

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00208
Patent 8,251,997 B2

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 1–8 of U.S. Patent No. 8,251,997 B2 (Ex. 1002, “the ’997 patent”) pursuant to 35 U.S.C. §§ 311-319.¹ On

¹ 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 (Paper 16) (“Dec. on Inst.”).

Subsequent to institution, Warsaw Orthopedic, Inc. (“Patent Owner”) filed a Patent Owner Response (Paper 29) (“PO Resp.”), and Petitioner filed a Reply (Paper 40) (“Pet. Reply”). Patent Owner also filed a Motion to Exclude Evidence. Paper 50. Petitioner filed an Opposition to Patent Owner’s Motion to Exclude (Paper 56) (“Opp.”), and Patent Owner filed a Reply (Paper 57) (“PO Reply”). An Oral Hearing was conducted on June 5, 2014, pursuant to a request for oral hearing filed by Petitioner (Paper 49) and Patent Owner (Paper 51).

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 1–8 of the ’997 patent are unpatentable.

A. *The ’997 Patent (Ex. 1002)*²

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. A spinal implant I is introduced through the extended outer sleeve and

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

installed across the disc space. Ex. 1002, 15:64–65; 16:24–26; Figs. 19, 22, 23, 30, and 30A.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the '997 patent, and is reproduced as follows:

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;
 - 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 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

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, 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)
Alcareu	EP 0567424	Oct. 27, 1993	(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, and Michelson '247	§103	1 and 8
Jacobson, Leu, and Brantigan	§103	1 and 8
Jacobson, Leu, Michelson '247, and Alacreu	§103	2–7
Jacobson, Leu, Brantigan, and Frey	§103	2–7

E. Claim Interpretation

The parties appear to agree with the interpretation of various claim terms of the '997 patent as described in the Decision on Institution with additions or modifications as set forth below. We incorporate our previous analysis for the non-disputed claim terms.

1. “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” (claim 1)

Patent Owner argues that an “axis lying in a coronal plane” should be construed as an axis that is lying in “a plane at right angles to a sagittal plane.” PO Resp. 10–11. Petitioner does not contest Patent Owner’s assertion that one of ordinary skill in the art would understand that a “coronal plane” would be oriented “at right angles to a sagittal plane.” Pet. Reply 1. Thus, no further construction of this term is necessary.

2. “non-bone interbody intraspinal implant” (claim 1)

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