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Paper 10
Entered: April 25, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
and MEDTRONIC COREVALVE, LLC
Petitioner

v.

TROY R. NORRED, M.D.
Patent Owner

Case IPR2014-00111
Patent 6,482,228 B1

Before JOSIAH C. COCKS, SHERIDAN K. SNEDDEN, and
BARRY L. GROSSMAN, *Administrative Patent Judges.*

GROSSMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic Corevalve, LLC (collectively, "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 ("Corrected Pet."). Patent Owner, Troy R. Norred, M.D. ("Patent Owner"), filed a Patent Owner Preliminary Response. Paper 9 ("Prelim. Resp.").

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a):

> THRESHOLD – The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the Petition, Preliminary Response, and the submitted exhibits, we determine that the information presented in the petition establishes that there is a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of claims 20-24.

A. Related Proceedings

Petitioner states that the '228 patent is the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Kansas in *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.

B. The '228 Patent

The invention in the challenged claims of the '228 patent relates generally to a percutaneous aortic heart valve made of a tissue material that is placed by a

catheter or other means and held in place with a stent system without the need for surgery. Ex. 1001, col. 1, ll. 7-9, col. 8, ll. 30-31.

C. Illustrative Claim

Claim 20 of the '228 patent is the only independent claim challenged in the Corrected Petition. Challenged claims 21-24 depend directly or indirectly on 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.

D. References Relied Upon

Petitioner relies upon the following prior art references:

Reference	Pat. Number or Other Identifier	Asserted Date	Exhibit Number
Spiegel Online Article	"A Foldable, Artificial Heart Valve"	Mar. 3, 2000	Ex. 1003/1004 (translation)
Figulla	Published German Pat. Appl. 195-46-692.6	Jun. 19, 1995	Ex. 1005/1006 (translation)

Fraunhofer	Published German Pat. Appl. 198-57-887 A1	Jul. 6, 2000	Ex. 1007/1008 (translation)
Schreck	US 6,454,799	Apr. 6, 2000	Ex. 1009
Garrison	US 6,425,916	Feb. 10, 1999	Ex. 1010
Ersek	US 3,657,744	Apr. 25, 1972	Ex. 1011
Shu	US 6,139,575	Apr. 2, 1999	Ex. 1012

E. The Asserted Grounds

Petitioner asserts the following twelve grounds of unpatentability:

Ground	**Claims Challenged**	**Statutory Basis**	**References**
1	20-24	§ 102(a)	Spiegel Online Article
2	20-24	§ 102(b)	Figulla
3	20-24	§ 102(a)	Fraunhofer
4	20-24	§ 102(e)	Schreck
5	20-24	§ 102(e)	Garrison
6	20-24	§ 102(b)	Ersek
7	20-23	§ 103	Spiegel Online Article and Shu
8	20-23	§ 103	Figulla and Shu
9	20-23	§ 103	Fraunhofer and Shu
10	22-23	§ 103	Schreck and Shu
11	20-23	§ 103	Garrison and Shu
12	20-23	§ 103	Ersek and Shu

Corrected Pet. 7.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, "[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); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48764, 48,766 (Aug. 14, 2012) (Claim Construction); *In re Am. Acad. of Sci. Tech. Ctr*., 367 F.3d 1359, 1364 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). "[W]hen interpreting a claim, words of the claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor." *Id.* 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." Corrected Pet. 8. Patent Owner proposes specific constructions for these same two claim terms. Prelim. Resp. 16. Patent Owner also proposes a specific construction for the claim term "ring member." *Id.* at 15.

1. "*Tissue*"

Petitioner proposes that the claim term "tissue" is a "biological tissue, such as cadaver and porcine tissue." Corrected Pet. 8. Patent Owner proposes the identical construction. Prelim. Resp. 16.

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 that may prove valuable" to the "technique" disclosed in the written description include the use of "biological tissue incorporated valves, such as cadaver/porcine valves placed within a percutaneously

stented system." *Id.* at 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 only the term "tissue." The claims do not specify the type of tissue or the source of the tissue, e.g., "cadaver" or "porcine" tissue. "While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Comark Communications, Inc. v. Harris Corp*., 156 F.3d 1182, 1186 (Fed. Cir. 1998) (citation omitted), *see also Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed.Cir.1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."). Accordingly, the broadest reasonable construction in light of the Specification of the claim term "tissue" is generally "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. Pet. 8. Petitioner also asserts that the '228 patent describes the structure for performing the claimed function as "connecting rods 104," which anchor valve 100 along the root of the aortic valve. *Id.* (citing Ex. 1001, col. 6, ll. 4-5). Petitioner thus concludes that the "means" for performing the claimed function are "connecting rods" or an equivalent structure. Pet. 8.

