UNITED STATES -	S PATENT AND TRADEMAI	RK OFFICE
BEFORE THE F	PATENT TRIAL AND APPEA	L BOARD
	INC., MEDTRONIC VASCUL EDTRONIC COREVALVE, LL Petitioner	
	v.	
Γ	TROY R. NORRED, M.D. Patent Owner	

PATENT OWNER REPLY IN SUPPORT OF MOTION TO AMEND PURSUANT TO 37 C.F.R.  $\S$  42.121

Case IPR2014-00395 Patent 6,482,228



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# I. The Amendments Do Not Enlarge The Scope Of The Claims And Are Responsive To A Ground Of Unpatentability

The proposed amendments substitute independent Claim 25 for independent Claims 16 and 20. Claim 16 is eliminated in its entirety. The language of Claim 20 is carried forward in Claim 25 with modifications that narrow the claim. In place of the means-plus-function limitation of Claim 20—"means for maintaining said ring member in said seated position about the aortic wall"—Claim 25 specifies the ring member is "anchor[ed] ... in said seated position against the aortic wall" by "a stent system having a plurality of interconnected rods." This is consistent with the Board's interpretation of the original claim language. The Board held "the combination of rods 104 interacting with stent 28 ... is the structure comprising the means for maintaining called for in claims 19-20." Paper 13 at 13. Dependent claim 26 is added to require that the stent system extend into the ascending aorta, as described in the specification. (Ex. 1001, 2:67, 3:8, Figs. 4 & 5.)

Petitioner argues the proposed amendments broaden Claim 16 by eliminating the "means for mounting" language in that claim. Paper 25 at 6-7. This argument is misplaced. Claim 16 is eliminated in its entirety. None of the language of the claim is carried forward in the proposed amendments.

Petitioner argues the proposed amendments broaden Claim 20 by eliminating interconnected rods 104 from the claim. Paper 25 at 7. This is not true. Claim 25 makes specific reference to "a plurality of interconnected rods," and requires that the



ring member be connected to "one or more of said plurality of interconnected rods."

Petitioner argues that in original Claim 20, rods 104 are "part of the valve" and "separate and distinct from stent 28." Paper 25 at 6. Yet, Fig. 18—where rods 104 are shown—is described as depicting the "valve and stent system." (Ex. 1001, 2:48.) Moreover, Dr. Timothy Catchings testified on cross-examination that rods 104 "form the distal part of the stent itself." (Ex. 1001, Fig. 18; Ex. 1023, 129:11-130:22.)

#### II. <u>Claim Constructions Are Not Needed For New Terms</u>

The terms in Claim 25 should be given their ordinary and customary meanings, consistent with the Specification, as those terms would be understood by one with ordinary skill in the art. Special claim constructions are not required because the terms are not subject to dispute. Drs. Catchings and Norred do not disagree about the meaning of the term "pliable." Dr. Catchings testified that a superelastic stent [as described in DiMatteo] is a stent that is "easily malleable ... [and] can be twisted, turned, moved into shape easily without permanent deformity." (Ex. 1023, 181:10-15.) Dr. Norred did not contest this point. (Ex. 1024, 84:5-85:5.) Instead, he stated that once deployed, the DiMatteo stent must maintain a perfectly circular shape. See IPR2014-00110, Paper 15 (Response) at 35-36. This means it must be rigid. *Id.* Otherwise, it will conform to the irregular shape of the aortic wall and the valve leaflets will misalign. *Id.* (See also Ex. 1023, 247:11-248:12; Ex. 2332 (illustration).) Petitioner's own witness, Alexander Hill, agreed this could occur. (Ex. 2353, 188:14-192:13; Ex. 2332.)



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