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Paper 46
Entered: April 23, 2015

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

SNEDDEN, *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 Petition requesting *inter partes* review of claims 16–19 (Paper 4, "Pet.") of US 6,482,228 B1 (Ex. 1001, "the '228 patent"). We instituted trial for the challenged claims on the following grounds of unpatentability asserted by Petitioner:

Reference	Basis	Claims Challenged
DiMatteo[1]	§ 102(e)	16–19
Wolfe[2]	§ 102(b)	16–18

Decision to Institute (Paper 10, "Dec."), 15.

After institution, Troy R. Norred, M.D. ("Patent Owner") filed a Patent Owner's Response (Paper 15, "Resp."). Petitioner filed a Reply (Paper 25, "Reply").

Petitioner relies upon the declaration of Alexander J. Hill, Ph.D. (Ex. 1018, "Hill Decl.") in support of its Petition.

Patent Owner relies upon the declarations of Timothy T. Catchings, M.D., (Ex. 2095, "Catchings Decl."), Troy R. Norred, M.D. (Exhibit 2093, "Norred Decl."), James J. Kernell (Ex. 2094, "Kernell Decl."), Dr. Stephen J. Lombardo (Ex. 2096, "Lombardo Declaration"), and Dr. Carl T. Rutledge (Ex. 2097, "Rutledge Decl.") in support of its Response.

Patent Owner filed a Motion to Amend Claims (Paper 18, "Mot. to Amend"). Petitioner filed an Opposition to Patent Owner's Motion to

[1] DiMatteo, US 6,440,164 B1, issued Aug. 27, 2002 (Ex. 1003).

[2] Wolfe, US 4,030,142, issued June 21, 1977 (Ex. 1006).

Amend (Paper 26, "Opp."). Patent Owner filed a Reply in Support of Patent Owner's Motion to Amend (Paper 31, "Amend Reply").

Oral argument was conducted on January 27, 2015. A transcript is entered as Paper 45 ("Tr.").

This Final Written Decision addresses challenges to the patentability of claims 16–19. Petitioner has shown by a preponderance of the evidence that claims 16–19 of the '228 patent are unpatentable.

Patent Owner's Motion to Amend Claims is denied.

A. Related Matters

The parties represent that the '228 patent is the subject of a district court case filed February 6, 2013, by Patent Owner against Petitioner in the U.S. District Court for the District of Kansas, entitled *Troy R. Norred, M.D. v. Medtronic, Inc.*, Case No. 2:13-cv-02061. Pet. 1; Paper 6, 2; Paper 13.

The '228 patent is the subject of two other *inter partes* review proceedings: IPR2014-00111 and IPR2014-00395.

B. 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, 1:29–31. Figures 10 and 13 of the '228 patent are reproduced below.

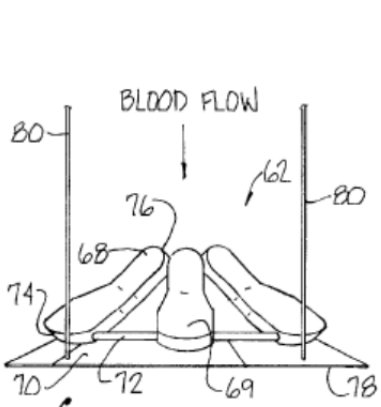


Fig. 10

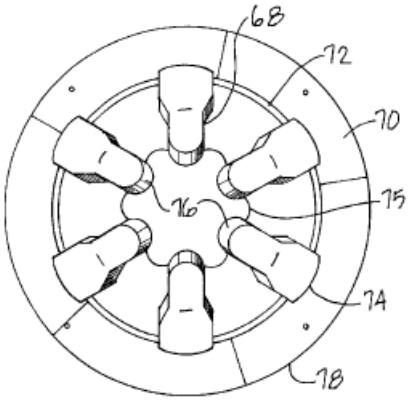


Fig. 13

Figures 10 and 13 show different views of a cone-shaped aortic valve. Valve 66 consists of interconnected fingers 68, a 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 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 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 stents. *Id.* at 5:21–23.

C. 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.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *accord In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. 2015). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed.

Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The "means for mounting" recited in claim 16 is the claim term that requires analysis to resolve arguments related to the patentability of the challenged claims. 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. 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 Med. Inc., v. Abbott Labs.*, 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 Int'l, Inc.*, 582 F.3d 1288, 1299 (Fed. Cir. 2009).

