

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Michelson  
U.S. Patent No.: 8,444,696 Attorney Docket No.: 13958-0113IP2  
Issue Date: May 21, 2013  
Appl. Serial No.: 13/235,998  
Filing Date: September 19, 2011  
Title: ANATOMIC SPINAL IMPLANT HAVING ANATOMIC BEARING SURFACES

**DECLARATION OF Dr. JOHN W. BRANTIGAN, M.D.**

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

**QUALIFICATIONS**

1. I am an orthopaedic surgeon board certified by the American Board of Orthopaedic Surgery, and I have extensive experience in spine surgery. I received my medical degree from the Johns Hopkins University in 1970. I performed an internship at the Department of Surgery, University of Minnesota from 1970-1971, a residency in general surgery at the University of Utah from 1973-1974, a residency at Shriners Hospital for Crippled Children (Spokane, WA) from 1976-77, and a residency in orthopaedic surgery at the University of Washington from 1974-1978. From 1978 to 1990, I was in private practice as an orthopaedic surgeon at Immanuel Medical Center (Omaha, NE), Memorial Hospital of Dodge County (Fremont, NE), and St. Joseph Hospital (Omaha, NE). From 1990 to 1992, I was an orthopaedic surgeon at Cleveland Spine and Arthritis Center of Lutheran Medical Center (Cleveland, OH). From 1992 to 1997, I served as the Associate Professor of Orthopaedic Surgery and Chief of Spinal Reconstructive Surgery at Creighton University (Omaha, NE). In 1997, I returned to private practice as an orthopaedic surgeon at South Texas Orthopaedic and Spinal Surgery Associates (San Antonio, TX), after which I retired in 2004. I have performed over 1,000 spinal surgeries, including hundreds of surgeries involving spinal fusion implants. I provided training to others in various spine surgical techniques in the U.S., England, Germany, France, Sweden, Norway, Belgium, Spain, Italy, Netherlands, Japan, Korea, Taiwan, Venezuela, Mexico, New Zealand, and Australia. I participated in more than twenty teaching trips to Japan, each

lasting more than a week and visiting universities and hospitals throughout the country. I am listed as an inventor on at least 7 U.S. patents and additional foreign patents, including 5 U.S. patents directly related to spinal fusion implants I invented in the 1980s and early 1990s. I have published over 70 publications, including nearly 50 publications pertaining to spinal implants and spinal surgical methods (many of which were published in the early 1990s). I also co-edited the textbook INTERVERTEBRAL FUSION USING CARBON FIBER REINFORCED POLYMER IMPLANTS, Quality Medical Publishing, Inc., St. Louis, 2006. Additionally, I was awarded a Distinguished Alumnus Award from Johns Hopkins University in 2009 for my many years of work related interbody fusion devices.

2. Based upon my knowledge and experience in this field, I am aware of the needs and the challenges orthopaedic surgeons face in performing spinal fusion procedures. I routinely performed and observed these spinal fusion procedures, and I am familiar with the various types of spinal fusion implants that were used in 1995 and earlier. I have personal knowledge of what was considered by my peers and me to be ordinary and conventional design options for spinal fusion implants prior to June 7, 1995, and indeed I personally invented and then used a number of spinal fusion implants during the 1980s and early 1990s. One of my implant inventions is still being offered to surgeons by DePuy Synthes under the name ALIF I/F CAGE® system. See <http://www.depuy.com/uk/healthcare-professionals/product-details/brantigan-alif-if-cage-system>. I am keenly aware of the conventional design options that were available to persons of ordinary skill during the early 1990s. I was a practicing spine surgeon prior to June 7, 1995 and I am familiar with the state of spinal fusion surgery prior to June 7, 1995. I have formulated my analysis on this matter based on this personal experience and what was considered standard and conventional by one skilled in the art prior to June 7, 1995.

3. I am not, and never was, an employee or clinical research consultant for NuVasive, Inc. I have been engaged in the present matter to provide my independent analysis of the issues raised in the above-mentioned *inter partes* review of U.S. Patent No. 8,444,696 ("the '696 patent"). I was previously

engaged by NuVasive to provide fact testimony about my implant inventions in connection with NuVasive's pending challenge to the validity of another of Dr. Michelson's implant patents (U.S. Pat. No. 5,860,973). I received no compensation for this declaration beyond my normal hourly compensation based on my time actually spent studying the matter, and I will not receive any added compensation based on the outcome of this *inter partes* review of the '696 patent.

4. While I am not an expert in patent law, I have reviewed the '696 patent and its prosecution history from the view point of an experienced spine surgeon. Additionally, I have reviewed the following publications: (1) U.S. Pat. No. 5,607,424 to Tropiano ("Tropiano"); (2) U.S. Pat. No. 5,015,247 to Michelson ("Michelson '247"); (3) PCT Pub. No. WO89/009035 to Brantigan ("Brantigan '035"); (4) PCT Pub. No. WO95/008306 to Beckers and the certified English translation thereof (collectively referred to as "Beckers"); and (5) U.S. Pat. No. 5,443,514 to Steffee ("Steffee"). I am listed as an inventor on the Brantigan '035 reference. I also have reviewed additional references cited in this Declaration but not included in the list above.

