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 IPR2021-00310

U.S. Patent No. 9,510,941

PETITION FOR *INTER PARTES* REVIEW

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1047	Collection of printouts from the following URLs: • https://web.archive.org/web/20040103082651/http://circ.ahajournals.org/cgi/content/full/106/24/3006 • https://web.archive.org/web/20040224074417/http://circ.ahajournals.org/cgi/reprint/106/24/3006.pdf • https://web.archive.org/web/20031013145957/http://circ.ahajournals.org/content/vol106/issue24/index.shtml • https://web.archive.org/web/20030701173919/http://circ.ahajournals.org:80/cgi/content/abstract/106/24/3006 • https://web.archive.org/web/20021213153959/http://www.circ.ahajournals.org:80/misc/stats.shtml including at pages 1 to 3 Cribier et al., Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
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1051	Declaration of Crena Pacheco

Pursuant to §§311-319 and §42.1, Medtronic CoreValve LLC and Medtronic, Inc. ("Petitioners") petition for *inter partes* review ("IPR") of claims 1-8, 10, 12-14, and 16 ("Claims") of U.S. Patent 9,510,941 ("'941") (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 Claims.

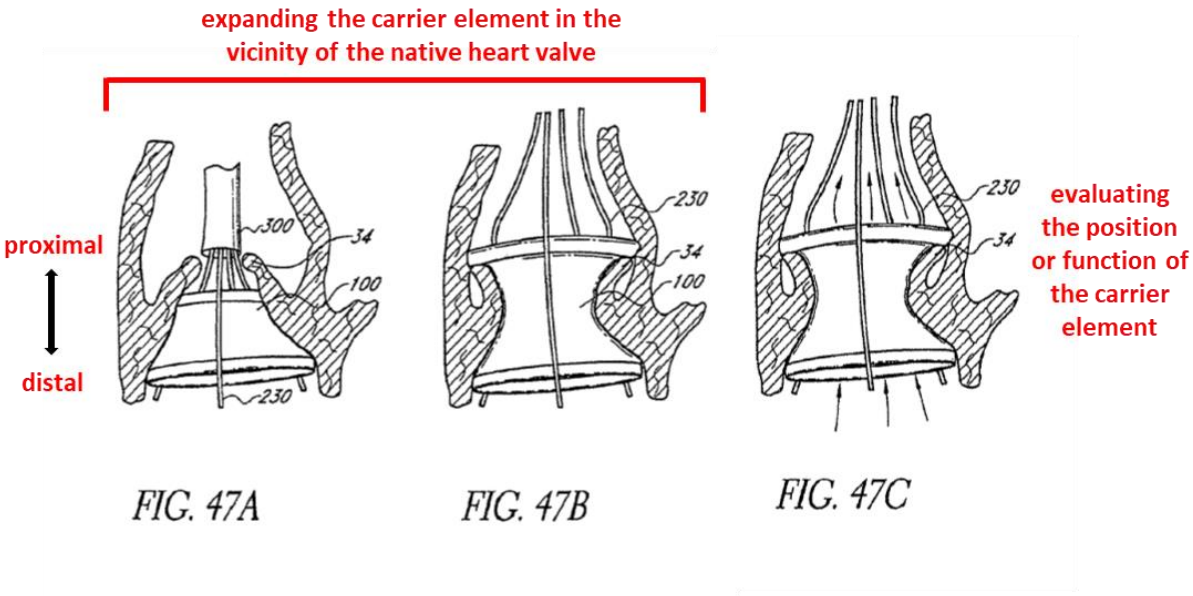
I. INTRODUCTION

The '941 is directed to a method for deploying a prosthetic heart valve. The claimed prosthesis is expanded without urging its proximal end toward its distal end, and—after distal end expansion and before proximal end expansion—permits unidirectional blood flow. But all claimed steps and features were well-known in the art before the time of the invention. Drasler ¶¶36-40.

The '941 recites a method for deploying a prosthetic heart valve, including endovascularly delivering and deploying it at a native valve from a collapsed to

[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. Added figure annotations generally quote the Claims' language for reference. All citations are exemplary and not meant to be limiting.

expanded configuration (Fig. 47A-C), without urging the proximal end toward the distal end. Drasler ¶¶36, 241.



As ’941 admits, this was a well-developed field and endovascular delivery was well-known in the art. ’941, 3:52-55; Drasler ¶¶37-39. For example, **Leonhardt**, which was applied in a rejection during prosecution, teaches a prosthesis (in red below), such as a “[b]iological valve 22” within “stent 26,” that operates to impose unidirectional blood flow after distal end expansion, but before proximal end expansion. Leonhardt, 10:53-11:22, 6:23-31; Drasler ¶101.

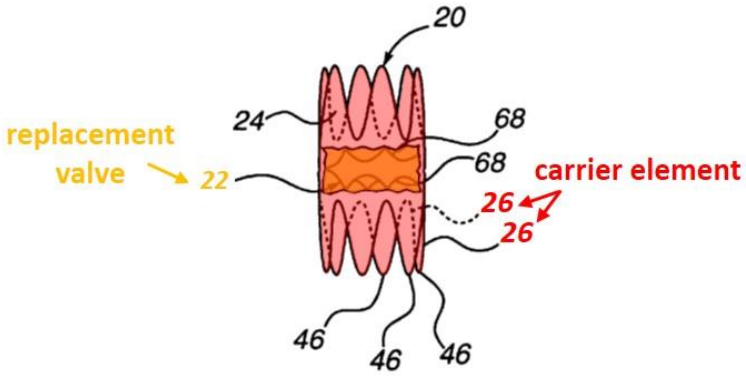


FIG. 4

Leonhardt further discloses treating a patient in accordance with the claimed steps: transluminally delivering at the native valve the prosthesis and expanding it from a collapsed to expanded configuration without urging the carrier element's ("carrier's") proximal end towards its distal end. Leonhardt, 10:53-11:58; Drasler ¶¶103, 106. The only alleged point of novelty identified by PO during prosecution over **Leonhardt** was the requirement that the prosthesis permit unidirectional blood flow after distal end expansion and before proximal end expansion. *E.g.*, Ex. 1003 ("'941FH"), 1761. However, the Examiner and PO missed a crucial disclosure in **Leonhardt** of the valve operating to permit unidirectional blood flow at a later point during carrier's expansion. **Leonhardt** further teaches selecting a properly sized valve/stent, removing the valve/stent from the patient, such that the procedure can be repeated with a properly sized valve/stent to avoid open heart surgery. Leonhardt, 3:4-11, 5:2-10, 9:50-55, 11:37-58. **Leonhardt** alone renders obvious nine Claims. Drasler ¶237.

These claims are further obvious in further view of **Bailey** and **Seguin** to the extent the Claims require valve function before any proximal end expansion (contrary to the intrinsic evidence). **Bailey** teaches an expansion balloon with an "irregular inflation profile[]," permitting blood flow around the balloon and **Seguin** teaches blood flow out of the prosthesis' proximal end, even when it is still collapsed in the catheter, through the catheter's lateral openings—such that blood flows around **Leonhardt's** expansion balloon on the distal end and through the stent valve's proximal end before any proximal end expansion. Bailey ¶¶[0070], [0072]; Seguin, 7, 11-12, Cl. 11; Drasler ¶¶123, 186.

The remaining Claims are obvious in further view of **Stevens, Cribier** or **Svanidze**. **Stevens** and **Cribier** teach methods for monitoring physiological properties during the procedure. Stevens, 4:4-9; Cribier, 17. **Svanidze** teaches "support posts" that couple the prosthesis' proximal and distal ends to provide for increased stability. Svanidze ¶¶[0084], [0086].

Importantly, neither **Bailey**, **Seguin**, **Cribier**, **Svanidze**, **Stevens** nor any substantially similar reference was considered in combination with **Leonhardt**. As demonstrated herein, **Leonhardt** alone and alternatively in further view of **Bailey**, **Seguin**, **Stevens**, **Cribier** and/or **Svanidze** renders obvious the 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 ¶¶95-99.

Petitioners request that the Board institute trial and find the 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

Petitioners are challenging the '941 in three petitions (see also IPR2021-00240 and IPR2021-00241) due to the length of the claims challenged, and provide a further explanation of these parallel petitions in Ex. 1049.

The '941 is currently the subject of 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); IPR2021-00242 (USP

10,449,040); IPR2021-00239 (USP 8,377,118); and IPR2021-00244 (USP 9,603,708).

C. Lead and Back-Up Counsel and Service Information

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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. 102760-0209-654.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioners certify the '941 is available for IPR. Petitioners are not barred or estopped from requesting IPR challenging the '941's claims 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. '941 claims priority to 11/579,723, filed as PCT/US2005/015617 on 5/5/2005 and multiple provisionals. Drasler ¶82.

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)
Stevens	1046	U.S. 5,370,685	07/16/1991	12/06/1994	(a), (b)
Cribier	1048, 16-18	Cribier, Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis, *Circulation*, vol.		11/25/2002	(a), (b)

		106, no. 24 (Dec. 2002)			
Svanidze	1012	U.S. App. Pub. 2005/0075726	10/06/2003	04/07/2005	(a), (e)

Cribier was publicly accessible to POSITAs and interested researchers well before May 2004 through the well-known journal Circulation and via indexing by author, subject matter, and title. Ex. 1048, 5 (online 11/2002), 9-10, 13 (indexed), 5-7 (text), 15-18 (pdf); Ex. 1047, 17-19; Drasler ¶¶311-318; Ex. 1057 (citing Cribier). Indicia of publication on Cribier's face, including its publishers, Circulation and the American Heart Association, further indicate Cribier's public accessibility by May 2004. *Giora George Angres, Ltd. v. Tinny Beauty & Figure, Inc.*, 1997 WL 355479, at *7 (Fed. Cir. June 26, 1997) (unpublished) (finding "no reason to suspect [a reference published by an established publisher] was not publicly available"); *Microsoft Corp. v. IPA Techs., Inc.*, IPR2018-00794, Pap. 11, *10-11 ("indicia of publication…on [reference's] face…are particularly persuasive"). For established publishers, "absent some indication that the reference was not publicly available,…a date of publication is alone sufficient..." *Microsoft*, Pap. 11, *10-11.

2. Statutory Grounds on Which the Challenge Is Based

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

§103 Ground	Claim(s)	Prior Art
1	1-2, 4-6, 10, 12-14	Leonhardt
2	2	Leonhardt in view of Bailey
3	1-2, 4-6, 10, 12-14	Leonhardt in view of Bailey and Seguin
4	3	Leonhardt in view of Stevens
5		Leonhardt in view of Bailey, Seguin and Stevens
6	7-8	Leonhardt in view of Cribier
7		Leonhardt in view of Bailey, Seguin and Cribier
8	16	Leonhardt in view of Svanidze
9		Leonhardt in view of Bailey, Seguin and Svanidze

3. How the Claims Are Unpatentable

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

V. '941

'941 discloses a prosthesis for replacing an abnormal or diseased cardiac valve. '941, 4:15-17, 11:57-59, Fig. 2 (below). The claimed method is generally directed to (1) endovascularly delivering a prosthesis to a native valve and (2) expanding the prosthesis from a collapsed configuration, shown in Figs. 47A-C and 2 below. '941, 5:48-55, 50:45-51:24, 75:14-67; Drasler ¶¶41, 53.

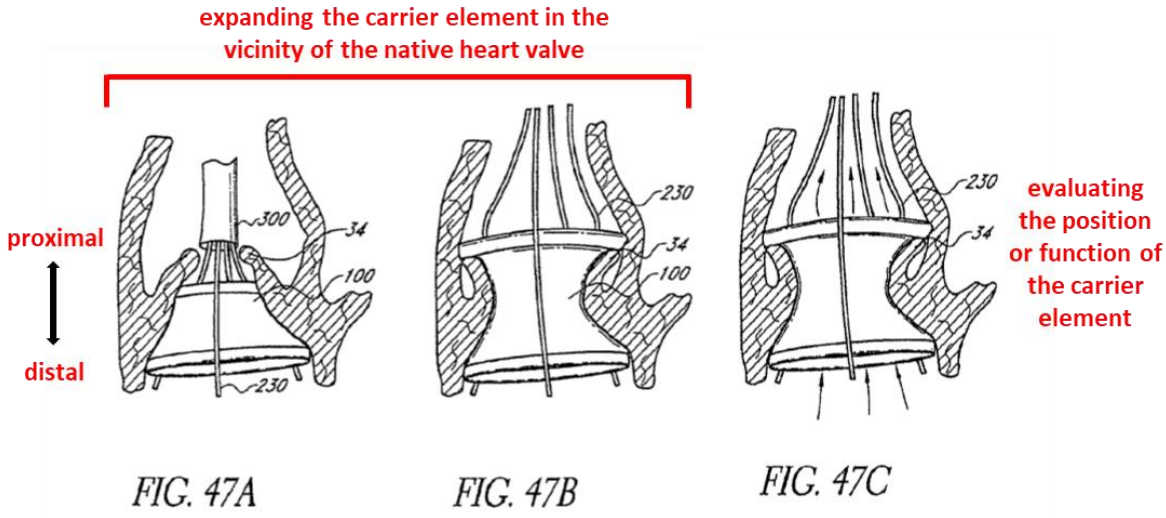

FIG. 47A FIG. 47B FIG. 47C

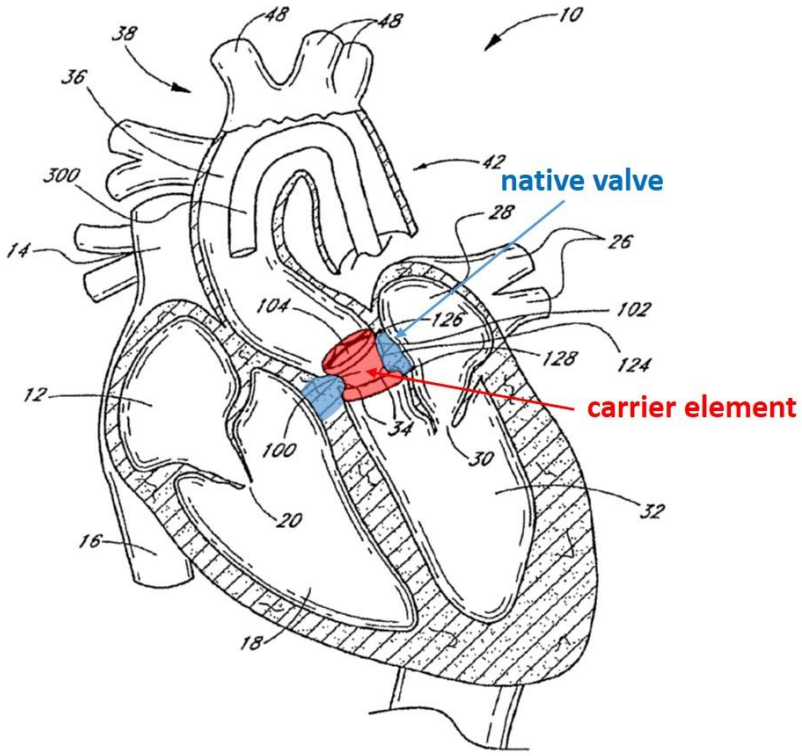

FIG. 2

The prosthesis comprises a valve and a carrier. '941, 12:14-17, 28:9-12. In one embodiment, the carrier includes stents 756 at either end and a flexible fabric

cuff 752 coupled to valve 754. '941, 12:4-13, 27:56-66, Fig. 25F (below); Drasler ¶¶42-44.[2]

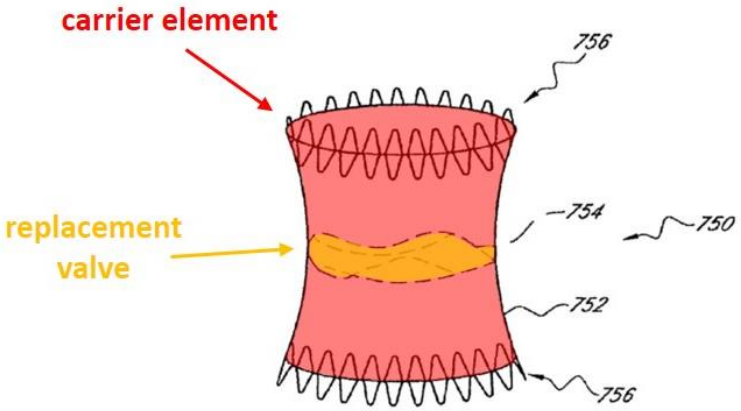

FIG. 25F

Stent alternatives include inflatable cuffs. '941, 4:3-12, 12:14-17, 67:11-13.

