IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,251,997 Attorney Docket No.: 13958-0112IP1
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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EXHIBITS

NUVASIVE1001	Declaration of Dr. McAfee, M.D., M.B.A.
NUVASIVE1002	U.S. Patent No. 8,251,997 to Michelson ("'997 Patent")
NUVASIVE1003	Select Prosecution History of the '997 patent
NUVASIVE1004	U.S. Pat. No. 4,545,374 to Jacobson ("Jacobson")
NUVASIVE1005	Leu et al., *Percutaneous Fusion of the Lumbar Spine*, Spine Vol. 6, No. 3, pp. 593-604 (September 1992) ("Leu")
NUVASIVE1006	U.S. Pat. No. 5,192,327 to Brantigan ("Brantigan")
NUVASIVE1007	U.S. Pat. No. 4,917,704 to Frey et al. ("Frey")
NUVASIVE1008	U.S. Pat. No. 5,015,247 to Michelson ("Michelson '247")
NUVASIVE1009	European Pub. No. EP 0567424A1 to Alacreu ("Alacreu")
NUVASIVE1010	Baulot et al., *Adjuvant Anterior Spinal Fusion Via Thorascopy*, Lyon Chirurgical Vol. 90, No. 5, pp. 347-51 (1994) ("Baulot")
NUVASIVE1011	English Translation of Baulot and Certificate of Translation
NUVASIVE1012	Rosenthal et al., *Removal of a Protruded Thoracic Disc Using Microsurgical Endoscopy*, Spine Vol. 19, No. 9, pp. 1087-91 (1994) ("Rosenthal")
NUVASIVE1013	U.S. Pat. No. 4,573,448 to Kambin ("Kambin")
NUVASIVE1014	WO 94/28824 to Michelson ("Michelson PCT")

NUVASIVE1015	U.S. Pat. No. 5,772,661 to Michelson (“Michelson ‘661”)
NUVASIVE1016	U.S. Pat. No. 8,343,224 to Lynn et al. (“Lynn”)

NuVasive, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42 of claims 1-8 of U.S. Patent No. 8,251,997 (the `997 patent). A second petition is being filed concurrently challenging claims 9-30. Below, NuVasive demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one claim identified as unpatentable in this petition.

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 any pending prosecution concerning the `997 patent. Petitioner is aware of a Certificate of Correction for the `997 patent. Also, Petitioner is a named defendant in a litigation concerning the '997 patent, styled *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.* (originally filed in N.D. Indiana as Case No. 3:12-cv-00438-JD-CAN, on Aug. 17, 2012, and then transferred to S.D. Cal. on November 8, 2012, as Case No. 3:12-cv-02738-CAB (MDD)). The '997 patent was added to the litigation by way of a first amended complaint filed Aug. 28, 2012, and 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)

Petitioner provides the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
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D. Service Information

Please address all correspondence and service to both counsel listed in Section I(C) of this Petition, at the addresses identified in that Section. Petitioner also consents to electronic service by email at APSI@fr.com (referencing Attorney Docket No. 13958-0112IP1).

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

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 06-1050 for the fee set in 37 C.F.R. § 42.15(a) for this Petition and further authorizes payment of any additional fees to be charged 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 that the `997 patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR. The present petition is being filed within one year of service of the original complaint against Petitioner in the district court litigation, which was filed on Aug. 17, 2012 (the complaint naming the '997 patent was served on Aug. 28, 2012).

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

Petitioner requests IPR of claims 1-8 of the `997 patent on the grounds set forth in the table below and requests that each of the claims be found unpatentable. An explanation of how claims 1-8 are unpatentable under the statutory grounds identified below, including

the identification of where each element can be found in the prior art patents or publications and the relevance of the prior art references, is provided in the form of detailed claim charts. Additional explanation and support for each ground of rejection is set forth in the Declaration of Dr. McAfee, M.D. (NUVASIVE1001).

Ground	`997 Patent Claims	Basis for Rejection
Ground 1	**1 and 8**	Obvious under § 103 by Jacobson in view of Leu and Brantigan
Ground 2	**2-7**	Obvious under § 103 by Jacobson in view of Leu, Brantigan, and Frey
Ground 3	**1 and 8**	Obvious under § 103 by Jacobson in view of Leu and Michelson '247
Ground 4	**2-7**	Obvious under § 103 by Jacobson in view of Leu, Michelson '247, and Alacreu
Ground 5	**1 and 8**	Obvious under § 103 by Baulot in view of Rosenthal and Kambin
Ground 6	**2-7**	Obvious under § 103 by Baulot in view of Rosenthal, Kambin, and Frey
Ground 7	**1 and 8**	Obvious under § 103 by Michelson PCT in view of Jacobson and Brantigan
Ground 8	**2-7**	Obvious under § 103 by Michelson PCT in view of Jacobson, Brantigan, and Alacreu
Ground 9	**1-8**	Obvious under § 103 by Michelson '661 in view of Lynn

Jacobson, Leu, Brantigan, Michelson '247, Frey, Alacreu, and Kambin each qualify as prior art under at least 35 U.S.C. § 102(b) because they were published more than one year prior to February 27, 1995. Baulot and Rosenthal qualify as prior art under at least 35 U.S.C. § 102(a) or (b) because they were published in 1994. Michelson PCT qualifies as prior art under at least 35 U.S.C. § 102(a) because it was published in December 1994. Finally, Michelson '661 is prior art under 35 U.S.C. § 102(b) and Lynn is prior art 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 Ground 9 below). Some of these references (Jacobson, Leu, Brantigan, Michelson '247, Michelson PCT, Rosenthal, Kambin and Michelson '661) were cited in an IDS shortly before allowance, but none of these prior art references was considered in an Office Action or addressed in Applicant's remarks during the prosecution of the `997 patent.

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). This means that the words of the claim are given their plain meaning unless that meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).[1] Petitioner submits that, for purposes of this IPR, all claim terms should be given their plain meaning, and provides two specific constructions below to the extent that these interpretations may be considered different from a plain meaning.

1. "said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies" (claim 1)

First, the broadest reasonable construction of "said distal end of said third surgical

[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).

instrument is proximate a lateral aspect of the vertebral bodies" includes one of either the nearside lateral aspect (closer to the skin incision) **or** the opposite aspect (positioned opposite from the skin incision). The opposite lateral aspect is included because it is within the plain meaning of the claim language ("a lateral aspect", without limitation as to any specific lateral aspect) and because it is the only embodiment supported in the '997 patent specification, as shown by the distal end 146 (FIG. 6) being positioned next to the opposite lateral aspect (FIG. 7). To the extent that the nearside lateral aspect does not fall within the plain meaning (and is not described or enabled by the '997 patent specification), the nearside lateral aspect is also included in the interpretation in light of what Petitioner believes Patent Owner's infringement allegations may be. Namely, the Patent Owner may assert that the claimed distal end being positioned next to the nearside lateral aspect also falls within the claims, which is not supported by the '997 specification. Petitioner contends that this unsupported breadth in claiming renders 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).

2. "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" (claim 1)

Second, the broadest reasonable construction of "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 depth of the disc space" recited in claim 1 includes within its scope lengths of implants that, when positioned in a pa-

tient, occupy less than the full transverse width of the patient's two adjacent vertebral bodies, but greater than the depth of the patient's 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 length 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 application 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

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 direct or far lateral approach to the spine for performing a spinal fusion procedure pre-dated the '997 patent's claimed 1995 priority by a long shot, having been disclosed at least as early as a 1982 paper by Dr. Henry Crock of Australia and also in a patent by Dr. Robert Jacobson that was 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). Moreover, 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). In the face of this, Patent Owner separately pursued the continuation application that became the '997 patent, and in it presented claims that recited 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 I" 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 in the claim charts below, prior art references, some which were cited in an IDS but never mentioned in any Office Action or Remarks during prosecution, plainly demonstrate the limitations of method claim 1 and its dependent claims. These references show that the `997 patent claims are merely a combination of "prior art elements according to known methods 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). For this reason, there exists a reasonable likelihood that at least one claim of the '997 patent is unpatentable.

Immediately below, select features of Jacobson are mapped to elements of claim 1 to preview the correspondence of the prior art to the claim elements which is set forth in

greater detail within the claim charts that follow, thus demonstrating the existence of a reasonable likelihood of prevailing in this challenge for at least claim 1. Claim 1 of the `997 patent is directed to a surgical method that includes making an incision near the lateral 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 1 also recites, in part, three "advancing" steps, namely, advancing a first instrument (e.g., guide pin 30 in FIG. 1), advancing a second instrument (e.g., distractor 100 in FIG. 2) over at least a portion of the length of the first instrument, and advancing a third instrument (e.g., outer sleeve 140 in FIG. 7) over at least a portion of the length of the second instrument. NUVASIVE1002 at claim 1. Further, claim 1 recites, in part, the step of inserting a "non-bone interbody intraspinal implant" (e.g., threaded implant "I" in FIG. 19) through the third surgical instrument.

