Trials@uspto.gov
Tel: 571-272-7822

Paper 12
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 IPR2018-00109
Patent 6,821,297 B2

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

WEATHERLY, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

A. BACKGROUND

St. Jude Medical, LLC ("Petitioner") filed a petition (Paper 3, "Pet.") to institute an *inter partes* review of claims 18 and 20 (the "challenged

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

claims") of U.S. Patent No. 6,821,297 B2 (Ex. 1001, "the '297 patent"). 35 U.S.C. § 311. Snyders Heart Valve LLC ("Patent Owner") timely filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Institution of an *inter partes* review is authorized by statute when "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." 35 U.S.C. § 314(a); 37 C.F.R. § 42.4. Based on our review of the record, we conclude that Petitioner is reasonably likely to prevail with respect to at least one of the challenged claims.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102 and/or 103 based on the following grounds (Pet. 19–68):

References	Basis	Claims challenged
U.S. Patent No. 5,957,949 (Ex. 1017, "Leonhardt")	§ 102	18 and 20
Leonhardt	§ 103	18 and 20
Leonhardt and U.S. Patent No. 4,339,831 (Ex. 1021, "Johnson")	§ 103	18 and 20

Generally, Patent Owner contends that the Petition should be denied in its entirety. 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). For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of success in establishing that Leonhardt anticipates claim 18 of the

'297 patent. In accordance with the Court's decision in *SAS*, we institute an *inter partes* review of all challenged claims of the '297 patent on all grounds alleged by Petitioner.

B. RELATED PROCEEDINGS

The parties identified as a related proceeding the co-pending district court proceeding of *Snyders Heart Valve LLC v. St. Jude Medical SC, Inc., et al*, Case Number 4:16-cv-00812 (E.D. Tex.). Pet. 1; Paper 5, 2. Patent Owner also identified *Snyders Heart Valve LLC v. Medtronic, Inc. et al*, 4:16-cv-00813 (E.D. Tex.). Paper 5, 2. Petitioner identified three petitions for *inter partes* review filed in IPR2018-00105, -00106, and -00107 as being related. *See* Pet. 1 (identifying these proceedings using Petitioner's docket numbers).

C. THE '297 PATENT

The '297 patent, titled "Artificial Heart Valve, Implantation Instrument and Method Therefor," issued November 23, 2004, with claims 1–46. Ex. 1001, (54), (45), 19:11–24:65. The '297 patent is directed to "artificial heart valves for repairing damaged heart valves." *Id.* at 1:15–16. Figures 2 and 3 of the '297 patent are reproduced below.

FIG. 2

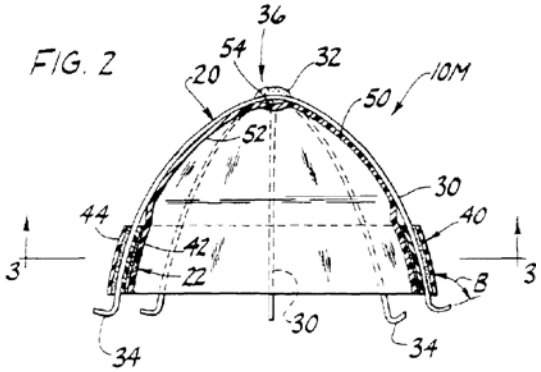

FIG. 3

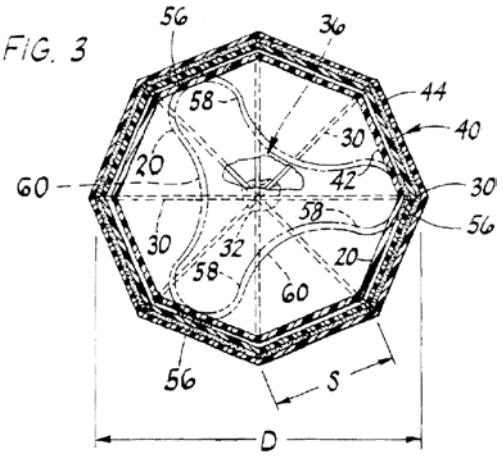

Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:11–13. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although the '297 patent also discloses an artificial valve configured to repair a damaged pulmonary heart valve. *Id.* at 4:33–5:5.

Artificial valve 10M comprises flexibly resilient external frame 20 and flexible valve element 22. *Id.* at 5:17–19. Frame 20 includes U-shaped stenting elements 30 that are joined together generally midway between their respective ends at junction 32. *Id.* at 5:20–30. 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 5:30–38. 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 5:58–62. Frame 20 further includes central portion 36 located between peripheral anchors 34. *Id.* at 6:4–7.

