Trials@uspto.gov
571-272-7822

Paper 15
Entered: May 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, LLC,
Petitioner,

v.

SNYDERS HEART VALVE LLC,
Patent Owner.

Case IPR2018-00105
Patent 6,540,782 B1

Before PATRICK R. SCANLON, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges.*[1]

SCANLON, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

[1] Director Andrei Iancu has taken no part in this Decision due to recusal.

I. INTRODUCTION

St. Jude Medical, LLC ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of U.S. Patent No. 6,540,782 B1 (Ex. 1001, "the '782 patent"). Snyders Heart Valve LLC ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a).

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim, and we institute *inter partes* review on all challenged claims.

II. BACKGROUND

A. Related Matters

The parties indicate that the '782 patent is at issue in *Snyders Heart Valve LLC v. St. Jude Medical SC, Inc.*, No. 4:16-cv-00812 (E.D. Tex.). Pet. 1; Paper 5, 2. Related *inter partes* review proceeding IPR2018-00106 also involves the '782 patent. In addition, U.S. Patent No. 6,821,297 B2, which is related to the '782 patent, is the subject of related *inter partes* review proceedings IPR2018-00107 and IPR2018-00109.

B. The '782 patent

The '782 patent, titled "Artificial Heart Valve," issued April 1, 2003, with claims 1–30. Ex. 1001, (54), (45), 10:22–16:39. The '782 patent is directed to "artificial heart valves for repairing damaged heart valves." *Id.* at 1:11–12. Figures 2 and 3 of the '782 patent are reproduced below.

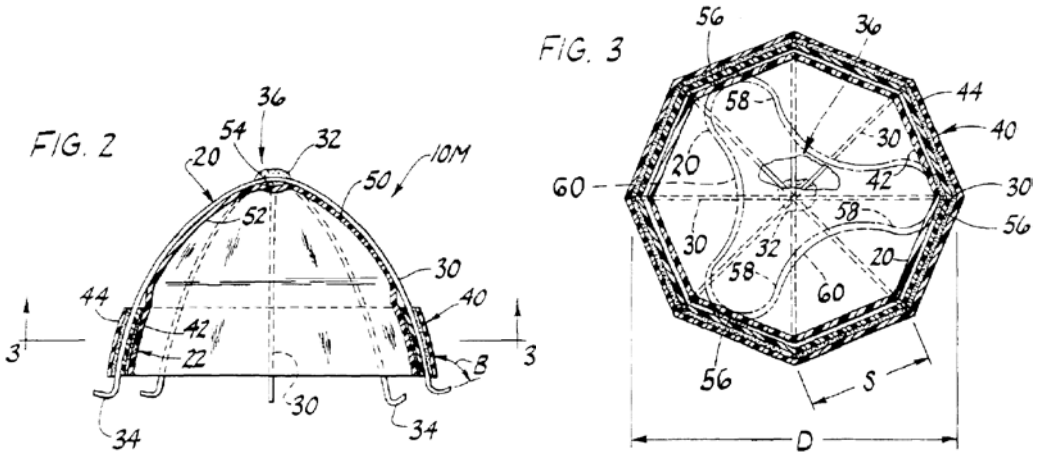


Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:8–10. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although the '782 patent also discloses an artificial valve configured to repair a damaged pulmonary heart valve. *Id.* at 4:30–33.

Artificial valve 10M comprises flexibly resilient external frame 20 and flexible valve element 22. *Id.* at 4:48–50. Frame 20 includes U-shaped stenting elements 30 that are joined together generally midway between their respective ends at junction 32. *Id.* at 4:51–58. U-shaped elements 30 are sufficiently compressible to allow valve 10M to be compressed into a configuration for implantation and sufficiently resilient to hold valve 10M in position between the cusps of a native heart valve after implantation while

holding the cusps open. *Id.* at 4:61–5:2. Peripheral anchors 34 are formed at each end of the U-shaped elements to attach frame 20 in position between an upstream region and a downstream region. *Id.* at 5:13–17. Frame 20 further includes central portion 36 located between peripheral anchors 34. *Id.* at 5:26–29.

Artificial valve 10M also comprises band 40 that extends around frame 20 between U-shaped frame elements 30 to limit maximum spacing between the frame elements, but permit the frame elements to be pushed together so flexibly resilient frame 20 can be collapsed to a collapsed configuration. *Id.* at 5:30–37. Band 40 preferably includes internal strip 42 and external strip 44 joined in face-to-face relation. *Id.* at 6:5–7.

