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Paper 13
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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.

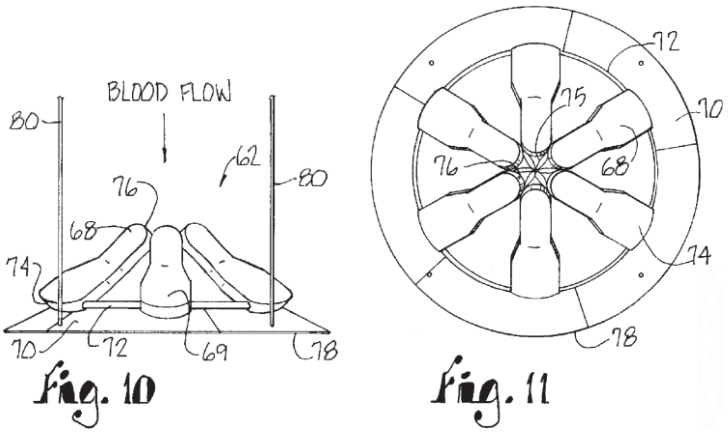


Fig. 10 Fig. 11

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

that the figure presented in Ex. 2203 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, at this stage in the proceeding, we are not persuaded that the claims of the '228 patent are entitled to a priority date earlier than November 14, 2000.

B. Claim Interpretation

As a step in our analysis for determining whether to institute a trial, we interpret the claims. Consistent with the statute and the legislative history of the AIA, we analyze patentability using the broadest reasonable interpretation of the claims. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); 37 CFR § 42.100(b).

Under the broadest reasonable interpretation standard, we interpret claim terms according to their ordinary and customary meaning as they would have been 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).

We have interpreted all terms according to their ordinary meaning as an ordinarily skilled artisan would have understood them in light of the '228

patent. For clarity in this Decision, however, we explicitly set forth the ordinary meaning for the following terms.

1. Ring Member

"Ring member" appears in independent claims 16 and 20 and, thus, in all challenged claims. Dr. Norred proposes that the phrase "ring member" means "a ring made of a pliable, biocompatible material which seals against the aorta to reduce peri-valvular leaks." Prelim. Resp. 16–17. Dr. Norred cites the Specification as support for this proposed claim interpretation. *Id.* (citing Ex. 1001, 1:26–51, 6:1–9). Medtronic does not propose an explicit interpretation for "ring member."

We do not interpret "ring member" as limited to a specific material. Claims 16 and 19–24 do not recite the material from which the ring member is made, and Dr. Norred cites no persuasive evidence that we should import into the claims limitations from the Specification regarding the material from which the ring member is made. Dr. Norred also offers no persuasive evidence that the ordinary and customary meaning of the term "ring member" is limited to a pliable, biocompatible material.

We also do not interpret "ring member" as requiring that the ring member "seals against the aorta to reduce peri-valvular leaks." Claims 16 and 20–24[1] state that the outer circumference of the ring member is "adapted to *seat* . . . about an aortic wall surrounding an aortic channel." Ex. 1001, 8:1–2 (emphasis added). The challenged claims 16 and 19–23 do not state that the ring member *seals* against anything.

[1] We interpret "ring member" as recited in claim 16 to be consistent with our interpretation of "ring member" in claim 20.

Additionally, dependent claim 24 further limits the ring member to one that not only seats but also "seals said ring against the aortic channel wall to reduce blood flow therearound." *Id*. at 8:57–59. As a dependent claim, claim 24 must further limit claim 20 from which it depends. 35 U.S.C. § 112, paragraph 4. Thus, seating the ring member about an aortic wall surrounding an aortic channel, as recited in claim 20, cannot define the same structure or relationship as sealing the ring member against the aortic channel wall, as recited in claim 24.

The Specification also distinguishes between seating and sealing. *See, e.g.*, Ex. 1001, 5:17–21 ("Base 70 is seated . . . rim 78 . . . seals against the root of the native aortic valve 34. . . ."). The claims do not state the purpose of the claimed seated arrangement. Dr. Norred has not provided any persuasive argument or evidence that we should ignore the language of the claims as written and interpret the claim as he proposes. *Chef America, Inc. v. Lamb-Weston, Inc*., 358 F. 3d 1371, 1374 (Fed. Cir. 2004) ("Thus, in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it.").

