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 IPR2020-01454

U.S. Patent No. 9,125,739

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 1-5 ("Claims") of U.S. Patent 9,125,739 ("'739") (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 '739's purported invention is a replacement heart valve formed by a valve inside of a self-expanding stent, which is delivered to the heart via a vein or artery. For delivery, the valve/stent is collapsed over a pusher member and kept in place with a moveable outer sheath. The valve/stent is deployed by pushing the pusher member out of the sheath. '739, 5:16-21. The stent has a tubular structure that flares at both ends in a trumpet-like configuration when expanded, but no additional valve reinforcing members exist inside the stent. *Id.*, cl. 1. Drasler ¶34.

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

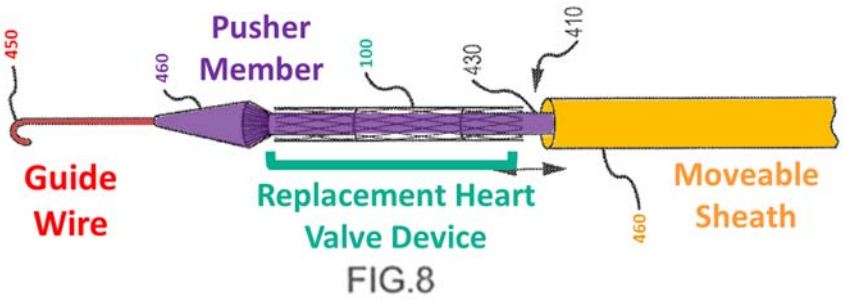


FIG.8

'739 concedes that prosthetic heart valves, *e.g.*, formed of three leaflets of fixed pericardium tissue, were known prior to the alleged invention. The AAPA also makes clear that the claimed delivery system (percutaneous, transluminal, transcatheter delivery systems) for insertion of prosthetic heart valves was also known prior to the invention. '739, 3:1-10, 3:41-44, 4:21-25, 4:51-53; Drasler ¶¶35-37.

The only purportedly novel element of the Claims is requiring "no reinforcing members reside within the inner channel of the stent member." '739, cl. 1; *see* §VI (discussing the prosecution history). Drasler ¶59. But, as discussed herein, it was already well known to construct and deploy a valve without additional reinforcing members within the stent structure in the claimed manner. Drasler ¶¶38, 70.

For example, **Garrison** (Ex. 1005) teaches a known prosthetic valve 6A comprising a valve portion 38 (annotated blue) that does not have any reinforcing members and resides entirely within support structure 26/26A (annotated red) both axially and radially.

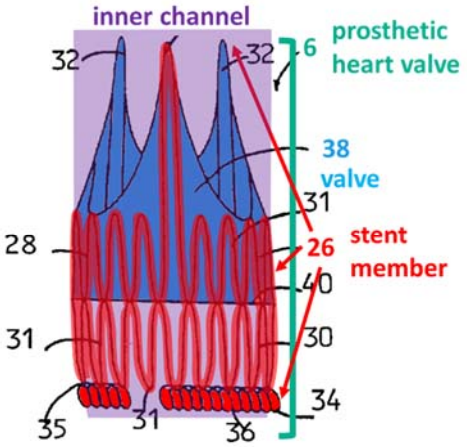


FIG. 10

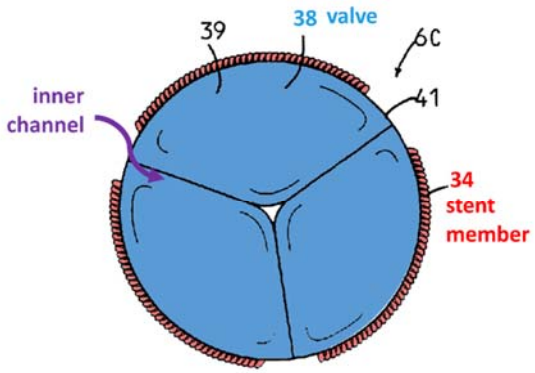


FIG. 11

Garrison, 5:19-46, 8:13-16, Figs. 10-11 (annotated), 9:64-66. **Garrison** further discloses that the support structure 26/26A can have the same features as the valve displacer 8, which flares at both ends in a trumpet-like configuration.

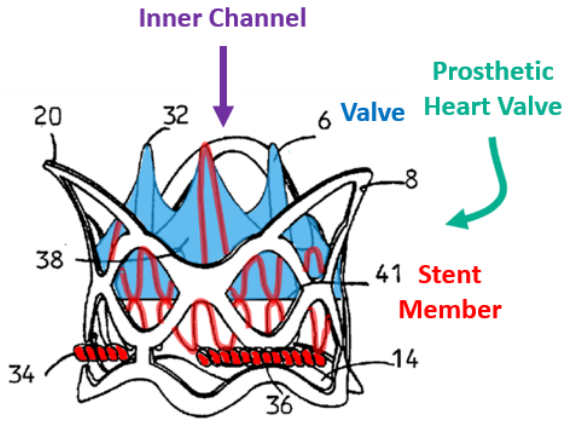


FIG. 9

Garrison, 2:8-11, 4:54-57, 4:66-5:1, Fig. 9. Furthermore, **Garrison** teaches a delivery assembly in which the prosthetic valve 6A (annotated green) is collapsed onto inner rod 78/pusher element 80 (annotated purple) and held in place by the

distal end of moveable sheath 74 (outer wall of catheter 4A). Furthermore, **Garrison** teaches a delivery assembly in which the prosthetic valve 6A (annotated yellow).

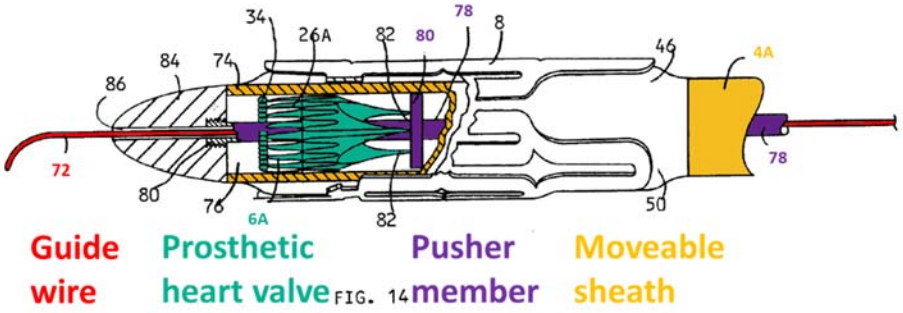


FIG. 14

Garrison, 8:24-28, 8:45-47, Fig. 14 (annotated). **Leonhardt** (Ex. 1006) further discloses a prosthetic heart valve in which the valve resides entirely within a stent with flared ends, without reinforcing members.

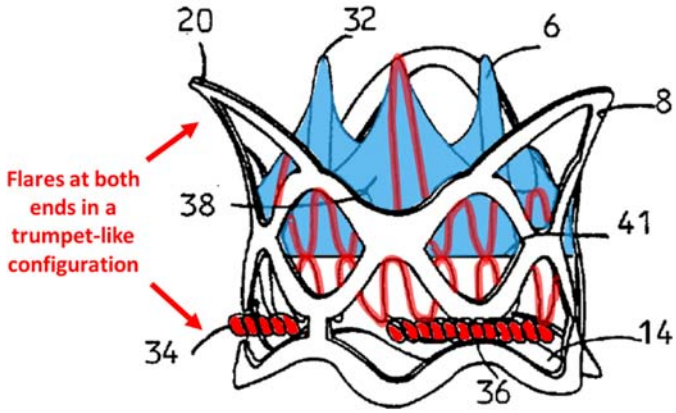


FIG. 9

Leonhardt, Fig. 4, 6:23-31. As a further example, **Andersen** (Ex. 1013) teaches a prosthetic cardiac valve that includes a valve (annotated blue) mounted entirely within a self-expanding "cylindrical support" stent (annotated red), such that the valve and stent fold and expand together.

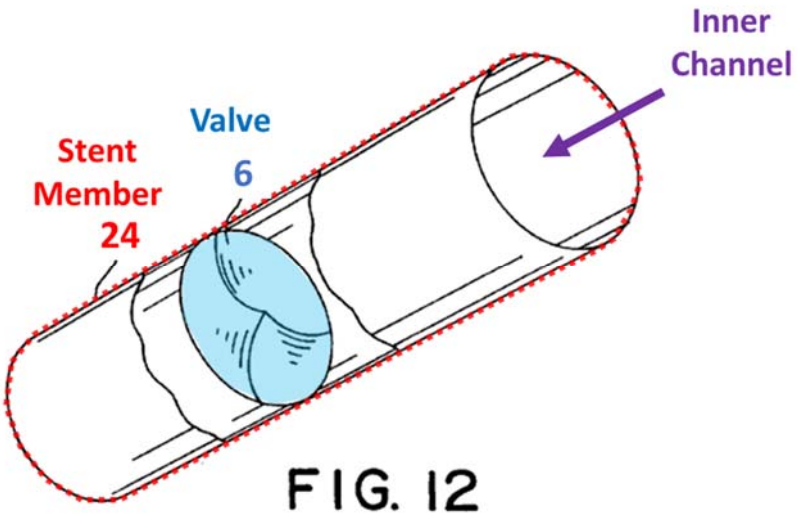
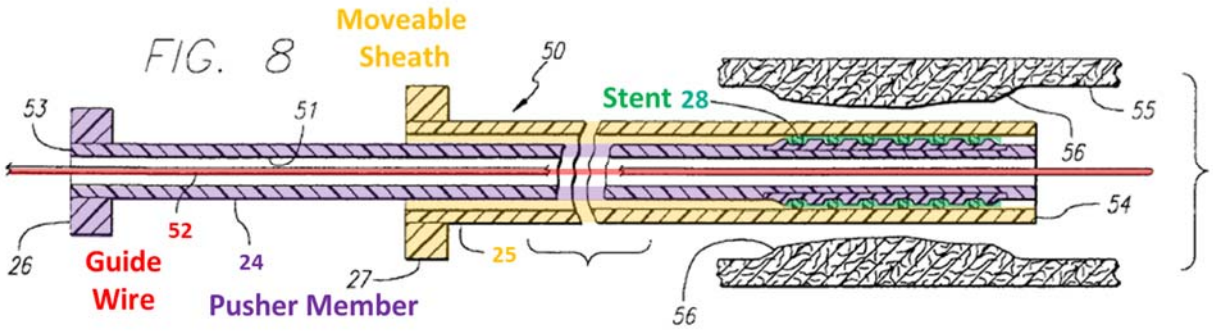


FIG. 12

Andersen, 1:27-33, 2:28-33, 5:29-30, Fig. 12 (annotated). **Andersen** discloses that "any prior art technique" can be used to implant the prosthesis. Andersen, 4:36-40. **Limon** (Ex. 1008) discloses a detailed, transcatheter delivery system for implanting such stents.



Limon, 5:41-44, Fig. 8 (annotated). **Gabbay** and **Phelps** also disclose a self-expanding stent with flared ends to help secure the replacement to the anatomy. *E.g.*, Gabbay, 3:64-4:8, Fig. 2; Phelps, 7:57-59, Fig. 8.

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 arrangement of elements are rendered obvious by **Garrison** (and alternatively in further view of **Leonhardt**) and are also rendered obvious by **Andersen** in view of **Limon** and **Gabbay** (or alternatively **Phelps**). And **Garrison** provides additional teachings 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 **Leonhardt**, **Andersen**, **Limon**, **Phelps,** or any other reference providing analogous disclosures during '739's prosecution. The USPTO did not consider the same embodiments of **Garrison** or substantially the same arguments regarding any of the references relied on herein during prosecution. And even if the Office had considered substantially the same art or arguments, it would have erred in allowing the Claims. *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

'739 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 May 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 December 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 the counsel identified above.

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fee required by §42.15(a) and any additional fees that might be due to Deposit Account No. 18-1945, under Order No. 102760-0210-652.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioner certifies '739 is available for IPR. Petitioner is not barred or estopped from requesting IPR challenging the '739 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. '739 matured from 14/253,650 ("'650 Application"), filed 04/15/2014, and claims priority through continuations and a continuation-in-part to Application 10/037,266 (Ex. 1018), filed on Jan. 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 propriety of the priority claims as the art presented herein pre-dates the earliest possible filing date. 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)
Andersen	1013	U.S. 5,840,081	2/19/1997	11/24/1998	(a), (b), (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)
Nguyen	1020	U.S. 5,961,549	4/3/1997	10/5/1999	(a), (b), (e)

[3] Although PO threatened to swear behind art during prosecution, it did not attempt to do so, nor can it swear behind the art here. During prosecution of '739's parent, PO submitted documentation indicating the first alleged conception of any delivery system was 3/24/2001, and even then the assembly identified did not include critical concepts (*e.g.*, pusher member, flared ends and trumpet-like configuration). Ex. 1016, 149, 152-236; Ex. 1019, 6. Further, PO failed to show diligence in 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. *See* Ex. 1015 (file history of App. No. 09/659,882), 15-29; MPEP 2136; Drasler ¶166.

2. Statutory Grounds on Which the Challenge Is Based

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

§103 Ground	Claim(s)	Prior Art
1	1-5	Garrison
2		Garrison in view of Leonhardt
3		Garrison in view of Nguyen
4		Garrison in view of Leonhardt and Nguyen
5	1-3, 5	Andersen in view of Limon and Gabbay
6		Andersen in view of Limon and Phelps
7		Andersen in view of Limon, Phelps and Nguyen
8	4	Andersen in view of Limon, Gabbay and Garrison
9		Andersen in view of Limon, Phelps and Garrison
10		Andersen in view of Limon, Phelps, Nguyen, and Garrison

3. How the Claims Are Unpatentable

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

V. ’739 PATENT

’739 generally refers to an implantable replacement heart valve and delivery system for treating a native heart valve in a patient. ’739, Abstract, 6:49-51, 11:55-59. The claimed prosthetic heart valve is generally directed to: (1) a collapsible stent that flares at both ends; (2) a valve made of fixed pericardial tissue that does not have any reinforcing members and resides entirely within the stent. The delivery system is generally directed to a multi-catheter assembly, with an internal pusher member that the valve is collapsed onto, and an outer moveable sheath that restrains the collapsed valve onto the pusher member. Drasler ¶41.

