

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TROY R. NORRED, M.D.,  
Patent Owner.

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Case IPR2014-00111  
Patent 6,482,228 B1

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

GROSSMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

## I. INTRODUCTION

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic Corevalve, LLC (collectively, “Petitioner”) filed a Corrected Petition requesting an *inter partes* review of claims 20–24 of U.S. Patent No. 6,482,228 B1 (“the ’228 patent”). Paper 4 (“Pet.”). On April 25, 2014, we instituted an *inter partes* review of claims 20–24 under 35 U.S.C. § 102 as anticipated by Schreck (Ex. 1009)<sup>1</sup>, and claims 22 and 23 under 35 U.S.C. § 103 for obviousness over Schreck and Shu (Ex. 1012)<sup>2</sup>. Paper 10 (“Decision”). Troy R. Norred, M.D. (“Patent Owner”), filed a Patent Owner Response. Paper 15 (“PO Resp.”). Petitioner filed a reply. Paper 25 (“Pet. Reply”).

Patent Owner filed a Substitute Motion to Amend. Paper 18 (“PO Mot. Amend”). Petitioner filed an Opposition to the Motion to Amend. Paper 26 (“Opp. Mot. Amend”). Patent Owner filed a Reply in Support of the Motion to Amend. Paper 31 (“PO Reply”).

Neither party filed motions to exclude evidence.

An oral hearing was held on January 27, 2015. A transcript of the hearing is included in the record. Paper 45 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine Petitioner has shown, by a preponderance of the evidence, that claims 20–24 are unpatentable.

### A. *Related Proceedings*

The ’228 patent is the subject of a district court case brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Kansas in

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<sup>1</sup> US Patent 6,454,799 B1, filed April 6, 2000, patented September 24, 2002.

<sup>2</sup> US Patent 6,139,575, filed April 2, 1999, patented October 31, 2000.

*Troy R. Norred, M.D. v. Medtronic, Inc.*, No. 2:13-cv-02061 (D. Kan. Feb. 6, 2013).

Claims 16–19 of the '228 patent are the subject of pending IPR2014-00110.

Claims 16 and 19–24 of the '228 patent are the subject of pending IPR2014-00395.

### *B. The '228 Patent*

The invention disclosed in the '228 patent relates generally to a percutaneous aortic heart valve made of a tissue material. Ex. 1001, col. 1, ll. 7–9, col. 8, ll. 30–31. Figure 4 of the '228 patent is reproduced below.

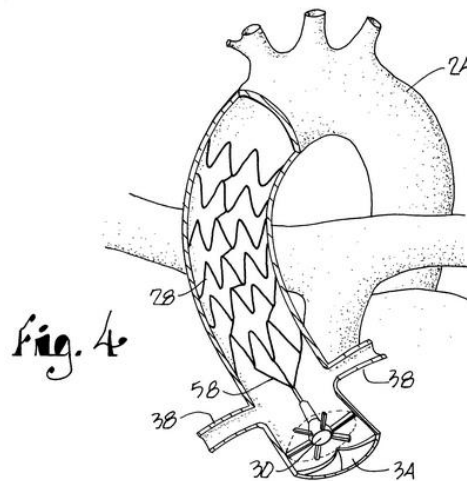


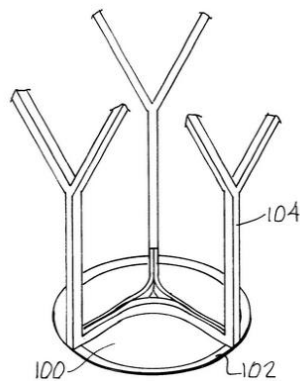
Figure 4 of the '228 patent illustrates an exemplary placement of valve 30 above aortic valve 34 and below coronary arteries 38.

As shown generally in Figure 4 of the '228 patent, stent system 28 anchors aortic valve replacement, or artificial valve, 30 in ascending aorta 32 (*see* Figs. 1–3). *Id.* at col. 1, ll. 30–31, col. 2, ll. 55–60. Valve 30 is placed “percutaneously,” that is, without the need for open-heart surgery. *Id.* at Abstract, col. 1, ll. 26–27. Valve 30 is positioned above native aortic valve 34 and below coronary arteries 38 so that coronary arteries 38 are not unobstructed. *Id.* at col. 3, ll. 1–6. Stent system 28 comprises a series of interconnected rods, which form an expandable cylindrical

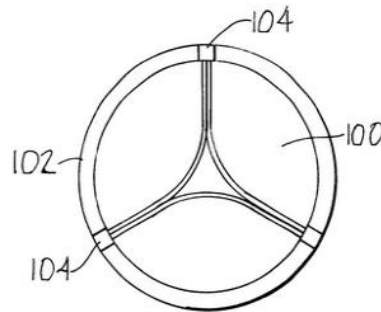
lattice or scaffolding. *Id.* at col. 2, ll. 61–63. Using valve 30 and stent system 28 avoids the need to remove native aortic valve 34. *Id.* at col. 3, ll. 31–32.

The '228 patent discloses four different embodiments for generic artificial valve 30: an “umbrella” aortic valve, shown in Figures 6–9; a first “cone-shaped” aortic valve, shown in Figures 10–13; a second “cone-shaped” aortic valve, shown in Figures 14–17; and a “cadaver/porcine,” or “natural” or “tissue,” replacement aortic valve, shown in Figures 18 and 19. *E.g., id.* at col. 2, ll. 24–51; Tr. 34, ll. 1–5.

Challenged claims 20–24 recite that the claimed aortic valve is “a tissue valve having an interior member made of a tissue material.” Ex. 1001, col. 8, ll. 30–31. The only “tissue” valve disclosed in the Specification is in the context of Figures 18 and 19. The Specification states: “[o]ther valvular designs which may prove valuable to this technique include the usage of *biological tissue* incorporated valves, *such as cadaver/porcine valves*, placed within a percutaneously stented system the benefits of favorable flow and hematologic characteristics (see FIGS. 18 and 19).” *Id.* at col. 5, ll. 63–67 (emphasis added), *see also*, col. 2, ll. 48–51 (“FIG. 18 is a diagrammatic view of a cadaver/porcine incorporated valve and stent system”). Claims 20–24, thus, are directed to the embodiment disclosed in Figures 18 and 19, reproduced below.



*Fig. 18*



*Fig. 19*

Figures 18 and 19 of the '228 patent illustrate an embodiment of valve 100 incorporating a tissue material.

As shown in Figures 18 and 19, cadaver/porcine, or tissue, valve 100 is retained in base ring 102. Ex. 1001, col. 6, l. 1. Ring 102 is made of a pliable biocompatible material which seals against the root of native aortic valve 34. *Id.* at col. 6, ll. 2–4. Valve 100 is anchored along the root of the aortic valve by connecting rods 104 connected to ascending aortic stents 28. *Id.* at col. 6, ll. 4–6.

#### *C. Illustrative Claim*

Claim 20 of the '228 patent is the only independent claim challenged in the Petition. Challenged claims 21–24 depend directly or indirectly from independent claim 20. Claim 20, shown below, is illustrative of the claimed invention:

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;

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