UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC, and

MEDTRONIC, INC.

Petitioners,

v.

SPEYSIDE MEDICAL, LLC,

Patent Owner.

Case IPR2021-00242

U.S. Patent No. 10,449,040

PETITION FOR *INTER PARTES* REVIEW

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Pursuant to §§311-319 and §42.1, Medtronic CoreValve LLC and Medtronic, Inc. ("Petitioners") petition for *inter partes* review ("IPR") of claims 7-10 ("Challenged Claims") of U.S. Patent 10,449,040 ("'040") (Ex. 1001), assigned to Speyside Medical, LLC ("PO").[1] There is a reasonable likelihood that at least one challenged claim is unpatentable as explained herein. Petitioners request review and cancellation of the Challenged Claims.

I. INTRODUCTION

The '040 is directed to a method for deploying a prosthetic heart valve. The claimed prosthetic valve lacks an interlocking lock mechanism, and—after expanding its distal end and before expanding its proximal end—operates to permit unidirectional blood flow. But, all steps of the Challenged Claims were well-known in the art at the time of the invention, and the claimed features were taught in the art well before the time of the alleged invention.

[1] Section cites are to 35 U.S.C. (pre-AIA) or 37 C.F.R. as context indicates. All emphasis/annotations added unless noted. Annotations added to the figures herein generally quote the language of the Challenged Claims for reference. All citations herein are exemplary and not meant to be limiting.

The ’040 patent claims recite a method for deploying a prosthetic heart valve without an interlocking locking mechanism, including transluminally delivering via a blood vessel and deploying at a native heart valve a prosthetic valve from a collapsed to expanded configuration (Fig. 47A-B); testing a performance characteristic of the prosthetic valve (Fig. 47C); at least partially reversing the deployment of the prosthetic valve (Fig. 47D); repositioning the prosthetic valve (Fig. 47E); and re-deploying the prosthetic valve (Fig. 47E). ’040, Figs. 47A-E; Drasler ¶36.

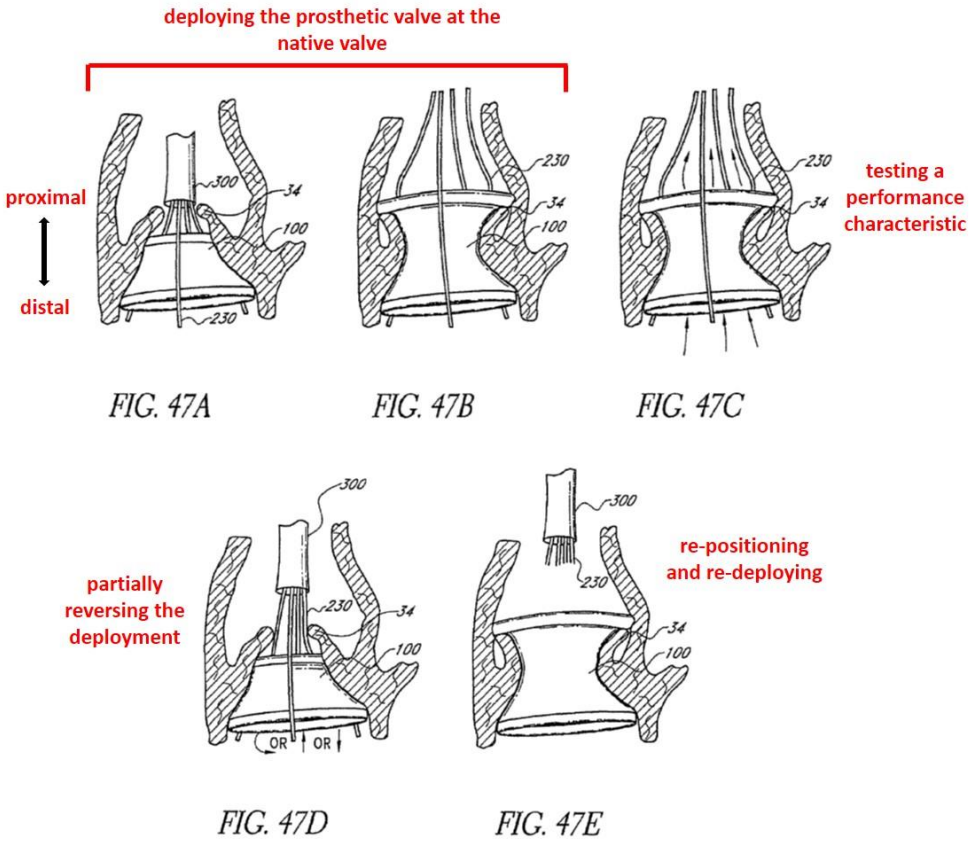

FIG. 47A FIG. 47B FIG. 47C

FIG. 47D FIG. 47E

The ’040 admits that at the time of the invention, this was a well-developed field and the endovascular delivery steps were well-known in the art. ’040, 3:55-58; Drasler ¶¶37-40. For example, **Leonhardt**, which was applied in a rejection during prosecution, teaches a prosthetic valve (in red below) without an interlocking locking mechanism (as depicted in Fig. 1 below), and that operates to permit only unidirectional blood flow after distal end expansion, but before proximal end expansion. Leonhardt, 10:53-11:22; Drasler ¶¶85, 129.

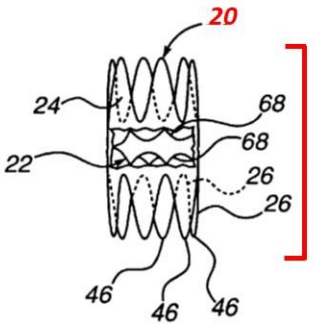

FIG. 4

prosthetic valve

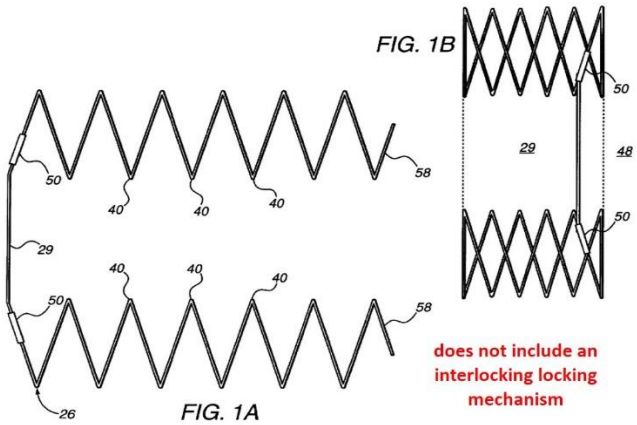

FIG. 1A

Leonhardt further discloses treating a patient with its prosthetic valve in accordance with the claimed steps: transluminally advancing and deploying at the native valve the prosthesis from a collapsed to expanded configuration, testing a performance characteristic such as “function” and “leakage,” reversing deployment, repositioning, and re-deploying. Leonhardt, 10:53-11:59; Drasler ¶¶84-85, 97, 120-121. The only alleged point of novelty in the Challenged Claims identified by PO during prosecution over **Leonhardt** was the requirement that the prosthetic valve

permit unidirectional blood flow after expansion of the distal end and before expansion of the proximal end of the valve. *E.g.*, Ex. 1003 ("'040FH"), 724-25.

However, while **Leonhardt's** expansion balloon is used to expand its prosthesis's ends and hold the prosthesis in place during release thereby obstructing blood flow when expanded, **Bailey** instead teaches the improvement of using an expansion balloon with an "irregular inflation profile[]" permitting blood flow around the balloon even when the balloon is expanded, such as when it is used to expand a prosthesis. Bailey ¶¶[0070], [0072]; Drasler ¶99. Indeed, **Bailey** expressly cites **Leonhardt** in discussing its improvement thereto. In addition, **Seguin** teaches blood flow through a prosthesis such as **Leonhardt**'s even when the proximal end of the prosthesis remains inside the catheter during deployment by allowing the blood to flow through lateral openings in the catheter (Seguin, 7, 11-12, Claim 11). Importantly, neither **Bailey** nor **Seguin** nor any substantially similar reference was considered during prosecution with **Leonhardt**.

As will be demonstrated herein, **Leonhardt** in view of **Bailey** and alternatively in further view of **Seguin** renders obvious the Challenged Claims, which are directed to an obvious combination of prior art elements combined according to known methods to yield predictable results. At most, the combination amounts to nothing more than a "predictable use of prior art elements according to

their established functions." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); Drasler ¶¶161-163.

Petitioners request that the Board institute trial and find the Challenged Claims unpatentable.

II. MANDATORY NOTICES (§42.8)

A. Real Party-In-Interest

Pursuant to §42.8(b)(1), Petitioners identify Medtronic CoreValve LLC and Medtronic, Inc. as real parties-in-interest. No other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition.

B. Related Matters

The '040 is currently the subject of a district court litigation: *Speyside Medical, LLC v. Medtronic CoreValve LLC et al.*, No. 20-cv-00361 (D. Del., filed March 13, 2020). Medtronic is filing IPR petitions against the other patents asserted in that district court litigation: IPR2021-00243 (USP 9,445,897); IPR2021-00240, IPR2021-00241 and IPR2021-00310 (USP 9,510,941); IPR2021-00239 (USP 8,377,118); and IPR2021-00244 (USP 9,603,708).

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Petitioners consent to electronic service of documents to the email addresses of the counsel identified above.

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fee required by §42.15(a) and any additional fees that might be due to Deposit Account No. 18-1945, under Order No. 102760-0209-655.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioners certify the '040 is available for IPR. Petitioners are not barred or estopped from requesting IPR challenging the claims of the '040 on the grounds identified herein.

B. Identification of Challenge

Pursuant to §42.104(b), Petitioners request IPR of the Claims, and that the Board cancel the same as unpatentable. The '040 claims priority to 13/069,209 ("'209 Application") filed 3/22/2011 and 11/579,723, filed as PCT/US2005/015617 on 5/5/2005 and multiple provisionals. Drasler ¶64.

1. The Specific Art on Which the Challenge Is Based

Petitioners rely upon the following prior art:

Name	Exhibit	Patent / Publication	Priority Date	Issued / Published	Prior Art Under at Least §102
Leonhardt	*1004	U.S. 5,957,949	05/01/1997	09/28/1999	(a), (b)
Bailey	*1005	U.S. App. Pub. 2003/0023300	12/31/1999	01/30/2003	(a), (b)
Seguin	*1006	WO01/35870	11/15/2000	05/25/2001	(a), (b)

2. Statutory Grounds on Which the Challenge Is Based

Petitioners respectfully request cancellation of the Challenged Claims on the following grounds:

§103 Ground	Claim(s)	Prior Art
1	7-10	Leonhardt in view of Bailey
2		Leonhardt in view of Bailey and Seguin

3. How the Challenged Claims Are Unpatentable

Petitioners provide the information required under §§42.104(b)(4)-(5) in §X.

V. '040 PATENT

The '040 discloses an aortic valve prosthesis for replacing an abnormal or diseased aortic valve 34. '040, Abstract, 4:18-20, 11:57-64, Fig. 2 (below). The claimed method is generally directed to (1) transluminally delivering a prosthetic valve to a native heart valve and deploying the prosthetic valve from a collapsed delivery configuration to an expanded configuration, (2) testing a performance characteristic of the prosthetic valve, (3) at least partially reversing the deployment of the prosthetic valve, (4) repositioning the prosthetic valve, and (5) re-deploying the prosthetic valve, as illustrated in Figs. 47A-E and 2 below. '040, Abstract, 5:50-57, 50:48-51:24, 76:17-76:2. Drasler ¶41.

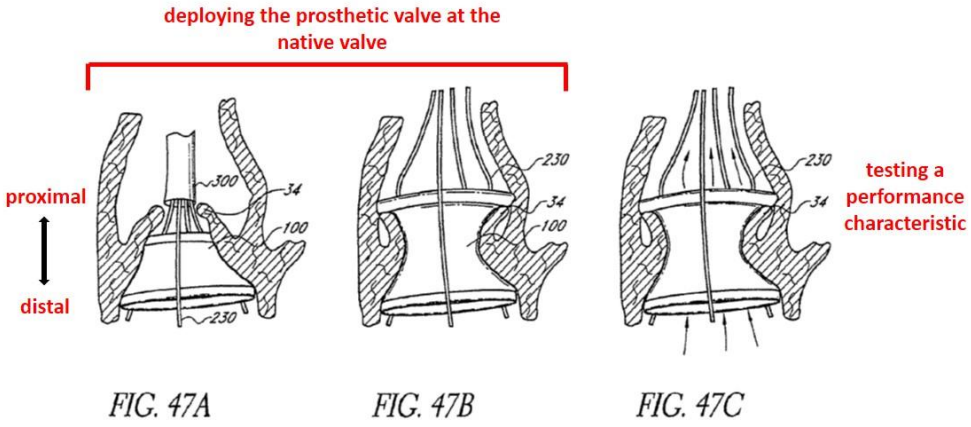

FIG. 47A FIG. 47B FIG. 47C

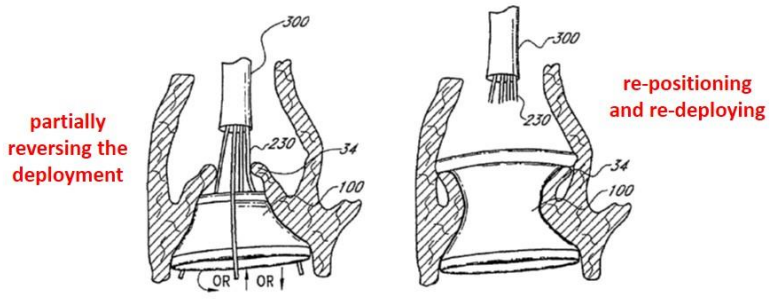

FIG. 47D FIG. 47E

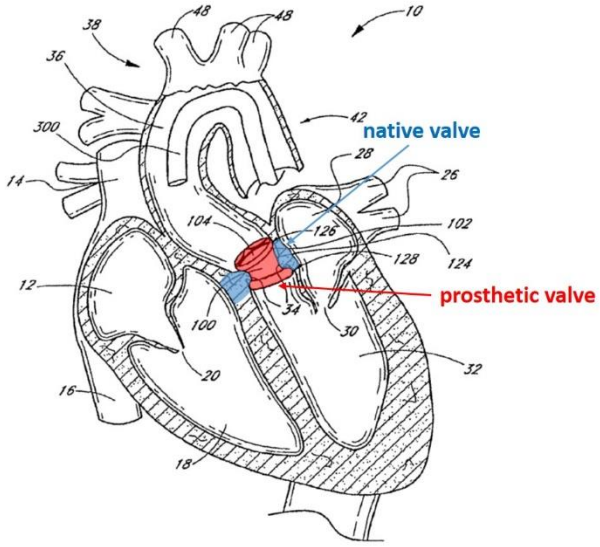

FIG. 2

The prosthetic valve comprises a valve, which includes leaflets, a carrier element, and additional components. '040, 28:2-12. In one embodiment, the carrier element includes stents 756, positioned at the prosthesis's proximal and distal ends, and a flexible fabric cuff 752 coupled to the two stents and valve 754. '040, 12:4-13, 27:56-28:3, Fig. 25F (below).[2]

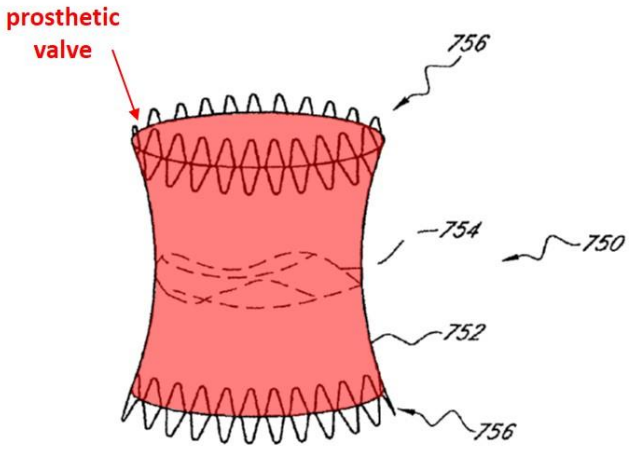

FIG. 25F

Alternative embodiments use inflatable cuffs instead of stents. '040, 4:7-15, 7:19-21, 12:14-17, 67:11-13; Drasler ¶43.

