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Paper 41
Entered: June 25, 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 IPR2014-00395
Patent 6,482,228 B1

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

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

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

an *inter partes* review of claims 16 and 19–24 (the "challenged claims") of U.S. Patent No. 6,482,228 B1 (Exhibit 1001, "the '228 patent"). 35 U.S.C. § 311. Troy R. Norred, M.D. ("Dr. Norred" or "Patent Owner") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). On June 27, 2014, we instituted an *inter partes* review of all challenged claims, Paper 13 ("Dec." or "Institution Decision"), on the following grounds:

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

Dec. 20.

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

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

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

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

B. Related Matters

Medtronic and Dr. Norred identified, as related proceedings, the co-pending litigation titled *Troy R. Norred, M.D. v. Medtronic, Inc.*, No. 2:13-CV-02061 (D. Kan.). Pet. 1; Paper 11, 5. Two proceedings before the Board involving the same parties, IPR2014-00110 and IPR2014-00111, also are identified as related proceedings. Pet. 1; Paper 11, 5–6.

C. The '228 Patent

The '228 patent relates to a percutaneous aortic heart valve that is placed by catheter and held in place with a stent system. Ex. 1001, 1:6–9, 1:29–31. Figures 10 and 11 of the '228 patent are reproduced below.

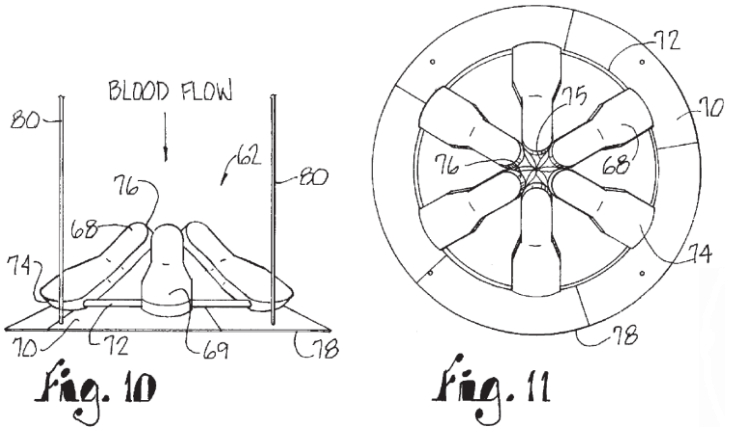


Fig. 10 Fig. 11

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, generally ring-shaped base 70, and ring 72 secured to base 70. *Id*. at 4:54–64. Base 70 may be seated against the root of the aortic valve. *Id*. at 5:17–19. Rim 78 of base 70 is made of a pliable biocompatible material and seals against the root of the native aortic valve to reduce peri-valvular leaks. *Id*. at 5:18–20. Valve 66 is anchored along the root of the aortic valve with connecting rods 80, which are connected to ascending aortic stents 28. *Id*. at 5:21–23.

The ’228 patent describes additional embodiments of an aortic heart valve in which the valve structures differ. *See, e.g.*, *id*. at 4:5–52 (describing umbrella valve 30 illustrated in Figures 6–9), 5:33–62 (describing trihedral valve 82 illustrated in Figures 14–17), 5:63–6:8 (describing biological valve 100 illustrated in Figures 18 and 19). Nevertheless, the illustrated embodiments of the aortic valves are held in place via a mechanical attachment to a stent that seats against the aortic wall. *See id*. at 4:8–9, 5:21–23, 5:48–51, 6:3–7 (describing connecting rods that attach valves to stent).

Claims 16 and 20, which are the only independent claims among the challenged claims, recite:

> 16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:
>
> a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;
>
> a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and
>
> means for mounting said first open end of said membrane about said ring aperture with said second open end displaced

> therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

Ex. 1001, 7:59–8:12.

> 20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:
>
> a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;
>
> a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;
>
> means for maintaining said ring member in said seated position about the aortic wall,
>
> said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.

Id. at 8:27–42.

II. ANALYSIS

A. Claim Interpretation

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

(Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question." (internal quotation marks omitted)). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999).

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." In our Institution Decision, we interpreted the "means for maintaining" recited in claims 19 and 20 under 35 U.S.C. § 112, ¶ 6. Dec. 12. Based on our review of the Specification, we identified the combination of rods 104 interacting with stent 28 as the structures for performing the recited "maintaining" function. We, therefore, interpreted the "means for maintaining" as rods 104[1] interacting with stent 28 and equivalent structures. *Id*. at 12–13.

During the trial, Dr. Norred argued that the "means for maintaining" refers not only to a stent, but also requires that the stent be configured to extend into the ascending aorta. PO Resp. 10. Medtronic suggests that a "more precise construction" is "rods 104 **to interact with** stent 28." Reply 8 n.12. For the reasons expressed below, we maintain our previous interpretation of "means for maintaining" as referring to the combination of

[1] Other structures identified in the Specification for performing the maintaining function are connecting rods 80 interacting with stent 28. Ex. 1001, 5:47–50. We refer to connecting rods 104 throughout our analysis for convenience.

rods 104 interacting with stent 28 and their equivalent structures and we reject both parties' arguments for altering that interpretation.

