UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC,

Petitioner,

v.

COLIBRI HEART VALVE LLC,

Patent Owner.

Case IPR2020-01453

U.S. Patent No. 8,900,294

PETITION FOR *INTER PARTES* REVIEW

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Pursuant to §§311-319 and §42.1 Medtronic CoreValve LLC ("Petitioner") petitions for *inter partes* review ("IPR") of claims 1-4 ("Claims") of U.S. Patent 8,900,294 ("'294") (Ex. 1001), assigned to Colibri Heart Valve LLC ("PO").[1] There is a reasonable likelihood that at least one challenged claim is unpatentable as explained herein. Petitioner requests review of the Claims, and judgment finding them unpatentable under §103.

I. INTRODUCTION

The '294's purported invention is implanting a replacement heart valve device, formed by a valve inside a stent, which is delivered to the heart via a vein or artery. For delivery, the replacement valve/stent is collapsed over a pusher member and kept in place with a moveable outer sheath. The valve/stent is partially deployed by pushing the pusher member out of the sheath, and can be recovered back inside the sheath. '294, 5:16-21, cl. 1.

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

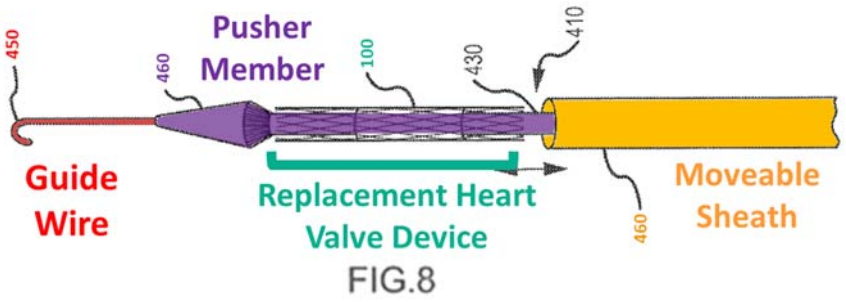


FIG.8

The ’294 concedes that insertion (e.g. through the femoral artery) of replacement heart valves (e.g., formed of three leaflets of fixed pericardium tissue) were well-known prior to the alleged invention. ’294, 3:1-10, 3:41-44, 4:21-25, 4:51-53; Drasler ¶34-38. The claimed delivery steps were also known prior to the invention. Drasler ¶34-38. Indeed, Boretos (U.S. 4,056,854; Ex. 1004), which PO admits is prior art (*id.*), teaches loading, advancing the delivery system, and deploying a replacement heart valve collapsed inside a sheath, and recovering the valve inside the sheath for and “repositioning” or “remov[al].” Boretos, 1:51-63, 2:64-3:45.

The Claim’s only purportedly novel element is “pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device.” ’294, cl. 1; *see* §VI. But as discussed herein, it was already well known to push a pusher member out of the moveable sheath to partially deploy a cardiac valve during transcatheter implantation of replacement cardiac valve devices in the claimed manner. Drasler ¶¶77-80, 110-113, 135-134, 169-177, 213-218.

For example, **Garrison** (Ex. 1005) teaches partially deploying replacement valve 6A out of moveable sheath 74 (outer wall of catheter 4A) by pushing rod 78 and its pusher member 80. Garrison, 8:24-28, 8:45-47. As the rod and pusher member are pushed, the distal end (the end away from the user) of cardiac valve 6A is exposed, but part of valve 6A remains collapsed over rod 78 and inside of and thus coupled to catheter 4A for repositioning. *Id.*, 8:58-61. Once manipulating catheter 4A places cardiac valve 6A in the correct position, it is fully deployed. Garrison, 8:56-58; 8:61-64.

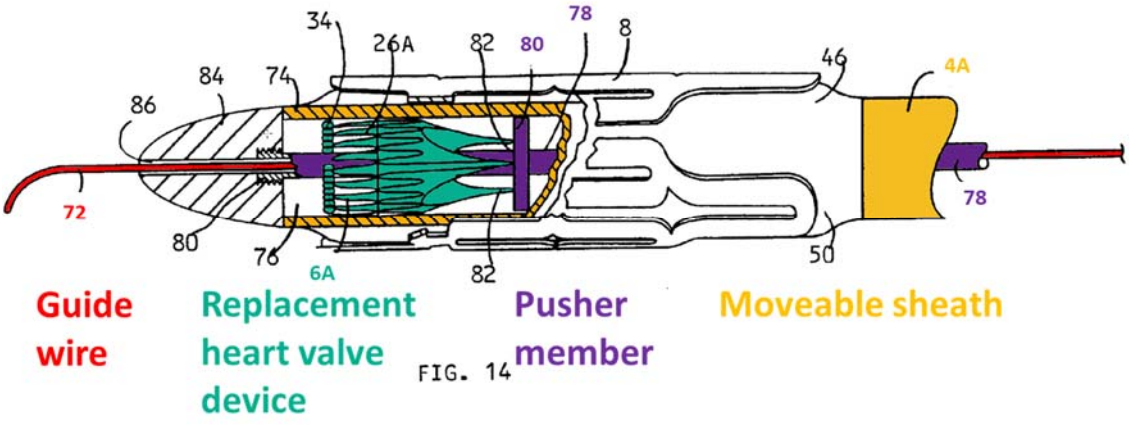
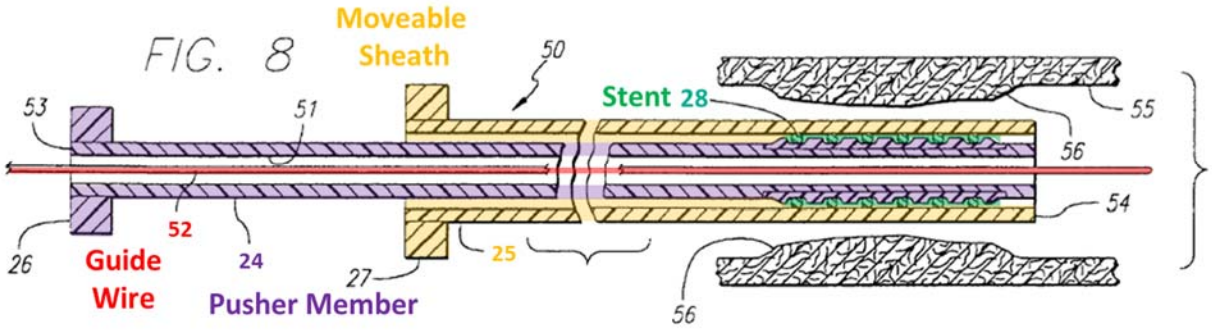


FIG. 14

Additional references such as **Leonhardt** (Ex. 1006) further disclose recovering a replacement heart valve device into a sheath for repositioning. Leonhardt, 11:37-58.

As a further example, **DiMatteo** (Ex. 1007) teaches transluminal delivery of a replacement heart valve mounted inside known stent designs. DiMatteo, 2:22-26, 5:3-7. And **Limon** (Ex. 1008) discloses a detailed, transluminal delivery method for implanting such stents without replacement heart valves, including partially

deploying the stent by pushing inner member 24 out of outer member 25 and recovering the stent for repositioning. Limon, 2:48-3:12, 5:41-44.



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 **Garrison** (and alternatively in further view of **Leonhardt)** and are also rendered obvious by **DiMatteo** in view of **Limon** (and alternatively in further view of **Gabbay** or **Phelps** for dependent claim 4). At most, the combination amounts to nothing more than a "predictable use of prior art elements according to their established functions." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

The USPTO did not consider **DiMatteo**, **Limon**, **Gabbay** or **Phelps** or any other reference providing analogous disclosures during '294's prosecution. Moreover, while the Examiner properly rejected the claims over **Garrison** alone and in view of **Leonhardt** during prosecution, the Examiner materially erred in

subsequently allowing the Claims by: 1) finding that the claims require "manipulating the catheter after partial deployment to properly position the valve device"—the limitation is not recited, 2) finding that Garrison does not disclose a moveable sheath despite express disclosures of "retracing" (typo—retracting) the sheath and that the sheath is "withdrawn"; and 3) failing to rely on Leonhardt's disclosures of a moveable sheath. *See* §VII.A.

Petitioner requests 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), Petitioner identifies 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

'294 is currently the subject of a district court litigation: *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847 (C.D. Cal., filed 5/4/2020). PO dismissed a prior action against Medtronic involving the same patent: *Colibri Heart Valve LLC v. Medtronic CoreValve LLC, et al.*, No. 8:19-cv-02351 (C.D. Cal., filed 12/5/2019).

C. Lead and Back-Up Counsel and Service Information

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Petitioner consents to electronic service of documents to the email addresses of 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. 102760-0210-651.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioner certifies '294 is available for IPR. Petitioner is not barred or estopped from requesting IPR challenging '294's Claims on the grounds identified herein.

B. Identification of Challenge

Pursuant to §42.104(b), Petitioner requests IPR of the Claims, and that the Board cancel the same as unpatentable. '294 matured from 14/253,656 ("'656 Application"), and claims priority through several continuations and a continuation-in-part to Application 10/037,266 filed on 1/4/2002.[2]

1. The Specific Art on Which the Challenge Is Based

Petitioner's grounds rely upon the following prior art:

[2] Petitioner takes no position as to the priority claims' propriety as the art presented herein pre-dates the earliest possible filing date. Drasler ¶¶39-40. Petitioner reserves the right to challenge these priority claims.

Name	Exhibit	Patent / Publication	Priority Date	Issued / Published	Prior Art Under at Least §102[3]
Garrison	1005	U.S. 6,425,916	2/10/1999	7/30/2002	(a), (e)
Leonhardt	1006	U.S. 5,957,949	5/1/1997	9/28/1999	(b)
DiMatteo	1007	U.S. 6,440,164	10/21/1999	8/27/2002	(e)
Limon	1008	U.S. 6,077,295	7/15/1996	6/20/2000	(a), (b), (e)
Gabbay	1009	U.S. 7,025,780	9/12/2000[4]	4/11/2006	(e)
Phelps	1010	WO 00/15147	9/10/1999	3/23/2000	(a), (b)
Cox	1021	U.S. 5,713,950	11/1/1993	2/3/1998	(a), (b), (e)

[3] Although PO threatened to swear behind art during prosecution, it did not attempt to do so, nor can it here. During prosecution of '294's parent, PO submitted documentation indicating the first alleged conception of any delivery system was 3/24/2001, and even then the identified delivery system omitted critical concepts (*e.g.*, pushing the pusher member). Ex. 1016, 149, 152-236; Ex. 1019, 6. PO also failed to show diligent reduction to practice.

[4] **Gabbay** is entitled to an effective filing date of 9/12/2000 as its earlier application has the same disclosures as those cited herein. Ex. 1015 (file history of App. No. 09/659,882), 15-29; MPEP 2136. Drasler ¶233.

2. Statutory Grounds on Which the Challenge Is Based

Petitioner respectfully requests cancellation of the Claims on the following grounds:

§103 Grounds	Claim(s)	Prior Art
1	1-4	Garrison
2		Garrison in view of Leonhardt
3		Garrison in view of Cox
4		Garrison in view of Leonhardt and Cox
5	1-3	DiMatteo in view of Limon
6	4	DiMatteo in view of Limon and Gabbay
7		DiMatteo in view of Limon and Phelps

3. How the Claims Are Unpatentable

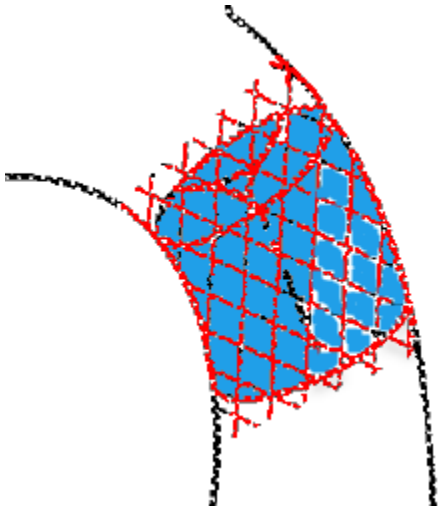
Petitioner provides the information required under §§42.104(b)(4)-(5) in §X.

V. '294 PATENT

The '294 generally refers to methods for controlled release of an implantable replacement heart valve in a patient. '294, Abstract, 6:49-51, 11:55-59; Drasler ¶¶41-53. The claimed method is generally directed to: (1) obtaining a replacement heart valve device, (2) loading the device into a valve delivery and implantation

system, (3) percutaneously and transluminally advancing the loaded delivery system to the native valve, (4) partially deploying the replacement valve at the native valve's location, and (5) recovering the valve's deployed portion for repositioning. Drasler ¶43.

The replacement heart valve device comprises a cylindrical "stent member 100" (red annotation below), preferably "self-expanding," formed from nitinol, and having flared ends in a "trumpet-like configuration" (not shown) with a "valve means 200…disposed within the cylindrical stent member" (blue annotation). '294, 6:57-67, 7:55-57, 7:62-63; Drasler ¶¶43-44. '294 concedes that a POSITA would have known that most tissue valves were leaflets constructed from "pericardial sac of cows or pigs and sew[n]…to a stent." '294, 3:41-46; Drasler ¶43. The valve is attached to the stent member's proximal portion.



'294, 10:38-40, 14:1-3, Fig. 4 (annotated excerpt); Drasler ¶¶43-53.

Prior to introduction into the patient, the valve device (green annotation below) is collapsed over pusher member 420 (purple annotation), and held in that collapsed position by a moveable sheath (orange annotation). ’294, 5:16-20, 11:40-51, 12:11-15, 14:10-16, Fig. 8. The pusher member and moveable sheath are coaxial, and move relative to each other.

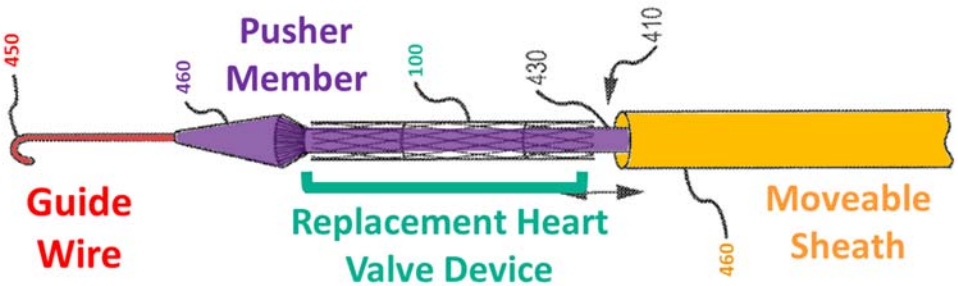


FIG.8

The loaded delivery and implantation system is introduced percutaneously (through the skin) and advanced transluminally (through the lumen of a blood vessel) into the patient to the native heart valve. ’294, 11:44-58, 12:16-24; Drasler ¶45. In an alternative embodiment, a guidewire 450 (annotated red) runs through a lumen within the pusher member and the loaded delivery system is advanced over the guidewire. ’294, 11:44-58, 12:16-24; Drasler ¶45. Then, pusher member is pushed out of the moveable sheath, exposing a “distal portion of the replacement heart valve

device," permitting that portion to partially expand. '294, 11:51-55.[5] While partially deployed, the stent is "restrained so that it doesn't pop out." '294, 11:55-59. According to the '294, this arrangement allows the replacement heart valve device to be "recovered if there is a problem with the positioning." '294, 11:55-59; Drasler ¶45.

