IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,251,997 Attorney Docket No.: 13958-0112IP2
Issue Date: August 28, 2012
Appl. Serial No.: 13/306,583
Filing Date: November 29, 2011
Title: METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,251,997 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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NuVasive, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42 of claims 9-30 of U.S. Patent No. 8,251,997. Below, NuVasive demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of claims 9-30 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)

NuVasive, Inc. is the real party-in-interest for the instant petition.

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 `997 patent, and is aware of a Certificate of Correction. Petitioner is a named defendant in litigation concerning the '997 patent, *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.* (originally filed in N.D. Ind. as Case No. 3:12-cv-00438-JD-CAN on Aug. 17, 2012, and transferred to S.D. Cal. on Nov. 8, 2012, as Case No. 3:12-cv-02738-CAB (MDD)). The '997 patent was added by amended complaint filed Aug. 28, 2012, served on Petitioner that same day. Petitioner is concurrently filing an IPR petition for claims 1-8 of the '997 patent.

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 and service to both counsel listed above. Peti-

tioner consents to service by email at APSI@fr.com (ref.: Docket No. 13958-0112IP2).

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

Petitioner authorizes the PTO to charge Dep. Account 06-1050 for the fee set in 37 C.F.R. § 42.15(a), and authorizes payment of any additional fees to this Deposit Account.

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 `997 patent is eligible for IPR and Petitioner is not barred or estopped from requesting IPR. This petition is being filed within one year of service of a complaint against Petitioner in district court litigation (as discussed above).

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

Petitioner requests IPR of claims 9-30 on the grounds set forth below, and requests that the claims be found unpatentable. An explanation of how claims 9-30 are unpatentable is provided below in the claim charts, including where each element can be found in the prior art publications and the relevance of the prior art references. Additional explanation and support is in the Declaration of Dr. McAfee, M.D., M.B.A. (NUVASIVE 1001).

Ground	`997 Patent Claims	Basis for Rejection
Ground 1	**9 and 16**	Obvious under § 103 by Jacobson in view of Leu, McAfee, and Michelson '247
Ground 2	**10-15**	Obvious under § 103 by Jacobson in view of Leu, McAfee, Michelson '247, and Frey
Ground 3	**17 and 23**	Obvious under § 103 by Jacobson in view of Leu and Brantigan
Ground 4	**18-22**	Obvious under § 103 by Jacobson in view of Leu, Brantigan, and Frey
Ground 5	**24 and 30**	Obvious under § 103 by Jacobson in view of Leu and Mi-

Ground	`997 Patent Claims	Basis for Rejection
		chelson '247
Ground 6	**25-29**	Obvious under § 103 by Jacobson in view of Leu, Michelson '247, and Frey
Ground 7	**9-16**	Obvious under § 103 by Michelson '661 in view of McAfee and Lynn
Ground 8	**17-30**	Obvious under § 103 by Michelson '661 in view of Lynn

Jacobson, Leu, Brantigan, Frey, and Michelson '247 are prior art under 35 U.S.C. § 102(b), having been published more than a year before the earliest claimed priority of Feb. 27, 1995. McAfee is prior art under at least 35 U.S.C. § 102(e), having been filed in January 1995. Michelson '661 is prior art under 35 U.S.C. § 102(b) and Lynn under at least 35 U.S.C. § 102(e) to the extent the claims of the '997 patent are not entitled to the earliest claimed priority date (as described in Grounds 7-8). Some of these references (Jacobson, Leu, Brantigan, Michelson '247, and Michelson '661) were cited in an IDS, but none were addressed during prosecution.

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

A claim subject to IPR is given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Thus, the words of the claim are given their plain meaning unless that meaning is inconsistent with the specifi-

cation. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).[1] Petitioner submits that, for purposes of this proceeding, all claim terms except those specifically addressed below should be given their plain meaning. Petitioner contends that some or all of the claim limitations addressed below render the '997 patent claims invalid under 35 U.S.C. § 112, but this is not the proper forum to address such invalidity. 37 C.F.R. § 42.104(b)(2). As a result, the Petitioner suggests, for the sake of rational analysis only, that the broadest reasonable construction to be applied in this proceeding for these limitations is at least as broad as what Patent Owner is believed to be asserting in the pending litigation.

1. "a single elongated portion removably attached to said distal end of said third surgical instrument" (claim 9)

This phrase is interpreted to include a removable ring with at least one (and not necessarily only one) elongated portion, such as the removable anchor ring structure 1104 (FIG. 35) that removably attaches to the outer tubular member 1102. *See* NUVASIVE 1001 at ¶ 16. Throughout the '997 patent, this removable anchor ring structure 1104 is the only structure that is "removably attached" to any type of instrument (tubular member 1102) that might be considered a third surgical instrument. Because the '997 patent discloses only methods for using the detachable ring structure 1104 in which the third surgical instrument

[1] Because the standards of claim interpretation applied in litigation differ from PTO proceedings, any interpretation of claim terms in this IPR is not binding upon Petitioner in any litigation related to the `997 patent. *See In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

(tubular member 1102) is entirely removed from the patient before the spinal implant is inserted (and, thus, no implant can be inserted through the tubular member 1102 as required by the claims), such inconsistencies give rise to issues under 35 U.S.C. § 112 that are not addressed in this Petition. NUVASIVE 1002 at 21:39-22:35; FIG. 35.

2. "positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space" (claim 9)

The term "positioning" in this phrase is interpreted to include circumstances in which the single elongated portion (e.g., ring 1104 in FIG. 35) is transiently moved through a location where the single elongated portion is disposed over the disc space prior to penetrating into the disc space. Although transiently moving through a location is normally understood as being different from the plain meaning of "positioning" (e.g., NUVASIVE 1002 at 22:3-7), Patent Owner's allegations of infringement require this unconventional meaning. Such inconsistencies give rise to issues under 35 U.S.C. § 112 not addressed herein.

3. "positioning said third surgical instrument such that at least part of one of said at least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae" (claim 17)

The term "positioning" in this phrase is interpreted to include circumstances in which the two elongated portions (e.g., prongs 149 and 150 in FIGS. 7 and 7A) are transiently moved through a location where the two elongated portions are disposed over the respective vertebrae prior to penetrating into the vertebrae. Although this is different from the plain meaning of "positioning" (e.g., NUVASIVE 1002 at 12:37-44), Patent Owner's allegations of

infringement require this unconventional meaning. Such inconsistencies give rise to issues under 35 U.S.C. § 112 not addressed herein.

> 4. "positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae" (claim 24)

The term "positioning" in this phrase is interpreted to include circumstances in which the first, second, and third elongated portions (e.g., extension member 148 and prongs 149, 150 in FIGS. 7 and 7A) are transiently moved through a location where the first, second, and third elongated portions are disposed over the designated portions of the spine prior to penetrating into those designated portions. This is different from the plain meaning of "positioning" (e.g., NUVASIVE 1002 at 12:37-44), Patent Owner's allegations of infringement require this unconventional meaning. Such inconsistencies give rise to issues under 35 U.S.C. § 112 not addressed herein.

> 5. "the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space" (claims 9 and 17)

This "implant length" limitation of claims 9 and 17 includes within its scope lengths of implants that, when positioned in a patient, occupy less than the full transverse width of the two adjacent vertebral bodies, but greater than the depth of the disc space. This broadest reasonable construction is supported by the '997 specification, which does not provide written description support for implants that span the entire transverse width, but only discloses

implants that are shorter than that. *See, e.g.,* NUVASIVE1002, FIGS. 19, 23, 30A, 30; NUVASIVE1001, ¶¶ 18-19. In addition, for typical vertebrae the full transverse width of the two vertebrae adjacent a disc space is greater than the depth of the disc space. *See, e.g.,* NUVASIVE1002, FIGS. 30, 30A, 32 & 33; NUVASIVE1001, Exhibit C.

Notably, the '997 specification provides no guidance on what the modifier "substantially" in claim 1 means. For example, the '997 specification provides no disclosure of example implant sizes, and no example measurements comparing the size of an implant with the size of the full transverse width of the two adjacent vertebrae. Instead, the '997 specification only provides figures that are not drawn to scale and thus have limited value in what they teach. For example, FIG. 30, upon which Patent Owner has relied most heavily in arguing that the '997 specification discloses a long implant, is not anatomically accurate (its transverse width is exaggerated), thus rendering FIG. 30 entirely unhelpful in quantifying what "substantially" means in claim 1. Moreover, the view being shown in FIG. 30 – as defined in FIG. 29 – is a view looking upward toward the smaller L3 vertebra above the disc space D, not a view of the larger L4 vertebra below. Accordingly, Petitioner contends these defects in claim 1 render claims 1-8 invalid under 35 U.S.C. § 112, but this is not the proper forum to address such invalidity. 37 C.F.R. § 42.104(b)(2). In addition, as will be discussed below, to the extent the "length occupying substantially the full transverse width" claim limitation is read narrowly to distinguish prior art implants in existence before the priority appli-

cation filing in 1995, then the '997 claims are not supported by the original 1995 priority document disclosure, and must be afforded a later priority date in determining validity.

> 6. "the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space" (claim 24)

This "implant length" limitation is also interpreted to include within its scope lengths of implants that, when positioned in a patient, occupy less than the full transverse width of the two adjacent vertebral bodies, but greater than the depth of the disc space. This broadest reasonable construction is supported by the '997 specification, which does not provide written description support for implants that span the entire transverse width, but only discloses implants that are shorter than that. *See, e.g.,* NUVASIVE1002, FIGS. 19, 23, 30A, 30; NUVASIVE1001, ¶ 18-19. Clearly, the length limitation of claim 24 (which does not include the modifier "substantially") is not supported by the '997 specification, thus rendering claims 24-30 invalid under 35 U.S.C. § 112, but this is not the proper forum to address such issues. In addition, as will be discussed below (Ground 8), claims 24-30 must be afforded a later priority date in determining validity.

IV. SUMMARY OF THE `997 PATENT

A. Brief Description

The `997 patent discloses a method and instruments for "performing surgery [i.e., a spinal fusion procedure] on the spine along its lateral aspect (side) and generally by a lateral or anterolateral surgical approach." NUVASIVE1002, col. 3:34-37; NUVASIVE1001 ¶ 10 (providing illustration of lateral and anterolateral approaches). The use of a lateral ap-

proach to the spine for performing a spinal fusion procedure pre-dated the '997 patent's claimed 1995 priority, having been disclosed at least as early as a 1982 paper by Dr. Crock and also in a patent by Dr. Robert Jacobson filed in 1982. NUVASIVE1001 ¶ 11. Patent Owner itself recognized that a lateral approach to the spine was known prior to February 27, 1995. Indeed, the priority application (issued as U.S. 5,772,661) acknowledged that fact (see '661 patent, col. 1:43-44), and shortly after invalidity contentions against the '661 patent based on Jacobson prior art were presented by NuVasive in litigation in 2009, Patent Owner sought to narrow the claims of the '661 patent in reissue, but that attempt failed. *See* App. Serial No. 12/655,178 (expressly abandoned after narrowed '661 patent claims were finally rejected). Patent Owner thus separately pursued the continuation application that became the '997 patent, and in it, presented claims that recite a specific set of tools and fusion implant features that were well known in the prior art before 1995, as will be discussed in more detail below.

B. Summary of the Prosecution History of the `997 Patent

The '997 patent claims priority, via two intervening applications, back to a 1995 application that issued as U.S. 5,772,661 (NUVASIVE1015). The '661 patent claims a lateral method for spinal fusion, and as discussed above, Patent Owner failed in its attempt to narrow its claim scope to an allowable form through a reissue proceeding, and expressly abandoned it. The application that became the '997 patent was filed on Nov. 29, 2011 – while the '661 reissue proceeding was pending, and after a final rejection in the reissue – as a "Track

l" filing (prioritized examination). Before Patent Owner had filed an information disclosure statement (IDS), the Examiner, in a first Action mailed Jan. 19, 2012, allowed the sole pending claim over the art, and entered only a Section 112 rejection. In response, the Patent Owner canceled the sole claim, and inserted thirty new claims (the claims in the issued '997 patent). NUVASIVE1003 at pp. 25-36 and 54-63. Also, in that the new claims recited a path of approach "lying in a coronal plane"—a phrase not used in the '997 specification—Patent Owner included an explanation of this phrase, with a figure illustrating it. NUVASIVE1003 at pp. 25-36 and 54-63. The Patent Owner also, for the first time, filed its IDS with hundreds of references. Sixteen days later, the examiner allowed the 30 new claims. NUVASIVE1003 at pp. 22-24.

The examiner provided no reasons for allowance, and nothing in the record indicates what the examiner or the Patent Owner deemed to be the most pertinent prior art, how the allowed claims were different from the prior art, or why the rejection in the '661 patent reissue proceeding (based in part on Jacobson) did not apply. The Patent Owner then filed a request for continued examination (RCE) to expunge some of the cited documents that were subject to a Court protective order, and after that was done, the examiner again allowed the claims without reasons for allowance. NUVASIVE1003 at pp. 1-3.

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE `997 PATENT IS UNPATENTABLE

As detailed below, prior art references show independent claims 9, 17 and 24, and their dependents, are merely a combination of "prior art elements according to known meth-

ods to yield predictable results" and/or the "[u]se of known technique[s] to improve similar devices (methods, or products) in the same way." MPEP § 2143(A, C). As such, there exists a reasonable likelihood that at least one of the challenged claims is unpatentable.

