

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,444,696 Attorney Docket No.: 13958-0113IP1
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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. 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 patents and publications: (1) U.S. Patent No. 5,645,596 to Kim et al. ("Kim"); (2) PCT Publication WO 89/09035 to Brantigan ("Brantigan '035"); (3) U.S. Patent No. 5,192,327 to Brantigan ("Brantigan '327"); (4) PCT Publication WO93/01771 to Senter et al. ("Senter"); (5) PCT Publication WO90/00037 to Michelson ("Michelson '037"); and (6) U.S. Patent No. 5,306,309 to Wagner et al. ("Wagner"). I am listed as an inventor on both the Brantigan '035 reference and the Brantigan '327 reference. I also have reviewed additional references cited in this Declaration but not included in the list above.

5. My findings explained below, and my conclusions concerning the obviousness of the implant configurations claimed by the '696 patent as explained below, are all based on my education, experience, and background in the field 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. Based upon my knowledge and experience in this field, I am aware of the challenges orthopaedic surgeons faced in performing spinal fusion procedures during the early 1990s, and 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.

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 prior art 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 parent 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 well-known "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 helps to maintain the "lordosis," or natural forward curve, of particular portions of the spine. These "lordotic" implants were well known by the time of Dr. Michelson's June 1995 patent filing, which may explain why most of the '696 patent claims (including claims 1-6) do not appear to require a "lordotic" implant or an implant that is otherwise "wedge-shaped" despite the '696 patent's assertion of this main feature in the background and summary sections. Compare '696 patent at cls. 1-6, with '696 patent at cl. 7.

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 for use in the human spine 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 (showing the option of using of

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