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 IPR2021-00240

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

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

LIST OF EXHIBITS

Exhibit ("Ex.")	Description
1001	U.S. Patent No. 9,510,941 ("941")
1002	Declaration of William Drasler, Ph.D. ("William Drasler")
1003	File History of U.S. Patent No. 9,510,941 ("'941FH")
1004	U.S. Patent No. 5,957,949 to Leonhardt ("Leonhardt")
1005	U.S. Patent Publication No. US2003/0023300 to Bailey ("Bailey")
1006	Certified Translation of PCT Application No. WO01/35870 to Seguin ("Seguin")
1007	U.S. Patent Publication No. US2005/0137697 to Salahieh ("Salahieh-697")
1008	U.S. Patent Publication No. US2005/0137686 to Salahieh ("Salahieh-686")
1009	U.S. Patent No. 6,117,106 to Wasicek et al. ("Wasicek")
1010	Speyside Medical, LLC v. Medtronic Corevalve, LLC and Medtronic, Inc., Case 1:20-cv-00361-LPS, Amended Complaint
1011	Reserved
1012	U.S. Patent Publication No. US2005/0075726 to Svanidze ("Svanidze")
1013	U.S. Patent No. 8,377,118 to Lashinski et al. ("Lashinski")
1014	U.S. Patent No. 4,056,854 to Boretos ("Boretos")
1015	U.S. Patent Publication No. US2004/0059351 to Eigler ("Eigler")

1016	U.S. Patent Publication No. US2002/0161378 to Downing ("Downing")
1017	U.S. Patent Publication No. US2003/0050694 to Yang ("Yang")
1018	U.S. Patent No. 6,425,916 to Garrison et al. ("Garrison")
1019	U.S. Patent No. 3,671,979 to Moulopoulos ("Moulopoulos")
1020	U.S. Patent Provisional Application No. 60/572,561
1021	U.S. Patent Provisional Application No. 60/581,664
1022	U.S. Patent Provisional Application No. 60/586,002
1023	U.S. Patent Provisional Application No. 60/586,005
1024	U.S. Patent Provisional Application No. 60/586,006
1025	U.S. Patent Provisional Application No. 60/586,054
1026	U.S. Patent Provisional Application No. 60/586,055
1027	U.S. Patent Provisional Application No. 60/586,110
1028	U.S. Patent Provisional Application No. 60/588,106
1029	U.S. Patent Provisional Application No. 60/603,324
1030	U.S. Patent Provisional Application No. 60/605,204
1031	U.S. Patent Provisional Application No. 60/610,269
1032	U.S. Patent Provisional Application No. 60/568,402
1033	U.S. Patent No. 5,411,552 to Andersen ("Andersen-552")
1034	U.S. Patent No. 6,168,614 to Andersen ("Andersen-614")
1035	U.S. Patent No. 6,582,462 to Andersen ("Andersen-462")
1036	U.S. Patent No. 5,554,185 to Block

1037	PCT Application No. WO 98/29057 to Letac
1038	File History of U.S. Patent Application No. 16/564,098
1039	File History of U.S. Patent Application No. 15/297,282
1040	File History of U.S. Patent Application No. 11/579,723
1041	Reserved
1042	Speyside Medical, LLC v. Medtronic Corevalve, LLC and Medtronic, Inc., Case 1:20-cv-00361-LPS, Scheduling Order
1043	U.S. Patent No. 8,257,428 to Khairkhahan ("Khairkhahan")
1044	U.S. App. Pub. No. 2003/0216790 to Hill ("Hill")
1045	U.S. App. Pub. No. 2003/0018358 to Saadat ("Saadat")
1046	U.S. Patent No. 5,370,685 to Stevens ("Stevens")
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
1048	Reserved
1049	Explanation of Multiple Petitions
1050	U.S. App. Pub. No. 2003/0078671 to Lesniak ("Lesniak")

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 17, 19-27 ("Challenged 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 Challenged 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 expanding its distal end and before expanding its proximal end—operates to permit unidirectional blood flow. But all steps of the Challenged Claims were well-known in the art at the time of the invention, and the claimed features were taught in the art well before the time of the alleged invention. Drasler ¶¶36-40.

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

The ’941 patent claims recite a method for deploying a prosthetic heart valve, including endovascularly delivering via a blood vessel and deploying at a native heart valve a prosthesis from a collapsed to expanded configuration (Fig. 47A-C), without urging the proximal end toward the distal end. Drasler ¶¶ 41, 95.

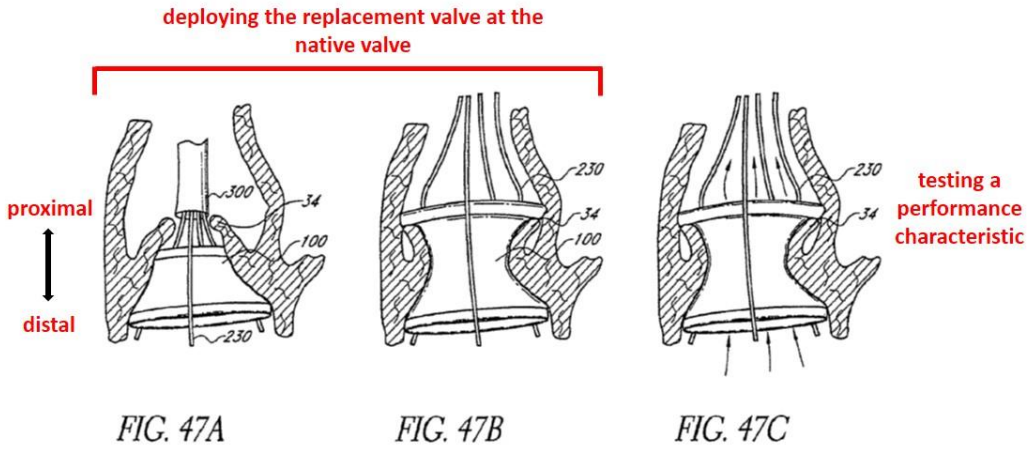

FIG. 47A FIG. 47B FIG. 47C

The ’941 admits that at the time of the invention, this was a well-developed field and the endovascular delivery steps were well-known in the art. ’941, 3:52-55; Drasler ¶¶37-38. For example, **Leonhardt**, which was applied in a rejection during prosecution, teaches a prosthesis (in red below), such as a “[b]iological valve 22” that fits within “stent 26,” that operates to permit only unidirectional blood flow after distal end expansion, but before proximal end expansion. Leonhardt, 10:53-11:22; Drasler ¶101.

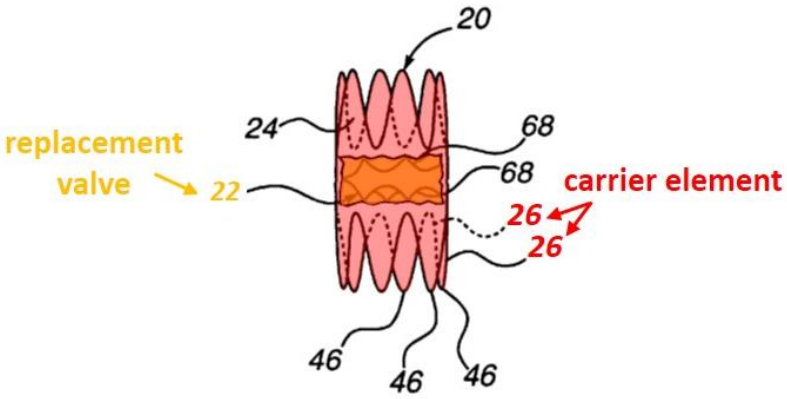

FIG. 4

Leonhardt further discloses treating a patient with its prosthesis 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 proximal end towards its distal end. Leonhardt, 10:53-11:58; Drasler ¶¶100, 103, 194. The only alleged point of novelty in the Challenged Claims identified by PO during prosecution over **Leonhardt** was the requirement that the prosthesis permit unidirectional blood flow after expansion of the carrier element's distal end and before expansion of its proximal end. *E.g.*, Ex. 1003 ('941FH), 1761.

However, while **Leonhardt's** expansion balloon is used to expand its prosthesis's ends and hold the prosthesis in place during release thereby obstructing blood flow when expanded, **Bailey** instead teaches the improvement of using an expansion balloon with an "irregular inflation profile[]," permitting blood flow around the balloon even when the balloon is expanded—such as when it is used to

expand a prosthesis. Bailey ¶¶[0070], [0072]; Drasler ¶100. Indeed, **Bailey** expressly cites **Leonhardt** in discussing its improvement thereto. In addition, **Seguin** teaches blood flow through a prosthesis such as **Leonhardt**'s even when the proximal end of the prosthesis remains inside the catheter during deployment by allowing the blood to flow through lateral openings in the catheter (Seguin, 7, 11-12, Claim 11). Regarding claim 27, **Svanidze** teaches "support posts" that couple the proximal and distal ends of the prosthesis together to provide for increased stability. Svanidze, ¶¶[0084]-[0086]. Importantly, neither **Bailey**, **Seguin**, **Svanidze,** nor any substantially similar reference was considered during prosecution with **Leonhardt**.

As will be demonstrated herein, **Leonhardt** in view of **Bailey** and alternatively in further view of **Seguin** and/or **Svanidze** render obvious the Challenged Claims, which are directed to an obvious combination of prior art elements combined according to known methods to yield predictable results. At most, the combination amounts to nothing more than a "predictable use of prior art elements according to their established functions." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); Drasler ¶¶95-99.

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

II. MANDATORY NOTICES (§42.8)

A. Real Party-In-Interest

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

B. Related Matters

Petitioners are challenging the '941 in three petitions (see also IPR2021-00241 and IPR2021-00310) 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. The '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	WO 01/35870	11/15/2000	05/25/2001	(a), (b)
Svanidze	*1012	U.S. App. Pub. 2005/0075726	10/06/2003	04/07/2005	(a), (e)

2. Statutory Grounds on Which the Challenge Is Based

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

§103 Ground	Claim(s)	Prior Art
1	17, 19-26	Leonhardt in view of Bailey
2		Leonhardt in view of Bailey and Seguin
3	27	Leonhardt in view of Bailey and Svanidze
4		Leonhardt in view of Bailey, Seguin, and Svanidze

3. How the Challenged Claims Are Unpatentable

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

V. '941 PATENT

The '941 discloses an aortic valve prosthesis for replacing an abnormal or diseased aortic valve 34. '941, Abstract, 4:15-17, 11:57-59, Fig. 2 (below). The claimed method is generally directed to (1) endovascularly delivering a prosthesis to a native heart valve and (2) expanding the prosthesis from a collapsed delivery configuration, as illustrated in Figs. 47A-C and 2 below. '941, Abstract, 5:48-55, 50:45-51:24, 75:14-67. Drasler ¶¶41, 53.

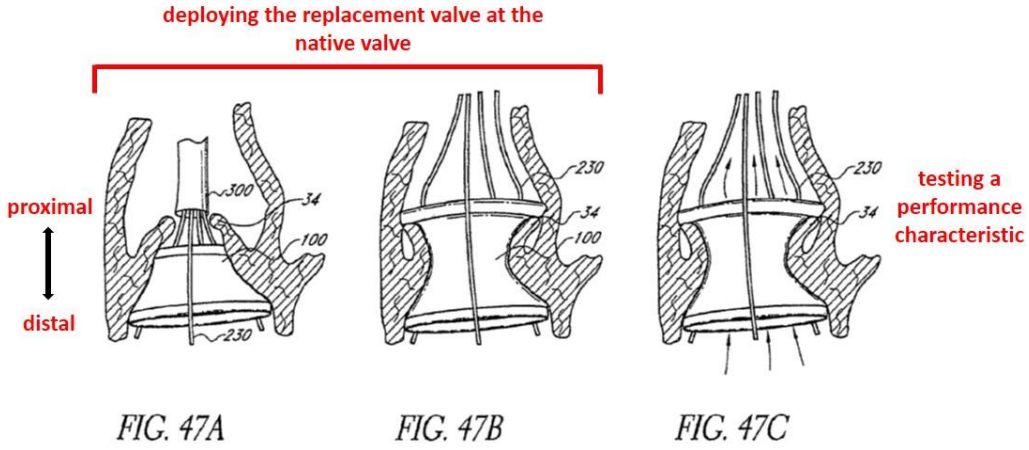


FIG. 47A FIG. 47B FIG. 47C

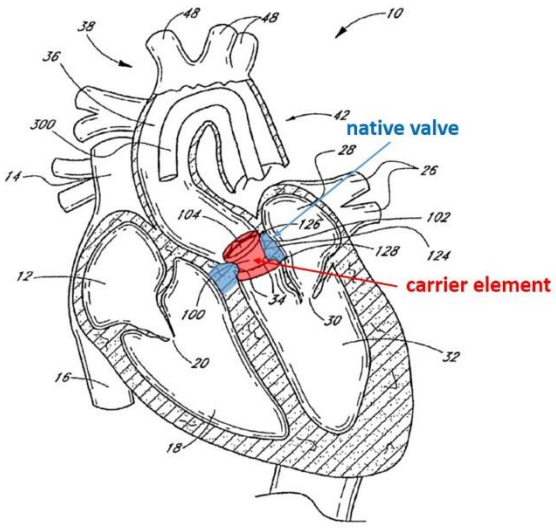


FIG. 2

The prosthesis comprises a valve, which includes leaflets, a carrier element, and additional components. '941, 12:14-17, 28:8-12. In one embodiment, the carrier element includes stents 756, positioned at the prosthesis's proximal and distal ends,

and a flexible fabric cuff 752 coupled to the two stents and valve 754. '941, 12:4-13, 27:56-66, Fig. 25F (below); Drasler ¶42.[2]

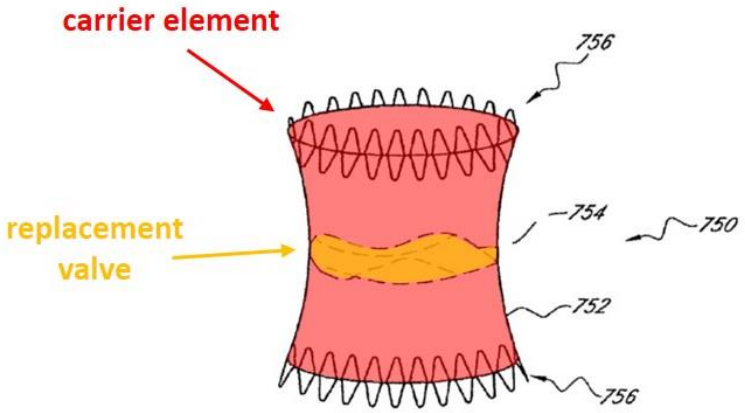


FIG. 25F

Alternative embodiments use inflatable cuffs instead of stents. '941, 4:3-12, 12:14-17, 67:11-13; Drasler ¶44.