The prosthesis is "loaded" in its collapsed reduced-profile form between outer and inner sheaths of an intravascular delivery catheter and delivered "minimally invasively." '941, 11:53-56, 13:55-60, 41:36-38, Figs. 34, 36. The prosthesis is "translumenally advanced" through an access site (e.g., femoral artery) to the native

[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." '918, 12:4-13; Drasler ¶¶43.

valve while the heart is "beating," with stents 756 collapsed. '941, 5:18-25, 6:27-32, 27:59-64, 44:17-19, 77:12-34, Fig. 57A; Drasler ¶¶45. Figures 46B-C depict the collapsed prosthesis either held a distance from, or partially within, the sheath during withdrawal (the reverse process used for deployment):

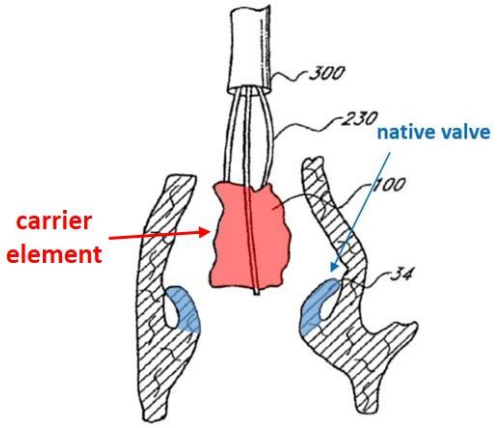

FIG. 46B

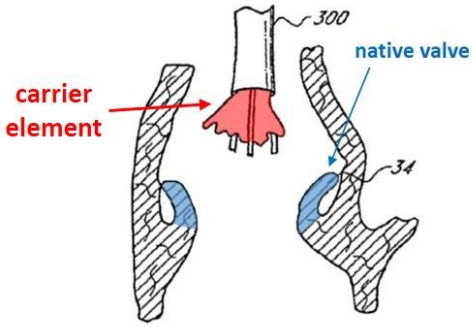

FIG. 46C

A deployment control device—*e.g.*, control wires 230 (e.g., Figs. 46, 47A-E) detachably coupled to the prosthesis's ends or proximal extension—positions the implant and renders it recoverable. '941, 41:47-50, 49:17-28, 75:51-54, 77:38-65. At the implantation site, the catheter's outer sheath is withdrawn, expanding the prosthesis's distal end while the prosthesis is held stationary using the control device. '941, 74:43-49, Figs. 45A-C.

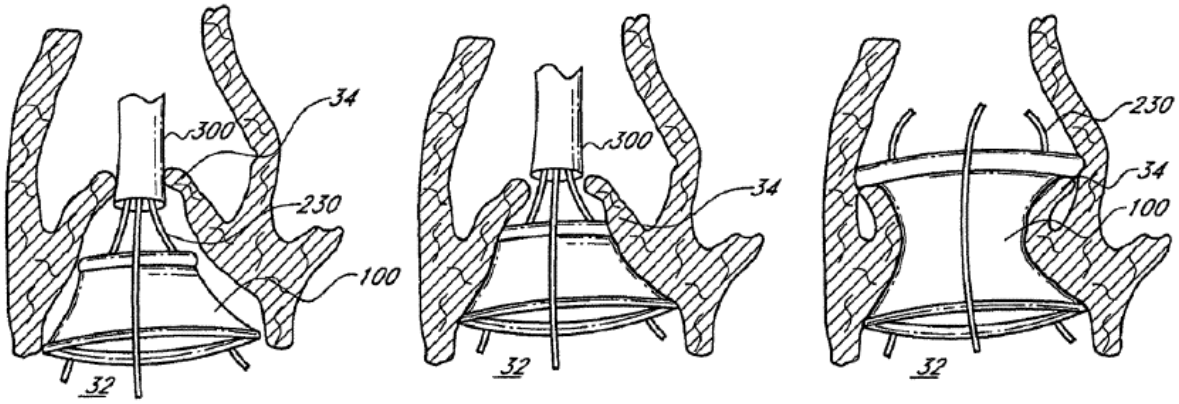

FIG. 45A FIG. 45B FIG. 45C

The prosthesis is "withdrawn across the native valve annulus" (Fig. 45B) by withdrawing control wires, and then "fully inflated" (inflatable cuff) or fully expanded (self-expanding stent). '941, 74:49-53, 75:28-31, 75:43-67; *see also* '941, Figs. 47A-B (above); Drasler ¶¶46-47. The valve functions once fully inflated or expanded. '941, 75:22-31, 74:50-52, 77:49-54, 61:9-34.

While the "sheath is retracted far enough" to "allow" the prosthesis "to function" before withdrawing the prosthesis across the native valve, the valve is not functional until it is both seated (Fig. 45A) and fully inflated/expanded—which "enable[s] the valve to function." '941, 61:9-34, 75:23-51, 74:44-51, 77:46-54; Drasler ¶¶48-50. A functioning valve imposes unidirectional flow. '941, 4:12-14, 12:17-24. After expanding stents 756 at the native annulus, the prosthesis's ends extend further radially outwards than its center "similar to a tubular hyperbola," *e.g.*, Figure 25F. '941, 14:5-16, 78:40-42, Figs. 25F, 45C, 46A, 47B; Drasler, ¶¶51-54.

So deployed, the prosthesis "excludes the native valve" and "replaces its function." '941, 11:46-51, 14:12-16, 78:40-42, Fig. 2A (below).

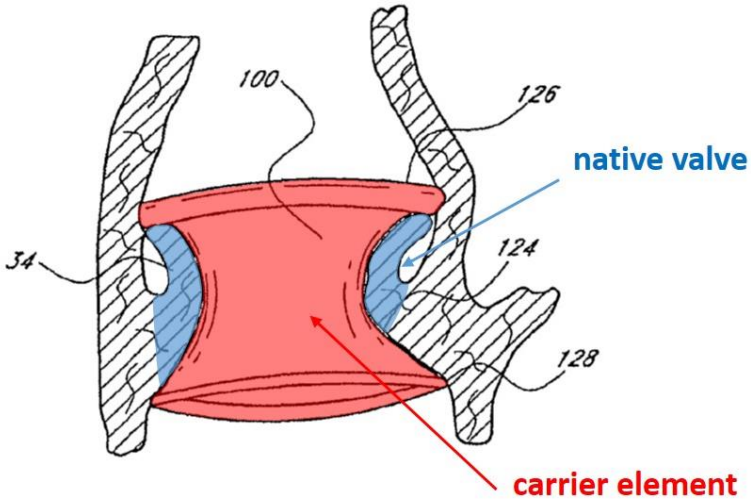

FIG. 2A

After the valve is functioning, "an additional dilatation" using a balloon "after implantation…ensure[s] the device is apposed to the [annulus's] wall…and seated properly." '941, 75:1-3; Drasler ¶¶55-56. It was well-known to "use…a perfusion balloon" "to allow significant perfusion through the balloon during deployment." '941, 74:13-21 (citing Wasicek (Ex. 1009)).

Using "diagnostic techniques," the prosthesis's "securement and function" may be monitored and, if "valve function, sizing, or securement" is "not sufficient or ideal," the valve may be repositioned (e.g., "rotat[ed] or translat[ed]") or recaptured (e.g., "complete removal and exchange") by partially or completely deflating/collapsing and re-expanding the prosthesis. '941, 42:20-25, 50:63-51:22,

51:56-59, 74:50-51, 75:10-13, 75:30-39, 77:14-19, 77:53-65, Figs. 47C-D (below); Drasler ¶¶53, 57-58.

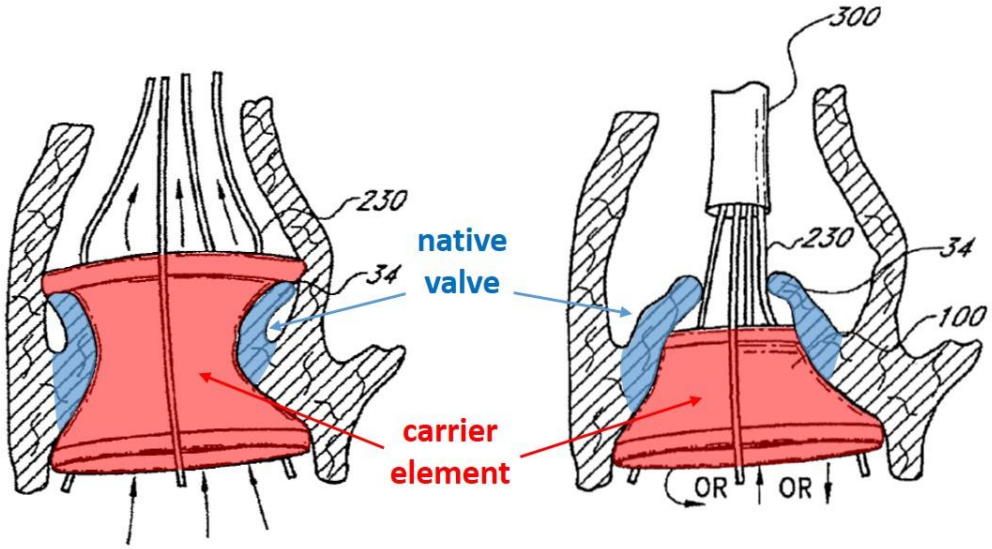

FIG. 47C FIG. 47D

'941 allegedly solves a problem for "valve replacement[s]" because, once fully deployed for testing, prior valves cannot be "removed." '941, 75:4-13, 75:43-51. '941 discloses "proximal extension[s]" proximal of the carrier, formed of "open" "cell[s]" or "individual wires" to avoid blocking the "ostia" (that branch off from the aorta) post-deployment. '941, 75:55-67. The extension acts as a deployment control device, such that the stent can be removed or repositioned after full deployment for testing. '941, 75:45-54; Drasler ¶¶59-60. The control device allows

implant movement after full expansion, until the control device is removed from the prosthesis. '941, 51:1-5, 74:57-60, Figs. 46A-C.

VI. '941 PROSECUTION HISTORY

In Application 13/069,209, which matured into the '941, issued claim 1 (prosecution claim 44) as originally-filed was generally directed to "method[s] for replacing a patient's native heart valve," and recited a prosthesis allowing unidirectional blood flow during carrier expansion. '941FH, 14; Drasler ¶76.

To overcome a rejection over Salahieh-686 (Ex. 1008), PO amended claim 1 to require that, during expansion, "a distal end of the first[/second] carrier…is fully expanded prior to a proximal end…being fully expanded,"[3] contending Salahieh-686 teaches only "*simultaneous[]*" end expansion. '941FH, 1705-1706, 1713 (emphasis original); Drasler ¶77.

The Examiner rejected claim 1 as anticipated by Leonhardt, relying on Figures 9B-9C, which show that valve stent 20's distal end is expanded via expansion balloon prior to proximal end expansion. '941FH, 1729. In response, and after an interview, PO amended claim 1 to require the prosthesis to allow unidirectional blood flow "after expanding the distal end of the first[/second] carrier…and prior to

[3] Applicant removed the word "fully" after a written description rejection. '941FH, 1727-1728, 1751-1752.

expanding the proximal end..." *Id.*, 1751-1752, 1760-1761. PO argued that Leonhardt failed to disclose only that the "replacement valve allows" unidirectional flow "after expanding the distal end of the first carrier…and prior to expanding the proximal end." *Id.*, 1761. PO argued that Leonhardt's prosthesis is "not operational until it fully exits…deployment catheter 100" because Leonhardt utilizes a "balloon that obstructs blood flow" and "graft material" that prevents blood flow until its proximal end exits the catheter. *Id.* The examiner did not cite, nor did PO address, Leonhardt's optional secondary balloon expansion. '941FH, 1761; Drasler ¶78.

In an interview, the Examiner noted that although PO's amendment "appears to overcome" Leonhardt, "further search and consideration" is required. '941FH, 1772. The Examiner then rejected claim 1 as obvious over Salahieh-686, without mentioning Leonhardt. *Id.*, 1780-1784; Drasler ¶79. The Examiner argued that although Salahieh-686 did not specify that its prosthesis allows unidirectional blood flow after expanding the carrier's distal end and prior to expanding its proximal end, applying this feature would have been obvious. *Id.*, 1780-1781. PO amended issued claim 1 to require the proximal end expansion "without urging the proximal end…toward the distal end…," arguing Salahieh-686 teaches such urging. *Id.*, 1796-1797, 1805-1806.

After PO's amendment, the Examiner allowed the claim. *Id.*, 1819-1827. The Examiner found that Salahieh-686 was the "closest prior art," without mentioning

Leonhardt. *Id.*, 1825-1826. The sole reason for allowance was that Salahieh-686's expansion "mov[es] the [valve support's] proximal end…towards the distal end," whereas the amended claims required expansion without such urging. *Id.*, 1825-1826; Drasler ¶¶80-81.

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

A. §325(d)

Considering *Advanced Bionics*'s two-part framework, the Board should not exercise its §325(d) discretion to deny institution.

