UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TROY R. NORRED, M.D.
Patent Owner

Case IPR2014-00395
Patent 6,482,228

PATENT OWNER MOTION FOR OBSERVATION PURSUANT TO 37 C.F.R. § 42.121

Patent Owner Troy R. Norred, M.D., respectfully moves the Board to observe the following testimony from the cross examination of Alexander J. Hill, Ph.D. ("Hill"):

1. In Ex. 2353, on page 33, line 23, through page 35, line 20, Hill testified that his first experience with developing a heart valve was in 2006 when he joined Medtronic's vascular division, and that he did not work with any stent technology at Medtronic prior to that time. This testimony is relevant to paragraphs 31 and 32 of Ex 1026. The testimony is relevant because it shows Hill did not qualify as a person of ordinary skill in the art, as he has defined such person, during the time frame he has defined as the relevant for purposes of this *inter partes* review.

2. In Ex. 2353, on page 22, line 12, through page 23, line 15, Hill testified that he does not have a medical degree, has never implanted a stent or artificial valve in a live human patient, and has never treated or helped treat a patient suffering from aortic stenosis. This testimony is relevant to paragraphs 34, 35, 60, 68 and 71 of Ex. 1026. The testimony is relevant because it bears upon the weight that should be afforded Hill's testimony about where and how a prosthetic aortic valve should be placed.

3. In Ex. 2353, on page 62, lines 15 though 25, Hill testified that the junction where the aortic commissures are hinged, known as the sinotubular junction, could be interpreted as the transition point from the aortic root to the ascending aorta. This testimony is relevant to paragraph 66 of Ex. 1026. The testimony is relevant because it contradicts Hill's statement that the Schreck valve extends into ascending aorta.

4. In Ex. 2353, on page 62, lines 5 through 25, Hill acknowledged that in a medical textbook he edited entitled, *Heart Valves: From Design to Clinical Implantation*, the ascending aorta is depicted as beginning at and extending upward from the sinotublar junction. This testimony is relevant to paragraph 66 of Ex. 1026. The testimony is relevant because it contradicts Hill's statement that the Schreck valve extends into ascending aorta.

5. In Ex. 2353, on page 63, line 5, through page 67, line 2, Hill testified that that the aorta expands and contracts during each cardiac cycle, that the commissures move with the aortic wall as it expands and contracts, that the commissures are attached to the aortic valve leaflets, and that the expansion of the aorta can open the aortic valve. This testimony is relevant to paragraph 35 of Ex. 1026. The testimony is relevant because it contradicts Hill's statement that the commissures do not cause any movement of the leaflets.

6. In Ex. 2353, on page 68, lines 2 through 25, Hill testified that during diastole, when the aortic valve is closed, blood is directed to the right and left coronary arteries to supply blood to the heart, and that if the coronary arteries are blocked, the patient could die. This testimony is relevant to paragraphs 34 and 68 and of Ex. 1026. The testimony is relevant because it qualifies Hill's testimony that placement and positioning of prosthetic aortic valves is within the discretion of the physician.

7. In Ex. 2353, on page 69, line 16 through page 70, line 11, Hill testified that in order for the cardiac cycle to work effectively and efficiently, it is important that the aortic valve not allow blood to flow back into the left ventricle into the aorta, and that if this occurs, it could cause the heart to fail. This testimony is relevant to paragraph 70 of Ex. 1026. The testimony is relevant because it qualifies Hill's testimony that a prosthetic valve that provides less than complete fluid integrity between adjacent valve leaflets would still achieve desired performance parameters.

8. In Ex. 2353, on page 73, lines 6 through 17, Hill agreed that a prosthetic heart valve must necessarily function in the same manner as the natural valve it replaces, and thus passive prosthetic valves utilize the pressure gradient created during systole and diastole to open and close. This testimony is

relevant to paragraph 52 of Ex. 1026. The testimony is relevant because it qualifies Hill's testimony that Figs. 18 and 19 of the '228 patent do not disclose a structure performing the function of "'moving the membrane second end' between open and closed positions."

9. In Ex. 2353, on page 80, line 10 through page 82, line 2, Hill testified that in the case of Medtronic's CoreValve prosthetic aortic valve, the physician was given guidance about where the valve should be placed and "malposition/malplacement" was listed as a "Potential Adverse Event." This testimony is relevant to paragraphs 34 and 68 and of Ex. 1026. The testimony is relevant because it qualifies Hill's testimony that placement and positioning of prosthetic aortic valves is within the discretion of the physician.

10. In Ex. 2353, on page 84, line 3 through page 86, line 3, Hill testified that a person of ordinary skill in the art, as he has defined such person, need not have taken any medical classes. This testimony is relevant to paragraph 31 of Ex. 1026. The testimony is relevant because it bears upon whether Hill's definition of a person or ordinary skill the art should be accepted for purposes of this *in partes* review.

11. In Ex. 2353, on page 86, line 16 through page 87, line 1, Hill testified that a person with no medical training at all, who sits in his garage and

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