

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

SECOND DECLARATION OF DR. PAUL McAFEE, M.D., M.B.A.

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I, Dr. Paul McAfee, M.D., M.B.A., of Sparks Glencoe, Maryland, declare that:

I. Introduction

1. On March 21, 2013 I provided an initial Declaration in this matter. I reaffirm the opinions stated in that Declaration. This Second Declaration is in rebuttal to statements made in the Patent Owner's Response and the accompanying Sachs Declaration submitted on December 20, 2013. I disagree with any statements and positions that contradict or are inconsistent with my initial Declaration. In this Second Declaration, I will address some of these errors and contradictions set forth in the Patent Owner Response and supporting Sachs declaration.

2. I have reviewed the following documents:

a. In the *inter partes* review proceeding IPR2013-00208:

i. Warsaw's Preliminary Response;

ii. Warsaw's Patent Owner Response;

iii. Ex. 2038, Declaration of Barton L. Sachs;

iv. Ex. 1001, 1002, 1006, 1014, 1033-1037, 1039, 1041-1044, 1047, 1051-1069, 1073; and

v. Ex. 2001-2009, 2018, 2039, 2041, 2042, 2055.

b. In the *inter partes* review proceeding IPR2013-00206:

i. Warsaw's Preliminary Response;

ii. Warsaw's Patent Owner Response;

- iii. Ex. 2038, Declaration of Barton L. Sachs;
- iv. Ex. 1001, 1002, 1006, 1014, 1033-1037, 1039, 1041-1044, 1047, 1051-1069, 1073; and
- v. Ex. 2001-2009, 2018, 2039, 2041, 2042, 2055.

I have also reviewed additional references cited in this Declaration but not included in the list above. Further, I have reviewed the March 2014 Declaration of Dr. Robert E. Jacobson, the March 2014 Declaration of Patrick Miles, and the March 2014 Declaration of Dr. John W. Brantigan, which I was informed are to be submitted in the *inter partes* review proceedings IPR2013-00206 and IPR2013-00208 as Exhibits 1030-1032.

II. Rebuttal of Dr. Sachs' testimony regarding background

3. In ¶ 29 of the Sachs declaration, Dr. Sachs presents images alleged to “illustrate the boundaries of a typical vertebral endplate, and indicate that the endplates are distinct from the apophyseal ring.” The images presented are simplified artwork, not images of actual human anatomy. The simplified artwork in ¶ 29 is generally accurate to show approximate positioning of various tissue, but are not accurate for Dr. Sachs' purpose of showing “distinct” boundaries. The boundaries between the vertebral endplate, the apophyseal ring, and the cortical rim are not “distinct” and in fact are often not discernible in an actual human spine, and most certainly not in a typical spine of patients suffering from some spinal conditions requiring a fusion surgery. In reality, the endplate and apophyseal ring are confluent with one another, especially in mature adults suffering from some spinal

conditions requiring a fusion surgery, such that the end plate includes the entire apophyseal ring and more (the more central regions of cortical bone and compacted cancellous bone). See Ex. 2039 at 48:9-10 (“the apophyseal ring and cortical bone are parts of the end plate”), 48:18-20. In fact, those of ordinary skill in the art of spine surgery and even Warsaw (the Patent Owner) often refer to the apophyseal ring as merely part of the vertebral endplate, not distinct from it. See, e.g., Warsaw’s U.S. Patent No. 8,613,769 (Ex. 1056) at 5:48-6:2 and 17:17-22 (“the apophyseal ring of the vertebral endplates”); Warsaw’s European Patent No. EP2108341 (Ex. 1057) at para. 0075 (“the apophyseal ring of the vertebral endplate”). Also, in the context of the ‘997 patent, at least the apophyseal ring and the cortical rim in the area of the implant I would be destroyed and removed from the spine during the procedures illustrated in FIGS. 18-24 and 29-30 of the ‘997 patent, as explained in more detail below. So the simplified and undamaged vertebra drawings in ¶ 29 of the Sachs declaration are not accurate in the context of inserting the implant I in the procedure disclosed and illustrated in FIGS. 29-30 and 16-23 of the ‘997 patent.

4. In ¶ 30, Dr. Sachs testified that “interbody spinal fusion is one of many types of spinal fusion procedures.” I agree with this statement, and indeed it is the exact type of spinal fusion procedure suggested by Jacobson, which discloses that a lumbar disc space is targeted and disc material is removed and that a “fusion” can also be performed through the laterally inserted cannula 11. See Jacobson (Ex. 1004) at FIGS. 6-8; col. 6, lines 9-13; First McAfee Decl. (Ex. 1001), ¶¶ 11 and 22. By the early 1990s, a spinal surgeon of ordinary

skill in the art reviewing the Jacobson patent would have understood that Jacobson's express suggestion for performing a fusion through the laterally inserted cannula 11 should be implemented using an interbody implant in the targeted disc space so that the disc space would not collapse and so that bony fusion would be achieved. See March 2014 Jacobson Decl. (Ex. 1030), ¶ 10. By that time in the early 1990s, such fusion procedures were commonly performed using implants formed from bone (e.g., an allograft bone dowel implant) or formed from a combination of artificial material and bone (e.g., a metal cage with bone material therein). See *id.*; First McAfee Decl. (Ex. 1001), ¶¶ 27-28. In accordance with the usage of the term "implant" in the '997 patent, the term "implant" in the context of spinal fusion was and is broadly understood to include implant structures formed from bone (e.g., an allograft bone dowel implant) or formed from an artificial material. This fact is consistent with the '997 patent specification, which broadly uses the term "implant" to refer to implant structures formed from bone (e.g., an allograft bone dowel implant) or formed from an artificial material. See '997 patent (Ex. 1002) at col. 17:23-26 and 43 ("an implant such as a bone dowel") and at col. 16:29-30 ("titanium"). However, Dr. Sachs also testified that "fusions of the posterior column are often performed without an implant." Sachs Decl. (Ex. 2038), ¶ 30. Although such procedures in the "posterior column" are possible, those procedures are not relevant to any of the Grounds proposed in Petitions for the *inter partes* review proceedings IPR2013-00208 and IPR2013-00206, which all rely upon primary references (such as Jacobson) that target a spinal disc space in the anterior column of the

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