[2] Proximal and distal have their plain and ordinary meaning: closer and farther away from the deployment system's operator, respectively, such that, for a typical delivery via the aorta, "distal means closer to the heart while proximal means further from the heart." '040, 12:4-13; Drasler ¶¶42.

The prosthesis is "loaded" in its collapsed reduced-profile form between outer and inner sheaths of an intravascular delivery catheter and delivered "minimally invasively" using the delivery catheter. '040, 11:53-55, 27:59-61, 41:36-38, Figs. 34, 36. The collapsed prosthetic valve is "translumenally advanced" through the access site (e.g., the femoral artery) to the native valve while the heart is "beating." '040, 5:21-24, 6:28-33, 44:17-19, Fig. 57A. Figures 46B-C depict the collapsed valve either held a distance from, or partially within, the sheath during withdrawal (the reverse process used for deployment):

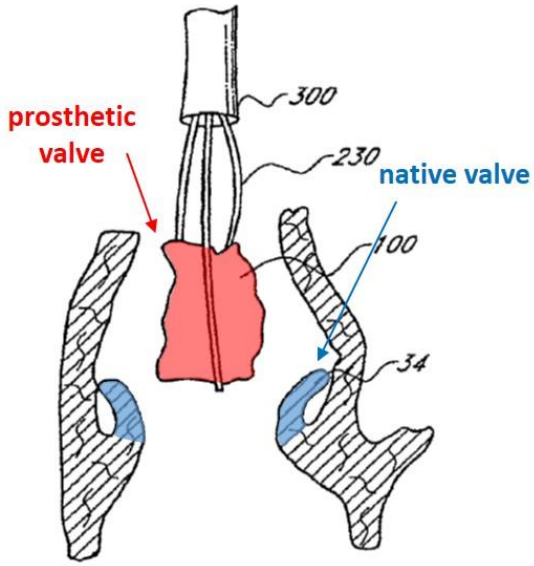

FIG. 46B

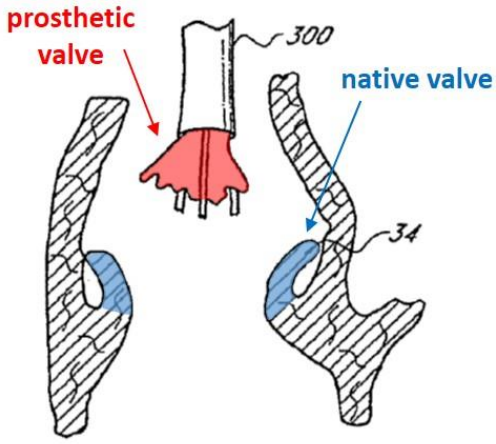

FIG. 46C

During advancement, stents 756 are collapsed. '040, 27:59-64, 77:12-19, 77:28-34; Drasler ¶44. The operator uses a deployment control device—such as control wires 230 (e.g., Figs. 46, 47A-E) detachably coupled to the prosthesis's proximal and

distal ends or a proximal extension to the prosthesis—to position the implant and render it recoverable. '040, 49:17-31, 75:53-56, 77:38-65.

At the implantation site, the catheter is "advanced across the aortic valve" into the left ventricle. '040, 74:46-47. The outer sheath is withdrawn from the prosthesis, which is held in position using the deployment control device. '040, 74:46-49. The prosthesis's distal end is expanded. '040, 74:49-50, Fig. 45A-C.

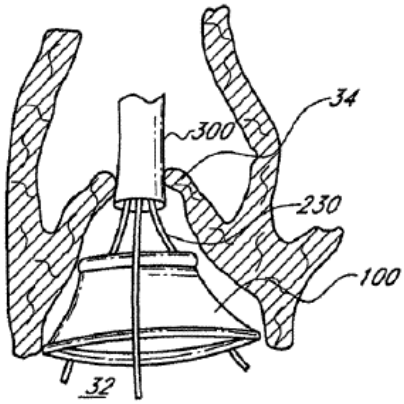

FIG. 45A

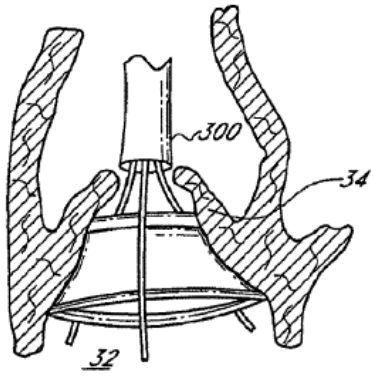

FIG. 45B

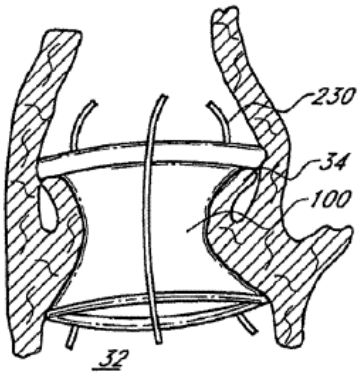

FIG. 45C

To ensure "the [prosthesis's] outflow tract is not blocked at any time during the implantation process," the outer sheath is then "retracted far enough" proximally along the "deployment control wires." '040, 73:41-44, 74:50-67. The prosthesis is then "withdrawn across the native valve annulus" (e.g., Fig. 45B) by withdrawing the control wires, and the "device is then fully inflated" (for the inflatable cuff embodiment—e.g., Fig. 45C) or fully expanded (for the self-expanding recoverable stent embodiment). '040, 74:52-56, 75:31-34, 75:45-76:2, *see also* '040, Figs. 47A-

B (above). The valve functions once fully inflated or expanded. '040, 75:25-34, 74:49, 77:49-54, 61:9-34; Drasler ¶45.

While the "sheath is retracted far enough" that the control wires "allow" the prosthetic valve "to function" before the device is withdrawn across the native valve annulus, the valve is not seated at this point (e.g., Fig. 45A) and is not functional prior to full inflation of the inflatable cuffs: "[t]he device is then fully inflated, enabling the valve to function." '040, 75:32-33; *see also* 74:45-52, 77:46-54 (describing sheath retraction as necessary to allow the valve to function, but not disclosing valve actually functioning until "fully inflated"). Similarly, the '040 discloses that the "self-expanding recoverable stent" "function[s]" once "fully deployed." '040, 75:45-53. The '040 consistently describes the valve as "function[ing]" only once fully deployed. *See also* '040, 75:25-34, 74:46-54 (testing valve function only after fully inflated), 77:49-54 (same), 61:9-34 (mitral valve prosthesis operational after both ends inflated); Drasler ¶¶46-47.

When functioning, the valve moves between an "open" configuration permitting blood flow in a first direction and a "closed" configuration where "blood is prevented from back flowing" in a second direction. '040, 12:17-24.

Stents 756 are "self-expandable or balloon expandable," and "provide structure" to the prosthesis to "allow" valve 754 to function and to position the valve "in the native annulus." '040, 27:63-28:3. After expansion of stents 756 at the native

annulus, the prosthesis's proximal and distal ends extend further radially outwards than the prosthesis's central portion in a "shape similar to a tubular hyperbola," as shown, *e.g.*, in Figure 25F above. '040, 14:5-16, 78:40-42, Figs. 25F, 45C, 46A, 47B; Drasler ¶¶48-50.

So deployed, the prosthesis "excludes the native valve" or "extends over the former location of the native valve," and "replaces its function." '040, 14:5-10, 14:12-16, 11:46-51, 78:40-42, Figs. 2A (below), 25F (*see* discussion above).

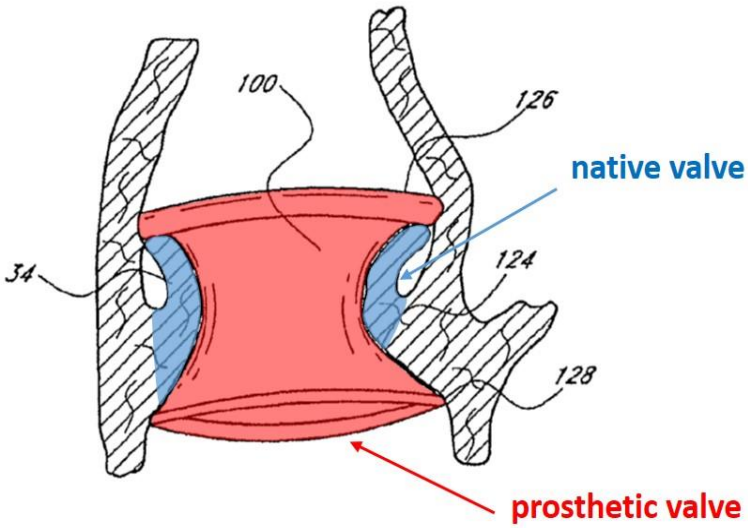

FIG. 2A

The prosthesis's proximal and distal ends (126, 128) form rings on either side of the native aortic valve to form a seal and "inhibit the device from migrating proximally or distally." '040, 37:5-7, 13:56-58, 14:10-12, 14:21-27, 78:65-67, 79:10-11, 37:5-7, 78:8-9, Fig. 2A; Drasler ¶¶51-52.

As discussed above, the ’040 teaches that the valve is fully expanded to enable the valve to function (and thus be tested before being repositioned or removed), *e.g.*, by using a proximal extension of the stent. With respect to a further prosthesis expansion after it is functioning, the ’040 teaches “an additional dilatation” using a balloon “after implantation to ensure the device is apposed to the wall of the annulus and seated properly.” ’040, 75:4-6. The ’040 further discloses that during the balloon expansion it was known to “use…a perfusion balloon with a balloon expandable support structure” “to allow significant perfusion through the balloon during deployment,” ensuring the balloon does not block flow. ’040, 74:16-24 (citing Wasicek (Ex. 1009, USP 6,117,106)); Drasler ¶53.

Using “diagnostic techniques,” the prosthesis’s “securement and function” may be monitored and, if the “valve function, sizing, or securement” is “not sufficient or ideal,” the valve may be repositioned or recaptured by partially or completely deflating/collapsing and re-expanding the prosthesis. ’040, 50:64-67, 74:53-54, 75:33-39, 77:53-54, 51:56-59, 51:16-20, 77:14-19, Figs. 47C-D (below).

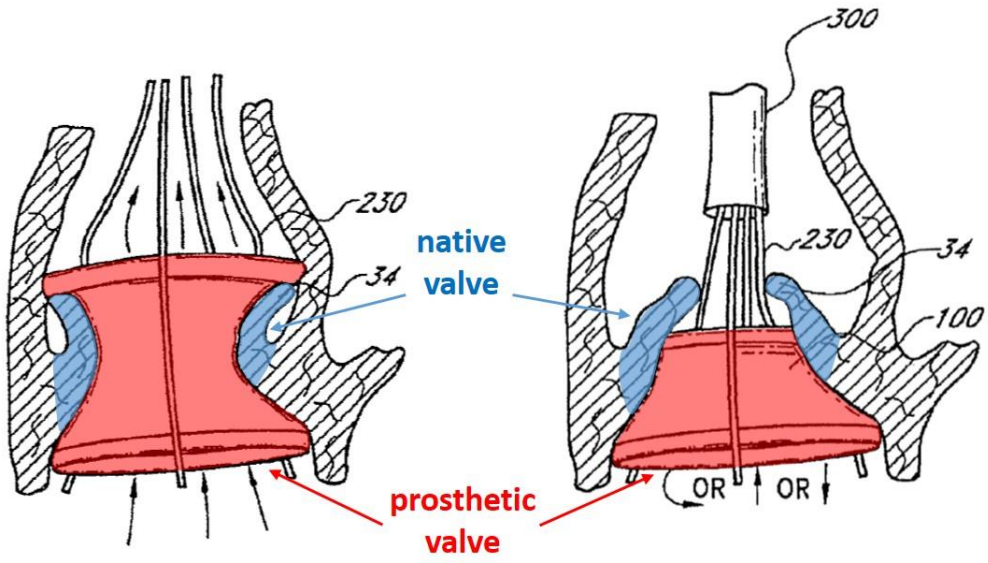

FIG. 47C FIG. 47D

The ’040 asserts that it is solving a problem for “current percutaneous valve replacement devices” because, once fully deployed for testing, the valve cannot be “removed.” ’040, 75:7-16. For example, with respect to “a known self-expanding recoverable stent…adapted to a valve support structure,” the ’040 discloses that the valve needs to be “fully deployed” to test its function, but once fully expanded could not be recovered. ’040, 75:45-53. The ’040 discloses the use of a “proximal extension” of the support structure that extends proximally either in the form of an “open” “cell structure” or “individual wires” to not block flow through the “ostia” that branch off from the aorta when fully deployed. ’040, 75:57-76:2. The extension acts as a deployment control device, such that the stent can be removed or

repositioned after the valve is "fully deployed" for testing. '040, 75:47-56; Drasler ¶¶54-57.

Repositioning may include "rotation or translation" of the implant or a "complete removal and exchange" for a different implant. '040, 42:23-25. The deployment control device allows the operator to move the implant after full expansion, so long as the deployment control device remains coupled to the prosthesis. '040, 74:60-63, 51:1-5, Figs. 46A-C; Drasler ¶58. If the "valve function is sufficient," the deployment control device is disconnected or released and the catheter is withdrawn. '040, 74:55-56, Fig. 47E.

To facilitate a reduced delivery profile, the '040 also teaches optional use of a locking mechanism in the prosthesis, *e.g.*, "a suture, an adhesive, or a mechanical snap together type lock actuated by [a] tension wire." '040, 25:59-67 ("may utilize a locking means"), Figs. 17A-18C (see "latch or lock mechanism 181"); Drasler ¶59. The Challenged Claims, however, require the ***absence*** of an ***interlocking*** locking mechanism (*e.g.*, a mechanical snap together type lock or the like). '040, cl. 7; Drasler ¶59. Such absence is taught in, for example, the Figure 25F embodiment described above. '040, 12:4-13, 27:56-28:3, Fig. 25F.