Jacobson alone discloses nearly all features recited in claim 1, 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. For example, 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. NUVASIVE1004 at FIGS. 3 and 8; col. 2:23-33; col. 2:40-43; col. 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 col. 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). NUVASIVE1005 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. Furthermore, prior art references such as Brantigan show that when a non-bone fusion implant is inserted laterally (in accordance with Jacobson's method), the implant should include the basic structural elements recited in claim 1 and the implant length should be sized to reach the "perimeter of the vertebrae." NUVASIVE1006 at col. 2:2-4; col. 2:64-66; FIG. 10. For the reasons described below, there is a reasonable likelihood that claim 1 of the `997 patent is unpatentable based upon Jacobson in view of Leu and Brantigan.

As an alternative to Brantigan, Michelson '247 discloses a threaded cage implant similar to the '997 patent, and furthermore suggests to a skilled artisan that the threaded cage implant 50 should extend longitudinally across the full disc space in the axial direction of insertion. NUVASIVE1008 at FIG. 5. Thus, for substantially the same reasons described

above (and in Ground 3 below), there is a reasonable likelihood that claim 1 of the `997 patent is unpatentable based upon the obvious combination of Jacobson in view of Leu and Michelson '247.

Additionally, claim 1 recites that the surgical method can also be used in the "thoracic" spine (not just the "lumbar" spine), and prior art references also disclose this. Indeed, Applicant originally acknowledged that, by the time the priority application had been filed on February 27, 1995, surgeons had begun performing procedures in the thoracic region using a lateral approach, although Patent Owner delete that admission from the specification when the '997 application was filed. NUVASIVE1015, 1:43-45; *compare* NUVASIVE1002, 1:38-39. The Baulot reference discloses a surgical method for accessing a targeted thoracic disc space, and furthermore discloses nearly all elements of method claim 1, except for a direct lateral path (to the extent claim 1 is interpreted to require such a direct lateral path) for the working cannula/third surgical instrument and the use of a guide wire/dilator to define the path for the working cannula/third surgical instrument. As described in the chart below (Ground 5), Rosenthal discloses a lateral approach to the spine and collectively, the Rosenthal and Kambin references show that the claim features missing from Baulot were commonly used in similar spinal access procedures. NUVASIVE1012 at FIGS. 1 and 3; p. 1087 (Rosenthal suggesting that the access path to the thoracic disc space can be directly lateral with instruments inserted along the "middle axillary line"); NUVASIVE1013 at col. 4:33-44 (Kambin suggesting the use of a guide wire and cannulated trocar/dilator to define the inser-

tion path for the larger working cannula); FIGS. 3, 4, and 6. Thus, for the reasons described in Ground 5 below, there is a reasonable likelihood that claim 1 of the `997 patent is unpatentable based upon the obvious combination of Baulot in view of Rosenthal and Kambin.

Furthermore, as described in Ground 7 below, the inventor's own prior art publication (Michelson PCT) discloses nearly all features recited in claim 1, except for the location of the incision/insertion path to the spine, the use of an initial guide pin before the second instrument/distractor, and the relative length of the implant. For example, Michelson PCT discloses virtually the same method of use for the distractor 100 (second instrument), outer sleeve 140 (third instrument), and implant structure "I". NUVASIVE1014 at FIGS. 1, 7A, and 16. Even though Michelson PCT does not expressly describe the claimed incision location/insertion path and the claimed first-instrument/guide pin, such surgical steps were widely known long before 1995. For example, Jacobson discloses a lateral approach to the lumbar spine that includes an initial guide needle or wire inserted along a coronal plane path to serve as a guide for a second instrument. NUVASIVE1004 at FIG. 3; col. 5:38-44. As described in greater detail in the claim charts below (Ground 7), a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's lateral approach path and initial guide wire so as to avoid "major back support muscles" that "would otherwise have to be cut or retracted," and for the additional reasons described below. *Id.* at col. 2:31-33. Furthermore, prior art references such as Brantigan show that when Michelson PCT's implant is inserted laterally (as described

above), the length of the implant should be sized to reach the "perimeter of the vertebrae." NUVASIVE1006 at col. 2:2-4; col. 2:64-66; FIG. 10. Accordingly, there is a reasonable likelihood that claim 1 of the `997 patent is unpatentable based upon Michelson PCT in view of Jacobson and Brantigan.

Finally, for reasons described below (Ground 9), at least claims 1-8 of the '997 patent are not entitled to the alleged priority date (Feb. 25, 1995). As such, there is a reasonable likelihood that claim 1 of the `997 patent is unpatentable based upon the obvious combination of Michelson '661 in view of Lynn (wherein Michelson '661 is deemed a § 102(b) publication and Lynn a § 102(e) publication).

These obvious combinations, alone or in combination with various secondary references, provide all elements of claims 1-8, thus raising a reasonable likelihood of prevailing (RLP) with respect to at least one of the claims challenged in this Petition.

VI. [GROUND 1] – Obviousness under §103 by Jacobson in view of Leu and Brantigan

As shown in the claim chart below, limitations recited by claims 1 and 8 of the `997 patent are obvious under §103 based upon Jacobson in view of Leu and Brantigan.

1. 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. NUVASIVE1004 at FIGS. 3 and 8; col. 2:23-33; col. 2:40-43; col. 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; col. 5:28-31; col. 5:42-45 (describing a guide wire having a diameter of nearly "3-mm," which would require formation of small skin incision); NUVASIVE1001 at ¶ 23. Second, Jacobson also discloses that the laterally-located incision point is further incised to "an approximately one centimeter long skin incision." *Id*. at col. 5:45-46. Thus, Jacobson plainly teaches that the skin is incised at a location that is proximate to a path having an axis lying in a coronal plane, as recited in claim 1.

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;

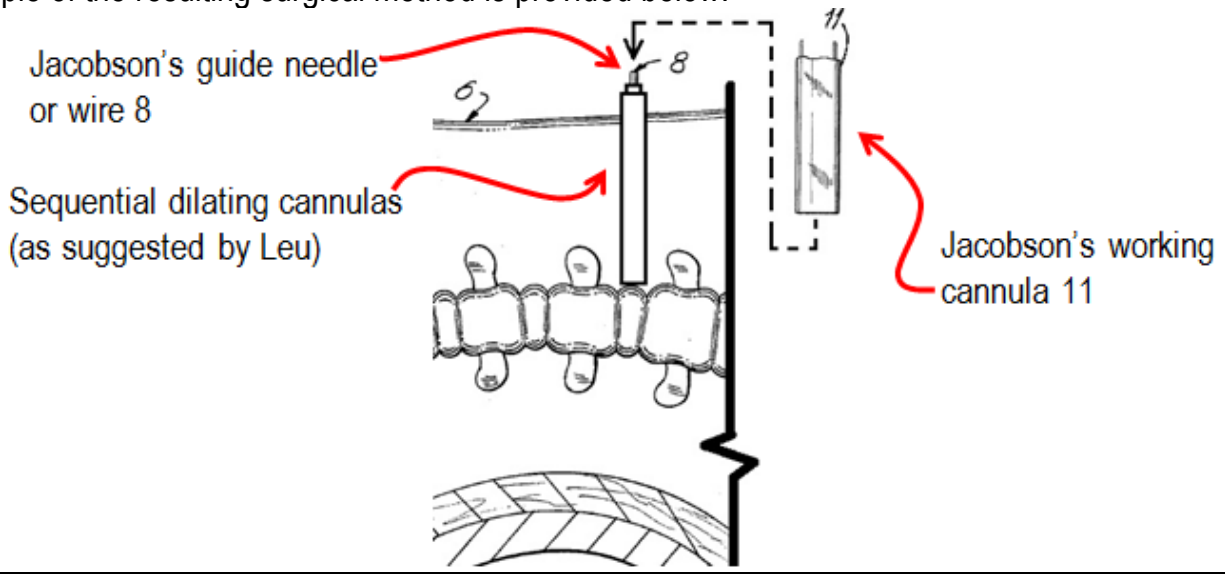
Jacobson teaches that, during the lateral surgical approach to the spine, a first surgical instrument (e.g., Jacobson's guide needle or wire 8) is advanced into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes. *Id.* at FIG. 3; col. 5:28-31; col. 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 col. 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 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 col. 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 sequential 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. NUVASIVE1001 at ¶ 24-25. For example, Leu discloses a surgical method for accessing a lumbar disc space via a working cannula to deliver a spinal fusion implant. NUVASIVE1005 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 non-bone 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. NUVASIVE1001 at ¶ 24-25. One example of the resulting surgical method is provided below:



NUVASIVE1004 at FIG. 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over the guide wire). In addition, 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) 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 ¶ 24-25. 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." NUVASIVE1005 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. NUVASIVE1001 at ¶ 24-25.

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. Namely, each sequential dilator would be advanced through the incision and over a portion of Jacobson's initial guide needle or wire 8 using a central passageway of the sequential dilator. NUVASIVE1001 at ¶ 24-25.

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 1. As previously described, Jacobson's working cannula 11 (the "third surgical instrument" as recited in claim 1) 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 "acts as a conduit for insertion of surgical instruments" and may act as an instrument conduit for a "fusion" procedure. *Id.* at FIGS. 5-6.

