IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Curran et al.
U.S. Patent No.: 8,361,156 Attorney Docket No.: 108136.00029
Issue Date: January 29, 2013
Appl. Ser. No.: 13/441,092
Filing Date: April 6, 2012
Title: SYSTEMS AND METHODS FOR SPINAL FUSION

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

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EXHIBITS

MSD 1101 - Declaration of Richard Hynes, M.D. Regarding U.S. Patent No. 8,361,156

MSD 1102 – Declaration of Mary Phelps Regarding Telamon Verte-Stack PEEK Vertebral Body Spacer

MSD 1103 – U.S. Patent Application Publication No. 2002/0165550

MSD 1104 – U.S. Patent Application Publication No. 2003/0028249

MSD 1105 – U.S. Patent No. 5,860,973

MSD 1106 - Synthes Vertebral Spacer-PR Brochure

MSD 1107 - Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure

MSD 1108 – Telamon Implantation Guide

MSD 1109 – Prosecution History of U.S. Patent No. 8,187,334

MSD 1110 – Prosecution History of U.S. Patent No. 7,918,891

MSD 1111 - 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 1112 – *Curriculum Vitae* of Richard Hynes, M.D.

MSD 1113 – 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 1114 – U.S. Patent No. 6,241,770

MSD 1115 – U.S. Patent No. 8,361,156

Medtronic, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-8, 10-14, 19, 20, and 23-27 of U.S. Patent No. 8,361,156 (the "'156 patent"). As set forth below, Petitioner demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of claims 1-14, 19, 20, and 23-27 identified in this petition as being unpatentable.

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

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

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

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

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '156 patent. Petitioner is a named counterclaim-defendant in litigation concerning the '156 patent, *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.*, originally filed in the Northern District of Indiana as Case No. 3:12-cv-00438-JD-CAN on August 17, 2012, and transferred to the Southern District of California on November 8, 2012, as case No. 3:12-cv-02738-CAB-MDD. The '156 patent was added by counterclaim filed on March 7, 2013.

[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 '156 patent on five 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
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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. 108136.00021).

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

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

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

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

Petitioner certifies the '156 patent is eligible for IPR and Petitioner is not barred or estopped from requesting IPR. This petition is filed within one year of service of a counterclaim against Petitioner in district court litigation in which the '156 patent was asserted.

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

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

Ground	'156 Patent Claims	Basis for Rejection
Ground 1	1-14, 19, 20, and 23-27	Obvious under § 103(a) by Synthes Vertebral Spacer–PR ("SVS-PR") (Exhibit MSD 1106) and in view of U.S. Patent Appl. Pub. No. 2002/0165550 to Frey ("Frey") (Exhibit MSD 1103), U.S. Patent Appl. Pub. No. 2003/0028249 to Baccelli ("Baccelli") (Exhibit MSD 1104), and/or U.S. Patent No. 5,860,973 to Michelson ("Michelson") (Exhibit MSD 1105) or Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure ("Telamon Brochure") (Exhibit MSD 1107) and Implantation Guide ("Telamon Guide") (Exhibit MSD 1108) (collectively, "Telamon")[2]
Ground 2	1-14, 19, 20, and 23-27	Obvious Under § 103 over Telamon in view of Frey, Baccelli and/or Michelson or SVS-PR

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. Michelson qualifies as prior art under at least 35 U.S.C. § 102(b) because it issued

[2] The Telamon Brochure and the Telamon Guide both describe the same implant. As such, Petitioner is treating their combined disclosure as a single publication. Alternatively, because they do in fact disclose the same implant, it would have been obvious to combine their disclosures. *See* Hynes Decl., at 54.

more than one year prior to March 29, 2004. The SVS-PR, as shown in a printed and publicly available brochure as of May 2002, qualifies as prior art at least under 35 U.S.C. § 102(b). The Telamon Brochure and the Telamon Guide, printed and publicly available brochures as of 2003, qualify as prior art at least under 35 U.S.C. § 102(a). *See* Declaration of Mary Phelps Regarding Telamon Verte-Stack PEEK Vertebral Body Spacer (Exhibit MSD 1102). None of these references were cited in a rejection during prosecution of the '156 patent.

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

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

1. Distal Wall / Proximal Wall

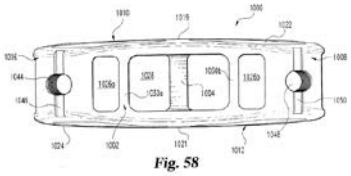


Fig. 58

Under the broadest reasonable construction, the distal wall is the side or end of the implant that generally enters the patient first, i.e. the leading end wall, opposite the proximal or trailing end wall. The proximal wall is the side or end of the implant that enters patient last; opposite of the distal wall.

Further, as discussed in detail in Section IV.B., *infra*, the PTO has previously taken the position that the apertures (1044) shown in the prior art spinal fusion implant figures reproduced 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.

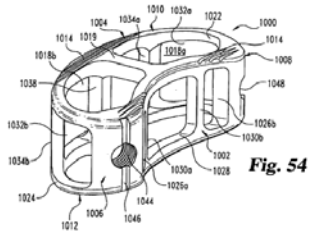


Fig. 54

2. Releasably Mate

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

3. Extend Generally Perpendicular to Said Longitudinal Length

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

4. Elongate Body

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

5. Generally Rectangular and Generally Oblong in Shape

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

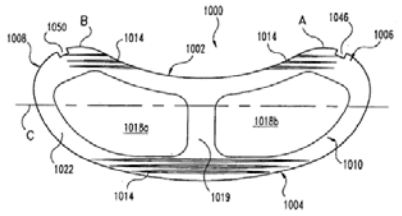


Fig. 53

support of such construction, as discussed in further 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

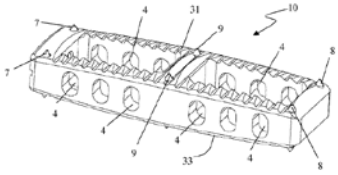
Under the broadest reasonable construction, this term is construed as being oriented generally or roughly along the Y-axis (up and down) or oriented generally or roughly in a direction running from the top to the bottom. *See id.*

IV. SUMMARY OF THE '156 PATENT

A. Overview of the '156 Patent

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

The ‘156 patent is directed to a spinal fusion implant of non-bone construction that is positionable in the interbody space between first and second vertebrae. *See, e.g.,* ‘156 patent, 1:66 to 2:2. As described and claimed, the implant of the ‘156 patent has a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. The length of the implant extending from the proximal wall to the distal wall is greater than the maximum width of the implant, as defined by greatest distance between the two sidewalls. The upper and lower surfaces of the implant contain anti-migration elements that come in contact with the first and second vertebrae. At least one fusion aperture that is longer than it is wide and extends from the top surface to the bottom surface is included in the implant. The claimed implant also contains at least two radiopaque markers oriented generally parallel to the height of the implant, with at least one in the first sidewall, and one in the second sidewall. The ‘156 patent



describes the implant as being manufactured from a radiolucent material so that the markers "will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant 110 during implantation and/or the placement of the implant 110 after implantation." '156 patent, 10:2-9. The '156 patent does not discuss whether or how the size, shape, location, or orientation of the markers is critical to, or otherwise may affect the ability of the surgeon to track the progress or placement of the implant.

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

The prosecution histories of the '156 patent, and of its parent patent, the "'891 patent", as obtained from PAIR, are submitted herewith as Exhibits MSD 1109 and MSD 1110.

The parent '891 patent, like the continued '156 patent, has claims directed to a spinal fusion implant of non-bone construction. The '891 patent issued from U.S. 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 Claim 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 1110, 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.*

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 1110, at 1029-30.

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

C. Legal Standard for Obviousness

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

items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id*. at 1742.

If "a patent 'simply arranges old elements with each performing the function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 1740. When "design incentives and other market forces . . . prompt variations of [an existing device] . . . [and] a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* In short, "a court must ask whether the improvement is more than a predictable use of prior art elements according to their established function." *Id*.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

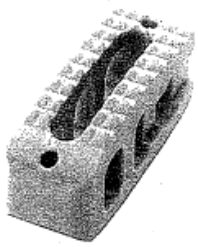
The challenged claims recite spinal fusion implants with features that were well known prior to the earliest possible priority date of the '156 patent. *See e.g.,* Declaration of Richard Hynes, M.D. Regarding U.S. Patent No. 8,361,156 (hereinafter, the "Hynes Decl."), attached hereto as Exhibit 1101, at ¶ 57. As detailed in claim charts below, prior art reference both anticipate and, alternatively, render obvious the challenged claims of the '156 patent.

A. Ground 1 – Claims 1-14, 19, 20, and 23-27 Are Obvious Under § 103 over the SVS-PR in view of Frey, Baccelli and/or Michelson or Telamon

As shown in the claim chart below, claims 1-14, 19, 20, and 23-27 of the '156 patent are obvious under 35 U.S.C. § 103 over the Synthes Vertebral Spacer-PR Brochure ("SVS-PR") in view of Frey, Baccelli, and/or Michelson or Telamon. The specific combinations for each claim are as follows:

Claim	Combination of References
1-4, 7, 8, 11, 12, 14, 19, 20, 23, 24, and 26	SVS-PR and Baccelli
5-8	SVS-PR, Baccelli, and Frey; or SVS-PR, Baccelli, and Michelson
9	SVS-PR, Baccelli, and Michelson
10, 27	SVS-PR and Baccelli, or SVS-PR, Baccelli, and Frey
13	SVS-PR and Baccelli; SVS-PR, Baccelli, and Frey; or SVS-PR, Baccelli, and Michelson
25	SVS-PR, Baccelli, and Telamon; or SVS-PR, Baccelli, and Frey