The prosthesis is "loaded" in its collapsed reduced-profile form between outer and inner sheaths of an intravascular delivery catheter and delivered "minimally invasively" using the delivery catheter. '941, 11:53-56, 13:55-60, 41:36-38, Figs.

[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.

34, 36. The collapsed prosthesis is "translumenally advanced" through the access site (e.g., femoral artery) to the native valve while the heart is "beating." '941, 5:18-25, 6:27-32, 44:17-19, Fig. 57A; Drasler ¶45. Figures 46B-C depict the collapsed valve either held a distance from, or partially within, the sheath during withdrawal (the reverse process used for deployment):

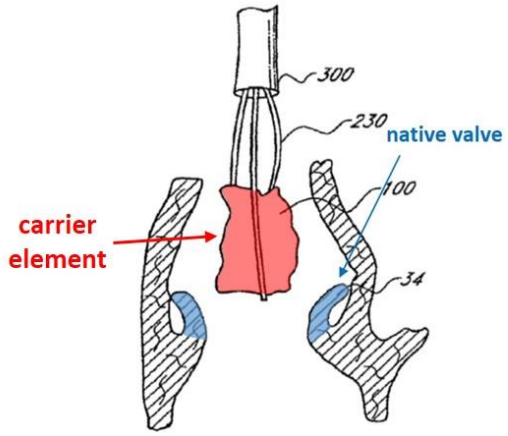


FIG. 46B

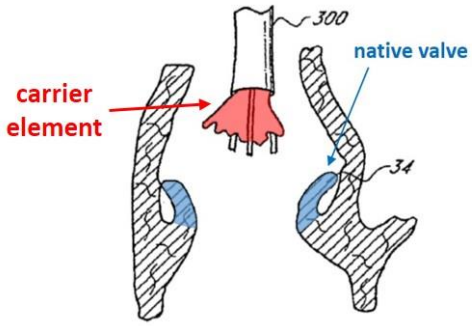


FIG. 46C

During advancement, stents 756 are collapsed. '941, 27:59-64, 77:12-19, 77:28-34; Drasler ¶46. The operator uses a deployment control device—such as control wires 230 (e.g., Figs. 46, 47A-E) detachably coupled to the prosthesis's proximal and distal ends or a proximal extension to the prosthesis—to position the implant and render it recoverable. '941, 49:17-28, 41:47-50, 75:51-54, 77:38-65.

At the implantation site, the catheter is "advanced across the aortic valve" into the left ventricle. '941, 77:45-46. The outer sheath is withdrawn from the prosthesis,

which is held in position using the deployment control device. '941, 74:46-49. The prosthesis's distal end is expanded. '941, 74:46-47, Figs. 45A-C.

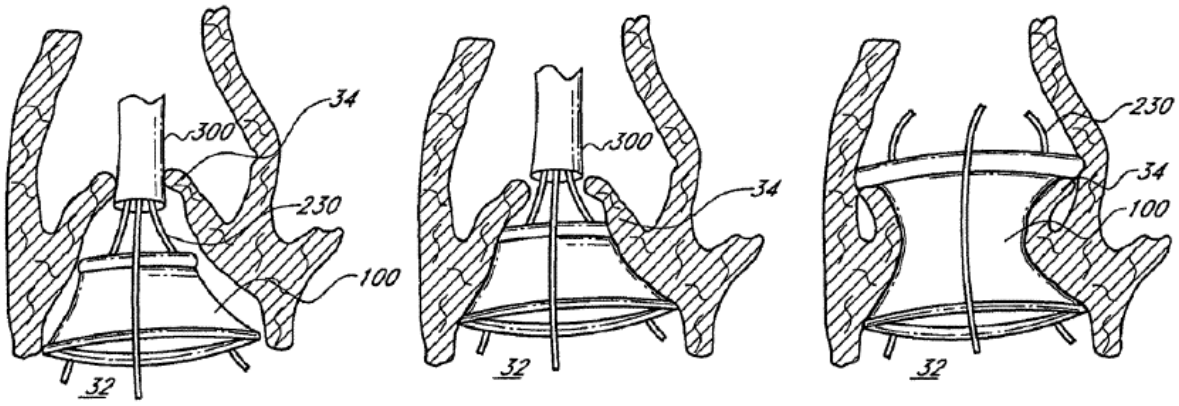


FIG. 45A FIG. 45B FIG. 45C

To ensure "the [prosthesis's] outflow tract is not blocked at any time during the implantation process," the outer sheath is then "retracted far enough" proximally along the "deployment control wires." '941, 73:39-42, 74:47-64. The prosthesis is then "withdrawn across the native valve annulus" (e.g., Fig. 45B) by withdrawing the control wires, and the "device is then fully inflated" (for the inflatable cuff embodiment—e.g., Fig. 45C) or fully expanded (for the self-expanding recoverable stent embodiment). '941, 74:49-53, 75:28-31, 75:43-67; *see also* '941, Figs. 47A-B (above). The valve functions once fully inflated or expanded. '941, 75:22-31, 74:50-52, 77:49-54, 61:9-34; Drasler ¶¶47-48.

While the "sheath is retracted far enough" that the control wires "allow" the valve "to function" before the device is withdrawn across the native valve annulus,

the valve is not seated at this point (e.g., Fig. 45A) and is not functional prior to full inflation of the inflatable cuffs: "[t]he device is then fully inflated, enabling the valve to function." '941, 75:23-31; *see also* '941, 74:44-51, 77:46-54 (describing sheath retraction as necessary to allow the valve to function, but not disclosing valve actually functioning until "fully inflated"). Similarly, the '941 discloses that the "self-expanding recoverable stent" "function[s]" once "fully deployed." '941, 75:43-51. The '941 consistently describes the valve as "function[ing]" only once fully deployed. *See also* '941, 75:22-31, 74:43-51 (testing valve function only after fully inflated), 77:49-54 (same), 61:9-34 (mitral valve prosthesis operational after both ends inflated); Drasler ¶¶48-49.

When functioning, the valve moves between an "open" configuration permitting blood flow in a first direction and a "closed" configuration where "blood is prevented from back flowing" in a second direction. '941, 12:17-24, 4:12-14; Drasler ¶¶50-51.

Stents 756 are "self-expandable or balloon expandable," and "provide structure" to the prosthesis to "allow" valve 754 to function and to position the valve "in the native annulus." '941, 27:63-28:3. After expansion of stents 756 at the native annulus, the prosthesis' proximal and distal ends extend further radially outwards than the prosthesis's central portion in a "shape similar to a tubular hyperbola," as

shown, *e.g.*, in Figure 25F above. '941, 14:5-16, 78:40-42, Figs. 25F, 45C, 46A, 47B; Drasler ¶52.

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

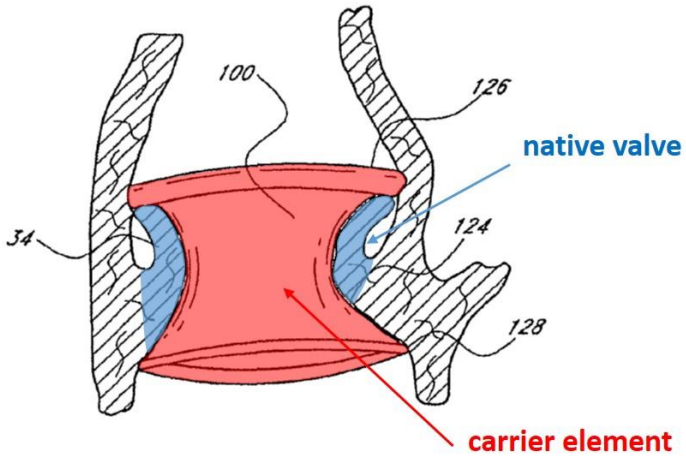


FIG. 2A

The prosthesis's proximal and distal ends (126, 128) form rings on either side of the native aortic valve to form a seal and "inhibit the device from migrating proximally or distally." '941, 37:5-7, 13:56-58, 14:5-12, 14:21-25, 78:65-67, 79:10-11, 37:5-7, 78:8-9, Fig. 2A; Drasler ¶¶54-55.

As discussed above, the '941 teaches that the valve is fully expanded to enable the valve to function (and thus be tested before being repositioned or removed), *e.g.*, by using a proximal extension of the stent. With respect to a further prosthesis

expansion after it is functioning, the '941 teaches "an additional dilatation" using a balloon "after implantation to ensure the device is apposed to the wall of the annulus and seated properly." '941, 75:1-3. The '941 further discloses that during the balloon expansion it was known to "use…a perfusion balloon with a balloon expandable support structure" "to allow significant perfusion through the balloon during deployment," ensuring the balloon does not block flow. '941, 74:13-21 (citing Ex. 1009 (USP 6,117,106)); Drasler ¶56.

Using "diagnostic techniques," the prosthesis's "securement and function" may be monitored and, if the "valve function, sizing, or securement" is "not sufficient or ideal," the valve may be repositioned or recaptured by partially or completely deflating/collapsing and re-expanding the prosthesis. '941, 50:63-67, 51:16-22, 51:56-59, 74:50-51, 75:10-13, 75:30-39, 77:14-19, 77:53-65, Figs. 47C-D (below); Drasler ¶¶57-58.

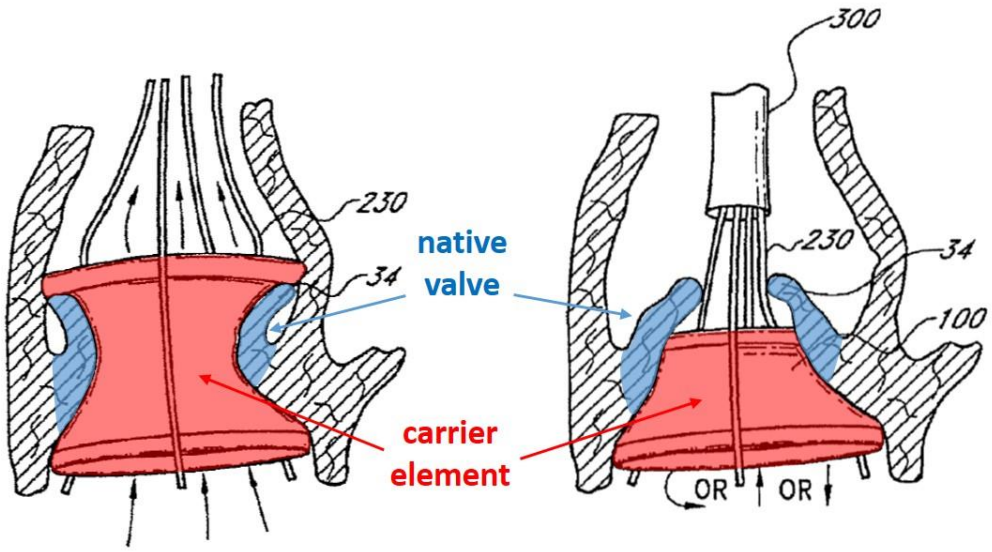


FIG. 47C FIG. 47D

The ’941 asserts that it is solving a problem for “current percutaneous valve replacement devices” because, once fully deployed for testing, the valve cannot be “removed.” ’941, 75:4-13. For example, with respect to “a known self-expanding recoverable stent…adapted to a valve support structure,” the ’941 discloses that the valve needs to be “fully deployed” to test its function, but once fully expanded could not be recovered. ’941, 75:43-51. The ’941 discloses the use of a “proximal extension” of the support structure that extends proximally either in the form of an “open” “cell structure” or “individual wires” to not block flow through the “ostia” that branch off from the aorta when fully deployed. ’941, 75:55-67. The extension acts as a deployment control device, such that the stent can be removed or

repositioned after the valve is "fully deployed" for testing. '941, 75:45-54; Drasler ¶59.

Repositioning may include "rotation or translation" of the implant or a "complete removal and exchange" for a different implant. '941, 42:20-25. The deployment control device allows the operator to move the implant after full expansion, so long as the deployment control device remains coupled to the prosthesis. '941, 74:57-60, 51:1-5, Figs. 46A-C. If the "valve function is sufficient," the deployment control device is disconnected or released and the catheter is withdrawn. '941, 74:53-55, Fig. 47E; Drasler ¶60.

VI. '941 PROSECUTION HISTORY

In Application 13/069,209, which matured into the '941, issued claim 17 (prosecution claim 46) as originally-filed was generally directed to "a method for replacing a patient's native heart valve," and recited that the replacement valve allows unidirectional blood flow during the carrier element's expansion. Ex. 1003 ('941FH), 14; Drasler ¶61.

To overcome a rejection over Salahieh-686 (U.S. App. Pub. 2005/0137686), PO amended claim 17 to require that "during expansion of the carrier element, a distal end of the carrier element is fully expanded prior to a proximal end of the

carrier element being fully expanded,"[3] contending Salahieh-686 teaches only that the distal and proximal ends are fully expanded "*simultaneously*." '941FH, 1705-1706, 1713 (emphasis original).

The Examiner then rejected claim 17 as anticipated by Leonhardt, relying on Leonhardt's disclosure of "tip [sic]" balloon expansion of the distal and then proximal ends, which occur after the stent's self-expansion—noting that "blood is flowing" and thus the valve is functioning during this time. '941FH, 1731 (Examiner apparently meant to refer to the expansion balloon as the tip balloon is not referenced discussed in the cited passage—Leonhardt, 11:3-22). In response, and after a telephonic interview, PO amended claim 17 to require the replacement valve to allow unidirectional blood flow "during the expansion of the carrier element, after expanding the distal end of the carrier element, and prior to expanding the proximal end of the carrier element." '941FH, 1752-1754 (underline shows addition), 1760-1761. For claim 17, PO argued that Leonhardt failed to disclose only the limitation in which the "replacement valve allows" unidirectional "flow of blood…after expanding the distal end of the first carrier element and prior to expanding the proximal end of the first carrier element as claimed." *Id.*, 1761. PO

[3] Applicant later removed the word "fully" after a rejection for lack of written description. '941FH, 1727-1728, 1752-1754.

argued that Leonhardt instead teaches a replacement valve that is "not operational until it fully exits the deployment catheter 100 to expand the proximal end" because it utilizes a "balloon that obstructs blood flow" and a "cover or sheath of graft material" that prevents blood flow before the proximal end's release from the catheter. *Id.* PO addressed neither the disclosures identified by Examiner nor the optional secondary balloon expansion taught by Leonhardt. '941FH, 1761; Drasler ¶¶62-63.

