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Paper 10

Tel: 571-272-7822 Entered: April 25, 2014

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 IPR2014-00110 Patent 6,482,228 B1

Before JOSIAH C. COCKS, SHERIDAN K. SNEDDEN, and BARRY L. GROSSMAN, *Administrative Patent Judges*.

SNEDDEN, Administrative Patent Judge.

DECISION Institution of *Inter Partes* Review 37 C.F.R. § 42.108



I. INTRODUCTION

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic Corevalve, LLC (collectively "Medtronic") filed a corrected petition to institute an *inter* partes review of claims 16-19 (Paper 4; "Pet.") of US 6,482,228 B1 (Ex. 1001; "the '228 patent"). Troy R. Norred, M.D. ("Dr. Norred") filed a patent owner preliminary response. Paper 9 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 6. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

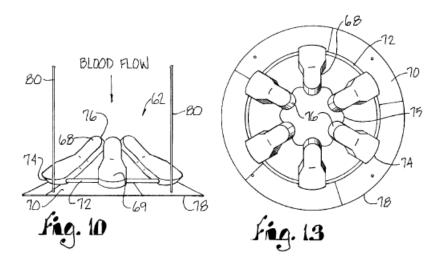
THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the above-mentioned petition and preliminary responses, we conclude that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. Accordingly, we grant the petition to institute an *inter partes* review as to claims 16-19.

A. The '228 Patent (Ex. 1001)

The '228 patent relates to a percutaneous aortic heart valve that is placed by catheter and held in place with a stent system. Ex. 1001, 1:6-9 and 1:29-31. Figures 10 and 13 of the '228 patent are reproduced below.





Figures 10 and 13 show different views of a cone-shaped aortic valve in a closed position. The valve 66 consists of interconnected fingers 68, a generally ring-shaped base 70 and a ring 72 secured to the base 70. *Id.* at 4:54-64. Base 70 may be seated against the root of the aortic valve 34. *Id.* at 5:17-19. Rim 78 of base 70 is made of a pliable biocompatible material and seals against the root of the native aortic valve 34 to reduce peri-valvular leaks. *Id.* at 5:18-20. Valve 66 is anchored along the root of the aortic valve with connecting rods 80 which are connected to ascending aortic stents. *Id.* at 5:21-23.

B. Challenged Claims

Challenged claims 16-19 are reproduced below:

- 16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:
- a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;
- a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and



means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

- 17. The aortic valve as claimed in claim 16 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.
- 18. The aortic valve as claimed in claim 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.
- 19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.

C. The Prior Art and Supporting Evidence

Petitioner relies on the following prior art:

DiMatteo, US 6,440,164 B1, published Aug. 27, 2002 (Ex. 1003).

Kischer, US 3,548,417, published Dec. 22, 1970 (Ex. 1004).

Shaolian, US 6,299,637 B1, published Oct. 9, 2001 (Ex. 1005).

Wolfe, US 4,030,142, published Jun. 21, 1977 (Ex. 1006).



D. The Asserted Grounds

Petitioner challenges claims 16-19 of the '228 patent on the following grounds. Pet. 8.

Reference[s]	Basis	Claims challenged
DiMatteo	§ 102(e)	16-19
Kischer	§ 102(b)	16-18
Shaolian	§ 102(e)	16-19
Wolfe	§ 102(b)	16-18

II. ANALYSIS

A. Priority of Invention

Dr. Norred contends he conceived of his invention no later than December 1998. Prelim. Resp. 7 (citing Ex. 2003). Dr. Norred draws our general attention to Exs. 2001 to 2079 as documentary evidence demonstrating reasonable diligence between the date of conception and filing date for the patent application. Prelim. Resp. 8-13. Dr. Norred, however, does not sufficiently explain the contents of the exhibits. Dr. Norred also does not sufficiently map each claim limitation to supporting evidence in a manner that would enable us to determine if there had been an actual reduction to practice of the claimed subject matter. For example, Dr. Norred contends that the figure presented in Ex. 2003 is similar to Figure 4 of the '228 patent. We note, however, that Figure 4 is not relied



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