It is well established that the use of the term "means" triggers a rebuttable presumption that § 112, ¶ 6 governs the construction of the claim term. *Williamson v. Citrix Online, LLC*, No. 2013-1130, 2015 WL 3687459, at *7 (en banc) (Fed. Cir. June 16, 2015); *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 "means for maintaining" is a "means plus function" phrase that is interpreted under § 112, ¶ 6.

The first step in the construction of a means-plus-function claim element is to identify the particular claimed function. *Micro Chem., Inc. v. Great Plains Chem. Co., Inc.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999). The second step in the analysis is to look to the specification and identify the corresponding structure for that function. *Id.* "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 Med. Inc., v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). Claim interpretation under § 112, ¶ 6 does not "permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem*, 194 F.3d at 1258.

The function recited in the "means for maintaining" of claims 19 and 20 is "maintaining said ring member in said *seated* position about the aortic wall."[2] Ex. 1001, 8:37–38 (emphasis added). Thus, the focus is on the "ring member," and a determination of the structure that maintains ring member 102 in a *seated* position about the aortic wall.

Based on Medtronic's suggested "more precise" construction, the parties' constructions for the "means for maintaining" phrase appear to be similar, but, in fact, are very different. Medtronic asserts that the challenged claims are limited to an aortic valve. Reply 8 n.2 ("the claims are directed to the 'aortic valve' and not a valve/stent combination"); *see also* Tr. 16:3–7 ("[t]he claims are all directed to a valve . . . [t]he claims are really directed to the valve alone"). Thus, Medtronic's proposed construction, including the "more precise" suggestion in Medtronic's Reply (Reply 8 n.2), does *not* include the stent as an element of the "means for maintaining."

Dr. Norred agrees that claim 16 is directed solely to the valve, but maintains that claims 19–24, which recite the "means for maintaining," are

[2] Claim 19 recites substantially the same function using slightly different phrasing as follows: "means for maintaining said ring member in said seat about the aortic wall." Ex. 1001, 8:25–26. We do not consider the different phrasing to be material to our analysis.

directed to the combination of a valve and stent. Tr. 37:25–38:4.[3] Dr. Norred asserts that "the rods cannot maintain the valve in place by itself. It is the interaction with the stent system" that maintains the ring member in a seated position about the aortic wall. Tr. 37:2–3. We are persuaded that Dr. Norred's construction is correct.

The Specification discloses rods that are part of the stent and rods that connect the valve to the stent system. Stent system 28 comprises a small slotted stainless steel tube or series of *interconnected rods*, which form an expandable cylindrical lattice or scaffolding. Ex. 1001, 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 along the root of the aortic valve with rods 104 *connected to* stents 28. *Id.* at 6:4–6, *see also id.* at 4:6–9 (valve 30 is anchored with rod 56 connected to stent struts 58), 5:21–23 (valve 66 is anchored with rods 80), 5:47–50 (valve 82 is anchored with connecting rods, not shown). The Specification also states, generally, that the valve is anchored "by a stent system," and the rods connect the valve to the stent. Ex. 1001, 1:30–31, 1:63–64. Thus, rods 104 on valve 100 and stent system 28 are related inextricably in performing the function of maintaining the valve, and hence the ring member, which is part of the valve, anchored along the root of the aortic valve.

[3] Q. "would you agree that Claim 16 is directed solely to the valve?
MR. KERNELL [counsel for Patent Owner]: Yeah. You know, I think that's fair that that is the valve as it's maintained or that the valve that's implanted and that Claim 19 [and claims 20–24] adds the means for maintaining, which is the stent system, the ascending aortic stent system."

The function recited in the "means for maintaining" in claims 19 and 20 is maintaining the ring member in a "*seated* position about the aortic wall." Ex. 1001, 8:37–38 (emphasis added). The written description in the Specification distinguishes between *seating* and *sealing*. *See, e.g.*, Ex. 1001, 5:16–20 ("Base 70 is *seated* against the root of the aortic valve . . . The rim 78 of base 70 is made of a pliable biocompatible material which *seals* against the root of the native aortic valve.") (emphasis added). In the written description, ring 102 is described as "made of a pliable biocompatible material which *seals* against the root of the native aortic valve 34." Ex. 1001, 6:1–9 (emphasis added). The Specification describes valve 100 as "anchored" along the root of the aortic valve. *Id.* There is no explicit disclosure about ring 102 seating about the aortic wall.