Flexible valve element 22 is attached to central portion 36 of frame 20 and has convex upstream side 50 facing an upstream region and concave downstream side 52 facing a downstream region. *Id.* at 6:24–32. With this arrangement, "valve element 22 moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in FIG. 3) and a closed position (as shown in solid lines in FIG. 3)." *Id.* at 6:35–39. Flexible valve element 22 permits flow between the upstream and downstream regions when in its open position and blocks flow between the upstream and downstream regions when in its closed position. *Id.* at 6:39–43.

More specifically, apex 54 of upstream side 50 is attached to junction 32 of frame 20. *Id.* at 7:1–3. As shown in Figure 3, flexible valve element 22 also is attached to band 40 at several attachment points 56, such that flexible valve element 22 defines flaps 58 between adjacent attachment

points. *Id.* at 7:10–14. Flaps 58 and corresponding portions of band 40 define openings 60 when valve element 22 moves to its open position. *Id.* at 7:14–17.

Figure 4 of the '782 patent is reproduced below.

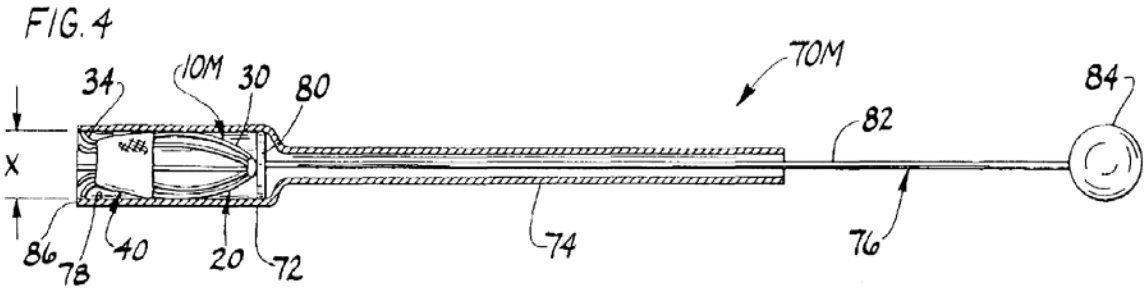


Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:11–13. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* at 7:34–36. The instrument further includes ejector 76 that is positioned in the hollow interior of holder 72 for ejecting an artificial heart valve from the holder. *Id.* at 7:36–39.

C. Challenged Claims

As noted above, Petitioner challenges claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent. Claims 1, 10, 17, 18, 28, 29, and 30 are independent. Claims 2 and 4–8 depend, directly or indirectly, from independent claim 1, and claims 19, 21, 22, and 25–27 depend, directly or indirectly, from independent claim 18. Independent claim 29 is reproduced below:

> 29. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument

for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:

an artificial valve including

a plurality of flexibly resilient U-shaped frame elements sized and shaped for insertion between the upstream region and the downstream region, each of said plurality of frame elements having opposite ends, said elements being joined together generally midway between their respective ends thereby forming a frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region, the frame being collapsible to a configuration having a maximum width less than about 18 mm, and

a flexible valve element attached to the frame having a convex upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

> an instrument including
>
> a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration,
>
> an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region, and
>
> an ejector mounted in the hollow interior of the holder for ejecting the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

Ex. 1001, 14:57–16:2.

D. The Prior Art

Petitioner's asserted grounds of unpatentability for the challenged claims rely on the following references:

Andersen	US 5,411,552	May 2, 1995	Ex. 1006
Leonhardt	US 5,957,949	Sept. 28, 1999	Ex. 1017
Imachi	US 5,413,599	May 9, 1995	Ex. 1020
Johnson	US 4,339,831	July 20, 1982	Ex. 1021

Petitioner also relies on the declaration testimony of Dr. Lakshmi Prasad Dasi (Ex. 1003).

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent on the following grounds:

Reference(s)	**Basis**	**Claims Challenged**
Leonhardt	§ 102	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30

Reference(s)	Basis	Claims Challenged
Leonhardt and Andersen	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Leonhardt, Johnson, and Imachi	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art to which the '782 patent pertains "is a medical doctor or has an advanced degree (at least a master's degree) in a relevant engineering discipline with several years of experience or someone who holds a lesser degree with more experience in the field of artificial heart valves." Pet. 13–14 (citing Ex. 1001; Ex. 1006; Ex. 1008; Ex. 1009; Ex. 1010; Ex. 1020; Ex. 1003, ¶¶ 15–17). Patent Owner does not dispute this contention at this stage of the proceeding, nor does Patent Owner offer its own definition of the level of ordinary skill in the art.