VI. '040 PROSECUTION HISTORY

In Application 15/297,282, which matured into the '040, issued claim 7 (prosecution claim 13) was generally directed to a "method of treating a patient"

comprising the steps of (1) translumenally advancing a prosthetic valve a position proximate a native valve of the heart, (2) fully deploying the prosthetic valve at the cardiovascular site, (3) testing a performance characteristic of the prosthetic valve, (4) at least partially reversing the deployment of the prosthetic valve, (5) repositioning the prosthetic valve, and (6) re-deploying the prosthetic valve. Ex. 1003 ("'040FH"), 182; Drasler ¶60. During prosecution, the Examiner issued only one office action regarding issued claim 7, rejecting it as anticipated by Leonhardt. '040FH, 645-655. (The other challenged claims—issued claims 9-10—were only added after the office action.)

In response to the office action, the Applicant amended issued claim 7 and newly added issued claims 9-10. *Id.*, 719-720. The Applicant amended issued claim 7 to require that (a) the prosthetic valve is deployed from a collapsed delivery configuration to an expanded configuration wherein a distal end of the prosthetic valve is expanded before a proximal end of the valve; (b) the prosthetic valve does not include an interlocking locking mechanism, and (c) the prosthetic valve blocks the flow of blood in a first direction and allows the flow of blood in a second direction during the expansion of the valve, after expanding the distal end and prior to expanding the proximal end of the valve. *Id.*, 719. To overcome Leonhardt, the Applicant argued only that Leonhardt fails to disclose the third of these newly-added limitations: "…the prosthetic valve prevents the flow of blood through the valve in

a first direction and allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve, after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve as claimed." *Id.*, 723-725; Drasler ¶61. The Applicant argued that Leonhardt instead "teaches a method using an expansion balloon which *occludes* the flow of blood through the prosthetic valve in the second direction during the expansion of the prosthetic valve." '040FH, 724-725 (emphasis in original).

After PO amended the claims, the Examiner subsequently allowed them without any further office actions or an examiner interview. *Id.*, 738-740. The Examiner found the no-interlocking-locking-mechanism limitation supported by disclosure of element 181. '040FH, 738-39. Although the Examiner initially rejected issued claim 7 over Leonhardt, after amendment, the Examiner found instead that Salahieh-687 (U.S. App. Pub. No. 2005/0137687) (Ex. 1008) was the "closest prior art" to issued claim 7 without comparing the claim to Leonhardt again. '040FH, 738. Indeed, the Notice of Allowance does not mention Leonhardt at all. *Id.*, 738-740. When comparing Salahieh-687 to issued claim 7, the Examiner's only reason for allowance was that Salahieh-687 "includes an interlocking locking mechanism" and is "thus excluded by the claims" as amended. '040FH, 738-739. The Examiner never expressly addressed dependent claims 9-10. *See id.*; Drasler ¶¶62-63.

VII. THE BOARD SHOULD NOT EXERCISE ITS DISCRETION TO DENY INSTITUTION

A. §325(d)

Considering the two-part framework discussed in *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Pap. 6, *8-9, the Board should not exercise its §325(d) discretion to deny institution.

Neither the art nor the arguments in Grounds 1-2 are the same or substantially the same as those considered during prosecution. As an initial matter, neither the Examiner nor PO discussed or applied **Bailey** (all Petition Grounds) or **Seguin** (Ground 2) during the '040's prosecution. **Leonhardt** in view of **Bailey** and alternatively in further view of **Seguin** teach the sole limitation that PO argued was missing from Leonhardt: "wherein the prosthetic valve...allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve…" (*see* §§X.A.3[7.8], X.B).[3] The Office did not consider any

[3] While '040 also discusses whether **Leonhardt** blocks "aortic outflow" at times during deployment ('040, 74:4-15) (as Leonhardt's outer sheath blocks outflow until retracted at least partially from the openings between proximal distensible fingers), the Challenged Claims recite a valve operating to allow unidirectional flow at certain

materially similar references that expressly taught permitting blood flow around a balloon during expansion (**Bailey**) or blood flow through openings in the catheter during valve deployment (**Seguin**).[4] Additionally, the Office has not previously considered the expert testimony submitted herewith with regard to these combined teachings. Ex. 1002.

Where a petition's ground relies on at least one reference the Examiner never considered for limitation(s) the PO or Examiner found lacking in the prior art of record—as with **Bailey** and **Seguin**—the Petition's art and arguments are not the same or substantially the same as those before the Office during prosecution.

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times and do not recite a limitation requiring that the aortic outflow cannot be blocked at any point during deployment. Drasler ¶98.

[4] Similarly, during prosecution of '040's parent, PO argued a different limitation was missing from **Leonhardt**, "after expanding the distal end of the first carrier element and prior to expanding the proximal end of the first carrier element." Ex. 1041, 1761. **Leonhardt** teaches this limitation for the reasons discussed in §§X.A.1, X.A.3.[7.8], but regardless **Leonhardt** in view of **Bailey** and **Seguin** also satisfy this limitation. Nor did the Office consider a prior art reference or combination disclosing a prosthetic valve allowing unidirectional blood flow during expansion of the valve in the absence of an interlocking locking mechanism.

Church & Dwight Co., Inc. v. Batinkoff, IPR2020-00168, Pap. 11, *10-11 (declining to exercise §325(d) discretion in such circumstances); *Kolbe & Kolbe Mill Work Co. v. Sierra Pac. Indus.*, IPR2019-00933, Pap. 14, 46 (finding *no Becton* factors weighed in favor of denial where "none of the specific prior art combinations presented here was considered"); *Apple Inc. v. Maxell, Ltd.*, IPR2020-00200, Pap. 11, 26-30 (finding first *Adv. Bionics* step not met where each combination included art not previously before the Office).

Even if the art and arguments were substantially the same, the Examiner erred in a manner material to the Claims' patentability. The exercise of §325(d) discretion is not appropriate here.

Even if the Examiner had considered substantially the same art as that relied upon herein (the Examiner did not for Grounds 1-2), the Examiner erred in allowing the Challenged Claims. During prosecution of the '040's parent (US9,510,941, "'941"), PO argued that **Leonhardt** only fails to disclose *one* limitation of prosecution claim 44, which contains similar language to '040 claim 7: "where[in] the…replacement valve allow[s] the flow of blood through the…replacement valve in a first direction and prevent[s] the flow of blood through the…valve in a second direction [during the expansion of the carrier element,] after expanding the distal end of the…carrier element[,] and prior to expanding the proximal end of the…carrier element." Ex. 1041 ("'941FH"), 1752 (claim 46), 1761 (PO addressed prosecution

claim 44 as exemplary limitation; quote altered to reflect claim 46). The Examiner never considered Leonhardt's secondary balloon expansion whereby the "[t]ip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" after the valve is "function[ing]"—thus allowing unidirectional blood flow. *See* Leonhardt, 11:28-33; '941FH, 1729-30 (failing to cite Leonhardt 11:28-33), 1772, 1780-81.[5] After the Applicant amended claims 44 and 46 to require the valve to allow the unidirectional flow of blood after distal expansion and before proximal expansion, the Examiner instead shifted focus to another reference. '941FH, 1777. Unfortunately, the '941 record does not include the Examiner's reasoning for shifting away from **Leonhardt**. *E.g.*,'941FH, 1772. Given the disparity in disclosures that Examiner and PO highlighted in **Leonhardt**, the lack of record of the Examiner's reasoning, and the better disclosures in Leonhardt, the Examiner erred in failing to cite a "better component" of Leonhardt and failing to adjust the mapping of the claim in response to an amendment. *Versa Prods v. Varidesk, LLC*, IPR2020-00387, Pap. 13, *15-18;

[5] Examiner's reference to Leonhardt's "tip balloon" being used to "seat" the proximal end ('941FH, 1730 (discussing prosecution claim 45 and citing Leonhardt, 11:3-22)) is a typo as the cited passage referring to seating the proximal end is discussing the "expansion balloon."

see also Arrows Up, LLC v. Oren Techs., LLC, IPR2018-01231, Pap. 7, *11-12 (finding error where Examiner misunderstood reference).

To allow the Challenged Claims, however, the Examiner must have erred in at least one of the following ways, which each independently demonstrates that §325(d) discretion should not be exercised:

First, the Examiner erred by failing to reapply **Leonhardt** in response to PO's amendment. In particular, Leonhardt's secondary balloon expansion using tip balloon offers a better disclosure of the valve functioning after distal expansion, and prior to proximal expansion (*see* §X.A.3[7.8]) than that relied on by the Examiner, and mirrors the teachings in the '040 specification (*see* §V). With respect to a further prosthesis expansion after it is functioning, the '040 teaches "an additional dilatation" using a balloon "after implantation to ensure the device is apposed to the wall of the annulus and seated properly." '040, 75:4-6. The '040 further discloses that during the balloon expansion it was known to "use…a perfusion balloon with a balloon expandable support structure" "to allow significant perfusion through the balloon during deployment," ensuring the balloon does not block flow. '040, 74:16-24 (citing Wasicek).

The Examiner should have rejected the amended claims over Leonhardt's superior disclosure, but there is no indication in the file history that the Examiner considered Leonhardt's secondary balloon expansion. *Versa Prods. v. Varidesk,*

LLC, IPR2020-00387, Pap. 13, *15-17 (finding examiner erred in failing to cite to "better component" and again by failing to adjust mapping of a claim in response to amendment).

Second, to the extent the Examiner may have understood the claims to require that the valve impose unidirectional blood flow *before any proximal end expansion*, such an interpretation is error. That construction is not supported by the specification (see §V), nor would flow be possible before any such expansion with the system and method taught in the '040. (*see, e.g.*, '040, 75:23-33 ("[t]he device is then fully inflated, enabling the valve to function")). [6]

Third, where the "Examiner did not expressly consider" **Bailey** or **Seguin**, it is difficult, if not impossible, to explain "why the Examiner allowed the claims" or "how the Examiner might have considered the arguments presented in the Petition" and §325(d) discretion should not be exercised. *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00379, Pap. 14, *20 (declining to exercise discretion).

[6] Even if '040's disclosure of retracting the sheath to "allow…the valve to function" (75:29-31) were misread to disclose actual functionality before full expansion (*see* §V), as shown in Figure 45A, the proximal end of the valve at this point has already been expanded relative to the collapsed version inside the catheter shown in Figures 46B-C. '040, 50:48-51, 51:5-10, 75:29-31; Drasler ¶¶44, 76.

Fourth, the Examiner erred in failing to consider a combination of **Leonhardt** with a reference (1) disclosing an expansion balloon allowing blood flow to the valve during prosthesis expansion—such as **Bailey** (Grounds 1-2), and/or (2) disclosing lateral distal openings in the catheter to maintain blood flow while the proximal end of the prosthesis is still within the catheter during deployment—such as **Seguin** (Ground 2). Such combinations render the Challenged Claims obvious. *See* §X. For at least these reasons, the Board should not exercise its §325(d) discretion to deny institution.

B. §314(a)

Co-pending district court proceedings do not warrant the exercise of discretion under §314(a) based on the six factors considered in *Apple Inc. v. Fintiv, Inc.* IPR2020-00019, Pap. 11. **1:** Petitioners intend to seek a stay of the related District of Delaware (D. Del.) proceeding pending the outcome of this IPR and Nos. IPR2021-00239, IPR2021-00240, IPR2021-00241, IPR2021-00243, IPR2021-00244 and IPR2021-00310 concerning the other asserted patents. **2:** Trial is scheduled for October 11, 2022, more than three months after a final written decision will issue in this IPR. Ex. 1042, 14. **3:** To date, the court has not issued any substantive orders related to the '040, and Petitioners have moved to dismiss pending claims. PO served infringement contentions but depositions have not begun, and claim construction briefing has not yet begun. *Id.* **4:** The same grounds, arguments

and evidence could not be presented in litigation after the earlier-expected final written decision. Moreover, the Petition challenges at least one claim not at issue in the litigation. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong as shown herein, particularly considering Applicant's admissions during prosecution that the majority of limitations were disclosed by Leonhardt (*see* '941FH, 723-725) and the Examiner's failure to consider Leonhardt's secondary balloon expansion disclosure that addresses the Applicant's only contended point of novelty over Leonhardt—due to the Examiner's mistake, the public interest warrants correction; discretion under §314(a) is overcome by such an apparent error in the Examiner's analysis. Additionally, the Petition presents arguments not substantially the same as those previously before the Office.

The Board should not exercise its discretion to deny institution.

VIII. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art ("POSITA"), at the purported time of invention, would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor's degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants. Additional graduate education could substitute for professional experience, or

significant experience in the field could substitute for formal education. Drasler ¶¶32-35.

IX. CLAIM CONSTRUCTION

Claim terms subject to IPR are construed using the *Phillips* standard. §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Only terms necessary to resolve the controversy need construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Because the prior art asserted herein discloses embodiments within the Challenged Claims' indisputable scope, the Board need not construe the claims' outer bounds, while the district court may need to in addressing other issues, *e.g.*, infringement. All claim terms should be construed according to their plain and ordinary meaning as would have been understood by a POSITA in view of the specification. Drasler ¶65.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X; Drasler ¶66.

B. "proximate a native valve" (All Challenged Claims)

Regardless of the exact metes and bounds of this term (i.e., "proximate"), the prior art discloses this limitation. *See* §X.A.3.[7.1]; Drasler ¶¶67-68.

C. "does not include an interlocking locking mechanism" (All Challenged Claims)

"[D]oes not include an interlocking locking mechanism" should be afforded its plain and ordinary meaning, and is disclosed by the prior art for the reasons discussed in §X. The term is not a means-plus-function limitation covered by §112 ¶6 as the remainder of limitation [7.7] does not recite a function. Even if it were a means-plus-function term—e.g., if "mechanism" is a "nonce term" that a POSITA would not have understood to have a "sufficiently definite meaning as the name for structure"—and additional structure beyond [7.7] were required, the function/structure would be the function of a prosthetic valve without an interlocking locking mechanism, and the structure would be any of the various carrier elements without an interlocking locking mechanism taught in the '040 specification, which are disclosed by the art as discussed in §X. Such mechanisms include inflatable cuffs, self-expanding meshes, and the combined stent/cuff embodiment of '040 Figure 25F. '040, 12:4-13, 27:56-28:3, Fig. 25; Drasler ¶¶69-70; *see also* §V.

Under either construction, the prior art relied on herein for the limitation does not contain an "interlocking locking mechanism," and thus satisfies the Challenged Claims. *See* §X.A.3[7.7].

D. "being expanded" / "during the expansion" / "[after / prior to] expanding the [distal / proximal end]" (All Challenged Claims)

The "expansion" limitations should be accorded their plain and ordinary meaning, as they would have been understood by a POSITA in view of the specification to refer to any amount of expansion that satisfies the individual limitations in which they occur. Drasler ¶¶71-72. Thus, under the plain and ordinary meaning, the phrases alone are not limited to a "first," "partial, "full" or "complete" expansion of the prosthetic valve or either of its ends.

