

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NUVASIVE, INC.,  
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,  
Patent Owner.

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Case IPR2013-00206  
Patent 8,251,997 B2

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Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU,  
*Administrative Patent Judges.*

SIU, *Administrative Patent Judge.*

FINAL WRITTEN DECISION  
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

NuVasive, Inc. (“Petitioner”) filed a petition (Paper 5) (“Pet.”) seeking *inter partes* review of claims 9–30 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, “the ’997 patent”) pursuant to 35 U.S.C. §§ 311–319.<sup>1</sup> On

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<sup>1</sup> We cite to Petitioner’s Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997 B2, filed April 3, 2013. Paper 5.

September 23, 2013, the Board instituted an *inter partes* review of all claims on six grounds of unpatentability (Paper 17) (“Dec. on Inst.”).

Subsequent to institution, Warsaw Orthopedic, Inc. (“Patent Owner”) filed a Patent Owner Response (Paper 32) (“PO Resp.”), and Petitioner filed a Reply (Paper 43) (“Pet. Reply”). Patent Owner also filed a Motion to Exclude Evidence. Paper 53. Petitioner filed an Opposition to Patent Owner’s Motion to Exclude (Paper 59) (“Opp.”), and Patent Owner filed a Reply (Paper 60) (“PO Reply”). An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 52) and Patent Owner (Paper 54).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 17–23 of the ’997 patent are unpatentable, but has not shown by a preponderance of the evidence that claims 9–16 and 24–30 of the ’997 patent are unpatentable.

A. *The ’997 Patent (Ex. 1002)*<sup>2</sup>

The ’997 patent describes methods and instrumentation for performing surgery on the spine along its lateral aspect. Ex. 1002, 3:34–36; Figs. 1 and 2. Guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for distractor 100 that is placed over the guide pin and inserted into the disc space to distract the vertebrae. Ex. 1002, 8:52–53; 9:12–14; 10:10–12; Figs. 2–5. Extended outer sleeve 140 is placed over the distractor and inserted into the disc space. Ex. 1002, 10:22–25, Fig. 12.

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<sup>2</sup> We refer to Ex. 1002 submitted by Petitioner and dated March 22, 2013.

A spinal implant I is introduced through the extended outer sleeve and installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

*B. Illustrative Claim*

Claim 9 is illustrative of the claimed subject matter of the '997 patent, and is reproduced as follows:

9. A method comprising:

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

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;

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;

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;

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

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

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

*C. Cited Prior Art*

The pending grounds of unpatentability in this *inter partes* review are based on the following prior art:

Jacobson	US 4,545,374	Oct. 8, 1985	(Ex. 1004)
Brantigan	US 5,192,327	Mar. 9, 1993	(Ex. 1006)
Frey	US 4,917,704	Apr. 17, 1990	(Ex. 1007)
Michelson '247	US 5,015,247	May 14, 1991	(Ex. 1008)
McAfee	US 5,569,290	Oct. 29, 1996	(Ex. 1009)

Hansjörg F. Leu and Adam Schreiber; *Percutaneous Fusion of the Lumbar Spine: A Promising Technique*, 6(3) SPINE: STATE OF THE ART REVIEWS 593 (Sept. 1992) (Ex. 1005, "Leu").

*D. Pending Grounds of Unpatentability*

This *inter partes* review involves the following asserted grounds of unpatentability:

Reference(s)	Basis	Claims challenged
Jacobson, Leu, McAfee, and Michelson '247	§103	9 and 16
Jacobson, Leu, McAfee, Michelson '247, and Frey	§103	10–15
Jacobson, Leu, and Brantigan	§103	17 and 23
Jacobson, Leu, Brantigan, and Frey	§103	18–22
Jacobson, Leu, and Michelson '247	§ 103	24 and 30
Jacobson, Leu, Michelson '247, and Frey	§ 103	25–29

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