RLP for Claims 9-16

Claim 9 of the `997 patent is directed to a method that starts with an incision in the side of a patient ("proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae"). Claim 9 also recites three "advancing" steps, namely, advancing a first instrument (e.g., guide pin 30 in FIG. 1), a second instrument (e.g., distractor 100 in FIG. 2) over the first, and a third instrument (e.g., outer tube 1102 in FIG. 35) over the second. Claim 9 describes that a single elongate portion (detachable anchor ring 1104 in FIG. 35) is removably attached to the third instrument (outer tube 1102). Further, claim 9 recites a step of inserting a "non-bone interbody intraspinal implant" (e.g., threaded implant "I" in FIG. 19) through the third surgical instrument.

First regarding Grounds 1-2, Jacobson alone discloses nearly all features recited in claim 9, except for the use of sequential dilators over Jacobson's guide needle (in lieu of Jacobson's speculum 10), an anchor tip that is "removably attached" to the outer tube, and the traditional structure of a fusion implant. For example, in comparison to the '997 patent, Jacobson discloses virtually the same method of use for the guide needle or wire 8 (first instrument), the working cannula 12 (third instrument), and the direct lateral access path.

NUVASIVE 1004 at FIGS. 3 and 8; 2:23-33; 2:40-43; 6:13 (describing a "fusion" procedure through the direct lateral working cannula). Jacobson discloses that a speculum 10 (not sequential dilators) may be advanced over the initial guide needle or wire 8 so as to widen the surgical access path for subsequent insertion of the final working cannula 11. *Id.* at 5:48-54; FIGS. 4-5. By the early 1990s, however, surgeons commonly employed the obvious choice of using one or more sequential dilators (rather than Jacobson's speculum 10) over the initial guide needle to widen the surgical access path for thereafter introducing the final working cannula (Leu provides an example of this general prior art practice). NUVASIVE 1005 at p. 594; p. 596. As described in greater detail in the claim charts below (in which claim language is set forth in bold font), a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue.

Regarding the claimed "single elongate portion" that is removably attached to the third surgical instrument (refer to the anchor ring 1104 that is removably attached to the outer tube 1102 in FIG. 35), Jacobson also suggests using anchor elements at the distal end of the working cannula (NUVASIVE 1004 at 10:1-6), but does not expressly disclose that the anchor elements should be "removably attached" to the working cannula. As described in greater detail in the claim charts below, it was traditionally known in the prior art that such anchor elements can be removably attached to a distal end of a cannula. For ex-

ample, McAfee plainly teaches the conventional configuration in which a ring bearing the anchoring teeth is removably attached to the end of the working cannula. NUVASIVE 1009 at 3:37-41; FIGS. 2 and 5 (reproduced below, showing that the length and width of each anchoring tooth is greater than the thickness); 5:63-67. Here, a person of ordinary skill in the art would have been prompted to include McAfee's removably attached anchoring tip on the end of Jacobson's working cannula for the reasons described in the claim chart below.

Regarding the claimed implant structure, Jacobson suggests a "fusion" procedure, but does not specify the structure of the implant to be used. NUVASIVE 1004 at 6:13. A number of prior art references, such as Michelson '247, explicitly show that a threaded spinal implant should extend longitudinally across nearly the full disc space in the axial direction of insertion. NUVASIVE 1008 at FIG. 5; NUVASIVE 1001 at ¶ 28-29. Thus, when such a fusion implant is inserted laterally (in accordance with Jacobson's method), the threaded implant would extend longitudinally across nearly the full disc space in the axial direction of insertion for the multiple reasons described in in the claim chart below. NUVASIVE 1001 at ¶ 28-29. As described herein, there is a reasonable likelihood that claim 9 is unpatentable based upon Jacobson in view of Leu, McAfee, and Michelson '247.

Also, as described below under Ground 7, claims 9-16 are not entitled to the earliest claimed priority of Feb. 25, 1995. Thus, there is a reasonable likelihood that claims 9-16 are unpatentable based upon the obvious combination of Michelson '661 in view of McAfee and Lynn (wherein Michelson '661, McAfee and Lynn are prior art under § 102(b) or § 102(e)

(for Lynn) for Ground 7).

RLP for Claims 17-23

Regarding Grounds 3-4, Jacobson discloses nearly all features recited in claim 17, except for the use of sequential dilators over Jacobson's guide needle (in lieu of Jacobson's speculum 10), and the traditional structure of a fusion implant. Similar to the '997 patent, Jacobson discloses virtually the same method of use for the guide needle or wire 8 (first instrument), the working cannula 12 (third instrument), and the direct lateral access path. NUVASIVE 1004 at FIGS. 3 and 8; 2:23-33; 2:40-43; 6:13. As described above (and as described in greater detail in the claim charts below), a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue.

Regarding the claimed implant structure, Jacobson suggests a "fusion" procedure but does not specify the structure of the implant to be used. NUVASIVE 1004 at 6:13. A number of prior art references, such as Brantigan, show that when a traditional fusion implant is inserted laterally (in accordance with Jacobson's method), the implant should include the basic structural elements recited in claim 17 and the implant length should be sized to reach the "perimeter of the vertebrae." NUVASIVE 1006 at 2:2-4; 2:64-66; FIG. 10. For the reasons described below (Ground 3), there is a reasonable likelihood that claim 17 of the `997 patent is unpatentable based upon Jacobson in view of Leu and Brantigan.

Also, as described below under Ground 8, claims 17-23 are not entitled to the earliest claimed priority of Feb. 25, 1995. Thus, there is a reasonable likelihood that claim 17 of the `997 patent is unpatentable based upon the obvious combination of Michelson '661 in view of Lynn (wherein Michelson '661 and Lynn are prior art under § 102(b) or § 102(e) (for Lynn) for Ground 8).

RLP for Claims 24-30

Regarding Grounds 5-6, Jacobson discloses nearly all features recited in claim 24, except for the use of sequential dilators over Jacobson's guide needle (in lieu of Jacobson's speculum 10), the three elongated portions at the distal end of the working tube, and the traditional structure of a fusion implant. Again, Jacobson discloses the virtually the same method of use for the guide needle or wire 8 (first instrument), the working cannula 12 (third instrument), and the direct lateral access path. NUVASIVE 1004 at FIGS. 3 and 8; 2: 23-33; 2: 40-43; 6:13. As previously described above (and as described in greater detail in the claim charts below), a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue.

Regarding the "first, second, and third elongated portions" of the third surgical instrument (the outer tube), Jacobson also suggests using anchor elements are at the distal end of the working cannula (NUVASIVE 1004 at 10:1-6), but does not expressly illustrate

the dimensions of those anchor elements. Such conventional anchor elements, however, commonly included the structural features of the claimed first, second, and third elongated portions. For example, Michelson '247 shows a similar anchoring tip with sharp tines in which the length of each anchoring tooth is greater than the width and thickness. NUVASIVE 1008 at FIGS. 1-3. For the particular reasons described below (Ground 5), a person of ordinary skill in the art would have been prompted to include Michelson '247's anchoring teeth on Jacobson's anchoring tip of the working cannula.

Regarding the claimed implant structure, Jacobson suggests a "fusion" procedure, but does not specify the structure of the implant to be used. NUVASIVE 1004 at 6:13. Michelson '247, however, explicitly show that a threaded spinal implant should extend longitudinally across nearly the full disc space in the axial direction of insertion. NUVASIVE 1008 at FIG. 5; NUVASIVE 1001 at ¶ 28-29. Thus, for the reasons described in detail below (Ground 5), there is a reasonable likelihood that claim 24 is unpatentable based upon Jacobson in view of Leu and Michelson '247.

Also, as described under Ground 8, claims 24-30 are not entitled to the earliest claimed priority of Feb. 25, 1995.. Thus, there is a reasonable likelihood that claims 24-30 are unpatentable based upon the obvious combination of Michelson '661 in view of Lynn (wherein Michelson '661 and Lynn are prior art under § 102(b) or § 102(e) (for Lynn) for Ground 8).

VI. [GROUND 1] – Obviousness under §103 by Jacobson in view of Leu, McAfee, and Michelson '247

As shown in the claim chart below, claims 9 and 16 of the `997 patent are obvious under § 103 based upon Jacobson in view of Leu, McAfee, and Michelson '247.

9. A method comprising:

Jacobson discloses a surgical method of accessing a spinal disc space that, much like the '997 patent, includes a lateral approach path to the spine. For example, Jacobson expressly describes a "lateral" approach for accessing a disc space between two adjacent vertebrae via a working cannula for purposes of performing a discectomy and, optionally, a vertebral fusion procedure. NUVASIVE 1004 at FIGS. 3 and 8; 2:23-33; 2:40-43; 6:13 (describing a "fusion" procedure which would include an interbody implant in the disc space to achieve fusion).

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Similar to many prior art lateral spinal surgeries that accessed the spine through an outer tubular cannula, Jacobson discloses the claimed step of making a laterally-located incision to gain access to a disc space between two adjacent vertebrae located within a portion of the lumbar spine. For example, Jacobson discloses the laterally-located incision point in at least two instances. First, Jacobson teaches that the laterally-located incision point is formed when the initial guide member 8 (needle or 3-mm wire) penetrates the skin. *Id*. at FIG. 3; 5:28-31; 5:42-45 (describing a guide wire having a diameter of nearly "3-mm," which would require formation of small skin incision); NUVASIVE 1001 at ¶ 24. Second, Jacobson also discloses that the laterally-located incision point is further incised to "an approximately one centimeter long skin incision." *Id*. at 5:45-46.

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to

the transverse processes;

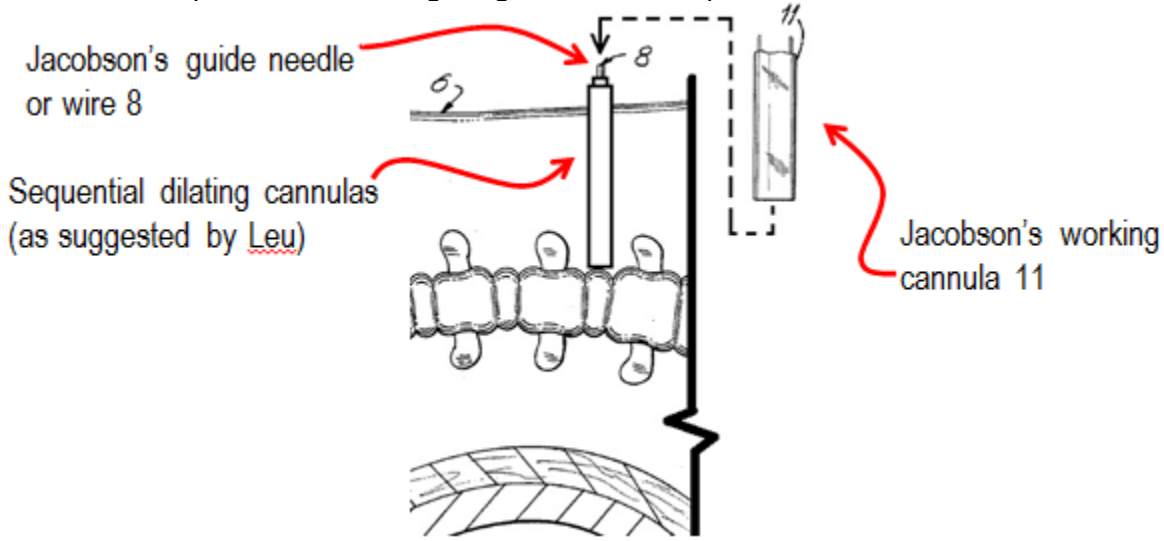
Jacobson teaches that, during the lateral surgical approach to the spine, a first surgical instrument (e.g., Jacobson's guide needle or wire 8) is advanced into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes. *Id.* at FIG. 3; 5:28-31; 5:42-45 (disclosing a nearly 3-mm guide wire instead of the guide needle). As taught by Jacobson, the initial guide needle or wire 8 extends along the lateral path (anterior to the transverse processes) until proximate to the targeted spinal disc and thereafter serves "as a guide member" for a second instrument that is subsequently advanced over the guide needle or wire 8 towards the targeted spinal disc. *Id.* at 5:39-41; FIG. 3.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

Jacobson discloses that a speculum 10 (not sequential dilators) may be advanced over the initial guide needle or wire 8 so as to widen the surgical access path for subsequent insertion of the final working cannula 11. *Id.* at 5:48-54; FIGS. 4-5. Jacobson's speculum 10 is different from the claimed "second surgical instrument" because this claim later requires that the third surgical instrument be advanced "over . . . said second instrument" (rather than between blades of the speculum 10). By the early 1990s, however, surgeons commonly employed the obvious choice of using one or more dilators (rather than Jacobson's speculum 10) to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. NUVASIVE 1001 at ¶ 25-26. For example, Leu discloses a surgical method for accessing a lumbar disc space via a working cannula to deliver a spinal fusion implant. NUVASIVE 1005 at p. 594 (describing a technique of "percutaneous lumbar interbody fusion"); p. 596 (describing "four cannulas" used for sequential dilation and a "working cannula"); p. 603 (suggesting the use of fusion implants ("composite grafts") through the working cannula). In such prior art surgical methods, Leu expressly teaches the general prior art practice in which sequential dilators ("four cannulas of increasing diameter are stepwise overslipped, one upon the other") are advanced over the "central guide needle" to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. *Id.* at p. 596.