Neither the art nor arguments in Grounds 2-9 are the same/substantially the same as those considered during prosecution. Neither the Examiner nor PO discussed or applied **Bailey**, **Seguin**, **Stevens**, **Cribier**, **Svanidze** or substantially the same art during prosecution. Additionally, **Leonhardt** in view of **Bailey** and **Seguin** teach the sole limitation that PO argued was missing from Leonhardt: imposing unidirectional flow "after expanding the [carrier's] distal end…and prior to expanding the proximal end...." '941FH, 1761; *see* §§X.B-C, IX.C.[4] The Office

[4] While '941 discusses whether **Leonhardt** blocks "aortic outflow" at times during deployment ('941, 74:1-12) (as Leonhardt's outer sheath blocks outflow until retracted at least partially, *see* §X.C), the Claims recite a valve allowing

did not consider any materially similar references that expressly taught permitting blood flow during deployment around an expanded balloon (**Bailey**) or through openings in the catheter (**Seguin**). The Office has not previously considered expert testimony regarding these combined teachings. Ex. 1002.

Where a ground relies on at least one reference the Examiner never considered for limitation(s) the 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 previously before the Office. *Church & Dwight Co., Inc. v. Batinkoff*, IPR2020-00168, Pap. 11, *10-11 (declining to exercise §325(d) in such circumstances); *Kolbe & Kolbe Mill Work Co. v. Sierra Pac. Indus.*, IPR2019-00933, Pap. 14, *46 (***no*** *Becton* factors favored denial where no prior art combination previously 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.

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unidirectional flow at certain times and do not require that the aortic outflow cannot be blocked at any point during deployment. Drasler ¶122.

Even if the Examiner had considered substantially the same art (the Examiner did not for at least Grounds 2-9), the Examiner erred in allowing the Claims. During prosecution, PO argued that **Leonhardt** fails to disclose only *one* limitation of issued claim 1 (prosecution claim 44): allowing unidirectional flow after expanding the carrier's distal end and prior to expanding its proximal end. *See* '941FH, 1751-52, 1761. The Examiner never indicated consideration of **Leonhardt's** secondary balloon expansion on the record whereby "[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 (not citing Leonhardt 11:28-33), 1772, 1780-81.[5] After PO amended claim 1 to require the valve to allow the unidirectional flow after distal expansion and before proximal expansion, the Examiner shifted to another reference. '941FH, 1751-1754, 1777. The record does not include the Examiner's reasoning for shifting away from Leonhardt. *E.g.*, '941FH, 1772. Given the disparity in disclosures that Examiner

[5] Examiner's reference to Leonhardt's "tip balloon" being used to "seat" the proximal end ('941FH, 1730-31 (discussing similar limitations in prosecution claims 45-46 and citing Leonhardt, 11:3-22)) is a typo as the cited passage discusses the "expansion balloon."

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 claim mapping post-amendment. *Versa Prods v. Varidesk, LLC*, IPR2020-00387, Pap. 13, *15-18; *see also Arrows Up, LLC v. Oren Techs., LLC*, IPR2018-01231, Pap. 7, *11-12 (finding error where Examiner misunderstood reference).

Specifically, 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. **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.[1.2], [1.4]) than that relied on by the Examiner, and mirrors the teachings in the '941 specification (*see* §V (discussing using a "perfusion balloon" for "additional dilatation" after the prosthesis is functional "to ensure the device is…seated properly)). The '941 further discloses that it was well-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. '941, 74:13-21 (citing Wasicek).

The Examiner should have rejected the amended claims over this superior disclosure, but there is no indication 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 "better component" and again by failing to adjust mapping of a claim post-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 §IX.C), nor would flow be possible before any such expansion with the '941's teachings (*see* §V; *e.g.*, '941, 75:23-31 ("[t]he device is then fully inflated, enabling the valve to function")).[6]

Third, where the "Examiner did not expressly consider" **Bailey**, **Seguin**, **Stevens**, **Cribier**, or **Svanidze**, it is difficult, if not impossible, to explain "why the Examiner allowed the claims" or "how the Examiner might have considered the

[6] Even if '941's disclosure of retracting the sheath to "allow the…valve to function" were misread to disclose actual functionality before full expansion (*see* §V), as shown in Figure 45A, the valve's proximal end has already been expanded relative to the collapsed version inside the catheter shown in Figures 46B-46C. '941, 50:45-48, 51:5-10; Drasler ¶¶41, 92.

[Petition's] arguments" and §325(d) discretion should not be exercised. *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00379, Pap. 14, *20 (declining to exercise discretion).

Fourth, the Examiner erred in failing to consider a combination of **Leonhardt** with a reference disclosing (1) an expansion balloon allowing blood flow when expanded—such as **Bailey** (Grounds 2-3, 5, 7, 9), (2) distal openings in the catheter to maintain blood flow while the prosthesis's proximal end is still within the catheter during deployment—such as **Seguin** (Grounds 3, 5, 7, 9), (3) monitoring blood flow with echocardiography—such as **Stevens** (Grounds 4-5), (4) sensors incorporated into catheters to measure blood flow or pressure—such as **Cribier** (Grounds 6-7), or (5) supports connecting the prosthesis's proximal and distal ends—such as **Svanidze** (Grounds 8-9). Such combinations render the 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 to -00244 concerning this patent and the other asserted patents. **2:**

Trial is scheduled for October 11, 2022—more than three months after a final written decision will issue. Ex. 1042, 14. **3:** To date, the court has not issued any substantive orders related to the '941, 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. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong, particularly considering Applicant's admissions during prosecution that nearly all limitations were disclosed by Leonhardt (*see* '941FH, 1761) 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. 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). 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 asserted prior art discloses embodiments within the 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 ¶83.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X.A.2[1.pre]; Drasler ¶84.

B. "vicinity of the native heart valve" (All Claims)

Regardless of the exact metes and bounds of this term (i.e., "vicinity"), the prior art discloses this limitation. *See* §§X.A.3.[1.1], [1.3], [1.8]; Drasler ¶¶85-86.

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

The "expansion" limitations should be accorded their plain and ordinary meaning, as a POSITA would have understood them to refer to any amount of expansion that satisfies the individual limitations in which they occur. Drasler ¶¶87-88. Thus, the phrases alone are not limited to a "first," "partial, "full" or "complete" expansion of the prosthesis or either of its ends.

In contrast to the Claims' other expansion limitations, PO chose to qualify the expansion limitations related to the first carrier's expansion in claim 1, in dependent claims 10, 13, 26 and 30, and in claims of '941's parent. '941, cl. 1 ("partially expanded," *see* §§X.A.3.[1.3], [1.6]), cls. 26 ("fully expanded"), 30 ("initially expanded"); Lashinski (Ex. 1013), cls. 6 ("during the entire expansion"), 7 ("at least partially during expansion"); Drasler ¶89.[7] Such qualifiers should not be read into the Claims' other expansion limitations. *Retractable Techs., Inc. v. Becton,*

[7] The '941 and '118 patents share a specification, other than corrections and a single sentence not relevant here.

Dickinson & Co., 653 F.3d 1296, 1313 (Fed. Cir. 2011) (declining to limit term to modifier "explicitly" used in dependent claims).

The plain and ordinary meaning is consistent with the specification. 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. Drasler ¶90. The specification further discusses "partially" and "fully" expanding/inflating as well as compressing/deflating the valve. *E.g.*, '941, 60:58 ("inflate the implant fully"), 74:50 ("device is then fully inflated."), 77:52-53 (same), 75:30-31 ("device is then fully inflated, enabling the valve to function."), 75:33-35 ("valve may be partially deflated…and then reinflated or the valve may be fully deflated and retracted…"), 77:55-57 (same), *see also* 5:49-55, 50:50-52, 51:5-10, 51:18-24. Reading in any limitation requiring, *e.g.*, that "expansion" must be a first, complete, full, partial, or continuous expansion would be improper. *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 prosecution. PO amended claim 1 to recite "a distal end…is *fully* expanded prior to a proximal end…being *fully* expanded." '941FH, 1704-1705; Drasler ¶91. The Office rejected the amended claim because "[t]he specification does not describe [carrier's] distal end …being *fully expanded* prior to a proximal end…being fully expanded." '941FH, 1727-1728

(emphasis in original) (quoting '941, 74:43-50 (disclosing that the valve is "fully inflated" after being withdrawn across the native valve)); *see also* '941, Fig. 47A-E. PO subsequently removed the term "fully" from the claim. '941FH, 1751-1752, 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 that Leonhardt does not teach the limitation requiring unidirectional blood flow prior to proximal end expansion because the Leonhardt's valve "is not operational until it fully exits the deployment catheter 100 to expand the proximal end" ('941FH, 1761) similarly does not limit the claims' scope. Drasler ¶¶92-93. First, PO's argument is wrong as discussed in §§X.A.1-3 (Leonhardt expressly discloses the valve "function[s]" prior to proximal end expansion with the tip balloon). Second, such construction is inconsistent with the '941 specification, which never discloses a valve functioning before any proximal end expansion (*see* §V). *See also* §VI and n.6 (supra). Third, PO's argument does not contain a clear disavowal of claim scope.

Thus, 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. Under that meaning, the prior art discloses these limitations. *See* §§X.A.3.[1.3], [1.6], [10], [13]; Drasler ¶94. Even under a narrower interpretation,

wherein, e.g., "prior to…expanding the proximal end" means prior to the *first* proximal end expansion, the Claims are still rendered obvious. *See* §X.C.

X. GROUNDS OF UNPATENTABILITY

Although the '941 purports to have invented a method for replacing a patient's native heart valve by (1) endovascularly delivering a prosthesis to the native valve, and (2) expanding it from a collapsed to an expanded configuration, such methods were well-known. The Claims are unpatentable as obvious. Drasler ¶¶95-322.

Leonhardt discloses a method of endovascularly delivering a prosthesis for maintaining one-way flow within a biological passage, wherein the valve's distal end is expanded before its proximal end. **Leonhardt** teaches expanding the prosthesis's proximal end without urging that end toward its distal end. And **Leonhardt** teaches that the prosthesis imposes unidirectional flow after expanding its distal end and before expanding its proximal end. **Leonhardt** discloses the same functionality taught in the '941 (valve operation before and after secondary balloon expansion). *See* §§V, X.A.1-2. **Leonhardt** further discloses retrieving the deployed prosthesis for removal and selecting an appropriately sized prosthesis.

Even if PO argues the Claims are limited to functionality not described in the '941 (*e.g.*, valve operation before any proximal end expansion), **Leonhardt** in view of **Bailey** and **Seguin** still renders such claims obvious. *See* §X.C. **Bailey** teaches a balloon that permits blood flow when expanded, and **Seguin** teaches lateral

openings in the catheter, allowing blood flow even when the prosthesis's proximal end is within the catheter—enabling **Leonhardt's** prosthesis to allow unidirectional blood flow prior to any proximal end expansion.

While **Leonhardt** discloses monitoring physiological characteristics near the native valve during the procedure, **Cribier** discloses further details regarding monitoring blood pressure. **Svanidze** discloses further details regarding the prosthesis's form.

This art renders the 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 '941's alleged invention. Drasler ¶¶1-325.

A. Ground 1: Claims 1-2, 4-6, 10, and 12-14 Are Obvious Over Leonhardt[8]

1. Overview of Leonhardt

Leonhardt, a Medtronic-owned patent, teaches transluminally delivering an expandable valve/stent to a 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"—preferably porcine —"attached to stent 26," as shown in Figure 4. Leonhardt, 4:14-16, 6:23-31, 10:64-67, Fig. 4. Valve/stent 20 is covered with graft material

[8] §X.B addresses Claim 2.

"cut out" at the open ends of the stent's sinusoids, forming "distensible fingers" at either end:

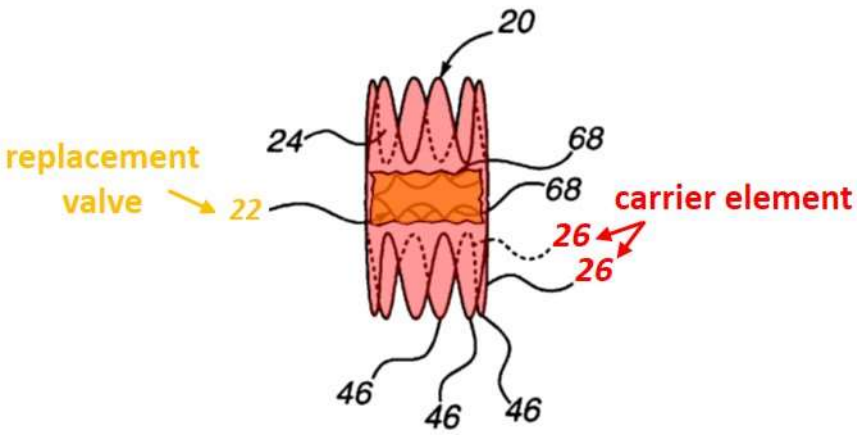


FIG. 4

Leonhardt, Fig. 4, 6:9-22; Drasler ¶¶101-102.

The valve/stent is loaded into a deployment catheter's outer sheath, which is inserted over the flexible guidewire and transluminally advanced to a placement site. Leonhardt, 6:13-17, 6:35-65, 9:49-55, 9:63-10:11. During catheter insertion, tip balloon may be partially inflated to perform valvuloplasty. Leonhardt, 10:11-16. Once the deployment catheter is positioned, valve/stent deployment is "procedurally the same for all potential placement sites," including mitral and aortic valves. Leonhardt, 9:63-10:6, 10:22-30, 10:43-44, 6:36-38, Figs. 2, 9A-9D; Drasler ¶103. The outer sheath is withdrawn from the stent's distal end to initiate deployment. Leonhardt, 10:53-58.

