UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
and MEDTRONIC COREVALVE, LLC
Petitioner

v.

TROY R. NORRED, M.D.
Patent Owner

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Case IPR2014-00111
Patent 6,482,228 B1

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Attorney Docket No. 058888-0000018

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PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATION REGARDING CROSS-EXAMINATION OF ALEXANDER J. HILL, PH.D.

Pursuant to the Order dated April 25, 2014 (Paper 11), Petitioner submits this response to Patent Owner's Motion for Observation Pursuant to 37 C.F.R. § 42.121 regarding the cross-examination testimony of Alexander J. Hill, Ph.D.

1. Response to Observation No. 1

Patent Owner states that Dr. Hill was not a person of ordinary skill in the art at the time the '228 patent was filed. This observation is irrelevant because it is based on the incorrect assumption that an expert's knowledge must be gained prior to the invention date. *See Disney Enterprises, Inc. v. Kappos*, 923 F.Supp.2d 788 (E.D. Va. 2013)(An "expert must be qualified to testify about what a person with ordinary skill in the art must have understood at the time of the invention, but the expert's knowledge may have come later."). Dr. Hill defines a person of ordinary skill as having a bachelor's degree in mechanical or biomedical engineering and direct experience developing heart valves. Ex. 1026 (Hill Decl.), ¶31. As to educational experience, Dr. Hill has M.S. and Ph.D. degrees in Biomedical Engineering, a minor in Mechanical Engineering, and a B.A. in Biology. Hill Decl., ¶¶21-24; *see also,* Hill Decl., ¶25-29 and Ex. 2236 ("Hill Tr."), 27:4-15. As to heart valve experience, over the past nine years Dr. Hill has researched and developed heart valve replacements, including percutaneous aortic valve replacements, such as those disclosed in the '228 patent. Hill Decl., ¶¶5-16. Dr. Hill "has personally designed and tested numerous percutaneous heart valves, and have implanted valves into both

live and isolated hearts," conducted research and managed a group that conducts research "focused on percutaneous, minimally invasive, and surgical heart valve replacement and repair," and was involved with products designed to treat the aortic valve. *Id.*; *see also*, Hill Tr., 35:21-36:5, 38:12-41:3. Finally, Dr. Hill worked with stents while a research assistant and has personally deployed stents in isolated hearts. Hill Tr., 31:8-33:19.

2. Response to Observation No. 2

Patent Owner suggests that Dr. Hill's testimony regarding placement of a prosthetic aortic valve should be discounted because he lacks a medical degree and is not involved in the direct treatment of patients with aortic stenosis. Patent Owner's observation is irrelevant. With respect to medical knowledge, Dr. Hill is a Clinical Assistant Professor in the Department of Surgery at the University of Minnesota Medical School, an Instructor of Advanced Cardiac Anatomy & Physiology at the University of Minnesota, an Instructor of advanced cardiac anatomy didactic and dissection for electrophysiology and cardiology fellows, and an Instructor of Advanced Cardiac Anatomy & Physiology within Medtronic. Hill Decl., ¶¶10, 27-29. As a Graduate Research/Teaching Assistant, Dr. Hill worked in a cardiovascular research laboratory studying mammalian cardiac anatomy, physiology, and pathology; and taught human physiology and advanced cardiac anatomy and physiology. Hill Decl., ¶¶25-26; Hill Tr., 28:9-19. Dr. Hill has also evaluated the clinical out-

comes of aortic valve replacements and was involved with transcatheter valve products to treat aorta stenosis. Hill Tr., 35:23-36:5; 39:24-40:23.

3. Response to Observation No. 3

Patent Owner states that Dr. Hill's testimony that the sinotubular junction "could be interpreted as the transition point from the aortic root to the ascending aorta" contradicts his statement that the Schreck valve extends into the ascending aorta. However, when Dr. Hill was asked if the sinotubular junction is the transition point from the aortic root to the ascending aorta, he responded, "I think that's **one** interpretation." Hill Tr. 62:15-25 (emphasis added); *see also,* Hill Tr. 156:20-161:3. Dr. Hill explained that "in other descriptions, the ascending aorta includes the entirety of the aortic root." Hill Tr. 165:1-13; *see also,* Hill Decl., ¶¶33, 65-68, 71.

4. Response to Observation No. 4

Patent Owner states that Dr. Hill's testimony regarding the sinotubular junction contradicts his statement that the Schreck valve extends into the ascending aorta. However, when Dr. Hill was asked if the sinotubular junction is the transition point from the aortic root to the ascending aorta, he responded, "I think that's **one** interpretation." Hill Tr. 62:15-25 (emphasis added); *see also,* Hill Tr. 156:20-161:3. Dr. Hill explained that "in other descriptions, the ascending aorta includes the entirety of the aortic root." Hill Tr., 165:1-13; *see also,* Hill Decl., ¶¶33, 65-68, 71.

5. Response to Observation No. 5

Patent Owner states that Dr. Hill's testimony regarding expansion and contraction of the aorta contradicts his statement that the commissures do not cause any movement of the leaflets. However, Dr. Hill testified that the commissures do not cause the leaflets to move and that instead the commissures and leaflets move because of pressure changes due to contractions in the heart. Hill Tr., 63:1-64:23, Hill Decl., ¶35; *see also,* Hill Tr. 105:18-106:1, 106:12-23, 109:1-6.

6. Response to Observation No. 6

Patent Owner suggests that Dr. Hill's testimony regarding blockage of the coronary arteries qualifies his testimony that placement and positioning of prosthetic aortic valves within the aorta is within the discretion of the physician. However, Dr. Hill already testified that with respect to the physician's discretion that "[p]lacement is based on, among other things, anatomical aspects of a particular patient." Hill Decl., ¶34. Dr. Hill also explained that physicians can place devices "wherever they want outside or within the instructions for use" but that they would take surrounding structures into account. Hill Tr., 90:16-22, 129:11-130:1.

7. Response to Observation No. 7

Patent Owner suggests that Dr. Hill's testimony regarding regurgitation qualifies his testimony that "a prosthetic valve that provides less than complete fluid integrity between adjacent valves leaflets would still achieve desired performance param-

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