IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Curran et al.
U.S. Patent No.: 8,187,334 Attorney Docket No.: 108136.00020
Issue Date: May 29, 2012
Appl. Ser. No.: 13/079,645
Filing Date: April 4, 2011
Title: SYSTEM AND METHODS FOR SPINAL FUSION

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# PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,187,334 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

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MSD 1008 – Prosecution History of U.S. Patent No. 8,187,334

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. 8,187,334

Medtronic, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-5, 10, 11, 14-28 of U.S. Patent No. 8,187,334 (the "'334 patent") (Exhibit MSD 1013). As set forth below, Petitioner demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of claims 1-5, 10, 11, 14-28 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 '334 patent. Petitioner is a named counterclaim-defendant in litigation concerning the '334 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 District of California on November 8, 2012, as case No. 3:12-cv-02738-CAB-MDD. The '334 patent was added by counterclaim filed on March 7, 2013.

[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.

Petitioner is concurrently filing an IPR petition for the '334 patent on two additional grounds not presented herein.

### 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<br>1030 15th Street, NW<br>Washington, DC 20005 | Seth A. Kramer, Reg. No. 67,813<br>2000 Market Street, 20th Floor<br>Philadelphia, PA 19103 |

### D. Service Information

Please address all correspondence to both counsel listed above. Petitioner consents to service by email at ipdocket@foxrothschild.com (referencing Attorney Docket No. 108136.00020).

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

Petitioner authorizes the United States Patent and Trademark Office ("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 '334 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 '334 patent was asserted.

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

Petitioner requests IPR of claims 1-5, 10, 11, 14-28 of the '334 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 Declaration of Richard A. Hynes, M.D., and the appendices attached thereto.

| Ground | '334 Patent Claims | Basis for Rejection |
|---|---|---|
| Ground 1 | 1-3, 10, 14, 15, and 19-28 | Anticipated under § 102(b) by U.S. Patent Appl. Pub. No. 2002/0165550 to Frey ("Frey") (Exhibit MSD 1003) |
| Ground 2 | 1-5, 10, 11, 14-17, and 19-28 | Obvious under § 103(a) by Frey in view of U.S. Patent Appl. Pub. No. 2003/0028249 to Baccelli ("Baccelli") (Exhibit MSD 1004) |
| Ground 3 | 1-3, 10, 14, 15, and 19-28 | Obvious under § 103(a) by Frey in view of U.S. Patent Appl. Pub. No. 2003/0139813 to Messerli ("Messerli") (Exhibit MSD 1007) |
| Ground 4 | 1-5, 10, 11, 14, 15, and 18-28 | Obvious under § 103(a) by Frey in view of U.S. Patent No. 5,860,973 to Michelson ("Michelson") (Exhibit MSD 1005) |
| Ground 5 | 1-3, 10, 14, 15, and 19-28 | Obvious under § 103(a) by Frey in view of U.S. Patent Appl. Pub. No. 2003/0100950 to Moret ("Moret") (Exhibit MSD 1006) |

Frey and Baccelli 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. Michelson qualifies as prior art under at least 35 U.S.C. § 102(b) because it issued more than one year prior to March 29, 2004. 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 '334 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 Frey prior art spinal

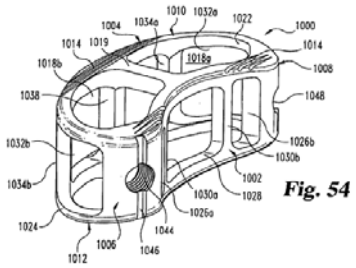


Fig. 54

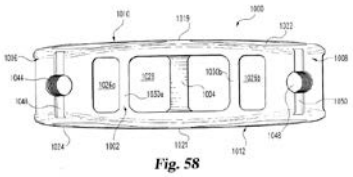


Fig. 58

fusion implant figures reproduced above are located on the proximal wall of the implant. The Applicant implicitly acquiesced to the USPTO 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.

2. Releasably Mate

Under the broadest reasonable construction, the term "releasably mate" as used in the '334 patent should be construed as "an impermanent stabilized connection." In the '334 patent, this term is used to describe the connecting relationship between the implant and insertion tool. *See* '334 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 a 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

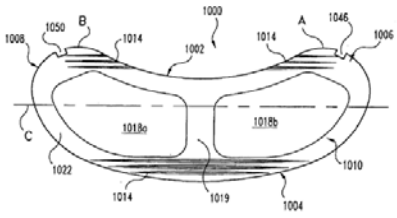


*Fig. 53*

detail in Section IV.B., *infra*, the USPTO 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

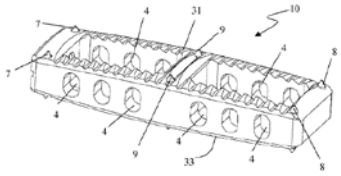
Under the broadest reasonable construction, this term is construed as being oriented generally or roughly along the Y-axis (up and down) or oriented generally or roughly in a direction running from the top to the bottom. *See id*.

## IV. SUMMARY OF THE '334 PATENT

### A. Overview of the '334 Patent

The application that issued as the '334 patent was filed on April 4, 2011, and is a continuation of U.S. Patent No. 7,918,891 (the "'891 patent"), filed on March 29, 2005, which claims the benefit U.S. Provisional Application Ser. No. 60/557,536, filed on March 29, 2004.

The ‘334 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.*, ‘334 patent, 1:66 to 2:2. As described and claimed, the implant of the ‘334 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 40 mm[2] and is at least two and a half times greater than the maximum width of the implant, as defined by greatest distance between the two sidewalls. 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 three radiopaque markers, with at least one in the proximal wall, one in the distal wall and one in the central region of the implant. The ‘334 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.” ‘334 patent, 10:2-9. The ‘334 patent does not



[2] The disclosure of a 40mm length in the specification was added to the specification in a Preliminary Amendment.

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.

Claim 1, the only independent claim of the '334 patent, reads as follows:

| |
|---|
| 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: |
| [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, |
| [C]: a distal wall, a proximal wall, a first sidewall and a second sidewall, |
| [D]: said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material; |
| [E]: wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall; |
| [F]: wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, |
| [G]: wherein said longitudinal length is at least two and half times greater than said maximum lateral width; |
| [H]: 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, |
| [I]: 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 |
| [J]: at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region. |

### B. Summary of the Prosecution History of the '334 Patent

The prosecution histories of the ‘334 patent, and of its parent patent, the ‘891 patent, as obtained from PAIR, are submitted herewith as Exhibits MSD 1008 and MSD 1009.

1. Prosecution of ‘334 Patent

During prosecution of the ‘334 patent, the Specification was amended in a Preliminary Amendment filed April 4, 2012. Notably, in the Preliminary Amendment, the Applicants amended the description of the dimensions of implant as follows: “The spinal fusion implant 10 of the present invention may be dimensioned, by way of example only, having a width ~~length~~ ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ~~width~~ ranging between 25 and 45 mm.” Exhibit MSD 1008, at 140.

Additionally, the claims were amended in preliminary amendments, but were never rejected by the PTO. The Reasons for Allowance set forth in the Notice of Allowability for the ‘334 patent read as follows:

> The following is an examiner’s statement of reasons for allowance: the claims in the instant application have not been rejected using prior art because no references or reasonable combination thereof could be found which disclose or suggest a spinal fusion implant comprising upper and lower surfaces with anti-migration elements, distal, proximal, and side walls comprising radiolucent materials, a first fusion aperture with a longitudinal length extending parallel to the longitudinal length of the implant, the central portion defines a maximum lateral width between first and second sidewalls, and at least three radiopaque markers, as set forth in clam 27.

*Id.* at 164-65. The Applicant filed a Response to Notice of Allowance on April 18, 2012, stating that the Applicant "does not concede that the Examiner's stated reasons for allowance are the only reasons for which the claims are allowable," and that "the claims are allowable for other reasons – including the inventive combination of all the recited claim elements." *Id.* at 190. Notwithstanding these statements, the Applicant did not specifically identify any additional features recited in claim 27, or any of its dependent claims, that would distinguish those claims over the prior art.

2. Prosecution of the parent '891 Patent

The parent '891 patent, like the continued '334 patent, has claims directed to a spinal fusion implant of non-bone construction. The '891 patent issued from U.S. Patent Appl. Ser. No. 11/093,409 (the "'409 application", which was filed with two independent claims (i.e., Claims 1 and 14) and twenty-four dependent claims (i.e., Claims 2-13 and 15-26).

During prosecution of the '409 application, Applicants amended Claim 1 to recite as follows:

| |
|---|
| Claim 1 [A]: A spinal fusion ~~system~~ implant positionable within an interbody space between a first vertebral endplate and a second vertebral endplate, said interbody space being at least partially defined by a posterior aspect, and [sic] anterior aspect, and opposing lateral aspects, said implant comprising: |
| [B]: ~~an interbody spinal fusion implant, including at least in part~~ a top surface including a plurality of ridges to engage said ~~for contacting a~~ first vertebral endplate when said implant is positioned within the interbody space, a bottom surface including a plurality of ridges to engage said ~~for contacting a~~ second |

vertebral endplate when said implant is positioned within the interbody space, ~~at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate,~~ a distal side, a proximal side, ~~having a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument, and two lateral sides; and~~ a first side wall defining an anterior side when said implant is positioned within the interbody space, and a second side wall defining a posterior side when said implant is positioned within the interbody space;

[C]: wherein said implant has a length extending from said proximal side to said distal side, a width extending from said first side wall to said second side wall, and a height extending from said top surface to said bottom surface;

[D]: wherein said 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;

[E]: wherein said width is greater than said height;

[F]: said implant further including first and second fusion apertures that each extend between the top and bottom surfaces and permit bone growth between the first vertebral endplate and the second vertebral endplate when said implant is positioned within the interbody space, said first and second fusion apertures being adjacent to one another and separated by a medial support;

[G]: said implant further including at least one radiopaque marker situated between said top and bottom surfaces.