For placement at the aortic valve, the delivery catheter containing the prosthesis is transluminally advanced in the retrograde direction (against blood flow): into a femoral artery then through the aorta to the aortic valve. Leonhardt, 9:63-10:6; Drasler ¶104. For such placement, a POSITA would have understood that blood flows from the left ventricle, into the prosthesis's distal end, through the prosthesis, and out the prosthesis's proximal end up into the aorta and that the valve/stent displaces the valve and its leaflets such that the valve seals both ends of the aortic valve. Leonhardt, 9:63-10:6, 10:55-58, 10:67-11:13; Drasler ¶104; *see also* Bailey, Fig. 6A (to illustrate anatomy):

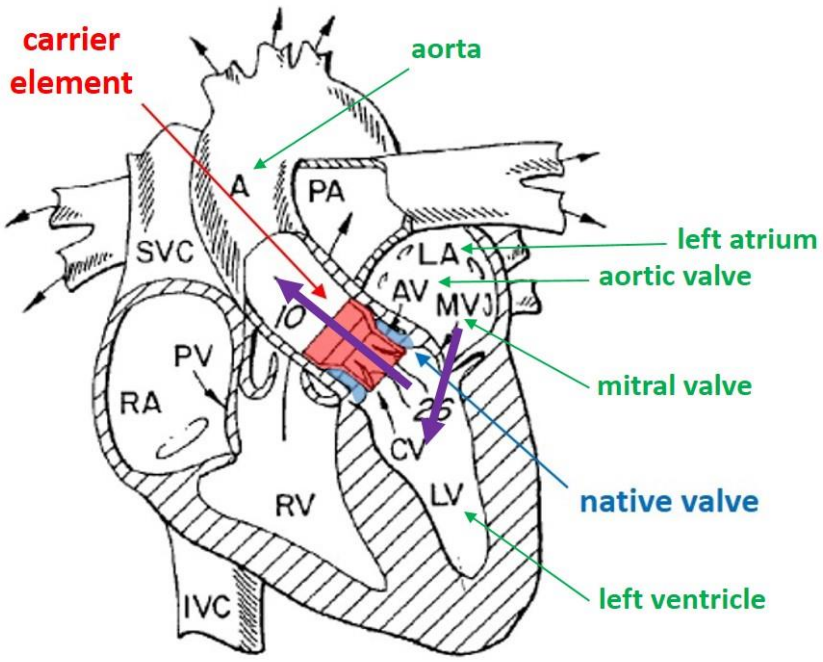


Fig. 6A

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, 10:21-28, Figs. 2, 9A-9D; Drasler ¶105.

The collapsed valve/stent is expanded via three separate mechanisms. ***First***, self-expansion occurs when the sheath is initially withdrawn, permitting the prosthesis's distal distensible fingers to self-expand against the vasculature due to its "continuous outward force." Leonhardt, 10:53-58, 11:34-35, Fig. 9B (mitral deployment); Drasler ¶¶106-107. Whereas for mitral valve placement the valve/stent's distal end displaces the valve leaflets upon expansion (shown below), for aortic valve placement, the valve/stent's distal end is expanded prior to displacing the native valve and its leaflets with the valve/stent's remainder. Drasler ¶107.

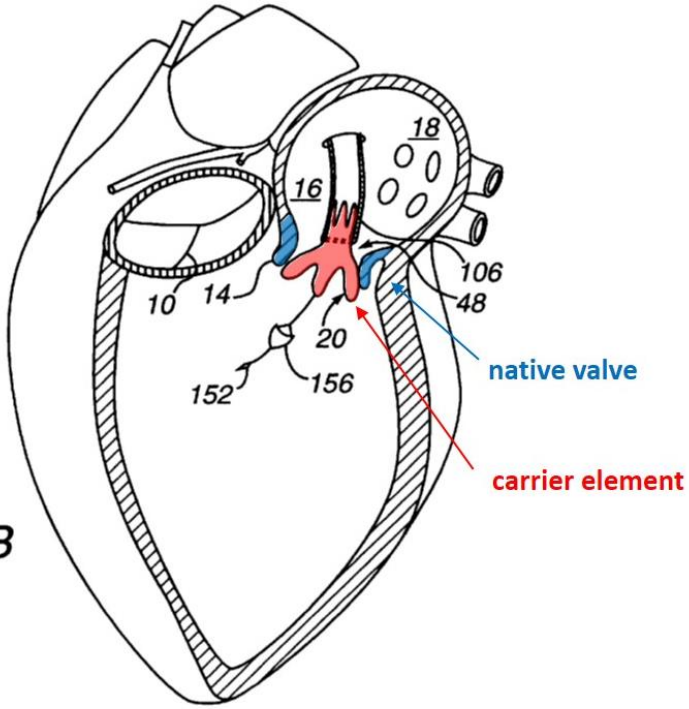


FIG. 9B

Second, expansion balloon 154 is inflated, without overlapping the valve, such that valve/stent 20 molds itself to the "living tissue…[to] achieve a patent seal" (Fig. 9C below). Leonhardt, 10:64-11:9 (valve's base "must be free from contact" with balloon); Drasler ¶108.[9]

[9] The valve's leaflets "may" be "slightly overlapped" by the balloon—an optional teaching not relied upon herein. Leonhardt, 10:64-67; Drasler ¶108.

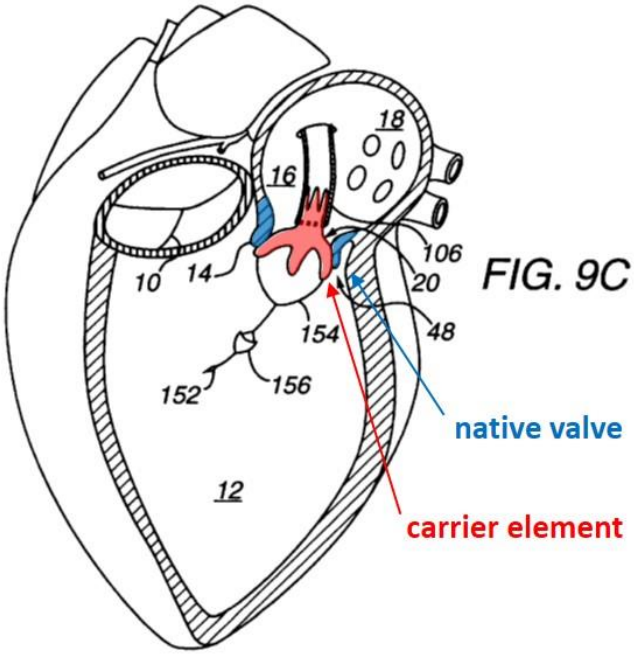


FIG. 9C

With the expansion balloon holding the distal end, the sheath is completely retracted, allowing self-expansion of the valve/stent's remainder, and proper placement is verified. Leonhardt, 11:10-15; Drasler ¶¶109-110.

Leonhardt then uses the expansion balloon to expand the stent's proximal end. Expansion balloon is "deflated" and the inner catheter withdrawn to position "expansion balloon 154…on the [biological valve's] proximal side but within [valve/stent 20's] proximal end." Leonhardt, 11:14-19. Expansion balloon further expands the stent's proximal side to "seat" it and is then deflated and withdrawn:

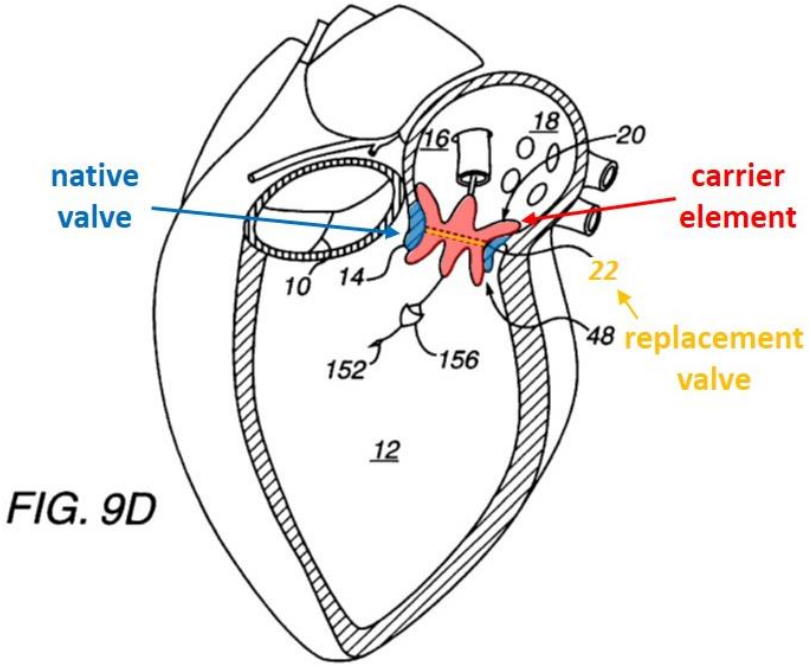


FIG. 9D

Leonhardt, Fig. 9D; 9:63-10:6, 11:16-18; Drasler ¶111.

The valve now allows unidirectional blood flow and is "monitored for proper function and patency." Leonhardt, 3:59-60, 5:46-52, 7:17-21, 11:23-30, 12:28-30; Drasler ¶¶112-113.

Third, 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, Figs. 5, 9A-D, mirroring '941's "additional [carrier] dilatation" post-deployment, '941, 75:1-3; *see* §V; Drasler ¶114.

"[O]nce properly placed," valve/stent 20's "function and leakage are verified"—if necessary, it can be collapsed "for repositioning or removal" regardless of whether it is "fully or partially deployed." Leonhardt, 11:37-60, Figs. 7A-7B.

Valve/stent's proximal distensible fingers are compressed by means of sutures while the "artificial valve" remains in place maintaining unidirectional flow, then outer sheath 106 is "advance[d]…over valve stent 20." Leonhardt, 1:11-14, 6:9-19, 11:37-58. For repositioning, the same process described above is used. Leonhardt, 11:37-60; Drasler ¶¶115, 120. Fully deployed and expanded valve/stent has a non-cylindrical profile (Fig. 2 below): both ends are wider in diameter than the central portion as the valve/stent's ends "flair." Leonhardt, 3:33-38, 4:63-65, 6:9-23, 9:63-10:6, Figs. 2, 9d. After proper placement, the catheters are withdrawn. Leonhardt, 11:63-5; Drasler ¶121.

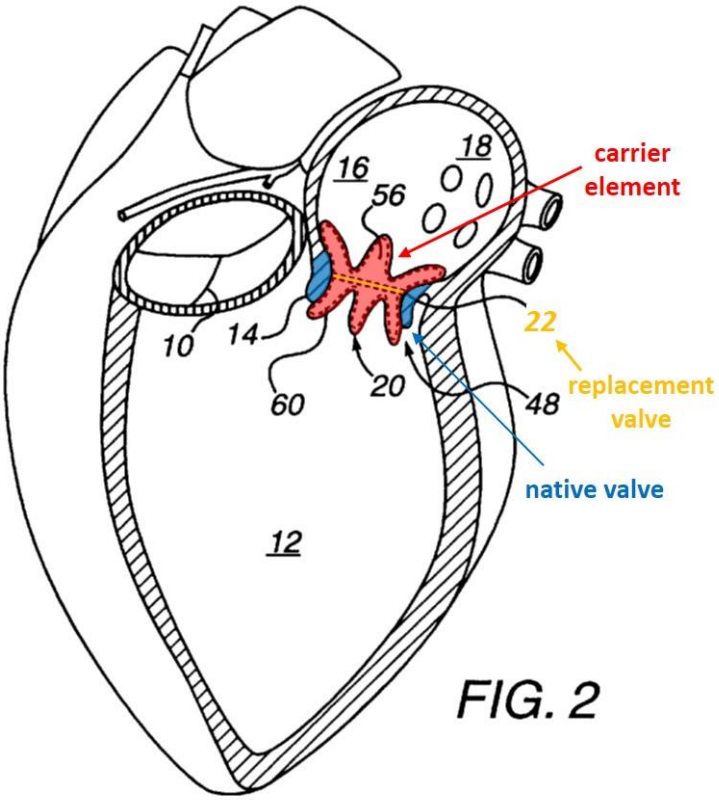


FIG. 2

Leonhardt teaches the benefits of avoiding open heart surgery by "percutaneously" placing the prosthesis and, where the prosthesis is "misplac[ed] or fail[ed]," "percutaneously" "remov[ing]" it. Leonhardt 3:4-30. Consistent with these same teachings, a POSITA would have understood that, when a prosthesis failed or was misplaced, the same procedure should be followed with another prosthesis to again avoid open heart surgery. Drasler ¶116. At minimum, a POSITA would have found it obvious to do so for the same reasons. Drasler ¶116. Additionally, it was well-known in the art to replace the prosthesis post-removal—further motivating a POSITA. *E.g.*, Moulopoulos (Ex. 1019; issued 6/27/1972), 1:61-65 ("valve…periodically removed and replaced"); Drasler ¶116.

At a minimum, it would have been obvious to try to implant a second prosthesis in the event the first functions poorly to achieve a functional replacement for these same reasons. Drasler ¶117. After removing the first prosthesis, only the following identified, predictable solutions were available: 1) open heart surgery, which **Leonhardt** taught to avoid, 2) implanting a second prosthesis percutaneously with the possibility of achieving a functional replacement, and 3) not treat the patient, which could be fatal. Drasler ¶117. Given **Leonhardt's** teachings, a POSITA would have found it obvious to choose the second option—implanting a second prosthesis—with a reasonable expectation of success in light of **Leonhardt's** teachings. Drasler ¶117. Moreover, a POSITA would have implanted the second

prosthesis using the same delivery route as the first, the route having worked initially. Drasler ¶¶117, 119.

Leonhardt also teaches that prosthesis size is critical and must be selected before implantation. Leonhardt, 5:2-10, 6:19-21, 6:28-31, 9:51-55. If the first prosthesis fails during implantation, Leonhardt teaches to remove the prosthesis and a POSITA would have understood that the failed prosthesis would be removed and another used—e.g., a different size or style. Drasler ¶118. **Leonhardt** teaches that after the valve/stent is deployed it "is now monitored for proper function and patency," which is specifically tied to valve "size" (i.e., "length or "diameter"): "[e]ach end is pre-sized in diameter" to fit "the largest diameter of the tissue against which the valve stent…will seal" and the "length of stent 26 is also pre-sized to be sufficient to maintain patency." Leonhardt, 5:2-10, 11:23-39; Drasler ¶118. If the valve/stent does not seal (and thus function) properly, a different "diameter" needs to be used. Leonhardt 5:2-10. If the valve/stent's "patency" is incorrect, a different "length" needs to be used. *Id.* A POSITA would have thus understood that if the first valve/stent does not have the proper function or patency, the next valve/stent implanted would be of a different length or diameter. Drasler ¶118. At minimum, a POSITA would have been motivated and found it obvious to try a valve of a different size for these same reasons. Khairkhahan (Ex. 1043, filed 05/12/2003), 13:4-7 ("wrong size" prosthesis "completely removed"**)**; Drasler ¶118.

Well-known "monitoring and visualization" equipment and techniques are used throughout these procedures to monitor, e.g., blood flow and pressure at the placement site. *Id.*, 9:55-62; Drasler ¶¶112-113. A POSITA would have understood, and at a minimum found it obvious, using fluoroscopy to monitor blood flow, e.g., to advantageously verify valve/stent 20's proper operation. *E.g.*, Salahieh-686, ¶[0087] ("operation of the valve may be observed under fluoroscopy"); Eigler, cl. 73 ("adequacy of the repair…is assessed by fluoroscopy"); Leonhardt, 9:55-61, 10:46-47 (injecting "[c]ontrast media").