VI. '294 PROSECUTION HISTORY

In Application 14/253,656, which matured into the '294, the originally filed claims were generally directed to a method of "controlled release of a percutaneous replacement heart valve" by "providing a replacement heart valve device and a delivery and implantation system," advancing the system into the patient and positioning the valve for deployment, "partially deploying" and then "recovering" the valve for repositioning. Ex. 1003 (File History '294), 6-12.

The Examiner rejected the issued claims (prosecution claims 34, 36-38) as anticipated by **Garrison** (issued claims 1-3) and/or as obvious over **Garrison** in view of **Leonhardt** (issued claims 1-4). *Id.*, 1814-1821. Applicant amended claim 34 to specify the replacement valve is "made of fixed pericardial tissue" and resides "entirely within an inner channel of the stent member," and to further require

[5] Distal refers to the portion away from the system's operator, whereas proximal refers to the portion near the operator. *E.g.*, '294, 11:40-55, cl. 1; Drasler ¶¶46-52.

"loading" the valve into the delivery catheter and "restraining" the valve "so that it…is held for controlled release." *Id.*, 1900-1907. Applicant also added three new independent claims 55, 61, and 68. *Id.*, 1900-1928. The Examiner then erroneously stated that with respect to "Garrison's disclosure of manipulating the catheter after partial deployment to properly position the valve device…, the manipulation and movement of 4a and 4b appears to be referring to manipulation and movement of *the entire catheter system as a whole* (outer sheath, inner pusher, and valve as one unit), and *not solely the outer sheath moving relative the valve,*" and dropped the rejections regarding Garrison alone and in view of Leonhardt. *Id.*, 1944-1952 (emphasis original). The Examiner allowed amended independent claim 34 and rejected newly added independent claims 55, 61, and 68. Unlike claims 55, 61, and 68, claim 34 required "pushing out the pusher member." *Id.*, 1901-1907. After Applicant cancelled the rejected independent claims (*id.*, 1944-1953), the Examiner allowed claims 34 and 36-38 without providing reasons for allowance. *Id.*, 1980.

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

A. §325(d)

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

Grounds 5-7: neither the art nor the arguments in Grounds 5-7 are the same or substantially the same as those considered during prosecution (step-one of *Advanced Bionics*). **DiMatteo**, **Limon**, **Gabbay** and **Phelps** were not discussed or applied during '294's prosecution. Nor are these references cumulative. For example, **Limon** teaches at least one limitation that the Examiner erroneously believed missing from the prior art: partially deploying the stent by pushing out the pusher member (*see* §§VI, X.D.2), and **DiMatteo** teaches that its stent-mounted replacement valve can use known stent designs (*see* §X.D.1). Necessarily, the Office also has not previously considered the expert testimony submitted herewith with regard to these combined teachings. Ex. 1002.

Where the "Examiner did not expressly consider" **DiMatteo**, **Limon**, **Gabbay** and **Phelps**, 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). Even if the examiner had considered substantially the same art as that relied on herein, the examiner would have erred in allowing the claims based upon the mistaken analysis explained below. For these additional reasons, an exercise of §325(d) discretion is not appropriate here.

Grounds 1-4: Despite properly rejecting the claims over **Garrison** alone and in view of **Leonhardt** (Ex. 1003, 1812-1821), the Examiner subsequently

committed multiple errors material to patentability (violating step-two of *Advanced Bionics*). The Examiner dropped the rejections after erroneously finding "upon further review" that **the claims** required "manipulating the catheter after partial deployment to properly position the valve device," and **Garrison's** disclosure of "the manipulation and movement of 4a and 4b appears to be referring to manipulation and movement *of the entire catheter system as a whole* (outer sheath, inner pusher, and valve as one unit), and *not solely the outer sheath moving relative the valve*." Ex. 1003, 1944 (emphasis original). The Examiner committed at least two material errors.

First, the Examiner erred in misunderstanding the claims to require "manipulating the catheter after partial deployment to properly position the valve device" (*id.*); no such limitation is recited in the prosecution or issued claims. *See* Ex. 1003, 6-12, 103-109, 1900-1907, 1972-1974; '294, claim 1.

Second, the Examiner erred in misunderstanding **Garrison** as not disclosing a moveable sheath. Ex. 1003, 1944. As demonstrated by the Examiner's initial rejection and her subsequent rejections in other related applications, **Garrison *expressly discloses moving the sheath (4A) relative to the valve-stent (6A)***, including retracting and withdrawing the sheath ***after*** partially releasing the valve-stent by pushing the rod: "cardiac valve 6A is advanced ***out of a chamber 76*** [the outer wall of 4A]…by advancing a rod," "catheter 4A is ***retraced*** a predetermined

amount ***so that the protrusions 34 are exposed*** outside the distal end of the catheter 4A" then "the rod 78 is…advanced far enough to completely release the cardiac valve 6A." Garrison, 8:25-30, 8:53-56, 8:61-64; *see also* Garrison, 2:33-37, 8:65-9:1 (catheter 4B is the "same [as] or similar" to catheter 4A), 9:51-53 ("The ***catheter 4B is then withdrawn further so that the support structure 26A expands*** to the fully deployed position of FIG. 20."); Ex. 1011, 1940-1951 ('739 patent file history) (Examiner asserting Garrison discloses these limitations); Drasler ¶¶101 ("retracing" refers to retracting to expose the valve's protrusions), 54-58. Tellingly, Applicant did not dispute the Examiner's finding as to this limitation in the '739 prosecution. Ex. 1011, 1977-1979. As the Board has repeatedly found, this misunderstanding of Garrison 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); *NFL Enters. LLC v. OpenTV, Inc.*, IPR2017-02092, Pap. 7, *16 (declining to exercise discretion where Office reached different conclusions on the same evidence). *See also* §X.A.2.[1.3].

The Board should not exercise its §325(d) discretion to deny institution.

B. §314(a)

Co-pending district court proceedings also do not warrant the exercise of discretion under §314(a) based on the six *Apple/Fintiv* factors. **1:** Petitioner intends to seek a stay of the related district court litigation pending the outcome of this IPR and IPR2020-01454 concerning the other asserted patent. **2:** While the parties have proposed a February 2022 trial date, Petitioner will be moving for a stay promptly and does not believe a trial date should be set. Moreover, in practice, the median time to trial for a patent case in this district is 2 years 6 months, putting the trial date in November 2022—approximately seven months or more after the Final Written Decision would issue in this proceeding. Ex. 1022. **3:** To date, the court has not issued any substantive orders related to '294 and Petitioner has moved to dismiss pending claims. **4:** Contentions have not been served in the litigation and Petitioner has stipulated that it will not pursue the same grounds raised herein in the litigation if this Petition is instituted (Ex. 1023). **5:** The litigation and PTAB parties are the same. **6:** The merits of this Petition are particularly strong as shown herein particularly in light of '294's admissions that the majority of the limitations were known in the art (*see* §I), and the fundamental errors by the Examiner in the original prosecution that led to the issuance of this patent.

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 '294 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 percutaneously, transluminally implantable cardiac prosthetic devices. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education. Drasler ¶¶30-33.

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 claims' outer bounds, while the district court may need to in addressing other issues, e.g., infringement. All claim terms should be construed according to their plain and ordinary meaning as would be understood by a POSITA in view of the specification. Drasler ¶59.

A. "a potential that the replacement heart valve device can be recovered…to address a problem with the position of the replacement heart valve device within the patient" (claim 1)

Regardless of whether this term is limiting (*see* MPEP 2111.04, §II (contingent method limitations not limiting)), the prior art discloses this limitation. *See* §§X.A.2.[1.7], X.D.3.[1.7]; Drasler ¶¶60-61.

B. "trumpet-like" (claim 4)

Regardless of this term's exact metes and bounds, the increasingly flared openings taught by the art relied on herein discloses the limitation. §§X.A.2.[4], X.B, X.E-F. Drasler ¶¶62-64, 123-130, 131-156, 230-241.

X. GROUNDS OF UNPATENTABILITY

Although '294 purports to have invented implanting a replacement heart valve device (a collapsible, expandable stent within which is a valve made of fixed pericardial tissue) using a particular delivery system (which pushes out a pusher member to partially deploy the device from and recovers the device into a sheath), such methods were well known in the art. As explained below, the Claims are unpatentable as obvious. Drasler ¶¶65-248.

Grounds 1-4: ***As to the replacement valve/stent***: **Garrison** discloses a replacement heart valve device comprising a collapsible, self-expanding stent containing a valve, and it would have been obvious to apply the well-known teachings of a prosthetic valve made of fixed pericardial tissue as '294 concedes.

Alternatively, **Cox** teaches such a valve. And **Garrison** and alternatively **Leonhardt** disclose claim 4's requirement that the stent's ends flare in a trumpet-like configuration. ***As to the valve delivery system***: **Garrison** discloses loading the device in a sheath and collapsed onto a pusher member and partially deploying the device by pushing out the pusher member from the sheath. **Garrison** and alternatively **Leonhardt** disclose or render obvious recovering the device in the sheath. Drasler ¶¶68-161.

Grounds 5-7: ***As to the replacement valve/stent***: **DiMatteo** discloses a collapsible, self-expanding stent containing a valve made of fixed pericardial tissue. **Gabbay** and alternatively **Phelps** disclose that the stent flare at both ends in a trumpet-like configuration. ***As to the valve delivery structure***: **DiMatteo** discloses implanting the stent/valve device using a delivery catheter and **Limon** teaches deploying and recovering a self-expanding stent using a transcatheter delivery system with a pusher member and moveable sheath. Drasler ¶¶162-241.

The prior art renders the Claims unpatentable. This Petition is supported by the Declaration of Dr. William Drasler, which describes the prior art's scope and content at the time of the alleged '294 invention. Drasler (Ex. 1002) ¶¶1-241.

A. Ground 1: Claims 1-4 Are Rendered Obvious by Garrison

1. Overview of Garrison

Garrison teaches "methods and devices for implanting replacement cardiac valves." Garrison, 1:5-9. The valve includes a "collapsed position," and an "expanded position," and is implanted using a "delivery catheter." Garrison, 3:7-9, 4:11-22. As shown in annotated Figures 10-11, the replacement device has a "valve portion 38" (annotated blue) mounted within an "expandable support structure" 26/26A (a stent—annotated red). Stent 26/26A forms an inner channel (annotated purple) that extends from protrusions 34 to the tip of posts 32, which are part of the stent.

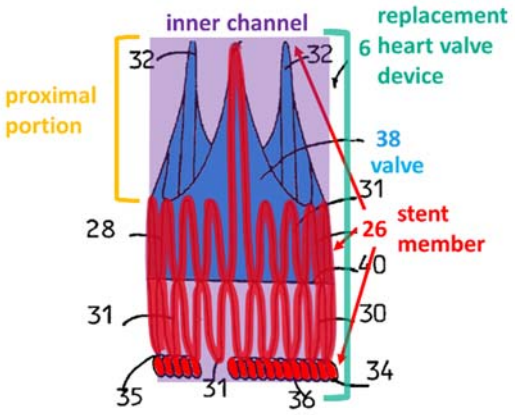


FIG. 10

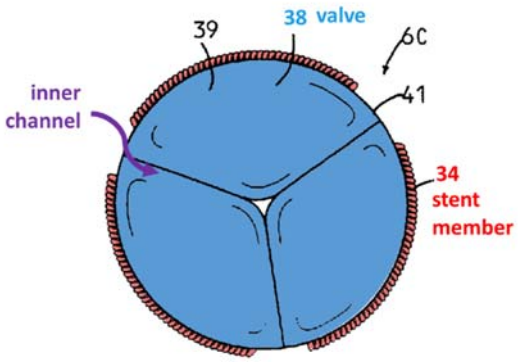


FIG. 11

Garrison, 5:19-46; Drasler ¶¶69-71. As shown, the valve and its leaflets are entirely within (both radially and axially) the stent's inner channel. Garrison, 5:42-43, 6:42-48; Drasler ¶¶69-70. As **Garrison** notes, system 2A, including valve 6A, uses "the

same or similar reference numbers [to] refer to the same or similar structures" as other discussions referring to system 2 and valve 6, including support structure 26A (the stent), which is the same as 26 except 26A is self-expanding. Garrison 8:10-16, 8:45-47. **Garrison** also teaches that the valve portion 38 is preferably a "stentless tissue valve" with a "tri-leaflet" configuration. Garrison, 5:42-46; Drasler ¶70.

Garrison also teaches a valve displacer 8 deployed before the valve to force open native valve leaflets and within which cardiac valve 6/6A can be placed, for example, as shown in annotated Figure 9.

