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 IPR2021-00239

U.S. Patent No. 8,377,118

PETITION FOR *INTER PARTES* REVIEW

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1060	U.S. Patent Provisional Application No. 60/568,402
1061	Declaration of Crena Pacheco

Pursuant to §§311-319 and §42.1, Medtronic CoreValve LLC and Medtronic, Inc. ("Petitioners") petition for *inter partes* review ("IPR") of claims 1-2, 5, 7-11, 13-14, and 18-23 ("Claims") of U.S. Patent 8,377,118 ("'118") (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 these Claims.

I. INTRODUCTION

'118 is directed to a method for replacing a patient's aortic heart valve with a prosthesis that "extends over" the aortic valve in a sealing fashion and "replaces its function." '118, 13:58-61, 11:27-32, 13:51-58. The claimed prosthesis (annotated in orange below) is delivered to the aortic valve (annotated in green) in a collapsed configuration via an intravascular delivery catheter (annotated in purple). '118, 11:34-36, 40:42-44, 72:65-66. There, it is expanded across the aortic valve and tested. '118, 73:1-6. If the valve needs to be repositioned, it may be partially collapsed, repositioned and redeployed. '118, 75:67-76:4, 50:50-53, cl. 1.

[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 Claims' language for reference. All citations herein are exemplary and not meant to be limiting.

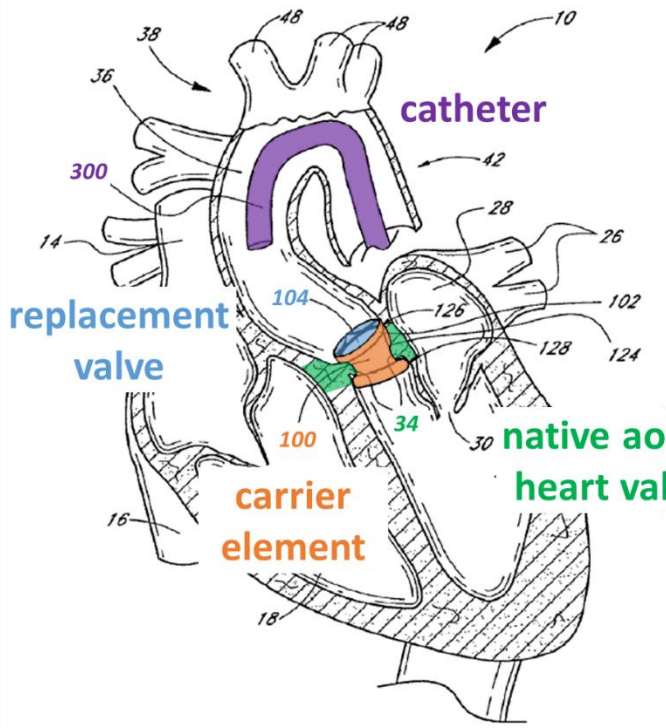


FIG. 2

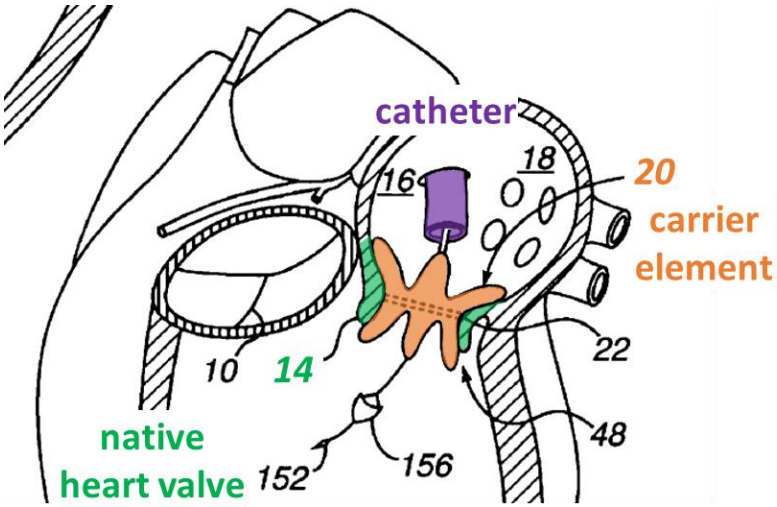
'118, Fig. 2 (depicting a valve after deployment from the catheter).

'118 concedes that implanting a prosthesis using a catheter by expanding it from a collapsed configuration (*e.g.*, a valve that expands as a sheath is retracted from the delivery catheter's distal portion) was well-known prior to the alleged invention. '118, 64:21-25, 72:24-34, 74:18-20; Drasler ¶¶35-38. The claimed positioning and repositioning steps were also known prior to the alleged invention. Drasler ¶¶35-38. Boretos (Ex. 1014; issued 11/8/77), which PO admits is prior art ('118, 3:26-30, 61:63-65, 63:1-4, 63:58-62), teaches loading, advancing the delivery system, and deploying a replacement valve collapsed inside a sheath, and recovering

the valve inside the sheath for "repositioning" or "removal." Boretos, 1:51-63, 2:64-3:45.

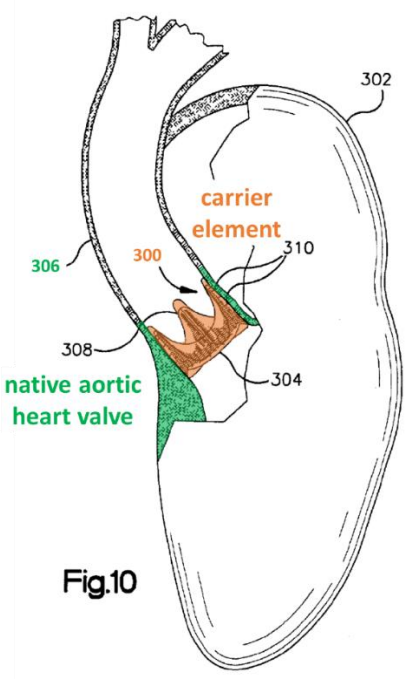
The Examiner allowed Claim 1 after Applicant's amendment requiring "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration." '118, cl. 1; Ex. 1003 ("'118FH"), 2093-2094, 2113-2115; *see* §VI. But as discussed herein, it was already well known to do so in the claimed manner. Drasler ¶¶68, 134-137. Other Claim limitations such as excluding an aortic valve and repositioning the carrier element after the carrier element's expansion were similarly well-known. Drasler ¶¶35, 38, 68.

For example, **Leonhardt** (Ex. 1004) teaches excluding a patient's aortic valve with an artificial valve. Leonhardt, 1:5-8, 3:15-20, 9:64-67, Fig. 9D (below).



Leonhardt discloses repositioning the carrier element after expansion and that the carrier element's length in the moveable configuration is substantially equal to its length in the expanded configuration. Leonhardt, 1:19-21, 11:36-52, 5:28-34, 4:41-46.

Additional references such as **Gabbay** (Ex. 1046) disclose excluding the aortic valve by implanting the prosthesis over the aortic valve. Gabbay ¶[0068], Fig. 10 (below).



With respect to dependent claim 7 (directed to the valve functioning during expansion), while **Leonhardt's** expansion balloon obstructs blood flow when used to expand the prosthesis's ends, **Bailey** (Ex. 1005) teaches using an expansion

balloon with an "irregular inflation profile[]" that permits blood flow around the balloon. Bailey ¶¶[0070], [0072]; Drasler ¶¶221-241.

And with respect to dependent claim 18, which is directed to removing and exchanging the carrier element, while **Leonhardt** discloses that valve/stent 20 may be removed, **Moulopoulos** (Ex. 1019) teaches removal of an implanted cardiac valve and "reinsertion of the replacement valve." Moulopoulos, 1:58-65; Drasler ¶¶242-247.

As demonstrated herein, the prior art renders obvious the Claims, which are directed to an obvious combination of prior art elements combined according to known methods to yield predictable results. The claimed elements and the claimed arrangement of elements are rendered obvious by **Leonhardt** in view of **Gabbay** and alternatively in further view of **Bailey** or **Moulopoulos**.

While the Examiner erred in finding that **Leonhardt** does not disclose using the replacement valve to replace leaflet actuation of the aortic valve, nevertheless, the Examiner did not consider **Gabbay's** teachings of this limitation during prosecution. *See* §VII.A.

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

II. MANDATORY NOTICES (§42.8)

A. Real Party-In-Interest

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

B. Related Matters

'118 is currently the subject of district court litigation: *Speyside Medical, LLC v. Medtronic CoreValve LLC et al.*, No. 20-361-LPS (D. Del., filed March 13, 2020). Medtronic is filing IPR petitions against the other patents asserted in that district court litigation: IPR2021-00243 (USP 9,445,897); IPR2021-00240, IPR2021-00241 and IPR2021-00310 (USP 9,510,941); IPR2021-00242 (USP 10,449,040); 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. 102760-0209-653.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioners certify the '118 is available for IPR. Petitioners are not barred or estopped from requesting IPR challenging the claims of the '118 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. '118 matured from 11/579,723 ("'723 Application"), PCT filed 05/05/2005, and claims priority to several provisional applications filed in 2004.

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)
Gabbay	1046	U.S. App. Pub. 2002/0032481	09/12/2000	03/14/2002	(a), (b)
Bailey	1005	U.S. App. Pub. 2003/0023300	12/31/1999	01/30/2003	(a), (b)
Moulopoulos	1019	U.S. 3,671,979	09/23/1969	06/27/1972	(a), (b)

2. Statutory Grounds on Which the Challenge Is Based

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

§103 Ground	Claims	Prior Art
1	1-2, 5, 7-11, 13-14, and 18-23	Leonhardt in view of Gabbay
2	7	Leonhardt in view of Gabbay and Bailey
3	18	Leonhardt in view of Gabbay and Moulopoulos

3. How the Claims Are Unpatentable

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

V. '118 PATENT

'118 discloses a prosthesis for replacing an aortic valve 34. '118, 5:8-9, 11:27, 11:38-40, Fig. 2 (below).

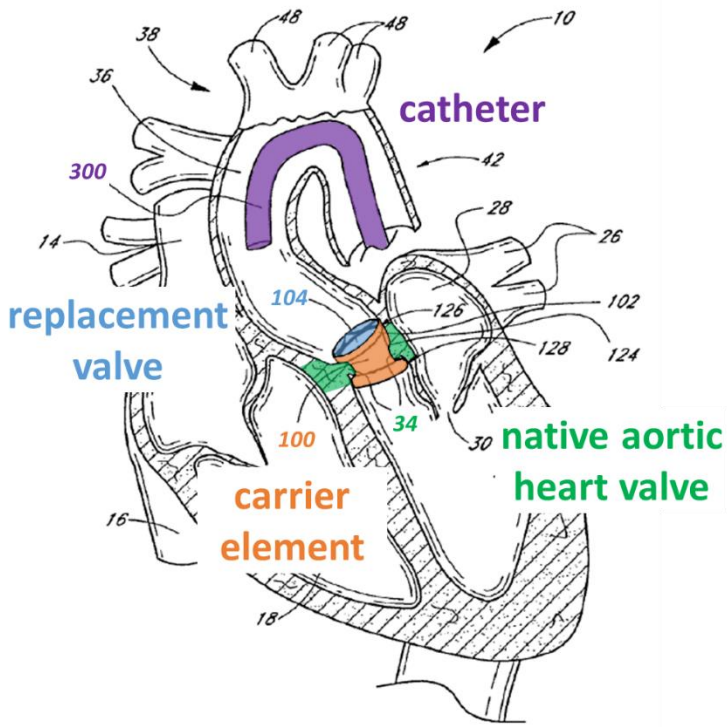

FIG. 2

The claimed method is generally directed to (1) endovascularly delivering a carrier element with an artificial valve in a collapsed delivery configuration and expanding it to exclude the aortic valve, (2) evaluating its position, and (3) at least partially collapsing, repositioning, and re-deploying the carrier element. '118, Abstract, 5:37-44, 49:41-50:17, 73:35-74:17, Figs. 47A-E; Drasler ¶39.

The prosthesis includes a valve with leaflets and a carrier element. '118, 11:61-64, 27:27-35. The carrier element includes stents 756, at the proximal/distal

ends, and a flexible fabric cuff 752 coupling the two stents and the valve. '118, 11:51-60, 27:13-26, Fig. 25F (below).[2]

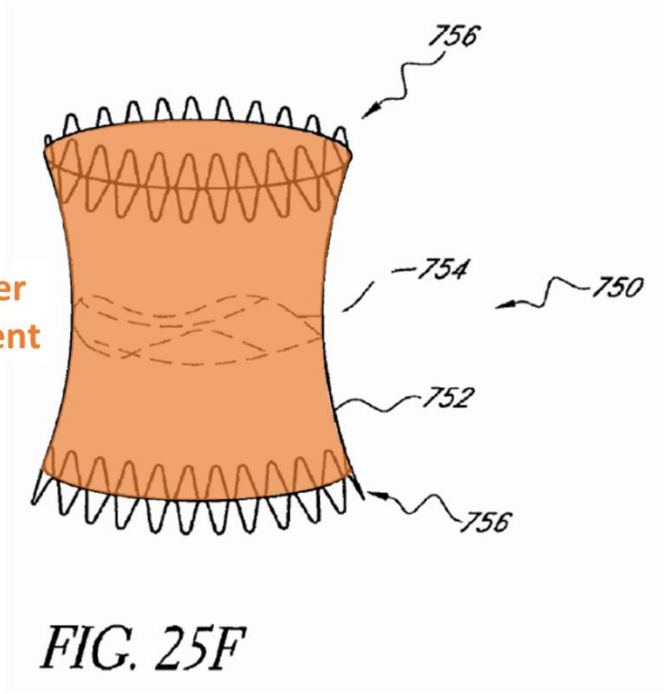

FIG. 25F

Alternative embodiments use inflatable cuffs instead of stents. '118, 3:63-4:3, 7:7-10, 11:27, 11:61-64, 65:46-48, Fig. 3A.

The prosthesis is "loaded" between outer and inner sheaths of a delivery catheter. '118, 11:34-36, 13:34-39, 40:42-44, Figs. 34, 36. The collapsed prosthesis

[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." '118, 11:51-60; Drasler ¶41.

is "translumenally advanced" through an access site to the aortic valve while the heart is "beating." '118, 5:9-12, 6:22-29, 43:19-21, 27:13-21, 75:26-47, Fig. 57A; Drasler ¶¶40, 42-43. At the implantation site, the catheter's outer sheath is withdrawn to expand the prosthesis's distal end, while the prosthesis is held in position using a deployment control device (*e.g.*, control wires 230 (*e.g.*, Figs. 47A-E)). '118, 40:53-56, 72:65-73:2, 75:45-76:2, Fig. 45A-C.

