

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TROY R. NORRED,
Petitioner,

v.

MEDTRONIC CV LUXEMBOURG S.à.r.l.,
Patent Owner.

Case IPR2015-00477
Patent 7,914,569 B2

Before JOSIAH C. COCKS, WILLIAM V. SAINDON, and
JAMES A. WORTH, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 1–18 of U.S. Patent No. 7,914,569 B2 (Ex. 1001, “the ’569 patent”). Paper 4 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon consideration of the Petition, Preliminary Response, and the papers and exhibits cited therein, we do not institute an *inter partes* review on any of the challenged claims.

A. Related Matters

The parties report no current related matters. Pet. 1; Paper 6.

B. The ’569 Patent

The ’569 patent is directed to a heart valve prosthesis. Valve prosthesis 10 is made of expandable frame 12 with valve body 14 affixed thereto. Ex. 1001, 5:32–34. Frame 12 is formed of zig-zaging struts that serve to define cells, with varying cell size serving to create varying compressibility, expansion characteristics, radial strength, and contour for the frame. *Id.* at 5:48–59, Fig. 1B. Frame 12 generally defines a tri-level asymmetric hourglass shape, as shown in Figure 1A, reproduced below:

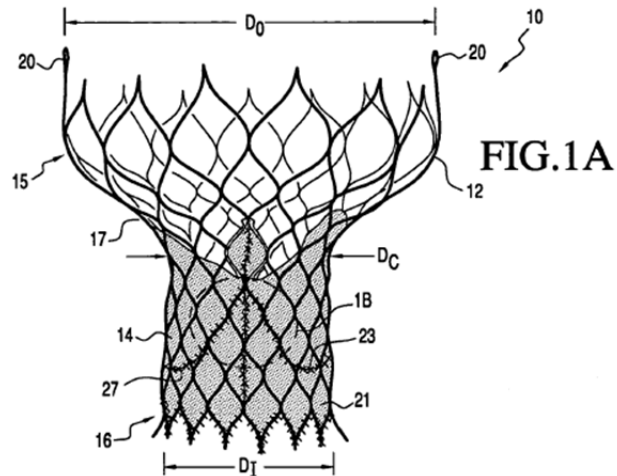


Figure 1A depicts a tri-level asymmetric hourglass shape wherein a diameter at the inflow of the valve D_I is greater than a diameter of constricted region D_C . Ex. 1001, 5:60–63, 6:12–20. Both of these diameters are, in turn, smaller than a diameter of an outflow portion D_O . *Id.*

Valve body 14 is attached to frame 12 in a particular manner such that the attachment points align with the struts of the frame. For example, the bottom portion of commissures 24 (where valve leaflet 22 is attached to valve skirt 21) align with the zig-zag pattern of the struts of frame 12 to evenly distribute the forces. *Id.* at 7:11–13, Figs. 1A, 5. End tabs 39 also are affixed to the struts of the frame. *Id.* at 8:31–32, Fig. 5. Lastly, flaps 36 of adjacent leaflets are affixed in a manner that serves “to span a cell of the frame to support commissures 24.” *Id.* at 8:28–31, Figs. 1A, 5. Figure 5, reproduced below, details the locations and manner by which valve body 14 is affixed to frame 12:

