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 IPR2018-00106
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 IPR2018-00105 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.

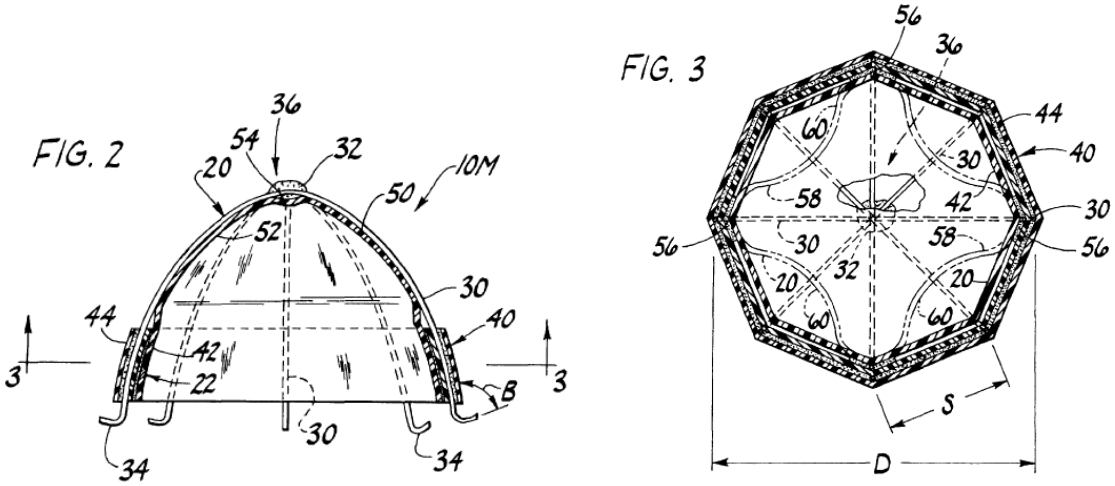

Figure 1 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:8–10. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although 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.

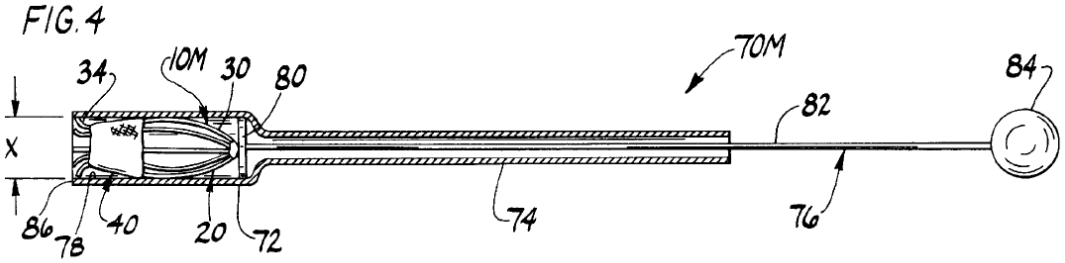

Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:11–13. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* 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 1 is reproduced below:

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors;
>
> a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band, said valve element having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position 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.

Ex. 1001, 10:22–60.

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
Bessler	US 5,855,601	Jan. 5, 1999	Ex. 1008
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**
Bessler	§ 102	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Bessler and Andersen	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Johnson, Bessler, and Imachi	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Bessler, 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. 14–15. 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. 16–17 (citing Ex. 1040; Ex. 1041).

Patent Owner proposes a construction only for the phrase "each of said frame elements has a distance between its respective ends." Prelim. Resp. 3–5. Specifically, Patent Owner proposes that "each of said frame elements has a distance between its respective ends" should "be construed to have its plain and ordinary meaning." *Id.* at 5.

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. 43–45. Specifically, Patent Owner argues that Petitioner circumvented the limit "by eliminating spaces between words many hundreds of times in its petition." *Id.* at 43. 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. 41–42. 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. 42–43. 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. 42–43.

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 all grounds of unpatentability asserted in the Petition. Prelim. Resp. 35–41. Specifically, Patent Owner contends that Johnson "was explicitly considered by the Examiner in both of the Office Actions during prosecution of the '782 Patent." *Id.* at 36–37. Patent Owner also contends that Bessler "is explicitly discussed in the Background of the '782 Patent." *Id.* at 37. Specifically, Patent Owner notes that the '782 patent states: "U.S. Pat. No. 5,885,601 (Bessler) describes a transluminal valve implantation but does not describe the specific valve construction.

