#### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC. Petitioner

۷.

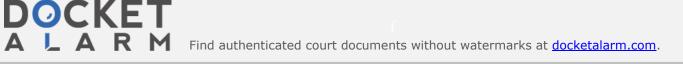
WARSAW ORTHOPEDIC, INC. Patent Owner

Patent Number: 8,251,997 B2 Issue Date: August 28, 2012

METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

Case IPR2013-00208

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE



## TABLE OF CONTENTS

I.	Introduction1		
II.	I. Claim interpretations		
	A. "Coronal plane" path to spine (claims 1, 9, 17 and 24)1		
	B. "Non-bone implant" (Claim 1)1		
	C. Implant length/vertebrae width ratio: "Substantially the full traverse width (claims1, 9 and 17		
III.	Jacobson discloses a direct lateral approach that meets the "coronal plane" path limitation and inherently teaches the insertion of a fusion implant		
IV.	Brantigan '327 discloses the lateral insertion of an implant, and even if it didn't that is not necessary for an obviousness finding7		
V.	Brantigan '327 meets the "substantially the full transverse width of the vertebrae" claim limitation9		
VI	Michelson '247, when inserted laterally according to the teachings of Jacobson, would meet the "substantially the full transverse width of the vertebrae" limitation		
VII	The "non-combinable" arguments of Warsaw have no merit		
VIII	Warsaw's secondary considerations arguments for patentability cannot pass scrutiny		
XI	Conclusion		

Case IPR2013-00208 U.S. Patent No. 8,251,997 Our Ref. 13958-0112IP1

DOCKET

#### **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., <i>Percutaneous Fusion of the Lumbar Spine</i> , 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., <i>Adjuvant Anterior Spinal Fusion Via Thorascopy</i> , Lyon Chirurgical Vol. 90, No. 5, pp. 347-51 (1994) ("Baulot")
NUVASIVE1011	English Translation of Baulot and Certificate of Translation
NUVASIVE1012	Rosenthal et al., <i>Removal of a Protruded Thoracic Disc Using</i> <i>Microsurgical Endoscopy</i> , 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")

::

Case IPR2013-00208 U.S. Patent No. 8,251,997 Our Ref. 13958-0112IP1

DOCKET

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 1017	Affidavit of Mr. Frank E. Scherkenbach in support of Petitioner's Motion for <i>Pro Hac Vice</i> Admission
NUVASIVE 1018	Resume of Mr. Frank E. Scherkenbach, provided as an exhibit to Petitioner's Motion for <i>Pro Hac Vice</i>
NUVASIVE 1019	Cover page and Affidavit of Henry Vernon Crock, AO, MD, MS, FRCS, FRACS, FRCS Ed (Hon), D. Sc (Horaris causa), of Melbourne, Australia, made September 11, 2012
NUVASIVE 1020	Exhibit HVC-1 to Affidavit of Henry Vernon Crock, being a copy of Federal Court of Australia Practice Note CM7
NUVASIVE 1021	Exhibit HVC-2 to Affidavit of Henry Vernon Crock, being a copy of the curriculum vitae of Henry Vernon Crock
NUVASIVE 1022	Exhibit HVC-3 to Affidavit of Henry Vernon Crock, being a copy of Crock, "Observations on the Management of Failed Spinal Operations," in <u>The Journal of Bone and Joint Surgery</u> , Vol. 58-B, No. 2, pp. 193-199, May 1976
NUVASIVE 1023	Exhibit HVC-4 to Affidavit of Henry Vernon Crock, being a copy of Crock, "Anterior Lumbar Interbody Fusion – Indications for its Use and Notes on Surgical Technique," in <u>Clinical Orthopedics</u> <u>and Related Research</u> , No. 165, May 1982

:::

Case IPR2013-00208 U.S. Patent No. 8,251,997 Our Ref. 13958-0112IP1

DOCKET

NUVASIVE 1024	Exhibit HVC-5 to Affidavit of Henry Vernon Crock, being a copy of Fujimaki et al., "The Results of 150 Anterior Lumbar Interbody Fusion Operations Performed by Two Surgeons in Australia," in in <u>Clinical Orthopedics and Related Research</u> , No. 165, May 1982
NUVASIVE 1025	Exhibit HVC-5 to Affidavit of Henry Vernon Crock, being a copy of Crock, <u>A Practice of Spinal Surgery</u> , Springer-Verlag, Wein, New York, Revised 1 <sup>st</sup> Edition, 1983
NUVASIVE 1026	Exhibit to HVC-5 Affidavit of Henry Vernon Crock, being a copy of Crock, <u>A Short Practice of Spinal Surgery,</u> Springer-Verlag, Wein, New York, Revised 2 <sup>nd</sup> Edition, 1993
NUVASIVE 1027	Page 29 of NUVASIVE 1003, hand-annotated by Dr. Sachs during Feb. 25, 2014 Deposition
NUVASIVE 1028	Transcript of Deposition of Dr. Barton Sachs, Conducted Feb. 25, 2014
NUVASIVE 1029	Second Declaration of Dr. Paul McAfee, M.D., M.B.A.
NUVASIVE 1030	Declaration of Dr. Robert Jacobson, M.D.
NUVASIVE 1031	Declaration of Dr. John Brantigan, M.D.
NUVASIVE 1032	Declaration of Patrick Miles
NUVASIVE 1033	U.S. Patent No. 6,241,770 to Michelson
NUVASIVE 1034	U.S. Patent No. 5,397,364 to Kozak et al.

# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

# **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

#### E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.