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 6:52–56.

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 7:7–18. 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 7:17–22. 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 7:22–27.

More specifically, apex 54 of upstream side 50 is attached to junction 32 of frame 20. *Id.* at 7:55–57. 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 56. *Id.* at 7:57–8:1. Flaps 58 and corresponding portions of band 40 define openings 60 when valve element 22 moves to its open position. *Id.* at 8:1–5.

Figure 4 of the '297 patent is reproduced below.

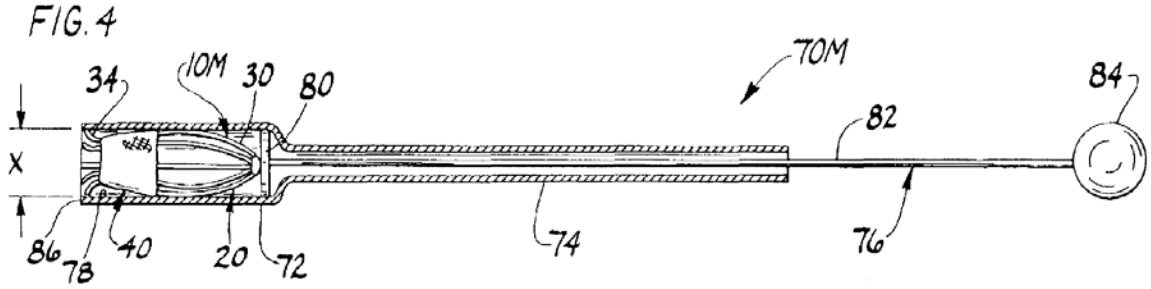

Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:14–16. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* at 8:28–31. 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 8:31–34.

Claims 18 and 20 each recite a "transluminal method of inserting an artificial valve as set forth in claim 1." *Id*. at 21:1–25 (claim 18), 21:31–50 (claim 20). Claims 1 and 18, which are representative, recite:

> 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 along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;
>
> a flexible valve element attached to the central portion of the frame 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 flexible 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 flexible valve element permits downstream flow between said upstream region and said downstream region and

a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region,

wherein the flexible 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 flexible 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 opening extending through at least one of said frame and said flexible valve element for receiving an implement.

Id. at 19:11–52 (with line breaks added for clarity).

18. A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of an elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel;

positioning the end adjacent the plurality of cusps of the damaged heart valve;

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart;

retrieving the artificial valve into the end of the instrument;

repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

Id. at 21:1–25.

II. ANALYSIS

A. ALLEGED PROCEDURAL BASES FOR DENYING THE PETITION

Patent Owner argues that we should deny the Petition for two reasons that are independent of the merits of patentability presented in the Petition. We address each in turn below.

1. Unconstitutionality of Inter Partes Review under Article III and the Seventh Amendment

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. 26. This argument, however, is not persuasive in light of the Supreme Court's decision in *Oil States Energy Services, LLC v. Greene'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").

2. Unconstitutionality of Inter Partes Review under Article II

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. 27–28. 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. 27.

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.

B. CLAIM INTERPRETATION

"A claim in an unexpired patent that will not expire before a final written decision is issued 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 Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (affirming that USPTO has statutory authority to construe claims according to Rule 42.100(b)). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the

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

Petitioner indicates that the parties filed a Joint Memorandum on Claim Construction (Ex. 1041) in the related district court action identified above. Pet. 21. 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. *Id*. at 22. Based on these alleged constructions from the district court action, Petitioner proposes constructions for "frame," "peripheral anchors," "central portion located along a centerline extending between the plurality of peripheral anchors," "flexible valve element," "opening extending through at least one of said frame and said flexible valve element for receiving an implement," and "flexibly resilient." *Id*. at 23–24 (citing Ex. 1040; Ex. 1041).

Patent Owner proposes constructions only for the term "central portion." Prelim. Resp. 3–6. Specifically, Patent Owner proposes that "'central portion of the frame' . . . should be construed as 'central *structural* frame portion.'" *Id.* at 4, 6.

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. LEGAL STANDARDS

Petitioner challenges the patentability of claims 18 and 20 on the grounds that the claims are either anticipated or obvious in light of various references including: Leonhardt and Johnson. "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., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is reasonably likely to be unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406. With these standards in mind, we address each challenge below.

