IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Curran et al.
U.S. Patent No.: 8,361,156 Attorney Docket No.: 108136.00033
Issue Date: January 29, 2013
Appl. Ser. No.: 13/441,092
Filing Date: April 6, 2012
Title: SYSTEMS AND METHODS FOR SPINAL FUSION

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Patent Trial and Appeal Board
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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,361,156 PURSUANT TO 35 U.S.C. §§ 311-319, 37 C.F.R. § 42

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EXHIBITS

MSD 1001 – Declaration of Richard Hynes, M.D. Regarding U.S. Patent No. 8,187,334

MSD 1002 – Declaration of Steven D. DeRidder Regarding U.S. Patent Application Publication No. 2002/0165550

MSD 1003 – U.S. Patent Application Publication No. 2002/0165550

MSD 1004 – U.S. Patent Application Publication No. 2003/0028249

MSD 1005 – U.S. Patent No. 5,860,973

MSD 1006 – U.S. Patent Application Publication No. 2003/0100950

MSD 1007 – U.S. Patent Application Publication No. 2003/0139813

MSD 1008 – Prosecution History of U.S. Patent No. 8,361,156

MSD 1009 – Prosecution History of U.S. Patent No. 7,918,891

MSD 1010 – First Amended Complaint, filed on October 6, 2008, and Judgment Following Jury Verdict, entered on September 29, 2011, in *Warsaw Orthopedics, Inc. v, NuVasive, Inc.*, Case No. 3:08-CV-01512, Southern District of California

MSD 1011 – *Curriculum Vitae* of Richard Hynes, M.D.

MSD 1012 – S.H. Zhou et al., *Geometrical Dimensions of the Lower Lumbar Vertebrae – Analysis of Data from Digitised CT Images*, 9 EUR SPINE J 242, 244 (2000)

MSD 1013 – U.S. Patent No. 8,361,156

MSD 1014 – Gray, H., *Gray's Anatomy* 489 (Peter L. Williams et al. eds., 37th ed. 1989)

Medtronic, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-14, 19, 20, and 23-27 of U.S. Patent No. 8,361,156 (the "'156 patent") (Exhibit MSD 1013). This Petition presents new arguments and provides new evidence to cure any noted deficiencies in Petitioner's previously filed petition for IPR, now styled *Medtronic, Inc. v. NuVasive, Inc.*, Case No. IPR2013-00504 (LMG) (the "'504 IPR"). In light of this newly offered information, as set forth below, Petitioner demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of claims 1-14, 19, 20, and 23-27 identified in this petition as being unpatentable.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

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

Petitioner is the real party-in-interest for the instant petition.[1]

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

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '156 patent. Petitioner is a named counterclaim-defendant in litigation concerning the '156 patent, *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.*, originally filed in the Northern District of Indiana as Case No. 3:12-cv-00438-JD-CAN on August 17, 2012, and transferred to the Southern

[1] Other parties that have an interest in the instant petition include Petitioner's co-counterclaim defendants in Case No. 3:12-cv-00438-JD-CAN; including: Medtronic Sofamor Danek U.S.A., Inc. and Medtronic Sofamor Danek Deggendorf, GmbH.

District of California on November 8, 2012, as case No. 3:12-cv-02738-CAB-MDD. The '156 patent was added by counterclaim filed on March 7, 2013.

On August 14, 2013, Petitioner filed two Petitions for *Inter Partes* Review requesting review of claims 1-14, 19, 20, and 23-27 of the '156 patent, now styled *Medtronic, Inc. v. NuVasive, Inc.*, Case No. IPR2013-00504 (LMG) ("'504 IPR") and *Medtronic, Inc. v. NuVasive, Inc.*, Case No. IPR2013-00506 (LMG) ("'506 IPR"). The Patent Trial and Appeal Board ("PTAB") instituted the '506 IPR for all of the requested claims. The '504 IPR, which contained similar grounds to those included in the present Petition, was denied by the PTAB. In its decision to deny institution of the '504 IPR, the PTAB noted that "Medtronic does not explain how the maximum lateral width of the [Frey] implant is along a medial plane that is generally perpendicular to the longitudinal length as required by independent claim 1 [of the '156 patent]." Petitioner submits this Petition to provide such explanation. Additionally, Petitioner adds new arguments and evidence as to the length disclosure of U.S. Patent Appl. Pub. No. 2002/0165550 to Frey ("Frey").

While Petitioner is mindful of 35 U.S.C. § 325(d), the denial of the '504 Petition has no bearing on this Petition because instead of containing "the same or substantially the same . . . argument previously presented to the Office," it is responding to a noted deficiency with new argument and new evidence supporting these new arguments to further explain how these previously propounded prior art

references render claims 1-14, 19, 20, and 23-27 of the '156 patent invalid. Additionally, the grounds presented in this Petition are not redundant to those in the granted '506 IPR because those grounds are based on different prior art references and different arguments. Further, the Petition is being filed within the one year time period and the Petitioner has no other avenue to challenge these claims because the rules prohibit new argument in a request for rehearing.

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

LEAD COUNSEL	BACK-UP COUNSEL
Jeff E. Schwartz, Reg. No. 39,019 1030 15th Street, NW Washington, DC 20005	Seth A. Kramer, Reg. No. 67,813 2000 Market Street, 20th Floor Philadelphia, PA 19103

D. Service Information

Please address all correspondence and service to both counsel listed above. Petitioner consents to service by email at ipdocket@foxrothschild.com (referencing Attorney Docket No. 108136.00033).

II. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the PTO to charge Deposit Account No. 50-1943 for any fees due as a result of the filing of the present petition.

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies the '156 patent is eligible for IPR and Petitioner is not barred or estopped from requesting IPR. This petition is filed within one year of

service of a counterclaim against Petitioner in district court litigation in which the '156 patent was asserted.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests IPR of claims 1-14, 19, 20, and 23-27 of the '156 patent on the grounds set forth in the table below and requests that each of the claims be found unpatentable. A detailed explanation of the statutory grounds for the unpatentability of each claim is provided in the form of claim charts. Additional evidence supporting each ground is provided for in the Declarations of Richard A. Hynes, M.D. and Steven D. DeRidder, and the appendices attached thereto.

Ground	Claims	Basis for Rejection
1	1-8, 10-14, 19, 20, and 23-27	Obvious under § 103 by U.S. Patent Appl. Pub. No. 2002/0165550 to Frey ("Frey") (Exhibit MSD 1003) in view of U.S. Patent Appl. Pub. No. 2003/0028249 to Baccelli ("Baccelli") (Exhibit MSD 1004)
2	1-8, 10-14, 19, 20, and 23-27	Obvious under § 103 by Frey in view of Baccelli and in further view of U.S. Patent Appl. Pub. No. 2003/0139813 to Messerli ("Messerli") (Exhibit MSD 1007)
3	1-14, 19, 20, and 23-27	Obvious under § 103 by Frey in view of Baccelli and further in view of U.S. Patent No. 5,860,973 to Michelson ("Michelson") (Exhibit MSD 1005)
4	1-8, 10-14, 19, 20, and 23-27	Obvious under § 103 by Frey in view of Baccelli and further in view of U.S. Patent Appl. Pub. No. 2003/0100950 to Moret ("Moret") (Exhibit MSD 1006)
5	1-8, 10-14, 19, 20, and 23-27	Obvious under § 103 by Baccelli in view of Frey and/or Michelson

Frey, Baccelli, and Michelson each qualify as prior art under at least 35 U.S.C. § 102(b) because they were published more than one year prior to March

29, 2004. Messerli qualifies as prior art under 35 U.S.C. § 102(a) because it was published on July 24, 2003. Moret qualifies as prior art under 35 U.S.C. § 102(a) because it was published on May 29, 2003. None of these references were cited in a rejection during prosecution of the '156 patent.

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

In an IPR, the claim terms are given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). The claims terms are understood by their plain and ordinary meanings except where construed in the specification. The broadest reasonable construction is the broadest reasonable interpretation of the claim language. *See In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 2004). Consistent with this standard, a proposed interpretation for certain claim terms is provided below.

1. Distal Wall / Proximal Wall

Under the broadest reasonable construction, the distal wall is the side or end of the implant that generally enters the patient first, i.e. the leading end wall, opposite the proximal or trailing end wall. The proximal wall is the side or end of the implant that enters patient last; opposite of the distal wall. Further, as discussed in detail in Section IV.B., *infra,* the PTO has previously taken the position that the apertures (1044) shown in the prior art spinal fusion implant figures reproduced at

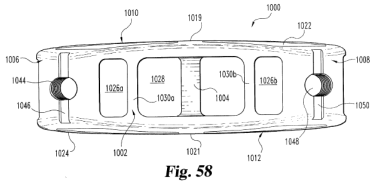


Fig. 58

right are located on the proximal wall of the implant. The Applicant implicitly acquiesced to the PTO on its interpretation. Therefore, the broadest reasonable construction of the terms "distal wall" and "proximal wall" include the regions, for example, of the Frey implant disclosed above where apertures 1044 and 1048 are located.

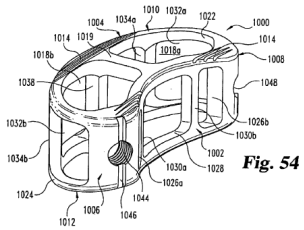


Fig. 54

2. Releasably Mate

Under the broadest reasonable construction, the term "releasably mate" as used in the '156 patent should be construed as "an impermanent stabilized connection." In the '156 patent, this term is used to describe the connecting relationship between the implant and insertion tool. *See* '156 patent, at 8:26-33 ("In order to secure the spinal fusion implant 10 onto the threaded connector 24 of the inserter instrument 20, the clinician employs the thumbwheel 34 to rotate the inserter shaft 44 and threaded connector 24. The rotation of the threaded connector 24 will releasably engage the receiving aperture of the spinal fusion implant 10 and stabilize the insertion instrument 20 relative to the spinal fusion implant 10.").

3. Extend Generally Perpendicular to Said Longitudinal Length

Under the broadest reasonable construction, this term is construed as extending approximately in a direction that crosses a plane along the general direction of the longitudinal length of the implant at generally or roughly a right angle. The "longitudinal length" in its broadest reasonable interpretation, is the

dimension measured from end to end of the implant, or from insertion/leading end to trailing end. For example, Webster's Third New International Dictionary of the English Language Unabridged (2002) at page 1293, defines "length" to mean "the extent from end to end." Similarly, The New Shorter Oxford English Dictionary (1993) at page 1565 defines "length" as "the linear extend of anything as measured from end to end." *See* Manual of Patent Examining Procedure, Section 2111.01 ("Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification. . . . Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say.").

4. Elongate Body

Under the broadest reasonable construction, an "elongate body" is construed as a body longer than it is wide. *See id.*

5. Generally Rectangular and Generally Oblong in Shape

Under the broadest reasonable construction, the term "generally rectangular and generally oblong in shape is construed as a shape having portions roughly approximating sides and being elongated in at least one dimension. In support of such construction, as discussed in further detail in

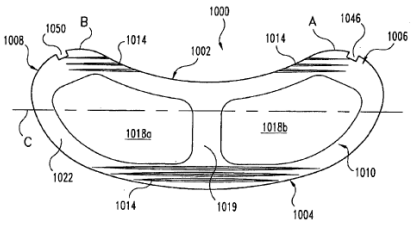


Fig. 53

Section IV.B., *infra,* the PTO has previously taken the position that the fusion apertures (1018a, 1018b) shown in the Frey prior art spinal fusion implant figure reproduced above are generally rectangular and elongated in at least one direction.

6. A Lateral Width of the Distal End of Said Distal Wall/A Lateral Width of Said Proximal End of Said Proximal Wall

Under the broadest reasonable construction, these terms are construed as being a width of the most distal end of the distal wall extending in a direction from the first side wall to the second sidewall and a width of the most proximal end of the proximal wall extending in a direction from the first side wall to the second sidewall. *See* MPEP, Section 2111.01.

7. Oriented Generally Parallel to a Height of the Implant

Under the broadest reasonable construction, this term is construed as being oriented generally or roughly along the Y-axis (up and down) or oriented generally or roughly in a direction running from the top to the bottom. *See id.*

IV. SUMMARY OF THE '156 PATENT

A. Overview of the '156 Patent

The application that issued as the '156 patent was filed on April 6, 2012, and is a continuation of U.S. Patent No. 8,246,686, filed on April 5, 2012, which is a continuation of U.S. Patent No. 8,187,334, filed on April 4, 2011, which is a continuation of 7,918,891 (the "'891 patent"), filed on March 29, 2005, which claims the benefit U.S. Prov. Appl. Ser. No. 60/557,536, filed on March 29, 2004.