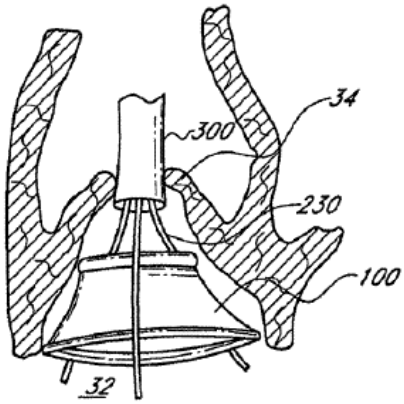

FIG. 45A

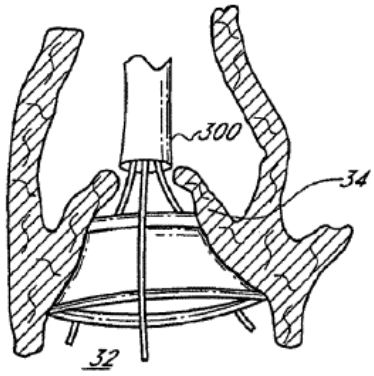

FIG. 45B

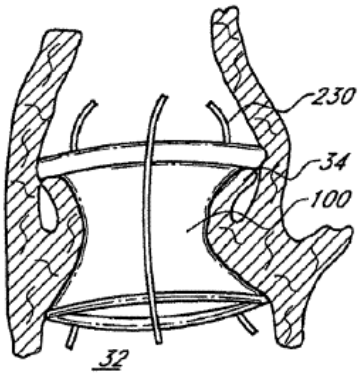

FIG. 45C

The prosthesis is "withdrawn across the native valve annulus" by withdrawing control wires (*e.g.*, Fig. 45B), and "fully inflated" (for the inflatable cuff embodiment—*e.g.*, Fig. 45C) or fully expanded (for the self-expanding embodiment). '118, 73:3-5, 73:48-74:17, Figs. 47A-B.

While the "sheath is retracted far enough" to "allow" the prosthesis "to function" before withdrawing the device 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—which "enabl[es] the valve to function." '118, 73:43-50, 72:66-73:6, 75:59-67. The "self-expanding recoverable stent" "function[s]" once "fully deployed." '118, 73:63-66, 59:56-60:14; Drasler ¶¶44-46. A functioning valve permits unidirectional blood flow. '118, 11:64-12:4, 4:4-6.

After expansion of stents 756 at the native annulus, the prosthesis's proximal/distal ends extend further radially outwards than its central portion—the material stretching from one stent to the other curves in a "hyperboloid shape." '118, 13:51-58, 27:20-26, Figs. 25F, 47B; Drasler ¶47. The length of flexible fabric cuff 752 coupling the prosthesis's proximal/distal end stents thus determines the maximum distance between them—meaning the prosthesis's length in the collapsed and expanded configurations can be substantially equal as claimed.[3] Drasler ¶47.

[3] The limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than [its] length…in the first expanded configuration" (claim 1) was added during prosecution with only Figs. 47A-E cited as support. *See* §VI. Fig. 47B shows the implant "fully deployed" while Fig. 47D shows the implant being "deflated and moved." '118, 50:10-14. These figures appear to visually show that the carrier element's length when being "deflated and moved" (moveable configuration; Fig. 47D) is less than the carrier element's "fully deployed" length (first expanded configuration; Fig. 47B). However, there is no disclosure in '118 of

So deployed, the prosthesis "excludes the native valve" or "extends over the former location of the native valve" and "replaces its function." '118, 13:58-61, 11:27-32, 76:50-53, Fig. 2A (below).

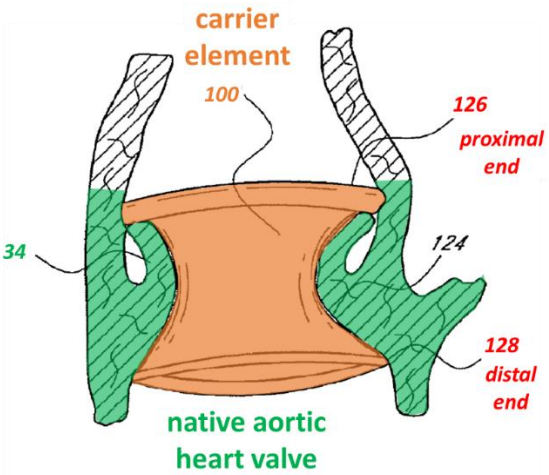

FIG. 2A

The prosthesis's proximal and distal ends (126, 128) form rings on either side of the aortic valve to seal and "inhibit the device from migrating proximally or distally." '118, 13:51-67, 77:8-10, 79:19-21, 26:17-19, 76:21-22, 14:2-3, Fig. 2A.

With respect to further expansion after the valve is functioning, "additional dilatation" using a balloon (e.g., a "perfusion balloon" that does not block blood flow) "after implantation…ensure[s] the device is apposed to the wall of the annulus and seated properly." '118, 73:22-24, 72:36-44.

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these figures being drawn to scale or that the carrier element's length is shortened in the moveable configuration. MPEP §2125; Drasler ¶48.

Using "diagnostic techniques," the prosthesis's location may be monitored and, if it is "not sufficient or ideal," the valve may be repositioned by partially or completely deflating/collapsing and re-expanding the prosthesis. '118, 73:5-6, 73:35-37, 73:50-55, 50:50-53, 50:10-15, Figs. 47C-D (below). Repositioning may include "rotation or translation" of the implant or a "complete removal and exchange" for a different implant. '118, 41:25-30.

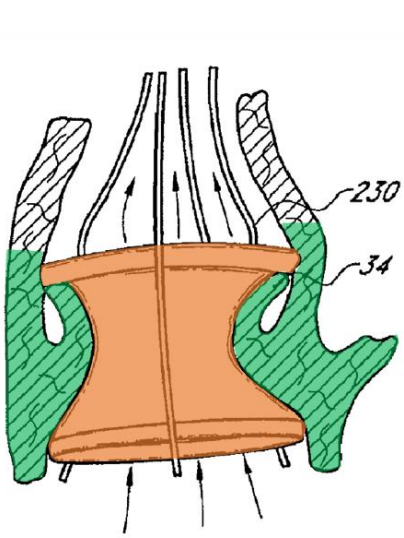


FIG. 47C

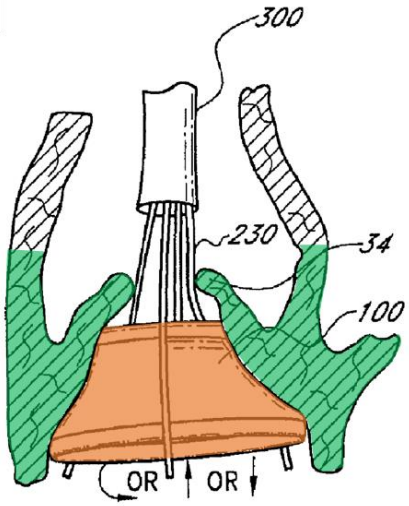


FIG. 47D

'118 discloses 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. '118, 74:5-17. 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. '118, 73:25-34, 73:61-74:5. Drasler ¶¶49-55.

VI. '118 PROSECUTION HISTORY

In response to a 3/29/2011 Office Action rejecting pending claims over U.S. Patent 5,554,185 ("Block"), on 7/29/2011 Applicant amended the claims to recite "using the carrier element to exclude the native valve," and "using the replacement valve to replace the function of the native valve." '118FH, 1903-1910. On 9/28/2011, the Examiner rejected the pending claims as anticipated by Leonhardt. '118FH, 2020-2031. Following an Examiner interview, Applicant's 12/27/2011 response amended the pending claims to be limited to "aortic valve[s]." '118FH, 2036-2044. In the 1/4/2012 interview, the Examiner rejected Applicant's arguments that Leonhardt does not disclose the repositioning limitations, but agreed to consider Applicant's proposed amendments limiting the claims to an "aortic valve" instead of any "native heart valve." '118FH, 2052-2054 ("Examiner noted that Leonhardt describes re-positioning or removal using suture loops 174 (fig. 7A-B), and teaches that these suture loops can be used apparently 'at any time it is necessary to retrieve valve stent 20 for repositioning or removal.").

On 7/5/2012, the Examiner rejected the pending claims as being anticipated by U.S. Patent Publication 2005/0137686 ("Salahieh-686") or rendered obvious in further view of Block. '118FH, 2075-2085. Following a 10/17/2012 examiner

interview where Applicant attempted to distinguish the Salahieh-686 valve that purportedly "undergoes foreshortening when transitioning from the collapsed state to the expanded state," Applicant's 11/5/2012 response amended the claims to recite "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration" citing only "Figs. 47A-47E" in support of this amendment. '118FH, 2090, 2092-2101; *see also* '941FH (Ex. 1041), 1730; Drasler ¶59. Applicant argued that Salahieh-686 does not disclose this limitation because Salahieh-686's "carrier element significantly lengthens in the moveable configuration." '118FH, 2099-2101.

The Examiner subsequently issued a notice of allowance on 12/6/2012, but did not provide specific reasons for allowance. '118FH, 2109-2115.

Nevertheless, as explained in detail below, the recited limitations of the Claims were indeed well-known in the art at the earliest possible priority date. Drasler ¶¶56-61.

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

A. §325(d) Does Not Apply.

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.

The grounds raised by this Petition are not the same or substantially the same as the art and arguments raised during '118's prosecution. The Examiner did not consider **Gabbay** (all Grounds), **Bailey** (Ground 2), **Moulopoulos** (Ground 3), or art with substantially the same disclosures during prosecution. For example, **Gabbay** teaches at least one limitation that the Examiner erroneously believed was not found in the prior art: using the carrier element to exclude the native aortic heart valve (such that it is covered and sealed off by the prosthesis) (*see* §X.A.3.[1.5]). **Bailey** teaches a balloon that permits blood flow around a replacement valve at least partially while the balloon and the replacement valve are expanded (*see* §X.B). **Moulopoulos** teaches removing a prosthesis and exchanging it with another (*see* §X.C). The Office also has not previously considered the expert testimony submitted herewith. Ex. 1002.

Moreover, where the "Examiner did not expressly consider" **Gabbay, Bailey** or **Moulopoulos**, 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." *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00379, Pap. 14, *20 (declining to exercise §325(d) discretion). For these reasons, an exercise of §325(d) discretion is not appropriate here.

Even if the art and arguments were substantially the same, the Examiner erred in a manner material to the patentability of the Claims. Despite properly rejecting the claims over **Leonhardt** alone (Ex. 1003, 2020-2031), the Office subsequently erred in a manner material to patentability (violating step-two of *Advanced Bionics*) by failing to maintain the rejection after the Claims were amended to be limited to the "aortic valve"—*see* §VI. While the Examiner had previously relied on **Leonhardt's** teachings of the claimed method relative to the mitral valve, **Leonhardt** alternatively teaches that the same method could also be applied "in the…aortic valve." Leonhardt, 9:64-65. **Leonhardt** recognized the need for an artificial heart valve "which may be placed percutaneously at any point as well as directly over an existing vascular or cardiac valve." Leonhardt, 3:15-20. The Examiner was misled by Applicant's false assertions that "Leonhardt does not disclose replacing the leaflet actuation of the native *aortic* heart valve." Ex. 1003, 2043. Once the artificial valve is placed in/over the native aortic valve, it replaces the leaflet actuation of the native valve. Cox (Ex. 1047; issued 1/2/96), 2:4-11; Drasler ¶¶58, 75, 129. As the Board has found, this misapplication of **Leonhardt** is

a material error. *E.g.*, *Arrows Up, LLC v. Oren Techs., LLC*, IPR2018-01231, Pap. 7, *11-12 (finding examiner erred in misunderstanding prior art reference); *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). As further discussed below in §X.A, **Leonhardt** discloses the remaining limitations of the Claims, including those added in response to the rejections over Salahieh-686.

The Examiner further erred by not identifying art similar to **Gabbay** (*see* §X.A.2), which also discloses implanting a valve over the aortic valve to replace its function, **Bailey** (*see* §X.B), which discloses a balloon that permits blood flow around a replacement valve at least partially while the balloon and the replacement valve are expanded, and **Moulopoulos** (*see* §X.C), which discusses exchanging one prosthesis for another, and not combining **Gabbay**, **Bailey**, and/or **Moulopoulos** with **Leonhardt** in a rejection.

In failing to properly consider these disclosures and allowing the Claims, the Office erred in a manner material to the patentability of the Claims.

For the foregoing reasons, the Board should institute and should not exercise its §325(d) discretion.

B. §314(a) Does Not Apply.

Co-pending district court proceedings also do not warrant the exercise of discretion under § 314(a) based on the six factors considered in *Apple Inc. v. Fintiv* 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, IPR2020-00243, IPR2021-00240, IPR2021-00241, IPR2021-00310, IPR2021-00242, and IPR2020-00244 concerning the other asserted patents. **2:** Trial is scheduled for October 2022, more than three months after a final written decision will issue in this IPR. Ex. 1045. **3:** To date, the court has not issued any substantive orders related to '118, Petitioners have moved to dismiss pending claims and infringement contentions were served on 12/4/20, but invalidity contentions have not yet been served, depositions have not begun, and claim construction briefing has not begun. *Id.* **4:** The same grounds, arguments and evidence could not be presented in litigation after the earlier-expected final written decision. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong as shown herein and 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 time '118 or its parent applications were filed, 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 ¶¶31-34.

IX. CLAIM CONSTRUCTION

Claim terms subject to IPR are to be 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 to be construed. *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 indisputable scope of the claims, the Board need not construe the outer bounds of the claims, while the district court may need to do so 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 ¶64.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X; Drasler ¶65.

B. "length of the carrier element in a moveable configuration is substantially equal to or less than a length of the carrier element in the expanded configuration"

Regardless of the exact metes and bounds of this term (*i.e*., "substantially"), the prior art discloses this limitation. *See* §X.A.3.[1.9]; Drasler ¶¶66-67.

X. GROUNDS OF UNPATENTABILITY

Although '118 purports to have invented a method of ***expanding a carrier element*** to exclude an aortic valve and ***repositioning the carrier element*** by partially collapsing it after expansion (such that a length of the carrier element in a moveable configuration is substantially equal to or less than a length of the carrier element in the expanded configuration), such methods were well-known. As explained below, the Claims are unpatentable as obvious. Drasler ¶¶1-254.

Ground 1: ***As to expanding the carrier element***: **Leonhardt** discloses a valve/stent that radially expands to replace the aortic valve and allows unidirectional blood flow. **Gabbay** discloses excluding the aortic valve (such that it is covered and sealed off) with a prosthesis. ***As to repositioning the carrier element***: **Leonhardt** discloses repositioning the valve/stent by partially collapsing it such that the valve/stent's length remains substantially the same in the collapsed and deployed configurations. Drasler ¶¶71-220.

Ground 2: **Bailey** teaches a balloon that permits blood flow around the expanded balloon, enabling **Leonhardt's** prosthesis to allow unidirectional blood flow during expansion and partial deployment. Drasler ¶¶221-241.

Ground 3: **Moulopoulos** teaches removing an implanted prosthesis and exchanging it with a replacement valve for reinsertion. Drasler ¶¶242-247.