In contrast to the '040's "expansion" limitations, PO chose to qualify the expansion limitations in some '040's parents' claims. '941, cls. 1 ("at least partially expanded configuration"), 26 ("fully expanded"), 30 ("initially expanded"); Ex. 1013 (USP 8,377,118), cls. 6 ("during the entire expansion"), 7 ("at least partially during expansion").[7] Such qualifiers should not be read into the Challenged Claims. *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1313 (Fed. Cir. 2011) (declining to limit a term to the "one-piece" modifier "explicitly" used in patent's dependent claims).

[7] The three parents share a specification, other than corrections and a single sentence, which are not relevant here.

The plain and ordinary meaning is consistent with the specification. For example, as discussed in §V, the specification discloses expanding/inflating, collapsing/deflating and re-expanding/re-inflating the prosthesis as well as its proximal and distal ends at multiple different points in time. The specification further discusses "partially" and "fully" expanding/inflating as well as compressing/deflating the valve. E.g., '040, 60:58 ("inflate the implant fully"), 74:53 ("The device is then fully inflated."), 77:52-53 (same), 75:32-33 ("The device is then fully inflated, enabling the valve to function."), 75:35-37 ("the valve may be partially deflated, and advanced or retracted, and then reinflated or the valve may be fully deflated and retracted…"), 77:55-57 (same), *see also* 5:51-57, 50:53-55, 51:5-10, 51:18-24, 77:52-53; Drasler ¶73-74. It thus would be improper to read in any limitation requiring, e.g., that "expansion" must be a first, complete, full, partial, or continuous expansion. *Retractable*, 653 F.3d at 1313 (use of modifier in written description implies that term "standing alone" is not inherently limited).

The plain and ordinary meaning is consistent with the file history. PO pursued a very similar claim to '040 claim 7 during prosecution of its parent—'941 prosecution claim 46. PO amended it to recite "wherein during expansion of the carrier element, a distal end of the carrier element is ***fully*** expanded prior to a proximal end…being ***fully*** expanded." '941FH, 1705-1706 (emphasis added). The Office rejected the amended claim because "[t]he specification does not describe a

distal end of the carrier element being ***fully expanded*** prior to a proximal end…being fully expanded." '941FH, 1727-28 (emphasis in original) (also quoting '941, 74:43-50 (disclosing that the valve is "fully inflated" after being withdrawn across the native valve annulus)); *see also* '040, 74:46-53, Fig. 47A-E; Drasler ¶75. PO subsequently removed the term "fully" from the claim. '941FH, 1752-1754, 1761; *see SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1318 (Fed. Cir. 2015) (declining to limit claim term broadened during prosecution).

PO's argument during prosecution of '040's parent that Leonhardt does not teach the limitation requiring unidirectional blood flow "prior to expanding the proximal end of the first carrier element" because the "valve in Leonhardt is not operational until it fully exits the deployment catheter 100 to expand the proximal end" ('941FH, 1761) similarly does not limit the scope of the claims. Drasler ¶76. First, PO's argument is wrong for the reasons discussed in §X.A.1-3 (Leonhardt expressly discloses the valve "function[s]" prior to expanding the proximal end with the tip balloon) and §X.A.4 (blood flows through the proximal fingers of Leonhardt's prosthesis prior to any expansion of the proximal end). Second, such a construction is also inconsistent with the '040 specification, which never discloses a valve functioning before any expansion of the proximal end as discussed in §V (specification teaches valve functioning after full expansion; proximal extensions permit valve to be repositioned after full expansion). *See also* §VII and n.6 (supra).

Third, PO's argument does not contain any expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.

For the foregoing reasons, these limitations should be afforded their plain and ordinary meaning, and should not be qualified as requiring a first, partial, full, complete, or continuous expansion.

The prior art discloses these limitations under their plain and ordinary meaning. *See* §§X.A.3.[7.2], [7.8]; Drasler ¶¶77-78. But even under a narrower interpretation, wherein, e.g., "prior to … expanding the proximal end" means prior to the first expansion of the proximal end, the Challenged Claims are still rendered obvious. *See* §§X.A.4, X.B.

X. GROUNDS OF UNPATENTABILITY

Although the '040 purports to have invented a method for replacing a patient's native heart valve by (1) translumenally delivering a prosthetic valve at the native heart valve and deploying it from a collapsed delivery configuration to an expanded configuration, (2) testing a performance characteristic of the prosthetic valve, (3) at least partially reversing the deployment of the prosthetic valve, (4) repositioning the prosthetic valve, and (5) re-deploying the prosthetic valve, such methods were well-known. As explained below, the Challenged Claims are unpatentable as obvious.

Leonhardt discloses a method of transluminally delivering and implanting a prosthetic valve for maintaining one-way flow within a biological passage, wherein

the valve's distal end is expanded prior to the valve's proximal end, testing a performance characteristic of the valve, and repositioning and re-deploying the valve. **Leonhardt** also teaches using a valve without an interlocking locking mechanism. **Bailey** teaches a balloon (for expansion and valvuloplasty) that permits blood flow even when expanded, and **Seguin** teaches lateral distal openings in the catheter to allow continued blood flow even when the proximal end of the prosthesis is still within the catheter—each teaching enabling **Leonhardt**'s prosthetic valve to allow unidirectional blood flow during expansion and partial deployment.

Leonhardt in view of **Bailey** discloses the same functionality taught in the '040 patent (valve operation during secondary balloon expansion). *See* §§V, X.A.1-3. And even if PO argues the Challenged Claims are limited to functionality not described in '040 (*e.g.*, valve operation before any proximal end expansion), **Leonhardt** in view of **Bailey** alone and in further view of **Seguin** still renders such claims obvious. See §§X.A.4, X.B.

The prior art renders the Challenged Claims unpatentable. This Petition is supported by the Declaration of William J. Drasler, Ph.D. which describes the prior art's scope and content at the time of the alleged '040 invention. Drasler (Ex. 1002) ¶¶79-83.

A. Ground 1: Claims 7-10 Are Rendered Obvious by Leonhardt in View of Bailey

1. Overview of Leonhardt

Leonhardt, a Medtronic-owned patent, teaches a method of percutaneously and transluminally delivering an expandable valve stent to a position proximate a patient's native heart valve. Leonhardt, Abstract, 1:11-13, 6:34-49, 9:64-67, 10:22-23. The prosthesis, "valve stent 20," comprises a "biological valve 22" including leaflets—preferably a treated porcine valve—"attached to stent 26" with sutures or a biocompatible adhesive, as shown in Figure 4. Leonhardt, 4:14-16, 6:23-31, 10:64-67, Fig. 4. The stent lacks an interlocking locking mechanism as it is "formed of a single piece of super elastic wire."[8] Leonhardt, 4:27-29; Fig. 1; Drasler ¶¶84-85. The valve/stent is covered with graft material, but the material is "cut out" at the open ends of the stent's sinusoid, forming "distensible fingers" at either end, as shown in Figure 4:

[8] Tube 50 of **Leonhardt** (as depicted in Fig. 1A) is not an interlocking locking mechanism because it does not lock, let alone releasably lock, nor does it involve any "interlocking." *See* Leonhardt, 4:47-49 (teaching using either crimping tube 50, permanent adhesives, or welding), 4:53-54, Fig. 1A; '040, 25:59-61, 78:57-63 ("…mechanically decoupling interlocked components…").

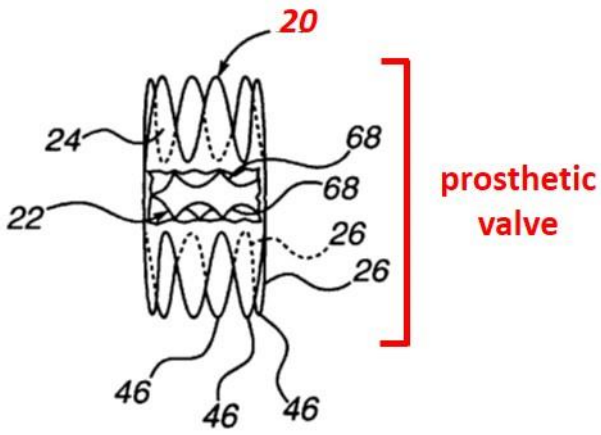


FIG. 4

Leonhardt, Fig. 4, 6:9-22.

Leonhardt discloses deploying a valve stent at a "placement site," *i.e.*, a native heart valve, such as the mitral valve (Leonhardt, 10:22-30, Figs. 2, 9A-9D) or the aortic valve (Leonhardt, 9:63-10:6). Leonhardt, 6:36-38; Fig. 2. Valve stent 20 is transluminally advanced to the site in a collapsed state. Leonhardt 9:49-54, 10:6-11. A flexible guide wire with a tip balloon is inserted through an entry point and advanced to the placement site. Leonhardt, 10:3-11. The collapsed valve/stent is loaded into the outer sheath of a deployment catheter, which is inserted over the flexible guidewire and advanced to the placement site. Leonhardt, 6:57-65, 9:50-55, 10:6-11. During deployment catheter insertion, the tip balloon may be partially inflated to perform valvuloplasty. Leonhardt, 10:11-16. Once the deployment catheter is positioned, deployment of valve stent 20 is "procedurally the same for all

potential placement sites," including mitral and aortic valves. Leonhardt, 10:43-44; Drasler ¶86. The outer sheath is withdrawn from the stent's distal end to initiate deployment of the valve stent's distal end. Leonhardt, 10:53-58.

When Leonhardt's valve stent is placed at the aortic valve, the delivery catheter containing the prosthetic valve is transluminally advanced in the retrograde direction (against blood flow): entry is made through the largest femoral artery and the prosthesis is advanced either into the aorta immediately above the aortic valve or further into the left ventricle immediately past the aortic valve. Leonhardt, 9:63-67; Drasler ¶87. For aortic valve prostheses, a POSITA would have understood that blood flows from the left ventricle, into the prosthesis's distal end, through the prosthetic valve, and out the prosthesis's proximal end up into the aorta. Leonhardt, 11:5-10; *see also* Bailey, Fig. 6A (below, to illustrate anatomy); Drasler ¶87.

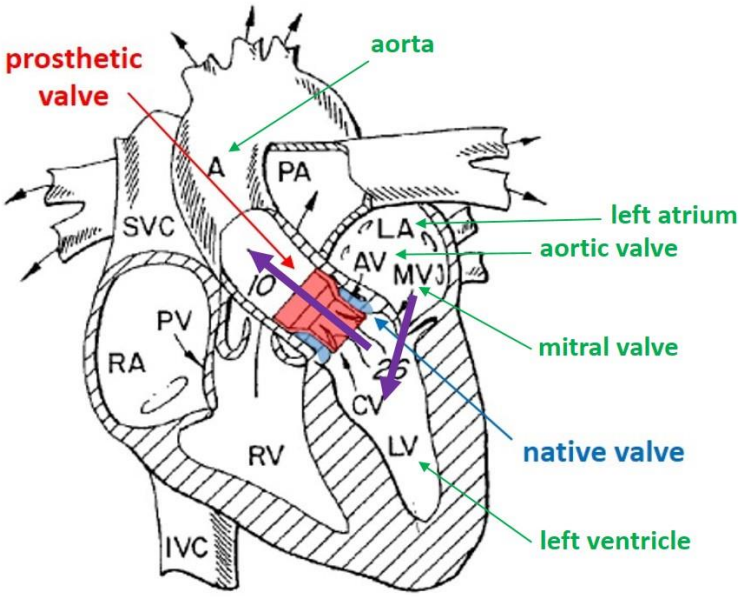


Fig. 6A

Leonhardt additionally discloses mitral valve deployment, where the prosthesis is instead delivered in the direction of blood flow (from left atrium to left ventricle), as a POSITA would have understood. Leonhardt, 10:22-30, Figs. 2, 9A-9D. Drasler ¶88.

The collapsed valve/stent is expanded via three separate mechanisms. The ***first*** is self-expansion. As discussed above, **Leonhardt** discloses a self-expanding stent held in a collapsed state by a sheath during delivery to the deployment site. Leonhardt, 6:57-65, 9:63-10:6 (aortic valve deployment), 10:53-55. Figure 9A depicts the valve stent held in place across the mitral valve within outer sheath 106:

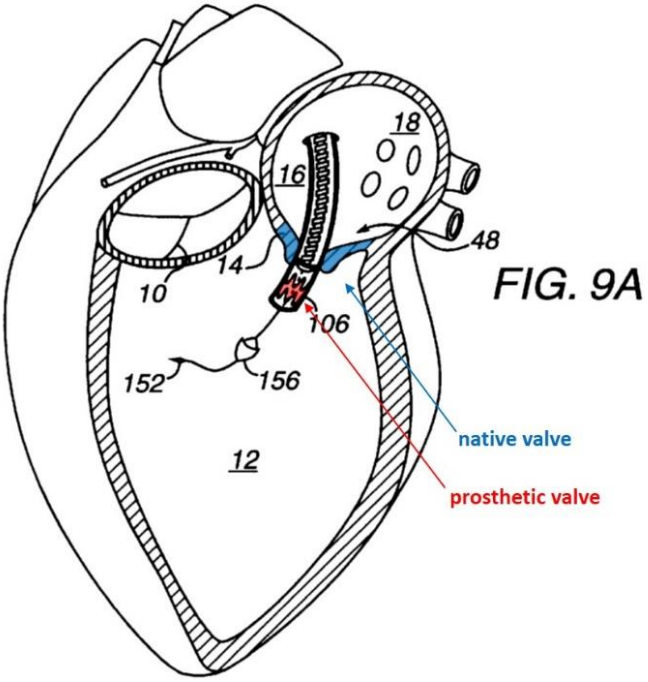


FIG. 9A

When the sheath is withdrawn from a portion of the stent, that portion self-expands due to its "continuous outward force." Leonhardt, 10:55-58, 11:34-35. Thus, the first valve/stent expansion occurs when the sheath is initially retracted from the stent's distal end, permitting the distal distensible fingers to expand against the vasculature, as shown in Figure 9B (mitral deployment) below. Leonhardt, 10:53-58; Drasler ¶¶89-90.