Accordingly, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue, and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready

for improvement to yield predictable results." MPEP § 2143(D). . NUVASIVE 1001 at ¶ 25-26. One example of the resulting surgical method is provided below:



NUVASIVE 1004 at FIG. 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over the guide wire). Even though Leu's specific surgical method employs four sequential dilators, Leu shows the more general prior art knowledge that surgeons could readily use sequential dilators "[o]ver a central guide needle" prior to inserting the "working cannula." NUVASIVE 1005 at p. 596. Here, the person of ordinary skill in the art would predictably select the particular number of sequential dilators according to the desired size of the surgical access path for receiving the final working cannula (Jacobson's working cannula 11 or a predictably larger version thereof for purposes of Jacobson's suggested "fusion" surgery as described below) over the last sequential dilator. NUVASIVE 1001 at ¶ 25-26. Thus, in the resulting surgical method, any one of the sequential dilators (as suggested by Leu) that are advanced over Jacobson's initial guide needle or wire 8 (the first instrument) along Jacobson's lateral approach path would provide the claimed second instrument. NUVASIVE 1001 at ¶ 25-26.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of advancing a third surgical instrument, as recited in claim 9. As previously described, Jacobson's working cannula 11 (the "third surgical instrument" as recited in claim 9) would be advanced through Jacobson's lateral incision location and over the sequential dilators (suggested by Leu above). Furthermore, Jacobson illustrates that the working cannula 11 includes a central lumen extending therethrough, through which the sequential dilators would pass, as the cannula 11 is advanced to the disc space. *Id.* at FIGS.

5-6. Much like the outer sleeve 140 of the '997 patent, Jacobson expressly discloses that the working cannula 11 "acts as a conduit for insertion of surgical instruments" and may act as an instrument conduit for a "fusion" procedure. NUVASIVE 1004 at 6:7-13; FIGS. 6-8.

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

Similar to the depicted embodiments in the '997 patent, Jacobson discusses that "anchor means may be used for the cannula. For example, sharp tines may be affixed to the cannula tip . . . ." NUVASIVE 1004 at 10:1-6. Jacobson, however, does not expressly describe that the sharp tines are "removably attached" to the cannula (as recited in claim 9), but it was traditionally known in the prior art that such tines may be removably attached to a distal end of a cannula. For example, McAfee discloses a working cannula 12 that includes a "cylindrical passageway 30 into which the surgeon inserts the surgical instruments to perform the surgical procedure on the patient's spine." NUVASIVE 1009 at 6:6-18. The working cannula 12 is "anchored by means of sharp prongs or serrated teeth into a spinal bone or vertebrae," and McAfee plainly teaches the conventional configuration in which a ring bearing the anchoring teeth is removably attached to the end of the working cannula. NUVASIVE 1009 at 3:37-41; FIGS. 2 and 5 (reproduced below, showing that the length and width of each anchoring tooth is greater than the thickness); 5:63-67.

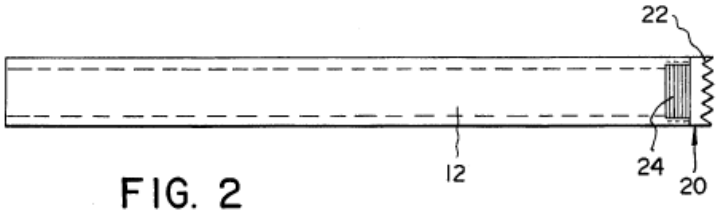


FIG. 2

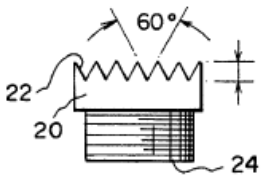
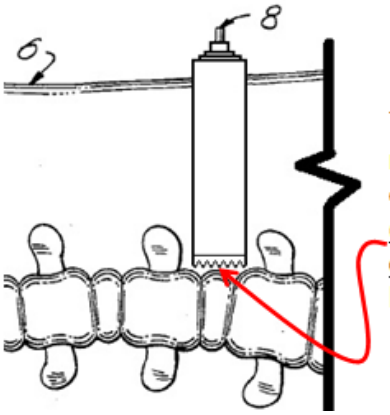


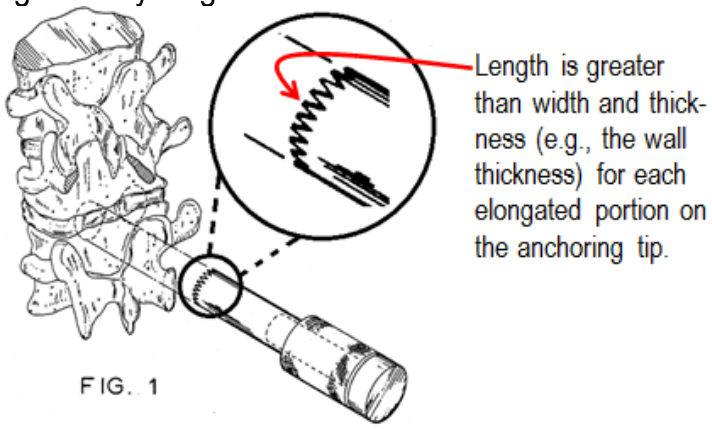
FIG. 5

Here, a person of ordinary skill in the art would have been prompted to include McAfee's removably attached anchoring tip on the end of Jacobson's working cannula in order to permit a surgeon to advantageously select from interchangeable anchoring tips (or a smooth end without any anchoring tip), thereby permitting the surgeon to tailor the surgical method depending upon the surgical site and the needs of the patient:



NUVASIVE 1001 at ¶ 27. Also, a person of ordinary skill in the art would have been prompted to include McAfee's removably attached anchoring tip on the end of Jacobson's working cannula because to do so would be nothing more than "[c]ombining prior art elements according to known methods to yield predictable results." MPEP § 2143(A); NUVASIVE 1001 at ¶ 27.

To the extent that the anchoring teeth illustrated in McAfee are not longer than they are wide, it was traditionally known to include teeth on the end of spinal access cannulas that were longer than they were wide, as evidenced by the Michelson '247 patent, which shows a similar anchoring tip with significantly longer teeth:



UVA 1008 at FIG. 1 (modified to show close up of the anchoring teeth on the spinal access cannula). Here, a person of ordinary skill in the art would have been prompted to include longer teeth on the removably attached anchoring tip (described above) so that the teeth are more firmly "seated" in the disc space and adjacent vertebrae, and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." MPEP § 2143(D); NUVASIVE1001 at ¶ 27; NUVASIVE 1008 at 9:22-25.

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

The resulting surgical method of Jacobson in view of Leu, McAfee, and Michelson '247 (described above) discloses that at least one of the many serrated teeth would be inserted into the disc space with a width oriented along a height of the disc space (see FIG. 1, above).

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

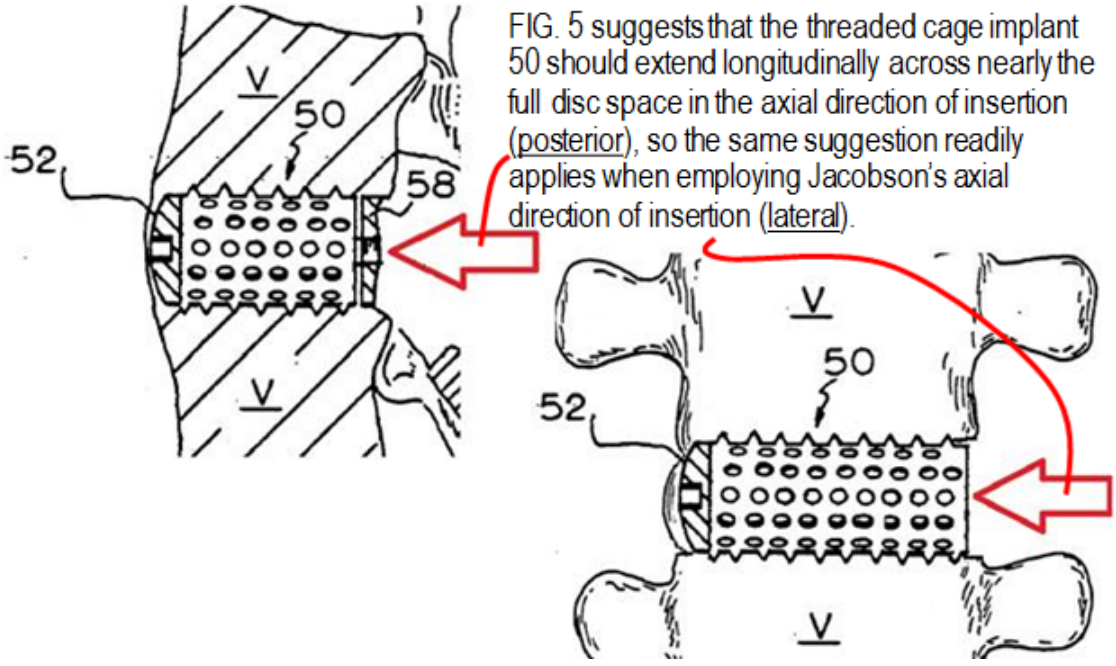
The resulting surgical method of Jacobson in view of Leu, McAfee, and Michelson '247 (described above) provides the claimed step of "inserting" an interbody intraspinal implant through the third surgical instrument, as recited in claim 9. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. NUVASIVE 1004 at FIGS. 6-8. Also, Jacobson then explains that, in the lateral surgical approach, the working cannula can also serve as the conduit for a "fusion" procedure (col: 6:13), which necessarily includes the insertion of an implant into the disc space. NUVASIVE 1001 at ¶ 28. Lastly, Leu expressly suggests that the interbody fusion implant can be a "composite graft" implant structure that is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae. NUVASIVE 1005 at p. 603. Thus, in accordance with the resulting surgical method of Jacobson in view of Leu, the working cannula/third surgical instrument (Jacobson's cannula 11) would be similarly positioned to receive the interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE 1001 at ¶ 28.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Jacobson, Leu, and McAfee do not disclose the specific dimensions of the interbody fusion implant that is described in claim 9, but implant structures similar to that described in the '997 patent were known in the prior art. Michelson '247 discloses a spinal fusion implant 50 (FIG. 5) having virtually the identical structure and function to the implant "I" illustrated in FIG. 18 of the '997 patent. NUVASIVE 1008 at FIGS. 4-5; 8:36-51. For example, Michel-

son '247 teaches that the implant 50 provides the claimed implant elements of opposed surfaces having bone engaging projections and a length of the implant being greater than the maximum height of the implant. *Id.* Because Michelson '247 does not expressly disclose that the implant 50 is inserted in a lateral approach, Michelson '247 does not expressly describe the claim limitation related to the "length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space." However, Michelson '247 plainly and expressly suggests to a skilled artisan that the threaded cage implant 50 should extend longitudinally across nearly the full disc space along the direction of insertion. *Id.* at FIG. 5 (at left below, plainly suggesting how far the length of the threaded cage should extend across the disc space in the direction of insertion). NUVASIVE 1001 at ¶ 29. Furthermore, Michelson '247 teaches one example in which the implant 50 has an example length of "26mm", which is certainly long enough to occupy substantially the full width of the adjacent vertebrae at particular levels of the spine (and most certainly in smaller patients). NUVASIVE 1001 at ¶ 29.

In the resulting surgical method of Jacobson in view of Leu, McAfee, and Michelson '247 (described above), the fusion implant is indeed inserted into the disc space via a lateral approach, so a person of ordinary skill in the art would have recognized from the suggestion in Michelson '247 that the size of the threaded cage implant 50 should be selected to extend longitudinally across nearly the full disc space along the direction of insertion (lateral insertion in this resulting surgical method).



NUVASIVE 1001 at ¶ 29; MPEP § 2144.04(IV) (citing *Gardner v. TEC Systems*, Inc., 725

F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984). Here, a person of ordinary skill in the art would have been prompted to use a longer threaded implant (as suggested by Michelson '247) for use in Jacobson's lateral insertion path so that the implant extends longitudinally across the disc space in the lateral insertion direction and advantageously provides improved mechanical support and reduces the likelihood of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. NUVASIVE 1001 at ¶ 26. Simply put, in the resulting surgical method of Jacobson in view of Leu, McAfee, and Michelson '247 (described above), the fusion implant is indeed inserted into the disc space via a lateral approach, so the relative dimensions of Michelson '247's implant 50 would have been predictably modified in accordance with the lateral insertion orientation, thereby providing a length of the implant that is "sized to occupy substantially the full transverse width of the vertebral bodies."

16. The method of claim 9, wherein said fusion implant is provided in combination with fusion promoting substances.

The resulting surgical method of Jacobson in view of Leu, McAfee, and Michelson '247 would provide the claimed fusion implant that is provided in combination with fusion promoting substances. Indeed, Leu expressly discloses the advantages of using the fusion implant in combination with "autologous bone marrow" and "bone-inducing proteins," and Michelson '247 plainly states that the threaded cage implant should be loaded with "pure cancellous bone." NUVASIVE 1005 at p. 603; NUVASIVE 1008 at 10:7-14.

VII. [GROUND 2] – Obviousness under §103 by Jacobson in view of Leu, McAfee, Michelson '247, and Frey

As shown in the claim chart below, claims 10-15 are unpatentable under 35 U.S.C. § 103(a) based upon Jacobson in view of Leu, McAfee, Michelson '247, and Frey.

