UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Patent Number: 8,187,334 B2
Issue Date: May 29, 2012

Case No. IPR2013-00507

DECLARATION OF PATRICK MILES

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NUVASIVE - EXHIBIT 2052
Alphatec Holdings Inc. et al. v. NuVasive, Inc.

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 to 1999, I worked at Sofamor Danek as Director of Marketing for Minimally Invasive Systems and Cervical Spine Systems, and remained there until Medtronic's acquisition of Sofamor Danek.

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, including the CoRoent XL interbody implants. 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 was also involved with the launch of the CoRoent XL implants at the NASS meeting in 2004. 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, including lateral surgical method and systems. I have witnessed or studied hundreds of spinal fusion procedures using the CoRoent XL interbody implants and other interbody fusion implants, and I understand the design constraints and difficulties associated with developing a new interbody fusion implant, especially one particularly suited for lateral, trans-psoas lumbar surgeries.

4. I submit this declaration in support of NuVasive's Patent Owner Response to the *inter partes* review related to U.S. Patent No. 8,187,334 ("the '334 patent").

5. My testimony is based on my education and experience in the spinal orthopedics field, including my work experience at 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.

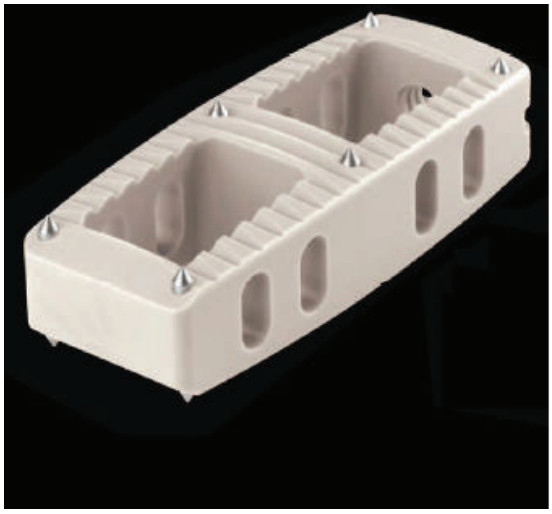
6. The development of the XLIF solution at NuVasive began in 2001. The XLIF systems and procedure were initially released at the North American Spine Society Annual Meeting in late 2003. Our commercialization efforts continued after the 2003 NASS meeting into 2004. The CoRoent XL family of interbody implants, used in XLIF procedures and inserted into the spine from a direct lateral, retroperitoneal, transpsoas approach to the lumbar spine, was commercially launched at NASS in 2004. The CoRoent XL implants were the first commercially available lumbar interbody implants having a length greater than

40mm, a maximum width of 18mm, and designed for insertion for a direct lateral, transpsoas approach to the lumbar spine.

7. Initially, NuVasive's XLIF solution was met with substantial skepticism within the spinal orthopedics community, including concern over the size of our implants. 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, NuVasive's success led to competitors in the marketplace, the first of those being Medtronic Sofamor Danek with its "DLIF" surgical technique and its Clydesdale lateral implants in the 2006/2007 timeframe—years after NuVasive pioneered the market for lateral, trans-psoas interbody fusion surgeries with the CoRoent XL implant. NuVasive currently has a patent infringement lawsuit pending in U.S. District Court against Medtronic, accusing its DLIF system, including its Clydesdale implants, 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 and transcontinental interbody implants 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. I understand the declaration testimony of Dr. Hansen Yuan (I was informed that Dr. Yuan's Declaration would be submitted contemporaneously with this Declaration) is that the CoRoent XL implant embodies claims of the'334 patent:



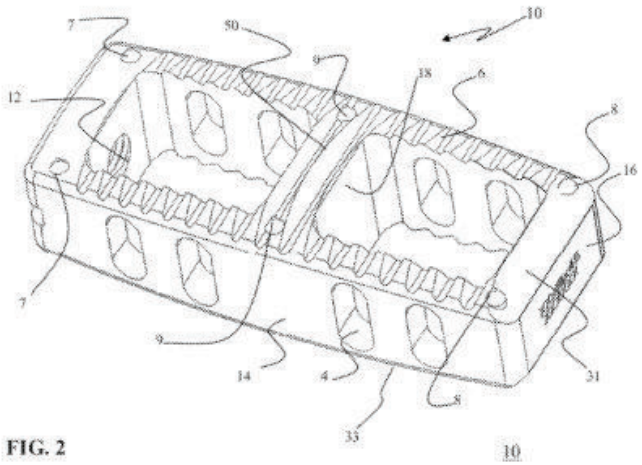


FIG. 2

See, e.g., Ex. 2022 at 4 (left); '334 patent, FIG. 2 (shown at right).

9. NuVasive's CoRoent XL implants have enjoyed commercial success. Even Petitioner Medtronic's own internal presentation (attached hereto in Appendix A) confirms that NuVasive "pioneered" the new approach to the spine for spinal fusion surgeries and that NuVasive had "100%" of the market for such lateral, trans-psoas interbody fusion implants during the first years (2004-05) after it created the market until Medtronic eventually entered the market years later in 2006-07:

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