Claim 16 recites a:

> 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.

"Means for mounting" is a "means-plus-function" limitation to be construed under 35 U.S.C. § 112, sixth paragraph.

Petitioner contends that, in the conical valve embodiment of Figs. 10–13 of the '228 patent, the "means for mounting" feature is disclosed as fingers 68 hingedly secured together by ring 72 secured to base 70, which may be seated against the root of aortic valve 34. Reply 2; Ex. 1001, 4:54–5:19. Based on that disclosure, Petitioner proposes that the structure of "means for mounting" feature should be construed as "fingers or arms hingedly attached or hingedly secured to the ring member and a free end spaced therefrom" and equivalents. *Id.* at 3.

Patent Owner does not contest Petitioner's proposed construction of the "means for mounting" element recited in claim 16.

We agree with Petitioner's analysis and construe the phrase "means for mounting" to mean "fingers or arms hingedly attached or hingedly

secured to the ring member and a free end spaced therefrom." In reaching that determination, we note that the '228 patent discloses that the membrane is "secured to the inside surfaces 69 of the fingers" (Ex. 1001, 4:56–61) or, in an alternative embodiment, the membrane is "secured to each arm 84 and base 88" (*id.* at 5:36–42). Furthermore, dependent claim 17 recites that the structure of the mounting means "comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom." The '228 patent thus discloses that the membrane is secured or mounted on arms or fingers.

B. Priority of Invention

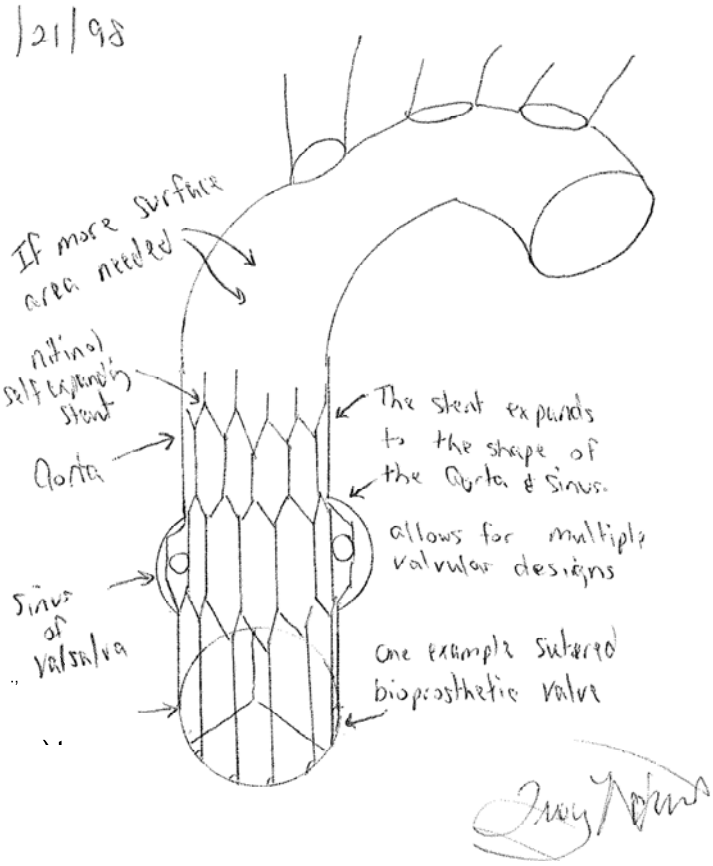
Patent Owner contends that DiMatteo does not anticipate claims 16–19 of the '228 Patent because Norred conceived his invention prior to DiMatteo, and exercised reasonable diligence in constructively reducing it to practice. For the reasons that follow, we are not persuaded that Dr. Norred conceived of the invention of the challenged claims prior to the October 21, 1999 filing date of DiMatteo.

Conception is "the formation, in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (citing *Gunter v. Stream*, 573 F.2d 77, 80 (CCPA 1978)) (emphasis omitted). This requires more than accidental creation; there must be evidence that the inventor appreciated that he made "something new." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063–64 (Fed. Cir. 2005). "The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot

prove possession of the complete mental picture of the invention." *Burroughs Wellcome Co. v. Barr Labs., Inc*., 40 F.3d 1223, 1228 (Fed. Cir. 1994).