~~an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and~~

~~a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.~~

Applicants also amended Claim 5 to recite:

Claim 5: The spinal fusion ~~system~~ implant of Claim 1, wherein ~~the implant further includes anti migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement~~ said first and second fusion apertures are one of generally rectangular and oblong in shape.

Additionally, Applicants added Claims 31-33, which recited:

| |
|---|
| Claim 31: The Spinal [sic] fusion implant of claim 1, further including at least one receiving aperture at least partially defined along said proximal side. |
| Claim 32: The spinal fusion implant of claim 31, wherein said receiving element is engageable with an insertion instrument. |
| Claim 33: The spinal fusion implant of claim 32, wherein said receiving element comprises a threaded aperture. |

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 first and second fusion apertures (1018a, 1018b) that are "generally rectangular and oblong in shape." Exhibit MSD 1009, at 1010. The PTO also cited the '570 patent as disclosing a threaded receiving element (1044) on the proximal side of the implant that is engageable with an insertion instrument. *See id.*

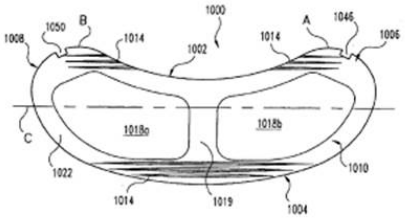


*Fig. 53*

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* MSD 1009, at 1029-30.

**C. Legal Standard**

1. Anticipation

A person is not entitled to a patent when the purported invention was used by others in the United States **or described in a printed publication** anywhere in the world **more than a year prior to the filing date of the application for patent**. 35 U.S.C. § 102(b) (emphasis added). Thus, a patent claim is anticipated where a single prior art reference expressly or inherently discloses each claim limitation. *See Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

2. 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 obviousness analysis is expansive and flexible. *KSR*, 127 S. Ct. at 1739. "The combination of familiar elements according to known methods is likely to be

obvious when it does no more than yield predictable results." *Id.* 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 '334 patent. *See e.g.*, Declaration of Richard Hynes, M.D. Regarding U.S. Patent No. 8,187,334 (hereinafter, the "Hynes Decl."), attached hereto as Exhibit 1001, at ¶ 58. As detailed in claim charts below, various prior art references render obvious the challenged claims of the '334 patent.

### A. Ground 1 – Claims 1-3, 10, 14, 15, and 19-28 Are Anticipated Under § 102 by Frey

As shown in the claim chart below, claims 1-3, 10, 14, 15, and 19-28 of the '334 patent are anticipated under 35 U.S.C. § 102(b) by Frey (or in the alternative, obvious in view of Frey under 35 U.S.C. § 103). With respect to Claim 1, Frey (a representative embodiment of Frey implant, Fig. 59, is reproduced below), which was not cited during prosecution of the '334 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 length of the Frey implant from the proximal wall to the distal wall is disclosed as being sufficient to span the disc

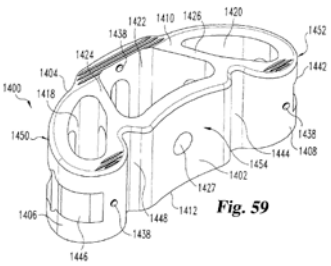


*Fig. 59*

space, which is inherently greater than 40 mm. 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 ¶ 61.

"[A] drawing teaches all that is reasonably discloses to a person of ordinary skill in the art." *Ex Parte Matsunaga*, 2012 WL 260128, at *1 (BPAI Jan. 25, 2012). As shown in more detail in the claim chart below, the drawings of Frey, specifically Figures 47, 55, 63 and 66 all disclose to one of skill in the art that the length of the implant is at least two and a half times its width. *See* Hynes Decl., at ¶ 62; Declaration of Steven D. DeRidder Regarding U.S. Patent Application Publication No. 2002/0165550 ("DeRidder Decl.") (attached hereto as Exhibit MSD 1002), at ¶ 7 (noting that Figures 47, 55, 63, and 66 are drawn to scale). Alternatively, such proportions are clearly obvious in view of these teachings contained in Frey. Additionally, such proportional limitation does 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). As stated by Dr. Hynes in his Hynes Decl., this limitation "is merely dictated by those anatomical constraints of the patients and the specific ratio obtained is a byproduct of those constraints, particularly when charged with the information provided by Frey or other prior art such as Michelson." *See* Hynes Decl., at ¶ 63.

The upper and lower surfaces of the Frey implant also contain anti-migration elements that come in contact with the first and second vertebrae. Additionally, the Frey implant contains at least one fusion aperture that is longer than it is wide (and would be obvious in view of the teachings of Frey) and extends from the top surface to the bottom surface. Additionally, the Frey implant includes at least three radiopaque markers, with at least one in the proximal wall, one in the distal wall and one in the central region of the implant.

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| 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, ¶ [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 . . .."). |

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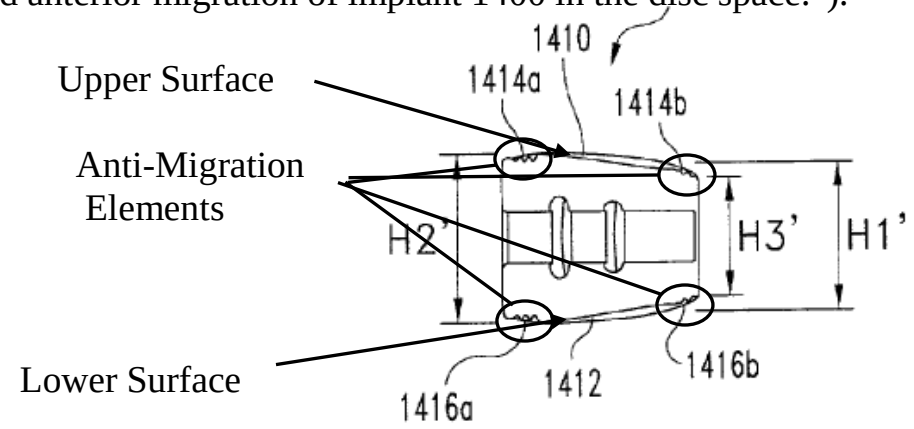
| Claim 1 [B]: an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, | 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, ¶ [0153] ("Upper bearing surface 1410 can further be provided with a number of first grooves 1414 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 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 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, | 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."). |

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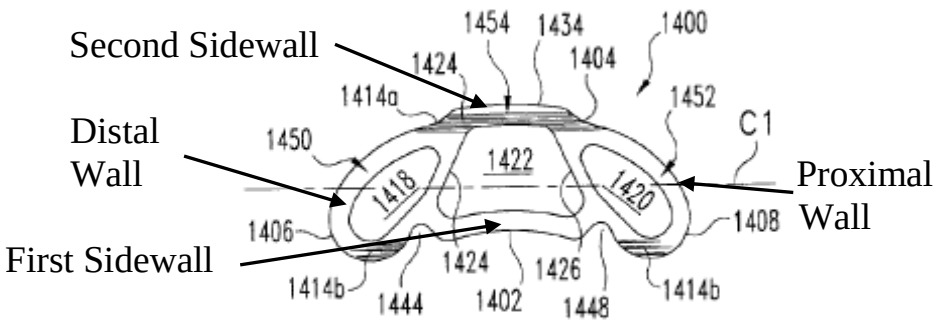
| |  |
| Claim 1 [D]: said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material; | Frey provides that the walls of the spinal fusion implant may comprise a radiolucent material. *See* Frey, ¶ [0156] ("A number of radiographic markers 1438 can also be provided 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.") |
| Claim 1 [E]: wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall; | Frey provides that the length of the implant is "sufficient to span the disc space." *See* Frey, ¶ [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 et al., *Geometrical Dimensions of the Lower Lumbar Vertebrae – Analysis of Data from Digitised CT Images*, 9 EUR SPINE J 242, 244 (2000) (Exhibit MSD 1012) ("The mean dimensions of the upper vertebral width was 40.9 ± 3.6 mm in females and 46.1 ± 3.2 mm in males at L3, 46.7 ± 4.7 mm in females and 50.8 ± 3.7 mm in males at L4, and 50.4 ± 4.4 mm in females and 54.5 ± 4.9 mm in males at L5."). |
| Claim 1 [F]: wherein a central region of said implant includes portions of the first and second sidewalls | Frey discloses that the spinal fusion implant includes a central region (middle portion 1454) that includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall. *See* Frey, ¶ [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 . . . |