10. The method of claim 9, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

To the extent that Jacobson in view of Leu, McAfee and Michelson '247 does not expressly disclose engaging a "spinal fixation device" to the adjacent vertebrae, such a process was commonly employed in the prior art. For example, Frey discloses the traditional practice of engaging a spinal fixation plate 6 (FIG. 5) to the adjacent vertebrae after insertion of the intradiscal implant 1 so that the plate 6 covers the trailing end of the intradiscal implant 1. NUVASIVE 1007 at FIG. 5; 3:14-23. According to Frey, the trailing end 5 of the implant 1 is "covered by" each plate 6, and each plate "is provided with a pair of openings 8 for the passage of bone screws in the adjacent vertebrae 9." *Id.* at 3:14-23. Here, a person of ordinary skill in the art would have been prompted to modify the method of Jacobson in view of Leu, McAfee, and Michelson '247 (described above) to further include a step of engaging a

spinal fixation plate to the vertebrae immediately adjacent to the implant (as suggested by Frey) so as to advantageously "improve a primary securement of the [implant] prior to ingrowth of bone tissue," and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." *Id.;* MPEP § 2143(D); NUVASIVE1001 at ¶ 30. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments. NUVASIVE 1001 at ¶ 30; MPEP § 2144.04(IV) (citing to *Gardner v.TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).)

11. The method of claim 10, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

As described in the analysis of claim 10 (above), the resulting surgical method of Jacobson in view of Leu, McAfee, Michelson '247, and Frey would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant. NUVASIVE 1007 at 3:16-17; FIG. 5 (showing the abutment between the plate 6 and the trailing end 5 of the implant 1).

12. The method of claim 9, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

As described in the analysis of claim 10 (above), Jacobson in view of Leu, McAfee, Michelson '247, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8) to prevent unwanted excursion. *Id.* at 3:16-17.

13. The method of claim 12, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

As described in the analysis of claim 10 (above), the resulting surgical method of Jacobson in view of Leu, McAfee, Michelson '247, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8). *Id*.

14. The method of claim 12, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

As described in the analysis of claim 10 (above), the resulting surgical method of Jacobson in view of Leu, McAfee, Michelson '247, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws engaged with the plate 6 in passageways 8) after insertion of the implant. *Id*.

15. The method of claim 9, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

The resulting surgical method of Jacobson in view of Leu, McAfee, Michelson '247 and Frey would provide a spinal fixation plate that is coupled to the implant in that the plate is integrally formed with the implant. *Id.* at FIG. 6; col. 3:25-30. One of skill in the art would modify an implant in this manner to take advantages of the fixation advantages afforded by an implant with an integral plate as taught by Frey. Such a plate would be coupled to the vertebrae using fixation means such as screws, as taught by Frey. *Id.* at FIG. 6; col. 3:19-20.

VIII. [GROUND 3] – Obviousness under §103 by Jacobson in view of Leu and Brantigan

As shown in the claim chart below, claims 17 and 23 of the `997 patent are obvious under §103 based upon Jacobson in view of Leu and Brantigan.

17. A method comprising:

Jacobson discloses a surgical method of accessing a spinal disc space that, much like the '997 patent, includes a lateral approach path to the spine. For example, Jacobson expressly describes a "lateral" approach for accessing a disc space between two adjacent vertebrae via a working cannula for purposes of performing a discectomy and, optionally, a vertebral fusion procedure. NUVASIVE 1004 at FIGS. 3 and 8; 2:23-33; 2:40-43; 6:13 (describing a "fusion" procedure which would include an interbody implant in the disc space to achieve fusion).

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Similar to many prior art lateral spinal surgeries that accessed the spine through an outer tubular cannula, Jacobson discloses the claimed step of making a laterally-located incision to gain access to a disc space between two adjacent vertebrae located within a portion of the lumbar spine. For example, Jacobson discloses the laterally-located incision point in at least two instances. First, Jacobson teaches that the laterally-located incision point is formed when the initial guide member 8 (needle or 3-mm wire) penetrates the skin. *Id*. at FIG. 3; 5:28-31; 5:42-45 (describing a guide wire having a diameter of nearly "3-mm," which would require formation of small skin incision); NUVASIVE 1001 at ¶ 24 and 31. Second, Jacobson also discloses that the laterally-located incision point is further incised to "an approximately one centimeter long skin incision." *Id*. at 5:45-46.

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to

the transverse processes;

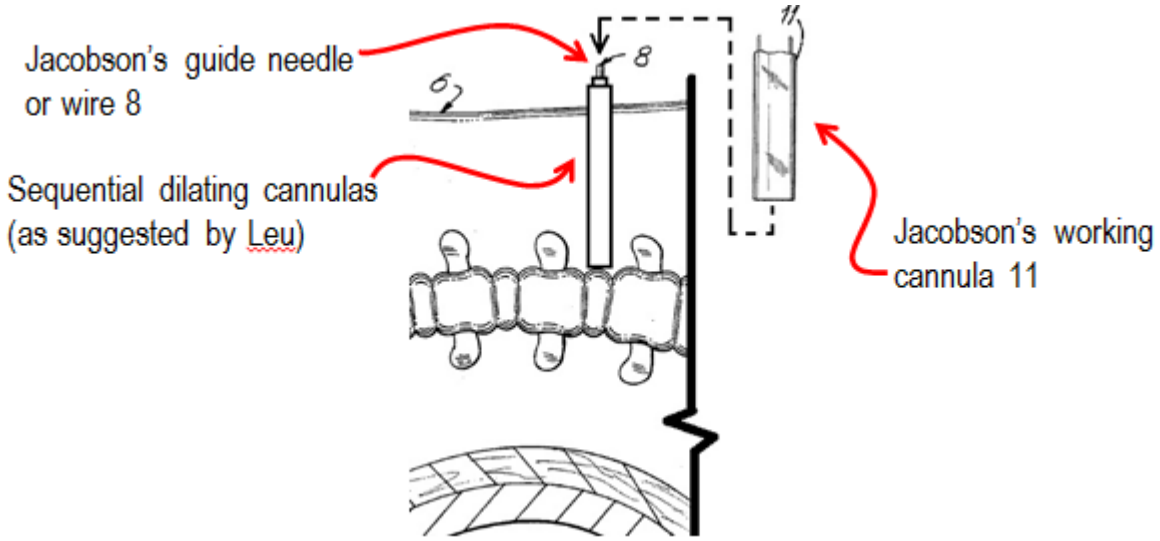
Jacobson teaches that, during the lateral surgical approach to the spine, a first surgical instrument (e.g., Jacobson's guide needle or wire 8) is advanced into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes. *Id.* at FIG. 3; 5:28-31; 5:42-45 (disclosing a nearly 3-mm guide wire instead of the guide needle). As taught by Jacobson, the initial guide needle or wire 8 extends along the lateral path (anterior to the transverse processes) until proximate to the targeted spinal disc and thereafter serves "as a guide member" for a second instrument that is subsequently advanced over the guide needle or wire 8 towards the targeted spinal disc. *Id.* at 5:39-41; FIG. 3.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

Jacobson discloses that a speculum 10 (not sequential dilators) may be advanced over the initial guide needle or wire 8 so as to widen the surgical access path for subsequent insertion of the final working cannula 11. *Id.* at 5:48-54; FIGS. 4-5. Jacobson's speculum 10 is different from the claimed "second surgical instrument" because this claim later requires that the third surgical instrument be advanced "over . . . said second instrument" (rather than between blades of the speculum 10). By the early 1990s, however, surgeons commonly employed the obvious choice of using sequential one or more dilators (rather than Jacobson's speculum 10) to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. NUVASIVE 1001 at ¶ 25-26 and 31. For example, Leu discloses a surgical method for accessing a lumbar disc space via a working cannula to deliver a spinal fusion implant. NUVASIVE 1005 at p. 594 (describing a technique of "percutaneous lumbar interbody fusion"); p. 596 (describing "four cannulas" used for sequential dilation and a "working cannula"); p. 603 (suggesting the use of fusion implants ("composite grafts") through the working cannula). In such prior art surgical methods, Leu expressly teaches the general prior art practice in which sequential dilators ("four cannulas of increasing diameter are stepwise overslipped, one upon the other") are advanced over the "central guide needle" to widen the surgical access path from a width of the initial guide needle to a width that is sufficient to introduce the final working cannula. *Id.* at p. 596.

Accordingly, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue, and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready

for improvement to yield predictable results." MPEP § 2143(D); NUVASIVE 1001 at ¶ 25-26 and 31. One example of the resulting surgical method is provided below:



NUVASIVE 1004 at FIG. 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over the guide wire). Even though Leu's specific surgical method employs four sequential dilators, Leu shows the more general prior art knowledge that surgeons could readily use sequential dilators "[o]ver a central guide needle" prior to inserting the "working cannula." NUVASIVE 1005 at p. 596. Here, the person of ordinary skill in the art would predictably select the particular number of sequential dilators according to the desired size of the surgical access path for receiving the final working cannula (Jacobson's working cannula 11 or a predictably larger version thereof for purposes of Jacobson's suggested "fusion" surgery as described below) over the last sequential dilator. NUVASIVE 1001 at ¶ 25-26 and 31. Thus, in the resulting surgical method, any one of the sequential dilators (as suggested by Leu) that are advanced over Jacobson's initial guide needle or wire 8 (the first instrument) along Jacobson's lateral approach path would provide the claimed second instrument. NUVASIVE 1001 at ¶ 25-26 and 31.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end,

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of advancing a third surgical instrument as recited in claim 17. As previously described, Jacobson's working cannula 11 (the "third surgical instrument" as recited in claim 17) would be advanced through Jacobson's lateral incision location and over the sequential dilators (suggested by Leu above). Furthermore, Jacobson illustrates that the working can-

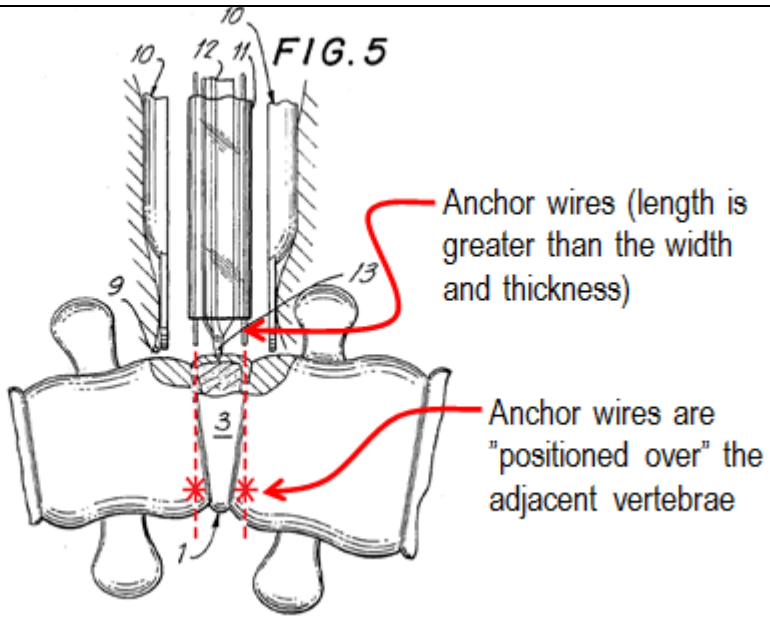
nula 11 includes a central lumen extending therethrough, through which the sequential dialators would pass, as the cannula 11 is advanced to the disc space. *Id.* at FIGS. 5-6. Much like the outer sleeve 140 of the '997 patent, Jacobson expressly discloses that the working cannula 11 "acts as a conduit for insertion of surgical instruments" and may act as an instrument conduit for a "fusion" procedure. NUVASIVE 1004 at 6:7-13; FIGS. 6-8.

said third surgical instrument having at least two elongated portions for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, said length of each of said at least two elongated portions being greater than the width and the thickness of said at least two elongated portions, each of said at least two elongated portions have a cross section through the width and the thickness and perpendicular to the length of said at least two elongated portions, respectively, each cross section of said at least two elongated portions having a convex exterior surface, said convex surfaces of each of said at least two elongated portions having the same curvature;

The resulting surgical method of Jacobson in view of Leu (described above) involves a third surgical instrument that has at least two elongated portions for insertion into the patient. For example, Jacobson's cannula 11 includes at least two elongated portions (anchor wires) which penetrate the spine and "prevent relative shearing movement between the cannula and the disc." *Id.* at 7:6-7; FIG. 6. As shown in Jacobson, the anchor wires extending from the distal end of the working cannula 11 have a length that is greater than their width and thickness and furthermore have the same convex cross sections with the same curvatures. *Id.* at FIGS. 5-6 and 12-13 (showing the convex exterior of each anchor wire).

positioning said third surgical instrument such that at least part of one of said at least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae; and

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of positioning the respective elongated portions over the adjacent vertebrae. For example, Jacobson discloses that the distally extending tips of the "anchor wires" are "positioned over" the adjacent vertebrae, as explicitly depicted in the annotated figure, below:



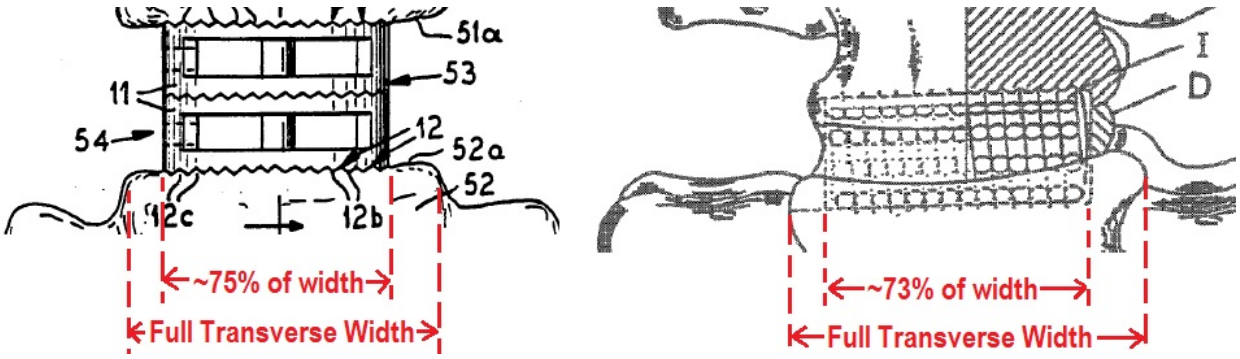
Id. at FIGS. 5 (annotated above) and FIG. 6; NUVASIVE 1001 at ¶ 31. Thus, in the resulting surgical method of Jacobson in view of Leu (described above), the anchor wires would likewise be positioned over portions of the vertebral bone (as shown above), and perhaps more so for the predictably larger version of the working cannula for fusion procedures (described above). NUVASIVE 1001 at ¶ 31.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of "inserting" an interbody intraspinal implant through the third surgical instrument, as recited in claim 17. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. NUVASIVE 1004 at FIGS. 6-8. Also, Jacobson then explains that, in the lateral surgical approach, the working cannula can also serve as the conduit for a "fusion" procedure (col: 6:13), which necessarily includes the insertion of an implant into the disc space. NUVASIVE 1001 at ¶ 28 and 31-32. Lastly, Leu expressly suggests that the interbody fusion implant can be a "composite graft" implant structure that is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae. NUVASIVE 1005 at p. 603. Thus, in accordance with the resulting surgical method of Jacobson in view of Leu, the working cannula/third surgical instrument (Jacobson's cannula 11) would be similarly positioned to receive the interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE 1001 at ¶ 28 and 31-32.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Jacobson and Leu do not disclose the specific dimensions of the interbody fusion implant as described in claim 1, but such implant structures were widely known in the prior art. NUVASIVE1001 ¶¶ 28, 32-33. For example, Brantigan discloses a non-bone spinal implant that can be inserted "laterally" and that meets all limitations of the claimed implant after positioning, including the "length" limitation. Brantigan's implant 11 provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. NUVASIVE1006 at FIGS. 8, 10, 11. Brantigan's implant meets the claimed "length" requirement. For example, Brantigan discloses that the implants are "generally oval shaped to conform with the general outline perimeter of the vertebrae." *Id.* at col. 2:2-4; *see also* col. 8:57-59 ("generally conforming in shape and size with opposing hard end plates of vertebrae"). Brantigan also discloses that the implants are "bottomed on the hard bone faces or end plates of adjacent vertebrae." *Id.* at col. 2:1-2; *see also* NUVASIVE1001 ¶ 32. In addition, Brantigan's FIG. 10 illustrates a non-bone fusion implant having been inserted laterally into a disc space, and a side-by-side comparison of figures from Brantigan (FIG. 10, which shows laterally inserted implants) and the '997 patent (FIG. 23) illustrates that Brantigan and the '997 patent are similar in lengths when implanted:



Compare NUVASIVE1006 at FIG. 10, *with* NUVASIVE1002 at FIG. 23. In addition, there can be no dispute that Brantigan discloses inserting an implant using a lateral approach, as that is specifically mentioned. NUVASIVE1006 at col. 2:64-65; 6:62-68. Also, as of 1991 when Brantigan was filed, lateral approaches were well known. NUVASIVE1001 at ¶ 11. FIG. 10 of Brantigan also specifically shows an implant that has been inserted laterally. Indeed, the transverse processes indicate that the view of FIG. 10 is anterior-to-posterior, the tool insertion holes for the implant (on the trailing end) are shown in hidden lines on the left side, and the ridges on opposing sides of the implant extend perpendicular to lateral to prevent expulsion laterally (in the direction of insertion).

Accordingly, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to employ an implant structure having a size/structure suggested by Brantigan in the surgical method of Jacobson in view of Leu so that the implant extends longitudinally across nearly the full disc space (to thereby "conform with the general outline perimeter of the vertebrae") and advantageously reduces the likelihood of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. NUVASIVE1001 at ¶ 32-33. In addition, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to employ an implant structure having a size/structure suggested by Brantigan in the aforementioned surgical method of Jacobson in view of Leu because to do so would be nothing more than "[c]ombining prior art elements according to known methods to yield predictable results." MPEP § 2143(A). In the resulting surgical method of Jacobson in view of Leu and Brantigan, the fusion implant (as suggested by Brantigan) would be inserted into the disc space via a lateral approach (as suggested by both Jacobson and Brantigan) so that the length of the implant is "sized to occupy substantially the full transverse width of the vertebral bodies" and is "greater than the depth of the disc space." NUVASIVE1001 at ¶ 28-29.

23. The method of claim 17, wherein said fusion implant is provided in combination with fusion promoting substances.

The resulting surgical method of Jacobson in view of Leu and Brantigan would provide the claimed fusion implant that is provided in combination with fusion promoting substances. Indeed, Leu expressly discloses the advantages of using the fusion implant in combination with "autologous bone marrow" and "bone-inducing proteins," and Brantigan plainly states that the fusion implant should be "packed with bone graft material to expedite fusion" of the vertebrae. NUVASIVE 1005 at p. 603; NUVASIVE 1006 at 4:50-56. Accordingly, in the resulting surgical method of Jacobson in view of Leu and Brantigan (described above), the fusion implant would likewise be provided in combination with fusion promoting substances.

IX. [GROUND 4] – Obviousness under §103 by Jacobson in view of Leu, Brantigan, and Frey

As shown in the claim chart below, claims 18-22 are unpatentable under 35 U.S.C. § 103(a) based upon Jacobson in view of Leu, Brantigan, and Frey.

18. The method of claim 17, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening. To the extent that Jacobson in view of Leu and Brantigan does not expressly disclose engaging a "spinal fixation device" to the adjacent vertebrae, such a process was commonly employed in the prior art. For example, Frey discloses the traditional practice of engaging a spinal fixation plate 6 (FIG. 5) to the adjacent vertebrae after insertion of the intradiscal implant 11 so that the plate 6 covers the trailing end of the intradiscal implant 1. NUVASIVE 1007 at FIG. 5; 3:14-23. According to Frey, the trailing end 5 of the implant 1 is "covered by" each plate 6, and each plate "is provided with a pair of openings 8 for the passage of bone screws in the adjacent vertebrae 9." *Id.* at 3:14-23. Here, a person of ordinary skill in the art would have been prompted to modify the method of Jacobson in view of Leu and Brantigan (described above) to further include a step of engaging a spinal fixation plate to the vertebrae immediately adjacent to the implant (as suggested by Frey) so as to advantageously "improve a primary securement of the [implant] prior to ingrowth of bone tissue," and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." *Id.*; MPEP § 2143(D); NUVASIVE1001 at ¶ 34. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments. NUVASIVE 1001 at ¶ 34; MPEP § 2144.04(IV) (citing to *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).)
19. The method of claim 18, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant. As described in the analysis of claim 18 (above), the resulting surgical method of Jacobson in view of Leu, Brantigan, and Frey would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant. NUVASIVE 1007 at 3:16-17; FIG. 5 (showing the abutment between the plate 6 and the trailing end 5 of the implant 1).
20. The method of claim 17, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine. As described in the analysis of claim 18 (above), Jacobson in view of Leu, Brantigan, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8) to prevent unwanted excursion. *Id.* at 3:16-17.

21. The method of claim 20, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

As described in the analysis of claim 18 (above), the resulting surgical method of Jacobson in view of Leu, Brantigan, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8). *Id*.

22. The method of claim 20, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

The resulting surgical method of Jacobson in view of Leu, Brantigan and Frey would provide a spinal fixation plate that is coupled to the implant in that the plate is integrally formed with the implant. *Id.* at FIG. 6; col. 3:25-30. One of skill in the art would modify an implant in this manner to take advantages of the fixation advantages afforded by an implant with an integral plate as taught by Frey. Such a plate would be coupled to the vertebrae using fixation means such as screws, as taught by Frey. *Id.* at FIG. 6; col. 3:19-20.

X. [GROUND 5] – Obviousness under §103 by Jacobson in view of Leu and Michelson '247

As shown in the claim chart below, claims 24 and 30 of the `997 patent are obvious under §103 based upon Jacobson in view of Leu and Michelson '247.

24. A method comprising:

Jacobson discloses a surgical method of accessing a spinal disc space that, much like the '997 patent, includes a lateral approach path to the spine. For example, Jacobson expressly describes a "lateral" approach for accessing a disc space between two adjacent vertebrae via a working cannula for purposes of performing a discectomy and, optionally, a vertebral fusion procedure. NUVASIVE 1004 at FIGS. 3 and 8; 2:23-33; 2:40-43; 6:13 (describing a "fusion" procedure which would include an interbody implant in the disc space to achieve fusion).

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal

plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Similar to many prior art lateral spinal surgeries that accessed the spine through an outer tubular cannula, Jacobson discloses the claimed step of making a laterally-located incision to gain access to a disc space between two adjacent vertebrae located within a portion of the lumbar spine. For example, Jacobson discloses the laterally-located incision point in at least two instances. First, Jacobson teaches that the laterally-located incision point is formed when the initial guide member 8 (needle or 3-mm wire) penetrates the skin. *Id*. at FIG. 3; 5:28-31; 5:42-45 (describing a guide wire having a diameter of nearly "3-mm," which would require formation of small skin incision); NUVASIVE 1001 at ¶ 24 and 35. Second, Jacobson also discloses that the laterally-located incision point is further incised to "an approximately one centimeter long skin incision." *Id*. at 5:45-46.

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

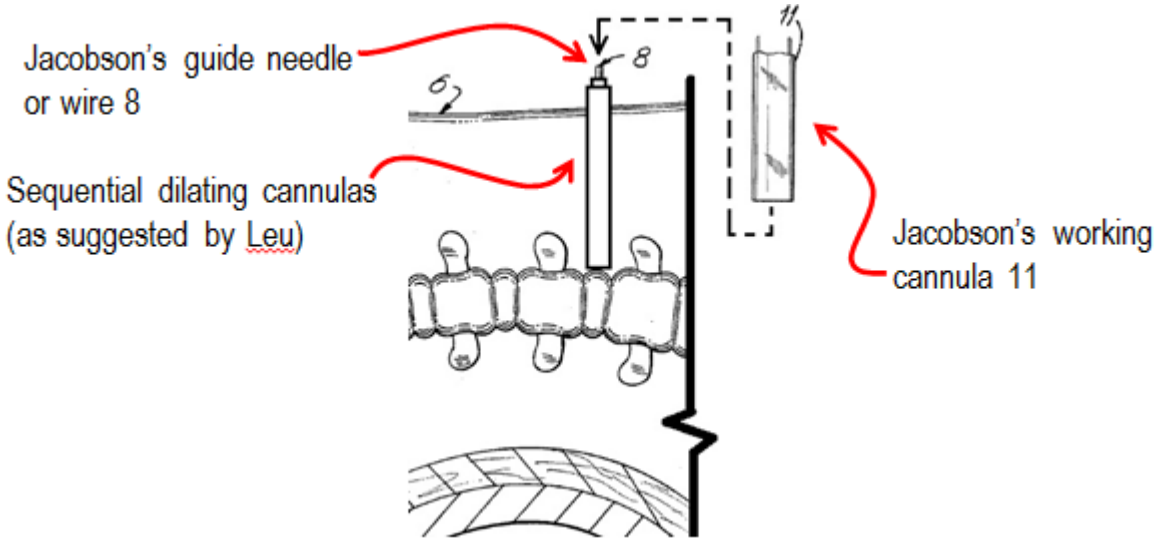
Jacobson teaches that, during the lateral surgical approach to the spine, a first surgical instrument (e.g., Jacobson's guide needle or wire 8) is advanced into the body of the patient through said incision and along said path and anterior to the transverse processes. *Id.* at FIG. 3; 5:28-31; 5:42-45 (disclosing a nearly 3-mm guide wire instead of the guide needle). As taught by Jacobson, the initial guide needle or wire 8 extends along the lateral path (anterior to the transverse processes) and thereafter serves "as a guide member" for a second instrument that is subsequently advanced over the guide needle or wire 8 towards the targeted spinal disc. *Id.* at 5:39-41; FIG. 3.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said second surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

Jacobson discloses that a speculum 10 (not sequential dilators) may be advanced over the initial guide needle or wire 8 so as to widen the surgical access path for subsequent insertion of the final working cannula 11. *Id.* at 5:48-54; FIGS. 4-5. Jacobson's speculum 10 is different from the claimed "second surgical instrument" because this claim later requires that the third surgical instrument be advanced "over . . . said second instrument" (rather than between blades of the speculum 10). By the early 1990s, however, surgeons commonly employed the obvious choice of using sequential one or more dilators (rather than Jacobson's speculum 10) to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. NUVASIVE 1001 at ¶ 25-26 and 35. For example, Leu discloses a surgical method for accessing a lumbar disc space via a working cannula to deliver a spinal fusion implant. NUVASIVE

1005 at p. 594 (describing a technique of "percutaneous lumbar interbody fusion"); p. 596 (describing "four cannulas" used for sequential dilation and a "working cannula"); p. 603 (suggesting the use of fusion implants ("composite grafts") through the working cannula). In such prior art surgical methods, Leu expressly teaches the general prior art practice in which sequential dilators ("four cannulas of increasing diameter are stepwise overslipped, one upon the other") are advanced over the "central guide needle" to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. *Id.* at p. 596.