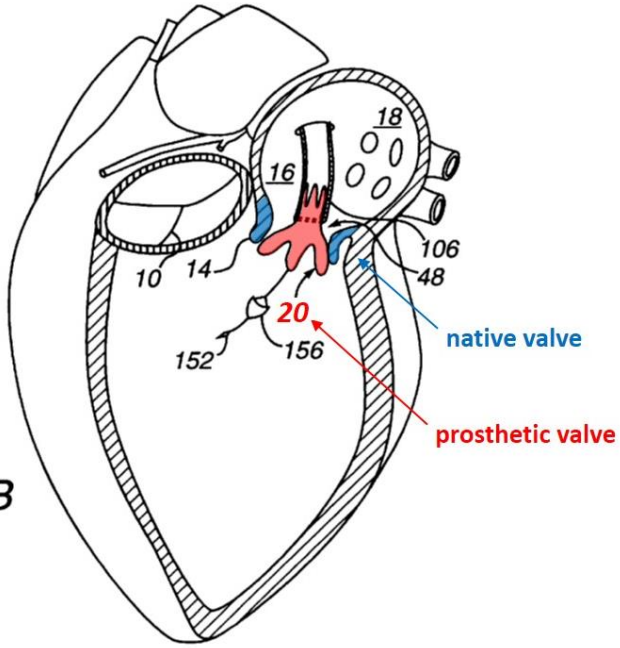


FIG. 9B

Leonhardt then employs a ***second*** mechanism: expansion of the valve/stent using expansion balloon 154. Expansion balloon is positioned at the stent's distal end, without overlapping the valve. Leonhardt, 10:64-67 (explaining that the valve's base "must be free from contact" with the balloon); Drasler ¶91.[9] Expansion balloon is inflated "to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue" ensuring that "proper placement is maintained during the remainder of [] deployment" and that "valve stent 20 [molds] itself quickly to the

[9] Leonhardt also discloses that the leaflets "may" be "slightly overlapped" by the balloon—an optional teaching not relied upon herein. Leonhardt, 10:64-67; Drasler ¶91.

living tissue at the placement site [to] achieve a patent seal," as shown in Figure 9C. Leonhardt, 11:3-9; Drasler ¶91.

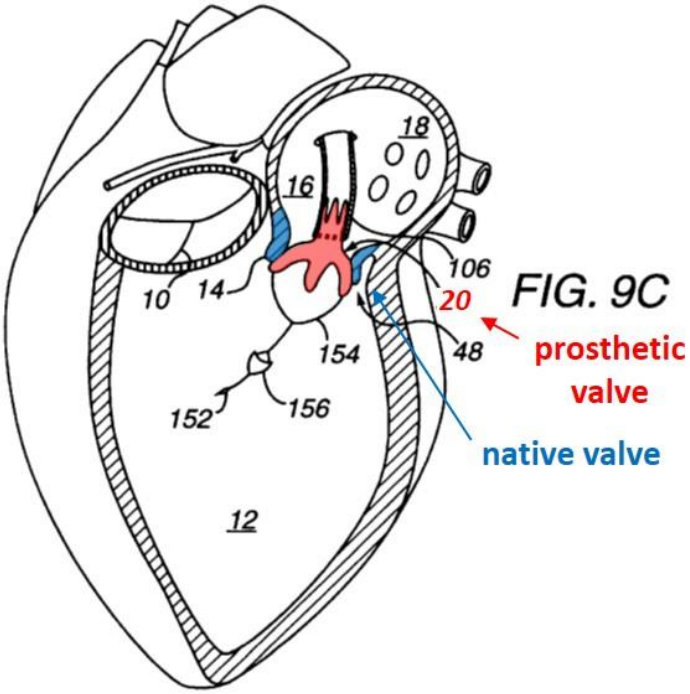


FIG. 9C

Leonhardt then relies on the first self-expansion mechanism again—with the expansion balloon holding the distal end in place, the sheath is completely retracted, allowing self-expansion of the remainder of the valve/stent. Leonhardt, 11:10-15; Drasler ¶92.

After the sheath is fully retracted from valve/stent and self-expansion is complete, proper placement is verified. Leonhardt, 11:10-15; Drasler ¶93.

Leonhardt then again uses the expansion balloon mechanism to expand the stent's proximal end. Expansion balloon is "deflated" and the inner catheter withdrawn to position "expansion balloon 154…on the proximal side of the

biological valve but within proximal end of valve stent 20 just deployed." Leonhardt, 11:14-19. Expansion balloon further expands the stent's proximal side: it is "inflated again to seat the proximal end of valve stent 20" and then deflated (*see* Figure 9d below), and withdrawn. Leonhardt, 11:16-18, 9:63-10:6; Drasler ¶94.

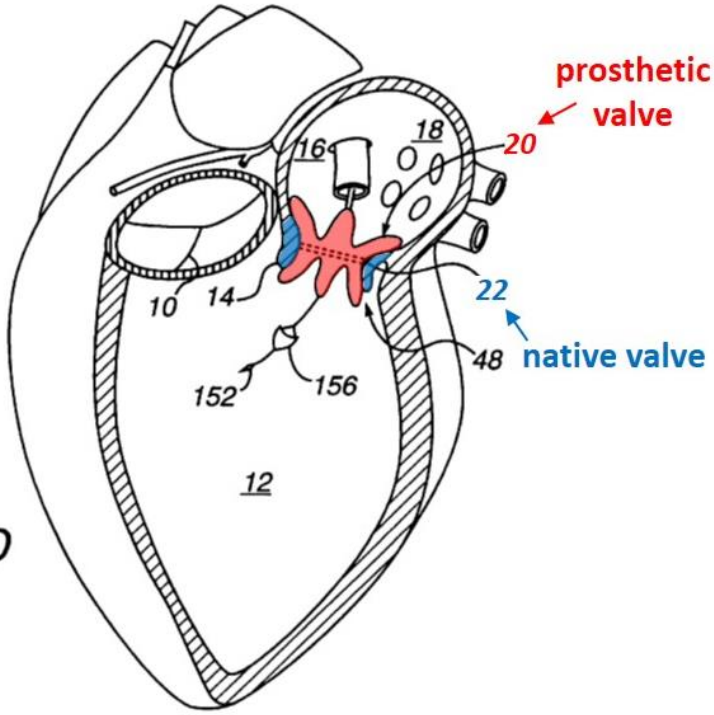


FIG. 9D

At this point, Leonhardt expressly teaches that the valve is functional such that "[v]alve stent 20 is now monitored for proper function and patency." Leonhardt, 11:23-30; Drasler ¶95.

Leonhardt teaches a ***third*** valve/stent expansion mechanism after checking for function: the tip balloon. After the valve is "function[ing]" and thus allowing for unidirectional blood flow, tip balloon 152 "may be advanced to either side of valve

stent 20 and reinflated to further mold valve stent 20 to the living tissue." Leonhardt, 11:28-33. When tip balloon is advanced to the stent's proximal end, the catheter and guidewire are proximal the valve, and neither the catheter nor guidewire passes through the replacement valve itself. Leonhardt, Figs. 5, 9A-D; Drasler ¶96. **Leonhardt's** tip balloon expansion procedure for the carrier element distal and proximate ends after the valve is "function[ing]" mirrors that of the '040's "additional dilatation" of the carrier element with a balloon, which occurs after the valve is functioning. '040, 75:4-6; *see* §V; Drasler ¶96.

"[O]nce properly placed, valve stent 20 function and leakage are verified" and, if necessary, valve stent 20 can be "retriev[ed] for repositioning or removal" regardless of "whether valve stent 20 is fully or partially deployed" by means of sutures. Leonhardt, 11:37-60, Figs. 7A-7B. When the valve stent is repositioned, the same process described above is used to place and expand the valve/stent. Leonhardt, 11:37-60; Drasler ¶97. As shown in Figure 2 below, fully deployed and expanded valve stent has a non-cylindrical profile: both ends are wider in diameter than the valve's central portion as the valve stent "flair[s]" at one or both ends. Leonhardt, 3:33-38, 4:63-65, 6:9-23, 9:63-10:6, Figs. 2, 9d. Once the valve/stent is deployed in the proper position, the catheters are withdrawn. Leonhardt, 11:63-64, 12:4-5; Drasler ¶97.

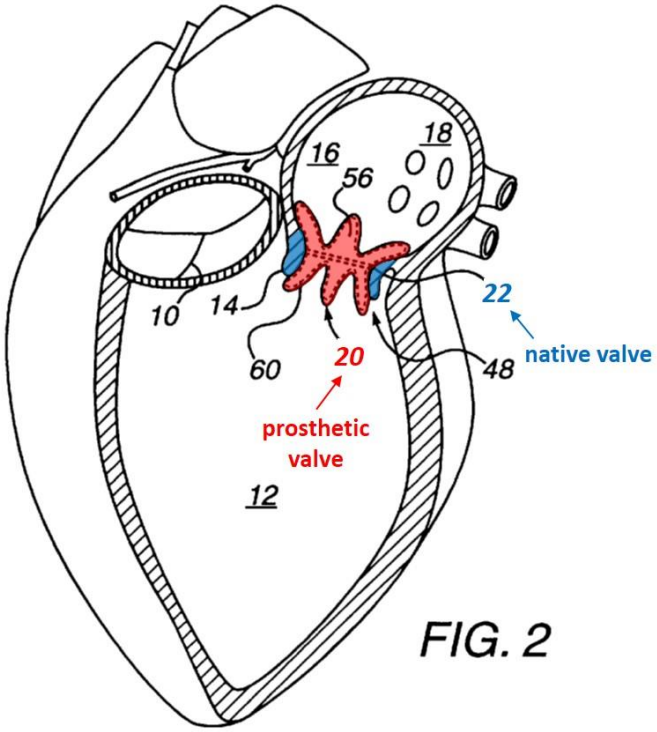


FIG. 2

2. Overview of Bailey and Motivation to Apply its Teachings to Leonhardt

While **Leonhardt** teaches unidirectional blood flow once valve stent 20 is seated and the sheath retracted, blood flow is occluded when tip balloon 152 or expansion balloon 154 is expanded. **Bailey** instead discloses an expansion balloon that permits blood flow through it when fully expanded and that can be used to expand transluminally-delivered prosthetic heart valve stents. Bailey ¶¶[0070], [0072]. **Bailey** expressly cites and seeks to improve upon **Leonhardt**'s valve and delivery method. Bailey ¶¶[0006], [0018]; Drasler ¶99. Specifically, **Bailey** discloses an expansion balloon with "irregular inflation profiles" or "channels or

ridges on the ablumenal surface of the balloon" to "facilitate continuous blood flow about the inflated balloon" during expansion of a transluminally-delivered expandable prosthetic heart valve. Bailey ¶¶[0070], [0072]; Drasler ¶¶99. Bailey discloses that this balloon can be used to "permit a quantum of blood flow to pass around [a] balloon in its inflated state" such that the balloon "does not fully occlude the anatomic lumen when inflated." Bailey ¶[0070]. The balloon may be used for valvuloplasty (*see* Figure 20B below) or for stent expansion during percutaneous and transluminal valvuloplasty and prosthetic valve implantation using a single catheter (*see* Figure 19 below). Bailey, Abstract, ¶¶[0069]-[0070], [0072]; Drasler ¶99.

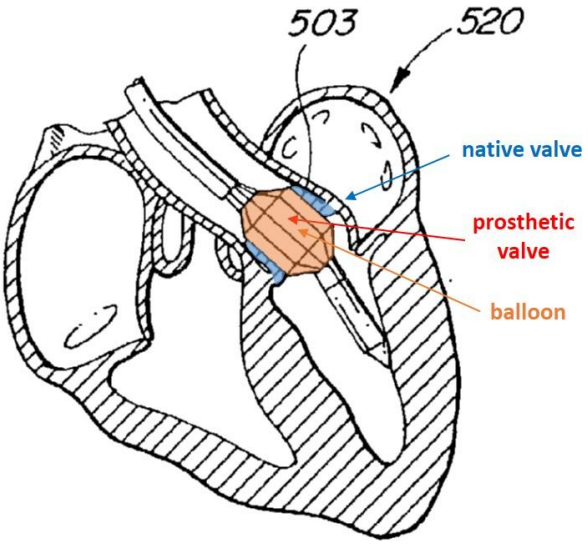
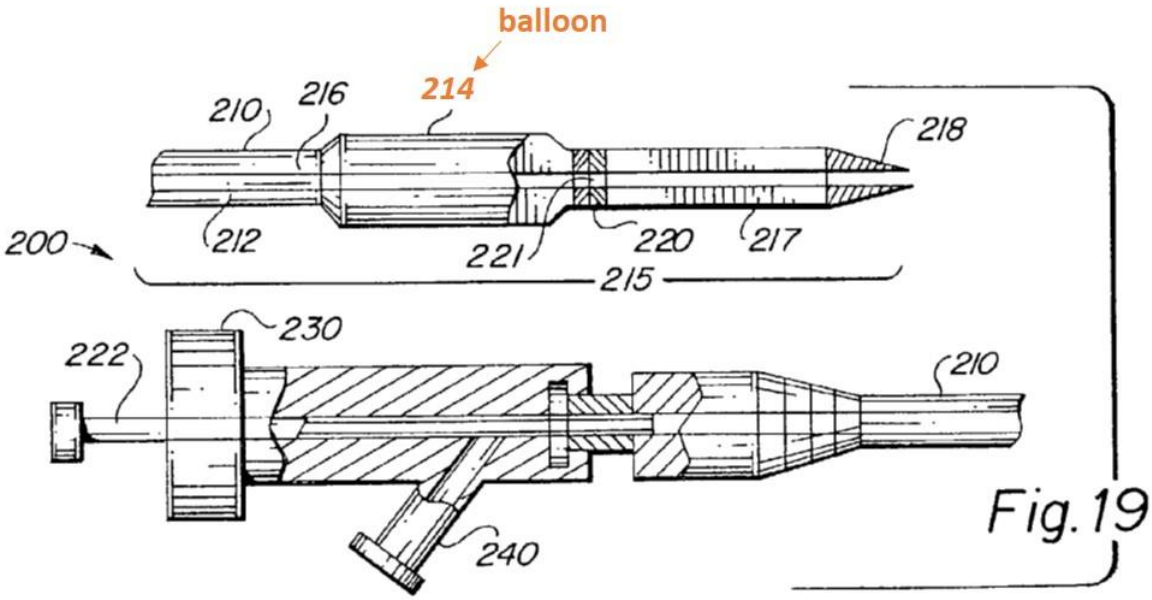


Fig. 20B



Leonhardt and **Bailey** are in the same field as the '040—prosthetic cardiac implants—and are reasonably pertinent to the alleged problem(s) identified in the '040: needing a method of treating a patient using an expandable prosthesis. '040, 3:58-61, 3:65-4:3; Leonhardt, 11:3-40; Bailey ¶¶[0069]-[0070], Figs. 20C-G; Drasler ¶100. Like **Leonhardt**, **Bailey** envisions both aortic and mitral valve replacement. Bailey, ¶¶[0056], [0061]. A POSITA would have been motivated to apply **Bailey**'**s** teaching of an expansion balloon permitting blood flow to **Leonhardt**'s expansion/tip balloons to yield the predictable and advantageous result of enabling blood flow through the valve during portions of the stent expansion. By providing a path for blood to flow, such as **Bailey's** teachings of an expansion balloon that permits blood flow around it, the force of the ventricular pressure is

greatly reduced, both reducing the risk of stent migration during implantation and reducing the need for rapid pacing. Drasler ¶101.

Bailey seeks to improve upon **Leonhardt**'s valve. Bailey ¶¶[0006], [0018]-[0019] ("Disadvantages of [Leonhardt's] device include…***complex delivery system and method*…***"*** "[T]here remains a need for…a ***single catheter delivery system and with short duration atraumatic procedure***..."); Drasler ¶102. Although **Bailey** refers to multiple Leonhardt "[d]isadvantages", **Bailey** identifies only one as of "questionable clinical utility and feasibility": light actuated anchoring means. Bailey, [0018]. **Leonhardt** teaches that such means are **optional**. Leonhardt, 3:41-45 ("***may*** be"), 8:42-45 ("preferred ***options***"). A POSITA reading these references would have been motivated to improve **Leonhardt** with **Bailey**'s teachings, using embodiments without such a mechanism. Drasler ¶102; *see also In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (simply because "alternatives exist…does not mean that an inferior combination is inapt"); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (finding no teaching away when teaching described as "inferior," but "usable").