2. Claim Chart

'941	**Leonhardt**
[1.pre] A method for replacing a patient's native heart valve, the method comprising:	**Leonhardt discloses a method for replacing a patient's native heart valve** (*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." • 1:6-9 ("The artificial valve disclosed may replace existing valves such as are in the heart….") • 1:11-14 ("The disclosed invention involves a ***percutaneously placed artificial valve*** to ***maintain bodily fluid flow in a single direction***….") • 1:21-22 ("Cardiac valve prostheses are well known in the ***treatment of heart disease***.") • Abstract ("A ***method of implanting the artificial valve***…") Drasler ¶¶238, 131-133.

[1.1] delivering an expandable first carrier element and a first replacement valve endovascularly to a vicinity of the native heart valve,	**Leonhardt discloses delivering an expandable first carrier element** (*e.g.*, "deformable self-expanding stent") **and first a replacement valve** (*e.g.* "biological valve," "percutaneously placed artificial valve") **endovascularly to a vicinity of the native heart valve** (*e.g.*, "percutaneous delivery of valve stent" to the "mitral valve" or "aortic 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 endovascular replacement valve delivery. Drasler ¶136. • 1:11-14 (*see* [1.pre]) • 6:36-38 ("Deployment catheter 100 is generally…tubular permitting ***percutaneous delivery of valve stent 20 to the placement site***.") • 4:15-17 ("[V]alve stent 20 [is] comprised of three elements…stent 26, ***biological valve 22***, and graft material 24.") • 5:46-52 ("…***deformable self expanding stent* 26**…") • 10:6-11 ("Deployment catheter 100…is…inserted through the entry point…***slowly advancing the deployment catheter 100 to the placement site***.") • 9:63-10:6 ("Depending on the placement site, ***an access passage is chosen to minimize trauma to the passage and the patient. If the placement site is in the aorta or aortic valve* 10**, entry may be made through the largest femoral artery…and into the aorta….A flexible guide wire…is …advanced…into left ventricle 12.") • 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 ¶¶239, 134-136.
[1.2] the first replacement valve configured to allow the flow of blood through the first replacement valve in a first direction and prevent the flow of blood through the first replacement valve in a second direction;	**Leonhardt discloses the first replacement valve** (*e.g.*, "biological valve 22") **configured to allow the flow of blood through the first replacement valve in a first direction and prevent the flow of blood through the first replacement valve in a second direction** (*e.g.*, "artificial valve…maintain[s] bodily fluid flow in a single direction"). ***E.g.*, Leonhardt:** Valve 22 "open[s] in the direction of blood flow" and is "capable of blocking flow" in the other direction so that blood "flow[s] in a single direction." • 1:11-14 (*see* [1.pre]) • 7:17-21 ("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. After placement, ***biological valve 22 should open in the direction of blood flow***.") • 12:28-30 ("a valve means ***capable of blocking flow in one direction***") • *See also* Abstract; 5:51-52. Drasler ¶¶240, 196-199.
[1.3] expanding the first carrier element from a collapsed delivery configuration to an at least partially expanded configuration	**Leonhardt discloses expanding the carrier element from a collapsed delivery configuration** (*e.g.*, "valve stent" while enclosed in the "outer sheath" of the "deployment catheter") **to an at least partially expanded configuration** (*e.g.*, "deployment of valve stent 20") **in the vicinity of the native heart valve** (*e.g.*, "secure the valve stent" to the "mitral valve" or "aortic valve")**, wherein during expansion of the first carrier element, a distal end of the first carrier element is expanded prior to a proximal end of the first carrier element 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

in the vicinity of the native heart valve, wherein during expansion of the first carrier element, a distal end of the first carrier element is expanded prior to a proximal end of the first carrier element being expanded, the proximal end of the first carrier element being expanded without urging the proximal end of the first carrier element toward the distal end of the first carrier element,	proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue")**, the proximal end of the first carrier element being expanded** (*e.g.*, "[e]xpansion balloon 154 may then be inflated again," "further mold valve stent 20 to the living tissue") **without urging the proximal end of the first carrier element toward the distal end of the first carrier element** (*e.g.*, "cylinders" on the ends of stent 26 "are spaced a predetermined distance from each other by a connecting bar 29" such that expansion does not change the length of stent 26). ***E.g.*, Leonhardt*:*** **Leonhardt** discloses "deployment of" valve/stent 20 at the "aortic valve" or "at [the] mitral valve," wherein valve/stent is delivered in a "collaps[ed]" condition in "deployment catheter." Leonhardt, 6:57-61, 10:44-45. After initial placement and expansion (*id.*, 10:53-11:22), the "function and patency" of valve/stent is monitored. *Id*. 11:29-34. 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*. The "stent 26" portion of valve/stent 20 includes a "connecting bar 29," which keeps "a predetermined distance" between valve/stent 20's distal and proximal ends during placement. *Id*. 5:32-33. Expansion occurs "without urging the [carrier's] proximal end…toward the distal end" because (1) connecting bar 29 maintains a "predetermined distance" between stent 26's ends; (2) deployment is done by "withdrawing outer sheath 106," not by pushing valve/stent 20; (3) expansion occurs through radial balloon- and self-expansion—not axial; and (4) there is no disclosure of a physician necessarily performing the claimed urging. Leonhardt, 5:31-34, 10:53-55, 11:3-9; Drasler, ¶¶242, 139. • Figs. 1A-1B

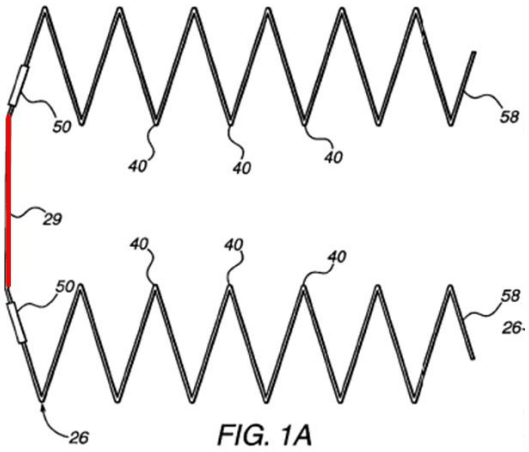


FIG. 1A

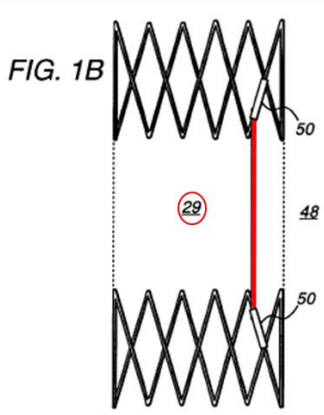


FIG. 1B

- Fig. 2

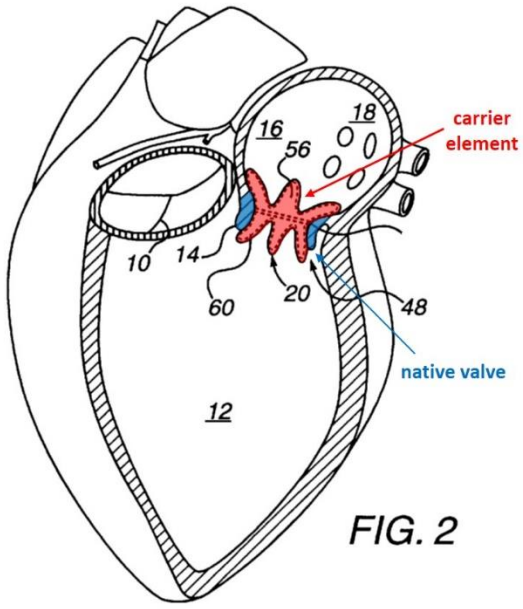
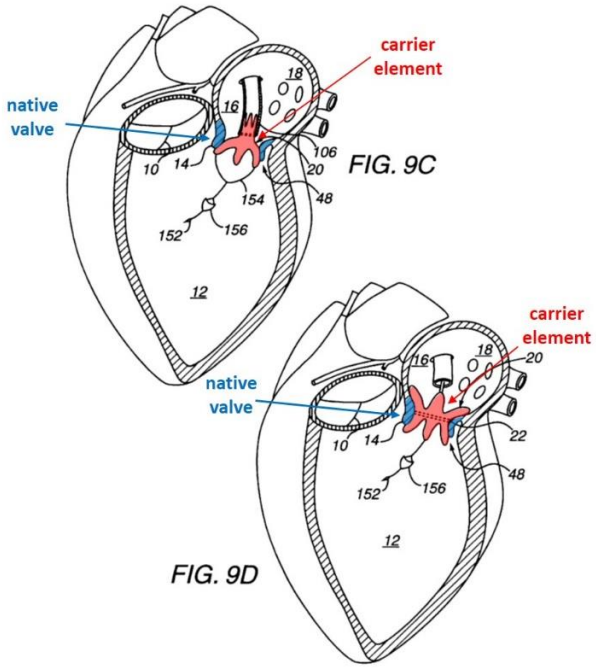


FIG. 2

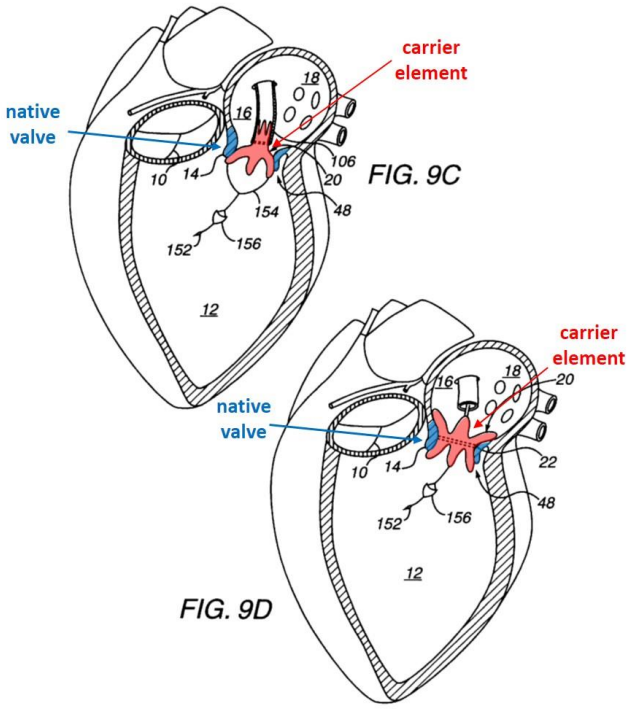
- Figs. 9C-9D



- 10:22-23 (*see* [1.1])
- 9:63-67 (*see* [1.1])
- 4:56-65 ("An outward force…sufficient to ***secure the valve stent***….")
- 10:44-45 ("From this point on, ***deployment of valve stent 20*** is procedurally the same for all potential placement sites.")
- 11:10-22 ("….Expansion balloon 154 may then be inflated again to seat the proximal end of valve stent 20 just deployed.")
- 11:29-36 ("Valve stent 20 is ***now monitored for proper function and patency***…. ***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***.")
- 5:27-39 ("Once crimped, ***stent 26 forms two cylinders, one at each end of stent 26***….The ***cylinders are spaced a predetermined distance from each other by a connecting bar 29*** which is the central part of the continuous wire from which stent 26 is formed….")

	• *See also* 1:6-9, 5:41-42, 5:46-52, 7:10-11, 9:64-67, 10:53-11:9, Figs. 9a-9b. Drasler ¶¶241-242, 137-139.
[1.4] the first replacement valve allowing the flow of blood through the first replacement valve in a first direction and preventing the flow of blood through the first replacement valve in a second direction after expanding the distal end of the first carrier element and prior to expanding the proximal end of the first	**Leonhardt discloses the first replacement valve allowing the flow of blood through the first replacement valve in a first direction and preventing the flow of blood through the first replacement valve in a second direction**[10] (*e.g.*, **"**artificial valve… maintain[s] bodily fluid flow in a single direction") **after expanding the distal end of the first carrier element and prior to expanding the proximal end of the first carrier element** (*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:** 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 valve/stent's proximal and distal ends. *Id*. Meanwhile, the valve is "function[ing]" to "maintain bodily fluid flow in a single direction." *Id*. When the tip balloon is in valve/stent's proximal end, there is no

[10] The terms "a first direction" and "a second direction" in [1.2] and [1.4] are independent. Neither refers to the other because no replacement heart valve would permit unidirectional flow in *both* directions; this would defeat the valve's purpose. Drasler ¶245.

carrier element;	catheter or guidewire running through the valve/stent. *Id.*, 1:11-14, 5:51-52, 11:24-36, Figs. 5, 9A-D; Drasler ¶¶244, 142. 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 ¶¶244, 142. • Figures 9C-9D  • 1:11-14 (*see* [1.pre]) • 11:29-36 (*see* [1.3]) • *See also* 1:6-9, 3:15-29, 5:51-52, 7:17-19, 7:61-63, 9:63-10:6, 10:18-21, 11:24-27, Figs. 9A-9B. Drasler ¶¶243-245, 202-206, 140-142.
[1.5] evaluating the position or function of the first carrier	**Leonhardt discloses evaluating the position or function of the first carrier element and the first replacement valve** (*e.g.*, "Valve stent 20 is…monitored for proper function and patency")**.** ***E.g.*, Leonhardt:**

element and the first replacement valve;	After "tip balloon 152" is "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" and "[v]alve stent 20 is…monitored for proper function and patency." • 11:29-34 (*see* [1.3]) Drasler ¶¶246-247, 167-169.
[1.6] at least partially collapsing the first carrier element from the at least partially expanded configuration to a moveable configuration;	**Leonhardt discloses at least partially collapsing the first carrier element from the at least partially expanded configuration to a moveable configuration.** (*e.g.*, "collaps[ing]" "valve stent 20" "for repositioning")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "advancing outer sheath to collapse" valve stent 20's distal end so that it is clear of living tissue "for repositioning or removal… whether valve stent 20 is fully or partially deployed." • 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….***whether valve stent 20 is fully or partially deployed from outer sheath 106….***Take up slack in suture loops 174 as outer sheath 106 is advanced by turning the spool handle….Next, while holding outer sheath 106 and push rod 112 stationary, 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, again while holding push rod 112 stationary, ***advance outer sheath 106 over valve stent 20…until outer sheath 106 completely covers valve stent 20. Valve stent 20 may now be repositioned or removed***….[I]f repositioning is desired…***collaps[ing] the distal end of valve stent 20*** so that it is clear of living tissue may be sufficient.") Drasler ¶¶248-249, 207-209.
[1.7] completely removing the first carrier	**Leonhardt discloses completely removing the first carrier element and exchanging the first carrier element with a second carrier element having a second replacement valve** (*e.g.* "[v]alve stent 20 may now be…removed" and exchanged for a different