Accordingly, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to replace Jacobson's speculum with sequential dilators (as suggested by Leu) so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue, and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." MPEP § 2143(D); NUVASIVE 1001 at ¶ 25-26 and 35. One example of the resulting surgical method is provided below:



NUVASIVE 1004 at FIG. 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over the guide wire). Even though Leu's specific surgical method employs four sequential dilators, Leu shows the more general prior art knowledge that surgeons could readily use sequential dilators "[o]ver a central guide needle" prior to inserting the "working cannula." NUVASIVE 1005 at p. 596. Here, the person of ordinary skill in the art would predictably select the particular number of sequential dilators according to the desired size of the surgical access path for receiving the final working cannula (Jacobson's working cannula 11 or a predictably larger version thereof for purposes of Jacobson's suggested "fusion" surgery, as described below) over the last sequential dilator. NUVASIVE 1001 at ¶ 25-26 and 35. Indeed, Leu expressly describes the prior art knowledge that in "fusion" pro-

cedures, the working cannula should "larger than the types used for" procedures that merely remove some disc material. NUVASIVE 1005 at p. 596. Thus, in the resulting method, any one of the sequential dilators (as suggested by Leu) that are advanced over Jacobson's initial guide needle or wire 8 (the first instrument) along Jacobson's lateral approach path would provide the claimed second instrument. NUVASIVE 1001 at ¶ 25-26 and 35.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end,

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of advancing a third surgical instrument, as recited in claim 24. As previously described, Jacobson's working cannula 11 (the "third surgical instrument," as recited in claim 24) would be advanced through Jacobson's lateral incision location and over the sequential dilators (suggested by Leu above). Furthermore, Jacobson illustrates that the working cannula 11 includes a central lumen extending therethrough, through which the sequential dilators would pass, as the cannula 11 is advanced to the disc space. *Id.* at FIGS. 5-6. Much like the outer sleeve 140 of the '997 patent, Jacobson expressly discloses that the working cannula 11 "acts as a conduit for insertion of surgical instruments" and may act as an instrument conduit for a "fusion" procedure. NUVASIVE 1004 at 6:7-13; FIGS. 6-8.

said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

Jacobson's working cannula 11 (the "third surgical instrument" as recited in claim 24) has "anchor means for anchoring it to the disc. . . . the anchor means is one or more anchor wires 33, which pierce the [sic] disc capsule and prevent shearing movement between the disc and cannula." NUVASIVE 1004 at 9:41-45 (emphasis added). As an alternative to the depicted anchor wires, Jacobson expressly suggests that "[o]ther forms of anchor means

may be used for the cannula. For example, sharp tines may be affixed to the cannula tip . . . ." NUVASIVE 1004 at 10:1-6. Jacobson does not illustrate the "sharp tines" at the tip of the working cannula 11, but this conventional configuration is illustrated by Michelson '247, which shows a similar anchoring tip with sharp tines:

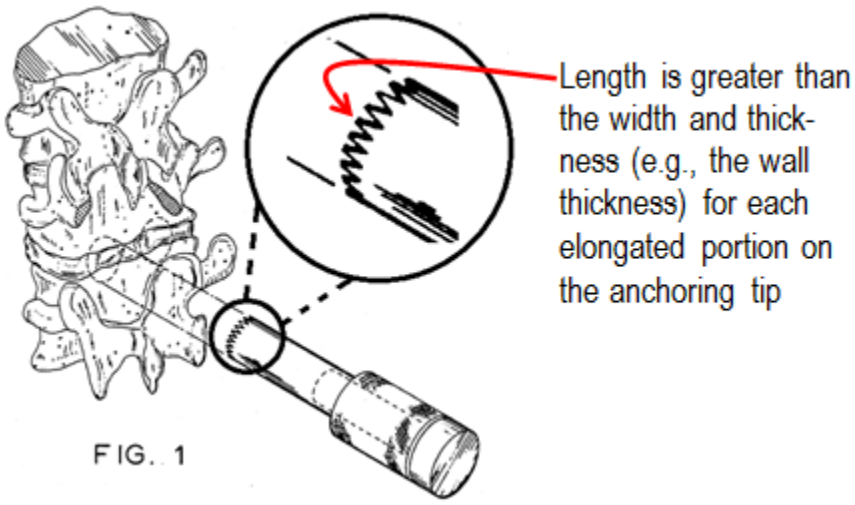
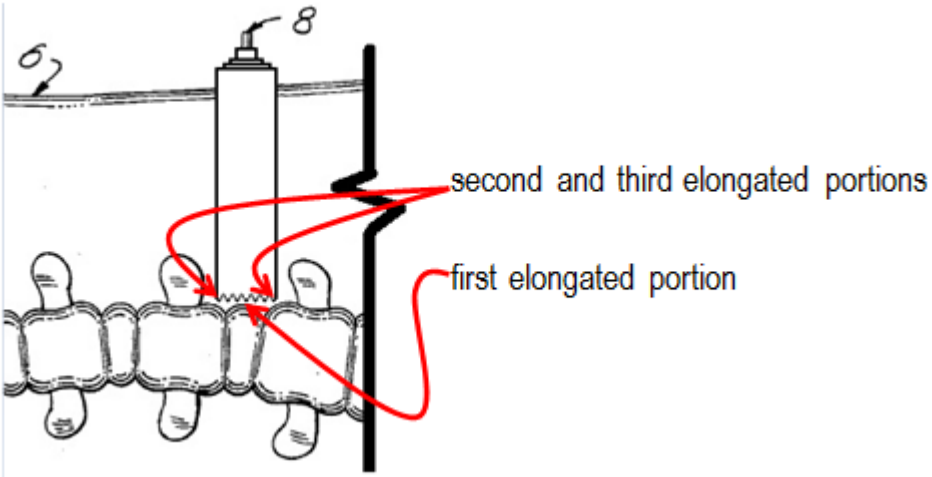


FIG. 1

NUVASIVE 1008 at FIG. 1 (modified to show close up of the anchoring teeth on the spinal access cannula). Michelson '247 shows the well-known structure for such anchoring teeth in which the length is greater than the width and thickness. *Id.* at FIGS. 2-3; NUVASIVE 1001 at ¶ 35. Here, a person of ordinary skill in the art would have been prompted to include Michelson '247's teeth on the distal end of Jacobson's working cannula so that the teeth are firmly "seated" in the disc space and adjacent vertebrae, and because Jacobson indicates that the anchor means may be sharp tines. NUVASIVE 1008 at 9:22-25. Moreover, a person of ordinary skill in the art would have been prompted to include teeth (as evidenced by Michelson '247) because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." MPEP § 2143(D); NUVASIVE 1001 at ¶ 35.

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

Jacobson's cannula (modified to include Michelson '247's teeth, as described above) would include a first tooth over the disc space, a second tooth over an adjacent vertebrae, and a third tooth over a third vertebrae, as shown in the figure below.



In the figure above, the cannula is shown with a width that is sufficient to permit insertion of an implant for the "fusion" procedure that is expressly suggested by Jacobson and Leu (refer to the analysis of the "advancing a second surgical instrument" step above). NUVASIVE 1004 at 6:7-13; NUVASIVE at p. 596; NUVASIVE 1001 at ¶ 35. Further, even with Jacobson's originally illustrated working cannula 11 (sized for a disc removal procedure), the resulting anchoring teeth would be positioned over the disc space and the adjacent vertebrae (refer to the analysis of claim 17 above).

withdrawing said second surgical instrument and said first surgical instrument from the body; and

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of withdrawing the second surgical instrument and the first surgical instrument from the body. For example, Jacobson shows in Figure 6 that all introductory instruments should be withdrawn from the working cannula 11 so that a surgeon may introduce surgical tools into the cannula 11. NUVASIVE 1004 at FIGS. 6-8. In the resulting surgical method of Jacobson in view of Leu, a person of ordinary skill in the art would have recognized that the surgeon would remove the guide needle or wire 8 and the sequential dilators (suggested by Leu, as described above) from the working cannula so as to provide an access conduit for the surgical instruments (as illustrated by Jacobson).

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of "inserting" an interbody intraspinal implant through the third surgical instrument, as recited in claim 24. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening

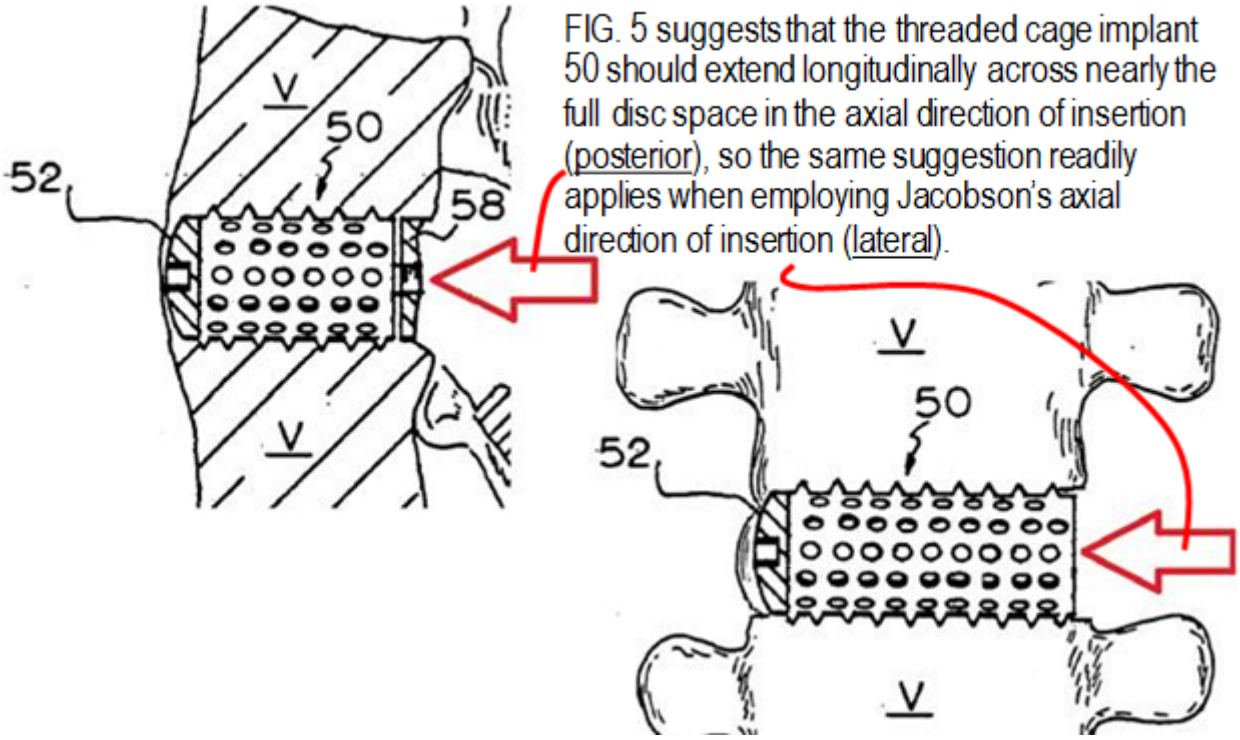
is created in the lumbar spine. NUVASIVE 1004 at FIGS. 6-8. Also, Jacobson then explains that, in the lateral surgical approach, the working cannula can also serve as the conduit for a "fusion" procedure (col: 6:13), which necessarily includes the insertion of an implant into the disc space. NUVASIVE 1001 at ¶ 28 and 35-36. Lastly, Leu expressly suggests that the interbody fusion implant can be a "composite graft" implant structure that is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae. NUVASIVE 1005 at p. 603. Thus, in accordance with the resulting surgical method of Jacobson in view of Leu, the working cannula/third surgical instrument (Jacobson's cannula 11) would be similarly positioned to receive the interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE 1001 at ¶ 28 and 35-36.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Jacobson and Leu do not disclose the specific dimensions of the interbody fusion implant that is described in claim 24, but implant structures similar to that described in the '997 patent were known in the prior art. For example, Michelson '247 discloses a spinal fusion implant 50 (FIG. 5) having virtually the identical structure and function to the implant "I" illustrated in FIG. 18 of the '997 patent. NUVASIVE 1008 at FIGS. 4-5; 8:36-51. For example, Michelson '247 teaches that the implant 50 provides the claimed implant elements of opposed surfaces having bone engaging projections and a length of the implant being greater than the maximum height of the implant. *Id.* Because Michelson '247 does not expressly disclose that the implant 50 is inserted in a lateral approach, Michelson '247 does not expressly describe the claim limitation related to the "length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space." However, Michelson '247 plainly and expressly suggests to a skilled artisan that the threaded cage implant 50 should extend longitudinally across nearly the full disc space along the direction of insertion. *Id.* at FIG. 5 (at left below, plainly suggesting how far the length of the threaded cage should extend across the disc space in the axial direction of insertion). NUVASIVE 1001 at ¶ 35-36. Furthermore, Michelson '247 teaches one example in which the implant 50 has an ex-

ample length of "26mm", which is certainly long enough to extend substantially the full width of the adjacent vertebrae at particular levels of the spine (and most certainly in smaller patients). NUVASIVE 1001 at ¶ 35-36.