In an interview, the Examiner noted that while an amendment requiring that the "valve allows flow in a first direction and prevents flow in a second direction after expansion of the distal end and prior to expansion of the proximal end" "appears to overcome" Leonhardt, "further search and consideration" is required. '941FH, 1772. Moreover, "Salahieh (2005/0137686) may teach allowing/preventing blood flow in an intermediate deployment stage" and "more careful consideration of the prior art is needed." *Id.* The Examiner then issued a third office action rejecting claim 17 as obvious over Salahieh-686, without mentioning Leonhardt. *Id.*, 1780-1784. The Examiner argued that although Salahieh-686 did not specify that the replacement valve allows unidirectional blood flow after expanding the carrier element's distal end and prior to expanding its proximal end, applying this feature would have been obvious to a POSITA. *Id.*, 1780-1781. The Examiner argued that Salahieh-686 disclosed all other limitations

of issued claim 17. *Id*. PO then amended issued claim 17 to require "the proximal end of the carrier element being expanded without urging the proximal end of the carrier element toward the distal end of the carrier element," arguing Salahieh-686 teaches "relative" movement of the proximal end toward the distal end during the proximal end's expansion. *Id.*, 1797-1799, 1806; Drasler ¶¶64-65.

After PO amended the claim, the Examiner subsequently allowed it. *Id.*, 1819-1827. The Examiner found that Salahieh-686 was the "closest prior art," without mentioning Leonhardt. *Id.*, 1825-1826. The Examiner's only reason for allowance was that Salahieh-686 "relies on expansion via foreshortening, that is, by moving the proximal end of the valve support towards the distal end of the valve support," whereas the amended claims required "the proximal end of the carrier element being expanded without urging the proximal end…toward the distal end…." *Id.*, 1825-1826 (identifying support in '941 specification); Drasler ¶¶66-68.

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

A. §325(d)

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

Neither the art nor the arguments in Grounds 1-4 are the same/substantially the same as those considered during prosecution. Neither the Examiner nor PO discussed or applied **Bailey** (Grounds 1-4), **Seguin** (Grounds 2, 4) or **Svanidze** (Grounds 3-4) or substantially the same art during prosecution. **Leonhardt** in view of **Bailey** and alternatively in further view of **Seguin** and/or Svanidze (Grounds 1-4) teach the sole limitation that PO argued was missing from Leonhardt: "where the…replacement valve [prevents] the flow of blood through the…replacement valve in a first direction and [allows] the flow of blood through the…valve in a second direction [during the expansion of the carrier element,] after expanding the distal end of the…carrier element[,] and prior to expanding the proximal end of the first carrier element." '941FH, 1761 (PO addressed prosecution claim 44 as exemplary limitation; quote altered to reflect issued claim 17); *see* §§X.A.3[17.3], X.B.[4] The Office did not consider any materially similar references that expressly

[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 from the openings between proximal distensible fingers), the Challenged Claims recite a valve operating to allow unidirectional flow at certain times and do not recite a limitation requiring that the aortic outflow cannot be blocked at any point during the deployment. Drasler ¶122.

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

Where a petition's ground relies on at least one reference the Examiner never considered for limitation(s) the PO or Examiner found lacking in the prior art of record—as with **Bailey**, **Seguin,** and **Svanidze**—the Petition's art and arguments are not the same or substantially the same as those before the Office during prosecution. *Church & Dwight Co., Inc. v. Batinkoff*, IPR2020-00168, Pap. 11, *10-11 (declining to exercise §325(d) discretion in such circumstances); *Kolbe & Kolbe Mill Work Co. v. Sierra Pac. Indus.*, IPR2019-00933, Pap. 14, *46 (finding *no Becton* factors weighed in favor of denial where "none of the specific prior art combinations presented here was considered"); *Apple Inc. v. Maxell, Ltd.*, IPR2020-00200, Pap. 11, *26-30 (finding first *Adv. Bionics* step not met where each combination included art not previously before the Office).

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

Even if the Examiner had considered substantially the same art as that relied upon herein (the Examiner did not for Grounds 1-4), the Examiner erred in allowing

the Challenged Claims. During '941's prosecution, PO argued that **Leonhardt** only fails to disclose *one* limitation of prosecution claim 44, which contains similar language to '941 claim 17: "the…replacement valve allow[s] the flow of blood through the…replacement valve in a first direction and prevent[s] the flow of blood through the…replacement valve in a second direction [during the expansion of the carrier element,] after expanding the distal end of the…carrier element, and prior to expanding the proximal end of the…carrier element." *See* '941FH, 1752 (claim 46), 1761 (PO addressed prosecution claim 44 as exemplary limitation; quote altered to reflect claim 46). The Examiner never considered Leonhardt's secondary balloon expansion whereby the "[t]ip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" after the valve is "function[ing]"—thus allowing unidirectional blood flow. *See* Leonhardt, 11:28-33; '941FH, 1729-30 (failing to cite Leonhardt 11:28-33), 1772, 1780-81.[5] After the Applicant amended claims 44 and 46 to require the valve to allow the unidirectional flow of blood after distal

[5] Examiner's reference to Leonhardt's "tip balloon" being used to "seat" the proximal end ('941FH, 1731 (discussing prosecution claim 46 and citing Leonhardt, 11:3-22)) is a typo as the cited passage referring to seating the proximal end is discussing the "expansion balloon."

expansion and before proximal expansion, the Examiner instead shifted focus to another reference. '941FH, 1751-1754, 1777. Unfortunately, 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 and PO highlighted in Leonhardt, the lack of record of the Examiner's reasoning, and the better disclosures in Leonhardt, the Examiner erred in failing to cite a "better component" of Leonhardt and failing to adjust the mapping of the claim in response to an amendment. *Versa Prods v. Varidesk, LLC*, IPR2020-00387, Pap. 13, *15-18; *see also Arrows Up, LLC v. Oren Techs., LLC*, IPR2018-01231, Pap. 7, *11-12 (finding error where Examiner misunderstood reference).

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

First, the Examiner erred by failing to reapply Leonhardt in response to PO's amendment. In particular, Leonhardt's secondary balloon expansion using tip balloon offers a better disclosure of the valve functioning after distal expansion, and prior to proximal expansion (*see* §§X.A.3[17.2]-[17.3]) than that relied on by the Examiner, and mirrors the teachings in the '941 specification (*see* §V (discussing use of a "perfusion balloon" for "additional dilatation" after valve provides for unidirectional blood flow)). With respect to a further prosthesis expansion after it is

functioning, the '941 teaches "an additional dilatation" using a balloon "after implantation to ensure the device is apposed to the wall of the annulus and seated properly." '941, 75:1-3. The '941 further discloses that during the balloon expansion it was known to "use…a perfusion balloon with a balloon expandable support structure" "to allow significant perfusion through the balloon during deployment," ensuring the balloon does not block flow. '941, 74:13-21 (citing Ex. 1009 (USP 6,117,106)).

The Examiner should have rejected the amended claims over this superior disclosure, but there is no indication in the file history that the Examiner considered Leonhardt's secondary balloon expansion. *Versa Prods. v. Varidesk, LLC*, IPR2020-00387, Pap. 13, *15-17 (finding examiner erred in failing to cite to "better component" and again by failing to adjust mapping of a claim in response to amendment).

Second, to the extent the Examiner may have understood the claims to require that the valve impose unidirectional blood flow *before any proximal end expansion*, such an interpretation is error. That construction is not supported by the specification (see §IX.C), nor would flow be possible before any such expansion

with the system and method taught in the '941 (*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** or **Svanidze**, it is difficult, if not impossible, to explain "why the Examiner allowed the claims" or "how the Examiner might have considered the arguments presented in the Petition" and §325(d) discretion should not be exercised. *Bowtech, Inc. v. MCP IP, LLC,* IPR2019-00379, Pap. 14, *20 (declining to exercise discretion).

Fourth, the Examiner erred in failing to consider a combination of **Leonhardt** with a reference (1) disclosing an expansion balloon allowing blood flow to the valve during prosthesis expansion—such as **Bailey** (Grounds 1-4), or (2) disclosing lateral distal openings in the catheter to maintain blood flow while the proximal end of the prosthesis is still within the catheter during deployment—such as **Seguin** (Grounds 2, 4). Such combinations render the Challenged Claims obvious. *See* §X. For at

[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 at this point 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.

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 IPR2021-00241, IPR2021-00310, IPR2021-00243, IPR2021-00242, IPR2021-00239, and IPR2021-00244 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 in this IPR. 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. Moreover, the Petition challenges at least one claim not at issue in the litigation. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong as shown herein, particularly considering Applicant's admissions during prosecution that the majority of limitations were disclosed by Leonhardt (*see* '941FH, 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 in the Examiner's analysis. Additionally, the Petition presents arguments not substantially the same as those previously before the Office.

The Board should not exercise its discretion to deny institution.

VIII. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art ("POSITA"), at the purported time of invention, would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor's degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education. Drasler ¶¶32-35.

IX. CLAIM CONSTRUCTION

Claim terms subject to IPR are construed using the *Phillips* standard. §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Only terms necessary to resolve the controversy need construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Because

the prior art asserted herein discloses embodiments within the Challenged Claims' indisputable scope, the Board need not construe the claims' outer bounds, while the district court may need to in addressing other issues, *e.g.*, infringement. All claim terms should be construed according to their plain and ordinary meaning as would have been understood by a POSITA in view of the specification. Drasler ¶83.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X.A.3[17.pre]; Drasler ¶84.

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

Regardless of the exact metes and bounds of this term (i.e., "vicinity"), the prior art discloses this limitation. *See* §X.A.3.[17.1]-[17.2], [26.2]-[26.3]; Drasler ¶¶85-86.

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

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

In contrast to claim 17's "expansion" limitations, PO chose to qualify the expansion limitations in dependent claims 26 and 30 and in claims of '941's parent. '941, cls. 26 ("fully expanded"), 30 ("initially expanded"); Ex. 1013 (USP 8,377,118), cls. 6 ("during the entire expansion"), 7 ("at least partially during expansion"); Drasler ¶89.[7] Such qualifiers should not be read into the Challenged Claims. *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1313 (Fed. Cir. 2011) (declining to limit a term to the "one-piece" modifier "explicitly" used in patent's dependent claims).

The plain and ordinary meaning is consistent with the specification. For example, as discussed in §V, the specification discloses expanding/inflating, collapsing/deflating and re-expanding/re-inflating the prosthesis as well as its proximal and distal ends at multiple different points in time. 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 ("The device is then fully inflated."), 77:52-53 (same), 75:30-31 ("The device is then fully inflated, enabling the valve to function."), 75:33-35 ("the valve may be partially deflated, and advanced or retracted, and then reinflated or the valve may be

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

fully deflated and retracted…"), 77:55-57 (same), *see also* 5:49-55, 50:50-52, 51:5-10, 51:18-24. It thus would be improper to read in any limitation requiring, *e.g.*, that "expansion" must be a first, complete, full, partial, or continuous expansion. *Retractable*, 653 F.3d at 1313 (use of modifier in written description implies that term "standing alone" is not inherently limited).

The plain and ordinary meaning is consistent with the file history. PO amended claim 17 (prosecution claim 46) to recite "wherein during expansion of the carrier element, a distal end of the carrier element is *fully* expanded prior to a proximal end…being *fully* expanded." '941FH, 1705-1706 (emphasis added); Drasler ¶91. The Office rejected the amended claim because "[t]he specification does not describe a distal end of the carrier element being *fully expanded* prior to a proximal end…being fully expanded." '941FH, 1727-28 (emphasis in original) (also quoting '941, 74:43-50 (disclosing that the valve is "fully inflated" after being withdrawn across the native valve annulus)); *see also* '941, Fig. 47A-E. PO subsequently removed the term "fully" from the claim. '941FH, 1752-1754, 1761; *see SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1318 (Fed. Cir. 2015) (declining to limit claim term broadened during prosecution).

PO's argument during prosecution that Leonhardt does not teach the limitation requiring unidirectional blood flow "prior to expanding the proximal end of the first carrier element" because the "valve in Leonhardt is <u>not</u> operational until

it fully exits the deployment catheter 100 to expand the proximal end" ('941FH, 1761) similarly does not limit the scope of the claims. Drasler ¶¶92-93. First, PO's argument is wrong for the reasons discussed in §X.A.1-3 (Leonhardt expressly discloses the valve "function[s]" prior to expanding the proximal end with the tip balloon) and §X.A.4 (blood flows through the proximal fingers of Leonhardt's prosthesis prior to any expansion of the proximal end). Second, such a construction is also inconsistent with the '941 specification, which never discloses a valve functioning before any expansion of the proximal end as discussed in §V (specification teaches valve functioning after full expansion; proximal extensions permit valve to be repositioned after full expansion). *See also* §VI and n.6 (supra). Third, PO's argument does not contain any expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.

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

The prior art discloses these limitations under their plain and ordinary meaning. *See* §§X.A.3.[17.2]-[17.3]; Drasler ¶94. But even under a narrower interpretation, wherein, e.g., "prior to…expanding the proximal end" means prior to the first proximal end expansion, the Challenged Claims are still rendered obvious. *See* §§X.A.4, X.B.

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 prosthetic valve to the native heart valve, and (2) expanding it from a collapsed to an expanded configuration, such methods were well-known. As explained below, the Challenged 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 prior to 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 in a subsequent balloon expansion. **Bailey** teaches a balloon (for expansion and valvuloplasty) that permits blood flow even when expanded and **Seguin** teaches lateral distal openings in the catheter to allow continued blood flow even when the proximal end of the prosthesis is still within the catheter—each teaching enabling **Leonhardt**'s prosthesis to allow unidirectional blood flow during expansion and partial deployment.

Leonhardt in view of **Bailey** discloses the same functionality taught in the '941 patent (valve operation during secondary balloon expansion). *See* §§V, X.A.1-3. And even if PO argues the Challenged Claims are limited to functionality not

described in '941 (*e.g.*, valve operation before any proximal end expansion), **Leonhardt** in view of **Bailey** alone and in further view of **Seguin** still renders such claims obvious. See §§X.A.4, X.B. In addition, **Svanidze** discloses support posts for added valve/stent stability for claim 27. *See* §X.C.