The prosthetic heart valve comprises a cylindrical “stent member 100” (red annotation below), preferably “self-expanding” and 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). ’739, 5:27-28, 6:57-67, 7:55-63. ’739 concedes that a POSITA would have known that most tissue valves were leaflets constructed from “the pericardial sac of cows or pigs and sew[n]…to a stent.” ’739, 3:41-46. The valve does not have any reinforcing members and resides entirely within the stent.

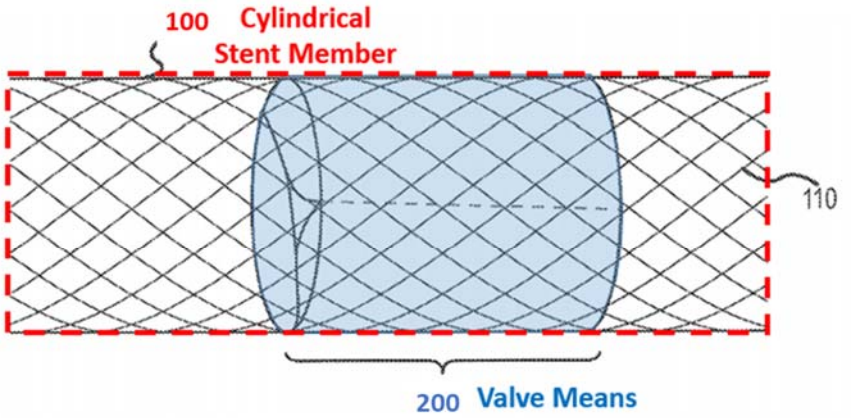


FIG.5

'739, 5:64-67, 6:57-67, cl. 1, Fig. 5 (annotated). Additionally, the "stent member 100" preferably "carries a plurality of barbs" that extend from the outer surface, allowing it to be fixed in a desired position. '739, 8:11-20; Drasler ¶¶42-44.

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). '739, 5:16-20, 11:40-51, 12:11-15, 14:10-23, Fig. 8. In the collapsed position, the prosthetic valve's distal end is located at the moveable sheath's distal end when loaded into the delivery system. '739, Fig. 8.[5] The pusher member and moveable sheath are coaxial, and move relative to each other.

[5] Distal refers to the portion away from the user of the device, whereas proximal refers to the portion near the user. '739, 11:40-55, cl. 1.

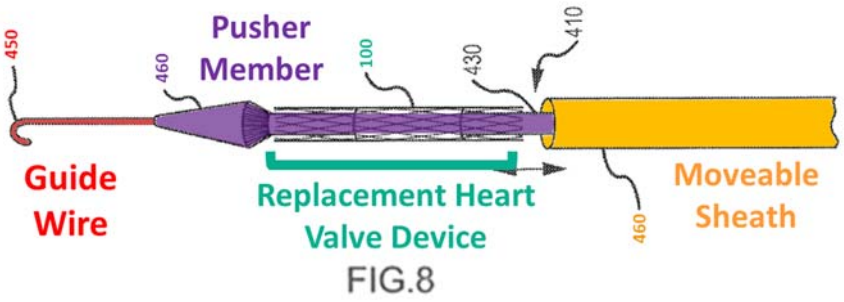


FIG.8

'739, 5:16-20. 12:11-15, 14:19-23; Drasler ¶45.

The loaded delivery system is introduced percutaneously and transluminally into the patient, in some embodiments over guidewire 450 (annotated red), to the native heart valve. '739, 11:44-58, 12:15-24. Then, pusher member 420 is pushed out of the moveable sheath, deploying the valve. '739, 11:51-59; Drasler ¶¶46-53.

VI. '739 PROSECUTION HISTORY

In Application 14/253,650, which matured into '739, the originally filed claims were generally directed to a "percutaneous bioprosthetic heart valve and a delivery and implantation system" with "a stent member…and a valve means," and a catheter including a "pusher member and a moveable sheath." Ex. 1003, 44-50, 69-70. The prosthetic heart valve resides "in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the moveable sheath." *Id.*, 69-70. Drasler ¶¶39-40, 54-55.

The Examiner rejected the issued claims (prosecution claims 34-38) over Garrison alone and U.S. Publication 2002/0032481A1 ("'481 Gabbay") in view of Garrison. Ex. 1003, 1793-1797. Applicant amended prosecution claim 34 to be

directed towards "[a]n assembly for treating a native heart valve in a patient…for use in combination with a guidewire" and specified the valve means is "made of fixed pericardial tissue…attached to a proximal and wider part of the stent member" and the pusher member "includ[es] a guidewire lumen." *Id.*, 1867-1879. After an Examiner Interview, Applicant amended prosecution claim 34 to specify that the "distal end of the prosthetic heart valve is located at a distal end of the moveable sheath" when loaded in the delivery system. *Id.*, 1913-1916, 1923. In a final rejection, the Examiner rejected prosecution claims 34-38 over multiple grounds, including Garrison in view of Cribier and '481 Gabbay. *Id.*, 1941-1951. Specifically, the Examiner relied on the embodiment of Garrison with an inverted valve 6D, depicted in Figs. 31-38." *Id.* In response, Applicant distinguished this embodiment of Garrison by amending to require the valve means be attached "closer to the proximal and wider part of the stent" (a limitation not in the issued claims) and reside entirely within the inner channel of the stent member in both "collapsed" and "unrestrained" configurations. *Id.*, 1968-1984. Applicant separately addressed Garrison's support structure 26 (depicted in Fig. 10) despite it not being part of the rejection. *Id.*, 1978-1979. Applicant never disputed that support structure 26 of Garrison discloses a valve entirely within the inner channel of the stent member, but instead argued that it failed to have a "trumpet-like" configuration because this was only a feature of a separate "valve displacer 8"—ignoring Garrison's disclosure that

"all features of any valve displacer…may also form part of any of the cardiac valves described." *Id*; Garrison 4:52-57. Drasler ¶¶56-58.

After another examiner interview, the Examiner entered an Examiner Amendment and issued a Notice of Allowance. Ex. 1003, 2148-2150. The Amendment specified that the "no reinforcing members reside within the inner channel of the stent member" limitation was added to more clearly overcome a previous rejection in view of Bailey, but the Examiner did not provide additional reasons for allowance. *Id*.; Drasler ¶59.

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 Office has not previously considered the same or substantially the same art or arguments presented herein, and even if it had, the Office would have erred "in a manner material to the patentability of challenged claims." The Board therefore should not exercise its §325(d) discretion to deny institution.

Grounds 3-6 do not rely on the same or substantially the same art and arguments raised during '739's prosecution. Andersen and **Limon** were not previously considered; and no considered reference is substantially similar to them.

For example, **Andersen** teaches at least one limitation that the Examiner erroneously believed was not found in the prior art: valve means wherein no reinforcing members reside within the inner channel of the stent member (*see* §X.C.4[1.3]). **Andersen** also teaches that its valve is implanted via any prior art technique, and **Limon** teaches the techniques claimed (*see* §X.C.4[1.4]-[1.5]).[6] The Office also has not previously considered the expert testimony submitted herewith. Ex. 1002.

Moreover, where the "Examiner did not expressly consider" at least **Andersen**, **Limon**, 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). Thus, for this further reason, an exercise of §325(d) discretion is not appropriate here.

Grounds 1-2 do not rely on the same or substantially the same art and arguments raised during '739's prosecution. Leonhardt (Ground 2) was not cited by the Examiner during '739's prosecution. And while the Examiner rejected claims over **Garrison** alone and '481 Gabbay in view of **Garrison** (Ex. 1003, 1794-

[6] **Gabbay** and **Phelps** are relied on for only the well-known stent shape with flared ends and pericardial tissue limitations (Grounds 3-6) and **Garrison** is relied on only for its teachings of stent barbs as required in dependent claim 4 (Grounds 5-6).

1797), the Examiner relied on different components in **Garrison**. The Examiner relied on an inverted valve attached only at its base to a circumferential ring 111 as shown in Fig. 38 (below). Ex. 1003, 1794-1795; Garrison, 10:51-62; *see also* Ex. 1003, 1795-97 (not relying on Garrison's non-inverted valve/stent disclosure). Grounds 1-2 instead rely on another embodiment, e.g., Fig. 9 (annotated below). *E.g.*, Garrison, 4:66-5:3, 5:42-48. The Examiner does not appear to have considered **Garrison's** separate disclosure that the support structure 26 (a stent member) can have the same features as the valve displacer 8, which would include its increasingly flared ends. *E.g.*, Garrison, 4:52-57. *See* §VI.

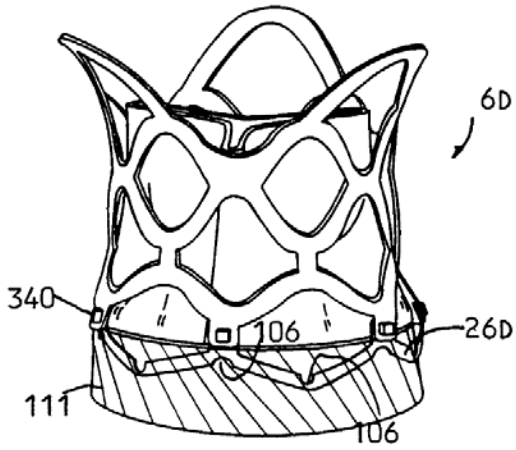


FIG. 38

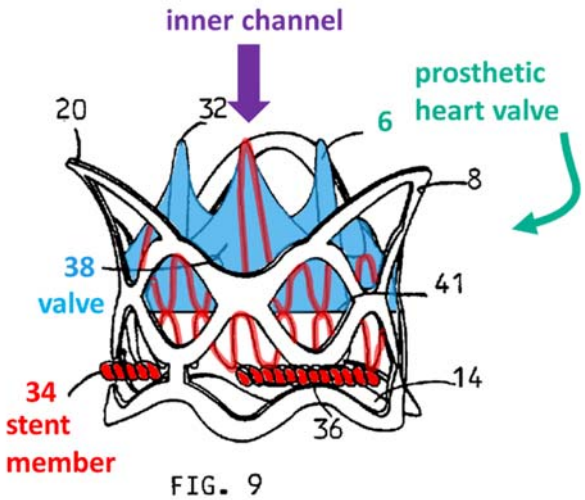


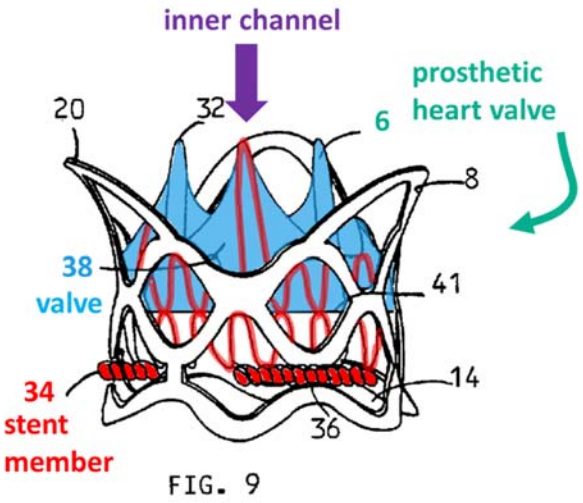
FIG. 9

Because Grounds 1-2 present argument based on different embodiment disclosures than those considered by the Office, the art and arguments are not substantially the same as those previously considered. *NFL Enters. LLC v. OpenTV, Inc.*, IPR2017-02092, Pap. 7, *16 (finding arguments and evidence were not before

the Office where the Examiner focused on one embodiment, overlooking another); *Limelight Networks, Inc. v. Akamai Techs.*, Inc., IPR2016-01711, Pap. 10, *21 (finding arguments not the same where there was "no indication" that Examiner considered whether reference's preferred embodiment taught certain limitations). Additionally, the expert declaration submitted herewith was not previously considered. Ex. 1002.

Even if the Examiner had considered substantially the same art or arguments including the embodiments of Garrison on which Grounds 1-2 rely, the Examiner also committed multiple errors material to patentability. Despite initially rejecting the claims over **Garrison** alone and/or '481 Gabbay in view of **Garrison** (Ex. 1003, 1794-1797), the Examiner subsequently and erroneously failed to maintain the **Garrison** rejections after the claims were amended to require the valve be "made of fixed pericardial tissue" and that "no reinforcing members reside within the inner channel of the stent member." *See* §VI. '739 concedes that a POSITA would have known that "[m]ost tissue valves are constructed" using fixed pericardial tissue. '739, 3:41-46. And while the Examiner's earlier rejections focused on Garrison's valve displacer 8 as the stent, Garrison's support structure 26A is also a stent, which does not have any reinforcing members within its inner chamber, and is disclosed as potentially having the same features of the valve displacer, which would include its flared-ends in a trumpet-like configuration as

further discussed in §X.A and illustrated in Fig. 9 (annotated). And to the extent that Applicant attempted to argue that the "inverted" embodiment in Fig. 35 did not reside entirely within the stent member, Applicant never disputed that these features are disclosed by the other embodiments of Garrison, including the embodiments relied on in this petition.



Moreover, Leonhardt, which was not cited during '739's prosecution, further provides these same teachings that would have been obvious to apply to Garrison as discussed in §X.B and illustrated in Figures 4 and 2 (annotated and excerpted).

