

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.
Petitioner

v.

WARSAW ORTHOPEDIC, INC.
Patent Owner

Patent Number: 8,444,696
Issue Date: May 21, 2013

Case No. IPR2013-00396

SECOND DECLARATION OF DR. JOHN W. BRANTIGAN, M.D.

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-145

I, Dr. John W. Brantigan, M.D., of Shaw Island, WA, declare that:

INTRODUCTION

1. On June 24, 2013, I provided an initial Declaration in each of the IPR2013-00395 and IPR2013-00396 proceedings. See Ex. 1001 for IPR2013-00395 and Ex. 1101 for IPR2013-00396. I reaffirm the opinions stated in that Declaration. I provide this Second Declaration in response to statements made in the April 11, 2014 Patent Owner's Response and the accompanying April 10, 2014 Declaration of Dr. Charles L. Branch, Jr. ("Branch Declaration") submitted in this proceeding. In this Second Declaration, I will respond to some of the technical errors and mischaracterizations of my prior testimony that are contained in the Patent Owner Response and supporting Branch Declaration.

2. I have reviewed the '696 patent (Ex. 1002) and its prosecution history (Ex. 1003) from the view point of an experienced spine surgeon. Additionally, I have reviewed the following patents and publications: (1) PCT Publication WO93/01771 to Senter et al. ("Senter," Ex. 1007); (2) PCT Publication WO 89/09035 to Brantigan ("Brantigan '035," Ex. 1005); (3) U.S. Patent No. 5,192,327 to Brantigan ("Brantigan '327," Ex.1006); (4) PCT Publication WO90/00037 to Michelson ("Michelson '037," Ex. 1008); (5) U.S. Pat. No. 5,443,514 to Steffee ("Steffee," Ex. 1108); and (6) U.S. Patent No. 5,645,596 to Kim et al. ("Kim," Ex. 1110). I also have reviewed the Corrected Petition for *Inter Partes* Review in each of the IPR2013-00395 and IPR2013-00396 proceedings, and my initial Declarations signed on June 24, 2013 (Ex. 1001 for IPR2013-00395 and Ex. 1101 for IPR2013-00396). I

also have reviewed the Patent Owner's Response in each of the IPR2013-00395 and IPR2013-00396 proceedings submitted on April 11, 2014, the accompanying Branch Declaration (Ex. 2005), the other accompanying exhibits (including Exhibits 2003 (the Brantigan '757 patent), 2004 (the Brantigan '772 patent), and 2009 (transcript of my April 7, 2014 Deposition in this proceeding), the transcript of the April 23, 2014 Deposition of Dr. Branch ("Branch Depo.") in this proceeding, and the December 20, 2013 Board Decision in each of the IPR2013-00395 and IPR2013-00396 proceedings.

SENER IN VIEW OF BRANTIGAN '035

3. On pages 26-29 of the Patent Owner's Response (IPR2013-00395), Warsaw argues that the implant of Senter does not provide the claimed "upper and lower bearing surfaces . . . being convex." See also Ex. 2005 at ¶ 35. This argument, however, appears to be based upon a narrower interpretation of claims 1 and 4 than my earlier analysis (first Brantigan Declaration at ¶ 29), and incorporates requirements into the claims that are not present in the claim language. I understand that the December 20, 2013 Board Decision stated that "the claim language does not require that the convexity be along the entire length of the implant." See Board Decision, p. 9. Based on my reading of the claims, I agree with the Board's interpretation that one of skill in the art in June of 1995 would not have interpreted the claims to require that the convexity extend along the entire length of the implant. As such, the plain meaning of the claim language ("upper and lower bearing

surfacesbeing convex”) does not exclude the convexity shown in Senter. Additionally, a person of ordinary skill in the art in June 1995 would not have recognized the claimed convexity of the upper and lower bearing surfaces as being restricted to a specific degree of convexity (“convex curvatures conforming to the anatomic endplates”). See Patent Owner’s Response (IPR2013-00395) at pp. 16-17, 29; Ex. 2005, ¶ 35. If the claimed convexity of the upper and lower bearing surfaces recited in claims 1 and 4 was restricted to only “convex curvatures conforming to the anatomic endplates,” the requisite “curvature” of the bearing surfaces would be patient-dependent, unknown, and undefined because the curvature of anatomic endplates varies from patient to patient. Ex. 2005, ¶ 60 (describing the variations in endplate curvature); Branch Depo. at 89:10-22.

MODIFICATION OF SENTER TO INCLUDE RATCHETINGS AS SUGGESTED BY BRANTIGAN ‘035

4. On pages 33 to 34 of the Patent Owner’s Response (IPR2013-00395), Warsaw implies that modification of the implant of Senter to include ratchetings, such as the directional teeth 122 shown in Brantigan ‘035, on the convex upper and lower bearing surfaces of Senter would cause forward movement of the implant once the implant is put in place between two vertebrae. Additionally, in his deposition, Dr. Branch stated that modifying Senter to include the ratchetings of Brantigan ‘035 would cause the implant to be “propel[led]” toward the spinal cord once the implant is in place. See Branch Depo., 70:3-19; see also Ex. 2005, ¶¶ 87, 91. A person of ordinary skill in the art would have

recognized that this contention is not consistent with the clinical realities of inserting a spinal implant before June 1995 (and even today).

5. Contrary to pages 33 to 34 of the Patent Owner's Response (IPR2013-00395) and Dr. Branch's testimony (Deposition p. 70:3-19 and Branch Declaration at ¶¶ 87, 91, and others), such "ratchetings" as they are called in the Michelson '696 patent (which are more commonly called "teeth" or directional teeth), oriented with a primary purpose of resisting implant back-out as taught by the Brantigan '035 patent and other references, would not "propel" an implant forward. Instead, such directional "ratchetings" or teeth resist both implant back-out and forward movement of the implant, and a person of ordinary skill in the art before June 7, 1995 would have recognized this plain fact. Of course, with directional ratchetings or teeth, the resistance to forward movement of the implant can be less than the resistance to implant back-out, but such ratchetings or teeth nevertheless resist forward movement also. The resistance to movement in the forward direction is simply a matter of physics and anatomy. The angling of the forward-facing ratchet face, in combination with the presence of the ridge of the ratcheting which digs into the adjacent vertebrae end faces when the adjacent vertebrae are forced against the bearing surfaces of the implant, causes that resistance to the forward movement of the implant. See, e.g., Ex. 1005, 19:29-31 (teaching that such ratchetings "provid[e] a roughened surface, biting into and gripping" the vertebral bone adjacent to the implant). This anchoring effect would be especially true for anteriorly inserted implants such as Senter, in which it was common practice to distract the

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