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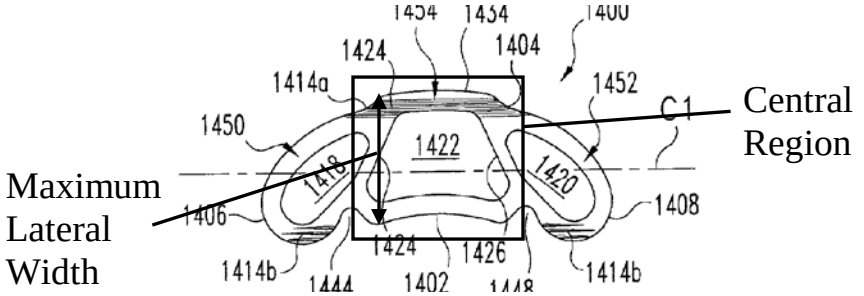
| positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, | .”).<br>  <br> |
| Claim 1 [G]: wherein said longitudinal length is at least two and half times greater than said maximum lateral width; | The actual values of angles B3, B4 and B5 as shown in Figure 66 of Frey match the values provided in the Specification of Frey. *See* Frey, ¶ [0167] (“Lateral offset 1528 extends along axis 1529 forming an angle [B3] of or about 55 degrees. The distal portion of implant engaging portion 1526 extends along axis 1527 forming angle B4 of or about 65 degrees with lateral offset portion 1528. Axis C1 of implant 1400 forms an angle B5 of or about 65 degrees with axis 1527 of the distal portion of implant engaging portion 1526.”). Therefore, Figure 66 of Frey, or at least the portion Figure 66 that is associated with these angles, is drawn to proportion and reasonably discloses to one skilled in the art that the implant disclosed in Frey has a longitudinal length that is at least two and half times the maximum lateral width. |

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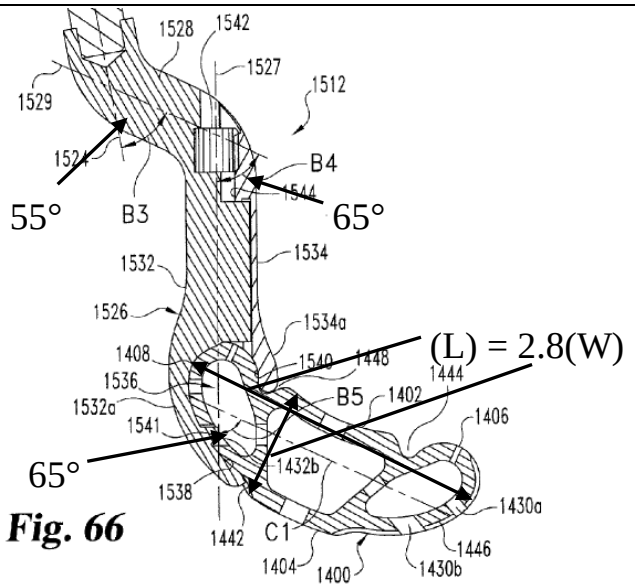
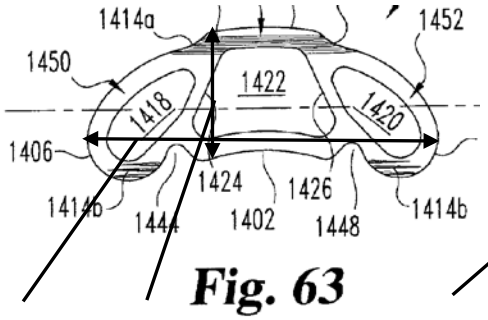
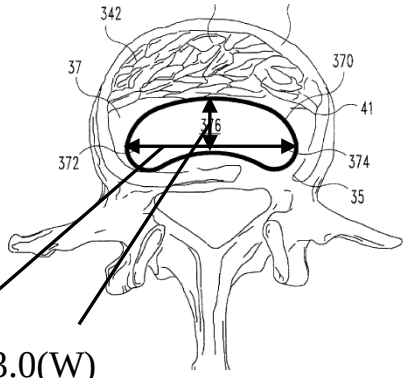
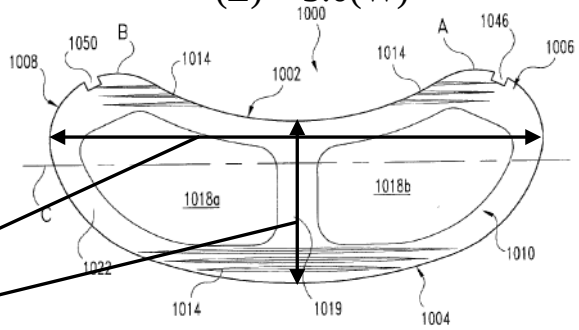
| |  <br>**Fig. 66**<br>(L) = 2.8(W)<br>Additionally, Figures 47, 55 and 63 of Frey all reasonably disclose to one skilled in the art that the implant disclosed in the '550 Application has a longitudinal length that is at least two and half times the maximum lateral width. *See* Hynes Decl., at ¶ 62; DeRidder Decl., at ¶ 7 (noting that Figures 47, 55, 63 and 66 are drawn to scale).<br>  <br>**Fig. 63**<br>  <br>(L) = 2.6(W)<br>(L) = 3.0(W)<br>  <br>(L) = 3.0(W)<br>**Fig. 55** |
| Claim 1 [H]: at least a first | Frey discloses that the spinal fusion implant includes a first fusion aperture, chamber 1422, that is configured to allow bone |

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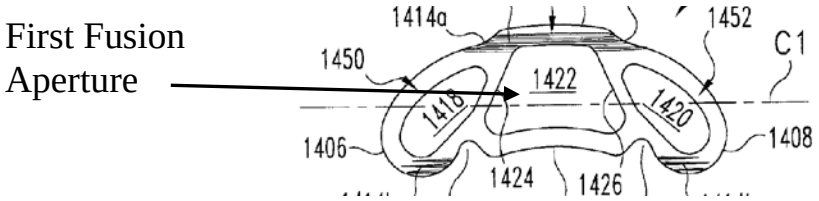
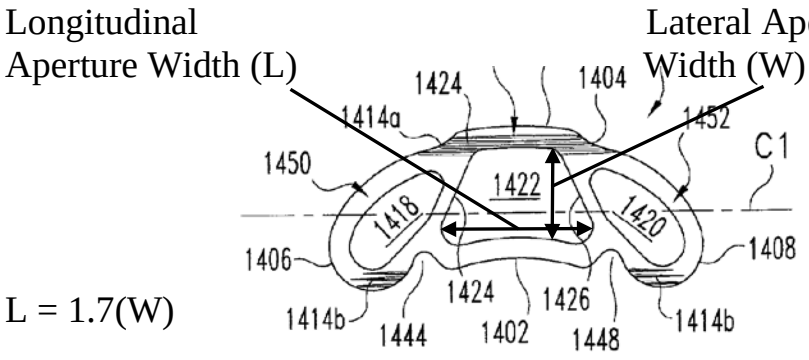
| fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, | growth between the first vertebra and the second vertebra after proper positioning 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. In particular, leading end portion 1450 includes first chamber 1418 and trailing end portion 1452 includes second chamber 1420. Middle portion 1454 includes a middle chamber 1422.").   |
| Claim 1 [I]: 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 | 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*** |

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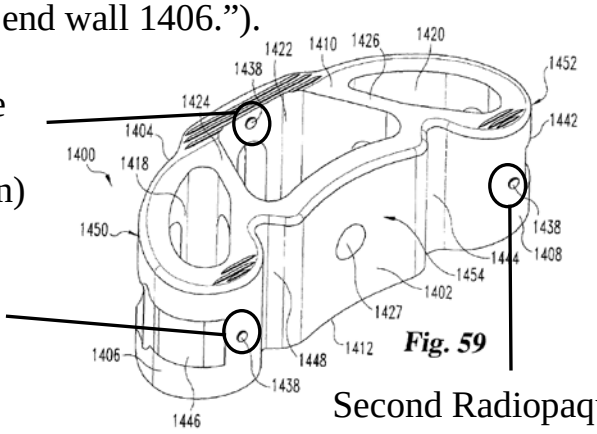
| is greater than the lateral aperture width; and | |
| Claim 1 [J]: at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region. | Frey provides that the spinal fusion implant includes at least three radiopaque markers. *See* Frey, ¶ [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 posterior-most points of trailing end wall 1408 and leading end wall 1406.").<br>Third Radiopaque Marker (in Central Region)<br>First Radiopaque Marker (in Distal Wall)<br>  <br>Second Radiopaque Marker (in Proximal Wall) |

Claims 2 and 3 add limitations directed to a receiving aperture located on the proximal wall of the implant. Frey discloses the claimed receiving aperture, and discloses that it is configured to releasably mate with an inserter tool. Notably, as

explained in more detail above in Section IV.B., *supra*, during prosecution of the '409 application, the parent application of the '334 patent, the USPTO found that the '570 patent, of which disclosure is completely included in Frey, disclosed a receiving aperture on the proximal wall of the implant, and that the receiving aperture was engageable with an insertion instrument. *See* Exhibit [prosecution history of '409 Application, OA of August 27, 2009].