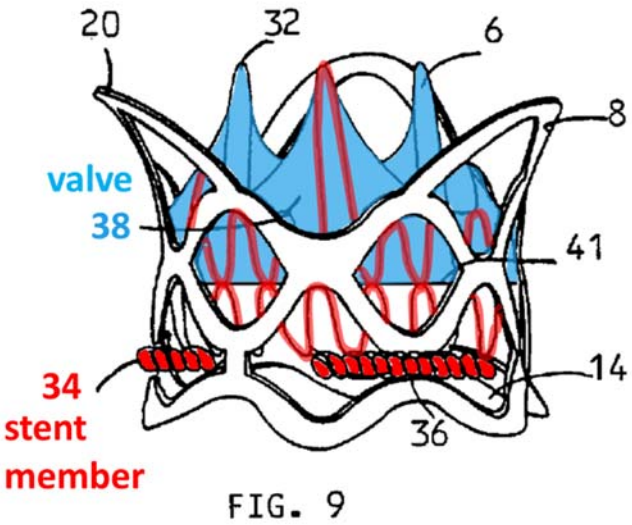


FIG. 9

Garrison, 8:48-64, Fig. 13. **Garrison** further teaches that the valve (including its support structure) can have the same features of the valve displacer, which includes the valve displacer's flared structure on either end. Garrison, 2:5-10. Indeed, both the support structure and valve displacer are disclosed as being self-expanding when deployed from a sheath and made of nitinol. Garrison, 8:13-16, 8:18-21, 9:2-3, 9:7-

10; Drasler ¶¶69-71. A POSITA thus would have understood **Garrison** to disclose, or at minimum it would have been obvious to implement, a support structure 26A with flared ends (and the valve portion remaining entirely within and attached to the support structure) to achieve the advantageous and predictable result of ensuring the valve device conforms to the valve displacer or directly to the vessel wall. Drasler ¶¶73-76. Indeed, this support stent structure was well-known and a POSITA would have been motivated to implement it to better hold the valve in the valve displacer and similarly shaped surrounding vasculature, and would have understood it to work as expected. Drasler ¶¶73-76. For example, **Letac** (WO 98/29057, Ex. 1012), **Gabbay**, **Leonhardt**, and **Phelps** each teach this flared shape that enables the device to better engage the surrounding structure and mitigate movement to reduce risk of displacement. Letac, Figs. 3a-3b, 9:19-21, 9:7-9 (expandable valve support); Gabbay, Fig. 2, 3:36-4:8, 2:5-15, 8:14-43 (self-expanding valve support deployed from a sheath); Leonhardt, Fig. 2, 6:17-22, 5:45-48, 10:53-64 (same); Phelps, Fig. 8, 10:7-17, 10:25-29 (same). Drasler ¶¶73-76.

Garrison teaches a "delivery catheter" that is inserted through the femoral artery and navigated to the heart. Garrison, 7:29-33. Figure 14 (annotated below) illustrates a delivery catheter adapted for use with the "self-expanding" cardiac valve replacement device.

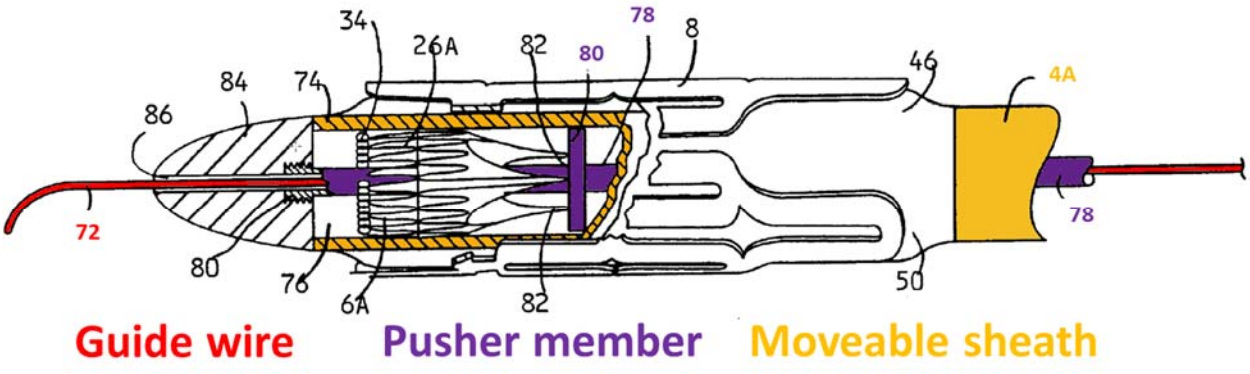


FIG. 14

Garrison, 8:24-28; Drasler ¶¶71-72. As shown in Fig. 14, the device is collapsed onto "rod 78" connected to "pusher element 80" (both annotated purple and together form the claimed pusher member) and the device is held in place by delivery catheter 4A's "outer wall 74" (the sheath—annotated yellow). Garrison, 8:24-44. **Garrison** teaches "rod 78"/"pusher element 80" have a "guidewire lumen 86" with a guidewire 72 running therethrough. *Id.* After introduction of the guidewire, the delivery catheter is "advanced over the guidewire" to a location "between the [native] valve leaflets." Garrison, 7:36-42, 9:36-40. The cardiac valve is then "advanced out of a chamber 76" formed by "outer wall 74 of the delivery catheter 4A" by pushing "rod 78"/"pusher element 80." Garrison, 7:36-42, 8:24-28, 9:36-40. **Garrison** also teaches that when part of the valve 6A has not been deployed from the sheath and thus remains collapsed onto rod 78, the valve remains "coupled to the catheter," allowing "for accurate positioning and deployment" of the valve by

"manipulat[ing]" "catheter 4A." Garrison, 8:53-61, 5:61-67. Drasler ¶¶71-72, 77-78.

A POSITA would have understood that, because the valve remains coupled to the catheter when only partially deployed, the valve can also be recovered back into the catheter chamber 76 by "manipulat[ing]" catheter 4A, and at minimum would have found it obvious to do so as part of repositioning the valve, e.g., particularly where the partially deployed valve is proximal or distal to the desired location and such that the valve can be repositioned without connecting to the valve displacer in the wrong location or at the wrong angle. *Id.*; Drasler ¶¶79; Ex. 1003, 1818 (Examiner agreeing). Indeed, '294 discloses only this prior art arrangement for withdrawing the valve back into the catheter. Indeed, Boretos, which PO admits is prior art, teaches withdrawing the prosthetic valve back into the sheath for repositioning. '294, 4:21-32; Boretos, 3:39-45; Drasler ¶79.

Garrison leaves the tissue valve's construction details to the POSITA. Garrison, 5:42-46. However, '294 admits the use of fixed pericardial tissue was well-known, stating that "[m]ost tissue valves are constructed…by constructing valve leaflets from the pericardial sac… and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity." '294, 3:41-46. Drasler ¶81.

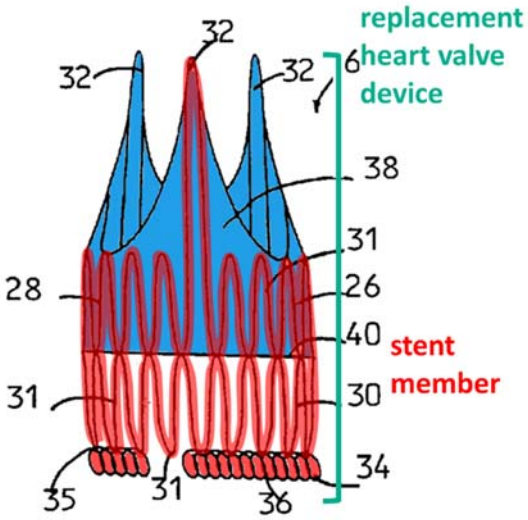
A POSITA would have been motivated to apply had a reasonable expectation of success in applying these teachings to **Garrison**'s porcine tissue valve to advantageously alleviate antigenicity and reduce the risk of an immune response to the new device using one of the most common ways of creating a tissue valve and to use a material with known benefits—strong for its relatively low profile and relatively easy to manipulate to the desired shape. Drasler ¶82; Cox, 4:35-50 (similar teachings as '294); *KSR*, 550 U.S. at 417.

Garrison is in the same field as the '294—percutaneously, transluminally implantable cardiac prosthetic devices—and reasonably pertinent to '294's alleged problem(s) of transluminally implanting heart prostheses. '294, Title, Abstract, 1:25-27, 2:52-3:17, 3:41-44, 4:4-9, 4:13-32, 4:63-5:1, 5:16-28, 6:41-42; Garrison, Abstract, 1:5-6, 1:55-65, 2:61-64, 4:24-40. Drasler ¶80.

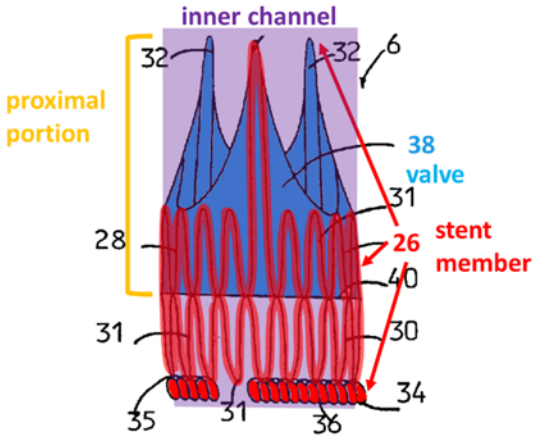
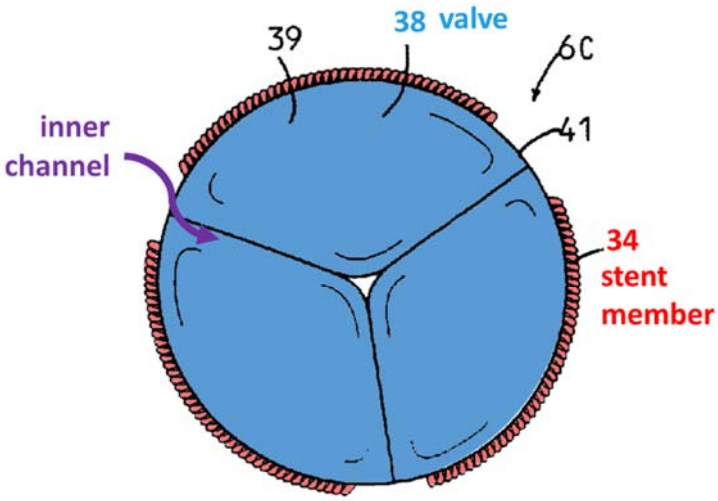
2. Claim Chart

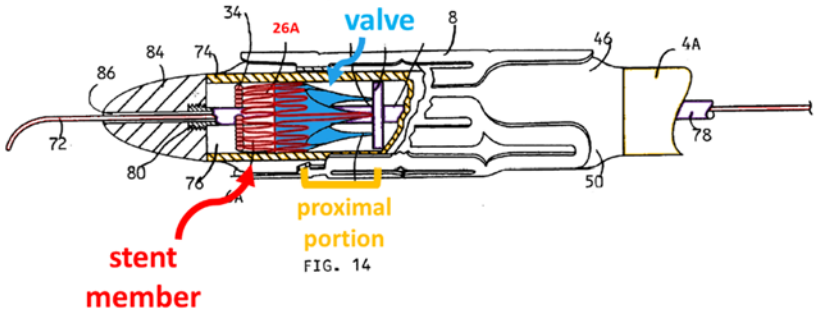
Claim Element	**Garrison**
[1.pre] "A method of controlled release of a percutaneous replacement heart valve at a location of a native heart valve in a patient, the method comprising:"	**To the extent the preamble is limiting, Garrison discloses a method of controlled release** (*e.g.*, "[t]he valve…remains coupled to the catheter…until the valve 6A engages the valve displacer") **of a percutaneous replacement heart valve** (*e.g.*, "replacement cardiac valves" "introduced…percutaneously") **at a location of a native heart valve in a patient** (*e.g.*, "valve implanted in the native valve position"). ***E.g.*, Garrison:**

Claim Element	**Garrison**
	Garrison discloses a method "for implanting replacement cardiac valves" by percutaneously introducing and advancing a delivery catheter "coupled to" the replacement valve for release at "the native valve position" in a patient. • 1:5-6 ("…methods and devices for implanting replacement cardiac valves.") • 4:32-35 ("…[D]elivery ***catheter 4 may be introduced*** by surgical cutdown or ***percutaneously***….") • 3:5-6 ("FIG. 6 shows the valve displacer and ***valve implanted in the native valve position***.") • 8:51-64 ("…[V]alve **6A** preferably remains coupled to the catheter **4A** while the protrusions **34** are exposed for manipulation of the valve **6A** until the valve **6A** engages the valve displacer **8**….") • Fig. 6, 10:26-27, 8:45-47. Drasler ¶¶84-86.
[1.1] "obtaining a replacement heart valve device and a delivery and implantation system: the replacement heart valve device including: a stent member that is collapsible, expandable and configured for	**Garrison discloses obtaining a replacement heart device** (*e.g.,* "cardiac valve 6A" consisting of "valve portion 38" and "support structure 26A") **and a delivery and implantation system** (*e.g.,* "delivery catheter 4A")**: the replacement heart valve device including: a stent member that is collapsible, expandable** (*e.g.*, "expandable support structure" with "collapsed" and "expanded" positions) **and configured for percutaneous delivery** (*e.g.*, valve is "preferably introduced through a peripheral vessel," "percutaneously"). ***E.g.*, Garrison:** **Garrison** discloses a replacement "cardiac valve 6A [that] is self-expanding" such that "support structure 26A

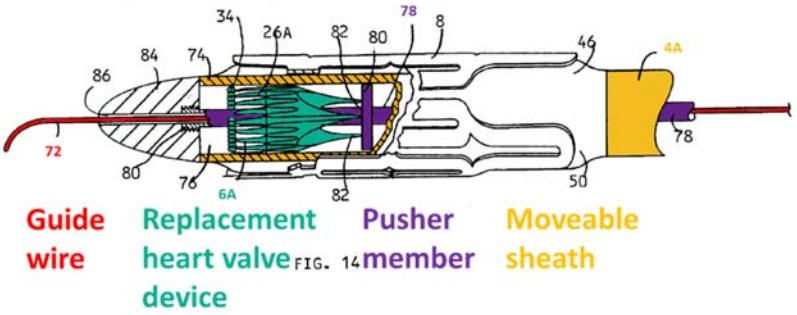
Claim Element	**Garrison**
percutaneous delivery; and”	is…naturally bias[ed]…to the expanded position,” but can be in a “collapsed position” where the valve 6A is introduced percutaneously by delivery catheter 4A “through a peripheral vessel.” • Fig. 10 (annotated)  FIG. 10 • 8:24-25 (“The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A.”) • 4:24-35 (“The cardiac valve 6 is preferably introduced through a peripheral vessel…. [D]***elivery catheter 4 may be introduced*** by surgical cutdown or ***percutaneously***....”) • 5:19-21 (“The cardiac valve 6 has an ***expandable support structure*** 26 ***which moves from the collapsed position*** of FIGS. 4 and 10 ***to the expanded position*** of FIGS. 5 and 9.”) • 5:42-50 (“[P]*osts 32* ***support a valve portion 38*** which performs the functions of the patient’s malfunctioning native valve….)