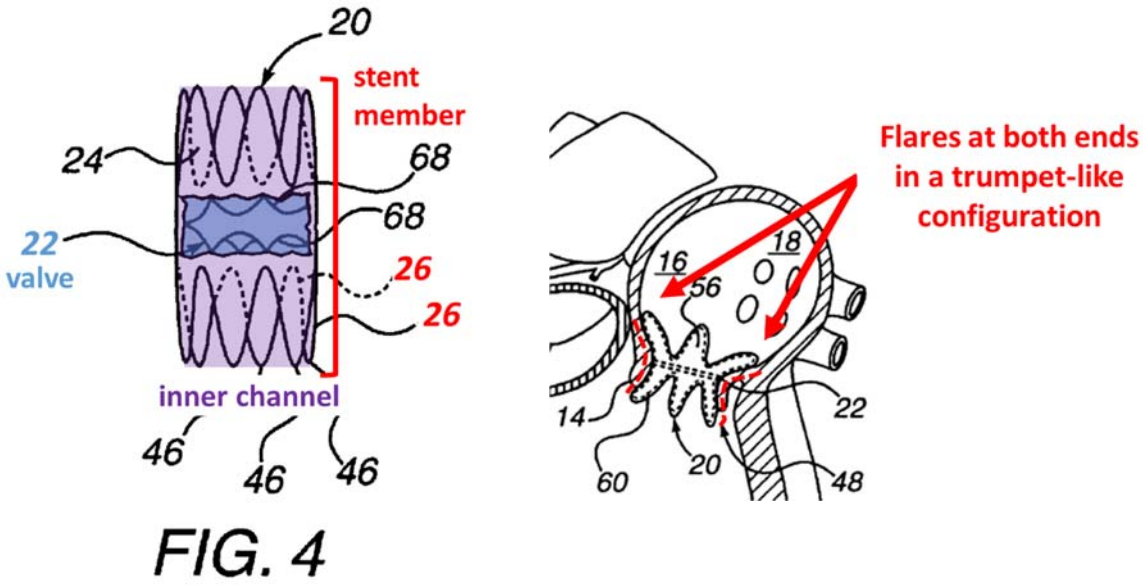


FIG. 4

The Examiner erred in failing to reject the claims over **Garrison** in view of the **AAPA** and alternatively in further view of **Leonhardt**. *See 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); *Arrows Up, LLC v. Oren Techs., LLC*, IPR2018-01231, Pap. 7, *11-12 (finding Examiner erred in misunderstanding prior art reference); *NFL Enters.*, IPR2017-02092, Pap. 7, *16 (declining to exercise discretion where Office reached different conclusions on the same evidence); *Power Integrations, Inc. v. Semiconductor Components Indus., LLC*, IPR2018-01539, Pap. 13, *28-29 (finding error where Examiner failed to substantively analyze potential contributions of prior art of record or identify purported "deleterious effects" counseling against combination).

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 IPR2020-01453 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 '739 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 '739's admissions that the majority of the limitations were known in the art (*see* §I).

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 '739 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 outer bounds of the claims, 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 ¶60.

A. "trumpet-like" (claim 1)

Regardless of the exact meets and bounds of this term, the increasingly flared openings taught by the art relied on herein discloses the limitation. *See* §X; Drasler ¶¶61-63.

B. "valve means" (claim 1)

"Valve means" is not a means-plus-function limitation covered by §112 ¶6 given that the remainder of limitation [1.3] does not recite a function, and is disclosed by the prior art for the reasons discussed in §X. And even if it were a means-plus-function term and additional structure beyond [1.3] were required, the function/structure would be the function and structure of a valve, which were well-known as '739 concedes ('739, 3:18-4:32) and are disclosed by the art as discussed in §X. Even if PO attempts to improperly read in additional structure from the specification beyond that disclosed by the art discussed herein, which would also go beyond the structure required to perform the function of a valve, the art nevertheless discloses the structure's equivalent by performing substantially the same function (operating as a valve) ('739, 5:9-11), in substantially the same way (a valve that is secured to and entirely within the inner channel formed by the stent, and has two to four leaflets) ('739, 10:27-32, 6:64-67, 7:5-8), to achieve the same result (allowing blood to flow in one direction and preventing it from flowing in the other) ('739, 5:9-11). Drasler ¶¶64-67.

C. "controlled release mechanism" (claim 5)

This term is presumptively not covered by §112 ¶6 as claim 5 does not recite "means for." But, even if it were, the function would be: controlling release of device during deployment; and the corresponding structure would be: a pusher member that can be activated by pushing out the pusher member and the prosthetic heart valve partially from the sheath such that the stent member partially expands, but is restrained so it doesn't pop out. '739, 11:51-59, 12:24-28. As discussed in §§X.A.2.[5], X.C.4.[5], the prior art discloses these limitations. Even if PO attempts to improperly read in additional structure from the specification beyond that disclosed by the art discussed herein, which would also go beyond the structure required to perform the function, the art nevertheless discloses the structure's equivalent by performing substantially the same function (controlling release of the prosthetic heart valve) ('739, 11:55-59), in substantially the same way (pushing the pusher member and the valve partially out of the sheath such that a portion of the stent remains collapsed onto the pusher member) ('739, 11:48-62), to achieve the same result (the valve and its stent do not pop out of the sheath) ('739, 11:55-59); Drasler ¶¶68-69.

X. GROUNDS OF UNPATENTABILITY

Although '739 purports to have invented a prosthetic heart valve (composed of a collapsible, expandable stent with flared ends within which is a valve made of

two to four leaflets of fixed pericardial tissue, and that does not have any reinforcing members) and a transcatheter delivery system (with a pusher member and a moveable sheath, where the valve is collapsed onto the pusher member and restrained in that position by the sheath), such assemblies were well-known in the art. As explained below, the claims are unpatentable as obvious. Drasler ¶¶70-232.

Grounds 1-4: ***As to the replacement valve/stent***: **Garrison** discloses a replacement heart valve device comprising a collapsible stent containing a valve, wherein there are no reinforcing members within the stent. It would have been obvious to apply the well-known teachings of a prosthetic valve made of fixed pericardial tissue as '739 concedes; alternately, this is disclosed by **Nguyen**. **Garrison** and alternatively **Leonhardt** disclose that the stent flares at both ends in a trumpet-like configuration. ***As to the valve delivery system***: **Garrison** discloses a delivery system in which the valve is collapsed onto a pusher member and held in place by a moveable sheath. Drasler ¶¶73-153.

Grounds 5-10: ***As to the replacement valve/stent***: **Andersen** discloses a collapsible stent containing the claimed valve prosthesis, wherein there are no reinforcing members within the stent. It would have been obvious to apply the well-known teachings of a prosthetic valve made of fixed pericardial tissue; alternately, this is disclosed by **Gabbay** or **Nguyen**. **Gabbay** discloses a nitinol stent that flares at both ends in a trumpet-like configuration, which is alternatively disclosed by

Phelps. ***As to the valve delivery structure***: **Andersen** discloses that any prior art technique may be used to implant the valve and **Limon** teaches a catheter delivery system with a pusher member and moveable sheath. Drasler ¶¶154-225.

The prior art renders the Claims unpatentable. This Petition is supported by the Declaration of Dr. William Drasler, which describes the scope and content of the prior art at the time of the alleged '739 invention. Drasler (Ex. 1002) ¶¶34-232.

A. Ground 1: Claims 1-5 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 Figures 10-11, the replacement device has a "valve portion 38" (annotated blue) mounted within "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:

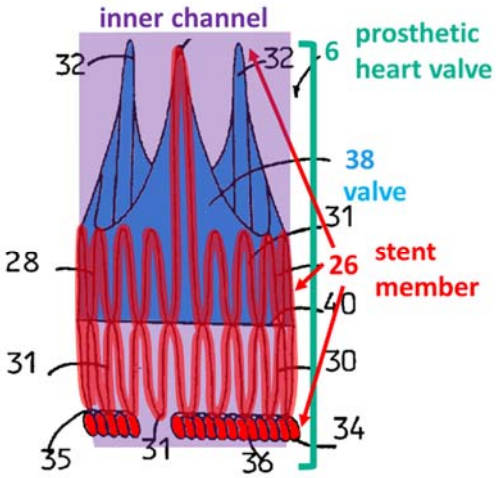


FIG. 10

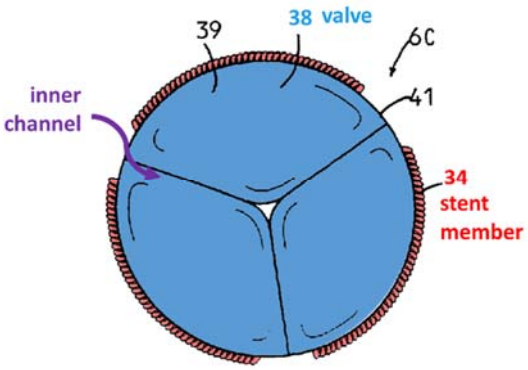
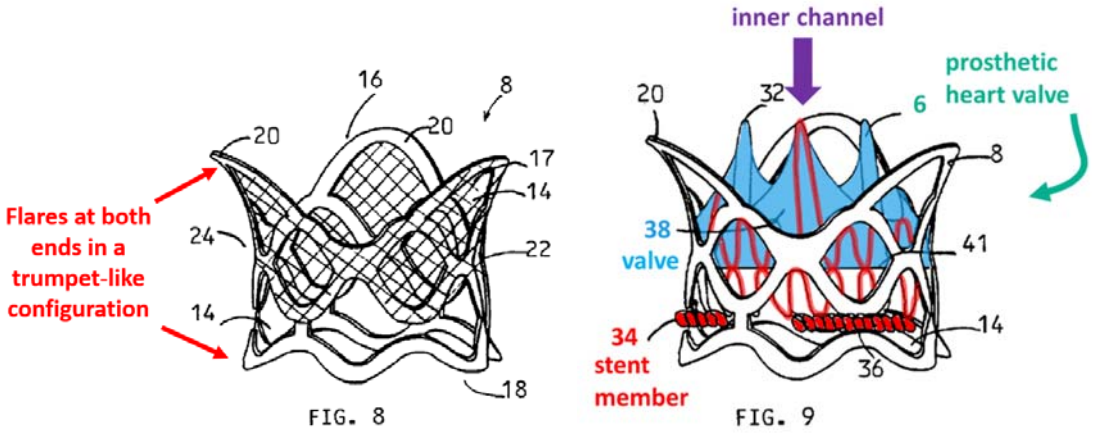


FIG. 11

Garrison, 5:19-46; Drasler ¶74. As shown, the valve and its leaflets are entirely within (both radially and axially) the stent's inner channel. Garrison, 5:43-43, 6:42-48; Drasler ¶75. As **Garrison** notes, "system 2A for implanting a cardiac 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 ¶75.

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 Figures 8-9.



Garrison, 8:48-64, 4:46-5:3, Fig. 13. **Garrison** further teaches that the valve (including its support structure) can be "integrated into a single structure" with the displacer, or have the same features of the valve displacer, which includes the valve displacer's flared structure. Garrison, 2:5-10, 4:52-57. 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. 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 ¶¶76-79. 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 as well as the surrounding vasculature and would have understood that it would have worked

as expected. Drasler ¶78. 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 ¶78. In some embodiments, **Garrison** further teaches that the valve may contain "barbs" that extend outwards, enabling the valve to be firmly affixed in place once it is deployed. Garrison, 5:29-41, 9:64-10:9; Drasler ¶80.

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.

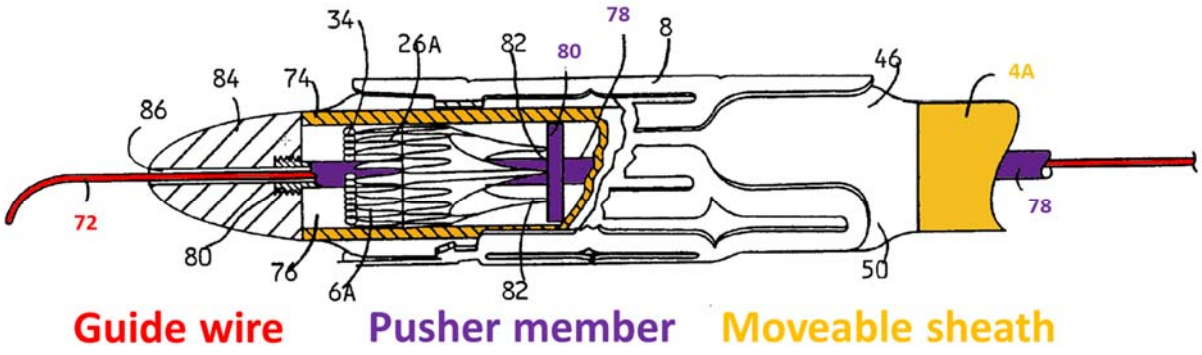


FIG. 14

Garrison, 8:10-23; Drasler ¶81. As shown in Figure 14, the device is collapsed onto "rod 78" and onto the connected "pusher element 80" (which are both annotated purple and together form the claimed pusher member) and the device is held in place by the "outer wall 74" (the sheath—annotated yellow) of the delivery catheter 4A. Garrison, 8:24-44. **Garrison** teaches "rod 78"/"pusher element 80" have a "guidewire lumen 86" with a guidewire 72 running therethrough. 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 on the rod 78, the valve remains "coupled to the catheter," allowing "for accurate positioning and deployment" of the valve. Garrison, 8:53-61, 5:61-67. The valve is then positioned by "manipulat[ing]" "catheter 4A." Garrison, 8:56-58; Drasler ¶¶82-84.

Garrison states that the valve is a "tissue valve such as a tri-leaflet 39 stentless porcine valve," but leaves the construction details of the tissue valve to the POSITA. Garrison, 5:42-46. However, '739 admits the use of fixed pericardial tissue was well-known general knowledge for a POSITA, 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." '739, 3:41-46; Drasler ¶86.

A POSITA had a reasonable expectation of success in applying these teachings to **Garrison**'s porcine tissue valve to advantageously alleviate antigenicity

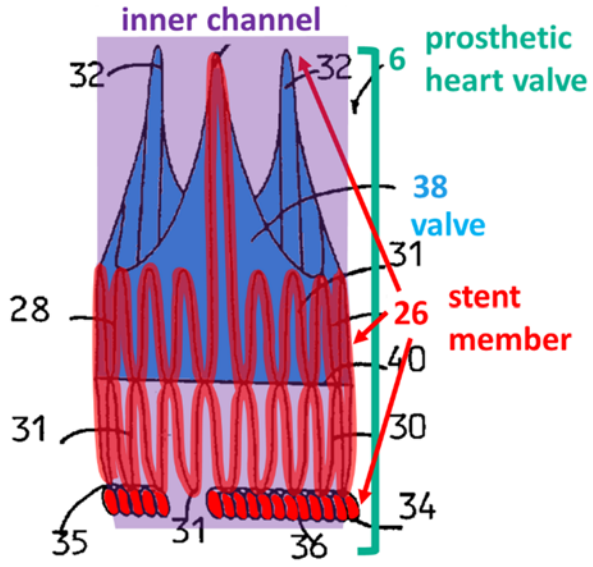
and reduce the risk of an immune response to the new device using one of the most common ways of creating a tissue valve and to use a material with known benefits—strong for its relatively low profile and relatively easy to manipulate to the desired shape. Drasler ¶¶87-88.; *KSR*, 550 U.S. at 417.

