

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

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NUVASIVE - EXHIBIT 2002
Alphatec Holdings Inc. et al. v. NuVasive, Inc.
IPR2019-00362

MSD 1165
IPR2013-00506
IPR2013-00508

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.

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."

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

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

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