For purposes of this Decision, "ring member" as recited in claims 16 and 19–23 does not require a particular sealing function. We do, however, interpret claim 24 to require that the ring member seals against the aortic wall sufficiently to reduce blood flow around the ring member, because the claim explicitly requires the ring member to so seal.

2. Membrane

"Membrane" appears in claim 16 and its dependent claim 19. Medtronic contends that the term "membrane" should be construed to include fabrics or polymers, but not tissue. Pet. 12–13. As support for this

position, Medtronic relies on particular embodiments of aortic valves having fabric and polymer membranes disclosed in the Specification. *Id*. (citing Ex. 1001, 4:59–62 and 5:40–41). Nevertheless, the Specification also describes valves with membranes comprising biological tissue. Ex. 1001, 5:63–6:9.

We decline to limit the term "membrane" as Medtronic proposes. The disclosure of specific embodiments does not, by itself, require a narrow interpretation of a claim term. We find no evidence on this record suggesting that the term "membrane" excludes a tissue membrane.

3. Tissue

"Tissue" appears in independent claim 20 and its dependent claims 21–24. Medtronic proposes that the claim term "tissue" is a "biological tissue, such as cadaver and porcine tissue." Pet. 14. Dr. Norred proposes the identical construction. Prelim. Resp. 17.

The written description in the '228 patent uses the word "tissue" only once. Ex. 1001, 5:64. This sole use is in the context of describing various valve designs and states that "designs that may prove valuable" to the "technique" disclosed in the written description include the use of "biological tissue incorporated valves, such as cadaver/porcine valves placed within a percutaneously stented system." *Id.* at 5:63–66. The Specification refers to Figures 18 and 19, which illustrate "a cadaver/porcine incorporated valve and stent system." *Id.* at 5:67; 2:48–51.

The claims recite only the term "tissue." The claims do not specify the type of tissue or the source of the tissue, e.g., "cadaver" or "porcine" tissue. "While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that

limitations from the specification may be read into the claims." *Comark Communications, Inc. v. Harris Corp*., 156 F.3d 1182, 1186 (Fed. Cir. 1998) (citation omitted), *see also Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed.Cir.1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."). Accordingly, the broadest reasonable interpretation in light of the Specification of the claim term "tissue" is generally "biological tissue."

4. Means 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. 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, the parties agree that "means for mounting" is a "means plus function" phrase to be interpreted under § 112, sixth paragraph. Pet. 13; Prelim. Resp. 18.

"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).

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. *Compare* Pet. 13 *with* Prelim. Resp. 18. We understand the parties' position to be that the structure required is a hinge. This proposed construction of the "means for mounting" is the broadest reasonable interpretation at this stage of the proceeding and we therefore adopt it for the purposes of this decision.

5. Means for Maintaining

Claim 19 recites a "means for maintaining said ring member in said seat about the aortic wall." Similarly, independent claim 20 and, thus, also its dependent claims 21–24 recite "means for maintaining said ring member in said seated position about the aortic wall." Dr. Norred contends that the "means for maintaining" is stent system 28 or an equivalent structure.

Prelim. Resp. 18 (citing Ex. 1001, 1:29–31, 59–67, 5:22–25, 48–51). Medtronic contends that Dr. Norred "seems to have ignored the means plus function strictures of this claim [term]." Pet. 14. Medtronic also concedes that Dr. Norred's proposed construction of "means for maintaining" "is the construction applied to the limitation for purposes of this *inter partes* review." *Id*.

The Federal Circuit's decision in *In re Donaldson Co., Inc*., 16 F.3d 1189 (Fed. Cir. 1994) (en banc) demands otherwise. "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." *Id*. at 1193. This is the "broadest reasonable interpretation" of "means-plus-function" language. *Id.* at 1194–95. Therefore, we look to the Specification of the '228 patent to identify structures that perform the "maintaining" function.

The '228 patent discloses four valve designs: (1) figures 6–9 disclose an umbrella aortic valve; (2) figures 10–13 disclose a cone-shaped aortic valve; (3) figures 14–17 disclose another version of a cone-shaped valve; and (4) 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 claims 19–24. We therefore adopt this construction for the term "means for maintaining" for the purposes of this Decision.

C. The Challenges to Patentability

Medtronic contends that each of Leonhardt, Andersen, and Bailey anticipate all challenged claims. Pet. 15–21. Medtronic also contends that each of Figulla, Jayaraman, and Ersek anticipate claims 16 and 19. Pet. 22–27. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). With this standard in mind, we address each alleged anticipation challenge below.

