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Paper 47
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 IPR2014-00111
Patent 6,482,228 B1

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

GROSSMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

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

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

Neither party filed motions to exclude evidence.

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

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

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

A. Related Proceedings

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

[1] US Patent 6,454,799 B1, filed April 6, 2000, patented September 24, 2002.
[2] US Patent 6,139,575, filed April 2, 1999, patented October 31, 2000.

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

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

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

B. The ’228 Patent

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

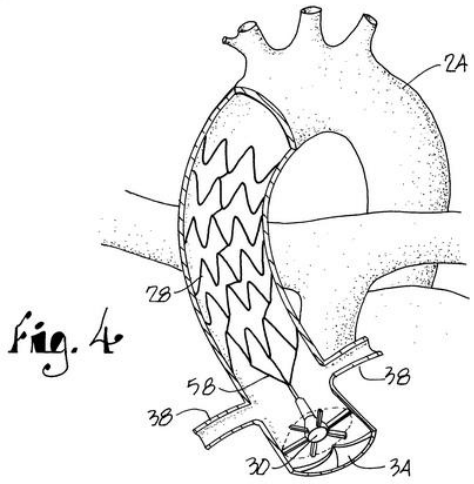

Figure 4 of the ’228 patent illustrates an exemplary placement of valve 30 above aortic valve 34 and below coronary arteries 38.

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

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

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

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

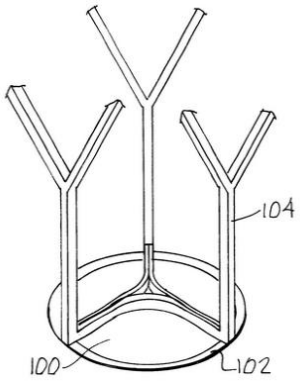

Fig. 18

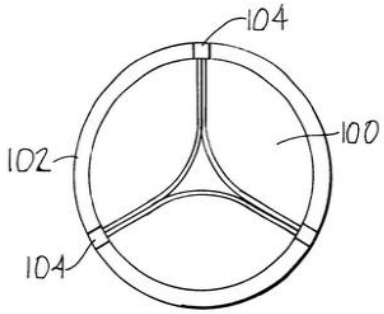

Fig. 19

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

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

C. Illustrative Claim

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

> 20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:
>
> a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;
>
> a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

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.

II. ANALYSIS

A. Claim Construction

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 Technologies LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. 2015) ("Congress implicitly adopted the broadest reasonable interpretation standard in enacting the AIA," and "the standard was properly adopted by PTO regulation."). Claim terms also 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).

If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). If a feature is not necessary to give meaning to what the inventor means by a claim term, it would be "extraneous" and should not be read into the claim. *Renishaw PLC*, 158 F.3d at 1249; *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co*., 849 F.2d 1430, 1433 (Fed. Cir. 1988).

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).

Against this background of general principles, we construe relevant terms in the ’228 patent.

Petitioner proposes specific constructions for the claim terms “tissue” and “means for maintaining.” Pet. 8. Patent Owner does not propose any specific claim constructions in the Patent Owner Response.

1. “*Tissue*”

Petitioner proposes that the claim term “tissue” is a “biological tissue, such as cadaver and porcine tissue.” Pet. 8.

The written description in the ’228 patent uses the word “tissue” only once. Ex. 1001, col. 5, l. 64. This sole use is in the context of describing various valve designs and states that “designs which 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 col. 5, ll. 63–66. The Specification refers to Figures 18 and 19, which illustrate “a cadaver/porcine incorporated valve and stent system.” *Id.* at col. 5, l. 67, col. 2, ll. 48–51.

The claims recite the term “tissue” without specifying 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 Commc’ns, 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

construction in light of the Specification of the claim term "tissue" is "biological tissue."

2. "Means for Maintaining"

Petitioner asserts the phrase "means for maintaining said ring member in said seated position about the aortic wall," as used in claim 20, is to be construed as a "means plus function" limitation under 35 U.S.C. § 112 ¶ 6.[3] Pet. 8. 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. *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.*, 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

[3] Section 4(c) of the Leahy-Smith America Invents Act ("AIA") re-designated 35 U.S.C. § 112 ¶ 6, as 35 U.S.C. § 112(f). Pub. L. No. 112-29, 125 Stat. 284, 296 (2011). Because the '228 patent has a filing date before September 16, 2012 (effective date of § 4(c)), we will refer to the pre-AIA version of § 112.

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 claim 20 is "maintaining said ring member in said *seated* position about the aortic wall." Ex. 1001, col. 8, ll. 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.