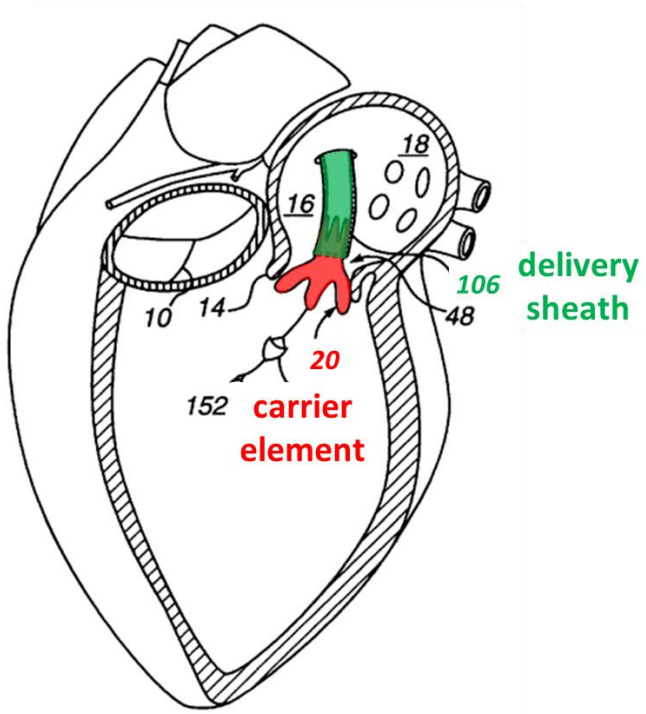
element and exchanging the first carrier element with a second carrier element having a second replacement valve, the second replacement valve configured to allow the flow of blood through the second replacement valve in the first direction and prevent the flow of blood through the second replacement valve in the second direction; and	"valve sent 20," "biological valve 22," *see* [1.1])**, the second replacement valve configured to allow the flow of blood through the second replacement valve in the first direction** (*e.g.*, "open in the direction of blood flow," *see* [1.2]) **and prevent the flow of blood through the second replacement valve in the second direction** (*e.g.*, "blocking flow in one direction," *see* [1.2])**.** ***E.g.*, Leonhardt:** ***See* [1.1], [1.2].** **Leonhardt** discloses selecting a valve/stent of a particular size for deployment based on the placement site and access path anatomy. Leonhardt, 9:51-55. **Leonhardt** further discloses that valve stent 20 may be removed endovascularly, Leonhardt, 11:37-55, and that the ability to endovascularly remove and exchange a "fail[ed]" prosthesis is critical for patients "intoleran[t] to surgery," Leonhardt 3:6-11. As discussed above in §X.A.1, a POSITA would have understood, and at minimum found obvious, that, in the event the initial valve/stent 20 failed to function sufficiently (e.g., insufficient patency) or was the wrong size, valve/stent 20 would be removed and another valve/stent 20 would be implanted. Drasler ¶253. • 11:37-55 (*see* [1.6]) • 6:55-56 ("The ***size of outer sheath 106 depends on the size of valve stent 20*** to be implanted. Common sizes range from 12 FR to 20 FR.") • 9:50-61 ("It is assumed…that an ***appropriately sized valve stent 20 has been selected***…. It is further assumed that certain equipment used for monitoring and visualization purposes is available for use by a surgeon skilled in the art….includ[ing] a freely positional C-arm having high resolution fluoroscop***y***…") • 3:6-11 ("One drawback…is that none of the devices may be removed…once they are expressed... ***Any misplacement or failure requires major open heart surgery***….Many ***patients which receive the valve percutaneously because of their intolerance to surgery would face a very uncertain outcome*** from…failure.")

	Drasler ¶¶250-253.
[1.8] expanding the second carrier element from a collapsed delivery configuration to an expanded configuration to secure the second carrier element in the vicinity of the native heart valve, wherein during expansion of the second carrier element, a distal end of the second carrier element is expanded prior to a proximal end of the second carrier element being expanded, the proximal end of the second carrier element being expanded without urging the proximal end of the	**Leonhardt discloses [1.8]** for the same reasons discussed in [1.3] when the process is repeated with another valve/stent, which is secured in the vicinity of the native heart valve. Drasler ¶254-256.

second carrier element toward the distal end of the second carrier element,	
[1.9] the second replacement valve allowing the flow of blood through the second replacement valve in a first direction and preventing the flow of blood through the second replacement valve in a second direction after expanding the distal end of the second carrier element and prior to expanding the proximal end of the second carrier element.	**See [1.4]** (same process is followed); Drasler ¶257-258.
[4] The method of claim 1, wherein evaluating the position or function of the first carrier	***See* [1].** **Leonhardt discloses evaluating the position or function of the first carrier element and the first replacement valve** (*see* [1.5]) **comprises evaluating a position of a radiopaque portion** (*e.g.*, "Valve stent 20 may have radio opaque markers…to aid in…placement") **of the first carrier element using fluoroscopy**

element and the first replacement valve comprises evaluating a position of a radiopaque portion of the first carrier element using fluoroscopy.	(*e.g.*, "high resolution fluoroscopy" for "monitoring and visualization purposes")**.** ***E.g.*, Leonhardt:** ***See* [1.5].** Valve/stent 20 has "radio opaque markers…to aid…deployment and placement," and is monitored using "a freely positional C-arm having high resolution fluoroscopy." • 5:20-22 ("***Valve stent 20 may have radio opaque markers*** in predetermined positions ***to aid in*** deployment and ***placement***.") • 9:50-61 (*see* [1.7]) • *See also* claim 3. Drasler ¶¶259-262.
[5] The method of claim 1, wherein evaluating the position or function of the first carrier element and the first replacement valve comprises monitoring the flow of blood using fluoroscopy.	***See* [1].** **Leonhardt discloses evaluating the position or function of the first carrier element and the first replacement valve** (*see* [1.5]) **comprises monitoring the flow of blood using fluoroscopy** (*e.g.*, "high resolution fluoroscopy" for "monitoring and visualization" blood flow around "placement site")**.** ***E.g.*, Leonhardt:** ***See* [1.5].** **Leonhardt** discloses using a "freely positional C-arm having high resolution fluoroscopy" capabilities for "monitoring and visualization purposes." Leonhardt, 9:50-61. As discussed in §X.A.1, a POSITA would have understood, and at a minimum found it obvious, fluoroscopy is used to monitor the flow of blood. Drasler ¶266. • 9:50-61 (*see* [1.7])

	• 11:29-32 (*"…**The placement site is also monitored*** to ensure no damage has occurred to the living tissue*."*) Drasler ¶¶263-266.
[6] The method of claim 5, wherein contrast is injected to enhance visualization by fluoroscopy.	***See* [5].** **Leonhardt discloses contrast is injected** (*e.g.*, "introduction of…contrast dye" "into the patient") **to enhance visualization by fluoroscopy** (*e.g.*, "fluoroscopy" "for monitoring and visualization," *see* claim [4])**.** ***E.g.*, Leonhardt*:*** ***See* [4].** Additionally, **Leonhardt** discloses introducing "contrast dye[] through [deployment catheter's] outer sheath 106." Leonhardt, 6:67-7:2. A POSITA would have understood that contrast dye is used to enhance visualization in implementing **Leonhardt**'s fluoroscopic imaging. Drasler ¶270. • 6:67-7:2 ("Outer sheath 106 has a side port means 116….***Side port means 116 provides access for transporting fluid, such as***…***contrast dye, through*** outer sheath 106 passage and ***into the patient***.") • 10:67-11:2 ("Proper ***placement of valve stent 20 is verified by*** known means, including ***the introduction of additional contrast dye***...") • *See also* 10:46-50. Drasler ¶¶267-270.
[10] The method of claim 1, wherein expanding the first carrier element from	***See* [1].** **Leonhardt discloses expanding the first carrier element from the collapsed delivery configuration to the at least partially expanded configuration** (*see* [1.3]) **comprises unsheathing the first carrier element from a delivery sheath** (*e.g.*, "outer sheath 106 is…withdrawn from valve stent 20")**.**

the collapsed delivery configuration to the at least partially expanded configuration comprises unsheathing the first carrier element from a delivery sheath.	***E.g.*, Leonhardt:** ***See* [1.3]**. Additionally, **Leonhardt** discloses that "valve stent 20" is delivered in a collapsed configuration with its "[c]ollapsing distensible fingers 46" compressed "within outer sheath 106," which is withdrawn to "release" the stent. • 6:56-61 ("***Collapsing distensible fingers 46*** of valve stent 20 together forms a conical tip which allows…easy ***loading by sliding outer sheath 106 over the tip and on until valve stent 20 resides within outer sheath 106***…") • Fig. 9B  • 11:10-22 ("…***outer sheath 106 is again withdrawn from valve stent 20*** while maintaining the position of push rod 112. ***The proximal end of valve stent 20 is released once outer sheath 106 clears the proximal end of valve stent 20***….") • *See also* 10:53-11:9

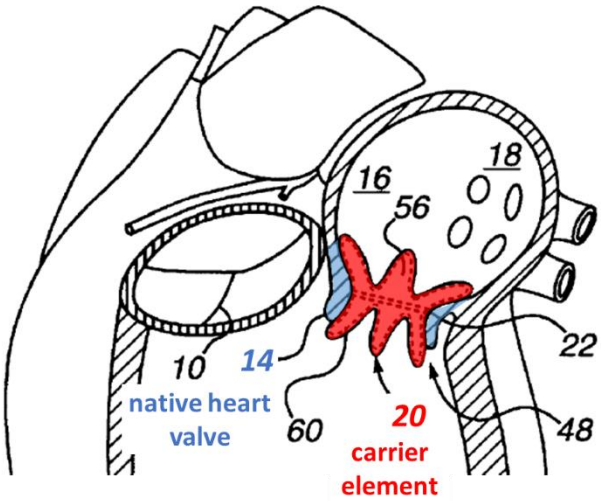
	Drasler ¶¶271-274.
[12] The method of claim 1, wherein the second carrier element has at least one of a different diameter, length or style than the first carrier element.	***See* [1].** **Leonhardt discloses the second carrier element** (*see* [1.7]) **has at least one of a different diameter, length or style than the first carrier element** (*e.g.*, different "size of valve sent 20")**.** ***E.g.*, Leonhardt:** As discussed in [1.7], **Leonhardt** renders obvious removing and exchanging a first valve/stent 20 for an appropriately sized valve/stent with a different diameter and/or length as discussed in §X.A.1. Drasler ¶278. • 9:51-55 (*see* [1.7]) • 11:29-30 (see [1.3]) • *See also* 5:2-10. Drasler ¶¶275-278.
[13] The method of claim 1, wherein a length of the first carrier element in the moveable configuration is substantially equal to or less than a length of the carrier element in the at least partially expanded configuration.	***See* [1].** **Leonhardt discloses a length of the carrier element in the moveable configuration is substantially equal to or less than a length of the carrier element in the at least partially expanded configuration** (*e.g.*, "connecting bar 29" holds opposing "cylinders" of "valve stent 20" "a predetermined distance from each other" in either configuration). ***E.g.*, Leonhardt:** ***See* [1.6].** The length of valve/stent 20 in the repositioning configuration is substantially equal to its length in the fully deployed configuration because it comprises "two cylinders…at each end" "spaced a predetermined distance from each other by a connecting bar 29" in either configuration. Leonhardt, 11:40-52, 5:28-34, 4:41-46. Just as '941 discloses that flexible fabric cuff 752 holds stents 756 at the prosthetic implant's proximal and distal ends a maximum distance from each other and may be expanded into a "hyperboloid" shape

	('941, 14:5-12, 27:66-28:3, Fig. 25F; *see* §V), valve/stent 20 of **Leonhardt** holds its two ends a "predetermined distance" from each other and may be expanded into a hyperboloid shape.[11] Drasler ¶282. • 11:39-55 (*see* [1.6]) • 5:27-39 (*see* [1.3]) • *See also* FIG. 1a, 4:41-46. Drasler ¶¶279-282.
[14.1] The method of claim 1 further comprising: displacing the native heart valve with the first carrier element; and	***See* [1].** **Leonhardt discloses displacing the native heart valve with the first carrier element** (*e.g.*, "deploy[ing]" "valve stent 20" "in the location" of the existing valve by displacing native valve)**.** ***E.g.*, Leonhardt:** On expansion (*see* [1.3]), valve/stent 20 "mold[s] itself quickly into the living tissue at the placement site" in the "aortic valve" during deployment to "conform and seal to the tissue" and thus exclude the native aortic valve. Leonhardt, 11:5-9, 9:64-67, 6:16-22. **Leonhardt** illustrates this relative to the native mitral valve in Fig. 2, where valve/stent 20 replaces the mitral valve by sealing "with

[11] As discussed in §V, the lengths of '941's prosthesis in the collapsed and expanded hyperboloid configurations can be substantially equal because flexible cuff 752's maximum length is fixed. Drasler ¶52. Therefore, regardless of this term's exact metes and bounds, the length between the two cylinders of **Leonhardt's** valve/stent 20 being substantially equal in collapsed and expanded configurations discloses this limitation. Drasler ¶52.

the tissue of mitral valve 14" to create "a patent one way fluid passageway." Leonhardt, 5:41-52.

- Fig. 2



- 6:16-22 ("***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***.")

- 5:41-52 ("…***valve stent 20 fully deployed*** in the location of mitral valve 14…***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***. The deployed valve stent 20 creates a patent one way fluid passageway.")

- 10:53-11:13 ("***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. This ensures proper placement during the remainder of the deployment procedure and ***allows valve stent 20 to mold itself quickly into the living tissue at a placement site and achieve a patent seal.*** [¶]…outer sheath 106 is again withdrawn from valve stent 20 while maintaining the position of push rod 112.")

- *See also* Figs. 9A-9D, 11:30-34.

Drasler ¶¶283, 161-164.

[14.2] displacing the native heart valve with the second carrier element,	**See [14.1]** (same process followed); Drasler ¶284.
[14.3] wherein the distal end of the first carrier element is expanded prior to displacing the native heart valve with the first carrier element, and	**Leonhardt discloses the distal end of the first carrier element is expanded prior to displacing the native heart valve with the first carrier element** (*e.g.*, "distal end of valve stent 20 will distend as the distal end is released from outer sheath 106," "Expansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue" at the location of aortic valve after which sheath is retracted, releasing remainder of stent to displace native leaflets with valve/stent's remainder)**.** ***E.g.*, Leonhardt:** ***See* [1.3], [10].** As discussed in §X.A.1, when placed over the aortic valve, the valve/stent's distal end of is expanded prior to displacing the native valve and its leaflets with the valve/stent's remainder. • 5:41-42 (*see* [1.3]) • 9:63-10:6 (see [1.1]) • 10:55-58 (*see* [1.3]) • 10:67-11:13 (*see* [14.1]) • *See also* 11:32-35. Drasler ¶¶285-287, 165-166.
[14.4] wherein the distal end of the second carrier element is expanded	**See [14.3]** (same process is followed); Drasler ¶288.

prior to displacing the native heart valve with the second carrier element.	