Patent Owner has a different view. Patent Owner asserts that the "means for maintaining" is the stent system 28 or an equivalent structure. Prelim. Resp. 16 (citing Ex. 1001, Abstract; col. 1, ll. 29-31, 59-67; col. 5, ll. 22-25, 48-51).

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 claim phrase is a "means plus function" phrase that is interpreted under § 112, ¶ 6.

"The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure." *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc). This is the "broadest reasonable interpretation" of "means-plus-function" language. *Id.* at 1194-95. The structure disclosed in the written description of the specification is the corresponding structure only if the written description of the specification or the prosecution history clearly links or associates that structure to the function recited in a means-plus-function claim limitation. *B. Braun Medical Inc., v. Abbott Laboratories*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). Claim interpretation under § 112, ¶ 6 does not "permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

The function recited in the means-plus-function claim limitation in claim 20 is "maintaining said ring member in said seated position about the aortic wall." Ex. 1001, col. 8, ll. 36-37. Thus, the initial focus is on the "ring member" and a determination of the structure that maintains the ring member in a seated position.

The ’228 patent discloses four valve designs: figures 6-9 disclose an umbrella aortic valve; figures 10-13 disclose a cone-shaped aortic valve; figures 14-17 disclose another version of a cone-shaped valve; and figures 18-19 disclose a cadaver/porcine valve. Ex. 1001, col. 2, ll. 24-51. The term “ring” is used in the context of the two cone-shaped valves and the cadaver/porcine valve: “ring 72” is referred to in the valve shown in Figures 10-13; “ring 86” is referred to in the context of Figures 14-17; and “ring 102” is referred to in the context of Figures 18-19.

Ring 102 is in the context of a tissue valve specifically recited in claim 20. Ex. 1001, col. 6, ll. 1-4. 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). We have not been directed to any disclosure that describes *how* ring 102 seals against the root of the native aortic valve. We also have not been directed to any disclosure of *how* ring 102 is maintained in “seated position about the aortic wall,” as called for in independent claim 20, or *what* structure maintains the ring in this claimed position.

Two types of “rods” are disclosed: rods that are part of the stent; and rods that are part of the valve. 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, col. 2, ll. 61-63. There also are rods that are part of the valve. In the context of the embodiment disclosed in Figures 18 and 19, the Specification states that *valve* 100 (*not ring* 102) is anchored with rods 104 connected to stents 28. *Id.* at 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); *id.* at col. 5, ll. 21-23 (valve 66 is anchored with rods 80); *id.* at 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 merely connect the valve to the stent. Ex. 1001, col. 1, ll. 30-31 and 63-64

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 28 that anchor valve 100 and seat ring member 102. In that regard, it is rods 104 interacting with stent 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 at this stage of the proceeding, and we therefore adopt it for purposes of this Decision.

We also give ordinary meaning to the functional phrase of maintaining the ring in a "seated position about the aortic wall," recited in claim 20. 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 seals against the root of the native aortic valve"). For purposes of this Decision, this phrase means that the ring is positioned against the aortic wall. We decline to require the ring to seal with the aortic wall because the evidence of record does not support such a special meaning.

3. Ring Member

Patent Owner proposes that the phrase "ring member," as used in the challenged claims, means "a ring made of a pliable, biocompatible material which seals against the aorta to reduce peri-valvular leaks." Prelim. Resp. 15. Patent Owner cites the Specification for support for this proposed claim construction. *Id.* Petitioner does not propose a specific construction for the phrase "ring member."

We do not to limit the claim phrase "ring member" to a specific material, as proposed by Patent Owner. Claims 20-24 do not state the material from which the

ring member is made, and there is no argument or evidence asserted by Patent Owner that persuades us to read limitations concerning the material from which the ring member is made from the Specification into the claims. *Comark Communications*, 156 F.3d at 1186; *Texas Instruments*, 805 F.2d at 1563. Patent Owner offers no persuasive evidence that the ordinary and customary meaning of the term "ring member" is limited to a pliable, biocompatible material.

We also do not limit the claim phrase "ring member" to include the functional limitation that the ring member "seals against the aorta to reduce peri-valvular leaks." Claims 20-23 state that the outer circumference of the ring member is "adapted to *seat* about an aortic wall surrounding an aortic channel" (emphasis added)." The challenged claims 20-23 do not state that the ring *seals* against anything. Dependent claim 24 adds the limitation that the ring member *seals* against the aortic channel wall. As a dependent claim, claim 24 must further limit claim 20 from which it depends. Thus, seating the ring member about an aortic wall surrounding an aortic channel, as recited in claim 20, cannot define the same structure or relationship as sealing the ring member against the aortic channel wall, as recited in claim 24. The Specification also distinguishes between seating and sealing. *E.g.*, Ex. 1001, col. 5, ll. 17-21 ("Base 70 is seated . . . rim 78 . . . seals against the root of the native aortic valve 34. . ."). The claims do not state the purpose of the claimed seated arrangement. Patent Owner has not provided any persuasive argument or evidence that we should ignore the language of the claims as written and interpret the claim as proposed by Patent Owner. *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F. 3d 1371, 1374 (Fed. Cir. 2004) ("Thus, in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it.").