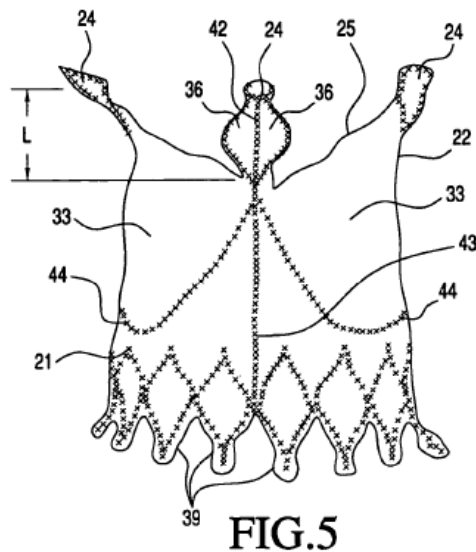


Figure 5 depicts valve body 14 as it would appear when affixed to frame 12, but with frame 12 omitted to better illustrate where the valve body is affixed to the frame. *Id.* at 8:25–27. For example, Figure 5 shows flaps 36 attached to where the struts of frame 12 would be, to support commissures 24. *Id.* at 8:28–30. Figure 5 also shows joining seam 42 of commissure 24, the seam running across where a cell of frame 12 would be. *See id.* at 7:2–4, 8:13–14, Figs. 4A, 4B.

C. Illustrative Claim

Petitioner challenges each claim of the '569 patent. Claims 1 and 18 are independent. Independent claim 1 is reproduced below.

1. A valve prosthesis comprising:
 - a valve body comprising a plurality of leaflets sewn to a skirt, adjoining leaflets sewn together to form commissures; and
 - a self-expanding frame comprising a plurality of cells, the frame having a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow section and the outflow section, wherein the constriction region is configured to avoid blocking blood flow to the

coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration,

wherein, when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region,

wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,

wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,

wherein each commissure is configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures,

wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation, and

wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.

D. Asserted Ground and Prior Art

Petitioner asserts that claims 1–18 of the '569 patent are unpatentable over the following grounds:

References	Basis	Claims Challenged
Svanidze ¹	§ 102	1–18
Schwammenthal ²	§ 102	1–18
Spenser ³	§ 102	1–18
Svanidze and Lashinski ⁴	§ 103	1–18
Schwammenthal and Svanidze	§ 103	1–18
Spenser and Schwammenthal	§ 103	1–18
Schwammenthal, Svanidze, and Lashinski	§ 103	1–18
Spenser, Schwammenthal, and Lashinski	§ 103	1–18

Petitioner also relies on the testimony of Carl. T. Rutledge, Ph.D. Ex. 1007.

II. ANALYSIS

A. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1281–82 (Fed. Cir. 2015). Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be

¹ U.S. Patent No. 7,044,966 B2, issued May 16, 2006, published Apr. 7, 2005 (Ex. 1003).

² U.S. Patent No. 7,201,772 B2, issued Apr. 10, 2007, filed Dec. 30, 2004 (Ex. 1004).

³ U.S. Patent No. 6,730,118 B2, issued May 4, 2004, published June 19, 2003 (Ex. 1005).

⁴ U.S. Patent No. 7,320,704 B2, issued Jan. 22, 2008, filed May 5, 2005 (Ex. 1006).

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). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner and Patent Owner propose the following constructions:

Party	Term	Proposed Construction
Petitioner	“commissure”	seam where two materials are joined together
Petitioner	“coaptation”	free edge where two materials come together
Petitioner	“catenary”	natural U-shaped curve assumed by a free edge when supported at its ends
Patent Owner	“cell”	the spaces defined by the frame structure
Patent Owner	“span”	to extend across

Pet. 9–10; Prelim. Resp. 11–12.

Patent Owner indicates that it does not concede Petitioner’s proposed constructions, but “use[s]” them for purposes of its Preliminary Response. Prelim. Resp. 11. We have reviewed these proposed constructions and the ’569 patent specification and determine that they are consistent with the broadest reasonable interpretation of the term in light of the specification. Accordingly, we adopt them for purposes of this Decision.