Garrison is in the same field as '739—percutaneously, transluminally implantable cardiac prosthetic devices—and reasonably pertinent to the alleged problem(s) identified in '739 of transluminally implanting heart prostheses. '739, 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 ¶85.

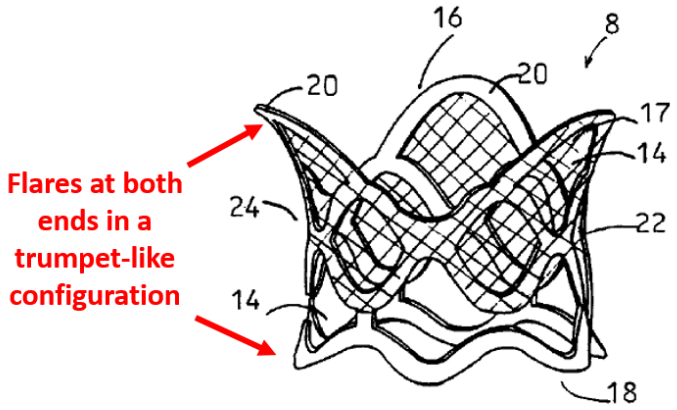
2. Claim Chart

Claim Element	Garrison
[1.pre] "An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:"	**To the extent the preamble is limiting, Garrison discloses an assembly to treat a native heart valve in a patient** (*e.g.*, "devices" for "implanting replacement cardiac valves"), **the assembly for use in combination with a guidewire** (*e.g.*, "lumen…for receiving the guidewire"). ***E.g.*, Garrison:** **Garrison** discloses "methods and devices" for "implanting replacement cardiac valves" percutaneously using a "delivery catheter" with a "guidewire" running through it. • 1:5-6 ("The present invention is directed to methods and ***devices for implanting replacement cardiac valves***.") • 3:5-6 ("FIG. 6 shows the valve displacer and ***valve implanted in the native valve position***.")

Claim Element	Garrison
	• 8:25-34 ("…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***.") • 4:11-22, 7:29-33. Drasler ¶¶89-91.
[1.1] "a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein"	**Garrison discloses a prosthetic heart valve** (*e.g.*, a "cardiac valve 6A" including "valve portion 38" and "support structure 26A") **including: a stent member having an inner channel** (*e.g.*, "support structure 26A"), **the stent member collapsible, expandable** (*e.g.*, "expandable support structure" with "collapsed" and "expanded" positions) **and configured for transluminal percutaneous delivery** (*e.g.*, valve is "preferably introduced through a peripheral vessel," "percutaneously"). ***E.g.*, Garrison:** **Garrison** discloses that the replacement "cardiac valve 6A" includes a "valve portion 38" mounted in a "support structure 26A" (a stent member) that can be collapsed and expanded. Garrison, 5:19-21, 5:42-48, 8:10-18; Drasler ¶94. The replacement valve—including the support structure—is configured to be implanted "percutaneously" using a delivery catheter. Garrison, 4:24-35. • Fig. 10 (annotated)

Claim Element	Garrison
	 FIG. 10 • 4:14-15 ("The system 2 includes a delivery catheter 4, a cardiac valve 6 and a valve displacer 8"). • 4:24-35 ("*[C]**ardiac valve 6 is preferably introduced through a peripheral vesse***l such as the femoral artery (FIGS. 1A and 2) or femoral vein (FIG. 1B)….by surgical cutdown or ***percutaneously*** using the Seldinger technique.") • 5:19-21 ("[C]ardiac 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.") • 8:10-18 ("…***[C]ardiac valve 6A is similar to the cardiac valve 6 described above***, however, the cardiac valve 6A is self-expanding….***26A is made of a resilient material to naturally bias the support structure 26A to the expanded position***.") • 5:42-48, 7:16-18, 8:45-47, Fig. 11.

Claim Element	Garrison
	Drasler ¶¶92-95.
[1.2] "the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and"	**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…flare 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 discloses a support structure that "flare[s] outwardly" in a similar manner in order 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 vessel walls in light of this disclosure. *Id.*, 4:52-57, 4:66-5:1; Drasler ¶¶98-99. 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 other discussions regarding the support structure in claim 1 similarly apply to the embodiment integrated with the valve displacer. Garrison, 2:5-10, 4:52-57; Drasler ¶99. • Fig. 8 (annotated)

Claim Element	Garrison
	 FIG. 8 • 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 ("Referring to FIG. 8, first and second ends 16, 18 of the ***valve displacer 8 flare outwardly to form a circumferential recess 24 at a central section 22***….") • 2:23-28. Drasler ¶¶96-99.
[1.3] "a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides entirely within the inner channel of	***See* §IX.B.** **Garrison discloses a valve means** (*e.g.*, "valve portion 38") **including two to four individual leaflets** (*e.g.*, "tri-leaflet")**, wherein the valve means resides entirely within the inner channel of the stent member** (*e.g.*, "stentless tissue valve" residing within "support structure"), **and wherein no reinforcing members reside within the inner channel of the stent member** (*e.g.*, "stentless tissue valve").

Claim Element	Garrison
the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;"	***E.g.*, Garrison:** **Garrison** discloses a "valve portion 38" of the replacement cardiac valve is a "tissue valve such as a tri-leaflet 39 stentless porcine valve," secured to the internal surface of and located entirely within "support structure 26" (both axially and radially), as shown in Figs. 10-11 and discussed in §X.A.1. Garrison, 5:42-48. During prosecution, PO never disputed that this embodiment of Garrison discloses a valve means "wherein the valve means resides entirely within the inner channel of the stent member." Ex. 1003, 1865-1879, 1912-1916. The valve portion is a "stentless tissue valve"—meaning it does not have reinforcement members inside support structure 26 (which includes posts 32). *Id.* 5:44-48; Drasler ¶103. • 5:42-50 ("The ***posts 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 may be stored separately from support structure 26 and attached to the support structure 26 before the procedure***.") • Fig. 10 (annotated)

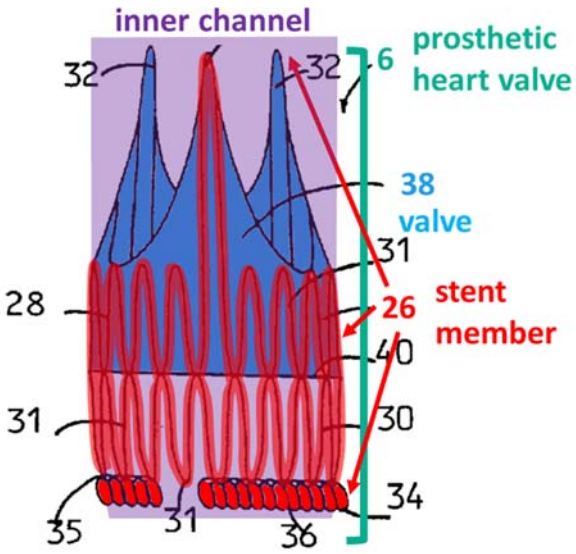


FIG. 10

- Fig. 11 (annotated)

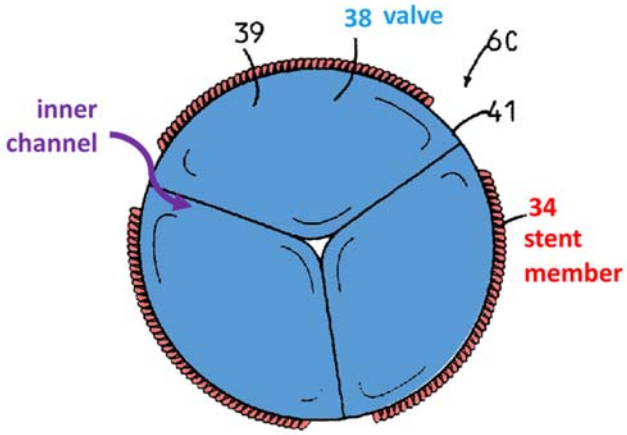
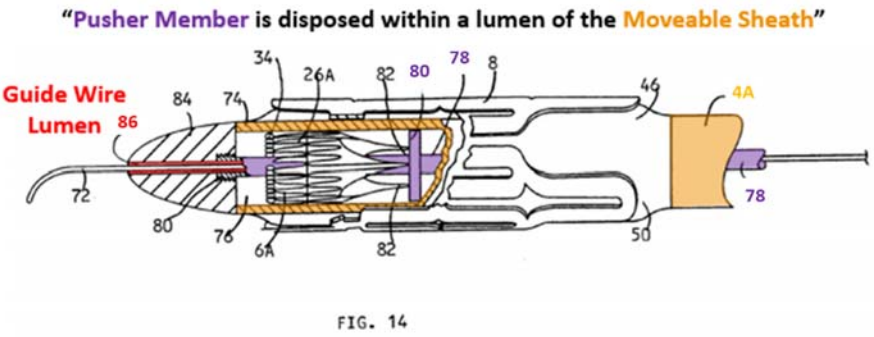


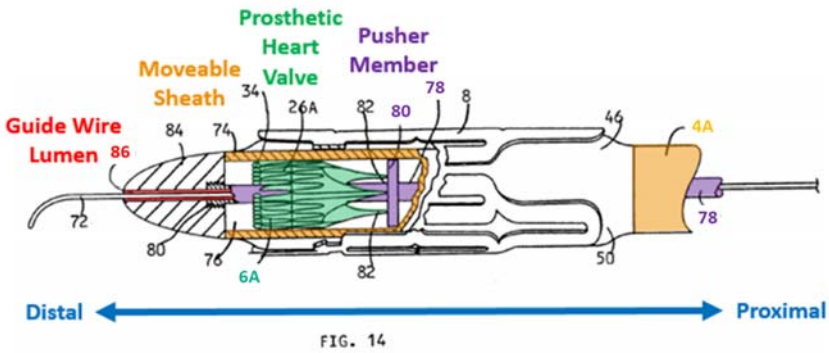
FIG. 11

- 8:3-4, 8:45-47.

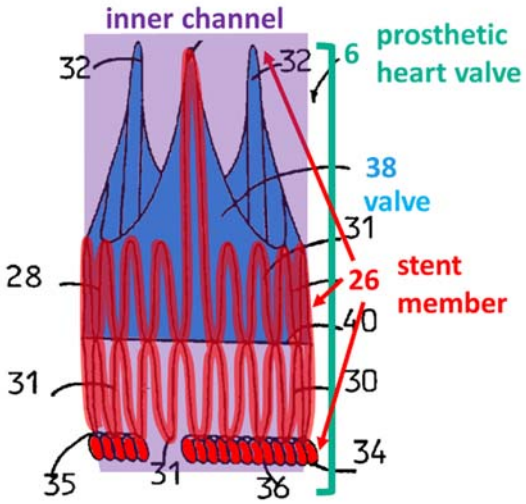
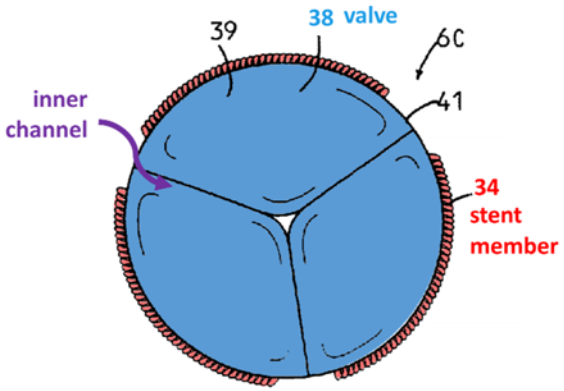
'739 admits that a valve made of fixed pericardial tissue was known in the art (*e.g.*, "[m]ost tissue valves are constructed…by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent.

Claim Element	Garrison
	The porcine or bovine tissue is chemically treated to alleviate any antigenicity."). '739, 3:41-46. As discussed in §X.A.1, a POSITA would have been motivated to apply the known design teachings of a valve made 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 to reduce antigenicity. Drasler ¶¶104-106. Drasler ¶¶100-106.
[1.4] "a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein"	**Garrison discloses a delivery system** (*e.g.*, "delivery catheter 4A") **including a pusher member** (*e.g.*, "rod 78" "having a pusher element 80") **and a moveable sheath** (*e.g.*, "outer wall" of "catheter 4A"), **the pusher member including a guidewire lumen** (*e.g.*, "guidewire lumen 86"), **wherein the pusher member is disposed within a lumen of the moveable sheath** (*e.g.*, "outer wall" of "second catheter" 4A creates "chamber" for "rod," "pusher element," and "valve"). ***E.g.*, Garrison:** **Garrison** discloses a "delivery catheter 4A" for deploying the cardiac valve. Garrison, 7:29-33, 8:24-28. The valve is loaded onto a "pusher element" that rests inside the "outer wall" of the delivery catheter. *Id.* 8:24-44. Delivery catheter 4A, including outer wall 74, is "retrac[table]." *Id.*, 8:53-58 ("retracing"—typo). The pusher element can slide relative to the outer wall, and includes a "guidewire lumen 86 for receiving the guidewire 72." *Id.* 6:57-59, 8:24-44, 8:53-58. A POSITA would have understood catheter 4A is moveable in light of these disclosure, 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 in order to deploy the valve. *Id.* 8:65-9:1, 9:51-53; Drasler ¶110.

