

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 B1

Before WILLIAM V. SAINDON, MICHAEL R. ZECHER, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

DECISION

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

INTRODUCTION

A. Background

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic Corevalve, LLC (collectively “Medtronic” or “Petitioner”) filed a petition (Paper 4, “Pet.”) requesting an *inter partes* review of claims 16 and 19–24 (the “challenged claims”) of U.S. Patent 6,482,228 B1 (Exhibit 1001, the “’228 patent”). 35 U.S.C. § 311. Troy R. Norred, M.D. (“Dr. Norred” or “Patent

Owner”) timely filed a Preliminary Response. Paper 11 (“Prelim. Resp.”). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

(a) 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.

35 U.S.C. § 314(a).

Based on our review of the record, we conclude that Medtronic is reasonably likely to prevail in demonstrating that at least one of the challenged claims is not patentable.

Medtronic contends that the challenged claims are unpatentable under 35 U.S.C. § 102 based on the following grounds (Pet. 9–28 and App.):

References	Basis	Claims challenged
U.S. Patent No. 5,957,949, (“Leonhardt”) (Ex. 1004)	§ 102(b)	16 and 19–24
U.S. Patent No. 5,411,552, (“Andersen”) (Ex. 1005)	§ 102(b)	16 and 19–24
U.S. Patent No. 6,458,153 B1, (“Bailey”) (Ex. 1006)	§ 102(b)	16 and 19–24
German Application No. DE 195 46 692, (“Figulla”) (Ex. 1007 with English translation at Ex. 1008)	§ 102(b)	16 and 19
U.S. Patent No. 5,855,597, (“Jayaraman”) (Ex. 1009)	§ 102(b)	16 and 19
U.S. Patent No. 3,657,744, (“Ersek”) (Ex. 1010)	§ 102(b)	16 and 19

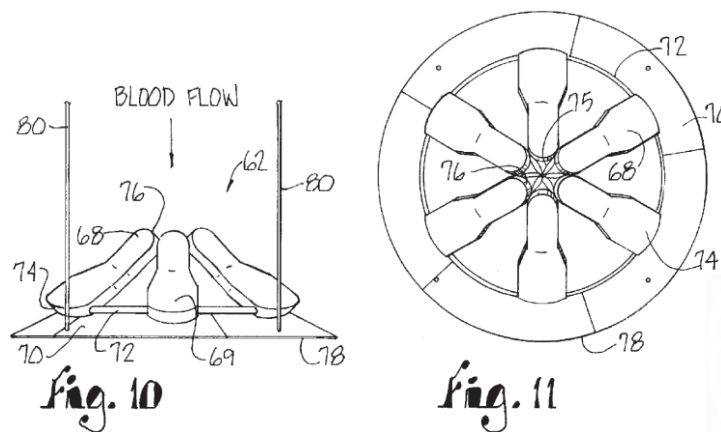
For the reasons described below, we institute an *inter partes* review of claims 16 and 19–24 based on anticipation by Leonhardt or Bailey. We decline to institute an *inter partes* review of claims 16 and 19–24 on the remaining alleged grounds of unpatentability because we find those grounds to be redundant to the grounds on which we institute review.

B. Related Proceedings

Medtronic and Dr. Norred identified, as related proceedings, the co-pending litigation titled *Troy R. Norred, M.D. v. Medtronic, Inc., et al.*, No. 2:13-CV-02061 (D. Kan.). Pet. 1; Prelim. Resp. 5. Proceedings before the Board involving the same parties including IPR2014-00110 and IPR2014-00111 also are identified as related proceedings. Pet. 1; Prelim. Resp. 5–6.

C. The '228 Patent

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 11 of the '228 patent are reproduced below.



Figures 10 and 11 illustrate a diagrammatic and plan view of one embodiment of Dr. Norred's cone-shaped aortic valve in a closed position.

Id. at 2:31–34.

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. *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 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 28. *Id.* at 5:21–23.

The '228 patent describes additional embodiments of an aortic heart valve in which the valve structures differ. *See, e.g., id.* at 4:5–52 (describing umbrella valve 30 illustrated in Figures 6–9), 5:33–62 (describing trihedral valve 82 illustrated in Figures 14–17), and 5:63–6:8 (describing biological valve 100 illustrated in Figures 18 and 19). Nevertheless, the illustrated embodiments of the aortic valves are held in place via a mechanical attachment to a stent that seats against the aortic wall. *See id.* at 4:8–9, 5:21–23, 5:48–51, and 6:3–7 (describing connecting rods that attach valves to stent).

Claims 16 and 20, which are the only independent claims among the challenged claims, recite:

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.

Ex. 1001, 7:59–8:12.

20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:

a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;

a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall,

said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.

Id. at 8:27–42.

ANALYSIS

A. Priority of invention

Dr. Norred contends he conceived of his invention no later than December 1998. Prelim. Resp. 11 (citing Ex. 2203). Dr. Norred draws our general attention to Exs. 2201–79 as documentary evidence demonstrating reasonable diligence between the date of conception and filing date for the patent application. Prelim. Resp. 8–15. Dr. Norred, however, does not explain sufficiently the content of the exhibits. Dr. Norred also does not map sufficiently 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

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