B. Analysis

1. Anticipation by Svanidze

Petitioner asserts that each claim of the ’569 patent is anticipated by Svanidze. Pet. 13–20, 39–45. Petitioner generally relies on the replacement valve shown in Figures 11 and 12 of Svanidze, reproduced below:

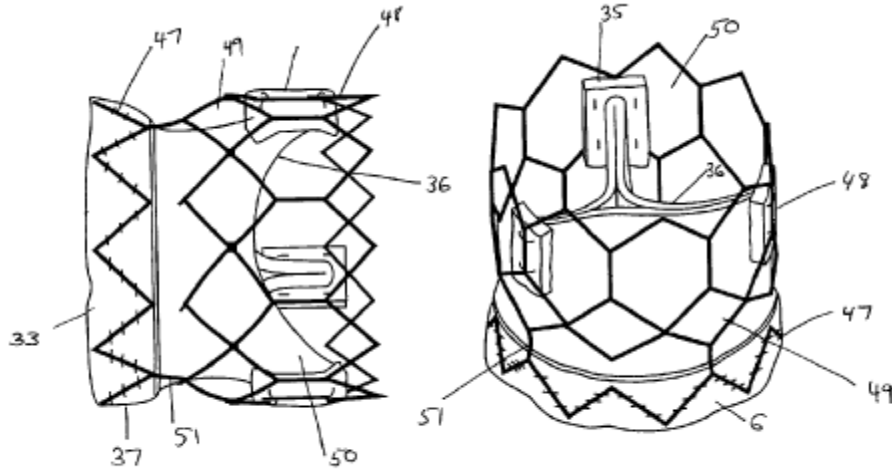


FIG. 11

FIG. 12

Figures 11 and 12 of Svanidze show flared-out inflow section 47, flared-out outflow rim 48, and valve 32 having commissural tabs 35 stitched directly to hexagon shaped elements 50. Ex. 1003, 13:5–11, 22–25.

Petitioner also relies on the embodiment shown in Figure 14 of Svanidze, reproduced below:

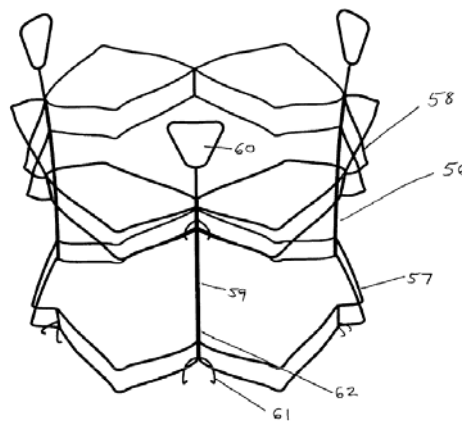


FIG. 14

Figure 14 of Svanidze shows a different anchoring structure (frame) having tab attachment windows 60 to create an interference fit between the anchoring structure and the commissural tabs. *Id.* at 14:18–21. Figure 14

depicts the windows 60 as extending past distal end 58 and does not depict the valve.

As to the limitations in independent claims 1 and 18 requiring the “commissure [to be] sewn to the frame along a region of the frame that increases in diameter” and to be “configured to span a cell of the frame,” Petitioner asserts that Svanidze describes these limitations and cites to various figures and passages. Pet. 15, 18–19, 40, 44 (citing Ex. 1003, Figs. 11, 12, 14, 7:9–19, 9:15–22, 11:18–38, 13:5–40, 13:58–14:35).

Patent Owner argues that Svanidze does not disclose a commissure configured to “span a cell” “along a region of the frame that increases in diameter.” Prelim. Resp. 15–18. Specifically, Patent Owner argues that commissure tabs 35 are attached *along a strut* of the frame and, thus, do not “span” (i.e., extend across) a cell of the frame. *Id.* at 16. Patent Owner also argues that the portion of the frame at which commissure tabs 35 are attached is not increasing in diameter, but rather is at a constant diameter. *Id.* at 17. With respect to Petitioner’s citation to Figure 14 of Svanidze, Patent Owner argues that this figure does not show how commissures would be attached, such as to know whether they “span” the cell in the manner required by the claims, nor does the frame appear to be widening at this point. *Id.* at 17–18.

