMed Brochure (Ex. 1007) or Tisserand (Ex. 1009)
The implantable device of claim 1,	See above regarding claim 1.
wherein the acute angle is between one degree and twenty degrees	"[T]he cage features a wedge of seven degrees from anterior to posterior, consistent with the physiological sagittal plane alignment of the cervical spine." (Ex. 1007 at 5.) "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. 1009 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.)

5. Challenged Claim 50

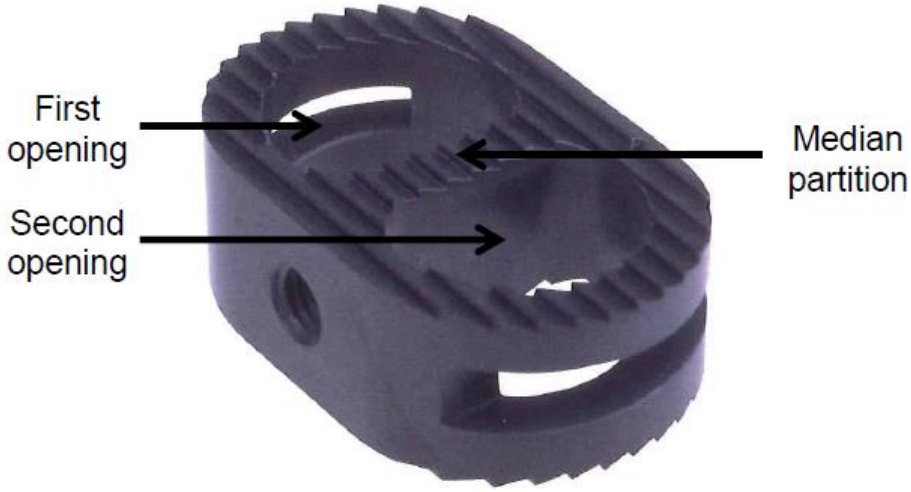
Challenged Claim 50 depends from claim 1 and further recites "wherein the body further includes a second opening extending through the upper surface and the lower surface configured to allow bone growth through the body, the second opening being generally straight." This limitation is disclosed in both the AcroMed Brochure and Tisserand.

a. The AcroMed Brochure

The AcroMed Brochure discloses several interbody fusion implants for anterior column support and restoration of the physiological alignment of the

spine. (Ex. 1007 at 2.) Among other implantable devices, the AcroMed Brochure discloses the Anterior Lumbar I/F Cage pictured below in Figure 30.

Figure 30: Anterior Lumbar I/F Cage
disclosed in the AcroMed Brochure (annotated)