D. ANTICIPATION BY LEONHARDT

Petitioner contends that Leonhardt anticipates claims 18 and 20 under 35 U.S.C. § 102(a), (e). Pet. 3, 24–42. Petitioner supports its contentions with the testimony of Lakshmi Prasad Dasi, Ph.D. *Id.* Patent Owner disputes Petitioner's contentions. Prelim. Resp. 9–14. For the reasons

expressed below, we determine that Petitioner has demonstrated a reasonable likelihood that it will establish that Leonhardt anticipates claim 18.

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. We reproduce Figure 4 of Leonhardt at right, which is a side view of Leonhardt's valve stent 20. Valve stent 20 comprises 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 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.

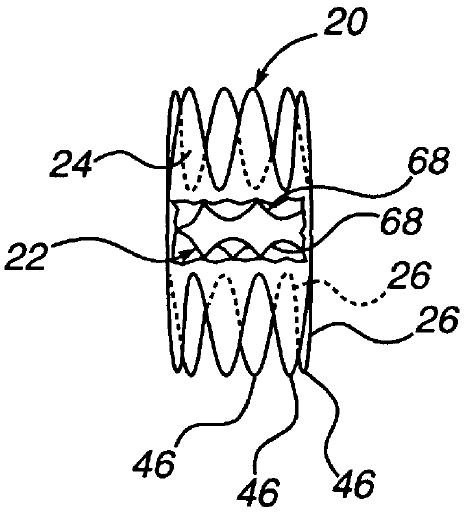

FIG. 4

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. Petitioner's Argument and Evidence Regarding Claim 18

Petitioner contends that Leonhardt anticipates claim 18 and identifies specific portions of Leonhardt that describe each element of the method of inserting the artificial valve of claim 18. Pet. 24–42 (citing Ex. 1017, 1:5–21, 2:43–50, 3:15–49, 4:53–5:52, 6:9–34, 7:10–17, 8:42–9:5, 9:49–11:36, 11:59–12:5, FIGS. 1B, 1C, 2–4, 9A–9D). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id*. (citing Ex. 1003 ¶¶ 71–96).

3. Patent Owner's Counter Arguments and Evidence Regarding Claim 18

Patent Owner contends that Leonhardt fails to anticipate claim 18 for two reasons. Prelim. Resp. 9–14. For the reasons expressed below, we determine that neither argument is persuasive at this stage of the proceeding.

First, Patent Owner contends that Leonhardt fails to describe a "flexible valve element attached to the central portion of the frame." *Id*.

at 9–12. Petitioner contends that Leonhardt describes a porcine valve element that is sutured or glued to stent 26, graft material 24, or both. Pet. 38 (citing Ex. 1017, 6:23–34, FIG. 4). Stent 26 includes two cylindrical sections that are joined by connecting bar 29, which is the "central part of the continuous wire from which stent 26 is formed." Ex. 1017, 5:31–33. Connecting bar 29 is also sutured, and thus attached, to graft material 24. *Id*. at 5:36–37. Because connecting bar 29 is a "central part" of stent 26 and valve 22 may be secured to both stent 26 and graft material 24, we determine that Petitioner has sufficiently demonstrated a reasonable likelihood that Leonhardt describes a "flexible valve element attached to the central portion of the frame" as required in claim 18.

Second, Patent Owner contends that Leonhardt fails to describe a valve that opens in response to greater pressure in the upstream region and closes in response to greater pressure in the downstream region. Prelim. Resp. 12–14. Petitioner points out that Leonhardt describes an artificial valve that "may be placed where fluid flow needs to be maintained in one direction only." Pet. 39 (citing Ex. 1017, 1:5–8, 1:10–21). The cited passages of Leonhardt indicate 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.

4. Conclusion Regarding Claim 18

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that Leonhardt anticipates claim 18 of the ’297 patent.

III. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that at least one claim of the ’297 patent is unpatentable. In accordance with the Court’s decision in *SAS Institute, Inc. v. Iancu*, No. 16-969, 2018 WL 1914661 (U.S. Apr. 24, 2018), we institute an *inter partes* review of all challenged claims of the ’297 patent on all grounds alleged by Petitioner. This Decision does not reflect a final determination on the patentability of any claim. We note that the burden remains on the Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

IV. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review is instituted of claims 18 and 20 of the ’297 patent with respect to the following grounds of unpatentability:

(1) Leonhardt anticipates claims 18 and 20 under 35 U.S.C. § 102(a) or (e);

(2) Leonhardt renders claims 18 and 20 unpatentable under 35 U.S.C. § 103; and

(3) the combination of Leonhardt and Johnson renders claims 18 and 20 unpatentable under 35 U.S.C. § 103; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '297 patent is 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 given of the institution of a trial.

PETITIONER:

Michael H. Teschner
Stephen M. Lund
Maegen 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