In the resulting surgical method of Jacobson in view of Leu and Michelson '247 (described above), the fusion implant is indeed inserted into the disc space via a lateral approach, so a person of ordinary skill in the art would have recognized from the suggestion in Michelson '247 that the size of the threaded cage implant 50 should be selected to extend longitudinally across nearly the full disc space in the direction of insertion (lateral insertion in this resulting surgical method).



NUVASIVE 1001 at ¶ 35-36; MPEP § 2144.04(IV) (citing *Gardner v.TEC Systems*, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984)). Here, a person of ordinary skill in the art would have been prompted to use a longer threaded implant (as suggested by Michelson '247) for use in Jacobson's lateral insertion path so that the implant extends longitudinally across the disc space in the lateral insertion direction and advantageously provides improved mechanical support and reduces the likelihood of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. NUVASIVE 1001 at ¶ 35-36. Simply put, in the resulting surgical method of Jacobson in view of Leu and Michelson '247 (described above), the fusion implant is indeed inserted into the disc space via a lateral approach, so the relative dimensions of Michelson '247's implant 50 would have been predictably selected in accordance with the lateral insertion orientation, thereby providing a length of the implant that

is "sized to occupy the full transverse width of the vertebral bodies."

30. The method of claim 24 wherein said fusion implant is provided in combination with fusion promoting substances.

The resulting surgical method of Jacobson in view of Leu and Michelson '247 would provide the claimed fusion implant that is provided in combination with fusion promoting substances. Indeed, Leu expressly discloses the advantages of using the fusion implant in combination with "autologous bone marrow" and "bone-inducing proteins," and Michelson '247 plainly states that the threaded cage implant should be loaded with "pure cancellous bone." NUVASIVE 1005 at p. 603; NUVASIVE 1008 at 10:7-14.

XI. [GROUND 6] – Obviousness under §103 by Jacobson in view of Leu, Michelson '247, and Frey

As shown in the claim chart below, claims 25-29 are unpatentable under at least 35 U.S.C. § 103(a) based upon Jacobson in view of Leu, Michelson '247, and Frey.

25. The method of claim 24 further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.
To the extent that Jacobson in view of Leu and Michelson '247 does not expressly disclose engaging a "spinal fixation device" to the adjacent vertebrae, such a process was commonly employed in the prior art. For example, Frey discloses the traditional practice of engaging a spinal fixation plate 6 (FIG. 5) to the adjacent vertebrae after insertion of the intradiscal implant 1 so that the plate 6 covers the trailing end of the intradiscal implant 1. NUVASIVE 1007 at FIG. 5; 3:14-23. According to Frey, the trailing end 5 of the implant 1 is "covered by" each plate 6, and each plate "is provided with a pair of openings 8 for the passage of bone screws in the adjacent vertebrae 9." *Id.* at 3:14-23. Here, a person of ordinary skill in the art would have been prompted to modify the method of Jacobson in view of Leu and Michelson '247 (described above) to further include a step of engaging a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Frey) so as to advantageously "improve a primary securement of the [implant] prior to ingrowth of bone tissue," and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." *Id.*; MPEP § 2143(D); NUVASIVE1001 at ¶ 37. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments. NUVASIVE 1001 at ¶ 37; MPEP § 2144.04(IV) (citing to *Gardner v.TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).)

26. The method of claim 25 wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant. As described in the analysis of claim 25 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Frey would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant. NUVASIVE 1007 at 3:16-17; FIG. 5 (showing the abutment between the plate 6 and the trailing end 5 of the implant 1).
27. The method of claim 24 further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine. As described in the analysis of claim 25 (above), Jacobson in view of Leu, Michelson '247, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8) to prevent unwanted excursion. *Id.* at 3:16-17.
28. The method of claim 27 wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member. As described in the analysis of claim 25 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8). *Id*.
29. The method of claim 27 wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening. The resulting surgical method of Jacobson in view of Leu, Michelson '247 and Frey would provide a spinal fixation plate that is coupled to the implant in that the plate is integrally formed with the implant. *Id.* at FIG. 6; col. 3:25-30. One of skill in the art would modify an implant in this manner to take advantages of the fixation advantages afforded by an implant with an integral plate as taught by Frey. Such a plate would be coupled to the vertebrae using fixation means such as screws, as taught by Frey. *Id.* at FIG. 6; col. 3:19-20.

XII. [GROUND 7] – Obviousness under §103 by Michelson '661 in view of McAfee and Lynn

As shown in the claim chart below, claims 9-16 are obvious under §103 based upon Michelson '661 in view of McAfee and Lynn. This ground for rejection is premised upon the conclusion that claims 9-16 are not entitled to the earliest claimed priority date (Feb. 27, 1995), but instead recite at least two claim limitations added no earlier than the '997 patent's Nov. 29, 2011 filing date, and that were not previously disclosed in priority applications.

First, claim 9 and its dependents require a method in which "a single elongated por-

tion [is] ***removably attached*** to said distal end of said third surgical instrument," which is allegedly supported by the embodiment depicted in FIG. 35 of the '997 patent (e.g., the distal tip 1104 is removably attached to the tubular sleeve 1102). Claim 9, however, requires "inserting" an implant "***through said third surgical instrument.***" The only surgical method described in connection with FIG. 35 is that the tubular sleeve 1102 is entirely removed from the patient ***before*** the implant is inserted under "direct vision"; as such, the implant never passes through the tubular sleeve 1102 as claimed. NUVASIVE 1002 at 21:39 to 22:35. In other words, the '997 patent never discloses a method in which the "third surgical instrument" provides *both* elements of removably attaching to a single elongated portion *and* receiving the implant inserted therethrough. *Id.*; NUVASIVE 1001 at ¶16. For this reason alone, claims 9-16 are not entitled to the Feb. 25, 1995 priority date, and are instead entitled only to the date that such disclosure was first added to the application—the March 20, 2012 Amendment.

In addition, claims 9-16 recite a "length" limitation discussed in the claim interpretation section above, namely, "the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." But, all the implants disclosed in the '997 patent fall short of the "full transverse width of the vertebral bodies." NUVASIVE 1002 at FIGS. 18-20, 22-24, and 29-34; NUVASIVE 1001 at ¶ 17-20. This fact was at issue in the reissue proceedings for U.S. 5,772,661, in which it was found that the '661 specification (similar in these respects to the '997 specification) does not dis-

close positioning an implant to contact at least a portion of a cortical rim (i.e., the outside portion) of the adjacent vertebrae. Indeed, Patent Owner – in that reissue proceeding – relied on FIG. 30 of the '661 patent (i.e., FIG. 30 of the '997 patent) in support of an argument that the '661 specification discloses such a positioning. But, the Examiner rejected that contention, reasoning as follows:

> Fig. 30 of Applicant's disclosure is a two-dimensional representation of a three dimensional structure. The actual points of contact of the ends of the implant with each of the adjacent vertebrae are different due to the curvature of the implant in a sagittal plane. Since, the surface of an end of the implant curves away from the cortical rim due to the curvature of the implant in a sagittal plane, Applicant's argument that "The area of contact of the implant I with the vertebra L inherently includes the cortical rim thereof" is not persuasive.

U.S. Patent Application Serial No. 12/655,178, filed Dec. 23, 2009, Final Rejection, p. 13 (Aug. 11, 2011). Given that the implant does not contact the cortical rim, it cannot extend across the full transverse width of the adjacent vertebrae.

In addition, the inventor in the '997 patent made statements to the Patent Office highlighting that the implants of the '661 specification (and consequently the '997 specification) do not rest upon the hard outer apophyseal rim of adjacent vertebrae, and thus are less than the full transverse width of the adjacent vertebrae. In particular, Michelson U.S. Patent No. 6,241,770, filed in 1999, shows the '661 patent's implant in a "prior art" figure 11, and states that the '661 ('997) implant leaves "little of the implant sitting on the apophyseal rim," and in addition stated that "[t]he configuration of prior art implants prevents the utilization of the apophyseal rim bone, located at the perimeter of the vertebral body to support

the implants at their trailing ends." '770 patent, at 3:57-4:12.

If it is determined that the implant length limitation of the '997 imposes restrictions that distinguish the prior implants discussed above (e.g., Brantigan), then similarly the requirement must not be supported by either the priority application (the '661 patent) or the '997 patent. As such, the proper priority date for the claims would be the first date that a claim having the recited length limitation was presented, which was Nov. 29, 2011 at the earliest. It deserves mention that the fact that similar claim limitations were presented in the '661 reissue proceeding is of no help, because the '997 patent does not claim priority to that reissue application; nor could it.

Accordingly, if it is found that the priority applications do not support claim under either of the above two reasons, Michelson '661, McAfee, and Lynn are prior art under 35 U.S.C. § 102(b), or § 102(e) for Lynn.

9. A method comprising: making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses a method having the claimed "making an incision" step as recited in claim 9. In particular, Michelson '661 discloses an incision is made to gain access to a disc space between two adjacent vertebrae, the incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane. NUVASIVE 1010 at 3:46-56; FIGS. 1-2 and 23-24.

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a first surgical instrument" step as recited in claim 9. In particular, Michelson '661 discloses a guide pin 30 inserted laterally toward a thoracic disc space. *Id.* at FIGS. 1-2; 9:9-11.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a second surgical instrument" step as recited in claim 9. In particular, Michelson '661 discloses that a distractor 100 is advanced laterally over the guide pin 30, and the distractor 100 includes a passageway 107 to receive the guide pin 30. *Id.* at FIG. 2; 9:36-34.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a third surgical instrument" step as recited in claim 9. In particular, Michelson '661 discloses that an outer tubular member 1102 is advanced laterally over the distractor 100, and the outer tubular member 1102 includes a distal opening to receive the distractor 100. *Id.* at FIG. 35; 22:33-39; 10:47-50.

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed step of "positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space" as recited in claim 9. In

particular, Michelson '661 discloses that the outer tubular member 1102 is part of a "convertible" outer sleeve 1100, and that a distal tip portion 1104 is removably attached to the outer tubular member 1102 for purposes of a particular surgical method that would provide "direct vision." *Id.* at FIG. 35; 22:19-55 (explaining that the distal tip 1104 is removably attached to the outer tubular member 1102 for purposes of detaching and withdrawing the outer tubular member before the implant is inserted, thereby providing "direct vision" to the vertebrae for the surgeon). Under a broadest reasonable interpretation of this claim language, the removable distal tip 1104 includes the structures of the single elongated portion as recited in claim 9.

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed step of "inserting said single elongated portion into the disc space" as recited in claim 9. For example, Michelson '661 discloses that an extension member 1120 of the removably distal tip 1104 is "seated in the disc space." *Id.* at 22:43.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

Michelson '661 does not disclose that an implant is inserted through the same surgical instrument (e.g., the "third surgical instrument" in claim 9) that is removably attached to the claimed single elongated portion. In particular, this claim requires "inserting" an implant "through said third surgical instrument," which is also the same instrument to which the "single elongated portion" is removably attached (refer to the "position" method step above). This claimed method is plainly different from the only surgical method described in connection with FIG. 35 (the claimed removable single elongated portion). In the surgical method disclosed in connection with FIG. 35, the "third surgical instrument" (the outer tubular sleeve 1102) is entirely removed from the patient before the implant is inserted under "direct vision" (the implant never passes through the tubular sleeve 1102 in the disclosed method). *Id.* at FIG. 35; 22:19-55. In other words, Michelson '661 never discloses any surgical method in which the "third surgical instrument" provides both elements of removably attaching to a single elongated portion and receiving the implant inserted therethrough. *Id.*

McAfee, however, discloses the prior art knowledge that spinal surgery tools can be inserted through *both* an outer tubular member 12 and a removable attached anchor tip 20—not merely through the anchor tip alone like in the method of Michelson '661. In particular, McAfee plainly teaches the conventional configuration in which an anchoring ring 20 is removably attached to the end of the working cannula 12 during both the initial delivery to the spine and during the subsequent surgical method steps when the surgical tools pass

through the passageway defined by the cannula 12 and the removable tip 20. NUVASIVE 1009 at 3:37-41; 5:63-67; 7:55-64 and FIGS. 2, 5 and 6 (showing the surgical tool being advanced through both the cannula 12 and the removable tip 20).

Here, a person of ordinary skill would have been prompted to modify the surgical method of Michelson '661 so that the implant of Michelson '661 is inserted through both the outer tubular member and the removably attached anchoring tip (as suggested by McAfee) so that the outer tubular member is advantageously anchored to the surgical site while the outer tubular member maintains the access path clear of intervening bodily tissue between the skin incision and the spinal site, and also because to do so would be nothing more than "[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results." MPEP § 2143(D); *see* NUVASIVE1009 at FIG. 6.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses that the implant "I" provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of the implant being greater than the maximum height of the implant. *Id.* at FIGS. 18, 19, and 23.

As previously described, the Patent Office has already concluded that Michelson '661 does not disclose the claimed "length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." In particular, the Patent Office specifically determined that in a reissue application of Michelson '661 that the same specification fails to support this claimed "length" limitation. See U.S. Patent Application Serial No. 12/655,178, filed Dec. 23, 2009, Final Rejection, p. 13 (Aug. 11, 2011).