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros*.). We find, based on our review of the record before us, that Petitioner's stated level of ordinary skill in the art is reasonable because it is consistent with the evidence at this

stage of the proceeding, including the asserted prior art and, for the purposes of this Decision only, we adopt Petitioner's definition.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (concluding that 37 C.F.R. § 42.100(b) "represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office"). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

Petitioner indicates that the parties filed a Joint Memorandum on Claim Construction (Ex. 1041) in the related district court action identified above. Pet. 14. Petitioner also indicates that Patent Owner, in the related district court action, served infringement contentions (Ex. 1039) including an exhibit (Ex. 1040) indicating how Patent Owner "defines and/or construes" the challenged claims. Pet. 15. Based on these alleged constructions from the district court action, Petitioner proposes constructions for "frame," "peripheral anchor(s)," "central portion located between the plurality of peripheral anchors," "band," "first band," "second band,"

"flexible valve element," "U-shaped elements/U-shaped frame elements," "flexibly resilient," "junction," "convex upstream side," and "concave downstream side." Pet. 15–17 (citing Ex. 1040; Ex. 1041).

Patent Owner proposes constructions only for the term "central portion" and the phrase "each of said frame elements has a distance between its respective ends." Prelim. Resp. 3–8. Specifically, Patent Owner proposes that "'central portion of the frame' . . . should be construed as 'central structural frame portion,'" and "each of said frame elements has a distance between its respective ends" should "be construed to have its plain and ordinary meaning." *Id.* at 4, 8.

In view of our analysis discussed below, construing these terms is not necessary for us to assess the asserted grounds of unpatentability. Therefore, we determine that no claim term requires express construction at this juncture. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("claim terms need only be construed 'to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Alleged Bases for Denying the Petition

1. Word Count Limit

Patent Owner argues that the Board should deny the Petition because it exceeds the 14,000-word limit set forth in 37 C.F.R. § 42.24(a)(1)(i). Prelim. Resp. 46–49. Specifically, Patent Owner argues that Petitioner circumvented the limit "by eliminating spaces between words many hundreds of times in its petition." *Id.* at 47. We resolved this issue before

entering this Decision. Paper 12. Accordingly, Patent Owner's argument with respect to the word count of the Petition is moot.

2. Constitutional Issues

Patent Owner raises two constitutional issues. First, Patent Owner argues that *inter partes* reviews are unconstitutional because they "violate both Article III and the Seventh Amendment by improperly removing patent validity cases from the federal courts." Prelim. Resp. 45. This argument, however, is not persuasive in light of the Supreme Court's decision in *Oil States Energy Services, LLC v. Green's Energy Group, LLC*, No. 16-712, 2018 WL 1914662, at *12 (U.S. Apr. 24, 2018) ("inter partes review does not violate Article III or the Seventh Amendment").

Second, Patent Owner argues that *inter partes* review should not be instituted "because it is carried out by a final order issued by Administrative Patent Judges who have not been nominated by the President and confirmed by the Senate." Prelim. Resp. 45–46. According to Patent Owner, Administrative Patent Judges are "principal Officers" under the Constitution's Appointments Clause (U.S. Const. Art. II, § 2, Cl. 2), meaning they must be nominated by the President and confirmed by the Senate in order to exercise their authority constitutionally with respect to *inter partes* reviews. Prelim. Resp. 46.

Patent Owner, however, does not direct us to any authority holding that Administrative Patent Judges are principal Officers under the Appointments Clause. Furthermore, in 2008, Congress changed the law to provide that Administrative Patent Judges be appointed by the Secretary of Commerce in consultation with the Director. Pub. L. 110–313, 122 Stat

3014 (Aug.12, 2008). Accordingly, we are not persuaded that Administrative Patent Judges conducting *inter partes* reviews is unconstitutional.