The Bessler procedure includes excision, vacuum removal of the native valve, cardio-pulmonary bypass and backflushing of the coronary arterial tree." *Id.* (quoting Ex. 1001, 2:14–19). Thus, according to Patent Owner, "the '782 Patent spells out that the entire premise of the patent is that its invention is better than the Bessler device." *Id.* Patent Owner also argues Andersen "is explicitly discussed in the Background of the '782 Patent," and Imachi "was also before the Examiner." *Id.* at 38–39.

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, that the '782 patent describes its invention as being better than the Bessler device is not relevant to the question of whether the same or substantially the same prior art or arguments have been previously presented to the Office. Moreover, Patent Owner merely asserts that Bessler, 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 Bessler

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 Bessler

Bessler "relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and to the method and device useful for such placement." Ex. 1008, 1:8–11. Figure 4 of Bessler is reproduced below.

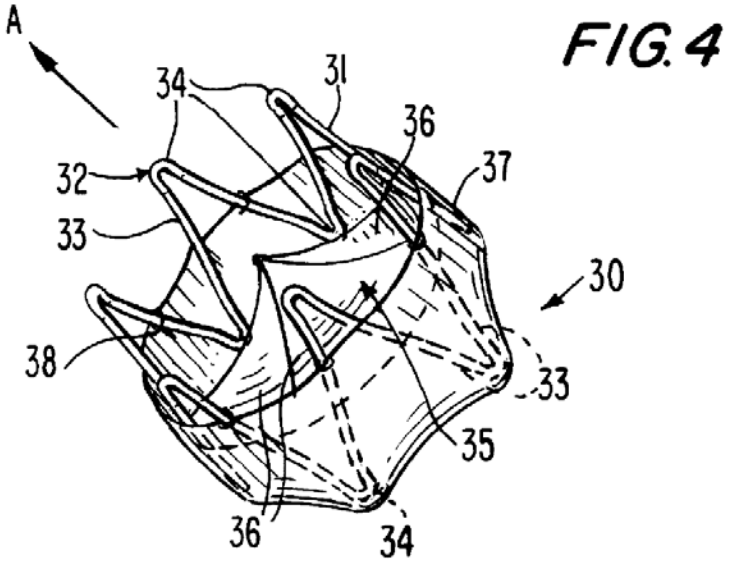

FIG. 4

Figure 4 depicts artificial heart valve 30 having a generally cylindrical shape defined by stent member 32. *Id.* at 5:28–31. Stent member 32 is a wire formed into a closed zig-zag configuration having straight sections 33

joined by bends 34. *Id.* at 5:31–34. Flexible valve member 35 extends across the cylindrical stent and includes a plurality of leaflets 36. *Id.* at 5:34–37. Leaflets 36 "are the actual valve and allow for one-way flow of blood." *Id.* at 5:37–38. Cuff portion 37 extends from the periphery of the leaflet portion and along walls 31 of stent member 32 and is attached to the stent member by sutures 38. *Id.* at 5:38–42. In another embodiment, the stent member includes a plurality of barbs 64 for holding the valve in place. *Id.* at 5:67–6:2, Fig. 7.

The configuration and flexible, resilient material of construction of stent member 32 allows the valve to collapse into relatively small cylinder 40. *Id.* at 5:43–45, Fig. 5. Bessler also discloses device 90 including flexible catheter 91 for percutaneous and transluminal delivery of a heart valve to the desired site. *Id.* at 7:26–30, Figs. 12, 13. Device 90 includes hollow pusher member 93 disposed within catheter 91 and guidewire 94 disposed within pusher member 93 to guide the distal end of the catheter to the desired site. *Id.* at 7:33–38. Means 96 disposed with pusher member 93 holds a collapsed valve in the distal end of catheter 91 and allows the valve to be released when desired. *Id.* at 7:38–40.

2. Independent claim 1

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 "Bessler describes a valve for replacement of a diseased or defective heart valve comprised of a frame, a band, and a [flexible valve element] to be disposed in a native valve annulus between upstream and downstream regions." Pet. 19 (citing Ex. 1008, 2:25–28,

2:57–62, 3:46–4:21, 7:26–67, Figs. 1–7, 14, 15; Ex. 1003 ¶ 56); *id.* at 29. 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. Bessler's artificial heart valve 30 is intended to replace diseased or defective heart valves. Ex. 1008, 2:55–57.

b) a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region

Petitioner argues that Bessler's stent is a flexibly resilient frame. Pet. 19 (citing Ex. 1003 ¶ 57); *id.* at 30. Petitioner also argues that this frame "is sized and shaped for insertion or placement between upstream and downstream regions." *Id.* at 19 (citing Ex. 1008, 2:25–28, 2:57–62, 4:53–5:3, 7:26–67); *id.* at 30.