B. Ground 2: Claim 2 is Rendered Obvious by Leonhardt in View of Bailey

Claim 2 recites: "The method of claim 1, wherein the first and second replacement valves prevent the flow of blood through the valve in the direction and allows the flow of blood through the first and second replacement valves in the first direction ***during the expansion*** of the first and second carrier elements."[12] As discussed in §§X.A.3.[1.3]-[1.4], [1.8]-[1.9], **Leonhardt** discloses claim 2, apart from the emphasized "during the expansion" limitation. To the extent "during the expansion" refers to any point during the expansion process, even if the valve/stent is not actively being expanded, **Leonhardt** renders obvious claim 2 for the same reasons discussed in §X.A.3.[1.4]—unidirectional blood flow prior to expanding the proximal end is during expansion. Alternatively, claim 2 is also rendered obvious in further view of **Bailey**, whose teachings of an expansion balloon that does not

[12] Reference to "the direction" and "the first direction" should be understood to refer to the prosthesis imposing unidirectional flow in a single, appropriate direction in the context of claim 2; otherwise the valve would not be usable.

block blood flow allows **Leonhardt's** tip and expansion balloons allow the valve to continue to allow unidirectional blood flow during expansion by the balloons as discussed in §§X.A.1, X.A.3.[1.4].

While **Leonhardt** teaches blood flow is occluded when tip balloon 152 or expansion balloon 154 is expanded, **Bailey** discloses an expansion balloon with "irregular inflation profiles" or "channels or ridges" on the balloon's "ablumenal surface" to "facilitate continuous blood flow about the inflated balloon" when expanding a transluminally-delivered prosthetic heart valve. Bailey ¶¶[0070], [0072]. Thus, while **Leonhardt** does not explicitly disclose unidirectional flow "during the [valve's] expansion", **Bailey** discloses allowing blood to flow through the stent valve during valve/stent expansion. *Id.*; Drasler ¶¶289, 123.

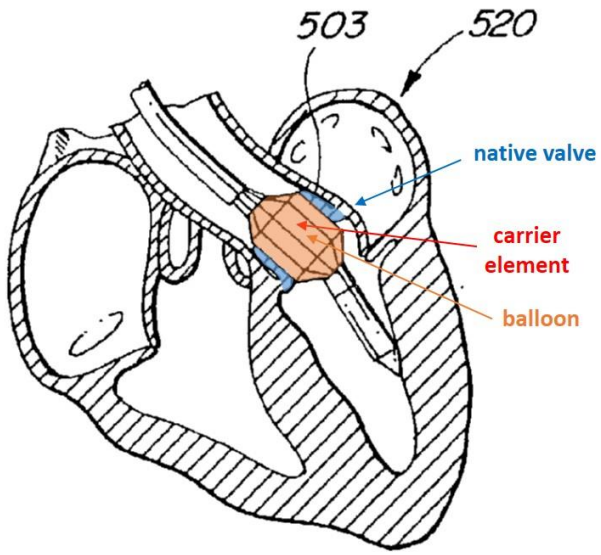
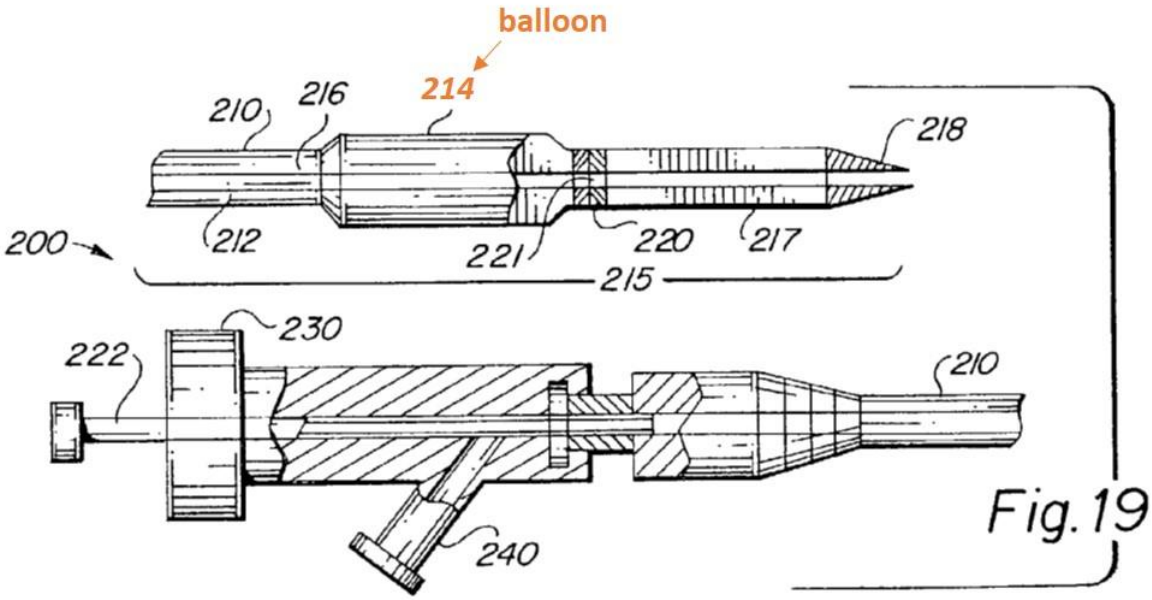


Fig. 20B



Like **Leonhardt, Bailey** is in the same field as '941—prosthetic cardiac implants—and is reasonably pertinent to the alleged problem(s) identified in '941: needing a method of treating a patient using an expandable prosthesis. *See* §X.A.2; Bailey ¶¶[0069]-[0070], Figs. 20C-G; Drasler ¶¶124-125. 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 advantageously no longer occlude flow during Leonhardt's balloon expansion, a well-known benefit. Leonhardt, 3:15-29 (less traumatic/invasive procedures requiring less recuperation time beneficial), 11:26-28 (blood flow obstructions potentially problematic); Eigler (Ex. 1015, filed 7/28/2003), [0005]-[0008] (identifying benefits of blood flow during valve repair, including avoiding "death,

severe injury, and disability"); Downing (Ex. 1016, published 10/31/2002), [0013] (noting benefit of avoiding "cardiopulmonary bypass"); Drasler ¶¶127-128. **Leonhardt** teaches minimizing the consequences of obstructing blood flow.[13] Leonhardt, 9:61-62 (slowing heart or dropping pressure), 11:23-29 (avoid sudden pressure changes); Drasler ¶128. **Bailey** sought to advantageously teach a stent expansion balloon that does not obstruct blood flow even when fully expanded, thus avoiding occlusion and further reducing risk, Bailey ¶¶[0018]-[0019], [0070], [0072], and motivating a POSITA to apply **Bailey's** teachings to **Leonhardt**. Drasler ¶129.

Moreover, **Bailey** seeks to improve upon **Leonhardt**'s valve. Bailey ¶¶[0006], [0018]-[0019]; Drasler ¶126. Although **Bailey** identified **Leonhardt**'s light-actuated anchor as disadvantageous (Bailey, ¶[0018]), **Leonhardt** teaches that such means are **optional**, Leonhardt, 3:41-45 ("may"), 8:42-45 ("options"), and a POSITA would have used embodiments without such a mechanism. Drasler ¶126; *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*

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

Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994) (finding no teaching away when teaching "inferior" but "usable").

A POSITA would have had a reasonable expectation of success in applying **Bailey**'s teachings to **Leonhardt**'s balloons. Drasler ¶129. **Bailey**'s and **Leonhardt**'s balloons are delivered similarly (transluminally delivered via catheter) for the same purposes (valvuloplasty and valve/stent balloon expansion). Bailey, Abstract ¶¶[0069]-[0072], Figs. 19, 20B; Leonhardt, 7:55-63, 10:13-16, 11:3-5, Fig. 5; Drasler ¶130. Moreover, permitting flow about a balloon was well-known. *E.g.*, Yang (Ex. 1017, published 3/13/2003), [0065] (disclosing a "star shape[d]" "stabilization balloon" "permit[ing] blood flow in the expanded configuration" for "beating heart surgeries"); Drasler ¶¶129-130. A POSITA would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶130.

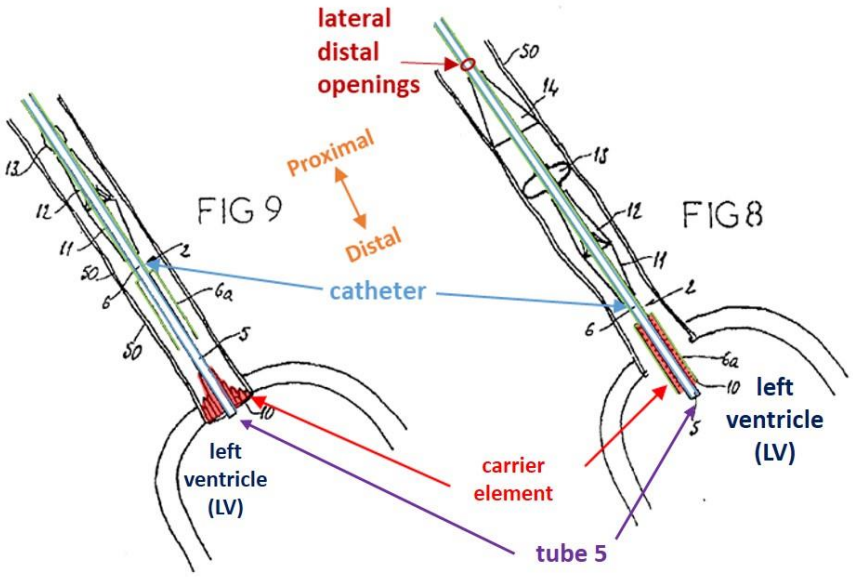
C. Ground 3: Claims 1-2, 4-6, 10, and 12-14 Are Rendered Obvious by Leonhardt in View of Bailey and Seguin

To the extent the Claims are limited to requiring unidirectional blood flow prior to any proximal end expansion (*see* §§X.A.3.[1.4], [1.9], X.B) contrary to the intrinsic evidence (*see* §IX.C), **Leonhardt** in view of **Bailey** and **Seguin** nonetheless renders the Claims obvious. Drasler ¶¶290-291. **Seguin** teaches proximal openings in the catheter that permit the flow of blood even when the prosthesis's proximal end

remains unexpanded in the catheter. When **Bailey's** teachings of allowing blood flow about the expansion balloon (*see* §X.B) and **Seguin's** teachings of catheter openings are applied, blood flow through the valve/stent occurs and the valve functions to permit unidirectional blood flow prior to any proximal end expansion.[14]

Seguin teaches a catheter comprising "lateral distal openings…to allow the blood to reach," e.g., "the ascending aorta," during transluminal prosthetic deployment. Seguin, 7, 11-12, cl. 11. During deployment, "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, cl. 11, Figs. 8-9 (lateral distal openings added); Drasler ¶186. The openings are placed distally such that "the length of catheter across which the blood passes is as short as possible." Seguin, 7, 11, cl. 11.

[14] This combination renders obvious the '941's only disclosure of a valve functioning during expansion, after distal end expansion, and prior to proximal end expansion by using a "perfusion balloon" to further "dilat[e]" the device "to ensure the device is apposed to the wall…and seated properly." *See* §V, §VII, §IX.C, n.6; '941, 71:10-18, 74:13-21, 75:1-3; Drasler ¶56, 146, 233.



Like **Leonhardt** and **Bailey, Seguin** is in the same field as the '941—prosthetic cardiac implants—and is reasonably pertinent to the alleged problems identified in the '941, *e.g.*, a need for a method of treating a patient using an expandable cardiac prosthesis. §X.B; Seguin, 6-7, 11-13, Claim 11; Drasler ¶187.

A POSITA would have been motivated to apply **Seguin's** lateral distal opening teachings to **Leonhardt's** outer sheath to yield the predictable, advantageous result of enabling blood flow through valve/stent 20's proximal end prior to its release from outer sheath 106—thereby avoiding pressure buildup that could cause prosthesis migration.[15] Drasler ¶¶188-189; Seguin, 7, 11-12, cl. 11;

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

Leonhardt, Abstract, 1:11-14, 6:36-38, 9:64-10:11, 10:22-23, 11:29-36; §X.B (discussing similar motivations for applying Bailey's teachings that apply here); Drasler ¶¶188-189. Pressure is normally managed by imperfect rapid pacing devices, and the combination advantageously decreases the need for such devices. Drasler ¶188. Per **Seguin's** teachings, the openings would be placed near **Leonhardt's** sheath's distal tip. Seguin, 7, 11-12; Drasler ¶188. **Leonhardt** recognizes the importance of maintaining blood flow during deployment and avoiding sudden removal of obstructions (*see* §X.B). **Bailey's** teachings of a non-obstructing balloon (*see* §X.B) and **Seguin's** teachings additionally improve **Leonhardt**—**Seguin's** additional teachings of lateral openings advantageously "allow the blood to reach the bodily vessel" after passing through valve/stent 20's proximal end. Seguin, 7, 11-12; Drasler ¶188. 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 through **Leonhardt's** prosthesis at multiple points during deployment for a longer time period than just applying one teaching—blood would flow regardless of whether a balloon is inflated or valve/stent's proximal end remains inside the catheter. Drasler ¶188. The additional blood flow through Leonhardt's prosthesis further allows the valve to allow unidirectional blood flow. Drasler ¶188. A POSITA would have known that such a combination (yielding the

claimed limitations) would predictably work and provide the expected functionality of the valve allowing unidirectional blood flow prior to any proximal end expansion.[16] Drasler ¶¶188-189.

As explained in §X.A.1, **Leonhardt's** valve is free to open and collapse onto the inner catheter (thus allowing unidirectional flow) because the balloon does not overlap with the valve. Drasler ¶¶180. 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 ¶180; *see also* Ex. 1010, 13 (amended complaint asserting limitation met despite the presence of a catheter through a valve). 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 and **Seguin**'s teachings are applied, the valve also functions when blood flows through the sheath's lateral openings prior to any proximal end expansion—advantageously allowing unidirectional blood flow earlier in the procedure. Drasler ¶¶180-181; *see also* Salahieh-697 (Ex. 1007), Figs. 9A-10B; Bailey ¶[0074] (teaching replacement valve operation before stent's proximal

[16] The plunging seal on **Leonhardt's** push rod's distal end is optional when using sutures to enable repositioning, and therefore no obstacle to applying **Seguin's** lateral openings to **Leonhardt's** sheath. Leonhardt, 8:31-38; Drasler ¶188.

end released from catheter); Letac (Ex. 1037), Figs. 9a-11b (valve collapses onto self); Boretos (Ex. 1014), Figs. 4A-4B (valve collapses onto support).[17]

As further discussed in §X.A.1, **Leonhardt** discloses retracting outer sheath 106 off of the valve/stent's proximal end, allowing it to self expand, and then using expansion balloon 154 to further expand the proximal end. A POSITA would have understood that, when **Bailey's** balloon teachings and **Seguin**'s lateral openings are applied, **Leonhardt's** valve would also allow unidirectional flow during expansion, after distal end expansion, and prior to proximal end expansion: (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 ¶¶182-185, 291.