The ‘156 patent is directed to a spinal fusion implant of non-bone construction that is positionable in the interbody space between first and second vertebrae. *See, e.g.,* ‘156 patent, 1:66 to 2:2. As described and claimed, the implant of the ‘156 patent has a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. The length of the implant extending from the proximal wall to the distal wall is greater than the maximum width of the implant, as defined by greatest distance between the two sidewalls along a medial plane of the implant. The upper and lower surfaces of the implant contain anti-migration elements that come in contact with the first and second vertebrae. At least one fusion aperture that is longer than it is wide and extends from the top surface to the bottom surface is included in the implant. The claimed implant also contains at least two radiopaque markers oriented generally parallel to height of the implant, with at least one in the first sidewall, and one in the second sidewall. The ‘156 patent describes the implant as being manufactured from a radiolucent material so that the markers “will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant 110 during implantation and/or the placement of the implant 110 after implantation.” ‘156 patent, 10:2-9. The ‘156 patent does not discuss whether or how the size, shape, location, or orientation of the markers is

critical to, or otherwise may affect the ability of the surgeon to track the progress or placement of the implant.

B. Summary of the Prosecution History of the '156 Patent

The prosecution histories of the '156 patent, and of its parent patent, the "'891 patent", as obtained from PAIR, are submitted herewith as Exhibits MSD 1008 and MSD 1009.

The parent '891 patent, like the continued '156 patent, has claims directed to a spinal fusion implant of non-bone construction. The '891 patent issued from U.S. Pat. Appl. Ser. No. 11/093,409 (the "'409 application"), which was filed with two independent claims (Claims 1 and 14) and twenty-four dependent claims (Claims 2-13 and 15-26). During prosecution of the '409 application, Applicants amended the claims to recite limitations that are similar to the limitations currently found in the '156 patent. For example, Claim 1 was amended to include the limitation that "the length is so dimensioned as to extend between lateral aspects of said interbody space and is at least two and a half times greater than said width;" Claim 5 was amended to recite that the "first and second fusion apertures are one of generally rectangular and oblong in shape;" and new Claims 31-33 were added and were directed to a threaded receiving aperture "at least partial defined along said proximal side" of the implant. *See* MSD 1009, at 996-998.

In an Office Action dated August 27, 2009, the PTO rejected these claims. In support of these rejections, the PTO cited U.S. Patent No. 6,830,570 to Frey (the "'570 patent") as disclosing, *inter alia*, first and second fusion apertures (1018a, 1018b) that are "generally rectangular and oblong in shape." *Id.* at 1010. The PTO also cited the '570 patent as disclosing a threaded receiving element (1044) on the proximal side of the implant that engages with an insertion instrument. *See id.*

With respect to the limitation regarding the proportional relationship between the length and the width of the implant, the PTO explained that "[i]t would have been obvious to one having ordinary skill in the art at the time of invention was made to have the length be at least two and a half times greater than the width, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." *See id.* (citing *In re Boesch*, 617 F.2d 272 (CCPA 1980)).

The Applicants did not argue past these rejections, but instead amended the claims to add the element of a medial support extending parallel to the proximal and distal sides and between the top and bottom surfaces of the implant thereby separating the fusion apertures of the implant to avoid the rejections based on the Frey '570 patent. *See* Exhibit MSD 1009, at 1029-30.

During prosecution of the '156 patent, the claims were amended in preliminary amendments, but were never rejected by the PTO.

C. Legal Standard for Obviousness

A claim is obvious, and therefore invalid, under 35 U.S.C. § 103(a) if, at the time the invention was made, "the combined teachings of the prior art, taken as a whole, would have rendered the claimed invention obvious to one of ordinary skill in the art." *In re Napier*, 55 F. 3d 610, 613 (Fed. Cir. 1995). The scope and content of the prior art drive the obviousness analysis. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406, 127 S. Ct. 1727, 1734, 167 L. Ed. 2d 705 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 127 S. Ct. at 1739. There is no requirement to find precise teachings directed to specific subject matter of a claim; common sense, inferences, and creative steps that a person of ordinary skill in the art would employ should be considered. *Id*. at 1741. Obviousness is not confined to a formalistic conception of "teaching, suggestion, and motivation" or by overemphasis on published articles and explicit content of issued patents. *Id.* Courts should apply common sense, recognizing that "familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id*. at 1742.

If "a patent 'simply arranges old elements with each performing the function it had been known to perform' and yields no more than one would expect from

such an arrangement, the combination is obvious." *Id.* at 1740. When "design incentives and other market forces . . . prompt variations of [an existing device] . . . [and] a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* In short, "a court must ask whether the improvement is more than a predictable use of prior art elements according to their established function." *Id.*

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The challenged claims recite spinal fusion implants with features that were well known prior to the earliest possible priority date of the '156 patent. *See e.g.,* Declaration of Richard Hynes, M.D. Regarding U.S. Patent No. 8,361,156 (hereinafter, the "Hynes Decl."), attached hereto as Exhibit MSD 1001, at ¶ 59. As detailed in claim charts below, prior art references render obvious the challenged claims of the '156 patent.

A. Ground 1 – Claims 1-8, 10-14, 19, 20 and 23-27 Are Obvious Under § 103 over Frey in View of Baccelli

As shown in the claim chart below, claims 1-8, 10-14, 19, 20, and 23-27 of the '156 patent are obvious under 35 U.S.C. § 103 over Frey in view of Baccelli. Both Frey and Baccelli are artificial intervertebral implants used for spinal fusion procedures. Baccelli offers alternative locations and orientations for its radiographic markers to supplement the teachings of Frey, but otherwise a person of skill would be motivated to look to the teachings of Baccelli for information

pertaining to such markers and also to various means for interfacing a tool with an implant to be inserted.

With respect to Claim 1, Frey, which was not cited during prosecution of the '156 patent, discloses a spinal fusion implant having a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. The implant is described for use in various "approaches to the disc space, such as lateral, anterior or antero-lateral approaches" for insertion of implant 1400 as well as "for insertion from a postero-lateral or uni-lateral approach into [a] disc space . . . ." Frey, at ¶ [0150]. The curvatures of the opposing sidewalls are generally the same so the maximum lateral width of the implant, as measured from sidewall to sidewall in a direction perpendicular to that of the longitudinal length of the implant, is located at least at and near the exact center of the middle portion, including a medial plane of the implant, as well as along the other areas of the middle portion where the opposing sidewalls maintain generally the same curve. *See* Hynes Decl., at ¶ 38; Declaration of Steven D. DeRidder Regarding U.S. Patent Application Publication No. 2002/0165550 ("DeRidder Decl.") (attached hereto as Exhibit MSD 1002), at ¶ 10.

To the extent that Frey does not explicitly teach that the lateral width is largest in the precise center of the implant, a person of ordinary skill in the art would find it obvious to provide approximately the same width along the middle

portion of the implant for ease of manufacture and to allow for easy insertion of the device during implantation. *See* Hynes Decl., at ¶ 38. Additionally, it would have been obvious to include the maximum lateral width in the middle portion of the implant to better fill the disc space, thus providing optimal load support capacity. *See* Frey, at ¶ [0149] ("The shape and location of the bars, struts and walls positions the load bearing members at the strong bony surfaces of the vertebral endplates to provide maximum load support capacity and avoid implant subsidence into the vertebral endplates."); Hynes Decl., at ¶ 38; DeRidder Decl., at ¶ 11. Under either scenario, because the middle portion of the implant encompasses a medial plane of the implant – i.e., a plane at or towards the middle of the implant – the maximum lateral width is necessarily found along this medial plane. Frey further discloses that its implant's longitudinal length is greater than the maximum lateral width along the medial plane. *See* Hynes Decl., at ¶¶ 38 and 63; DeRidder Decl., at ¶¶ 7-9 (noting that Figs. 47, 55, 59, 63, 64 and 66 are drawn to scale).

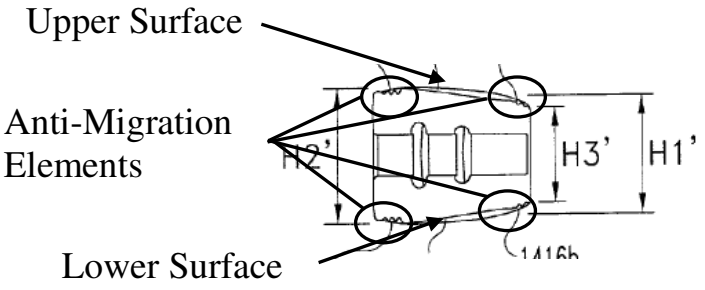
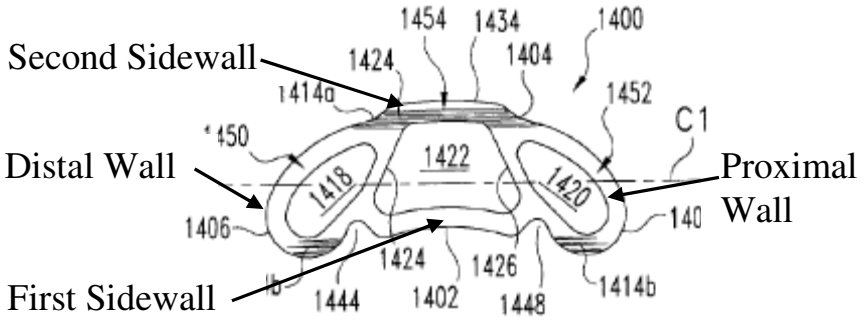
The upper and lower surfaces of the Frey implant contain anti-migration elements that come in contact with the first and second vertebrae. Additionally, the Frey implant discloses and makes obvious the inclusion of at least one fusion aperture that extends from the top surface to the bottom surface and has a longitudinal length that is greater than its lateral width. *See* Hynes Decl., at ¶ 63.

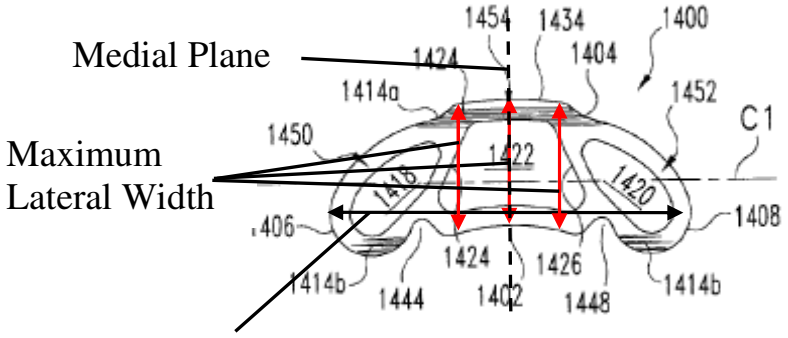
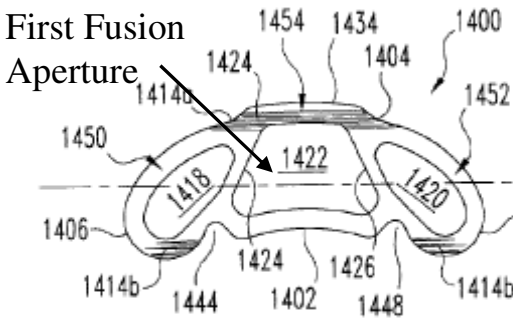
Frey also discloses the use of radiopaque markers in its distal and proximal walls and at least one of its sidewalls for radiographic imaging. As in the '156 patent, Frey teaches the use of such markers for radiographic imaging to determine the location of the implant after insertion into the patient. *See* Frey, at ¶ [0156] ("A number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body.").

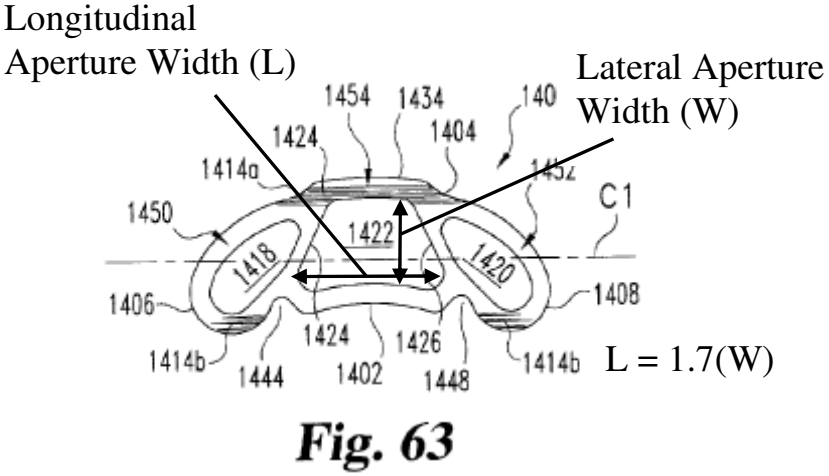
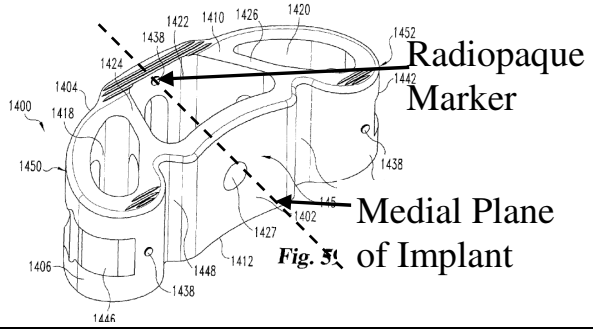
Baccelli, likewise, discloses the use of radiopaque markers with a spinal fusion implant. Baccelli specifically discloses the use of at least first and second radiopaque markers that extend into a first sidewall and a second sidewall at positions proximate to a medial plane of the implant. Like the '156 patent, Baccelli explicitly teaches the use of such markers to assist a surgeon in tracking the progress and placement of the implant during and after surgery. *See* Baccelli, at ¶¶ [0050]-[0051] ("[T]he cage can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. . . . The spikes 24 . . . too can be made of a material that is opaque to X-rays."). Accordingly, it would have been obvious one of ordinary skill in the art at the time of invention to combine the teachings of Baccelli with those of Frey to provide additional information regarding the orientation or location of an implant during