The claims themselves provide substantial guidance as to the meaning of particular claim terms. Independent claim 20 states the ring member has "an outer circumference" adapted "to *seat*" the ring member about an aortic wall surrounding an aortic channel. *Id.* at 8:33–36 (emphasis added). Claim 24, dependent from claim 20, states that the ring member "contacts the wall of the aortic channel and *seals* said ring against the aortic channel wall." *Id.* at 8:56–59 (emphasis added).

Dependent claims must further limit the claim from which they depend. 35 U.S.C. § 112, ¶ 4 ("a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) ("the presence of a dependent claim that adds a particular limitation gives rise to a

presumption that the limitation in question is not present in the independent claim"). Thus, the presumption is that a ring member that *seals*, as recited in claim 24, is different from a ring member that *seats*, as recited in claim 20.

In describing the general relationship of the valve and stent system, the Specification states that when the valve/stent combination is in position, an angioplasty balloon inflates to expand the stent scaffolding and force the stent system against the inner walls of the ascending aorta to anchor the valve in place. Ex. 1001, 3:7–10. We construe the requirement to "seat" in the "means for maintaining" clause in claim 20 to mean that the ring is anchored, or forced, against the aortic wall. We decline to require that seating and sealing are synonymous because the evidence of record does not support such a construction.

Thus, based on the Specification, it is the combination of rods 104 interacting with stent system 28 that anchors valve 100 and seats ring member 102. Without the stent, there is no structure to maintain the ring member in seated position. Accordingly, it is rods 104 interacting with stent system 28 that is the structure corresponding to the "means for maintaining" called for in claims 19 and 20. This corresponding structure, and equivalents thereof, is the broadest reasonable construction of the "means for maintaining" the ring member in seated position. We are not persuaded to modify this construction as suggested by either party.

B. The Challenges to the Claims

"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 challenge below.

Our Scheduling Order in this case cautioned Dr. Norred that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 14, 2–3. 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) 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. at 12 (PTAB Jan. 29, 2015) (Paper 41).

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

In the Patent Owner's Response, Dr. Norred presents argument and evidence to establish that both Leonhardt and Bailey fail to disclose the "ring member" (required by claims 16 and 19–24) and "means for maintaining" (required by claims 19–24). Dr. Norred does not present

persuasive evidence or argument on the remaining elements of the claims, that is, those elements other than the "ring member" and the "means for maintaining." Thus, the record now contains the same arguments and evidence regarding the merits of Leonhardt's and Bailey's alleged anticipation with regard to the remaining elements of the claims as it did at the time of our Institution Decision. Thus, the preponderance of the evidence of record developed at trial supports our conclusion that Medtronic has set forth how these remaining limitations of the challenged claims are taught by Leonhardt and Bailey. Accordingly, we do not address these remaining limitations in our discussion below.

1. Anticipation of Claims 16 and 19–24 by Leonhardt

Leonhardt generally describes a percutaneously placed artificial valve "to maintain bodily fluid flow in a single direction" to "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.

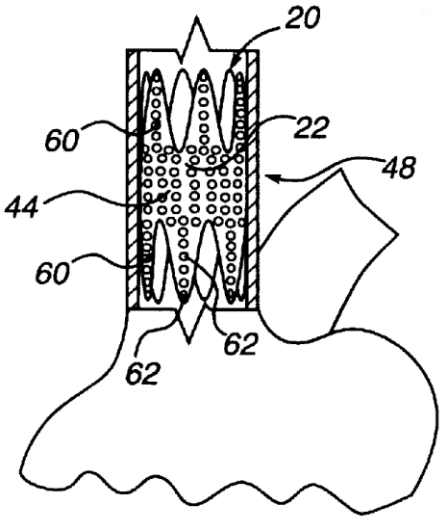


FIG. 3

Figure 3 depicts Leonhardt's valve stent 20 fully deployed with the aorta above the aortic valve.

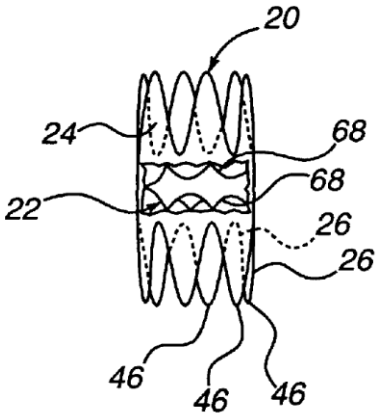


FIG. 4

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 heart valve discloses each element of all challenged claims. Pet. 15–17, App. A-1. Dr. Norred argues that Medtronic's showing that Leonhardt anticipates claims 16 and 19–24 is deficient for two reasons, and we address each in turn below.

a) Ring Member—Claims 16 and 19–24

(1) Claims 16 and 19–23

Dr. Norred contends that Leonhardt fails to disclose the claimed ring member because Leonhardt's stent 26 is not made of a pliable material. PO Resp. 8–10. Even if we were to accept Dr. Norred's contention that the

claimed ring member must be made of a pliable material,[4] Dr. Norred's argument is unpersuasive. Leonhardt's stent 12 is preferably formed of superelastic nitinol wire. Ex. 1004, 3:48–56, 4:27–29, 4:63–5:2. Dr. Norred's expert witness, Dr. Catchings, testified that he considers nitinol to be a pliable material. Ex. 1023, 195:8–10. Therefore, we find that Leonhardt describes a ring member that is made of pliable material and reject Dr. Norred's argument that Leonhardt fails to teach the ring member recited in claims 16 and 19–24.