At this stage of the proceeding, we are persuaded by Petitioner's position. Bessler discloses that "[t]he configuration of the stent member 32 and the flexible, resilient material of construction allows the valve to collapse into a relatively small cylinder," but the "valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 32 will cause the artificial heart valve to take its expanded configuration." Ex. 1008, 5:43–49. In view of this disclosure, we agree that Bessler's stent is a flexibly resilient frame.

In response, Patent Owner argues

> *Bessler* requires *removal* of the native heart valve prior to insertion of the bioprosthetic valve, (Ex. 1008 at

> 2:55-57 and 2:63-67), so there is no "damaged heart valve having a plurality of cusps" remaining to separate the "upstream region" from the "downstream region." As stated in the '782 Patent's Background of the Invention, "[t]he Bessler procedure includes excision [and] vacuum removal of the native valve[.]" (Ex. 1001 at 2:16-17). At best, *Bessler's* valve is "sized and shaped for insertion" in the much larger space left following the excision and removal of a damaged heart valve, not "sized and shaped for insertion" into a damaged heart valve having a plurality of cusps. Thus *Bessler* does not disclose a valve with a frame that is "sized and shaped for insertion between the upstream region and the downstream region."

Prelim. Resp. 10.

We are not persuaded by this argument. Removal of the damaged heart valve that separates the upstream and downstream regions does not mean that the upstream and downstream regions no longer exist. These regions still exist and are separated by the artificial valve that Bessler describes is placed at the same location from which the damaged heart valve is removed. *See* Ex. 1008, 2:63–66 ("A cutting mechanism is used to remove the diseased or defective heart valve, and then the replacement valve is inserted percutaneously to the site."). Furthermore, Patent Owner's assertion that Bessler's valve is inserted in a "much larger space left following the excision and removal of a damaged heart valve" is not persuasive because the claim language requires only that the frame is sized and shaped for insertion *in a position* between the upstream region and the downstream region. The claim language does not require the frame be sized and shaped for insertion into a damaged heart valve.

> *c) the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and*

the downstream region and a central portion located between the plurality of peripheral anchors

Petitioner argues that Bessler's barbs 64 are peripheral anchors. Pet. 20 (citing Ex. 1008, 4:12–21, 5:67–6:2, 7:26–67, Fig. 7; Ex. 1003 ¶¶ 60–61); *id.* at 30–31. Alternatively, Petitioner argues that bends 34 of Bessler's stent member 32 can constitute peripheral anchors. *Id.* at 20–21 (citing Ex. 1008, 5:19–21, 5:28–35, 5:51–60, 6:7–11, Figs. 1–4; Ex. 1003 ¶¶ 60–61); *id.* at 30–31. In addition, Petitioner argues that the claimed central portion "would be the straight sections 33, 53 between the bends 34, 54 . . . or the portions of the stent disposed between the first and second circles of barbs." *Id.* at 21 (citing Ex. 1008, 4:12–21, 5:28–35, 5:55–6:2, 7:43–67, FIGS.1, 4, 6, 7, 14, 15; Ex. 1003 ¶¶ 59–62); *id.* at 31.

At this stage of the proceeding, we find Petitioner's contention that Bessler's barbs 64 are peripheral anchors persuasive. Bessler discloses that barbs 64 hold the valve in place once it has been appropriately positioned. Ex. 1008, 5:67–6:2. And Figure 7 of Bessler depicts barbs 64 as being located on the periphery of stent member 32. We are also persuaded that the portion of Bessler's stent member located between the upper and lower sets of barbs as shown in Figure 7 defines a central portion of the frame.

d) a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors

Petitioner points to Bessler's cuff as being the claimed band. Pet. 23 (citing Ex. 1008, 3:54–64, 4:4–11, 5:24–27, Figs. 1–5, 7); *id.* at 31–32. Petitioner asserts that this band limits spacing between adjacent anchors (i.e., barbs 64) because Bessler's cuff "is shown as being tight against the self-expanding stent" and, thus, "would restrict the expansion of the self-

expanding frame." *Id.* at 24 (citing Ex. 1008, 5:15–27, 40–43, Figs.1, 4; Ex. 1003 ¶ 70).

We are persuaded by Petitioner's assertion that Bessler's cuff portion 34 is a band. Patent Owner does not challenge this assertion, but disputes that the cuff limits spacing between adjacent anchors. Prelim. Resp. 14–15. Specifically, Patent Owner argues that Bessler's written disclosure does not suggest the cuff is "tight against the self-expanding stent." *Id.* Petitioner, however, asserts that the cuff is *shown* in Bessler as being tight against the self-expanding stent, and we agree that Figure 4 of Bessler shows cuff portion 37 closely encompassing stent member 32. Furthermore, Dr. Dasi testifies that, based on this depiction, one of ordinary skill in the art "would expect that this cuff would restrict the expansion of the self-expanding frame." Ex. 1003 ¶ 70. We credit Dr. Dasi's uncontroverted testimony, and, thus, at this stage of the proceeding, we are persuaded by Petitioner's argument that Bessler discloses a band that is attached to the frame limits spacing between adjacent anchors.