Petitioner asserts that the structure described in the '228 patent for performing the claimed function is "connecting rods 104," which anchors valve 100 along the root of the aortic valve. Pet. 8 (citing Ex. 1001, col. 6, ll. 4–5). Petitioner, thus, concludes that the "means" for performing the claimed function is "connecting rods" or an equivalent structure. *Id.*

Patent Owner does not argue a specific construction for the "means for maintaining phrase, but states that "[t]he "means for maintaining" disclosed in claim 20 is "rods 104 interacting with stent 28." PO Resp. 27. This is the construction adopted in the Decision to Institute. Decision 9. Petitioner suggests that a "more precise" construction than the construction in our Decision to Institute is "rods 104 **to interact with** stent 28." Pet. Reply 3, n. 1.

As explained below, we maintain and adopt the claim construction for the "means for maintaining" phrase stated in our Decision to Institute.

Based on Petitioner's suggested "more precise" construction, the parties' constructions for the "means for maintaining" phrase appear to be similar, but, in fact, are very different. Petitioner asserts that the challenged claims are limited to an aortic valve. Pet. Reply 3, n. 1("the claims are directed to the 'aortic valve' and not a valve/stent combination"); *see also*, Tr. 15, ll. 17–23 ("[t]he claims are all directed to a valve . . . [t]he claims are really directed to the valve alone"). Thus, Petitioner's proposed construction, including the "more precise" suggestion in Petitioner's Reply (Pet. Reply 3, n. 1), does *not* include the stent as an element of the "means for maintaining" phrase.

Patent Owner agrees that claim 16[4] is directed solely to the valve, but maintains that claims which recite the "means for maintaining" clause, which includes all the claims challenged in this proceeding, are directed to the combination of a valve and stent. Tr. 36, l. 13–Tr. 37, l. 21.[5] Patent Owner asserts that "the rods cannot maintain the valve in place by itself. It is the interaction with the stent system" that maintains ring member in a seated position about the aortic wall. Tr. 36, ll. 19–20. We are persuaded that Patent Owner'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, col. 2, ll. 61–63. In the context of the

[4] Claim 16 is not challenged in this proceeding.
[5] 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."

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 col. 6, ll. 4–6, *see also id.* at col. 4, ll. 6–9 (valve 30 is anchored with rod 56 connected to stent struts 58), col. 5, ll. 21–23 (valve 66 is anchored with rods 80), col. 5, ll. 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, col. 1, ll. 30–31, 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.

The function recited in the "means for maintaining" in claim 20 is maintaining the ring member in a "*seated* position about the aortic wall." Ex. 1001, col. 8, ll. 37–38 (emphasis added). The written description in the Specification distinguishes between *seating* and *sealing*. *See, e.g.*, Ex. 1001, col. 5, ll. 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, col. 6, ll. 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.*, col. 8, ll. 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.*, col. 8, ll. 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, col. 3, ll. 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, in the context of the tissue valve disclosed in Figures 18 and 19, 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 are the structure corresponding to the "means for maintaining" called for in claim 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 Petitioner.

3. Ring Member

The parties dispute whether the phrase "ring member," as used in the challenged claims, means a ring made of a pliable, biocompatible material. Petitioner asserts that the "[r]ing member is not limited to a pliable material." Tr. 5, l. 20–Tr. 6, l. 8; Ex. 1026 ¶¶ 39–42. Patent Owner asserts exactly the opposite, asserting that the ring member "has to be a pliable ring member." Tr. 38, ll. 1–7; Ex. 2195 ¶ 33. Patent Owner's explanation of its position is that, unless the ring member is pliable, "the ring member does not adapt to the aortic channel. The aortic channel adapts to that ring member." Tr. 38, ll. 1–7.

Claim 20 states that the ring member is "adapted to seat" about an aortic wall. Claim 24 states that the ring member contacts the wall of the aortic channel and seals against the aortic channel. We are not directed to any persuasive evidence that supports Patent Owner's position that the claims require the ring member to adapt or conform to the channel. The ring member must seat against the aortic wall (claim 20) or seat against the aortic wall and also seal against the aortic channel (claim 24). The specific implementation as to how it achieves the seated or sealed configuration is not recited in the claims.

Petitioner's Declarant, Alexander J. Hill, Ph.D.,[6] opined that:

> while pliability could be a factor relating to a sealing function, heart valve seals are often created with relatively rigid ring structures. This can be easily achieved because the aorta itself is pliable and will conform to the shape of a relatively rigid heart valve ring member. In addition, besides pliability, several other factors relate to a sealing function with the aorta, such as the surface area of the ring and amount of contact with the aorta.

Ex. 1026 ¶ 41. Thus, according to Dr. Hill, the ring need not be "pliable" because the aorta itself is pliable.