(2) Claim 24

Claim 24 further recites that "said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound." Ex. 1001, 8:56–59. Dr. Norred contends that Leonhardt's stent 26 is merely temporarily sealed to the wall of the aorta using a light-activated bioadhesive and, therefore, fails to "seal" against the aortic channel wall. PO Resp. 9. Dr. Norred reasons that the temporary nature of Leonhardt's seal is evident because the stent 26 may be repositioned or removed after it is fully implanted. *Id*. (citing Ex. 1004, 3:4–6, 3:27–30, 11:37–53).

We are not persuaded by Dr. Norred's argument. Dr. Norred identifies no basis for interpreting claim 24 such that its seal must be permanent. A temporary seal is a seal within the meaning of "seal" as

[4] The parties dispute whether the claims recite a "ring member" that must be made from pliable material. We need not resolve that dispute here because we find that Medtronic has identified a structure in each of Leonhardt and Bailey as the claimed ring member and each of those structures is made of a pliable material.

recited in claim 24. Even if we were to conclude that claim 24 requires a permanent seal, we remain unpersuaded by Dr. Norred's argument. Claim 24 by its plain terms refers to a seal that "reduce[s] blood flow" around the ring member. Leonhardt meets this limitation as well. For example, Leonhardt describes that the stent is sized "to be approximately thirty percent (30%) larger in diameter than the largest diameter of the tissue against which the valve stent 20 (FIG. 3) will seal." Ex. 1004, 5:3–5. The seal that Leonhardt describes is precisely the type of seal recited in claim 24. Accordingly, we reject Dr. Norred's argument that Leonhardt fails to describe the ring member recited in claim 24.

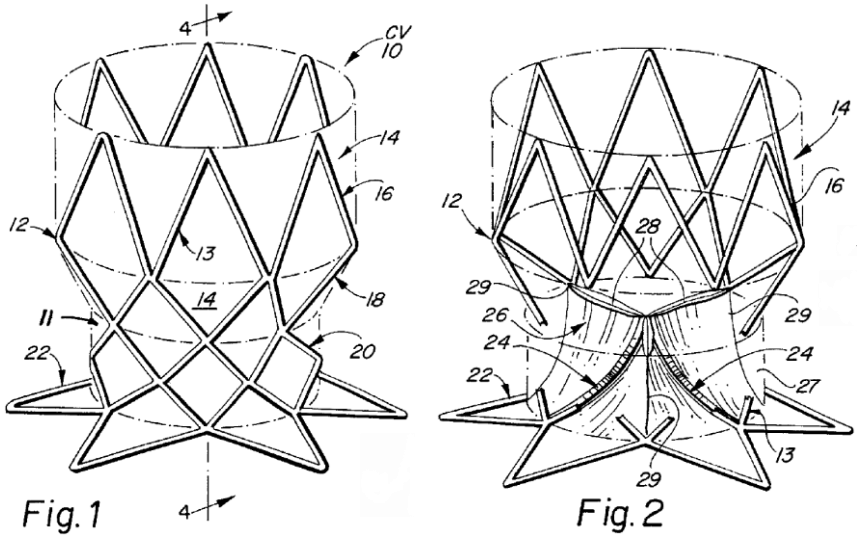
b) Means for Maintaining—Claims 19–24

Dr. Norred argues that Leonhardt fails to describe the "means for maintaining." PO Resp. 10–11. Dr. Norred's argument is premised upon our acceptance of his proposed limitation on the claimed "means for maintaining" that would require the claimed means to be positioned in the ascending aorta. For reasons expressed in part II.A above, we decline to interpret the "means for maintaining" as being so limited. Even if we were to accept Dr. Norred's proposed interpretation, the argument would remain unpersuasive because Leonhardt's stent is "fully deployed within the aorta above the aortic valve." Reply 2 (citing Ex. 1004, 3:59–60, Fig. 3). Accordingly, we reject Dr. Norred's argument that Leonhardt fails to describe the "means for maintaining" recited in claims 19–24.

2. Anticipation of Claims 16 and 19–24 by Bailey

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, 6B. Bailey's artificial valve is held in place by two different anchor sections, proximal anchor flange 22 and distal anchor portion 16. *Id*. at 5:61–6:7, 8:40–43.