When **Bailey**'s balloon teachings are applied to **Leonhardt**'s expansion/tip balloons, **Leonhardt**'s balloons advantageously no longer occlude flow when expanded, a benefit both references recognized and was well-known in the art. **Leonhardt** describes as beneficial procedures that are less traumatic/invasive and

require less recuperation time (Leonhardt, 3:15-29) and describes problems resulting from blood flow obstructions, including their sudden removal (Leonhardt, 11:26-28 ("damage to the downstream vessels and migration of valve stent")). Drasler ¶¶103-104. Leonhardt teaches minimizing the consequences of obstructing blood flow.[10] Leonhardt, 9:61-62 (slowing heart or dropping pressure), 11:23-29 (avoid sudden pressure changes); Drasler ¶104. **Bailey** sought to overcome that disadvantage of temporarily obstructing blood flow by advantageously teaching a stent expansion balloon that does not obstruct blood flow even when fully expanded, thus avoiding any occlusion and further reducing risk. Bailey ¶¶[0018]-[0019] (proposing improvements over Leonhardt for "atraumatic procedure"), [0070], [0072]; Drasler ¶104. The benefits of minimizing obstruction were well-known. *See* Ex. 1015, [0005]-[0008] (Eigler, filed 7/28/2003) (identifying benefits of allowing blood flow and a beating heart during valve repair, including avoiding "death, severe injury, and disability"); Ex. 1016, [0013] (Downing, published 10/31/2002) (noting benefit of avoiding "need for cardiopulmonary bypass"); Drasler ¶104.

A POSITA would have had a reasonable expectation of success in applying **Bailey**'s teachings of an expansion balloon permitting blood flow when inflated to

[10] To the extent **Leonhardt** teaches using the tip balloon to "block blood flow," (Leonhardt, 7:62-63), such use is optional and not relied on herein.

Leonhardt's balloons. Drasler ¶105. **Leonhardt** already teaches using an expansion balloon to expand valve/stent 20's ends and a POSITA would have found it obvious to use a balloon with "channels," "ridges," or an "irregular inflation profile[]" as disclosed in **Bailey** to permit blood flow when inflated. Bailey ¶[0070]; Leonhardt, 11:29-30; Drasler ¶105; *see also* Ex. 1017, [0065] (Yang, published 3/13/2003) (disclosing a "star shape[d]" "stabilization balloon" to "permit[] blood flow in the expanded configuration" for "beating heart surgeries"). **Bailey**'s and **Leonhardt**'s balloons are delivered similarly (transluminally delivered attached to a catheter) and are used for the same purposes (valvuloplasty and valve/stent balloon expansion). Bailey, ¶¶[0070]-[0072]; Leonhardt, 7:55-63, 10:13-16, 11:3-5, Fig. 5; Drasler ¶106. A POSITA would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶106.

3. Claim Chart

'040 Patent	**Leonhardt in view of Bailey**
[7.pre] "A method of treating a patient, comprising:"	**Leonhardt discloses a method of treating a patient** (*e.g.*, "percutaneously placed artificial valve" for "the treatment of heart disease" in patients) ***E.g.*, Leonhardt:** **Leonhardt** discloses a "method of implanting [an] artificial valve" for "the treatment of heart disease."

	• 1:11-14 ("The disclosed invention involves a percutaneously placed artificial valve to maintain bodily fluid flow in a single direction. It opens and closes with pressure or flow changes.") • 1:21-22 ("Cardiac valve prostheses are well known in the ***treatment of heart disease***.") • Abstract ("A method of implanting the artificial valve is also disclosed.") Drasler ¶¶107-109.
[7.1] "transluminally advancing a prosthetic valve to a position proximate a native valve of the heart; and"	**Leonhardt discloses transluminally advancing a prosthetic valve** (*e.g.*, "percutaneous delivery of valve stent") **to a position proximate a native valve of the heart** (*e.g.*, "to the placement site" "in the…aortic valve" or "at [the] mitral valve"). ***E.g.*, Leonhardt:** **Leonhardt** discloses "percutaneous delivery of valve stent 20" from an entry point at the femoral artery to the "aorta or aortic valve" using a "[d]eployment catheter." Leonhardt, 6:36-38, 9:64-67, 10:22-23. A POSITA would have understood percutaneous delivery via deployment catheter over a guidewire from the femoral artery to a placement site in the heart to refer to transluminal advancement of the prosthesis. Drasler ¶112. • 6:36-38 ("Deployment catheter 100 is generally long and tubular permitting ***percutaneous delivery of valve stent 20 to the placement site***.") • 10:6-11 ("Deployment catheter 100…is then inserted through the entry point and into the patient…over the flexible guide wire and ***slowly advancing the deployment catheter 100 to the placement site***.") • 9:63-67 ("…***If the placement site is in the aorta or aortic valve* 10**, entry may be made through the largest femoral artery in the groin area and into the aorta.")

	• 10:22-23 ("If valve stent 20 is ***to be placed at mitral valve*** **14**, entry may be made through the right internal jugular vein.") • *See also* 10:18-21 Drasler ¶¶110-112.
[7.2] "deploying the prosthetic valve at the native valve from a collapsed delivery configuration to an expanded configuration, a distal end of the prosthetic valve being expanded prior to a proximal end of the prosthetic valve being expanded;"	**Leonhardt discloses deploying the prosthetic valve at the native valve** (*e.g.*, deployed "in the…aortic valve" or "at [the] mitral valve") **from a collapsed delivery configuration** (*e.g.*, "valve stent" while enclosed in the "outer sheath" of the "deployment catheter") **to an expanded configuration** (*e.g.*, "deployment of valve stent 20")**, a distal end of the prosthetic valve being expanded prior to a proximal end of the prosthetic valve being expanded"** (*e.g.*, "tip balloon 152" is "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" before being moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue"). ***E.g.*, Leonhardt:** **Leonhardt** discloses "deployment of valve stent 20" at the "aorta or aortic valve" or "at [the] mitral valve," wherein valve stent 20 is delivered in a "collaps[ed]" condition in "deployment catheter." Leonhardt, 6:57-61, 9:64-67, 10:44-45. After the initial placement and expansion of the valve stent (*id.*, 10:53-11:22), the "function and patency" of valve stent 20 is monitored. *Id.* 11:28-34. Then, "tip balloon 152" is "advanced" to the distal end of "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" before being moved to the proximal end of "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue." *Id.* • Fig. 2

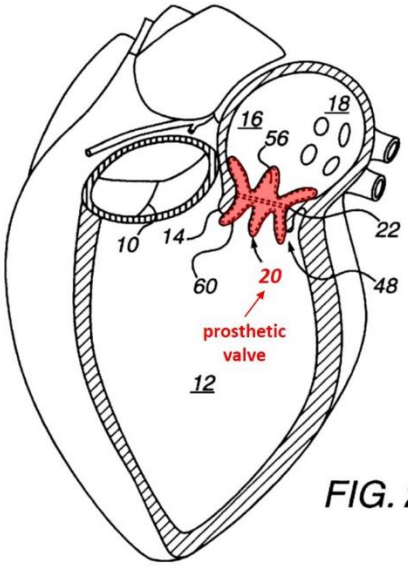


FIG. 2

- Fig. 9C-9D

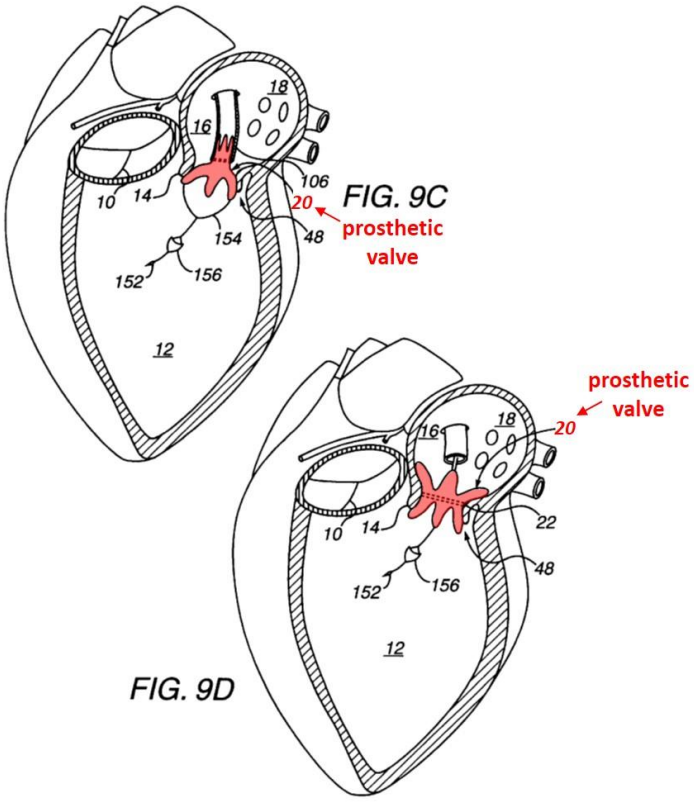


FIG. 9C

FIG. 9D

- 5:41-42 ("FIG. 2 presents a complete pre-sized valve stent 20 ***fully deployed in the location of mitral valve* 14**.")

- 10:22-23 (*see* [7.1])

	• 7:10-11 ("Biological valve 22 should be in an open position when valve stent 20 is ***loaded into outer sheath*** 106.") • 5:46-51 ("Valve stent 20 comprises a malleable graft material 24 enclosing ***deformable self expanding stent* 26** to which a biological valve 22 is attached. Stent 26 biases the proximal and distal ends of valve stent 20 into conforming and sealingly fixed engagement with the tissue of mitral valve 14.") • 9:64-67 (*see* [7.1]) • 10:44-45 ("From this point on, ***deployment of valve stent 20*** is procedurally the same for all potential placement sites.") • 10:48-55 ("***Deployment catheter*** 100 is positioned so outer sheath 106 is extending through mitral valve 14… ¶ ***Deployment of the distal end of valve stent 20 is initiated by withdrawing outer sheath 106***…") • 11:28-36 ("Valve stent 20 is now monitored for proper function and patency. The placement site is also monitored to ensure no damage has occurred to the living tissue. ***Tip balloon 152*** or expansion balloon 154 ***may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue if necessary***….") • *See also* 1:6-9, 4:56-65, 9:64-67, Figs. 9a-9b. Drasler ¶¶113-115.
[7.3] "testing a performance characteristic of the prosthetic valve;"	**Leonhardt discloses testing a performance characteristic of the prosthetic valve** (*e.g.*, "function" and "leakage" are verified). ***E.g.*, Leonhardt:**

	Leonhardt discloses that after the valve is deployed "positioning," "function," and "patency" of the valve are "verified," which a POSITA would have understood includes testing these characteristics using a well-known process or protocol. Drasler ¶118; *see, e.g.*, Leonhardt, 6:20-22 ("radio opaque markers" for "placement"), 9:55-62 (visualization/monitoring equipment for, *e.g.*, "fluoroscopy"). • 8:49-51 ("Once deployment is complete and ***positioning and function verified***, a light source (not shown) is inserted and energized.") • 11:28-34 ("Valve stent 20 is now ***monitored for proper function and patency***. The placement site is also monitored to ensure no damage has occurred to the living tissue. Tip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue if necessary.") • 11:59-63 ("Once properly placed, valve stent 20 ***function and leakage are verified***, microembolic filter tube 182 is collapsed such that pockets 184 are flush against outer sheath 106, and suture loops 174 are cut and removed using optional blade 180 if provided.") • 12:2-3 ("An optical or other catheter may be inserted to ***verify any microleaks are closed or closing***.") • *See also* 6:20-22, 9:55-62, 10:67-11:2, 11:15-17, 11:22. Drasler ¶¶116-118.
[7.4] "at least partially reversing the deployment of the prosthetic valve;"	**Leonhardt discloses at least partially reversing the deployment of the prosthetic valve** (*e.g.*, "retrieve valve stent 20 for repositioning"). ***E.g.*, Leonhardt:** **Leonhardt** discloses "retriev[ing] valve stent 20 for repositioning or removal…whether valve stent 20 is fully or

	partially deployed" by compressing proximal distensible fingers until outer sheath may be advanced over valve stent 20. • 11:37-58 ("If at any time it is necessary ***to retrieve valve stent 20 for repositioning or removal***, the following procedure may be used. This procedure is ***applicable whether valve stent 20 is fully or partially deployed*** from outer sheath 106....") • 11:45-52 ("Next,…turn the spool handle until distended fingers 46 of the proximal end of valve stent 20 are compressed to the diameter of outer sheath 106. Finally…advance outer sheath 106 over valve stent 20…") Drasler ¶¶119-121.
[7.5] "repositioning the prosthetic valve and;"	**Leonhardt discloses repositioning the prosthetic valve** (*e.g.*, "valve stent 20 may now be repositioned"). ***E.g.*, Leonhardt:** **Leonhardt** discloses that "valve stent 20 may now be repositioned." • 11:37-58 ("If at any time it is necessary ***to retrieve valve stent 20 for repositioning or removal***, the following procedure may be used. This procedure is applicable whether valve stent 20 is fully or partially deployed from outer sheath 106….***Valve stent 20 may now be repositioned or removed.*** …") • *See also* 9:7-10. Drasler ¶¶122-124.
[7.6] "re-deploying the prosthetic valve;"	**Leonhardt discloses re-deploying the prosthetic valve** (*e.g.*, after the valve is "repositioned," it is "placed"). ***E.g.*, Leonhardt:** **Leonhardt** discloses that after "valve stent 20 [is] repositioned" it is placed at the deployment site.