In the context of stating his opinion about the interpretation of claim 20, Patent Owner's Declarant, Timothy T. Catchings, M.D.,[7] opined that the ring member recited in claim 20 means "a ring made of pliable, biocompatible material." Ex. 2195 ¶ 33. Dr. Catchings also opined that "the ring member has a pliable circumference in order to seat about the aortic wall *and seal* against the root of the native aortic valve to reduce perivalvular leaks." *Id.* ¶ 39 (emphasis added). As discussed above, there is no requirement in claim 20 that the ring member seal against anything.

Based on the arguments and evidence, including the differing views of two expert declarants, we decline to limit the "ring member" to a specific material, as proposed by Patent Owner. There is no argument or evidence asserted by Patent

[6] Dr. Hill is a Senior Research Manager in the Cardiac and Vascular Group, Coronary and Structural Heart, for Petitioner Medtronic, Inc. *Id.* ¶ 11. He is also a Clinical Assistant Professor, Department of Surgery, at the University of Minnesota Medical School. *Id.* ¶ 10. He has approximately 15 years of experience in this field. *Id.* ¶¶ 7–20. Dr. Hill earned a Ph.D. degree in Biomedical Engineering in 2004.

[7] Dr. Catchings is a Board certified interventional cardiologist. *Id.* ¶ 6. He earned his medical degree in 1978. Dr. Catchings also is a Retired Captain in the Medical Corps of the U.S, Navy Reserve, and served in various medical positions with the Navy before entering private medical practice. *Id.* ¶¶ 8–9.

Owner that persuades us to read limitations concerning the material from which the ring member is made from the Specification into the claims. *Comark Commc'ns*, 156 F.3d at 1186 ("limitations from the specification are not to be read into the claims"); *Texas Instruments*, 805 F.2d at 1563 ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.").

B. Asserted Grounds of Unpatentability

1. Anticipation of Claims 20–24 by Schreck

Petitioner asserts that "each element recited in claims 20–24 is anticipated by Schreck," which qualifies as prior art under 35 U.S.C. § 102(e). Pet. 15.

Patent Owner asserts two reasons why Schreck does not anticipate claims 20–24 of the '228 patent. First, according to Patent Owner, Schreck does not anticipate the challenged claims "because Norred [the inventor and Patent Owner] conceived his invention prior to Schreck, and exercised reasonable diligence in constructively reducing it to practice." PO Resp. 6–7. Second, Patent Owner asserts that "Schreck does not disclose all of the prior art elements as arranged in claims 20–24." *Id.* at 7.

"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.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). "[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the

limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

a. Conception and Diligence

Schreck was filed on April 6, 2000, and issued on September 24, 2002. The application that matured into the '228 patent was filed on November 14, 2000. Schreck is available as prior under 35 U.S.C. §102(e)(2) as of April 6, 2000, against the challenged claims unless Patent Owner establishes that the invention in the challenged claims was invented before April 6, 2000 and diligently reduced to practice as of the filing date, November 14, 2000.[8]

Patent Owner asserts that the invention in the challenged claims was conceived no later than December 21, 1998 (PO Resp. 8) and was diligently reduced to practice from the conception date until the application that matured into the '228 patent was filed on November 14, 2000 (*id.* at 13).[9] Patent Owner bears the burden to establish the facts necessary to overcome Schreck'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). Patent Owner may meet its burden by providing evidence that the effective date of the

[8] 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)

[9] Page 13 of Patent Owner's Response states November 20, 2000, as the application filing date. The application filing date of the '228 patent is November 14, 2000. Ex. 1001, Cover Page.

reference is not "before the invention by the applicant for patent," that is, antedating the Schreck reference. 35 U.S.C. § 102(e) (2000).

We evaluate Patent Owner's arguments and evidence to establish an invention date prior to April 6, 2000, under the general standards established in 37 C.F.R. § 1.131. Rule 131(a) states:

> When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, [or] the owner of the patent under reexamination . . ., 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."

37 C.F.R. § 1.131(a). The standards by which we evaluate the invention date claimed are stated in Rule 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 to be thereafter to be applied in practice." *Dawson v. Dawson*, 710 F. 3d 1347, 1352 (Fed. Cir. 2013). 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.*

Patent Owner asserts that the invention was conceived "no later than December 21, 1998." PO Resp. 8 (citing Ex. 2103 and Ex. 2193 ¶ 27). According to Petitioner, Exhibit 2103 "depicts each limitation set forth in claims [20–24] of the '228 Patent." *Id.*

Exhibit 2103 is a sketch dated "12/21/98." Exhibit 2103, annotated to identify more clearly the labeled elements, is reproduced below.