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 argues that Medtronic's showing that Bailey anticipates claims 16 and 19–24 is deficient for three reasons, and we address each in turn below.

a) Dr. Norred's Alleged Priority of Invention over Bailey

Dr. Norred asserts that he conceived subject matter of the challenged claims no later than December 21, 1998, and diligently reduced that subject

matter to practice from that conception date until filing the application that matured into the '228 patent on November 14, 2000.[5] PO Resp. 12–30. Dr. Norred bears the burden to establish the facts necessary to overcome Bailey's filing date. *In re Facius*, 408 F.2d 1396, 1403–04 (CCPA 1969) (holding, in a prosecution context, that an earlier filed reference was prima facie available as prior art and placing the burden on the party claiming prior invention to overcome that reference). Dr. Norred may meet his burden by providing evidence that the effective date of the reference is not "before the invention by the applicant for patent," that is, antedating the Bailey reference. 35 U.S.C. § 102(e) (2000).

The application resulting in the issuance of Bailey was filed on December 31, 1999, and Bailey issued on October 1, 2002. The application that matured into the '228 patent was filed on November 14, 2000. Bailey is available as prior against the challenged claims under 35 U.S.C. § 102(e)(2) as of December 31, 1999, unless Dr. Norred establishes that he conceived the claimed subject matter before December 31, 1999, and diligently worked to reduce that subject matter to practice until November 14, 2000.[6] We

[5] Dr. Norred states that November 20, 2000, is the filing date of the application leading to issuance of the '228 patent. PO Resp. 21. Nevertheless, that application was filed on November 14, 2000. Ex. 1001, Cover Page.

[6] The governing statute provides: "A person shall be entitled to a patent unless . . .

> (e) the invention was described in . . . (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent."

35 U.S.C. § 102(e) (2000).

evaluate Dr. Norred's arguments and evidence under the general standards established in 37 C.F.R. § 1.131, which states:

> When any claim of an application or a patent under reexamination is rejected, the applicant or patent owner may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.

37 C.F.R. § 1.131(a). The standards by which we evaluate Dr. Norred's asserted date of invention are stated in 37 C.F.R. § 1.131(b), which states:

> The showing of facts for an oath or declaration under paragraph (a) of this section shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

37 C.F.R. § 1.131(b).

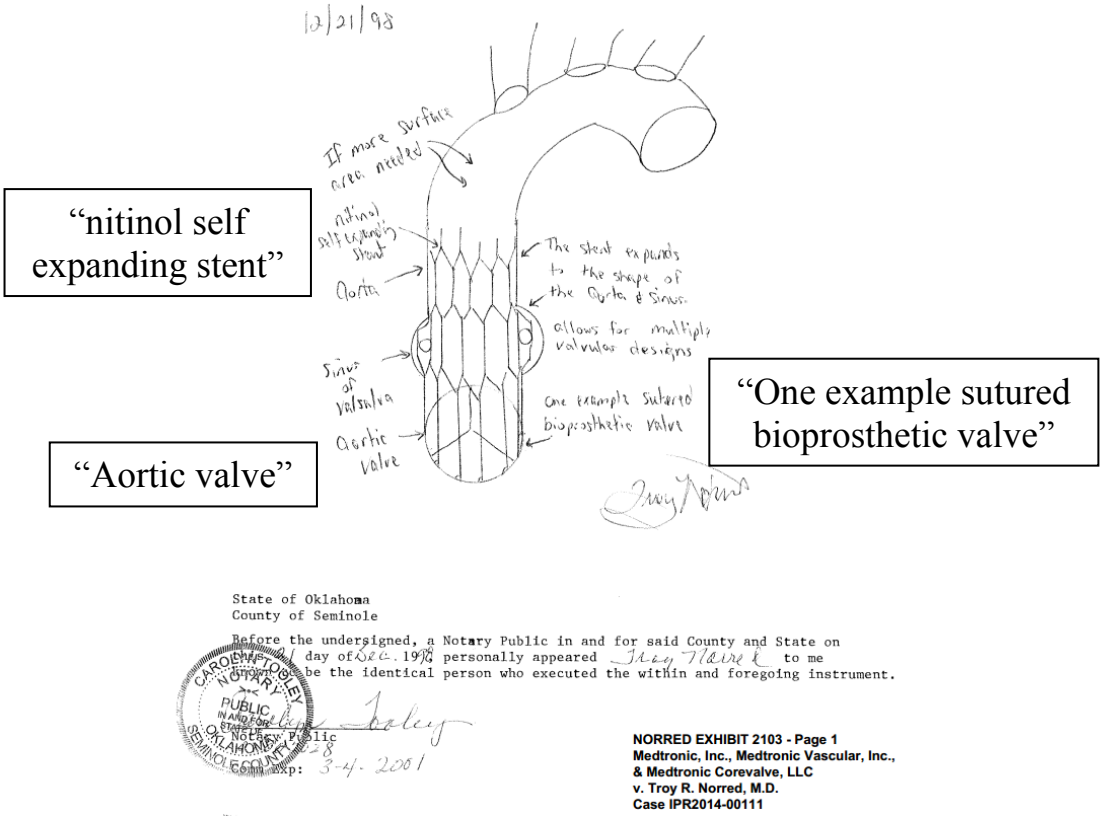
The required conception of the invention is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Dawson v. Dawson*, 710 F. 3d 1347, 1352 (Fed. Cir. 2013); *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (citing *Gunter v. Stream*, 573 F.2d 77, 80 (CCPA 1978)). Based on that definition, our reviewing court has held that "[c]onception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation," and that "[a]n idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Id.*

Thus, conception 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).