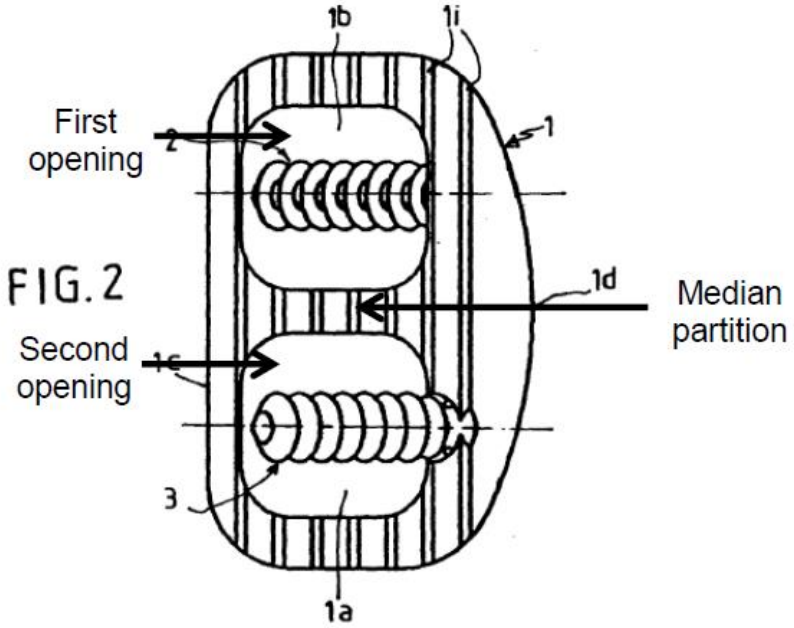


(Id. at 4.) As can be seen, the Anterior Lumbar I/F Cage has two generally straight openings created by a median partition. (Ex. 1002 at ¶ 121.) The AcroMed Brochure teaches that these opening are for "graft placement." (Ex. 1007 at 4.) As Dr. McMillin explains, therefore, the person of ordinary skill in the art would understand that the openings are configured to allow bone growth through the body of the cage. (Ex. 1002 at ¶ 121.)

b. Tisserand

Tisserand also discloses two generally straight openings created by a median, as seen in Figure 31 below. (Id. at ¶ 122.)

Figure 31: Fig. 2 of Tisserand



(Id. at 122.) Tisserand further discloses that the openings are configured to "each receive cancellous grafts." (Ex. 1009 at p. 3, ll. 9-10.) Therefore, as Dr. McMillin explains, the person of skill would understand that the grafts would facility bone growth through the openings and thus through the body of the implantable device. (Ex. 1002 at ¶ 122.)

c. Modifying Benezech in View of the AcroMed Brochure and/or Tisserand Was Obvious

A person of ordinary skill in the art would have known, as Dr. McMillin explains, that adding the median partition of the AcroMed Brochure and/or Tisserand to Benezech would not only serve to reinforce the cage and increase its structural integrity, but also decrease the likelihood that the cage would subside into the bottom vertebra over time by increasing the surface area of the cage. (Id.

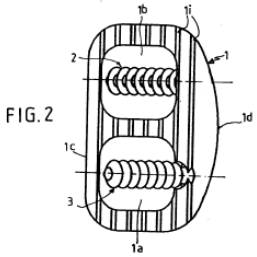
at ¶ 123.) The person of ordinary skill in the art would therefore have had incentive to modify the body of Benezech according to the teachings of the AcroMed Brochure and/or Tisserand. (Id.) As discussed above, the Board has already found it reasonably likely that a person of ordinary skill would have been motivated to modify the body of Benezech in view of other prior art teachings. (Supra at 22-23.)

Modifying the body of Benezech with a median partition to provide a plurality of openings as disclosed in the AcroMed Brochure and/or Tisserand would have been routine to the person of ordinary skill in the art and produced the predictable result of providing a structurally strengthened intervertebral fusion system suitable that would be less likely to subside into the bottom vertebral plate over time. (Id. at ¶ 123.) 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 the AcroMed Brochure and/or Tisserand disclose the additional elements of Challenged Claim 50 and render the claim invalid as obvious.

Table 14: Challenged Claim 50 is Obvious over Benezech in view of AcroMed Brochure or Tisserand

Challenged Claim 50	**Benezech (Ex. 1006), the AcroMed Brochure (Ex. 1007), Tisserand (Ex. 1009)**
The implantable device of claim 1,	See above regarding claim 1.
wherein the body further includes a	Figure 32: Anterior Lumbar I/F Cage

second opening extending through the upper surface and the lower surface configured to allow bone growth through the body, the second opening being generally straight.	 "The Anterior Lumbar I/F Cage design, modeled on the concept of a femoral ring with an outer ring of composite material surrounding a larger inner area for graft placement, may minimize many of the problems associated with donor bone grafts." (Ex. 1007 at 4.) Figure 25: Fig. 2 of Tisserand  Said element (1) is arranged to receive cancellous grafts (G) and to allow their interbody fusion." (Ex. 1008 at p. 3, ll. 9-10.)

D. 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 Claims 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 1, 2, 3, 14, 44, 45, 47, 48 and 50 of the '363 patent are unpatentable as obvious. Petitioners therefore request that the Board grant *inter partes* review to cancel these claims.

Respectfully submitted,

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Dated: December 29, 2015

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct coy of **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT No. 8,795,363 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 addresses for the subject patent pursuant to 37 C.F.R § 42.105:

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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:

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