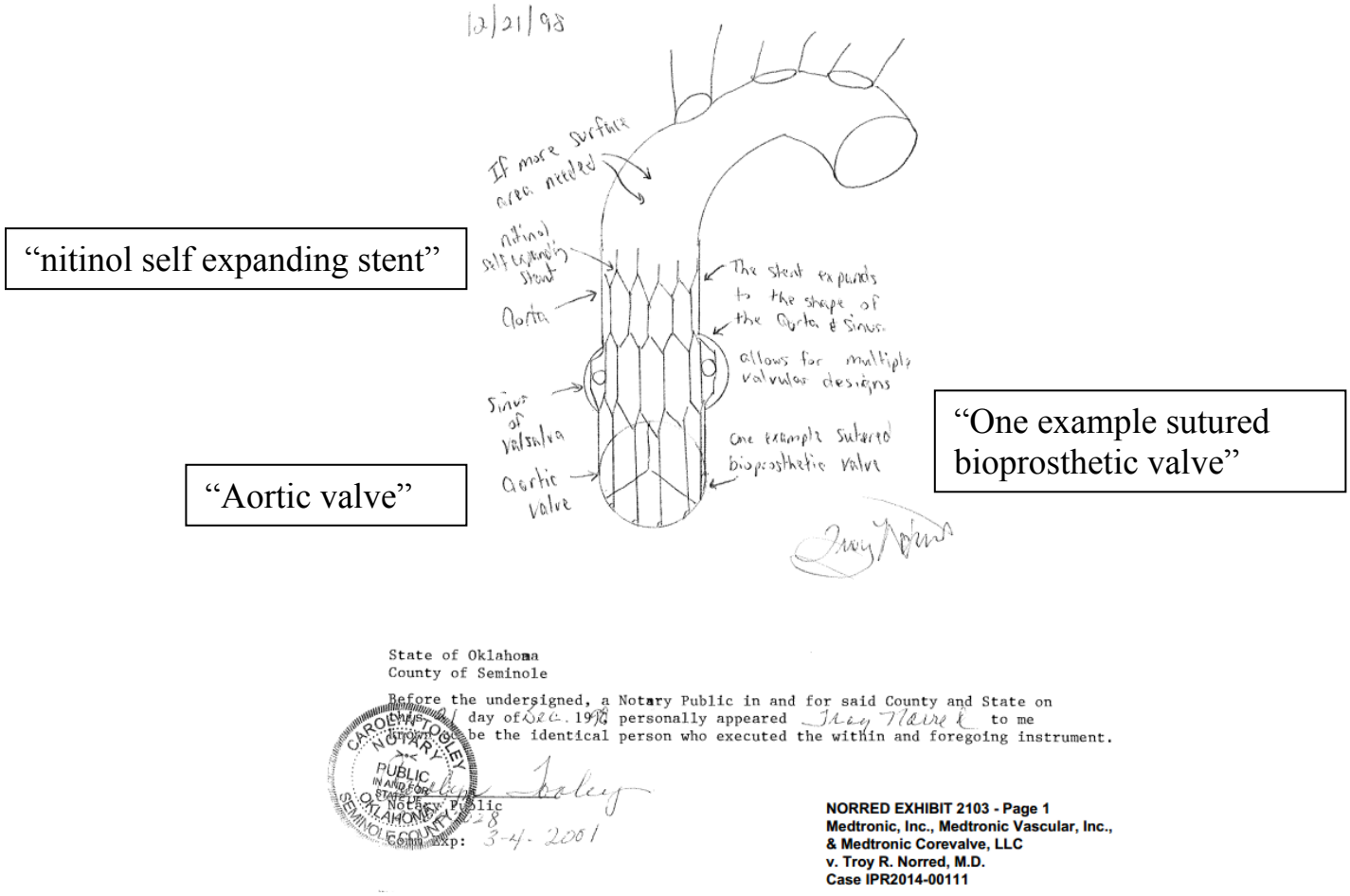

Exhibit 2103 is notarized as being signed by "Troy Norred" on December 21, 1998. Patent Owner states that Exhibit 2103 shows "the stent system as

deployed in the aorta, attached through connecting rods to the ring member." PO Resp. 11.

Petitioner asserts that Ex. 2103 "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.'" Pet. Reply 4. According to Petitioner, Exhibit 2103 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. Both the ring member and the "means for maintaining" are required in claims 20–24.

We agree with Petitioner that Exhibit 2103 does not address the limitations of claims 20–24 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 claim 20.

We also note that Exhibit 2103 illustrates a *sutured* bioprosthetic valve. Dr. Norred submitted a Declaration in this case that states that the aortic valve claimed as his invention was intended to "seal the device against the root of the native valve upon placement *without sutures*." Ex. 2193 ¶ 61 (emphasis added). Dr. Norred also states that "[m]y invention 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 statements in his Declaration (Ex. 2193) about eliminating the need for sutures and surgery are 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, col. 1, ll. 6–9. Accordingly, the sutured valve shown in Exhibit 2103 does not provide persuasive evidence that Dr. Norred conceived a valve that eliminates the need for sutures that he states was his "invention."