The prior art renders the Challenged Claims unpatentable. This Petition is supported by the Declaration of William J. Drasler, Ph.D., which describes the prior art's scope and content at the time of the alleged '941 invention. Drasler (Ex. 1002) ¶¶1-325.

A. Ground 1: Claims 17 and 19-26 Are Rendered Obvious by Leonhardt in View of Bailey

1. Overview of Leonhardt

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

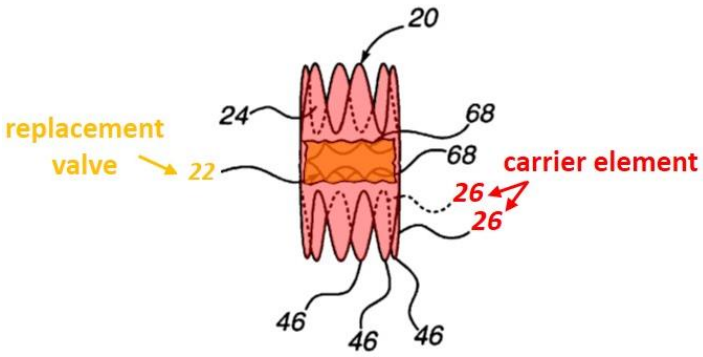


FIG. 4

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

Leonhardt discloses deploying a valve/stent at a "placement site," *i.e.*, a native heart valve, such as the mitral valve (Leonhardt, 10:22-30, Figs. 2, 9A-9D) or the aortic valve (Leonhardt, 9:63-10:6). Leonhardt, 6:36-38; Fig. 2. Valve stent 20 is transluminally advanced to the site in a collapsed state. Leonhardt, 9:49-54, 10:6-11. A flexible guide wire with a tip balloon is inserted through an entry point and advanced to the placement site. Leonhardt, 10:3-11. The collapsed valve/stent is loaded into the outer sheath of a deployment catheter, which is inserted over the flexible guidewire and advanced to the placement site. Leonhardt, 6:57-65, 9:50-55, 10:6-11. During deployment catheter insertion, the tip balloon may be partially inflated to perform valvuloplasty. Leonhardt, 10:11-16. Once the deployment catheter is positioned, deployment of valve stent 20 is "procedurally the same for all potential placement sites," including mitral and aortic valves. Leonhardt, 10:43-44;

Drasler ¶103. The outer sheath is withdrawn from the stent's distal end to initiate deployment of the valve stent's distal end. Leonhardt, 10:53-58.

When **Leonhardt's** valve stent is placed at the aortic valve, the delivery catheter containing the prosthesis is transluminally advanced in the retrograde direction (against blood flow): entry is made through the largest femoral artery and the prosthesis is advanced either into the aorta immediately above the aortic valve or further into the left ventricle immediately past the aortic valve. Leonhardt, 9:63-10:6; Drasler ¶104. For aortic valve prostheses, 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. Leonhardt, 11:5-14; *see also* Bailey, Fig. 6A (below, to illustrate anatomy); Drasler ¶104.

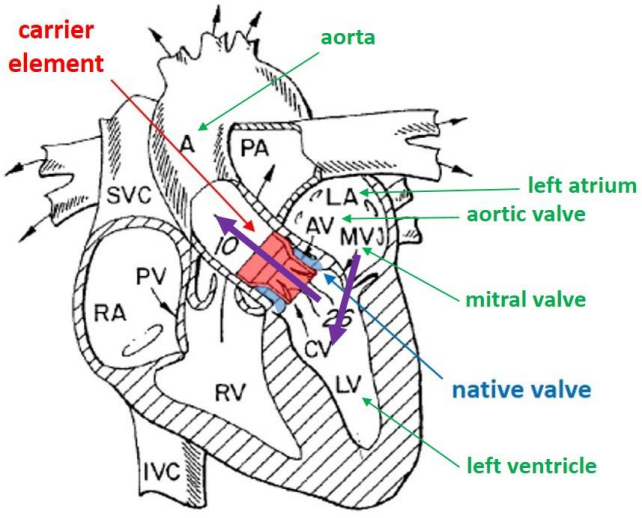


Fig. 6A

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

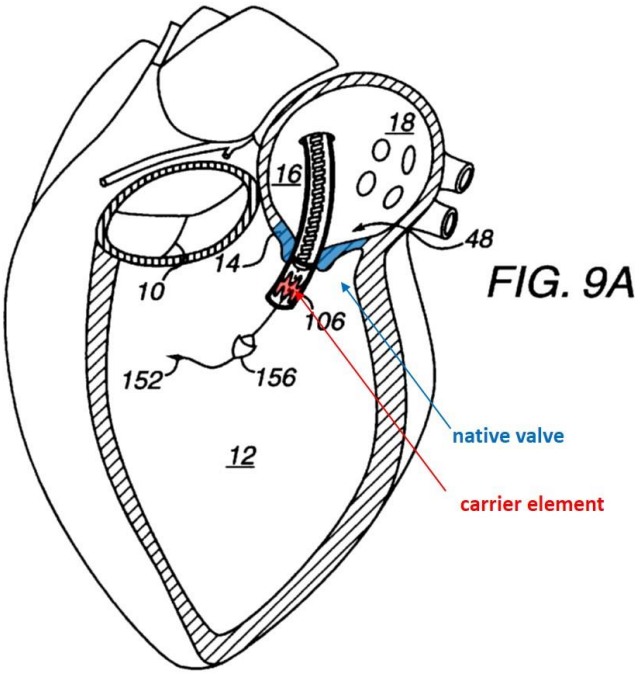


FIG. 9A

When the sheath is withdrawn from a portion of the stent, that portion self-expands due to its "continuous outward force." Leonhardt, 10:55-58, 11:34-35. Thus, the

first valve/stent expansion occurs when the sheath is initially retracted from the stent's distal end, permitting the distal distensible fingers to expand against the vasculature, as shown in Figure 9B (mitral deployment) below. Leonhardt, 10:53-58, Drasler ¶¶106-107.

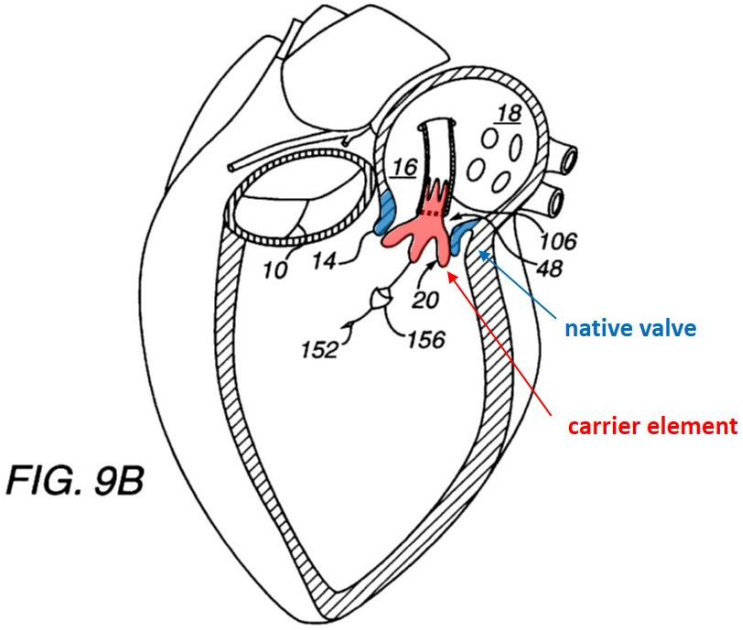


FIG. 9B

Leonhardt then employs a ***second*** mechanism: valve/stent expansion using expansion balloon 154. Expansion balloon is positioned at the stent's distal end, without overlapping the valve. Leonhardt, 10:64-67 (explaining that the valve's

base "must be free from contact" with the balloon); Drasler ¶108.[8] Expansion balloon is inflated "to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue" ensuring that "proper placement is maintained during the remainder of [] deployment" and that "valve stent 20 [molds] itself quickly to the living tissue at the placement site [to] achieve a patent seal," as shown in Figure 9C. Leonhardt, 11:3-9; Drasler ¶108.

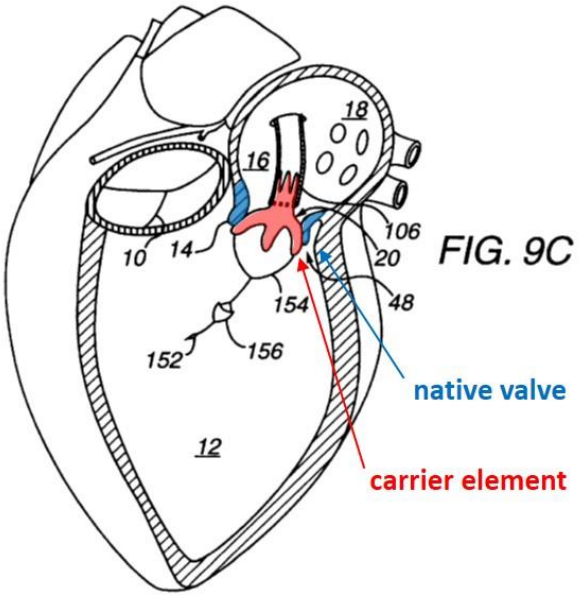


FIG. 9C

Leonhardt then relies on the self-expansion mechanism again—with the expansion balloon holding the distal end in place, the sheath is completely retracted,

[8] Leonhardt discloses that the leaflets "may" be "slightly overlapped" by the balloon—an optional teaching not relied upon herein. Leonhardt, 10:64-67; Drasler ¶108.

allowing self-expansion of the valve/stent's remainder. Leonhardt, 11:10-15; Drasler ¶109.

After the sheath is fully retracted from valve/stent and self-expansion is complete, proper placement is verified. Leonhardt, 11:10-15; Drasler ¶110.

Leonhardt then again uses the expansion balloon mechanism to expand the stent's proximal end. Expansion balloon is "deflated" and the inner catheter withdrawn to position "expansion balloon 154…on the proximal side of the biological valve but within proximal end of valve stent 20 just deployed." Leonhardt, 11:14-19. Expansion balloon further expands the stent's proximal side: it is "inflated again to seat the proximal end of valve stent 20" and then deflated (*see* Figure 9d below) and withdrawn. Leonhardt, 11:16-19, 9:63-10:6; Drasler ¶111.

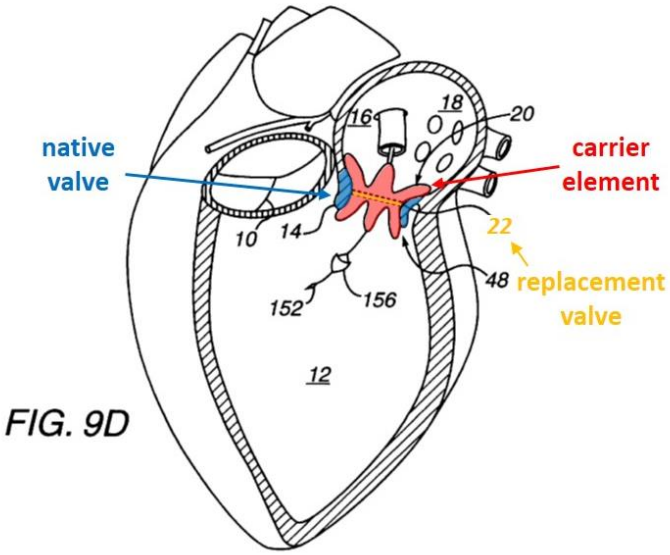


FIG. 9D

At this point, **Leonhardt** expressly teaches that the valve is functional such that "[v]alve stent 20 is now monitored for proper function and patency." Leonhardt, 11:23-30; Drasler ¶¶ 112-113.

Leonhardt teaches a ***third*** valve/stent expansion mechanism after checking for function: the tip balloon. After the valve is "function[ing]" and thus allowing for unidirectional blood flow, tip balloon 152 "may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue." Leonhardt, 11:28-33. When tip balloon is advanced to the stent's proximal end, the catheter and guidewire are proximal the valve—and neither the catheter nor guidewire passes through the replacement valve itself. Leonhardt, Figs. 5, 9A-D; Drasler ¶114. **Leonhardt's** tip balloon expansion procedure for the carrier element distal and proximate ends after the valve is "function[ing]" mirrors that of the '941's "additional dilatation" of the carrier element with a balloon, which occurs after the valve is functioning. '941, 75:1-3; *see* §V; Drasler ¶114.

"[O]nce properly placed, valve stent 20 function and leakage are verified" and, if necessary, valve stent 20 can be "retriev[ed] for repositioning or removal" regardless of "whether valve stent 20 is fully or partially deployed" by means of sutures. Leonhardt, 11:37-60, Figs. 7A-7B. Valve stent 20 is collapsed by "tak[ing] up slack in suture loops 174," causing the tips of valve stent 20's proximal end's distended fingers 46 to move radially inward until "distended fingers 46…are

compressed to the diameter of outer sheath 106." Leonhardt, 11:37-58. When the valve stent is repositioned, the same process described above is used to place and expand the valve/stent. Leonhardt, 11:37-60; Drasler ¶¶115-120. As shown in Figure 2 below, fully deployed and expanded valve stent has a non-cylindrical profile: both ends are wider in diameter than the valve's central portion as the valve stent "flair[s]" at one or both ends. Leonhardt, 3:33-38, 4:63-65, 6:9-23, 9:63-10:6, Figs. 2, 9d. Once the valve/stent is deployed in the proper position, the catheters are withdrawn. Leonhardt, 11:63-64, 12:4-5; Drasler ¶121.

