

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC.
Petitioners,

v.

NUVASIVE, INC.,
Patent Owner.

Case No. IPR2019-00362
Patent No. 8,361,156

DECLARATION OF CARL R. MCMILLIN, PH.D.

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I, Carl R. McMillin, declare as follows:

I. QUALIFICATIONS

1. I received a B.S. in Mechanical Engineering with a material science major from the General Motors Institute of Technology and a M.S. and a Ph.D. in Macromolecular Science from the Case Western Reserve University.

2. I have extensive experience in the field of biomedical engineering. From 1974 to 1975, I served as a visiting scientist at the Artificial Internal Organs Department of the Cleveland Clinic Foundation. From 1983 to 1989, I held an Associate Professor position in the Department of Biomedical Engineering at The University of Akron where I taught MS/PhD level Biomaterials and Artificial Organs courses. I also served as the Director of the Cardiovascular Laboratory and researched accelerated rubber fatigue, blood-materials interactions, implant associated infections, hemodynamics of artificial hearts, and consulted for AcroMed Corporation on the initial development of artificial spinal discs and carbon fiber composite spine fusion plates.

3. Between 1989 and 1997 I worked at AcroMed Corporation where I served in various positions including Senior Scientist and Director of R&D. I conducted and directed research, development, evaluation, and commercialization of many metal, polymer, polymer/carbon fiber composite and elastomer-based

orthopedics products. My work and research at AcroMed Corporation was primarily focused on designing orthopedic products for the spine.

4. Through my work, I helped design and optimize the world's first carbon fiber composite posterior lumbar interbody fusion (PLIF) cages and the world's first carbon fiber composite anterior lumbar interbody fusion (ALIF) cages. I also helped to design the first functional artificial spinal discs implanted in patients in the U.S.A., as well as stackable implant systems for variable heights of artificial vertebral bodies. My efforts on these devices involved numerous considerations, including material selection and validation, cadaver spine measurements, strength vs. size optimization, etc.

5. I have served on numerous committees and/or advisory boards in the biomedical industry. For example, between 1994 and 1998, I served on the Editorial Advisory Board of the *Medical Plastics and Biomaterials* for Canon Communications. Between 1990 and 1996, I served as an Executive Editor for the international journal, *Bio-Medical Materials and Engineering*. I also served on the External Advisory Board (1994-1998) at the Center for Cardiovascular Biomaterials and have been on technical review panels for the NIH. I have also served on the Commercialization Cabinet 1997-2002; the Scientific Advisory Council (1992-1994), and the Executive Advisory Committee (1992-1996), at the Edison Biotechnology Center and Omeris.

6. I routinely attend key seminars and conferences in the industry including the all of the annual meetings for the Society for Biomaterials and every fourth year World Congress for Biomaterials for the last 30+ years to the present, and other meetings such as the North American Spine Society meeting in 2011. I have also presented at over 75 national and international meetings as an author or co-author.

7. Throughout my career, I have published over 100 journal articles, book chapters, theses, etc. I am the inventor on U.S. Patent No. 5,294,391 (“Method of Making a Fiber Reinforced Composite Structure Including Randomizing the Reinforcing Fibers”) and U.S. Patent No. 5,429,863 (Fiber Reinforced Composite Structure”) which are the method and device patents on the PEEK/PEKEKK composite structure that was used in the initial Brantigan PLIF and ALIF cages I am also an inventor on other spine and orthopedic patents including U.S. Patent No. 5,824,094 (“*Spinal Disc*”); U.S. Patent No. 6,669,732 (“*Spinal Disc*”); and U.S. Patent No. 6,162,252 (“*Artificial Spinal Disc*”).

8. My professional *curriculum vitae* is attached as EX2058. It details my education, experience, and publications, as briefly summarized above, as well as an overview of some of my experience that is relevant to the matters set forth in this declaration.

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