Based on the totality of the evidence on which Patent Owner relies, the evidence does not establish that the subject matter recited in claims 20–24 was conceived prior to April 6, 2000. Thus, Schreck is prior art under 35 U.S.C. § 102(e).

b. Claim 20

Schreck discloses expandable heart valves for minimally invasive valve replacement surgeries. Ex. 1009, Abstract. The Schreck valve is particularly useful in replacing the aortic valve. *Id.* at col. 5, ll. 39–42. Petitioner focuses on the disclosure shown and described for Figure 6 in Schreck. Pet. 15.

The embodiment in Figure 6 of Schreck is a two-part heart valve having leaflet subassembly 102 adapted to connect to tissue-engaging base 104. Ex.1009, col. 8, ll. 63–65. These two components, subassembly 102 and base 104, provide a structure Schreck refers to as a "tissue-engagement ring." *Id.* at col. 9, ll. 5–6. Leaflet subassembly 102 includes wireform 106 supporting a plurality of prosthetic leaflets 108 and fabric skirt 110. *Id.* at col. 9, ll. 11–13. In a preferred embodiment, each leaflet 108 is formed from pericardial tissue, such as bovine or equine pericardium, or a synthetic material that has been suitably treated to render it biocompatible. *Id.* at col. 9, ll. 46–50. Thus, interior elements 108 may be made from a tissue material, as required by claim 20.

i. Ring Member

In its Petition, Petitioner asserted that the entire leaflet subassembly 102 is the "ring member" as recited in claims 20–24. Pet., App. A-4, 13–14. Petitioner did not distinguish among the three components forming subassembly 102, i.e.,

wireform 106, leaflets 108, and skirt 110. Ex. 1009, col. 9, ll. 11–13. In its Reply, Petitioner clarifies its position and asserts that wireform 106 and skirt 110 of subassembly 102, but not leaflets 108, comprise the ring member called for in the claims. Pet. Reply 12, n. 2. Petitioner also states that base 104 is not asserted as part of the claimed ring member. *Id.*

In the Petition, Petitioner asserts that "leaflets 108 are surrounded by leaflet subassembly 102 ('ring member')." Pet., App. A-4, 14. Petitioner's clarified position in the Reply is that wireform 106 and skirt 110 of subassembly 102, but not base 104, comprise the ring member that surrounds leaflets 108.

Petitioner asserts that Schreck discloses that the outer circumference of the ring member is adapted to seat about an aortic wall surrounding an aortic channel, as recited in claim 20 because "during implantation, fabric skirt 110 is 'captured between the tubular member 140 and the surrounding tissue, and is in direct contact therewith.'" *Id*. (citing Ex. 1009, col. 13, ll. 20–26). Tubular member 140 is part of tissue-engaging base 104. Ex. 1009, col. 13, ll. 5–6. Thus, Petitioner's position is that skirt 110 is the outer circumference of Schreck's ring member, because it is skirt 110 that seats against the aortic wall.

Patent Owner agrees with Petitioner on the structure and function of the ring member disclosed in Schreck. Patent Owner states that:

> fabric skirt 110 drapes around the outside of the tissue-engaging base 104. When this device is placed in the native annulus, the tissue-engaging base 104 radially expands into contact with the annulus tissue. The fabric skirt 110 is captured between the tubular member 140 and the annulus tissue to form a flow channel for blood entering the inflow end of the valve.

PO Resp. 25.

ii. Means for Maintaining

As discussed above, we have construed the "means for maintaining" clause to be the combination of rods 104 interacting with stent 28, and equivalents thereof, that anchor valve 100 and seat ring member 102.

Schreck discloses "an expandable stent system adapted to be delivered in a collapsed state to an implantation site and expanded, and a plurality of prosthetic leaflets attached to the stent system." Ex. 1009, col. 2, ll. 17–20. In the context of valve 100, tubular member 140 is "plastically-expandable" (*id.*, col. 9, l. 67–col. 10, l. 1) and forms a support to which the leaflet subassembly is attached (*id.* at col. 11, ll. 51–64). A plurality of posts 146, 148 are attached to the tubular member 140. Ex. 1009, col. 10, ll. 2–7. Posts 146 couple tubular member 140 to commissures 112 of wireform 106, whereas posts 148 couple tubular member 140 to the cusps 114 of wireform 106. *Id.* at col. 10, ll. 8–11. Thus, posts 146, 148, which connect tubular member 140 to wireform 106, and tubular member 140 are the "means for maintaining" the outer circumference of the "ring member," i.e., skirt 110, in its seated position. This is the interpretation and application of Schreck adopted in our Decision instituting this *inter partes* review. Decision 14–15. Patent Owner states that this finding "was in error." PO Resp. 26.

