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Paper 10
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.

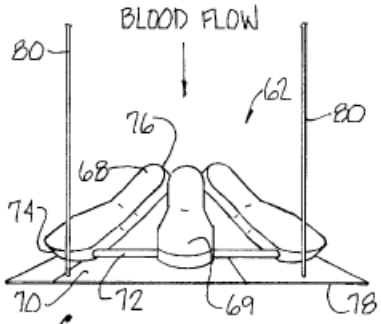

Fig. 10

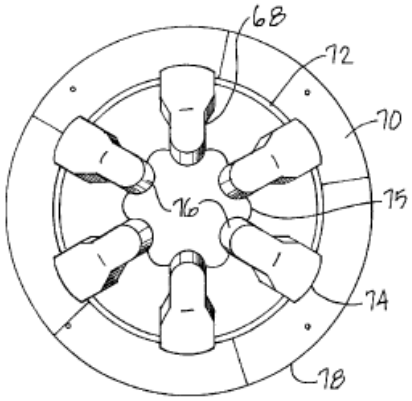

Fig. 13

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

upon in the ’228 patent to illustrate the feature of a ring member. *See e.g.*, Ex. 1001, 3:1-13. Accordingly, we are not persuaded that the claims of the ’228 patent are entitled to an earlier priority date.

B. Claim Interpretation

Consistent with the statute and legislative history of the America Invents Act (AIA), we interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[].” 37 C.F.R. § 42.100(b); *see also Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012).

Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). “Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

All claim terms have been given their ordinary meaning as would be understood by a skilled artisan in light of the ’228 patent. For clarity in this Decision, however, we explicitly set forth the ordinary meaning for the following terms.

1. "membrane"

Medtronic contends that the term "membrane" should be construed to include fabrics or polymers, but not tissue. As support for this position, Medtronic relies on particular embodiments of aortic valves having fabric and polymer membranes disclosed in the specification of the '228 patent. Pet. 8-9 (citing Ex. 1001, 4:59-62 and 5:40-41).

We decline to limit the term "membrane" as offered by Medtronic. The disclosure of specific embodiments does not, by itself, necessitate a narrow interpretation of a claim term. We find no evidence on this record suggesting that the term "membrane" carries a meaning other than its ordinary and customary meaning. Medtronic offers no evidence that the ordinary and customary meaning of the term "membrane" excludes a tissue membrane.

2. "ring member having a circumference adapted to seat about an aortic wall"

In the preliminary response, Dr. Norred sets forth what he considers to be the ordinary meaning for claim terms "ring member having a circumference" in light of the specification. Prelim. Resp. 14 (citing Ex. 1001, 6:1-9). Dr. Norred construes "ring member" to mean a ring made of a pliable, biocompatible material that seals against the aorta to reduce perivalvular leaks. *Id.* Medtronic does not provide a proposed construction for "ring member."

The '228 patent does not set forth specific definitions for the claim terms "ring member having a circumference" and we have no basis to conclude that the words of the claims should not be given their ordinary

meaning. We therefore give those terms their ordinary meaning: a ring having a circumference that is part of a larger structure. We decline to require the ring to be made of any particular material.

We also give ordinary meaning to the terms "adapted to seat about an aortic wall"—that is, the ring is capable of sitting against the aortic wall. We decline to require the ring to necessarily form an immediate seal with the aortic wall as the evidence of record does not support such a special meaning.

3. "means for maintaining"

It is well established that the use of the term "means" triggers a rebuttable presumption that § 112, sixth paragraph governs the construction of the claim term. *Inventio AG v. ThyssenKrupp Elevator Ams. Corp*., 649 F.3d 1350, 1356 (Fed. Cir. 2011) (citing *TriMed, Inc. v. Stryker Corp*., 514 F.3d 1256, 1259 (Fed. Cir. 2008)). Here, it is clear, and there is no dispute among the parties, that the claim phrase is a "means plus function" phrase interpreted under § 112, sixth paragraph.