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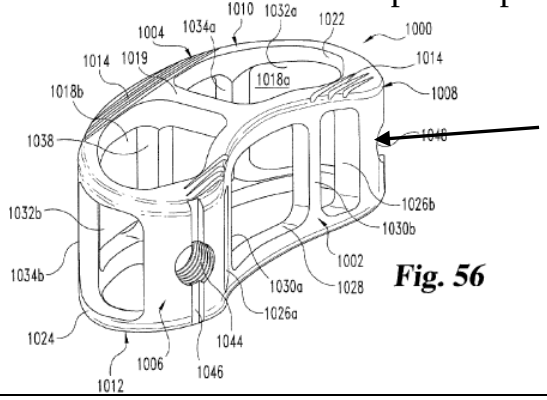
| Claim 2: The spinal fusion implant of claim 1, further including at least one receiving aperture position is [*sic*, in] said proximal wall. | Frey provides that the spinal fusion implant may include a receiving aperture in the proximal wall. *See* Frey, ¶ [0158] ("Trailing end wall 1408 and leading 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 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 3: The spinal fusion implant of claim 2, wherein said 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, ¶ [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."); *see also* Frey, ¶ [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 10, which recites that the anti-migration elements on the upper and lower surfaces of the implant comprise a plurality of ridges, is anticipated by Frey.

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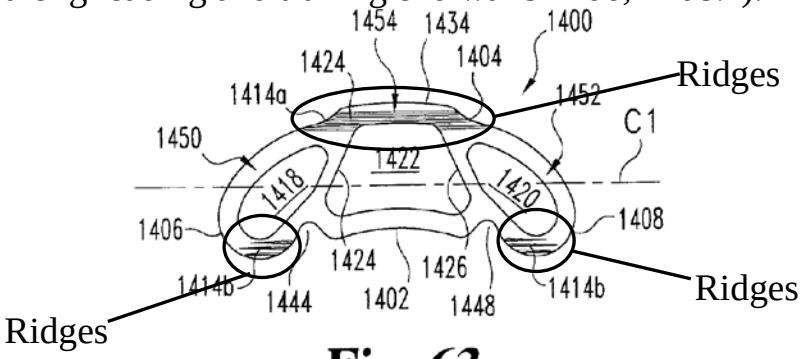
| Claim 10: The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges. | Frey provides that the anti-migration elements on the upper surface of the implant may comprise a plurality of grooves, or ridges. *See* Frey, ¶ [0153] ("Upper 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.").   ***Fig. 63*** |

Claims 14 and 15 add limitations with respect to the claimed radiopaque markers. Claim 14 recites that at least one of the radiopaque markers is an elongate body that extends generally perpendicular to the implant's longitudinal length. Under the broadest reasonable claim construction of the terms of this claim, Frey discloses such radiopaque markers. The radiopaque markers 1438 of Frey are shown as extending through the thickness of wall portion 1434. Because the diameter of the marker 1438 extending along the wall portion 1434 cannot be substantially increased from that depicted in Figs. 59 & 60 due to the adjacent upper bearing surface 1410 and wall opening 1428, the markers 1438 are elongated bodies as depicted in the figures. Additionally, as shown in the claim chart below,

the radiopaque markers of Frey are located in the walls of the implant approximately in a direction that crosses a plane along the general direction of the length of the Frey implant at generally a right angle. Accordingly, Frey anticipates Claim 14. Further, it would be intuitive and common sense to provide elongated markers if one might want to see a particular orientation or position of the marker on X-ray, the elongated marker presumably providing a longer image on the X-ray in certain orientations relative to picture being taken. *See* Hynes Decl., at ¶ 92.

Claim 15 recites that the elongate body of the radiopaque marker of Claim 14 is shorter than a height of the implant. Because the maximum length of the radiopaque marker of Frey is approximately equal to the thickness of the implant wall (*see e.g.*, Figs. 59, 60, 63), Frey discloses radiopaque markers that are shorter than a height of the implant. Accordingly, Frey anticipates Claim 15.

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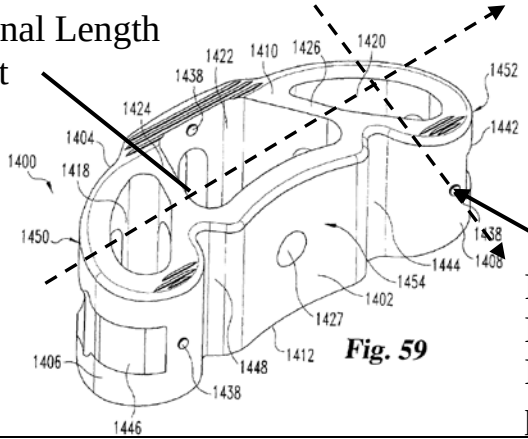
| Claim 14: The spinal fusion implant of claim 1, wherein at least one of said three radiopaque markers comprises an elongate body extending generally perpendicular to said longitudinal length. | As shown in Figures 59 and 60, Frey discloses that the radiopaque markers included on the implant are elongate bodies that are in the walls of the implant generally perpendicular to the longitudinal length of the implant. *See* Frey, Figs. 59-60.<br><br>Longitudinal Length of Implant<br>  <br>*Fig. 59*<br>Radiopaque Marker Extending perpendicular. |

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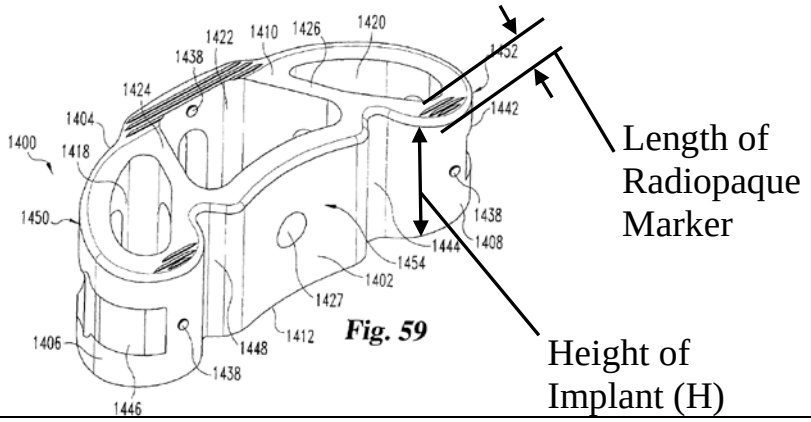
| Claim 15: The spinal fusion implant of claim 14, wherein said elongate body of at least one of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface. | As shown in Figure 59, Frey provides that the elongate bodies of the radiopaque markers 1438 are shorter than a 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 19 recites that the radiolucent material of the implant comprises polyether ether ketone (PEEK). Frey discloses such limitation and therefore anticipates Claim 19.

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| Claim 19: 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 20 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.

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| Claim 20: The spinal fusion | Frey discloses that the implant may include an aperture extending through both the first sidewall (posterior opening |

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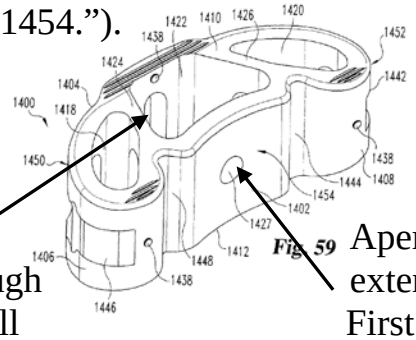
| implant of claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall. | 1427) and the second sidewall (anterior opening 1428). *See* Frey, ¶ [0155] ("Posterior wall 1402 includes a posterior opening 1427 along middle portion 1454, and anterior wall 1404 includes an anterior opening 1428 along middle portion 1454.").  Aperture extending through Second Sidewall Aperture extending through First Sidewall |

Claims 21 and 22 add limitations with respect to the angular relationship between the upper and lower surfaces of the implant. Frey anticipates Claim 21 as Frey discloses that the upper and lower surfaces of the implant may be generally parallel to each other. Frey also anticipates Claim 22 as it 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.

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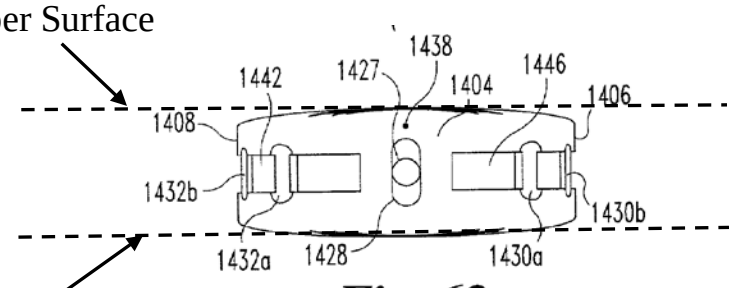
| Claim 21: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another. | As shown in Figures 58 and 62, Frey discloses that the upper and lower surfaces of the implant are generally parallel to one another. *See* Frey, Fig. 62. Plane of Upper Surface  Plane of Lower Surface **Fig. 62** |
| Claim 22: The spinal fusion implant of claim 1, | 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, ¶ |

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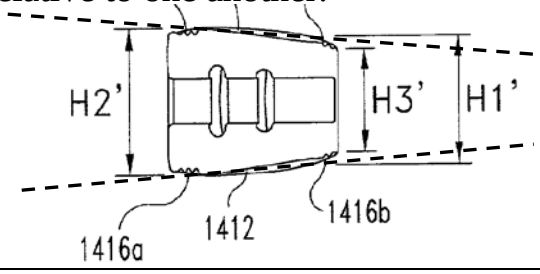
| wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space. | [0152] ("Implant 1400 has a height H1′ at the medial portion of posterior wall 1402 and a second 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.<br>  |

Claim 23 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 previously 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, and therefore, anticipates Claim 23.