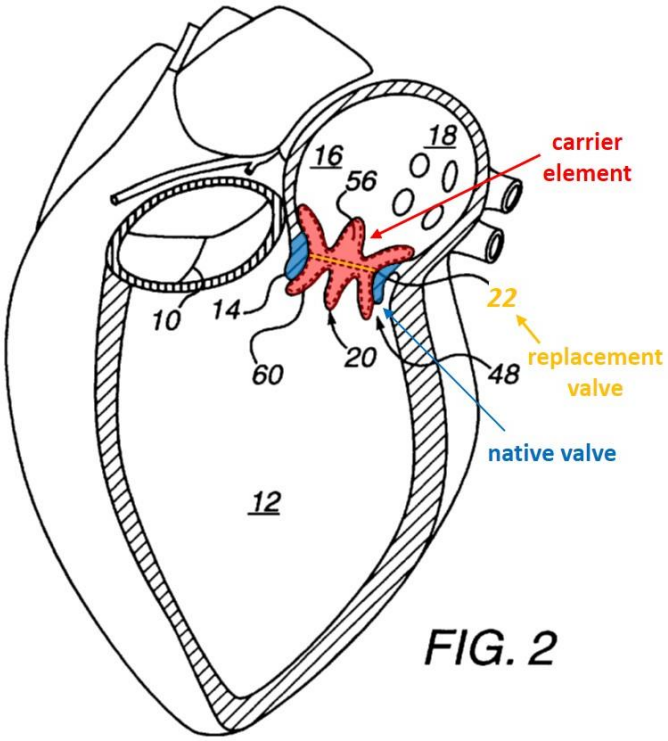


FIG. 2

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

While **Leonhardt** teaches unidirectional blood flow once valve/stent 20 is seated and the sheath retracted, blood flow is occluded when tip balloon 152 or expansion balloon 154 is expanded. **Bailey** instead discloses an expansion balloon that permits blood flow through it when fully expanded and that can be used to expand transluminally-delivered prosthetic heart valve stents. Bailey ¶¶[0070], [0072]. **Bailey** expressly cites and seeks to improve upon **Leonhardt**'s valve and delivery method. Bailey ¶¶[0006], [0018]; Drasler ¶123. Specifically, **Bailey** discloses an expansion balloon with "irregular inflation profiles" or "channels or ridges on the ablumenal surface of the balloon" to "facilitate continuous blood flow about the inflated balloon" during expansion of a transluminally-delivered expandable prosthetic heart valve. Bailey ¶¶[0070], [0072]; Drasler ¶123. Bailey discloses that this balloon can be used to "permit a quantum of blood flow to pass around [a] balloon in its inflated state" such that the balloon "does not fully occlude the anatomic lumen when inflated." Bailey ¶[0070]. The balloon may be used for valvuloplasty (*see* Figure 20B below) or for stent expansion during percutaneous and transluminal valvuloplasty and prosthesis implantation using a single catheter (*see* Figure 19 below). Bailey, Abstract, ¶¶[0069]-[0070], [0072]; Drasler ¶123.

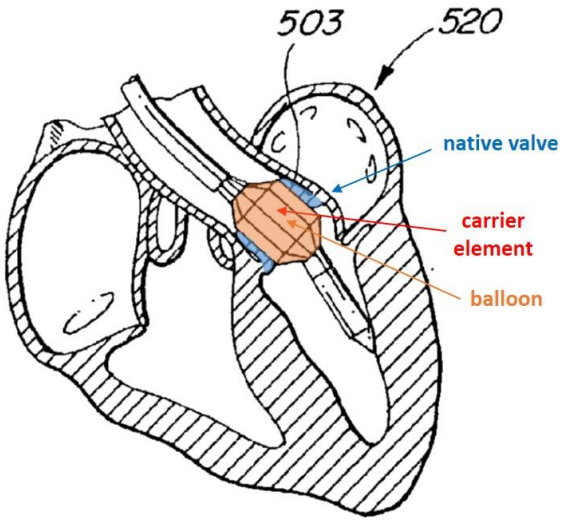


Fig. 20B

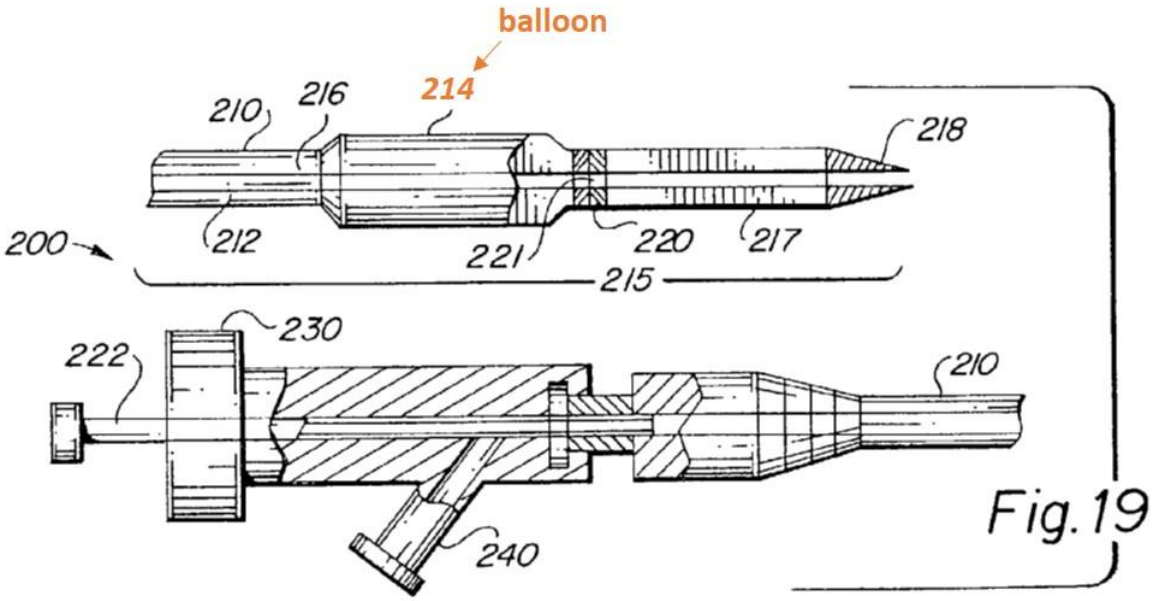


Fig. 19

Leonhardt and **Bailey** are in the same field as the '941—prosthetic cardiac implants—and are reasonably pertinent to the alleged problem(s) identified in the '941: needing a method of treating a patient using an expandable prosthesis. '941, 3:55-59, 3:65-4:3; Leonhardt, 11:3-40; 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.

Bailey seeks to improve upon **Leonhardt**'s valve. Bailey ¶¶[0006], [0018]-[0019] ("Disadvantages of [Leonhardt's] device include…***complex delivery system and method***…***"*** "[T]here remains a need for…a ***single catheter delivery system and with short duration atraumatic procedure***..."); Drasler ¶126. Although **Bailey** refers to multiple Leonhardt "[d]isadvantages", **Bailey** identifies only one as of "questionable clinical utility and feasibility": light actuated anchoring means. Bailey, [0018]. **Leonhardt** teaches that such means are **optional**. Leonhardt, 3:41-45 ("***may*** be"), 8:42-45 ("preferred ***options***"). A POSITA reading these references would have been motivated to improve **Leonhardt** with **Bailey**'s teachings, using embodiments without such a mechanism. Drasler ¶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 Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (finding no teaching away when teaching described as "inferior," but "usable").

When **Bailey**'s balloon teachings are applied to **Leonhardt**'s expansion/tip balloons, **Leonhardt**'s balloons advantageously no longer occlude flow when

expanded, a benefit both references recognized and was well-known in the art. **Leonhardt** describes as beneficial procedures that are less traumatic/invasive and require less recuperation time (Leonhardt, 3:15-29) and describes problems resulting from blood flow obstructions, including their sudden removal (Leonhardt, 11:26-28 ("damage to the downstream vessels and migration of valve stent")). Drasler ¶127. Leonhardt teaches minimizing the consequences of obstructing blood flow.[9] Leonhardt, 9:61-62 (slowing heart or dropping pressure), 11:23-29 (avoid sudden pressure changes); Drasler ¶128. **Bailey** sought to overcome that disadvantage of temporarily obstructing blood flow by advantageously teaching a stent expansion balloon that does not obstruct blood flow even when fully expanded, thus avoiding any occlusion and further reducing risk. Bailey ¶¶[0018]-[0019] (proposing improvements over Leonhardt for "atraumatic procedure"), [0070], [0072]; Drasler ¶128. The benefits of minimizing obstruction were well-known. *See* Ex. 1015, [0005]-[0008] (Eigler, filed 7/28/2003) (identifying benefits of allowing blood flow and a beating heart during valve repair, including avoiding "death, severe injury, and disability"); Ex. 1016, [0013] (Downing, published 10/31/2002) (noting benefit of avoiding "need for cardiopulmonary bypass"); Drasler ¶¶127-128.

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

A POSITA would have had a reasonable expectation of success in applying **Bailey**'s teachings of an expansion balloon permitting blood flow when inflated to **Leonhardt**'s balloons. Drasler ¶129. **Leonhardt** already teaches using an expansion balloon to expand valve/stent 20's ends and a POSITA would have found it obvious to use a balloon with "channels," "ridges," or an "irregular inflation profile[]" as disclosed in **Bailey** to permit blood flow when inflated. Bailey ¶[0070]; Leonhardt, 11:29-30; Drasler ¶129; *see also* Ex. 1017, [0065] (Yang, published 3/13/2003) (disclosing a "star shape[d]" "stabilization balloon" to "permit[] blood flow in the expanded configuration" for "beating heart surgeries"). **Bailey**'s and **Leonhardt**'s balloons are delivered similarly (transluminally delivered attached to a catheter) and are used for the same purposes (valvuloplasty and valve/stent balloon expansion). Bailey, ¶¶[0070]-[0072]; Leonhardt, 7:55-63, 10:13-16, 11:3-5, Fig. 5; Drasler ¶130. A POSITA would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶130.

3. Claim Chart

'941 Patent	**Leonhardt in view of Bailey**
[17.pre] "A method for replacing a patient's native heart valve, the	**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:**

method comprising:"	**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. It opens and closes with pressure or flow changes.") • 1:21-22 ("Cardiac valve prostheses are well known in the ***treatment of heart disease***.") • Abstract ("A method of implanting the artificial valve…") Drasler ¶¶131-133.
[17.1] "delivering an expandable carrier element and a replacement valve endovascularly to a vicinity of the native heart valve; and"	**Leonhardt discloses delivering an expandable carrier element** (*e.g.*, "deformable self-expanding stent") **and 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* [17.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.") • 10:6-11 ("Deployment catheter 100…is then inserted through the entry point and into the patient… ***slowly advancing the deployment catheter 100 to the placement site***.") • 9:63-67 ("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.") • 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.") • 5:46-52 ("Valve stent 20 comprises a malleable graft material 24 enclosing ***deformable self expanding stent*** **26** to which a biological valve 22 is attached. Stent 26 biases the proximal and distal ends…into conforming and sealingly fixed engagement with the tissue of mitral valve 14.") • *See also* 10:18-21 Drasler ¶¶134-136.
[17.2] "expanding the carrier element from a collapsed delivery configuration to an expanded configuration to secure the carrier element in the vicinity of the native heart valve,	**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 expanded configuration** (*e.g.*, "deployment of valve stent 20") **to secure the carrier element 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 carrier element, a distal end of the carrier element is expanded prior to a proximal end of the 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 proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue")**, the proximal end of the carrier element being expanded** (*e.g.*, "expansion balloon 154 may then be

wherein during expansion of the carrier element, a distal end of the carrier element is expanded prior to a proximal end of the carrier element being expanded, the proximal end of the carrier element being expanded without urging the proximal end of the carrier element toward the distal end of the carrier element;"	inflated again," "further mold valve stent 20 to the living tissue") **without urging the proximal end of the carrier element toward the distal end of the 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 "aorta or aortic valve" or "at [the] mitral valve," wherein valve stent 20 is delivered in a "collaps[ed]" condition in "deployment catheter." Leonhardt, 6:57-61, 10:44-45. After initial placement and expansion (*id.*, 10:53-11:22), the "function and patency" of valve stent 20 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 the distal and proximal ends of valve/stent 20 during its placement. *Id.* 5:32-33. Expansion occurs "without urging the [carrier element'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 pushing; 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, ¶139. • Fig. 1A-1B

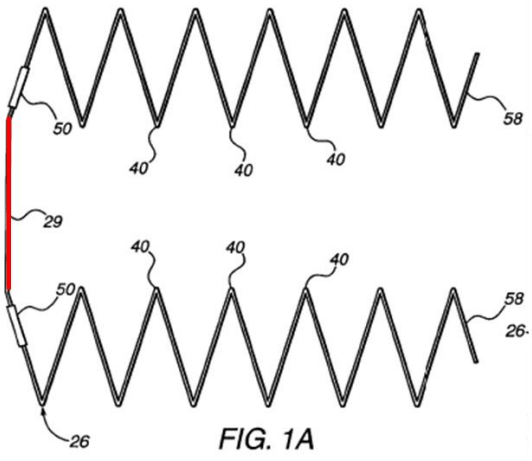


FIG. 1A

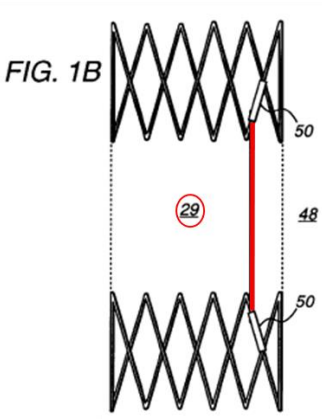


FIG. 1B

- Fig. 2

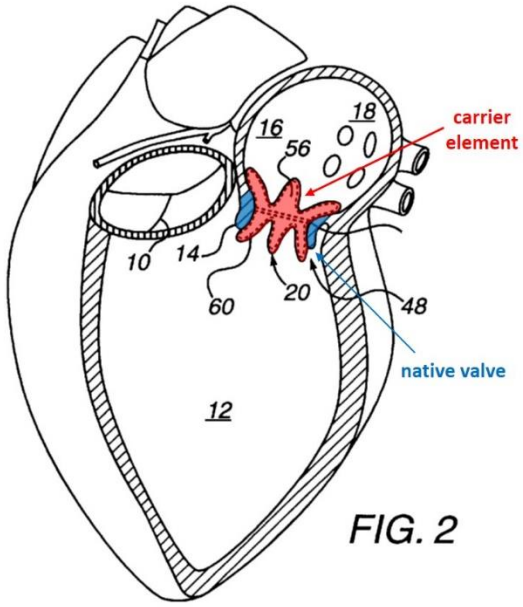
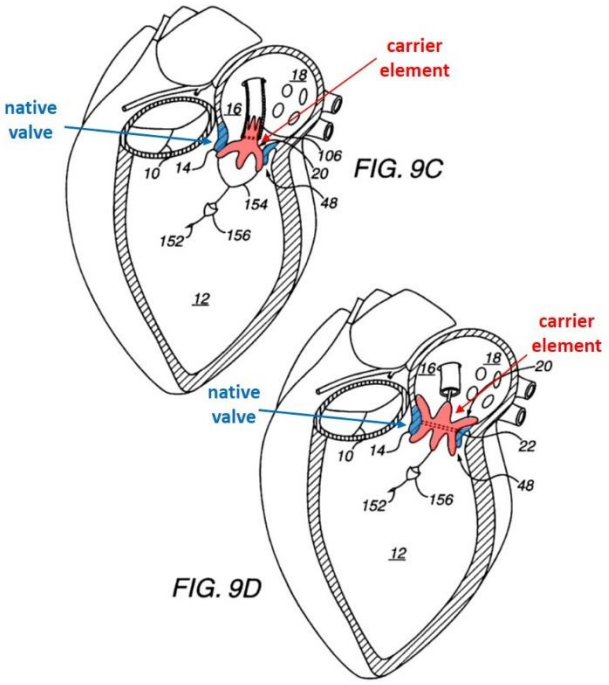