Proof of conception must be by "corroborating evidence which shows that the inventor disclosed to others his 'completed thought expressed in such clear terms as to enable those skilled in the art' to make the invention." *Coleman*, 754 F.2d at 359 (citing *Field v. Knowles*, 183 F.2d 593, 601 (CCPA 1950)); *see also Mahurkar v. C.R. Bard, Inc*., 79 F.3d 1572, 1577 (Fed. Cir. 1996) (corroboration requirement "arose out of a concern that inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent"). The sufficiency of corroboration is determined according to a "rule of reason." *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993). This, however, does not dispense with the requirement that some independent evidence provide corroboration. *Coleman*, 754 F.2d at 360. The requirement of "independent" corroboration requires evidence other than the inventor's testimony. *In re NTP, Inc*., 654 F.3d 1279, 1291–92 (Fed. Cir. 2011).

In the case at hand, Patent Owner has offered evidence of prior invention in the form of Exhibit 2003, which is a sketch that is signed and notarized and bears a date of "12/21/98." Resp. 7–14. A copy of the drawing in Ex. 2003 is reproduced below.



Patent Owner contends that the sketch contained in Ex. 2003 served as the basis for Figures 4 and 18 of the '228 patent and depicts each limitation set forth in claims 16 and 19. *Id.* (citing Norred Decl. ¶ 8).

After review of Ex. 2003 and Patent Owner's arguments related thereto, we are not persuaded that the drawing provides sufficient detail to establish possession of an embodiment of the invention having the particular limitations set forth in the claims. Rather, we agree with Petitioner that the sketch only identifies two elements of a device to be inserted into the aorta: (1) a "nitinol self-expanding stent" that "expands to the shape of the aorta

and sinus;" and (2) a "sutured bioprosthetic valve." Reply 5. The detail in the sketch is insufficient to describe each element of the claims such as, for example, a "ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel" (claim 16) or "at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom" (claim 17).

Upon reviewing the record as a whole, however, we cannot conclude that the record establishes, by corroborated evidence, that Dr. Norred conceived of the invention of the challenged claims prior to the October 21, 1999 filing date of DiMatteo. Thus, DiMatteo is prior art under 35 U.S.C. § 102(e).

C. Asserted Grounds of Unpatentability

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

a. Summary of DiMatteo (Ex. 1003)

DiMatteo discloses an implantable prosthetic valve having a tubular scaffold portion and a leaf valve portion. Ex. 1003, 6:30–31. The two body portions of the valve are summarized in the following excerpt from DiMatteo:

> A prosthetic valve . . . [having a] cylindrical radially collapsible valve body scaffold defining a fluid passageway therethrough for retentive positioning within the lumen. A radially collapsible leaf valve member is supported by the scaffold includes a number of valve leafs deflectable between a closed position restricting fluid flow through the passageway and an open position permitting fluid flow through the passageway. The leaf valve member includes an interior leaf valve frame defining a valve leaf aperture which is sealed by a

> fluid impermeable nonthrombogenic lining to prevent fluid flow therethrough.

Ex. 1003, Abstract.

Figure 1 of DiMatteo illustrates an embodiment of the disclosed valve and is reproduced below.

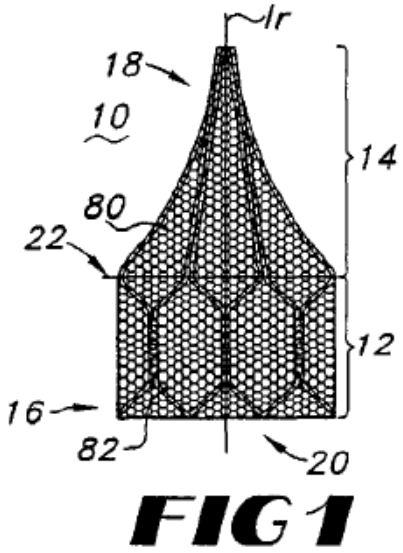


FIG 1

Figure 1 shows prosthetic valve 10 that includes elongate tubular scaffold portion 12 and leaf valve portion 14. *Id.* at 7:44–61. The scaffold portion includes a tubular open body defining fluid passageway 20 therethrough. *Id.* DiMatteo discloses that the scaffold portion of the valve is designed to "eventually provide fluid-tight engagement with the body lumen." *Id.* at 3:29–33.