Claim Element	**Garrison**
	• 8:13-18 ("The cardiac valve 6A is similar to the cardiac valve 6 described above, however, the cardiac valve 6A is self-expanding…. The support structure 26A is made of a resilient material to naturally bias the support structure 26A to the expanded position.") • 4:14-15, 8:10-18, 8:45-47. Drasler ¶¶87-89.
[1.2] "a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member, the valve including two to four individual leaflets made of fixed pericardial tissue;"	**Garrison discloses a valve residing entirely within an inner channel of the stent member** (*e.g.*, "valve portion 38" is a "stentless tissue valve" residing entirely within "support structure") **and attached to a proximal portion of the stent member** (*e.g.*, "attached to the support structure" including "posts 32," as shown in Fig. 10), **the valve including two to four individual leaflets** (e.g., "tri-leaflet")**.** ***E.g.*, Garrison:** **Garrison** discloses the replacement cardiac valve's "valve portion 38" is a "tissue valve such as a tri-leaflet 39 stentless porcine valve," sutured to both the base and posts 32 of "the support structure 26." Garrison, 5:42-50. As shown in Figs. 10 and 14, the posts are on the proximal portion (closer to the user) of the stent member. *Id.*, 5:42-50. And even if proximal were wrongly read to mean closer to the heart, the valve's lower portion is also attached to the stent's proximal portion as shown in Fig. 10. The "valve portion 38" is attached to the internal surface of "support structure 26," and resides entirely within the inner channel formed by "support structure 26," as shown in Figs. 10-11. *Id.*, 5:42-50. • Fig. 10 (annotated)

Claim Element	**Garrison**
	 FIG. 10 • Fig. 11 (annotated)  FIG. 11 • Fig. 14 (annotated)

Claim Element	**Garrison**
	 FIG. 14 • 5:42-50 ("**[P]*osts 32 support a valve portion 38*** which performs the functions of the patient's malfunctioning native valve. Referring to FIGS. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a ***tri-leaflet*** 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown)….") • Figs. 10, 14, 29, 30, 8:3-4, 8:13-15, 8:45-47. During prosecution, PO did not dispute that the limitation "residing entirely within the inner channel of the stent member" was met by this embodiment, PO disputed only whether Garrison's *inverted* valve/stent discloses this limitation. Ex. 1003, 1908-1928. '294 admits that a valve made of fixed pericardial tissue was well-known in the art (*e.g.*, "[m]ost tissue valves are constructed…by constructing valve leaflets from the pericardial sac…and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity."). '294, 3:41-46. As discussed in §X.A.1, a POSITA would have been motivated to apply the known design teachings of a valve of fixed pericardial tissue to **Garrison's** valve with the predictable result of improving **Garrison's** device by using one of the most readily available valve construction materials with well-known advantageous characteristics,

Claim Element	**Garrison**
	which is fixed to reduce antigenicity. Drasler ¶¶81-82, 95-97. Drasler ¶¶90-97.
[1.3] "the delivery and implantation system including: a pusher member and a moveable sheath, wherein the pusher member includes a guide wire lumen, and wherein the moveable sheath includes a lumen configured for receiving the pusher member;"	**Garrison discloses the delivery and implantation system** (*e.g.*, "delivery catheter 4A") **including: a pusher member** (*e.g.*, "rod 78 having a pusher element 80 attached thereto") **and a moveable sheath** (*e.g.*, "outer wall" of "catheter 4A"), **wherein the pusher member includes a guide wire lumen** (*e.g.*, "guidewire lumen"), **and wherein the moveable sheath includes a lumen configured for receiving the pusher member** (*e.g.*, "outer wall" of "delivery catheter 4A" creates "chamber" for "rod," "pusher element," and "valve"). ***E.g.*, Garrison:** **Garrison** discloses "an outer wall 74 of the delivery catheter 4A" contains rod 78 connected to pusher member 80. Garrison, 8:24-28. Delivery catheter 4A, including outer wall 74, is "retrac[table]." *Id.*, 8:53-58 ("retracing"—typo). A POSITA would have understood catheter 4A is moveable in light of these disclosures, but nevertheless Garrison also subsequently discloses withdrawing catheter 4B, which is the "same or similar" to 4A, to expose the support structure, and at minimum a POSITA would have been motivated to apply Garrison's teachings regarding 4B to 4A to deploy the valve. *Id.* 8:65-9:1, 9:51-53; Drasler ¶101. Rod 78 has a "guidewire lumen 86 for receiving the guidewire 72." Garrison, 8:33-34. Valve 6A is pushed "out of a chamber 76 [formed by outer wall 74] in the delivery catheter 4A by advancing...rod 78" and "pusher element 80." Garrison, 8:25-44, Fig. 14.

Claim Element	**Garrison**
	• Fig. 14 (annotated):  FIG. 14 • 8:24-34 ("The cardiac ***valve 6A*** is contained ***within an outer wall 74 of the delivery catheter 4A***. The cardiac ***valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by advancing a rod 78 having a pusher element 80 attached thereto***…. The ***rod 78 has a guidewire lumen 86*** for receiving the guidewire 72.") • 8:53-58 ("After the valve displacer 8 has been expanded, the catheter 4A is ***retraced a predetermined amount*** so that the protrusions 34 are exposed outside the distal end of the catheter 4A. The catheter 4A may then be manipulated as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8.") • 9:51-53 ("***catheter 4B is then withdrawn*** further so that the support structure 26A expands to the fully deployed position….") • 8:65-9:1 Drasler ¶¶98-101.
[1.4] "after the obtaining step, loading the replacement heart valve device into	**Garrison discloses after the obtaining step, loading the replacement heart valve device into the lumen of the moveable sheath** (*e.g.*, "loading the cardiac valv[e]" "in the chamber" formed by "outer wall" of "delivery catheter") **such that the replacement heart valve device**

Claim Element	**Garrison**
the lumen of the moveable sheath such that the replacement heart valve device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath;"	**is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member** (*e.g.*, "valve" is "in a collapsed condition during introduction" on the "rod," which is connected with "pusher element") **and is restrained in the collapsed configuration by the moveable sheath** (*e.g.*, "self-expanding" "valve" "is contained within an outer wall" of "delivery catheter 4A"). ***E.g.*, Garrison:** ***See* [1.1].** In addition, **Garrison** discloses "loading the cardiac valve 6A in the chamber 76" such that "self-expanding" valve 6A is "contained within outer wall 74 of delivery catheter 4A" "in a collapsed condition [onto rod 78] during introduction" to the heart or blood vessel such that "cardiac valve 6A" is collapsed onto combined structure 78/80. • Fig 14 (see [1.3]) • 8:24-44 ("***The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A****….**The pusher element 80 engages posts 82 on the cardiac valve 6A**….***[R]***od 78 has threaded connections 80, 82 with a tip 84 and the pusher element 80 to facilitate assembling the delivery catheter 4A and loading the cardiac valve 6A in the chamber 76****….**") • 8:13-16 ("[C]ardiac valve 6A is ***self-expanding****….**") • Abstract ("[V]alve displacer and ***valve are in a collapsed condition during introduction*** and are expanded to deploy the valve displacer and valve.") Drasler ¶¶102-105.

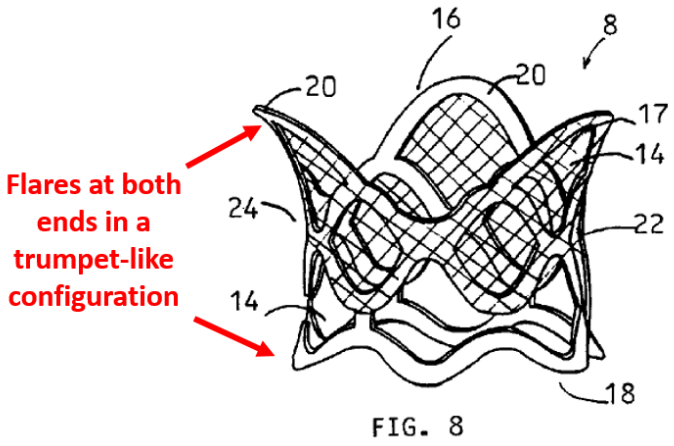
Claim Element	**Garrison**
[1.5] "after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient to position the replacement heart valve device for deployment within the patient at the location of the native heart valve;"	**Garrison discloses after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient** (*e.g.*, "delivery catheter" "is advanced over the guidewire") **to position the replacement heart valve device for deployment within the patient at the location of the native heart valve** (*e.g.*, support structure and "valve may be positioned in the native position"). ***E.g.*, Garrison:** ***See* [1.4].** In addition, **Garrison** discloses advancing "guidewire 72…across the aortic valve," then advancing the loaded delivery catheter 4A over the guidewire such that "valve displacer 8[, and the valve and support structure stored within it, are] positioned between the [native] valve leaflets" prior to deployment. • 7:36-39 ("The guidewire 72 is then advanced ahead of the…catheters…across the aortic valve."). • 8:49-51 ("…FIG. 13 shows the catheter 4A extending through the femoral artery with the *valve displacer 8 positioned between the valve leaflets prior to expansion*.") • 9:36-40 ("[G]uidewire 72 is advanced ahead of the catheter 4B into the ascending aorta and the ***delivery catheter 4B is advanced over the guidewire 72***. The delivery catheter 4B is then advanced between the valve leaflets.") • 10:26-27 ("The valve may be positioned in the ***native valve position***...")

Claim Element	**Garrison**
	• 8:47-49, 8:45-47, 6:57-65; Figs. 9, 13-14. Drasler ¶¶106-109.
[1.6] "after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device;"	**Garrison discloses after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member** (*e.g.*, "advancing a rod…having a pusher element" to deploy "cardiac valve") **from the moveable sheath** (*e.g.*, from within "outer wall…of" "delivery catheter") **to expose the distal portion of the replacement heart valve device** (*e.g.*, "protrusions" of valve "are exposed outside the distal end of the catheter"). ***E.g.*, Garrison:** ***See* [1.5].** In addition, **Garrison** discloses after the cardiac valve is "positioned between the [native] valve leaflets," and the valve displacer is deposited, the cardiac valve is partially deployed "out of…the delivery catheter 4A" by pushing "a rod 78 having a pusher element 80," such that "protrusions 34," located at the valve's distal end as shown in Figure 14, "are exposed outside the distal end of the catheter 4A." As shown in Figure 14 in [1.3], when distal end of rod 78 is pushed out of the sheath, protrusions 34 of valve 6A are pushed out of the sheath. • 8:25-28 ("The ***cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A***. The cardiac valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by ***advancing a rod 78 having a pusher element 80 attached thereto***.") • 8:49-61 ("…After the valve displacer 8 has been expanded, the ***catheter 4A is retraced a predetermined***

Claim Element	**Garrison**
	amount so that the protrusions 34 are exposed outside the distal end of the catheter 4A….") Drasler ¶¶110-113.
[1.7] "after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release, with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient."	**Garrison discloses after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release** (*e.g.*, support structure and "valve…preferably remains coupled to the catheter 4A", "time for accurate positioning…of the valve," "manipulate[]" the catheter "as necessary"). ***E.g.*, Garrison:** ***See* [1.6].** In addition, **Garrison** discloses the cardiac valve "remains coupled to the catheter 4A while the protrusions 34 are exposed for manipulation of the valve 6A until the valve 6A engages the valve displacer 8" to allow for "accurate positioning and deployment of the valve 6." • 8:53-61 ("…[C]atheter 4A may then be manipulated as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8. ***The valve 6A preferably remains coupled to the catheter 4A while the protrusions 34 are exposed for manipulation of the valve 6A until the valve 6A engages the valve displacer 8***.") • 5:64-67 ("The temporary valve mechanism 40 ensures proper blood flow regulation when the leaflets are held open by the valve displacer 8 to provide ***time for accurate positioning and deployment of the valve 6***.") • 8:45-47.

Claim Element	**Garrison**
	To the extent the requirement of "with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient" is limiting (*see* §IX.A), **Garisson discloses or at least renders obvious the limitation**. A POSITA would have understood based on Garrison, and at minimum found it obvious over, to recover the valve within the delivery catheter by either withdrawing the rod and pusher member or "manipulate[ing]" catheter 4A to advantageously recover and reposition the valve as discussed in §X.A.1. Drasler ¶¶78-79, 118. Drasler ¶¶114-118.
[2] "The method of claim 1, wherein the stent member is self-expanding."	***See* [1].** **Garrison discloses the stent member is self-expanding** (*e.g.*, "cardiac valve," which "has an expandable support structure," "is self-expanding"). ***E.g.*, Garrison:** • 5:19-21 ("The ***cardiac valve 6 has an expandable support structure*** 26….") • 8:13-22 ("The cardiac valve 6A is similar to the cardiac valve 6 described above, however, the ***cardiac valve 6A is self-expanding***….") • 8:45-47. Drasler ¶¶119-121.
[3] "The method of claim 2, wherein the	***See* [2].**

Claim Element	**Garrison**
stent member comprises nitinol."	**Garrison discloses the stent member comprises nitinol** (*e.g.*, "support structure…made of…nitinol")**.** ***E.g.*, Garrison:** • 8:16-21 ("…***[S]upport structure*** 26A may be ***made of*** …***nitinol***.") Drasler ¶122.
[4] "The method of claim 1, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration."	***See* [1].** **Garrison discloses the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration** (e.g., "support structure" has "features of … valve displacer," which "is substantially cylindrical" and its "first and second ends are…flared outwardly")**.** ***E.g.*, Garrison:** **Garrison** teaches the support structure may have "all features" of the valve displacer, which is "substantially cylindrical" and has "first and second ends...flared outwardly to form a circumferential recess around the central portion." Garrison, 2:5-10, 4:52-65, Fig. 8. As discussed in §X.A.1, a POSITA thus would have understood, and at minimum found it obvious, that Garrison also discloses a support structure that "flare[s] outwardly" in a similar manner to have the same features as the displacer and at minimum would have been motivated to use a support structure having this structure to advantageously conform the valve to the valve displacer or the vessel walls in light of this disclosure. *Id.*, 4:52-57; Drasler ¶¶124-126. Alternatively, a POSITA would have understood, and at minimum found it obvious, that Garrison also discloses an integrated valve displacer and cardiac valve such that the support structure "flare[s] outwardly," and the prior discussions regarding the stent

Claim Element	**Garrison**
	support in claim 1 similarly apply to the valve displacer. Garrison, 2:5-10, 4:52-57; Drasler ¶¶127-128. • Fig. 8 (annotated)  FIG. 8 • 2:5-10 ("…[V]alve displacer has a first end, a second end and *a central section* between the first and second ends. *The first and second ends are preferably flared outwardly* to form a circumferential recess around the central portion.") • 4:52-65 ("…[V]alve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately. Thus, ***all features of any valve displacer described herein may also form part of any of the cardiac valves described herein***…. The valve displacer 8 is ***substantially cylindrical*** in the collapsed condition….") • 4:66-5:4. Drasler ¶¶123-130.

B. Ground 2: Claims 1-4 Are Rendered Obvious by Garrison in View of Leonhardt

To the extent further disclosure is required beyond Garrison for [1.2], [1.7], and [4] (*see* §X.A), the Claims are obvious in further view of **Leonhardt**.