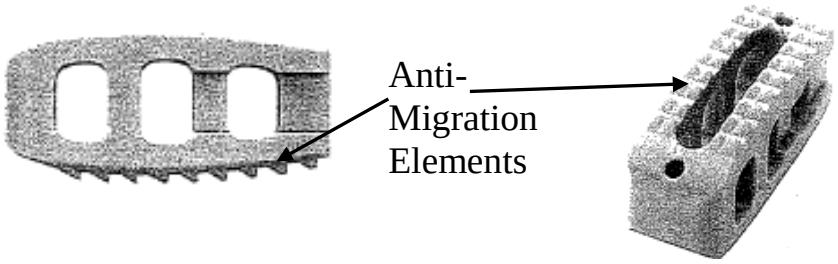
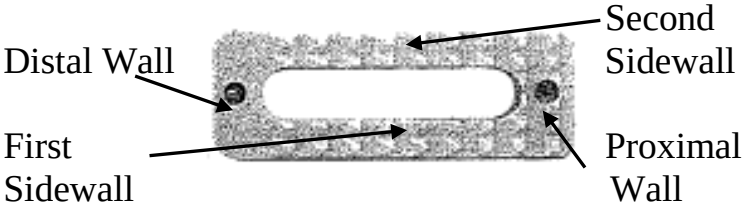
With respect to Claim 1, the SVS-PR Brochure (a representative embodiment of the SVS-PR, is reproduced below), which was not cited during prosecution of the '156 patent, discloses a spinal fusion implant having a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. Additionally, the SVS-PR has a longitudinal length that is greater than its maximum lateral width. The upper and lower surfaces of the SVS-PR also contain anti-migration elements that come in contact with first and second vertebrae. Additionally, the SVS-PR contains at least one fusion aperture

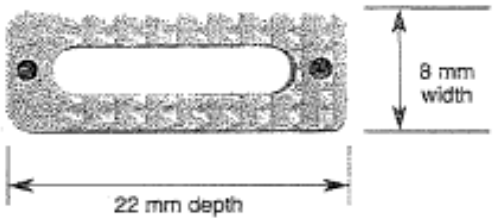


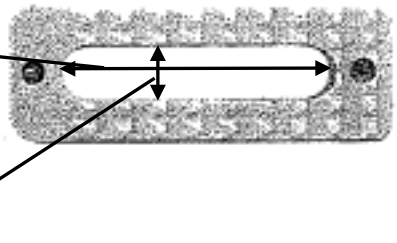
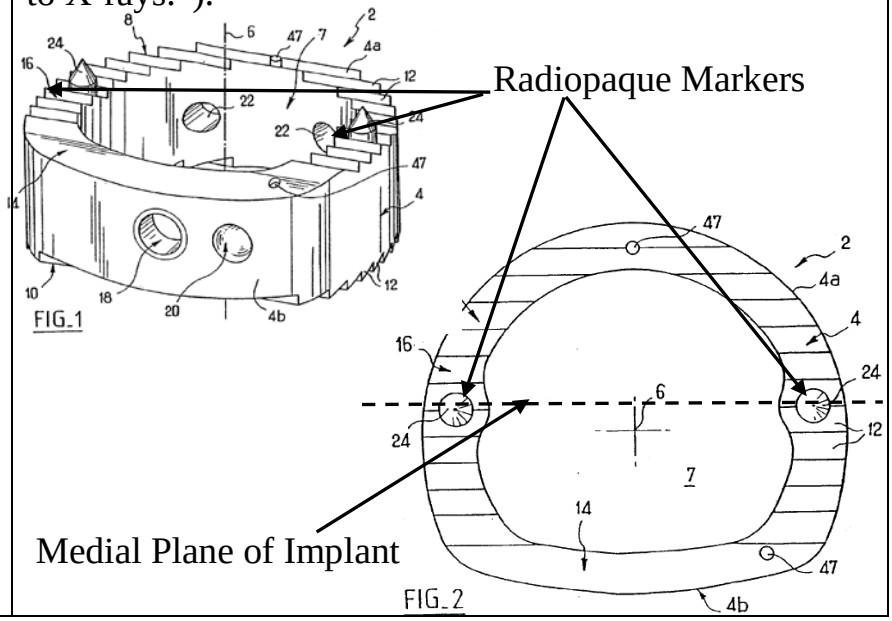
that extends from the top surface to the bottom surface. The fusion aperture of the SVS-PR has a longitudinal length that is greater than its lateral width.

The SVS-PR also discloses the use of radiopaque markers in its distal and proximal walls. Baccelli likewise teaches the use of such markers in a spinal fusion implant, to assist a surgeon in tracking the progress and placement of the implant during and after surgery. *See* Baccelli, at ¶¶ [0050]-[0051] (". . . [T]he cage can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. . . . The spikes 24 . . . too can be made of a material that is opaque to X-rays."). 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. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the SVS-PR implant to provide radiographic markers in the first and second sidewalls thereof as taught by Baccelli, to provide additional information regarding the orientation or location of an implant during surgery and after implantation. *See* Hynes Decl., at ¶ 67. Modifying the SVS-PR implant based on teachings of Baccelli represents nothing more than an application of known prior art elements to improve a similar device in the same way. Furthermore, the SVS-PR modified in accordance with the teachings of Baccelli is

merely a combination of prior art elements according to known methods to yield predictable results. *See id*. Accordingly, such modification of the SVS-PR implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

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:	The SVS-PR describes a spinal fusion implant constructed from a biocompatible radiolucent polymer, which is intended for implantation between first and second vertebral endplates.
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,	The upper and lower surfaces of the SVS-PR have anti-migration elements to contact the first and second vertebrae. SVS-PR Brochure, at 1 ("Saw-tooth pattern on superior and inferior surfaces of implant is designed to provide secure engagement with adjacent vertebral bodies."). 
Claim 1 [C]: a distal wall, a proximal wall, a first sidewall and a second sidewall generally opposite from the first sidewall,	The SVS-PR has a distal wall, a proximal wall, a first sidewall and a second sidewall generally opposite from the first sidewall. *See* SVS-PR Brochure, at 1. 
Claim 1 [D]: wherein said distal wall,	The SVS-PR is constructed from a "[b]iocompatible radiolucent polymer [that] allows clear assessment of

proximal wall, first sidewall, and second sidewall comprise a radiolucent material;	bony fusion." SVS-PR Brochure, at 1.
Claim 1 [E]: wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and said longitudinal length is greater than said maximum lateral width;	The SVS-PR Brochure provides that the SVS-PR has a longitudinal length that is two and half times greather than the maximum lateral width. *See* SVS-PR Brochure, at 1 (disclosing that implant has an axial footprint of 22 mm by 8 mm). 
Claim 1 [F]: at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space,	The SVS-PR includes a "single axial canal [that] receives autograft to allow fusion to occur through the implant." As shown in the figure below, this first fusion aperture extends through the upper surface to the lower surface. *See* SVS-PR Brochure, at 1.  First Fusion Aperture
Claim 1 [G]: said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of	The first fusion aperture of the SVS-PR has a longitudinal length greater than its lateral width. *See* SVS-PR Brochure, at 1.

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	
Claim 1 [H]: at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane.	Baccelli discloses a spinal fusion implant having at least first and second radiopaque markers (spikes 24) that extend into a first sidewall and a second sidewall at positions proximate to a medial plane of the implant. *See* Baccelli, at ¶ [0041] ("The cage has spikes 24, in this case four such spikes, i.e. two associated with each of the main faces 8 and 10. Each spike has a pointed end and it projects from the associated main face. The two spikes on each face are disposed symmetrically to each other about the sagittal midplane. In addition, they extend in the frontal midplane containing the axis 6. Each spike on one face extends in register with a spike on the other face."); ¶ [0051] ("The spikes 24 can be inserted and fixed rigidly in the ducts formed in the cage. They too can be made of a material that is opaque to X-rays."). 

Claims 2-4 add limitations directed to the radiopaque markers featured in the implant. Baccelli discloses the additional limitation of claim 2, as Baccelli teaches first and second radiopaque markers that are substantially equally spaced apart from the proximal end of the proximal wall of the implant by a first longitudinal distance. With respect to claim 4, Baccelli discloses that its radiopaque markers (spikes 24) can extend entirely through a height of the walls of the implant. Therefore, modification of the markers 47, located in the proximal and distal walls to be similar to the spikes 24 of Baccelli to extend entirely through the height of the end walls is merely a trivial tweak of this known feature of Baccelli in a predictable and common sense manner. *See* Hynes Decl., at ¶¶ 72, 74.

It would have been obvious to one of ordinary skill at the time of invention to modify the SVS-PR implant to incorporate the additional features of claims 2 and 4 based on the teachings of Baccelli. One of ordinary skill would have found it obvious to configure the radiographic markers of the SVS-PR implant as disclosed in Baccelli, to facilitate additional imaging information regarding the orientation or location of an implant during surgery and after implantation, in response to known a design need to "identify the position and/or the presence of the implant when x-rays are taken during the operation." *See* Hynes Decl., at ¶ 69. Modifying the SVS-PR implant based on teachings of Baccelli represents nothing more than an application of known prior art elements to improve a similar device

in the same way. *See id*. Furthermore, the SVS-PR modified in accordance with the teachings of Baccelli is merely a combination of prior art elements according to known methods to yield predictable results. *See id*. Accordingly, such a modification of the SVS-PR implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

With respect to claim 3, the SVS-PR teaches a radiopaque marker that extends into the implant's distal wall, and a radiopaque marker that extends into the implant's proximal wall.

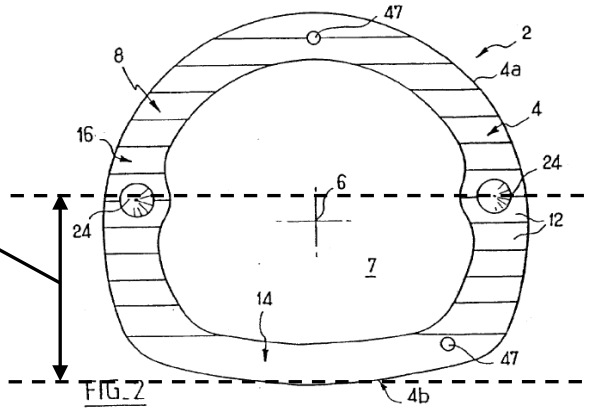
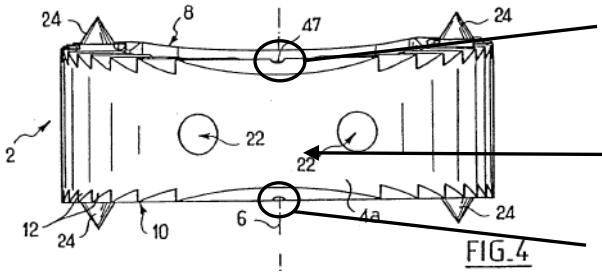
<table>
<tr>
<td>Claim 2: The spinal fusion implant of claim 1, wherein the first and second radiopaque markers are substantially equally spaced apart from said proximal end of said proximal wall by a first longitudinal distance.</td>
<td>The radiopaque markers (spikes 24) present on the implant described in Baccelli are both located the same distance, a first longitudinal distance, away from the proximal wall of the implant. See Baccelli, at ¶ [0041] ("The two spikes on each face are disposed symmetrically to each other about the sagittal midplane.").
First Longitudinal Distance
 

FIG. 2</td>
</tr>
<tr>
<td>Claim 3: The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and</td>
<td>The SVS-PR has a radiopaque marker that extends into the distal wall and a radiopaque marker that extends into the proximal wall. See SVS-PR Brochure, at 1.
Radiopaque Marker in Distal Wall
 
Radiopaque Marker in Proximal Wall</td>
</tr>
</table>

a fourth radiopaque marker that extends into said proximal wall.	
Claim 4: The spinal fusion implant of claim 3, wherein said third radiopaque marker extends entirely through a height of said distal wall, and wherein said fourth radiopaque marker extends entirely through a height of said proximal wall.	SVS-PR and Baccelli each disclose a radiopaque marker extends along a height of the distal wall, and a radiopaque marker extends along a height of the proximal wall. *See* Baccelli, at ¶ [0050] ("In this case, there are two markers 47 . . . inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall."); Fig. 49 (showing marker 47 extending along a height of distal wall). 