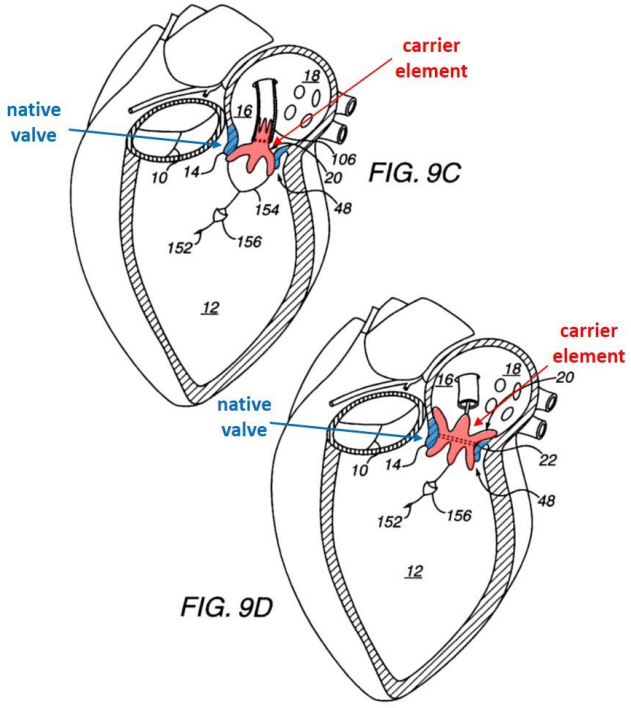
FIG. 2

- Fig. 9C-9D



- 5:41-42 ("FIG. 2 presents a complete pre-sized valve stent 20 ***fully deployed in the location of mitral valve*** **14**.")
- 10:22-23 (*see* [17.1])
- 7:10-11 ("Biological valve 22 should be in an open position when valve stent 20 is ***loaded into outer sheath*** 106.")
- 5:46-52 (*see* [17.1])
- 9:64-67 (*see* [17.1])
- 10:44-45 ("From this point on, ***deployment of valve stent 20*** is procedurally the same for all potential placement sites.")
- 10:48-58 ("***Deployment catheter*** 100 is positioned so outer sheath 106 is extending through mitral valve 14… ¶ Deployment of the distal end of valve stent 20 is initiated by withdrawing outer sheath 106 approximately 11 to 13 mm while holding push rod 112 stationary. Distensible fingers 46 on the distal end of valve stent 20 will distend as the distal end is released from outer sheath 106 as is shown in FIG. 9b.")

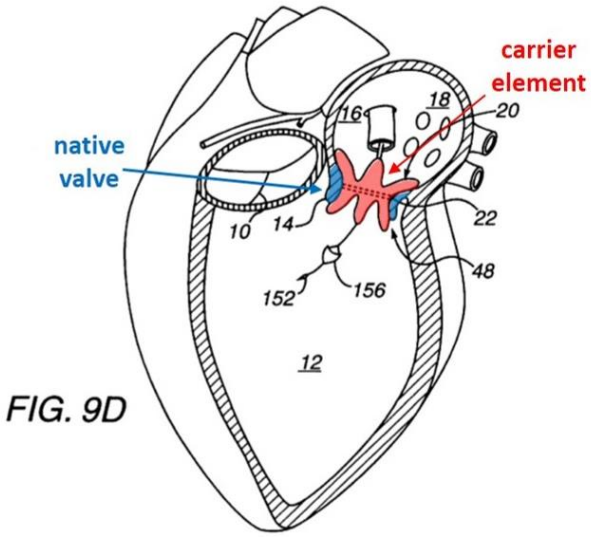
	• 11:28-36 ("Valve stent 20 is now monitored for proper function and patency.…***Tip balloon 152*** or expansion balloon 154 ***may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue if necessary***.") • 11:20-22 ("***Expansion balloon 154 may then be inflated again*** to seat the proximal end of valve stent 20 just deployed.") • 5:32-33 ("***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, 4:56-65, 9:64-67, Figs. 9a-9b. Drasler ¶¶137-139.
[17.3] "wherein the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction during the expansion of the carrier element, after expanding the distal end of the carrier	**Leonhardt discloses that the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction** (*e.g.*, **"**artificial valve… maintain[s] bodily fluid flow in a single direction") **after expanding the distal end of the carrier element, and prior to expanding the proximal end of the 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:** **Leonhardt** discloses that the "artificial valve" "function[s]" to "maintain bodily fluid flow in a single direction" after it is initially expanded and before "tip balloon 152" is again "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue" and again moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue." *Id.* 1:11-14, 5:51-52, 11:24-27, 11:29-30, 11:32-36. By further "mold[ing]" the valve stent to the tissue, the tip balloon expands the

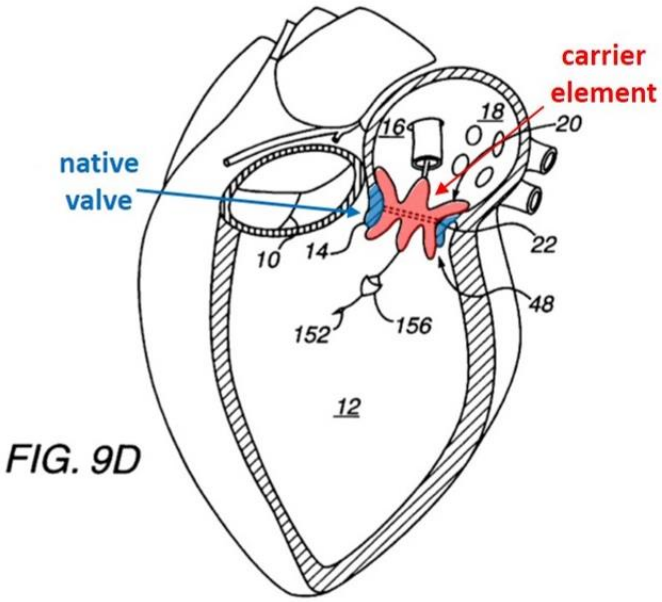
element, and prior to expanding the proximal end of the carrier element."	proximal and distal ends of the valve stent. *Id.* Meanwhile, the valve is "function[ing]" to "maintain bodily fluid flow in a single direction." *Id.* When the tip balloon is in the proximal end of the valve stent, there is no catheter or guidewire running through the replacement valve. *Id.*, 1:11-14, 5:51-52, 11:24-27, 11:29-30, 11:32-36, Figs. 5, 9A-D; Drasler ¶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 ¶¶ 112, 142. • Figures 9C-9D  FIG. 9C FIG. 9D • 7:17-19 ("Valve stent 20 is loaded either end first into outer sheath 106, the correct choice depending upon the access path taken and the fluid flow direction at the placement site.") • 12:28-30 ("…[A] valve means ***capable of blocking flow in one direction***…") • 1:11-14 (*see* [17.pre])

	• 11:29-36 (*see* [17.2]) • 3:15-29 ("The need remains for an artificial heart valve…***which does not require***…stopping the heart or ***using a heart-lung machine during placement***….") • 5:51-52 ("The ***deployed valve stent 20 creates a patent one way fluid passageway***.") • *See also* 1:6-9, 7:61-63, 9:63-10:6, 10:18-21, 11:24-27, Fig. 9a and Fig. 9b. **Bailey discloses a replacement valve allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve** (e.g., "balloon expansion of the deployed stent valve" using "irregular inflation profiles" to "facilitate continuous blood flow about the inflated balloon"). ***E.g.*, Bailey:** While **Leonhardt's** tip balloon does not allow blood flow through the prosthesis during balloon valve expansion, **Bailey** discloses an expansion balloon that uses "irregular inflation profiles" to "facilitate continuous blood flow about the inflated balloon." Bailey ¶[0070]. Thus, **Bailey** discloses allowing blood flow through the valve/stent during valve/stent expansion. *Id.*; Drasler ¶144. As discussed in §X.A.2, a POSITA would have been motivated to modify **Leonhardt's** tip balloon in view of **Bailey** to permit balloon expansion while allowing blood flow through the valve/stent during expansion. Drasler ¶¶145, 124-130. For example, in applying **Bailey's** teachings, **Leonhardt's** tip balloon would allow blood flow through the valve/stent such that it can continue to "function" to "maintain bodily fluid flow in a single direction" during proximal end expansion of **Leonhardt's** valve stent to further "mold" it to the tissue. Leonhardt, 1:11-13, 11:29-30, 11:32-34; Drasler ¶145. When the tip balloon is used for proximal end expansion of the valve/stent, no catheter or guidewire is protruding through the

	stent—thus allowing it to "function" and "maintain bodily fluid flow in a single direction." Drasler ¶145.[10] • ¶[0070] ("…Alternatively, it may be advantageous to ***configure the balloon such that it does not fully occlude the anatomic lumen when inflated, but permits a quantum of blood flow to pass around the balloon in its inflated state.*** This may be accomplished by providing channels or ridges on the ablumenal surface of the balloon. Additionally, irregular inflation profiles of the balloon may facilitate continuous blood flow about the inflated balloon.") • ¶[0072] ("….***This would also allow for post-deployment balloon expansion of the deployed stent valve without the need to traverse the prosthetic valve in a retrograde fashion.***") • *See also* ¶¶[0021], [0048]. Drasler ¶¶140-146, 124-130.
[19] "The method of claim 17, wherein the carrier element	***See* [17].** **Leonhardt discloses that the carrier element is configured to conform to the patient's anatomy upon expansion** (*e.g.*, "valve

[10] The combination of **Leonhardt** and **Bailey** renders obvious the '941's only disclosure of a valve functioning when deployed "at the native valve" ([17.2]) during carrier element 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 of the annulus and seated properly." *See* §V, §VII, §IX.C, n.6; '941, 74:13-21, 75:1-3; Drasler ¶146.

is configured to conform to the patient's anatomy upon expansion."	stent 20" is "capable of substantial deformation so as to conform to the interior surface of a patient's internal passage")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses that "valve stent 20" is configured to substantially deform "so as to conform to the interior surface of a patient's internal passage." • Fig. 9D  FIG. 9D • 5:48-52 (*see* [17.2]) • 6:19-22 ("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***.") • 4:60-65 ("The super elasticity of the material allows it to deform to forces exerted on it only at those points experiencing the deforming force. All other points will seek their permanent shape. This allows ***stent 26 to conform to and seal against the dramatically different structures occurring within vessel walls and valve locations with one basic stent shape***.") Claim 1 ("***A percutaneously implanted valve stent*** comprising:***...graft***…***capable of substantial deformation so as to***

	conform to the interior surface of a patient's internal passage….") Drasler ¶¶147-149.
[20] "The method of claim 17, wherein the only native anatomical feature displaced by the carrier element is the native valve."	***See* [17].** **Leonhardt discloses that the only native anatomical feature displaced by the carrier element is the native valve** (*e.g.*, "deploy[ing]" "valve stent 20" "in the location" of the existing valve by displacing native leaflets)**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses that valve/stent 20 is "deployed in the location of mitral valve 14" or "aortic valve 10." Leonhardt, 1:6-8, 5:41-45, 9:63-67, Figs. 2, 9D. As illustrated in Figs. 2, 9D, no anatomical feature other than the "existing valve[]" is displaced. *Id.* 1:6-8, 3:15-30. • Fig. 9D  FIG. 9D • 5:41-45 ("FIG. 2 presents ***a complete pre-sized valve stent 20 fully deployed in the location of mitral valve 14***….***Mitral valve 14 has been prepared for deployment by valvuloplasty to remove plaque and fistulas*** if necessary.")

	• 6:19-22 (*see* [19]) • 9:63-67 (*see* [17.1]) • 10:22-23 (*see* [17.1]) • *See also* 1:6-8, 3:15-30, 5:32-61, 10:53-11:9, 6:16-22, 11:30-34, Fig. 2. Drasler ¶¶150-152.
[21] "The method of claim 17, wherein proximal and distal ends of the carrier element form a seal with respective native anatomical features proximate opposing sides of the native valve."	***See* [17].** **Leonhardt discloses that proximal and distal ends of the carrier element form a seal with respective native anatomical features proximate opposing sides of the native valve.** (*e.g.*, "the proximal and distal ends of valve stent 20 in[]…sealingly fixed engagement with the tissue of mitral valve 14")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "the proximal and distal ends of valve stent 20" seal against "the tissue of mitral valve 14." Leonhardt, 5:48-52, 6:19-22, 4:60-65. Because valve/stent 20 is "deployed in the location of mitral valve 14," valve stent 20's proximal and distal ends coincide with native anatomical features proximate mitral valve 14's opposite sides. *Id.* 5:41-45, Figs. 2, 9D. • Fig. 9D