Further evidence of Frey's anticipation of this limitation is found in the specification of Frey, which 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]. One of ordinary skill in the art therefore would understand the aperture 1422 to be generally rectangular and generally oblong in shape, as depicted in the figures, to maximize the volume and contact surface area as discussed in the specification. *See* Hynes Decl., at ¶ 120.

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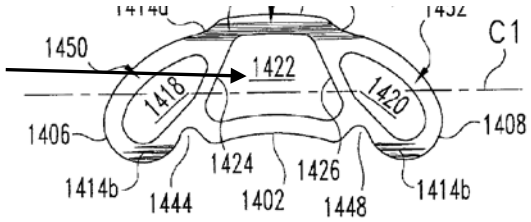
| Claim 23: The spinal fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape. | Frey discloses that the first fusion aperture is generally rectangular and oblong in shape. *See* Frey, Fig. 63.<br>First Fusion Aperture  <br>***Fig. 63*** |

Claims 24-27 add proportional limitations to the implant claimed in Claim 1. Claim 24 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 and therefore anticipates claim 24. Alternatively, such proportions are clearly obvious to one of ordinary skill in the art in view of these teachings contained in Frey. *See* Hynes Decl., at ¶¶ 122-23.

Claim 25 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 ¶ 125; DeRidder Decl., at ¶ 7 (noting that Figure 59 is drawn to scale). Accordingly, Frey anticipates Claim 25. In addition, as discussed above in relation to Claim 1, 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, while the maximum lateral width is not so limited, 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 implant as being less than its width. Alternatively, such proportions are clearly obvious to one of ordinary skill in the art in view of these teachings contained in Frey. *See* Hynes Decl., at ¶ 125.

Claim 26 recites that the maximum height of the implant, found in the central region of the implant, is greater than the heights of the proximal and distal walls of the implant. Frey discloses that the maximum height, denoted as H2' in Figure 64, of the central region of the implant is greater that heights of the proximal and distal walls, denoted as H3'. *See* Hynes Decl., at ¶ 133; DeRidder Decl., at ¶ 7 (noting that Figure 64 is drawn to scale). Accordingly, Frey

anticipates claim 26. 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 ¶ 133.

Claim 27 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 ¶ 136; DeRidder Decl., at ¶ 7 (noting that Figure 63 is drawn to scale). Accordingly, Frey anticipates Claim 27. Alternatively, such proportions are clearly obvious to one of ordinary skill in the art in view of these teachings contained in Frey. *Id*.

In addition, as discussed above in relation to claim 1, 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]. Accordingly, one of ordinary skill in the art would have understood Frey to teach minimizing the wall thickness of the insert to maximize the volume of the middle chamber 1422, thereby indicating that that relative proportions of the middle

chamber 1422 and the first and second sidewalls (the posterior wall 1402 anterior wall 1404) depicted in the drawings are accurate.

Additionally, the proportional limitations contained in Claims 24-27 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).

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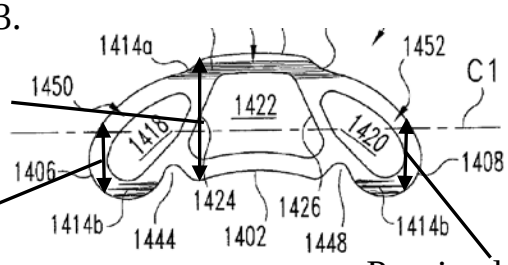
| Claim 24: The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall. | Frey discloses that the maximum lateral width of 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.<br>Maximum Lateral Width<br>  <br><br>Distal End of Distal Wall<br>**Fig. 63**<br>Proximal End of Proximal Wall |
| Claim 25: The spinal fusion implant of claim 1, wherein said implant has a height extending | 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. 69; Hynes Decl., at ¶ 125; DeRidder Decl., at ¶ 7 (noting that Figure 59 is drawn to scale). |

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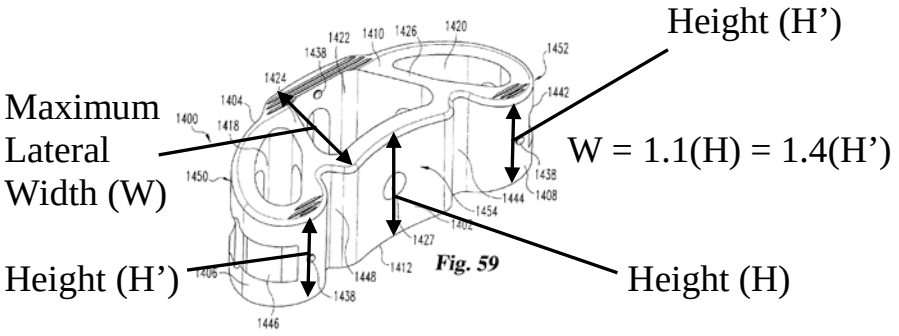
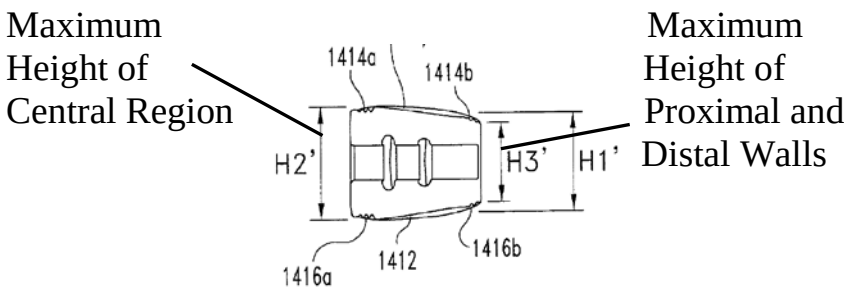
| from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height. |  <br>Fig. 59 |
| Claim 26: The spinal fusion implant of claim 1, wherein said central region includes a maximum height of said implant extending from said upper surface to said lower surface, wherein said maximum height is greater than a height of said distal wall and is greater than a height of said proximal wall. | Frey provides that the maximum height (H2') of the central region of the implant is greater that heights of the proximal and distal walls (H3'). *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 H1′ in order to correspond to the anatomy of the vertebral endplates on each side of disc space D1. Leading end wall 1406 and trailing end wall 1408 each have a height H3′ that is less than H1′ and H2′ . . . .").  <br>**Fig. 64** |
| Claim 27: The spinal fusion implant of claim 1, wherein the lateral aperture width of said first fusion aperture is more than two time greater than a lateral thickness of said first sidewall and is more than two time greater | 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. |

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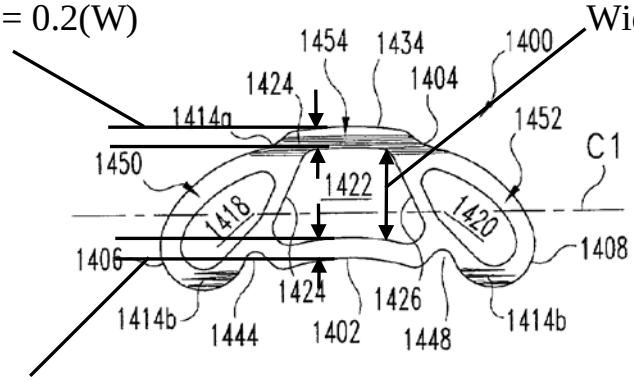
| than a lateral thickness of said second sidewall. | Width of Second Sidewall = 0.2(W)<br>  <br><br>Width of First Sidewall = 0.2(W)<br>***Fig. 63*** |

Claim 28 adds the limitation that "osteoinductive material [is] positioned with [sic] 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. Accordingly, Frey anticipates Claim 28.

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| Claim 28: 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, ¶ [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 1-5, 10, 11, 14-17, and 19-28 Are Obvious Under § 103 Over Frey in View of Baccelli

As shown in the claim chart below, claims 1-5, 10, 11, 14-17, and 19-28 of the '334 patent are rendered obvious under 35 U.S.C. § 103(a) by Frey in view of Baccelli (or alternatively Baccelli in view of Frey). 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 Claims 1-3, 10, and 19-28, the same analysis for the invalidity of these claims over Frey as discussed in Ground 1 is applicable for this ground. *See* Section V.A., *supra*. As discussed below, Claims 4, 5, 11, and 14-17 are rendered obvious by a combination of Frey and Baccelli.

Claims 4 and 5 further define the receiving aperture located in the proximal wall of the implant. Claim 4 adds the limitation that the receiving aperture recited in Claim 3 is threaded and has a central axis that is generally parallel to the longitudinal length of the implant. Frey discloses a threaded receiving aperture that has a central axis. Baccelli discloses a similar threaded receiving aperture with a central axis that is generally parallel to the longitudinal length of the implant.

Claim 5 adds the limitation of a pair of lateral grooves being positioned in the proximal wall and extending laterally of the threaded receiving aperture. Such lateral grooves are disclosed by Frey.