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies 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 third surgical instrument as recited in claim 1. In particular, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula 11 (the "third surgical instrument") should be positioned proximate to the lateral aspect of the vertebral bodies of the two adjacent vertebrae. *Id.* at FIGS. 6-8; col. 2:25-30; col. 5:1-4; col. 6:9-13. Accordingly, in accordance with the resulting surgical method of Jacobson in view of Leu, the working cannula 11 would be similarly positioned proximate to the lateral aspect of the vertebral bodies (after advancing over the sequential dilators as described above) so as to achieve the aforementioned benefits of the lateral surgical approach. NUVASIVE1001 at ¶ 26.

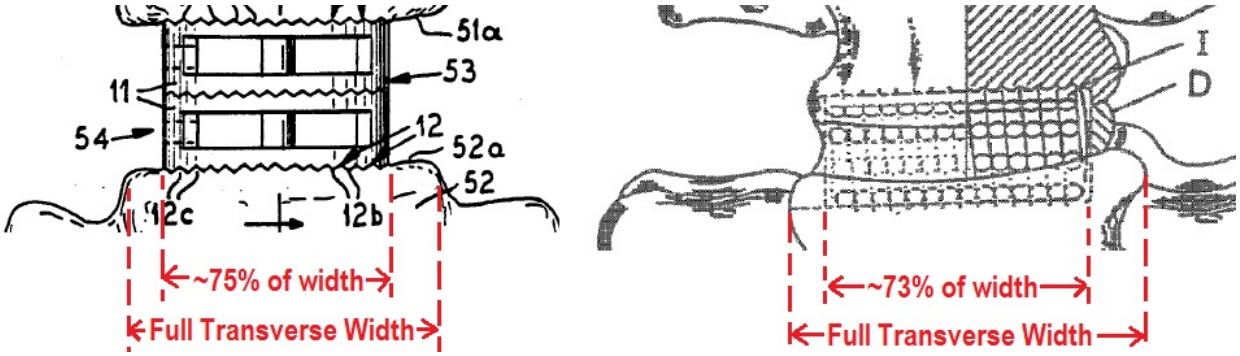
inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine,

The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. 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. NUVASIVE1004 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. NUVASIVE1001 at ¶ 27. Lastly, Leu expressly suggests that the interbody fusion implant can be a non-bone, "composite graft" implant structure that is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae. NUVASIVE1005 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 non-bone interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE1001 at ¶ 27.

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 bod-

ies 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 ¶¶ 28-29. 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 ¶ 29. 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 reduce the likelihood of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. NUVASIVE1001 at ¶ 28-29. 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.

8. The method of claim 1, 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. NUVASIVE1005 at p. 603; NUVASIVE1006 at col. 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.

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

As shown in the claim chart below, limitations recited by claims 2-7 of the `997 patent are unpatentable under at least 35 U.S.C. § 103(a) as being obvious over Jacobson in view of Leu, Brantigan, and Frey.

2. The method of claim 1, further comprising engaging a spinal fixation device to the

adjacent vertebrae after inserting of said implant into the laterally facing opening.

As previously described in the analysis of claim 1, the resulting combination of Jacobson in view of Leu and Brantigan provides all elements of claim 1 and, more specifically, results in the step of inserting of said implant into the laterally facing opening. To the extent these references do 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 instradiscal implant 1. NUVASIVE1007 at FIG. 5; col. 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 col. 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." *Id.* Furthermore, 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) 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 ¶ 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. NUVASIVE1001 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).)

3. The method of claim 2, 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 2 (above), the resulting surgical method of Jacobson in view of Leu, Brantigan, and Frey would provide a spinal fixation plate that covers at least a portion of the trailing end of the implant. NUVASIVE1007 at col. 3:16-17; FIG. 5 (showing the abutment between the plate 6 and the trailing end 5 of the implant 1).

4. The method of claim 1, 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 2 (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.* at col. 3:16-17. Accordingly, in the resulting surgical method, the spinal fixation plate would prevent unwanted excursion of the implant from the spine.

5. The method of claim 4, wherein the engaging of said plate includes attaching a por-

tion of said plate to each of the adjacent vertebrae with a fastening member.

As described in the analysis of claim 2 (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*.

6. The method of claim 4, 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 2 (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 engaged with the plate 6 in passageways 8) after insertion of the implant. *Id*.

7. The method of claim 1, 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, 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. NUVASIVE1007 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. NUVASIVE1007 at FIG. 6; col. 3:19-20.

VIII. [GROUND 3] – Obviousness under §103 by Jacobson in view of Leu and Michelson '247

As shown in the claim chart below, limitations recited by claims 1 and 8 of the `997 patent are obvious under §103 based upon Jacobson in view of Leu and Michelson '247.

1. 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. NUVASIVE1004 at FIGS. 3 and 8; col. 2:23-33; col. 2:40-43; col. 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 an 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; col. 5:28-31; col. 5:42-45 (describing a guide wire having a diameter of nearly "3-mm," which would require formation of small skin incision); NUVASIVE1001 at ¶ 23 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 col. 5:45-46. Thus, Jacobson plainly teaches that the skin is incised at a location that is proximate to a path having an axis lying in a coronal plane, as recited in claim 1.

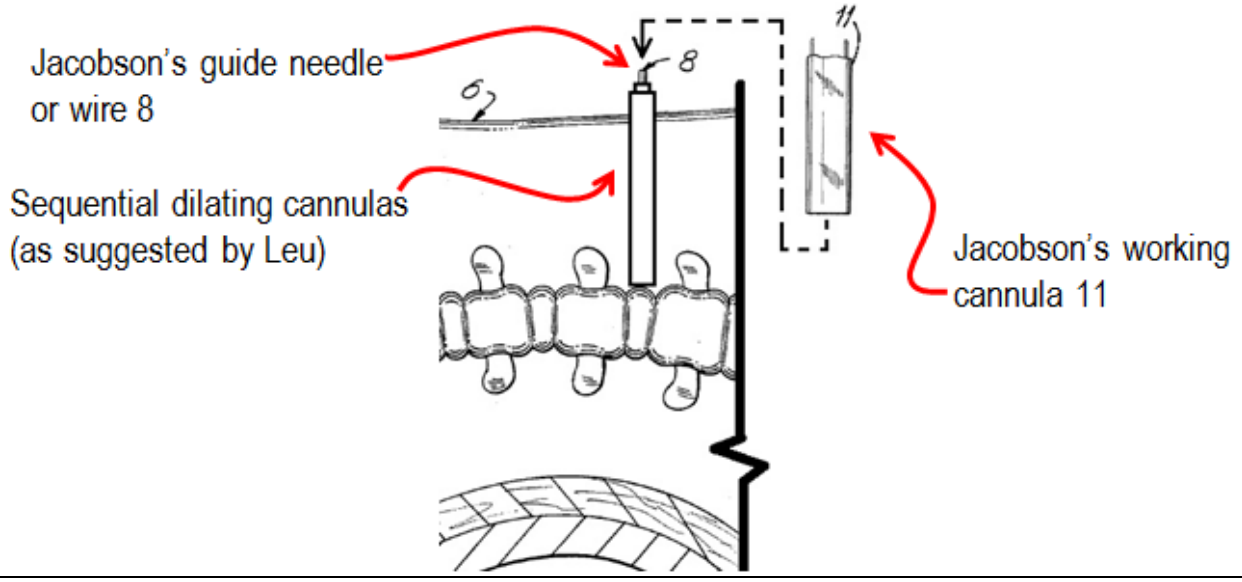
advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

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; col. 5:28-31; col. 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. *Id.* at col. 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 col. 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 sequential dilators (rather than Jacobson's speculum 10) to widen the surgical access path from the width of the initial guide needle for thereafter introducing the final working cannula. NUVASIVE1001 at ¶ 24-25 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. NUVASIVE1005 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 non-bone 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 for thereafter introducing 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 width of the initial guide needle in a manner that reduces the trauma to the intervening tissue. NUVASIVE1001 at ¶ 24-25 and 31. One example of the resulting surgical method is provided below:



NUVASIVE1004 at FIG. 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over the guide wire). In addition, 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) 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 ¶ 24-25 and 31. 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 Jacobson's working cannula 11 (described below) over the last sequential dilator. NUVASIVE1001 at ¶ 24-25 and 31. 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." NUVASIVE1005 at p. 596.

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. Namely, each sequential dilator would be advanced through the incision and over a portion of Jacobson's initial guide needle or wire 8 using a central passageway of the sequential dilator. NUVASIVE1001 at ¶ 24-25 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 1. Indeed, 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. NUVASIVE1004 at col. 6:7-13; FIGS. 6-8. As previously described, Jacobson's working cannula 11 (the "third surgical instrument" as recited in claim 1) would be advanced through Jacobson's lateral incision location and over the sequential dilators (as suggested by Leu above). Furthermore, Jacobson illustrates that the working cannula 11 includes a central lumen extending therethrough that would insert over the sequential dilators when advanced to the lateral aspect of the disc space. *Id.* at FIGS. 5-6.