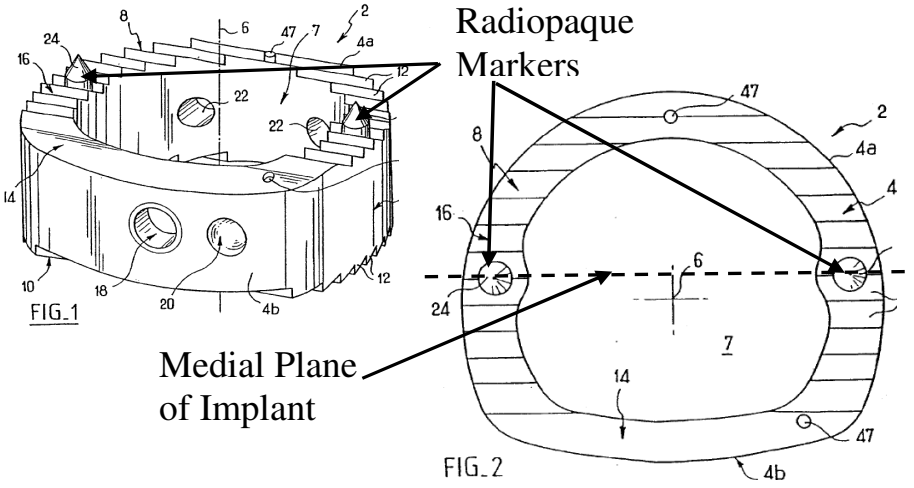
surgery and after implantation. Frey and Baccelli are from the same field of artificial implants used in spinal fusion by insertion in the intervertebral disc space and having a space provided in the implant to fill with bone growth promoting substances to enhance the fusion, and both references expressly teach the use of radiographic markers to track the placement of such implants within the patient. *See* Hynes Decl., at ¶ 64. Thus, a spinal implant incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 1 [A]: A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:	Frey discloses a spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra. *See, e.g.*, Frey, at ¶ [0150] ("Implant 1400 is an interbody fusion device or cage that can be packed with bone growth material or other known substance and inserted into disc space D1 to promote bony fusion between adjacent vertebrae V1 and V2."); ¶ [0181] ("The implants described herein can be made from any biocompatible material, including synthetic . . ..").
Claim 1 [B]: an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including	Frey provides that the spinal fusion implant has an upper surface and a lower surface, both of which contain anti-migration elements that contact the first and second vertebra, respectively. *See* Frey, at ¶ [0153] ("Upper bearing surface 1410 can further be provided with a number of first grooves 1414 a along anterior wall 1404 and second grooves 1414 b along leading and trailing end walls 1406, 1408. Lower bearing surface 1412 can be provided with a number of grooves 1416 a along anterior wall 1404 and second grooves 1416 b along leading and trailing end walls 1406, 1408. Grooves 1414 a, 1414 b and 1416 a, 1416 b increase

anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space,	frictional resistance between the adjacent vertebral endplate and the bearing surfaces 1410, 1412 to resist posterior and anterior migration of implant 1400 in the disc space.”). 
Claim 1 [C]: a distal wall, a proximal wall, a first sidewall and a second sidewall generally opposite from the first sidewall,	Frey discloses that the spinal fusion implant has a distal wall (leading end wall 1406), a proximal wall (trailing end wall 1408), a first sidewall (posterior wall 1402) and a second sidewall (anterior wall 1404). *See* ¶ [0151] (“Implant 1400 includes a body having a leading end portion 1450, a trailing end portion 1452, and a middle portion 1454 therebetween. A concave posterior wall 1402 and an opposite convex anterior wall 1404 extend along middle portion 1454, and also along at least part of the corresponding side of leading end portion 1450 and trailing end portion 1452. Implant 1400 further includes an arcuate leading end wall 1406 extending along leading end portion 1450 between posterior wall 1402 and anterior wall 1404. Implant 1400 also includes an arcuate trailing end wall 1408 extending along trailing end portion 1452 between posterior wall 1402 and anterior wall 1404.”). 
Claim 1 [D]: wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent	Frey provides that the walls of the spinal fusion implant may comprise a radiolucent material. *See* Frey, at ¶ [0156] (“A number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body. Such markers are particularly useful for an implant 1400 made from radiolucent material.”).

material;	
Claim 1 [E]: wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and said longitudinal length is greater than said maximum lateral width;	Frey provides that the implant has a longitudinal length that extends from the proximal wall to the distal wall. As shown in Figure 63 of Frey, the maximum lateral width extending from the first side wall to the second sidewall along a plane that is perpendicular to the length of the implant, is found at the medial plane of the implant. This maximum lateral width is also found along a section of the implant's middle portion where the curves of the opposing sidewalls are generally the same. As further shown in Figure 63, the longitudinal length is perpendicular to, and greater than, this maximum lateral width that is found along the medial plane of the Frey implant.  ***Fig. 63***
Claim 1 [F]: at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody	Frey discloses that the spinal fusion implant includes a first fusion aperture, chamber 1422, that is configured to allow bone growth between the first vertebra and the second vertebra after proper positioning of the device. *See* Frey, ¶ [0154] ("In order to provide avenues for bone growth through implant 1400, the walls of implant 1400 form a number of chambers opening at upper bearing surface 1410 and lower bearing surface 1412. . . . Middle portion 1454 includes a middle 

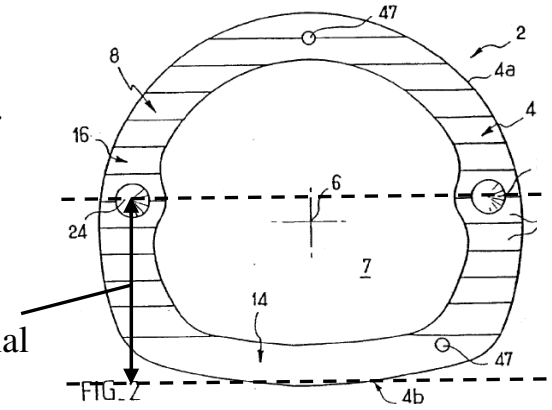
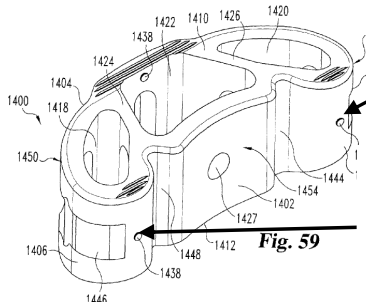
space,	chamber 1422.”).
Claim 1 [G]: said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and	Figure 63 of Frey reasonably discloses to one skilled in the art that the first fusion aperture of the spinal implant disclosed in Frey has a longitudinal aperture width greater than its lateral aperture width.  ***Fig. 63***
Claim 1 [H]: at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate	Frey provides that the spinal fusion implant includes at least three radiopaque markers. *See* Frey, at ¶ [0156] (“A number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body.”). Frey further provides that a first radiopaque marker is located at least partially in the distal wall of the implant, a second radiopaque marker is located at least partially in the proximal wall of the device, and a third radiopaque marker is located at least partially in the central region. *See id.* (“In the illustrated embodiment, markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434. Markers 1438 are also provided at the  ***Fig. 51***

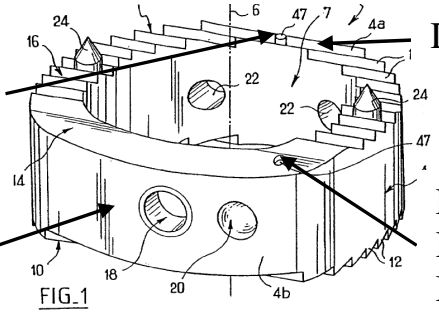
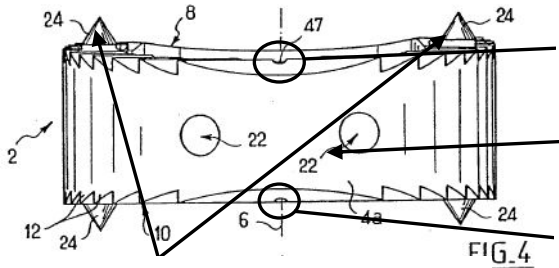
to said medial plane.	posterior-most points of trailing end wall 1408 and leading end wall 1406."). Baccelli discloses an implant having at least first and second radiopaque markers (spikes 24) that extend into a first sidewall and a second sidewall at positions proximate to a medial plane. *See* Baccelli, at ¶ [0041] ("The cage has spikes 24, in this case four such spikes, i.e. two associated with each of the main faces 8 and 10. Each spike has a pointed end and it projects from the associated main face. The two spikes on each face are disposed symmetrically to each other about the sagittal midplane. In addition, they extend in the frontal midplane containing the axis 6. Each spike on one face extends in register with a spike on the other face."); ¶ [0051] ("The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays."). 

Claims 2-4 add limitations directed to the radiopaque markers featured in the implant. Baccelli discloses the added limitation of claim 2, as it discloses first and second radiopaque markers that are substantially equally spaced apart from the proximal end of the proximal wall of the implant by a first longitudinal distance.

With respect to claim 3, both Frey and Baccelli disclose a radiopaque marker that extends into the implant's distal wall, and a radiopaque marker that extends into the implant's proximal wall. With respect to claim 4, Baccelli discloses that its radiopaque markers (spikes 24) can extend entirely through a height of the walls of the implant. Therefore, modification of the markers 47, located in the proximal and distal walls to be similar to the spikes 24 of Baccelli to extend entirely through the height of the end walls is merely a trivial tweak of this known feature of Baccelli in a predictable and common sense manner. *See* Hynes Decl., at ¶ 74.

It would have been obvious to one of ordinary skill at the time of invention to modify Frey to configure the radiographic markers as disclosed in Baccelli to facilitate additional imaging information in response to the known design need to "identify the position and/or the presence of the implant when X-rays are taken during or after the operation." *See* Baccelli, at ¶ [0050]. As discussed *supra*, Frey and Baccelli are from the same field of artificial implants used in spinal fusion, and both teach the use of radiographic markers to generate X-ray imaging information the help locate the implant during and after insertion. Thus, a spinal implant incorporating the teachings of these references is merely an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive, to achieve predictable results. *See KSR*, 550 U.S. at 418.

Claim 2: The spinal fusion implant of claim 1, wherein the first and second radiopaque markers are substantially equally spaced apart from said proximal end of said proximal wall by a first longitudinal distance.	The radiopaque markers (spikes 24) present on the implant described in Baccelli are both located the same distance, a first longitudinal distance, away from the proximal wall of the implant. *See* Baccelli, at ¶ [0041] ("The two spikes on each face are disposed symmetrically to each other about the sagittal midplane.").  First Longitudinal Distance FIG. 2
Claim 3: The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall.	Frey provides that the spinal fusion implant includes a radiopaque marker located in the distal wall and a second radiopaque marker located at least in the proximal wall. *See* Frey, at ¶ [0156] ("A number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body. . . . Markers 1438 are also provided at the posterior-most points of trailing end wall 1408 and leading end wall 1406.").  Fig. 59 Radiopaque Marker in Proximal Wall Radiopaque Marker in Distal Wall Baccelli provides that the implant may also include a third radiopaque marker (marker 47) that extends into the distal wall of the implant, and a fourth radiopaque marker (marker 47) that extends into the proximal wall of the implant. *See* Baccelli, at ¶ [0050] ("The cage can be made of a material that is transparent to X-rays, e.g. out of poly-ether-ether-ketone (PEEK). In which case, the cage can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. . . . In this

	case, there are two markers 47 . . . inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.”). Third Radiopaque Marker Distal Wall Proximal Wall Fourth Radiopaque Marker  FIG_1
Claim 4: The spinal fusion implant of claim 3, wherein said third radiopaque marker extends entirely through a height of said distal wall, and wherein said fourth radiopaque marker extends entirely through a height of said proximal wall.	Frey discloses markers in the distal and proximal walls. Baccelli also provides a radiopaque marker (marker 47) that extends along a height of the distal wall, and another radiopaque marker (marker 47) that extends along a height of the proximal wall. *See* Baccelli, at ¶ [0050] (“In this case, there are two markers 47 . . . inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall.”); Fig. 49 (showing marker 47 extending along a height of distal wall). Top End of Radiopaque Marker Distal Wall Bottom End of Radiopaque Marker Longer Radiopaque Markers  FIG_4

Claims 5-8 add limitations directed to a receiving aperture located on the proximal wall of the implant. Frey discloses the claimed threaded receiving aperture having a central axis, and discloses that it is configured to releasably mate with an inserter tool. As explained in Section IV.B., *supra*, during prosecution of the ‘409 application, the parent application of the ‘156 patent, the PTO found that

the ‘570 patent, of which disclosure is included in Frey, taught a receiving aperture on the proximal wall of the implant, and that the receiving aperture was engageable with an insertion instrument. *See* Exhibit MSD 1009, at 1010.