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 ¶ 80. Frey and Baccelli are from the same field of artificial implants used in intervertebral spinal fusion and having a space provided in the implant for 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 ¶ 58.

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| Claim 4: The spinal fusion implant of claim 3, wherein said receiving aperture comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal | 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.").<br><br>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."). |

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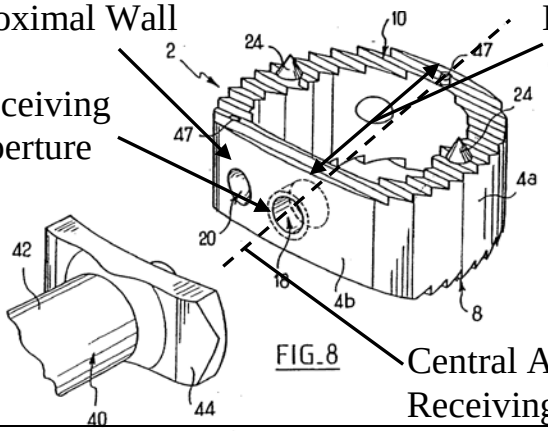
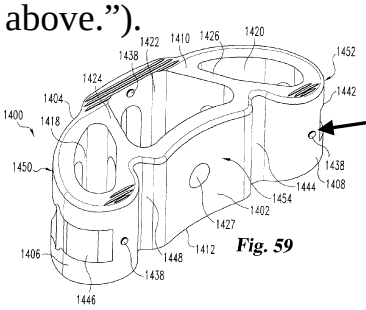
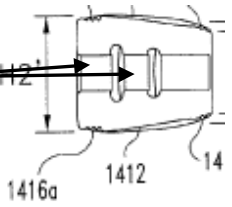
| length of said implant. | Proximal Wall<br>Receiving Aperture<br>Longitudinal Length of Implant<br>  <br><br>FIG. 8<br>Central Axis of Receiving Aperture |
| Claim 5: The spinal fusion implant of claim 4, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally 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.").<br>  <br><br>*Fig. 59*<br>Pair of Lateral Grooves in Proximal Wall<br>  <br><br>**Fig. 64** |

Claim 11, which depends from Claim 10, 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. Bacelli 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 ¶ 116. 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; Hynes Decl., at ¶ 58.

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| Claim 11: The spinal fusion implant of claim 10, wherein said plurality of ridges extend generally perpendicular to said longitudinal length. | 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.").<br><br>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."). |

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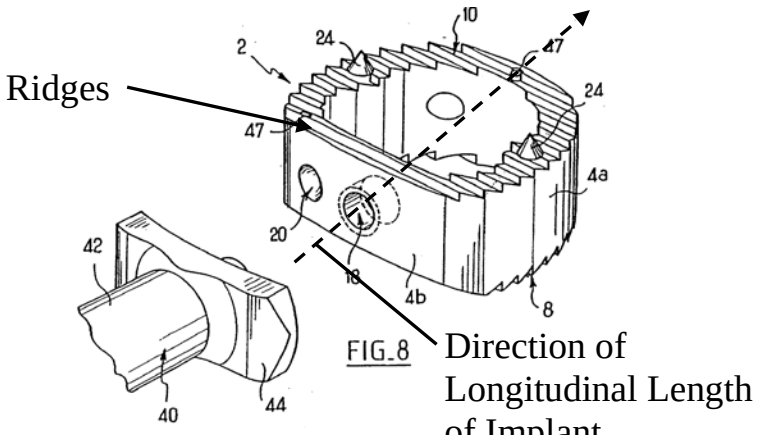
| |  |

As discussed above in Ground 1, Claims 14 and 15 add limitations with respect to the claimed radiopaque markers. Claim 14 recites that at least one of the radiopaque markers is an elongate body that extends generally perpendicular to the implant's longitudinal length. While Petitioner asserts that Frey discloses such radiopaque markers, alternatively, 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 '334 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* Bacelli, 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. *See* Hynes Decl., at ¶ 92.

Claim 15 recites that the elongate body of the radiopaque marker of Claim 14 is shorter than a height of the implant. While Petitioner asserts that Frey discloses such limitation, alternatively, Baccelli also discloses radiopaque markers that are shorter than a height of the implant. As with the limitation of Claim 14, it would have been obvious to modify the implant of Frey to include the radiopaque marker described in Baccelli to provide additional information regarding the orientation and location of the implant during surgery and after implantation. *See* Hynes Decl., at ¶ 94.

As noted above, 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, and both references expressly teach the use of radiographic markers to track the placement of such implants within the patient. *See* Hynes Decl., at ¶ 62. 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; Hynes Decl., at ¶ 58.

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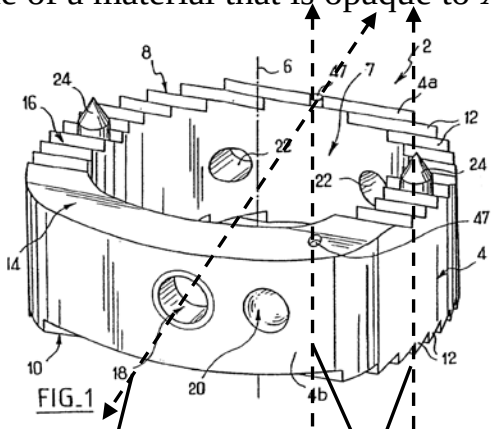
| Claim 14: The spinal fusion implant of claim 1, wherein at least one of said three radiopaque markers comprises an elongate body extending generally perpendicular to said longitudinal length. | Baccelli provides that all of the radiopaque markers, including markers 47 and spikes 24, used in the implant comprise elongate bodies that extend generally perpendicular to the longitudinal length of the implant. *See* Baccelli, ¶ [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."); ¶ [0041] ("Each spike [24] on one face extends in register with a spike on the other face."); ¶ [0051] ("The spikes 24 can . . . be made of a material that is opaque to X-rays.").<br>  <br><br>Direction of Longitudinal Length of Implant<br>Direction of Extension of Radiopaque Markers |
| Claim 15: The spinal fusion implant of claim 14, wherein said elongate body of at least one | 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. |

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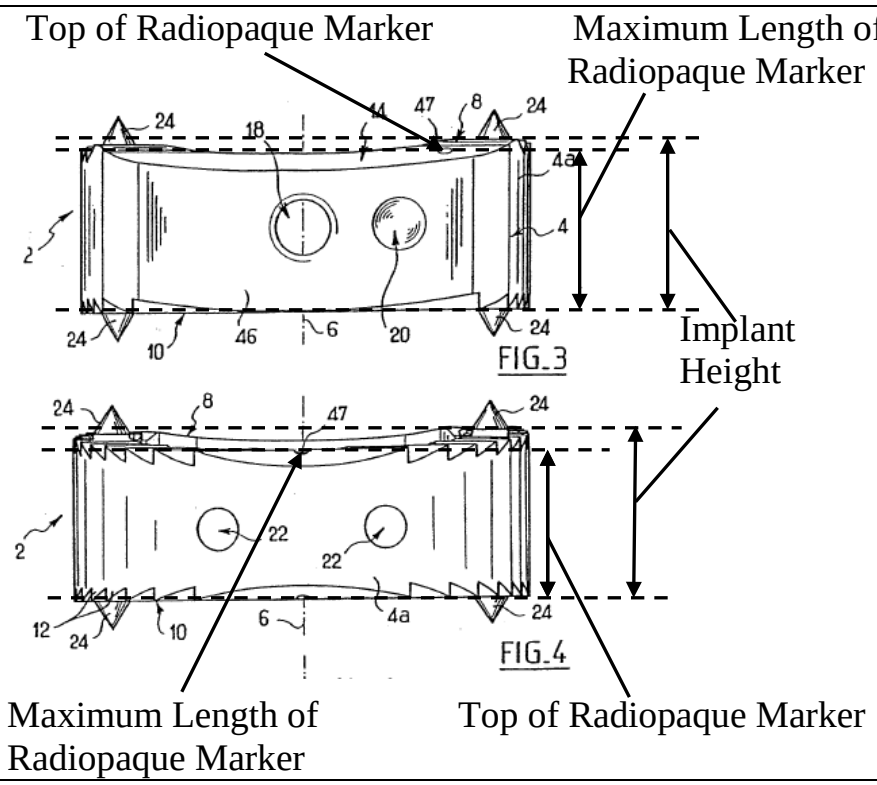
| of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface. |  |

Claim 16 recites the addition of a fourth radiopaque marker to the implant, with this additional marker being placed in the central region of the implant spaced away from the third radiopaque marker. Frey discloses the use of at least three markers, at least one at each end and one in the middle. Baccelli discloses the use of four radiopaque markers, with one in the proximal wall, one in the distal wall, and two in the central region of the implant. The two in the central region of the Baccelli implant are spaced apart, and therefore, read on the claimed third and fourth radiopaque markers. It would have been obvious to modify the implant described in Frey to include the fourth radiopaque marker of Baccelli as a second radiopaque marker in the central region of the implant to provide additional information regarding the orientation and location of the implant during surgery

and after implantation. *See* Hynes Decl., at ¶ 100. 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 ¶ 62. 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; Hynes Decl., at ¶ 58.