Claims 5-8 add limitations directed to a receiving aperture located on the proximal wall of the implant. The SVS-PR includes a receiving aperture on the proximal wall that has a central axis that is generally parallel to the longitudinal length of the implant from insertion to trailing end, and discloses that the aperture is configured to releasably mate with an inserter tool. Frey, Michelson and Baccelli each disclose the use of a threaded receiving aperture. It would have been obvious to modify the SVS-PR to include such a threaded receiving aperture to provide, *inter alia*, more axial stability in the temporary connection between the implant and the inserter tool during implantation. *See* Hynes Decl., at ¶ 87. This obvious combination applies known prior art elements to improve a similar device

in the same way. *See id*. Furthermore, the combination represents a combination of prior art elements according to known methods to yield predictable results. *See id*. Accordingly, such a modification of the SVS-PR would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predicable solution to a known design need. *See id*.

Claim 5 also recites that the longitudinal length of the implant is greater than 40 mm. With respect to the length of the implant, Frey discloses 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 laterally or anterolaterally implanted lumbar spinal implant. *See* Hynes Decl., at ¶ 81. Similarly, Michelson discloses a spinal fusion implant that may have 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."). One of ordinary skill in the art would have been motivated to apply the teachings of Frey or Michelson to the SVS-PR implant to include a longitudinal length greater than 40 mm extending from a proximal end of the proximal wall to a distal end of the distal wall to span the disc space and allow the implant to provide more stable support for the vertebra and bear against the relatively stronger apophyseal ring. *See* Hynes Decl., at ¶ 81.

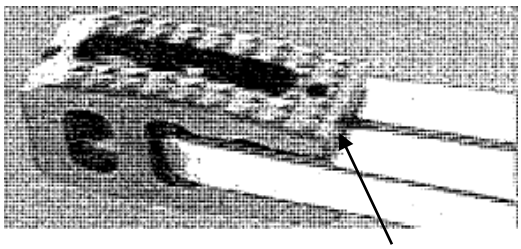
See also e.g., U.S. Patent No. 6,241,770 (the "'770 patent") at 7:65–8:14 ("It can be seen that in one embodiment of the implant 100 of the present invention, trailing end 104 is arcuate to be in conformation to the peripheral profile of the anterior aspect of the vertebral bodies where the implant is in contact with the vertebral bodies so as to allow the implant to have both a maximum safe width and length, and to sit on the peripheral vertebral body rim, including the anterior cortex and/or the apophyseal rim. This allows the implants of the present invention to have the maximum surface area of contact with the vertebrae, the greatest volume for holding osteogenic material, to sit upon the very good structural bone present at the periphery of the vertebral bodies, to have a greater surface over which to have bone engaging surface irregularities, and as a result of this combination to have the greatest stability of the implant itself and in turn to stabilize the vertebrae relative to each other.").

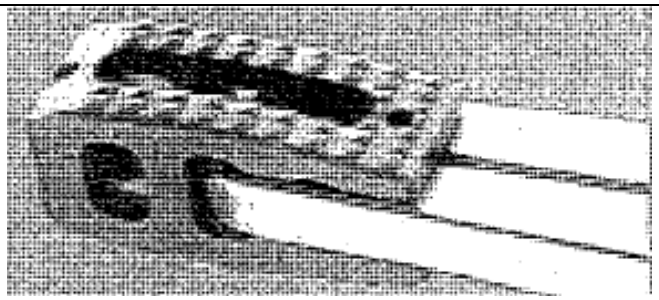
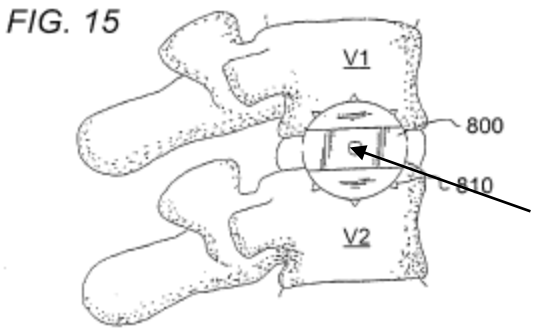
Moreover, where, as here, a skilled artisan were inclined to provide an implant for lateral insertion, the artisan would have been taught by Michelson to make the length of the implant 40 mm or greater. In particular, the '156 patent indicates that the claimed length of 40 mm or greater is specifically tailored to an implant intended for lateral insertion. '156 patent, at 11:58-63 ("FIG. 20 illustrates an implant 10 dimensioned particularly for use in a lateral approach (XLIF^{TM} by NuVasive) having (by way of example only) . . . a length ranging between 40 and

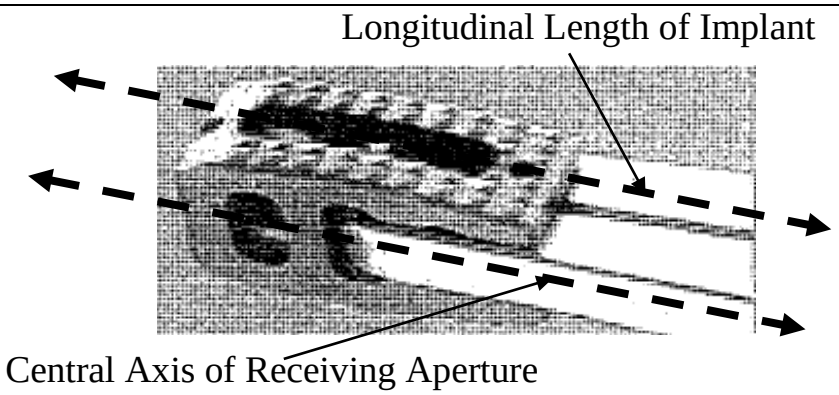
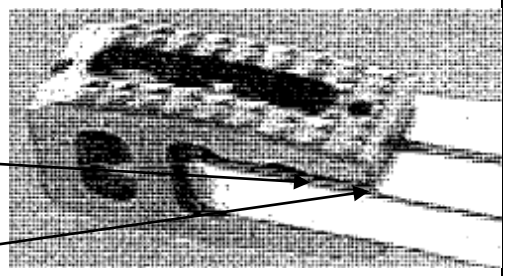
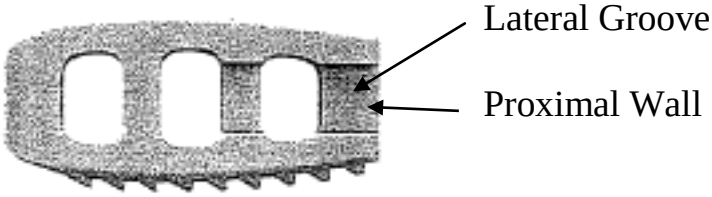
45 mm.); 5:29-31 ("The implant 10 is particularly suited for introduction into the disc space via a lateral (trans-psoas) approach to the spine . . . ."). The implant of Michelson likewise is identified as being configured for lateral insertion. *See e.g.*, Michelson, at 1:16-19 ("This invention relates generally to spinal fusion implants, and more particularly to spinal fusion implants for insertion from the side of a patient (translateral) across the transverse width of the spine and between two adjacent vertebrae."). Thus, in view of the explicit teaching of Michelson to make an implant with a preferred length of 42 mm, as well as the implicit teaching in Michelson (as exemplified in the explicit teachings in the Michelson '770 patent) with regard to the desire to seat a laterally inserted implant to preferably sit on the apophyseal ring, the 40mm or greater length claimed in the '156 patent represents nothing more than an application-specific dimensional optimization in accordance with the prior art. *See* Hynes Decl., at ¶ 81.

Accordingly, increasing the length of the SVS-PR implant to 40mm or greater would have involved nothing more than routine optimization, combining prior-art elements according to known methods to yield predictable results, and the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

The SVS-PR also includes a pair of lateral grooves positioned in its proximal wall and extending laterally of the threaded receiving aperture as recited in Claim 8.

Claim 5[A]: The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall	 The SVS-PR includes a receiving aperture positioned in the proximal wall of the implant. *See* SVS-PR Brochure, at 1. Receiving Aperture in Proximal Wall
Claim 5 [B]: wherein said longitudinal length is greater than 40 mm.	Both Frey and Michelson provide that a spinal fusion implant may have a longitudinal length that is greater than 40 mm. *See* Michelson at 10:41-46 ("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."); Frey at ¶ [0130] ("[I]mplant 370, which can have features such as those described below with respect to implant 1000, is placed in the disc space D1 and has a length sufficient to span the disc space from the distal portion 37 to the proximal portion 41.") . With respect to Frey, 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) ("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 6: The spinal fusion implant of claim 5, wherein said threaded receiving	As shown in the SVS-PR Brochure, the receiving aperture of the SVS-PR is configured to releasably mate with an inserter tool. *See* SVS-PR Brochure, at 1.

aperture is configured to releasably mate with an inserter tool.	 Baccelli, Michelson and Frey each disclose threaded receiving apertures located on the proximal wall of the implant. *See* Baccelli at ¶ [0044] ("To put the cage into place, it is advantageous to use a fitting tool 40 such as the tool shown in FIGS. 8 and 9. . . . The tool has a threaded endpiece 48 emerging from the center of the face 46 of the head and movable relative thereto, being drivable from the other end of the tool. This endpiece is suitable for threaded engagement with the mounting orifice 18 of the cage."); Frey, at ¶ [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."); Michelson, at 6:28-35 (incorporated disclosure describing engaging end in Michelson for example, of Figures 1, 3, 5, 8, 10, 13, 15).  Threaded Receiving Aperture of Michelson
Claim 7: The spinal fusion implant of claim 6, wherein said receiving	The receiving aperture of the SVS-PR has a central axis generally parallel to the longitudinal length of the implant. The threaded nature of the aperture is discussed above regarding claim 6 in view of Baccelli or Michelson threaded aperture along the longitudinal axis.

aperture comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant.	
Claim 8: The spinal fusion implant of claim 7, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally of said threaded receiving aperture.	The SVS-PR includes a pair of lateral grooves position in the proximal wall that extend laterally of the receiving aperture. See SVS-PR Brochure, at 1.  