Dr. Norred asserts that he conceived the invention "no later than December 21, 1998." PO Resp. 12 (citing Ex. 2203 and Ex. 2293 ¶ 27). According to Dr. Norred, Exhibit 2203 "depicts each limitation set forth in

claims 16 and 19 of the '228 Patent." PO Resp. 13–19. Exhibit 2203 is a sketch dated "12/21/98." Exhibit 2203, annotated to identify more clearly the labeled elements, is reproduced below.



Annotated Exhibit 2203 is a handmade sketch of a stent and valve notarized as being signed by "Troy Norred" on December 21, 1998.

Dr. Norred states that Exhibit 2203 shows "the stent system as deployed in the aorta, attached through connecting rods to the ring member." PO Resp. 19.

Medtronic asserts that Exhibit 2203 "only identifies two elements of an aortic device: (1) a 'nitinol self-expanding stent' that 'expands to the shape of the aorta and sinus;' and (2) a 'sutured bioprosthetic valve.'" Reply 7. According to Medtronic, Exhibit 2203 fails to show a ring member surrounding a tissue valve (*id.*), or rods interacting with a stent to form the

"means for maintaining" structure discussed above. The ring member is recited in claims 16 and 19–24, and the "means for maintaining" is recited in claims 19–24.

After reviewing Exhibit 2203 and Dr. Norred's supporting arguments, we are not persuaded that the drawing supports Dr. Norred's assertion that he conceived the claimed valve as of December 21, 1998. Rather, we agree with Medtronic 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 7. The detail in the sketch is insufficient to describe, for example, a "ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel" (claims 16 and 19) or a "ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall" (claims 20–24). The circle in the sketch that Dr. Norred identifies as the ring member is described in the sketch itself as "a sutured bioprosthetic valve." Dr. Norred has testified that his invention was intended to "seal the device against the root of the native valve upon placement *without sutures*." Ex. 2293 ¶ 61 (emphasis added). Dr. Norred also states that the invention of the '228 patent "relies on the stent system alone to anchor the device and *eliminate the need for sutures* and other means of active fixation." *Id.* ¶ 62 (emphasis added). According to Dr. Norred, if "sutures were necessary to create a seal, then surgery would be necessary to create a seal, and my invention could not serve the purpose for which it was intended." *Id.* ¶ 61. Dr. Norred's testimony about eliminating the need for sutures and surgery is consistent with the disclosure in the '228 patent, which states that the

disclosed invention is placed "percutaneously," that is, without the need for surgery. Ex. 1001, Abstract, 1:6–9. Accordingly, the sutured valve shown in Exhibit 2203 does not provide persuasive evidence that Dr. Norred conceived a valve, as of the creation of the sketch, that eliminates the need for sutures that he states was his "invention." The annotations on the sketch, thus, appear to be inconsistent with Dr. Norred's testimony that the sketch illustrates a ring member. Because the sketch does not clearly show a ring member, Dr. Norred's contentions otherwise constitute uncorroborated testimony created for this proceeding, more than fifteen years after the sketch was made. Ex. 2293 ¶¶ 7, 86.

Dr. Norred bears the burden to establish the facts necessary to overcome Bailey. *In re Facius*, 408 F.2d at 1403–1404 (holding that an earlier filed reference was *prima facie* available as prior art and placing the burden on the party claiming prior invention to overcome that reference). Based on the totality of the evidence on which Dr. Norred relies, the evidence does not establish that the subject matter recited in claims 16 and 19–24 was conceived prior to December 31, 1999. Thus, we conclude that Bailey is prior art to the claims at issue under 35 U.S.C. § 102(e).

b) Ring Member—Claims 16 and 19–24

(1) Claims 16 and 19–23

Dr. Norred contends that Bailey fails to disclose the claimed ring member because Bailey's stent 12 is not made of a pliable material. PO Resp. 33–35. Even if we were to accept Dr. Norred's contention that the claimed ring member must be made of a pliable material, Dr. Norred's argument is unpersuasive. Bailey's stent 12 is preferably formed of superelastic nitinol. Ex. 1006, 8:33–34. Dr. Norred's expert witness, Dr.

Catchings, testified that he considers nitinol to be a pliable material. Ex. 1023, 195:8–10. Therefore, we find that Bailey describes a ring member that is made of pliable material and reject Dr. Norred's argument that Bailey fails to teach the ring member recited in claims 16 and 19–23.