For purposes of this Decision, the phrase "ring member" does not require a particular sealing function.

B. Asserted Grounds of Unpatentability

1. Anticipation of Claims 20-24 by Schreck

As one of twelve grounds asserted in the Corrected Petition, Petitioner asserts that "each element recited in claims 20-24 is anticipated by Schreck." Corrected Pet. 15. "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).

Patent Owner asserts that "Schreck does not constitute prior art and cannot serve as a basis to invalidate the '228 Patent pursuant to 35 U.S.C. § 102(e)." Prelim. Resp. 24. The basis for this assertion is that "Schreck was filed on April 6, 2000, approximately 16 months after Norred invented the aortic valve described in the '228 Patent." *Id.*

The effective filing date of Schreck is April 6, 2000. Ex. 1009, 1. The filing date of the '228 patent is November 14, 2000. Thus, Schreck is prior art under the

applicable provision of 35 U.S.C. § 102(e) unless Patent Owner establishes that the inventions in the challenged claims were invented before April 6, 2000.

Patent Owner cites Exhibit 2103 in support of the asserted date of invention 16 months prior to Schreck's filing date. Prelim. Resp. 24. Exhibit 2103 is a sketch dated "12/21/98." The sketch is notarized as being signed by "Troy Norred" on December 21, 1998. The sketch shows an "aortic valve" positioned in the aorta. Patent Owner states that Exhibit 2103 "clearly depicts a percutaneous aortic heart valve held in place with a stent system," and "bears a striking similarity to Figure 4 of the '228 patent." *Id.* at 9.

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. As such, the evidence on which Patent Owner relies does not establish that the invention in claims 20-24 was invented prior to April 6, 2000. Thus, for purposes of this Decision, based on the evidence and arguments asserted by Patent Owner, Schreck is prior art under 35 U.S.C. § 102(e).

a. 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. Corrected 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 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

Petitioner asserts that the entire leaflet subassembly 102 is the "ring member" as recited in claims 20-24. Corrected Pet., App. A-4, p. App. 13. Petitioner does 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. Petitioner then asserts that "leaflets 108 are surrounded by leaflet subassembly 102 ('ring member')." *Id.* at App. A-4, p. App. 14. Since leaflets 108 are part of subassembly 102, leaflets 108 cannot surround themselves. More precisely, wireform 106, skirt 110 of subassembly 102, and base 104 surround leaflets 108. Thus, consistent with Schreck's disclosure, wireform 106 and skirt 110 of subassembly 102, and base 104, provide a tissue-engagement ring. *Id.* at col. 9, ll. 5-6.

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.'" Corrected Pet. App. A-4, p. App. 14 (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.

Based on the present record, this interpretation of Schreck appears to be correct.

Patent Owner asserts that posts 146 and cusp posts 148 prevent the leaflet subassembly from seating about the aortic channel. Prelim Resp. 25 (citing Ex. 1009, Figures 6, 7, 10, 13, and 15). Based on our review of these figures and the Schreck disclosure, the evidence does not appear to support Patent Owner's assertion. Figure 10 of Schreck, cited by Patent Owner, appears to illustrate skirt 110 on the exterior of post 146. This is consistent with Figure 6. It also is consistent with Schreck's disclosure, which states fabric skirt 110 is captured between tubular member 140 and the surrounding tissue, and is in direct contact therewith. Ex. 1009, col. 13, ll. 20-22. Direct contact with the surrounding tissue establishes that the outer circumference of Schreck's ring member is adapted to seat against the aortic wall. Also, Schreck discloses that while posts 146, 148 are desirably located on the outside of tubular member 140, the "reverse configuration" also may be used. Ex. 1009, col.10, ll. 18-27. Thus, this appears to allow posts 146 and 148 to be positioned so that fabric skirt 110 is in direct contact with the surrounding tissue, consistent with the Schreck disclosure.

ii. Means for Maintaining

We have construed the "means for maintaining" clause to be the combination of rods 104 interacting with stent 28 that anchor valve 100 and seat ring member 102, and equivalents thereof. Neither Petitioner nor Patent Owner asserted this construction, as discussed above in Section II-A of this Decision.