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies 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 third surgical instrument as recited in claim 1. In particular, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula 11 (the "third surgical instrument") should be positioned to engage the lateral aspect of the vertebral bodies of the two adjacent vertebrae. *Id.* at FIGS. 6-8; col. 2:25-30; col. 5:1-4; col. 6:9-13. Accordingly, in accordance with the resulting surgical method of Jacobson in view of Leu, the working cannula 11 would be similarly positioned to engage the lateral aspect of the vertebral bodies (after advancing over the sequential dilators as described above) so as to achieve the aforementioned benefits of the lateral surgical approach. NUVASIVE1001 at ¶ 26 and 31.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone 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,

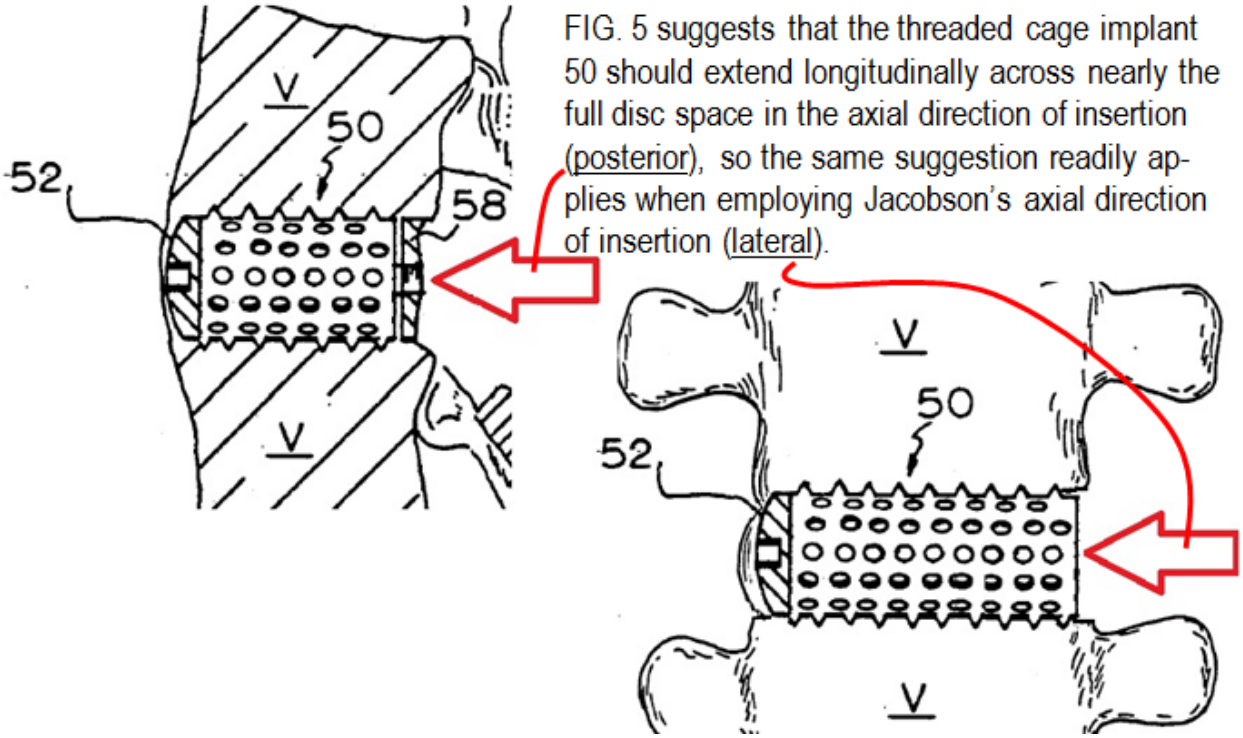
The resulting surgical method of Jacobson in view of Leu (described above) provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. NUVASIVE1004 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. NUVASIVE1001 at ¶ 27 and 31. Lastly, Leu expressly suggests that the interbody fusion implant can be a non-bone, "composite graft" implant structure that is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae. NUVASIVE1005 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 non-bone interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE1001 at ¶ 27.

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 bod-

ies 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 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" that is illustrated in FIG. 18 of the '997 patent. NUVASIVE1008 at FIGS. 4-5; col. 8:36-51. For example, Michelson '247 teaches that the implant 50 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*. 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 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); NUVASIVE1001 at ¶ 31. 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). NUVASIVE1001 at ¶ 31.

In the resulting surgical method of Jacobson in view of Leu (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 the full disc space in the direction of insertion (lateral insertion in this resulting method):



NUVASIVE1001 at ¶ 31; 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. NUVASIVE1001 at ¶ 31. 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 substantially the full transverse width of the vertebral bodies" and that is "greater than the depth of the disc space."

8. The method of claim 1, 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." NUVASIVE1005 at p. 603; NUVASIVE1008 at col. 10:7-14. Accordingly, in the resulting surgical method of Jacobson in view of Leu and Michelson '247 (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, Michelson '247, and Alacreu

As shown in the claim chart below, limitations recited by claims 2-7 of the `997 patent are unpatentable under at least 35 U.S.C. § 103(a) as being obvious over Jacobson in view of Leu, Michelson'247, and Alacreu.

2. The method of claim 1, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

As previously described in the analysis of claim 1, the resulting combination of Jacobson in view of Leu and Michelson '247 provides all elements of claim 1 and, more specifically, results in the step of inserting of said implant into the laterally facing opening. To the extent these references do not expressly disclose a "spinal fixation device" that is engaged to the adjacent vertebrae, such devices were commonly employed in the prior art. For example, Alacreu discloses the traditional practice of engaging a spinal fixation plate 3 to a trailing end of a spinal implant (via a bolt 16) and to the vertebrae immediately contacting the spinal implant (via screws 14). NUVASIVE1009 at col. 2:6-11; col. 3:34-39; FIG. 11. According to Alacreu, the spinal fixation plate 3 is "attached by screws laterally to the next above and the next below vertebras, contributing to stabilization by preventing . . . movements" of the spinal implant. *Id.* at col. 2:6-11. 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 Alacreu) so as to advantageously "contribute to the stabilization" of the spinal implant site and to prevent movements of the implant. *Id.* Furthermore, 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 Alacreu) 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 ¶ 32.

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. NUVASIVE1001 at ¶ 32; 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).) Indeed, given that the implant in the resulting method is smaller than the implant in Alacreu, it follows that the spinal fixation plate would likewise be significantly smaller than that illustrated in Alacreu. Nevertheless, Alacreu's more general suggestion to engage a spinal fixation plate after insertion of the spinal implant is readily and predictably applicable to the resulting method as described above.

3. The method of claim 2, 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 2 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Alacreu would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant (and can be coupled thereto via a bolt).

4. The method of claim 1, 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 2 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Alacreu would provide a spinal fixation plate that engages to the implant (via a bolt 16) and to the adjacent vertebrae (via screws 14). Accordingly, in the resulting surgical method, the spinal fixation plate would prevent unwanted excursion of the implant from the spine.

5. The method of claim 4, 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 2 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Alacreu would provide a spinal fixation plate that attaches to each of the adjacent vertebrae with a corresponding bone screw.

6. The method of claim 4, 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 2 (above), the resulting surgical method of Jacobson in view of Leu, Michelson '247, and Alacreu would provide a spinal fixation plate that engages with the implant (via a bolt 16) after insertion of the implant.

7. The method of claim 1, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

As described in the analysis of claim 2 (above), the resulting surgical method of Jacob-

son in view of Leu, Michelson '247, and Alacreu would provide a spinal fixation plate that couples to the implant (via a bolt 16) and engages to the adjacent vertebrae (via screws 14).

X. [GROUND 5] – Obviousness under §103 by Baulot in view of Rosenthal and Kambin

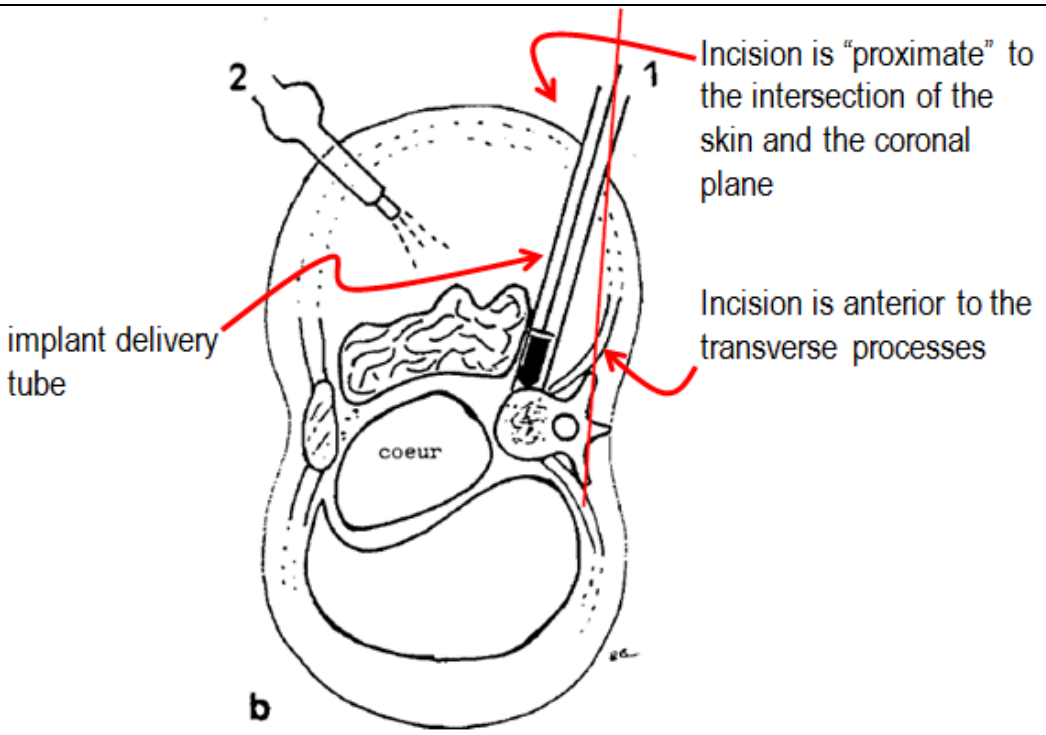
As shown in the claim chart below, limitations recited by claims 1 and 8 of the `997 patent are obvious under §103 based upon Baulot in view of Rosenthal and Kambin.