Patent Owner acknowledges that "[t]ubular member 140 is designed to exert radial force against the annulus of the native valve in order to seat the device, while the leaflet subassembly 102 floats above it in the ascending aorta." *Id.* at 26 (citing the Declarations of Dr. Catchings and Dr. Norred). The basis for the asserted error is that tubular member 140 in Schreck "does not extend into the ascending aorta." *Id.* Patent Owner also asserts that "high pressures within the aorta" ultimately will cause failure of Schreck's structure.

Claim 20 does not require the valve, stent, or any of their components to extend into the ascending aorta. Claim 20 requires only that the ring member be adapted to seat "about an aortic wall surrounding an aortic channel." Patent Owner has not directed us to any persuasive evidence that the valve recited in claim 20 must be located in the ascending aorta.

Dr. Hill stated in his Declaration that placement and positioning of prosthetic aortic valves within the aorta is typically within the discretion of the physician. Ex. 1026 ¶ 34. According to Dr. Hill, placement is based on, among other things, anatomical aspects of a particular patient. *Id.* Dr. Hill also stated that it is well-known by those skilled in the art that aortic valves can be placed at different positions within the aorta, such as the lower portions of the aortic root or more upwardly in the ascending aorta. *Id.*

Patent Owner also asserts that Schreck's structure for maintaining the ring member seated against the aortic wall "stands in stark contrast" to the rods and stent structure disclosed in the '228 patent and recited in claim 20. PO Resp. 27. As described above, both the structure in claim 20 (stent system 28) and the structure in Schreck (tubular member 140) are an expanding element that maintains the ring of a valve seated against the aortic wall; and both the structure in claim 20 (rods 104) and the structure in Schreck (posts 146, 148) use similar structures to connect the valve to the expanding element.

Patent Owner also asserts that "high pressures within the aorta" ultimately will cause failure of Schreck's structure. PO Response 26 (citing the Declarations of Dr. Catchings and Dr. Norred). Patent Owner has not directed us to any facts or data to support this assertion, and thus we give it little or no probative weight. 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Moreover, the fact that the Schreck structure ultimately may fail is irrelevant to its effect as an anticipating reference under 35 U.S.C. § 102. The enablement requirement for prior art to anticipate under section 102 does not require utility. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325–26 (Fed.Cir.2005) ("[A] prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102."). Proof of efficacy is not required for a prior art reference to be enabling under section 102. *Id.* at 1326.

iii. Responsive to Changes

Schreck discloses that valve 100 has inflow end 120 and outflow end 122. Ex. 1009, col. 9, ll. 36–37. In describing the general operation of its valve, Schreck discloses that the valve opens and closes depending on blood flow forces. *Id.* at col. 8, l. 2. Schreck states that when the pressure differential is such that blood flows into the inflow end of the valve, the leaflets spread apart and the valve opens. *Id.* at col. 8, ll. 5–7. When the pressure differential reverses, the leaflets come together, or "coapt," to close the valve. *Id*. Thus, the Schreck valve is responsive to changes of conditions, as required by claim 20.

Based on the analysis herein, the preponderance of the evidence establishes that each element set forth in claim 20 is found in Schreck with the elements arranged as required by the claim. Accordingly, claim 20 is unpatentable as anticipated by Schreck under 35 U.S.C. § 102(e).

b. Claim 21

Claim 21 depends from claim 20 and requires the tissue valve interior member to be responsive to changes in blood pressure to open and close the valve. As described above, the Schreck valve opens and closes in response to blood pressure. *Id.* at col. 8, ll. 1–9; *see* Ex. 1020 ¶¶ 22, 23, and 25–27. Based on that analysis, the preponderance of the evidence establishes that each element set forth

in claim 21 is found in Schreck with the elements arranged as required by the claim. Patent Owner's Response has not directed us to any persuasive evidence to the contrary. Accordingly, claim 21 is unpatentable as anticipated by Schreck under 35 U.S.C. § 102(e).

c. Claim 22

Claim 22 depends from claim 21 and requires the tissue valve interior member to move to its open position in response to systolic ejection of blood from the left ventricle in which the blood pressure is greater than the blood pressure in the aortic channel. Based on the Declaration of Dr. Vassiliades, this is how the Schreck valve operates. Ex. 1020 ¶¶ 24, 26. Patent Owner's Response has not directed us to any persuasive evidence to the contrary. We therefore conclude that the preponderance of the evidence establishes that each element set forth in claim 22 is found in Schreck with the elements arranged as required by the claim. Accordingly, claim 22 is unpatentable as anticipated by Schreck under 35 U.S.C. § 102(e).