The prior art renders the Claims unpatentable. This Petition is supported by the Declaration of Dr. William Drasler, which describes the scope and content of the prior art at the time of the alleged '118 invention. Drasler (Ex. 1002) ¶¶1-254.

A. Ground 1: Claims 1-2, 5, 8-11, 13-14, and 18-23 Are Rendered Obvious by Leonhardt in view of Gabbay[4]

1. Overview of Leonhardt

Leonhardt, a Medtronic-owned patent, teaches transluminally delivering an expandable valve/stent to the heart to "replace [an] existing valve[]." Leonhardt, Abstract, 1:5-8, 5:59-60. Valve/stent 20 comprises a "biological valve 22" "attached to stent 26." Leonhardt, 4:14-16, 6:23-31, 10:64-67, Fig. 4 (below); Drasler ¶71.

[4] §X.B addresses claim 7.

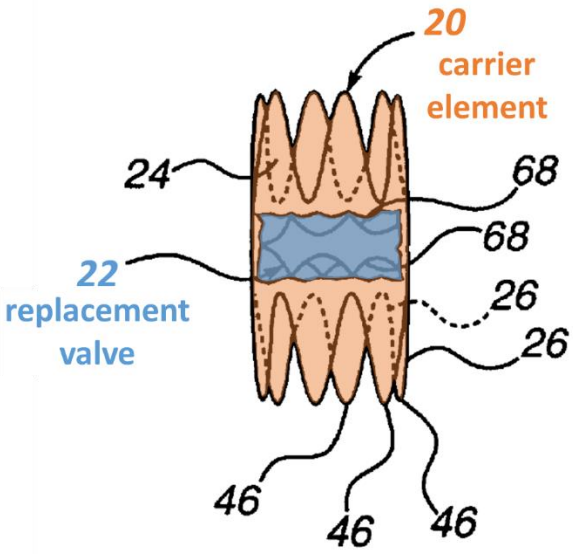


FIG. 4

The valve/stent is covered with graft material 24 "cut out" at the open ends of the stent's sinusoid, forming "distensible fingers 46." Leonhardt, 6:9-22, Fig. 4. Stent 26's distal and proximal end structures are "spaced a predetermined distance from each other by a connecting bar 29." Leonhardt, 4:66-67, 5:11-13, 5:28-33. The connecting bar defines the "central part of the continuous wire from which stent 26 is formed" (s*ee* Fig. 1A (below)).

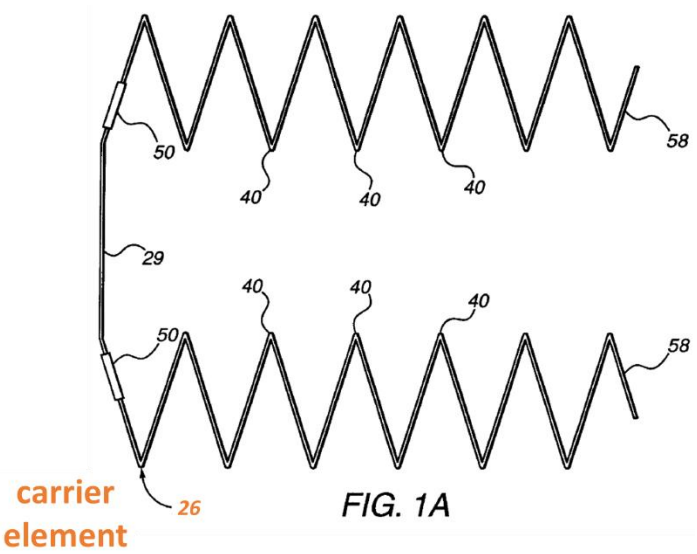


FIG. 1A

Leonhardt, 5:31-33, Fig. 1A; Drasler ¶73.

The valve/stent is loaded into a deployment catheter's outer sheath and transluminally advanced to a placement site. Leonhardt, 6:13-17, 6:35-65, 9:49-55, 9:63-10:11 (aortic valve deployment), Fig. 5, Fig. 9A (below; showing valve/stent held in place across the mitral valve within outer sheath); Drasler ¶74.

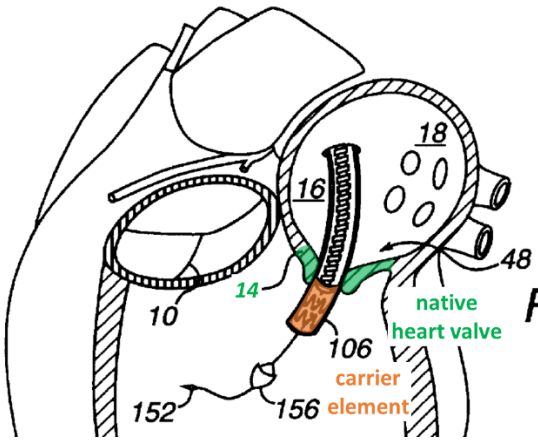


FIG. 9A

Once the catheter is positioned, valve/stent's deployment is "procedurally the same for all potential placement sites," including the mitral (Leonhardt, 10:22-30, Figs. 2,

9A-9D) and aortic valves (Leonhardt, 9:63-10:6). Leonhardt, 10:43-44, 6:36-38; Fig. 2; Drasler ¶¶74-75.

The collapsed valve/stent is expanded via the following mechanisms. The ***first*** is self-expansion, which occurs when the sheath is initially retracted, permitting the stent's distal end's distensible fingers to self-expand against the vasculature due to "continuous outward force." Leonhardt, 10:53-11:9, 11:34-35, Fig. 9C (mitral deployment; below); Drasler ¶¶76-79.

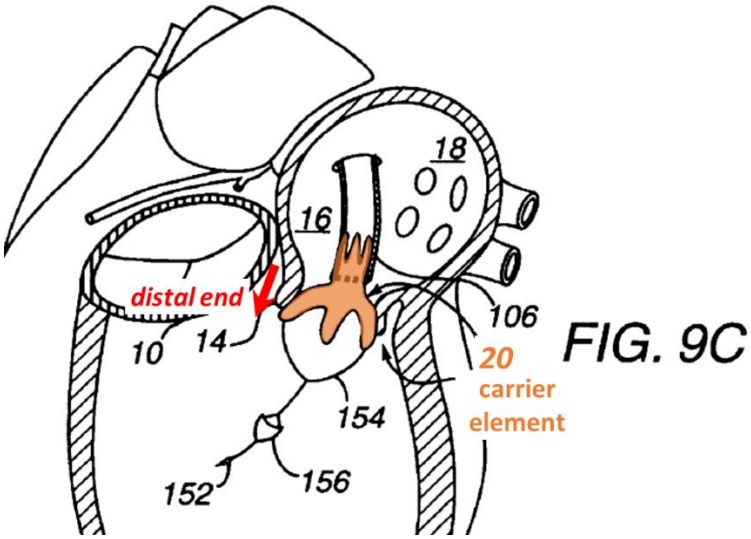
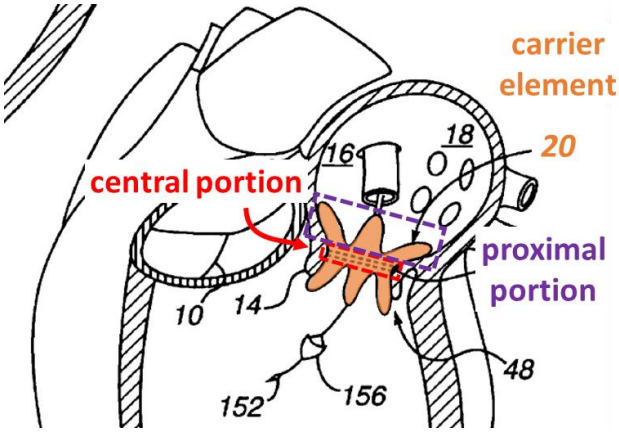


FIG. 9C

Leonhardt then employs a ***second*** mechanism. Expansion balloon 154 is inflated, without overlapping the valve, such that valve/stent 20 molds itself to the "living tissue at the placement site [to] achieve a patent seal" (*see* Fig. 9C above). Leonhardt, 11:3-9, 10:64-67 (valve's base "must be free from contact" with

balloon); Drasler ¶80.[5] With the expansion balloon holding the distal end, the sheath is completely retracted, allowing self-expansion of the valve/stent's remainder. Leonhardt, 11:10-15; Drasler ¶81. Once the sheath is sufficiently retracted to expose any portion of the proximal distensible fingers, there is no obstruction to valve/stent outflow because the fingers are designed to permit blood flow between them. Drasler ¶81. During deployment of valve/stent at the "aortic" or "mitral" valve as it completes its self-expansion, the fingers are placed such that blood flows between them to "other vessels" such as coronary arteries. Leonhardt, 6:17-19, 6:57-61, 9:63-10:6 (aortic valve deployment), 10:32-45; Drasler ¶81. The expansion balloon mechanism is then "deflated" and positioned "to seat the proximal end of valve stent 20." Leonhardt, 11:14-21, 9:63-10:6, Fig. 9D (below); Drasler ¶¶82-83.



[5] **Leonhardt** discloses that leaflets "may" be "slightly overlapped" by the balloon—an optional teaching not relied upon herein. Leonhardt, 10:64-67; Drasler ¶80.

At this point, the valve is functional, allowing for unidirectional blood flow, and is "monitored for proper function and patency." Leonhardt, 11:23-30, 5:46-52, 3:59-60, 7:17-21, 12:28-30; Drasler ¶84.

Leonhardt teaches a ***third*** valve/stent expansion mechanism: the tip balloon. After the valve is "function[ing]," allowing 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, 11:31-33, Figs. 5, 9A-D; Drasler ¶85. This mirrors '118's "additional dilatation" of the carrier element with a balloon after the valve is functioning. '118, 73:22-24; *see* §V; Drasler ¶85.

"Once 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 it is "fully or partially deployed." Leonhardt, 11:37-60, Figs. 7A-7B. Distended fingers on the valve/stent's proximal end are compressed using sutures and outer sheath 106 is advanced over valve/stent 20. Leonhardt, 11:40-52. It is "not necessary to advance outer sheath 106 completely over valve stent 20" for repositioning. Leonhardt, 11:52-55. A POSITA would have understood that where the valve/stent's distal end was properly placed but the valve/stent's proximal end was not, *e.g.*, it was obstructing the coronary arteries, only valve/stent's proximal end needs repositioning. Drasler ¶¶86, 90. 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 ¶¶91-92.

Leonhardt teaches the benefits of avoiding open heart surgery by "percutaneously" placing the prosthesis and, where the prosthesis is "misplac[ed] or fail[ed]," "percutaneously" "remov[ing]" it. Leonhardt 3:4-30. Therefore, a POSITA would have understood and at minimum found it obvious that, when a prosthesis failed or was misplaced, the same procedure should be followed with another prosthesis to again avoid open heart surgery. Drasler ¶87. Additionally, it was well-known in the art to replace the prosthesis post-removal—further motivating POSITA. Moulopoulos (Ex. 1019; issued 6/27/1972), 1:61-65; Drasler ¶87.

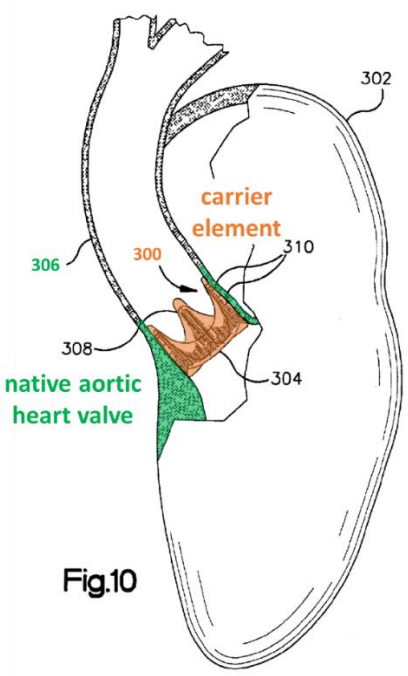
At minimum, it would have been obvious to try to implant a second prosthesis in the event the first functions poorly to achieve a functional replacement for these same reasons. Drasler ¶88. After removing the first prosthesis, only the following identified, predictable solutions were available: 1) open heart surgery, which **Leonhardt** taught to avoid, 2) implanting a second prosthesis percutaneously with the possibility of achieving a functional replacement, and 3) not treat the patient, which could have fatal consequences. Drasler ¶88. In light of **Leonhardt's** teachings, a POSITA would have found it obvious to choose the second option with a reasonable expectation of success in light of **Leonhardt's** teachings. Drasler ¶88.

Leonhardt also teaches that prosthesis size is critical and must be selected before implantation. Leonhardt, 5:2-10, 6:19-21, 6:28-31, 9:51-55. If the first prosthesis fails during implantation, **Leonhardt** teaches to remove the prosthesis and a POSITA would have understood another prosthesis would be used—e.g., a different size or style. Drasler ¶89. **Leonhardt** teaches that after the valve/stent is deployed it "is now monitored for proper function and patency," which is specifically tied to the "size" of the valve. Leonhardt, 5:5-10, 11:23-39; Drasler ¶89. A POSITA would have thus understood that if the first valve/stent does not have the proper function or patency, the next valve/stent that is implanted would be of a different size. Drasler ¶89. At minimum, a POSITA would have been motivated and found it obvious to try a valve of a different size for these same reasons. **Khairkhahan** (Ex. 1043, filed 05/12/2003), 13:4-7; Drasler ¶89.

2. Overview of Gabbay and Motivation to Apply Its Teachings to Leonhardt

Gabbay discloses a prosthesis, including a "stent portion" and a "valve portion," to "replace" a defective heart valve. Gabbay ¶¶[0050], [0037], [0039], Fig. 2. The prosthesis is delivered to an "aortic position" in the heart by a catheter in a "compressed condition" where it "expands" and engages with "the surrounding tissue" such that its "inflow end 304" is "annularized with respect to the annulus of

the aorta 306" and "outflow portion 308" extends "axially into the aorta 306." Gabbay ¶¶[0064]-[0066], [0068], Fig. 9A, Fig. 10 (below).



Therefore, a POSITA would have understood that the prosthesis is implanted over and excludes the native aortic valve. Drasler ¶¶93-94.

Gabbay and **Leonhardt** are in the same field of endeavor as '118—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s) identified in '118 of a need for a minimally invasive heart valve deployment system. '118, 7:30-33, 11:34-36; Leonhardt, 3:15-17; Gabbay ¶[0006]; Drasler ¶95. Both **Gabbay** and **Leonhardt** disclose delivering a compressed prosthesis to an implantation site at the aortic valve and deploying it by expansion. Gabbay

¶¶[0065], [0068], Fig. 9A, Fig. 10; Leonhardt, 6:56-61, 9:63-67, 10:53-11:9; Drasler ¶95.

While **Leonhardt** teaches placing the artificial valve at the aortic valve, **Gabbay** expressly specifies that the prosthesis is implanted over the aortic valve. Leonhardt, 1:5-8, 9:63-67; Gabbay ¶[0068]; Drasler ¶96. A POSITA thus would have been motivated to apply **Gabbay's** teachings of excluding the aortic valve to **Leonhardt's** prosthesis placement to achieve the beneficial and predictable result of improved prosthesis placement and operation. Drasler ¶96.

