UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.
Petitioner

v.

WARSAW ORTHOPEDIC, INC.
Patent Owner

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

Case IPR2013-00206

DECLARATION OF PATRICK MILES

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I, Patrick Miles of San Diego, California, declare that:

1. I am currently President of Global Products and Services at NuVasive, Inc., in San Diego, California. I have worked at NuVasive since January of 2001. Prior to my current position, I served as President of the Americas from January 2010 to October 2011, Executive Vice President of Product Marketing and Development from January 2007 to December 2009, Senior Vice President of Marketing from December 2004 to January 2007, and Vice President of Marketing from January 2001 to December 2004.

2. Prior to starting with NuVasive in 2001, I worked for ORATEC from 1999 through 2001. ORATEC is a medical device company outside the spinal field. Prior to that, from 1996 through April 1999, I worked at Sofamor Danek (which was acquired by Medtronic in 1998, becoming Medtronic Sofamor Danek) as Director of Marketing for Minimally Invasive Systems and Cervical Spine Systems.

3. Throughout my time at NuVasive, I have been involved at varying levels with the research, development, and marketing of NuVasive's XLIF (eXtreme Lateral Interbody Fusion) system and procedure. I started working on the XLIF products and systems in 2001. I was involved with the launch of the XLIF procedure and products at the North American Spine Society ('NASS") meeting in 2003. I have been involved in the commercialization and development of XLIF and its associated products since its launch. I am currently listed as an inventor on 51 issued U.S. patents assigned to NuVasive, many of which are related to NuVasive's XLIF solution.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

4. I submit this declaration to correct certain facts and positions stated by Warsaw Orthopedics in Patent Office proceedings related to the validity of U.S. Patent No. 8,251,997 to Dr. Gary Michelson (the "'997 patent"), specifically matter numbers IPR2013-00208 and IPR2013-00206. In connection with providing my rebuttal testimony, I have reviewed the following documents:

- U.S. Patent No. 8,251,997 to Michelson (Exhibit 1002).
- In the *inter partes* review proceeding IPR2013-00208:
  - Warsaw's Patent Owner Response (especially pages 55-60);
  - Ex. 2038, Declaration of Barton L. Sachs (especially ¶¶136-139);
- In the *inter partes* review proceeding IPR2013-00206:
  - Warsaw's Patent Owner Response (especially pages 55-60);
  - Ex. 2038, Declaration of Barton L. Sachs (especially ¶¶136-139).
- Additional exhibits cited below.

5. My testimony, explained below, is based on my education and experience in the spinal orthopedics field, including my work experience at Sofamor Danek (and later Medtronic Sofamor Danek) from 1996 to 1999 and at NuVasive from 2001 to present, my in depth experience with NuVasive's XLIF solution and the competitive landscape, and my personal knowledge and involvement in certain events.

6. On page 57 of the Patent Owner Response, Warsaw states that "[t]he success of these embodying products is due to the patent features of the '997 patent."

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

NuVasive's XLIF solution, including its family of CoRoent XL fusion implants for use in XLIF, have enjoyed commercial success in the spinal orthopedics market place, and in fact created the market for lateral fusion products. It is my opinion that XLIF's success is due to NuVasive's own proprietary innovation and its extensive efforts to commercialize XLIF.

7. The development of the XLIF solution at NuVasive began in 2001. The XLIF systems and procedure were initially released at the North American Spine Society Annual Meeting in late 2003. Our commercialization efforts continued after the 2003 NASS meeting into 2004. Initially, NuVasive's XLIF solution was met with substantial skepticism within the spinal orthopedics community. During those early years, we put substantial resources into training the spinal community to overcome that skepticism and show the spinal community that the XLIF solution was indeed a safe and effective solution for spinal fusion especially in the lower lumbar region. We have continued to improve the XLIF solution, specifically expanding its usability to treat a wider array of spinal issues. Eventually, our success led to competitors in the marketplace, the first of those being Medtronic Sofamor Danek with its "DLIF" surgical technique and equipment in the 2006/2007 timeframe. *See* Medtronic DLIF Marketing Plan (Ex. 1053), p. 8 (Medtronic's own document admitting that "NuVasive pioneered the approach" and that the approach is "Innovative"). NuVasive currently has a patent infringement lawsuit pending in U.S. District Court against Medtronic, accusing its DLIF system of infringing NuVasive patents. Additional competitors have also entered the market with lateral fusion solutions that incorporate many of the important innovations

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

developed by NuVasive. Those other companies include, among others, Globus Medical, Inc. with its Lateral Lumbar Interbody Fusion ("LLIF") solution introduced in the 2010 timeframe. *See id.* NuVasive also has a patent infringement lawsuit pending in U.S. District Court against Globus Medical because Globus' LLIF solution also infringes NuVasive patents.

8. The success of NuVasive's XLIF procedure and system is due, in part, to the fact that our XLIF solution provides a safe and reproducible minimally disruptive lateral access path through the psoas muscle (i.e., "trans-psoas") using tools and techniques that minimize tissue trauma, reduce blood loss, and allow direct visualization and customization of the operative corridor during lumbar spinal fusion procedures. XLIF allows a greater number of spine surgeons with varying skills and experience to perform a lateral approach to the lumbar spine through the highly innervated psoas muscle. Prior to XLIF, the lateral approach, which dates back to at least the 1980s, was limited to a handful of highly skilled surgeons performing techniques that were quickly abandoned because they provided mixed results. Those prior lateral techniques failed to achieve any level of success in the marketplace.

9. Some key factors to XLIF's success include: (A) a surgical finger-sweep and finger guidance technique to help create a safe passage through the retroperitoneal space and deliver surgical instruments safely to the spine (*see, e.g.*, U.S. Patent No. 7,905,840, Exhibit 1059); (B) a minimally disruptive access system with integrated nerve monitoring

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.