Leonhardt teaches percutaneous, transcatheter implantation of a replacement valve stent device via a delivery system. Leonhardt, 1:4-8. As shown in Fig. 4 (annotated below), **Leonhardt** teaches that the valve may be a "biological valve 22" (annotated blue) pre-sized to "fit within the internal diameter of cylinder 48 formed by stent 26" (annotated red).

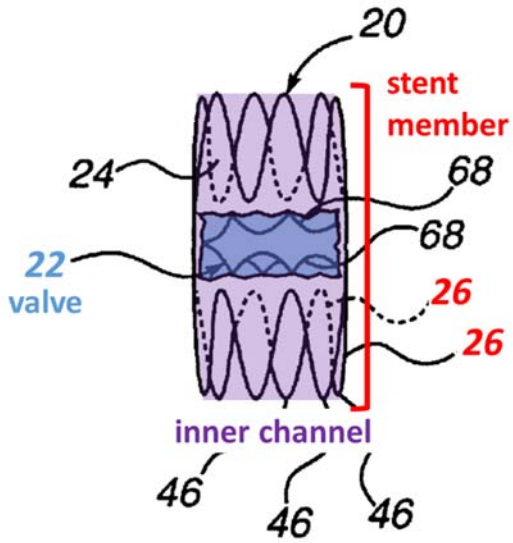
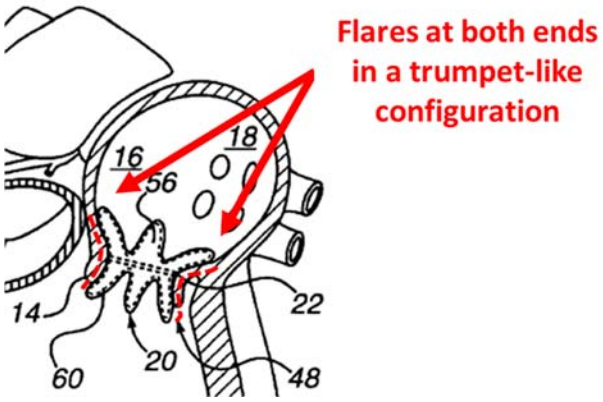


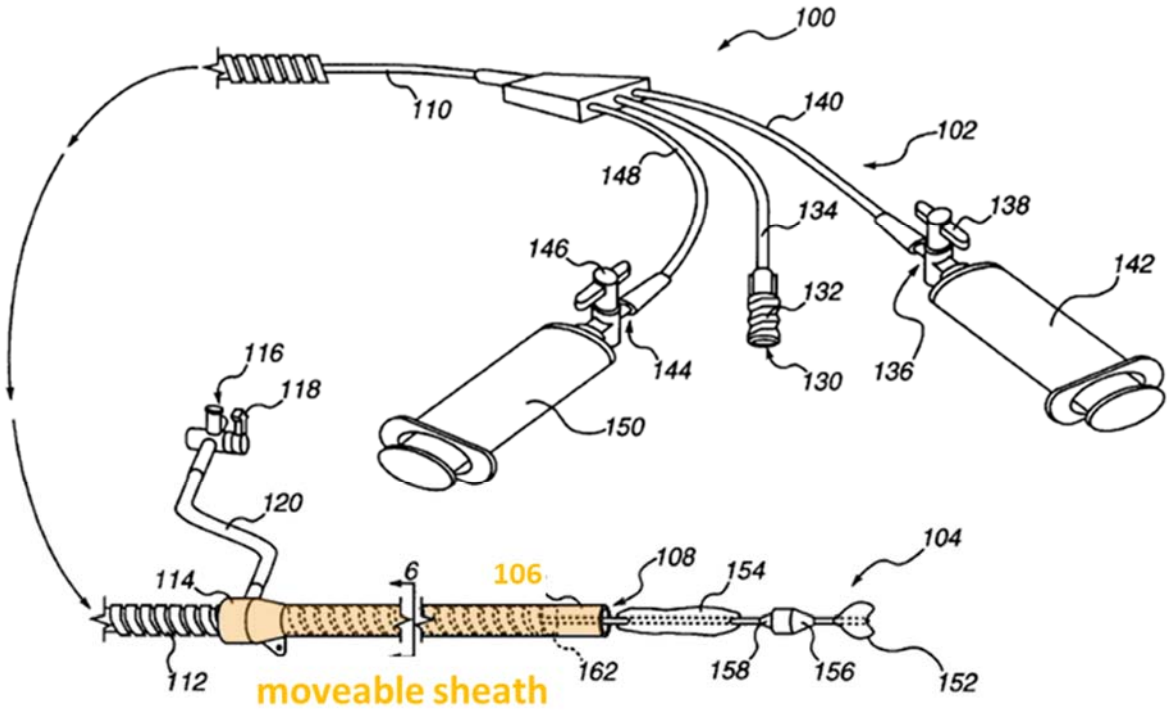
FIG. 4

Leonhardt, 6:23-31; Drasler ¶¶131-133. **Leonhardt** discloses that the deployed device will "flair [sic] at…both ends." Leonhardt, 6:9-22; Drasler ¶134. For

example, as shown in Fig. 2 (annotated excerpt below), the stent's ends flare out in a trumpet-like configuration to help it "conform and seal" to the tissue.



Leonhardt, 6:17-22. As shown in Fig. 5 (annotated below), the device is loaded into outer catheter/sheath 106, over inner catheter 110 and pushed out using "push rod 112."



Leonhardt, 8:23-41; Drasler ¶¶135-136. **Leonhardt** teaches recovering the device for repositioning by recapturing it into sheath 106. Leonhardt, 11:37-58. For example, **Leonhardt** discloses "suture loops 174" threaded from the device's proximal end, through push rod 112, to a spool, which can recapture a "fully or partially deployed" device by preventing distal movement of the valve while "advanc[ing] outer sheath 106 over valve stent 20…until outer sheath 106 completely covers valve stent 20." Leonhardt, 3:16-30, 8:23-41, 11:37-58; Drasler ¶137.

Like **Garrison**, **Leonhardt** is in the same field as '294 and reasonably pertinent to '294's alleged problem(s), e.g., of transluminally implanting heart prostheses. Leonhardt, Title, Abstract, 1:4-16, 2:5-6, 3:15-17, 9:63-10:11; *see* §X.A.1; Drasler ¶138.

In light of the above and as discussed below, a POSITA would have found it routine, straightforward and advantageous to apply **Leonhardt's** teachings of a valve within a stent, recovering the valve stent's distal portion within an outer sheath for repositioning, and a trumpet-like configurations on the stent's ends in implementing **Garrison's** cardiac valve and delivery method and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶¶138-144.

[1.2]: While a POSITA would have understood that **Garrison** discloses that the valve is entirely within the inner channel formed by the stent (§§X.A.1, X.A.2.[1.2]), **Leonhardt expressly teaches a valve residing entirely within an inner channel of the stent member** (*e.g.*, as shown in Fig. 4).

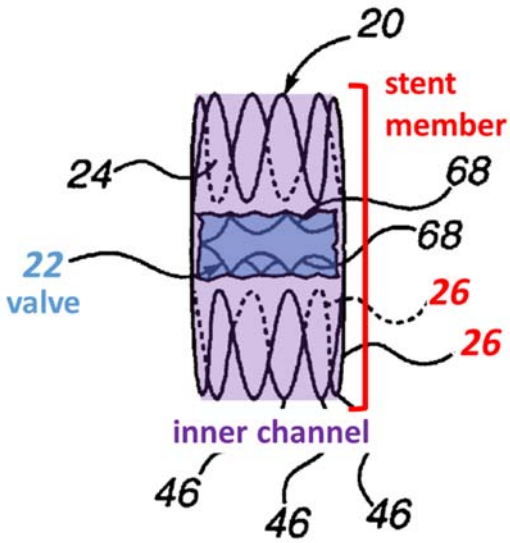


FIG. 4

Leonhardt, 6:23-31("valve…pre-sized to fit within the internal diameter of cylinder 48 formed by stent"); Drasler ¶¶146-148. A POSITA would have been motivated to apply **Leonhardt's** teachings of placing the valve axially and radially entirely inside the stent to **Garrison's** support structure 26A such that the valve portion 38 is advantageously protected by the support structure—avoiding valvular damage caused by the valve residing outside (e.g., axially) the stent's more protected inner channel and increasing the surface area over which the support structure presses and

seals against the valve displacer to better secure the prosthesis. *E.g.*, Garrison, 4:15-20 ("prevent contact between the blood vessel and the cardiac valve 6"); Leonhardt, 7:10-20 (discussing risk (albeit negligible) that the valve may be damaged); Ex. 1013 (U.S. 5,840,081, filed 2/19/1997, "Andersen"), 4:3-17 (increasing stent surface area that "abuts the inner wall of the channel" helps secure "the valve prosthesis"); Drasler ¶¶139, 148.

[1.7]: To the extent the latter half of [1.7] is limiting (see §IX.A) and further disclosure of recovering the valve within the sheath to reposition the device within the patient is required beyond **Garrison** (§§X.A.1, X.A.2.[1.7**]**, **Leonhardt expressly teaches a potential that the replacement heart valve device can be recovered if there is a problem with positioning** (*e.g.*, "retrieve valve stent 20 for repositioning")**; and after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed** (*e.g.*, "advance outer sheath" "until outer sheath…completely covers valve stent") **in order to address a problem with the position of the replacement heart valve device within the patient** (*e.g.*, "valve stent…may now be repositioned or removed")**.** Leonhardt, 9:6-10, 11:37-40, 11:47-53; Drasler ¶¶149-152. A POSITA would have been motivated and found it straightforward to apply **Leonhardt**'s teaching of recovering the valve stent within the sheath to advantageously address the valve stent's positioning to **Garrison**'s delivery system, such that the rod 78

carrying the valve can be pulled back or the catheter 4A can be moved forward to recover the partially exposed portion of the valve back into the catheter such that the valve can advantageously be repositioned. Garrison, 8:24-64; Drasler ¶¶142-143, 152; *see also* §X.A.1; Leonhardt, 3:4-30 ("any misplacement or failure [of the valve] requires major open heart surgery"). While it is unnecessary to also apply **Leonhardt's** additional teachings of using sutures to hold "cardiac valve 6A" in place while moving outer catheter over it in light of **Garrison's** teachings, a POSITA would have alternatively been motivated and found it straightforward to also apply these teachings as an alternative mechanism to recapture "cardiac valve 6A" into the sheath. Drasler ¶¶142-143, 152. Indeed, **Leonhardt** teaches passing suture loops through a separate lumen, e.g., through the pusher member, to allow the user to control the sutures and thus the location of the valve. Leonhardt, 8:34-39, 9:8-25. Drasler ¶143.

[4]: While a POSITA would have understood that **Garrison** discloses or at least renders obvious a stent with flared trumpet-like configurations on both ends (§§X.A.1, X.A.2.[4]), **Leonhardt expressly teaches the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration** (*e.g.*, "valve stent" "flair[s] at…both ends," as shown in Fig. 2). Leonhardt, 5:47-50, 6:9-13, 6:19-22, Figs, 2, 9D; Drasler ¶¶153-156. A POSITA would have been motivated to apply **Leonhardt**'s teaching of a specific

stent shape to **Garrison**'s support structure to advantageously conform and seal the support structure 26a to the valve displacer or the vasculature in the desired location as discussed in §X.A.1. Drasler ¶¶140-141, 156. Like Leonhardt, **Garrison** teaches applying its methods to replacement mitral valves. Garrison, 7:10-13. **Leonhardt** recognizes that some prostheses, such as some mitral valves, "must flair [sic] at one or both ends as is shown in Fig 2" to ensure the stent "conform[s] and seal[s] to the tissue." Leonhardt, 3:57-58, 6:9-22, Fig. 2. As discussed in §X.A.1, **Letac**, **Gabbay**, and **Phelps** further confirm a POSITA would have been motivated to apply Leonhardt's teachings. Drasler ¶¶75, 155-156.

C. Grounds 3-4: Claims 1-4 Are Rendered Obvious by Garrison in View of Cox or Leonhardt and Cox

To the extent further disclosure of "leaflets made of fixed pericardial tissue" is required for [1.2] (see §§X.A.1, X.A.2.[1.2]), Cox discloses replacement aortic valves containing leaflets from "chemically treat[ed]" "pericardial sac…of cows or pigs." Cox, 4:35-45, 25:58-62, Fig. 5; *see also id.* 24:3-17 (discussing an embodiment in a stent); Drasler ¶¶157-161. Cox is in the same field as '294 of implantable cardiac prosthetic devices and addresses the same problem of making replacement heart valve devices with improved durability and anatomic compatibility with humans. '294, Abstract, 2:58-64, 3:33-54, 4:45-55; Cox,

Abstract, 1:11-12, 2:59-60, 4:35-45, 4:56-67, 6:32-39, 24:3-17; *see also* §X.A.1. Drasler ¶160.

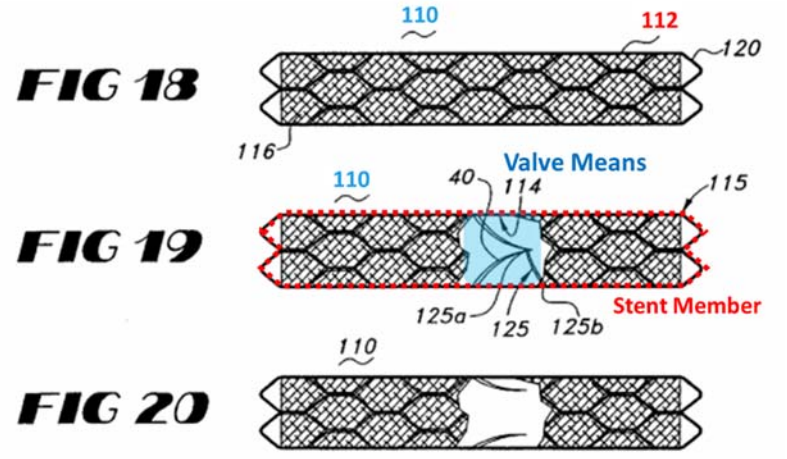
For the same reasons discussed in §X.A.1, a POSITA would have been motivated to apply **Cox's** teachings of leaflets made of pericardial tissue to **Garrison's** leaflets to achieve the predictable and beneficial result of using a well-known, highly durable material with successful use in humans and would have had a reasonable expectation of success in doing so. Cox, 4:35-50, 24:3-17; Drasler ¶160; *see also* '294, 3:41-46; Gabbay 3:38-42, 7:4-7 (valves made from "chemically fixed" "natural tissue," such as "pericardium"). Indeed, a POSITA would have found that application routine, straightforward and advantageous and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶161.