d. Claim 23

Claim 23 depends from claim 21 and requires the tissue valve interior member to move to the closed position in response to diastolic filling of the left ventricle when the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle. Based on the Declaration of Dr. Vassiliades, this is exactly how the Schreck valve, and other prosthetic valves cited in the Petition, operate. Ex. 1020 ¶¶ 24, 26. Patent Owner's Response has not directed us to any persuasive evidence to the contrary. We therefore conclude that the preponderance of the evidence establishes that each element set forth in claim 23 is found in Schreck with the elements arranged as required by the claim. Accordingly, claim 23 is unpatentable as anticipated by Schreck under 35 U.S.C. § 102(e).

e. Claim 24

Claim 24 depends from claim 20 and requires the "ring member" to contact the wall of the aortic channel and seal against the aortic channel wall. Petitioner asserts that the ring member in Schreck forms the required seal because fabric skirt 110 is in direct contact with surrounding tissue. Pet., App. A-4, 16–17 (citing Ex. 1009, col. 13, ll. 20–26). The cited passage states that the fabric skirt forms a flow channel for blood entering inflow end 120 of valve 100. Schreck discloses that once in position within the annulus of the valve being replaced, a balloon (or other expanding means) causes the tubular base and fabric to expand into contact with the annulus, which are compressed against the host annulus. Ex. 1009, col. 8, ll. 49–61, *see* col. 12, ll. 7–14. We understand this disclosure to mean that a sealed relationship is established between the ring member and the aortic channel wall, as claimed in claim 24. Patent Owner's Response has not directed us to any persuasive evidence to the contrary. We therefore conclude that the preponderance of the evidence establishes that each element set forth in claim 24 is found in Schreck with the elements arranged as required by the claim. Accordingly, claim 24 is unpatentable as anticipated by Schreck under 35 U.S.C. § 102(e).

2. Obviousness of Claims 22 and 23 over Schreck and Shu

Petitioner asserts that Shu discloses how a native heart valve works, and the fact that a prosthetic heart valve is designed to mimic the operation of the native heart valve. Pet. 23. As discussed above, based on the Schreck disclosure and the Declaration of Dr. Vassiliades, we have determined that the Schreck valve functions in the same manner as the natural heart valve it replaces. *See* Ex. 1020 ¶¶ 19, 23–27; Ex. 1009, col. 8, ll. 1–9. We recognize, however, that the tests for anticipation and obviousness are different. *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F. 3d 1351, 1364 (Fed. Cir. 2008); *see, e.g.*, *Duro-Last, Inc. v. Custom*

Seal, Inc., 321 F.3d 1098, 1107–08 (Fed.Cir.2003) ("Succinctly put, the various . . . defenses that may be raised by a defendant—. . . , the several forms of anticipation and loss of right under § 102, and obviousness under § 103—require different elements of proof.").

Shu discloses that during each cardiac cycle, the natural heart valves alternatively open to allow blood to flow through them and then close to block blood flow. Ex. 1012, col. 1, ll. 11–13. During systole, the aortic and pulmonary valves open to allow blood flow into the aorta and pulmonary arteries. *Id.* at col. 1, ll. 13–17. Conversely, during diastole, the aortic and pulmonary valves close to prevent reverse blood flow from the aorta and pulmonary arteries into the ventricles. *Id.* at col. 1, ll. 17–20. The cardiac valves open and close passively in response to blood pressure changes operating against the valve leaflet structures. *Id.* at col. 1, ll. 21–23.

Petitioner asserts that a person of ordinary skill in the art would understand Schreck in view of Shu to teach a prosthetic tissue valve as one that opens during systole, as recited in Claim 22, and closes during diastole, as recited in Claim 23. Pet. 23–24.

Patent Owner repeats the asserted deficiencies of Schreck that we have found unpersuasive above. PO Resp. 28–29. Patent Owner also asserts that Shu discloses a rigid valve that must be surgically placed, and that the two "designs literally could not be combined." *Id.* at 29. As stated above, however, Petitioner does not propose to combine the two structures. Shu is relied upon only for its disclosure of how a native heart valve works, and the fact that a prosthetic heart valve is designed to mimic the operation of the native heart valve. Pet. 23.

Moreover, the obviousness inquiry does not ask "whether the references could be physically combined but whether the claimed inventions are rendered

obvious by the teachings of the prior art as a whole." *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc); *see also In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.")

Here, Shu discloses that the established functions for the prior elements disclosed in Schreck are the predictable use of those elements according to established functions. Accordingly, we are persuaded that the preponderance of the evidence establishes that claims 22 and 23 are unpatentable for obviousness under 35 U.S.C. § 103 based on Schreck and Shu.

III. MOTION TO AMEND

Because we have found claims 20–24 to be unpatentable, we turn to Patent Owner's Substitute Motion to Amend Claims. In its Motion to Amend, Patent Owner moves to substitute claim 26 for challenged claim 20. Proposed substitute claim 26 is shown below in markup form as compared to the original claim 20 for which it is proposed as a substitute.