5. My findings below and my conclusions concerning the lack of novelty or non-obviousness of the spinal implants claimed by the '696 patent, as explained below, are based on my education, experience, and background in the fields discussed above.

#### **BACKGROUND KNOWLEDGE ONE OF SKILL IN THE ART WOULD HAVE HAD PRIOR TO THE FILING OF THE '696 PATENT**

6. By way of background, the human spine is made up of 33 vertebrae, including 24 articulating vertebrae and nine fused vertebrae of the sacrum and coccyx. The articulating vertebrae have discs positioned between adjacent vertebrae which allow the articulation movement. Each disc forms a joint that allows slight movement of the vertebrae, and acts as a ligament to hold the vertebrae together. Spinal fusion is a surgical procedure that fuses adjacent vertebrae to one another or to an intermediate

implant (e.g., via bone ingrowth) so that the adjacent vertebrae act as a single construct with no relative motion. This is done in some cases to eliminate motion in the spine to decrease or eliminate back pain created by the motion, and in other cases to correct various spinal deformities. By the 1980s, spinal fusion procedures typically involve removing all or a portion of an intervertebral disc (sometimes referred to as a "discectomy"), and implanting a fusion implant in the disc space to cause bone growth between two adjacent vertebrae.

7. The '696 patent is entitled "Anatomic Spinal Implant Having Anatomic Bearing Surfaces," and its disclosure relates to spinal fusion implants that are inserted into a disc space between adjacent vertebrae of patients with degenerative disc disease. Implants of this type were invented at least as early as the early 1980's, and provide structural stability while bone grows between the adjacent vertebrae to fuse them together. Specifically, the '696 patent discloses an assortment of isolated embodiments of spinal fusion implants, which in some cases, are mutually exclusive to one another both in terms of structure and implantation techniques. *Compare* '696 patent at FIGS. 13-17 (showing one implant 300 that is much wider than it is tall, and is thus not rotated after insertion into the disc space as shown in FIG. 7a), *with* FIGS. 18-23 (showing an alternative implant 400 that is taller than it is wide and is inserted using the conventional insert-and-rotate implantation technique as described at col. 10, lines 53-64). The '696 patent claims priority through seven generations of patents, the first of which was filed on June 7, 1995 (now U.S. Patent No. 5,609,635), and which, in turn, was a continuation-in-part of an earlier application family going back to June 28, 1988 (published as the Michelson '037 reference). Unlike the related U.S. Patent No. 5,609,635, I understand that the '696 patent does not claim priority back to the June 28, 1988 application family.

8. The stated main difference between earlier spinal fusion implants (such as Dr. Michelson's earlier 1988 patent application family published as the Michelson '037 reference) and the '696 patent is the disclosure in the latter of implants having a lordotic design, meaning they have a "wedge-shape" in an

elevation side view. See, e.g., '696 patent at col. 1:27-2:8 (citing to the earlier 1988 patent application family); FIGS. 3-4, 7A, 9, 14, 18, 20, 25, and 30-32. Such a "wedge-shape" implant, given that it is implanted with the higher end of the wedge in the anterior, or front, portion of the disc space, helps to maintain the "lordosis," or forward curve, of the lower (lumbar) spine. These "wedge-shape" implants were well known by the time of Dr. Michelson's June 1995 patent filing, and in fact were commonly used in spinal fusion procedures employing the traditional insert-and-rotate implant structures before June 1995.

9. In the late 1980s and early 1990s (and long before the '696 patent's alleged priority date of June 7, 1995), I invented and developed a number of new spinal fusion implants. See, e.g., U.S. Patent 4,743,256; U.S. Patent 4,834,757; U.S. Patent 4,878,915; PCT Publication WO 89/09035 (the "Brantigan '035" reference, and claiming priority to U.S. Patent 4,834,757 but having a different specification); U.S. Patent 5,192,327 (the "Brantigan '327" reference); U.S. Patent 5,425,772. My implant designs ushered in a new era of spinal fusion implant design and provided those of ordinary skill in the art at the time with a set of basic design options that were well-understood by spine surgeons and implant designers by the early 1990s. For example, the Brantigan '035 reference provides examples non-bone fusion constructs having large chambers for retaining bone ingrowth material (e.g., to promote fusion) while also disclosing a number of additional options that added convenience for the surgeon or improved safety for the patient. See, e.g., Brantigan '035 at pp. 19-21; FIGS. 2-3 and 6-10 (showing the addition of a recessed portion and threaded hole in the trailing face of the implant—regardless of whether the implant was cylindrical or non-cylindrical in shape—for purposes of providing a convenient and mechanically secure connection with a releasable inserter instrument); FIGS. 18-19 (illustrating the option of using of ratchetings along the upper and lower bearing surfaces of, and around the bone fusion aperture of, a spinal fusion implant for purposes of inhibiting the implant from backing out of the disc space after implantation). The Brantigan '035 reference was published in October 1989, and thus by the early 1990s, the various design options disclosed in the Brantigan '035 reference were not considered to be exclusive to the implants shown in my

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