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Paper 17
Date: September 23, 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.
Petitioner

v.

WARSAW ORTHOPEDIC, INC.
Patent Owner

Case IPR2013-00206
Patent 8,251,997 B2

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

SIU, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

NuVasive, Inc. ("Petitioner") requests *inter partes* review of claims 9-30 of U.S. Patent No. 8,251,997 (Ex. 1002, "the '997 patent") pursuant to 35 U.S.C. §§ 311 *et seq.*[1] Warsaw Orthopedic, Inc. ("Patent Owner") filed a preliminary response ("Prelim. Resp.") on June 25, 2013. Paper No. 11. We have jurisdiction under 35 U.S.C. § 314. The standard for instituting *inter partes* review is set forth in 35 U.S.C. § 314 (a) which provides:

> THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

We determine based on the record that there is a reasonable likelihood that Petitioner would prevail in showing unpatentability of all challenged claims 9-30. Accordingly, we authorize institution of an *inter partes* review of claims 9-30 of the '997 patent.

A. Related Proceedings

Petitioner indicated that the '997 patent is involved in co-pending litigation captioned *Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.* (originally filed in N.D. Ind. as Case No. 3:12-cv-00438-JD-CAN on Aug. 17, 2012 and transferred to S.D. Cal. on Nov. 8, 2012 as Case No. 3:12-cv-02738-CAB(MDD)). Pet. 1. Petitioner

[1] We cite to Petitioner's Corrected Petition for *Inter Partes* Review of United States Patent No. 8,251,997, filed April 3, 2013. Paper No. 5.

also filed a petition seeking *inter partes* review of claims 1-8 of the '997 patent (IPR2013-00208).

B. The '997 Patent (Ex. 1002)

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. A guide pin 30 is inserted from the lateral approach to the spine and functions as a guide post for a distractor 100. The distractor 100 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. An 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 installed across the disc space. Ex. 1002, 15:64-65; 16:24-26; Figs. 19, 22, 23, 30, and 30A.

C. Exemplary Claim

Of the challenged claims, claims 9, 17 and 24 are independent claims. Each of the dependent claims 10-16 depend either directly or indirectly from claim 9. Each of the dependent claims 18-23 depend either directly or indirectly from claim 17. Each of the dependent claims 25-30 depend either directly or indirectly from claim 24. Claim 9 is exemplary 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.

D. The Prior Art

Petitioner relies on the following prior art:

US 4,545,374 (**Jacobson**)	Oct. 8, 1985	Ex. 1004
US 5,192,327 (**Brantigan**)	March 9, 1993	Ex. 1006
US 4,917,704 (**Frey**)	April 17, 1990	Ex. 1007
US 5,015,247 (**Michelson '247**)	May 14, 1991	Ex. 1008
US 5,569,290 (**McAfee**)	Oct. 29, 1996	Ex. 1009
US 5,772,661 (**Michelson '661**)	June 30, 1998	Ex. 1010
US 8,343,224 B2 (**Lynn**)	Jan. 1, 2013	Ex. 1011

Hansjörg F. Leu and Adam Schreiber; "Percutaneous Fusion of the Lumbar Spine: A Promising Technique," 6(3) Spine: State of the Art Reviews 593 , (September 1992) ("**Leu**") (Ex 1005.)

E. The Alleged Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

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