

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 SHERIDAN K. SNEDDEN, BARRY L. GROSSMAN, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

DECISION
Final Written Decision
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic Corevalve, LLC (collectively, “Medtronic”) filed a Petition (Paper 4, “Pet.”) requesting

IPR2014-00395
Patent 6,482,228 B1

an *inter partes* review of claims 16 and 19–24 (the “challenged claims”) of U.S. Patent No. 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.”). On June 27, 2014, we instituted an *inter partes* review of all challenged claims, Paper 13 (“Dec.” or “Institution Decision”), on the following grounds:

References	Basis	Claims Reviewed
U.S. Patent No. 5,957,949, (“Leonhardt”) (Ex. 1004)	§ 102(b)	16 and 19–24
U.S. Patent No. 6,458,153 B1, (“Bailey”) (Ex. 1006)	§ 102(e)	16 and 19–24

Dec. 20.

After we instituted review, Dr. Norred filed a Patent Owner Response, Paper 18 (“PO Resp.”), in opposition to the Petition, and supported by the declarations of Timothy T. Catchings, M.D. (Ex. 2295) and Troy R. Norred, M.D. (Ex. 2293). Medtronic filed a Reply in support of the Petition, Paper 22 (“Reply”), supported by the Declaration of Alexander J. Hill, PhD (Ex. 1026).

Dr. Norred also filed a Motion to Amend, Paper 17 (“Mot. Amend”), seeking to substitute claim 25 for independent claims 16 and 20 and claim 26 for dependent claim 24 contingent upon our holding unpatentable any of the original claims for which substituted claims were submitted. Mot. Amend 1. Medtronic opposed the Motion to Amend. Paper 25 (“Amend Opp.”). Dr. Norred filed a reply in support of its Motion to Amend. Paper 28 (“Amend Reply”).

Oral argument was conducted on January 27, 2015. A transcript is entered as Paper 40 (“Tr.”).

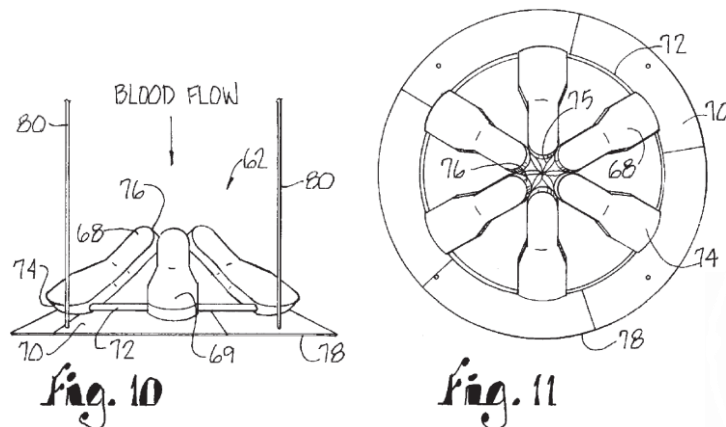
For the reasons expressed below, we conclude that Medtronic has demonstrated, by a preponderance of evidence, that each of Leonhardt and Bailey anticipates claims 16 and 19–24. Dr. Norred’s Motion to Amend is denied.

B. Related Matters

Medtronic and Dr. Norred identified, as related proceedings, the co-pending litigation titled *Troy R. Norred, M.D. v. Medtronic, Inc.*, No. 2:13-CV-02061 (D. Kan.). Pet. 1; Paper 11, 5. Two proceedings before the Board involving the same parties, IPR2014-00110 and IPR2014-00111, also are identified as related proceedings. Pet. 1; Paper 11, 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, 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, generally ring-shaped base 70, and ring 72 secured to 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), 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, 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.

II. ANALYSIS

A. Claim Interpretation

“A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b); *accord In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. 2015). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257

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