Claim 9 recites that the implant has a maximum lateral width that is approximately 18 mm. Michelson discloses a spinal fusion implant having a width in the range of 14 to 26 mm and also specifically discloses an incorporated 18 mm lumbar spinal fusion implant embodiment. One of ordinary skill in the art would have been motivated to apply this teaching of Michelson to modify the SVS-PR 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."). *See* Hynes Decl., at ¶ 98. If a person were inclined to provide an implant for lateral insertion to obtain a more stable construct and/or increased surface area it would have been obvious to combine the teaching of Michelson with the SVS-PR to achieve the combination as set forth in the '156 patent claims below. *See* Hynes Decl., at ¶ 98. The combination represents a combination of prior art elements according to known methods to yield predictable results. *See id*. The SVS-PR and Michelson are from the same field of intervertebral artificial implants used in spinal fusion and share many similar attributes for obtaining the same or similar results, like the NuVasive XLIF implant disclosed in the '156 patent found to infringe the Michelson claims. *See id*; *see also* 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 (Exhibit MSD 1111). Accordingly, such a modification of the SVS-PR implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

Claim 9: The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.	Michelson discloses a laterally implanted spinal fusion implant having a maximum lateral width in the range of 14 to 26 mm. *See* Michelson, at 7:26-30. ("In the thoracic spine such implants would have a length in the range of 12-30 mm, and 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 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 . . .").

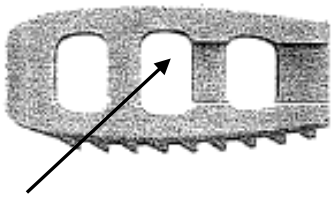
Claim 10 recites that the radiolucent material of the implant comprises polyether ether ketone (PEEK). The SVS-PR Brochure discloses that the SVS-PR is "manufactured from a biocompatible radiolucent polymer material, which allows the surgeon to radiographically assess the presence of fusion in the segment in which the [SVS-PR] has been implanted." SVS-PR, at 2. The SVS-PR brochure further discloses that this polymer has a modulus of elasticity that approximates

that of human cortical bone. *See id.* This material is PEEK or something very similar to PEEK. *See* Hynes Decl., at ¶ 101. Moreover, numerous other spinal fusion implants, including Frey and Baccelli, disclose the use of PEEK. *See e.g.*, Baccelli, at ¶ [0050]. In the alternative, to the extent the brochure is interpreted otherwise, it would have been an obvious modification of the SVS-PR applying known prior art elements to provide a similar device in the same way made of PEEK. *See* Hynes Decl., at ¶ 102. Furthermore, the combination represents a combination of prior art elements according to known methods to yield predictable results. *See id.*

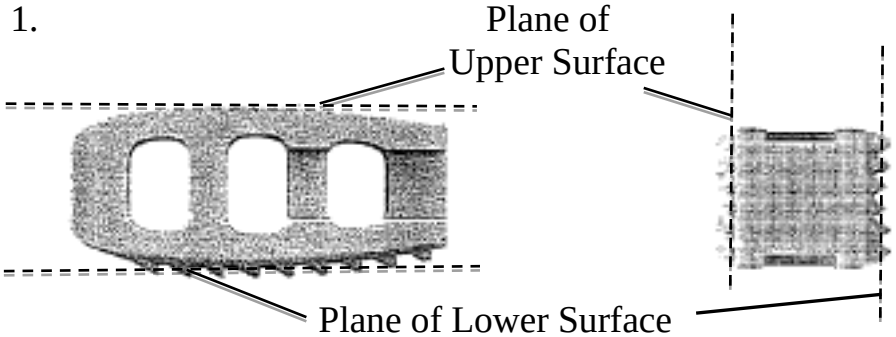
Claim 10: The spinal fusion implant of claim 1, wherein said radiolucent material comprises PEEK.	The SVS-PR Brochure discloses that the SVS-PR implant is "manufactured from a biocompatible radiolucent polymer material, which allows the surgeon to radiographically assess the presence of fusion in the segment in which the [SVS-PR] has been implanted." SVS-PR, at 2. Frey provides that its spinal implant may be made from PEEK, which is a biocompatible radiolucent polymer. *See* Frey, ¶ [0181] ("The implants described herein can be made from any biocompatible material, including synthetic . . . and can be . . . non-resorbable nature. . . . 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."). Additionally, Baccelli provides that radiolucent material of the spinal fusion implant may comprise PEEK. *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).").

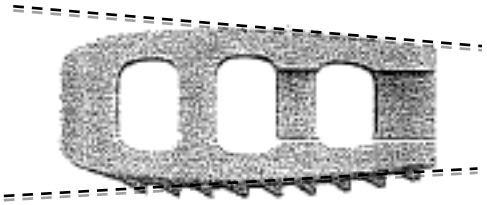
Claim 11 recites the inclusion of at least one visualization aperture extending through at least one of the first or second sidewalls. The SVS-PR includes the

claimed visualization apertures in both the first and second sidewalls of the implant.

Claim 11: The spinal fusion implant of claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.	The SVS-PR includes visualization apertures on both the first and second sidewalls. *See* SVS-PR Brochure, at 1.  Visualization Aperture

Claims 12 and 13 add limitations with respect to the angular relationship between the upper and lower surfaces of the implant. The SVS-PR teaches the claimed limitation of Claim 12 because the upper and lower surfaces of the implant are generally parallel to each other. The SVS-PR also teaches the limitation recited in Claim 13 as it discloses that the upper and lower surfaces are angled relative to one another to correspond to the anatomy of the spine. In the alternative, it would have been obvious, if inserting this implant laterally, to design it to impart lordosis in the appropriate directions as taught by Frey or Michelson. *See* Hynes Decl., at ¶ 107.

Claim 12: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another.	The SVS-PR has upper and lower surfaces that are generally parallel to each other. *See* SVS-PR Brochure, at 1. 

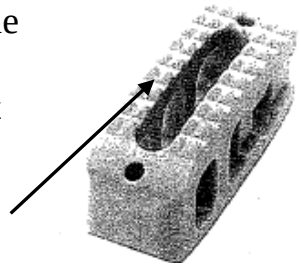
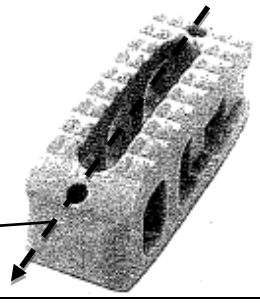
Claim 13: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.	The SVS-PR has upper and lower surfaces that are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when the implant is positioned within the interbody space. *See* SVS-PR Brochure, at 1 ("Convex superior and inferior surfaces enhance anatomical interface with vertebral endplates."). Alternatively, Frey and Michelson provide implants with top and bottom surfaces that angled relative to each other to correspond to lordosis. *See* Frey, ¶ [0152] ("[T]he 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."); Michelson, at 3:39-43 ("The height of such an implant . . . may be wedged so as to reproduce anatomic lordosis."). 

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

Claim 14: The spinal	The fusion aperture of the SVS-PR is one of generally

fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.	rectangular and generally oblong in shape. *See* SVS-PR Brochure, at 1. 

Claims 19 and 20 further describe the anti-migration elements located on the upper surface of the implant. Claim 19, which recites that the anti-migration elements on the upper and lower surfaces of the implant comprise a plurality of ridges, is taught by the SVS-PR. Claim 20, which recites that the plurality of ridges extend generally perpendicular to the longitudinal length of the implant is also taught by the SVS-PR.

Claim 19: The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges.	The anti-migration elements of the SVS-PR comprise a plurality of ridges. *See* SVS-PR Brochure, at 1. 
Claim 20: The spinal fusion implant of claim 10, wherein said plurality of ridges extend generally perpendicular to said longitudinal length.	The plurality of ridges present on the SVS-PR extend generally perpendicular to the longitudinal lenth of the implant. *See* SVS-PR Brochure, at 1. 

Claims 23-25 add proportional limitations to the implant claimed in Claim 1. Claim 23 recites that the "maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width

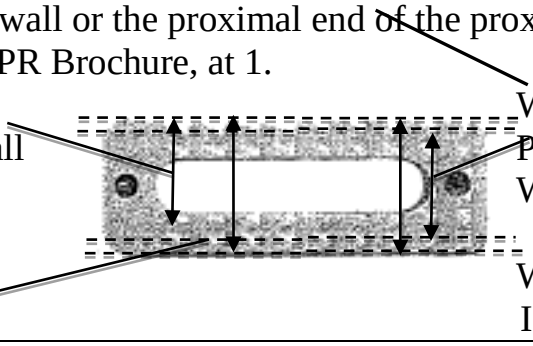
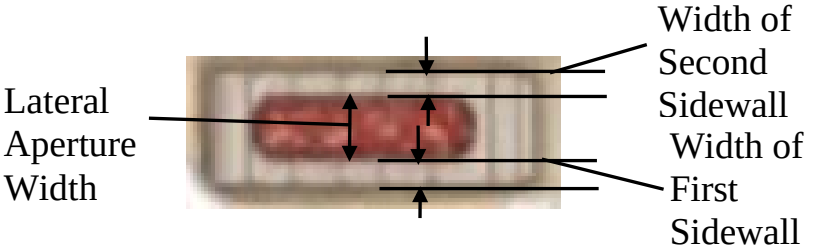
of the proximal end of said proximal wall." Due to the generally rectangular shape and rounded corners of the SVS-PR, the maximum lateral width of the implant is necessarily greater than the lateral width of either the distal end of the distal wall or proximal end of the proximal wall. Alternatively, it would have been obvious to modify the SVS-PR to reduce the width at the distal and proximal ends as disclosed in Frey to fit the anatomical constraints of the patient and/or ease insertion. *See* Hynes Decl., at ¶ 119.