3. Section 325(d)

Patent Owner argues that the Board should use its discretion under 35 U.S.C. § 325(d) to deny the two asserted grounds of unpatentability based on obviousness. Prelim. Resp. 39–44. Specifically, Patent Owner contends that Johnson "was explicitly considered by the Examiner in both of the Office Actions during prosecution of the '782 Patent," Andersen "is explicitly discussed in the Background of the '782 Patent," and Imachi "was also before the Examiner." *Id.* at 40–42. Patent Owner also contends that, although Leonhardt was not before the Examiner, this reference is used in the obviousness grounds "in a manner that is entirely cumulative to Teitelbaum." *Id.* at 42.

This argument, however, does not persuade us to exercise our discretion under 35 U.S.C. § 325(d) to deny any of the asserted grounds of unpatentability. The evidence of record does not demonstrate that the Examiner considered the references in the combinations relied upon by Petitioner or addressed arguments similar to those Petitioner now presents before the Board as the basis for the unpatentability of the challenged claims. In addition, Patent Owner's assertion that the frame of Teitelbaum is similar to the frame of Leonhardt does not persuade us that Leonhardt is used in a manner entirely cumulative to Teitelbaum." *See id.* 42. Moreover, Patent Owner merely asserts that Andersen and Imachi were of record during the examination of the '782 patent, but does not inform us as to

extent to which these references were evaluated during examination, or the extent of overlap between arguments made during examination and the manner in which Petitioner relies on these references in this proceeding. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01587, slip op. at 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) (discussing non-exclusive factors for evaluating whether to exercise our discretion under § 325(d)). For these reasons, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny any of the asserted grounds of unpatentability.

D. Asserted Anticipation by Leonhardt

Petitioner contends claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 are anticipated under 35 U.S.C. § 102(a), (e) by Leonhardt. Pet. 3, 18–42. Petitioner relies upon the testimony of Dr. Dasi (Ex. 1003) in support of its contentions. *Id.* Patent Owner disputes Petitioner's contentions. Prelim. Resp. 11–28.

1. Overview of Leonhardt

Leonhardt "relates to artificial valves, specifically those placed percutaneously by a catheter" to replace existing valves, such as valves in the heart. Ex. 1017, 1:4–7. Figure 4 of Leonhardt is reproduced below.

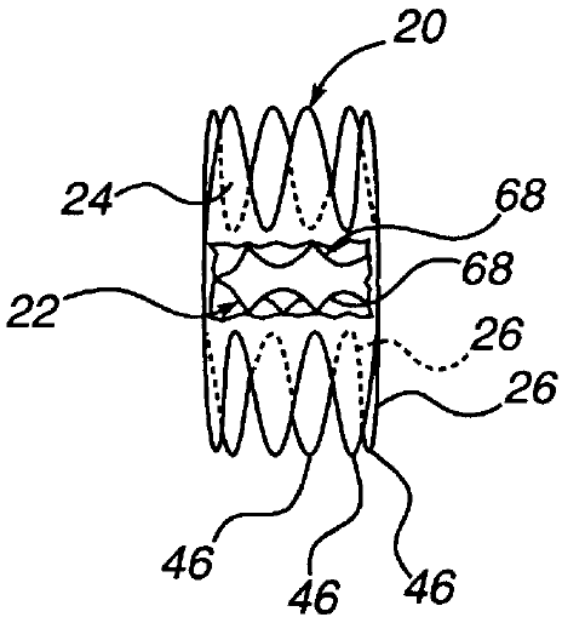


FIG. 4

Figure 4 depicts valve stent 20 comprising stent 26, biological valve 22, and graft material 24. *Id.* at 4:14–16. Stent 26, which is shown in more detail in Figures 1a–1c, is a single piece of super elastic wire formed into top and bottom portions that are substantially symmetrical to each other and have a wavy form or zig-zags 40. *Id.* at 4:27–38, Fig. 1a. Each end 58 of stent 26 is connected to another portion of the stent by crimping tubes 50 to define imaginary cylinder 48. *Id.* at 4:41–56, Figs. 1b, 1c. In other words, once crimped, stent 26 comprises a pair of cylinders at opposing ends of the stent. *Id.* at 5:27–30. Connecting bar 29, which is a central part of the continuous wire from which the stent is formed, holds these cylinders at a predetermined distance apart. *Id.* at 5:31–33; Figs. 1a, 1b.