"The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure." *In re Donaldson Co., Inc*., 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc). This is the "broadest reasonable interpretation" of "means-plus-function" language. *Id.* at 1194-95. The structure disclosed in the written description of the specification is the corresponding structure only if the written description of the

specification or the prosecution history clearly links or associates that structure to the function recited in a means-plus-function claim limitation. *B. Braun Medical Inc., v. Abbott Laboratories*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). Claim interpretation under § 112, sixth paragraph does not "permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc. v. Great Plains Chem Co*., 194 F.3d 1250, 1258 (Fed. Cir. 1999).

A challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure - or an equivalent - was present in the prior art. *Fresenius USA, Inc. v. Baxter Intern., Inc*., 582 F. 3d 1288, 1299 (Fed. Cir. 2009).

Claim 19 recites a "means for maintaining said ring member in said seat about the aortic wall." Petitioner asserts that the '228 patent describes the structure for performing the claimed function as "connecting rods," which anchor valve 100 along the root of the aortic valve. Pet. 10 (citing Ex. 1001, 5:21-22 and 48-49). Dr. Norred contends that the "means for maintaining" is the stent system or an equivalent structure. Prelim. Resp. 15 (citing Ex. 1001, 1:29-31, 59-67 and 5:22-25, 48-51).

The '228 patent discloses four valve designs: figures 6-9 disclose an umbrella aortic valve; figures 10-13 disclose a cone-shaped aortic valve; figures 14-17 disclose another version of a cone-shaped valve; and figures 18-19 disclose a cadaver/porcine valve. Ex. 1001, 2:24-51. The stent system 28 is made up of a small slotted stainless steel tube or series of interconnected rods, which form an expandable cylindrical lattice or scaffolding. *Id.* at 2:61-63. In the context of the embodiment disclosed in figures 18 and 19, the specification states that valve 100 (not ring 102) is

anchored with rods 104 connected to stents 28. *Id.* at 6:4-6; *see also id.* at 4:6-9 (rod 56 on valve 30); *id*. at 5:21-23 (valve 66 is anchored with rods 80); *id*. at 5:47-50 (valve 82 is anchored with connecting rods, not shown).

Based on the review of the specification summarized above, it appears that it is the combination of rods 104 interacting with stent 28 that is the structure comprising the "means for maintaining" called for in claim 19. We therefore adopt this construction for the terms "means for maintaining" for the purposes of this Decision.

4. "mean for mounting"

Claim 16 recites a means for mounting a first open end of a membrane about a ring aperture. "Means for mounting" is a "means plus function" limitation to be construed under 35 U.S.C. § 112, sixth paragraph. Medtronic and Dr. Norred generally agree that the '228 patent discloses that the membrane is "hingedly secured" (Ex. 1001, 4:56-61) or "hingedly attached" (*id.* at 5:35-39) about the aperture of the ring. Pet 9-10. *Cf.* Prelim. Resp. 15. This proposed construction of the "means for mounting" is reasonable at this stage of the proceeding and we therefore adopt it for the purposes of this decision.

C. Asserted Grounds of Unpatentability

1. Anticipation of Claims 16-19 by DiMatteo (Ex. 1003)

Medtronic contends that DiMatteo anticipates claims 16-19. Pet. 11-12 and Appendix A-1. DiMatteo discloses implantable prostheses such as an aortic valve. Ex. 1003, 1:4-6 and 7:38-41. DiMatteo's valve includes a tubular scaffold portion and a leaf valve portion. The scaffold portion of the

valve is designed to "eventually provide fluid-tight engagement with the body lumen." *Id.* at 3:29-33. The leaf valve portion includes a valve leaf frame and valve leaf cover. *Id.* at 2:27-50. The valve leaf cover may be made of Dacron, polyethylene (PE), polyethylene terephthalate (PET), silk, or Rayon. *Id.*

Figure 1 of DiMatteo is reproduced below.