1. Leonhardt—Claims 16 and 20–24

Leonhardt generally describes a percutaneously placed artificial valve "to maintain bodily fluid flow in a single direction" and "be placed anywhere flow control is desired." Ex. 1004, 1:11–14. The aorta is among those locations at which Leonhardt contemplates deploying its artificial valve. *Id*. at 3:59–60, 9:64–10:21. Leonhardt's Figures 3 and 4 are reproduced below.

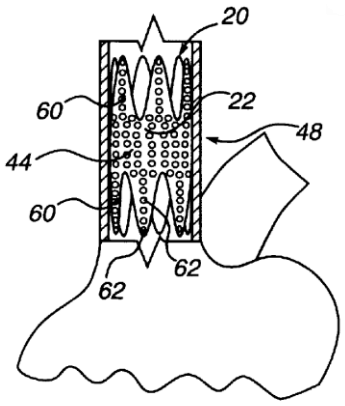


FIG. 3

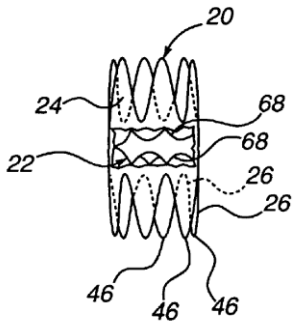


FIG. 4

> Figure 3 depicts Leonhardt's valve stent 20 "fully deployed with the aorta above the aortic valve." Leonhardt's Figure 4 depicts a partial sectional view of valve stent 20 incorporating porcine valve 22.

Id. at 3:59–62, 6:23–33.

Medtronic contends that Leonhardt discloses the claimed aortic valve and provides claim charts that identify in detail how Leonhardt's description of its artificial valve discloses each element of all challenged claims. Pet. 15, Appendix A-1.[2] Medtronic also provides the Declaration of Dr. Thomas Vassiliades, Jr., in which Dr. Vassiliades testifies that Leonhardt's artificial valve inherently operates to open and close in response to the pressure gradient created by the heart during systole and diastole. Ex. 1018 ¶¶ 20–28. This testimony is related to the claimed features of the valve set forth in dependent claims 21–23. Dr. Norred admits that Leonhardt describes these claimed features. Prelim. Resp. 34–35.

Dr. Norred contends that Leonhardt does not anticipate the challenged claims because Leonhardt fails to describe the "means for maintaining" recited in claims 19–24 or the "ring member" recited in claims 16 and 19–

[2] We note that the Appendix is a section within the Petition having separate pagination, and not a separate document.

24. Regarding the "means for maintaining," Dr. Norred contends that Leonhardt describes a stent structure that, except for distensible fingers, "must be below the coronary artery." Prelim. Resp. 20 (citing Ex. 1004, 5:40–52, Figure 2). Dr. Norred's contention rests upon the presumption that the "means for maintaining" imposes specific requirements on the location at which a valve is positioned within the aorta. We disagree because the "means for maintaining" refers to specific structures of the claimed aortic valve that maintain the ring member seated "about the aortic wall," rather than a specific location within the aorta relative to coronary arteries.

Dr. Norred also contends that Leonhardt fails to describe the "ring member" recited in claims 16 and 19–24 because Leonhardt's stent structure does not "seal the device against the aorta and reduce perivalvular leaks." Prelim. Resp. 21. More specifically, Dr. Norred contends that the seal created by Leonhardt's adhesive coating "ultimately degrades" and "differs markedly" from the use of radial force described in the '228 patent. *Id.* We find Dr. Norred's contention unpersuasive in connection with claims 16 and 19–23 because those claims do not require that the ring member seal the device against the aortic wall.

Claim 24 recites that the "ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound." Nevertheless, Medtronic points out that Leonhardt describes that the "valve graft may be completely sealed to the living tissue by light activated biocompatible tissue adhesive between the outside of the tubular graft and the living tissue." Pet. App. A-1, p. 6 (citing Ex. 1004, 3:42–45). Thus, at this stage of the proceeding, we are not persuaded by Dr.

Norred's argument that Leonhardt fails to describe the "ring member" of claims 16 and 19–24.

We determine, on the record before us, that Medtronic has demonstrated a reasonable likelihood of prevailing in establishing that Leonhardt anticipates claims 16 and 19–24.