	• 11:37-58 (*see* [7.5]) • 11:59-63 (*see* [7.3]) • *See also* 9:7-10. Drasler ¶¶125-126.
[7.7] "wherein the prosthetic valve does not include an interlocking locking mechanism, and"	**Leonhardt discloses that the prosthetic valve does not include an interlocking locking mechanism** (*e.g.*, stent is "formed of a single piece of super elastic wire" and contains no interlocking locking mechanism as shown in Figs. 1, 4). ***E.g.*, Leonhardt:** Regardless of the meaning of this term (*see* §X.C), **Leonhardt** discloses the valve stent is "formed of a single piece of super elastic wire" and thus does not include an interlocking locking mechanism under the term's plain and ordinary meaning. Leonhardt 4:26-28; Drasler ¶129. To the extent the term is a means-plus-function term (it is not, *see* §IX.C), Leonhardt's covered stents serve the function of a prosthetic valve without an interlocking locking mechanism using the structure taught in '040 Figure 25. *Compare* '040, 12:4-13, 27:56-28:3, Fig. 25F (two stents connected with fabric cuff), *with* Leonhardt 4:27-29, Figs 1A-1B, 4 (two stents connected with graft and connecting bar 29). Nor does Leonhardt teach the structure the Examiner described as an "interlocking locking mechanism" during prosecution. '040FH, 719, 738-39; *compare* Ex. 1008 (US2005/0137687) ¶[0102] (cited in notice of allowance) *with* Leonhardt 4:27-29; Drasler ¶129. Instead, based on Leonhardt Figures 1A-1B, 4, a POSITA would have understood that valve stent 20 does not include an interlocking locking mechanism, as valve stent 20 is formed of a single piece of super elastic wire without "a mechanical snap together type lock" or other interlocking locking means. '040, 25:59-67; Drasler ¶129. • Fig. 1

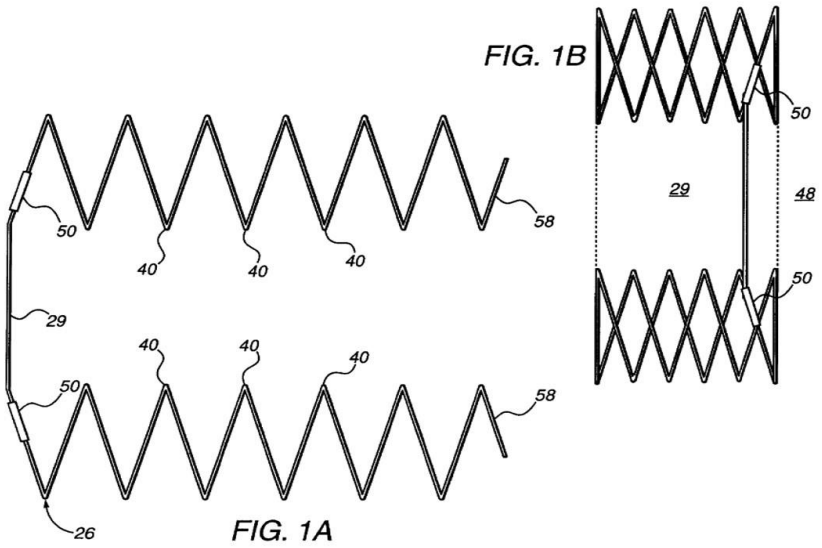


FIG. 1A

- Fig. 4

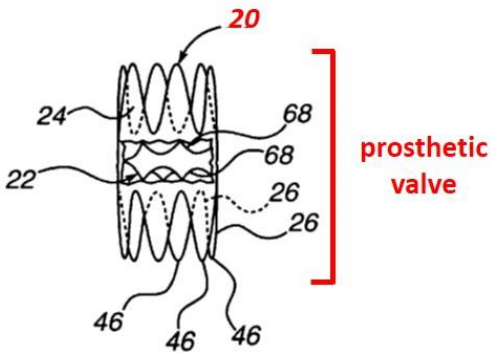


FIG. 4

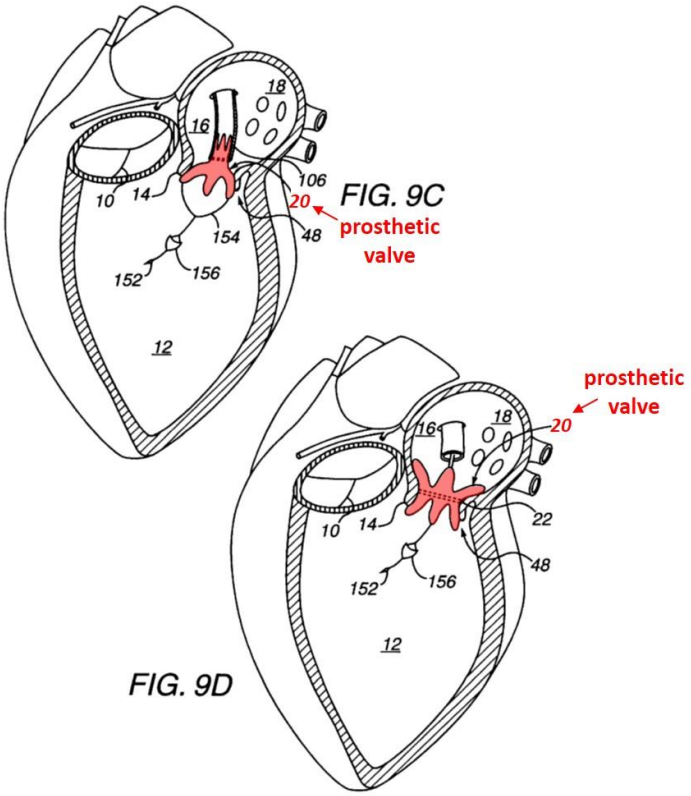
- 4:27-29 ("FIG. 1a shows stent 26 ***formed of a single piece of super elastic wire***, preferably nitinol wire, with two crimping tubes 50.")

- 4:38-40 ("The preferred embodiment ***has six (6) zig-zags* 40** which optimizes its compressed diameter and outward force, but more or less may be used.")

Drasler ¶¶127-129.

[7.8] "wherein the	**Leonhardt discloses that the prosthetic valve prevents the flow of blood through the valve in a first direction and allows**

prosthetic valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve, after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve."	**the flow of blood through the prosthetic valve in a second direction** (*e.g.*, "artificial valve…maintain[s] bodily fluid flow in a single direction"), **after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve** (*e.g.*, "Valve stent 20" "function[s]" before and after "tip balloon 152" is "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" and before being moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue"). ***E.g.*, Leonhardt:** **Leonhardt** discloses that the "artificial valve" "function[s]" to "maintain bodily fluid flow in a single direction" after it is initially expanded and before "tip balloon 152" is again "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" and again moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue." *Id.* 1:11-14, 5:51-52, 11:24-27, 11:29-30, 11:32-36. By further "mold[ing]" the valve stent to the tissue, the tip balloon expands the proximal and distal ends of the valve stent. *Id.* Meanwhile, the valve is "function[ing]" to "maintain bodily fluid flow in a single direction." *Id.* When the tip balloon is in the proximal end of the valve stent, there is no catheter or guidewire running through the replacement valve. *Id.*, 1:11-14, 5:51-52, 11:24-27, 11:29-30, 11:32-36, Figs. 5, 9A-D; Drasler ¶132. A POSITA would have understood, and at least would have found it obvious, that the valve would impose unidirectional blood flow after distal expansion before reinflation of the proximal end because at that time, the valve stent had already been "monitored for proper function" and nothing would be blocking blood flow during the monitoring of function. Leonhardt, 11:28-33; Drasler ¶132. • Figures 9C-9D



- 7:17-19 ("Valve stent 20 is loaded either end first into outer sheath 106, the correct choice depending upon the access path taken and the fluid flow direction at the placement site.")

- 1:11-14 (*see* [7.pre])

- 11:28-36 (*see* [7.2])

- 3:15-29 ("The need remains for an artificial heart valve…***which does not require*** general anesthesia or stopping the heart or ***using a heart-lung machine during placement***….")

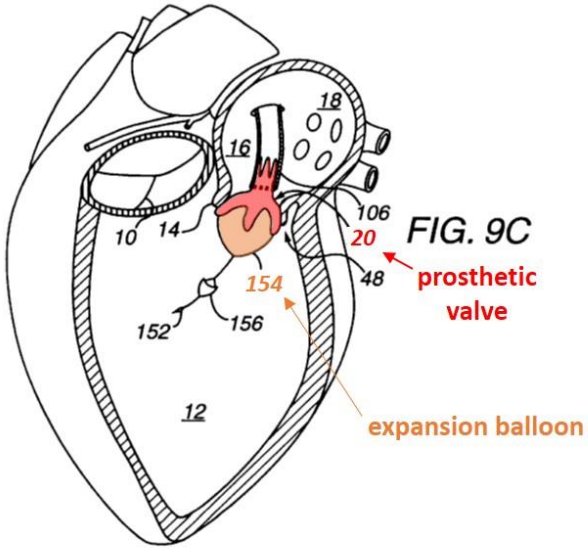
- 5:51-52 ("The ***deployed valve stent 20 creates a patent one way fluid passageway***.")

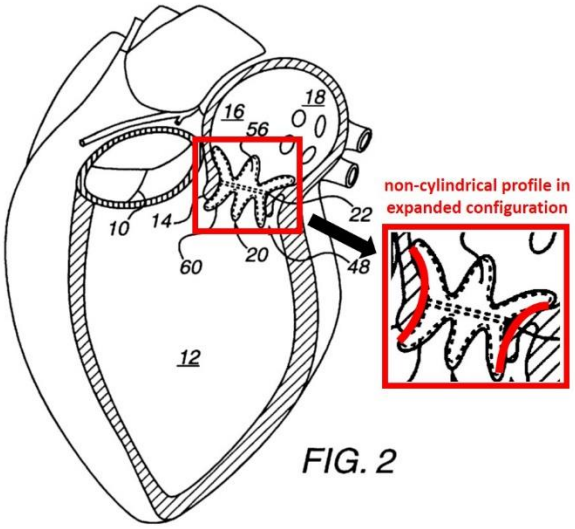
- *See also* 1:6-9, 7:61-63, 9:63-10:6, 10:18-21, 11:24-27, Fig. 9a and Fig. 9b.

	Bailey discloses a prosthetic valve allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve (e.g., "balloon expansion of the deployed stent valve" using "irregular inflation profiles" to "facilitate continuous blood flow about the inflated balloon"). ***E.g.*, Bailey:** While **Leonhardt's** tip balloon does not allow blood flow through the prosthetic valve during balloon valve expansion, **Bailey** discloses an expansion balloon that uses "irregular inflation profiles" to "facilitate continuous blood flow about the inflated balloon." Bailey ¶[0070]. Thus, Bailey discloses allowing blood to flow through the valve/stent during valve/stent expansion. *Id.*; Drasler ¶134. As discussed in §X.A.2, a POSITA would have been motivated to modify Leonhardt's tip balloon in view of Bailey to permit balloon expansion while allowing blood flow through the valve/stent during expansion. Drasler ¶135. For example, in applying Bailey's teachings, Leonhardt's tip balloon would allow blood flow through the valve/stent such that it can continue to "function" to "maintain bodily fluid flow in a single direction" during expansion of the proximal end of Leonhardt's valve stent to further "mold" it to the tissue. Leonhardt, 1:11-13, 11:29-30, 11:32-34; Drasler ¶135. When the tip balloon is used for proximal end expansion of the valve/stent, no catheter or guidewire is protruding through the stent—thus allowing it to "function" and "maintain bodily fluid flow in a single direction." Drasler ¶135.[11]

[11] Indeed, the combination of **Leonhardt** and **Bailey** renders obvious the '040's only disclosure of a valve functioning when deployed "at the native valve" ([7.2]) after distal end expansion and prior to proximal end expansion by further "dilat[ing]" the device "to ensure the device is apposed to the wall of the annulus and seated properly." *See* §V, §VII, n.6; '040 75:4-6; Drasler ¶136.

	• ¶[0070] ("***Alternatively, it may be advantageous to configure the balloon such that it does not fully occlude the anatomic lumen when inflated, but permits a quantum of blood flow to pass around the balloon in its inflated state. This may be accomplished by providing channels or ridges on the ablumenal surface of the balloon. Additionally, irregular inflation profiles of the balloon may facilitate continuous blood flow about the inflated balloon.***") • ¶[0072] ("In accordance with the present invention, it is also contemplated that the position of the balloon 214 and capture sheath 217 may be reversed, such that the balloon 214 is distal the capture sheath 217. …***This would allow for post-deployment balloon expansion of the deployed stent valve without the need to traverse the prosthetic valve in a retrograde fashion.***") • *See also* ¶[0048], [0021]. Drasler ¶¶130-136, 100-106.
[8] "The method of claim 7, wherein the prosthetic valve is expanded to the expanded configuration using an inflation media."	***See* [7].** **Leonhardt discloses that the prosthetic valve is expanded to the expanded configuration using inflation media** (*e.g.,* "expansion balloon 154 is [] inflated" with "fill fluid" to expand "valve stent 20" and hold it "secure against the living tissue")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses a "expansion balloon 154," which is inflated with "fill fluid" to expand "valve stent 20" "to a pressure sufficient to hold … valve stent 20 secure against the living tissue." • Figure 9(c) :

	 FIG. 9C • 7:58-60 ("***Second inner track 126 allows filling and emptying tip balloon 152*** and third inner track 128 allows filling and emptying expansion balloon 154.") • 7:64-7:67 ("Balloons are preferably polyurethane and act in a calibrated pressure compliant manner such that ***injecting a known amount of fill fluid into the balloons relates to a known expansion in the diameter of the balloons***.") • 11:3-5 ("Expansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue as seen in FIG. 9c.") Drasler ¶¶137-140.
[9] "The method of claim 7, wherein the prosthetic valve has a non-cylindrical profile in the expanded	***See* [7].** **Leonhardt discloses that the prosthetic valve has a non-cylindrical profile in the expanded configuration** (*e.g.*, "valve stent 20 must flair at one or both ends as is shown in FIG. 2")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses a "valve stent 20," which "conform[s] to and seal[s] against the dramatically different structures occurring

configuration.”	within vessel walls and valve locations” such that either end “flairs” radially outward from its central portion. • Figure 2  FIG. 2 • 6:9-23 (“Where other vessels or passages leave the vessel receiving valve stent 20 at a placement site, or when ***valve stent 20 must flair at one or both ends as is shown in FIG. 2***, graft material 24 may be cut out between the plurality of distensible fingers 46 formed by zig-zags 40 of stent 26….***Stent 26*** is pre-sized to open beyond the width of the natural valve mouth and ***will flair sufficiently to conform and seal to the tissue***.”) • 5:46-48 (“Valve stent 20 comprises a malleable graft material 24 enclosing ***deformable self-expanding stent 26 to which biological valve 22 is attached***.”) • 4:63-65 (“This allows stent 26 to ***conform to and seal against the dramatically different structures occurring within vessel walls*** and valve locations with one basic stent shape.”

	• 5:59-61 ("The middle portion of graft material 24 is tapered to a smaller cross-sectional area than its ends to prevent bunching of the material once placed within the patient.") • *See also* Fig. 9d. Drasler ¶¶141-144.
[10] "The method of claim 7, wherein a proximal portion of the prosthetic valve extends further radially outwardly than a central portion of the prosthetic valve."	***See* [7].** **Leonhardt discloses that a proximal portion of the prosthetic valve extends further radially outwardly than a central portion of the prosthetic valve** (*e.g.*, "valve stent 20 must flair at one or both ends as is shown in FIG. 2")**.** See [9]. Drasler ¶¶145-148.