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* [*sic*] *a predetermined amount***….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….") • 7:46-48, 8:65-9:1, 9:39-43. Drasler ¶¶107-110.
[1.5] "the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed	**Garrison discloses the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member** (*e.g.*, "valve 6A" is "in a collapsed condition during introduction" on the "rod 78," which is connected with "pusher element 80" such that posts 32 abut pusher element

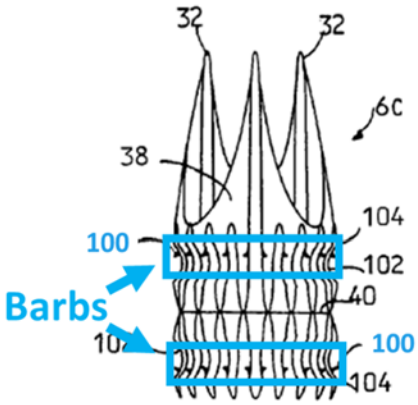
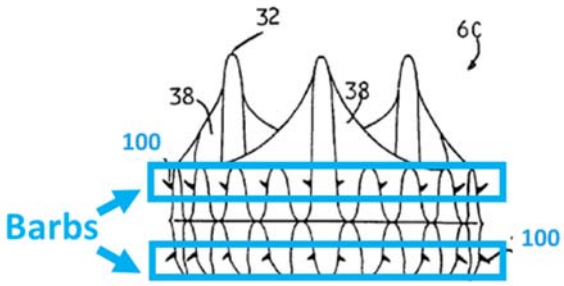
Claim Element	Garrison
configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and wherein"	80) **and is restrained in the collapsed configuration by the moveable sheath** (*e.g.*, "self-expanding" "valve" "is contained within an outer wall" of "delivery catheter 4A"), **wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath** (*e.g.*, distal end of the valve having the protrusions is located at "distal end of catheter" such that "protrusions…are exposed outside when the catheter is "retraced"). ***E.g.*, Garrison:** **Garrison** discloses the valve 6A is collapsed onto a "rod" and "pusher element" in a "collapsed condition," and held in place by an "outer wall" of catheter 4A, as shown by Fig. 14. Garrison Abstract, 8:24-44. As shown in Figure 14, the distal end of the valve is located at the distal end of the moveable sheath in the loaded configuration, wherein distal refers to the direction away from the user. *Id.* Fig. 14. To the extent it is argued that further disclosure of the distal end of the stent flush with the distal end of the outer member is required, the two ends are flush as the stent is deployed and stent "protrusions 34" are "exposed outside the distal end of the catheter 4a." *Id*, 8:53-56, Drasler ¶114. Moreover, a POSITA would have been motivated to locate the distal end of the stent at the distal end of the outer member such that deployment is achieved by simply pushing the inner member out of the end of the sheath. Drasler ¶115. • Fig. 14 (annotated):  FIG. 14

Claim Element	Garrison
	• 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.*** The rod 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 ("[T]he valve displacer and ***valve are in a collapsed condition during introduction*** and are expanded to deploy the valve displacer and valve.") • 8:53-56 ("After the valve displacer 8 has been expanded, the catheter 4A is retraced [*sic*] a predetermined amount so that the ***protrusions 34 are exposed outside the distal end of the catheter 4A***.") • 8:3-4, 8:45-47. Drasler ¶¶111-115.
[1.6] "the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient."	**Garrison discloses the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient** (*e.g.*, "stentless tissue valve" residing entirely within "support structure"). ***E.g.*, Garrison:** **Garrison** discloses that "valve portion 38" is attached to the base and posts inside of "support structure 26," as shown in Fig. 10. Garrison, 5:42-50, Fig. 10. The valve remains entirely within (both radially and axially) the support structure, which includes posts 32, when the replacement valve is "collapsed," and remains inside the support

Claim Element	Garrison
	structure once the device is deployed and "expanded" as shown in Figs. 9-11, 14. *Id.* 3:53-56. • Fig. 10 (annotated)  FIG. 10 • Fig. 11 (annotated)  FIG. 11 • 5:42-50 ("The ***posts 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). ***The***

Claim Element	Garrison
	valve portion 38 may be stored separately from support structure 26 and attached to the support structure 26 before the procedure.") • Figs. 9, 14, 8:3-4, 8:45-47. Drasler ¶¶116-119.
[2] "The assembly 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 ¶¶120-122.
[3] "The assembly of claim 2, wherein the stent member comprises nitinol."	***See* [2].** **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 ¶¶123-124.

Claim Element	Garrison
[4] "The assembly of claim 1, wherein the stent member includes two circles of barbs on an outer surface of the stent member."	***See* [1].** **Garrison discloses that the stent member** (*e.g.*, "support structure") **includes two circles of barbs on an outer surface of the stent member** (*e.g.*, "barbs…which extend outwardly from the cardiac valve…in the expanded condition")**.** ***E.g.*, Garrison:** **Garrison** discloses that "support structure 26 may also have barbs." 5:26-41. For example, as shown in Figs. 29-30, "cardiac valve 6C has barbs 100" that form two circles that "extend outwardly" from the support structure of the "cardiac valve." *Id.* 9:64-10:1, Figs. 29-30. A POSITA would have been motivated to apply **Garrison's** teaching of using barbs to **Garrison's** embodiment with a self-expanding stent with the predictable and advantageous result of more securely attaching the self-expanding stent to the valve displacer or vessel wall. Drasler ¶128. • 9:64-10:9 ("The cardiac valve 6C is similar to the cardiac valves 6[,] 6A except that the ***cardiac valve 6C has barbs 100 which extend outwardly from the cardiac valve 6C in the expanded condition of FIG. 30***. The barbs 100 secure the cardiac valve 6C to the valve displacer 8 or directly to the vessel wall…."**)** • 10:20-24 ("***The barbs 100 may be long enough to pierce and anchor in the native valve leaflets*** or may be designed to merely pass into and engage the sides of the openings 14.") • Fig. 29 (annotated):

Claim Element	Garrison
	 FIG. 29 • Fig. 30 (annotated):  FIG. 30 • 5:26-41, 8:45-47. Drasler ¶¶125-128.
[5] "The assembly of claim 1, wherein the pusher member includes a controlled release	***See* [1], §IX.C.** **Garrison discloses that the pusher member includes a controlled release mechanism that can be activated** (*e.g.*, "cardiac valve 6A is advanced out of a chamber…by advancing a rod")**.**

Claim Element	Garrison
mechanism that can be activated."	***E.g.*, Garrison:** **Garrison** discloses that the "cardiac valve" is pushed using "rod 78 having a pusher element 80 attached thereto." Garrison, 8:25-44. As discussed in §X.A.1, the valve "remains coupled to the catheter" and manipulated, prior to the rod "advanc[ing] far enough to completely release the cardiac valve," such that the rod/pusher element have a controlled release mechanism that is activated by distally moving the rod/pusher element to partially deploy the valve, such that a portion of the valve remains collapsed on the rod inside the catheter and the valve remains coupled to the catheter, and then pushing the valve out further to completely release the valve. *Id.* 8:51-64. • 8:25-44 ("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….") • 8:48-64 ("…***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. … ***[T]he rod 78 is then advanced far enough to completely release the cardiac valve 6A.***") Drasler ¶¶129-131.

B. Ground 2: Claims 1-5 Are Rendered Obvious by Garrison in View of Leonhardt

To the extent further disclosure is required beyond Garrison for [1.2], [1.3], and [1.6] (*see* §X.A), the Claims are obvious in further view of **Leonhardt**. Drasler ¶141.

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).

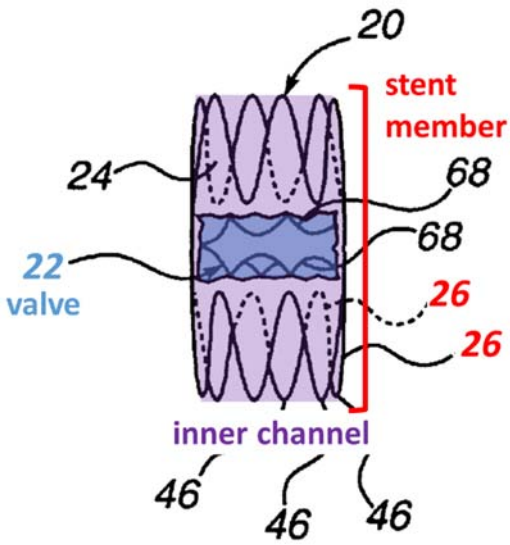
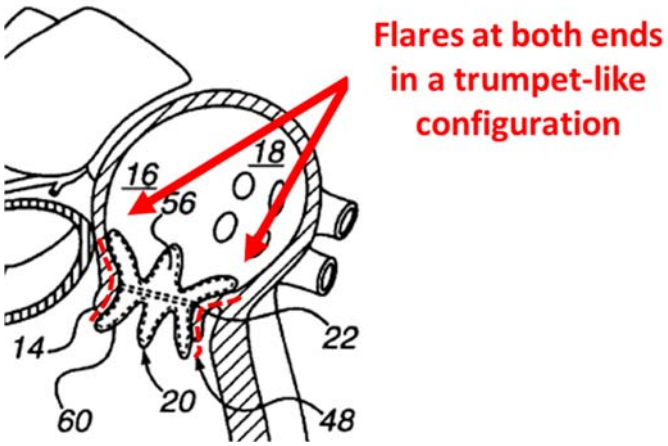
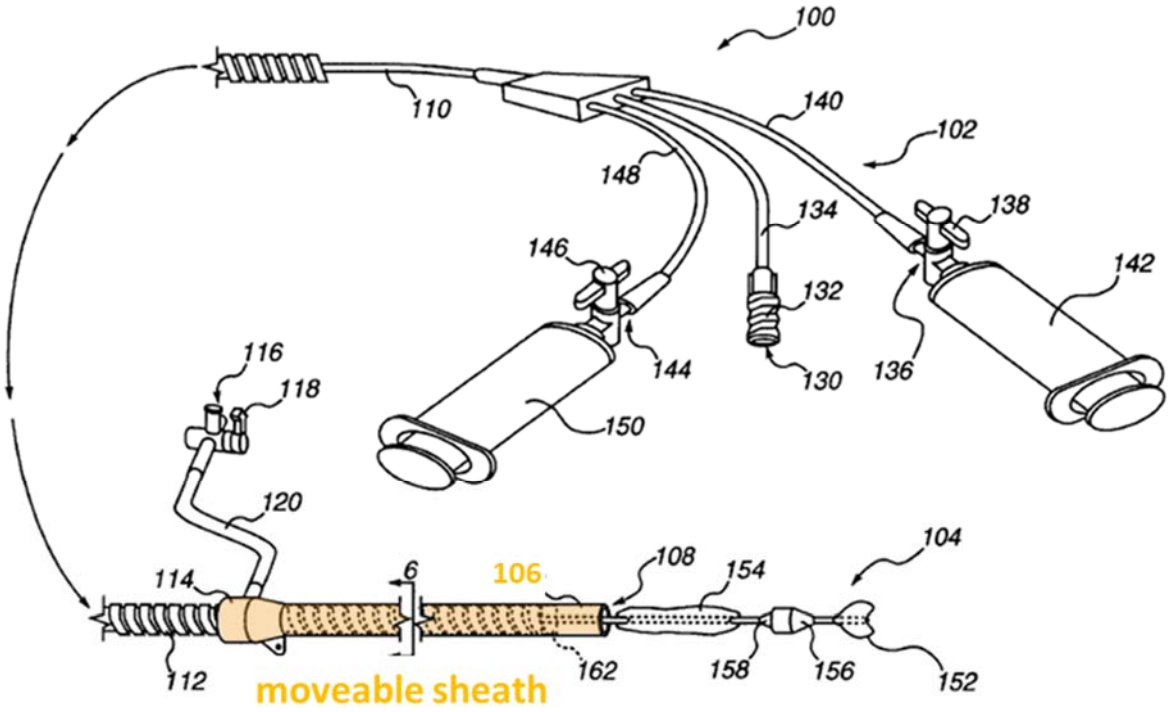


FIG. 4

Leonhardt, 6:23-31; Drasler ¶¶132-133. Additionally, **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 ends of the stent 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.

Like **Garrison**, **Leonhardt** is in the same field as '739 and reasonably pertinent to the alleged problem(s) identified in '739, e.g., of transluminally implanting heart prostheses. Leonhardt, Title, Abstract, 1:4-16, 2:5-6, 3:15-17, 9:63-67; see §X.A.1; Drasler ¶137.

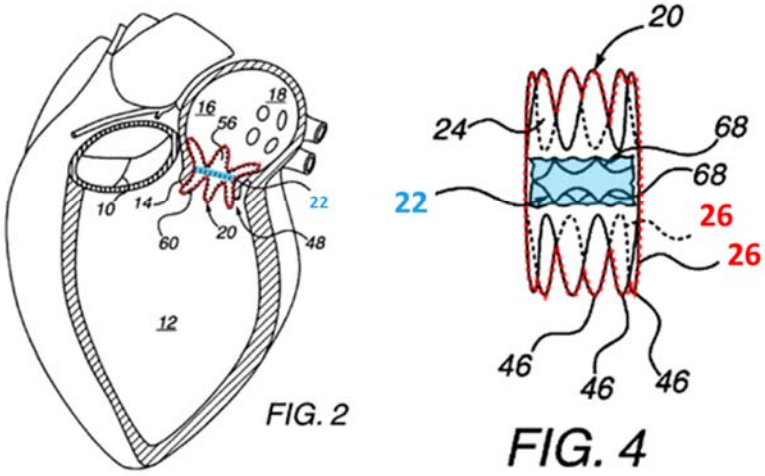
In light of the above and as discussed below, a POSITA would have found it routine, straightforward and advantageous to apply **Leonhardt's** teachings of a valve within a stent, and a trumpet-like configurations on the stent's ends, in implementing **Garrison's** cardiac valve and delivery method and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

[1.2]: While a POSITA would have understood that **Garrison** discloses or at least renders obvious a stent with flared trumpet-like configurations on both end (*see* §§X.A.1, X.A.2.[1.2]), **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] [sic] at…both ends" as shown in Fig. 2). Leonhardt, 5:47-50, 6:9-13, 6:19-22, Figs, 2, 9D; Drasler ¶¶142-145. 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 ¶¶139-140. 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…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 ¶¶140, 142-145.