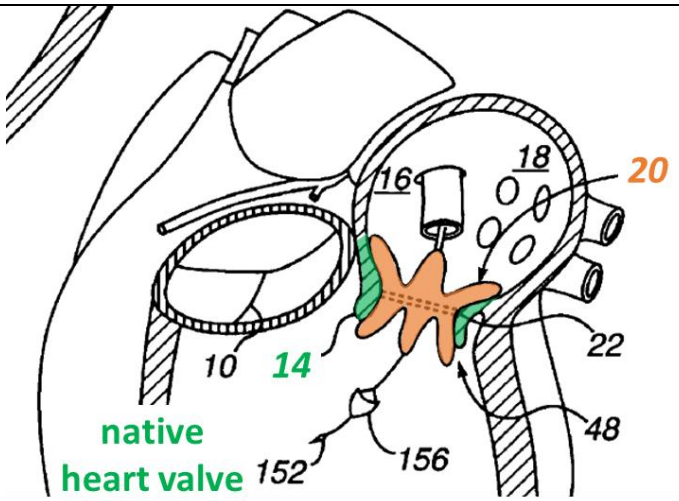
If the prosthesis was placed further up the aorta rather than at the "aortic position" as taught by **Gabbay**, blood flow through the aorta and aortic root would be compromised by a damaged native aortic valve located downstream. Drasler ¶97. Similarly, if the prosthesis did not cover or seal the aortic valve, as taught by **Gabbay**, some blood would improperly flow through the damaged native aortic valve. Drasler ¶97. Additionally, a POSITA would have understood that the prosthesis would be placed upstream of the ostia so as to block the aortic valve's leaflets to ensure perfusion of the coronary arteries. Drasler ¶97. Given limited space between the ostia that branch off from the coronary arteries and the annulus of the aortic valve, a POSITA would have understood that the prosthesis's placement at the aortic position across the annulus, as taught by **Gabbay**, would cover and seal the aortic valve. Drasler ¶97. A POSITA would have thus understood that

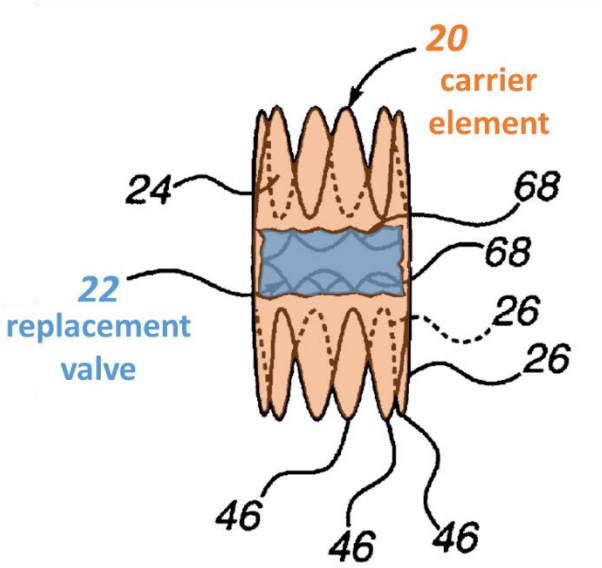
Gabbay's teachings provide additional detail on proper prosthesis placement over the aortic valve and would have improved **Leonhardt's** prosthesis placement by better opening up and excluding the aortic valve. Drasler ¶97.

In light of the above teachings, a POSITA would have had a reasonable expectation of success in applying **Gabbay's** teachings of excluding the aortic valve to **Leonhardt's** prosthesis placement in the aortic valve. Indeed, **Leonhardt** explicitly recognized the need for a valve "which may be placed percutaneously…directly over an existing…cardiac valve." Leonhardt, 3:15-20. A POSITA would have therefore found it obvious and straightforward to apply **Gabbay's** teachings to placing **Leonhardt's** prosthesis over the aortic valve. Drasler ¶98.

3. Claim Chart

'118 Patent	**Leonhardt in view of Gabbay**
[1.pre] A method for replacing a patient's native aortic heart valve in a heart, the method comprising:	**Leonhardt discloses a method for replacing a patient's native aortic heart valve in a heart** (*e.g.*, "artificial valve disclosed may replace existing valves such as are in the heart," "in the…aortic valve") ***E.g.*, Leonhardt:** "[A]rtificial valve" may "replace existing valves," *e.g.*, the heart's "aortic valve." • Fig. 9D

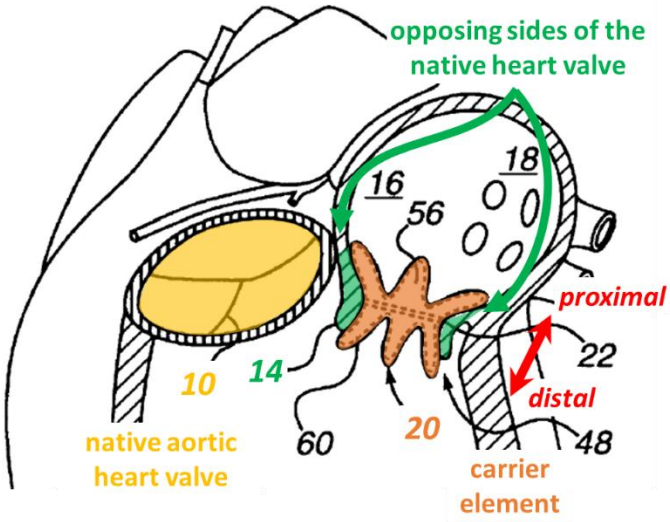
	 • 1:5-8 ("The artificial valve…may ***replace existing valves*** such as are ***in the heart***…") • 9:64-67 ("If the placement site is ***in the*** aorta or ***aortic valve*** 10, entry may be made through the largest femoral artery…into the aorta.") • *See also* 3:59-60. Drasler ¶¶99-101.
[1.1] delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating, the carrier element	**Leonhardt discloses delivering an implantable expandable carrier element** (*e.g.*, "self-expanding" "super elastic spring stent" 26) **and an implantable replacement valve having leaflets** (*e.g.*, "leaflets of biological valve 22") **endovascularly to a vicinity of the native aortic heart valve** (*e.g.*, "placement site is in the…aortic valve 10, entry may be made through the largest femoral artery…into the aorta") **while the heart is beating** (*e.g.*, "heart has been slowed" for "implant[ation]"), **the carrier element having proximal and distal ends** (*e.g.*, "[s]tent 26…having a distal end and a proximal end"). ***E.g.*, Leonhardt:** **Leonhardt** discloses a "self-expanding stent 26 to which a biological valve 22 is attached." Leonhardt, 5:46-48. Valve 22 includes leaflets and replaces the native valve. Leonhardt, 10:64-67. Prior to placement, the heart is "slowed," not

having proximal and distal ends	stopped. Leonhardt, 3:15-27, 9:50-62. Stent 26 and valve 22 are delivered endovascularly via "femoral artery" to a "placement site…in the aorta." Leonhardt, 9:50-67. • Fig. 4  FIG. 4 • 3:47-50 ("FIG. 1*a* is an perspective view of the ***super elastic spring stent*** in its permanent shape prior to attaching the ends to form the cylindrical walls.") • 4:27-29 ("…***stent 26*** formed of a single piece of ***super elastic wire***…with two crimping tubes 50.") • 5:46-48 ("Valve stent 20 comprises…***deformable self-expanding stent 26*** to which a ***biological valve 22*** is attached.") • 10:64-67 ("The ***leaflets of biological valve 22*** may be slightly overlapped by expansion balloon 154, but the base of biological valve must be free from contact with expansion balloon 154.") • 9:64-67 (*see* [1.pre])

	• 3:15-27 ("The need remains for ***an artificial heart valve which…does not require***…***stopping the heart*** or using a heart-lung machine during placement…") • 9:50-62 ("…***a method of*** surgically ***implanting valve stent 20.*** It is assumed…an appropriately sized valve stent 20 has been selected and pre-loaded within…deployment catheter 100…***the patients heart has been slowed***….") • *See also* 3:15-29, 4:66-67, 6:24-26, 10:18-21, 11:24-26. Drasler ¶¶102-105.
[1.2] the replacement valve configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction	**Leonhardt discloses the replacement valve** (*e.g.*, "biological valve 22") **configured to allow the flow of blood through the replacement valve in a first direction** (*e.g.*, "open in the direction of blood flow") **and prevents the flow of blood through the replacement valve in a second direction** (*e.g.*, "blocking flow in one direction"). ***E.g.*, Leonhardt:** Valve 22 "open[s] in the direction of blood flow" and is "capable of blocking flow" in the other direction so blood "flow[s] in a single direction." • 1:11-14 ("…artificial valve to maintain ***bodily fluid flow in a single direction***. It opens and closes with pressure and/or flow changes.") • 7:17-21 ("After placement, ***biological valve 22 should open in the direction of blood flow***.") • 12:28-30 ("a valve means ***capable of blocking flow in one direction***") • *See also* Abstract. Drasler ¶¶106-108.

[1.3] positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve;	**Leonhardt discloses positioning the proximal and distal ends of the carrier element** (*e.g.*, "valve stent 20") **proximate opposing sides of the native aortic heart valve** (*e.g.*, "valve stent mold[s] itself quickly into the living tissue at the placement site and achieve[s] a patent seal" "in the…aortic valve 10" (see Fig. 2 for the mitral valve))**.** ***E.g.*, Leonhardt:** The valve/stent is placed "in the…aortic valve" by advancing it to the placement site. Leonhardt, 9:64-65, 10:3-22, 10:53-55. Proper placement "mold[s]" valve/stent 20 in the "aortic valve" to "conform and seal to the tissue." Leonhardt, 11:5-9, 9:64-67, 6:16-22. A POSITA would have understood that by placing the valve/stent in the aortic valve, valve/stent's proximal/distal ends are placed proximate opposing sides of the aortic valve. Drasler ¶111. For example, Fig. 2 (below) shows valve/stent 20 placed in such configuration for the mitral valve, which is consistent with the '118 specification showing "opposing flat sides" of the implant using labels 128a in Fig. 2H. '118, 14:51-53 ("either side" of mitral valve is below annulus), 14:57-59. The same would apply when placed in the aortic valve (also annotated in Fig. 2 below). Drasler ¶111.[6] • Fig. 2

[6] **Leonhardt's** valve/stent 20 placed in such configuration is positioned as claimed even if "opposing sides" are interpreted as the proximal and distal ends of the native valve on either side of the annulus. '118, 14:60-64, 49:46-48; Drasler ¶112.



- Fig. 9A

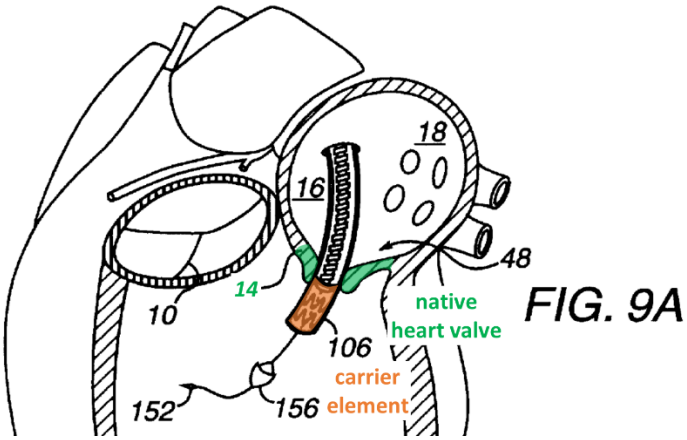


FIG. 9A

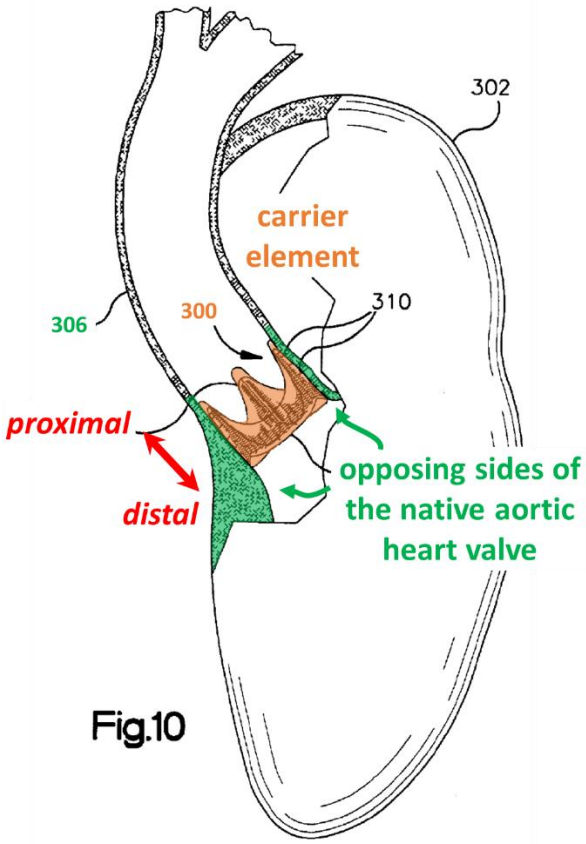
- 3:15-20 ("…***artificial heart valve***…which will seal at the outside wall of the valve with the living tissue… may be ***placed***…***directly over an existing vascular or cardiac valve***…")

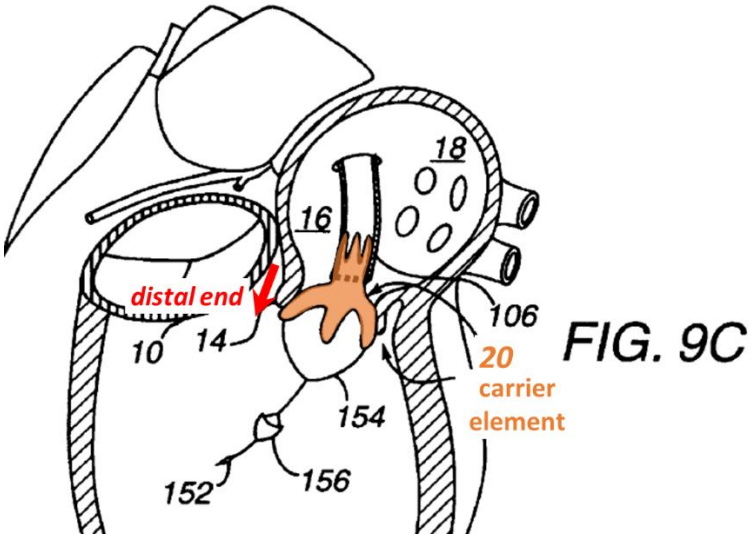
- 11:5-9 ("…proper placement…allows ***valve stent 20 to mold itself quickly into the living tissue at the placement site and achieve a patent seal***.")