Graft material 24 "is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric" that encloses, and is sutured to, stent 26. *Id.* at 5:46–48, 53–63. Graft material 24 "is heat pressed to

conform to the distal and proximal cylindrical ends of stent." *Id.* at 5:63–65. In addition, when valve stent 20 must flare at one or both ends, "graft material 24 may be cut out between the plurality of distensible fingers 46 formed by zig-zags 40 of stent 26." *Id.* at 6:9–13.

Biological valve 22 fits within the internal diameter of the imaginary cylinder defined by stent 26 and is attached to stent 26, graft material 24, or both. *Id.* at 6:25–30. Although "preferably a porcine valve treated and prepared for use in a human," biological valve 22 could also be "a mechanical valve or a synthetic leaflet valve." *Id.* at 6:23–24, 31–33.

Leonhardt also discloses deployment catheter 100 for the percutaneous delivery of valve stent 20 to the placement site. *Id.* at 6:34–37, Figs. 5, 6. Deployment catheter 100 includes outer sheath 106 having axially extending sheath passage 108, which receives push rod 112. *Id.* at 6:42–45. In use, valve stent 20 is loaded into outer sheath 106, and push rod 112 causes valve stent 20 to be deployed. *Id.* at 7:17–18, 10:53–58.

2. Independent claim 29

a) an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region

Petitioner argues that "Leonhardt describes a percutaneously delivered self-expanding heart valve. Valve stent 20 can be positioned within the native aortic or mitral valve, *i.e.*, between upstream and downstream regions." Pet. 18 (citing Ex. 1017, 3:57–59, 4:14–15, 5:40–52, 9:63–67; Ex. 1003 ¶ 54); *id.* at 30. Although the burden remains on the Petitioner to prove unpatentability (*see Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*,

800 F.3d 1375, 1378 (Fed. Cir. 2015)), we note that Patent Owner does not dispute Petitioner's assertion.

At this stage of the proceeding, we are persuaded by Petitioner's argument. Leonhardt's valve stent 20 is a "percutaneously implanted artificial valve" that can be deployed within the mitral valve or the aorta above the aortic valve. Ex. 1017, 3:33, 57–60.

> *b) a plurality of flexibly resilient U-shaped frame elements sized and shaped for insertion between the upstream region and the downstream region, each of said plurality of frame elements having opposite ends, said elements being joined together generally midway between their respective ends thereby forming a frame*

Petitioner argues that Leonhardt's stent is a flexibly resilient frame. Pet. 19 (citing Ex. 1003 ¶ 55); *id.* at 30–31. Petitioner also argues that "Leonhardt's frame includes a plurality of 'U-shaped' members" that are "joined to each other along the zig-zag or 'wavy form' at respective points 40 illustrated in FIGS.1A, 1B." *Id.* at 22 (citing Ex. 1017, 4:35–40, 4:53–5:22, 5:40–52; Ex. 1003 ¶¶ 60–62); *id.* at 31. According to Petitioner, although "Leonhardt illustrates sharp zig-zags, it also teaches curved apices which are both 'U-shaped.'" *Id.* at 22. Furthermore, Petitioner argues that Figures 2, 3, and 9 of Leonhardt show its "device is sized and shaped to be placed in a native annulus." *Id.*

Petitioner contends that "adjacent apices are attached at a point which is midway between their respective ends," and to demonstrate this contention provides Figures E and F in which "U-shaped members are indicated in red or yellow and with an 'A' and the junction midway between respective ends is indicated in green or blue and with a 'B.'" *Id.* at 22–23

(citing Ex. 1017, 5:23–27, Fig. 1B; Ex. 1003 ¶¶ 63–64). Petitioner's Figures E and F are reproduced below.

FIG.E

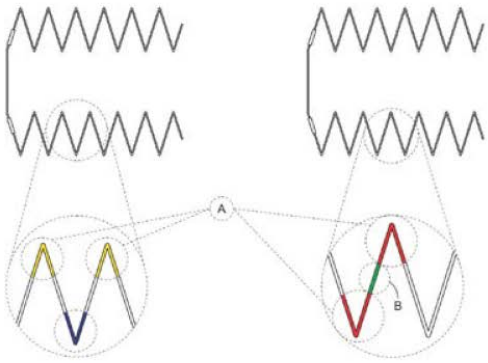
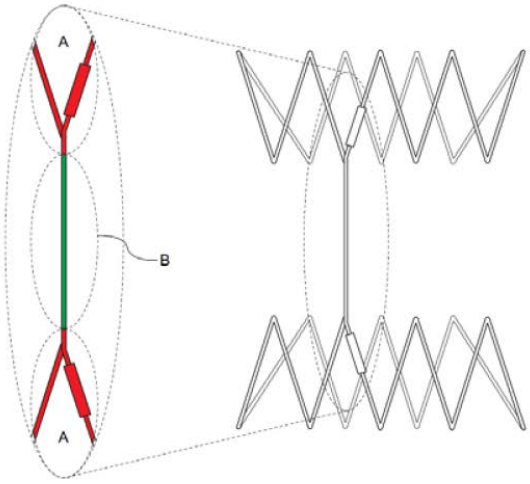