Reviewing the portions of Svanidze cited by Petitioner and taking into consideration Patent Owner’s Preliminary Response, we find Patent Owner’s arguments persuasive. We agree with Patent Owner that Figures 11 and 12 of Svanidze do not show the frame to be widening where the commissures are attached (the walls of the frame appear to be parallel). In addition, we agree that the commissures appear to be attached along the struts of the

frame or across a portion of the cell, and, in either case, we are not persuaded that the commissures in Svanidze extend across a cell of the frame. Further, we agree with Patent Owner that Figure 14 does not show how the commissures would be attached to the frame, such that it is unclear whether the commissures span a cell of the frame.⁵ Accordingly, we determine that Petitioner has not shown sufficiently how Svanidze discloses a commissure that spans a cell or is sewn to a frame in a region that increases in diameter.

We also are persuaded by Patent Owner's arguments that Svanidze does not show the outflow section having a larger diameter than the inflow section, as required by claim 1. Prelim. Resp. 18–19. Petitioner asserts that Svanidze describes this limitation and cites to various figures. Pet. 15, 40 (citing Ex. 1003, Figs. 3, 6A, 6C, 11–13, 26, 27B, 28B). Reviewing these figures and Petitioner's analysis, however, we are not persuaded that the outflow section has a larger diameter than the inflow section in these figures. Accordingly, Petitioner's ground is deficient for this additional reason.

In view of the above, we are persuaded that Petitioner has not demonstrated a reasonable likelihood that Svanidze anticipates the subject matter of independent claims 1 and 18. Petitioner's ground with respect to dependent claims 2–17 is deficient for the same reasons.

2. Anticipation by Schwammenthal

Petitioner asserts that each claim of the '569 patent is anticipated by Schwammenthal. Pet. 20–27, 45–50. Schwammenthal is directed to prosthetic devices useful for the treatment of aortic stenosis in the aortic

⁵ Indeed, as depicted, the attachment windows appear past the frame.

valve of a heart. Ex. 1004, 1:15–17. Figure 19b of Schwammenthal is illustrative of its disclosure and is reproduced below:

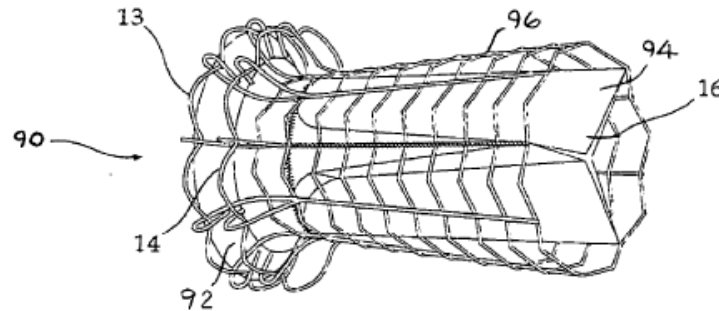


FIG.19b

Figure 19b of Schwammenthal depicts a device having valve 16, which in turn has outlet 94 attached to the struts of the connecting structure 96 (frame). *Id.* at 12:54–57.

As with Svanidze, Patent Owner argues that the commissures in Schwammenthal do not span a cell of the frame, as required by independent claims 1 and 18, but rather are attached along the struts. Prelim. Resp. 21–23. Petitioner simply asserts that the commissures span a cell, but does not provide any persuasive explanation. See Pet. 22–23, 26, 46, 50. The Figures cited by Petitioner (Figs. 4, 5, 18a, 19b) are directed largely to different embodiments and each appear to depict the commissures as aligned with and attached along the struts of the frame, rather than across a cell of the frame. See, e.g., Ex. 1004, Fig. 19b. Accordingly, we are not persuaded that Petitioner has shown sufficiently that the commissures “span” a cell in Schwammenthal in the manner required by independent claims 1 and 18.

In view of the above, we are persuaded that Petitioner has not demonstrated a reasonable likelihood that Schwammenthal anticipates the subject matter of independent claims 1 and 18. Petitioner’s ground with respect to dependent claims 2–17 is deficient for the same reasons.