- 9:64-67 (*see* [1.pre])

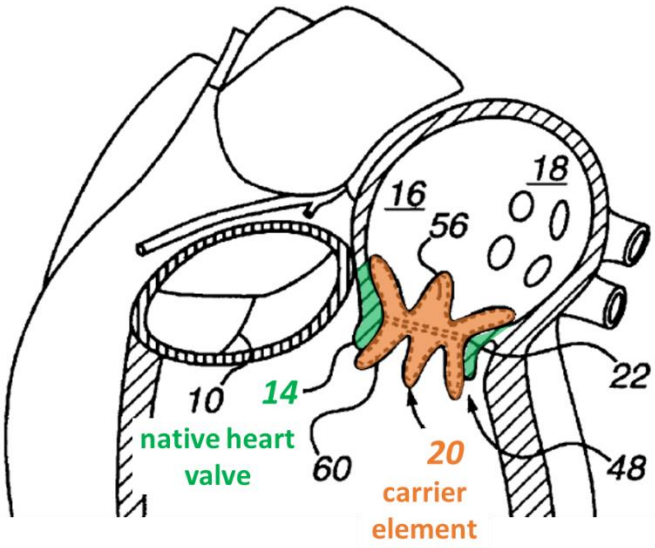
- 6:16-22 ("Valve stent 20 may be placed such that other vessels are not blocked by placing distensible fingers 46 on either side of the vessel junction. ***Stent 26 is pre-***

	sized to open beyond the width of the natural valve mouth and will flair sufficiently to conform and seal to the tissue.") • *See also* 10:3-22, 10:53-55. **To the extent it is argued that further disclosure is required by Leonhardt in this regard, Gabbay explains that positioning includes positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve** (*e.g.*, "implant[ing] by using a catheter" the "valvular prosthesis…in the aortic position"). ***E.g.*, Gabbay:** **Gabbay** discloses implanting a "valvular prosthesis 300…in the aortic position" to "engage a valve wall"—meaning the stent's proximal/distal ends are positioned proximate opposing sides of the aortic valve and excluding the aortic valve as shown, *e.g.*, in Fig. 10 (below). Gabbay ¶¶[0069], [0050]. The prosthesis is implanted over and excludes the remainder of the aortic valve. §X.A.2; Gabbay ¶[0068]; Drasler ¶¶113-114. As discussed in §X.A.2, a POSITA would have been motivated to apply **Gabbay's** known placement teachings—positioning a valve across the aortic valve—to **Leonhardt's** method of positioning a similar valve and support structure with the predictable result of improving **Leonhardt's** method when it is necessary to replace the aortic valve. **Leonhardt** explicitly recognized the need for a valve "which may be placed percutaneously at any point as well as ***directly over an existing***…***cardiac valve.***" Leonhardt, 3:15-20. • Fig. 10

	 Fig.10 • ¶[0050] ("…at a desired implantation position, the prosthesis may…***engage a valve wall*** or other surrounding tissue at the ***desired position***.") • ¶[0069] ("The valvular prosthesis 300 may be…***implanted in the aortic position***…***using a catheter***…") • ¶[0068] ("FIG. 10 illustrates an example of a valvular prosthesis 300 implanted in a heart 302 in an aortic position.") • *See also* ¶[0066]. Drasler ¶¶109-115.
[1.4] expanding the carrier element from a collapsed	**Leonhardt discloses expanding the carrier element from a collapsed delivery configuration** (*e.g.*, "valve stent 20" enclosed in the "outer sheath" of the "deployment catheter") **to a first expanded configuration** (*e.g.*, "by withdrawing

delivery configuration to a first expanded configuration;	[the] outer sheath," "distensible fingers…of valve stent 20 will distend," and "[e]xpansion balloon is then inflated…to hold the distal end of the valve stent 20 secure," then "proximal end of valve stent 20 is released" and "expansion balloon" is "inflated again to seat the proximal end of the valve stent")**.** ***E.g.*, Leonhardt:** Valve/stent 20 is delivered in a collapsed configuration with its "[c]ollapsing distensible fingers 46" compressed "within outer sheath 106." Leonhardt, 6:56-61. Valve/stent 20 is expanded for deployment. As outer sheath 106 is withdrawn from valve/stent 20's distal end, "fingers 46 on the distal end of valve stent 20 will distend" outwardly. Leonhardt, 10:53-11:5. An "expansion balloon 154" is positioned within valve/stent 20's distal end and inflated to "hold the distal end of valve stent 20 secure" at the placement site. *Id.* Outer sheath 106 is withdrawn further to "release[]…the proximal end of valve stent 20" and the expansion balloon is positioned and reinflated "to seat the proximal end of valve stent 20" within the native valve. Leonhardt, 10:53-11:22. • Fig. 9c  FIG. 9C • 6:56-61 ("***Collapsing distensible fingers 46*** of valve stent 20 together forms a conical tip which

	allows…easy ***loading by sliding outer sheath 106 over the tip and on until valve stent 20 resides within outer sheath 106***…") • 10:53-11:9 ("Deployment of the distal end of valve stent 20 is initiated by withdrawing outer sheath 106…***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…Inner catheter 110 is then moved to position expansion balloon 154 on the distal side of biological valve 22 yet within the distal end of valve stent 20 just deployed…***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…and ***allows valve stent 20 to mold itself quickly into the living tissue at a placement site and achieve a patent seal.***") • 11:10-22 ("With expansion balloon 154 maintaining a friction fit against distal end of valve stent 20, ***outer sheath 106 is again withdrawn***…***The proximal end of valve stent 20 is released once outer sheath 106 clears the proximal end of valve stent 20***…[E]xpansion balloon 154 is deflated as seen in FIG. 9d…***Expansion balloon 154 may then be inflated again to seat the proximal end of valve stent* 20**…") • 11:30-34 ("…Tip balloon 152 or expansion balloon 154 may be ***advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue*** if necessary.") • *See also* 5:46-51, 7:10-11. Drasler ¶¶116-118.
[1.5] using the carrier element to exclude the	**Leonhardt discloses using the carrier element to exclude the native aortic heart valve in the first expanded configuration** *(e.g.*, when expanded, the "valve stent mold[s]

native aortic heart valve in the first expanded configuration;	itself quickly into the living tissue at the placement site and achieve[s] a patent seal" "in the…aortic valve 10" (see Fig. 2 for the mitral valve))**.** ***E.g.*, Leonhardt:** On expansion (*see* [1.4]), valve/stent 20 "mold[s] itself quickly into the living tissue at the placement site" in the "aortic valve" during deployment to "conform and seal to the tissue" and thus exclude the aortic valve. Leonhardt, 11:5-9, 9:64-67, 6:16-22. **Leonhardt** illustrates this relative to the native mitral valve in Fig. 2, where valve/stent 20 replaces the mitral valve by sealing "with the tissue of mitral valve 14" to create "a patent one way fluid passageway." Leonhardt, 5:41-52. • Fig. 2  • 6:16-22, 9:64-67, 11:5-9 (*see* [1.3]) • 10:53-11:9, 11:30-34 (*see* [1.4]) • 5:41-52 ("…***valve stent 20 fully deployed*** in the location of mitral valve 14…***Stent 26 biases the proximal and distal ends of valve stent 20 into conforming and sealingly fixed engagement with the***

	tissue of mitral valve 14. The deployed valve stent 20 creates a patent one way fluid passageway.") • *See also* FIGs. 9a-9d. **To the extent further disclosure of excluding the native aortic heart valve is required, Gabbay discloses using the carrier element to exclude the native aortic heart valve** (*e.g.*, as shown in Fig. 10). ***See*** **[1.3], §X.A.2.** Drasler ¶¶119-123.
[1.6] forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration;	**Leonhardt discloses forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration** *(e.g.*, "valve stent…achieve[s] a patent seal" "in the…aortic valve 10")**.** ***See*** **[1.5].** Drasler ¶¶124-126.
[1.7] using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration;	**Leonhardt discloses using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration** (*e.g.*, "[a]fter placement" "in the…aortic valve 10," "biological valve 22" including its "leaflets" "should open in the direction of blood flow")**.** ***E.g.*****, Leonhardt:** Valve 22's "leaflets" "open in the direction of blood flow." Leonhardt, 10:64-67, 7:20-21. A POSITA would have understood these leaflets imitate aortic valve leaflet actuation for "proper function" (*e.g.*, opening in the direction of blood flow). Drasler ¶129. • 10:64-67 (*see* [1.1]) • 7:20-21 (*see* [1.2]) • 11:29-36 ("Valve stent 20 is now monitored for ***proper function*** and patency…***Tip balloon 152*** or expansion

	balloon 154 ***may be advanced to either side of valve stent 20 and reinflated to further mold valve stent 20 to the living tissue if necessary***…") • 9:64-67 (*see* [1.pre]) **To the extent it is argued that further disclosure of placement in the native aortic heart valve is required by Leonhardt, Gabbay explains that positioning includes positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve**. ***See*** **[1.3], §X.A.2.** Drasler ¶¶127-130.
[1.8] evaluating the position of the carrier element;	**Leonhardt discloses evaluating the position of the carrier element** (*e.g.*, "proper placement" of valve stent 20 "is verified")**.** ***E.g.*****, Leonhardt:** **Leonhardt** discloses verifying "placement" of valve/stent 20 at the placement site. • 11:19-21 ("Expansion balloon 154 may then be inflated again …proper placement is verified.") • 11:29-31 ("***The placement site is also monitored*** to ensure no damage has occurred to the living tissue.") • *See also* 11:37-40. Drasler ¶¶131-133.
[1.9] at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration, a	**Leonhardt discloses at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration** (*e.g.*, "compress[ing]" "valve stent 20" and "advance[ing] outer sheath over valve stent…until outer sheath 106 completely covers valve stent")**, a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration** (*e.g.*, "connecting bar 29" holds opposing

length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration;	"cylinders" of "valve stent 20" "a predetermined distance from each other" in either configuration). ***E.g.*, Leonhardt:** After valve/stent 20 has been expanded and deployed (*see* [1.4]), valve/stent 20's proximal end is partially collapsed by compressing it "to the diameter of outer sheath 106." Leonhardt 11:39-55. Outer sheath 106 is "advance[d]" over "compressed" valve/stent 20 until it "covers valve stent 20" so it may be "repositioned." *Id.* Valve/stent 20's length in the repositioning configuration is substantially equal to its length in the fully deployed configuration because it comprises structures at each end "spaced a predetermined distance from each other by a connecting bar 29" in either configuration. Leonhardt, 11:40-52, 5:28-34, 4:41-46. Just as '118 discloses that flexible fabric cuff 752 holds stents 756 at the proximal end and distal end of the prosthetic implant a maximum distance from each other and may be expanded into a "hyperboloid" shape ('118, 13:51-58, 27:23-26, Fig. 25F; *see* §V), **Leonhardt's** valve/stent 20 holds its two ends a "predetermined distance" from each other and may be expanded into a hyperboloid shape.[7] Drasler ¶137.

[7] As discussed in §V, the lengths of '118's prosthesis in the collapsed and expanded hyperboloid configurations can be substantially equal because the maximum length of flexible cuff 752 is fixed. Drasler ¶137. Therefore, regardless of this term's exact metes and bounds, the length between the two cylinders of **Leonhardt's** valve/stent 20 being substantially equal in collapsed and expanded configurations discloses this limitation. Drasler ¶¶66-67, 137.

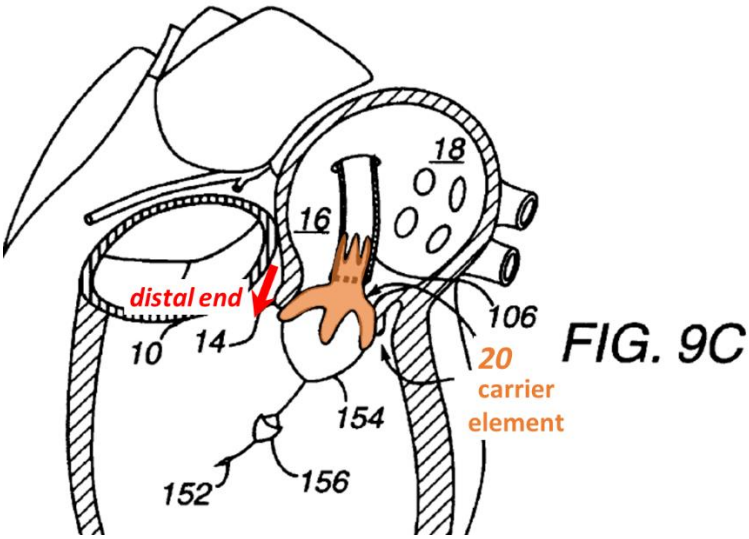
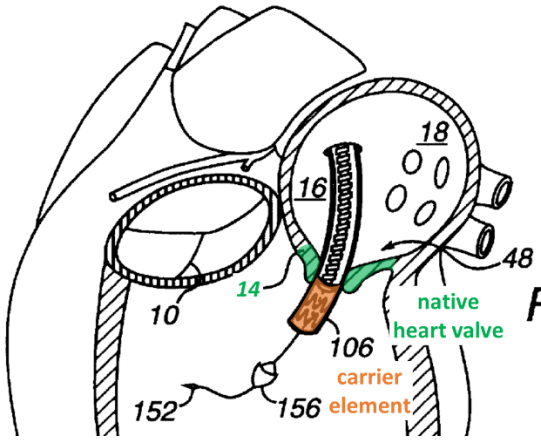
	• 11:39-55 ("***This procedure is applicable whether valve stent 20 is fully or partially deployed from outer sheath 106***. First advance outer sheath 106 and push rod 112 to the proximal end of valve stent 20. Take up slack in suture loops 174 as outer sheath 106 is advanced by turning the spool handle…until ***distended fingers 46 of the proximal end of valve stent 20 are compressed to the diameter of outer sheath 106***. Finally…***advance outer sheath 106 over valve stent 20…until outer sheath 106 completely covers valve stent 20***. ***Valve stent 20 may now be repositioned*** or removed. It may not be necessary to advance outer sheath 106 completely over valve stent 20 if repositioning is desired.") • 5:27-39 ("…***stent 26 forms two cylinders, one at each end of stent 26***. Each cylinder is substantially directly above or below the other cylinder. 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. ***Connecting bar 29 is also biased outward*** to conform to the living tissue…Connecting bar 29 provides torsional stability for valve stent 20.") • *See also* FIG. 1a, 4:41-46. Drasler ¶¶134-137.
[1.10] repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve;	**Leonhardt discloses repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve** (*e.g., see* [1.3], "repositioning" the "valve stent" "in…aortic valve 10")**.** ***E.g.*, Leonhardt:** ***See* [1.3], [1.9].**