FIG.F



Id. at 23. Dr. Dasi testifies that Figure E "provides an exploded view of a portion of the stent in FIG.1A of Leonhardt," and Figure F "provides an exploded view of the assembled stent of Leonhardt's FIG.1B." Ex. 1003 ¶ 63.

At this stage of the proceeding, we are persuaded by Petitioner's position. Both the top and bottom portions of Leonhardt's stent 26 comprise a series of zig-zags 40 defining a wavy form. Ex. 1017, 4:36–38. Although zig-zags 40 are depicted in Figures 1a and 1b as having a sharp V-shape, Figure 4 shows the zig-zags as forming curved, U-shaped fingers 46. Thus, we are persuaded that stent 26 is a frame comprising a plurality of U-shaped frame elements. We also are persuaded that these frame elements are flexibly resilient.

Patent Owner argues that Petitioner has not adequately explained how Leonhardt meets the limitation that the U-shaped frame elements are sized and shaped for insertion between upstream and downstream regions. Prelim. Resp. 20–22. In particular, Patent Owner argues that the portion of Leonhardt's stent 22 that Petitioner identifies as "U-shaped frame elements" in Figures E and F "are two adjacent elements that constitute only a portion of the stent and are not sized and shaped for insertion in the position between the upstream region and the downstream region." *Id.* at 21.

We are not persuaded by this argument. The "U-shaped frame elements" identified by Petitioner are portions of stent 26. Stent 26 is designed to "conform to and seal against the dramatically different structures occurring within vessel walls and valve locations" of a patient's heart, including a location between left atrium 18 (upstream region) and left ventricle 12 (downstream region). Ex. 1017, 4:63–65, Fig. 2. As such, the portions of stent 26 that Petitioner identifies as the "U-shaped frame elements" are also positioned between the upstream and downstream regions and, therefore, must be sized and shaped for insertion into this position. The

claim language does not require each U-shaped frame element individually to span the annulus defined at the position between the upstream and downstream regions.

Patent Owner also argues that Petitioner has not adequately explained how Leonhardt meets the limitation that the U-shaped frame elements are joined together generally midway between their respective ends. Prelim. Resp. 20. As noted above, Petitioner relies on Figures E and F to demonstrate its assertion that Leonhardt discloses this limitation. Petitioner's Figure F, in particular, shows two zig-zags that are connected at their respective apices by an elongated member. Pet. 23. Although not an exact replica of Leonhardt's Figure 1b, we determine that Figure F fairly depicts what is shown in Figure 1b. Namely, that two zig-zags 40 are connected at their respective apices by connecting bar 29. Each of these apices is midway between the respective ends of the corresponding zig-zag. Accordingly, Leonhardt discloses two U-shaped frame members[2] joined together generally midway between their respective ends. These two members represent a "plurality" of members as required by claim 29; we note that claim 29 does not preclude additional U-shaped frame members that are not joined together generally midway between their respective ends.

[2] As noted above, although zig-zags 40 are depicted in Figures 1a and 1b as having a sharp V-shape, Figure 4 depicts these elements as U-shaped.

c) the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region

Petitioner argues that the top and bottom cylindrical portions of Leonhardt's stent 26 are peripheral anchors. Pet. 20 (citing Ex. 1003 ¶ 58; Ex. 1040, 4–5); *id.* at 31–32. Alternatively, Petitioner argues that Leonhardt discloses that stent 26 can flare at one or both ends and these flared ends constitute peripheral anchors. *Id.* at 20–21 (citing Ex. 1017, 6:9–22); *id.* at 31–32.