D. Ground 5: Claims 1-3 Are Rendered Obvious by DiMatteo in View of Limon

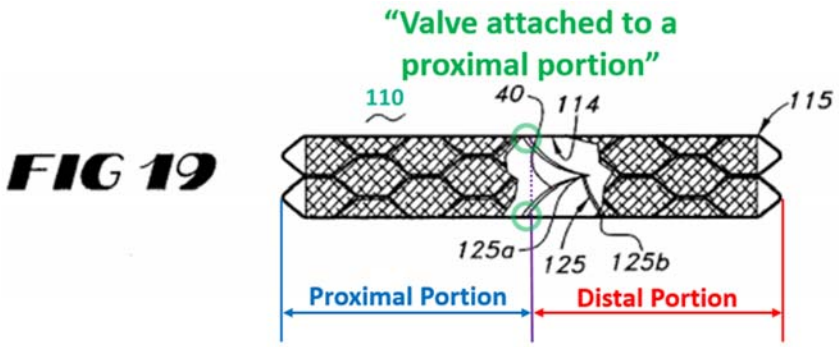
1. Overview of DiMatteo

DiMatteo teaches "radially collapsible" "prosthetic cardiac, aortic, and venous valves" "implanted using a minimally-invasive…technique" "via catheter." DiMatteo, 1:4-7, 2:22-25, 2:44-48, 6:49-61. As shown in Figs. 18-20, **DiMatteo** teaches the valve (annotated blue) is "attached to the interior luminal surface 114 of," and resides entirely within, a "collapsible tubular fluid conduit 112" (annotated

red)—a self-expanding stent selected from "known stent" designs. DiMatteo, 8:53-67, 13:52-57, 15:66-16:2.



Drasler ¶¶165, 172. DiMatteo teaches the valve leaves point in the direction of permitted fluid flow from the proximal end toward the valve stent's distal end (see Fig. 19 annotated below). DiMatteo, 9:27-38 (describing Fig. 9), 16:21-24 (describing Fig. 26A), 2:34-38, 14:6-13; Drasler ¶165.



Moreover, a POSITA would have understood and at minimum found it obvious that the valve is attached to the stent's proximal portion (closer to the catheter user) in order to implant the valve in the direction of desired fluid flow for delivery via

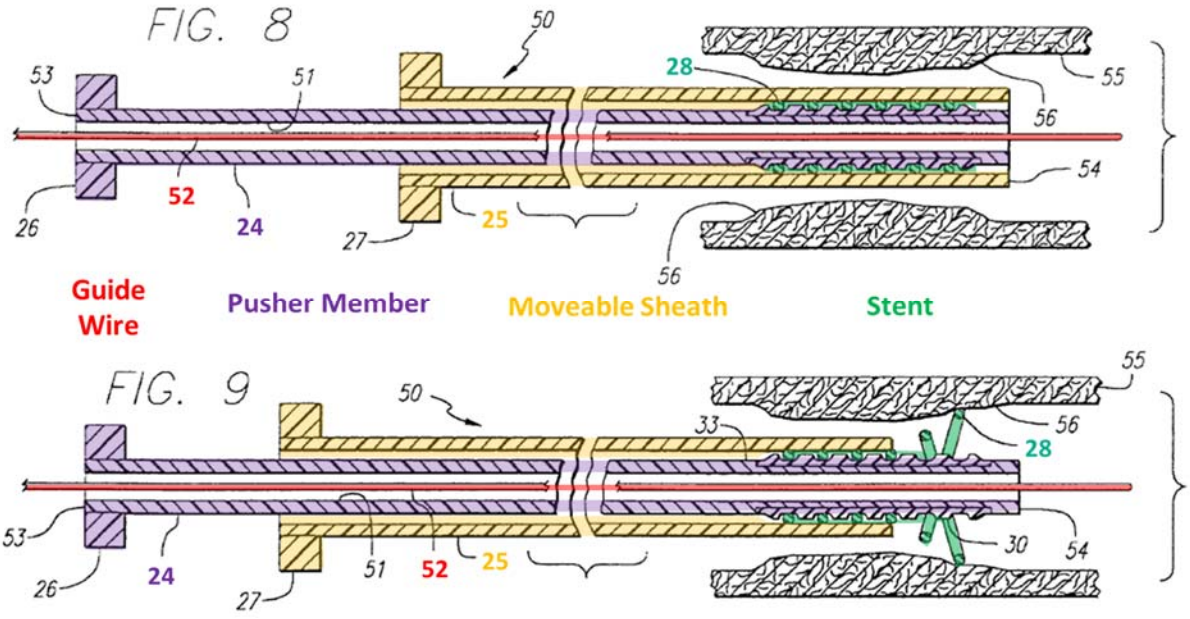
certain paths. Drasler ¶¶166-167 (e.g., antegrade (with flow) delivery of replacement mitral valve); *see also* DiMatteo, 5:3-7 (teaching known stent designs—and thus valve placement positions—can be used); U.S. 6,676,698 (Ex. 1014, "McGuckin") 15:55-59, Figs. 38-40 (filed 12/5/2001, teaching "valves can be attached at the proximal end, distal end, or intermediate the proximal and distal end"); Leonhardt, 7:17-20 (valve/stent "loaded either end first" such that implanted valve properly oriented). Moreover, a POSITA would have been motivated to attach the valve to the stent's proximal portion to achieve the advantageous result of more easily recovering the valve/stent after partial deployment—otherwise the bulkier portion with the valve would be deployed first. Drasler ¶168.

DiMatteo also discloses that the valve mechanism includes, e.g., a bicuspid valve or "three valve leafs" (DiMatteo 3:43-45, 18:18-20), formed of "bovine pericardial tissue" (DiMatteo, 10:26-32); Drasler ¶163. A POSITA would have understood, and at minimum, it would have been obvious, that the tissue is fixed to advantageously avoid antigenicity as '294 also concedes. '294, 3:34-44, 4:51-53; Drasler ¶164.

2. Overview of Limon and Motivation to Apply Its Teachings to DiMatteo

DiMatteo leaves it to the POSITA to determine which catheter delivery system should be used to deploy the device and teaches that any "known stent"

design can be used for the self-expanding stent. DiMatteo, 2:22-26, 5:5-7, 8:53-67, 13:52-57, 15:66-16:2; Drasler ¶172. **Limon** teaches an implantation technique using a "stent-delivery catheter system" to deliver a "self-expanding stent" in a patient's body lumen via vein or artery using a set of "control handles" that a POSITA would have been motivated to apply to **DiMatteo**. Limon, Abstract, 2:32-40; Drasler ¶¶169-174. As shown in Figures 8-9 (annotated below), **Limon** discloses the stent (annotated green) is mounted onto an "inner member 24" of the delivery catheter (annotated purple), and held in place by an "outer member 25" (annotated yellow).



Limon, 5:27-54; Drasler ¶169. To deploy the stent, the delivery catheter is advanced over a "guide wire" (annotated red), which runs through "guide wire lumen 51" extending through the delivery catheter. Limon, 5:27-40. As Figure 9 shows, once the stent is in the proper location, the inner member is pushed out (moved) "distally"

while the outer member is moved "proximally," pushing out the stent from the delivery catheter's distal end. Limon, 5:40-62**.** As the "self-expanding stent" is pushed out of the delivery catheter, the portion that is no longer covered by the outer member will "expand radially" to fill the space and contact the vessel wall. Limon, 5:46-49**. Limon** also discloses recovery of a partially deployed stent to reposition the stent to a correct location. Limon, 3:5-12. Drasler ¶171.

A POSITA would have been motivated to apply **Limon**'s teachings for transcatheter implantation of stent prostheses to **DiMatteo**'s transcatheter implantation of stented valve devices. Drasler ¶¶172-177**.** Like **DiMatteo**, **Limon** is in the same field and is analogous art to the '294—both are in the same field related to percutaneously, transluminally implantable cardiac prosthetic devices. '294, Title, Abstract, 4:63-5:1, 5:16-28; DiMatteo, 2:23-25; Limon, Title, Abstract, 1:39-47, 1:61-64; Drasler ¶173. **DiMatteo** and **Limon** are also reasonably pertinent to '294's alleged problem(s) of percutaneously and transluminally implanting heart prostheses and of controlling release of such prostheses during implantation. '294, 2:58-3:17, 11:55-59, cl. 1; DiMatteo, 1:4-7, 2:22-28, 1:34-51, 6:49-61; Limon, Abstract, 1:28-29, 3:66-4:3, 1:53-58, 2:1-3, 2:58-62. Drasler ¶173.

A POSITA would have been motivated to apply **Limon**'s advantageous teachings of (i) controlled release, (ii) a "stent-delivery catheter system" with inner and outer members, (iii) the specific steps of loading the valve device, advancing the

delivery system, partially deploying, restraining, and recovering to **DiMatteo's** replacement of heart valves. Drasler ¶174**. Limon**'s teachings advantageously allow a user to "recapture" and "reposition" a partially deployed stent (Limon, 2:64-3:12), and better control the stent's axial position throughout the procedure (Limon, 1:53-57). A POSITA would have had a reasonable expectation of success because **DiMatteo**'s teaches that "known stent" designs can be used (13:52-57), and **Limon** provides an example of such a self-expanding stent, along with the details for how the stent would be delivered. Drasler ¶¶172-177. Moreover, while it is not necessary to apply **Limon's** teachings of using attachment projections 30 (e.g., as shown in Fig. 9 above) to help hold the stent in place because the tension between the collapsed stented valve and the inner and outer members allows for controlled delivery, a POSITA would have also been motivated to apply the attachment projection teachings as they provide sufficient grip to maintain attachment to a valve/stent (even if it is mostly deployed) and can be formed of a material that is "soft by design"/"relatively soft" to advantageously cushion the stented valve of **DiMatteo** and hold it in place. Limon, 4:52-5:26, 5:41-54; Drasler ¶175. Collapsing the valve onto the "soft" attachment projections further helps protect the valve and would have worked as expected—indeed, it was well-known to collapse valves onto expansion balloons. Drasler ¶175; e.g., Garrison, 8:3-8, 6:35-40, Figs. 3-6; *see also KSR*, 550 U.S. at 417.

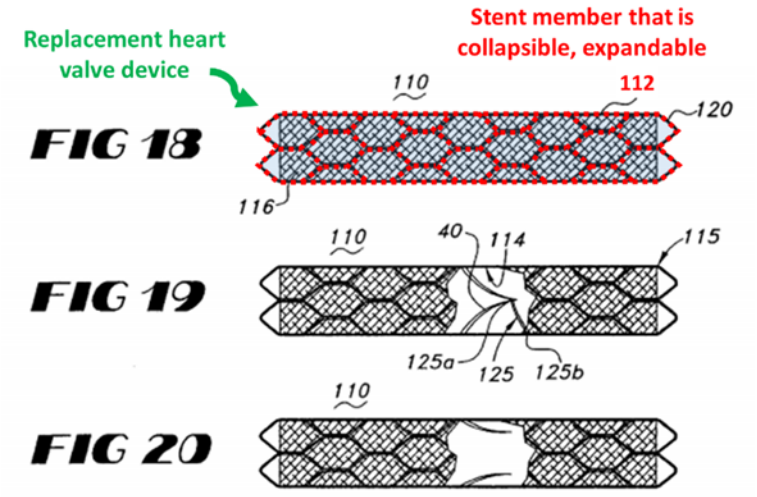
In light of the foregoing, a POSITA would have found it obvious and straightforward to apply **Limon**'s teachings as to stent implantation in implementing **DiMatteo**'s replacement of valve devices, and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶177.

3. Claim Chart

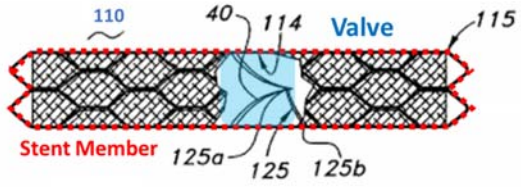
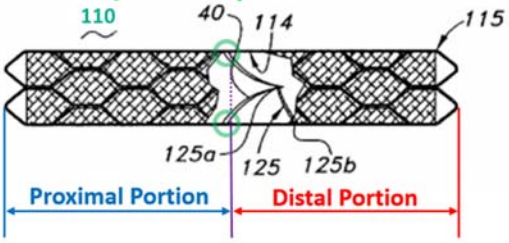
Claim Element	**DiMatteo in view of Limon**
[1.pre] "A method of controlled release of a percutaneous replacement heart valve at a location of a native heart valve in a patient, the method comprising:"	**To the extent the preamble is limiting, DiMatteo discloses a method of release of a percutaneous replacement heart valve** (*e.g.*, "method and apparatus for providing" "implantable prosthetic cardiac, aortic, and venous valves," "via catheter") **at a location of a native heart valve in a patient** (*e.g.*, "replacement of a cardiac, arterial, or venous valve")**.** ***E.g.*, DiMatteo:** **DiMatteo** discloses an "implantable prosthetic cardiac, aortic, and venous valve[]" delivered "via catheter through the body lumen in which it will be emplaced" using a "minimally invasive…technique" to implant the replacement valve at the native valve's location. • 1:4-7 ("…[T]he present invention relates to…***implantable prosthetic cardiac, aortic, and venous valves***.") • 2:22-26 ("The present invention is directed to providing a fully prosthetic valve…using a ***minimally-invasive, endoscopic technique***.") • 6:49-61 ("The present invention relates generally to ***method and apparatus for providing a fluid flow check valve*** for a body lumen. …. The valve includes a

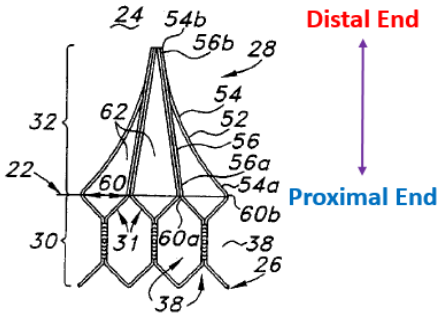
Claim Element	DiMatteo in view of Limon
	radially-collapsible scaffold portion and a ***radially-collapsible leaf valve portion which allows the valve to be delivered via catheter through the body lumen in which it will be emplaced***.") • 7:38-41 ("Valve 10 is provided for implantation within the fluid passageway of a body lumen, ***such as for replacement of a cardia[c], arterial, or venous valve***…") A POSITA would have also understood, and at minimum found it obvious, that the replacement valve is deployed at the location of the native valve to replace its functionality. Drasler ¶181; *see also* DiMatteo, 1:34-57 (discussing prior art for implanting valve at location of native valve), 7:38-41. **Limon discloses controlled release of a [stent]** (e.g., "stent is removably attached to a catheter," "partially deploy the stent")**.** ***E.g.*, Limon:** **Limon** discloses a stent that is removably attached to a catheter so that the stent remains in position on the catheter and does not dislodge or move axially while the stent is fully or partially deployed. • 1:61-2:3 ("…[A] self-expanding stent delivery system in which a self-expanding stent is ***removably attached to a catheter so that the stent remains in position*** on the catheter until it is implanted. ***Unlike prior art stents, which may have a tendency to dislodge or move axially*** on the catheter shaft…the present invention provides means for removably attaching the stent to the catheter….")