	Additionally, **Leonhardt** discloses "repositioning" valve/stent 20 "in the aorta of aortic valve" after it has been "compressed" within and "cover[ed]" by outer sheath 106. • 11:37-39 ("If ***at any time*** it is necessary to retrieve ***valve stent 20 for repositioning*** or removal, the following procedure may be used.") • 11:39-55 (*see* [1.9]) • 9:64-67 (*see* [1.pre]) **To the extent further disclosure of positioning in the vicinity of the native aortic heart valve is required, Gabbay discloses positioning the carrier element in the vicinity of the native aortic heart valve**. ***See*** **[1.3], §X.A.2.** Drasler ¶¶138-142.
[1.11] expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve,	**Leonhardt discloses expanding the carrier element from the moveable configuration to a second expanded configuration** (*see* [1.4]—the same process is followed) **to secure the carrier element in the vicinity of the native aortic heart valve** (*e.g.*, "placement site is in…aortic valve 10," *see* [1.3], [1.5])**.** ***E.g.*****, Leonhardt:** ***See*** **[1.3]-[1.5].** From its "compressed" position within outer sheath 106 allowing repositioning (*see* [1.9], [1.10]), valve/stent 20 is re-expanded and deployed in the vicinity of the aortic valve using the same process described above for [1.3]-[1.5]. • 11:40-53 (*see* [1.9]) • 10:53-58, 11:3-5, 11:17-22 (*see* [1.4]) • 9:64-67 (*see* [1.3])

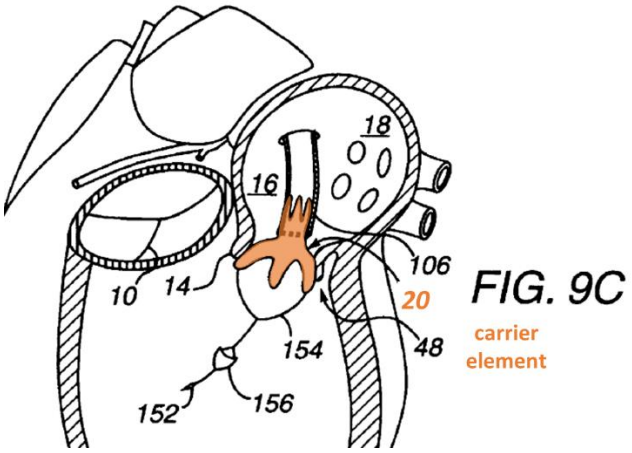
	To the extent further disclosure of expanding in the vicinity of the native aortic heart valve is required, Gabbay discloses expanding the carrier element in the vicinity of the native aortic heart valve. ***See*** **[1.3], §X.A.2.** Drasler ¶¶143-147.
[1.12] the proximal and distal ends of the carrier element being proximate opposing sides of the native aortic heart valve in the second expanded configuration;	**See [1.3], [1.5]** (same process is followed); Drasler ¶148.
[1.13] using the carrier element to exclude the native aortic heart valve in the second expanded configuration;	**See [1.5]** (same process is followed); Drasler ¶149.
[1.14] forming a seal between the carrier element and one or more anatomical features in the second expanded configuration; and	**See [1.6]** (same process is followed); Drasler ¶150.

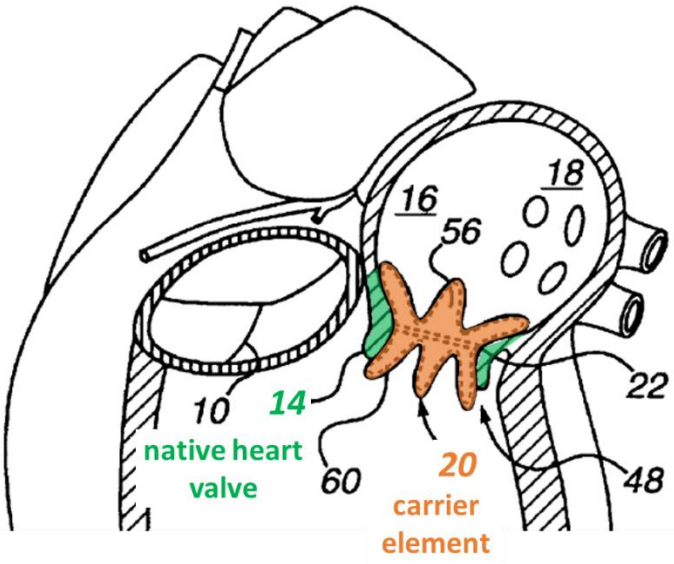
[1.15] using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the second expanded configuration.	**See [1.7]** (same process is followed); Drasler ¶151.
[2] The method of claim 1, wherein the carrier element is at least partially secured within the vicinity of the native aortic heart valve when in the first expanded configuration.	***See* [1].** **Leonhardt discloses that the carrier element is at least partially secured within the vicinity of the native aortic heart valve when in the first expanded configuration**. ***See* [1.5].** **To the extent further disclosure of the carrier element at least partially secured within the vicinity of the native aortic heart valve is required, Gabbay discloses that the carrier element is at least partially secured within the vicinity of the native aortic heart valve**. ***See* [1.3], §X.A.2.** Drasler ¶¶152-154.
[5] The method of claim 1, wherein repositioning of the carrier element includes at least one of rotating or translating the carrier element.	***See* [1].** **Leonhardt discloses that repositioning of the carrier element includes at least one of rotating or translating the carrier element** (*e.g.*, "valve stent 20" is "retrieved into outer sheath 106" for "repositioning" and "rotat[ing] and slightly advanc[ing] or withdraw[ing]" the deployment catheter)**.** ***E.g.*, Leonhardt:** ***See* [1.10].**

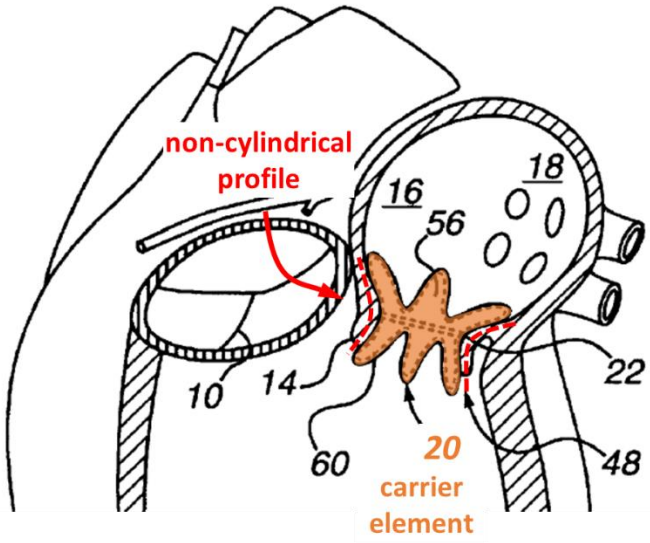
	Additionally, valve/stent 20 may be repositioned by: (i) "retriev[ing]" valve/stent 20 "into outer sheath 106," (ii) "rotat[ing] and slightly advanc[ing] or withdraw[ing]" the deployment catheter comprising outer sheath 106, and thus valve stent/20 contained therein. • 9:7-24 ("Spool apparatus 170 allows valve stent 20 to be retrieved into outer sheath 106 if ***repositioning*** or removal is necessary…") • 11:37-39 (*see* [1.10]) • 11:39-55 (*see* [1.9]) • 10:53-61 ("While valve stent 20 is beginning to protrude from outer sheath 106, ***deployment catheter 100 may again be rotated and slightly advanced or withdrawn to optimize placement of valve stent 20***.") Drasler ¶¶155-158.
[8] The method of claim 1, wherein the replacement valve prevents the flow of blood through the replacement valve in the second direction and allows the flow of blood through the replacement valve in the first direction during collapsing of the carrier element.	***See* [1].** **Leonhardt discloses that the replacement valve prevents the flow of blood through the replacement valve in the second direction** (*e.g.*, "blocking flow in one direction") **and allows the flow of blood through the replacement valve in the first direction** (*e.g.*, "open in the direction of blood flow") **during collapsing of the carrier element** (*e.g.*, "compress[ing]" "valve stent 20")**.** ***E.g.*, Leonhardt:** *See* [1.2], [1.9]. A POSITA would have understood that valve 22 would continue to function such that blood "flow[s] in a single direction" while valve/stent 20 is collapsed for repositioning. Drasler ¶162. When deployed, distensible fingers 46 on the proximal end of valve/stent 20 flair outward. *See* [1.9]. In

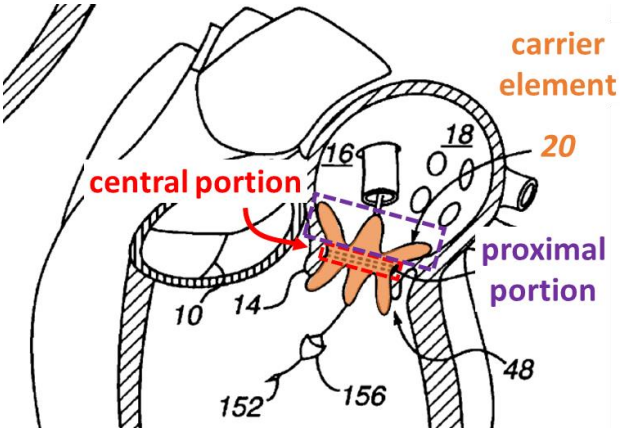
	the first step of collapsing valve/stent 20, these fingers are gradually "compressed to the diameter of outer sheath 106." Leonhardt, 11:40-53, Figs. 2 and 3; Drasler ¶162. Compression of these fingers does not interfere with functioning of the valve at least until the fingers are completely sheathed in outer sheath 106. Drasler ¶162. • Fig. 9C  FIG. 9C • Fig. 9A  FIG. 9A • 1:11-13, 7:17-21, 12:28-30 (*see* [1.2])

	• 11:39-55 (*see* [1.9] "…distended fingers 46 of…proximal end of valve stent 20 are ***compressed to…diameter of outer sheath 106***…") Drasler ¶¶159-162.
[9] The method of claim 1, wherein the replacement valve prevents the flow of blood through the replacement valve in the second direction and allows the flow of blood through the replacement valve in the first direction during repositioning of the carrier element.	***See* [1].** **Leonhardt discloses the replacement valve prevents the flow of blood through the replacement valve in the second direction** (*e.g.*, "blocking flow in one direction," *see* [1.2]) **and allows the flow of blood through the replacement valve in the first direction** (*e.g.*, "open in the direction of blood flow," *see* [1.2]) **during repositioning of the carrier element** (*e.g.*, "repositioning" the "valve stent," *see* [1.10])**.** ***E.g.*, Leonhardt:** *See* [1.2], [1.10], [8]. As discussed in relation to claim 8, a POSITA would have understood that valve 22 would continue to function such that blood "flow[s] in a single direction" while valve/stent 20 is compressed for repositioning. Additionally, a POSITA would have been motivated and found it obvious to reposition the prosthesis by pulling on sutures attached to the prosthesis's proximal end to slightly reposition the prosthesis advantageously without needing to completely collapse the prosthesis and such that the prosthesis would have continued to operate during this time as discussed in §X.A.1. Drasler ¶¶163-165.
[10] The method of claim 1, wherein the carrier element is configured to conform to the patient's anatomy upon expansion.	***See* [1].** **Leonhardt discloses that the carrier element is configured to conform to the patient's anatomy upon expansion** (*e.g.*, "Stent 26…will flair sufficiently to conform and seal to the tissue")**.** ***E.g.*, Leonhardt:**

	***See* [1.5].** Additionally, upon expansion valve/stent 20 "mold[s] itself" into tissue at the "placement site" and "flair[s] sufficiently to conform and seal to the tissue." • Fig. 9c  FIG. 9C • 5:41-52 (*see* [1.5]) • 6:16-22 (*see* [1.3]) • 10:53-11:9 (*see*[1.4]) • 4:60-65 ("…stent 26 to conform to and seal against…structures occurring within vessel walls and valve locations…") Drasler ¶¶166-169.
[11] The method of claim 1, wherein the only native anatomical feature displaced by the carrier element is the	***See* [1].** **Leonhardt discloses that the only native anatomical feature displaced by the carrier element is the native aortic heart valve** (*e.g.*, "valve stent 20" in a "conforming and sealingly fixed engagement with the tissue of [natural] valve" at the "aortic valve" placement site (see Fig. 2 for the mitral valve))**.**

native aortic heart valve.	***E.g.*, Leonhardt:** ***See* [1.5]-[1.7].** Additionally, valve/stent 20 conforms and molds to natural valve tissue at the aortic placement site to create a patent seal. Leonhardt, 5:41-52, 11:5-9. It replaces the aortic valve, but does not displace other anatomical features: "other vessels are not blocked" and "no damage" occurs to living tissue. Leonhardt, 6:16-22, 11:29-31. • Fig. 2  • 5:41-52 (*see* [1.5]) • 10:53-11:9 (*see* [1.4]) • 9:64-67 (*see* [1.pre]) • 6:16-22, 11:5-9 (*see* [1.3]) • 11:29-31 (*see* [1.8]) Drasler ¶¶170-174.
[13] The method of claim 1, wherein the carrier element	***See* [1].** **Leonhardt discloses that the carrier element has a non-cylindrical profile in the first and second expanded**

has a non-cylindrical profile in the first and second expanded configurations.	**configurations** (*e.g.*, when deployed "valve stent 20" "flair[s] [sic] at one or both ends" (see Fig. 2 for the mitral valve))**.** ***E.g.*, Leonhardt:** ***See* [1.4], [1.11].** Additionally, valve/stent 20 "must flair at one or both ends" to "conform and seal to the tissue" upon deployment to seal off the mitral valve. Leonhardt, 6:9-22, Fig. 2. Similarly, valve/stent 20 has a non-cylindrical profile when deployed over the aortic valve. Drasler ¶178. The diameter of a flared end is greater than the diameter of the central part of valve/stent 20 and presents an overall non-cylindrical profile. • 6:9-13 ("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…") • Fig. 2  • 6:16-22 (*see* [1.3]) • *See also* 5:47-50.

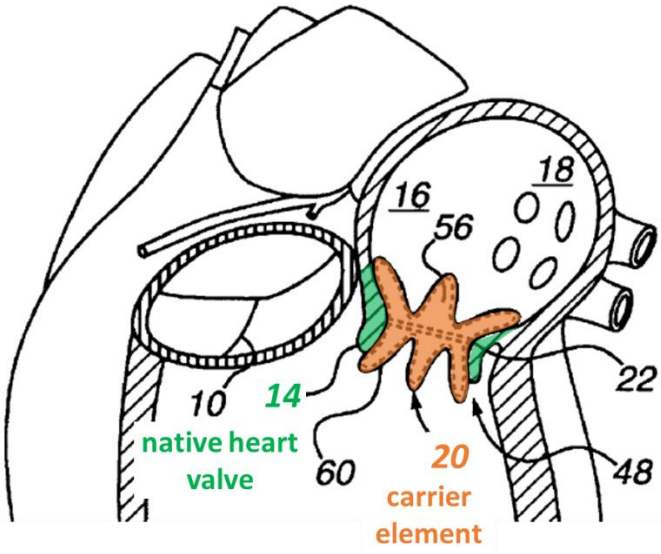
	Drasler ¶¶175-178.
[14] The method of claim 1, wherein a proximal portion of the carrier element extends further radially outwardly than a central portion of the carrier element.	***See* [1].** **Leonhardt discloses that a proximal portion of the carrier element extends further radially outwardly than a central portion of the carrier element** (*e.g.*, "valve stent" "flair[s] [sic] at…both [proximal and distal] ends" away from a "central part" (see Fig. 2 for the mitral valve))**.** ***E.g.*, Leonhardt:** ***See* [13].** Additionally, the proximal flared end extends further radially outward than the central part of valve/stent 20. • Fig. 9D  • 5:27-39 (*see* [1.9]). Drasler ¶¶179-182.
[18.pre] The method of claim 1, wherein the carrier element includes a first carrier element and the method further comprising:	***See* [1].** **Leonhardt discloses that the carrier element includes a first carrier element** (*e.g.*, "self-expanding" "super elastic spring stent" 26; *see* [1.1]). ***See* [1.1]**; Drasler ¶¶183-185.