1. 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,

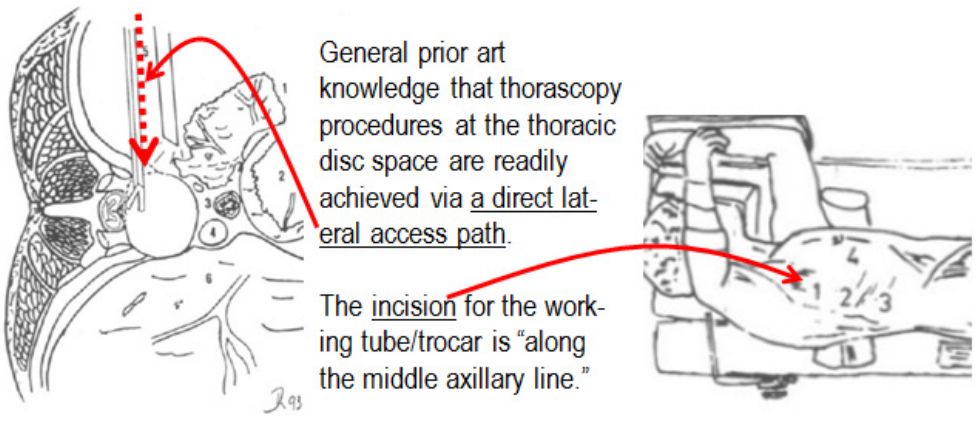
Baulot discloses a surgical method for accessing a thoracic disc space between two adjacent vertebrae. NUVASIVE1010 at FIG. 2(b); NUVASIVE1011 at p. 4 (describing a method of inserting the "hydroxyapatite graft[]" within the T5-T6 disc space after the removal of the disc material). Baulot's spinal access method includes making a "3 cm incision" that eventually receives the "guide tube" to deliver the fusion implant. NUVASIVE1011 at pp. 2 and 4; FIG. 2(b). Further, as described below, a person of ordinary skill in the art would recognize that this incision for the working cannula tube would be slightly smaller in size when the working cannula tube (Baulot's implant delivery tube in FIG. 2(b)) is advanced to the spine over traditional guide wire/trocar instruments (as suggested by Kambin and described in more detail below).

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;

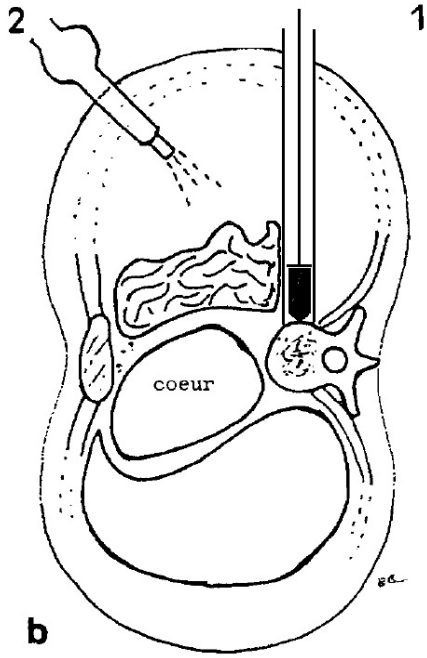
Baulot discloses (under the broadest reasonable interpretation of "proximate") that the incision is proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes:



NUVASIVE1011 at FIG. 2(b). To the extent that this claim element is interpreted more narrowly to require a direct lateral approach, the prior art plainly discloses that Baulot's approach path to the thoracic disc space could be shifted slightly to a more direct lateral approach. For example, Rosenthal discloses a similar spinal surgical method that uses thorascopy and a trocar tube providing a direct lateral access path to the thoracic disc space for the surgical instruments:



NUVASIVE1012 at FIGS. 3 and 1; p. 1087 (describing the access paths, including the working path for the surgical instruments, inserted along the "middle axillary line"). Applying the teachings of Rosenthal to Baulot yields the following:

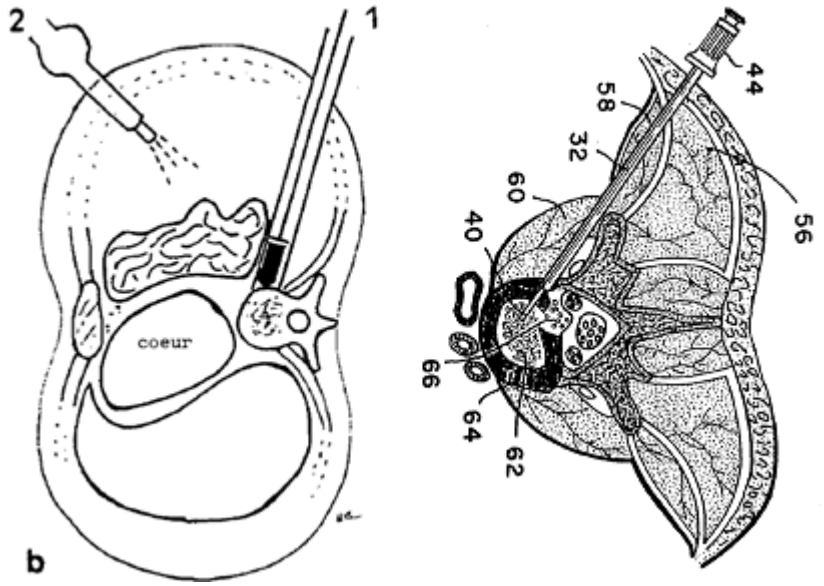


Here, a person of ordinary skill in the art would have been prompted to modify Baulot's surgical method to orient the working corridor at a slightly more lateral position (e.g., a more direct lateral access path as suggested by Rosenthal) so as to provide "a wide exposure of the thoracic spine by changing only the insertion site of the trocars." *Id.* at p. 1090. A person of ordinary skill in the art would also have been prompted to modify Baulot's surgical method to orient the working corridor at a slightly more lateral position (e.g. a more direct lateral access path as suggested by Rosenthal) to avoid a postero-lateral trajectory, which angles generally toward the front of the disc space and thus toward the great vessels (aorta and vena cava), and thereby reduce risk of injury to those vascular structures. In addition, a person of ordinary skill in the art would have been prompted to modify Baulot's surgical method to orient the working corridor at a slightly more lateral position (as suggested by Rosenthal) 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 ¶ 33-34. Thus, in the resulting surgical method, the incision would be located proximate to the intersection of the skin and the path having an axis lying in a coronal plane, and furthermore would be anterior to the transverse processes (refer to modified FIG. 2(b) of Baulot, at right).

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;

Baulot teaches that the implant delivery tube (e.g., the "third surgical instrument" in the

context of claim 1) is advanced to the thoracic disc space, but Baulot does not expressly describe the precursor guide instruments that are used to define the insertion path for Baulot's implant delivery tube. NUVASIVE1011 at FIG. 2(b). Numerous prior art references, however, explain the conventional prior art knowledge that such larger working tubes for accessing the spine were typically advanced to the spine after a set of guidance instruments (e.g., a guide wire and a cannulated dilator/trocar) established the insertion path. For example, Kambin provides a typical example of this commonly used prior art method. Kambin discloses a surgical access method to a targeted spinal disc that, similar to Baulot, uses a larger working cannula 32 for insertion of the surgical instruments. NUVASIVE1013 at FIG. 10 (showing the working cannula 32). Indeed, Kambin's working cannula 32 has a structure much like Baulot's implant delivery tube:



NUVASIVE1011 at FIG. 2(b); NUVASIVE1013 at FIG. 10. Kambin explains the general prior art knowledge that such a working cannula (Kambin's cannula 32 or Baulot's implant delivery tube) should be advanced to the targeted disc space after a first instrument (e.g., a guide wire 18) initially defines the insertion path and a second instrument (e.g., a cannulated trocar/dilator 20) dilates the path to a size sufficient to receive the working cannula. NUVASIVE1013 at col.3:16-46; 4:33-44; FIGS. 3, 4, and 6.