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 forms a support stent to which the leaflet subassembly is attached. 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.

iii. Responsive to Changes

Schreck discloses that valve 100 has an inflow end 120 and an outflow end 122. Ex. 1009, col. 9, ll. 36-37. In describing the general operation of the disclosed valves, 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, each element set forth in claim 20 is found, either expressly or inherently described, in Schreck, in as complete detail as is contained in claim 20, with the elements arranged as required by the claim. Accordingly, we are persuaded that, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claim 20 is anticipated by Schreck.

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, 25-27. Accordingly, we are persuaded that, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claim 21 is anticipated by Schreck.

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, and other prosthetic valves cited in the Petition, operate. Ex. 1020 ¶¶ 24, 26. Accordingly, we are persuaded that, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claim 22 is anticipated by Schreck.

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. Accordingly, we are persuaded that, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claim 23 is anticipated by Schreck.

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. Corrected Pet., App. A-4, p. App.

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 and 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. Accordingly, we are persuaded that, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claim 24 is anticipated by Schreck.

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. Corrected Pet. 23. As discussed above, based on the Schreck disclosure and the Declaration of Dr. Vassiliades, we have determined, for purposes of this Decision, 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 structure. *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. Corrected Pet. 23-24.

Patent Owner asserts that Shu fails to disclose a valve that can be placed non-surgically/percutaneously. Prelim. Resp. 30. The challenged claims recite an aortic valve structure, and do not recite the surgical method for inserting the valve. Thus, this asserted deficiency is not persuasive.

Patent Owner argues that Shu teaches away from using a "tricuspid valve." Prelim. Resp. 31. The challenged claims are not limited to a tricuspid valve. Thus, this asserted deficiency is not persuasive.

Patent Owner asserts that Shu fails to disclose a "ring member," as recited in claims 22 and 23. Prelim. Resp. 31-32. Petitioner relies on Schreck for the structure of the valve called for in claims 22-23, including the ring member. Petioner relies on Shu for the disclosure of how a native or prosthetic heart valve works. Thus, Shu's asserted failure to disclose a "ring member" does not address what Schreck and Shu, considered together, would suggest to a person of ordinary skill in the relevant technology.

Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the

predictable use of prior art elements according to their established functions. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). In determining whether an invention would have been obvious to a person of ordinary skill, we recognize that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 420.

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, on the record before us, Petitioner has demonstrated a reasonable likelihood of prevailing on the ground that claims 22 and 23 are unpatentable for obviousness under 35 U.S.C. § 103 based on Schreck and Shu.

3. Other Asserted Grounds

As summarized in Section I-E of this Decision, Petitioner asserts twelve grounds of unpatentability. Six grounds were asserted based on Section 102; six grounds were asserted based on Section 103. The Section 102 grounds included assertions under Sections 102(a), (b), and (e). The Section 103 grounds all merely added Shu to each of the six references asserted under Section 102.

Under 37 C.F.R. § 42.108(a), the Board has discretion to "authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim." The Board also "may deny some or all grounds for unpatentability for some or all of the challenged claims." 37 C.F.R. § 42.108(b). In making such determinations, the Board considers 37 C.F.R § 42.1(b), which requires "the just, speedy, and inexpensive resolution of every proceeding."

We have determined to institute a trial on two of the twelve grounds. In this case, the decision not to authorize *inter partes* review on the other ten

unpatentability challenges was based on the finding that the challenges rely on the same prior art facts as the challenges for which *inter partes* review has been authorized. The determination not to proceed on all of the proposed unpatentability challenges by Petitioner is, therefore, grounded on a determination that the same facts were being applied to the claims, albeit using different prior art references to establish the facts. These redundant unpatentability challenges would impede "the just, speedy, and inexpensive resolution" of this proceeding. Considering multiple different references to establish the same factual premise, the structure and function of a heart valve, would consume, unnecessarily, the time and resources of the Board and all parties involved. Petitioner did not provide a persuasive, meaningful distinction between each of the redundant challenges.

III. CONCLUSION

For the foregoing reasons, based on the information presented in the Corrected Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in establishing the unpatentability of each of claims 20-24 of the '228 patent.

IV. ORDER

For the reasons given, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '228 patent is hereby instituted with respect to the following claims, grounds, and references:

1. Claims 20-24 under 35 U.S.C. § 102 as anticipated by Schreck;

2. Claims 22 and 23 under 35 U.S.C. § 103 for obviousness over Schreck and Shu.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '228 patent is hereby instituted commencing on the entry date of this

Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that no challenge other than that specifically granted above is authorized for the *inter partes* review; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 11 a.m. Eastern Time on May 28, 2014. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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