[1.3], [1.6]: While a POSITA would have understood that **Garrison** discloses that the valve is entirely within the inner channel formed by the stent (*see* §§X.A.1, X.A.2.[1.3], X.A.2.[1.6]), **Leonhardt expressly teaches a valve residing entirely within an inner channel of the stent member** (*e.g.*, as shown in Fig. 4).

"Valve Means resides entirely within the inner channel of the Stent Member"



Leonhardt, 6:23-31 ("valve…pre-sized to fit within the internal diameter of cylinder 48 formed by stent"); Drasler ¶¶146-150. A POSITA would have been motivated to

apply Leonhardt's teachings of placing the valve axially and radially 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 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. *See, 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); Andersen, 4:3-17 (increasing stent surface area that "abuts the inner wall of the channel" helps secure "the valve prosthesis"); Drasler ¶150.

C. Ground 5: Claims 1-3 and 5 Are Rendered Obvious by Andersen in View of Limon and Gabbay

1. Overview of Andersen

Andersen teaches a "valve prosthesis," used as a replacement "cardiac valve." Andersen, 1:21-31. The prosthesis uses a self-expandable stent that is "radially collapsible and re-expandable" along with a "collapsible valve," and is implanted via "catheterization" (percutaneously and transluminally) through a "channel in the body." Andersen, 2:27-33, 2:44-58. As shown in Fig. 12, **Andersen** teaches the valve (annotated blue) has three leaflets residing entirely within an inner channel of a "stent" (annotated red).

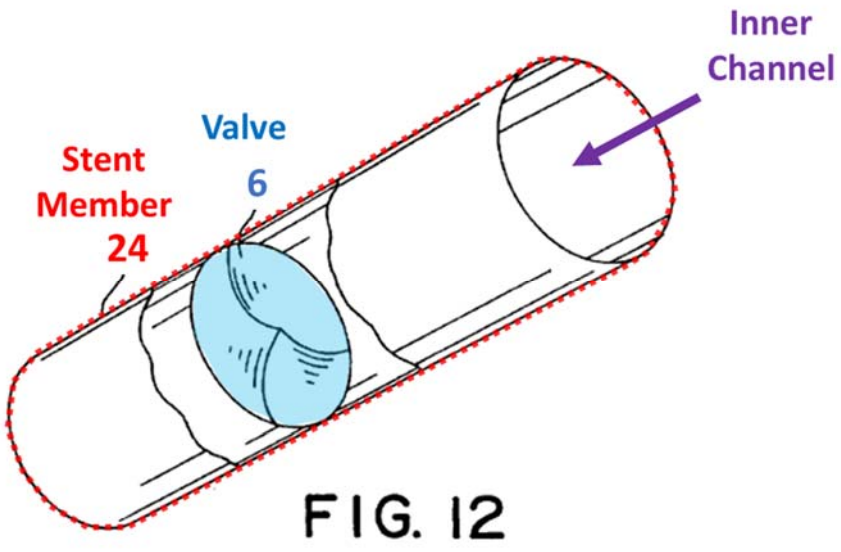
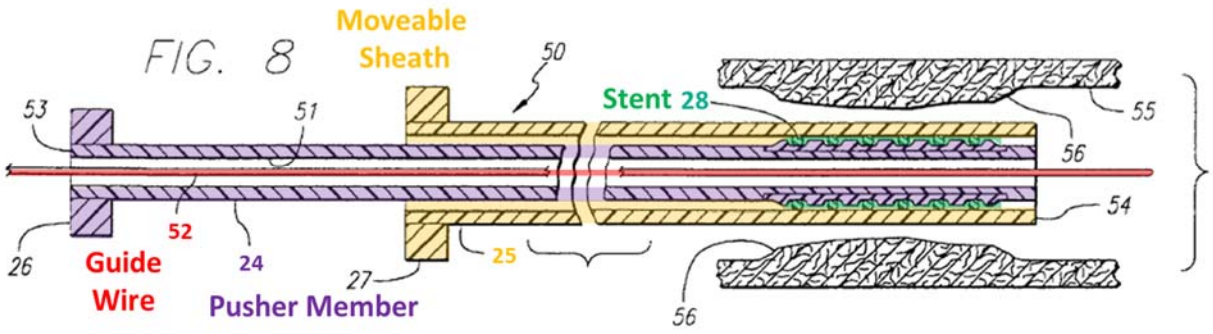


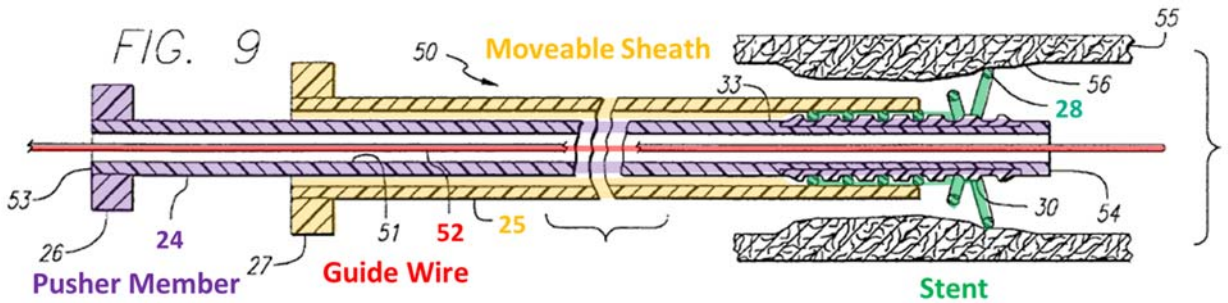
FIG. 12

Andersen, 2:28-33, 6:62-63. Andersen teaches "biological valve 6 was removed from a slaughtered pig…." Andersen, 5:18-19. But in view of **Andersen's** further teaching that any collapsible valve can be used (Andersen, 6:60-62), a POSITA would have been motivated to use the well-known fixed pericardial tissue valve, as admitted in '739. *See* §X.A.1. **Andersen** discloses that the stent is designed "for folding and expanding together with the collapsible valve," and a POSITA would have understood the valve remains entirely within the inner channel of the stent member when it is collapsed, and when it is deployed. Andersen, 1:27-33, Fig. 12; Drasler ¶157. **Andersen** also teaches that "any prior art technique" can be used during implantation to "supervise an accurate introduction and positioning of the valve prosthesis," including the use of "guide wires" and a "catheter." Andersen, 4:36-41. Drasler ¶¶155-157.

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

Andersen leaves it to the POSITA to select a delivery system for the valve. Andersen, 4:36-41; Drasler ¶158. **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 **Andersen**. Limon, Abstract, 2:32-40; Drasler ¶158. 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), such that the distal end of the stent is located at the distal end of the outer member sheath.





Limon, 5:27-54. Drasler ¶158. To deploy the stent, the delivery catheter is advanced over a "guide wire" (annotated red), which runs through "guide wire lumen 51" that extends through the delivery catheter. Limon, 5:27-54. As Figure 9 shows, once the stent is in the proper location, the control handles are used to push out (move) the inner member (the pusher member) "distally" while the outer member is moved "proximally," pushing out the stent from the distal end of the delivery catheter. Limon, 2:64-3:5, 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 ¶¶159-161.

A POSITA would have been motivated to apply Limon's teachings for transcatheter implantation of stent prostheses to Andersen's transcatheter implantation of stented valve devices. Drasler ¶162. Like Andersen, Limon is in the same field and is analogous art to '739—both are in the same field related to percutaneously, transluminally implantable cardiac prosthetic devices. '739, Title, Abstract, 4:63-5:1, 5:16-28; Andersen, 1:51-53, 2:28-34; Limon, Title, Abstract, 1:39-47, 1:61-64. Andersen and Limon are also reasonably pertinent to the alleged problem(s) identified in '739 of transluminally implanting heart prostheses and of controlling release of such prostheses during implantation. '739, 1:25-28, 2:58-3:17,

11:55-59; Andersen, 2:28-34; Limon, Abstract, 1:28-29, 1:61-2:3, 3:66-4:3, 1:53-58, 2:58-62. Drasler ¶162.

A POSITA would have been motivated to apply **Limon**'s advantageous delivery system teachings to **Andersen**'s transcatheter stented valve devices. Drasler ¶163**.** For example, **Limon**'s teachings advantageously allow a user to "recapture" and "reposition" a partially deployed stent (Limon, 2:64-3:1), and better control the axial position of the stent throughout the procedure (Limon, 1:53-57). A POSITA would have had a reasonable expectation of success because **Andersen** teaches that "any prior art technique" can be used during implantation for "accurate introduction and positioning of the valve prosthesis," and "it is possible to modify the valve prosthesis [or the catheter used in implantation] depending on the desired use" (4:36-41, 6:49-52), and **Limon** provides an example of such a delivery system. Drasler ¶163. While it is not necessary to apply **Limon's** teachings of using attachment projections 30, as illustrated in Figure 9, to control the stent 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 projections teachings as they provide sufficient grip to maintain attachment to a valve/stent, even if mostly deployed, and can be formed of a material that is "soft by design"/"relatively soft" to cushion the stented valve of **Andersen** and hold it in place. Limon, 4:52-5:26, 5:41-54; Drasler ¶164. 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 ¶164; 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 delivery system teachings to Andersen's transcatheter stented valve devices, and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶165.

3. Overview of Gabbay and Motivation to Combine with Andersen

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 the self-expanding "stent portion 14" for a heart valve is formed from a "shape memory alloy," such as nitinol, that will "flare outwardly" at the ends in its expanded state.

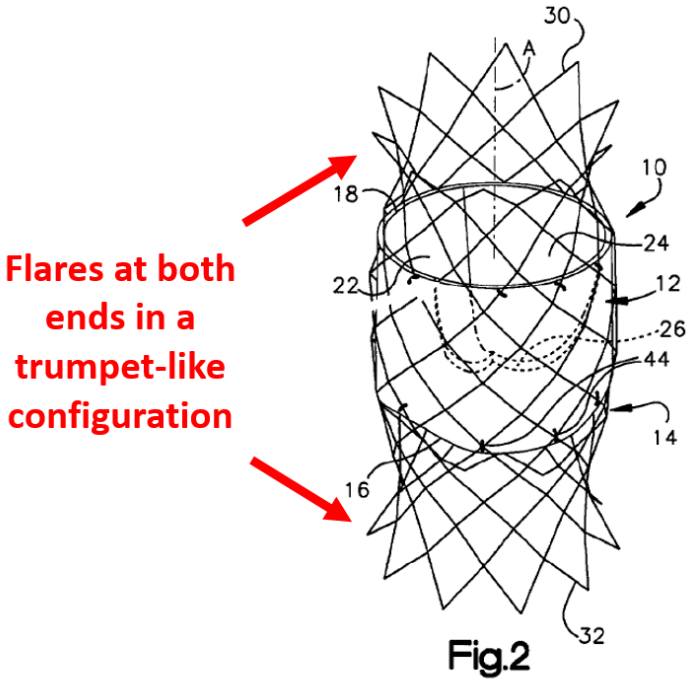


Fig.2

Gabbay, 3:63-4:8, 4:18-23, 4:53-58, 10:46-58; Drasler ¶166 . **Gabbay** also teaches that the "valve portion" of the prosthesis is formed from "three leaflets" (Gabbay, 3:20-25) using "natural tissue" that is "chemically fixed" (Gabbay, 3:38-52), and an exemplary natural tissue is "pericardium" (Gabbay, 7:4-6). A POSITA would have understood, or at least found it obvious, that this discloses valve leaflets made of fixed pericardial tissue (as '739, 3:41-46, concedes). Drasler ¶167.

A POSITA would have been motivated to apply **Gabbay's** teachings of a nitinol self-expanding stent that flares outward in its expanded state to **Andersen's** stented valve device because **Gabbay** teaches that it will "expand" when exposed to "ambient temperature[s]" in the body, and become a flared shape that enables the device to better engage with the surrounding tissue and "mitigate movement,"

thereby reducing the risk of displacement. Gabbay 3:36-4:8, 8:14-23; Drasler ¶¶168-169; §§X.A.1 and X.B (**Letac**, **Phelps** and **Leonhardt**, disclose same motivations). A POSITA would have also been motivated to apply **Gabbay's** teachings of a fixed pericardial tissue valve to **Andersen's** valve to advantageously alleviate antigenicity using one of the most common ways of creating a tissue valve, as '739 concedes. Drasler ¶170; '739, 3:41-46; §X.A.1. Additionally, **Andersen** discloses "that it is possible to modify the valve prosthesis depending on the desired use" (6:49-52), which would include the application of the Gabbay's flared-end design and fixed pericardial tissue. Drasler ¶171. While PO attempted to distinguish **Gabbay** during prosecution based on its delivery mechanism, Ground 3 does not rely on **Gabbay's** delivery mechanism. Drasler ¶172.

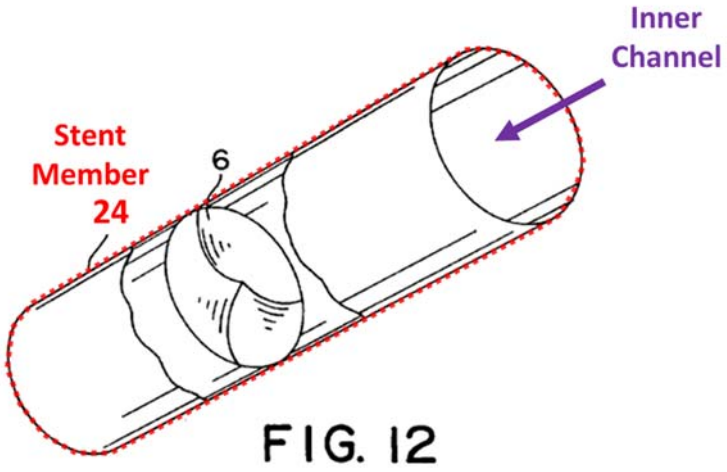
Like **Andersen** and **Limon**, **Gabbay** is also in the same field as '739 and reasonably pertinent to the alleged problem(s) identified in '739 of transluminally implanting heart prostheses. '739, 2:58-3:17; Gabbay, Abstract, 1:13-15, 2:5-8, 5:27-31, 9:15-17; *see also* §X.A.1. Drasler ¶168.