D. Grounds 4-5: Claim 3 is Rendered Obvious by Leonhardt in view of Stevens and Alternatively in Further View of Bailey and Seguin

Claim 3 recites: "The method of claim 1, wherein evaluating the position or function of the first carrier element and the first replacement valve comprise

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

monitoring the flow of blood through chambers of the patient's heart using echocardiography." **Leonhardt** in view of **Stevens** renders claim 3 obvious. Drasler ¶292. **Leonhardt** discloses using "monitoring and visualization" equipment to "verif[y]" "proper placement" and "function" of valve/stent, including valve/stents placed with one end in a heart chamber. Leonhardt, 11:29-32, 9:55-62, Figs. 9A-9D. While Leonhardt provides examples of such equipment and techniques, it leaves it to a POSITA to identify and select additional ones. *Id.* **Stevens** provides further information on well-known imaging techniques for monitoring blood flow during cardiac procedures, including assessing prosthetic function. Stevens, 4:4-21. **Stevens** discloses utilizing "[t]ransesophageal echocardiography" during endovascular valve replacement to improve the "precision…of the replacement." Stevens, 4:4-9; *see also* 9:47-53 (performing echocardiography to monitor prosthesis function). Thus, when transesophageal echocardiography is used during mitral valve replacement (which extends from one heart chamber to another), blood flow through heart chambers is monitored. Drasler ¶292.

Like **Leonhardt**, **Bailey**, and **Seguin**, **Stevens** is in the same field as '941—prosthetic cardiac valves—and is reasonably pertinent to the alleged problem(s) identified in '941: needing a method of treating a patient using an expandable prosthesis. *See* §X.A.2; Stevens, 3:43-49, 3:57-62; Drasler ¶293.

A POSITA would have been motivated to apply **Steven**'s echocardiography teachings to **Leonhardt**'s monitoring of the valve/stent's position or function (with the procedure alternatively also modified by Bailey and Seguin as discussed above) to yield the predictable, advantageous result of continuous blood flow monitoring, including evaluating the valve/stent's position and function. Drasler ¶294. A POSITA would have had a reasonable expectation of success in applying **Stevens**'s detail teachings to **Leonhardt**'s percutaneous valve replacement procedure (and, alternatively, as modified by Bailey/Seguin as discussed above). Drasler ¶294. **Stevens** and **Leonhardt** recognize the importance of visualizing prosthesis's placement and function. Stevens, 3:43-45, 3:53-62, 4:7-21; Leonhardt, 3:33-38, 9:51-60, 11:29-34; Drasler ¶294. Moreover, using echocardiography to monitor blood flow during such procedures was well-known and advantageously generates "state of the art…detailed two dimensional images" for assessing valve function. *E.g.*, Svanidze ¶[0182]; Lesniak (Ex. 1050), ¶[0041]; Downing, ¶¶[0086], [0123]; Drasler ¶294. A POSITA would have known that such combinations (yielding the claimed limitations) would predictably work and provide the expected functionality. *Id*.

E. Grounds 6-7: Claims 7-8 Are Rendered Obvious by Leonhardt in View of Cribier and Alternatively in Further View of Bailey and Seguin

1. Overview of Cribier and Motivation to Apply Its Teachings to Leonhardt

Leonhardt in further view of **Cribier** renders obvious claims 7-8. *See* §§X.A, X.C. **Cribier** describes a procedure for "percutaneously implant[ing] heart valves" at a patient's aortic valve. Cribier, 16. Cribier discloses advancing a "5F catheter" through the left femoral artery for "continuous blood pressure monitoring." Cribier, 17. Cribier further teaches measuring the "mean transvalvular gradient"—the pressure difference across the valve—immediately after deployment as an indicator of function. *Id.*; Drasler ¶295.

Like **Leonhardt, Bailey,** and **Seguin**, **Cribier** is in the same field as the '941—prosthetic cardiac implants—and is reasonably pertinent to the alleged problems identified in the '941, *e.g.*, a need for a less-invasive method of implanting interventional cardiac devices. §§X.A.1, X.B, X.C; Cribier, 16 ("The design of a percutaneous implantable prosthetic heart valve has become an important area for investigation…."), 4; Drasler ¶296.

A POSITA would have been motivated to apply **Cribier**'s teachings of monitoring blood pressure, including across a prosthetic valve, in implementing **Leonhardt**'s monitoring of valve/stent's function and placement (with Leonhardt's

procedure alternatively also modified by Bailey and Seguin as discussed above) to yield the predictable, advantageous result of accurately evaluating the valve/stent's placement and function before withdrawal. Cribier, 17-18; Leonhardt, 9:55-10:3; Drasler ¶297. While **Leonhardt** provides some examples of "monitoring and visualiz[ing]," it leaves it to a POSITA to select additional techniques. *Id.* **Cribier** provides further information regarding the characteristics monitored and techniques to do so—such as a "5F catheter…for continuous blood pressure monitoring" and measuring the "transvalvular gradient." *Id.* Monitoring blood pressure was well-known to advantageously facilitate proper placement and function. Leonhardt, 9:55-62; Boretos (Ex. 1014), 9:28-37 (using "left ventricular…pressures" to evaluate the prosthesis performance); Hill (Ex. 1044) ¶¶[0036] (blood pressure sensor), [0098] (monitoring during cardiac valve replacement), [0065], [0020]; Saadat (Ex. 1045) ¶[0017] (measuring "flow rates, pressure" via delivery catheter sensor); Drasler ¶297. As taught by **Cribier**, monitoring the "mean transvalvular gradient"—blood pressure difference across the valve—advantageously enables the physician to determine valvular cross-sectional area and throughput. Cribier, 17; Drasler ¶297. Measuring the gradient involves measuring the blood pressure in the aorta and the left ventricle, and in the right atrium and the left ventricle, in the aortic and mitral valves respectively as depicted in Bailey, Fig. 6A (see §X.A.1). Drasler ¶297.

Given the above teachings, a POSITA would have had a reasonable expectation of success in applying **Cribier**'s express teachings of monitoring blood pressure and assessing a transvalvular pressure gradient in implementing **Leonhardt**'s placement site monitoring during a valve replacement procedure (with Leonhardt's procedure alternatively also modified by Bailey and Seguin as discussed above). Drasler ¶298. A POSITA would have known that such combinations (yielding the claimed limitations) would predictably work and provide the expected functionality. *Id*.; Drasler ¶298.

2. Claim Chart

'941	**Leonhardt**
[7] The method of claim 1, wherein evaluating the position or function of the first carrier element and the first replacement valve comprises monitoring a blood pressure of the patient.	***See* [1].** **Leonhardt discloses evaluating the position or function of the first carrier element and the first replacement valve** (*see* [1.5]). ***E.g.*, Leonhardt:** ***See* [1.5], [3].** Additionally, **Leonhardt** discloses "monitoring" valve/stent's function and placement and properties near the placement site. Leonhardt, 9:55-62. • 9:55-62 ("…***certain equipment used for monitoring and visualization purposes is available for use by a surgeon skilled in the art***…. Finally, it is assumed ***the patients heart has been slowed and blood pressure dropped*** if necessary.") • 10:64-11:29 ("Proper placement of valve stent 20 is verified by known means…[¶]…Once more proper placement is verified. [¶]…Valve stent 20 is now monitored for proper

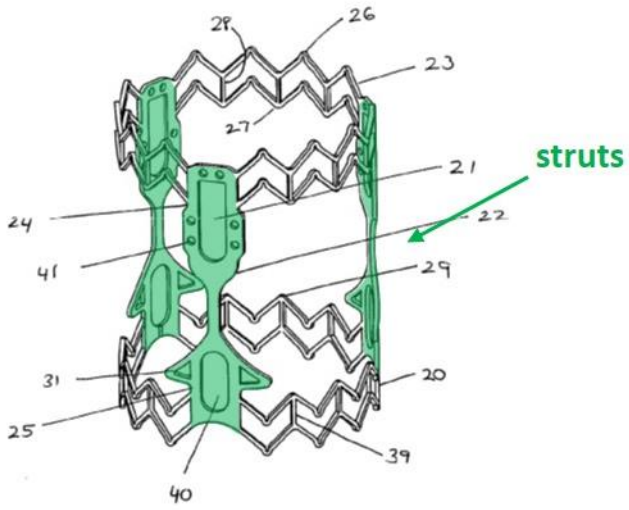
	function and patency. The placement site is also monitored….") **Cribier discloses monitoring a blood pressure of the patient** (*e.g.*, "blood pressure monitoring" during the procedure)**.** ***E.g.*, Cribier**: **Cribier** discloses using a second catheter for "continuous blood pressure monitoring" during percutaneous heart valve replacement procedures, including measuring "mean transvalvular gradient" to assess valve function. Cribier, 17. As discussed in §X.E.1, measuring function using blood pressure was well-known, and a POSITA would have been motivated to apply **Cribier**'s implementation detail teaching of blood pressure monitoring techniques to **Leonhardt**'s valve function and placement monitoring. Drasler ¶304. • 17 ("***A 5F catheter*** from the left femoral artery ***was used for continuous blood pressure monitoring***….[¶]… ***Immediately after the procedure, mean transvalvular gradient was 6 mm Hg***, left ventricular end-diastolic pressure 25 mm Hg, …and calculated aortic valve are 1.9 cm^2 according to Gorlin's formula.") • *See also* 1, 2. Drasler ¶¶296-304.
[8] The method of claim 7, wherein the blood pressure includes a ventricular blood pressure.	***See* [7].** **Cribier discloses the blood pressure includes a ventricular blood pressure** (*e.g.*, "left ventricular…pressure"). ***E.g.*, Cribier**: **Cribier** discloses measuring the valve's "transvalvular gradient" and "left ventricular…pressure." Cribier, 17. As discussed in §X.E.1 and §X.E.2.[7], a POSITA would have understood that measuring a transvalvular pressure gradient for an aortic or mitral valve includes measuring left ventricular pressure, a variety of well-

	known measurement techniques were available prior to delivery catheter withdrawal, and a POSITA would have been motivated to apply Cribier's teachings to Leonhardt. • 17 (see [7]). Drasler ¶¶305-309, 296-298.

F. Grounds 8-9: Claim 16 Is Rendered Obvious by Leonhardt in View of Svanidze and Alternatively in Further View of Bailey and Seguin

Grounds 1 and 3 in further view of **Svanidze** render obvious claim 16, which recites that "The method of claim 1, wherein the first carrier element includes at least three struts spaced around the first carrier element and coupling the distal end of the first carrier element to the proximal end of the first carrier element." *See* §§X.A, X.C. **Svanidze discloses the carrier element** [of claim 1] **includes at least three struts spaced around the first carrier element and coupling the distal end of the first carrier element to the proximal end of the first carrier element** (*e.g.*, "support posts that extend longitudinally" between "anchoring structure" ends). **Svanidze** discloses "a replacement valve assembly compris[ing] a collapsible and expandable anchoring structure" containing "support posts that extend longitudinally" between the anchoring structure's proximal and distal ends. Svanidze, ¶¶[0082], [0084], Fig. 6C. **Svanidze**'s support posts "stabiliz[e]" the anchoring structure/replacement valve assembly to, e.g., "preclude valve stretching

or distortion upon compression of the device." Svanidze, ¶[0085]; Drasler ¶¶310, 190.



Svanidze Fig. 6C

Like **Leonhardt**, **Bailey,** and **Seguin**, **Svanidze** is in the same field as the '941—prosthetic cardiac implants—and is reasonably pertinent to the alleged problems identified in the '941, *e.g.*, a need for a method of treating a patient using an expandable cardiac prosthesis. §§X.A.2, X.B-C; Svanidze, ¶¶[0001], [0006]-[0009] ("need for a valve replacement system comprising a collapsible and expandable valve assembly"); Drasler ¶¶310, 191.

A POSITA would have been motivated to apply **Svanidze**'s express teaching of three support posts to **Leonhardt**'s valve/stent (alternatively in view of the additional teachings from **Bailey,** and/or **Seguin** as discussed above) to yield the predictable, advantageous result of "stabiliz[ing]" the valve/stent and protecting it

from "distortion [or injury] upon compression of the device" during endovascular delivery by keeping the ends apart. Svanidze, ¶¶[0084]-[0086]; Leonhardt, 5:31-40; Drasler ¶¶310, 192. **Svanidze** discloses that the number of support posts can be changed and "are configured to coincide with the [replaced valve's] natural commissural posts." Svanidze, ¶[0086]. A POSITA would have understood that aortic valves have three such posts. Leonhardt, 6:23-25; Bailey [0070], Fig. 6A; Drasler, ¶192. A POSITA would have understood that **Leonhardt**'s valve/stent with a singular connecting bar would offer limited stability, and thus would have been motivated to alter **Leonhardt**'s valve/stent to contain at least three connecting bars, coinciding with the three natural commissural posts in the aortic valve. Svanidze, ¶[0086]; Leonhardt, 5:39-40; Drasler, ¶310, 192.

Given the detailed disclosure **Svanidze**'s support posts and **Leonhardt**'s existing connecting bar, a POSITA would have had a reasonable expectation of success in applying **Svanidze**'s express teaching of three support posts to **Leonhardt**'s valve/stent (in view of the additional teachings from **Bailey,** and/or **Seguin** as discussed above). Drasler, ¶¶310, 193.

XI. SECONDARY CONSIDERATIONS

There is no evidence in the '941's prosecution history 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 Claim. *See generally* '941FH; Drasler ¶319. As demonstrated by the above-referenced prior art, any purported solutions or unexpected results in the '941 were already well known. Drasler ¶319. To the extent PO asserts the existence of any secondary considerations in response, Petitioners reserve the right to address any such evidence.

XII. CONCLUSION

Substantial, new, and noncumulative technical teachings have been presented for the '941's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to the Claims. *Inter partes* review of claims 1-8, 10, 12-14, and 16 is accordingly requested.

Dated: January 20, 2021

Respectfully submitted,

/James L. Davis, Jr./
James L. Davis, Jr.
Reg. No. 57,325

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MEDTRONIC COREVALVE LLC,
and MEDTRONIC, INC.

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 13,993 words as counted by the word processing program used to prepare the paper.

Dated: January 20, 2021

/James L. Davis, Jr./
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 '941 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

By: /Crena Pacheco/
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