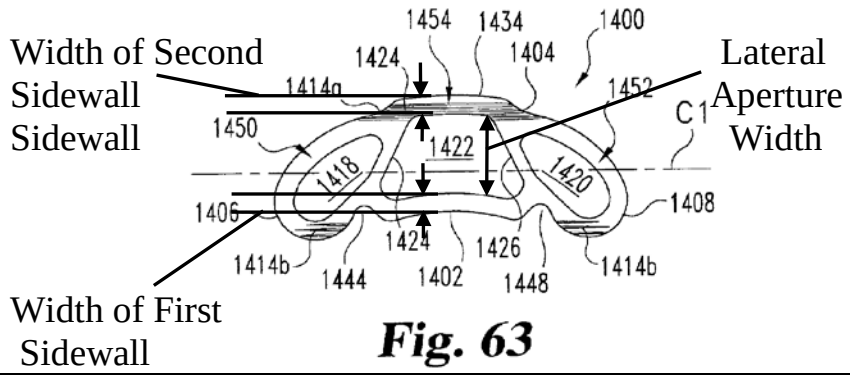
Claim 24 recites that the implant's height is less than its maximum lateral width. The SVS-PR Brochure provides that the implant may have a 7 mm height, which is less than its maximum lateral width of 8 mm.

Claim 25 requires that the lateral aperture width of the first fusion aperture is more than two times greater than a lateral thickness of the first sidewall and more than two times greater than a lateral thickness of the second sidewall. This feature would either be obvious in view of the SVS-PR or obvious in combination with the aperture disclosed in the Telamon, *infra*. *See* Hynes Decl., at ¶ 129.

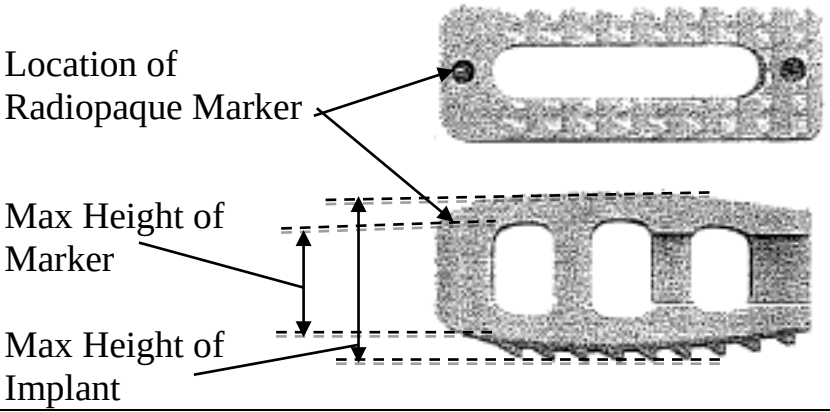
Additionally, the proportional limitations contained in Claims 23-25 do not impact the functionality of the device so as to make it patentably distinct from the prior art implant disclosed in Frey. *See Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984)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

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

Claim 23: The implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall.	The SVS-PR has a maximum lateral width that is larger than the width of either the widths of the distal end of the distal wall or the proximal end of the proximal wall. *See* SVS-PR Brochure, at 1. 
Claim 24: The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.	The SVS-PR Brochure provides that the implant may have a height of 7 mm, which is less than the disclosed 8 mm width of the implant. *See* SVS-PR Brochure, at 1-2.
Claim 25: 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 than a lateral thickness of said second sidewall.	Telamon Brochure and the Telamon Guide that the width of the first fusion aperture of the Telamon is more than two times greater than the thickness of its first and second sidewalls. See Telamon Brochure, at 1; Telamon Guide, at 7. Additionally, Frey and Baccelli disclose that the width of the first fusion aperture of the respective implants is more than two times greater than the thickness of its first and second sidewalls. *See* Frey, at Fig. 63; Baccelli, at Fig. 2. 

	 ***Fig. 63***

Claim 26 recites that the elongate body of at least one of the radiopaque markers described in Claim 1 is shorter than the height of the implant. Because the maximum height of the radiopaque marker of the SVS-PR is limited to the height of the distal or proximal wall, due to the shorter height of the implant ends and markers that do not protrude above the surface of the implant, the SVS-PR Brochure discloses radiopaque markers that are shorter than the height of the implant in its central region.

Claim 26: The spinal fusion implant of claim 1, wherein said elongate body of at least one of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface.	The elongate body of a radiopaque marker of the SVS-PR is shorter than the height of the implant due to the convex shape of the upper and lower surfaces of the implant. *See* SVS-PR Brochure, at 1. 

Claim 27 adds the limitation that "osteoinductive material [is] positioned with[in] said first fusion aperture." The SVS-PR Brochure provides that the SVS-PR may include osteogenic material placed within its fusion aperture. In the alternative, it would have been obvious to combine with such material as was well known in the field. *See* Hynes Decl., at ¶ 137; *see also* Frey, at ¶ [0140] ("Implant 1000 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 vertebrae V1 and V2.").

Claim 27: The spinal fusion implant of claim 1, further comprising an osteoinductive material positioned with said first fusion aperture.	The SVS-PR includes an osteoinductive material positioned with the first fusion aperture. *See* SVS-PR Brochure, at 1 ("Axial canal receives autograft or other graft material to allow fusion to occur through the implant.").

B. Ground 2 – Claims 1-14, 19, 20, and 23-27 Are Obvious Under § 103 over Telamon in view of Frey, Baccelli and/or Michelson or SVS-PR

As shown in the claim chart below, claims 1-14, 19, 20, and 23-27 of the '156 patent are obvious under 35 U.S.C. § 103 over the Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure ("Telamon Brochure") and the Telamon Implantation Guide ("Telamon Guide") (collectively, "Telamon") in view of Frey, Baccelli, and/or Michelson or SVS-PR. The specific combinations for each claim are as follows:

Claims	Combination of References
1, 2, 4, 7, 10-14,	Telamon and Baccelli

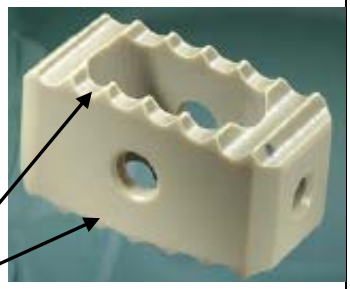
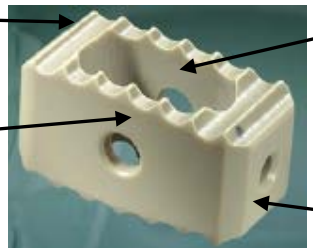
19, 20, and 23-27	
3	Telamon and Baccelli, or Telamon, Baccelli and Frey
5-7	Telamon, Baccelli, and Frey, or Telamon, Baccelli, and Michelson
8	Telamon, Baccelli, Frey, and SVS-PR or Telamon, Baccelli, and Michelson
9	Telamon, Baccelli, and Michelson

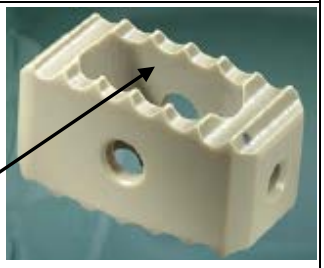
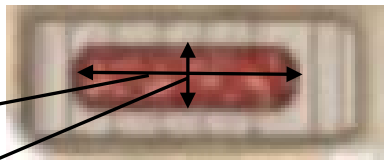
With respect to Claim 1, Telamon Brochure (a representative embodiment of the Telamon implant, is reproduced below), which was not cited during prosecution of the '156 patent, disclose a spinal fusion implant having a distal wall, a proximal wall, and two sidewalls, with the walls being at least partly constructed from a radiolucent material. Additionally, the Telamon implant has a longitudinal length that is greater than its maximum lateral width. The upper and lower surfaces of the Telamon implant also contain anti-migration elements that come in contact with first and second vertebrae. Additionally, the Telamon implant contains at least one fusion aperture that extends from the top surface to the bottom surface. The fusion aperture of the Telamon implant has a longitudinal length that is greater than its lateral width.

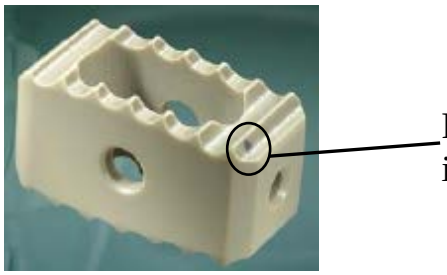
The Telamon Brochure and the Telamon Guide both disclose the use of radiopaque markers in the implant's distal and proximal walls. Baccelli likewise teaches the use of such markers in a spinal fusion implant, to assist a surgeon in tracking the progress and placement of the implant during and after surgery. *See*

Baccelli, at ¶¶ [0050]-[0051] (". . . [T]he cage can have one or more markers 47 included therein and serving, because they are opaque to X-rays, to identify the position and/or the presence of the implant when X-rays are taken during or after the operation. . . . The spikes 24 . . . too can be made of a material that is opaque to X-rays."). 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. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Telamon implant to provide radiographic markers in the first and second sidewalls thereof as taught by Baccelli, to provide additional information regarding the orientation or location of an implant during surgery and after implantation. Modifying the SVS-PR implant based on teachings of Baccelli represents nothing more than an application of known prior art elements to improve a similar device in the same way. *See* Hynes Decl., at ¶ 67. Furthermore, the Telamon implant modified in accordance with the teachings of Baccelli is merely combination represents a combination of prior art elements according to known methods to yield predictable results. *See id.* Accordingly, such a modification of the Telamon implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id.*