(2) Claim 24

Claim 24 further recites that "said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound." Ex. 1001, 8:56–59. Dr. Norred contends that Bailey's stent (ring member) fails to seal against the aortic channel. PO Resp. 34–35 (citing Ex. 1006, 10:15–24). Dr. Norred contends that Bailey expressly contemplates the removal of struts from its stent body member 12, which necessarily would destroy the seal against the aortic channel. PO Resp. 34–35.

We are not persuaded by Dr. Norred's argument. Claim 24 merely requires a seal sufficient to reduce blood flow around the ring member, which we read as being between the wall of the aortic channel and the ring member. Dr. Norred cites no persuasive evidence that removing any of the struts in Bailey's stent would result in blood flowing between the remaining struts in Bailey's stent and the wall of the aorta or that Bailey describes removing so many struts that the stent no longer has a circumference as recited in the claims. In support of this argument, Dr. Norred cites a portion of Bailey that reads:

> Similarly, the stent struts of the CV valve stent 10 may be oriented in such a manner as to create interstices of greater or smaller area between adjacent struts, to accommodate a particular patient anatomy. For example, where the stent struts in the distal anchor section 16 would overly [sic] an artery branching from the aorta, such as the coronary ostreum arteries,

> it may be desirable to either eliminate certain stent struts, or to configure certain stent struts to define a greater interstitial area to accommodate greater blood flow into the coronary ostreum.

Ex. 1006, 10:15–24. This passage merely indicates that portions of the stent may be removed to allow blood to flow into the aorta through an artery that discharges into the aorta. We see no indication that blood flowing through the aorta would flow between the remaining portions of the stent and the wall of the aorta. Accordingly, we reject Dr. Norred's argument that Bailey fails to describe the ring member recited in claim 24.

c) Means for Maintaining—Claims 19–24

Dr. Norred contends that Bailey fails to disclose the "means for maintaining" that is recited in claims 19–24. PO Resp. 35–38. Dr. Norred contends that Bailey's stent 12 may only describe the "means for maintaining" if "insubstantial differences" exist between Bailey's stent and the "means for maintaining." PO Resp. 35 (citing *Pacific Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, 739 F.3d 694, 700 (Fed. Cir. 2014)). Dr. Norred then argues that the presence in Bailey's stent 12 of proximal anchor flange 22 precludes a finding that Bailey's stent 12 is a "means for maintaining" because "the flange likely will pierce the aortic wall" and create to other problems for the patient. PO Resp. 36–38.

Dr. Norred's argument rests upon an incorrect formulation of the legal standard for evaluating whether a structure in the prior art is the same or equivalent to a structure claimed as a means-plus-function format. The standard is not simply reduced to whether the two structures being compared have "insubstantial differences." The Federal Circuit described the test for determining whether a claimed means for performing a function covers a

structure in another device in the context of performing an infringement analysis as follows:

> "Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent" to the structure identified in the written description as corresponding to the recited function. . . . For the relevant structure in the accused device to be equivalent to the structure in the written description, differences between the two must be insubstantial. . . . For example, the structure in the accused device must perform the claimed function in substantially the same way to achieve substantially the same result as the structure in the written description.

JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1333 (Fed. Cir. 2005) (citing *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999)). Accordingly, the inquiry is whether Bailey's stent 12 performs the "maintaining" function in substantially the same way to achieve substantially the same result.

Medtronic contends that Bailey's stent meets these requirements because Bailey's stent 12 engages the tissue of the aortic wall to retain the valve in position. Pet. 20, App. A-3 at 14 (citing Ex. 1006, 1:28–38, 5:61–6:9, 7:58–8:19). These passages of Bailey indicate that stent 12 includes distal anchor section 16, which "radially expands to contact the vascular wall and retain the prosthesis in position." Ex. 1006, 6:5–7. Bailey's stent 12 also includes intermediate annular section 20 to which valve arms 24 are connected. Ex. 1006, 9:25–29. We have determined that the "means for maintaining" refers to connecting rods 104 interacting with stent 28 and equivalent structures. The Specification describes stent system 28 as maintaining the ring member in its seated position in the same manner as Bailey's distal anchoring portion 16 of Bailey's stent 12, namely by

expanding against the inner wall of the aorta. Ex. 1001, 3:7–10. The Specification also describes rods 104 as being connected to stent 28 to assist in maintaining the ring member in its seated position. Bailey's intermediate annular section 20 maintains valve body 26 in its intended location relative to stent 12. Ex. 1006, Fig. 4.

III. MOTION FOR OBSERVATION

Dr. Norred's Motion for Observation pertains to the testimony of Alexander J. Hill, Ph.D. on cross-examination. We have considered Dr. Norred's observations (Paper 32) and Medtronic's responses (Paper 34).