Here, a person of ordinary skill in the art would have been prompted to modify the surgical method of Baulot in view of Rosenthal (described above) to include a guide wire and cannulated trocar (as suggested by Kambin) for defining the insertion path of Baulot's working tube so that the larger working tube can reach the targeted disc space in a procedure that provides reduced trauma to the intervening tissues and "low post-operative morbidity." *Id.* at col. 1:58 to col. 2:2; col. 5:16-21 ("post-operative back pain was minimal"). In addition, a person of ordinary skill in the art would be prompted to modify the surgical method of Bau-

lot in view of Rosenthal (described above) to include a guide wire and cannulated trocar (as suggested by Kambin) for defining the insertion path of Baulot's working tube 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 ¶ 35. Thus, in the resulting surgical method, a guide wire ("first surgical instrument") would be advanced through the incision and along the direct lateral insertion path (described above) until proximate the targeted thoracic disc space.

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;

As previously described in the analysis of the previous element, the resulting surgical method of Baulot in view of Rosenthal and Kambin would provide both the "first surgical instrument" (a guide wire) and the "second surgical instrument" (a cannulated trocar for dilation over the guide wire) inserted in the direct lateral path, in accordance with the general prior art practices evidenced by Kambin. NUVASIVE1013 at col. 3:16-46; 4:33-44; FIGS. 3, 4, and 6. Kambin expressly teaches that the second surgical instrument/dilating trocar has a "passage 22" for receiving the first surgical instrument/guide wire. NUVASIVE1013 at col. 3:28-31. Thus, for the multiple reasons described above, a person of ordinary skill in the art would have been prompted to modify the surgical method of Baulot in view of Rosenthal (described above) to include a guide wire and cannulated trocar (as suggested by Kambin) for defining the insertion path of Baulot's working tube.

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;

As previously described in the analysis of the "advancing a first surgical instrument" step, the resulting surgical method of Baulot in view of Rosenthal and Kambin would provide Baulot's implant delivery tube (FIG. 2(b)) that is advanced in the direct lateral path over the "second surgical instrument" (a cannulated trocar for dilation over the guide wire), in accordance with the general prior art practices evidenced by Kambin. NUVASIVE1011 at FIG. 2(b) NUVASIVE1013 at col. 3:16-46; 4:33-44; FIGS. 3, 4, and 6. Baulot explicitly illustrates that the implant delivery tube (the "third surgical instrument") has an open distal end for insertion over the second surgical instrument. NUVASIVE1011 at FIG. 2(b).

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

Baulot expressly teaches that the implant delivery tube (the "third surgical instrument") is positioned such that the third surgical instrument is proximate a lateral aspect of the thoracic vertebral bodies. NUVASIVE1011 at FIG. 2(b). Additionally, Rosenthal also discloses that the surgical instruments inserted through the lateral working path should access a lateral aspect of the thoracic vertebral bodies. NUVASIVE1012 at FIG. 3. Thus, the resulting surgical method of Baulot in view of Rosenthal and Kambin would plainly provide the claimed step of "positioning said third surgical instrument" as recited in claim 1.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone 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 Baulot in view of Rosenthal and Kambin provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Baulot express teaches that the non-bone fusion implant ("hydroxyapatite graft[]" or "a block of porous apatite") is inserted through Baulot's implant delivery tube (the "third surgical instrument"). NUVASIVE1011 at pp. 4 and 6; FIG. 2(b). Also, in the resulting surgical method (described above), Baulot's implant delivery tube would be advanced in a direct lateral path (an example is illustrated above), and Baulot's implant would be inserted through "a hole in the external face of the disc." *Id.* at p. 4. Thus, in accordance with the resulting surgical method of Baulot in view of Rosenthal and Kambin, the non-bone implant would be inserted through the third working instrument and into a laterally facing opening in the thoracic spine. NUVASIVE1001 at ¶ 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 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.

Baulot describes the spinal fusion implant as "a block of porous apatite" and illustrates the structure in FIGS. 2(b), 3(e)-(f), and 5. NUVASIVE1011 at p. 6. From this disclosure, Baulot teaches the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections (resulting from the upper and lower "porous" surfaces), 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. 2(b), 3(e)-(f), and 5; p. 4 (teaching that the porous block is "35 mm in length" for insertion into the thoracic disc space); NUVASIVE1001 at ¶ 37(explaining that the roughened surface of the "porous block" provides frictional projections for engaging the opposing vertebrae)]. In addition, Baulot's FIG. 5 clearly illustrates that the fusion implant has a length that is "sized to occupy substantially the full transverse width of the vertebral bodies" and that is "greater than the depth of the disc space." *Id.* at FIG. 5; *see also* FIG. 2(b). NUVASIVE1001 at ¶ 37. Thus, in accordance with the resulting surgical method of Baulot in view of Rosenthal and Kambin, the non-bone implant would include the claimed structural elements and relative dimensions. NUVASIVE1001 at ¶ 37.

8. The method of claim 1, wherein said fusion implant is provided in combination with fusion promoting substances.

The resulting surgical method of Baulot in view of Rosenthal and Kambin would provide the claimed fusion implant that is provided in combination with fusion promoting substances. Indeed, Baulot expressly discloses that the fusion implant includes a "hydroxyapatite graft[]," which was known to promote bone ingrowth and ongrowth and was known to absorb over time. NUVASIVE1011 at 4; *see also* NUVASIVE1001 at ¶ 38.

XI. [GROUND 6] – Obviousness under §103 by Baulot, Rosenthal, Kambin, and Frey

As shown in the claim chart below, limitations recited by claims 2-7 of the `997 patent are unpatentable under at least 35 U.S.C. § 103(a) as being obvious over Baulot, Rosenthal, Kambin, and Frey.

2. The method of claim 1, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

As previously described in the analysis of claim 1, the resulting combination of Baulot in view of Rosenthal and Kambin provides all elements of claim 1 and, more specifically, results in the step of inserting of said implant into the laterally facing opening. To the extent

these references do 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. NUVASIVE1007 at FIG. 5; col. 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 col. 3:14-23. Here, a person of ordinary skill in the art would have been prompted to modify the method of Baulot in view of Rosenthal and Kambin (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." *Id.* Furthermore, a person of ordinary skill in the art would have been prompted to modify the method of Baulot in view of Rosenthal and Kambin (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) 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 ¶ 39. 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. NUVASIVE1001 at ¶ 39; 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).)

3. The method of claim 2, 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 2 (above), the resulting surgical method of Baulot in view of Rosenthal, Kambin, and Frey would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant. NUVASIVE1007 at col. 3:16-17; FIG. 5 (showing the abutment between the plate 6 and the trailing end 5 of the implant 1).

4. The method of claim 1, 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 2 (above), the resulting surgical method of Baulot in view of Rosenthal, Kambin, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8). *Id.* at col. 3:16-17. Accordingly, in the resulting surgical method, the spinal fixation plate would prevent unwanted excursion of the implant from the spine.

5. The method of claim 4, 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 2 (above), the resulting surgical method of Baulot in view of Rosenthal, Kambin, and Frey would provide a spinal fixation plate that engages the adjacent vertebrae (via bone screws in passageways 8). *Id*.

6. The method of claim 4, 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 2 (above), the resulting surgical method of Baulot in view of Rosenthal, Kambin, 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*.

7. The method of claim 1, 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 Baulot in view of Rosenthal, Kambin, and Frey would provide a spinal fixation plate that is coupled to the implant in that the plate is integrally formed with the implant. NUVASIVE1007 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. NUVASIVE1007 at FIG. 6; col. 3:19-20.

XII. [GROUND 7] – Obviousness under §103 by Michelson PCT in view of Jacobson and Brantigan

As shown in the claim chart below, claims 1 and 8 of the `997 patent are obvious under §103 based upon Michelson PCT in view of Jacobson and Brantigan.

1. 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,

Michelson PCT discloses a surgical method for accessing a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine. NUVASIVE1014 at FIGS. 1, 6, 11B, and 17; pp. 1-2 (describing a "method of inserting the

implant within the interverbral space left after the removal of the disc material"); p. 9 (disclosing that the method "can be utilized in the cervical, thoracic, and lumbar spine"). Michelson PCT's spinal access method includes making a skin incision so as to form the access path to the disc space, or else outer sleeve 140 and other instruments would not access the spine. *Id.* at p. 19 (describing a "single surgery providing for an integrated discectomy, fusion, and interbody internal spinal fixation," all of which include a skin incision for the access instruments). Further, as described in the element below, Jacobson also discloses a skin incision.

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;

Michelson PCT does not expressly disclose that the skin incision is located proximate to a path having an axis lying in a coronal plane, but instead discloses "posterior" or "anterior" approaches to the spine. *Id.* at p. 65 (disclosing the "posterior" and "anterior" approaches, and furthermore explaining that "the method for installation of a large, singular midline graft will become obvious"). However, the claimed location of the skin incision was commonly employed in other surgical methods for similarly accessing the spine through an outer tubular sleeve. For example, Jacobson expressly describes a "lateral" approach for accessing a disc space between two adjacent vertebrae for purposes of performing a discectomy and, optionally, a vertebral fusion procedure. NUVASIVE1004 at FIGS. 3 and 8; col. 2:23-33; col. 2:40-43; col. 6:13 (describing a "fusion" procedure that necessarily includes an interbody implant). 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; col. 5:28-31; col. 5: 42-45 (describing a guide wire having a diameter (nearly 3-mm) which would require formation of small skin incision). Second, Jacobson also discloses that the laterally-located incision point is further incised to "an approximately one centimeter long skin incision." Id. at col. 5:45-46.