A POSITA would have found it obvious and straightforward to apply **Gabbay's** teaching of a nitinol stent with flared ends and the use of a fixed pericardial tissue in implementing **Andersen's** stented valve in view of **Limon's** delivery system teachings, and would have known that such an application (yielding the claimed limitations) would predictably work and provide the expected

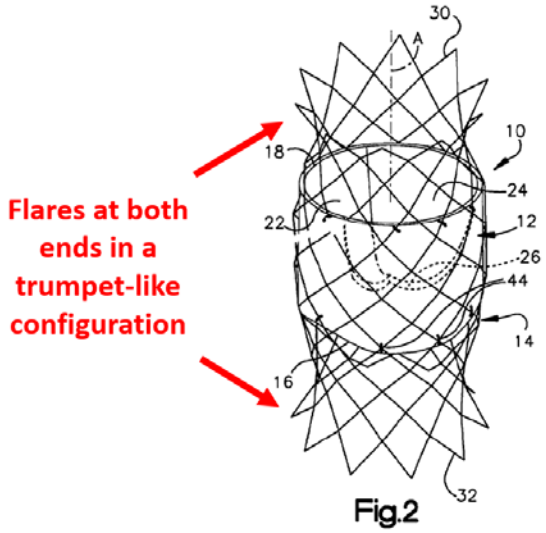
functionality, particularly in light of the aforementioned disclosures as well as Leonhardt and Phelps, which each disclose the delivery of a similarly shaped self-expanding stent delivered via a mechanism similar to Limon. *See* §X.B (discussing Leonhardt); Phelps, 2:31-34, 10:25-29, Figs. 7-8. Drasler ¶173.

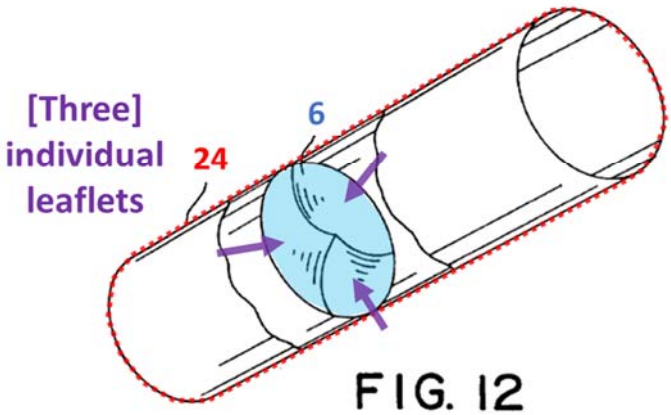
4. Claim Chart

Claim Element	Andersen in view of Limon and Gabbay
[1.pre] "An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:"	**To the extent the preamble is limiting, Andersen discloses an assembly to treat a native heart valve in a patient** (*e.g.*, "cardiac valve prosthesis, for implantation" by catheter)**, the assembly for use in combination with a guidewire** (*e.g.*, "guide wires for the catheter" used during implantation)**.** ***E.g.*, Andersen:** **Andersen** discloses a "cardiac valve prosthesis" implanted using "guide wires" and a "catheter" in order to replace a natural valve. • 1:14-20 ("The present invention relates to a ***valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body***…."). • 4:37-41("In connection with the implantation, any prior art technique may be used…. ***Thus, guide wires for the catheter…may be used***.") • 1:21-22, 2:27-33. Drasler ¶¶174-176.
[1.1] "a prosthetic heart valve including: a stent member having an inner channel, the stent member	**Andersen discloses a prosthetic heart valve** (*e.g.*, see [1.pre], "cardiac valve prosthesis") **including: a stent member having an inner channel** (*e.g.*, the "stent is made from a…cylindrical support" with a channel inside it), **the stent member collapsible, expandable** (*e.g.*, the stent is "radially collapsible and re-expandable") **and configured**

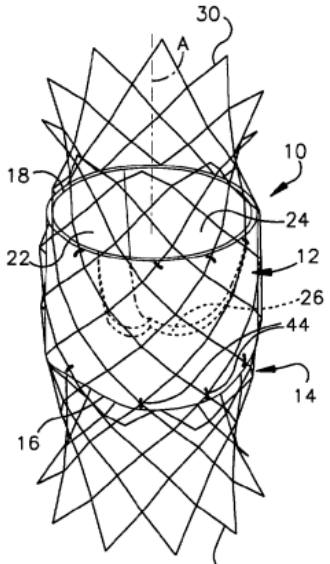
Claim Element	Andersen in view of Limon and Gabbay
collapsible, expandable and configured for transluminal percutaneous delivery, wherein”	**for transluminal percutaneous delivery** (*e.g.*, the valve prosthesis is implanted by a “catheterization” technique.) ***E.g.*, Andersen:** **Andersen** discloses the “cardiac valve prosthesis” includes a “cylindrical” stent that is “radially collapsible and re-expandable,” and implanted via a catheter transluminally and percutaneously (e.g., through a vein). • Fig. 12 (annotated)  FIG. 12 • 1:14-20 (“The present invention relates to a…cardiac valve prosthesis…comprising a collapsible elastic valve which is mounted on ***an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent***.”). • 2:29-33 (“[T]he stent is made from ***a radially collapsible and re-expandable cylindrical support means*** for folding and expanding together with the collapsible valve for implantation in the body ***by means of a technique of catheterization***.”) • 2:66-3:6 (“The valve prosthesis [requires…] ***a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place***….”)

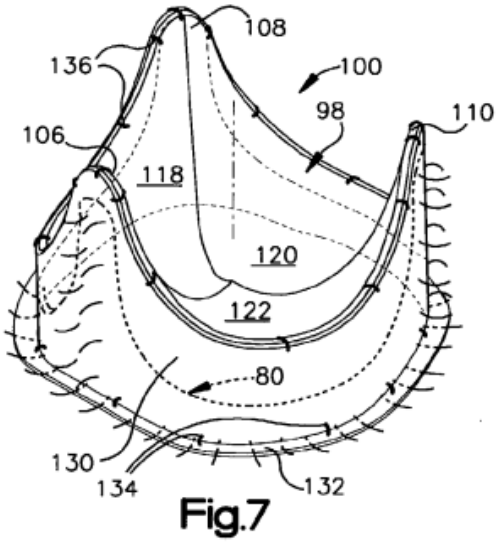
Claim Element	Andersen in view of Limon and Gabbay
	• 4:37-41. Drasler ¶¶177-179.
[1.2] "the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and"	**Andersen discloses the stent member includes a tubular structure** (e.g., the "stent is made from a…cylindrical support means")**.** *See* [1.1]. **Gabbay 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.*, a "cylindrical stent" will "flare outwardly for engagement with surrounding tissue when implanted"). ***E.g.* Gabbay:** **Gabbay** discloses a self-expanding stent for a "heart valve" that is formed from a "shape memory alloy" that will "flare outwardly" at the ends in its expanded state. As discussed in §X.C.3, a POSITA would have been motivated to apply **Gabbay's** teachings of a stent that flares outward in its expanded state to **Andersen's** stent of the cardiac valve prosthesis to advantageously reduce the risk of displacement as taught by Gabbay. Gabbay, 3:36-4:8; Drasler ¶184. • Fig. 2 (annotated)

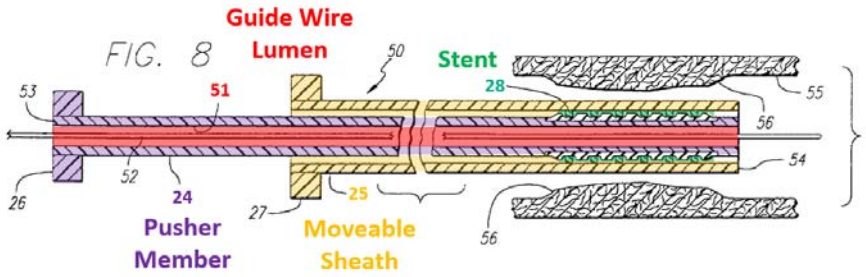
Claim Element	Andersen in view of Limon and Gabbay
	 Fig.2 • 1:60-2:4 ("…The valve can…expand from the reduced cross-sectional dimension to the expanded cross-sectional dimension ***such as to replace an insufficient heart valve or an insufficient venous valve***.") • 3:63-4:8 ("…***The stent portion 14[ ]inflow and outflow ends 30 and 32 of the stent, which, when implanted, may engage and/or be urged into the surrounding tissue to mitigate movement thereof***.") • 4:65-4:67 ("…[T]he valve portion 12 is disposed generally coaxially within the ***cylindrical stent portion 14*** relative to the central axis A.") • 4:53-58, 10:46-58, Fig. 1B. Drasler ¶¶180-184.
[1.3] "a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve	***See* §IX.B.** **Andersen discloses a valve means** (*e.g.*, "valve") **including two to four individual leaflets** (*e.g.*, Fig. 12 depicts the valve with three leaflets)**, wherein the valve means resides entirely within the inner channel of the stent member** (*e.g.*, the valve "is mounted…in the tubular means 24")**, and wherein no reinforcing members reside**

Claim Element	Andersen in view of Limon and Gabbay
means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;"	**within the inner channel of the stent member** (*e.g.*, no reinforcing members inside the channel of the "tubular means 24"). ***E.g.*, Andersen** **Andersen** discloses that the "valve 6 is mounted in a central position in the tubular means 24" (the stent member). Andersen 6:64-7:8. As shown in Fig. 12, the valve itself includes three individual leaflets, and does not include any additional reinforcing members inside the inner channel of the "tubular means." • 6:62-7:8 ("It is ***also possible to use valves with more or fewer flaps than three***. [¶] It is possible to make the valve prosthesis with a closed cylinder surface....***In FIG. 12 an embodiment is shown where the valve 6 is mounted in a central position in the tubular means 24.***") • Fig. 12 "Valve Means resides entirely within the inner channel of the Stent Member"  FIG. 12 **Andersen renders obvious a valve made of fixed pericardial tissue**. As discussed in §§X.C.1 and X.A.1, a POSITA would have found it obvious to use the well-

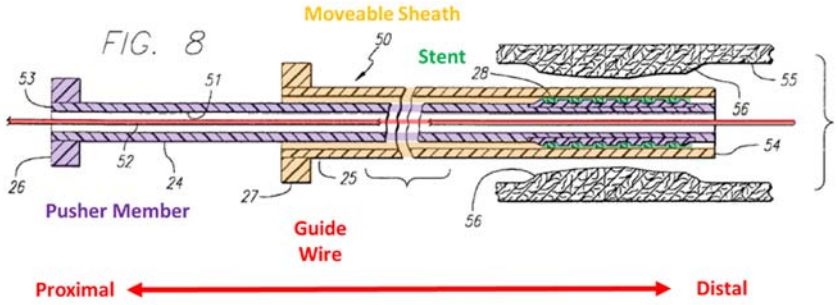
Claim Element	Andersen in view of Limon and Gabbay
	known fixed pericardial tissue valve to advantageously alleviate antigenicity and reduce the risk of an immune response to the new device using one of the most common ways of creating a tissue valve. Drasler ¶188. **To the extent it is argued that further disclosure is required, Gabbay discloses a valve made of fixed pericardial tissue** (*e.g.*, valve is made from "natural tissue pericardium" fixed with "glutaraldehyde")**.** ***E.g.* Gabbay:** **Gabbay** discloses the "valve portion" of a valvular prosthesis formed from "chemically fixed" "natural tissue," and an exemplary natural tissue is "pericardium," which a POSITA would have understood to disclose, or at least render obvious, leaflets made of fixed pericardial tissue. Drasler ¶¶189-190. As discussed in §X.C.3, a POSITA would have been motivated to apply **Gabbay's** teachings of a valve made from fixed pericardial tissue to **Andersen's** cardiac valve prosthesis to alleviate antigenicity concerns, reducing the risk of the patient forming an immune response to the new valve using one of the most common ways of creating a tissue valve. Drasler ¶191. • Fig. 2

Claim Element	Andersen in view of Limon and Gabbay
	 Fig.2 • 3:38-42 ("***If the valve portion 12 is formed of a natural tissue material**…**the valve should be chemically fixed***, such as in a suitable solution of glutaraldehyde in a closed condition (as is known in the art).") • 6:65-7:12 ("***FIG. 7 illustrates an example of a valvular prosthesis**….**The outer sheath 130 may be a sheath of natural tissue pericardium (e.g., bovine, equine, porcine, etc.)***…."). • Fig. 7

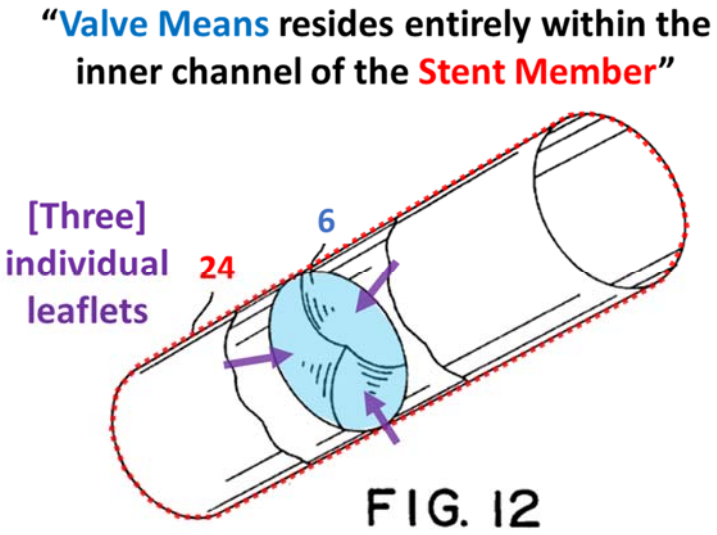
Claim Element	Andersen in view of Limon and Gabbay
	 Fig.7 • 3:20-25. Drasler ¶¶185-191.
[1.4] "a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein"	**Limon discloses a delivery 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"), **the pusher member including a guidewire lumen** (*e.g.*, "guide wire lumen 51"), **wherein the pusher member is disposed within a lumen of the moveable sheath** (*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" is possible. 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, 5:27-40.