3. Anticipation by Spenser

Petitioner asserts that each claim of the '569 patent is anticipated by Spenser. Pet. 27–34, 50–56. Spenser discloses a valve prosthesis useful for cardiac implantation. Ex. 1005, 1:10–12. Figures 17b and 28 of Spenser are illustrative and are reproduced below:

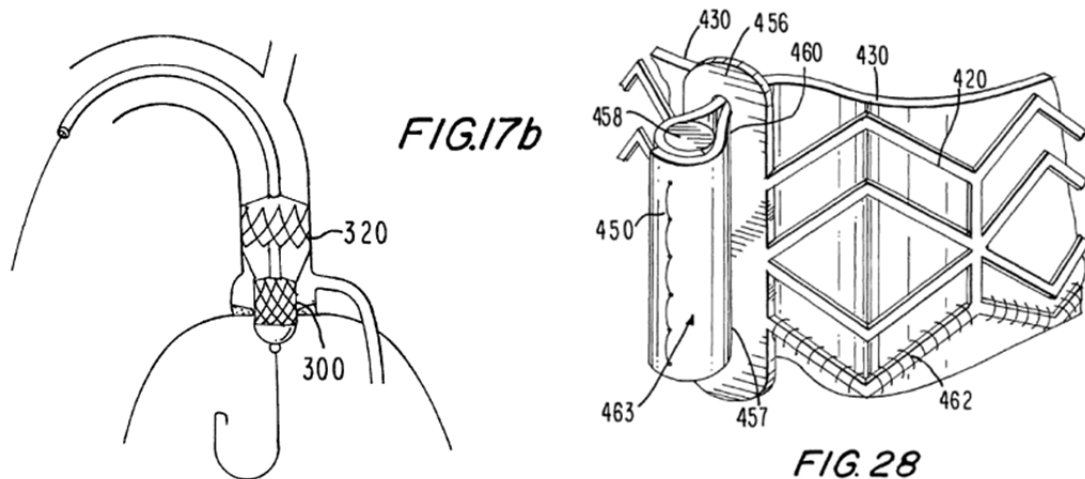


Figure 17b of Spenser shows a cardiac valve device being deployed in the aortic valve location using inflatable balloons. The valve device is divided into two stents: a larger-diameter distal stent 320, which serves to reduce device migration, and a smaller-diameter proximal stent 310 (misabeled 300 in Figure 17b), which contains the valve. *See id.* at 18:11–35. Figure 28 shows a partial view of a prosthetic valve detailing how the commissure is attached to the frame. The end portion of each leaflet 430 is fed through slit 457 and then the portions are attached to rigid bar 458. *Id.* at 22:18–23.

As with Svanidze, Patent Owner argues that the commissures in Spenser do not span a cell of the frame at a region that is increasing in diameter in the manner required by independent claims 1 and 18. Prelim. Resp. 25–27. Petitioner asserts that the commissures in Spenser are sewn to the frame in a region that is increasing in diameter and that each commissure

is configured to span a cell of the frame. Pet. 29–30, 33, 51–52, 55–56 (citing Figs. 16a–17b, 20a, 20b, 28, 31b, 32a, 33a, 33b, 37c, 44a, 12:40–49, 15:8–29, 16:1–24, 18:11–36, 22:51–56). Reviewing the laundry list of different embodiments Petitioner cites and the paucity of analysis, we are not persuaded that the valves disclosed at the citations provided depict a commissure that both spans a cell and does so at a portion where the frame is increasing in diameter. Indeed, in each of the figures depicting a valve, the frame appears to have parallel walls. See Ex. 1005, Figs. 20a, 20b, 28, 44a. The other figures show the commissural attachment only, or how to deploy the device, neither of which helps us determine the diameter of the frame at the commissure attachment point. In view of the above, Petitioner has not shown sufficiently how Spenser describes commissures that “span a cell” and are attached to the frame in a region “increas[ing] in diameter” as required by independent claims 1 and 18.