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| Claim 16: The spinal fusion implant of claim 1, further comprising a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position | Frey provides that the spinal fusion implant includes at least three radiopaque markers. *See* Frey, ¶ [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.").<br><br>Baccelli provides that the implant may also include four radiopaque markers (markers 47 and spikes 24). The markers 47 are located in the proximal and distal walls and the spikes 24 are located in the first and second sidewalls on opposite sides the central region of the implant. *See* Baccelli, ¶ [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 |

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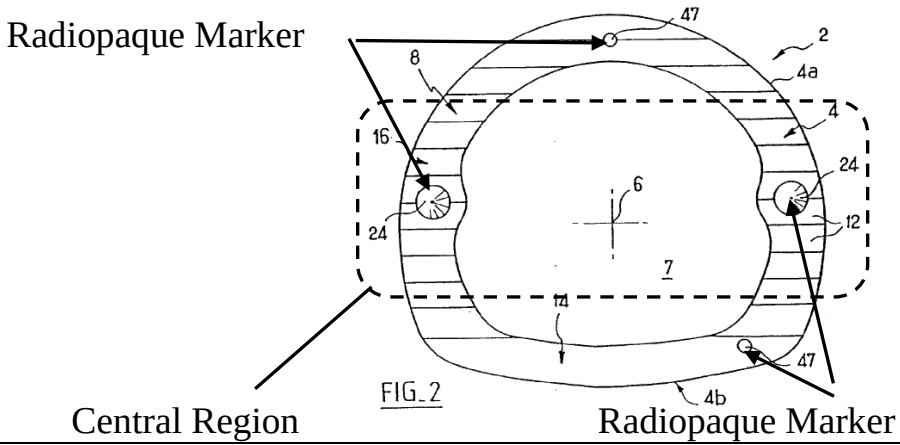
| spaced apart from said third radiopaque marker. | wall."); ¶ [0041] ("Each spike [24] on one face extends in register with a spike on the other face."); ¶ [0051] ("The spikes 24 can . . . be made of a material that is opaque to X-rays.").   |

Claim 17 adds the limitation that the radiopaque markers located in the proximal and distal walls are oriented generally perpendicular to the longitudinal length of the implant, and extend through the height of the respective wall. Baccelli discloses that the radiopaque marker in its proximal and distal wall are oriented generally perpendicular to the longitudinal length of the implant, and they extend along the height of the respective wall. It would have been obvious to modify the radiopaque markers used in the implant described in Frey to extend in a direction generally perpendicular to the longitudinal length of the implant along the height of the proximal and distal wall, to provide additional information regarding the orientation or location of an implant during surgery and after implantation if desired. *See* Hynes Decl., at ¶ 102. 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; Hynes Decl., at ¶ 58.

Additionally, it would have been a simple design choice to either modify end markers 47 to replicate the structure of spikes 24 or merely using identical markers 24 in the location of markers 47 and then combine either of those markers with Frey. *See* Hynes Decl., at ¶ 103.

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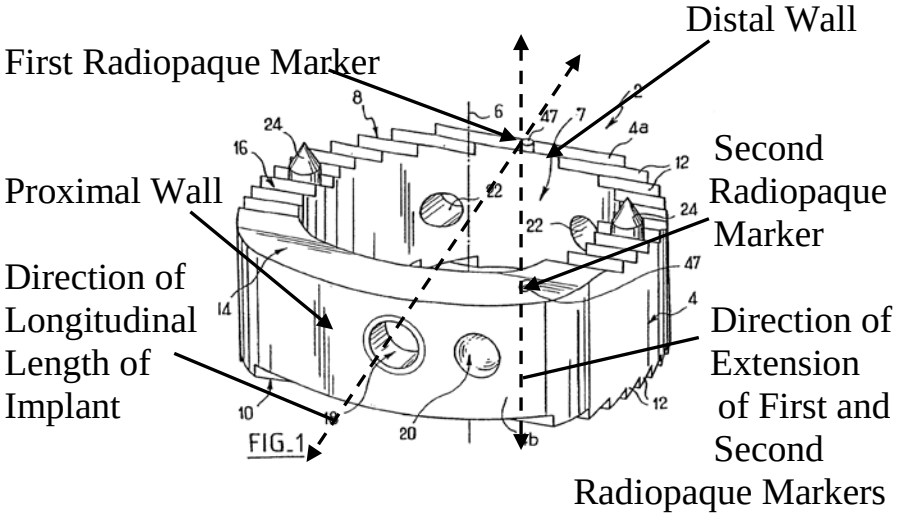
| Claim 17: The spinal fusion implant of claim 1, wherein said first radiopaque marker has an elongate body oriented generally perpendicular to said longitudinal length and extending entirely through a height of said distal wall, and wherein said second radiopaque marker has an elongate body oriented generally perpendicular to said longitudinal length and entirely through a height of said proximal wall. | Frey discloses radiopaque markers in the distal and proximal walls. Baccelli also provides a radiopaque marker (marker 47) that extends along a height of the distal wall of the implant, and another radiopaque marker (marker 47) that extends along a height the proximal wall of the implant. *See* Baccelli, ¶ [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).<br>  <br> |

### C. Ground 3 – Claims 1-3, 10, 14, 15, and 19-28 Are Obvious Under § 103 Over Frey in View of Messerli

As shown in the claim chart below, claims 1-3, 10, 14, 15, and 19-28 of the '334 patent are rendered obvious under § 103 by Frey in view of Messerli.

With respect to elements [A]-[F] and [H]-[J] of Claim 1, as well as Claims 2-3, 10, 19-24, and 26-28, the same analysis for the invalidity of these claims and claim elements over Frey as discussed in Ground 1 is applicable for this ground. *See* Section V.A., *supra*.

While Petitioner asserts that Frey discloses every limitation of Claim 1 (*see* Section V.A., *supra*), as an alternative ground, Petitioner asserts that the combination of Frey and Messerli renders Claim 1 obvious. Messerli provides a spinal fusion implant that has a longitudinal length that is at least two and a half times greater than its width. Due to Frey's similar shape and function to the implant disclosed in Messerli (*see* Figure 63 of Messerli) and its similar function, it would have been obvious to modify the implant disclosed in Frey to include the proportional characteristic in Messerli of being at least two and half times longer than its width to complement the dimensions of the disc space of lumbar vertebrae. (*See* Messerli, ¶ [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.")). Further, as put forth by the PTO in rejecting a similar claim limitation in the parent application of the '334 patent, "[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 time 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* [Exhibit File History, '409 Application] (citing *In re Boesch*, 617 F.2d 272 (CCPA 1980)).

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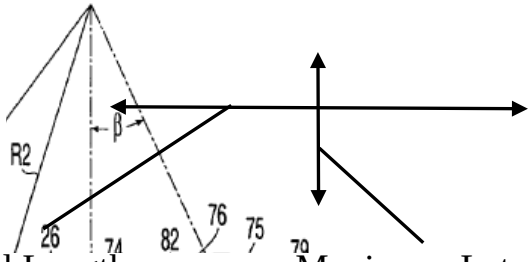
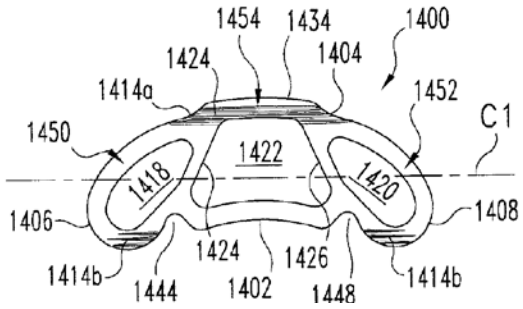
| Claim 1 [G]: wherein said longitudinal length is at least two and half times greater than said maximum lateral width; | Messerli discloses a spinal fusion implant that has a longitudinal length that is at least two and half times greater than its maximum lateral width. *See* Messerli, ¶ [0055] ("The implant may range from about 26 to about 32 mm in length, and have a width from about 9 to 11 mm."). <br> Implant of Messerli   <br> Longitudinal Length Maximum Lateral Width <br> Implant of Frey   |

As discussed above in Ground 1, Claims 14 and 15 add limitations with respect to the claimed radiopaque markers. Claim 14 recites that at least one of the radiopaque markers is an elongate body that extends generally perpendicular to the implant's longitudinal length. While Petitioner asserts that Frey discloses such markers, alternatively, Messerli, like Baccelli, also discloses at least one

radiopaque marker that is an elongate body that extends generally perpendicular to the implant's longitudinal length. It would have been obvious to modify the implant of Frey to include the radiopaque marker of Messerli to provide additional information regarding the orientation or location of an implant during surgery and after implantation. *See* Messerli, ¶ [0061] ("Pins 77 thus enable a physician to better evaluate a postoperative patient and monitor the position of the implant.").

Claim 15 recites that the elongate body of the radiopaque marker of Claim 14 is shorter than a height of the implant. While Petitioner asserts that Frey discloses such limitation, alternatively, Messerli also discloses radiopaque markers that are shorter than a height of the implant. As with the limitation of Claim 14, it would have been obvious to modify the implant of Frey to include the radiopaque marker described in Messerli to provide additional information regarding the orientation or location of an implant during surgery and after implantation. *See id*.

Frey and Messerli 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; Hynes Decl., at ¶ 58.