Claim 1 [A]: A spinal fusion implant of non-bone	The Telamon describes a spinal fusion implant constructed from a biocompatible radiolucent

construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:	polymer, which is intended for implantation between first and second vertebral endplates. *See, e.g.*, Telamon Brochure, at 1-3; Telamon Guide, at 1-8.
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,	The upper and lower surfaces of the Telamon have anti-migration elements to contact the first and second vertebrae. Telamon Brochure, at 1.  Anti-Migration Elements
Claim 1 [C]: a distal wall, a proximal wall, a first sidewall and a second sidewall generally opposite from the first sidewall,	TheTelamon has a distal wall, a proximal wall, a first sidewall and a second sidewall. *See* Telamon Brochure, at 1. Distal Wall Second Sidewall  First Sidewall Proximal Wall
Claim 1 [D]: wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;	The Telamon is constructed from PEEK, which is a radiolucent material. *See* Telamon Brochure, at 2.
Claim 1 [E]: wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said	The Telamon Brochure provides that the Telamon has a 10 mm width, and may have a length of 26 mm. *See* Telamon Brochure, at 2 (disclosing that implant has "[c]onsitent 10 mm width" and ceratain embodiments may have a 26 mm length).

implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and said longitudinal length is greater than said maximum lateral width;	
Claim 1 [F]: at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space,	The Telamon includes a fusion aperture that extends through the upper surface to the lower surface. *See* Telamon Brochure, at 1.  First Fusion Aperture
Claim 1 [G]: said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and	The fusion aperture of the Telamon has a longitudinal length greater than its lateral width. *See* Telamon Guide, at 7.  Longitudinal Length of Fusion Aperture Lateral Width of Fusion Aperture
Claim 1 [H]: at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a	The Telamon Brochure depicts the Telamon implant as having at least a radiopaque marker that partially positioned in the proximal wall. *See* Telamon Brochure, at 1. The Telamon Brochure additionally discloses the use of multiple radiopaque markers. *See* Telamon Brochure, at 1-2 (disclosing that a design feature of Telamon is "Tantalum

position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane.	Radiographic markers").  Baccelli discloses an implant having at least first and second radiopaque markers (spikes 24) that extend into a first a second sidewall at positions proximate to a medial plane of the implant. *See* Section V.A., Claim 1[H], *supra* (incorporated here).

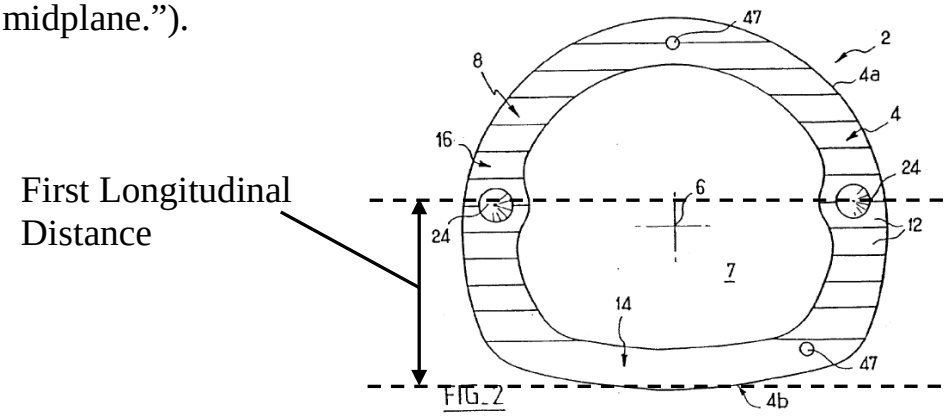
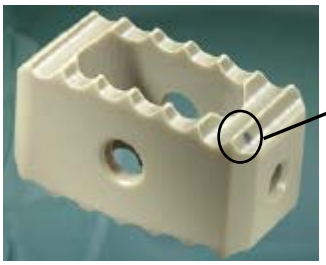
Claims 2-4 add limitations directed to the radiopaque markers featured in the implant. With respect to claim 3, the Telamon Brochure discloses that the implant may include at least one radiopaque marker in the proximal wall. By use of the term "markers" in the Telamon Brochure, it is inherent or, alternatively, obvious to provide a radiopaque marker in the distal wall. *See* Hynes Decl., at ¶ 71.

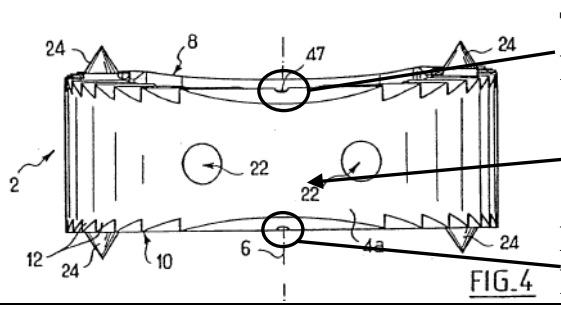
Baccelli discloses the added limitation of claim 2, as Baccelli teaches first and second radiopaque markers that are substantially equally spaced apart from the proximal end of the proximal wall of the implant by a first longitudinal distance. With respect to claim 4, Baccelli discloses that its radiopaque markers (spikes 24) can extend entirely through a height of the walls of the implant. Therefore, modification of the markers 47, located in the proximal and distal walls to be similar to the spikes 24 of Baccelli to extend entirely through the height of the end

walls is merely a trivial tweak of this known feature of Baccelli in a predictable and common sense manner. *See* Hynes Decl., at ¶¶ 72, 74.

It would have been obvious to one of ordinary skill at the time of invention to modify the Telamon implant to include incorporate the additional features of claims 2 and 4 based on the teachings of Baccelli. One of ordinary skill would have found it obvious to configure the radiographic markers of the SVS-PR implant as disclosed in Baccelli, to facilitate additional imaging information regarding the orientation or location of an implant during surgery and after implantation, in response to known a design need to "identify the position and/or the presence of the implant when x-rays are taken during the operation." Modifying the Telamon implant based on teachings of Baccelli represents nothing more than an application of known prior art elements to improve a similar device in the same way. *See* Hynes Decl., at ¶ 69. Furthermore, the SVS-PR modified in accordance with the teachings of Baccelli is merely a combination of prior art elements according to known methods to yield predictable results. *See id*. Accordingly, such a modification of the Telamon implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

Claim 2: The spinal fusion implant of claim 1, wherein the	The radiopaque markers (spikes 24) present on the implant described in Baccelli are both located the same distance, a first longitudinal distance, away from the proximal wall of the implant. *See* Baccelli, at ¶ [0041] ("The two spikes on each face

first and second radiopaque markers are substantially equally spaced apart from said proximal end of said proximal wall by a first longitudinal distance.	are disposed symmetrically to each other about the sagittal midplane."). 
Claim 3: The spinal fusion implant of claim 1, further comprising a third radiopaque marker that extends into said distal wall, and a fourth radiopaque marker that extends into said proximal wall.	The Telamon Brochure depicts the Telamon implant as having at least a radiopaque marker positioned in the proximal wall. *See* Telamon Brochure, at 1. The Telamon Brochure additionally discloses the use of multiple radiopaque markers. *See* Telamon Brochure, at 1-2 (disclosing that a design feature of Telamon is "Tantalum Radiographic markers").  Alternatively, Baccelli and Frey include a distal wall marker. *See, e.g.*, Baccelli at ¶¶ [0041] ("The cage has spikes 24, in this case four such spikes, i.e. two associated with each of the main faces 8 and 10. Each spike has a pointed end and it projects from the associated main face. The two spikes on each face are disposed symmetrically to each other about the sagittal midplane. In addition, they extend in the frontal midplane containing the axis 6. Each spike on one face extends in register with a spike on the other face."), [0051] ("The spikes 24 can . . . be made of a material that is opaque to X-rays."), [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."); Frey, at Figs. 59-62, ¶ [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. 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. Positioning markers 1438 at these locations provides an indication of the anterior and posterior placement of implant 1400 in the disc space, and also an indication of the lateral placement of implant 1400 in the disc space.").
Claim 4: The spinal fusion implant of claim 3, wherein said third radiopaque marker extends entirely through a height of said distal wall, and wherein said fourth radiopaque marker extends entirely through a height of said proximal wall.	Telamon discloses a marker in the distal wall. Baccelli provides a radiopaque marker (marker 47) extends along a height of the distal wall, and a radiopaque marker (marker 47) extends along a height of the proximal wall. *See* Baccelli, at ¶ [0050] ("In this case, there are two markers 47 . . . inserted in rectilinear ducts parallel to the axis 6 and formed in the wall of the cage. One of the ducts extends at the rear in the sagittal midplane, while the other extends at the left end of the front wall."); Fig. 49 (showing marker 47 extending along a height of distal wall). 

Claims 5-8 add limitations directed to a receiving aperture located on the proximal wall of the implant. The Telamon implant includes a receiving aperture on the proximal wall that has a central axis that is generally parallel to the

longitudinal length of the implant from insertion to trailing end, and discloses that the aperture is configured to releasably mate with an inserter tool. Frey, Michelson, Baccelli, and the Telamon each disclose the use of a threaded receiving aperture. *See* Hynes Decl., at 85. To the extent that it may be considered that the Telamon does not include a threaded receiving aperture, it would have been obvious to modify the Telamon implant to include such a threaded receiving aperture to provide, *inter alia*, more axial stability in the temporary connection between the implant and the inserter tool during implantation. *See id.*, at ¶ 87. This obvious combination applies known prior art elements to improve a similar device in the same way. *See id*. Furthermore, the combination represents a combination of prior art elements according to known methods to yield predictable results. *See id*. Accordingly, such a modification of Telamon would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predicable solution to a known design need. *See id*.

Claim 5 also recites that the longitudinal length of the implant is greater than 40 mm. With respect to the length of the Telamon implant, Frey discloses 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 laterally or anterolaterally implanted lumbar spinal implant. *See* Hynes Decl., at ¶ 81.