[18.1] completely removing the first carrier element endovascularly and exchanging the first carrier element with an implantable second carrier element and an implantable second replacement valve having leaflets, the second replacement valve configured to allow the flow of blood through the second replacement valve in the first direction and prevents the flow of blood through the second replacement valve in the second direction, the second carrier element having at least one of a different diameter, length or style than the first carrier element; and	**Leonhardt discloses completely removing the first carrier element** (*e.g.* "[v]alve stent 20 may now be…removed," *see* [1.10]) **endovascularly** ("placement site is in the…aortic valve 10, entry may be made through the largest femoral artery…into the aorta," *see* [1.1]) **and exchanging the first carrier element with an implantable second carrier element** (*e.g.*, exchanging the first valve stent with a different "size of valve sent 20") **and an implantable second replacement valve having leaflets** (*e.g.*, "leaflets of biological valve 22," *see* [1.1])**, the second replacement valve configured to allow the flow of blood through the second replacement valve in the first direction** (*e.g.*, "open in the direction of blood flow," *see* [1.2]) **and prevents the flow of blood through the second replacement valve in the second direction** (*e.g.*, "blocking flow in one direction," *see* [1.2])**, the second carrier element having at least one of a different diameter, length or style than the first carrier element** (*e.g.*, different "size of valve sent 20")**.** ***E.g.*, Leonhardt:** ***See* [1.1], [1.2], [1.10].** Additionally, **Leonhardt** discloses selecting a valve/stent 20 of a particular size for deployment based on the placement site's anatomy and access path. Leonhardt, 9:51-55. **Leonhardt** discloses that valve/stent 20 may be removed endovascularly (Leonhardt, 11:37-55), and the ability to endovascularly remove and exchange a "fail[ed]" prosthesis is critical for patients "intoleran[t] to surgery," Leonhardt 3:6-11. After the first valve/stent is implanted, its "function and patency" are monitored. Leonhardt 11:29-30. If the valve/stent does not seal (and thus function) properly, a valve/stent with a different "diameter" needs to be used. Leonhardt 5:2-10. Similarly, if the valve/stent's "patency" is incorrect, a valve/stent having a different "length" needs to be used. *Id.* As discussed in §X.A.1, a POSITA would have understood, and at minimum found obvious, that, in the event the initial valve/stent 20 failed to function sufficiently, valve/stent 20 would be removed and a differently sized

	valve/stent 20, either having a different length or diameter, would be implanted. Drasler ¶¶189-190. • 11:37-55 ("***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***.") • 6:55-56 ("The ***size of outer sheath 106 depends on the size of valve stent 20*** to be implanted. Common sizes range from 12 FR to 20 FR.") • 9:51-55 ("It is assumed that necessary mapping of the placement site and access path have been performed, and that an ***appropriately sized valve stent 20 has been selected***…") • 3:6-11 ("Any ***misplacement or failure requires major open heart surgery***…Many ***patients which receive the valve percutaneously because of their intolerance to surgery*** would face a very uncertain outcome from…failure.") • 5:2-10 ("Each end is ***pre-sized in diameter to be...larger***…than the largest diameter of the tissue against which the valve stent 20 (FIG.3) will ***seal***. The overall ***length*** of stent 26 is also ***pre-sized to be sufficient to maintain patency***….") • 11:29-30 (*see* [1.7]) Drasler ¶¶186-190.
[18.2] expanding the second carrier element from a collapsed delivery configuration to an expanded configuration to secure the second	**Leonhardt discloses expanding the second carrier element from a collapsed delivery configuration to an expanded configuration** (*e.g.*, "by withdrawing [the] outer sheath," "distensible fingers…of valve stent 20 will distend," *see* [1.4]) **to secure the second carrier element in the vicinity of the native aortic heart valve** (*e.g.*, "placement site is in…aortic valve 10," *see* [1.11]) **while the heart is beating** (*see* [1.1])**, the proximal and distal ends of the second carrier element being proximate opposing sides of**

carrier element in the vicinity of the native aortic heart valve while the heart is beating, the proximal and distal ends of the second carrier element being proximate opposing sides of the native aortic heart valve in the expanded configuration;	**the native aortic heart valve** (*see* [1.3], [1.12]) **in the expanded configuration** (*see* [1.4])**.** ***E.g.*, Leonhardt:** ***See* [1.1], [1.3]-[1.4], [1.11]-[1.12].** Additionally, when valve/stent 20 is expanded for deployment (*see* [1.4]), proper placement molds stent 20 in the aortic valve such that the proximal and distal ends of the valve/stent are secured proximate opposing sides of the native aortic heart valve (*see* [1.3], [1.11]). Drasler ¶¶191-194.
[18.3] using the second carrier element to exclude the native aortic heart valve in the expanded configuration;	**See [1.5]** (same process is followed); Drasler ¶195.
[18.4] forming a seal between the second carrier element and one or more anatomical features in the expanded configuration; and	**See [1.6]** (same process is followed); Drasler ¶196.

[18.5] using the leaflets of the second replacement valve to replace leaflet actuation of the native aortic heart valve in the expanded configuration.	**See [1.7]** (same process is followed); Drasler ¶197.
[19] The method of claim 1, wherein the carrier element displaces the native aortic heart valve and maintains the displacement of the native aortic heart valve while in the first and second expanded configurations.	***See* [1].** **Leonhardt discloses that the carrier element displaces the native aortic heart valve and maintains the displacement of the native aortic heart valve while in the first and second expanded configurations** (*e.g.*, "[v]alve stent 20" configured to "open beyond the width of the natural valve mouth and…conform and seal to the tissue" at the "aortic valve" "placement site" during "deployment…of valve stent 20," *see* [1.4]-[1.5], [11])**.** ***E.g.*, Leonhardt:** ***See* [1.4]-[1.5] and [11].** Additionally, valve/stent 20 is configured to "open beyond the width of the natural valve mouth" in its deployed configuration to seal to the tissue. Therefore, valve/stent 20 maintains displacement of the aortic valve when expanded both before and after repositioning. • Fig. 2

	 • 6:16-22 (*see* [11]) • 9:64-67 (*see* [1.3]) • 10:53-11:9 (*see* [1.4]) • *See also* 3:57-58. **To the extent further disclosure of displacing the native aortic heart valve is required, Gabbay discloses that the carrier element displaces the native aortic heart valve**. ***See* [1.3], §X.A.2].** Drasler ¶¶198-202.
[20] The method of claim 19, wherein displacing the native aortic heart valve includes at least partially opening the native aortic heart valve.	***See* [19].** **Leonhardt discloses that displacing the native aortic heart valve includes at least partially opening the native aortic heart valve** (*e.g.*, "[v]alve stent 20…is pre-sized to open beyond the width of the natural valve mouth" at the "aortic valve")**.** ***E.g.*, Leonhardt:** ***See* [19].**

	By "open[ing] beyond the width of the natural [aortic] valve mouth" the displacement of the native valve at least partially opens the native valve. • 6:16-22 (*see* [1.3]) • *See also* 5:27-39, 9:26-29. **To the extent further disclosure of displacing the native aortic heart valve is required, Gabbay discloses that the carrier element displaces the native aortic heart valve**. ***See*** **[1.3], §X.A.2.** Drasler ¶¶203-207.
[21] The method of claim 1, wherein expanding the carrier element from a collapsed delivery configuration to a first expanded configuration includes expanding the distal end of the carrier element prior to expanding the proximal end of the carrier element.	***See*** **[1].** **Leonhardt discloses that expanding the carrier element from a collapsed delivery configuration to a first expanded configuration includes expanding the distal end of the carrier element prior to expanding the proximal end of the carrier element.** ***See*** **[1.4].** Drasler ¶¶208-210.
[22] The method of claim 1, wherein at least partially collapsing the carrier element from the first	***See*** **[1].** **Leonhardt discloses that at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration includes keeping the distal end expanded** (*e.g.*, "advancing outer sheath 106 to collapse the

expanded configuration to a moveable configuration includes keeping the distal end expanded.	distal end of valve stent 20 so that it is clear of living tissue" but still partially expanded)**.** ***E.g.*, Leonhardt:** ***See* [1.9].** Additionally, when repositioning, "[i]t may not be necessary to advance outer sheath 106 completely over valve stent 20," thereby partially collapsing the distal end until it is "clear of living tissue," but remaining partially expanded. • 11:36-58 ("…***It may not be necessary to advance outer sheath 106 completely over valve stent 20*** if repositioning is desired…advancing outer sheath 106 to collapse the distal end of valve stent 20 so that it is clear of living tissue may be sufficient.") Drasler ¶¶211-214.
[23] The method of claim 1, wherein at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration does not include the distal end.	***See* [1].** **Leonhardt discloses at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration does not include the distal end** (*e.g.*, "compress[ing]" the proximal end of "valve stent 20" to "reposition," *see* [1.9])**.** ***E.g.*, Leonhardt:** ***See* [1.9].** Additionally, distensible fingers 46 on valve/stent's distal end are matched "to the structure" of the aortic valve for optimal placement and to ensure "that other vessels are not blocked." Leonhardt, 6:17-19, 10:50-52. **Leonhardt** teaches achieving this alignment by rotating delivery catheter 100, including when "valve stent 20 is beginning to protrude." Leonhardt, 10:58-61. After expansion during deployment, "valve stent 20 function and leakage are verified" and if required, the valve/stent is repositioned for "[p]roper placement." Leonhardt, 11:37-60, 10:67-11:2. A POSITA would have understood, and at least found it obvious, that where the valve/stent's distal end was properly placed, but valve/stent's proximal end was obstructing coronary arteries,

	only valve/stent's proximal end needs repositioning. Drasler ¶218. In such situations, the proximal end's distensible fingers, but not the distal end's, are collapsed from the first expanded configuration to a moveable configuration and rotated (and thus repositioned) as needed. Drasler ¶218. Consistent with **Leonhardt's** guidance to "advance outer sheath 106…over valve stent 20" only to the extent necessary for the repositioning (*e.g.*, making the distal end clear of living tissue) (Leonhard, 11:36-58), when merely rotating the proximal end of the valve/stent to align the fingers and/or repositioning the proximal end, a POSITA would have been motivated to not collapse the distal end when repositioning because it would have been unnecessary to do so, particularly where the distal end were already properly placed and collapsing the distal end would have undesirably displaced the end. Drasler ¶219. Additionally, a POSITA would have been motivated and found it obvious to reposition the prosthesis by pulling on sutures attached to the prosthesis's proximal end to slightly reposition the prosthesis advantageously without needing to collapse the prosthesis's distal end. Leonhardt, 11:40-52; Drasler ¶220. • 10:50-52 ("Deployment catheter 100 is rotated to ***match distensible fingers 46 to the structure of mitral valve 14*** if necessary.") • 10:58-61 ("While ***valve stent 20 is beginning to protrude*** from outer sheath 106, ***deployment catheter 100 may again 60 be rotated*** and slightly advanced or withdrawn to optimize placement of valve stent 20.") • 6:17-19 ("Valve stent 20 may be placed such that other vessels are not blocked by placing distensible fingers 46 on either side of the vessel junction.") • *See also* 11:36-58 (*see* [22]). Drasler ¶¶215-220.

B. Claim 7 Is Rendered Obvious by Leonhardt in view of Gabbay (Ground 1) and in further view of Bailey (Ground 2)

1. 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 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 ¶¶221-222. The balloon may be used for valvuloplasty (*see* Fig. 20B below) or for stent expansion and prosthesis implantation using a single catheter (*see* Fig. 19 below). Bailey, Abstract, ¶¶[0069]-[0070], [0072]; Drasler ¶222.

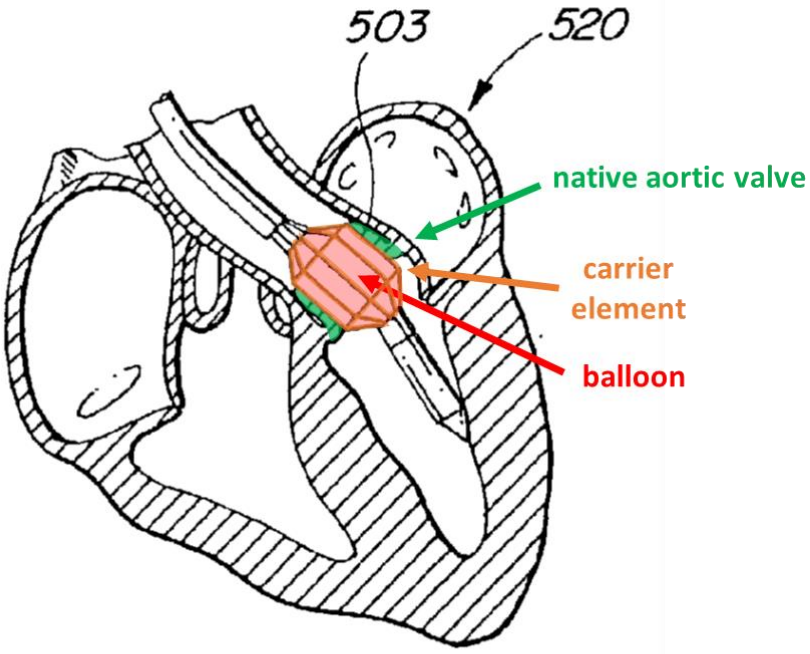


Fig. 20B

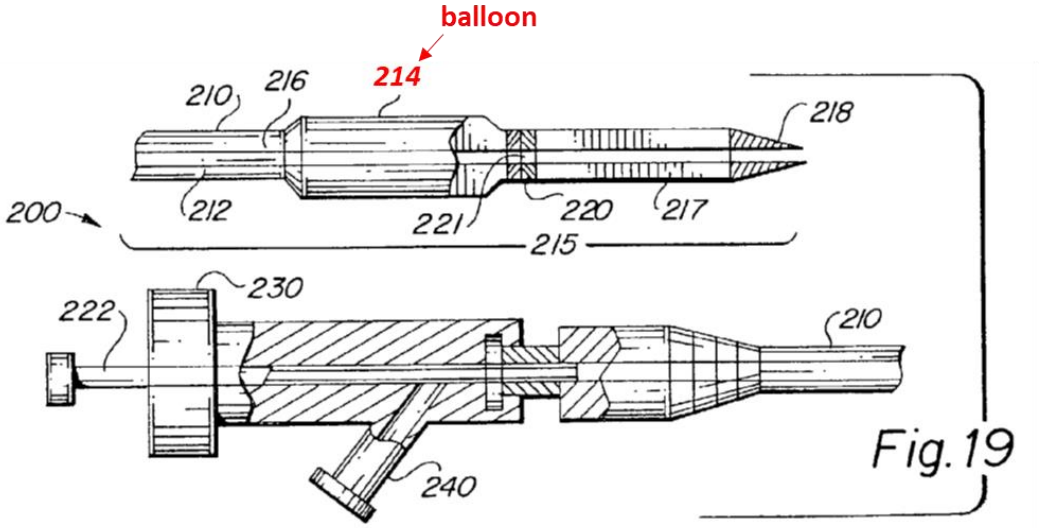


Fig. 19

Leonhardt and **Bailey** are in the same field as '118—prosthetic cardiac implants—and are reasonably pertinent to the alleged problem(s) identified in '118 of a need for a method of treating a patient using an expandable prosthetic valve.