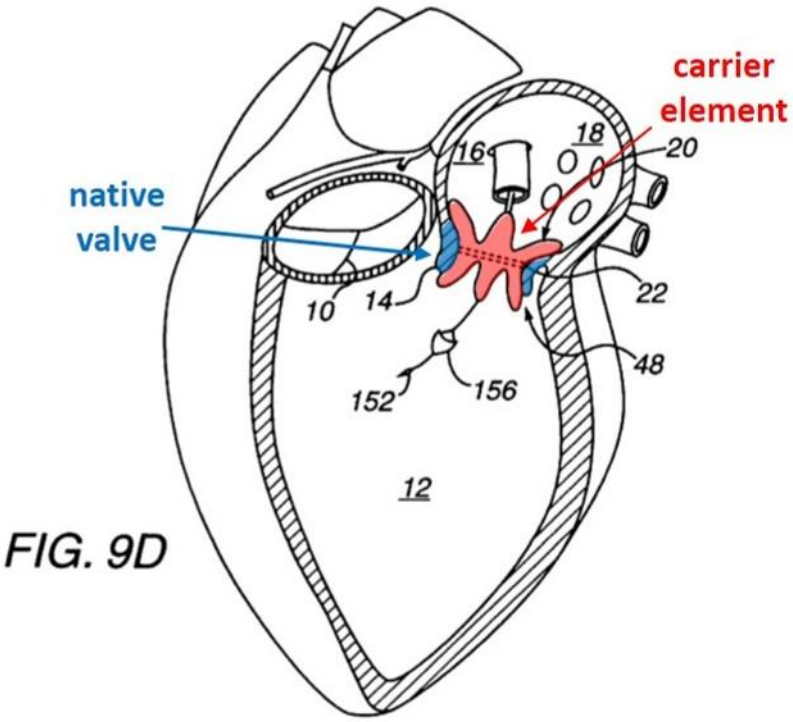
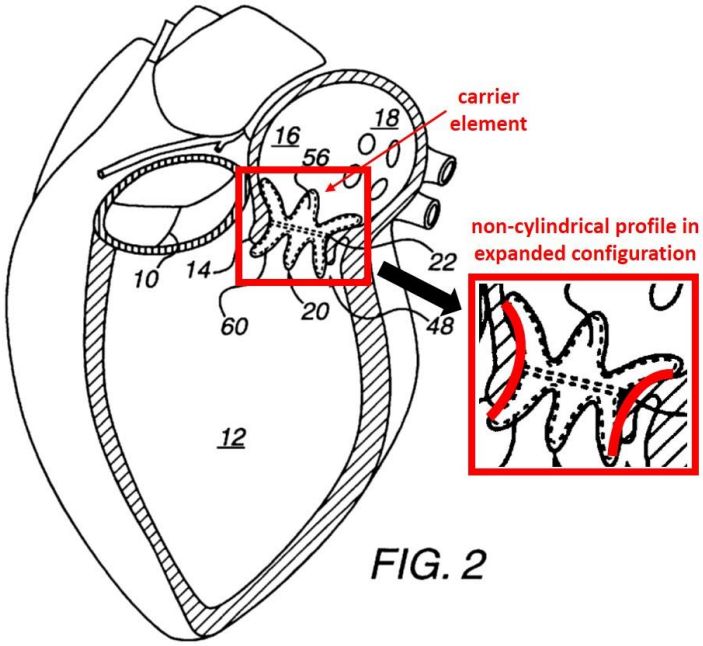


FIG. 9D

- 5:48-52 (*see* [17.2])
- 6:19-22 (*see* [19])
- 4:60-65 (*see* [19])
- 5:41-45 (*see* [20])
- 3:15-18 ("The need remains for an artificial heart valve which…will ***seal at the outside wall of the valve with the living tissue*** of the patient…")
- *See also* 3:42-45, 5:32-61, 11:3-9, 12:11-13, Fig. 2.

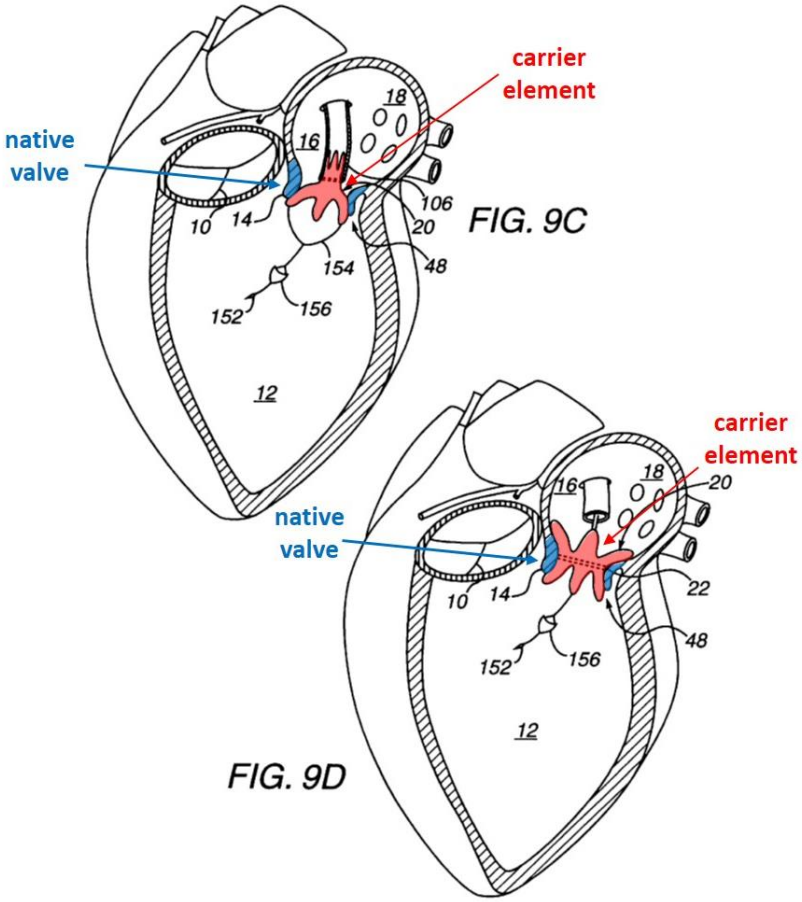
Drasler ¶¶153-155.

[22] "The method of claim 17, wherein the	***See* [17].**

carrier element has a non-cylindrical profile in the expanded configuration."	**Leonhardt discloses that the carrier element has a non-cylindrical profile in the expanded configuration** (*e.g.* "valve stent 20 must flair at one or both ends as is shown in FIG. 2")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses a "valve stent 20," which "conform[s] to and seal[s] against the dramatically different structures occurring within vessel walls and valve locations" such that either end "flairs" radially outward from its central portion. • Fig. 2  FIG. 2 • 6:9-23 ("Where other vessels or passages leave the vessel receiving valve stent 20 at a placement site, or when ***valve stent 20 must flair at one or both ends as is shown in FIG. 2***, graft material 24 may be cut out between the plurality of distensible fingers 46 formed by zig-zags 40 of stent 26….***Stent 26*** is pre-sized to open beyond the width of the natural valve mouth and ***will flair sufficiently to conform and seal to the tissue***.") • 5:46-48 (*see* [17.2])

	• 4:63-65 (*see* [19]) • 5:59-61 ("The middle portion of graft material 24 is tapered to a smaller cross-sectional area than its ends to prevent bunching of the material once placed within the patient.") • *See also* Fig. 9d. Drasler ¶¶156-158.
[23] "The method of claim 17, wherein a proximal portion of the carrier element extends further radially outwardly than a central portion of the carrier element."	***See* [17].** **Leonhardt discloses that a proximal portion of the carrier element extends further radially outwardly than a central portion of the carrier element** (*e.g.*, "valve stent 20 must flair at one or both ends as is shown in FIG. 2")**.** See [22]. Drasler ¶¶159-160.
[24.1] "The method of claim 17 further comprising: displacing the native heart valve with the carrier element,"	***See* [17].** **Leonhardt discloses displacing the native heart valve with the carrier element.** (*e.g.*, "deploy[ing]" "valve stent 20" "in the location" of the existing valve by displacing native valve)**.** ***See* [20].** • *See also*, 11:30-34, 6:16-22, 10:53-11:9. Drasler ¶¶161-164.
[24.2] "the distal end of the carrier	**Leonhardt discloses the distal end of the carrier element is expanded** (*e.g.*, "distal end of valve stent 20 will distend as the distal end is released from outer sheath 106") **prior to displacing**

element is expanded prior to displacing the native heart valve with the carrier element."	**the native heart valve with the carrier element** (*e.g.*, "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 "aortic valve" after which sheath is retracted, releasing remainder of stent to displace native leaflets)**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses that valve/stent 20 is "fully deployed" at the "aortic valve." Leonhardt, 5:41-45, 9:63-67. During deployment, first, "the distal end of the valve stent 20… distend[s] as the distal end is released from outer sheath 106…." *Id.* 10:55-58. "Expansion balloon 154 is then inflated" to "secure" the distal end of valve/stent 20 "against the living tissue." *Id.* 10:67-11:9. After distal expansion, outer sheath is withdrawn from remainder of valve/stent 20, which expands due to "continuous outward force" once released. *Id.* 11:34-35. As shown in Figs. 9C-D for mitral valve 14, the native leaflets are excluded by valve/stent 20's distal end. A POSITA would have understood that valve/stent 20 displaces the aortic valve after the distal end expands because the sheath is first withdrawn from the distal end—which expands distal of the aortic valve in the "left ventricle" (Leonhardt, 9:63-10:6)—then the sheath is withdrawn from the remainder of valve/stent 20, displacing the native valve. Drasler ¶166. • Figs. 9C-9D



- 5:41-45 (*see* [20])
- 9:63-67 (see [17.1])
- 10:55-58 ("Distensible fingers 46 on ***the distal end of valve stent 20 will distend as the distal end is released from outer sheath 106***...")
- 10:67-11:9 ("***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 is maintained during the remainder of the deployment procedure and ***allows valve stent 20 to mold itself quickly into the living tissue at the placement site*** and achieve a patent seal.")

	Drasler ¶¶165-166.
[25] "The method of claim 17 further comprising: after expanding the distal end of the carrier element and evaluating the position or function of the carrier element and the replacement valve, expanding the proximal end of the carrier element."	***See* [17].** **Leonhardt discloses after expanding the distal end of the carrier element** (*e.g.*, "tip balloon 152" is "advanced" distal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue"), **evaluating the position or function of the carrier element and the replacement valve** (*e.g.*, "Valve stent 20 is…monitored for proper function and patency")**, expanding the proximal end of the carrier element** (*e.g.*, "tip balloon 152" then moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue")**.** ***E.g.*, Leonhardt:** ***See* [17.2].** In addition, **Leonhardt** discloses that 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," and subsequently "tip balloon" may be moved proximal to "valve stent 20 and reinflated to further mold valve stent 20 to the living tissue." Leonhardt, 11:29-34. • 11:28-34 (*see* [17.2]) • *See also* 9:55-62. Drasler ¶¶167-169.
[26.1] "The method of claim 25 further comprising: after evaluating the position or function of the carrier element	***See* [25].** **Leonhardt discloses after evaluating the position or function of the carrier element and the replacement valve** (*e.g.*, see [25]) **and before expanding the proximal end of the carrier element** (*e.g.*, see [25])**, at least partially collapsing the carrier element to a moveable configuration.** (*e.g.*, "collaps[ing] the distal end of valve stent 20" "for repositioning")**.**

and the replacement valve and before expanding the proximal end of the carrier element, at least partially collapsing the carrier element to a moveable configuration;"	***E.g.*, Leonhardt:** ***See* [25].** In addition, **Leonhardt** discloses, "at any time," "collaps[ing] the distal end of valve stent 20" "for repositioning or removal… whether valve stent 20 is fully or partially deployed." Leonhardt, 11:37-58. • 11:36-58 ("If ***at any time*** it is necessary ***to retrieve valve stent 20 for repositioning or removal***, the following procedure may be used. This procedure is ***applicable whether valve stent 20 is fully or partially deployed*** from outer sheath 106....***Valve stent 20 may now be repositioned or removed***….[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 ¶¶170-172.
[26.2] "repositioning the carrier element in the moveable configuration in the vicinity of the native heart valve; and"	**Leonhardt discloses repositioning the carrier element in the moveable configuration** (*e.g.*, see [26.1], "valve stent 20 may now be repositioned") **in the vicinity of the native heart valve.** (*e.g.*, "in the location of mitral valve 14")**.** ***E.g.*, Leonhardt:** ***See* [26.1].** In addition, **Leonhardt** discloses that "valve stent 20 may…be repositioned" by "collaps[ing] the distal end of valve stent 20" and then moving it to ensure "proper placement" "in the location of mitral valve 14." Leonhardt, 11:37-58, 5:41-45. • 10:67-11:2 ("Proper placement of valve stent 20 is verified by known means…") • 11:37-58 (*see* [26.1]) • 5:41-45 (*see* [20])

	• *See also* 9:7-10. Drasler ¶¶173-175.
[26.3] "expanding the carrier element from the moveable configuration to a fully expanded configuration to secure the carrier element in the vicinity of the native heart valve."	**Leonhardt discloses expanding the carrier element from the moveable configuration** (*e.g.*, "valve stent 20 may now be repositioned") **to a fully expanded configuration** (*e.g.*, "Tip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and reinflated") **to secure the carrier element in the vicinity of the native heart valve** (*e.g.*, "to further mold valve stent 20 to the living tissue" "in the location of mitral valve 14")**.** ***E.g.*, Leonhardt:** ***See* [17.2]** In addition, **Leonhardt** discloses that partially or fully collapsed valve stent 20 is repositioned for redeployment, and "[o]nce properly placed, valve stent 20 function and leakage are verified," which "verif[ication]" a POSITA would have understood includes testing function and leakage using well-known processes or protocols. Drasler ¶178; Leonhardt, 11:59-63. Then "[t]ip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and reinflated to further mold," and thus secure, "valve stent 20 to the living tissue if necessary." *Id.* 11:29-54. • 11:37-58 (*see* [26.1]) • 11:59-63 ("Once properly ***placed***, valve stent **20** function and leakage are verified…") • 5:41-42 (*see* [17.2]) • 11:28-36 (*see* [17.2]) • *See also* 9:7-10. Drasler ¶¶176-178.

