

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Patent Number: 8,361,156 B2
Issue Date: January 29, 2013

Case IPR2013-00506

DECLARATION OF HANSEN A. YUAN, M.D.

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U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I. INTRODUCTION AND SCOPE OF WORK

1. My name is Hansen A. Yuan, M.D. I have been retained by Patent Owner NuVasive, Inc. (“NuVasive” or “Patent Owner”) in this *Inter Partes* Review (“IPR”) as an independent expert in the relevant art.

2. I have been asked to provide my opinions and analysis regarding the prior art identified by Petitioner Medtronic, Inc. (“Medtronic” or “Petitioner”) and its expert Richard Hynes, and on which the Patent Trial and Appeal Board (“PTAB”) has instituted this IPR related to U.S. Patent No. 8,361,156 (“the ’156 patent”), which is assigned to NuVasive. I have been asked to consider what one of skill in the art at the time of the filing of the application that matured as the ’156 patent would have understood from the ’156 patent, including the scientific and technical knowledge related to the ’156 patent. I have also been asked to consider whether the references relied on by the PTAB to institute this IPR disclose or suggest the features claimed by the ’156 patent. My independent analysis is set forth below.

3. My opinions and analysis are guided by my understanding and experience as a person of ordinary skill in the art at the time of the filing of the application that matured as the ’156 patent on or about March 29, 2004, the priority date for the ’156 patent.

II. SUMMARY OF OPINIONS

4. Based on my experience and expertise, discussed below, and my review of the prior art on which the PTAB instituted IPR for the ’156 patent, it is my opinion that the

cited references would not render Claims 1-14, 19, 20, and 23-27 of the '156 patent obvious. In addition, Petitioner did not present an articulated reason with a rational basis for combining or modifying the primary references on which this IPR was instituted so as to provide all elements of the invention claimed by the '156 patent.

III. BACKGROUND

5. I am an orthopaedic surgeon board certified by the American Board of Orthopaedic Surgery and fellowship trained in the treatment of Low Back and Cervical Pain, including in the use of surgery to treat such conditions. I received my medical degree from the University of Michigan Medical School Ann Arbor in 1969. I performed my orthopaedic surgery residency at the State University of New York ("SUNY") in Syracuse, New York from 1971-1974. I did my fellowship training with Professor Leon Wiltse at Long Beach Memorial Hospital and Rancho Los Amigos, affiliated with USC and UCLA. I have been a practicing spine surgeon since 1974.

6. I have performed more than 9,000 spine surgeries in my career, including anterior, posterior and lateral interbody procedures. In the cervical spine, such procedures include discectomies and fusions. In the thoracolumbar spine, I have performed Anterior Lumbar Interbody Fusions ("ALIF"), Posterior Lumbar Interbody Fusions ("PLIF"), Transforaminal Lumbar Interbody Fusions ("TLIF"), eXtreme Lateral Interbody Fusions ("XLIF"), lateral open procedures, posterior open procedures, and laproscopic fusions and discectomy procedures, among others.

7. I have held numerous academic appointments at SUNY, including serving as Professor and Chairman of Orthopaedic Surgery from 1987-1989. I was also Professor of Orthopaedic and Neurological Surgery at SUNY from 1990-2007. Since March 2007, I have served as Professor Emeritus in the Department of Orthopaedic and Neurological Surgery at SUNY. I have trained more than 200 spine fellows in the spine fellowship program at SUNY (25 of those being surgeons practicing in the United States and more than 180 additional spine fellows who are practicing worldwide). In addition, I have been invited numerous times to serve as visiting professor or present Grand Rounds at various academic institutions throughout the world, all related to orthopaedic surgery and specifically spine surgery. Some of the more recent examples include lecturing regarding (1) Kyphoplasty for Osteoporotic Compression Fractures at the Hospital for Special Surgery in New York, New York (2003), which is widely considered to have one of the finest orthopaedics departments in the nation; (2) Nucleus Replacement surgery at the Texas Back Institute; and (3) presenting Grand Rounds regarding the future of degenerative disc disease at Yale University in New Haven Connecticut, among many others.

8. I have received numerous honors and awards recognizing my work in the field of orthopaedic spine surgery, including among many others, the Best Clinical Paper Award (2008) and the Award for Best Overall Paper (2007) from the Spine Arthroplasty Society; the David Selby Award from the North American Spine Society ("NASS") which recognized my contributions to the art and science of spinal disorder management through

service to NASS, the Volvo Award for Low Back Research ("Vertebral burst fractures: An experimental Disc in Flexion-Compression and in Pure Compression") and the Leon Wiltse Award from NASS which recognized my leadership and clinical research in spine care. I am a past president of NASS and of the Spine Arthroplasty Society. I have also been granted a Lifetime Honorary Professorship by the Chinese Institute for Space Science and Medical Engineering, among other awards.

9. I have been actively involved in research related to spine surgery and spine care for most of the last three decades. I have presented more than 100 times on topics related to spine treatments, spine surgery or the use of spinal implants for the treatment of spine disease and disorders. I am listed as an author or co-author on more than 90 peer reviewed articles related to treatment, surgery or the use of implants in the spine. I have also authored or co-authored more than 15 book chapters related to treatment of spinal disorders, including spine surgery techniques. I have served on numerous editorial boards for peer-reviewed spine journals, including *Complications in Orthopaedics*, *Journal of Spine Disorders*, *Journal of Spine*, *Journal of Spinal Research*, *Spine Letter*, *The Spine Journal*, *Orthopaedics Today*, and *The Spine Arthroplasty Society Online Journal*, among others. I have been the Editor in Chief of the ISAAS online journal for the last six years. Further, I have been involved in the design and testing of several spinal implants and medical devices for use in spine surgery. Several of those designs have resulted in issued patents on which I am listed as a named inventor.

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