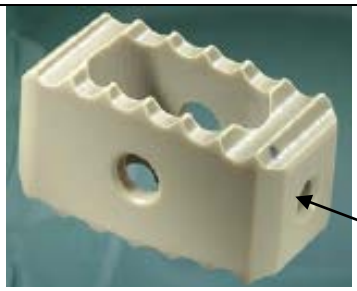
Similarly, Michelson discloses a spinal fusion implant that may have a longitudinal length greater than 40 mm. *See* Michelson, col. 10, lines 41-46 ("In the preferred embodiment, the spinal fusion implant 900 has a . . . length in the range of 32 mm to 50 mm, with 42 mm being the preferred length."). One of ordinary skill in the art would have been motivated to apply the teachings of Frey or Michelson to the Telamon implant to include a longitudinal length greater than 40 mm extending from a proximal end of the proximal wall to a distal end of the distal wall to span the disc space and allow the implant to provide more stable support for the vertebra and bear against the relatively stronger apophyseal ring. *See* Hynes Decl., at ¶ 81; *see also* '770 patent, at 7:65–8:14 ("It can be seen that in one embodiment of the implant 100 of the present invention, trailing end 104 is arcuate to be in conformation to the peripheral profile of the anterior aspect of the vertebral bodies where the implant is in contact with the vertebral bodies so as to allow the implant to have both a maximum safe width and length, and to sit on the peripheral vertebral body rim, including the anterior cortex and/or the apophyseal rim. This allows the implants of the present invention to have the maximum surface area of contact with the vertebrae, the greatest volume for holding osteogenic material, to sit upon the very good structural bone present at the periphery of the vertebral bodies, to have a greater surface over which to have bone engaging surface

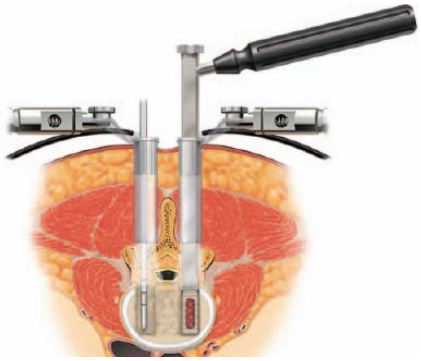
irregularities, and as a result of this combination to have the greatest stability of the implant itself and in turn to stabilize the vertebrae relative to each other.").

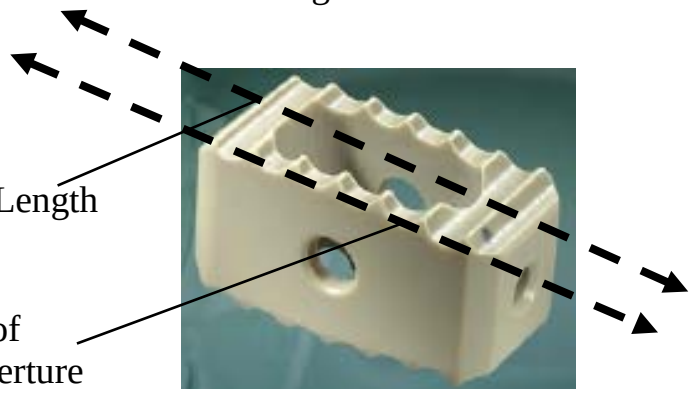
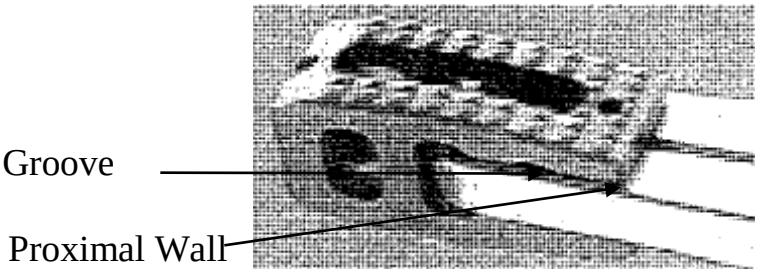
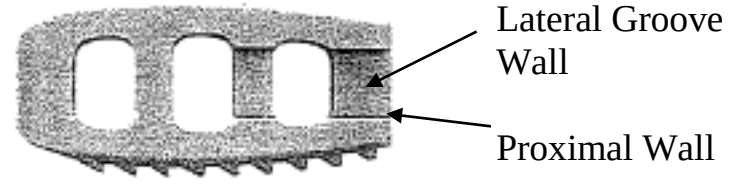
Moreover, where, as here, a skilled artisan were inclined to provide an implant for lateral insertion, the artisan would have been taught by Michelson to make the length of the implant 40 mm or greater. *See* Hynes Decl., at ¶ 81. In particular, the '156 patent indicates that the claimed length of 40 mm or greater is specifically tailored to an implant intended for lateral insertion. '156 patent, at 11:58-63 ("FIG. 20 illustrates an implant 10 dimensioned particularly for use in a lateral approach (XLIF^{TM} by NuVasive) having (by way of example only) . . . a length ranging between 40 and 45 mm.); 5:29-31 ("The implant 10 is particularly suited for introduction into the disc space via a lateral (trans-psoas) approach to the spine . . . ."). The implant of Michelson likewise is identified as being configured for lateral insertion. *See e.g.*, Michelson, at 1:16-19 ("This invention relates generally to spinal fusion implants, and more particularly to spinal fusion implants for insertion from the side of a patient (translateral) across the transverse width of the spine and between two adjacent vertebrae."). Thus, in view of the explicit teaching of Michelson to make an implant with a preferred length of 42 mm, the 40mm or greater length claimed in the '156 patent represents nothing more than an application-specific dimensional optimization in accordance with the prior art. *See* Hynes Decl., at ¶ 81.

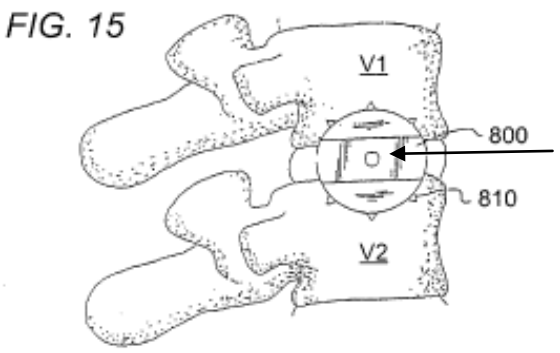
Accordingly, increasing the length of the Telamon implant to 40 mm or greater would have involved nothing more than routine optimization, combining prior-art elements according to known methods to yield predictable results, and the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

Claim 8 further requires a pair of lateral grooves in the proximal wall extending laterally of a threaded aperture. It would have been obvious to combine the Telamon with the similar teachings of the SVS-PR or Michelson to obtain the corresponding groove and threaded aperture combination required. *See* Hynes Decl., at ¶ 94. This type of insertion instrument interface was well known post-Michelson since the early 1990s. *See* Hynes Decl., at ¶¶ 92-94.

Claim 5[A]: The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall	 The Telamon includes a receiving aperture positioned in the proximal wall of the implant. *See* Telamon Brochure, at 1.
Claim 5 [B]: wherein said longitudinal length is greater than 40 mm.	Both Frey and Michelson provide that a spinal fusion implant may have a longitudinal length that is greater than 40 mm. *See* Michelson at 10:41-46 ("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."); Frey at ¶ [0130] ("[I]mplant 370, which can have features such as those described below with respect to implant 1000, is placed in the disc space D1 and has a length sufficient to span the disc space from the distal portion 37 to the proximal portion 41.") . With respect to

	Frey, for an implant to span the disc space of lumbar vertebrae, the length of the implant inherently includes a length greater than 40 mm. *See* S.H. Zhou et al., *supra*, at 244 ("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 6: The spinal fusion implant of claim 5, wherein said threaded receiving aperture is configured to releasably mate with an inserter tool.	As shown in the Telamon Brochure, the receiving aperture of the Telamon is configured to releasably mate with an inserter tool. *See* Telamon Guide, at 6.  This receiving aperture is threaded as is apparent explicitly from the disclosure and, in the alternative, inherent from the disclosure or obvious in view of the Telamon disclosure. Alternatively, Baccelli, Frey and Michelson each disclose threaded receiving apertures. *See, e.g.*, Baccelli at ¶ [0044] ("To put the cage into place, it is advantageous to use a fitting tool 40 such as the tool shown in FIGS. 8 and 9. The tool has a threaded endpiece 48 emerging from the center of the face 46 of the head and movable relative thereto, being drivable from the other end of the tool. This endpiece is suitable for threaded engagement with the mounting orifice 18 of the cage."); Frey at ¶ [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."); See Michelson aperture

	below in Claim 8 chart.
Claim 7: The spinal fusion implant of claim 6, wherein said receiving aperture comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant.	The receiving aperture of the Telamon has a central axis generally parallel to the longitudinal length of the implant. *See* Telamon Brochure, at 1. The threaded nature of this aperture is discussed above with regard to claim 6. 
Claim 8: The spinal fusion implant of claim 7, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally of said threaded receiving aperture.	The SVS-PR and Michelson each include a pair of lateral grooves position in the proximal wall that extend laterally of the receiving aperture. *See* SVS-PR Brochure, at 1; *See* Michelson, 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, the use of grooves extending laterally of the receiving aperture.  

Claim 9 recites that the implant has a maximum lateral width that is approximately 18 mm. Michelson discloses a spinal fusion implant having a width in the range of 14 to 26 mm and also specifically discloses an incorporated 18 mm width embodiment. One of ordinary skill in the art would have been motivated to apply this teaching of Michelson to modify the Telamon implant to have a width of 18 mm because the prior art, including Michelson, taught that an implant with "more surface area of contact . . . permits greater stability." *See* Michelson, at 7:11-20 ("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."). If a person were inclined to provide an implant for lateral insertion to obtain a more stable

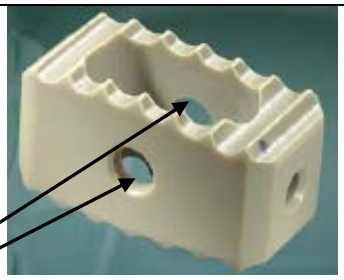
construct and/or increased surface area it would have been obvious to combine the teaching of Michelson with the Telamon to achieve the combination as set forth in the '156 patent claims below. *See* Hynes Decl., at ¶ 98. The combination represents a combination of prior art elements according to known methods to yield predictable results. *See id*. Telamon and Michelson are from the same field of intervertebral artificial implants used in spinal fusion and share many similar attributes for obtaining the same or similar results, like the NuVasive XLIF implant disclosed in the '156 patent found to infringe the Michelson claims. *See id*; *see also* Exhibit MSD 1111. Accordingly, such a modification of the Telamon implant would have involved nothing more than the exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need. *See id*.

Claim 9: The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.	Michelson discloses a laterally implanted spinal fusion implant having a maximum lateral width in the range of 14 to 26 mm. *See* Michelson, at 7:26-30. ("In the thoracic spine such implants would have a length in the range of 12-30 mm, and 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 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 '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 . . . .").