2. Bailey—Claims 16 and 19–24

Dr. Norred asserts that "Bailey does not constitute prior art and cannot serve as a basis to invalidate the '228 Patent pursuant to 35 U.S.C. § 102(e)." Prelim. Resp. 23. The basis for this assertion is that "Bailey was filed on December 31, 1999, approximately one year *after* Norred invented the aortic valve described in the '228 Patent." *Id.*

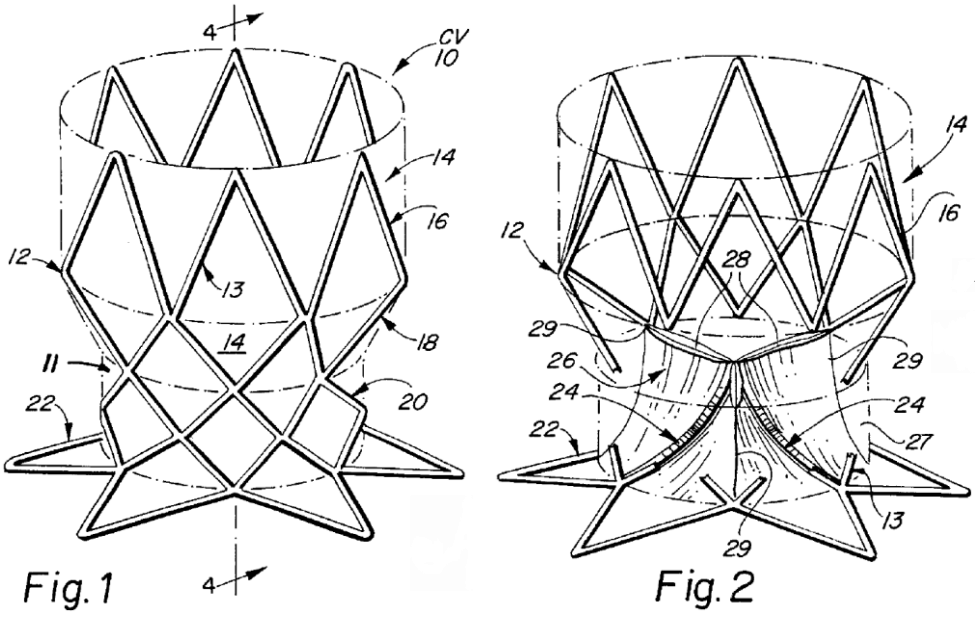
The effective filing date of Bailey is December 31, 1999. Ex. 1006 at (22). The filing date of the '228 patent is November 14, 2000. Ex. 1001 at (22). Thus, Bailey is prior art under the applicable provision of 35 U.S.C. § 102(e) unless Dr. Norred establishes that the inventions in the challenged claims were invented before December 31, 1999.

Patent Owner cites Exhibit 2203 in support of the asserted date of invention one year prior to Bailey's filing date. Prelim. Resp. 23. Exhibit 2203 is a sketch dated "12/21/98." The sketch is notarized as being signed by "Troy Norred" on December 21, 1998. The sketch shows an "aortic valve" positioned in the aorta. Dr. Norred states that Exhibit 2203 "clearly depicts a percutaneous aortic heart valve held in place with a stent system," and "bears a striking similarity to Figure 4 of the '228 patent." *Id.* at 10.

Exhibit 2203 does not address the limitations of claims 16 and 19–24 and does not establish possession of every feature recited in these claims. For example, there is no evidence that the sketch illustrates a "tissue valve,"

or that the sketch illustrates rods interacting with a stent that form the structure comprising the "means for maintaining" called for in claims 19 and 20. As such, the evidence on which Patent Owner relies does not establish that the invention in claims 16 and 19–24 was invented prior to December 31, 1999. Thus, based on the evidence and arguments asserted by Dr. Norred at this stage of the proceeding, we consider Bailey to be prior art to the challenged claims under 35 U.S.C. § 102(e).

Bailey generally describes a prosthetic cardiac valve comprising stent support member 12, graft member 11 covering at least a portion of stent 12, and biological xenograft valve flaps/leaflets 28. Pet. 20 (citing Ex. 1006, 1:6–21, 28–38, 5:61–6:9, 7:58–8:19). Bailey's Figures 1 and 2 are reproduced below.