'118, 3:48-51, 3:53-59; Leonhardt, 11:3-40; Bailey ¶¶[0069]-[0070], Figs. 20C-G; Drasler ¶223. 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. Drasler ¶224.

Bailey seeks to improve upon **Leonhardt's** valve. Bailey ¶¶[0006], [0018]-[0019]; Drasler ¶225. Although **Bailey** identifies **Leonhardt's** light actuated anchoring means as disadvantageous (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 ¶225; *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). Drasler ¶226. **Leonhardt** teaches minimizing the consequences of obstructing blood flow.[8] Leonhardt, 9:61-62 (slowing heart or dropping pressure), 11:23-29 (avoid sudden pressure changes); Drasler ¶¶226-227. **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], [0070], [0072]; Drasler ¶¶226-227. The benefits of minimizing obstruction were well-known. *See* Ex. 1015, (Eigler; published 3/25/2004) ¶¶[0005]-[0008]; Ex. 1016 (Downing; published 10/31/2002) ¶[0013]; Drasler ¶227.

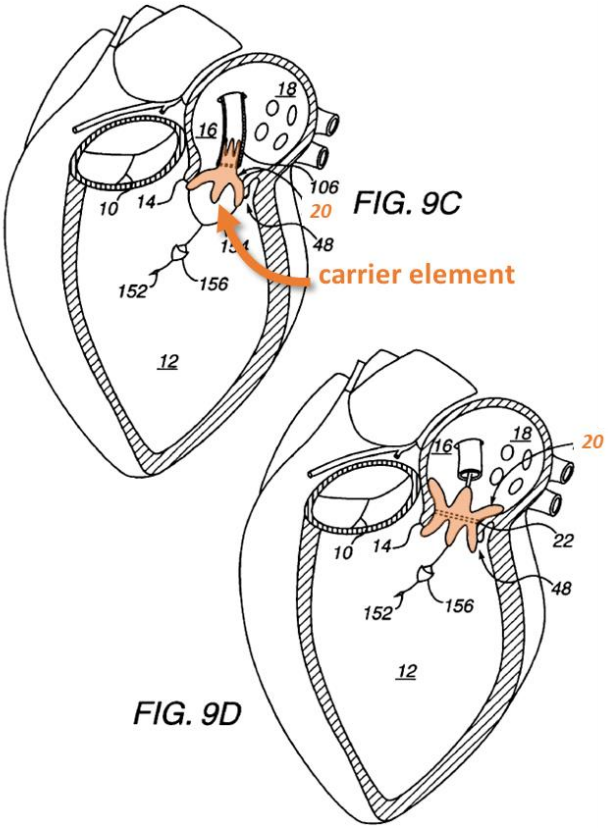
A POSITA would have had a reasonable expectation of success in applying **Bailey's** teachings of an expansion balloon permitting blood flow when inflated to **Leonhardt's** balloons. Salahieh-697 ¶[0074], Figs. 9A-10B; Drasler ¶228. **Leonhardt** already teaches using an expansion balloon to expand 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 ¶¶228-229; *see*

[8] 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. Drasler ¶227.

also Ex. 1017 (Yang; published 3/13/2003) ¶[0065]. **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 ¶229. A POSITA would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶229.

2. Claim Chart

[7] The method of claim 1, wherein the replacement valve prevents the flow of blood through the replacement valve in the second direction and allows the flow of blood through the replacement valve in the first direction at least partially during expansion of the carrier element to the second expanded configuration.	***See* [1].** **Leonhardt discloses that the replacement valve prevents the flow of blood through the replacement valve in the second direction and allows the flow of blood through the replacement valve in the first direction** (*e.g.*, "artificial valve…maintain[s] bodily fluid flow in a single direction") **and expands the carrier element to the second expanded configuration** (*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:** ***See* §§X.A.3.[1.2], [1.4].** Additionally, the prosthesis "function[s]" to maintain unidirectional blood flow after it is initially expanded and before "tip balloon 152" is again reinflated to mold valve/stent's proximal/distal ends "to the living tissue."

	Leonhardt, 1:11-14, 5:51-52, 11:24-36. By further "mold[ing]" the valve/stent to the tissue, the tip balloon expands the valve/stent's proximal/distal ends. *Id.* Meanwhile, the valve is "function[ing]" to "maintain bodily fluid flow in a single direction." *Id.* When the tip balloon is in the valve/stent's proximal end, 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 ¶¶233-235. • Figs. 9C-9D  • 7:17-19 ("Valve stent 20 is loaded either end first into outer sheath 106, the correct choice depending upon the access path taken and the fluid flow direction at the placement site.") • 1:11-14 (*see* [1.2])

	• 11:29-36 (*see* [1.7]) • 5:51-52 ("The deployed valve stent 20 creates a ***patent one way fluid passageway***.") • *See also* 1:6-9, 3:15-29, 7:61-63, 9:63-10:6, 10:18-21, 11:24-27, Figs. 9A and 9B. **Ground 1:** To the extent "during expansion" does not require the valve to actually be expanding at that moment, **Leonhardt** discloses that the valve allows unidirectional blood flow "during the expansion of the prosthetic valve" given that the valve will be "function[ing]" prior to the proximal end being expanded with the tip balloon as discussed above. Drasler ¶¶234-235. **Ground 2:** To the extent "during expansion" requires the valve to actually be expanding at that moment, **Bailey discloses a prosthetic valve allows the flow of blood through the prosthetic valve in a second direction at least partially 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"). Drasler ¶236. ***E.g.*, Bailey:** **Bailey's** expansion balloon uses "irregular inflation profiles" to "facilitate continuous blood flow about the inflated balloon," allowing blood flow through the valve/stent during valve/stent expansion. Bailey ¶[0070]; Drasler ¶237. As discussed in §X.B.1, 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 ¶238. For example, in applying **Bailey's** teachings, **Leonhardt's** tip balloon would allow blood flow through the valve/stent so it can continue to "function" to "maintain bodily fluid flow in a single direction" during expansion of **Leonhardt's** valve/stent's proximal end to further "mold" it to tissue.

	Leonhardt, 1:11-13, 11:29-30, 11:32-34; Drasler ¶238. When the tip balloon is used for valve/stent's proximal end expansion, no catheter or guidewire is protruding through the stent—thus allowing it to "function" and "maintain bodily fluid flow in a single direction." Drasler ¶238.[9] • ¶[0070] ("…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] ("…the position of the balloon 214 and capture sheath 217 may be reversed, such that the balloon 214 is distal the capture sheath 217…***This would allow for post-deployment balloon expansion of the deployed stent valve without the need to traverse the prosthetic valve in a retrograde fashion.***") • See *also* ¶¶[0021], [0048].

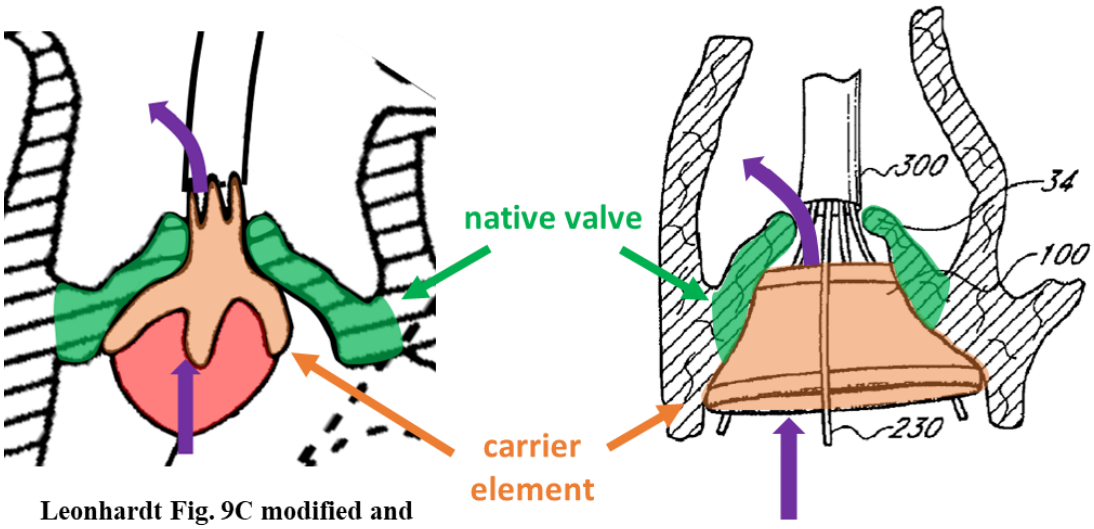
[9] **Leonhardt** in view of **Bailey** renders obvious '118's only disclosure of a valve functioning "during expansion" at the aortic valve ([7]) by further "dilat[ing]" the device "to ensure the device is apposed to the wall of the annulus and seated properly." '118, 73:22-24; *see* §V (specification teaches valve functioning after full expansion; proximal extensions permit valve to be removed after full expansion); Drasler ¶239.

	Drasler ¶¶230-239.

3. Leonhardt in View of Gabbay and Bailey Presents a Second Obviousness Basis

To the extent PO argues the Claims are instead limited to requiring unidirectional blood flow during the carrier element's initial expansion for [7] (*see* §§X.B.1, X.A.3.[7]), **Leonhardt** in view of **Gabbay** and **Bailey** nonetheless renders claim 7 obvious. A POSITA would have understood or least found it obvious that the same blood flow through the valve and functionality (to the extent present—*e.g.*, see annotated '118 Fig. 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 ¶¶240-241. For example, the figure on the left below has been modified from Leonhardt Fig. 9C to depict retrograde blood flow in the aortic valve and the orientation of the proximal stent fingers and cut-outs before proximal end expansion. *See* Garrison (Ex. 1018; published 6/30/2002), Fig. 17 (depicting aortic valve), 10:29-33); Drasler ¶¶240-241. As shown below, the valve functions as blood (purple) flows from the distal end, through a balloon modified with **Bailey's** (§X.B.1) teachings and out between the "cut outs" in the proximal fingers. *See* §§X.B.1-3; Drasler ¶¶240-241. As explained in §X.A.1, **Leonhardt's** valve and its leaflets are free to open and to collapse back onto the inner catheter (thus allowing unidirectional blood flow) because the balloon does not overlap with

the valve. Drasler ¶¶240-241. The catheter's presence would aid in blocking blood flow in one direction as the leaflets will need to close a smaller area of the valve. Drasler ¶¶240-241; *see also* Ex. 1044, 13 (PO's amended complaint asserting this limitation is met despite the presence of a catheter through the valve); Letac (Ex. 1037; published 7/9/98), Figures 9a-11b; Boretos, Figures 4A-4B; Salahieh-697 (Ex. 1007; published 6/23/05), Figs. 9A-10B, ¶[0074]. The valve would continue to function as the proximal end continues to self-expand and when the valve's proximal end is expanded with the expansion balloon as discussed in §X.A.1. Drasler ¶¶240-241.



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

'118 Fig. 47A

C. Ground 3: Claim 18 Is Also Rendered Obvious by Leonhardt in view of Gabbay and Moulopoulos

To the extent PO argues further disclosure of exchanging **Leonhardt's** valve/stent 20 with a different replacement is required for claim 18 (*see*

§X.A.3.[18]), **Leonhardt** in view **Gabbay** and in further view of **Moulopoulos's** teaching of exchanging of one artificial valve with another for reinsertion into the patient renders claim 18 obvious. Moulopoulos, 1:58-65; Drasler ¶242. **Moulopoulos** teaches the basic principle of replacing an implanted artificial valve "periodically" or "as conditions warrant." Moulopoulos, 1:58-65; Drasler ¶243.

Like **Leonhardt** and **Gabbay, Moulopoulos** is in the same field as '118—prosthetic cardiac implants—and is reasonably pertinent to the alleged problem(s) identified in '118 of a need for a method of treating a patient using an expandable prosthesis. *See* §X.A.2; '118, 3:26-30; Moulopoulos, Abstract; Drasler ¶244. Like **Leonhardt**, **Moulopoulos** envisions both aortic and mitral valve replacement. Moulopoulos, Abstract.

A POSITA would thus have been motivated to apply **Moulopoulos's** teaching of exchanging a previously implanted prosthesis with a replacement to **Leonhardt's** valve/stent 20 delivery to achieve the beneficial and predictable result of improved prosthesis fit and operation. Drasler ¶245. When **Moulopoulos's** teachings are applied to **Leonhardt's** valve/stent delivery, **Leonhardt's** valve/stent can advantageously be removed and exchanged with a better fitting replacement, a benefit that was well-known. **Leonhardt** recognized the importance of proper fit. Leonhardt, 9:51-55 (size of valve/stent 20 "selected" by "mapping" placement site). A POSITA would have thus understood that **Moulopoulos's** teachings would have

improved the fit and operation of **Leonhardt's** valve/stent that needs to be removed by exchanging it with a different valve/stent better sized (e.g., in diameter or length) to match the native valve. Leonhardt, 11:37-55; Drasler ¶¶245-246. In light of the above teachings, a POSITA also would have had a reasonable expectation of success in applying **Moulopoulos's** teachings of exchanging an artificial valve to **Leonhardt's** procedures of selecting an appropriately sized valve/stent and removing it if needed. Doing so was well-known. *E.g.*, Khairkhahan, 13:4-7; Drasler ¶247. A POSITA would have therefore found it obvious and straightforward to apply **Moulopoulos's** teachings to **Leonhardt**. Drasler ¶247.

XI. SECONDARY CONSIDERATIONS

There is no evidence in '118FH or any related application's prosecution that any arguments regarding secondary considerations exist, let alone that such evidence could overcome the strong showing of obviousness above or that there is a sufficient nexus to any of the Claims. *See generally* '118FH; Drasler ¶248. As demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in '118 were already well known. Drasler ¶248. 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 '118's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to claims 1-2, 5, 7-11, 13-14, and 18-23. *Inter partes* review of these claims 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 13,987 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 '118 patent:

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

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Dated: January 20, 2021

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