Here, a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space so as to avoid "major back support muscles" that "would otherwise have to be cut or retracted" and for the additional reasons described below. *Id.* at col. 2:31-33; NUVASIVE1001 at ¶ 40. In the resulting surgical method, the skin incision (as disclosed in both Michelson PCT and Jacobson) would be employed, but the location of the skin incision and the path of the initial guide wire would be proximate to a path having an axis lying in a coronal plane (as suggested in Jacobson). Additionally, a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space because the result-

ing surgical method would eliminate the "need to cut spinal laminae" that is customary in the posterior approach of Michelson PCT and because the patient "may be released from the hospital on the same day." *Id.* at col. 2:52-53 and 62-63. Finally, a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space 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).

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;

In the resulting surgical method of Michelson PCT in view of Jacobson (described above), 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. NUVASIVE1004 at FIG. 3; col. 5:28-31; col. 5:42-45. As taught by Jacobson, during the lateral approach, the initial guide needle or wire 8 extends along the lateral path until proximate to the targeted spinal disc and thereafter serves "as a guide member" for a second instrument that is subsequently advanced. *Id.* at col. 5:39-41; FIG. 3. Accordingly, the initial guide needle or wire 8 would be similarly used in the resulting surgical method of Michelson PCT in view of Jacobson so as to provide the same guidance benefits to the subsequent instruments. NUVASIVE1001 at ¶ 41.

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;

The resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of advancing a second surgical instrument as recited in claim 1. Michelson PCT discloses a distractor 100 that is virtually the identical structure of the claimed "second surgical instrument" (e.g., distractor 100 in FIG. 2) of the '997 patent. NUVASIVE1014 at FIGS. 1 and 4. Indeed, the distractor 100 of Michelson PCT has the same outer shape and serves a similar purpose as the distractor/second surgical instrument of the '997 patent. *Id.* at p. 22 (describing the distractor 100 as being "self-orienting" and "self-centralizing between opposed vertebral surfaces"); p. 47. As previously described, Jacobson expressly teaches that, in the lateral surgical approach, the guide needle or wire 8 should "act[] as a guide member" for the second instrument, and furthermore teaches that the second instrument should be cannulated or otherwise equipped with a guide bore. NUVASIVE1004 at

col. 5:39-41; col. 3:2-6 (teaching that the "guide means may be a bore"); col. 9:11-13 (teaching again that the guide means of the second instrument "is a tube 25" for sliding over the guide needle or wire 8). Thus, in the resulting surgical method of Michelson PCT in view of Jacobson (described above), the distractor 100 of Michelson PCT serves as the second instrument which is advanced over the initial guide needle or wire, and therefore this second instrument would be cannulated (as suggested by Jacobson) so as to provide a passageway configured to receive the initial guide needle or wire therein. NUVASIVE1004 at col. 5:39-41; col. 3:2-6 (teaching that the "guide means may be a bore"); col. 9:11-13; NUVASIVE1001 at ¶ 41. Additionally, a person of ordinary skill in the art would have been prompted to modify the distractor 100 of Michelson PCT so as to include a bore to receive the guide needle or wire (as suggested by Jacobson) 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).

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 Michelson PCT in view of Jacobson provides the claimed step of advancing a third surgical instrument as recited in claim 1. Indeed, Michelson PCT discloses an outer sleeve 140 that is structurally similar to the claimed "third surgical instrument" (e.g., outer sleeve 140 in FIG. 7) of the '997 patent. NUVASIVE1014 at FIG. 6. Much like the claimed "third surgical instrument" (e.g., outer sleeve 140 in FIG. 7) of the '997 patent, Michelson PCT's sleeve 140 serves as a working cannula for the surgical instruments and purportedly "places all of the delicate soft tissue structures, nerves, blood vessels, and organs outside of the path." *Id.* at p. 19. Also, Michelson PCT's sleeve 140 has "teeth for engaging the two adjacent vertebrae." *Id.* at p. 29; FIG. 6; *see also* FIG. 7 (suggesting prongs at the distal end). Michelson PCT also expressly teaches that the sleeve 140 is advanced into the body of the patient over at least a portion of the length of the second surgical instrument (the distractor 100). *Id.* at FIG. 6; p. 47 (teaching that the distal end of the sleeve 140 is "fitted over" the distractor to engage the vertebrae).

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

The resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of positioning the third surgical instrument as recited in claim 1. In particular, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula

should be positioned to engage the lateral aspect of the vertebral bodies of the two adjacent vertebrae. NUVASIVE1004 at FIGS. 6-8; col. 2:25-30; col. 5:1-4; col. 6:9-13. Accordingly, in accordance with the resulting surgical method of Michelson PCT in view of Jacobson, the working cannula/third surgical instrument (Michelson PCT's outer sleeve 140) would be similarly positioned to engage the lateral aspect of the vertebral bodies of the two adjacent vertebrae so as to achieve the aforementioned benefits of the lateral surgical approach. NUVASIVE1001 at ¶ 43.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone 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,

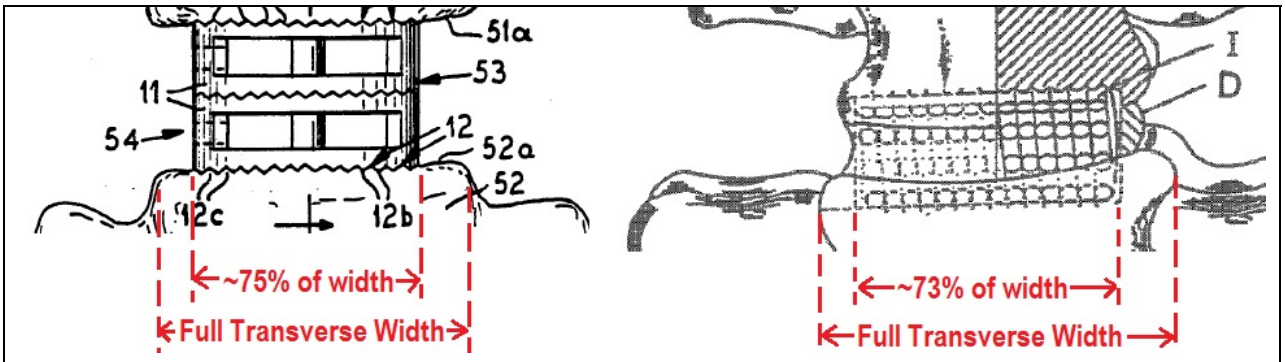
The resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. NUVASIVE1004 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 (Michelson PCT expressly states that the fusion implant is "necessary" for a fusion procedure at pp. 1-2). Lastly, Michelson PCT teaches that a non-bone implant should be inserted through the outer sleeve 140 (third instrument) and into the disc space so as to induce bony fusion between the adjacent vertebrae. NUVASIVE1014 at pp. 34 and 37; FIG. 17. Accordingly, in accordance with the resulting surgical method of Michelson PCT in view of Jacobson, the working cannula/third surgical instrument (Michelson PCT's outer sleeve 140) would be similarly positioned to receive the non-bone interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine. NUVASIVE1001 at ¶ 44.

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.

Michelson PCT discloses a fusion implant "I" in the form of a threaded titanium cage that is virtually identical to the structure of the implant "I" in FIG. 19 of the '997 patent. NUVASIVE1014 at FIG. 17. Indeed, Michelson PCT's 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. 13, 16-17. Michelson PCT also teaches an implant length spanning nearly the full distance of the adjacent vertebral bodies along the direction of insertion (albeit posterior and anterior, and not lateral). Because Michelson PCT does not expressly disclose that the implant "I" is inserted in a lateral approach, Michelson PCT does not expressly disclose 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."

However, in the resulting surgical method of Michelson PCT in view of Jacobson (described above), a fusion implant is inserted into the disc space via a lateral approach, so a person of ordinary skill in the art would have selected an implant sized appropriately given its eventual lateral orientation in the disc space. NUVASIVE1001 at ¶ 45-47. 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 ¶ 47. 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, in the resulting surgical method of Michelson PCT in view of Jacobson (described above), the fusion implant is indeed inserted into the disc space via a lateral approach, so the relative dimensions of Michelson PCT's implant "I" would have been predictably selected 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" and that is "greater than the depth of the disc space."

8. The method of claim 1, wherein said fusion implant is provided in combination with fusion promoting substances.

Michelson PCT expressly discloses that the implant "I" should be "loaded with fusion promoting materials, such as autogenus bone, for the purpose of materially influencing the adjacent vertebrae to perform a bony bond." NUVASIVE1014 at pp. 17-18; p. 59. Accordingly, in the resulting surgical method of Michelson PCT in view of Jacobson and Brantigan (described above), the fusion implant would likewise be provided in combination with fusion promoting substances.

XIII. [GROUND 8] – Obviousness under §103 by Michelson PCT in view of Jacobson, Brantigan, and Alacreu

As shown in the claim chart below, limitations recited by claims 2-7 of the `997 pa-

tent are unpatentable under at least 35 U.S.C. § 103(a) as being obvious over Michelson PCT in view of Jacobson, Brantigan, and Alacreu.