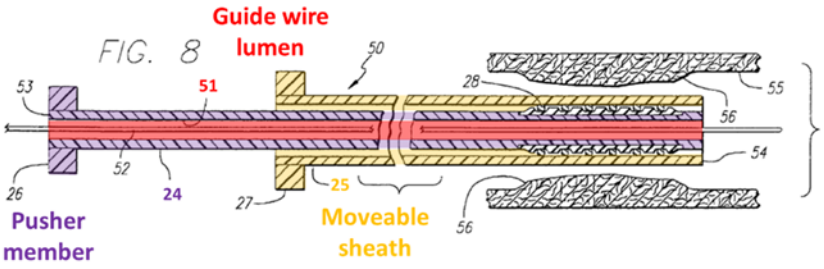
Claim Element	**DiMatteo in view of Limon**
	• 2:64-3:5 ("***One feature of the present invention is to permit the physician to partially deploy the stent***...") As discussed in §X.D.2, a POSITA would have been motivated to apply **Limon's** controlled stent delivery teachings to **DiMatteo's** stent and valve combination delivered via a catheter to advantageously control delivery of the valve. Drasler ¶¶178-184.
[1.1] "obtaining a replacement heart valve device and a delivery and implantation system: the replacement heart valve device including: a stent member that is collapsible, expandable and configured for percutaneous delivery; and"	**DiMatteo discloses obtaining a replacement heart device** (*e.g.*, obtaining "implantable prosthetic cardiac, aortic, and venous valves") **and a delivery and implantation system** (*e.g.*, valve "delivered via catheter through the body lumen in which it will be emplaced"): **the replacement heart valve device including: a stent member that is collapsible, expandable** (*e.g.*, a "stent" that is a "radially collapsible tubular fluid conduit 112" and "self-expandable") **and configured for percutaneous delivery** (*e.g.*, "prosthetic valve" implanted "by catheter to a location within a body lumen"). ***E.g.*, DiMatteo**: ***See* [1.pre].** In addition, **DiMatteo** discloses the implantable prosthetic valve is configured for "delivery by catheter to a location within a body lumen" via a "minimally invasive… technique." DiMatteo, 2:22-28, 2:44-48, 13:52-57. **DiMatteo**'s valve is "attached to…a second radially collapsible tubular fluid conduit." DiMatteo, 2:44-48, 13:52-57. The conduit is any "known stent and covered stent designs," such as "tubular-shaped wire stents and self-expandable spring-biased stent[s]." *Id.*, 8:53-58, 13:52-57. • Figs. 18-20 (annotated)

Claim Element	**DiMatteo in view of Limon**
	 • 1:5-7 ("[T]he present invention relates to ***implantable prosthetic cardiac, aortic, and venous valves***.") • 2:44-48 ("…radially-collapsing the leaf valve portion for ***delivery by catheter to a location within a body lumen***."). • 6:60-61("[T]he valve to be delivered via catheter through the body lumen in which it will be emplaced.") • 8:58-59 ("***Other stent types, such as tubular-shaped wire stents and self-expandable spring-biased stents are also contemplated***.") • 13:52-57 ("FIGS. 18-21 depict yet another embodiment…in which the valve leafs of an implantable prosthetic valve 110 are attached to the interior lumenal surface 114 of a second ***radially collapsible tubular fluid conduit 112. Second conduit 112 may be selected from many known stent and covered stent designs*** known in the art.") • 2:23-26 ("The present invention is directed to providing a fully prosthetic valve…using a ***minimally-invasive, endoscopic technique***.")

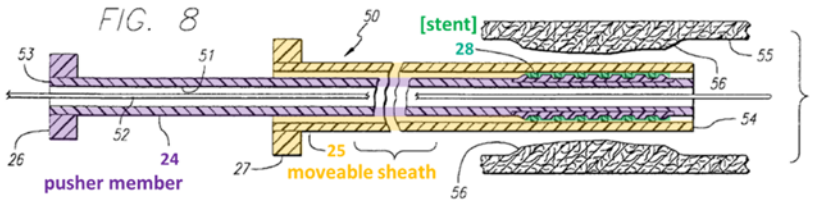
Claim Element	**DiMatteo in view of Limon**
	Drasler ¶¶185-188.
[1.2] "a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member, the valve including two to four individual leaflets made of fixed pericardial tissue;"	**DiMatteo discloses a valve residing entirely within an inner channel of the stent member** (*e.g.*, "valve 110 [is] attached to the interior lumenal surface" of the stent and "outer surface" of "second conduit…need not be covered") **and attached to a proximal portion of the stent member** (*e.g.*, valve is "attached to the interior" of the stent on the "proximal" side of the stent, as shown in Figure 19), **the valve including two to four individual leaflets** (*e.g.*, "bicuspid valve," "three valve leafs") **made of fixed pericardial tissue** (*e.g.*, "valve leaf cover 80 may be formed of…bovine pericardial tissue"). ***E.g.*, DiMatteo**: **DiMatteo** discloses the implantable prosthetic valve is "attached to the interior lumenal surface" of the radially collapsible tubular fluid conduit, or stent, such that the valve is entirely within the stent and the valve leafs are attached in a proximal portion of the stent member, as shown in Fig. 19 and discussed in §X.D.1. DiMatteo, 13:52-57. At minimum, it would have been obvious to attach the valve leafs in the proximal portion of the stent member as discussed in §X.D.1; Drasler ¶¶168, 194. The "bicuspid" or "three" valve leafs are "formed from a thin layer of…bovine pericardial tissue." *Id.*, 10:26-39, 18:18-20. To the extent it is argued further disclosure of "fixed" pericardial tissue is necessary, a POSITA would have understood **DiMatteo**'s disclosure of bovine pericardial tissue to mean chemically treated bovine pericardial tissue and at minimum would have found it obvious to do so to eliminate antigenicity as discussed in §X.D.1. Drasler ¶¶163-164, 196.

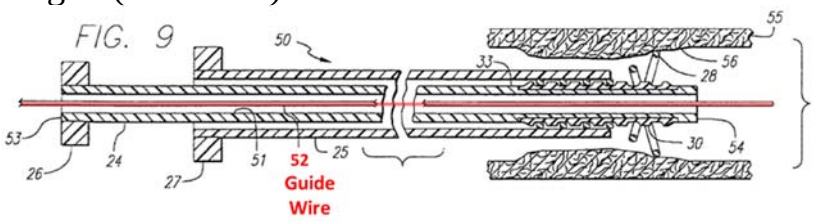
Claim Element	**DiMatteo in view of Limon**
	• 3:43-44 ("The bicuspid valve includes a pair of leaf frames which deflect about a hinge positioned downstream of the closable valve opening.") • 13:52-57 ("FIGS. 18-21 depict yet another embodiment of the present invention in which ***the valve leafs of an implantable prosthetic valve 110 are attached to the interior lumenal surface 114 of a second radially collapsible tubular fluid conduit 112***….") FIG 19  "Valve attached to a proximal portion" FIG 19  • 7:62-66 ("Leaf valve portion 14 may provide ***any number of valve leafs*** 40…, a ***bicuspid*** valve configuration is also contemplated….") • 9:27-29 ("***Each component leg 54 and 56 includes a proximal end 54a and 56a, and an opposed distal end 54b and 56b, respectively***.")

Claim Element	DiMatteo in view of Limon
	 FIG 5 • 14:2-5 ("Outer surface 115 of second conduit 112 need not be covered….") • 10:26-39 ("Valve leaf cover 80 may be formed from a thin layer of…***bovine pericardial tissue***….") • 18:18-20 ("three valve leafs") • 1:47-49, 2:11-13, 7:3-12, 7:58-61. Drasler ¶¶189-196.
[1.3] "the delivery and implantation system including: a pusher member and a moveable sheath, wherein the pusher member includes a guide wire lumen, and wherein the moveable sheath includes a lumen configured for receiving the pusher member;"	**Limon discloses the delivery and implantation system** (*e.g.*, "self-expanding stent delivery systems, which are used to implant a stent into a patient's body lumen") **including: a pusher member** (*e.g.*, "[i]nner member 24") **and a moveable sheath** (*e.g.*, "outer member 25"), **wherein the pusher member includes a guide wire lumen** (*e.g.*, "guide wire lumen 51"), **and wherein the moveable sheath includes a lumen configured for receiving the pusher member** (*e.g.*, "inner member 24 is slidably positioned within outer member 25"). ***E.g.*, Limon:** **Limon** discloses a "self-expanding stent delivery system[]… to implant a stent into a patient's body lumen" using a "catheter assembly 20" with an "inner member 24…slidably positioned within outer member 25" such that "relative axial movement between the two members"

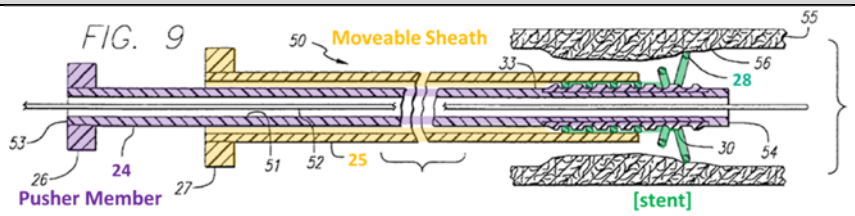
Claim Element	DiMatteo in view of Limon
	is possible. *E.g.*, Limon, 1:5-10, 4:26-31. **Limon** further discloses "inner member 24" has a "guidewire lumen 51," as shown in Figure 8, "to receive guidewire 52." Limon 4:26-31, 5:27-40. As discussed in §X.D.2 and [1.pre], a POSITA would have been motivated to apply **Limon's** specific teachings of a stent member and accompanying delivery system—a self-expanding stent delivered percutaneously using an over-the-wire catheter configuration—to **DiMatteo's** stent and valve combination delivered via a catheter to advantageously allow for controlled release of the valve. • Fig. 8 (annotated)  • 1:5-10 ("***The invention relates to self-expanding stent delivery systems, which are used to implant a stent into a patient's body lumen***…..") • 4:26-31 ("…***Inner member 24 is slidably positioned within outer member 25 and relative axial movement between the two members is provided*** by inner member control handle 26 and outer member control handle **27**.") • 5:27-40 ("…[C]atheter assembly 20 is used to implant the self-expanding stent in a body lumen….[A]***s depicted in FIGS. 8-10, over-the-wire catheter 50 has a guide wire lumen 51 which extends through the catheter and is configured to receive guide wire 52***….")

Claim Element	**DiMatteo in view of Limon**
	• 4:52-56, 4:60-67, 6:67-4. Drasler ¶¶197-200.
[1.4] "after the obtaining step, loading the replacement heart valve device into the lumen of the moveable sheath such that the replacement heart valve device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath;"	**DiMatteo discloses the replacement heart valve device** (see [1.pre]-[1.1])**.** **Limon discloses after the obtaining step, loading the [stent] into the lumen of the moveable sheath** (*e.g.*, "self-expanding stent … is mounted within the outer member") **such that the [stent] is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath** (*e.g.*, "the inner lumen 31 of outer member 25 covers self-expanding stent 28 and helps to retain the stent on the outer surface 33 of the inner member 24"). ***E.g.*, Limon:** ***See* [1.3].** In addition, **Limon** discloses the "self-expanding stent…is mounted within the outer member [25]" and collapsed onto inner member 24, as shown in Figure 2, such that "the inner lumen 31 of outer member 25 covers self-expanding stent 28 and…retain[s] the stent on the outer surface 33 of the inner member 24." As discussed in §X.D.2, [1.pre], and [1.3], a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **DiMatteo's** implantable prosthetic heart valve and delivery catheter such that **DiMatteo's** prosthetic heart valve is loaded into the lumen of the moveable outer member and collapsed onto the outer surface of the inner member and restrained in the collapsed configuration by the outer member.

Claim Element	**DiMatteo in view of Limon**
	• Fig. 8 (annotated)  • 2:4-11 ("A catheter assembly for removably attaching an intravascular stent is provided...***A self-expanding stent…is mounted within the outer member***.") • 4:60-67 ("[S]elf-expanding stent 28 is mounted on outer surface 33... ***Due to the coaxial arrangement between inner member 24 and outer member 25, the inner lumen 31 of outer member 25 covers self-expanding stent 28 and helps to retain the stent on the outer surface 33 of the inner member 24***.") Drasler ¶¶201-206.
[1.5] "after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient to position the replacement heart valve device for deployment within the patient at the location of the native heart valve;"	**DiMatteo discloses the replacement heart valve device** (see [1.pre]-[1.1]) **for deployment within the patient at the location of the native heart valve** (*e.g.*, for "replacement of a cardia[c], arterial, or venous valve," *see* [1.pre])**.** ***See* [1.pre]-[1.1], [1.4].** **Limon discloses after the loading step, advancing the delivery and implantation system transluminally** (*e.g.*, "catheter assembly 20 is used to implant the self-expanding stent in a body lumen") **over a guide wire within the patient to position the [stent] for deployment within the patient** (*e.g.*, "to implant self-expanding stent 28, guide wire 52 is positioned in a patient's body lumen;" "catheter 50 is advanced along the guide wire."). ***E.g.*, Limon:**

Claim Element	**DiMatteo in view of Limon**
	See* [1.4].** In addition, **Limon** discloses "catheter assembly 20 is used to implant the self-expanding stent in a body lumen" by advancing the catheter along the "guidewire 52…positioned in a patient's body lumen" until the "distal end 54 of catheter 50 is positioned" within the patient. 5:26-40. As discussed in §X.D.2 and [1.pre], a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **DiMatteo's** implantable prosthetic heart valve and delivery catheter such that the valve mounted on the catheter assembly (see [1.4]) is advanced transluminally over the guide wire to position the valve for deployment at the location of the native heart valve to replace the valve. • Fig. 9 (annotated)  • 5:26-40 ("In the preferred method of use, catheter assembly 20 is used to implant the self-expanding stent in a body lumen using an over-the-wire or rapid-exchange catheter configuration.…[T]o implant self-expanding stent 28, guide wire 52 is positioned in a patient's body lumen.... [C]atheter 50 is advanced along the guide wire until distal end 54 of catheter 50 is positioned within stenosed region 56***.") • Abstract, 7:52-56. Drasler ¶¶207-212.