Leaf valve portion 14 includes valve leafs 40. *Id.* at 7:44–61. Leaf valve portion 14 is deflectable with respect to body portion 12 about 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.*

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.*

b. Analysis

In its Response, Patent Owner contends that DiMatteo does not disclose a ring member as required by independent claim 16. Resp. 34–36. With regard to this feature of the claim, claim 16 requires "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."

Petitioner contends that DiMatteo, summarized above, discloses a ring member in the form of tubular body portion 12, which is expected to provide fluid-tight engagement with the body lumen. *Id.* at 3:29–33; Pet. 11–12, Appendix A-1.

Patent Owner argues that the recited "ring member" requires a ring made of pliable, biocompatible material and argues that DiMatteo does not disclose such a ring member. Resp. 34–36. Specifically, Patent Owner argues that "the purported ring member disclosed in DiMatteo—the liner 82/trellis 24 combination—is not and cannot be pliable." *Id.* at 35. Patent Owner further reasons that, because the liner 82/trellis 24 combination is not pliable, it cannot be "adapted to seat about an aortic wall" as required by claim 16. *Id.* at 36.

Petitioner responds with the contention that the ring member in DiMatteo is pliable, as the '228 patent discloses that trellis 24 of tubular portion 12 may be formed from shaped memory alloys having superelastic

properties. Reply 12–13 (citing Ex. 1003, 7:24–28, 8:60–67, 12:47, 15:7–16:2). In this regard, DiMatteo discloses as follows:

> Shaped memory alloys having superelastic properties generally made from specific ratios of nickel and titanium, commonly known as nitinol, are among the preferred trellis materials.

Ex. 1003, 8:64–67.

Petitioner contends also that Patent Owner's expert, Dr. Catchings, testified that super elastic material is pliable. Ex. 1009 (Catchings Tr.), 195:8–10.

After review of the evidence and argument summarized above, we are persuaded that DiMatteo's prosthetic valve discloses a ring member having a circumference adapted to seat about an aortic wall. DiMatteo's prosthetic valve may be made from superelastic material (Ex. 1003, 8:64–67) and is expected to sit on an aortic wall (*id.* at 1:5–6, 14:55–56) and facilitate tissue ingrowth for "assimilating the valve of the present invention into the body lumen" (*id.* at 3:29–33, 4:61–64). We determine that a preponderance of evidence supports a finding that the superelastic material of DiMatteo is pliable and thus capable of seating about an aortic wall. We are not persuaded by Patent Owner's attempt to distinguish the ring member element of the claims from the liner 82/trellis 24 combination used in DiMatteo's device on the basis of pliability. Resp. 34–36. Rather, we are persuaded by Petitioner's argument and evidence that DiMatteo discloses an aortic valve with a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel as required by the challenged claims.

Our Scheduling Order in this case cautioned Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 11, 3. The Board's Trial Practice Guide, furthermore, states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012) (emphasis added). Furthermore, as the Board has stated, our governing statute and Rules "clearly place some onus on the patent owner, once trial is instituted, to address the material facts raised by the petition as jeopardizing patentability of the challenged claims." *Johnson Health Tech Co. Ltd. v. Icon Health & Fitness, Inc*., Case IPR2013-00463, slip op. 12 (PTAB Jan. 29, 2015) (Paper 41).

In our Decision to Institute, we concluded that Petitioner had made a threshold showing that DiMatteo taught all the limitations of the challenged claims, sufficient for us to conclude that there was a reasonable likelihood that Petitioner would prevail in showing that the challenged claims were anticipated by DiMatteo. Dec. 10–12. We must now determine whether the preponderance of the evidence of record supports a finding that DiMatteo anticipates the challenged claims. 35 U.S.C. § 316(e).

In its Response, Patent Owner does not present argument or evidence attempting to distinguish any other feature of claims 16–19 over the device disclosed in DiMatteo. The record now contains the same arguments and evidence regarding the merits of DiMatteo's alleged anticipation with regard to the remaining elements of the claims as it did at the time of our Decision to Institute. Accordingly, the preponderance of the evidence of record now

supports a finding that Petitioner has set forth how these remaining limitations of the challenged claims are taught by DiMatteo.

Based on our review of the record before us, we find by a preponderance of the evidence that DiMatteo anticipates claims 16–19.

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

a. Summary of Wolfe (Ex. 1006)

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.