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| Claim 14: The spinal fusion implant of | Messerli discloses that the implant may also include radiopaque markers that extend generally perpendicular |

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| claim 1, wherein at least one of said three radiopaque markers comprises an elongate body extending generally perpendicular to said longitudinal length. | to the longitudinal length of the implant. *See* Messerli, ¶ [0061] ("The implant may be formed of a radiolucent material selected from the polyaryl ether ketone family (PAEK), such as polyether ether ketone (PEEK) or polyether ketone ketone (PEKK), and may include radiopaque markers, such as pins 77, that act as radiographic markers to aid in positioning and monitoring the position of the implant. Preferably, radiopaque pins 77 extend substantially through the height of the implant so that postoperative spinal scans indicate the size of the implant used in a given patient."). |
| Claim 15: The spinal fusion implant of claim 14, 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. | Messerli provides that the elongate body of the radiopaque marker is shorter than a height extending from the upper surface of the implant to the lower surface of the implant. *See* Messerli, ¶ [0061] ("Preferably, radiopaque pins 77 extend substantially through the height of the implant so that postoperative spinal scans indicate the size of the implant used in a given patient. For example, a radiolucent implant with a 7.0 mm height includes radiopaque pins on the order of 6.0 mm in length, while a 17.0 mm implant has pins on the order of 16.0 mm in length."). |

Claim 25 recites that the implant's height is less than its maximum width. While Petitioner asserts that Frey discloses such proportional limitation, alternatively, Messerli also provides an implant has a maximum width greater than its height. It would have been obvious to 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, ¶ [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 ¶ 129. Frey and

Messerli 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; Hynes Decl., at ¶ 58.

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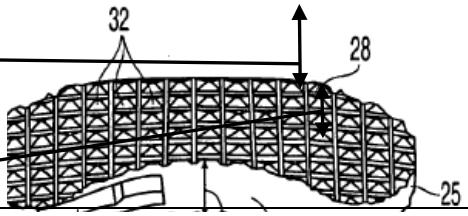
| Claim 25: The spinal fusion implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height. | Messerli provides that the spinal implant may include a maximum lateral width that is greater 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.").<br>Maximum Lateral Width<br>Height<br>  |

### D. Ground 4 – Claims 1-5, 10, 11, 14, 15, and 18-28 Are Obvious Under § 103 Over Frey in View of Michelson

As shown in the claim chart below, Claims 1-5, 10, 11, 14, 15, and 18-28 are rendered obvious under § 103 by Frey in view of Michelson.

With respect to elements [A]-[D] and [F]-[J] of Claim 1, as well as Claims 2-3, 10, 14, 15, 19-24, and 26-28, the same analysis for the invalidity of these claims and claim elements over Frey as discussed in Ground 1 is applicable for this ground. *See* Section V.A., *supra*. Alternatively and additionally, as explained below, claims 4, 5, 11, and 25 are obvious over a combination of Frey and

Michelson. Michelson itself discloses many of the limitations of the claims of the '334 patent, such as the threaded receiving aperture and lateral grooves on the proximal wall, a wider than tall implant, and anti-migration elements on the top and bottom surfaces of the implant perpendicular to the length, 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 ¶ 58.

As discussed above in Section V.A., *supra*, Petitioners assert that Frey discloses all of the limitations of Claim 1 of the '334 patent, including the limitation 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 to one skilled in the art a longitudinal length of 40 mm for a lateral or anterolateral lumbar spinal implant. As an alternative ground for invalidity, Petitioner contends that Michelson discloses this longitudinal length limitation. 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 explicitly disclosed in Michelson so that the implant could sufficiently span the lumbar disc space. *See* Frey, ¶ [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.").

Moreover, as discussed above, Frey discloses using the disclosed implant in lateral and anterolateral approaches to the disc space. It would, therefore, have been obvious to follow the teachings of Michelson for a lateral or anterolateral implant and related surgical technique, including the specific dimensions disclosed by Michelson for an implant inserted laterally or antero-laterally. Frey and Michelson 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, like the NuVasive XLIF implant disclosed in the '334 patent and found to infringe Michelson claims 24, 41, 42, 57 and 61. *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 example lateral fusion implants having an elongated shape, dimensions that are longer than wide and wider than tall 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 11, rendering claim 11 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 lateral grooves for mating with an insertion tool as set forth in claims 4 and 5, 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, in relevant part, 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 25 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. ¶ 58.

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| Claim 1 [E]: wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall; | Frey provides that the length of the implant is "sufficient to span the disc space." *See* Frey, ¶ [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."). Frey also provides that the implant may be inserted using a lateral or antero-lateral approach . *See id.*, at ¶ [0150] ("It is also contemplated that disc space D1 can be accessed and prepared for implant insertion using any other known techniques and instruments and other approaches to the disc space, such as lateral, anterior or antero-lateral approaches, for insertion of implant 1400.").<br><br>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 18 recites that the implant has a maximum lateral width that is approximately 18 mm. Michelson discloses a spinal fusion implant having a maximum width in the range of 14 to 26 mm and an 18 mm embodiment just as

disclosed in the '334 patent. 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 maximum lateral 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 ("As can be seen from FIG. 6, the surface area of the two spinal implants 150 and 152 in contact with the vertebra $V_1$ is substantially less than that of a single translateral spinal fusion implant 100 that is inserted across the transverse width W of the vertebra $V_1$. As a result, a more stable construct is achieved with the translateral spinal fusion implant 100 of the present invention than was previously possible with implants that are inserted from either the front or the back of the patient promoting from stability of the fusion construction."). 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 to obtain greater stability. *See* Hynes Decl., at ¶ 58.

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| Claim 18: The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately | Michelson discloses a laterally implanted spinal fusion implant having a 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. Patent Application Ser. No. 08/394,836 (issued as U.S. Patent No. 5,772,661 (the "'661 patent")) in its entirety by reference, which itself incorporated U.S. Patent Application Ser. No. 08/074,081 (issued as U.S. Patent No. 5,484,437 (the "'437 patent")) in its entirety by reference. The '661 patent discloses an |

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| 18 mm. | 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 ("For the purpose of this example, it will be assumed that by preoperative assessment it was determined that the correct implant would have an external diameter of 18 mm . . ."). |

### E. Ground 5 – Claims 1-3, 10, 14, 15, and 19-28 Are Obvious Under § 103 Over Frey in View of Moret

As shown in the claim chart below, Claims 1-3, 10, 14, 15, and 19-28 are rendered obvious under 35 U.S.C. § 103 by Frey in view of Moret.

With respect to elements [A]-[I] of Claim 1, as well as Claims 2-3, 10, 14, 15, and 19-28, the same analysis for the invalidity of these claims and claim elements over Frey 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 Frey discloses all of the limitations of Claim 1 of the '334 patent, including " at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region." As an alternative grounds, Petitioners contend that Moret also discloses that "a first of the at least three radiopaque markers is at least partially positioned in said distal wall, [and] a second of said at least three radiopaque

markers is at least partially positioned in said proximal wall." It would have been obvious to combine this teaching with the teachings of Frey so that the implant of Frey would include radiopaque markers extending through the proximal and distal walls of the implant to provide an alternative fluoroscopic view, if desired. *See e.g.*, Frey, ¶ [0156] (disclosing use of radiopaque markers for proper positioning of the insert). Additionally, Frey and Moret 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; Hynes Decl., at ¶ 58.

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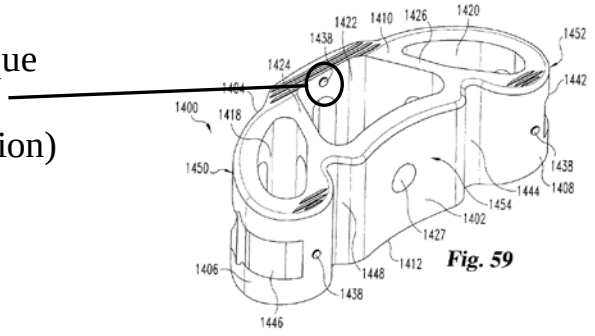
| Claim 1 [J]: at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially | Frey provides that the spinal fusion implant includes at least three radiopaque markers. *See* Frey, ¶ [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."). *See* Section V.A., claim 1[J], *supra*.<br><br>Third Radiopaque Marker (in Central Region)<br>  <br>*Fig. 59* |

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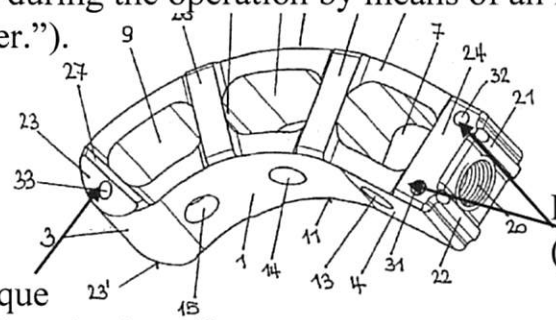
| positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region. | Moret describes a spinal fusion implant that includes radiopaque markers positioned in both the proximal wall and distal wall of the implant. *See* ¶ [0026] ("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 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 |

## VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for claims 1-5, 10, 11, 14-28 of the '334 patent.

Respectfully submitted,

Dated: 14 August 2013

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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 14th day of August 2013 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.

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