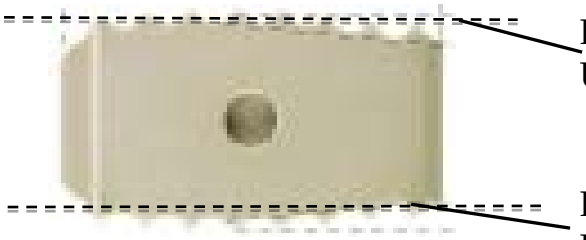
Claim 10 recites that the radiolucent material of the implant comprises polyether ether ketone (PEEK). The Telamon Brochure discloses that the Telamon implant is constructed from PEEK.

Claim 10: The spinal fusion implant of claim 1, wherein said radiolucent material comprises PEEK.	The Telamon Brochure discloses that the Telamon implant is manufactured from PEEK. *See* Telamon Brochure, at 1-2.

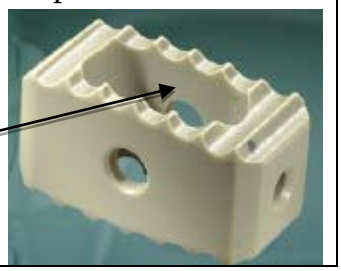
Claim 11 recites the inclusion of at least one visualization aperture extending through at least one of the first or second sidewalls. The Telamon implant includes the claimed visualization apertures in both the first and second sidewalls of the implant.

Claim 11: The spinal fusion implant of claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.	The Telamon implant includes visualization apertures on both the first and second sidewalls. *See* Telamon Brochure, at 1.  Visualization Aperture

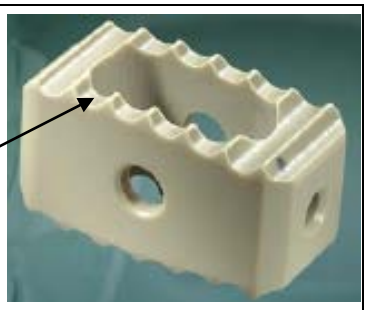
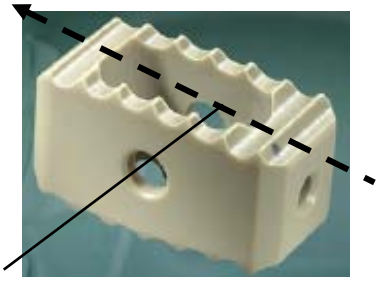
Claims 12 and 13 add limitations with respect to the angular relationship between the upper and lower surfaces of the implant. Telamon teaches the claimed limitation of Claim 12 because the upper and lower surfaces of the implant are generally parallel to each other. Telamon also teaches the limitation recited in Claim 13 as it discloses that the upper and lower surfaces are angled relative to one another to correspond to the anatomy of the spine.

Claim 12: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally parallel to one another.	The Telamon has upper and lower surfaces that are generally parallel to each other. *See* Telamon Brochure, at 2. 
Claim 13: The spinal fusion implant of claim 1, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.	The Telamon Brochure discloses that the upper and lower surfaces of the Telamon implant may be generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when the implant is positioned within the interbody space. *See* Telamon Brochure, at 2 (describing design features of Telamon implant as having "anatomical shape" and "3° lordosis"); alternately Michelson at 3:39-43 and Frey at ¶ [0152] each disclose lordotic surfaces as does Bacelli at 37-38 and 42 and Fig. 5.

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

Claim 14: The spinal fusion implant of claim 1, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.	The fusion aperture of the Telamon implant is one of generally rectangular and generally oblong in shape. *See* Telamon Brochure, at 1. Fusion Aperture 

Claims 19 and 20 further describe the anti-migration elements located on the upper surface of the implant. Claim 19, which recites that the anti-migration elements on the upper and lower surfaces of the implant comprise a plurality of ridges, is taught by Telamon. Claim 20, which recites that the plurality of ridges extend generally perpendicular to the longitudinal length of the implant is also taught by Telamon.

Claim 19: The spinal fusion implant of claim 1, wherein said anti-migration elements of said upper surface comprise a plurality of ridges.	The anti-migration elements of the Telamon implant comprise a plurality of ridges. *See* Telamon Brochure, at 1. Plurality of Ridges 
Claim 20: The spinal fusion implant of claim 10, wherein said plurality of ridges extend generally perpendicular to said longitudinal length.	The plurality of ridges present on the Telamon implant extend generally perpendicular to the longitudinal lenth of the implant. *See* Telamon Brochure, at 1.  Direction of Longitudinal Length of Implant

Claims 23-25 add proportional limitations to the implant claimed in Claim 1. Claim 23 recites that the "maximum lateral width of said implant is greater than a

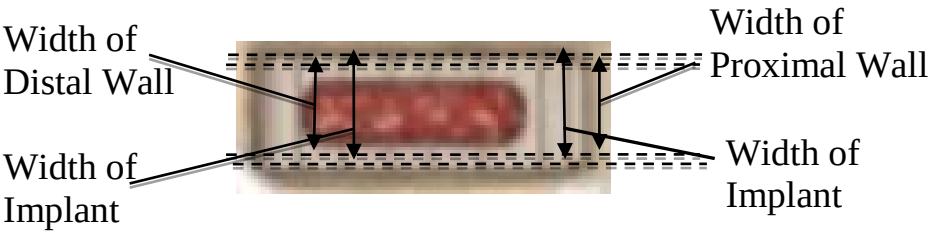
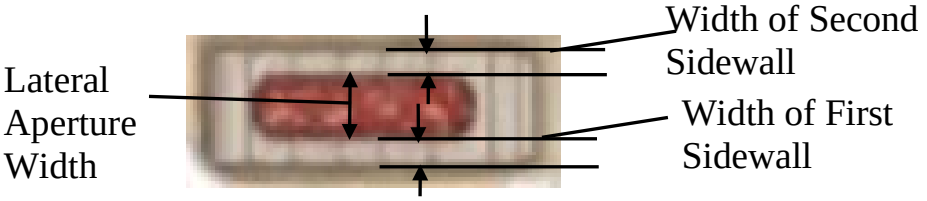
lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall." Due to the generally rectangular shape and rounded corners of the Telamon implant, the maximum lateral width of the implant is greater than the lateral width of either the distal end of the distal wall or proximal end of the proximal wall.

Claim 24 recites that the implant's height is less than its maximum lateral width. The Telamon Brochure provides that the implant may have an 8 mm height, which is less than its maximum lateral width of 10 mm.

Claim 25 adds the limitation that the width of the first fusion aperture is more than two time greater than a lateral thickness of both the first sidewall and the second sidewall. One skilled in the art would understand from the figures of the Telamon Brochure and the Telamon Guide that the width of the first fusion aperture of the Telamon is more than two times greater than the thickness of its first and second sidewalls. *See* Telamon Brochure, at 1; Telamon Guide, at 1; Hynes Decl., at ¶ 129.

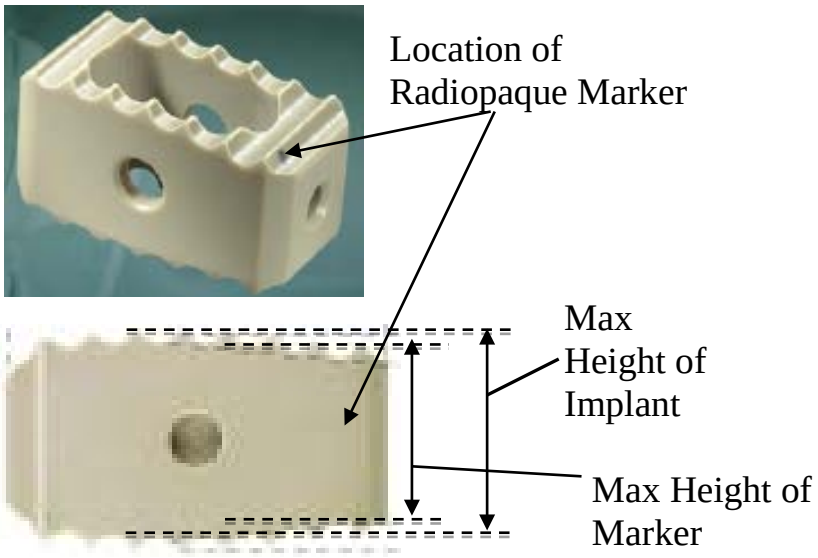
Additionally, the proportional limitations contained in Claims 23-25 do not impact the functionality of the device so as to make it patentably distinct from the prior art implant disclosed in Frey. *See Gardner*, 725 F.2d at 1349-1350 (holding that, where difference between prior art and claims was recitation of relative dimensions of claimed device and device having claimed relative dimensions

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

Claim 23: The implant of claim 1, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall.	The Telamon has a maximum lateral width that is larger than the width of either the widths of the distal end of the distal wall or the proximal end of the proximal wall. *See* Telamon Guide, at 7. 
Claim 24: The implant of claim 1, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.	The Telamon Brochure provides that the implant may have a height of 8 mm, which is less than the disclosed 10 mm width of the implant. *See* Telamon Brochure, at 2.
Claim 25: 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	Telamon Brochure and the Telamon Guide that the width of the first fusion aperture of the Telamon is more than two times greater than the thickness of its first and second sidewalls. See Telamon Brochure, at 1; Telamon Guide, at 7. 

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

Claim 26 recites that the elongate body of at least one of the radiopaque markers described in Claim 1 is shorter than the height of the implant. Because the maximum height of the radiopaque marker of the Telamon implant is limited to the shorter height of its proximal wall, thus, the Telamon Brochure discloses a radiopaque marker that is shorter than the height of the implant.

Claim 26: The spinal fusion implant of claim 1, wherein said elongate body of at least one of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface.	The elongate body of a radiopaque marker of the SVS-PR is shorter than the height of the implant due to the convex shape of the upper and lower surfaces of the implant. *See* SVS-PR Brochure, at 1. 

Claim 27 adds the limitation that "osteoinductive material [is] positioned with[in] said first fusion aperture." The Telamon Brochure provides that the Telamon may include osteogenic material placed within its fusion aperture.

Claim 27: The spinal fusion implant of claim 1, further comprising an osteoinductive material positioned with said first fusion aperture.	The Telamon implant may include an osteoinductive material positioned with the first fusion aperture. *See* Telamon Brochure, at 2 (noting that Telamon implant is designed to feature a large area for insertion of bone graft or other material).

VI. CONCLUSION

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

Dated: 14 August 2013

Respectfully submitted,

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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:

schaefer@fr.com;

hawkins@fr.com;

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

Dated: 14 August 2013

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