IV. MOTION TO AMEND

Because we have found claims 16 and 19–24 to be unpatentable as anticipated by each of Leonhardt and Bailey, we turn to Dr. Norred's Motion to Amend Claims. In the Motion to Amend, Dr. Norred moves to substitute claim 25 for challenged claims 16 and 20 and to substitute claim 26 for challenged claim 19.[7] Proposed substitute claim 25 is shown below in markup form as compared to the original claim 20[8] for which it is proposed as a substitute.

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[7] In the markup of proposed claim 26, Dr. Norred refers to claim 19 as the claim for which substitution is sought. The text of Dr. Norred's Motion to Amend states that proposed claim 26 is intended as a substitute for claim 24. The marked up version of proposed claim 26 reflects changes from original claim 19. We, therefore, understand the Motion to Amend to seek substitution of claim 26 for claim 19.

[8] Dr. Norred indicates in his Amend Reply that "[c]laim 16 is eliminated in its entirety. Amend Reply 1. Therefore, we understand the Motion to Amend to seek cancellation of claim 16 and substitution of proposed claim 25 for claim 20. Dr. Norred's marked up version of proposed claim 25 does not accurately reflect all changes between proposed claim 25 and original

25. (Proposed substitute for claims 16 and 20) An aortic valve for controlling a blood flow through an aortic channel upon percutaneous 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 a[[n]] pliable outer circumference adapted to seat said ring member ~~about~~ against an aortic wall surrounding an aortic channel and seal against a root of a native aortic valve; and

~~means for maintaining said ring member in said seated position about the aortic wall,~~ a stent system having a plurality of interconnected rods;

said ring member connected to one or more of said plurality of interconnected rods;

said stent system anchoring said ring member in said seated position against the aortic wall;

said tissue valve interior member responsive to pressure changes [~~of conditions~~] within the aorta for movement of said opening between said ~~a first~~ closed ~~position~~ and ~~a second~~ open positions;

said aortic valve having a first collapsed configuration for placement inside a catheter, and a second expanded configuration when deployed from said catheter and percutaneously placed.

26. (Proposed substitute for claim 19) The aortic valve as claimed in claim ~~20 further comprising means for maintaining said ring member in said seat about the aortic wall~~ 25 wherein

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claim 20. We have supplied a marked up version of proposed claim 25 that accurately reflects all the differences between proposed claim 25 and original claim 20.

> said stent system is expanded in the ascending aorta to anchor said aortic valve 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, Medtronic argues that proposed claim 25 is broader in scope as compared to original challenged claim 20. Amend Opp. 7. Medtronic contends that the proposed changes replacing the "means for maintaining" in claim 20 with "a stent system having a plurality of interconnected rods," broadens the claim by eliminating the connecting rods 104. *Id.*

Dr. Norred responds that the proposed change does not enlarge the scope of claim 20 because claim 20 recites affirmatively "a plurality of interconnected rods" along with a "stent system," which are the structures identified as performing the "maintaining" function in the "means for maintaining." Amend Reply, 1–2.

We are persuaded that Dr. Norred's proposed amendment impermissibly broadens the scope of claim 20. As discussed above, we construed the phrase "means for maintaining" to mean "connecting rods 104 interacting with stent 28" and equivalents of those structures. The proposed amendment now recites a "stent system having a plurality of interconnected rods." Mot. Amend 2. The Specification describes stent 28, which is merely part of the structure that performs the maintaining function, as follows: "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." Ex. 1001, 2:61–63. Accordingly, affirmatively reciting that the stent system has "a plurality of interconnected rods" merely describes what was already part of the stent system that is described in the '228 patent.

Proposed claim 25 would now cover devices that completely lacked the separately described connecting rods 104, which were previously required as part of the "means for maintaining." Accordingly, we conclude that proposed claim 25 impermissibly enlarges the scope of original claim 20. Proposed claim 26 depends from proposed claim 25 and does not narrow the improperly broadened limitation in proposed claim 25. For these reasons, we deny Dr. Norred's Motion to Amend.

V. CONCLUSION

We determine that Medtronic has demonstrated by a preponderance of the evidence that claim 16 and 19–24 are unpatentable as anticipated by Leonhardt under 35 U.S.C. § 102(b) and by Bailey under 35 U.S.C. § 102(e).

In addition, we determine that Dr. Norred has failed to demonstrate by a preponderance of the evidence an entitlement to entry of the proposed substitute claims 25 and 26. We, therefore, deny Dr. Norred's Motion to Amend.

VI. ORDER

For the reasons given, it is:

ORDERED that claims 16 and 19–24 of the '228 patent are held *unpatentable*;

FURTHER ORDERED that Dr. Norred's Motion to Amend is *denied*;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 318(b), upon expiration of the time for appeal of this decision, or the termination of any such appeal, a certificate shall issue canceling claims 16 and 19–24 in U.S. Patent No. 6,482,228 B1; 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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