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

To the extent PO argues the Challenged Claims are instead limited to requiring unidirectional blood flow during the initial expansion and prior to any proximal end expansion for [17.3] (*see* §§X.A.2, X.A.3.[17.3]), **Leonhardt** in view of **Bailey** nonetheless renders the Challenged Claims obvious. As discussed in §X.A.2, a POSITA would have been motivated to modify **Leonhardt's** expansion and tip balloons in view of **Bailey** to permit balloon expansion while allowing blood flow during expansion of the carrier element. Drasler ¶¶179, 124-130. When **Bailey's** teachings of allowing blood flow through the expansion balloon are applied, during the self-expansion process discussed in §X.A.1, once outer sheath 106 is sufficiently retracted to expose a portion of the proximal distensible fingers, valve/stent outflow occurs because the distensible fingers are designed to permit blood flow in the "cut out[s]" between them, as shown in Fig. 4:

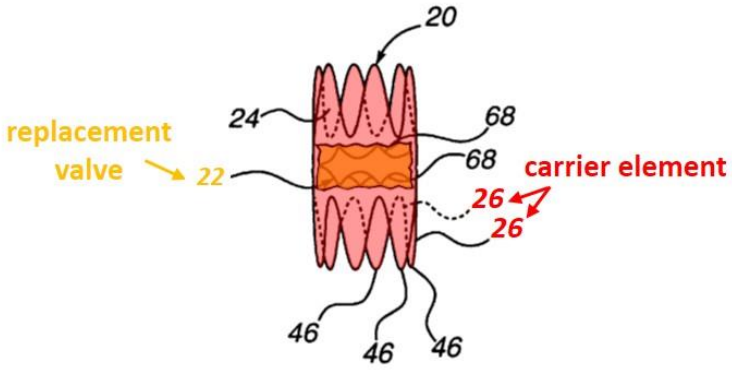


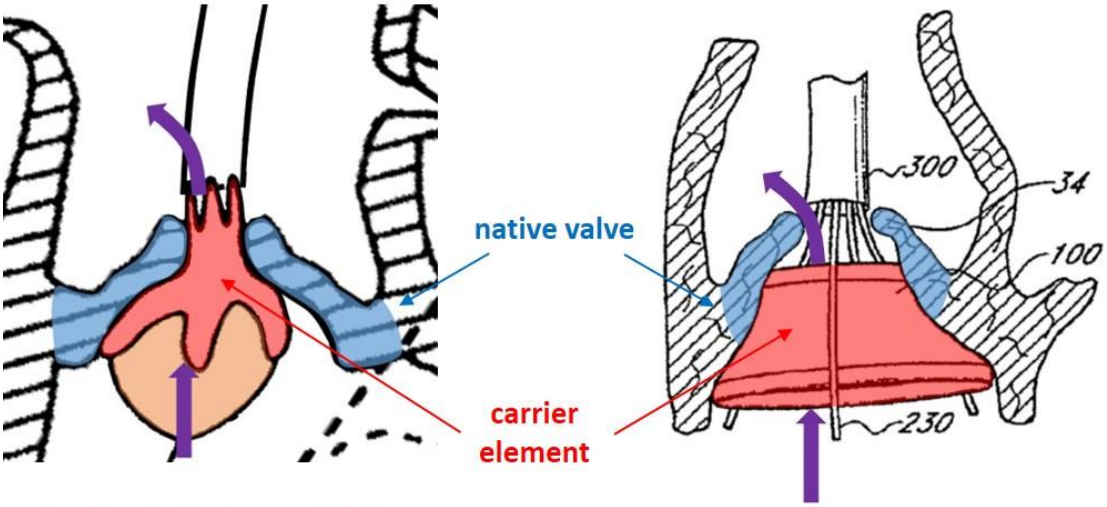
FIG. 4

Leonhardt, Fig. 4, 6:9-22; Drasler ¶179. Specifically, during "deployment of valve stent 20" at the "aortic valve" or "at [the] mitral valve," the "distensible fingers 46" are placed such that blood flows between the fingers to "other vessels," such as coronary arteries. Leonhardt, 6:17-19, 6:57-61, 9:63-10:6 (aortic valve deployment), Figs. 9B-9C. Similarly, when those same cutouts are exposed by retracting the outer sheath 106, blood flows through them before the proximal end is expanded. *See id.*; Drasler ¶179. For example, the figure on the left below has been modified from **Leonhardt** Figure 9C to depict retrograde blood flow in the aortic valve and capture the orientation of the proximal stent fingers and cut-outs before proximal end expansion. Drasler ¶¶179, 181. As shown in the figure, the valve functions as blood (purple) flows from the distal end, through a balloon modified with **Bailey's** teachings (see §X.A.2) and out between the "cut outs" in the proximal fingers. *See* §§X.A.1-3; Drasler ¶¶179, 181. Outflow remains

unobstructed as the proximal fingers are released and the valve stent completes its self-expansion. Drasler ¶179.

A POSITA would have understood or least found it obvious that the same blood flow through the valve and functionality to the extent present in '941 (e.g., as shown in annotated '941 Figure 47A on right below—blood flow annotated purple) would have existed in **Leonhardt** during the initial proximal end expansion when applying **Bailey's** balloon teachings. Drasler ¶180. As explained in §X.A.1, **Leonhardt's** valve and its leaflets are free to open and collapse back onto the inner catheter (thus allowing unidirectional blood flow) because the balloon does not overlap with the valve. Drasler ¶180. As illustrated above in Figure 4, when the cut-outs are exposed, the valve has also been deployed from the catheter such that it is free to function. Drasler ¶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 (PO's amended complaint asserting this limitation is met despite the presence of a catheter through the valve). Regardless, such operation is consistent with a well-known style of prosthetic valve, which blocks flow by collapsing material onto itself. *E.g.*, Letac (Ex. 1037), Figs. 9a-11b; Drasler ¶180. Early prosthetic valves (well-known for decades) blocked reverse flow by collapsing material onto supporting structures. *E.g.*, Boretos, Figs. 4A-4B; Drasler ¶¶37, 180. Thus, just as **Leonhardt** discloses that the valve "function[s]" prior to the second

balloon expansion (Leonhardt, 11:29-34), a POSITA would have understood and at least found it obvious, that when **Bailey's** teachings are applied to **Leonhardt**, the valve also functions when blood can flow through the cut-outs in the proximal end prior to any expansion of the proximal end—advantageously allowing blood flow and replacing the operation of the native valve earlier in the procedure. Drasler ¶180; *see also* Salahieh-697 (Ex. 1007), Figs. 9A-10B, ¶[0074] (teaching replacement valve operation before stent's proximal end released from catheter).[11]



Leonhardt Fig. 9C modified to instead depict an aortic valve

'941 Fig. 47A

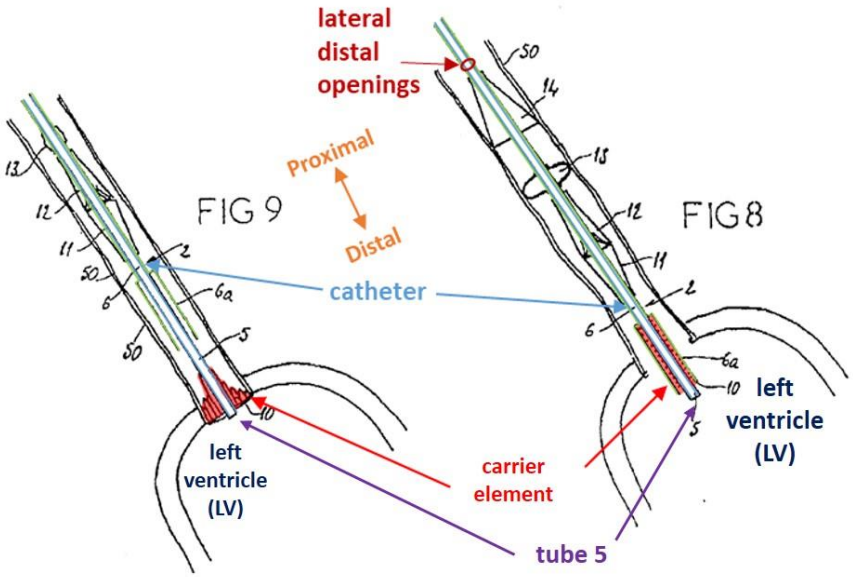
[11] Even if the Challenged Claims were entitled to the priority date of the provisional applications (they are not), Salahieh-697 is still relevant as evidence of knowledge of a POSITA at the time of the invention. *Yeda Research v. Mylan Pharms., Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018).

As further discussed in §X.A.1, **Leonhardt** discloses retracting the outer sheath 106 off of the proximal end of the valve stent and allowing it to self expand, and then using expansion balloon 154 to further expand the proximal end. A POSITA would have understood that, when **Bailey's** balloon teachings are applied, Leonhardt's valve would also impose unidirectional flow during expansion, after distal end expansion, and prior to proximal end expansion at two points in time: (1) immediately after outer sheath has been retracted, when the prosthesis's proximal end is self-expanding, and (2) while expansion balloon is expanding prosthesis's proximal end. Drasler ¶¶181-185.

B. Ground 2: Claims 17 and 19-26 Are Rendered Obvious by Leonhardt in View of Bailey and Seguin

To the extent PO argues further disclosure of blood flow through the proximal end of Leonhardt's prosthesis before any proximal end expansion is required for the valve to work (the upper purple arrow in Fig. 9C above in §X.A.4) for [17.3] (*see* §X.A), **Leonhardt** in view of **Bailey**'s balloon teachings and **Seguin**'s catheter opening teachings also discloses this functionality and renders the Challenged Claims obvious. Drasler ¶186. **Seguin** provides additional disclosure of a catheter comprising "lateral distal openings…to allow the blood to reach" the blood vessel, for example "the ascending aorta," during deployment of a prosthesis. Seguin, 7, 11-12, cl. 11. In particular, when the catheter is in the deployment position, "lateral

distal opening[s]" in the catheter proximal of the prosthesis's proximal end "allow the blood to reach the corporeal duct"—the blood vessel—such that blood advantageously continues to flow. Seguin, 7, 11-12, Claim 11, Figs. 8-9 (lateral distal openings added); Drasler ¶186. The openings are placed distally such that "the length of the catheter across which the blood passes is as short as possible…." Seguin, 7, 11, Claim 11.



A POSITA would have been motivated to apply **Seguin**'s teachings to **Leonhardt**'s outer sheath for the same reasons discussed in §X.A.2. Like **Leonhardt, Seguin** is in the same field as the '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; Seguin, 6-7, 11-13, Claim 11; Drasler ¶187.

A POSITA would have been motivated to apply **Seguin**'s express teaching of a catheter comprising distal lateral openings to **Leonhardt**'s outer sheath to yield the predictable, advantageous result of enabling blood flow through valve/stent 20's proximal end during expansion (and before any proximal end expansion) and exit to a bodily vessel, such as the aorta—thereby avoiding any pressure buildup that could cause prosthesis migration.[12] Drasler ¶¶188-189; Seguin, 7, 11-12, Claim 11; Leonhardt, Abstract, 1:11-14, 6:36-38, 9:64-67, 10:6-11, 10:22-23, 11:29-36; §X.A.2 (discussing similar motivations for applying Bailey's teachings); 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 of minimizing flow through the catheter, the lateral openings would be placed near the distal tip of **Leonhardt's** sheath. Seguin, 7, 11-12; Drasler ¶188. **Leonhardt** recognizes the importance of maintaining blood flow through a prosthesis during deployment and describes problems that result from blood flow obstruction during deployment that is suddenly removed (*see* §X.A.2). **Bailey's** teachings of a non-obstructing balloon (*see* §X.A.2) and **Seguin's** teachings additionally improve **Leonhardt—Seguin** provides additional teachings of a

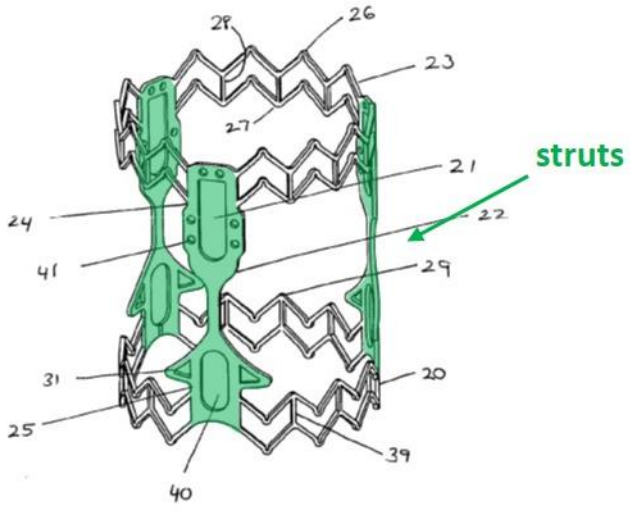
[12] The proposed combination does not rely on **Seguin's** particular stent or valve teachings.

catheter comprising lateral openings to advantageously "allow the blood to reach the bodily vessel" after passing through the proximal end. Seguin, 7, 11-12; Drasler ¶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 of the prosthesis for a longer period of time than just applying one teaching—blood would flow regardless of whether a balloon is inflated or the proximal end of the stent/valve is still inside the catheter. Drasler ¶¶188-189. The additional blood flow through the Leonhardt's prosthesis further allows the valve to function and allow for 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.[13] Drasler ¶¶188-189.

[13] **Leonhardt** teaches that the plunging seal on push rod's distal end is optional when using sutures to enable repositioning; thus, there is no obstacle to applying **Seguin's** teaching of distal lateral openings to **Leonhardt's** sheath. Leonhardt, 8:31-38; Drasler ¶188.

C. Grounds 3-4: Claim 27 Is Rendered Obvious by Leonhardt in View of Bailey and Svanidze, and Alternatively in Further View of Seguin

Leonhardt in view of **Bailey** and **Svanidze,** and alternatively in further view of **Seguin** renders obvious claim 27. *See* §§X.A-B. **Svanidze** further discloses ***the carrier element*** [of claim 17] ***includes at least three struts spaced around the carrier element and coupling the distal end of the carrier element to the proximal end of the carrier element*** ("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], Figure 6C. **Svanidze**'s support posts "stabiliz[e]" the anchoring structure/replacement valve assembly to, for example, "preclude valve stretching or distortion upon compression of the device." Svanidze, ¶[0085]; Drasler ¶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; Svanidze, ¶¶[0001], [0006]-[0009] ("need for a valve replacement system comprising a collapsible and expandable valve assembly"); Drasler ¶191.

A POSITA would have been motivated to apply **Svanidze**'s express teaching of three support posts to **Leonhardt**'s valve/stent to yield the predictable, advantageous result of "stabiliz[ing]" the valve stent and protecting the replacement valve 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 ¶192. **Svanidze** discloses that the number of support

posts can be changed and "are configured to coincide with the natural commissural posts" of the valve which is being replaced. 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 number of natural commissural posts in the aortic valve. Svanidze, ¶[0086]; Leonhardt, 5:39-40; Drasler, ¶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. Svanidze, ¶¶[0084]-[0086]; Drasler, ¶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 Challenged Claim. *See generally* '941FH; Drasler ¶319. As demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in the '941 were already well known. Drasler ¶¶319, 37-40. To the extent PO asserts the existence of any secondary

considerations in its responses, Petitioners reserve the right to address any such evidence.

XII. CONCLUSION

Substantial, new, and noncumulative technical teachings have been presented for the '941's Challenged Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to claims 17, 19-27. *Inter partes* review of claims 17, 19-27 is accordingly requested.

Dated: January 20, 2021

Respectfully submitted,

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

Counsel for Petitioners
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 13,991 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.
Reg. No. 57,325

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/
Name: Crena Pacheco
ROPES & GRAY LLP