2. The method of claim 1, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

As previously described in the analysis of claim 1, the resulting combination of Michelson PCT in view of Jacobson and Brantigan provides all elements of claim 1 and, more specifically, results in the step of inserting of said implant into the laterally facing opening. To the extent these references do not expressly disclose a "spinal fixation device" that is engaged to the adjacent vertebrae, such devices were commonly employed in the prior art. For example, Alacreu discloses the traditional practice of engaging a spinal fixation plate 3 to a trailing end of a spinal implant (via a bolt 16) and to the vertebrae immediately contacting the spinal implant (via screws 14). NUVASIVE1009 at col. 2:6-11; col. 3:34-39; FIG. 11. According to Alacreu, the spinal fixation plate 3 is "attached by screws laterally to the next above and the next below vertebras, contributing to stabilization by preventing . . . movements" of the spinal implant. *Id.* at col. 2:6-11. Here, a person of ordinary skill in the art would have been prompted to modify the method of Michelson PCT in view of Jacobson and Brantigan (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 Alacreu) so as to advantageously "contribute to the stabilization" of the spinal implant site and to prevent movements of the implant. *Id.* Furthermore, a person of ordinary skill in the art would have been prompted to modify the method of Michelson PCT in view of Jacobson and Brantigan (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 Alacreu) 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 ¶ 48.

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. NUVASIVE1001 at ¶ 48; MPEP § 2144.04(IV) (citing to *Gardner v.TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984) and *In*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).) Indeed, given that the implant in the resulting method is smaller than the implant in Alacreu, it follows that the spinal fixation plate would likewise be significantly smaller than that illustrated in Alacreu. Nevertheless, Alacreu's more general suggestion to engage a spinal fixation plate after insertion of the spinal implant is readily and predictably applicable to the resulting method as described above.

3. The method of claim 2, 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 2 (above), the resulting surgical method of Michelson PCT in view of Jacobson, Brantigan, and Alacreu would provide a spinal fixation plate that covers a least a portion of the trailing end of the implant (and can be coupled thereto via a bolt).
4. The method of claim 1, 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 2 (above), the resulting surgical method of Michelson PCT in view of Jacobson, Brantigan, and Alacreu would provide a spinal fixation plate that engages to the implant (via a bolt 16) and to the adjacent vertebrae (via screws 14). Accordingly, in the resulting surgical method, the spinal fixation plate would prevent unwanted excursion of the implant from the spine.
5. The method of claim 4, 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 2 (above), the resulting surgical method of Michelson PCT in view of Jacobson, Brantigan, and Alacreu would provide a spinal fixation plate that attaches to each of the adjacent vertebrae with a corresponding bone screw.
6. The method of claim 4, 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 2 (above), the resulting surgical method of Michelson PCT in view of Jacobson, Brantigan, and Alacreu would provide a spinal fixation plate that engages with the implant (via a bolt 16) after insertion of the implant.
7. The method of claim 1, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae. As described in the analysis of claim 2 (above), the resulting surgical method of Michelson PCT in view of Jacobson, Brantigan, and Alacreu would provide a spinal fixation plate that couples to the implant (via a bolt 16) and engages to the adjacent vertebrae (via screws 14).

XIV. [GROUND 9] – Obviousness under §103 by Michelson '661 in view of Lynn

As shown in the claim chart below, limitations recited by claims 1-8 of the `997 patent are obvious under §103 based upon Michelson '661 in view of Lynn. This ground for

rejection is premised upon the conclusion that claims 1-8 are not entitled to the earliest claimed priority date of the '997 patent (Feb. 27, 1995), but instead these claims all recite a claim limitation ("the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae") that if interpreted more narrowly than the broadest reasonable interpretation discussed above, was added no earlier than the November 29, 2011 filing date of the application that became the '997 patent.

All of the depicted implants in the '997 patent fall short of the "full transverse width of the vertebral bodies." NUVASIVE1002 at FIGS. 18-20, 22-24, and 29-34; NUVASIVE1001 at ¶ 17-20. This conclusion is consistent with the Patent Office's finding 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 disclose positioning an implant to contact at least a portion of a cortical rim (i.e., the outside portion) of the adjacent vertebrae. Patent Owner – in that reissue proceeding – relied on Figure 30 of the '661 patent (which is the same as Figure 30 of the '997 patent) in support of an argument that the 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). After suffering this rejection in the reissue application, the Patent Owner: (1) abandoned the reissue application, (2) filed, from a pending continuation branch of the '661 patent family, the application that resulted in the '997 patent, and (3) subsequently added the new claims therein that recited a "length of said implant" element.

Moreover, the inventor in the '997 patent made statements to the Patent Office highlighting that the implants of the '661 specification (and consequently the '997) 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 '997 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.

Nevertheless, if it is determined that the implant length limitation of the '997 patent imposes restrictions that distinguish the prior implants discussed above, then similarly the requirement must not be supported by both the priority application (the '661 patent) and 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, Michelson '661 is a prior art publication under 35 U.S.C. § 102(b), and Lynn a prior art publication under at least 35 U.S.C. § 102(e).

1. 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 1. 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. NUVASIVE1015 at col. 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 1. In particular, Michelson '661 discloses a guide pin 30 inserted laterally toward a thoracic disc space. *Id.* at FIGS. 1-2; col. 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 1. 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; col. 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 1. 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; col. 10:47-50.

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

To the extent that "said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies" is interpreted as a distal end 146 that is near the lateral aspect opposite from the claimed incision (the only embodiment supported by Michelson '661 and the '997 patent), Michelson '661 discloses the claimed "positioning said third surgical instrument" step as recited in claim 1 (under the broadest reasonable interpretation standard). In particular, Michelson '661 discloses that the outer sleeve 140 is positioned so that the distal end is proximate the lateral aspect of the vertebral bodies that is opposite from the incision:

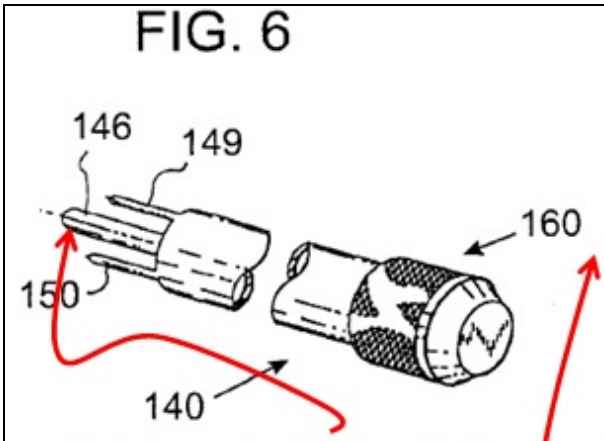


FIG. 6 shows the "distal end 146" of the outer sleeve 140 is at the tip of the distal extension 148

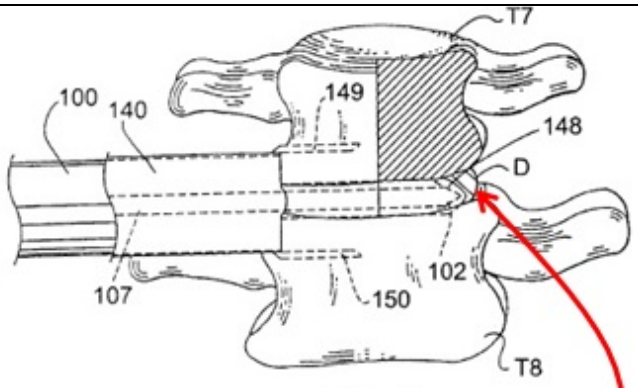


FIG. 7

FIG. 7 shows that the "distal end" of the outer sleeve 140 is proximate to the lateral aspect that is opposite from the skin incision

Id. at FIGS. 6-7.

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone 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 1. 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; col. 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 dis-

closes 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. NUVASIVE1016 at FIGS. 7A, 14, 16B, 16C & 21 (showing a laterally inserted fusion implant extending slightly more than the full transverse width of the adjacent vertebrae); 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.

2. The method of claim 1, 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 2. 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.

3. The method of claim 2, 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.

4. The method of claim 1, 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 4. 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.
5. The method of claim 4, 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.
6. The method of claim 4, 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.
7. The method of claim 1, 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 7. In particular, Michelson '661 discloses that a locking screw 416 couples 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. NUVASIVE1015 at FIG. 24; col. 17:23-30.
8. The method of claim 1, 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." NUVASIVE1015 at col. 16:14-16.

XV. CONCLUSION

The cited prior art references identified in this Petition contain pertinent technological teachings, either explicitly or inherently disclosed, that were not previously considered in the manner presented herein or relied upon on the record during original examination of the `997 patent. At least by virtue of disclosing the limitations that served as the basis for the Office's allowance of the claims at issue, the references relied upon herein should be con-

sidered important in determining patentability. In sum, these references provide new, non-cumulative technological teachings not previously considered and relied upon on the record, that indicate a reasonable likelihood of success as to Petitioner's claim that claims 1-8 of the `997 patent are not patent eligible pursuant to the grounds presented in this Petition. Accordingly, Petitioner respectfully requests institution of *inter partes* review for claims 1-8 of the `997 patent for each of the grounds presented herein.

Respectfully submitted,

Dated: Mar. 22, 2013

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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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