Bailey's Figures 1 and 2 illustrate an embodiment of a chamber-to-vessel valve stent in its fully deployed state with Figure 2 having a portion of the outermost graft layer removed to depict the valve apparatus within the stent.

Ex. 1006, 6:44–49. Bailey's artificial valve is implanted in the location of the natural aortic valve. *Id*. at 10:31–44, figs. 6A and 6B. Medtronic

contends that Bailey discloses the claimed aortic valve and provides claim charts that identify in detail how Bailey's description of its artificial heart valve discloses each element of all challenged claims. Pet. 19–21, App. A-3.

Dr. Norred contends that Bailey fails to describe the ring member recited in claims 16 and 19–24 because portions of Bailey's stent body member 12 "must be eliminated to prevent the coronary artery from being blocked." Prelim. Resp. 23. Dr. Norred argues that the elimination of portions of Bailey's stent body member 12 "creates gaps" and "prevents it from sealing against the aorta to reduce perivalvular leaks." *Id*. at 24. We are not persuaded by Dr. Norred's argument at this stage for two reasons. First, Bailey's stent body member 12 need not seal itself against the aortic wall to meet the claimed "ring member." *See supra* Part I.B.1. Second, Dr. Norred provides no evidence to support the argument that Bailey's structures would seal the perimeter of the valve to the aortic wall.

Dr. Norred also contends that Bailey fails to describe the "means for maintaining" recited in claims 19–24 because "the Bailey device anchors in a very different fashion than Norred's device." *Id*. at 24–25. Dr. Norred contends that Bailey's device is held in place by anchor flange 22, which extends radially outwardly, and that anchor flange 22 "likely would result in the stent piercing the aortic wall." *Id*. at 24. None of the portions of Bailey that Dr. Norred cites support the latter contention. Additionally, Dr. Norred's argument ignores Bailey's distal anchor section 16, which "expands to contact the vascular wall and retain the prosthesis in position." Ex. 1006, 6:5–7. Differences between the manner in which Bailey's and Norred's structures function to maintain the ring member in its seated position about the aortic wall must be established by evidence rather than

attorney argument. *See Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1562 (Fed. Cir. 1995) (denying summary judgment of infringement under doctrine of equivalents when alleged equivalency of accused subject matter supported solely by attorney argument). Therefore, at the current stage of the proceeding, Dr. Norred's contention is unsupported by evidence.

We determine, on the record before us, that Medtronic has demonstrated a reasonable likelihood of prevailing in establishing that Bailey anticipates claims 16 and 19–24.

3. The Remaining Challenges to Patentability

As summarized in Part I.A above, Medtronic asserts six grounds of unpatentability based on § 102. Under 37 C.F.R. § 42.108(a), we have discretion to "authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim." We also "may deny some or all grounds for unpatentability for some or all of the challenged claims." 37 C.F.R. § 42.108(b). In making such determinations, we consider 37 C.F.R § 42.1(b), which requires "the just, speedy, and inexpensive resolution of every proceeding."

We have determined to institute a trial on two of the six grounds proposed by Medtronic. In this case, the decision not to authorize *inter partes* review on the other four unpatentability challenges is based on our determination that the challenges rely on substantially similar prior art facts as the challenges for which *inter partes* review is authorized. Considering multiple different references to establish the same factual premise, the structure and function of a heart valve, would consume, unnecessarily, the

time and resources of the Board and all parties involved, as well as impede "the just, speedy, and inexpensive resolution" of this proceeding. Medtronic did not identify a persuasive, meaningful distinction between the two challenges for which we institute review and the four challenges for which we deny review due to redundancy.

CONCLUSION

For the foregoing reasons, based on the information presented in the Petition and Preliminary Response, we determine that Medtronic has shown a reasonable likelihood that it will prevail in establishing that claims 16 and 19–24 of the '228 patent are unpatentable.

ORDER

For the reasons given, it is:

ORDERED that *inter partes* review is instituted in connection with the following grounds of unpatentability:

1. that Leonhardt anticipates claims 16 and 19–24 under 35 U.S.C. § 102(b); and
2. that Bailey anticipates claims 16 and 19–24 under 35 U.S.C. § 102(e).

FURTHER ORDERED that the Petition is denied in connection with all other grounds of unpatentability relating to claims 16 and 19–24 of the '228 patent.

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '228 patent is 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 given of the institution of a trial.

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