4. Leonhardt in View of Bailey Presents a Second Obviousness Basis

To the extent PO argues the Challenged Claims are instead limited to requiring unidirectional blood flow during the initial expansion and prior to any proximal end expansion for [7.8] (*see* §§X.A.2, X.A.3.[7.8]), **Leonhardt** in view of **Bailey** nonetheless renders the Challenged Claims obvious. As discussed in §X.A.2, a POSITA would have been motivated to modify **Leonhardt's** expansion and tip balloons in view of **Bailey** to permit balloon expansion while allowing blood flow

during expansion of the carrier element. Drasler ¶149, 100-106. When **Bailey's** teachings of allowing blood flow through the expansion balloon are applied, during the self-expansion process discussed in §X.A.1, once outer sheath 106 is sufficiently retracted to expose a portion of the proximal distensible fingers, valve/stent outflow occurs because the distensible fingers are designed to permit blood flow in the "cut out[s]" between them, as shown in Fig. 4:

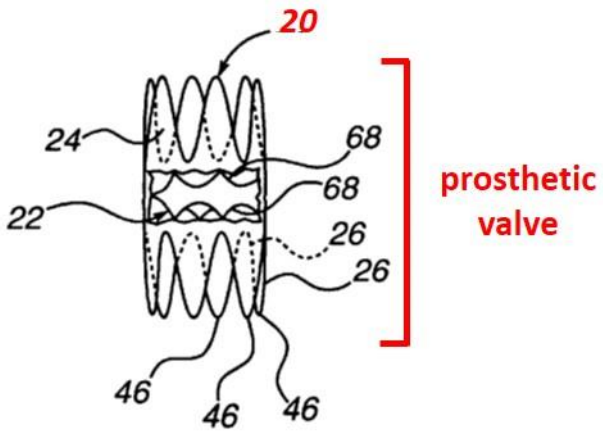
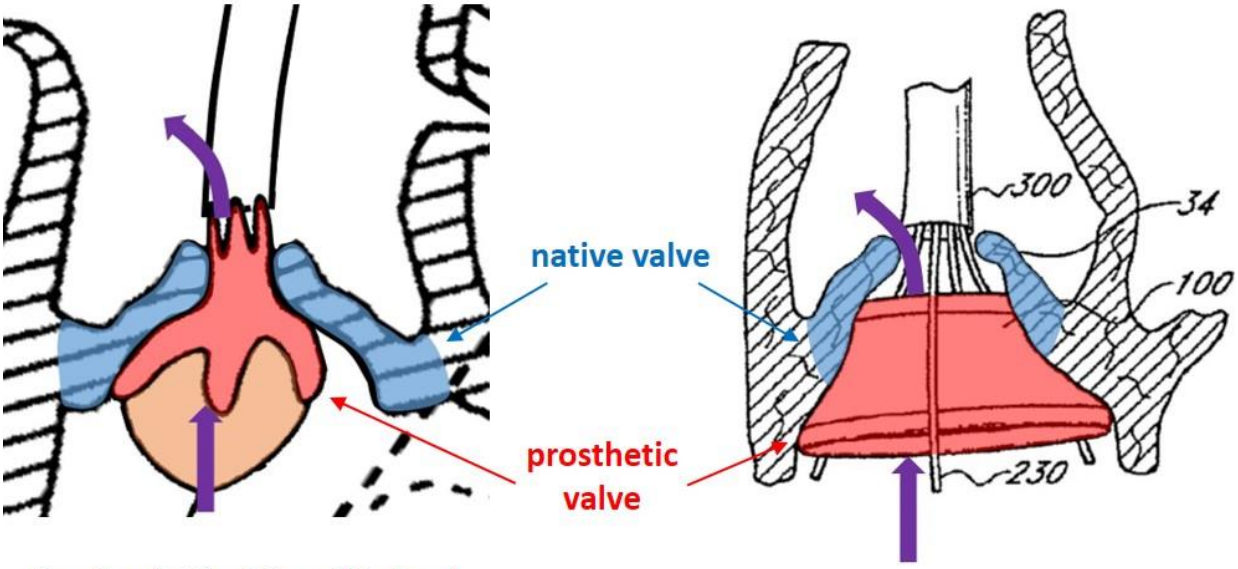


FIG. 4

Leonhardt, Fig. 4, 6:9-22; Drasler ¶¶149. Specifically, during "deployment of valve stent 20" at the "aortic valve" or "at [the] mitral valve," the "distensible fingers 46" are placed such that blood flows between the fingers to "other vessels" such as coronary arteries. Leonhardt, 6:17-19, 6:57-61, 9:63-10:6 (aortic valve deployment), Figs. 9B-9C. Similarly, when those same cutouts are exposed by retracting the outer sheath 106, blood flows through them before the proximal end

is expanded. *See id.*; Drasler ¶149. For example, the figure on the left below has been modified from Leonhardt Figure 9C to depict retrograde blood flow in the aortic valve and capture the orientation of the proximal stent fingers and cut-outs before proximal end expansion. Drasler ¶¶149-151. As shown in the figure, the valve functions as blood (purple) flows from the distal end, through a balloon modified with Bailey's teachings (see §X.A.2) and out between the "cut outs" in the proximal fingers. *See* §§X.A.1-3; Drasler ¶¶149-151. Outflow remains unobstructed as the proximal fingers are released and the valve stent completes its self-expansion. Drasler ¶¶149-151.

A POSITA would have understood or least found it obvious that the same blood flow through the valve and functionality to the extent present in '040 (*e.g.*, as shown in annotated '040 Figure 47A on right below—blood flow annotated purple) would have existed in **Leonhardt** during the initial proximal end expansion when **Bailey's** balloon teachings are applied. Drasler ¶¶150-151; Leonhardt, Fig 9C; Garrison, Fig. 17; '040, Fig. 47A:



Leonhardt Fig. 9C modified and juxtaposed on Garrison Fig. 17

'040 Fig. 47A

As explained in §X.A.1, **Leonhardt's** valve and its leaflets are free to open and collapse back onto the inner catheter (thus allowing unidirectional blood flow) because the balloon does not overlap with the valve. Drasler ¶150. As illustrated above in Figure 4, when the cut-outs are exposed, the valve has also been deployed from the catheter such that it is free to function. Drasler ¶150. The catheter's presence would also aid in blocking blood flow in one direction as the leaflets will need to close a smaller area. Drasler ¶150; *see also* Ex. 1010, 13 (PO's amended complaint asserting this limitation is met despite the presence of a catheter through the valve). Regardless, such operation is consistent with a style of prosthetic valve known in the art at the time of the purported invention, which blocks flow by collapsing material onto itself—for example, Ex. 1037, PCT International

Publication Number WO 98/29057 (Letac), Figures 9a-11b; Drasler ¶150. And some of the earliest prosthetic valves (well-known for decades) blocked reverse flow by collapsing material onto or around supporting structures, for example, Boretos, Figures 4A-4B; Drasler ¶¶36-40. Thus, just as **Leonhardt** discloses that the valve "function[s]" prior to the second balloon expansion (Leonhardt, 11:29-34), a POSITA would have understood, and at least found it obvious, that when **Bailey**'s teachings are applied to **Leonhardt**, the valve also functions when blood can flow through the cut-outs in the proximal end prior to any expansion of the proximal end—advantageously allowing blood flow and replacing the operation of the native valve earlier in the procedure. Drasler ¶150; *see also* Salahieh-697 (Ex. 1007), Figs. 9A-10B, ¶[0074] (teaching replacement valve operation before stent's proximal end released from catheter).[12]

As further discussed in §X.A.1, **Leonhardt** discloses retracting the outer sheath 106 off of the proximal end of the valve stent and allowing it to self-expand, and then using expansion balloon 154 to further expand the proximal end. A

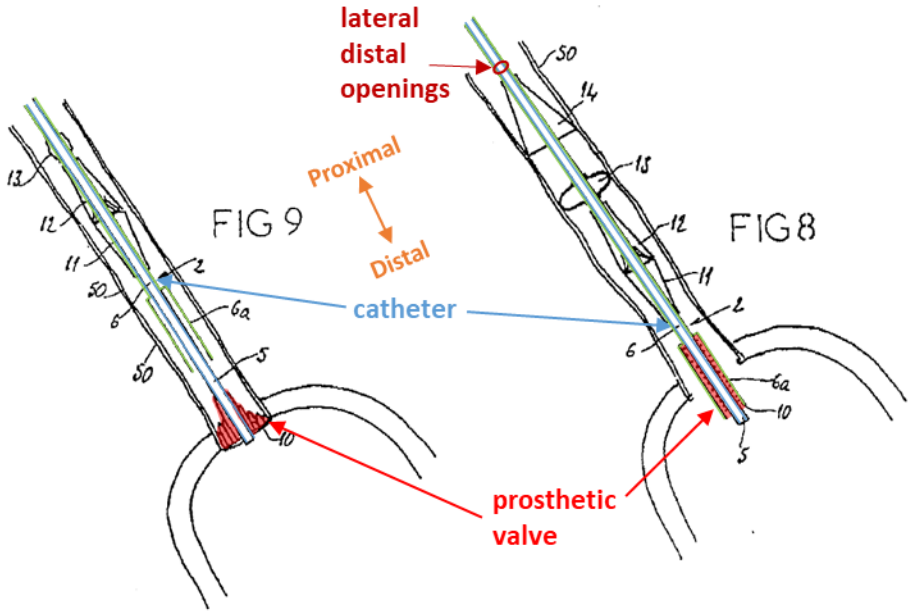
[12] Even if the Challenged Claims were entitled to the priority date of the provisional applications (they are not), Salahieh-697 is still relevant as evidence of knowledge of a POSITA at the time of the invention. *Yeda Research v. Mylan Pharms., Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018).

POSITA would have understood that, when **Bailey's** balloon teachings are applied, **Leonhardt's** valve would also impose unidirectional flow during expansion, after expansion of the distal end, and prior to expansion of the proximal end at two additional points in time: (1) immediately after outer sheath has been retracted, when the prosthesis's proximal end is self-expanding, and (2) while expansion balloon is expanding prosthesis's proximal end. Drasler ¶¶152-155.

B. Ground 2: Claims 7-10 Are Rendered Obvious by Leonhardt in View of Bailey and Seguin

To the extent PO argues further disclosure of blood flow through the proximal end of **Leonhardt's** prosthesis before any proximal end expansion is required for the valve to work (the upper purple arrow in Fig. 9C above in §X.A.4) for [7.8] (*see* §X.A), **Leonhardt** in view of **Bailey's** balloon teachings and **Seguin's** catheter opening teachings also discloses this functionality and renders the Challenged Claims obvious. Drasler ¶¶151, 156-159, 100-106. **Seguin** provides additional disclosure of a catheter comprising "lateral distal openings…to allow the blood to reach" the blood vessel, for example "the ascending aorta," during deployment of a prosthesis. Seguin, 7, 11-12, cl. 11. In particular, when the catheter is in the deployment position, "lateral distal opening[s]" in the catheter proximal of the prosthesis's proximal end, "allow the blood to reach the corporeal duct"—the blood vessel—such that blood advantageously continues to flow. Seguin, 7, 11-12, Claim

11, Figs. 8-9 (lateral distal openings added); Drasler ¶156. The openings are placed distally such that "the length of catheter across which the blood passes is as short as possible." Seguin, 7, 11, Claim 11.



A POSITA would have been motivated to apply **Seguin**'s teachings to **Leonhardt's** outer sheath for the same reasons discussed in §X.A.2. Like **Leonhardt, Seguin** is in the same field as the '040—prosthetic cardiac implants—and is reasonably pertinent to the alleged problems identified in the '040, *e.g.*, a need for a method of treating a patient using an expandable cardiac prosthesis. §X.A.2; Seguin, 6-7, 11-13, Claim 11; Drasler ¶157.

A POSITA would have been motivated to apply **Seguin**'s express teaching of a catheter comprising distal lateral openings to **Leonhardt**'s outer sheath to yield the predictable, advantageous result of enabling blood flow through valve/stent 20's

proximal end during expansion (and before any proximal end expansion) and exit to a bodily vessel, such as the aorta—thereby avoiding any pressure buildup or imperfect pacing devices.[13] Drasler ¶158; Seguin, 7, 11-12, Claim 11; Leonhardt, Abstract, 1:11-14, 6:36-38, 9:64-67, 10:6-11, 10:22-23, 11:29-36; §X.A.2 (discussing similar motivations for applying Bailey's teachings). Per **Seguin's** teachings of minimizing flow through the catheter, the lateral openings would be placed near the distal tip of **Leonhardt's** sheath. Seguin, 7, 11-12; Drasler ¶158. **Leonhardt** recognizes the importance of maintaining blood flow through a prosthesis during deployment and describes problems that result from blood flow obstruction during deployment that is suddenly removed (*see* §X.A.2). **Bailey's** teachings of a non-obstructing balloon (*see* §X.A.2) and **Seguin's** teachings additionally improve **Leonhardt—Seguin** provides additional teachings of a catheter comprising lateral openings to advantageously "allow the blood to reach the bodily vessel" after passing through the proximal end. Seguin, 7, 11-12; Drasler ¶158. Because **Bailey**'s teachings modify **Leonhardt's** balloon and **Seguin**'s teachings modify **Leonhardt's** catheter, a POSITA would have understood that applying both teachings to **Leonhardt** would advantageously allow blood flow

[13] The proposed combination does not rely on **Seguin's** particular stent or valve teachings.

through **Leonhardt**'s prosthesis at multiple points during deployment of the prosthesis for a longer period of time than just applying one teaching—blood would flow regardless of whether a balloon is inflated or the proximal end of the stent/valve is still inside the catheter. Drasler ¶158. The additional blood flow through Leonhardt's prosthesis further allows the valve to function and allow for unidirectional blood flow. Drasler ¶158. A POSITA would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality.[14] Drasler ¶¶158-159.

XI. SECONDARY CONSIDERATIONS

There is no evidence in the prosecution history of the '040 or any related application that any arguments regarding secondary considerations exist, let alone that any such evidence could overcome the strong showing of obviousness above or that there is a sufficient nexus to any Challenged Claim. *See generally* '040FH; Drasler ¶160. As demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in the '040 were already well known.

[14] **Leonhardt** teaches that the plunging seal on push rod's distal end is optional when using sutures to enable repositioning; thus, there is no obstacle to applying **Seguin's** teaching of distal lateral openings to **Leonhardt's** sheath. Leonhardt, 8:31-38; Drasler ¶158.

Drasler ¶160. To the extent PO asserts the existence of any secondary considerations in its responses, Petitioners reserve the right to address any such evidence.

XII. CONCLUSION

Substantial, new, and noncumulative technical teachings have been presented for the '040's Challenged Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to claims 7-10. *Inter partes* review of claims 7-10 is accordingly requested. Drasler ¶¶161-163.

Dated: January 20, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR §42.24(a) and (d), the undersigned hereby certifies that this Petition for Inter Partes Review complies with the type-volume limitation of 37 CFR §42.24(a)(i) because, exclusive of the exempted portions, it contains 12,831 words as counted by the word processing program used to prepare the paper.

Dated: January 20, 2021

/James L. Davis, Jr./
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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§42.6(e) and 42.105(b) on the Patent Owner by FedEx of a copy of this Petition for *Inter Partes* Review and supporting materials at the correspondence address of record for the '040 patent:

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Courtesy copies of the same documents were also served at the following email addresses of record for Speyside Medical, LLC's litigation counsel:

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Dated: January 20, 2021

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