Claim Element	DiMatteo in view of Limon
[1.6] "after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device;"	**DiMatteo discloses deploying the replacement heart valve device** (*e.g.*, see [1.pre]-[1.1], "a prosthetic valve for implantation within a body lumen")**.** ***See* [1.pre]-[1.1], [1.5]**; e.g., DiMatteo, 2:26-27**.** **Limon discloses after the advancing step, partially deploying a distal portion of the [stent] within the patient** (*e.g.*, "partially deploy the stent") **by pushing out the pusher member from the moveable sheath** (*e.g.*, "moving inner member in a distal direction" to implant the stent while "moving outer member 25 in a proximal direction") **to expose the distal portion of the [stent]** (*e.g.*, distal "portions of self-expanding stent 28 are no longer contained by outer member 24"). ***E.g.*, Limon**: ***See* [1.5].** In addition, **Limon** discloses "partially deploy[ing] the stent" by using control handles to push "the inner member axially in the distal direction" while moving "the outer member axially in a proximal direction" such that distal "portions of self-expanding stent 28" are pushed out from the outer member and "no longer contained by outer member" of the stent. As discussed in §X.D.2 and [1.pre], a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **DiMatteo's** implantable prosthetic heart valve and delivery catheter such that the valve is partially deployed by pushing out the inner member distally to expose the distal portion of the valve. • Fig. 9 (annotated)

Claim Element	**DiMatteo in view of Limon**
	 • 2:64-3:5 ("***One feature of the present invention is to permit the physician to partially deploy the stent***... For example, the control handles can be manipulated to simultaneously ***move the inner member axially in the distal direction and the outer member axially in a proximal direction*** to begin to deploy the stent.") • 5:41-49 ("As depicted in FIGS. 9 and 10, self-expanding stent 28 is implanted…by ***moving outer member 25 in a proximal direction while simultaneously moving inner member 24 in a distal direction…. As portions of self-expanding stent 28 are no longer contained by outer member 24, it will expand radially outwardly***…") Drasler ¶¶213-218.
[1.7] "after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release, with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and after the restraining step,	**DiMatteo discloses the replacement heart valve device** (see [1.pre]-[1.1]). **Limon discloses after the partially deploying step, restraining the [stent] so that it does not pop out and is held for controlled release** (*e.g.*, "stent will not move axially on the catheter shaft;" "retain the stent"). **To the extent the remainder of [1.7] is limiting** (*see* §IX.A), **Limon also discloses restraining…with a potential that the [stent] can be recovered if there is a problem with positioning** (*e.g.*, "recapture the partially deployed stent so that the stent can be repositioned in the proper location"); **and after the restraining step, recovering the distal portion of the [stent] within the moveable sheath that was exposed** (*e.g.*, "the outer

Claim Element	DiMatteo in view of Limon
recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient."	member can be moved axially to recapture the partially deployed stent") **in order to address a problem with the position of the [stent] within the patient** (*e.g.*, the recapture procedure is performed if the stent is "improperly positioned"). ***E.g.*, Limon:** ***See* [1.6].** In addition, **Limon** discloses the "inner lumen 31 of outer member 25 covers self-expanding stent 28…retain[ing] the stent on the outer surface 33 of the inner member 24" such that the stent "will not move axially on the catheter shaft as the inner member and the outer member are moved axially relative to one another." Limon, 2:55-62, 4:60-67. Further, **Limon** discloses if the stent "is improperly positioned, the outer member can be moved axially to recapture the partially deployed stent so that the stent can be repositioned in the proper location." *Id.*, 2:64-3:5. As discussed in §X.D.2 and [1.pre], a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **DiMatteo's** implantable prosthetic heart valve and delivery catheter such that the valve is partially deployed but restrained from popping out of the outer member, and the outer member can be moved axially to recapture the valve such that it can be repositioned in the patient to address a problem. • 2:64-3:5 ("…***[I]f [the stent] is improperly positioned, the outer member can be moved axially to recapture the partially deployed stent so that the stent can be repositioned in the proper location…."***)

Claim Element	**DiMatteo in view of Limon**
	• 2:55-62 ("…***The stent will not move axially on the catheter shaft as the inner member and the outer member are moved axially relative to one another,*** since the stent is removably attached to the inner member by attachment projections….") • 4:60-67 ("…Due to the coaxial arrangement between inner member 24 and outer member 25, ***the inner lumen 31 of outer member 25 covers self-expanding stent 28 and helps to retain the stent on the outer surface 33 of the inner member 24.***") • 3:5-12. Drasler ¶¶219-224.
[2] "The method of claim 1, wherein the stent member is self-expanding."	***See* [1].** **DiMatteo discloses wherein the stent member is self-expanding** (*e.g.*, "formed from a shape memory alloy, an elastic metal, or a polymer;" "self-expandable"). ***E.g.*, DiMatteo**: • 8:53-59 ("One example of a stent…is a slotted tubular stent…designed to radially expand…by ***forming the stent from a temperature-sensitive memory alloy which changes shape*** at a designated temperature or temperature range. Other stent types, such as tubular-shaped wire stents and ***self-expandable*** spring-biased stents are also contemplated.") • 13:66-14:1 ("Second conduit 112 includes a ***radially collapsible skeleton*** 120 which may be formed from a shape memory alloy, an elastic metal, or a polymer.") • 15:55-66. Drasler ¶¶225-227.

Claim Element	**DiMatteo in view of Limon**
[3] "The method of claim 2, wherein the stent member comprises nitinol."	***See* [2].** **DiMatteo discloses that the stent member comprises nitinol** (*e.g.*, "second conduit" "formed from a shape memory alloy" "commonly known as nitinol"). ***E.g.*, DiMatteo:** • 13:66-67 ("Second conduit 112…may be formed from a shape memory alloy….") • 15:66-16:2 ("Shaped memory alloys…made from specific ratios of nickel and titanium, commonly known as ***nitinol***....") Drasler ¶¶228-229.

E. Ground 6: Claim 4 Is Rendered Obvious by DiMatteo in View of Limon and Gabbay

Claim 4, which depends from claim 1 and recites that "the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration," is rendered obvious over **DiMatteo** in view of **Limon** (see §X.D) in further view of **Gabbay**. Drasler ¶¶230-237**. Gabbay** teaches examples of a "valvular prosthesis" to replace an "insufficient heart valve." Gabbay, 1:60-2:4. As shown in Fig. 2 (annotated below), **Gabbay** teaches that a heart valve's self-expanding "stent portion 14" is formed from a "shape memory alloy," such as nitinol, that will "flare outwardly" at the ends in its expanded state.

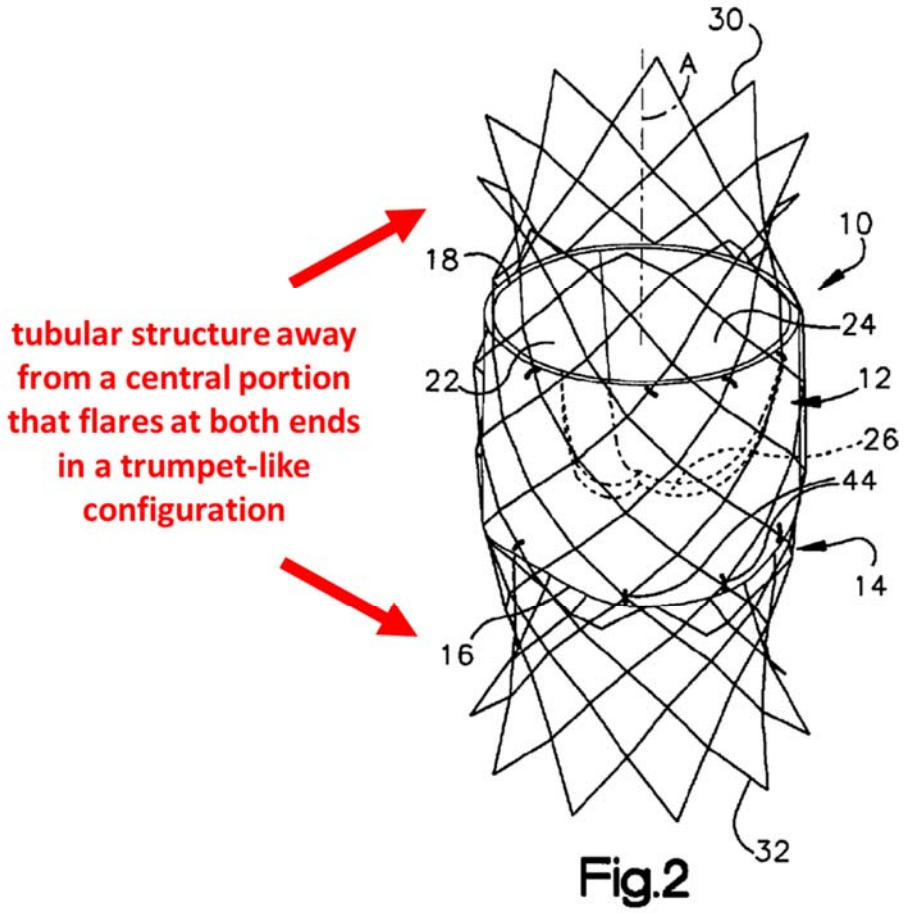


Fig.2

Gabbay, 3:63-4:8, 4:18-23, 4:53-58, 4:65-4:67, 10:46-58, Fig. 1B. Drasler ¶232.

A POSITA would have been motivated to apply **Gabbay's** teachings of a self-expanding stent that flares outward in a trumpet-like configuration in its expanded state to **DiMatteo's** valve device because **Gabbay** teaches that this flared shape enables the device to better engage with the surrounding tissue (or valve displacer), thereby reducing the risk of displacement and better sealing to the tissue. *See* Gabbay, 3:36-4:8; Drasler ¶75, 234; §§X.A.1, X.B (**Letac**, **Phelps** and **Leonhardt** disclose same motivations). Additionally, DiMatteo stent is selected from "known

stent" designs, which would include the Gabbay's flared-end design. DiMatteo, 13:52-57. While PO attempted to distinguish **Gabbay** during subsequent prosecution of a related patent based on its delivery mechanism (Ex. 1011, 1877-1879), Ground 6 does not rely on Gabbay's delivery mechanism.

Gabbay is also in the same field as '294 and reasonably pertinent to '294's alleged problem(s) of transluminally implanting heart prostheses. Gabbay, 1:60-2:15, 2:58-3:17; 9:15-17; *see also* §X.A.1. Drasler ¶234.

A POSITA would have found it obvious and straightforward to apply **Gabbay's** teaching of flared stent ends in implementing **DiMatteo's** stent, and would have known that such an application (yielding the claimed limitations) would predictably work and provide the expected functionality particularly in light of the aforementioned disclosures and Leonhardt and Phelps, which each disclose the delivery of a similarly shaped self-expanding stent delivered via a mechanism similar to Limon. *See* §X.B (discussing Leonhardt); Phelps, 2:31-34, 10:25-29, Figs. 7-8; Drasler ¶¶235-237.

F. Ground 7: Claim 4 Is Rendered Obvious by DiMatteo in View of Limon and Phelps

While PO should not be able to swear behind **Gabbay**, even if it were able to, **Phelps** also discloses a stent that flares at both ends in a trumpet-like configuration and a POSITA would have been motivated to apply these teachings to **DiMatteo** in

view of **Limon** and had a reasonable expectation of success in doing so for the same reasons as discussed in §X.E. Drasler ¶¶238-241. **Phelps** discloses a self-expanding stent with a valve in its interior, introduced via catheter over a guidewire, with flared edges, where the flared edges advantageously "maintain [the stent's] proper position in the heart…and provide a seal." Phelps, 2:31-34, 7:20-27 (describing stent as applicable to fluid flow between any space and vessel), 10:25-29 (describing valve-stent for coronary bypass); Figs. 7-8. Phelps is also in the same field as '294 of percutaneously, transluminally implantable cardiac prosthetic devices. Phelps, 2:1-13; Drasler ¶240. Phelps is also reasonably pertinent to the '294's alleged problem(s) of "fixing the heart valve device in a desired position." '294 8:11-13, 11:62-12:2; Phelps, 2:27-31 (flared ends to "to anchor [stent] in position"); Drasler ¶240.

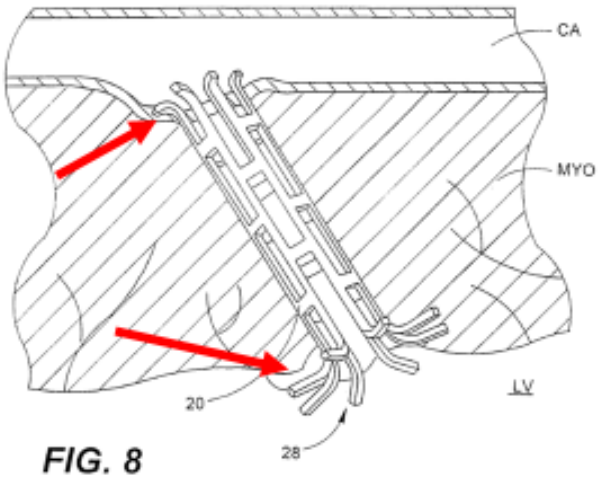


FIG. 8

XI. SECONDARY CONSIDERATIONS

There is no evidence in the prosecution history of '294 or any related application that any arguments regarding secondary considerations exist, let alone that any such evidence could overcome the strong showing of obviousness above or that there is a sufficient nexus to any claim. *See* Ex. 1003; Drasler ¶242. Indeed, as demonstrated by the prior art herein, any purported solutions to problems or unexpected results in '294 were already well known. Drasler ¶¶65-242. To the extent PO asserts the existence of any secondary considerations, Petitioner reserves the right to address any such evidence.

XII. CONCLUSION

Substantial, new, and noncumulative technical teachings have been presented for the '294's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioner will prevail as to claims 1-4. *Inter partes* review of claims 1-4 is accordingly requested.

Dated: September 2, 2020

Respectfully submitted,

/James L. Davis, Jr./
James L. Davis, Jr.

Counsel for Petitioner
MEDTRONIC COREVALVE LLC

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 13,999 words as counted using the word processing program.

Dated: September 2, 2020

/*James L. Davis, Jr.*/
James L. Davis, Jr.

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 '294 patent:

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Courtesy copies of the same documents were also served at the following email addresses of record for Colibri Heart Valve LLC's litigation counsel:

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