> *e) a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band*
>
> Petitioner argues
>
> According to Bessler "[t]he valve member is flexible, compressible, host-compatible, and non-thrombogenic." (Ex.1008 col.6:19-20 (emphasis added).) It can be porcine or synthetic. (*Id.* 6:20-31.) Bessler also teaches that the valve is mounted to the central portion of the frame — "central portion" having been discussed in connection with the flexibly resilient frame above. Indeed, as

> illustrated in FIG.7, FVE 63 can be disposed centrally and attached to "crowns" or the tops of "smaller waves" 61. (*Id.* 5:60-6:2, FIG.7.) Thus Bessler teaches a FVE attached to the frame and in particular to a central portion thereof as Defined. (*See* Claim Chart 1 Bessler "Flexible Valve Element"; Ex.1003 ¶¶72, 75.)

Pet. 24–25; *see also id.* 32 (portion of claim chart identifying passages and figures of Bessler allegedly disclosing the flexible valve element). Petitioner also argues that Bessler's flexible valve element is mounted in the central portion of the frame adjacent the band and substantially free of other connections. *Id.* at 26–27; *id.* at 32.

Patent Owner argues that "[a]lthough *Bessler* discloses that the *cuff* is attached to the stent, it does not disclose that the valve leaflets are attached to the stent or frame and therefore, the 'flexible valve element' is not attached to the frame as required by the claims." Prelim. Resp. 9. We disagree with this argument. Instead, at this stage of the proceeding, we find Petitioner's position persuasive. Bessler discloses a flexible valve member comprising leaflet portion 36 that extends across the cylindrical stent and a cuff portion 37 that extends from the periphery of the leaflet portion and is attached to stent member 32 by sutures 38. Ex. 1008, 5:34–42, Fig. 4. Figure 7 of Bessler shows a flexible valve member 63 having a similar configuration. *Id.* at 5:61–6:2. With this configuration, the leaflet portion, which corresponds to the claimed flexible valve element, is attached to the stent member (i.e., the frame) by virtue of being connected to the cuff portion, which is directly attached to the stent member. This indirect attachment of the leaflet portion to the stent member satisfies the claim language, which does not require a direct attachment.

> *f) said valve element having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region*

Petitioner argues that Bessler's flexible valve element has upstream and downstream sides because "Bessler notes that its valve device has upstream and downstream sides corresponding to inflow and outflow ends." Pet. 25 (citing Ex. 1008, 4:12–21 (barbs facing upstream and downstream directions on the inflow and outflow sides of the valve)).

At this stage of the proceeding, we are persuaded by Petitioner's argument that Bessler discloses a flexible valve element having an upstream side facing an upstream region and downstream side facing a downstream region, which Patent Owner does not dispute.

> *g) 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 1, among other claims, includes "lengthy recitations merely describing the general operation of native and replacement valves, which were known *per se*." Pet. 27 (citing Ex. 1001, 1:42–2:19; Ex. 1003 ¶ 76). Petitioner also argues that Bessler's flexible valve element functions the same way as a tricuspid valve and, therefore, meets these limitations. *Id.* (citing Ex. 1008, 3:65–4:3, 4:63–5:14, 5:36–43, 6:19–24, Fig. 4; Ex. 1003 ¶ 77); *id.* at 35–36.

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 Bessler's valve moves in the manner claimed. Prelim. Resp. 12–14.

We are not persuaded by these arguments. Bessler discloses that "[t]he arcuate portion of the valve means contains at least one slit to form leaflets which open in response to blood flow in one direction and close in response to blood flow in the opposite direction." Ex. 1008, 3:65–4:1; *see also id.* at 2:61–62 (disclosing valve means that permit flow in only one direction). As such, we are persuaded that Bessler's valve moves between open and closed positions in response to a difference in fluid pressure and allows flow in a single direction. Also, because Bessler discloses allowing flow in only one direction, one of ordinary skill in the art would understand that the valve would be positioned to allow downstream flow (between an upstream region and a downstream region), as opposed to upstream flow.

For these reasons, we are persuaded at this stage of the proceeding that Bessler discloses the valve movement limitations of claim 1.

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. 30. 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.* at 30–35.

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 1 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 1 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