Patent Owner also argues that Petitioner has not shown where Spenser describes a frame having a conical inflow section as required by independent claims 1 and 18. Prelim. Resp. 27–28. Petitioner asserts that Spenser discloses a “substantially conical inflow section 24.” Pet. 28–29 (citing Ex. 1005, Figs. 16a–17b, 12:40–49, 18:11–36); *id.* at 33 (citing to the same passages for claim 18); *id.* at 51, 55 (citing to the same passages in a claim table, for both claims 1 and 18). Reviewing the citations Petitioner provides, we are persuaded by Patent Owner’s argument that Spenser does not show a conical inflow section. We do not see any item labeled “24” in Figures 16a through 17b (i.e., those Figures cited by Petitioner for this limitation). The citations to columns 12 and 18 of Spenser likewise do not clearly describe a

conical inflow section. Figure 1 of Spenser, reproduced below, depicts an inflow section 24:

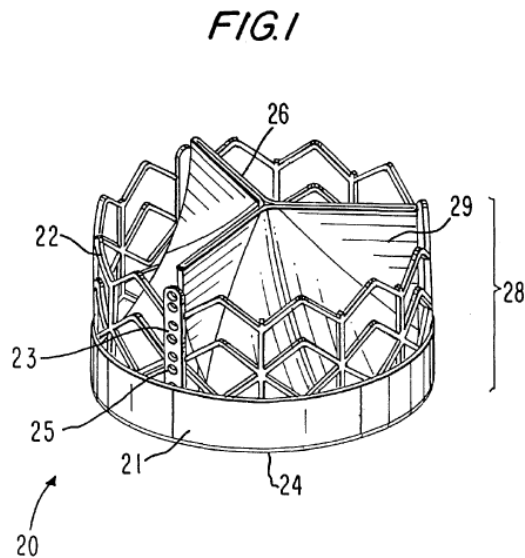


Figure 1 of Spenser depicts implantable prosthetic valve 20 having inlet 24 and outlet 26. Ex. 1005, 13:18–26. We are persuaded by Patent Owner's arguments and determine that neither Figure 1 of Spenser nor the citations provided by Petitioner establish sufficiently that inlet 24 of Spenser is conical.

Patent Owner lastly argues that Petitioner has not shown that Spenser describes a self-expanding stent. Prelim. Resp. 29–30. Petitioner cites to the same passages and figures as cited to for the conical inflow section limitation. See Pet. 28–29, 33, 51, 55. We have reviewed these passages and are not persuaded that they disclose Spenser to be a self-expanding stent. We agree with Patent Owner that, although Spenser discloses the stent may be made of a shape memory alloy (see Ex. 1005, 12:40–49), such a disclosure does not establish sufficiently that Spenser is self-expanding. See also Ex. 2003, 7:27–47, 9:52–10:6 (describing a shape memory alloy intravascular filter that requires an actuating wire to expand).

Consequently, Petitioner has not demonstrated a reasonable likelihood that Spenser anticipates the subject matter of independent claims 1 and 18. Petitioner's ground with respect to dependent claims 2–17 is deficient for the same reasons.

4. Obviousness Grounds

We have reviewed Petitioner's five obviousness grounds, each relying principally on Svanidze, Schwammenthal, and/or Spenser. *See* Pet. 34–38, 56–60. These grounds do not serve to remedy the underlying deficiencies identified above. Accordingly, we determine that Petitioner has not established a reasonable likelihood of prevailing on any of the asserted obviousness grounds.

5. Conclusion

Reviewing the Petition, Preliminary Response, and the evidence cited therein, we determine that Petitioner has not established a reasonable likelihood of prevailing on any of the asserted grounds.

III. ORDER

In view of the foregoing, it is hereby ORDERED that the Petition is DENIED and an *inter partes* review is NOT INSTITUTED.

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