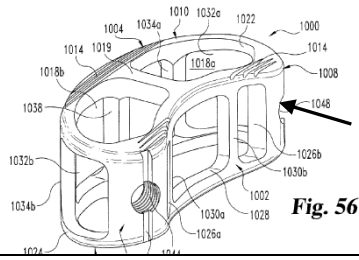
Claim 5 also recites that the longitudinal length of the implant is greater than 40 mm. Frey discloses this limitation by providing that the length of the implant from the proximal wall to the distal wall is sufficient to span the lateral width of the disc space. The disc space is defined as the space between the two vertebral bodies and the lateral width of that space is outlined by the outline of the vertebral bodies on the top and bottom of that space. *See* Gray, H., *Gray’s Anatomy* 489 (Peter L. Williams et al. eds., 37th ed. 1989) (Exhibit MSD 1014) (“Discal outlines correspond with the bodies which they connect . . . .”). One of ordinary skill in the art would understand that to “span the disc space” in the context of Frey’s disclosure of a lateral or antero-lateral approach to the disc space, as disclosing an implant with a length that approximates the width of normal vertebra in the lower lumbar region. *See* Hynes Decl., at ¶ 83. Because the average lateral width of the disc space at L3, L4 and L5 for both male and females – all of which are vertebral levels that the Frey implant is intended to treat – are greater than 40 mm, the length of the Frey implant inherently includes a length greater than 40 mm. *See* S.H. Zhou et al., *Geometrical Dimensions of the Lower Lumbar Vertebrae – Analysis of*

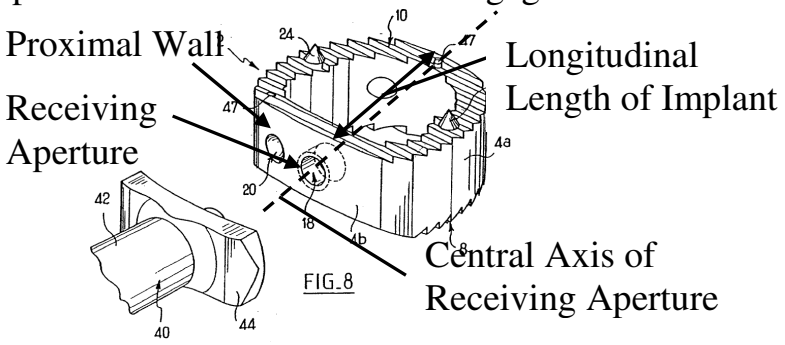
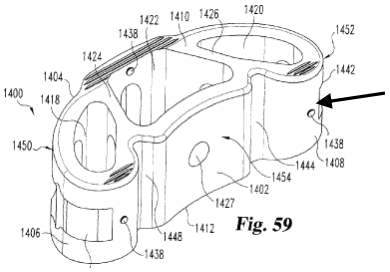
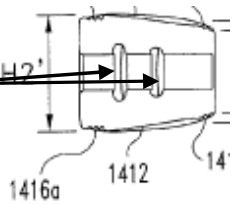
Data from Digitised CT Images, 9 EUR SPINE J 242, 244 (2000) (attached hereto as Exhibit MSD 1012); Hynes Decl. ¶ 83.

Alternatively, to the extent that such limitation is not inherently disclosed by Frey, a lateral or anterolateral spinal implant having a longitudinal length of greater than 40 mm would have been obvious to one of skilled in the art in view of the disclosure of Frey. *See* Hynes Decl., at ¶ 84.

Claim 7 requires that the receiving aperture "comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant." Baccelli discloses a threaded receiving aperture with a central axis that is generally parallel to the longitudinal length of the implant. It would have been obvious to modify the implant disclosed in Frey to include the aperture oriented as described in Baccelli so that the receiving aperture would open parallel to the length of the implant – to facilitate a surgeon implanting the device in a patient using a lateral approach as disclosed in Frey. *See* Hynes Decl., at ¶ 95. As discussed above, combinations made from Frey and Baccelli are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 5[A]: The spinal fusion implant of claim 1, further	Frey provides that the spinal fusion implant may include a receiving aperture in the proximal wall. *See* Frey, ¶ [0158] ("Trailing end wall 1408 and leading end wall 1406 could also include a threaded hole for engagement with an inserter, such as inserter 1100 described above."); ¶ [0146] ("Implant 1000 is also provided with an inserter engaging portion 1048 at trailing end

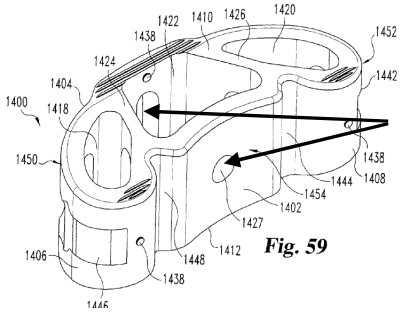
including at least one receiving aperture position at said proximal wall	1008 and an identical inserter engaging portion 1044 at leading end 1006 so that implant 1000 is insertable into disc space D1 from a unilateral approach taken on either side of the spinous process.”).  Receiving Aperture in Proximal / Trailing End Wall *Fig. 56*
Claim 5 [B]: wherein said longitudinal length is greater than 40 mm.	Frey provides that the length of the implant is “sufficient to span the disc space.” *See* Frey, at ¶ [0130] (“[I]mplant 370, which can have features such as those described below with respect to implant 1000, is placed in the disc space D1 and has a length sufficient to span the disc space from the distal portion 37 to the proximal portion 41.”). For an implant to span the disc space of a lumbar vertebra, the length of the implant inherently includes a length greater than 40 mm. *See* S.H. Zhou, *supra*, at 244-45; Hynes Decl. at ¶ 83.
Claim 6: The spinal fusion implant of claim 5, wherein said threaded receiving aperture is configured to releasably mate with an inserter tool.	Frey provides that the receiving aperture is configured to releasably mate with an inserter tool. *See* Frey, at ¶ [0158] (“Trailing end wall 1408 and leading end wall 1406 could also include a threaded hole for engagement with an inserter, such as inserter 1100 described above.”); ¶ [0146] (“Inserter engaging portions 1044, 1048 are preferably internally threaded and engageable with a distal end of an implant inserter, such as threaded end portion 1104 of inserter 1100 described above.”).
Claim 7: The spinal fusion implant of claim 6, wherein said receiving aperture comprises a threaded receiving aperture	Frey provides that the spinal fusion implant may include a threaded receiving aperture in the proximal wall. *See* Frey, ¶ [0158] (“Trailing end wall 1408 and leading end wall 1406 could also include a threaded hole for engagement with an inserter, such as inserter 1100 described above.”); ¶ [0146] (“Implant 1000 is also provided with an inserter engaging portion 1048 at trailing end 1008 and an identical inserter engaging portion 1044 at leading end 1006 so that implant 1000 is insertable into disc space D1 from a unilateral approach taken on either side of the spinous process.”).

extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant.	Baccelli provides a spinal fusion implant that has a receiving aperture (mounting orifice 18) that is threaded and configured to releasably mate with an inserter tool (fitting tool 40). Baccelli further provides that the threaded receiving aperture (mounting orifice 18) extends into the proximal wall and has a central axis generally parallel to the longitudinal length of the implant from insertion to trailing end. *See* Baccelli, ¶ [0044] ("To put the cage into place, it is advantageous to use a fitting tool 40 such as the tool shown in FIGS. 8 and 9. . . . The tool has a threaded endpiece 48 emerging from the center of the face 46 of the head and movable relative thereto, being drivable from the other end of the tool. This endpiece is suitable for threaded engagement with the mounting orifice 18 of the cage."). 
Claim 8: The spinal fusion implant of claim 7, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally of said threaded receiving aperture.	Frey discloses the use of "recessed surfaces" (1442, 1446) located on the proximal wall that can be used in combination with said receiving aperture. *See* ¶ [0158] ("Implant 1400 is provided with a first inserter instrument engaging receptacle 1448 at trailing end portion 1452 and a second inserter instrument engaging receptacle 1444 at leading end portion 1450. Each of the engaging receptacles 1444, 1448 are configured along with adjacent recessed area 1442, 1446 for engagement with an implant inserter instrument, such as inserter instrument 1500 described below. Trailing end wall 1408 and leading end wall 1406 could also include a threaded hole for engagement with an inserter, such as inserter 1100 described above.").  Pair of Lateral Grooves in Proximal Wall  **Fig. 64**

Claim 10 recites that the radiolucent material of the implant comprises polyether ether ketone (PEEK), which is disclosed by Frey.

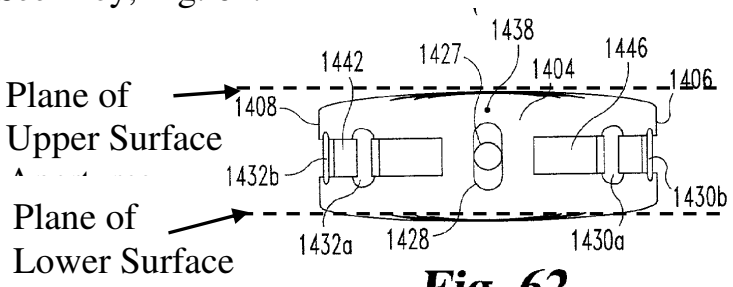
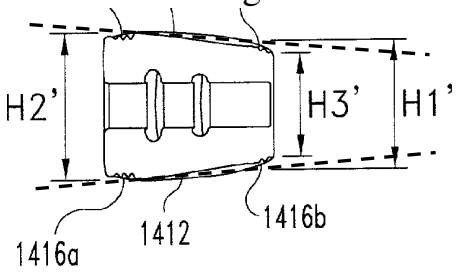
Claim 10: The spinal fusion implant of claim 1, wherein said radiolucent material comprises PEEK.	Frey provides that the implant may be made from PEEK. *See* Frey, at ¶ [0181] ("The implants described herein can be made from any biocompatible material, including synthetic . . . and can be . . . non-resorbable . . . Further examples of non-resorbable materials are non-reinforced polymers, carbon-reinforced polymer composites, PEEK and PEEK composites; . . . titanium and titanium alloys; . . . stainless steel; . . . and combinations thereof.").

Claim 11 recites the inclusion of at least one visualization aperture extending through at least one of the first or second sidewalls. Frey discloses the claimed visualization apertures in both the first and second sidewalls of the implant.

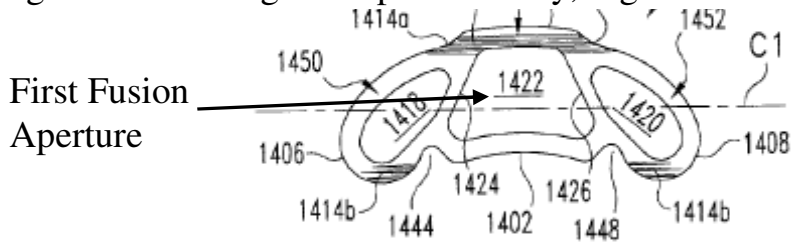
Claim 11: The spinal fusion implant of claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.	Frey discloses that the implant may include an aperture extending through both the first and second sidewalls (posterior opening 1427 and anterior opening 1428, respectively). *See* Frey, at ¶ [0155] ("Posterior wall 1402 includes a posterior opening 1427 along middle portion 1454, and anterior wall 1404 includes an anterior opening 1428 along middle portion 1454.").  ***Fig. 59***

Claims 12 and 13 add limitations with respect to the angular relationship between the upper and lower surfaces of the implant. Frey discloses that the upper and lower surfaces of the implant may be generally parallel to each other. Frey also discloses that the upper and lower surfaces may be angled relative to one

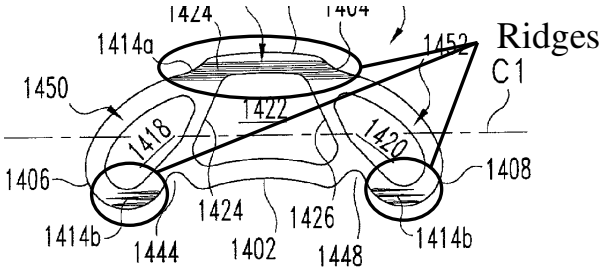
another to correspond to the anatomy of the spine, including the lordosis of the lumbar spine region. As recognized in the '156 patent, the top and bottom surfaces of the implant may be generally parallel to one another while also being generally angled relative to one another. *See* '156 patent, at 6:11-20; Hynes Decl. at ¶ 114.