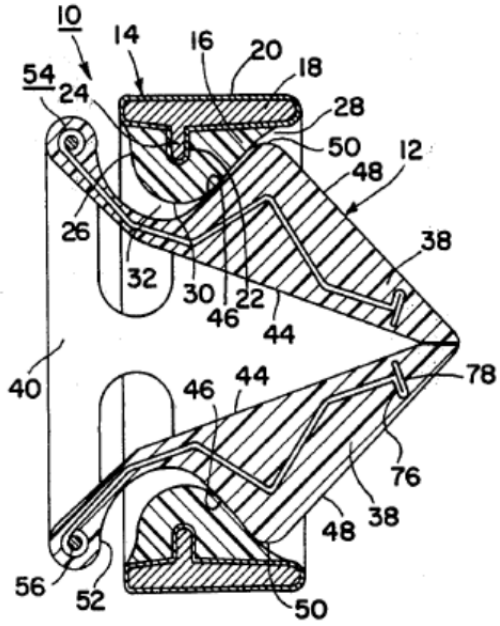


Figure 2A shows heart valve assembly 10 with occluder 12 disposed for movement within valve seat assembly 14. Valve seat assembly 14 includes soft seating ring 16, rigid cast supporting ring 18, and fixation cover 20. *Id.* at 3:51–64. Fixation cover 20 may be made of a Dacron mesh cloth and is initially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

then is 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, 3:51–5:11. Occluder 12 is constructed with armature 54 that includes 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.*

b. Analysis

Petitioner contends that Wolfe anticipates claims 16–18. Pet. 15–16, Appendix A-4. Petitioner contends that Wolfe, summarized above, discloses a membrane in the form of an occluder 12 having cuspids 38. *Id*. Cuspids 38 are configured to move radially to control the flow of blood through the valve (Ex. 1006, 1:60–2:4) and expected to provide fluid-tight engagement with the body lumen (*id.* at 3:29–33). Petitioner contends that Wolfe discloses the cuspids 38 hingedly connected to annular ring 56 at about passageway 32. Pet. at Appendix A-4 (citing Ex. 1006, 5:27–45).

Petitioner identifies valve seat assembly 14 as disclosed in Wolfe meeting the ring member element of claim 16. *Id.* at Appendix A-4 (citing Ex. 1006, Figs. 1, 2A, 2B).

In its Response, Patent Owner contends that Wolfe does not disclose a membrane hingedly secured or hingedly attached to "a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic

channel" as required by independent claim 16. Resp. 37–40. Patent Owner points out that "[w]hile valve seat assembly 14 may contact the aortic wall (though not adapted to seat about it), cuspid 38 is not mounted to valve seat assembly 14." *Id.* at 38.

In its Reply, Petitioner responds as follows:

> The limitations of claim 16 are met because, regardless of which portion of the ring member the cuspid is mounted to, valve seat assembly 14 is "seat[ed] about an aortic wall surrounding an aortic channel," the cuspid's first open end is mounted "about said ring aperture," and its second end is moved "between a first open position … and a second closed position" as recited in claim 16.

Reply 14–15 (citing Pet. Appendix 13–15; Hill Decl. ¶¶ 61–64).

As discussed above, we construe the phrase "means for mounting" to mean "fingers or arms hingedly attached or hingedly secured to the ring member and a free end spaced therefrom." After review of the evidence and argument summarized above, we agree with Patent Owner's analysis that Wolfe fails to disclose "fingers or arms hingedly attached or hingedly secured to the ring member," where the ring member is "adapted to seat about an aortic wall" as recited in claim 16. Rather, Wolfe discloses a heart valve assembly having two rings, the valve seat assembly 14 and annular ring 56. The valve seat assembly 14 is "adapted to seat about an aortic wall." Pet. 16, Appendix 4. Cuspids 38, however, are not connected to valve seat assembly 14. Instead, cuspids 38 are hingedly connected to annular ring 56 about passageway 32. *Id.* Annular ring 56 is not seated about the aortic wall, but instead is an element of occluder 12, which is movable between closed and opened positions within a seating-ring passage

of a valve seat assembly. Ex. 1006, 3:44–50, Figs. 2A, 2B. The occluder cannot be configured to seat against the aortic wall as required by claim 16, because the device of Wolfe requires this portion of the device to be movable.