> 26. (Proposed substitute for claim 20) An aortic valve for controlling a blood flow through an aortic channel upon <u>percutaneous</u> 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 <u>pliable</u> outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel <u>and seal against a root of a native aortic valve</u>; and
>
> ~~means for maintaining said ring member in said seated position about the aortic wall~~ <u>a stent system having a plurality of interconnected rods</u>;

> 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 about the aortic wall;
>
> said tissue valve interior member responsive to pressure changes within the aorta for movement of said opening between said ~~a first~~ closed 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, wherein 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).

Petitioner argues that the Motion to Amend

> should be denied because proposed amended claim 26 (1) impermissibly enlarges the scope of claim 20, (2) includes amendments that do not respond to grounds for unpatentability, (3) includes terms for which Norred has not proposed any construction, (4) is not supported by the specification of the '228 patent, and (5) has not been shown by Norred to be patentable over the prior art.

Opp. Mot. Amend 1. Regarding the contention that proposed claim 26 enlarges the scope of claim 20, Petitioner asserts that proposed substitute claim 26 eliminates the "means for maintaining" limitation from original claim 20 and replaces it with language that broadens the scope of the claim. *Id.* at 3–4. According to Petitioner, the phrase "a stent system having a plurality of interconnected rods" that replaces the "means for maintaining" limitation impermissibly seeks to enlarge the scope of claim 20 because it does not include rods 104 on the valve that interact with the rods forming the stent. *Id.*

Patent Owner asserts that proposed claim 26 is not broader than claim 20 because rods 104 shown in Figure 18 of the patent "are an integrated part of the stent system, connecting the stent to the ring 102." PO Reply 1.

As discussed above, we maintained the construction for the "means for maintaining" limitation adopted in or Decision to Institute. This construction is that it is rods 104 interacting with stent system 28 that are the structure corresponding to the "means for maintaining" called for in claim 20. As also discussed above in our construction of the "means for maintaining" limitation, the Specification discloses two types of "rods": *interconnected rods* that form an expandable cylindrical lattice or scaffolding (Ex. 1001, col. 2, ll. 61–63) (emphasis added); and connecting rods 104 that connect valve 100 to stent system 28 (*id.*, col. 6, ll. 4–7). In the context of the embodiment disclosed in Figures 18 and 19, the Specification states that valve 100 is anchored along the root of the aortic valve with rods 104 "*which are connected to the ascending aortic stents 28 shown in FIG. 4*." *Id.* at col. 6, ll. 4–7 (emphasis added). 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, col. 1, ll. 30–31 and 63–64. These rods 104, which *connect to* stent system 28, are not part of the stent system. The new phrase in claim 26 recites a stent system "having a plurality of interconnected rods." This claim language is nearly identical to the Specification's description of stent system 28, which is a "series of interconnected rods." *Id.*, col. 2, ll. 61–63. Thus, the new phrase in proposed claim 26 of a "stent system having a plurality of interconnected rods" does not include rods 104, which are included in claim 20. Because proposed claim 26 does not include an element that is included in claim 20, claim 26 is broader than claim 20.

We recognize that the Specification states that Figure 18 is a diagrammatic view of a "valve and stent system." *Id.*, col. 2, ll. 48–49. The Specification also states, however, that rods 104, shown in Figure 18, "are connected to the ascending aortic stents 28 shown in FIG. 4." *Id.* at col. 6, ll. 4–7. As we stated above, 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. Patent Owner argued that "the rods cannot maintain the valve in place by itself. It is the *interaction with the stent system*" that maintains ring member in a seated position about the aortic wall. Tr. 36, ll. 19–20 (emphasis added). Because the rods 104 and the stent system 28 are each essential parts of the "means for maintaining", however, does not mean that rods 104 and the rods forming the stent system are the same, or that rods 104 are part of the stent system. Patent Owner has not directed us to any persuasive evidence to construe rods 104 shown in Figure 18 as an expandable cylindrical lattice or scaffolding that is part of stent 28. The evidence is to the contrary.

Based on the analysis above, we conclude that the proposed claim 26 impermissibly enlarges the scope of the claim 20. Accordingly, we deny Patent Owner's Motion to Amend. We need not address Petitioner's additional bases for denying the Motion to Amend.

IV. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated, by a preponderance of the evidence, that claims 20–24 of the '228 patent are unpatentable under 35 U.S.C. § 102 based on Schreck, and that claims 22 and 23 are unpatentable under 35 U.S.C. § 103(a) for obviousness over Schreck and Shu.

V. ORDER

In consideration of the foregoing, it is hereby

ORDERED that, based on Petitioner's showing by a preponderance of the evidence, claims 20–24 of the '228 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend is DENIED.

This is a final 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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