Claim 12: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another.	As shown in Figures 58 and 62, Frey discloses that the upper and lower surfaces of the implant are generally parallel to one another. *See* Frey, Fig. 62.  ***Fig. 62***
Claim 13: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.	Frey discloses that in certain embodiments of the implant, the height of the anterior wall (the second sidewall) may be greater than the height of the posterior wall (the first sidewall) so as to correspond to the lordosis of the lumbar spine. *See* Frey, ¶ [0152] ("Implant 1400 has a height H1′ at the medial portion of posterior wall 1402 and a second height H2′ at the medial portion of anterior wall 1404. . . . and height H2′ is greater then [sic] H1′ in order to correspond to the anatomy of the vertebral endplates on each side of disc space D1. . . . Furthermore, the difference in heights between the upper and lower bearing surfaces at the anterior and posterior walls can be provided so as to establish lordosis when implant 1400 is inserted in the disc space. In one specific application, implant 1400 can be inserted from a postero-lateral approach to restore and maintain spinal lordosis."). As shown in Figure 64 of Frey, such height difference results in the upper and lower surfaces of the implant being generally angled relative to one another. 

Claim 14 recites that the "first fusion aperture is one of generally rectangular and generally oblong in shape." As discussed in Section III.C., *supra*, the broadest reasonable construction of the term "generally rectangular and generally oblong in shape," and the one implicitly adopted by the PTO, and not refuted by the Applicant, during prosecution of the '409 application is a shape having four portions roughly approximating sides, and being elongated in at least one dimension. Under this construction, Frey discloses the claimed fusion aperture.

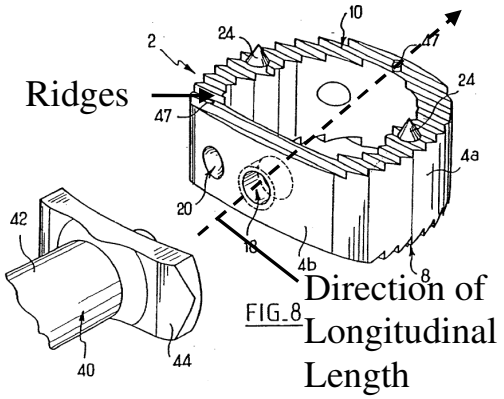
Claim 14: The spinal fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.	Frey discloses that the first fusion aperture is generally rectangular and oblong in shape. *See* Frey, Fig. 63. 

Claim 19, which recites that the anti-migration elements on the upper and lower surfaces of the implant comprise a plurality of ridges, is disclosed by Frey.

Claim 19: The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges.	Frey provides that the anti-migration elements on the upper surface of the implant may comprise a plurality of grooves, or ridges. *See* Frey, ¶ [0153] ("Upper bearing surface 1410 can further be provided with a number of first grooves 1414 a along anterior wall 1404 and second grooves 1414 b along leading and trailing end walls 1406, 1408."). 

Claim 20, which depends from Claim 19, adds the limitation that the "plurality of ridges [located on the top and bottom surfaces of the implant] extend generally perpendicular to said longitudinal length." Frey discloses ridges, as discussed *supra*. Baccelli discloses that its implant may feature ridges (teeth 12) that extend generally perpendicular to the direction of the longitudinal length of the implant. Baccelli states that ". . . the orientation of the teeth 12 limits the ability of the cage to move forwards from its position." Baccelli, at ¶ [0045]. Accordingly, it would have been obvious to modify the implant of Frey based on the explicit teachings of Baccelli to include ridges that extend generally perpendicular to the longitudinal length of the implant to prevent the implant from moving in a lateral direction after implantation. *See* Hynes Decl., at ¶ 122. Frey and Baccelli are from the same field of artificial implants used in intervertebral spinal fusion and having a space provided in the implant to fill with bone growth promoting substances to enhance the fusion. Thus, a spinal implant incorporating the teachings of these references is merely an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive to achieve predictable results. *See KSR*, 550 U.S. at 418.

Claim 20: The spinal fusion implant of claim 19, wherein said	Frey provides that the anti-migration elements on the upper surface of the implant may comprise a plurality of grooves, or ridges. *See* Frey, ¶ [0153] ("Upper bearing surface 1410 can further be provided with a number of first grooves 1414 a along anterior wall 1404 and second grooves 1414 b along leading and trailing end walls 1406, 1408.").

plurality of ridges extend generally perpendicular to said longitudinal length.	Baccelli provides that the plurality of ridges, or teeth 12, are formed parallel to the front wall, and therefore are perpendicular to the longitudinal length of the implant. *See* ¶ [0036] ("In a sagittal plane, i.e. parallel to the axis 6 and perpendicular to the front wall 4 b, it presents a toothed profile forming mutually parallel elongate teeth 12 parallel to the front wall 4 b."). 

Claims 23-26 add proportional limitations to the implant claimed in Claim 1. Claim 23 recites that the "maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall." As shown in Figure 63, Frey discloses such limitation. *See* Hynes Decl., at ¶ 124; DeRidder Decl., at ¶¶ 7-9 (noting that Figure 63 is drawn to scale). Alternatively, such proportions are obvious to one of ordinary skill in view of these teachings contained in Frey. *See id*., at ¶¶ 124-25.

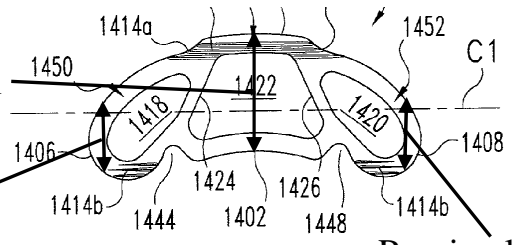
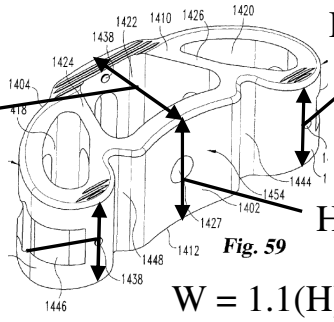
Claim 24 recites that the implant's height is less than its maximum lateral width. One skilled in the art would understand from Figure 59 of Frey that the maximum width of the implant disclosed in Frey is greater than its height. *See* Hynes Decl., at ¶ 127; DeRidder Decl., at ¶¶ 7-9 (noting that Figure 59 is drawn to scale). In addition, as discussed above in relation to Claim 14, the Frey specification states that "the openings and hollow interior maximize the volume

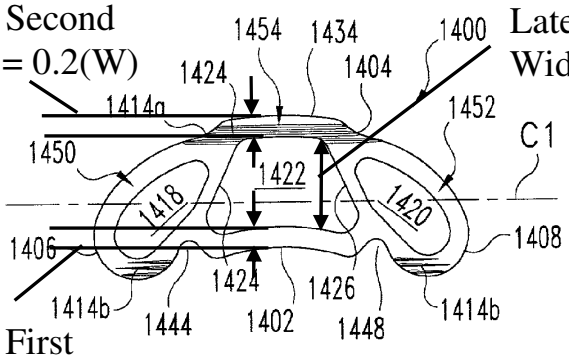
available to receive bone growth material and also maximize the contact surface area between the bone growth material and the adjacent boney structure." Frey, at ¶ [0149]. As the maximum height of the implant is limited by the space between the adjacent vertebrae, the maximum lateral width is not so limited, and the Frey specification inherently teaches making the width of the implant greater than its height to help maximize the volume and contact surface area. Accordingly, the drawings accurately depict the height of the insert as being less than its width. Alternatively, such proportions are obvious to one of ordinary skill in the art in view of these teachings contained in Frey. *See* Hynes Decl., at ¶ 127.

Claim 25 adds the limitation that the width of the first fusion aperture is more than two times greater than a lateral thickness of both the first sidewall and the second sidewall. One skilled in the art would understand from Figure 63 of Frey that the width of the first fusion aperture of Frey is more than two times greater than the thickness of its first and second sidewalls. *See* Hynes Decl., at ¶ 135; DeRidder Decl., at ¶¶ 7-9 (noting that Figure 63 is drawn to scale).

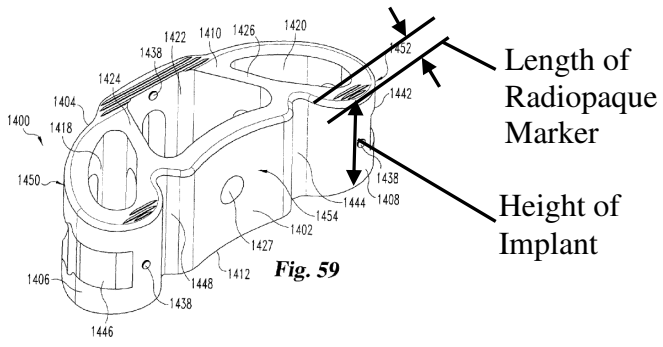
Additionally, the proportional limitations contained in Claims 23-25 do not impact the functionality of the device so as to make it patentably distinct from the prior art implant disclosed in Frey. *See Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984) (holding that, where difference between prior art and claims was recitation of relative dimensions of

claimed device and device having claimed relative dimensions would not perform differently than prior art device, claimed device was not patentably distinct from prior art device).

Claim 23: The implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall.	Frey discloses that the maximum lateral width of the implant is greater than the lateral widths of the distal end of the distal wall and the proximal end of the proximal wall. *See* Frey, Figure 63. Maximum Lateral Width  Distal End of Distal Wall ***Fig. 63*** Proximal End of Proximal Wall
Claim 24: The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.	Figure 59 of Frey reasonably discloses to one skilled in the art that the maximum lateral width of the implant disclosed in Frey is greater than even the maximum height, as designated below, of the implant. *See* Frey, Fig. 59; Hynes Decl., at ¶ 127; DeRidder Decl., at ¶¶ 7-9 (noting that Figure 59 is drawn to scale). Height (H') Maximum Lateral Width (W)  Height (H) Height (H') ***Fig. 59*** W = 1.1(H) = 1.4(H')
Claim 25: The spinal fusion implant of claim 1, wherein the lateral aperture width of said first fusion	Figure 63 of Frey reasonably discloses to one skilled in the art that the lateral aperture width of the spinal fusion implant described in Frey is more than twice the width of either the first side wall or the second sidewall. *See* Frey, at Fig. 63.

aperture is more than two time greater than a lateral thickness of said first sidewall and is more than two time greater than a lateral thickness of said second sidewall.	Width of Second Sidewall = 0.2(W)  Width of First Sidewall = 0.2(W) ***Fig. 63***

Claims 26 recites that the elongate body of at least one of the radiopaque markers described in Claim 1 is shorter than a height of the implant because the maximum length of the radiopaque marker of Frey is limited to thickness of the implant wall, which is shorter than a height of the implant.

Claim 26: The spinal fusion implant of claim 1, wherein said elongate body of at least one of said radiopaque markers is shorter than a height extending from said upper surface to said lower surface.	As shown in Figure 59, Frey provides that the elongate bodies of the radiopaque markers 1438 are shorter than the height of the implant extending from the upper surface to the lower surface. *See* Frey, at Fig. 59. Because it extends through the end wall, the maximum length of the body of the radiopaque member is the width of the end wall.  ***Fig. 59***

Claim 27 adds the limitation that "osteoinductive material [is] positioned with[in] said first fusion aperture." Frey discloses that the implant may include

osteogenic material placed within any of the chambers of the implant, including the first fusion aperture.

Claim 27: The spinal fusion implant of claim 1, further comprising an osteoinductive material positioned with said first fusion aperture.	Frey provides that the spinal fusion implant may also include an osteoinductive material positioned within said first fusion aperture. *See* Frey, at ¶ [0182] ("Any suitable osteogenetic material or composition is contemplated for placement within the chambers defined by the implants described herein. Such osteogenic material includes, for example, autograft, allograft, xenograft, demineralized bone, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors.").

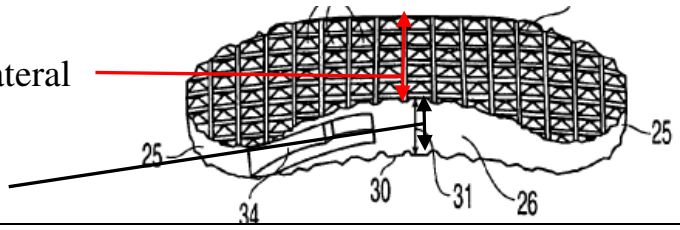
B. Ground 2 – Claims 1-8, 10-14, 19, 20, and 23-27 Are Obvious Under § 103 over Frey in view of Baccelli and Messerli

As shown in the claim chart below, claims 1-8, 10-14, 19, 20, and 23-27 of the '156 patent are rendered obvious under § 103 by Frey in view of Baccelli and in further view of Messerli.

With respect to Claims 1-8, 10-14, 19-23, and 25-28, the same analysis for the invalidity of these claims over Frey in view of Baccelli as discussed in Ground 1 is applicable for this ground. *See* Section V.A., *supra*.