Based on the record before us, we determine that Wolfe fails to disclose a means for mounting a membrane about the aperture of a ring member as recited in independent claim 16, which requires the ring member to have "a circumference adapted to seat about an aortic wall surrounding an aortic channel." We determine, consequently, that Wolfe fails to anticipate the subject matter of claims 16–18.

D. Conclusion

Petitioner has shown, by a preponderance of the evidence, that claims 16–19 of the '228 patent are unpatentable under 35 U.S.C. § 102(e) in view of DiMatteo.

Petitioner has failed to show, by a preponderance of the evidence, that claims 16–18 of the '228 patent are unpatentable under 35 U.S.C. § 102(b) in view of Wolfe.

III. MOTION FOR OBSERVATION

Patent Owner's Motion for Observation pertains to the testimony of Alexander J. Hill, Ph.D. on cross-examination. We have considered Patent Owner's observations (Paper 37) and Petitioner's responses (Paper 39).

IV. MOTION TO AMEND

Because we have found claims 16–19 to be unpatentable as anticipated by DiMatteo, we turn to Patent Owner's Motion to Amend

Claims. In its Motion to Amend, Patent Owner moves to substitute claim 25 for challenged claim 16. Proposed substitute claim 25 is shown below in markup form as compared to the original claim 16 for which it is proposed as a substitute.

> 25. (Proposed substitute for claim 16) An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon percutaneous placement therein, said valve comprising:
>
> a ring member having a pliable circumference adapted to seat about an aortic wall surrounding an aortic channel and seal against a root of a native aortic valve upon percutaneous placement, said ring member including an aperture for blood flow therethrough;
>
> an expandable stent system extending into the ascending aorta upon said percutaneous placement therein and connected to said ring member; and
>
> a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough;
>
> ~~means for mounting~~ said first open end of said membrane hingedly secured about said ~~ring~~ aperture of said ring member with said second open end displaced therefrom, ~~said means moving~~ said ~~membrane~~ second open end movable between a first open position to allow a blood flow therethrough and a second closed position to preclude blood flow therethrough;
>
> said aortic valve having a collapsed configuration for delivery inside a catheter, and an expanded configuration when deployed from said catheter and percutaneously placed in the aortic channel.

Mot. to Amend 1–2.

Proposed substitute claims may not enlarge the scope of original patent claims. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). In this regard, Petitioner argues that proposed claim 25 is broader in scope as compared to original challenged claim 16. Opp. 5–6. Petitioner contends

that the proposed changes eliminate the "means for mounting" language from claim 16 and replace it with purely functional language—"membrane hingedly secured about said aperture of said ring member"—and eliminates the structures that correspond to the original means element—"fingers or arms hingedly attached or hingedly secured to the ring member and a free end spaced therefrom." *Id.*

Patent Owner responds that the proposed change does not enlarge the scope of claim 16 because claim 16 is not limited to embodiments that include fingers or arms. Amend Reply 1. Patent Owner argues that the membrane attaches directly to the ring aperture and functions as a hinge, allowing the valve to move between a closed position and an open position. *Id.* (citing Ex. 2095 ¶ 35). As such, no other structures are necessary to perform the required function. *Id.*

As discussed above, we construed the phrase "means for mounting" to mean "fingers or arms hingedly attached or hingedly secured to the ring member and a free end spaced therefrom." We based this analysis on the disclosure in the '228 patent that describes the membrane "secured to the inside surfaces 69 of the fingers" (Ex. 1001, 4:56–61) or, in an alternative embodiment, "secured to each arm 84 and base 88" (*id*. at 5:36–42). Furthermore, dependent claim 17 recites that the structure of the mounting means "comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom." In view of the above disclosures in the '228 patent describing the membrane as secured to fingers or arm, we are not persuaded by Patent Owner's argument that these structures are not part of the "mean for mounting" feature of claim 16.

Proposed claim 25 replaces the "means for mounting" language of claim 16 with a limitation that reads as follows: "said first open end of said membrane hingedly secured about said ring aperture of said ring member with said second open end displaced therefrom." This change removes the limitation requiring the fingers or arms disclosed in the '228 patent, which are disclosed as structures for which to secure or mount the membrane to the ring member. As such, we conclude that the proposed claims impermissibly enlarge the scope of the claims, and we deny Patent Owner's Motion to Amend.

V. ORDER

For the reasons given, it is

ORDERED that claims 16–19 of the '228 patent are determined to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Amend is denied; and

FURTHER ORDERED that because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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