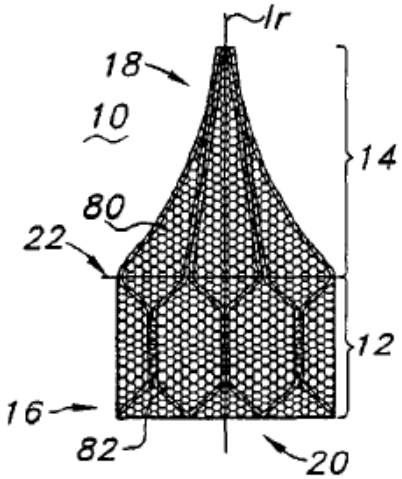

FIG 1

Figure 1 shows a prosthetic valve 10 that includes an elongate tubular body portion 12 and a leaf valve portion 14. *Id.* at 7:44-61. Leaf valve portion 14 includes valve leafs 40. The scaffold portion includes a tubular open body scaffold defining a fluid passageway 20 therethrough. *Id.* The leaf valve portion 14 is deflectable with respect to body portion 12 about a hinge line 22 between a closed configuration, in which fluid flow through the valve passageway is restricted, and an open configuration, in which fluid flow through the valve passageway is permitted. *Id.*

DiMatteo discloses that the trellis of the value may be mechanically joined to a collapsible scaffold by a wire. *Id.* at 13:43-51 and Figure 17.

The scaffold portion of the valve is expected to provide fluid-tight engagement with the body lumen. *Id.* at 3:29-33. Petitioner relies on this disclosure in DiMatteo to reach the "mean for maintaining" element of claim 19.

In support of its assertion that DiMatteo anticipates claims 16-19, Medtronic sets forth the foregoing teachings of DiMatteo and provides a detailed claim chart explaining how each claim limitation is disclosed in DiMatteo. Pet. 11–12 and Appendix A-1. Upon review of Medtronic's analysis and the evidence of record, we determine that Medtronic has demonstrated that there is a reasonable likelihood that it would prevail in showing that DiMatteo anticipates claims 16-19 of the '228 patent.

Dr. Norred attempts to distinguish the claimed subject matter from DiMatteo on the basis of the type of seal that is formed. Specifically, Dr. Norred contends that DiMatteo does not disclose a ring member designed to seal against the root of the native aortic valve to reduce peri-valvular leaks. Prelim. Resp. 18. Rather, DiMatteo discloses a liner/trellis combination designed to eventually form a seal due to tissue ingrowth. *Id.* (citing Ex. 1003, 3:29-33 and 4:61-62). We are not persuaded as we do not read the claims to require a particular type of seal; the claims require a circumference of a ring member "to seat about an aortic wall." Ex. 1001, claim 16.

2. Anticipation of Claims 16-18 by Wolfe (Ex. 1006)

Medtronic contends that Wolfe anticipates claims 16-18. Pet. 15-16 and Appendix A-4. Wolfe relates to center-flow occluders of prosthetic

heart valve assemblies that can be adapted to replace aortic valves. Ex. 1006, 1:45-51.

Figure 2A of Wolfe is reproduced below.