Claim 24 recites that the implant's height is less than its maximum lateral width. While Petitioner asserts that Frey in combination with Baccelli discloses the claimed proportional limitation, alternatively, Messerli also provides an implant has a maximum width greater than its height. It would have been obvious to further modify the implant disclosed in Frey to include the dimensional characteristic of having a maximum lateral width greater than the height of the

implant to complement the dimensions of the lumbar vertebrae. *See* Messerli, at ¶ [0055] ("The dimensions of implant 22 can be varied to accommodate a patient's anatomy, and the thickness of the implant is chosen based on the size of the disk space to be filled."); Hynes Decl., at ¶ 131. Frey and Messerli are from the same field of artificial implants used in intervertebral spinal fusion. Thus, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 24: The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.	Messerli provides that the spinal implant may include a maximum lateral width that is greater than the height of the implant. Specifically, Messerli discloses that the maximum lateral width is 11 mm, and the height, or thickness of the implant, can be as short as 7 mm. *See* Messerli, ¶ [0055] ("Preferably, implant 22 has a maximum thickness 31 at its mid-section of about 7.0 to about 17.0 mm . . . . The implant may . . . have a width from about 9 to 11 mm."). Maximum Lateral Width Height 

C. Ground 3 – Claims 1-14, 19, 20, and 23-27 Are Obvious Under § 103 over Frey in view of Baccelli and Michelson

As shown in the claim chart below, Claims 1-14, 19, 20, and 23-27 is obvious under § 103 by Frey in view of Baccelli and in further view of Michelson.

With respect to Claims 1-4, 6-8, 10-14, 19, 20 and 23-27, the same analysis for the invalidity of these claims over Frey in view of Baccelli as discussed in

Ground 1 is applicable for this ground. *See* Section V.A., *supra*. Alternatively, as explained below, Claims 5, 6, 8, 9, 20 and 24 are obvious over a combination of Frey, Baccelli and Michelson. Michelson itself discloses many of the limitations of the claims of the '156 patent, such as the threaded receiving aperture and lateral grooves on the proximal wall of Claims 5, 6 and 8, anti-migration elements on the top and bottom surfaces of the implant perpendicular to the length of the implant as required by Claim 20, a wider than tall implant as required by Claim 24, as well as the general elongated shape of the implant. Such shared characteristics with Frey support the obviousness of combining the references. *See* Hynes Decl., at ¶ 59.

As discussed in Section V.A., *supra*, Petitioners assert that with respect to Claim 5, Frey, by itself, discloses or makes obvious an implant having a longitudinal length greater than 40 mm. As an alternative ground for invalidity, Michelson discloses this limitation of claim 5 as it provides that length of the implant may range from 32 mm to 50 mm. As Frey provides that the length of the implant is "sufficient to span the disc space," it would have been obvious to modify the spinal fusion implant of Frey to have the longitudinal length disclosed in Michelson so that the implant could sufficiently span the lumbar disc space. *See* Hynes Decl., at ¶ 85-86. Moreover, as discussed above, Frey discloses using the disclosed implant in lateral and antero-lateral approaches to the disc space. It would, therefore, have been obvious for one of ordinary skill in the art to follow

the teachings of Michelson for a lateral or antero-lateral implant and related surgical technique, including the specific dimensions disclosed by Michelson for an implant inserted laterally or antero-laterally, to determine the proper technique for inserting a modified Frey implant, such as not requiring a pivoting of the implant during insertion. *See id.*, at ¶ 86.

Combinations of Frey and Michelson would be obvious because they are from the same field of artificial implants used in spinal fusion and placed in the intervertebral disc space like the NuVasive XLIF implant disclosed in the '156 patent that was found to infringe claims 24, 41, 42, 57 and 61 of Michelson. *See* First Amended Complaint, filed on October 6, 2008, and Judgment Following Jury Verdict, entered on September 29, 2011, in *Warsaw Orthopedics, Inc. v, NuVasive, Inc.*, Case No. 3:08-CV-01512, Southern District of California (attached hereto as Exhibit MSD 1010). Like Frey, Michelson discloses lateral fusion implants having an elongated shape with a large internal space for receiving osteoinductive material. *See e.g.,* Michelson, at 10:6 to 11:15 (describing spinal fusion implants comprising "a rectangular block 901 . . ."). These example implants include ridges and various other surface roughenings to resist migration running perpendicular to the length of the implant as required in claim 20, rendering claim 20 obvious in view of Frey in combination with Michelson. *See id.* at 10:22-25 ("The top and bottom surfaces 902 and 904 may comprise any of the surface roughenings

described herein for engaging the bone of the adjacent vertebrae to promote firm stability."). Michelson also discloses a threaded aperture and guide slots for mating with an insertion tool as set forth in claims 5, 6 and 8, rendering these claims obvious in view of Frey in combination with Michelson. *See id.*, at 6:28-35 (disclosing that implants are inserted by methods described in U.S. Patent Application Ser. No. 08/394,838 (the "'838 application"), and incorporating disclosure of '838 application by reference. The '838 application teaches that "[d]river 300 has at its distal end 302, a rectangular protrusion 304, which intimately engages the complimentary rectangular slot in the rear of implant I. Extending from the rectangular protrusion 304 is threaded portion 306, which extends as a rod through hollow shaft 308 and hollow barrel portion 310 to knob 312 where it can be rotationally controlled. Threaded portion 306 screws into a threaded aperture in the spinal implant I and binding them together such that driver 300 can be rotated via paired and diametrically opposed extending arms 314 and 316 and in either direction while maintaining contact with the spinal implant I."). Michelson also discloses that the upper and lower surfaces of its implant, like Frey, can be either parallel (*see id.*, at Figs. 16-20, 10:6 to 11:15) or angled towards each other to correspond to the lordosis of the lumbar spine. *See id.*, at 3:39-43 ("The height of such an implant . . . may be wedged so as to reproduce anatomic lordosis."). Additionally, like Frey, Michelson discloses a wider than tall

configuration for its implant as required in claim 24 and which, in the alternative, renders this claim obvious in view of the combination of Frey and Michelson. Michelson, at Fig 16, 17, and 10:6-47 ("height in the range of 8 mm to 16 mm, with the preferred height being 10-12 mm, a width in the range of 24 mm – 32 mm, with the preferred width being 26 mm"). Thus, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418; Hynes Decl., at ¶ 59.

Claim 5[A]: The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall	Frey provides that the spinal fusion implant may include a receiving aperture in the proximal wall. *See* Section V.A., Claim 5[A], *supra* (incorporated here).
Claim 5 [B]: wherein said longitudinal length is greater than 40 mm.	Michelson discloses a spinal fusion implant – that is used in a lateral or antero-lateral fashion like the implant of Frey – that has a longitudinal length greater than 40 mm. *See* Michelson, col. 10, lines 41-46 ("In the preferred embodiment, the spinal fusion implant 900 has a . . . length in the range of 32 mm to 50 mm, with 42 mm being the preferred length.").

Claim 9 recites that the implant has a maximum lateral width that is approximately 18 mm. Michelson discloses a spinal fusion implant having a width in the range of 14 to 26 mm and an embodiment having an 18 mm width. One of ordinary skill in the art would have been motivated to apply this teaching of Michelson to modify the implant disclosed in Frey to have a width of 18 mm because the prior art, including Michelson, taught that an implant with "more

surface area of contact . . . permits greater stability." *See* Michelson, at 7:11-20. One of ordinary skill in the art would have been further motivated to make this modification because both Frey and Michelson describe spinal implants that are implanted using a lateral or anterolateral approach. *See* Hynes Decl., at ¶ 104.

Claim 9: The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.	Michelson discloses a laterally implanted spinal fusion implant having a maximum lateral width in the range of 14 to 26 mm. *See* Michelson, at 7:26-30. ("In the thoracic spine such implants would have a . . . maximum diameter in the range of 14-26 mm, with the preferred diameter being 20 mm."); 6:28-35 (incorporating disclosure of U.S. Pat. App. Ser. No. 08/394,836 (issued as U.S. Pat. No. 5,772,661 (the "'661 patent")) in its entirety by reference, which itself incorporated U.S. Pat. App. Ser. No. 08/074,081 (issued as U.S. Pat. No. 5,484,437 (the "'437 patent")) in its entirety by reference. The '661 patent discloses an implant that has a width in the range of 10-30 mm, with 20 mm being preferred. *See* '661 patent, at 10:8-34. The '437 patent teaches, in relevant part, a lumbar intervertebral spinal fusion implant having a width of 18 mm. *See* '437 patent, at 14:58-61.

D. Ground 4 – Claims 1-8, 10-14, 19, 20, and 23-27 Are Obvious Under § 103 over Frey in view of Baccelli and Moret

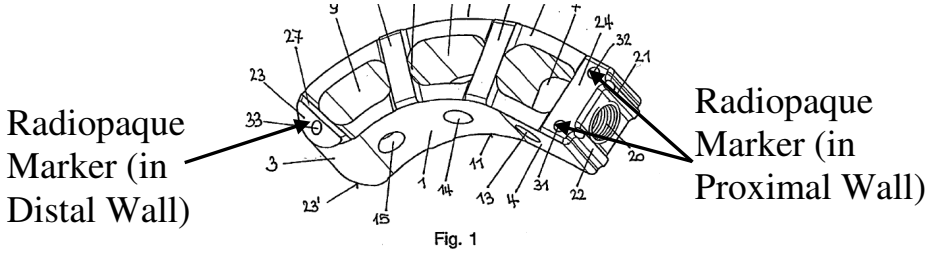
As shown in the claim chart below, Claims 1-8, 10-14, 19, 20, and 23-27 is obvious under § 103 by Frey in view of Baccelli and in further view of Moret.

With respect to Claims 1, 2, 4-8, 10-14, 19, 20 and 23-27, the same analysis for the invalidity of these claims over Frey in view of Baccelli as discussed in Ground 1 is applicable for this ground. *See* Section V.A., *supra*.

As discussed above in Section V.A., *supra*, Petitioners assert that Baccelli discloses the limitations of Claim 3 of the '156 patent. As an alternative ground

for invalidity of Claim 3, Petitioners contend that Moret discloses the limitations of Claim 3 that "the spinal fusion implant [has] a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall." It would have been obvious to combine the teachings of Frey, Baccelli and Moret so that the implant would include radiopaque markers extending through the proximal and distal walls of the implant to provide additional information regarding the orientation or location of an implant during surgery and after implantation. *See* Hynes Decl., at ¶¶ 72-73. Frey, Baccelli and Moret are from the same field of artificial implants used in intervertebral spinal fusion and having a space to fill with bone growth promoting substances to enhance the fusion. Thus, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418; Hynes Decl., at ¶ 73.

Claim 3: The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and a fourth	Frey provides that the spinal fusion implant includes at least three radiopaque markers. *See* Frey, at ¶ [0156] ("A number of radiographic markers 1438 can also be provided in implant 1400 to facilitate X-ray assessment of the locating and positioning of implant 1400 in the patient's body.") . *See id.* ("In the illustrated embodiment, markers 1438 are provided at the midline of anterior wall 1404 at the anterior most point defined by offset portion 1434. Markers 1438 are also provided at the posterior-most points of trailing end wall 1408 and leading end wall 1406."). Moret describes a spinal fusion implant that includes radiopaque markers extending through both the proximal wall and distal wall of the implant. *See* ¶ [0026] ("Holes 31, 32 or 33 are provided in the rear portion 4 and in the front portion 3, to receive a marker of a high density metal. Tantalum balls and/or pins are particularly suitable

radiopaque marker that extends into said proximal wall.	for this purpose. The pins are arranged in bores which are arranged either perpendicular or parallel to the bore 20. The position of the cage can thereby be observed and assessed during the operation by means of an image intensifier.”).  Fig. 1

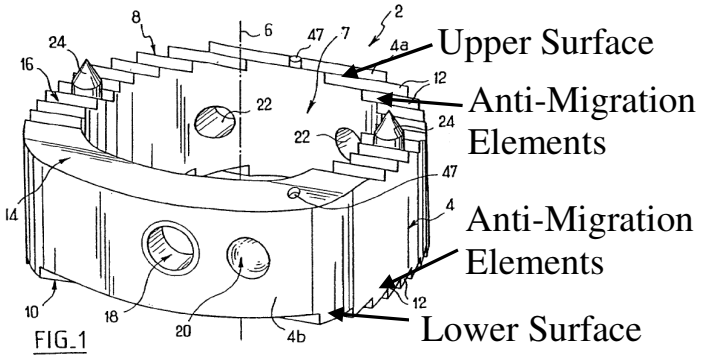
E. Ground 5 – Claims 1-8, 10-14, 19, 20, and 23-27 Are Obvious Under § 103 over Baccelli in view of Frey and/or Michelson

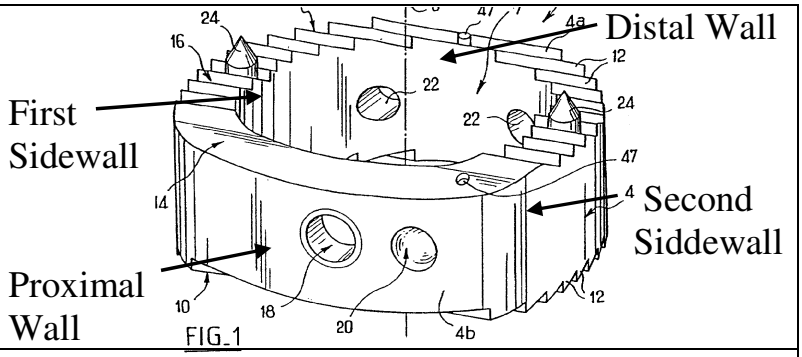
As shown in the claim chart below, claims 1-8, 10-14, 19, 20, and 23-27 of the ‘156 patent are rendered obvious under § 103 by Baccelli in view of Frey and/or Michelson.