We find Petitioner's contention that the flared ends of stent 26 constitute peripheral anchors persuasive. Leonhardt discloses that "[s]tent 26 is pre-sized to open beyond the width of the natural valve mouth and will flair [sic] sufficiently to conform and seal to the tissue." Ex. 1017, 6:19–22. Figure 2 of Leonhardt depicts flared ends of the valve stent conforming to the surrounding tissue in a manner that would anchor the valve stent in position. Accordingly, we are persuaded that the flared ends of stent 26 function as peripheral anchors.

d) the frame being collapsible to a configuration having a maximum width less than about 18 mm

Petitioner argues that "Leonhardt teaches that its valve may be collapsed to sizes between 12 FR and 20 FR." Pet. 23 (citing Ex. 1017, 6:54–65); *id.* at 36. Relying on the testimony of Dr. Dasi, Petitioner asserts that the abbreviation "FR" refers to the unit "French," and a "stent that is 12 FR is 4mm in diameter and one that is 20 FR is 6.67mm in diameter." *Id.* at 23 (citing Ex. 1009, 15:10–18; Ex. 1003 ¶ 65). Accordingly, Petitioner

argues that Leonhardt discloses a frame being collapsible to a maximum width less than about 18 mm. *Id.*

At this stage of the proceeding, we credit Dr. Dasi's testimony, which Patent Owner does not dispute, and, thus, we are persuaded by Petitioner's argument.

> *e) a flexible valve element attached to the frame having a convex upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region*

Petitioner points to Leonhardt's biological valve 22 as being a flexible valve element, noting that "Leonhardt uses a biological valve which is preferably an intact tricuspid porcine valve." Pet. 25–26 (citing Ex. 1017, 6:23–34; Ex. 1003 ¶¶ 75–76); *id.* at 33–34. Petitioner also argues that the limitations of the flexible valve element having a convex upstream side facing an upstream region and a concave downstream side facing a downstream region are met by a flexible valve element "having the general structure of a native tricuspid heart valve." *Id.* at 26; *id.* at 35–36.

In response, Patent Owner argues

> Instead of pointing to evidence that Leonhardt discloses a flexible valve element having "a convex upstream side" and "a concave downstream side," Petitioner points to Patent Owner's Infringement Contentions, stating "to the extent that the FVE in the Contentions has convex upstream and concave downstream sides, the biological valve of Leonhardt does as well." (Petition at 26–27). These conclusory statements are not the type of "detailed explanation"

> required of the Petitioner, and they cannot meet Petitioner's burden here.

Prelim. Resp. 15. Patent Owner adds that Petitioner "has pointed to no specific evidence showing that the valve in *Leonhardt* has a convex upstream side and a convex [sic] downstream side." *Id.* at 16–17.

We disagree with Patent Owner's arguments. Although Petitioner relies on Patent Owner's infringement contentions (Ex. 1040) and a joint claim construction statement (Ex. 1041) in support of its argument, Petitioner also asserts, as noted above, that (1) Leonhardt discloses using an intact tricuspid porcine valve; and (2) a native tricuspid heart valve has a convex upstream side and a convex downstream side. Pet. 25–27. This assertion is supported by the testimony of Dr. Dasi. Ex. 1003 ¶ 79. Accordingly, at this stage of the proceeding, we are persuaded by Petitioner's argument that Leonhardt discloses a flexible valve element having a convex upstream side and a convex downstream side.

> *f) said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region . . .*

Petitioner argues that claim 29, among other claims, includes "lengthy recitations merely describing the function of virtually any one-way (or check) valve, including the native heart valve and replacement valves, which were known *per se*." Pet. 27 (citing Ex. 1003 ¶¶ 81–82). Petitioner also argues that Leonhardt's porcine valve 22 meets these limitations. *Id.* at 28 (citing Ex. 1017, 1:10–21, 3:33–45, 5:50–52, 6:23–34; Ex. 1003 ¶ 82); *id.* at 37–38.

Patent Owner argues that Petitioner's assertions are "conclusory statements" that fail to meet Petitioner's burden, and Petitioner has not pointed to specific evidence showing that Leonhardt's valve moves in the manner claimed. Prelim. Resp. 19–20.