Lynn, however, suggests an implant structure that extends translaterally across the full transverse width of the vertebral body from a lateral aspect of the spine. NUVASIVE 1011 at FIGS. 7A, 14, 16B-C & 21 (showing a laterally inserted fusion implant extending slightly more than the full transverse width of the adjacent vertebral members); col. 15:59-61 (describing an implant "sized to generally span across the entire width of the adjacent vertebral

members"). Here, a person of ordinary skill in the art would have been prompted to select an implant with an appropriate length to span across the entire disc space and maximize the surface area of the vertebral bone in contact with the implant, when inserted laterally. Thus, the resulting combination of Michelson '661 in view of Lynn would provide all elements of the claimed method, including the claimed implant.

10. The method of claim 9, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "engaging a spinal fixation device" step as recited in claim 10. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae after inserting of the implant into the laterally facing opening. NUVASIVE 1010 at FIG. 24; 17:23-30.

11. The method of claim 10, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

Michelson '661 discloses that the spinal fixation device 400 has a plate configured to cover at least a portion of the trailing end of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

12. The method of claim 9, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

Michelson '661 discloses the claimed "engaging a plate" step as recited in claim 12. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae for purposes of preventing unwanted excursion of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

13. The method of claim 12, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

Michelson '661 discloses that the spinal fixation plate 400 has fastening members in the form of prongs 420, 422. NUVASIVE 1010 at FIG. 24; 17:23-30.

14. The method of claim 12, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

Michelson '661 discloses that a locking screw 416 engages the spinal fixation plate 400. NUVASIVE 1010 at FIG. 24; 17:23-30.

15. The method of claim 9, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "coupling a spinal fixation device" step and the claimed "engaging said spinal fixation device" step as recited in claim 15. In particular, Michelson '661 discloses that a locking screw 416 engages the spinal fixation plate 400 to the implant, and Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae using prongs 420, 422. NUVASIVE 1010 at FIG. 24; 17:23-30.

16. The method of claim 9, wherein said fusion implant is provided in combination

with fusion promoting substances.

Michelson '661 discloses that the implant is provided in combination with "substances consistent with bony fusion." NUVASIVE 1010 at 16:14-16.

XIII. [GROUND 8] – Obviousness under §103 by Michelson '661 in view of Lynn

As shown in the claim chart below, claims 17-30 are obvious under §103 based upon Michelson '661 in view of Lynn. This ground for rejection is premised upon a finding that claims 17-24 are not entitled to the earliest claimed priority date (Feb. 27, 1995), but instead recite "length of implant" limitations added no earlier than during the prosecution of the continuation application that became the '997 patent, meaning no earlier than Nov. 29, 2011.

Regarding claims 17-23, claim 17 has the same length limitation as claim 9 (with the modifier "substantially"). As discussed above, if it is determined that the implant length limitation of the '997 imposes restrictions that distinguish the prior art implants discussed above (e.g., Brantigan), then similarly the claimed length requirement lacks written description support in the priority application (i.e., the '661 patent), intervening applications, and in the continuation application that became the '997 patent. As such, the proper priority date for these claims would be the first date that a claim having the recited length limitation (with "substantially") was presented, which was Nov. 29, 2011 at the earliest. Again, it deserves mention that the fact that similar claim limitations were presented in the '661 reissue proceeding is of no help, because the '997 patent does not claim priority to that reissue application; nor could it. Thus, assuming a narrow construction of the length limitation is adopted for claims 17-23, Michelson '661 and Lynn are prior art publications, under 35 U.S.C. §

102(b), or § 102(e) for Lynn.

Regarding claims 24-30, claim 24 has a clearly unsupported implant length limitation in that it that it does not even include the modifier "substantially," as discussed in the claim interpretation section above. As discussed previously, the '997 specification includes no disclosure of implants that, when positioned, occupy the full transverse width of the adjacent vertebrae. They are all clearly shorter than the full transverse width. As such, the earliest possible priority date for claims 24-30 is the date this limitation was first added into the claims, March 20, 2012. As such, both Michelson '661 and Lynn are prior art publications, under 35 U.S.C. § 102(b), or § 102(e) for Lynn.

17. A method comprising: making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses a method having the claimed "making an incision" step as recited in claim 17. In particular, Michelson '661 discloses an incision is made to gain access to a disc space between two adjacent vertebrae, the incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane. NUVASIVE 1010 at 3:46-56; FIGS. 1-2 and 23-24.

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a first surgical instrument" step as recited in claim 17. In par-

ticular, Michelson '661 discloses a guide pin 30 inserted laterally toward a thoracic disc space. *Id.* at FIGS. 1-2; 9:9-11.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a second surgical instrument" step as recited in claim 17. In particular, Michelson '661 discloses that a distractor 100 is advanced laterally over the guide pin 30, and the distractor 100 includes a passageway 107 to receive the guide pin 30. *Id.* at FIG. 2; 9:36-34.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end,

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a third surgical instrument" step as recited in claim 17. In particular, Michelson '661 discloses that an outer sleeve 140 is advanced laterally over the distractor 100, and the outer sleeve 140 includes a distal opening to receive the distractor 100. *Id.* at FIGS. 6-7; 10:47-50.

said third surgical instrument having at least two elongated portions for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, said length of each of said at least two elongated portions being greater than the width and the thickness of said at least two elongated portions, each of said at least two elongated portions have a cross section through the width and the thickness and perpendicular to the length of said at least two elongated portions, respectively, each cross section of said at least two elongated portions having a convex exterior surface, said convex surfaces of each of said at least two elongated portions having the same curvature;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "third surgical instrument having at least two elongated portions" with the structures recited in claim 17. In particular, Michelson '661 discloses that the outer sleeve 140 has "two prongs 149 and 150 sufficiently spaced apart to penetrate and hold fixed the two adjacent vertebrae." *Id.* at 10:58-61; FIGS. 7 and 7A.

positioning said third surgical instrument such that at least part of one of said at

least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae; and

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "third surgical instrument having at least two elongated portions" with the structures recited in claim 17. In particular, Michelson '661 discloses that the two prongs 149 and 150 are positioned "to facilitate insertion into the vertebrae T_7 and T_8." *Id.* at 10:65-67.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "inserting" step as recited in claim 17. In particular, Michelson '661 discloses that a non-bone implant "I" is inserted laterally through the outer sleeve 140 into a laterally facing opening into the thoracic disc space. *Id.* at FIGS. 17 and 19; 16:10-37.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses that the implant "I" provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* at FIGS. 18, 19, and 23.

As previously described, the Patent Office has already concluded that Michelson '661 does not disclose that claimed "length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae." In particular, the Patent Office specifically determined that in a reissue application of Michelson '661 that the same specification fails to support this claimed "length" limitation. See U.S. Patent Application Se-

rial No. 12/655,178, filed Dec. 23, 2009, Final Rejection, p. 13 (Aug. 11, 2011).

Lynn, however, suggests an implant structure that extends translaterally across the full transverse width of the vertebral body from a lateral aspect of the spine. NUVASIVE 1011 at FIGS. 7A, 14, 16B-C & 21 (showing a laterally inserted fusion implant extending slightly more than the full transverse width of the adjacent vertebral members); col. 15:59-61 (describing an implant "sized to generally span across the entire width of the adjacent vertebral members"). Here, a person of ordinary skill in the art would have been prompted to select an implant with an appropriate length to span across the entire disc space and maximize the surface area of the vertebral bone in contact within the implant, when inserted laterally. Thus, the resulting combination of Michelson '661 in view of Lynn would provide all elements of the claimed method, including the claimed implant.

18. The method of claim 17, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "engaging a spinal fixation device" step as recited in claim 18. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae after inserting of the implant into the laterally facing opening. NUVASIVE 1010 at FIG. 24; 17:23-30.

19. The method of claim 18, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

Michelson '661 discloses that the spinal fixation device 400 has a plate configured to cover at least a portion of the trailing end of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

20. The method of claim 17, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

Michelson '661 discloses the claimed "engaging a plate" step as recited in claim 20. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae for purposes of preventing unwanted excursion of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

21. The method of claim 20, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

Michelson '661 discloses that the spinal fixation plate 400 has fastening members in the form of prongs 420, 422. NUVASIVE 1010 at FIG. 24; 17:23-30.

22. The method of claim 20, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

Michelson '661 discloses that a locking screw 416 engages the spinal fixation plate 400. NUVASIVE 1010 at FIG. 24; 17:23-30.

23. The method of claim 17, wherein said fusion implant is provided in combination with fusion promoting substances.

Michelson '661 discloses that the implant is provided in combination with "substances

consistent with bony fusion." NUVASIVE 1010 at 16:14-16.

24. A method comprising: making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses a method having the claimed "making an incision" step as recited in claim 24. In particular, Michelson '661 discloses an incision is made to gain access to a disc space between two adjacent vertebrae, the incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane. NUVASIVE 1010 at 3:46-56; FIGS. 1-2 and 23-24.

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a first surgical instrument" step as recited in claim 24. In particular, Michelson '661 discloses a guide pin 30 inserted laterally toward a thoracic disc space. *Id.* at FIGS. 1-2; 9:9-11.

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said second surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a second surgical instrument" step as recited in claim 24. In particular, Michelson '661 discloses that a distractor 100 is advanced laterally over the guide pin 30, and the distractor 100 includes a passageway 107 to receive the guide pin 30. *Id.* at FIG. 2; 9:36-34.

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical

instrument and an opposite proximal end,

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "advancing a third surgical instrument" step as recited in claim 24. In particular, Michelson '661 discloses that an outer sleeve 140 is advanced laterally over the distractor 100, and the outer sleeve 140 includes a distal opening to receive the distractor 100. *Id.* at FIGS. 6-7; 10:47-50.

said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "third surgical instrument having a first, a second, and a third elongated portion" with the particular structural features recited in claim 24. For example, Michelson '661 discloses that the outer sleeve 140 has "an extension member 148" (first elongated portion) and "two prongs 149 and 150" (second and third elongated portions) that are part of the outer sleeve 140 and that provide the claimed structural features of the first, second, and third elongated portions. *Id.* at 10:58-67; FIGS. 7 and 7A.

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed step of "positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae." For example, Michelson '661 discloses that the outer sleeve 140 is advanced laterally over the distractor 100 toward the disc space (10:47-50), and that the extension member 148 (first elongated portion) thereafter pene-

trates the disc space while the respective prongs 148 and 149 (the second and third elongated portions) penetrate the respective vertebrae T_7 and T_8. *Id.* at FIG. 7.

withdrawing said second surgical instrument and said first surgical instrument from the body; and

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed step of "withdrawing said second surgical instrument and said first surgical instrument from the body" as recited in claim 24. In particular, Michelson '661 discloses that the guide pin 30 and the distractor 100 are withdrawn. *Id.* at 9:60-62; 13:5-14.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "inserting" step as recited in claim 24. In particular, Michelson '661 discloses that a non-bone implant "I" is inserted laterally through the outer sleeve 140 into a laterally facing opening into the thoracic disc space. *Id.* at FIGS. 17 and 19; 16:10-37.

said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses that the implant "I" provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* at FIGS. 18, 19, and 23.

As previously described, the Patent Office has already concluded that Michelson '661 does not disclose the claimed "length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." In particular, the Patent Office specifically determined that in a reissue application of Michelson '661 that the

same specification fails to support this claimed "length" limitation. See U.S. Patent Application Serial No. 12/655,178, filed Dec. 23, 2009, Final Rejection, p. 13 (Aug. 11, 2011).

Lynn, however, suggests an implant structure that extends translaterally across the full transverse width of the vertebral body from a lateral aspect of the spine. NUVASIVE 1011 at FIGS. 7A, 14, 16B-C & 21 (showing a laterally inserted fusion implant extending slightly more than the full transverse width of the adjacent vertebral members); col. 15:59-61 (describing an implant "sized to generally span across the entire width of the adjacent vertebral members"). Here, a person of ordinary skill in the art would have been prompted to select an implant with an appropriate length to span across the entire disc space and maximize surface area of the vertebral bone in contact with the implant, when inserted laterally. Thus, the resulting combination of Michelson '661 in view of Lynn would provide all elements of the claimed method, including the claimed implant.

25. The method of claim 24 further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

Under a broadest reasonable interpretation of this claim language, Michelson '661 discloses the claimed "engaging a spinal fixation device" step as recited in claim 25. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae after inserting of the implant into the laterally facing opening. NUVASIVE 1010 at FIG. 24; 17:23-30.

26. The method of claim 25 wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

Michelson '661 discloses that the spinal fixation device 400 has a plate configured to cover at least a portion of the trailing end of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

27. The method of claim 24 further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

Michelson '661 discloses the claimed "engaging a plate" step as recited in claim 27. In particular, Michelson '661 discloses that spinal fixation plate 400 is engaged to the adjacent vertebrae for purposes of preventing unwanted excursion of the implant. NUVASIVE 1010 at FIG. 24; 17:23-30.

28. The method of claim 27 wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

Michelson '661 discloses that the spinal fixation plate 400 has fastening members in the form of prongs 420, 422. NUVASIVE 1010 at FIG. 24; 17:23-30.

29. The method of claim 27 wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

Michelson '661 discloses that a locking screw 416 engages the spinal fixation plate 400. NUVASIVE 1010 at FIG. 24; 17:23-30.

30. The method of claim 24 wherein said fusion implant is provided in combination with fusion promoting substances.

Michelson '661 discloses that the implant is provided in combination with "substances consistent with bony fusion." NUVASIVE 1010 at 16:14-16.

XIV. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for claims 9-30 of the `997 patent for each of the grounds presented.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.8(b)(4) and 42,105(b), the undersigned certifies that on March 22, 2013, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via FedEx, costs prepaid, to the Patent Owner by serving the correspondence address of record as follows:

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