With respect to Claim 1, Baccelli, which was not cited during prosecution of the ‘156 patent, discloses a spinal fusion implant having a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. The upper and lower surfaces of the Baccelli implant also contain anti-migration elements that come in contact with the first and second vertebrae. Additionally, the Baccelli implant contains at least one fusion aperture that extends from the top surface to the bottom surface. Baccelli also discloses that the implant has at least first and second radiopaque markers that extend into a first sidewall and a second sidewall proximate to the implant’s medial plane.

Frey, as explained in Section V.A., *supra*, discloses that the implant has a longitudinal length that is greater than the maximum lateral width of the implant found along the medial plane of the implant and that the longitudinal aperture length is greater than the lateral aperture width. Because Baccelli describes an implant that is designed to be used with the cervical spine, it would have been obvious to modify it to have a longitudinal length that is perpendicular to, and greater than, the maximum lateral width, which, as in Frey, would be located along the medial plane of the implant, and to have a longitudinal aperture length greater than its lateral aperture width to better complement the anatomy of the lumbar vertebrae. *See* Hynes Decl., at ¶ 64. As noted above in Section V.A. (and incorporated here), because Frey and Baccelli are from the same field of artificial implants used in intervertebral spinal fusion, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 1 [A]: A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:	Baccelli discloses a spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra. *See, e.g.*, Baccelli, at ¶ [0042] ("The cage as described above is particularly adapted to occupy a cervical intervertebral space.").

Claim 1 [B]: an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space,	Baccelli provides that the spinal fusion implant has an upper surface (superior main face 8) and a lower surface (inferior main space 10), both of which contain anti-migration elements (teeth 12) that contact the first and second vertebra, respectively. *See* Baccelli, at ¶ [0035] ("The cage has two main faces, a superior main face 8 and an inferior main face 10 that are opposite to each other and that extend generally in planes that are mutually parallel and perpendicular to the axis 6."); ¶ [0045] ("After facilitating insertion of the cage, the orientation of the teeth 12 limits the ability of the cage to move forwards from its position."). 
Claim 1 [C]: a distal wall, a proximal wall, a first sidewall and a second sidewall generally opposite from the first sidewall,	Baccelli discloses that the spinal fusion implant has a distal wall (part of portion 4a directly across from front wall 4b), a proximal wall (front wall 4b), a first sidewall (part of portion 4a) and a second sidewall (part of portion 4a). *See* Baccelli, at ¶¶ [0033]-[0034] ("With reference to FIGS. 1 to 5, the implant 2 is constituted by a cage having a wall 4 . . . . In plan view, the wall has a first portion a that is horseshoe shaped. . . . It extends over about 250° around the axis 6. The wall has a second portion 4 b that is also cylindrical in shape, extending over about 20° about its own axis, which is not the axis 6 but is an axis parallel thereto.").

	
Claim 1 [D]: wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;	Baccelli provides that the walls of the spinal fusion implant may comprise a radiolucent material. *See* Baccelli, at ¶ [0050] ("The cage can be made of a material that is transparent to X-rays, e.g. out of poly-ether-ether-ketone (PEEK).").
Claim 1 [E]: wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and said longitudinal length is greater than said maximum lateral width;	Frey provides that the implant has a longitudinal length that extends from the proximal wall to the distal wall and a maximum lateral width extending from the first side wall to the second sidewall along a medial plane that is generally perpendicular to the longitudinal length of the implant, with the longitudinal length being greater than the maximum lateral width. *See* Section V.A., Claim 1[E], *supra* (incorporated here).
Claim 1 [F]: at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space,	Baccelli discloses that the spinal fusion implant includes a first fusion aperture, central hole 7, that is configured to allow bone growth between the first vertebra and the second vertebra after proper positioning of the implant. *See* Baccelli, at ¶¶ [0012]-[0013] ("Advantageously, the implant has a central hole extending from one of the main faces to the other. Such a hole can, for example, receive the graft that facilitates vertebral bone integration.").
Claim 1 [G]: said first fusion	The first fusion aperture of the implant disclosed in

aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and	Baccelli has a longitudinal aperture length and lateral aperture width. Figure 63 of Frey reasonably discloses to one skilled in the art that the first fusion aperture of the spinal implant disclosed in Frey has a longitudinal aperture width greater than its lateral aperture width. *See* Section V.A., Claim 1[G], *supra* (incorporated here).
Claim 1 [H]: at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane.	Baccelli discloses a spinal fusion implant having at least first and second radiopaque markers (spikes 24) that extend into a first sidewall and a second sidewall at positions proximate to a medial plane of the implant. *See* Section V.A., Claim 1[H], *supra* (incorporated here).

Claims 2-4 add limitations directed to the radiopaque markers featured in the implant. As discussed above, and incorporated here, Baccelli discloses the limitations of these claims as Baccelli teaches first and second radiopaque markers that are substantially equally spaced apart from the proximal end of the proximal wall of the implant by a first longitudinal distance (Claim 2); a third radiopaque marker that extends into the implant's distal wall, and a fourth radiopaque marker that extends into the implant's proximal wall (Claim 3); and radiopaque markers

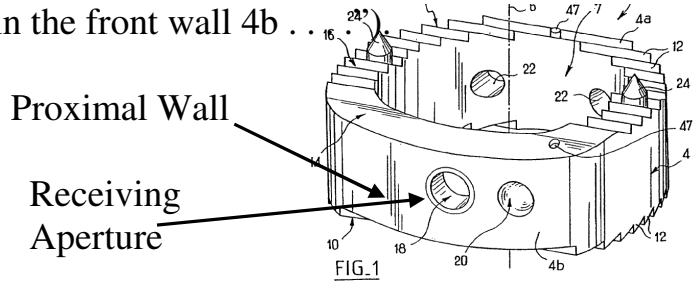
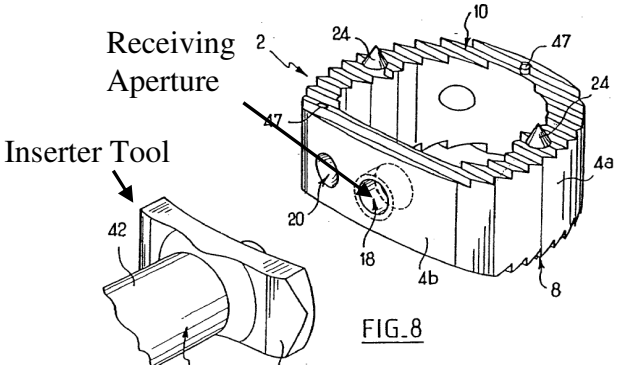
(spikes 24) that can extend entirely along a height of the walls of the implant (Claim 4). *See* Section V.A., Claims 2-4, *supra* (incorporated here).

Claim 2: The spinal fusion implant of claim 1, wherein the first and second radiopaque markers are substantially equally spaced apart from said proximal end of said proximal wall by a first longitudinal distance.	The radiopaque markers (spikes 24) present on the implant described in Baccelli are both located the same distance, a first longitudinal distance, away from the proximal wall of the implant. *See* Section V.A., Claim 2, *supra* (incorporated here).
Claim 3: The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall.	Baccelli provides that the implant may also include a third radiopaque marker (marker 47) that extends into the distal wall of the implant, and a fourth radiopaque marker (marker 47) that extends into the proximal wall of the implant. *See* Section V.A., Claim 3, *supra* (incorporated here).
Claim 4: The spinal fusion implant of claim 3, wherein said third radiopaque marker extends entirely through a height of said distal wall, and wherein said fourth radiopaque marker extends entirely through a height of said proximal wall.	Baccelli provides a radiopaque marker (marker 47) that extends along a height of the distal wall, and another radiopaque marker (marker 47) that extends along a height of the proximal wall. *See* Section V.A., Claim 4, *supra* (incorporated here).

Claims 5-8 add limitations directed to a receiving aperture located on the proximal wall of the implant. Baccelli discloses the claimed threaded receiving aperture, and discloses that it is configured to releasably mate with an inserter tool. Additionally, Baccelli provides that the receiving aperture may be located on the proximal wall of the implant and has a central axis that is generally parallel to the longitudinal length of the implant.

Claim 5 also recites that the longitudinal length of the implant is greater than 40 mm. As discussed in Section V.A., *supra*, Frey provides that the length of the implant from the proximal wall to the distal wall is sufficient to span the disc space, which is inherently greater than 40 mm, or alternatively makes obvious a longitudinal length of 40 mm for a laterally or anterolaterally implanted lumbar spinal implant to one of ordinary skill in the art. Alternatively, as discussed in Section V.C., supra, Michelson provides that the implant has a length greater than 40 mm. Because Baccelli describes an implant that is designed to be used with the cervical spine, it would have been obvious to modify the implant of Baccelli to have a longitudinal length greater than 40 mm like the Frey or Michelson implants to better complement the anatomy of the vertebra located in the lumbar region of the spine. *See* Hynes Decl., at ¶ 87.

Claim 8 adds the limitation of including a pair of lateral grooves in the proximal wall that extend laterally of the threaded receiving aperture, and Frey discloses that its implant may include such pair of lateral grooves. It would have been obvious to modify the implant of Baccelli to include such grooves in the proximal wall to better guide the inserter tool to properly mate with the receiving aperture. *See* Hynes Decl., at ¶ 100. As discussed above, combinations made from Frey and Baccelli are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 5[A]: The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall	Baccelli provides that the implant has a receiving aperture (mounting orifice 18) in the proximal wall. *See* Baccelli, at ¶ [0039] ("The cage has a threaded assembly and fixing orifice 18 extending in the sagittal midplane of the implant, in the front wall 4b . . . ."). 
Claim 5 [B]: wherein said longitudinal length is greater than 40 mm.	Frey provides that the length of the implant is "sufficient to span the disc space," which is inherently greater than 40 mm. *See* Section V.A., Claim 5[B], *supra* (incorporated here). Alternatively, Michelson provides that the implant length is greater than 40 mm. *See* Section V. C., Claim 5[B], *supra* (incorporated here).
Claim 6: The spinal fusion implant of claim 5, wherein said threaded receiving aperture is configured to releasably mate with an inserter tool.	Baccelli provides that the implant has a receiving aperture (mounting orifice 18) that is threaded and configured to releasably mate with an inserter tool (fitting tool 40). *See* Baccelli, at ¶ [0044] ("To put the cage into place, it is advantageous to use a fitting tool 40 such as the tool shown in FIGS. 8 and 9. . . . . The tool has a threaded endpiece 48 emerging from the center of the face 46 of the head and movable relative thereto, being drivable from the other end of the tool. This endpiece is suitable for threaded engagement with the mounting orifice 18 of the cage."). 
Claim 7: The spinal fusion implant of claim 6, wherein said receiving	Baccelli provides a spinal fusion implant that has a receiving aperture (mounting orifice 18) located on the proximal wall that is threaded and configured to releasably mate with an inserter tool (fitting tool 40), and has a central

aperture comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant.	axis generally parallel to the longitudinal length of the implant from insertion to trailing end. *See* Section V.A., Claim 7, *supra* (incorporated here).
Claim 8: The spinal fusion implant of claim 7, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally of said threaded receiving aperture.	Baccelli discloses the use of a hemisphercial cavity 20 that is located laterally to the threaded receiving aperture on the proximal wall of the implant. The cavity 20 is used to guide the inserter tool to ensure proper releasable mating between the implant and the inserter tool. *See* Baccelli, at ¶ [0039] ("On one side of this orifice 18, e.g. on the right side thereof, the outer face of the front wall has a hemispherical cavity 20 which is used for keying purposes . . . ."); ¶ [0044] ("The front face 46 of the head [of the inserter tool] has a spherical projection 47 suitable for penetrating in the front spherical cavity 20 of the cage when the endpiece 48 is connected to the orifice 18. The projection 47 and the cavity 20 together constitue keying means."). Frey discloses the use of "recessed surfaces" (1442, 1446) located on the proximal wall that can be used in combination with said receiving aperture. *See* Section V.A., Claim 8, *supra* (incorporated here).

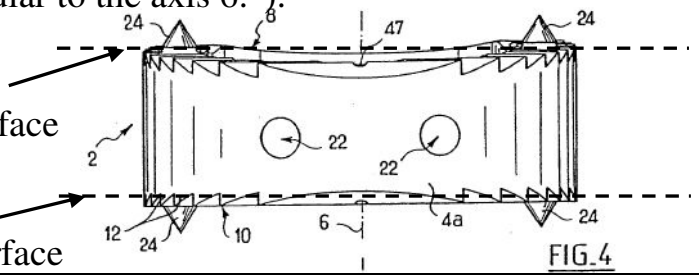
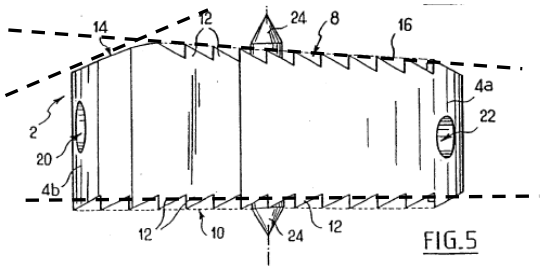
Claim 10 recites that the radiolucent material of the implant comprises polyether ether ketone (PEEK), which is disclosed by Baccelli.

