

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2014-00087
U.S. Patent 8,005,535

DECLARATION OF PATRICK MILES

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

I. BACKGROUND

1. I am currently President of Global Products and Services at NuVasive, Inc. (the Patent Owner), 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. 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 eXtreme Lateral Interbody Fusion ("XLIF") systems 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 October 2003. I have been involved in the

commercialization and development of XLIF and its associated products since its inception. I am currently listed as an inventor on 51 issued U.S. patents assigned to NuVasive, many of which relate to NuVasive's XLIF procedure and systems. I am one of the listed inventors on U.S. Patent Nos. 8,005,535 ("the '535 patent"), 8,000,782 ("the '782 patent"), 8,016,767 ("the '767 patent"), and 8,192,356 ("the '356 patent"), which are the subject of the instant *inter partes* reviews.

II. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

4. I am not offering an opinion regarding whether the '535, '782, '767, and/or '356 patents are obvious in light of the prior art raised by Medtronic in the *inter partes* review proceedings, which I understand turn on legal determinations that I have not been asked to address. It is my understanding, however, that the existence of one or more so-called "secondary considerations" or "objective indicia" of non-obviousness must be considered in determining whether a patent is obvious in light of prior art. I understand these objective indicia include:

- a. commercial success of a product due to the merits of the claimed invention;
- b. a long felt need for the solution provided by the claimed invention;
- c. unsuccessful attempts by others to find the solution provided by the claimed invention;
- d. copying of the claimed invention by others;
- e. unexpected and superior results from the claimed invention;

- f. acceptance by others of the claimed invention as shown by praise from others in the field or from the licensing of the claimed invention;
- g. teaching away from the conventional wisdom in the art at the time of the invention;
- h. other evidence tending to show non-obviousness; and
- i. other evidence tending to show obviousness.

5. It is my understanding that, in order to establish objective indicia of nonobviousness, NuVasive must show a nexus between the claims of the patent and the objective indicia such as commercial success of an embodiment of that patent. In the context of commercial success, for example, I understand this means the commercial success of XLIF as an embodiment of the '535, '782, '767, and/or '356 patents must be tied to the claims of the '535, '782, '767, and/or '356 patents. Below I discuss facts that I am aware of and documents that I have reviewed that support what I understand to be relevant objective indicia. To reiterate, however, I am providing only factual testimony pertinent to secondary considerations of non-obviousness and am not expressing any expert opinion on the validity of the claims or whether any surgical methods or tools practice those claims.

III. THE PATENT CLAIMS AND XLIF

6. I have reviewed the analysis of Dr. Frank Phillips matching the independent claims of the '535, '782, '767, and '356 patents to the XLIF procedure and/or systems, and I rely on his analysis in my discussion below. [Ex. 2020 (Phillips Decl.) at ¶¶ 22-27, Attachments B-E.]

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