We are not persuaded by these arguments. Petitioner points out that Leonhardt discloses that its artificial valve replaces existing valves, such as native heart valves, and "may be placed where fluid flow needs to be maintained in one direction only." Pet. 37 (citing Ex. 1017, 1:5–21). The cited passage of Leonhardt indicates that its artificial valve "opens and closes with pressure and/or flow changes." Ex. 1017, 1:13–14. As such, we are persuaded that Leonhardt's valve moves between open and closed positions in response to a difference in fluid pressure and allows flow in a single direction. Also, Figure 2 of Leonhardt shows valve stent 20 positioned in the location of mitral valve 14, between left atrium 18 and left ventricle 12. *Id*. at 5:41–52, Fig. 2. Although not explicitly described in Leonhardt, in this position, valve stent 20 would permit downstream flow between the upstream region (left atrium 18) and the downstream region (left ventricle 12) in its open position and block flow from the downstream region to the upstream region in its closed position.

For these reasons, we are persuaded at this stage of the proceeding that Leonhardt discloses the valve movement limitations of claim 29.

g) an instrument for inserting the artificial valve between the upstream region and the downstream region

Petitioner argues that Leonhardt discloses an instrument "comprising a holder having a hollow interior for holding the valve, an elongated

manipulator attached to the holder for manipulating the holder and an ejector mounted within the holder for ejecting the valve from the holder," as recited by claim 29. Pet. 28–29 (citing Ex. 1017, 6:34–8:42, Figs. 5–7A, 9A–9C); *id.* at 38–39. Specifically, Petitioner argues that Leonhardt's "valve stent 20 resides in the distal end of outer sheath 106, such that the distal end of [sheath] 106 constitutes the 'holder,'" and "[t]he portion of outer sheath 106 proximal to the distal end is usable to manipulate the distal end or holder and is the 'manipulator.'" *Id.* at 29 (citing Ex. 1017, 6:55–61, 7:16–21, 6:34–7:10, 7:21–8:22). Petitioner also argues that "'push rod 112' serves to eject the stent from the distal end of the sheath and is the claimed 'ejector.'" *Id.* (citing Ex. 1017, 6:34–49, 8:23–42; Ex. 1003 ¶ 84).

Leonhardt discloses a deployment catheter comprising outer sheath 106 having axially extending sheath passage 108, which receives push rod 112. Ex. 1017, 6:42–45, Fig. 5. Valve stent 20 is loaded into outer sheath 106, and push rod 112 causes valve stent 20 to be deployed (i.e., ejected from outer sheath 106). *Id.* at 7:17–18, 10:53–58.

Accordingly, at this stage of the proceeding, we are persuaded by Petitioner's argument that Leonhardt discloses the instrument for inserting an artificial valve as claimed, which Patent Owner does not dispute.

h) Secondary Considerations

Patent Owner asserts that numerous objective indications of non-obviousness, or secondary considerations, weigh heavily against finding the challenged claims obvious. Prelim. Resp. 34. In particular, Patent Owner proffers evidence that allegedly establishes the objective factors: (1) peer

recognition; (2) commercial success; (3) long-felt need; and (4) acceptance and adoption by industry. *Id.* 34–39.

Evidence of secondary considerations is not relevant to the asserted ground based on anticipation on which, as explained herein, we institute *inter partes* review. With respect to the asserted grounds of unpatentability based on obviousness, on which we institute *inter partes* review as discussed below, we note that the issue of secondary considerations is highly fact-specific. At this stage of the proceeding, the record regarding such secondary considerations is incomplete, and Petitioner has not had the ability to fully respond to the specific arguments raised by Patent Owner in the Preliminary Response. Our final decision will consider the parties' full record of secondary considerations evidence developed during trial as part of our obviousness analysis.

i) Conclusion

For the foregoing reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claim 29 of the '782 patent.

E. Institution

On April 24, 2018, the Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Inst., Inc. v. Iancu,* 2018 WL 1914661, at *10 (U.S. Apr. 24, 2018). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 29 of the '782 patent is unpatentable. Accordingly,

pursuant to the holding in *SAS*, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '782 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

PETITIONER:

Michael H. Teschner
Stephen M. Lund
Maegan A. Fuller
LERNER DAVID LITTENBERG KRUMHOLZ & MENTLIK LLP
MTeschner.ipr@ldlkm.com
slund@lernerdavid.com
MFuller.ipr@ldlkm.com

PATENT OWNER:

Matthew J. Antonelli
Zachariah S. Harrington
Larry D. Thompson, Jr
ANTONELLI, HARRINGTON & THOMPSON LLP
matt@ahtlawfirm.com
zac@ahtlawfirm.com
larry@ahtlawfirm.com