Claim 10: The spinal fusion implant of claim 1, wherein said radiolucent material comprises PEEK.	Baccelli provides that radiolucent material of the spinal fusion implant may comprise PEEK. *See* Baccelli, at ¶ [0050] ("The cage can be made of a material that is transparent to X-rays, e.g. out of poly-ether-ether-ketone (PEEK).").

Claim 11 recites the inclusion of at least one visualization aperture extending through at least one of the first or second sidewalls. Frey discloses the claimed visualization apertures in both the first and second sidewalls of the implant. It would have been obvious to modify the implant disclosed in Baccelli to include at least one such aperture to promote fusion as suggested by Frey. *See* Frey, at ¶ [0144] ("In order to promote fusion, the walls and bearing members of implant 1000 are provided with a number of openings."); Hynes Decl., at ¶ 111. Frey and Baccelli are from the same field of artificial implants used in intervertebral spinal fusion and having a space provided in the implant to fill with bone growth promoting substances to enhance the fusion. Thus, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

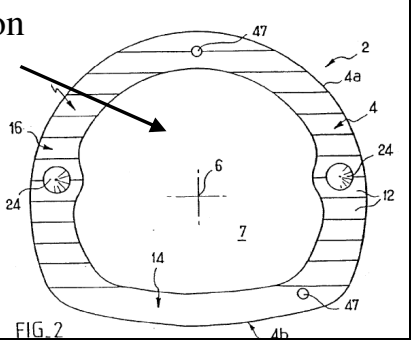
Claim 11: The spinal fusion implant of claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.	Frey discloses that the implant may include an aperture extending through both the first and second sidewalls. *See* Section V.A., Claim 11, *supra* (incorporated here).

Claims 12 and 13 add limitations with respect to the angular relationship between the upper and lower surfaces of the implant. Baccelli discloses that the upper and lower surfaces of the implant may be generally parallel to each other, or that the upper and lower surfaces may be angled relative to one another to correspond to the anatomy of the spine, including the lordosis of the spine.

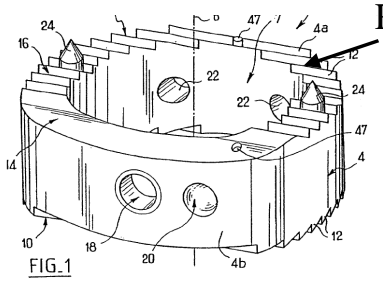
Claim 12: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another.	Baccelli discloses that the upper and lower surfaces of the implant are generally parallel to one another. *See* Baccelli, at ¶ [0035] ("The cage has two main faces, a superior main face 8 and an inferior main face 10 that are opposite to each other and that extend generally in planes that are mutually parallel and perpendicular to the axis 6.").  FIG. 4
Claim 13: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.	Baccelli discloses that front and rear segments of the upper surface slope towards the lower surface to provide the implant with a convex profile to complement the shape of the inferior plate of a vertebra. *See* Baccelli, at ¶¶ [0037]-[0038] ("In the above-specified sagittal plane, the superior face 8 has a profile that is made up of two segments 14 and 16 of generally rectilinear shape that are inclined relative to each other so as to give the profile a shape that is convex. The rear segment 16 is the longer of the two segments. In this plane, it extends over about 80% of the length of the cage. . . . The segment 16 slopes slightly towards the rear of the cage. It is therefore slightly inclined relative to the inferior face 10. The front segment 14 is inclined towards the front of the cage more steeply than the rear segment is inclined towards the rear."); ¶ [0042] ("In section on the sagittal midplane of FIG. 6, the superior plate 32 of the vertebra has a profile that is substantially horizontal and rectilinear while the inferior plate 34 has a profile that is concave, matching the profile of an airplane wing, and complementary to the convex profile of the superior face 8 of the cage.").  FIG. 5

Claim 14 recites that the "first fusion aperture is one of generally rectangular and generally oblong in shape." As discussed above in Section III.C., *supra*, the

broadest reasonable construction of the term "generally rectangular and generally oblong in shape," and the one implicitly adopted by the PTO, and not refuted by the Applicant, during prosecution of the '409 application is a shape having four portions roughly approximating sides, and being elongated in at least one dimension. Under this construction, Baccelli discloses the claimed fusion aperture.

Claim 14: The spinal fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.	Baccelli discloses that the first fusion aperture is generally rectangular and oblong in shape. *See* Baccelli, Figure 2. 

Claim 19, which recites that the anti-migration elements on the implant's upper and lower surfaces comprise a plurality of ridges, is disclosed by Baccelli.

Claim 19: The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges.	Baccelli provides that the anti-migration elements on the upper surface of the implant may comprise a plurality of ridges in the form of teeth 12. *See* Baccelli at ¶ [0037] ("The rear segment 16 is the longer of the two segments. In this plane, it extends over about 80% of the length of the cage. The segment has a profile that is toothed. All of the teeth 12 are identical to one another, and in particular they all have the same height."). 

Claim 20, which depends from Claim 19, adds the limitation that the "plurality of ridges extend generally perpendicular to said longitudinal length," which is disclosed by Baccelli.

Claim 20: The spinal fusion implant of claim 19, wherein said plurality of ridges extend generally perpendicular to said longitudinal length.	Baccelli provides that the plurality of ridges, or teeth 12, are formed parallel to the front wall, and therefore are perpendicular to the longitudinal length of the implant. *See* Section V.A., Claim 20, *supra* (incorporated here).

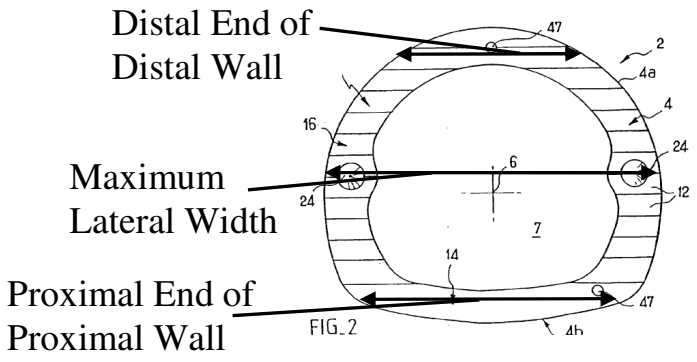
Claims 23-25 add proportional limitations to the implant claimed in Claim 1. Claim 23 recites that the "maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall." As shown in Figure 2, Baccelli discloses such limitation.

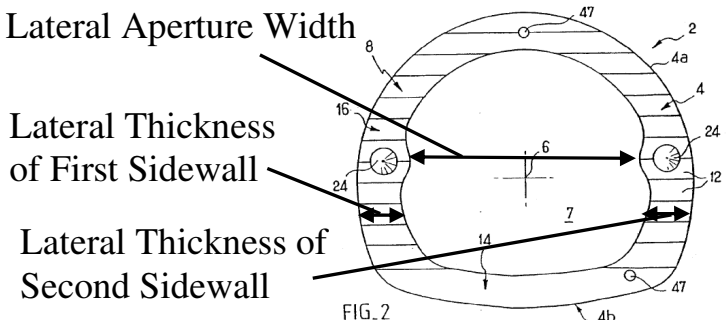
Claim 24 recites that the implant's height is less than its maximum lateral width. As discussed above, and incorporated here, one skilled in the art would understand from Figure 59 of Frey that the maximum width of the implant disclosed in Frey is greater than its height. *See* Section V.A., claim 24, *supra*. Further, as discussed above, combinations made from these references are merely simple combinations of known mechanical elements to achieve predictable results. *See KSR,* 550 U.S. at 418.

Claim 25 adds the limitation that the width of the first fusion aperture is more than two times greater than a lateral thickness of both the first and second

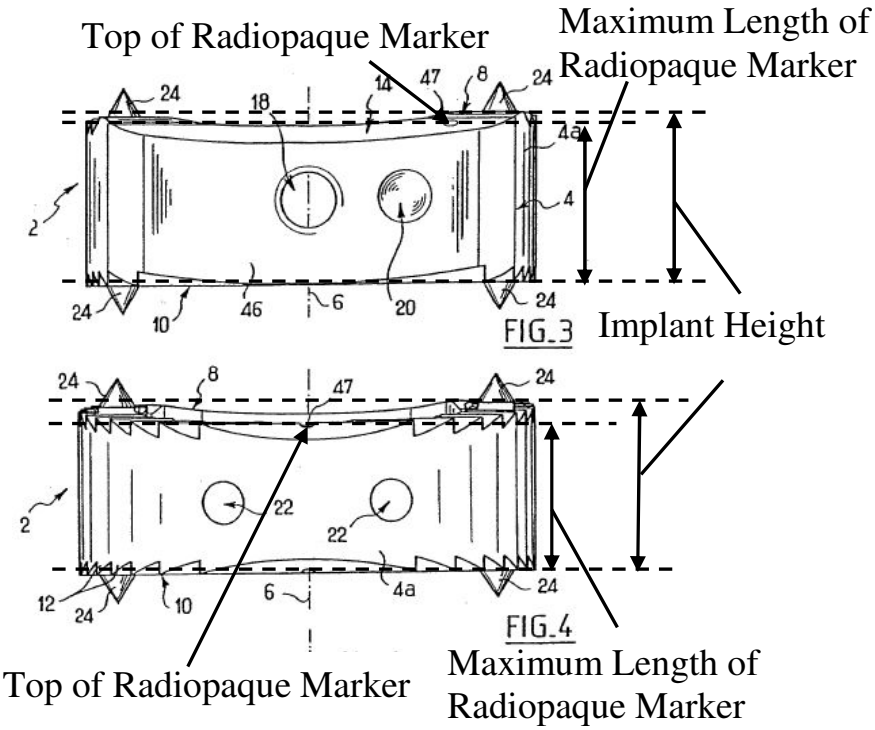
sidewalls. One skilled in the art would understand from Figure 2 of Baccelli that the width of the first fusion aperture of Baccelli is more than two times greater than the thickness of its first and second sidewalls. *See* Hynes Decl., at ¶ 135.

Additionally, such proportional limitation does not impact the functionality of the device so as to make it patentably distinct from the prior art implants disclosed in Frey and Baccelli. *See Gardner*, 725 F.2d at 1349-50.

Claim 23: The implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall.	Baccelli discloses that the maximum lateral width of the implant is greater than the lateral widths of the distal end of the distal wall and the proximal end of the proximal wall. *See* Baccelli, Figure 2. 
Claim 24: The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.	Figure 59 of Frey reasonably discloses to one skilled in the art that the maximum lateral width of the implant disclosed in Frey is greater than even the maximum height. *See* Section V.A., Claim 24, *supra* (incorporated here).
Claim 25: The spinal fusion implant of claim 1, wherein the lateral aperture width of said first fusion aperture is more than two time	As shown in Figure 2 of Baccelli, the lateral aperture width of the spinal fusion implant is more than twice the width of either the first side wall or the second side wall.

greater than a lateral thickness of said first sidewall and is more than two time greater than a lateral thickness of said second sidewall.	

Claims 26 recites that the elongate body of at least one of the radiopaque markers described in Claim 1 is shorter than the height of the implant. Due to the angular configuration of the Baccelli implant, the radiopaque markers utilized in the Baccelli implant are shorter than the height of the implant.

Claim 26: The spinal fusion implant of claim 1, wherein said elongate body of at least one of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface.	As shown in Figures 3 and 4 of Baccelli, due to the sloping nature of the upper surface of the implant disclosed in Baccelli, and the shorter height of the implant at the trailing end in comparison to the larger height in the middle of the implant, the radiopaque markers 47 are shorter than a larger central height of the implant. *See* Baccelli, Figures 3 and 4. 

Claim 27 adds the limitation that "osteoinductive material [is] positioned with[in] said first fusion aperture." Baccelli discloses that the implant may include a bone graft or other osteogenic material placed within its fusion aperture, hole 7.

Claim 27: The spinal fusion implant of claim 1, further comprising an osteoinductive material positioned with said first fusion aperture.	Baccelli provides that the spinal fusion implant may also include an osteoinductive material positioned within said first fusion aperture. *See* Baccelli, at ¶ [0045] ("Prior to mounting, the hole 7 receives a bone graft or any other substance for enabling bone growth.").

VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for claims 1-14, 19, 20, and 23-27 of the '156 patent.

Respectfully submitted,

Dated: __5 March 2014_

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CERTIFICATE OF SERVICE ON PATENT OWNER

UNDER 37 C.F.R. § 42.105(a)

Pursuant to 37 C.F.R. §§ 42.8(e) and 42.105(b), the undersigned certifies that on the 5th day of March 2014 a complete and entire copy of this Petition for Inter Partes Review and all supporting exhibits was provided via email to the Patent Owner by serving the following email addresses:

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Electronic service was used with the agreement of the Patent Owner's counsel.

Dated: _5 March 2014_

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