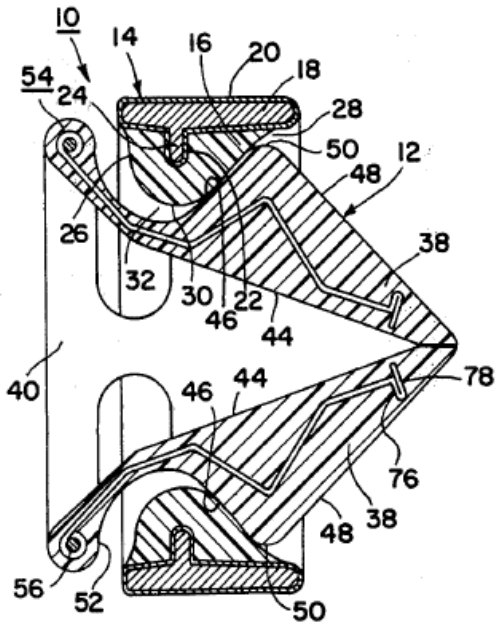

Figure 2A shows a heart valve assembly 10 with an occluder 12 disposed for movement within a valve seat assembly 14. Valve seat assembly 14 includes a soft seating ring 16, a rigid cast supporting ring 18, and a fixation cover 20. *Id.* at 3:51-64. Fixation cover 20 may be made of a Dacron mesh cloth and is initially secured to the heart tissue by suturing. *Id.* Thrombosis is then relied upon to retain valve seat assembly 14 in its proper position within the heart. *Id.*

Occluder 12 has four plastic cuspids 38 that engage each other in a closed position and flex outwardly relative to each other in an open position, thereby defining a central open passage to allow the flow of blood. *Id.* at 2:1-4 and 3:51-5:11. Occluder 12 is constructed with an armature 54 that includes an annular ring 56 and a plurality of reinforcing arms extending

through each cuspid to permit flexure of each arm relative to the annular ring. *Id.* at 5:23-45. The reinforcing arms are secured to the ring through hinge sections. *Id.*

In support of its assertion that Wolfe anticipates claims 16-18, Medtronic sets forth the foregoing teachings of Wolfe and provides a detailed claim chart explaining how each claim limitation is disclosed in Wolfe. Pet. 15-16 and Appendix A-4. Upon review of Medtronic's analysis and the evidence of record, we determine that Medtronic has demonstrated that there is a reasonable likelihood that it would prevail in showing that Wolfe anticipates claims 16-18 of the '228 patent.

Dr. Norred contends that Wolfe discloses a prosthetic heart valve that must be implanted through traditional open-heart surgery and does not disclose placement of an aortic valve percutaneously. Prelim. Resp. 24. We are not persuaded by this argument because the claims are not directed to a method of implanting a device and do not appear to require a valve capable of being implanted using any particular method.

Dr. Norred further contends that Wolfe fails to teach a ring member adapted to seat about an aortic wall surrounding an aortic channel because the "ring member" identified by Petitioner must be sutured to the artery wall. *Id.* at 24-25. We are not persuaded by this argument as we do not read the claimed language "to seat about an aortic wall" to exclude the use of sutures to hold the ring member in place.

Dr. Norred further contends that Wolfe does not teach a membrane movable between a first open position and a second closed position as claimed. *Id.* at 25. We are not persuaded by this argument because

Dr. Norred does not sufficiently explain why Wolfe's plastic cuspids are not properly considered "membranes" to a person of ordinary skill in the art.

3. Redundant Grounds

Petitioner also asserts the follow grounds of unpatentability:

(i) Claims 16-18 under 35 U.S.C. § 102(b) over Kischer (Ex. 1004); and

(ii) Claims 16-19 under 35 U.S.C. § 102(e) over Shaolian (Ex. 1005).

Upon review of those alternative grounds, we conclude that they are redundant in light of the grounds on the basis of which we institute review.

III. CONCLUSION

We institute an *inter partes* review of claims 16-19 based on the following grounds:

(1) Claims 16-19 under 35 U.S.C. § 102(e) over DiMatteo (Ex. 1003); and

(2) Claims 16-18 under 35 U.S.C. § 102(b) over Wolfe (Ex. 1006).

Petitioner's remaining grounds are denied as redundant.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is granted as to claims 16-19 of the '228 patent with respect to the following alleged grounds:

1. Claims 16-19 of the '228 patent under 35 U.S.C. § 102 as anticipated by DiMatteo; and
2. Claims 16-18 of the '228 patent under 35 U.S.C. § 102 as

anticipated by Wolfe.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '228 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the grounds listed in the Order. No other grounds are authorized.

FURTHER ORDERED that an initial conference call with the Board is scheduled for 11 AM Eastern Time on May 28, 2014. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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