Claim Element	Andersen in view of Limon and Gabbay
	As discussed in §X.C.2, a POSITA would have been motivated to apply **Limon's** teachings of a stent delivery system—a self-expanding stent delivered percutaneously using an over-the-wire catheter configuration—to **Andersen's** self-expandable valve prosthesis delivered via catheter. Drasler ¶195. • 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.") • 4:52-56 ("[I]nner member distal end 32 is made from a polymeric material that either is Soft by design….***The intent is to removably attach self-expanding stent 28 on outer surface 33 of inner member 24.***") • 4:60-67 ("[S]elf-expanding stent 28 is mounted on outer surface 33 at the inner member distal end 32 and the open lattice structure 29 is filled by attachment projections 30. ***Due to the coaxial arrangement between inner member 24 and outer member 25, the inner lumen 31 of outer member 25 covers self-***

Claim Element	Andersen in view of Limon and Gabbay
	expanding stent 28 and helps to retain the stent on the outer surface 33 of the inner member 24.") • 5:27-40 ("…***[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***....") • 6:67-7:4. Drasler ¶¶192-195.
[1.5] "the prosthetic heart valve 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, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and wherein"	**Andersen discloses the prosthetic heart valve device** (see [1.pre]-[1.1])**.** **Limon discloses the [stent] is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member** (*e.g.*, "self-expanding stent 28 is mounted on…the inner member distal end 32") **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"), **wherein a distal end of the [stent] is located at a distal end of the moveable sheath** (*e.g.*, "stent is mounted in the distal end of the outer member," such that the distal end of the "stent 28" is located at distal end of the "outer member 25")**.** ***E.g.*, Limon:** ***See* [1.4].** Additionally, **Limon** discloses the "self-expanding stent" is mounted "in the distal end of the outer member [25]" and collapsed onto inner member 24, 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." Limon, 2:4-11, 2:23-26, 4:60-67, Fig. 8. As shown in Figure 8, the distal end of the "stent" is located at the distal end of the "outer member" when it is loaded. *Id.*

Claim Element	Andersen in view of Limon and Gabbay
	To the extent it is argued that further disclosure of the distal end of the stent flush with the distal end of the outer member is required, the two ends are flush at least as the stent is deployed. Drasler ¶201. Moreover, a POSITA would have been motivated to locate the distal end of the stent at the distal end of the outer member such that deployment is achieved by simply pushing the inner member out of the end of the sheath. Drasler ¶202. As discussed in [1.4] and §X.C.2, a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **Andersen's** implantable valve prosthesis such that **Andersen's** valve prosthesis is collapsed onto the inner member and restrained by the outer member, wherein the distal end of the valve is located at the distal end of the outer member. Drasler ¶¶__. • Fig. 8 "[Stent] is collapsed onto the Pusher Member ... and restrained in the collapsed configuration by the Moveable Sheath"  • 2:23-26 ("….***This stent is mounted in the distal end of the outer member and is biased outwardly against the outer member.***") • 4:60-67 (" ***[S]elf-expanding stent 28 is mounted on outer surface 33 at the inner member distal end 32*** and the open lattice structure 29 is filled by attachment projections 30. ***Due to the coaxial arrangement between inner member 24 and outer member 25, the inner lumen 31 of outer member 25 covers self-***

Claim Element	Andersen in view of Limon and Gabbay
	expanding stent 28 and helps to retain the stent on the outer surface 33 of the inner member 24.") • 2:4-11, 7:25-30, 8:39-41, Figs. 5, 9. Drasler ¶¶196-202.
[1.6] "the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient."	**Andersen discloses the valve means resides entirely within the inner channel of the stent member** (see [1.1]-[1.3]) **in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient** (*e.g.*, the stent is configured for "folding and expanding together with the collapsible valve," and the valve remains mounted entirely within the stent at all times)**.** ***E.g.*, Andersen:** ***See* [1.1]-1.3].** Additionally, **Andersen** discloses that the valve prosthesis includes a "stent" made from a "re-expandable cylindrical support means for folding and expanding together with the collapsible valve." As discussed in §X.C.1, a POSITA would have understood that because the valve folds and expands together with the stent, it would remain entirely within the inner channel of the stent member when it is collapsed, and when it is deployed as shown in Fig. 12. Drasler ¶206. • 2:27-33 ("[T]he invention…is characterized in that the stent is made from a ***radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve*** for implantation in the body by means of a technique of catheterization.") • Fig. 12

Claim Element	Andersen in view of Limon and Gabbay
	 Drasler ¶¶203-206.
[2] "The assembly of claim 1, wherein the stent member is self-expanding."	***See* [1].** **Andersen discloses that the stent member is self-expanding** (*e.g.*, "the stent is expanded by self-expansion"). ***E.g.*, Andersen**: • 2:54-58 ("When the valve prosthesis is introduced and placed correctly, ***the stent is expanded by self-expansion***….") • 6:64-7:3. Drasler ¶¶207-208.
[3] "The assembly of claim 2, wherein the stent member comprises nitinol."	***See* [2].** **Gabbay discloses that the stent member comprises nitinol** (*e.g.*, the stent "may be formed of…a shape memory alloy material" such as "nitinol"). ***E.g.*, Gabbay:** **Andersen** leaves it to the POSITA to select a material for the self-expanding stent. As discussed in §X.C.3, a

Claim Element	Andersen in view of Limon and Gabbay
	POSITA would have been motivated to apply **Gabbay's** teachings of a self-expanding stent made from nitinol to **Andersen**'s cardiac valve prosthesis in order to advantageously create a structure that deforms into the desired shape once it is placed the body. Drasler ¶211. • 8:14-23 ("By way of example, ***the external stent of the valvular prosthesis 202 may be formed of a deformable material, such as a shape memory alloy material (e.g., nitinol)***…") • 2:5-15, 4:12-23. Drasler ¶¶209-211.
[5] "The assembly of claim 1, wherein the pusher member includes a controlled release mechanism that can be activated."	***See* [1], §IX.C.** **Limon discloses that the pusher member includes a controlled release mechanism that can be activated** (*e.g.*, "partially deployed…stent" can be manipulated with "control handles" and be "recaptured")**.** ***E.g.*, Limon:** **Limon** discloses that the delivery stent includes "control handles" that 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." Limon, 2:64-35. As discussed in [1.4] and §X.C.2, a POSITA would have been motivated to apply **Limon's** known stent delivery teachings to **Andersen's** valve prosthesis and catheter such that **Andersen's** prosthetic heart valve is delivered using control handles in order to control release of and recapture the valve if desired. Drasler ¶215. • 2:64-3:5 ("One feature of the present invention is to permit the physician to partially deploy the stent, and if it is improperly positioned, the outer member can be moved axially to recapture the partially deployed stent

Claim Element	Andersen in view of Limon and Gabbay
	so that the stent can be repositioned in the proper location. ***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. Drasler ¶¶212-215.

D. Ground 6: Claims 1-3 and 5 Are Rendered Obvious by Andersen 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 (as recited in [1.2]) and the use of nitinol for a self-expanding stent (as recited in [3]); a POSITA would have been motivated to apply these teachings to **Andersen** in view of **Limon** and had a reasonable expectation of success in doing so for the same reasons as discussed in §§X.C.3, X.C.4.[1.2] and X.C.4.[3]. Drasler ¶¶217-221. Specifically, **Phelps** discloses a self-expanding stent with a valve in its interior, designed to be 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, 2:24-26, 10:27-29, 14:3-5, 14:19-25 (describing valve stent for coronary bypass), Figs. 7-8; §IX.B. **Phelps** further discloses the use of nitinol as the material for the self-expanding stent, which is advantageously

biocompatible—further motivating a POSITA to apply **Phelps's** teachings. Phelps, 14:19-25; Drasler ¶¶218-221.

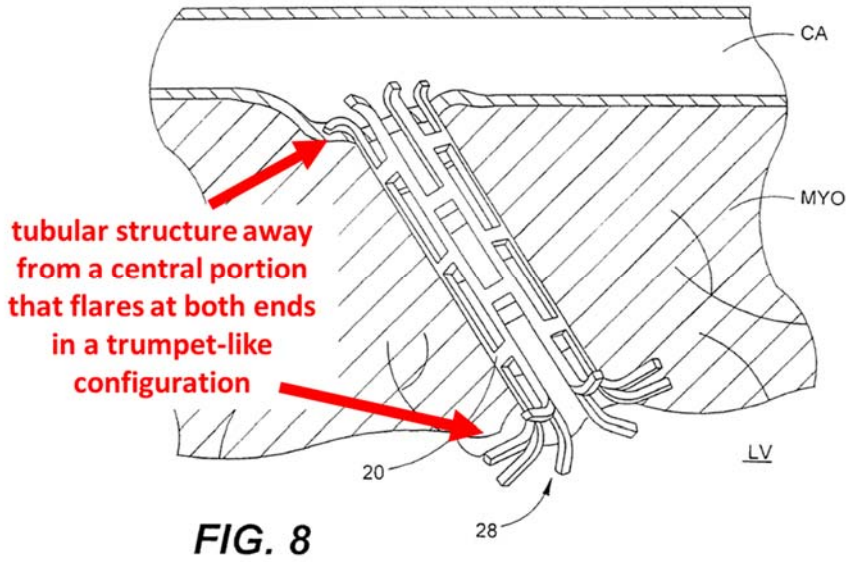


FIG. 8

Like **Andersen** and **Limon**, **Phelps** is also in the same field as '739 and reasonably pertinent to the alleged problem(s) identified in '739 of transluminally implanting heart prostheses and "fixing the heart valve device in a desired position." '739, 8:11-13, 11:62-12:2,. *See, e.g.*, Phelps, 2:6-12, 2:27-31, 7:20-27 (describing stent as applicable to fluid flow between any space and vessel), 10:7-12, Figs 26-29; Drasler ¶219.

In light of the foregoing, a POSITA would have found it obvious and straightforward to apply **Phelps's** teaching of a nitinol stent with flared ends in implementing **Andersen's** stented valve in view of **Limon's** delivery system teachings, and would have known that such an application (yielding the claimed

limitations) would predictably work and provide the expected functionality. Drasler ¶221.

E. Grounds 8-9: Claim 4 Is Rendered Obvious by Andersen in View of Limon, Garrison and Gabbay (Ground 8) or Phelps (Ground 9)

As discussed in §X.A.2.[4], **Garrison discloses that the stent member** (*e.g.*, "support structure") **includes two circles of barbs on an outer surface of the stent member** (*e.g.,* "barbs…which extent outwardly from the cardiac valve…in the expanded condition"). Drasler ¶¶80, 125-128, 222. For the same reasons discussed in §X.A.2.[4], a POSITA would have been motivated to apply **Garrison's** teaching of using barbs to **Andersen** in view of **Limon** and **Gabbay** (or alternatively **Phelps)** (*see* §§X.C-D) with the predictable and advantageous result of more securely attaching the self-expanding stent to the vessel wall. Garrison, 9:64-10:1, Figs. 29-30; Drasler ¶¶80, 125-128, 223-225. As discussed in §X.A.1, **Garrison** is analogous art. Moreover, Andersen teaches that "any prior art technique" can be used during implantation to "supervise an accurate introduction and positioning of the valve prosthesis," and "that it is possible to modify the valve prosthesis depending on the desired use." Andersen, 4:36-41, 6:49-52. A POSITA would have found it obvious and straightforward to apply **Garrison's** teachings of stent barbs to **Andersen**'s transcatheter stented valve devices in view of **Limon's** delivery system teachings and **Gabbay/Phelps's** nitinol flared self-expanding stent shape teachings, and would

have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶¶223-225.

F. Grounds 3-4, 7, 10: Grounds 1-2, 6 and 9 in further view of Nguyen

To the extent further disclosure of "leaflets made of fixed pericardial tissue" is required for [1.3] beyond **Garrison** for Grounds 1-2 (see §§X.A.1, X.A.2.[1.3]) and **Andersen** for Grounds 6 and 9 (see §§X.C.1, X.C.4.[1.3]), **Nguyen** discloses "[b]io-prosthetic valves" formed by "shaping a plurality of individual leaflets out of bovine pericardial tissue," which is "chemically fixed to…increase the tissue durability." Nguyen, 1:28-39; Drasler ¶¶86-88, 151-153, 216, 221, 223-225. **Nguyen** is in the same field as '739—implantable cardiac prosthetic devices—and addresses the same alleged problems: how to "improve both the durability and effectiveness of replacement heart valves" ('739, 1:25-28). *See* Nguyen, 1:5-9, 2:38-42, 9:32-40; Drasler ¶152. A POSITA would have been motivated to apply **Nguyen**'s teachings of leaflets made of fixed pericardial tissue to **Garrison's** leaflets (Grounds 3-4—*see* §§X.A-B) and **Anderson's** leaflets (Grounds 7, 10—*see* §§X.C-E) to advantageously improve durability using a material well-known to be suited for replacement heart valves. Nguyen, 1:28-39, 1:51-54; Drasler ¶153; *see also* Gabbay 3:38-42, 7:4-7 (valves made from "chemically fixed" "natural tissue," such as "pericardium"); U.S. 5,713,950 ("Cox") 4:35-50 ("Most tissue valves" have

"valve leaflets" constructed from "chemically treated" "pericardial" tissue.); '739, 3:41-46 (same language); *see also* §IV.B.2 (listing grounds). In light of these teachings, 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 ¶153.

XI. SECONDARY CONSIDERATIONS

There is no evidence in the prosecution history of this 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 of the Claims. *See generally* Ex. 1003; Drasler ¶226. Indeed, as demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in '739 were already well known. Drasler ¶226. 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 '739's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioner will prevail as to claims 1-5. *Inter partes* review of claims 1-5 is accordingly requested.

Dated: September 2, 2020

Respectfully submitted,

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Counsel for Petitioner
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR §42.24(a) and (d), the undersigned hereby certifies that this Petition for Inter Partes Review complies with the type-volume limitation of 37 CFR §42.24(a)(i) because, exclusive of the exempted portions, it contains 13,986 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 '739 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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Dated: September 2, 2020

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